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PRINCIPAL INVESTIGATOR: Katherine DuHamel, Ph.D.

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
New York, New York 10029

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Katherine DuHamel, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Mount Sinai School of Medicine
New York, New York 10029

E-Mail: Katherine.duhamel@mssm.edu

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The goal of this study is to improve the management of pain related to metastatic breast cancer (MBC) through psycho-social intervention. Although clinical guidelines for the treatment of MBC pain have been issued, under-treatment of pain remains a problem. This study builds upon prior research which has identified poor patient-provider communication as a key barrier to adequate cancer pain management. This study is the first application of a pain skills communication intervention to reduce pain and increase quality of life in MBC patients. MBC patients are being randomly assigned to either a pain knowledge and communication skills training or a nutrition education. To determine the effectiveness of the pain and communication skills intervention, patients receiving this treatment will be compared with those receiving nutrition education on standardized measures of pain, psychological adjustment, and quality of life. Patients participate in four interviews: prior to the intervention, post-intervention and at 1 and 3 month follow-ups. To date, nineteen patients have been recruited. The study results will provide evidence of the efficacy of a pain communication skills intervention in reducing pain and psychological distress, and increasing quality of life in MBC patients.

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INTRODUCTION

The goal of the proposed study is to improve the management of pain related to metastatic breast cancer through psycho-social intervention. Pain is a common and highly debilitating symptom for persons with metastatic breast cancer. Indeed, 60% to 90% of these patients report pain that interferes with their mood (makes them depressed, nervous), as well as their ability to sleep, work, and function sexually. Pain makes it difficult for these patients to enjoy life. Although clinical guidelines for the treatment of metastatic breast cancer pain have been recently issued, under-treatment of pain remains a persistent problem. The proposed study builds upon prior research which has identified poor patient-provider communication as being one of the key barriers to adequate cancer pain management. This study is the first application of a pain skills communication intervention to reduce pain and increase quality of life in metastatic breast cancer patients. The proposed research seeks to investigate the impact of a pain communication and skills training intervention created for metastatic breast cancer patients. The pain intervention will have two parts: (1) a one-on-one session with an interviewer that addresses misconceptions about pain treatment and teaches participants how to provide and elicit information about their pain and pain treatment; and (2) completion of a pain diary at prescribed intervals throughout the course of the study participation period. The intervention addresses: (1) participants' misconceptions about pain and pain treatment for those with metastatic breast cancer; (2) how to describe pain in terms of the 5 "L's": Length (or duration), Location (on the body), Like (i.e. what the pain feels like), Loss (i.e. the ways in which the pain has affected their sleeping patterns or ability to carry out daily activities), and Level of pain (i.e., pain intensity); (3) effective participant communication about pain via the use of role-play; and (4) how patients can question their physician/health care provider about their pain treatment. An ethnically diverse sample of patients will be randomly assigned (i.e. have a 50/50 chance of being assigned) to: a pain knowledge and communication skills training ("experimental condition"); or a nutrition education ("attention placebo"). To determine the effectiveness of the pain and communication skills intervention, the pain, psychological adjustment (i.e. mood), and quality of life (e.g., ability to work, have relationships with others) of metastatic breast cancer patients who receive this treatment will be compared to the patients who receive nutrition education (i.e. control condition). Patients will undergo a series of assessments using standardized measures (of pain, psychological adjustment and quality of life) before and after receiving the pain knowledge and communication skills training or nutrition education. The data will then be entered into a computerized data base and statistical analysis will be performed to investigate differences between the two groups and changes over time. The results of the proposed study will provide evidence of the efficacy of a pain communication skills intervention in reducing pain, psychological distress, and increasing quality of life in metastatic breast cancer patients. Information obtained from the proposed research will be used more generally to develop

treatment strategies to reduce the pain and suffering of breast cancer patients. The dissemination of information from this study will facilitate the implementation of such an intervention for breast cancer patients in other cancer centers and general medical settings. The proposed study will also extend the existing general knowledge base about patients' participation in the treatment of their pain.

BODY

The overall goal of this study is to improve pain management for metastatic breast cancer patients by addressing patients' misconceptions about pain treatment and by teaching them how to talk in more descriptive and specific terms about their pain symptoms to their main physician/health care provider (their oncologist). This study examines the impact of a pain and communication skills intervention on the pain, psychological adjustment (i.e., mood), and quality of life (e.g., ability to work, have relationships with others) of metastatic breast cancer patients randomized to this condition as compared to patients who are randomized to receive nutrition education. The primary study hypotheses are that for women with metastatic breast cancer, a pain communications skills intervention will lead to:(1) increased pain management and thus reduce pain; (2) reduced psychological distress; and (3) increased quality of life.

Procedure: The study recruitment for this randomized clinical trial has begun. Women with breast cancer are being recruited from Mt. Sinai's Oncology Outpatient Clinic, two Mt. Sinai-affiliated private practices, and Elmhurst's Oncology Outpatient Clinic. Women are being interviewed four times on three separate days. The first interview (Interview #1) occurs immediately prior to the participant's regularly scheduled appointment with their oncologist or physician/health care provider who is the main individual responsible for their cancer-related medical care. Participants are assessed on the following: pain (e.g., intensity, degree of relief, degree of interference with daily life and prescribed pain medications), satisfaction with their overall medical care, their current pain management, pain treatment misconceptions and pain communication skills (currently called Cancer Pain Barriers Questionnaire; CPBQ (1) this was formally called the PTMPCS); quality of life (MOS-SF-12 (2) a 14 item measure used in many medical populations replaces the CARES, a longer questionnaire); attitudinal barriers to pain management, distress, and self efficacy about health (CBI (3); as per memo of 7/12/99 the CBI replaces SCASS, and psychological well-being). The participants' Karnofsky Performance Status (as rated by the physician/health care provider) is also obtained. Following the interview, the interviewer sends the participant to a separate room where the health educator randomly assigns her to one of the two study arms. Participants then do the following: (1) receive either the 35 minute attention control or experimental intervention condition; (2) upon completion of the session, return to the waiting room area; and (3) see their physician/health care provider for their

scheduled appointment. Participants' main physician/health care provider is not informed as to which study arm the participant has been assigned. The second interview occurs after the medical visit (medical visit #1) on the same day as Interview #1. During this interview, participants complete standard measures of pain communication skills and questionnaire items on socio-demographics. They also provide information about their main physician/health care provider (e.g. length of time been his/her patient, gender).

The third interview occurs immediately after the participant's next medical visit (medical visit #2) and is conducted in person or over the telephone (approximately three to four weeks post-Assessment Time 1). Participants complete the CPBQ and questions concerning: degree of perceived involvement in medical care, distress, satisfaction with current medical care, pain level and pain medications currently being taken, quality of life, health care services utilization, self-efficacy about health care, functional status (Karnofsky scale), and quality of life. The fourth interview occurs approximately 12 weeks post-interview #1.

Immediately after medical visits #1, #2, and #3, participant's main cancer physician/health care providers complete a brief (approximately two minute), open-ended questionnaire concerning the participant's: current prescribed pain medications; whether the pain medication regimen has been changed during this visit and if so, in what ways (e.g. same medication but change in dosage level; or, new medication(s) prescribed); whether participant reported having any symptoms (and if so, what types and how many);whether the participant mentioned pain as a symptom, and if so, how the participant described the pain; the number of questions the participant asked and on what topics. (However, if either medical visit #2 or #3 is cancelled or postponed the corresponding interview will be conducted with the participant on the telephone. A telephone interview will help to minimize missing data from the breast cancer patients. However, if a telephone interview is conducted then the corresponding information will not be collected from the physician/health care provider. This missing data should be minimal and will not inhibit analyses of the physicians'/health care providers' data overall as physicians'/health care providers' data from the other times of assessment will be collected and not all participants will need to conduct the interview over the telephone).

Note: The medications indicated on our BPI (Brief Pain Inventory) questionnaire have been updated to include additional medication according to Dr. Joel Kreitzer's suggestions. Likewise our nutrition intervention has also been updated as per Linda Chio's, MS, RD, suggestions.

Training Accomplishments To Date: Two bi-lingual research assistants have been trained in the study assessments, intervention protocol, and implementation of the control condition. On-going supervision of the staff is provided which includes a review of a sample of the audio-taped

participant-educator session by DuHamel (see Quality Assurance Checks in grant application). Consultation with the project team is ongoing (e.g., with Drs. Winkel, Smith, Portenoy, Chio, Roter, Mezzich, Perrin). (As noted in memo of 8/25/99, Joel Kreizer, M..D., Director of Anaesthesiology at Mount Sinai replaced Paolo Manfredi, MD as our pain consultant as Dr. Manfredi relocated).

Research Accomplishments To Date: We are currently in month 25 of the study. We have accomplished everything that was included up until Month 07 of the Work Statement. The following tasks noted in months 07 through 30 of the Work Statement have been or are being accomplished: conducting study assessments, recruiting patients at all the sites, and implementing the two treatment arms, pain and nutrition. To date we have recruited 19 participants (see preliminary results below). Weekly staff meetings are held to review tape-recordings of interviews for quality assurance purposes. Data obtained from the study measures is being coded, scored and entered. Data is double-checked and cleaned on an ongoing basis. The recruitment of participants has been more difficult than anticipated due to a number of factors including the longer than anticipated set up of study procedure (consent forms were not approved until January 12, 2000). Due to the difficulties in accrual we are considering addition of a new study site.

Preliminary results: Nineteen patients experiencing moderate to severe pain have been recruited. The majority of the women were in mid-life (M = 52 years SD=6.29), not married (79% are divorced/widowed/never married and 5% are separated), low income (72% $20,000 or less), and well educated (53% reported post-high school education). In terms of ethnicity, 53% were Hispanic and 47% preferred that the intervention and interviews were conducted in Spanish. Preliminary analyses indicated that on a scale of 0 ("no pain") to 10 (" pain as bad as you can imagine") women reported that their worst and average pain in the past two weeks were 7.16 and 5.68, respectively. Many women report barriers to pain management. The most common barriers reported included; "Drowsiness from pain medication is really a bother" (95% endorsed) and "When you use pain medicine your body becomes used to its effects and pretty soon it won't work any more" (90% endorsed). Women's barriers to adequate pain management varied by their ethnicity (i.e., Hispanic, African-American, Caucasians) such that women who were Hispanic were more likely to agree with such beliefs than Caucasians ($F = 8.54$, $p < .01$). Analyses on the impact of the pain communication skills intervention which addresses these misconceptions and facilitates patient-provider communication will be conducted when a greater number of metastatic breast cancer patients have been accrued to the study.

Recent Literature: Recent literature provides additional support for the importance of patient-physician/health care provider communication about reducing patient barriers and pain management. First, Detmar and colleagues conducted a study of 240 female patients with incurable cancer (4) and evaluated the content of routine communication between oncologists and their patients. This study indicated that the despite the increasing recognition of the

importance of maintaining patients' health-related quality of life issues as a goal of palliative treatment, the amount of patient-physician/health care provider communication devoted to such issues remains limited. Second, Spencer and colleagues (5) assessed the concerns about breast cancer and relations to psychosocial well-being in a multiethnic sample of early-stage patients. Results from this study indicated that the strongest concerns were recurrence, pain, death, harm from adjuvant treatment, and bills. Moreover, it was found that pain concerns contributed to predicting emotional, psychosexual and social disruption. Additionally, the study also found that Hispanic women reported higher levels of concern on almost all indexes than African American women and non-Hispanic Whites. These findings are consistent with our hypotheses and goals to improve patient-physician/health care provider communication about pain management and to evaluate and amend patients' beliefs about pain treatment, thus resulting in improved pain-management and quality of life.

KEY RESEARCH ACCOMPLISHMENTS

- This study is being conducted as proposed at 2 hospitals.
- We are able to recruit a significant percentage of minority patients.
- Presentations are being conducted at study sites and nationally.
- Preliminary data analysis indicates that breast cancer patients report barriers to adequate pain management.
- Preliminary data analysis indicates that barriers to pain management are higher in minority breast cancer patients.

REPORTABLE OUTCOMES

To date, a description of the study and preliminary data has been presented by Dr. DuHamel in two forums: Medical Oncology Rounds, Mount Sinai School of Medicine, September 29, 2000 and a lecture series at Mount Sinai School of Medicine. In addition, one abstract was presented at the Society of Behavioral Medicine in Seattle (March 22-25, 2001) (appendices #1). A symposium proposal, with Dr. DuHamel presenting preliminary data from this study has been submitted for presentation at the American Pain Society 2002 Annual Scientific Meeting (March 14, 2002) (appendices #2). The proposed symposium has not been published.

CONCLUSIONS

The study staff has been hired and trained, and the study recruitment for this randomized clinical is ongoing. To date, preliminary analyses have been conducted. Consistent with prior research, our preliminary data indicates that many women have barriers to adequate pain management.

Also consistent with prior research, our data suggests that these barriers are more prevalent among minority breast cancer patients. As the number of subjects accrued is increased and the results analyzed, we will continue to investigate the impact of a pain communication skills intervention in reducing pain, psychological distress, and increasing quality of life in metastatic breast cancer patients. Information obtained from the proposed research will be used more generally to develop treatment strategies to reduce the pain and suffering of breast cancer patients. The dissemination of information from this study will facilitate the implementation of such interventions for breast cancer patients in other cancer centers and general medical settings. The proposed study will also extend the existing general knowledge base about patients' participation in the treatment of this pain.

REFERENCES:

1. Ward, S.E., Goldberg N, Miller-McCauley V. Patient-Related Barriers to Management of Cancer Pain. Pain 1993;52:319-324.

2. Ware, J.E., Kosinski, M., and Keller, S.D. A 12-Item Short-Form Health Survey (SF-12): construction of scales and preliminary tests of reliability and validity. Medical Care 1996;32: 220-233.

3. Merluzzi, T.V. and Sanchez, M.M. Assessment of Self-Efficacy and Coping With Cancer: Development and Validation of the Cancer Behavior Inventory. Health Psychology 1997;16:163-170.

4. Detmar SB, Muller MJ, Wever LDV, Schornagel JH, Aaronson NK. Patient-Physician Communication During Outpatient Palliative Treatment Visits. Journal of the American Medical Association 2001; 285(10): 1351-1357

5. Spencer SM, Lehman JM, Wynings C, Arena P, Carver CS, Antoni MH, Derhagopian RP, Ironson G, Love N. Concerns About Breast Cancer and Relations to Psychosocial Well-Being in a Multiethnic Sample of Early-Stage Patients. Health Psychology 1999; 18(2): 159-168

APPENDICES

1.) Abstract presented at the annual meeting of the Society of Behavioral Medicine in Seattle, WA, (March 22-25, 2001).

Resiliency and Adjustment to Living with Breast Cancer

Jennifer R. Egert, Ph.D., Katherine DuHamel, Ph.D., Karen J. Carapetyan, M.A., Meredith Smith, Ph.D., M.P.A., Mount Sinai School of Medicine

Individuals who show self-resilience, are able to meet the demands of their environment, form positive relationships with others and have a sense of purpose in life are likely to manage stressful experiences such as life-threatening illness better than those without such resiliency. This study examined the relationship of these four resiliency characteristics to adjustment in 27 breast cancer patients participating in a clinical trial aimed at improving pain management for which recruitment is ongoing. Participants were assessed at baseline in terms of resiliency characteristics (Ryff's Scales of Psychological Well-Being) and positive and negative psychological states (the Mental Health Index) such as feeling calm and cheerful versus anxious and depressed. The mean age of participants was 50.89 (sd = 8.57) and 59% had metastatic disease. Participants were primarily minority (48% Hispanic; 22% African American) and 26% had not completed high school. Regression analysis revealed that, after accounting for disease stage and average pain level over the prior two weeks, the four resiliency characteristics contributed significantly to explaining variation in positive psychological state (change in R-square = .37, p = .005) but not in negative psychological state. These findings support past research indicating that positive and negative psychological states may have different correlates. Interventions which target these specific resiliency characteristics may facilitate positive psychological adjustment but may not alleviate distress. Further longitudinal research is needed to evaluate causal relationships among resiliency characteristics and cancer adjustment.

(Unpublished)

2.) Symposium Proposal for the 2002 Annual Scientific Meeting

Enhancing Doctor-Patient Communication To Improve Pain Management for Minority Patients with Chronic Pain

Meredith Smith Ph.D., Katherine DuHamel, Ph.D., Karen O. Anderson, Ph.D.,
Karen Syrjala, Ph.D.

Pain is a common and highly debilitating symptom for many chronically ill patients, especially those with HIV/AIDS or late stage cancer . Despite this, chronic pain, particularly in minority patients, is often inadequately treated. Barriers to adequate pain management are numerous, and include both health care provider and patient-related factors. For example, health care providers may not know how to appropriately use opiates. Patients, on the other hand, may be reluctant to take pain medication for fear of addiction, of developing tolerance, or of being perceived as a "complainer." The proposed symposia will present data on barriers to pain management among minority cancer patients and preliminary data illustrating the beneficial impact of interventions designed to improve patient-doctor communication about pain, reduce patient's pain and distress, and enhance their quality of life. Four investigators will be featured in this symposium: three will present study findings, and the fourth will serve as a discussant. Dr. Smith will present data from a recently completed randomized clinical trial of minority persons living with HIV/AIDS (PWHAs) in New York City. The presentation will examine patient misconceptions about pain medication and how these misconceptions relate to perceived patterns of doctor-patient communication. Dr. DuHamel will present data from an ongoing randomized clinical trial investigating the impact of a pain communication skills intervention on minority breast cancer patients' pain beliefs, pain symptoms, quality of life and patient-provider communication. Dr. Anderson will report on the efficacy of a pain education intervention being tested in a third, ongoing randomized clinical trial with African-American and Hispanic cancer patients. She will report on preliminary findings regarding the efficacy of the pain management intervention. As the discussant, Dr. Syrjala will synthesize findings from the three studies, highlight the commonalities and differences in pain management barriers among the different ethnic/racial groups, and comment on implications for future research.