

AD-A286 860



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GRANT NUMBER: DAMD17-94-J-4475

TITLE: Effects of Meditation-Based Stress Reduction in Younger Women with Breast Cancer

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REPORT DATE: October 1995

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;  
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DTIC QUALITY INSPECTED 1

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering the data, reviewing the collected data, completing and reviewing the collection of information, sending the information to the agency, reviewing the agency's response, and performing the actions required by the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Office, Paperwork Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (leave blank)		2. REPORT DATE	3. REPORT TYPE AND DATES COVERED	
		October 1995	Annual 30 Sep 94 - 29 Sep 95	
4. TITLE AND SUBTITLE			5. FUNDING NUMBERS	
Effects of Mediation-Based Stress Reduction in Younger Women with Breast Cancer			DAMD17-94-J-4475	
6. AUTHOR(S)				
James R. Hebert, MSPH ScD				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)			8. PERFORMING ORGANIZATION REPORT NUMBER	
University of Massachusetts Medical Center Worcester, Massachusetts 01655				
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				
11. SUPPLEMENTARY NOTES			96-00556  AH	
12a. DISTRIBUTION / AVAILABILITY STATEMENT			12b. DISTRIBUTION CODE	
Approved for public release; distribution unlimited			96-00205 	
13. ABSTRACT (Maximum 200 words)				
<p>The Breast Research Initiative for Determining Effective Skills for coping with cancer (BRIDGES) consists of a prospective, randomized intervention trial with sixty women in each of three arms: 1) the University of Massachusetts mindfulness meditation-based Stress Reduction and Relaxation Program (SR&amp;RP); 2) a nutrition education program (NEP) developed specifically for BRIDGES; and 3) a usual care control group. The 180 women under age 65 with Stage I or Stage II breast cancer enrolling into this randomized trial are being evaluated for: 1) psychological and behavioral indices of function and coping; 2) Quality of Life (QOL) measures; 3) compliance with the interventions and with medical treatment regimes; and 4) biochemical/immunological measures consisting of cytokines and melatonin. Analyses will be conducted to test hypotheses related to the three specific aims of the study: SR&amp;RP effect on QOL; SR&amp;RP &amp; NEP effects on immune parameters; and durability/decay of intervention-related effects. As of 30 September 1995, the study had closely adhered to the Statement of Work agreed upon at the time the grant was awarded. Recruitment of subjects who have been randomized and been collected as per protocol stipulations.</p>				
14. SUBJECT TERMS			15. NUMBER OF PAGES	
psychosocial intervention; immune parameters/cytokines; quality of life; secondary prevention; nutrition; meditation Breast cancer			66	
16. PRICE CODE				
17. SECURITY CLASSIFICATION OF REPORT			18. SECURITY CLASSIFICATION OF THIS PAGE	
Unclassified			Unclassified	
19. SECURITY CLASSIFICATION OF ABSTRACT			20. LIMITATION OF ABSTRACT	
Unclassified			Unlimited	

96 3 14 001

FOREWORD

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## INTRODUCTION

An increasing body of research literature has shown that psychological states have clear impact on recovery and quality of life in women with breast cancer. Psychosocial variables such as emotional expression, coping styles, and factors related to social support appear to have the most promise for improving quality of life and increasing the probability of prolonged survival. There also is a small body of evidence indicating that women with breast cancer receiving psychosocial intervention may derive a beneficial effect in respect to improved response and disease-free survival. Psychological distress seems to be particularly acute in younger women with breast cancer, a population that seems particularly amenable to psychosocial interventions. This is due, in part, to the fact that breast cancer tends to be a more aggressive disease of young ages and younger women have more concern with issues related to body image and major disruptions to typically very busy lives.

In light of these findings, there is an important need for the development of cost-effective psychosocial interventions for women with breast cancer. A successful intervention will be one that can reduce emotional distress, promote effective coping with diagnosis and treatment for breast cancer, and be useful and adaptable to the diverse population of younger women with breast cancer. The current study seeks to adapt the University of Massachusetts Medical Center's Stress Reduction and Relaxation Program (SR&RP) for younger women with breast cancer. The SR&RP is a well-established intervention program with demonstrated effectiveness in improving emotional status and quality of life in individuals with a variety of serious medical problems. The program is educationally based. Currently, it functions in inner city health clinics with diverse populations.

Our research addresses aspects of two of the fundamental research issues in psychosocial effects of breast cancer and the role of our well-recognized (but hitherto untested in this population of patients) SR&RP intervention in quality of life and status of immune parameters that may themselves be important in determining disease prognosis. Specifically, this research is designed to: 1) examine the psychosocial impact of breast cancer; and 2) identify techniques for delivering cost-effective care to facilitate recovery, improve immunological response, and improve quality of life after treatment for breast cancer.

### Overall Goal

The primary goal of this proposal is to test the efficacy of the well-established, short-duration mindfulness meditation-based Stress Reduction and Relaxation Program (SR&RP) in women under 65 years old with newly diagnosed Stage I and Stage II breast cancer. The SR&RP intervention aims to influence a number of well-defined psychosocial factors which are suggested by a growing body of evidence as critically important for: adjustment to a potentially life-threatening diagnosis; enhancement of quality of life; and potentially, for enhancement of resistance to disease progression and survival in women with breast cancer. The study will consist of a prospective randomized three-arm design with 60 women enrolled into each arm: 1)

the SR&RP intervention, tailored to focus on issues specific to this population; 2) a nutrition education program (NEP) which will serve as an inactive attention control with regard to the psychosocial outcome measures and as a potentially active intervention with regard to effect on immune parameters (see Specific Aim 2); and 3) a usual care control group.

Specific Aim 1: To test the effect of SR&RP on Quality of Life (QOL), emotional awareness and expression, coping strategies and related perceptual and behavioral factors, and compliance with the intervention and with medical recommendations in women (under 65 years old) with newly diagnosed Stage I and II breast cancer. Because the SR&RP and NEP groups will have an equally intense group session component and the NEP group will receive none of the essential components of the SR&RP, the test between the two groups, SR&RP and NEP, will distinguish between the effect of the SR&RP intervention and non-specific group/therapist factors.

Primary Hypothesis: The SR&RP intervention will result in improved QOL and ability to cope, compared either to the NEP or to usual care alone.

Secondary Hypothesis: The SR&RP intervention will result in: a) improved perception of self and self in relationship to the world, as measured by increased self-esteem, sense of coherence, and decreased loneliness; b) a corresponding reduction in mood disturbance (e.g., anxiety and depression); c) increased use of active-behavioral and active-cognitive coping strategies, as measured by the Dealing with Illness Coping Inventory; and d) increased compliance with treatment regimens as compared to usual care alone.

Specific Aim 2: To test the relative effect of the SR&RP versus NEP and usual care on immune parameters specifically related to cytokines that activate Natural Killer (NK) cells and melatonin levels that may in turn affect response to breast cancer (1). Because NK activity may be related to recurrence (2) we have previously shown that low-fat diets enhance NK activity (3) and we have preliminary data that meditation may affect melatonin levels in women, we are particularly interested in relative differences between the two test groups, SR&RP and NEP, compared to usual care alone.

Specific Hypothesis: Relative to usual care, the SR&RP intervention will increase the immune responsiveness of Stage I and II breast cancer patients. This will result in an increase in the production of cytokines, e.g., Interleukins 2 and 4 (IL-2,4), which activate NK cells, and interferon (IFN)  $\gamma$ , which activates macrophages.

Specific Aim 3: To determine if the study effects (described in Aims 1 and 2), along with maintenance of the intervention practices, persist over 1-2 years of follow-up.

Specific Hypothesis: Psychosocial and immunological changes will be maintained over time and related to on-going practice of the SR&RP and NEP dietary practices, self-regulatory strategies and behaviors.

## WORK ACCOMPLISHED

It is important to note that when the grant was written, we stated that women who were under fifty years of age would be entered into our study. We have extended this criterion to include any women who is under sixty-five years old at time of diagnosis with breast cancer. The reasons for extending the age requirement are as follows: 1) typically women work until they are sixty-five years old, which means they lead lives as busy as those of women under age fifty in fact, we find they often are busier in respect to career development; 2) we found that these women also have concerns with issues related to body image; and 3) we had no reason to believe that these women would not obtain the same benefits from the interventions. The age of 65 years provides a natural and culturally widely appreciated demarcation between early middle age, and its concomitant demands and pressures, and late middle age, with its progressive decline in terms of life pressures.

Because the Statement of Work contained in effect at the time the grant was awarded, provides the framework for all activities undertaken since that time, we employ it here as the outline of all progress.

### Task 1: Run-in Phase Months 1-3

- a. Additional focus groups and preliminary data will be gathered as needed.

Weekly meetings were held for the first 6 months of the study. These were always attended by the four site coordinators and two Co-Principal Investigators from the University of Massachusetts. In the first 3 months, other investigators (mainly oncologists and surgeons) also attended the meetings. At these sessions, recruiting protocols were developed and patient communication and other issues were discussed and resolved. It was determined that sufficient preliminary data were collected prior to the grant application process in order to guide planning of the recruitment protocols and data collection instruments. Therefore, additional focus groups were not held.

- b. Based on focus group and preliminary studies, introductory and booster (therapy) sessions will be developed so that the content of the program will be most useful to younger women with early stage breast cancer.

Introductory and booster sessions were developed. We determined that there would be two introductory sessions for the SR&RP intervention. At these sessions, women discuss their experience with breast cancer and start learning about mindfulness-meditation. There are an average of twelve women in each of these classes. The size of the groups allows them to support one another's experiences and enables them to bond so that when they attend the SR&RP classes they are likely to know someone in their class. These sessions gives the women a chance to meet and talk with other women who are experiencing the same illness. It also allows them to ask questions or talk about whatever is important to them. There are four booster sessions which are held after the standard SR&RP classes. At these sessions, women

learn more about meditation and yoga, discuss their experiences in the SR&RP and continue to discuss their experiences with breast cancer. These sessions serve to review and reinforce what they have learned in the SR&RP and give the women a chance to talk about issues of personal concern to them.

- c. The Nutrition Education Program will be developed using the recently funded Women's Health Initiative as an appropriate low-fat model.

The Nutrition Education Program (NEP) was to be developed using the recently funded Women's Health Initiative (WHI) as an appropriate low-fat model. It was decided that we could design and implement a low-fat intervention superior to that of the WHI. Therefore, we invested the necessary resources and developed a program specific to BRIDGES. The NEP consists of an overview of diet and health with an emphasis on how change in diet can affect well-being and how it broadens rather than narrows dietary options. The program is held at a location close to the University of Massachusetts Medical School in Worcester and consists of 14 weekly sessions each ninety minutes long. There is an additional session on a Saturday or Sunday which lasts six hours. The participants are asked to do various homework (cooking and nutrition) assignments which helps them to incorporate the program information into their daily life. At these classes the women do hands-on preparation and tasting of low-fat, high-fiber foods. They are taught alternative methods of creating and enhancing flavors including the use of spices and herbs. The transition to low-fat eating also entails increased consumption of vitamins and minerals. The role of these nutrients plus various spices in health is discussed. The individuals assigned to this intervention develop personal eating plans and dietary goals so that they reduce the amount of fat in their diet to less than twenty percent of the calories that they eat.

- d. Instrument material will be piloted and finalized, where appropriate. Reliability tests will be conducted when necessary.

Because all instruments had been validated and checked for reliability in previous studies it was not necessary to conduct separate reliability tests for BRIDGES. All instrument materials were piloted and finalized as stipulated in the protocol. Most of the instruments are being used in our other studies and all have performed well in previous tests of validity and reliability. We omitted the interviewer-administered questionnaires (i.e., the Hamilton Anxiety and Depression Scales) because they were redundant to other self-assessment data. A copy of the instruments we are using are included in the appendix. Below is a list of instruments being utilized.

**Baseline questionnaire** Measures include: Background and Demographic Data: age; sex; marital status; education; number of children; number and dates of pregnancies; breast feeding history: (months for each child); and menopausal status (including surgical menopause). Personal Health History: present medical/psychiatric history and treatment (including history of exposure to estrogens, oral contraceptives, unusual menstrual problems). Family Health

History: history of breast cancer; history of other cancers. General Self Care: sleep; exercise frequency; and smoking status.

Besides data collected on the baseline instrument we also administer these other questionnaires:

Beck Anxiety Inventory  
 Beck Depression Inventory  
 Sense of Coherence  
 Revised UCLA Loneliness Scale  
 Rosenberg Self-Esteem Scale  
 Functional Assessment of Cancer Therapy (FACT)  
 Mini-Mac Scale  
 Dealing with Illness  
 Marlowe-Crowe Social Desirability (MCSD) scale (Personal Reaction Inventory)  
 Symptom Check List  
 Social Readjustment Rating Scale  
 Social Approval  
 Seven Day Dietary Recall (7DDR)

- e. An introductory video tape (to be used for recruitment) will be produced.

Dr Ockene directed this task. During the weekly meetings (which were discussed in 1a) the purpose of the video, along with the content of the script, was discussed. The Project Coordinator and a representative from each site were videotaped. The video is five minutes long. It includes information about the funding source, why the study is important, and how the study is designed. It is shown to most of the women who are interested in joining the study. The video tape is included in the appendix along with the script.

- f. The Project Coordinator will be hired and trained in conducting phone and in-person interviews by Drs. Clemow and Massion.

The Project Coordinator, Susan Druker, was hired. Due to her skills in conducting interviews, the training session was not needed. Also, as noted above, we decided not to include in the battery of psychosocial instruments the Hamilton Anxiety Scale and the Hamilton Depression Scale. Both of those scales are administered verbally. Ms. Druker worked with the three other site coordinators in developing numerous study protocols including ones for periodic interviewing.

- g. A database to be used in the will be constructed.

This task has been completed. The biostatistician along with a research fellow developed a plan for our database.

- h. Analysis of available run-in phase data will be done by Drs Hebert and Massion. We have conducted process-related analyses (to assure data collection steps have occurred) and performed simple univariate analyses. Thus far all data are completed, within range, and have good internal logic.

Task 2: Recruitment. Months 4-21:

- a. 180 women (age <50 years) with Stage 1 or 2 breast cancer from Worcester, Ma and Providence RI will be recruited as participants for the study.

Currently, 74 individuals have been enrolled into the study. To remain on schedule 72 would need to have been recruited by the end of September. As discussed previously, we extended the age eligibility to women who were diagnosed with Stage 1 or 2 breast cancer at age 65 or less. A patient brochure was developed along with a letter that is signed by one of their physicians (see appendix) in order to assist with recruitment.

- b. Baseline measures will be taken on all study parameters as stated in the protocol.

A baseline questionnaire was developed (see 1e and appendix). The following anthropometric measures were taken at baseline: height; weight; sitting height; and waist and hip circumference. Blood also was drawn and a twenty-four hour urine was collected. A medical questionnaire was developed (see appendix). The following information is being obtained: date of first positive cytology or positive biopsy; if individual had radiation, when and if there were major complications; what type of surgery was performed (i.e. lumpectomy alone, mastectomy, etc); histology; tumor size; tumor grade; tumor differentiation; axillary nodes samples; estrogen/progesterone receptor concentrations; stage of breast cancer and information about their chemotherapy treatment. A nutritional assessment is completed by all participants(see appendix). For this, we are using a seven-day diet recall(7DDR).

- c. Study subjects will be randomized into one of the three arms of the study 1) Stress Reduction and Relaxation (SR&RP); 2) Nutrition Education Program (NEP), and 3) Usual supportive care(UC).

Study subjects are randomized into one of the three arms of the study 1) the Stress Reduction and Relaxation (SR&RP); 2) the Nutrition Education Program (NEP), and 3) Usual supportive care (UC). We call the UC arm, the Individual Approach Condition and state in our patient brochures that they choose whatever strategy to cope that they think is best for them. An eligibility requirement form was developed (see appendix). Of the 72 subjects randomized 26 are in SR&RP, 25 are in NEP and 23 are in UC.

**Task 3: Intervention, months 6-27:**

- a. Participants will become involved in the intervention arm to which they are randomized. The SR&RP and NEP will be given four times per year at UMMC.

The interventions are given on a three-times per year schedule. The first intervention started 4/95 and lasted 14 weeks. The second intervention started 8/95 and will end in December. Three more interventions will be offered next year. The women involved in SR&RP and NEP give rave reviews of the interventions. We contact them on a monthly basis to obtain feedback and, without exception, everyone states very positive things about being involved in the study.

- b. Just prior to the interventions (or time-controlled for the women randomized to usual care) all parameters (except immuno-endocrine measures and diet) assessed at baseline will be reassessed.

Because of budgetary restrictions prior to final approval, we reduced measurements from five to four times over the period of each woman's involvement. To make best use of these data, we decided that all baseline measures (see 2b) would be taken just prior to the interventions. Therefore, there was no need to reassess these measures prior to the interventions. In April and September, just prior to the start of the intervention, all women in the study completed the psychosocial instruments, had their blood drawn, their anthropometric measures were taken and a 24 hour urine was collected.

- c. The SR&RP group will receive the standard SR&RP segment plus additional therapy sessions for a total of fifteen sessions.

The SP&RP group receive the standard SR&RP segment plus additional therapy sessions for a total of fifteen sessions. As stated previously, two introductory sessions plus four booster sessions are required for all women who enter the SR&RP arm of the study. For more information see 1b.

- d. The NEP group will receive their intervention on approximately the same schedule as women in the SR&RP arm of the study.

The NEP group receives their intervention at the same time as the women in SR&RP. Nutrition classes and SR&RP classes last for fourteen weeks and begin and end at the same time. The first intervention started the second week in April and the second group of classes began the second week in September.

**Task 4: Follow-up months 8-46:**

- a. All participants will be assessed just after the intervention (or time adjusted for all women in the UC) and at twelve months and twenty four months after recruitment. Assessment will include all the psychological and quality of life measurements, as well as immuno-endocrine parameters and the nutritional assessments. At twelve months melatonin will be assessed. Nutrition assessments will be made only at the twelve month and twenty four-month post recruitment points in order to account for seasonal differences in dietary intake.

All participants are assessed just after the intervention (or time adjusted for all women in the UC) and at twelve months and twenty-four months after baseline. Assessment includes all the psychological and quality of life measurements, as well as immuno-endocrine parameters and the nutritional assessments. At four and twenty-four months, melatonin is assessed. Nutrition assessments also are made at four months, twelve months, and twenty-four months after baseline. We decided to do the nutritional assessment at four months because the information gathered provides us with data as to whether women have changed their diet immediately subsequent to the intervention. Monthly phone calls also are utilized to gather data. It is during these phone calls that we check for compliance with the SR&RP protocol.

- b. Ongoing data collection, review for completeness, and preliminary testing of study hypotheses will occur.

All site coordinators review the questionnaires which are returned for completeness. The process of entering the data is ongoing. Much of the data are optically scanned. If there are any unanswered questions in the baseline instrument or medical questionnaire, we ask the individuals to answer these questions over the phone.

**Task 5: Final Data Analysis, Months 47-51**

- a. Perform all exploratory analyses to test for adherence to model assumptions.
- b. Perform all data simplification tasks (e.g. principal components analysis).
- c. Test study hypotheses.
- d. Conduct post-hoc analysis of study data.
- e. Prepare manuscripts.

Except for e., where we are preparing manuscripts, based on preliminary data (1, 4) or theoretical considerations (5), there has been no activity because we are in month 12 of the project.

## CONCLUSIONS

In summary, progress in the first year of this grant has been excellent. All of the deliverables that were promised have been completed successfully, recruitment figures are on track, and retention is excellent. Governance for the study has worked very well with most executive decision making happening in a small working group consisting of Drs. Hebert and Massion and Ms. Susan Druker. In some instances our decisions are provisional on their being broadcast to investigators at UMMC and other sites for final approval. Day-to-day operational issues have been decided mainly in the site coordinator's working group which is chaired by the Project Coordinator/UMASS Site Coordinator, Ms. Susan Druker. Because Susan Druker is a member of both of the functioning working groups, communications within UMMC site and across the four sites have been extraordinarily smooth and efficient. The overall Steering Committee Meeting has occurred twice in the first year. Occasionally, an executive decision has come out of these meetings. However, it has transpired that its main purpose is to provide information to investigators at the other sites and to rekindle enthusiasm in the study. Although there was no place to mention this above, it should be noted that the enthusiasm level for study and the dedication about which people feel regarding their own involvement and involvement in their patients has never been higher in any study with which I have been involved.

One of our major concerns in designing this study concerned issues around the asymmetry of intervention conditions where blinding is not possible. In the years of meetings before we formally proposed this study, we spent more time on this issue than anything else. Our concern was that an obvious imbalance between the intervention conditions would either lead to a low recruitment rate or there would be large differential dropout after women were randomized. With 40% of total recruitment currently completed and having begun the second round of interventions, we can confidently say that this has not been a problem. Currently, we are working on a manuscript that discusses issues around behavioral interventions that cannot be blinded. We feel that the experience of the BRIDGES Study provides practical lessons in how to deal with this ubiquitous, very obvious, and little attended to problem.

We hope that the extraordinary successes of the first year of the BRIDGES Study will continue for the remaining three years. I appreciate the opportunity to convey the excellent progress that we have had to date.

## REFERENCES

1. Massion AO, Teas J, Hebert JR, Wertheimer MD, Kabat-Zinn J. Meditation, melatonin, and breast/prostate cancer: hypothesis and preliminary data. *Medical Hypotheses* 1995;44:39-46.
2. Levy SM, Herberman RB, Lippman M, D'Angelo T, Lee J. Immunological and psychosocial predictors of disease recurrence in patients with early-stage breast cancer. *Behav Med* 1991;17:67-75.
3. Hebert JR, Barone J, Reddy MM, Backlund JYC. Natural killer cell activity in a longitudinal dietary fat intervention trial. *Clin Immunol Immunopathol* 1990;54:103-116.
4. Clemow LC, Hebert JK, Lundquist D, Solomon J, Ennis F. Quality of Life and Immune Variables In A Group For Young Women with Breast Cancer. *Annals of Behavioral Medicine* 1995;17:177.
5. Hebert JR, Kabat GC, Ockene IS, Clemow L. Special Problems in Trials of Behavioral and Nutritional Interventions: Blinding and Behavioral Effect Modification. In preparation 1996.

**APPENDIX**

Assessment Tools  
Video Tape and Script  
Patient Information/Brochures  
Medical Questionnaire  
Eligibility Form



WRITE-IN AREA 1

WRITE-IN AREA 2

WRITE-IN AREA 3

FOR OFFICE USE ONLY

1	(A)	(B)	(C)	(D)	(E)
2	(A)	(B)	(C)	(D)	(E)
3	(A)	(B)	(C)	(D)	(E)

NATIONAL  
COMPUTER  
SYSTEMS



(P)	(P)	P	P	P	P	P	P	P	P	P	P	P	P	P	P
(8)	(8)	8	8	8	8	8	8	8	8	8	8	8	8	8	8
(4)	(4)	4	4	4	4	4	4	4	4	4	4	4	4	4	4
(2)	(2)	2	2	2	2	2	2	2	2	2	2	2	2	2	2
(1)	(1)	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**BECK INVENTORY-A**

**INSTRUCTIONS:** Below is a list of common symptoms of anxiety. Please read each item in the list carefully. Indicate how much you have been bothered by each symptom during the **PAST WEEK, INCLUDING TODAY.**

5  
↓  
4  
↓  
3  
↓  
2  
↓  
1

Severely: I could barely stand it  
Moderately: It was very unpleasant but I could stand it  
Mildly: It did not bother me much  
Not at all

1. Numbness or tingling	1	2	3	4	5
2. Feeling hot	1	2	3	4	5
3. Wobbliness in legs	1	2	3	4	5
4. Unable to relax	1	2	3	4	5
5. Fear of the worst happening	1	2	3	4	5
6. Dizzy or lightheaded	1	2	3	4	5
7. Heart pounding or racing	1	2	3	4	5
8. Unsteady	1	2	3	4	5
9. Terrified	1	2	3	4	5
10. Nervous	1	2	3	4	5
11. Feelings of choking	1	2	3	4	5
12. Hands trembling	1	2	3	4	5
13. Shaky	1	2	3	4	5
14. Fear of losing control	1	2	3	4	5
15. Difficulty breathing	1	2	3	4	5
16. Fear of dying	1	2	3	4	5
17. Scared	1	2	3	4	5
18. Indigestion or discomfort in abdomen	1	2	3	4	5
19. Faint	1	2	3	4	5
20. Face flushed	1	2	3	4	5
21. Sweating (not due to heat)	1	2	3	4	5

**Rosenberg Self-esteem Scale**

Below is a list of statements with which you may agree or disagree. Please indicate whether you agree or disagree with each statement by marking one number to the right of each statement. Note that responses range from 1=Strongly Disagree 2=Disagree 3=Agree 4=Strongly Agree

1. I feel that I'm a person of worth, at least on an equal basis with others.	1	2	3	4	5
2. I feel that I have a number of good qualities.	1	2	3	4	5
3. All in all, I am inclined to feel that I am a failure.	1	2	3	4	5
4. I am able to do things as well as most other people.	1	2	3	4	5
5. I feel I do not have much to be proud of.	1	2	3	4	5
6. I take a positive attitude toward myself.	1	2	3	4	5
7. On the whole, I am satisfied with myself.	1	2	3	4	5
8. I wish I could have more respect for myself.	1	2	3	4	5
9. I certainly feel useless at times.	1	2	3	4	5
10. At times I think I am no good at all.	1	2	3	4	5

**(Please turn the page over and continue)**

CEC SCALE

Listed below are some of the reactions people have to certain feelings or emotions. Read through the items on each list and, by choosing the appropriate answer indicate how far each describes the way you generally react.

ALMOST ALWAYS 4  
OFTEN 3  
SOMETIMES 2  
ALMOST NEVER 1

		1	2	3	4	5
WHEN I FEEL ANGRY (VERY ANNOYED)	A. I keep quiet	1	2	3	4	5
	B. I refuse to argue or say anything	1	2	3	4	5
	C. I bottle it up	1	2	3	4	5
	D. I say what I feel	1	2	3	4	5
	E. I avoid making a scene	1	2	3	4	5
	F. I smother my feelings	1	2	3	4	5
	G. I hide my annoyance	1	2	3	4	5
WHEN I FEEL ANXIOUS (WORRIED)	H. I let others see how I feel	1	2	3	4	5
	I. I keep quiet	1	2	3	4	5
	J. I refuse to say anything about it	1	2	3	4	5
WHEN I FEEL UNHAPPY (MISERABLE)	K. I tell others about it	1	2	3	4	5
	L. I say what I feel	1	2	3	4	5
	M. I bottle it up	1	2	3	4	5
	N. I smother my feelings	1	2	3	4	5
	O. I refuse to say anything about it	1	2	3	4	5
	P. I hide my unhappiness	1	2	3	4	5
	Q. I put on a bold face	1	2	3	4	5
	R. I keep quiet	1	2	3	4	5
	S. I let others see how I feel	1	2	3	4	5
	T. I smother my feelings	1	2	3	4	5
	U. I bottle it up	1	2	3	4	5
		1	2	3	4	5
		1	2	3	4	5
		1	2	3	4	5
<b>BECK INVENTORY-D</b>						
The following are groups of statements. Please read each group carefully. Then pick out the one statement in each group which best describes the way how you have been feeling the PAST WEEK, INCLUDING TODAY.						
Mark (1) if it is true for you. Otherwise, leave it blank. If several statements in the group seem to apply equally well, mark each one true. Be sure to read all the statements in each group before making your choice.						
1.	0 I do not feel sad					
	1 I feel sad					
	2 I am sad all the time and I can't snap out of it					
	3 I am so sad or unhappy that I can't stand it					

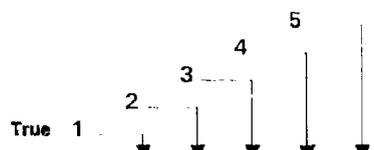
THIS IS UPSIDE DOWN. PLEASE TURN THE SHEET AROUND.

P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**INSTRUCTIONS:** This continues from the previous page.

We want to remind you that: The following are groups of statements. Please read each group carefully. Then pick out the one statement in each group which best describes the way you have been feeling the past week, including today. Mark true if it is true for you. Otherwise, leave it blank. If several statements in the group seem to apply equally well, mark each one true. Be sure to read all the statements in each group before making your choice.

**PLEASE NOTICE THAT THIS QUESTIONNAIRE CONTINUES ON THE OTHER SIDE OF THIS PAGE.**



	True	1	2	3	4	5
2. 0 I am not particularly discouraged about the future		1	2	3	4	5
1 I feel discouraged about the future		1	2	3	4	5
2 I feel I have nothing to look forward to		1	2	3	4	5
3 I feel that the future is hopeless and that things cannot improve		1	2	3	4	5
3. 0 I do not feel like a failure		1	2	3	4	5
1 I feel I have failed more than the average person		1	2	3	4	5
2 As I look back on my life, all I can see is a lot of failures		1	2	3	4	5
3 I feel I am a complete failure as a person		1	2	3	4	5
4. 0 I get as much satisfaction out of things as I used to		1	2	3	4	5
1 I don't enjoy things the way I used to		1	2	3	4	5
2 I don't get real satisfaction out of anything anymore		1	2	3	4	5
3 I am dissatisfied or bored with everything		1	2	3	4	5
5. 0 I don't feel particularly guilty		1	2	3	4	5
1 I feel guilty a good part of the time		1	2	3	4	5
2 I feel quit guilty most of the time		1	2	3	4	5
3 I feel guilty all the time		1	2	3	4	5
6. 0 I don't feel I am being punished		1	2	3	4	5
1 I feel I may be punished		1	2	3	4	5
2 I expect to be punished		1	2	3	4	5
3 I feel I am being punished		1	2	3	4	5
7. 0 I don't feel disappointed in myself		1	2	3	4	5
1 I am disappointed in myself		1	2	3	4	5
2 I am disgusted with myself		1	2	3	4	5
3 I hate myself		1	2	3	4	5
8. 0 I don't feel I am any worse than anybody else		1	2	3	4	5
1 I am critical of myself for myself for my weaknesses or mistakes		1	2	3	4	5
2 I blame myself all the time for my faults		1	2	3	4	5
3 I blame myself for everything bad that happens		1	2	3	4	5
9. 0 I don't have any thoughts of killing myself		1	2	3	4	5
1 I have thoughts of killing myself, but I would not carry them out		1	2	3	4	5
2 I would like to kill myself		1	2	3	4	5
3 I would like kill myself if I had the chance		1	2	3	4	5
10. 0 I don't cry anymore than usual		1	2	3	4	5
1 I cry more now than I used to		1	2	3	4	5
2 I cry all the time now		1	2	3	4	5
3 I used to be able to cry, but now I can't cry even though I want to		1	2	3	4	5
11. 0 I am no more irritated now than I ever am		1	2	3	4	5
1 I get annoyed or irritated more easily than I used to		1	2	3	4	5
2 I feel irritated all the time now		1	2	3	4	5
3 I don't get irritated at all by the things that used to irritate me		1	2	3	4	5

*(Please turn the page over and continue)*

True 1

2

3

4

5

12.	0 I have not lost interest in other people	1	2	3	4	5
	1 I am less interested in other people than I used to be	1	2	3	4	5
	2 I have lost most of my interest in other people	1	2	3	4	5
	3 I have lost all of my interest in other people	1	2	3	4	5
	13. 0 I make decisions about as well as I ever could	1	2	3	4	5
	1 I put off making decisions more than I used to	1	2	3	4	5
	2 I have greater difficulty in making decisions than before	1	2	3	4	5
	3 I can't make decisions at all anymore	1	2	3	4	5
14.	0 I don't feel I look any worse than I used to	1	2	3	4	5
	1 I am worried that I am looking old or unattractive	1	2	3	4	5
	2 I feel that there are permanent changes in my appearance that make me look unattractive	1	2	3	4	5
	3 I believe that I look ugly	1	2	3	4	5
	15. 0 I can work about as well as before	1	2	3	4	5
	1 It takes an extra effort to get started at doing something	1	2	3	4	5
	2 I have to push myself very hard to do anything	1	2	3	4	5
	3 I can't do any work at all	1	2	3	4	5
16.	0 I can sleep as well as usual	1	2	3	4	5
	1 I don't sleep as well as I used to	1	2	3	4	5
	2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep	1	2	3	4	5
	3 I wake up several hours earlier than I used to and can't get back to sleep	1	2	3	4	5
	17. 0 I don't get more tired than usual	1	2	3	4	5
	1 I get tired more easily than I used to	1	2	3	4	5
	2 I get tired from doing almost everything	1	2	3	4	5
	3 I am too tired to do anything	1	2	3	4	5
18.	0 My appetite is no worse than usual	1	2	3	4	5
	1 My appetite is not as good as it used to be	1	2	3	4	5
	2 My appetite is much worse now	1	2	3	4	5
	3 I have no appetite at all anymore	1	2	3	4	5
	19. 0 I haven't lost much weight, if any, lately	1	2	3	4	5
	1 I have lost more than 5 pounds	1	2	3	4	5
	2 I have lost more than 10 pounds	1	2	3	4	5
	3 I have lost more than 15 pounds	1	2	3	4	5
20.	0 I am no more worried about my health than usual	1	2	3	4	5
	1 I am worried about physical problems such as aches and pains; or upset stomach; or constipation	1	2	3	4	5
	2 I am very worried about physical problems and it's hard to think of much else	1	2	3	4	5
	3 I am so worried about my physical problems, that I can't think about anything else	1	2	3	4	5
	21. 0 I have not noticed any recent change in my interest in sex	1	2	3	4	5
	1 I am less interested in sex than I used to be	1	2	3	4	5
	2 I am much less interested in sex now	1	2	3	4	5
	3 I have lost interest in sex completely	1	2	3	4	5

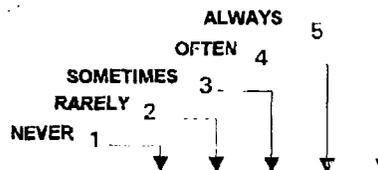
THIS IS UPSIDE DOWN. PLEASE TURN THE SHEET AROUND.



P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**DEALING WITH ILLNESS**

**INSTRUCTIONS:** The following is a list of things people do to deal with problems in their lives. Which of these things have you used to help you deal with your illness? Fill in only one circle for each problem and do not skip any items. If you change your mind, erase your first mark carefully. PLEASE NOTICE THAT THIS QUESTIONNAIRE CONTINUES ON THE OTHER SIDE OF THIS PAGE.



1. Thought about my illness but tried not to let it overly upset or overwhelm me	1	2	3	4	5
2. Tried to keep others from knowing how I was feeling	1	2	3	4	5
3. Prayed hard for a good ending to the situation	1	2	3	4	5
4. Thought about it one day at a time	1	2	3	4	5
5. Went out more socially	1	2	3	4	5
6. Accepted the reality of my diagnosis but not that I had to automatically accept a poor prognosis	1	2	3	4	5
7. Talked to people just to be able to talk about it	1	2	3	4	5
8. Thought about the positive changes in me since the illness	1	2	3	4	5
9. Went to a friend, or professional, for advice on how to change things in the situation	1	2	3	4	5
10. Avoided being with people	1	2	3	4	5
11. Tried to get someone, like a doctor, to do something about it	1	2	3	4	5
12. Took more vitamins and ate healthy foods	1	2	3	4	5
13. Simply refused to even think about the situation as I just couldn't face it	1	2	3	4	5
14. Went to a friend or a professional to help me feel better	1	2	3	4	5
15. Formed a plan of action in my mind	1	2	3	4	5
16. Thought more about the meaning of life	1	2	3	4	5
17. Trusted my belief in God	1	2	3	4	5
18. Talked with others in the same situation	1	2	3	4	5
19. Prepared for the worst	1	2	3	4	5
20. Turned to work or other activities to keep my mind off things	1	2	3	4	5
21. Enjoyed everyday things more than I used to	1	2	3	4	5
22. Developed myself as a person	1	2	3	4	5
23. Exercised more	1	2	3	4	5
Tried to reduce tension by :					
24. drinking more than usual	1	2	3	4	5
25. eating more than usual	1	2	3	4	5
26. smoking more than usual	1	2	3	4	5
27. taking drugs more than usual	1	2	3	4	5
28. sleeping more than usual	1	2	3	4	5
29. Worked on trying to solve some of the problems my illness brought on	1	2	3	4	5
30. Depended on others to cheer me up and make me feeling better	1	2	3	4	5
31. Used some kind of relaxation technique (includes hypnosis, imagery, and meditation)	1	2	3	4	5
32. Accepted this situation and got on with doing what needed to be done.	1	2	3	4	5
33. Felt that it was my doctor's responsibility to make treatment decisions for me	1	2	3	4	5
34. Tried to understand what brought on my illness	1	2	3	4	5
35. Tried to maintain/use positive thinking (kept a positive attitude)	1	2	3	4	5
36. I was assertive (with medical staff, family, friends) about what I thought was best for me	1	2	3	4	5
37. Tried to understand how other people in this situation were thinking or feeling	1	2	3	4	5
38. Released my feelings somehow (e.g., cried, yelled, laughed) instead of holding them in	1	2	3	4	5
39. Tried to find out more about my illness	1	2	3	4	5
40. Believed there was nothing I could do but wait since only time would make a difference	1	2	3	4	5

*(Please turn the page over and continue)*



P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**Mini-MAC Scale**

**DIRECTIONS:** A number of statements are given below which describe people's reactions to having cancer. Please darken the circle to the right of each statement, indicating how far it applies to you at present. Please respond to each item. Do not leave any blank.

Definitely applies to me **4**  
 Applies to me **3**  
 Does not apply to me **2**  
 Definitely does not apply to me **1**

	1	2	3	4
1. At the moment I take one day at a time				
2. I see my illness as a challenge				
3. I've put myself in the hands of God				
4. I feel like giving up				
5. I feel very angry about what has happened to me				
6. I feel completely at a loss about what to do				
7. It is a devastating feeling				
8. I count my blessings				
9. I worry about the cancer returning or getting worse				
10. I try to fight the illness				
11. I distract myself when thoughts about my illness come into my head				
12. I can't handle it				
13. I am apprehensive				
14. I am not very hopeful about the future				
15. I feel there is nothing I can do to help myself				
16. I think it is the end of the world				
17. Not thinking about it helps me cope				
18. I am very optimistic				
19. I've had a good life, what's left is a bonus				
20. I feel that life is hopeless				
21. I can't cope				
22. I am upset about having cancer				
23. I am determined to beat this disease				
24. Since my cancer diagnosis I now realize how precious life is and I'm making the most of it				
25. I have difficulty in believing that this happened to me				
26. I make a positive effort not to think about my illness				
27. I deliberately push all thoughts of cancer out of my mind				
28. I suffer great anxiety about it				
29. I am a little frightened				
<b>UCLA</b>				
For the following four questions: indicate how often you feel the way described after each of the questions. For each one, choose from the following alternatives:				
1- NEVER	2- RARELY	3- SOMETIMES	4- OFTEN	
1. How often do you feel in tune with the people around you?				
2. How often do you feel that no one really knows you well?				
3. How often do you feel that you can find companionship when you want it?				
4. How often do you feel that people are around you but not with you?				

*(Please turn the page over and continue)*



P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**FACT - B (Version 3)**

**INSTRUCTIONS:** Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past 7 days. Fill in only one circle for each problem and do not skip any items. If you change your mind, erase your first mark carefully. **PLEASE NOTICE THAT THIS QUESTIONNAIRE CONTINUES ON THE OTHER SIDE OF THIS PAGE.**

very much 5  
 ↓  
 quite a bit 4  
 ↓  
 somewhat 3  
 ↓  
 a little bit 2  
 ↓  
 not at all 1

**PHYSICAL WELL-BEING** During the past 7 days:

- 1. I have a lack of energy
- 2. I have nausea
- 3. Because of my physical condition, I have trouble meeting the needs of my family
- 4. I have pain
- 5. I am bothered by side effects of treatment
- 6. I feel sick
- 7. I am forced to spend time in bed
- 8. Looking at the above 7 questions, how much would you say your **PHYSICAL WELL-BEING** affects your quality of life?

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

**SOCIAL/FAMILY WELL-BEING** During the past 7 days:

- 9. I feel distant from my friends
- 10. I get emotional support from my family
- 11. I get support from my friends and neighbors
- 12. My family has accepted my illness
- 13. Family communication about my illness is poor
- 14. I feel close to my partner (or the person who is my main support)
- 15. Have you been sexually active during the past year? 1=Yes 2=No  
If yes: I am satisfied with my sex life?
- 16. Looking at the above 7 questions, how much would you say your **SOCIAL/FAMILY WELL-BEING** affects your quality of life?

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

**RELATIONSHIP WITH DOCTOR** During the past 7 days:

- 17. I have confidence in my doctor(s)
- 18. My doctor is available to answer my questions
- 19. Looking at the above 2 questions, how much would you say your **RELATIONSHIP WITH THE DOCTOR** affects your quality of life?

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

**EMOTIONAL WELL-BEING** During the past 7 days:

- 20. I feel sad
- 21. I am proud of how I'm coping with illness
- 22. I am losing hope in the fight against my illness
- 23. I feel nervous
- 24. I worry about dying
- 25. I worry that my condition will get worse
- 26. Looking at the above 6 questions, how much would you say your **EMOTIONAL WELL-BEING** affects your quality of life?

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

**FUNCTIONAL WELL-BEING** During the past 7 days:

- 27. I am able to work (include work in home)
- 28. My work (include work in home) is fulfilling
- 29. I am able to enjoy life
- 30. I have accepted my illness

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

*(Please turn the page over and continue)*

very much 5  
 ↓  
 quite a bit 4  
 ↓  
 somewhat 3  
 ↓  
 a little bit 2  
 ↓  
 not at all 1

31. I am sleeping well	1	2	3	4	5
32. I am enjoying the things I usually do for fun	1	2	3	4	5
33. I am content with the quality of my life right now	1	2	3	4	5
34. Looking at the above 7 questions, how much would you say your FUNCTIONAL WELL-BEING affects your quality of life?	1	2	3	4	5
<b>ADDITIONAL CONCERNS During the past 7 days:</b>					
35. I have been short of breath	1	2	3	4	5
36. I am self-conscious about the way I dress	1	2	3	4	5
37. My arms are swollen or tender	1	2	3	4	5
38. I feel sexually attractive	1	2	3	4	5
39. I have been bothered by hair loss	1	2	3	4	5
40. I worry about the risk of cancer in other family members	1	2	3	4	5
41. I worry about the effect of stress on my illness	1	2	3	4	5
42. I am bothered by a change in weight	1	2	3	4	5
43. I am able to feel like a woman	1	2	3	4	5
44. Looking at the above 8 questions, how much would you say these ADDITIONAL CONCERNS affect your quality of life?	1	2	3	4	5
For the next 11 questions please answer for the past 7 days, in general:					
45. I have felt that my life has been productive	1	2	3	4	5
46. I have felt a sense of purpose in my life	1	2	3	4	5
47. I have been able to reach down deep into myself for comfort	1	2	3	4	5
48. I have felt that my life seemed to lack meaning and purpose	1	2	3	4	5
49. I have found comfort in my faith/spirituality	1	2	3	4	5
50. I have found strength in faith/spirituality	1	2	3	4	5
51. My illness has strengthened my faith/spirituality	1	2	3	4	5
52. I have felt that what ever happens with my illness, things will be okay	1	2	3	4	5
53. I have felt a sense of connectedness with myself, a community, my family, and/or the world	1	2	3	4	5
54. I keep in believed that a sense of conectedness would give/gives me a greater ability to cope	1	2	3	4	5
55. I have felt that I am aware of my experience in the present moment (i.e., being less preoccupied with the past or future; living fully)	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5

**THIS IS UPSIDE DOWN. PLEASE TURN THE SHEET AROUND.**

P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**SCL-90-R**

**INSTRUCTIONS:** Below is a list of problems and complaints that people sometimes have. Please read each one carefully. After you have done so, please fill in one of the numbered spaces to the right that best describes HOW MUCH THAT PROBLEM HAS BOTHERED OR DISTRESSED YOU DURING THE PAST WEEK INCLUDING TODAY. Mark only one numbered space for each problem and do not skip any items. PLEASE NOTICE THAT THIS QUESTIONNAIRE CONTINUES ON THE OTHER SIDE.

EXTREMELY 5  
 QUITE A BIT 4  
 MODERATELY 3  
 A LITTLE BIT 2  
 NOT AT ALL 1

1. Headaches	1	2	3	4	5
2. Nervousness or shakiness inside	1	2	3	4	5
3. Repeated unpleasant thoughts that won't leave your mind	1	2	3	4	5
4. Faintness or dizziness	1	2	3	4	5
5. Loss of sexual interest or pleasure	1	2	3	4	5
6. Feeling critical of others	1	2	3	4	5
7. The idea that someone else can control your thoughts	1	2	3	4	5
8. Feeling others are to blame for most of your troubles	1	2	3	4	5
9. Trouble remembering things	1	2	3	4	5
10. Worried about sloppiness or carelessness	1	2	3	4	5
11. Feeling easily annoyed or irritated	1	2	3	4	5
12. Pains in heart or chest	1	2	3	4	5
13. Feeling afraid in open spaces or on the streets	1	2	3	4	5
14. Feeling low in energy or slowed down	1	2	3	4	5
15. Thoughts of ending your life	1	2	3	4	5
16. Hearing voices that other people do not hear	1	2	3	4	5
17. Trembling	1	2	3	4	5
18. Feeling that most people cannot be trusted	1	2	3	4	5
19. Poor appetite	1	2	3	4	5
20. Crying easily	1	2	3	4	5
21. Feeling shy or uneasy with the opposite sex	1	2	3	4	5
22. Feeling of being trapped or caught	1	2	3	4	5
23. Suddenly scared for no reason	1	2	3	4	5
24. Temper outbursts that you could not control	1	2	3	4	5
25. Feeling afraid to go out of your house alone	1	2	3	4	5
26. Blaming yourself for things	1	2	3	4	5
27. Pains in lower back	1	2	3	4	5
28. Feeling blocked in getting things done	1	2	3	4	5
29. Feeling lonely	1	2	3	4	5
30. Feeling blue	1	2	3	4	5
31. Worrying too much about things	1	2	3	4	5
32. Feeling no interest in things	1	2	3	4	5
33. Feeling fearful	1	2	3	4	5
34. Your feelings being easily hurt	1	2	3	4	5
35. Other people being aware of your private thoughts	1	2	3	4	5
36. Feeling others do not understand you or are unsympathetic	1	2	3	4	5
37. Feeling that people are unfriendly or dislike you	1	2	3	4	5
38. Having to do things very slowly to insure correctness	1	2	3	4	5
39. Heart pounding or racing	1	2	3	4	5
40. Nausea or upset stomach	1	2	3	4	5

*(Please turn the page over and continue)*

EXTREMELY 5  
 QUITE A BIT 4  
 MODERATELY 3  
 A LITTLE BIT 2  
 NOT AT ALL 1

41. Feeling inferior to others	1	2	3	4	5
42. Soreness of your muscles	1	2	3	4	5
43. Feeling that you are watched or talked about by others	1	2	3	4	5
44. Trouble falling asleep	1	2	3	4	5
45. Having to check and double-check what you do	1	2	3	4	5
46. Difficulty making decisions	1	2	3	4	5
47. Feeling afraid to travel on buses, subways, or trains	1	2	3	4	5
48. Trouble getting your breath	1	2	3	4	5
49. Hot or cold spells	1	2	3	4	5
50. Having to avoid certain things, places, or activities because they frighten you	1	2	3	4	5
51. Your mind going blank	1	2	3	4	5
52. Numbness or tingling in parts of your body	1	2	3	4	5
53. A lump in your throat	1	2	3	4	5
54. Feeling hopeless about the future	1	2	3	4	5
55. Trouble concentrating	1	2	3	4	5
56. Feeling weak in parts of your body	1	2	3	4	5
57. Feeling tense or keyed up	1	2	3	4	5
58. Heavy feelings in your arms or legs	1	2	3	4	5
59. Thoughts of death or dying	1	2	3	4	5
60. Overeating	1	2	3	4	5
61. Feeling uneasy when people are watching or talking about you	1	2	3	4	5
62. Having thoughts that are not your own	1	2	3	4	5
63. Having urges to beat, injure, or harm someone	1	2	3	4	5
64. Awakening in the early morning	1	2	3	4	5
65. Having to repeat the same actions such as touching, counting, washing	1	2	3	4	5
66. Sleep that is restless or disturbed	1	2	3	4	5
67. Having urges to break or smash things	1	2	3	4	5
68. Having ideas or beliefs that others do not share	1	2	3	4	5
69. Feeling very self-conscious with others	1	2	3	4	5
70. Feeling uneasy in crowds, such as shopping or at a movie	1	2	3	4	5
71. Feeling everything is an effort	1	2	3	4	5
72. Spells of terror or panic	1	2	3	4	5
73. Feeling uncomfortable about eating or drinking in public	1	2	3	4	5
74. Getting into frequent arguments	1	2	3	4	5
75. Feeling nervous when you are left alone	1	2	3	4	5
76. Others not giving you proper credit for your achievements	1	2	3	4	5
77. Feeling lonely even when you are with people	1	2	3	4	5
78. Feeling so restless you can't sit still	1	2	3	4	5
79. Feeling of worry	1	2	3	4	5
80. Feeling that something bad is going to happen to you	1	2	3	4	5

**THIS IS UPSIDE DOWN. PLEASE TURN THE SHEET AROUND.**





# SOCIAL READJUSTMENT RATING SCALE

**Instructions:** Check, in the first column, those life events that have occurred in the past year. In the second column, write in the number of times this event as occurred more than 1 year ago, but less than 5 years ago.

Life Events	# of times occurred within the past year	# of times occurred 1-5 years ago
Death of spouse or life partner	_____	_____
Divorce	_____	_____
Marital/life partner separation	_____	_____
Jail term	_____	_____
Death of close family member	_____	_____
Personal injury or illness	_____	_____
Marriage	_____	_____
Fired/layoff at work	_____	_____
Marital/partner reconciliation	_____	_____
Retirement	_____	_____
Change in health of family member	_____	_____
Pregnancy	_____	_____
Miscarriage	_____	_____
Abortion	_____	_____
Sexual difficulty	_____	_____
Gain of new family member(s)	_____	_____
Business readjustment	_____	_____
Change in financial state	_____	_____
Death of a close friend	_____	_____
Change to different line of work	_____	_____
Increase in number of arguments with spouse/partner	_____	_____
Decrease in number of arguments with spouse/partner	_____	_____
Mortgage over \$10,000	_____	_____
Foreclosure of mortgage or loan	_____	_____
Change in responsibilities at work	_____	_____
Son or daughter leaving home	_____	_____
Trouble with in-laws	_____	_____
Trouble with "ex" spouse or spouse's "ex"	_____	_____
Trouble with step-children	_____	_____
Outstanding personal achievement	_____	_____
Spouse/partner begins or stops working	_____	_____
Begin or end school (self)	_____	_____
Change in living conditions	_____	_____
Revision of personal habits	_____	_____
Trouble with boss/co-workers	_____	_____
Change in work hours or conditions	_____	_____
Change in residence	_____	_____
Change in schools (self)	_____	_____
Change in schools (children)	_____	_____
Change in recreation	_____	_____
Change in church activities	_____	_____
Change in social activities	_____	_____
Mortgage or loan less than \$10,000	_____	_____
Change in sleeping habits	_____	_____
Increase in number of family get-togethers	_____	_____
Decrease in number of family get-togethers	_____	_____
Change in eating habits	_____	_____
Vacation	_____	_____
Christmas stress	_____	_____
Minor violations of the law	_____	_____



Life is:

1	2	3	4	5	6	7
full of interest						completely routine

Until now your life has had:

1	2	3	4	5	6	7
no clear goals or purpose at all						very clear goals and purpose

Do you have the feeling that you're being treated unfairly?

1	2	3	4	5	6	7
very often						very seldom or never

In the past ten years your life has been:

1	2	3	4	5	6	7
full of changes without your knowing what will happen next						completely consistent and clear

Most of the things you do in the future will probably be:

1	2	3	4	5	6	7
completely fascinating						deadly boring

Do you have the feeling that you are in an unfamiliar situation and don't know what to do?

1	2	3	4	5	6	7
very often						very seldom or never

What best describes how you see life:

1	2	3	4	5	6	7
one can always find a solution to painful things in life						there is no solution to painful things in life

When you think about your life, you very often:

1	2	3	4	5	6	7
feel how good it is to be alive						ask yourself why you exist at all

When you face a difficult problem, the choice of a solution is:

1	2	3	4	5	6	7
always confusing and hard to find						always completely clear

16. Doing the things you do every day is:

1	2	3	4	5	6	7
a source of deep pleasure and satisfaction						a source of pain and boredom

17. Your life in the future will probably be:

1	2	3	4	5	6	7
full of changes without your knowing what will happen next						completely consistent and clear

18. When something unpleasant happened in the past your tendency was:

1	2	3	4	5	6	7
"to eat yourself up" about it						to say "ok, that's that, I have to live with it," and go on

19. Do you have very mixed up feelings and ideas?

1	2	3	4	5	6	7
very often						very seldom or never

20. When you do something that gives you a good feeling:

1	2	3	4	5	6	7
it's certain that you'll go on feeling good						it's certain that something will happen to spoil the feeling

21. Does it happen that you have feelings inside you that you would rather not feel?

1	2	3	4	5	6	7
very often						very seldom or never

22. You anticipate that your personal life in the future will be:

1	2	3	4	5	6	7
totally without meaning or purpose						full of meaning and purpose

23. Do you think that there will always be people whom you'll be able to count on in the future?

1	2	3	4	5	6	7
you're certain there will be						you doubt there will be



# SEVEN DAY DIETARY RECALL - INSTRUCTIONS

NAME: \_\_\_\_\_ DATE: \_\_\_\_\_

I.D. NUMBER									
0	0	0	0	0	0	0	0	0	0
1	1	1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2	2	2
3	3	3	3	3	3	3	3	3	3
4	4	4	4	4	4	4	4	4	4
5	5	5	5	5	5	5	5	5	5
6	6	6	6	6	6	6	6	6	6
7	7	7	7	7	7	7	7	7	7
8	8	8	8	8	8	8	8	8	8
9	9	9	9	9	9	9	9	9	9

This is a questionnaire that asks you to recall (remember) the foods you ate during the past week. It asks how big your usual portion was and how many times you ate each of the food items. Using the food models that we gave you may help in estimating portion size. Please answer each question as completely as possible. In recalling what you ate, please try to remember all seven days of the week ending yesterday. Include not only what you ate at meals but also such things as:

- *all between-meal and late night snacks*
- *foods eaten at restaurants*
- *foods eaten at parties or at meetings*
- *foods eaten in the car*
- *items put on salads, potatoes, toast, and other foods*
- *juices or other things taken with medicines*

It will not be easy to remember a whole week and you may not remember all of it—but people usually do much better than they first think they can. You may find it useful to use the worksheet on the next page to help you remember. Please try to recall what you had eaten each day and mark down the meals and snacks that you remember eating. It may help to think through what you were doing on each of the days. We have found this to be very useful in recalling foods eaten. If there are days or parts of days that you just can't remember, then mark in what would be typical meals and snacks for the day. It may also be helpful to scan through the food items to help "jog your memory" before you start filling out the questionnaire. **But please remember, it is important to account for all seven days of the past week.**

**DIRECTIONS** For each food item:

- FIRST, darken in a bubble in the column which indicates your typical portion size when compared to the "Comparison" portion. Although the machine can "read" pen, we suggest that you use a pencil so that you can make changes, if necessary. For example, if you drink coffee daily and your typical portion is 1 cup, darken in a bubble in the "Equal to Comparison" column as indicated below.
- SECOND, indicate the number of times you have eaten each food item during the week in the last column. For example, if you drink 2 cups of coffee each day, you would indicate this as 14 (2 cups per day multiplied by 7 days per week equals 14 cups per week) as shown below.

Food Item	Comparison Portion	Your Typical Portion			Number of times you ate this food in the past week:																			
		half the size	equal to comparison	twice the size																				
Coffee, tea	1 cup		●		<table style="width: 100%; text-align: center;"> <tr><td>●</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>3</td><td>●</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	●	20	30	40	50	60	70	80	90	0	1	2	3	●	5	6	7	8	9
●	20	30	40	50	60	70	80	90																
0	1	2	3	●	5	6	7	8	9															

**FOLLOWING ARE SOME EXAMPLES OF HOW THE FORM MIGHT BE FILLED OUT.**

1. If you have eaten two 1/4 pound cheeseburgers with mayonnaise dressing in the past week, you would respond as follows:

Food Item	Comparison Portion	Your Typical Portion			Number of times you ate this food in the past week:																			
		half the size	equal to comparison	twice the size																				
Hamburger/Ground beef (reg)	4 oz or 1/4 lb		●		<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>1</td><td>●</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	0	1	●	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
0	1	●	3	4	5	6	7	8	9															
Cheese on Hamburger	1 slice		●		<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>1</td><td>●</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	0	1	●	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
0	1	●	3	4	5	6	7	8	9															
Bread, any type (including sandwiches, bagels, rolls, pita)	1 slice or 1/2 bagel or roll			●	<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>1</td><td>●</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	0	1	●	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
0	1	●	3	4	5	6	7	8	9															
Mayonnaise (regular)	1 tablespoon		●		<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>1</td><td>●</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	0	1	●	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
0	1	●	3	4	5	6	7	8	9															

2. If you have eaten rice three times during the week and your typical portion is 1 cup, used 1/2 cup of low fat yogurt, and never had cornbread, you would respond as follows:

Rice (cooked)	1/2 cup			●	<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>1</td><td>2</td><td>●</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	0	1	2	●	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
0	1	2	●	4	5	6	7	8	9															
Yogurt (low-fat)	1 cup		●		<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>●</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	0	●	2	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
0	●	2	3	4	5	6	7	8	9															
Cornbread	one 3" piece				<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>●</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	●	1	2	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
●	1	2	3	4	5	6	7	8	9															

3. If the portion you eat of a food item is **more** than "twice the size" of our comparison portion, include as extra portions. For example, if you eat a 16 oz porterhouse steak count as two 8 oz steaks:

Beef steaks, roasts (reg)	4 oz			●	<table style="width: 100%; text-align: center;"> <tr><td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td></tr> <tr><td>0</td><td>1</td><td>●</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr> </table>	10	20	30	40	50	60	70	80	90	0	1	●	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90																
0	1	●	3	4	5	6	7	8	9															

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PLEASE DO NOT WRITE IN THIS AREA

01267

WORKSHEET (Please feel free to use this as a memory aid—we will not enter or analyze this information.)

MEAL	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
BREAKFAST							
SNACKS							
LUNCH							
SNACKS							
DINNER							
SNACKS							

Food Item <b>CATEGORY ONE</b>	Comparison Portion	Your Typical Portion			Number of times you ate this food in the past week:									
		half the size	equal to comparison	twice the size	0	1	2	3	4	5	6	7	8	9
Hamburger/ground beef (regular)	4 oz or 1/4 lb				0	1	2	3	4	5	6	7	8	9
Hamburger/ground beef (lean)	4 oz or 1/4 lb				0	1	2	3	4	5	6	7	8	9
Cheese on hamburger	1 slice				0	1	2	3	4	5	6	7	8	9
Hot Dog (regular)	1 hot dog				0	1	2	3	4	5	6	7	8	9
Hot Dog (low-fat)	1 hot dog				0	1	2	3	4	5	6	7	8	9
Regular lunch meats (bologna, pastrami)	1 slice				0	1	2	3	4	5	6	7	8	9
Low-fat lunch meats (ham, turkey)	1 slice				0	1	2	3	4	5	6	7	8	9
Beef steaks, roasts (regular)	4 oz				0	1	2	3	4	5	6	7	8	9
Beef steaks, roasts (lean) including round, flank, sirloin, tenderloin, eye of round, chuck	4 oz				0	1	2	3	4	5	6	7	8	9
Tuna fish (plain—all types)	1/2 of 7 oz can				0	1	2	3	4	5	6	7	8	9
Casseroles/salads including ham, seafood, tuna, chicken	1 cup				0	1	2	3	4	5	6	7	8	9
Fish (broiled, baked, stir-fried, poached)	4 oz				0	1	2	3	4	5	6	7	8	9
Fish (fried)	4 oz				0	1	2	3	4	5	6	7	8	9
Shellfish (steamed, boiled, etc.)	2 oz, 8 lg shrimp or 12 small clams				0	1	2	3	4	5	6	7	8	9
Shellfish (fried)	2 oz, 8 lg shrimp or 12 small clams				0	1	2	3	4	5	6	7	8	9
Chicken, turkey (baked or broiled, eaten w/o skin) (Sauces page 4)	3 oz				0	1	2	3	4	5	6	7	8	9
Chicken, turkey (baked or broiled, eaten w/skin)	3 oz				0	1	2	3	4	5	6	7	8	9
Chicken, fried	3 oz				0	1	2	3	4	5	6	7	8	9
Egg (scrambled, omelet, boiled, etc.)	1 egg				0	1	2	3	4	5	6	7	8	9
Egg substitutes (as above)	1/4 cup				0	1	2	3	4	5	6	7	8	9
Pork (regular)/smoked shoulder	4 oz				0	1	2	3	4	5	6	7	8	9
Pork (lean), including loin, leg, rump, tenderloin/baked ham	4 oz				0	1	2	3	4	5	6	7	8	9
Lamb (regular)	4 oz				0	1	2	3	4	5	6	7	8	9
Lamb (lean), including loin, or blade or shoulder chops and leg or sirloin roast	4 oz				0	1	2	3	4	5	6	7	8	9
Bacon	2 slices				0	1	2	3	4	5	6	7	8	9
Bacon substitute	2 slices				0	1	2	3	4	5	6	7	8	9
Sausage, breakfast	2 links, 1 patty				0	1	2	3	4	5	6	7	8	9
Sausage, including kielbasa, Italian	2 oz				0	1	2	3	4	5	6	7	8	9

Your Typical Portion

Food Item <b>CATEGORY ONE, cont.</b>	Comparison Portion	Your Typical Portion			Number of times you ate this food in the past week:									
		half the size	equal to comparison	twice the size	0	1	2	3	4	5	6	7	8	9
Sauces: meat, cheese, or cream-based	1/2 cup				0	1	2	3	4	5	6	7	8	9
Tomato sauce, vegetable-based sauce	1 cup				0	1	2	3	4	5	6	7	8	9
Chili with beef	1 cup				0	1	2	3	4	5	6	7	8	9
Chili with beans (no beef)	1 cup				0	1	2	3	4	5	6	7	8	9
Main dishes with regular cheese (e.g., enchiladas, lasagna, manicotti, macaroni & cheese, quiche)	1 cup				0	1	2	3	4	5	6	7	8	9
Main dishes using low-fat cheeses or cottage cheese	1 cup				0	1	2	3	4	5	6	7	8	9
Stews, pot pies, with beef/poultry	1 cup				0	1	2	3	4	5	6	7	8	9
Pizza plain or vegetables only	1 slice (lg pc)				0	1	2	3	4	5	6	7	8	9
Pizza with meat (large pizza)	1 slice				0	1	2	3	4	5	6	7	8	9
Tofu	4 oz (1/4 of 1lb block)				0	1	2	3	4	5	6	7	8	9

**CATEGORY TWO**

Whole milk (including beverages made with whole milk, such as chocolate milk or hot chocolate, and including milk on cereal but <u>excluding</u> milk in coffee)	8 oz glass				0	1	2	3	4	5	6	7	8	9
2% milk/milk beverage	8 oz glass				0	1	2	3	4	5	6	7	8	9
1% milk/milk beverages	8 oz glass				0	1	2	3	4	5	6	7	8	9
Skim milk/milk beverages	8 oz glass				0	1	2	3	4	5	6	7	8	9
Cheeses (regular)	1 slice or 1 oz				0	1	2	3	4	5	6	7	8	9
Cheeses (reduced fat)	1 slice or 1 oz				0	1	2	3	4	5	6	7	8	9
Cottage cheese, 2% or 4%	1/2 cup				0	1	2	3	4	5	6	7	8	9
Cottage cheese, non-fat or 1%	1/2 cup				0	1	2	3	4	5	6	7	8	9
Sour cream	2 tablespoons				0	1	2	3	4	5	6	7	8	9
Light sour cream	2 tablespoons				0	1	2	3	4	5	6	7	8	9
No-fat sour cream	2 tablespoons				0	1	2	3	4	5	6	7	8	9
Cream, half and half, <u>excluding</u> use in coffee or tea	1/2 cup				0	1	2	3	4	5	6	7	8	9
Non-dairy creamer, <u>excluding</u> use in coffee or tea	1/2 cup				0	1	2	3	4	5	6	7	8	9
Non-dairy topping	1/2 cup				0	1	2	3	4	5	6	7	8	9
Yogurt (regular) (not frozen)	1 cup				0	1	2	3	4	5	6	7	8	9
Yogurt (low-fat)	1 cup				0	1	2	3	4	5	6	7	8	9
Yogurt (non-fat)	1 cup				0	1	2	3	4	5	6	7	8	9



Food Item <b>CATEGORY FOUR, cont.</b>	Comparison Portion	Your Typical Portion			Number of times you ate this food in the past week:									
		half the size	equal to comparison	twice the size	10	20	30	40	50	60	70	80	90	
Granola cereals	1 cup				0	1	2	3	4	5	6	7	8	9
Plain pasta (see sauces, page 4)	1 cup				0	1	2	3	4	5	6	7	8	9
Hot cereals	1 cup				0	1	2	3	4	5	6	7	8	9
Pancakes, waffles, French toast	4", 1 slice				0	1	2	3	4	5	6	7	8	9

**CATEGORY FIVE** \*FOR PIES (Below) 1 SLICE = 1/7 of 9" PIE

Donuts, danish	1 each				0	1	2	3	4	5	6	7	8	9
Muffins, quick breads (e.g., banana, zucchini, etc.)	1 regular muffin (2-3/4" x 2")				0	1	2	3	4	5	6	7	8	9
Cakes (regular)	1 slice (see food model pictures)				0	1	2	3	4	5	6	7	8	9
Cakes (reduced fat) Angel Food Cake (plain)	1 slice (see food model pictures)				0	1	2	3	4	5	6	7	8	9
Cookies (regular)	2 cookies				0	1	2	3	4	5	6	7	8	9
Cookies (reduced fat) including fig bars, vanilla wafers	2 cookies				0	1	2	3	4	5	6	7	8	9
Ice cream, frozen desserts (regular, full-fat)	1/2 cup				0	1	2	3	4	5	6	7	8	9
Ice cream, frozen desserts (low-fat) including frozen yogurt	1/2 cup				0	1	2	3	4	5	6	7	8	9
Ice cream, frozen desserts (non-fat) including frozen yogurt, sherbet	1/2 cup				0	1	2	3	4	5	6	7	8	9
*Pies, fruit	1 slice				0	1	2	3	4	5	6	7	8	9
*Cream Pies, using cream or whole milk (including cream, custard, pecan, and cheesecake)	1 slice				0	1	2	3	4	5	6	7	8	9
*Cream Pies, using low-fat (1%) or skim milk	1 slice				0	1	2	3	4	5	6	7	8	9
Chocolate candy (e.g., M&M's)	1 small bar or 1 oz				0	1	2	3	4	5	6	7	8	9
Other candy	4 pieces				0	1	2	3	4	5	6	7	8	9
Puddings using whole or 2% milk	1/2 cup				0	1	2	3	4	5	6	7	8	9
Puddings using low-fat (1%) or skim milk	1/2 cup				0	1	2	3	4	5	6	7	8	9
Jellies, jams, honey, maple syrup	1 teaspoon				0	1	2	3	4	5	6	7	8	9

**CATEGORY SIX**

French fries, fried potatoes	1 cup				0	1	2	3	4	5	6	7	8	9
Oven baked "french fries"	1 cup				0	1	2	3	4	5	6	7	8	9
Starchy vegetables (including corn, potatoes not fried, peas, winter squash, sweet potato)	1/2 cup				0	1	2	3	4	5	6	7	8	9
Other vegetables, cooked or raw (e.g., carrots, green beans, green salads, tomato, etc.)	1/2 cup				0	1	2	3	4	5	6	7	8	9
Vegetables with cheese sauce	1 cup				0	1	2	3	4	5	6	7	8	9
Cream soups using cream or whole milk (including cream of tomato, New England Clam Chowder)	1 cup				0	1	2	3	4	5	6	7	8	9

Food Item <b>CATEGORY SIX, cont.</b>	Comparison Portion	Your Typical Portion			Number of times you ate this food in the past week:									
		half the size	equal to comparison	twice the size	0	1	2	3	4	5	6	7	8	9
Cream soups using low-fat or skim milk (or water)	1 cup				0	1	2	3	4	5	6	7	8	9
Broth-based soups—vegetable, minestrone, chicken	1 cup				0	1	2	3	4	5	6	7	8	9
Lentil, split pea soups	1 cup				0	1	2	3	4	5	6	7	8	9
Beans, such as baked beans, pintos, kidney, limas, and lentils	1/2 cup				0	1	2	3	4	5	6	7	8	9
Olives, green	4 each				0	1	2	3	4	5	6	7	8	9
Olives, black	4 each				0	1	2	3	4	5	6	7	8	9
Avocado, guacamole	1/2 avocado, 1/2 cup				0	1	2	3	4	5	6	7	8	9

#### CATEGORY SEVEN

Food Item	Comparison Portion	half the size	equal to comparison	twice the size	Number of times you ate this food in the past week:									
					0	1	2	3	4	5	6	7	8	9
Fruit juices (100% juice only)	1/2 cup				0	1	2	3	4	5	6	7	8	9
Banana	1 medium (7")				0	1	2	3	4	5	6	7	8	9
Other fruits fresh, frozen, canned, dried	1 medium or 1/2 cup pieces or 1/4 cup dried				0	1	2	3	4	5	6	7	8	9

#### CATEGORY EIGHT

Food Item	Comparison Portion	half the size	equal to comparison	twice the size	Number of times you ate this food in the past week:									
					0	1	2	3	4	5	6	7	8	9
Regular soft drinks, flavored seltzer	12 oz can				0	1	2	3	4	5	6	7	8	9
Diet soft drinks, plain seltzer	12 oz can				0	1	2	3	4	5	6	7	8	9
Beer	12 oz can				0	1	2	3	4	5	6	7	8	9
Wine	6 oz glass				0	1	2	3	4	5	6	7	8	9
Liquor (spirits)	1 shot/1.5 oz				0	1	2	3	4	5	6	7	8	9
Fruit drinks (excluding fruit juices)	4 oz glass				0	1	2	3	4	5	6	7	8	9
Coffee, tea	1 cup				0	1	2	3	4	5	6	7	8	9
Whole milk in coffee or tea	1 tablespoon				0	1	2	3	4	5	6	7	8	9
2% milk in coffee or tea	1 tablespoon				0	1	2	3	4	5	6	7	8	9
1% or skim milk in coffee or tea	1 tablespoon				0	1	2	3	4	5	6	7	8	9
Cream, half and half in coffee or tea	1 tablespoon				0	1	2	3	4	5	6	7	8	9
Non-dairy creamers in coffee or tea	1 tablespoon				0	1	2	3	4	5	6	7	8	9
Sugar (in coffee, tea or on cereals)	1 teaspoon				0	1	2	3	4	5	6	7	8	9

#### CATEGORY NINE

Food Item	Comparison Portion	half the size	equal to comparison	twice the size	Number of times you ate this food in the past week:									
					0	1	2	3	4	5	6	7	8	9
Aspirin, regular	2				0	1	2	3	4	5	6	7	8	9
Aspirin, extra strength	2				0	1	2	3	4	5	6	7	8	9

ADDITIONAL ITEMS (please list anything you have eaten that was not on the list provided):

Food Item	Your Usual Portion Size	How Many Times Eaten in the Past Week
1.		
2.		
3.		
4.		
5.		

1. During the past week which we asked you to respond on your dietary intake, would you say your diet was typical?

Yes                  No

2. How difficult was it to fill out this Seven Day Diet Recall?

Easy                                  Very Difficult  
 1       2       3       4       5

For the following questions we want you to think about the past year:

3. Do you exercise on a regular basis?

Yes                  No

4. If you exercise regularly:

How often do you exercise?  
 less than once/week  
 2 times/week  
 3 times/week  
 4 times/week  
 More than 4 times/week

AND

How long do you exercise?  
 less than 10 minutes/session  
 10-20 minutes/session  
 21-30 minutes/session  
 31-40 minutes/session  
 More than 40 minutes/session

What types of exercise do you perform?

Jogging/running  
 Brisk walking  
 Swimming  
 Bicycling  
 Weight lifting  
 Rowing  
 Bowling  
 Golfing  
 Tennis/racquetball  
 Hiking  
 Aerobic dance  
 Basketball  
 Other \_\_\_\_\_

How long have you been exercising regularly?

Less than 6 months  
 6-12 months  
 1-2 years  
 2-3 years  
 More than 3 years

155921-3/3

5. How would you rate your level of fitness in comparison to other people your own age?

- Poor
- Fair
- Average
- Above average
- Excellent

6. Do you take any vitamin or mineral supplements?

- Yes
- No

**IF NO, PLEASE STOP HERE. THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!**

7. On average, how many days in a week do you take your supplement(s)?

(Darken one) (1) (2) (3) (4) (5) (6) (7)

8. Please indicate how many tablets, on average, you take per day; as well as the amount of the following vitamins and minerals listed below that a single tablet contains:

**\*\* Please darken the correct unit of measure. For example, for Beta Carotene you would mark: ● IU or ○ RE**

**Vitamin/Mineral**

**Tablets/Day**

**Amount of Vitamin/Mineral per Tablet\*\***

**Beta Carotene  
(other carotenoids)**

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

● IU (international units) or

○ RE (retinol equivalents)

**Vitamin A  
(retinol, retinaldehyde  
retinoic acid)**

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

● IU  
or  
○ RE

**Number 8 continued on next page . . . .**

Number 8 continued . .

Vitamin/Mineral

Tablets/Day

Amount of Vitamin/Mineral per Tablet\*\*

Vitamin E  
(alpha tocopherol and  
other tocopherols)

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

IU  
or  
TE (tocopherol equivalents)

Vitamin C  
(ascorbic acid)

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mg (milligrams) or  
g (grams)

Iron  
(ferric, ferrous)

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mg

Calcium  
(calcium gluconate, etc.)

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mg

Number 8 continued  
on next page . . . .

Number 8 continued . .

Vitamin/Mineral

Tablets/Day

Amount of Vitamin/Mineral per Tablet\*\*

Zinc

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mg

Selenium

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mcg (micrograms)

Fish Oil  
(EPA, DHA)

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mg  
or  
g

Number 8 continued on next page . . . .



Number 8 continued . .

Vitamin/Mineral

Tablets/Day

Amount of Vitamin/Mineral per Tablet\*\*

Evening Primrose Oil

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mg  
or  
g

Cod Liver Oil

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

mg  
or  
g

9. What is the name or brand of the supplement(s) that you take? Please list all of them.

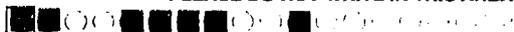
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**THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!**

PLEASE DO NOT WRITE IN THIS AREA



01267

FOR BRIDGES STAFF ONLY

DATE:

m m      d d      y y

Study ID No.

# BRIDGES



*Breast Research Initiative for DetermininG Effective Skills*

The Fallon Healthcare System  
The Miriam Hospital

The Medical Center of Central Massachusetts - Memorial  
University of Massachusetts Medical Center

## Patient Questionnaire

# BRIDGES

Please take the time to answer the following questions. All this information will be confidential.

1. NAME: \_\_\_\_\_  
(First) (Middle) (Last)
2. STREET ADDRESS: \_\_\_\_\_ 3. APT. No. \_\_\_\_\_
4. CITY or TOWN: \_\_\_\_\_ 5. STATE: \_\_\_\_\_ 6. ZIP: \_\_\_\_\_
7. PHONE (DAYTIME): (\_\_\_\_) \_\_\_\_\_ Ext. \_\_\_\_\_
8. PHONE (EVENING): (\_\_\_\_) \_\_\_\_\_
9. NEAREST CLOSEST RELATIVE PHONE: (\_\_\_\_) \_\_\_\_\_
10. a) DATE OF BIRTH \_\_\_\_ - \_\_\_\_ - \_\_\_\_ b) SS # \_\_\_\_ - \_\_\_\_ - \_\_\_\_  
m m d d y y
11. ARE YOU:  Single  Separated  
 Married  Divorced  
 Living with a Partner  Widowed
12. ARE YOU:  White (Non-Hispanic)  Black (Non-Hispanic)  
 Hispanic/White  Hispanic/Black  
 Asian  Other \_\_\_\_\_
13. How much school have you completed? (Check highest level)  
 No high school  Vocational/Trade School  Bachelor's Degree  
 Some high school  Some college  Graduate School  
 High school diploma  Associate Degree
14. Are you currently in school? (Check only one)  
 Yes, in school full-time  
 Yes, in school part-time  
 No
15. Are you presently employed? (Check only one)  
 Yes, employed full-time  
 Yes, employed part-time  
 No (If no, go to question #17)
16. What is your usual occupation? \_\_\_\_\_

17. If employed, how would you classify your present position? (Check only one)

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> skill or craft   | <input type="checkbox"/> scientific/technical work | <input type="checkbox"/> professional, managerial<br>or administrative |
| <input type="checkbox"/> machine operator | <input type="checkbox"/> service work              | <input type="checkbox"/> sales   |
| <input type="checkbox"/> manual labor     | <input type="checkbox"/> clerical or office        |  |

18. Are you married (or living with a partner)?  Yes  No (If no, go to question #24)

19. How much school has your partner completed? (Check highest level)

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> No high school      | <input type="checkbox"/> Vocational/Trade school | <input type="checkbox"/> Bachelor's Degree |
| <input type="checkbox"/> Some high school    | <input type="checkbox"/> Some college            | <input type="checkbox"/> Graduate School   |
| <input type="checkbox"/> High school diploma | <input type="checkbox"/> Associate Degree        |  |

20. Is your partner currently in school? (Check only one)

- Yes, in school full-time  
 Yes, in school part-time  
 No

21. Is your partner presently employed? (Check only one)

- Yes, employed full-time  
 Yes, employed part-time  
 No (If no, go to question #24)

22. What is your partner's usual occupation? \_\_\_\_\_

23. If your partner is employed, how would you classify the present position? (Check only one)

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> skill or craft   | <input type="checkbox"/> scientific/technical work | <input type="checkbox"/> professional,<br>managerial or administrative |
| <input type="checkbox"/> machine operator | <input type="checkbox"/> service work              | <input type="checkbox"/> sales   |
| <input type="checkbox"/> manual labor     | <input type="checkbox"/> clerical or office        |  |

24. Have you ever been pregnant?  Yes  No (If no, go to question #27)

25. a) Have you ever had a first trimester miscarriage or abortion?  
 Yes  No (If no, go to question #<sup>26</sup>~~25~~)

b) Please provide the number of first trimester miscarriages or abortions? \_\_\_\_\_

c) How old were you at the time of the first one of these? \_\_\_\_\_ yrs old

d) If you had more than one, how old were you at the time of the last one of these? \_\_\_\_\_ yrs old

*Please continue . . .*

26. Have you ever had a pregnancy that lasted beyond the first trimester (past the 1st three months)?  
 Yes  No (If no, go to question #27)

If yes, please list the dates of your pregnancies that lasted beyond the first trimester and the results (live birth, still birth, or any fetal loss after the first trimester). Also, if it was a live birth, did you breast feed? In the chart below include only your pregnancies that lasted beyond the first trimester.

Pregnancy	Date pregnancy ended (mm/dd/yy)	Result (live birth, still birth or any other fetal loss after first trimester)	Sex of child (M/F)	Did you breast feed? (Yes or No)	If breast fed, # of months?
a) 1st					
b) 2nd					
c) 3rd					
d) 4th					
e) 5th					

27. How many children do you have?  
 None (If none, go to question #31)

- a) number of biological children ..... \_\_\_\_\_  
 b) number of adopted children ..... \_\_\_\_\_  
 c) number of step children that you are currently taking care of ..... \_\_\_\_\_

28. How many children live with you? \_\_\_\_\_

29. What is the age of your youngest child? \_\_\_\_\_ years old

30. Do you have children in elementary school?  Yes  No

31. Have you ever taken oral contraceptives?  Yes  No (If no, go to question #32)

If yes,

- a) how old were you when you first used them? \_\_\_\_\_ years old  
 b) how old were you when you last used them? \_\_\_\_\_ years old (give current age if you are presently taking them)  
 c) how many years (total) did you use them? \_\_\_\_\_ year(s)

32. When did you begin your first menstrual period? \_\_\_\_\_ years old

33. Have you ever had menstrual problems?  Yes  No (If no, go to question #36)

34. If yes, what were they?

- cramps  irregular periods  heavy bleeding  other

35. If other, please describe \_\_\_\_\_  
 \_\_\_\_\_

36. Are you currently having any menstrual periods?  Yes  No (If no, go to #38)
37. How often have you had them in the past year? \_\_\_\_\_ (Go to #41)
38. Have you had a period within the last year?  Yes  No (If no, go to #39)
39. Did your period stop due to chemotherapy?  Yes  No
40. Did you have a hysterectomy?  Yes  No
41. Is there a history of female breast cancer in your family?  Yes  No (If no, go to #42)

If yes, who? Place a "✓" for those who apply. For blood-related sisters and aunts please write in how many sisters or aunts were affected (do not include half relatives).

Relative	Had breast cancer before menopause	Had breast cancer after menopause	Had breast cancer but not sure when	Had breast cancer in one breast	Had breast cancer in both breasts
a) Mother					
b) Father's mother					
c) Mother's mother					
d) Sisters (How many?)					
e) Aunts (How many?)					

42. How many sisters (i.e., with the same parents as you) do you have? \_\_\_\_\_ (include deceased)
43. How many aunts (related by blood) do you have? \_\_\_\_\_ (include deceased)
44. Did any of your male relatives ever have breast cancer?  Yes  No  Don't Know (If no, or don't know, go to question #46)
45. If yes, what was the relationship to you?  
 Father  Grandfather  Brother  Uncle
46. Have you smoked at least 100 cigarettes in your entire life?  Yes  No (If no, go to question #52)
47. Do you now smoke cigarettes?  Yes  No (If no, go to question #50)
48. On the average weekday (Monday-Friday) how many cigarettes do you smoke per day? \_\_\_\_\_
49. On the average weekend day (Saturday/Sunday) how many cigarettes do you smoke per day? \_\_\_\_\_
50. How long ago did you stop smoking? (Check the most appropriate answer)  
 \_\_\_\_\_ #  days ago  weeks ago  months ago  years ago

51. On average, how many cigarettes did you smoke per day prior to when you stopped smoking? \_\_\_\_
52. How tall are you? \_\_\_\_ ft \_\_\_\_ inches (without shoes)
53. a) What is the most you weighed (excluding pregnancy and up to 3 mos after delivery) \_\_\_\_ lbs  
 b) How old were you when you weighed this amount? \_\_\_\_ years old
54. How tall were you and how much did you weigh when you were 18 years old?  
 \_\_\_\_ ft \_\_\_\_ inches ..... \_\_\_\_ pounds
55. Have you seen a dietician or attended nutrition classes in the last three months?  Yes  No
56. How would you describe your religion? (Check only one)
- Roman Catholic       Protestant  
 Jewish                 Other (specify) \_\_\_\_\_
57. Do you regularly (at least once monthly) attend religious services?  Yes  No
58. Do you watch television on a regular basis for more than 30 minutes per day?  
 Yes  No  
 (If no, go to #61)
59. If yes, how much time do you spend watching television each day? \_\_\_\_ hours \_\_\_\_ min.
60. Please provide an estimate of how far away you are sitting from the television when you are watching it. \_\_\_\_ feet
61. On average, how many hours a night do you sleep?
- a) on week nights      \_\_\_\_ hours \_\_\_\_ minutes  
 b) on weekends        \_\_\_\_ hours \_\_\_\_ minutes
62. Are you ever regularly awake for more than 1 hour between 12:00 midnight and 5:00 a.m.?  Yes  No
63. a) Have you ever regularly slept under an electric blanket (not just to warm the bed before getting into it)?  Yes  No (If no, go to #64)  
 b) If yes, what was the total number of years of use? \_\_\_\_ years  
 c) How many nights per year? \_\_\_\_ nights  
 d) How many hours per night? \_\_\_\_ hours per night
64. Do you sleep more in one season than another?  Yes  No (If no, go to #67)
65. If yes, what is the seasonal difference in sleep between your longest and shortest sleep? \_\_\_\_ hours \_\_\_\_ minutes
66. If yes, in which season do you sleep the most?  
 summer       fall       winter       spring

67. How many hours do you spend outdoors each week in each of the seasons?

spring \_\_\_\_ hrs      summer \_\_\_\_ hrs      fall \_\_\_\_ hrs      winter \_\_\_\_ hrs

68. How many years have you kept the following pets? (Enter 00 if you never have kept such pets)

dogs \_\_\_\_ yrs      cats \_\_\_\_ yrs      birds \_\_\_\_ yrs

Other \_\_\_\_ yrs (please list \_\_\_\_\_)

69. Have you ever exercised regularly (at least 2-3 times a week)?       Yes       No (If no, go to #74)

70. If yes, how old were you when you began to exercise regularly (at least 2-3 times a week)?  
\_\_\_\_\_ years old

71. Did you stop exercising regularly?       Yes       No (If no, go to #73)

72. If yes, how old were you when you stopped exercising regularly?      \_\_\_\_\_ years old

**For the following questions please indicate your lifelong adult (over 18 years) average time spent for each type of exercise listed in question 73. We know it will be difficult to average exposure over such a long period of time, but want you to make the best possible estimate that you can.**

73. What kind of exercise have you done? (Please check any of these categories that may be appropriate to you.)

a) **vigorous aerobic exercise** (exercises that cause you to perspire and are vigorous, such as jogging, step aerobics, rowing, cross-country skiing, biking, basketball, and swimming)

how long for each session? \_\_\_\_\_ minutes  
how many sessions per week, on average per... (✓ one)       week       month       year  
how many years? \_\_\_\_\_ years

b) **moderate aerobic exercise** (exercises that cause you to lightly perspire such as walking, dancing, biking)

how long for each session? \_\_\_\_\_ minutes  
how many sessions per week, on average per... (✓ one)       week       month       year  
how many years? \_\_\_\_\_ years

c) **strengthening exercises** (such as weight lifting)

how long for each session? \_\_\_\_\_ minutes  
how many sessions per week, on average per... (✓ one)       week       month       year  
how many years? \_\_\_\_\_ years

d) **other**      Please describe: \_\_\_\_\_

how long for each session? \_\_\_\_\_ minutes  
how many sessions per week, on average per... (✓ one)       week       month       year  
how many years? \_\_\_\_\_ years

74. Have you ever regularly done stress reduction exercises or other spiritual practices (such as yoga, tai chi, meditation)?  Yes  No (If no, go to #75)

how long for each session? \_\_\_\_\_ minutes  
how many sessions per week, on average per... (✓ one)  week  month  year  
how many years? \_\_\_\_\_ years

a) Which form of stress reduction in question #74 have you done the most? \_\_\_\_\_

75. Are you currently being treated for nervous, emotional or psychological problems in counseling or psychotherapy? (If on medication, please list below, question #76).

Yes  No (If no, go to question 76)

a) If yes, what kind (please describe) \_\_\_\_\_

b) How often do you attend therapy? \_\_\_\_\_ times per week  
\_\_\_\_\_ times per month, or other (please indicate)

\_\_\_\_\_  
\_\_\_\_\_

76. Are you currently taking any medication (include any prescribed or over-the-counter medications, nutritional supplements and herbs)?

Yes  No (If no, STOP HERE! The questionnaire is completed!) *Thank you!*

If yes, please complete the following:

Medication	Dosage	Frequency (times per day)

*Thank you for taking the time to complete this questionnaire!*

BRIDGES VIDEO SCRIPT

PICTURES ARE IN P  
D

{BRIDGES GRAPHIC}

{SUE DRUKER, PROJECT COORDINATOR, UNIV MA MEDICAL CENTER on the bottom of picture} There is growing evidence that quality of life contributes to physical well-being and that this has an impact on illness and healing. {LETTERING OFF} To look at this more closely,

we designed a study, we call BRIDGES. The name BRIDGES refers to bridges between psychological and biological aspects of healing.

{BRIDGES} BRIDGES stands for Breast Research Initiative for Determining Effective Skills. {OFF} By skills, we mean whatever strategies you might use to cope with this illness effectively. I will be telling you about the study a little later. But first, you will hear from some of the people involved in your treatment.

{SLIDE OF HOSPITAL ALONG WITH NAME WRITTEN ON BOTTOM}

Our goal at the The University of Massachusetts Medical Center is to provide as complete an approach as possible to you and the treatment of your breast cancer. This means that we want to concern ourselves with more than your medical treatment. We would like to explore the most effective ways to help you maintain a high quality of life. Since no one really knows the best ways to cope with the emotional effects of early stage breast cancer, we are taking part in a research study to explore that question and, hopefully, find some answers. The University of Massachusetts Medical Center is one of four participating hospitals in MA and RI. The study is being coordinated by the University of Massachusetts Medical Center in Worcester, MA. Besides looking at coping strategies we also

would like to look at some of the physical responses of your body during the process of coping with breast cancer. The second part of this video gives more specific information about the study. We hope you will be willing to take part in this research. Your medical treatment here at the University of Massachusetts Medical Center will be the same whether or not you decide to take part in the study. By participating in this research, you will be contributing to improving our knowledge about breast cancer treatment. No matter what you decide we want to thank you for considering this study.

Now I'm going to tell you more about our study, BRIDGES. You might be interested to know how this study received funding. Breast cancer survivors worked with Congress to make these funds available from the defense budget of the US Army. **{GOAL}**The overall goal of this study is to **{identify effective ways to cope with breast cancer}**identify effective ways to cope with breast cancer and **[add enhance quality of life}**enhance quality of life. To do this we've identified **{three approaches}**three approaches. The first one is based on an **{add 1. individual approach}**individual approach with nothing specific required. The other two **{add 2. Stress Reduction and Relaxation Program 3. Nutrition Education Program}**have specific group programs, both of which will be held at UMMC. The **{individual approach}**individual approach means you choose whatever way you think is best for you. That means you would choose your own way to cope, when to use it, and how much time you spend doing it. Or it might mean doing nothing beyond the usual

treatment which you will receive. The {stress reduction and relaxation program}second approach involves a meditation-based stress reduction program. The third approach is a {nutrition education program}nutrition education program. The {individual approach} individual approach does not have a {underneath individual approach specific time commitment}specific time commitment. The other {stress reduction and relaxation program, nutrition education program}two approaches have a significant {underneath above, approximatly 30 hours over four months} time commitment of approximately 30 hours of class time over a four-month period. {sihouette of individuals going into the three boxes}We will assign you to 1 of these 3 approaches randomly. That means that you will have a one-out-of three chance of being assigned to any one of the three approaches. { same graphic only with question marks}The reason we are doing this random assignment is that we do not know which of these approaches would be best. To answer this question, we want to look at various coping strategies and your quality of life. In order to do this, we will ask everyone in the study to fill out {questionnaires}questionnaires at home and make a brief visit to the clinic or hospital to give a {blood and urine samples}blood and urine sample. The blood and urine samples will be used to measure biological aspects related to breast cancer. These assessments will be done {four times in two years}four different times over the next two years. Also, a research staff person will contact you {graphic of someone on the phone and the word monthly}monthly over the next two years. She will speak wih you briefly by phone or in person to find out how

you are doing, what your experience is like, what is helping or not helping along the way, and when you might be having the greatest difficulty. We would be happy to answer any question you might have. Thank you for taking the time to consider this study. We hope you will decide to participate and that we can work together in this effort to find better ways to treat breast cancer.

{THANK YOU}

# BRIDGES

## Nutrition Education Program

**F**ood and nutrition may be a factor in influencing the course of breast cancer. In countries around the world, when diet and breast cancer rates are compared, those women who traditionally eat low-fat and high-fiber diets have significantly lower rates of breast cancer. People in the United States typically have a high-fat diet, and often the sources of fat in the diet are not obvious. Fat is known to be associated with high rates of many diseases including breast cancer. Also, in our studies we have found that high dietary fat may reduce the ability of the immune system to prevent cancer. Therefore, we are offering you a special nutrition education and low-fat cooking program. It will include plenty of fresh vegetables and fruits and also be high in fiber. Our hope is that this kind of diet will influence well-being while living with breast cancer.

**T**he program will be held at the University of Massachusetts Medical School (UMass) in Worcester and will consist of 14 weekly sessions, each 1-½ to 3 hours in length. There will be an additional session on a Saturday or Sunday which will last about six hours. You will be asked to do various homework cooking and nutrition assignments which will help you incorporate the program information into your daily life.

### The nutrition education program will consist of:

1. An overview of diet and health, with an emphasis on how changes in diet can affect well-being.
2. Time in the UMass demonstration kitchen to do lots of hands-on food preparation and tasting of low-fat, high-fiber foods.
3. Alternative methods of creating and enhancing flavors including the use of spices and herbs. The transition to low-fat eating also entails increased consumption of vitamins and minerals. The role of these nutrients plus various spices will be discussed.
4. The development of personal eating plans and dietary goals so that you will reduce the amount of fat in your diet to less than 20% of the calories that you eat.
5. The course also will have time for talking with the other women in the program, all of whom have breast cancer.

There is no cost to you for this program.

We will contact you regarding the schedule for the program. In the meantime, if you would like more information, you may contact:

Sarah Ellis, 856-5272 or  
Nancy Saal, 856-3607

# BRIDGES

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# MEDICAL QUESTIONNAIRE

Date: \_\_\_\_\_  
month-day-year

Study ID: \_\_\_\_\_

Name of Patient: \_\_\_\_\_  
(First) (Last)

1. Date of first positive cytology or positive biopsy?

\_\_\_\_-\_\_\_\_-\_\_\_\_  
mm dd yy

2. Radiation: Yes  No

If yes, date started:

\_\_\_\_-\_\_\_\_-\_\_\_\_  
mm dd yy

If yes, date finished:

\_\_\_\_-\_\_\_\_-\_\_\_\_  
mm dd yy

Major complications? Yes  No

If yes (explain) \_\_\_\_\_

3. Surgery: (Check one)

- Lumpectomy alone
- Lumpectomy with axillary dissection
- Mastectomy (simple)
- Mastectomy (with axillary dissection)
- Mastectomy (with immediate reconstruction)

4. Chemotherapy:

- No
- Yes (See separate sheet)

# CHEMOTHERAPY

Date: \_\_\_\_\_  
month-day-year

Study ID: \_\_\_\_\_

Name of Patient: \_\_\_\_\_  
(First) (Last)

1. Was chemotherapy administered?     No     Yes

If yes, please answer the following questions:

2. What chemotherapy regimen was used?    (Circle one; if other, please describe)

Number of cycles

- |   |   |   |             |
|---|---|---|-------------|
| <input type="checkbox"/> Cytoxan, Adriamycin, 5 FU  | 4 | 6 | other _____ |
| <input type="checkbox"/> Cytoxan, Methotrexate 5 FU | 4 | 6 | other _____ |

3. What antiemetics were used?

- Zofran
- Decadron
- Compazine
- Norzine
- Kytril
- Benadryl
- Activan

4. What was the most severe toxicity the patient experienced during any of the cycles in the following categories?    (Check 4 for highest level of toxicity)

	0	1	2	3	4
Hematologic	<input type="checkbox"/>				
Infection	<input type="checkbox"/>				
Gastrointestinal	<input type="checkbox"/>				
Alopecia	<input type="checkbox"/>				
Neurologic	<input type="checkbox"/>				
Weight Gain	<input type="checkbox"/>				
Weight Loss	<input type="checkbox"/>				

Please turn this form in when patient has completed their chemotherapy.

# PATHOLOGY REPORT

Date: \_\_\_\_\_  
month-day-year

Study ID: \_\_\_\_\_

Name of Patient: \_\_\_\_\_  
(First) (Last)

Date of surgery: \_\_\_\_\_  
month-day-year

Pathology:

**A. Histology: (Check one)**

- Infiltrating ductal
- Invasive lobular
- mixture of 1 and 2
- mucinous
- tubular
- medullary
- other(please describe)

**B. Tumor size in cm (largest size by pathology) \_\_\_\_\_ cm**

**C. Grade (if specified)**

**D. Tumor differentiation (if specified): (Check one)**

- poor
- moderate
- well

**E. Axillary nodes sampled**

- Yes
- No

If yes, Number sampled \_\_\_\_\_

Number positive \_\_\_\_\_

**F. Estrogen Receptor: (Check one)**

- Positive
- Negative

Actual value \_\_\_\_\_

**G. Progesterone Receptor: (Check one)**

- Positive
- Negative

Actual value \_\_\_\_\_

**H. Stage of breast cancer: (Check one)**

- stage 1
- stage 2
- stage 3
- stage 4

**ELIGIBILITY CRITERIA FORM**

NAME: \_\_\_\_\_ DATE: \_\_\_\_\_

Medical Record # \_\_\_\_\_ Study ID # F \_\_\_ R \_\_\_  
 U \_\_\_ M \_\_\_

IF ALL ARE YES, THEN THE PATIENT IS ELIGIBLE

	Obtain Info.	Criteria	Yes	No*
1.	R	Date of Diagnosis ___/___/___ (mm/dd/yr) Is diagnosis within one year?		
2.	R P	Age: ___ years Under 55?		
3.	R D	Stage ___ Stage 1 or 2?		
4.	R P	No prior cancer other than non-melanoma skin cancer in the past five years		
5.	R P	ECOG performance status ___ Is it 0, 1, or 2?		
6.	R	No condition that would severely limit life expectancy to under 5 years		
7.	P	No active drug or alcohol abuse		
8.	P A	No psychotic disorder		
9.	P A	No current suicidality		
10.	P A	Compos mentis or no neurological or cognitive deficit that interferes with the study involvement including taking the interventions		
11.	P A	No severe PTSD that involves chronic sexual abuse		
12.	P A	Has not already taken the SR&RP or Leo's group		
13.	P	Understand written English at the 6th grade level		
14.	P	Working telephone		
15.	P	Willing to accept randomization		
16.	P	Willing to be contacted at home for psychosocial assessments		
17.	P	Plan to maintain residence in the area during the two years following recruitment		

**KEY**

P Questioning the patient      R Checking the medical record  
 D Questioning the physician    A Needs to be assessed during the interview.

\*If no, please explain on back of form.