

Syracuse University

SURFACE

Syracuse University Honors Program Capstone
Projects

Syracuse University Honors Program Capstone
Projects

Spring 5-1-2005

Determining the Effects of Psychosocial Interventions on Quality of Life for Cancer Patients: Analysis of Pilot Data and Recommendations for Full Experimental Design and Statistical Analysis

Sarah Julia Thomas

Follow this and additional works at: https://surface.syr.edu/honors_capstone



Part of the [Harmonic Analysis and Representation Commons](#)

Recommended Citation

Thomas, Sarah Julia, "Determining the Effects of Psychosocial Interventions on Quality of Life for Cancer Patients: Analysis of Pilot Data and Recommendations for Full Experimental Design and Statistical Analysis" (2005). *Syracuse University Honors Program Capstone Projects*. 669.

https://surface.syr.edu/honors_capstone/669

This Honors Capstone Project is brought to you for free and open access by the Syracuse University Honors Program Capstone Projects at SURFACE. It has been accepted for inclusion in Syracuse University Honors Program Capstone Projects by an authorized administrator of SURFACE. For more information, please contact surface@syr.edu.

Determining the Effects of Psychosocial Interventions on Quality of Life for Cancer Patients: Analysis of Pilot Data and Recommendations for Full Experimental Design and Statistical Analysis

Introduction

Anxiety, depression, and other symptoms of psychological stress are generally observed to be increased in patients diagnosed with cancer [1-4]. Attempts to alleviate these adverse consequences to quality of life experienced by cancer patients have led to the development of various psychological and psychosocial interventions, or “wellness” programs. One popular approach is called *mindful meditation* or *mindfulness based stress reduction*; in fact, Carlson et al.(2003) reported that there were over 240 such programs in North America [3]. The successful completion of a meditation program has been associated with improvements in quality of life, as measured by multiple psychometric scales, such as the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), the Profile of Mood States (POMS), Symptoms of Stress Inventory (SOSI) [5,6]. Similar benefit has also been seen in cancer patients who participate in yoga programs or who study yoga independently [6]. Aside from meditation, yoga, and other nontraditional wellness programs, more conventional psychological counseling programs are widely offered to oncology patients. Data in the literature suggest that a variety of wellness interventions is capable of leading to stress reduction in cancer patients, even for those patients receiving chemotherapy at the time [7].

Newell et al.(2002) noted in a review of the literature that over 600 papers have been published concerning the evaluation of psychological therapies for

cancer patients [8]. The papers reviewed by Newell et al. spanned many types of psychosocial programs, such as traditional counseling, cancer education, meditation, hypnosis, and music therapy; many forms of intervention administration, such as individual sessions, group sessions, and audiotape; and a wide range of targeted effects, such as decreased stress, hostility, depression, and anxiety, or improved immune response and overall quality of life. Although each study tended to give positive reports on the benefits of psychosocial interventions for cancer patients, Newell et al. were hesitant to acknowledge most of the reports as statistically significant, due to serious methodological deficiencies (see Recommendations for Experimental Design below) in many of the studies reviewed [8]. Obviously, there is still some debate in the medical world as to the actual utility of these types of wellness programs [8,9].

The popular press has always been keen to report any news associated with cancer research, and the use of psychosocial or other nontraditional therapies is no exception [10,11]. Typically, these reports tend to focus on small numbers of individuals who have experienced miraculous results, for instance, the long-term remission of cancer thought to be incurable by physicians after the patient had practiced rigorous meditation. These media reports must be viewed as purely anecdotal and are no basis for scientific proof that psychological therapies can “cure” cancer; however, these stories can be encouraging for individuals suffering the physical and psychological effects of cancer and cancer treatments, and patients are increasingly willing to enroll in psychosocial self-help programs [10,11].

The Hematology and Oncology Specialists Foundation was established in 2001 with the mission to improve the quality of life for the patients being treated by HOS physicians, and to provide the services for this purpose at no cost to the patient. Current services include: a mindful meditation group program, a yoga group program, personal psychological counseling, financial counseling and assistance, nutritional counseling, lymph edema management, and genetic counseling. See page A2 for full descriptions of these wellness programs. Since the inception of the HOS Foundation, 351 cancer patients have participated in one of the available wellness programs, and each year, the Foundation continues to increase its budget for these programs. The HOS Foundation has found that patients report considerable improvement in well-being after participating in every one of the available wellness interventions, and that evidence of improvement in quality of life can be observed with proper psychometric instruments. In light of these encouraging signs, the HOS Foundation now seeks to evaluate the effect of the Foundation's psychosocial intervention programs on the quality of life of HOS patients in an objective, scientific manner [12].

Study Objectives

The goal of this pilot study by the HOS Foundation is to collect some exploratory data from the patients currently participating in the wellness intervention programs offered by the Foundation; this data will hopefully support the hypothesis that participation in these programs helps to improve the overall quality of life experienced by cancer patients. The ultimate goal for the HOS

Foundation is to publish the results of a large-scale study of the benefits of the wellness intervention programs in a prestigious oncology journal. The HOS Foundation will have to seek financial support outside its own resources in order to fund a large-scale implementation of these wellness programs, to complete a comprehensive study of the effects of the programs, and to subsequently publish an article with the results of the study [12]. Pilot data are useful when designing an experiment because the parameters of the sample, such as mean and standard deviation, can be used as estimates for the true population parameters. Most notably, these estimates can be used to determine the ideal sample size for the full-scale experiment, without having to actually sample a large number of patients. The results from the exploratory data can then be included in proposals to obtain the necessary financial assistance.

In the initial study protocols developed by the Foundation for the Yoga, Meditation, and Counseling Interventions, the primary endpoint is identified as determining the overall change in quality of life by using the EORTC QLQ-C30. Some secondary endpoints are to determine the overall change in emotional well-being by using the Beck Anxiety Inventory (BAI) and Beck Depression Inventory (BDI-II) questionnaires, to evaluate the effectiveness of the wellness programs by using an internally developed patient survey, to identify the primary reasons why cancer patients seek participation in wellness programs, and to identify the impact of intervention on medical treatment for cancer, compared to planned treatment duration. The Foundation is interested in determining the mean percent change in

quality of life and emotional well-being for the entire patient sample and for the sample stratified by disease state.

Pilot Data

The data collected in this pilot study are the sole property of the HOS Foundation and are intended for internal use only. The author's access to this data is allowed only in the capacity as a statistical advisor for the HOS Foundation; therefore, the actual data set cannot be included with this paper. Relevant descriptive statistics and statistical analyses are summarized below.

Eleven patients completed Beck Stress Related Symptoms (BSRS) surveys both prior to participation in, and after completion of, an eight-week mindful meditation program offered by the HOS Foundation. The mean score prior to participation (BSRS pre-score) was 112.7, with a standard deviation of 43.7. The mean score after completion of the program (BSRS post-score) was 85.4, with a standard deviation of 33.5. The variable BSRS change, defined as BSRS pre-score minus BSRS post-score, has a mean of 27.4 and a standard deviation of 33.7.

Six patients completed BAI and BDI-II questionnaires both prior to participation in, and after completing a twelve-week counseling program offered by the Foundation. The mean BAI pre-score was 25.17, with a standard deviation of 12.12; the mean BAI post-score was 9.33, with a standard deviation of 6.62. The variable BAI change, defined as BAI pre-score minus BAI post-score, has a mean of 15.83 and standard deviation of 7.28. The mean BDI-II pre-score was

18.67, with a standard deviation of 6.59. The mean BDI-II post-score was 7.67, with a standard deviation of 6.31, and the variable BDI-II change, defined as BDI-II pre-score minus BDI-II post-score, has a mean of 11.0 and a standard deviation of 3.1. See page B1 for summary charts of descriptive statistics.

Analysis

All statistical analyses for this study were conducted with Minitab® Release 14 Statistical Software for Windows. The significance level (α) used throughout this paper is $\alpha = 0.05$.

Results

To test whether or not participation in the meditation program had an effect on BSRS scores, a one-sample t-test was used to test if the BSRS change variable is significantly different from zero. The researchers are interested in showing whether participation in these wellness program provides a benefit to patients, so in this case, it is logical to conduct a one-tailed t-test to test the alternate hypothesis that the mean of the BSRS change score is greater than zero. The t-score for this test is $t = 2.70$ ($p = 0.011$). Thus, the null hypothesis that the mean BSRS change is equal to or less than zero can be rejected, and it can be concluded that the true BSRS change mean is significantly greater than zero. A post hoc power analysis revealed that this one-tailed test has a power of 0.806 to detect a difference of 27.4, assuming a standard deviation of 33.7 and using a sample size of 11. This is a surprisingly high power for a small sample size.

Therefore, it is reasonable to conclude that participation in the meditation intervention decreased the patients' scores on the BSRS survey.

The same procedure can be used to test if the BAI change and BDI-II change scores are significantly greater than zero for the counseling intervention program; again, a one-tailed test was used in each instance. The t-score to test whether BAI change is greater than zero is $t = 5.33$ ($p = 0.002$); therefore, the null hypothesis that BAI change is equal to or less than zero can be rejected. A post hoc power analysis revealed a power of 0.997, which of course is very high. The t-score to test if BDI-II change is greater than zero is $t = 8.70$ ($p < 0.001$), so again, the null hypothesis that BDI-II change is equal to or less than zero can be safely rejected. A power analysis revealed an extremely high power > 0.999 . Thus, it is quite reasonable to conclude that participation in the counseling program reduced patients' scores on the BAI and BDI-II questionnaires. See page B1 for a summary of hypotheses tests.

The researchers should also be interested to see if the pilot data show any differences between effectiveness of the wellness interventions, as this is one of the questions they want to explore in the full-scale study. Unfortunately, for this pilot study, the two groups of patients completed different psychometric surveys, thus making it difficult to make any comparisons. Notice that patients enrolled in the meditation program improved their BSRS scores by an average of 24.3%, and that patients enrolled in the counseling program improved their BAI scored by an average of 62.8% and BDI-II scores by an average of 58.9%. However, comparing the mean percent changes in psychometric survey scores between

groups would not be very meaningful, as one survey measured stress levels, one measured anxiety levels, and the other measured depression levels.

Recommendations for Experimental Design

There are several methodological deficiencies evident regarding the original study schemas and the collection of the pilot data. The most glaring fault is the small size of the samples; the researchers were very fortunate to have obtained any significant results from such a small sample. In order to assure that a large-scale study will also yield significant results, if in fact the results truly *should* be significant, the sample size needs to be considered carefully.

Determining the appropriate sample size for a one-sample t-test is fairly straightforward; all the researchers need to do is decide how much of a decrease in stress or anxiety or depression scores is *medically* significant, and, given an estimate of variability within the population, a power analysis will give the sample size necessary for the same decrease to be *statistically* significant as well. However, when trying to determine the appropriate sample sizes for more complicated statistical procedures such as ANOVA, several other serious methodological problems become evident. See page B2 for tables of powers and sample sizes for one-tailed one-sample t-tests. See pages B3-B4 for a discussion on interpreting the meaning of power.

There was unnecessary and counterproductive variation regarding the administration of the different treatments and psychometric tools used in the pilot study. The patients in the meditation group and the patients in the counseling

group completed *different* sets of psychometric questionnaires; therefore, it was impossible to compare the change in quality of life between the two groups. The researchers are interested in whether meditation, yoga, or some other type of nontraditional therapy improves the quality of life for cancer patients to a different degree than a traditional psychological counseling program. In order to do this, the same measurement tool must be used for all treatment groups. If participation in these wellness programs really does have an effect on quality of life, then the data will show this, no matter which set of psychometric surveys is employed, for each of these surveys is widely accepted in psychological and medical research to be a credible and accurate indicator of psychological states.

Also, the pilot schema called for a 12-week program that met once a week for counseling and yoga, while the meditation program met twice a week for 8 weeks. In order to compare the effects of one program with the effects of another, it is important for the administration of treatments to be as homogenous as possible. For example, if participation in the meditation group results in a greater reduction in stress, it is possible that the full effect is not a result of the meditation itself, but that *any* intervention program that met *twice* a week versus once a week would have an effect similar to the meditation program. When setting up a scientific experiment that is intended to show the effect of one variable on another, it is very important to control and standardize all the other factors that may also have an effect on the response variable. Factors that cannot be completely controlled must either be completely randomized, or measured and tested for any effects on the response variable, as in the instance of covariates.

Finally, Newell et al.(2002) noted that a very important consideration absent from many studies of this nature is the inclusion of a control group [8]. It is important to have a control group to account for any natural time trends, for it is reasonable to expect that patients not participating in any intervention programs may experience some change in their mood or stress levels over a period of time. Comparing a measure such as the mean BAI change over a period of time for an intervention group to the mean BAI change for a control group will indicate whether participation in an intervention has a different effect on quality of life than non-participation over the same time period.

The easiest way to implement a control group for this type of study, where the patients constitute a convenience sample, is to create a randomized wait-list control group. In this instance, because there were three different planned treatments, the control group could be created in the following manner: take the group of patients who want to enroll in meditation practice and randomly assign 3/4 to the meditation group and 1/4 to the wait-list group; take the group of patients who want to enroll in yoga practice and randomly assign 3/4 to the yoga group and 1/4 to the wait-list group; similarly, take the patients who want to enroll in counseling and randomly assign 3/4 to the counseling group and 1/4 to the wait-list group. Thus, there will be a total of 4 groups: 3 treatment groups and 1 control group. Patients should be randomly distributed in terms of demographic variables such as age or type of cancer. See page A3 for a copy of the memo sent to the researchers at the HOS Foundation by the author, concerning these recommendations.

Revised Experimental Design

Based on the considerations presented above, the HOS Foundation has developed a revised study protocol. The relevant details of the new protocol are summarized below, along with additional discussion of the revised protocol.

The primary goal of the revised study will be to determine the effectiveness of each of the intervention programs in improving the patients' quality of life. Secondary objectives will be to determine the effectiveness of each intervention program versus the others, to determine whether the effectiveness of intervention programs differs for patients receiving adjuvant or non-adjuvant chemotherapy (patients with early stage cancer or late-stage cancer), and to determine if any other correlations exist between demographic or clinical parameters and the effect of participation in intervention programs on patients' quality of life.

The patient population consists of consecutive patients due to begin their prescribed chemotherapy and/or radiation therapy regimen after a diagnosis of cancer. Prior to beginning therapy, patients will be given an information packet describing the wellness intervention programs available from the HOS Foundation and the plans to evaluate these programs in a scientific study. All patients will have the option to participate in either the meditation group program or the yoga group program. Certain patients may be referred for psychological counseling by their physician, oncology nurse, or social worker, or self-referred for symptoms of psychological distress. Patients suffering from clinically evident

lymph edema may be referred for lymph edema therapy by their physician or oncology nurse. Patients may choose not to participate in any intervention if that is their wish. All patients, including those who do not wish to participate in an intervention program, will be asked to consent to participating in this study. It is the patient's right to refuse participation in the study without compromising the quality of treatments they will receive from the HOS Foundation or HOS physicians.

The HOS Foundation originally wanted to include financial counseling as a group in this study; however, the author will advise against this. Patients typically meet with a financial counselor for only one or a few sessions, not for six or 12 weeks, as the yoga, meditation, and personal counseling programs do. Also, the number of patients enrolled in the financial counseling program is much smaller than the number of patients participating in the yoga, meditation and personal counseling groups. These were two reasons why the HOS Foundation had previously decided to exclude nutritional counseling and genetic counseling from the study. Lymph edema management can be reasonably included in this study because lymph edema treatments, although based on individual patient need, are likely to last for at least six weeks, and probably for a long as the full 12-week length of the study. In addition to recruiting patients for the study who do not wish to participate in an intervention, the researchers will take the author's advise and create a wait-list control group consisting of patients who are interested in participating in either the meditation or yoga programs.

Thus, patients who consent to the study will be divided into the following treatment groups: (1) non-participation group: patients who do not want to participate in a wellness program; (2) wait-list group: patients who want to participate in either the meditation or yoga programs, who have been randomly assigned to the wait-list control group; (3) meditation group: patients who want to participate in the meditation program and have been randomly assigned to begin the program immediately; (4) yoga group: patients who want to participate in the yoga program and have been randomly assigned to begin the program immediately; (5) personal counseling group: patients who have been referred for psychological counseling; (6) lymph edema group: patients who have been referred for lymph edema treatment.

All patients participating in the study will be asked to complete the QLQ-C30 psychometric survey at three time points: just prior to beginning an intervention, six weeks after beginning the wellness intervention, and 12 weeks after beginning the wellness intervention. One exception is that the wait-list group will complete the surveys at time 1, then begin the wellness program of their choice at time 2 (six weeks later), and then continue to complete the psychometric surveys at the regular time intervals, as it is felt that 12 weeks would be too long for patients to wait to begin an intervention. In addition, the personal counseling group will complete BAI and BDI-II questionnaires at each time point, in order for therapists to monitor the anxiety and depression levels of their patients more closely. Patients referred for lymph edema management will be continuously monitored by circumferential limb measurements, as is standard

for this type of therapy. At any time, patients assigned to the non-participation or wait-list groups may immediately begin the appropriate intervention program if, in the opinion of the HOS staff, they would be harmed by undue delay. These patients should continue to complete the psychological questionnaires at the regular intervals, and, if possible, these data can be incorporated into the study. Clinical and demographic data will be obtained for each patient, according to HIPPA guidelines, and with patient consent.

The EORTC QLQ-C30 was chosen as the main psychometric instrument for this study because it is widely accepted in oncology literature to be the “gold standard” of quality of life measurements for cancer patients [7,12,13]. The QLQ-C30 was developed by the European Organization for Research and Treatment of Cancer in order to specifically measure the global health status and overall quality of life (QoL), as well as several “functional scales” (e.g. social functioning, physical functioning), and several common symptoms of cancer and cancer therapies (e.g. fatigue, nausea); several supplementary modules are also available to measure symptoms associated with specific types of cancer (e.g. breast cancer, lung cancer). The QLQ-C30 questionnaire is a popular choice for chemotherapy studies because of its efficiency; the questionnaire is only 30 questions long, and yet it provides several different measurements of quality of life for cancer patients. The QLQ-C30 has undergone extensive evaluation for internal validity reliability and is now in its 3rd version [5]. A higher number for global QoL and functional scales indicates a higher(better) level of QoL or functioning, while a higher number for symptoms scales represents a

higher(worse) level of symptoms. See pages A5-A8 for a specimen of the QLQ-C30 questionnaire and scoring instructions.

Recommendations for Statistical Analysis

Unfortunately, the small amount of pilot data collected for this study did not allow for a very sophisticated statistical analysis. In a study such as this, where there are several levels of treatments being tested simultaneously on a population defined by many characteristics, there are many types of statistical tools available to researchers. If the researchers can properly collect the data from the full-scale study, the statistical analysis should be quite interesting. Consider the data set on page B7; this is a completely fictitious data set which will merely serve as an example to illustrate the kinds of data and statistical procedures that may be appropriate to analyze when the study is complete. See page B6 for the definitions of the variables used in the data set. The following guideline for the statistical analysis for this study will focus on comparing the effectiveness of the different treatment groups by comparing the patients' scores on the EORTC QLQ-C30. Evaluation of the BAI and BDI-II scores collected from the counseling group and the limb measurements from the lymph edema therapy group would be analogous to the analysis done for the pilot data (one-sample, one-tailed t-tests).

The first step in any statistical analysis is always straightforward: describe the characteristics of the samples by calculating several univariate descriptive statistics, such as mean, median, variance, range etc. In this case, the researchers

will want to describe the demographic and clinical parameters of the patient samples, both overall, for each treatment group, and for each type of chemotherapy. The researchers will also want to summarize the scores from the QLQ-C30 at each time point, both overall, for each treatment group, and for each type of chemotherapy. The final part of this descriptive analysis should be to define “percent change” variables, for example, $\% \Delta \text{QoL}(2-1) = (\text{QoL}_2 - \text{QoL}_1) / \text{QoL}_1$ is the percent change in quality of life from week 0 to week 6, and $\% \Delta \text{SF}(3-1) = (\text{SF}_3 - \text{SF}_1) / \text{SF}_1$ is the percent change in social functioning from week 0 to week 12. Reporting the patients’ changes in quality of life in terms of percent change, rather than absolute change, will show the patients’ improvement relative to their initial QoL score before beginning an intervention. This will be a more appropriate measure of improvement because patients will begin the study with widely varied QoL scores. The researchers may decide to analyze all sub-scores from the QLQ-C30 (see page A8), or choose specific items to evaluate, for example, testing improvement in functional scales, but not for physical symptoms. Either way, the procedure for analyzing each sub-score will be exactly the same.

The next step should be to analyze the data to test the researchers’ hypothesis that participation in a wellness intervention programs improves the quality of life for cancer patients. Usually, in medical or psychological studies, statistical results are reported in terms of t-tests, regression equations, or ANOVA tables. A one-sample t-test will show whether a sample’s mean is significantly different from zero, a two-sample t-test will show whether the means of two

different groups are significantly different from each other, and an ANOVA table will show whether the means of several groups are significantly different.

Regression analysis can give a formula for predicting the value of one variable based on the value of other variables.

These statistical tests are easy to evaluate and report; if the p-value associated with the test statistic (either t or F) is less than the α -level, then the null hypothesis, that the means are all equal or equal to zero, can be rejected. However, to actually compute all these tests individually is inefficient. The ANOVA table is not difficult to compute, and a significant F statistic indicates that various two sample t-tests may further illuminate exactly which of the means of the treatment groups are actually different from each other. However, selecting the pairings for the tests and partitioning the data into the appropriate groups for each test is extremely tedious. Regression analysis can also be laborious at times. For example, the QoL scores can be regressed against variables such as age, sex, race, cancer, chemo, etc. if the categorical variables are first modified by a process known as coding dummy variables. A dummy variable takes the value one if the experimental unit exhibits that property, it takes the value zero otherwise. For instance, the variable “sex” can be renamed “female”, and instead of a column of Fs and Ms, the column will contain 1s and 0s. A much more efficient and elegant method for computing the exact same regression coefficients, F statistics, and t statistics as these separate procedures above is to evaluate a general linear statistical model (GLM).

The researchers are interested in the effects of each wellness program on the quality of life for the patients, but they are also interested to see if patients receiving adjuvant or non-adjuvant chemotherapy differ in their response to the wellness interventions. There are six different types of interventions (four wellness programs and two “control” groups), and there are two levels of chemotherapy; thus, the experimental design for this study is a 6×2 factorial design. However, there are also several variables which may also influence the patients’ quality of life measurements; the demographic and clinical variables to be recorded for each patient are: sex (male or female), age (≤ 50 years old or > 50 years old), race (Asian, Black, Hispanic, White etc.) and type of cancer (breast, colon, leukemia, lung, ovarian, prostate etc.). These variables should be included in the linear model as covariates. Thus the GLM is:

$$y_{ijk} = \mu + \beta_1(\text{sex}_k) + \beta_2(\text{age}_k) + \beta_3(\text{race}_k) + \beta_4(\text{cancer}_k) + \text{trtmnt}_i + \text{chemo}_j \\ + (\text{trtmnt}*\text{chemo})_{ij} + e_{ijk}; i = 1 \text{ to } 6; j = 1 \text{ to } 2; k = 1 \text{ to } n_k.$$

Where y_{ijk} is the psychometric survey score (QoL, PF, EF etc.) for the k th patient in the i th treatment group with the j th type of chemotherapy; μ is the grand mean of survey scores for the entire patient sample; β_1 is the coefficient of linear regression of y on the variable sex; β_2 is the regression coefficient of y on age; β_3 is the regression coefficient of y on race; β_4 is the regression coefficient of y on cancer; trtmnt_i is the fixed effect of treatment i ; chemo_j is the fixed effect of chemotherapy type j ; $(\text{trtmnt}*\text{chemo})_{ij}$ is the interaction effect between treatment i and chemotherapy type j ; and e_{ijk} is the experimental error.

In a model such as this, where the covariates are categorical variables, it may be helpful to think of them as different blocks and the effects that they produce on y as blocking effects; however, keep in mind that determining the regression coefficients will still be an important part of the analysis. The researchers should pre-determine the linear contrasts, such as ‘non-participation vs. others’ or ‘non-traditional therapies vs. psychological counseling’, they wish to estimate and test. An ANCOVA (Analysis of Covariance) of this model with the planned linear contrasts and solutions will automatically calculate all the F statistics, t statistics, and regression coefficients of interest. The F statistic for each β_r will show whether there is any significant correlation between survey scores and the demographic and clinical variables. A two-way ANOVA of the response variable by the two factors of treatment and chemotherapy type is automatically imbedded in the ANCOVA. The F-scores from the ANOVA will show whether there are any significant effects from the different treatments, from the two types of chemotherapy, or from any interaction between treatment and chemotherapy type. The tests of linear contrasts calculate the t-scores for the differences between the various groupings of patients as decided by the researchers. This ANCOVA procedure will give the same results as computing separate ANOVA tables, t-tests, and regression analysis, but it is much more efficient, especially with one of the many powerful statistical computing packages available.

The same model can be applied with the response variable defined as one of the “change” variables; in general terms, $y_{ijk} = (q_{ijk}^{(b)} - q_{ijk}^{(a)})/q_{ijk}^{(a)}$. The

ANCOVA for this model will show whether there are any significant regression coefficients. The automatic ANOVA will show whether there are significant differences in the percent change in quality of life experienced by the cancer patients in the different treatment and chemotherapy groups. Finally, the linear contrasts will show whether there is any difference in the percent change in quality of life between specific groups of patients.

Finally, the researchers should use an a priori power analysis to estimate the number of patients to recruit for this study. Recall the discussion of power from above (see page B3 for a further discussion). The researchers need to decide how much of an improvement in quality of life scores represents a significant medical or psychological improvement: 10%, 20%, etc. Then, using an estimate of the population variance, they can determine an estimate for the ideal sample size for each treatment group and overall. Unfortunately, at the time this paper was written, the author did not have such an estimate of variation in order to conduct the a priori power analysis because the researchers did not use the EORTC QLQ-C30 to collect any of the pilot data.

The researchers have two options: either collect more pilot data using the same psychometric instrument that they intend to use for the full-scale study, or search the relevant literature for a study that used the QLQ-C30 questionnaire on a similar population of patients and use the sample standard deviation reported in another study as an estimate of the population standard deviation. There are advantages and disadvantages for each option. Reviewing the literature would be less time consuming, but there is no guarantee that a suitable estimate of

population variance can be found. Collecting more pilot data would be more costly, but the researchers could be more confident that the estimate of the variance calculated would be more accurate for the present patient population.

The researchers should also be aware that some patients who begin the study may drop out before the study is complete. Patients may be lost to follow-up due to becoming too ill to participate in the programs or death. Patients may also simply drop out of the program for personal reasons, such as moving out of the area or are not enjoying the programs offered. In order to have a large enough sample for a powerful statistical analysis, the researchers should take these factors into consideration and overestimate the initial patient sample size to ensure that enough patients will complete the study.

Conclusion

The HOS Foundation strives to provide the best possible services for HOS patients, and an integral part of these services are several psychosocial interventions, or “wellness programs,” aimed at helping cancer patients to cope with the physical and psychological stresses of their disease. Non-traditional cancer therapies are becoming increasingly popular among patients, and research on the effects of these therapies features prominently in oncology literature. The HOS Foundation plans to evaluate the effectiveness of their wellness programs in a scientific study and later publish an article with the results of this study.

HOS Foundation first conducted a pilot study to collect some exploratory data. The pilot data showed that participation in a meditation program

significantly reduced the symptoms of stress experienced by the patients ($t = 2.70$, $p = 0.011$), and that participation in psychological counseling significantly reduced the anxiety and depression levels of the patients ($t = 5.33$, $p = 0.002$; $t = 8.70$, $p < 0.001$, respectively). Based on the results of the pilot data, assessment of the original study protocol, and a review of the relevant psycho-oncology literature, the author has developed an extensive guideline for the experimental design and statistical analysis for the full-scale study.

The HOS researchers are interested in determining the effects of six different treatment groups: non-participation, wait-list, yoga, meditation, psychological counseling, and lymph edema therapy, and two different types of chemotherapy: adjuvant and non-adjuvant, on the quality of life experienced by the HOS patients. Thus, the design for this experiment is a 6×2 factorial design, with several possible covariates: age, cancer diagnosis, race, and sex. Researchers should use an ANCOVA and ANOVA with planned linear contrasts to test the general hypothesis that participation in an intervention increases the quality of life experienced by the patients. Evaluation of a GLM will yield the same test statistics (F-scores, t-scores, and regression coefficients) as are commonly reported in medical and psychological journals; however, this procedure is much more efficient than performing many separate calculations.

This study will be an important contribution to the body of oncology literature. Many studies have reported on the benefits of various non-traditional cancer therapies; however, no study has yet to compare the effects of these types of wellness interventions to those of traditional psychological counseling.

References

1. Deogratias LR, Morrow GR, Fetting J. The prevalence of psychiatric disorders among cancer patients. *JAMA* 1983; 249:751-7.
2. Zabora JR, Blanchard CG, et al. Prevalence of psychological distress among cancer patients across the disease continuum. *J Psychosoc Oncol* 1997; 15:73-86.
3. Carlson LE, Speca M, et al. Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. *Psychosom Med* 2003; 65:571-81.
4. Norton TR, Manne SL, et al. Prevalence and predictors of psychological distress among women with ovarian cancer. *J Clin Oncol* 2004; 22:916-26.
5. Aaronson NK, Ahmedzai S, et al. The European Organization for Research and Treatment of Cancer QLQC30: A quality-of-life instrument for use in international trials in oncology. *J Nat Cancer Inst* 1993; 85:365-76.
6. Carlson LE, Ursuliak Z, et al. The effect of mindfulness based stress reduction on mood and symptoms of stress in cancer outpatients: 6 month follow-up. *Support Care Cancer* 2001; 9:112-23.
7. Cunningham AS, Philips C, et al. Fighting for life: A qualitative analysis of the process of psychotherapy assisted self-help in patients with metastatic cancer. *Integrative Cancer Therapies* 2002; 1:146-61.
8. Newell SA, Sanson-Fisher RW, et al. Systematic review of psychological therapies for cancer patients: overview and recommendations for future research. *J Nat Cancer Inst* 2002; 94:558-84.
9. Fox BH. The role of psychological factors in cancer incidence and prognosis. *Oncology* 1995; 9:245-53.
10. Cassileth BR, Chapman CC. Alternative and complementary cancer therapies. *Cancer* 1998; 77:1026-34.
11. Ernst E, Cassileth BR. The prevalence of complementary/alternative medicine in cancer: a systematic review. *Cancer* 1998; 83:777-82.
12. Thomas LC. Protocol: Evaluation of the effect on quality of life by various interventions provided by HOS Foundation to patients with cancer.
13. Speca M, Carlson LE, et al. A randomized, wait-list controlled clinical trial: The effect of a mindfulness meditation based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosom Med* 2000; 62:613-22.
14. Kuehl RO. Design of experiments: statistical principles of research design and analysis, 2nd ed. Pacific Grove: Duxbury Press, 2000.
15. Larsen RJ and Marx ML. An introduction to mathematical statistics and its applications, 3rd ed. Upper Saddle river, NJ: Prentice Hall, 2001.