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Title: Control & Illness: Blessing or Curse – Sense of Control, Modes of Control, and Quality of Life of Patients with Chronic Diseases

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Overall Significance/Relevance – Technological/scientific advances in medicine have resulted in the lengthening of human life. One result of this increase in life expectancy is a rise in the number of people living with various chronic diseases. This study seeks to examine issues related to quality of life among individuals living and coping with various chronic illnesses, specifically examining the role of sense of control in quality of life.

Does Study Test the Multidimensional Aspects of Control Theory & Research -- It appears the study does address aspects of control theory through its use of the Shapiro Control Inventory.

Methodology – The author appears to be proposing two separate studies although this is somewhat unclear (see below). The application refers first to a “Study 1” that seeks to understand whether sense of control and modes of control are associated with quality of life. A second study, “Study 2,” is then described as consisting of two stages. The first stage involves examining the relative influence of control variables on quality of life, 2-3 months after breast cancer diagnosis. In Stage 2 of this second study, the applicant states that “the analysis that was conducted in Study 1 will be enlarged to include two additional illnesses – breast cancer and diabetes,” representative of chronic illnesses of “harsh,” and “mild” severity respectively. The stated hypothesis here is that the importance of control will be more evident in diseases of greater severity.

Overall Comments/Suggestions –

1. There needs to be some significant clarification regarding how patients are to be recruited. For example, it would appear that these 500 plus patients may have already been recruited, possibly as part of another study although again this needs to be spelled out to determine the overall feasibility and design of the study). As another example, it states that Study 2 will be recruiting breast cancer patients before and after diagnosis but no details are provided regarding how many patients or how these women will be recruited.
2. The applicant states that Study 1 has already been completed. In the proposal, results are then reported for 143 heart disease patients, which suggest that control is associated with quality of life. It would appear from the analyses that the associations between control and quality of life are independent of other variables (such as physical/emotional functioning) although this is not entirely clear from the proposal.
3. It is also not clear from the proposal exactly what will be occurring in Study 2 (both stages), specifically whether this study represents a secondary analysis of data already collected (from Study 1) that will be focusing on specific illnesses of varying severity.

Introduction

As a result of the progress in the field of medicine over the last hundred years, human life expectancy has increased. Today, many people live with diseases that, until recently, used to cause death. This suggests the question: how does the lengthening of the human life span, affect the welfare of the individual?

One of the common variables that is often researched today is that of quality of life. The purpose of this research is to assess the extent to which personal characteristics such as sense of control and modes of control affect the quality of life of people who suffer from chronic diseases. The research is based on Shapiro's model of control (1994) which suggests a number of dimensions of the control variable: these include the sense of control and various modes of control, both positive and negative. In addition to examining the association between modes of control, sense of control and quality of life, the study will also examine the severity of the disease in subjective terms (the person's perception of the severity of the disease) as well as objective terms (medical variables) and the association of these variables to control variables and quality of life.

The research project includes two sections. The central hypothesis of Study No. 1 is that an association does exist between sense of control, modes of control and quality of life even if other variables that are known as contribute to quality of life are taking into consideration.

Study No. 2 will include two stages. In the first stage, prospective research will be conducted among women before and after the diagnosis of breast cancer, the purpose of which is to check the influence of control variables (sense and modes of control) on quality of life about two or three months after the diagnosis. In the second stage, the analysis that was conducted in study No. 1 will be enlarged to include two

additional chronic illnesses: breast cancer and diabetes, which were selected as representative of illnesses of harsh and mild severity, respectively. The severity of each disease will be evaluated within the category of the disease itself, and in relationship to all the diseases as a whole. The central hypothesis of this stage is that the more the disease is perceived as severe or harsh, the more important is the variable of control to the quality of life.

The project is intended to broaden the theoretical knowledge that relates to the connection between control and quality of life while enlarging Shapiro's model (1994).

Method

Participants of the study are men and women from the Southern (Negev) region in Israel who were referred to the Soroka University Hospital in Beer Sheva. The proposed research will include a research group (N= ~ 550) of people who suffer from chronic diseases: heart conditions (n=143), breast cancer (n=100) diabetes (n=200) and a control group of 100 healthy people (adjusted according to gender, age, education and family status). The diseases were selected according to an earlier study conducted among healthy population, as to which diseases represent or exemplify severe disease (cancer), disease of moderate severity (heart condition), and relatively mild chronic disease (diabetes). The participants will be administered the questionnaires at the hospital. All participants will sign an informed consent and be explained the purpose of the study. The relevant variables will be determined according to reliable and valid questionnaires (SCI - Shapiro Control Inventory, SF-12, Subjective QoL questionnaire- WHOQOL- BREF). In addition, the participants will fill out questionnaires created specifically for the study: a demographic questionnaire and a questionnaire to assess the severity of the disease in subjective

terms. The objective severity of the illness will be assessed by a medical physician specialist in the field.

In study No.1 Two sets of analyses were carried out. In the first set, Pearson correlations (for the continuous variables) and ANOVA (for the dichotomous variables) were carried out examining the relationships between the demographic variables, control variables and QoL in the different domains. In the second set, a hierarchical multiple regression analysis was conducted in order to determine the extent to which each set of independent variables contributed to the prediction of QoL.

Results

The initial results from a sample of people who suffer from heart disease (n=143) support this hypothesis and demonstrate that sense of control is linked to all realms of quality of life. This association transcends the severity of the disease (objective as well as subjective), level of functioning (physical and emotional) and the specific sense of control over the disease. The positive modes of control (positive assertive and positive yielding) are also found to be tied to various aspects of quality of life.

The study is unique in its prospective design and intends to expand the knowledge in the psychosocial field of chronic disease. The prospective nature of the proposed study will add information as to causality, broaden and verify the control model. The results will permit recommendations as to more effective interventions for people who suffer from chronic diseases and thus allow them to improve their quality of life.

Finances

Photocopies of questionnaires	\$250
Data entry	\$200
Statistical analysis	\$400
Miscellaneous	\$150

Grand Total: \$1000

Rock

Dear John,

First of all I would like to apologize for the delay in answering your mail, it is because I delivered my first son a few weeks ago and I took a break from my study.

Regarding the review's overall comments/ suggestions:

The present study is my PhD study, which I divided into two sections/studies for practical reasons, so it will be easier for me to explain all the steps in the study. The central hypothesis of Study No. 1 is that an association does exist between sense of control, modes of control and quality of life even if other variables that are known as contribute to quality of life are taken into consideration. This study contains a sample of 143 patients who suffer from heart disease, which I recruited from the Cardiology Division of "Soroka" University Medical Center, Beer Sheva, Israel. The results of this study support the study's hypothesis and demonstrate that sense of control is linked to all realms of quality of life. This association transcends the severity of the disease (objective as well as subjective), level of functioning (physical and emotional) and the specific sense of control over the disease. The positive modes of control (positive assertive and positive yielding) are also found to be tied to various aspects of quality of life.

Study No. 2 is running these days (and for this portion I'm asking the help in funding it from your control trust) and will include two stages. In the first stage, prospective research is conducted among women before and after the diagnosis of breast cancer, the purpose of this is to check the influence of control variables (sense and modes of control) on quality of life about two or three months after the diagnosis. Participants of the study are women from the Southern (Negev) region in Israel who arrive to the Breast Health Center in the "Soroka" University Medical Center - Beer-Sheva, in order to do a routine breast examination with no history of prior cancer and/or chronic disease. All women that receive a diagnosis of cancer will be invited to participate in the follow-up. It is estimated that about at least 50 women will be eligible for this group. A control group of 50 women whose diagnosis is negative will be asked to participate (Group means will be matched as to gender, age, education (years completed) and marital status). Medical data will be obtained from the patients' records.

The physician contacts the patients, and asks them to participate in the study. It is emphasized that participation is strictly voluntarily and that the participant can change her mind at any stage. All participants are signing an informed consent and receive an explanation about the purpose of the study.

In the second stage of study No. 2, the analysis that was conducted in study No. 1 will be enlarged to include two additional chronic illnesses: breast cancer and diabetes which were selected as representative of illnesses of harsh and mild severity, respectively. Participants with diabetes (~n=200) are patients who arrive to the "Soroka" University Medical Center - Beer-Sheva, in order to do a routine follow up concerning their disease. The severity of each disease will be evaluated within the category of the disease itself, and in relationship to all the diseases as a whole. The central hypothesis of this stage is that the more the disease is perceived as severe or harsh, the more important is the variable of control to the quality of life.