

Oncology Nursing Society

Annual Progress Report: 2008 Formula Grant

Reporting Period

July 1, 2010 – June 30, 2011

Formula Grant Overview

The Oncology Nursing Society received \$12,473 in formula funds for the grant award period January 1, 2009 through June 30, 2012. Accomplishments for the reporting period are described below.

Research Project 1: Project Title and Purpose

The SEA Preparatory Intervention for Women with Metastatic Breast Cancer - The purpose of this pilot randomized controlled project is to provide information to women newly diagnosed with metastatic breast cancer (MBC) that they can use at diagnosis and across the illness continuum to maintain quality of life and reduce distress.

Anticipated Duration of Project

1/1/2009 - 6/30/2012

Project Overview

Aims

- 1) To determine the feasibility (recruitment, attrition, acceptability) of the use of an anticipatory guidance intervention Support, Education and Advocacy (SEA) Intervention in women newly diagnosed with MBC.
- 2) To explore the efficacy of the SEA Intervention on quality of life, physical and emotional distress and symptom distress in women newly diagnosed with MBC over the first six months of illness as compared to care as usual.

Results of this study will then be used for development of a larger randomized controlled trial (RCT) to test efficacy of the SEA Intervention.

Methods

This is a pilot study, non-blinded, repeated-measures randomized controlled trial in women (n=48) from diagnosis of MBC through the first 6 months across the illness continuum. Measures of feasibility and acceptability will be assessed at baseline and at 2 time points (3 and 6 months). Outcomes of emotional distress (The Distress Thermometer and McCorkle Symptom Distress Scale) and quality of life (Functional Assessment of Cancer Therapy) will be assessed. Effect sizes for larger trial will be determined.

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Expected Research Outcomes and Benefits

The SEA Intervention has significant potential to advance the science of oncology nursing. This intervention fills a void in essential patient preparation for a specific disease trajectory. There are many written and electronic resources for women with breast cancer. There are few resources available specifically for women with metastatic breast cancer. This SEA Intervention provides immediate concrete information to women at a time when women need specific information to better adopt coping strategies and problem solving techniques for emotional and physical distress related to metastatic breast cancer. If efficacious, the SEA Intervention can be adopted by oncology nurses and used as a standard teaching intervention at the time of the diagnosis of MBC. It will be different from many other teaching materials incorporated into the cancer clinical setting because it has been developed based on the stated patient experience, respects the similarities and differences among racial and economic backgrounds, evaluated by the patient population intended to serve and will be empirically tested for acceptability and efficacy.

The SEA Intervention is designed to be patient driven and specifically tailored to enhance the woman's self care ability. The SEA Intervention includes:

- a. Support to promote ability to meet evolving emotional needs through identification of available resources;
- b. Education regarding 1) current treatment and side effects including physical sensations and symptoms to expect 2) temporal characteristics of the illness and symptom experience (when to expect them) 3) environmental features (what one might see and hear during an illness experience) and 4) causes of symptoms, sensations, and experiences; and
- c. Advocacy skills to enable communication regarding evolving concerns and provide resources for women to request further information and needed referrals.

Summary of Research Completed

This project aims to evaluate the ability of the SEA Intervention to have a positive impact on a woman's quality of life (The Functional Assessment of Cancer Therapy), overall distress (The Distress Thermometer) and symptom distress (The McCorkle Symptom Distress Scale) from the diagnosis of MBC through the first 12 to 18 months of illness.

Aim 1: To determine the feasibility (recruitment, attrition, acceptability) of the use of an anticipatory guidance intervention (The SEA Intervention) in women newly diagnosed with MBC.

Progress to Date

Recruitment

The SEA Intervention has been open to recruitment since March, 2010. During the reporting period, July 1, 2009-June 30, 2010, 16 patients were enrolled. During the current reporting period, July 1, 2010-June 30, 2011, an additional 13 patients were enrolled. Therefore, at the time of this report, a total 29 patients have been recruited, consented and enrolled in the study. The targeted recruitment of 48 patients has not been met as of now, but will be able to be achieved in the following year. In this reporting year, the research team has experienced a decrease in recruitment attributed in part to lack of subject interest for participation and clinician restriction on patients deemed "eligible" for recruitment. Reasons for patients not consenting and enrolling in the study after contact and recruitment by a researcher included: 1) not interested in being part of a research study, 2) not wanting to be "bothered" and 3) fearful of learning information about disease. Reasons for clinician restriction on "eligible" patients included: 1) age of patient, 2) progression of disease and 3) mental status.

We are confident that we will be able to recruit 19 additional patients in order to meet our target recruitment of 48 subjects by the end of the next reporting period, June 30, 2012.

Demographic information revealed that the participants well represent the Pittsburgh region with the majority married (62%), all high school graduates (100%), and adequate minority recruitment (20%) in the sample. See Table 1: Sociodemographic Characteristics.

Attrition

There has been no attrition due to failure to follow up with participants. There has been attrition due to death in three subjects. All three of these subjects completed baseline data but were deceased prior to completing time point 1 (3 months) and time point 2 (6 months) data. Reason for death included progression of disease status.

Acceptability

Acceptability of the SEA Intervention materials has been measured for all subjects randomized to the intervention group. An acceptability questionnaire is administered at the final time point (time point 2, 6 months) for all intervention group patients. The acceptability questionnaire consists of four 5-point Likert Scale questions assessing the timing, clarity, need and applicability of the intervention. Additionally, 8 open-ended questions assess the strengths and

weaknesses of the intervention materials as well as suggestions for improvement in the delivery and content of the intervention. All subjects who have completed the acceptability questionnaire (n=12) have rated the intervention as favorable and as “needed” information. See Table 5: Acceptability of Intervention.

Aim 2: To explore the efficacy of the SEA Intervention on quality of life, physical and emotional distress and symptom distress in women newly diagnosed with MBC over the first six months of illness as compared to care as usual.

Results of this study will then be used for development of a larger RCT to test efficacy of the SEA Intervention.

Progress to Date

To date, 29 subjects have completed baseline data collection, 26 subjects have completed time point 1 data collection, and 25 subjects have completed time point 2 data collection. The mean scores and standard deviations for the three outcome measures of quality of life (FACT), physical and emotional distress (Distress Thermometer) and symptom distress (McCorkle Symptom Distress) are listed in Tables 2-4.

Quality of Life

Quality of Life is measured using the Functional Assessment of Cancer Therapy (FACT), a validated 33-item general cancer quality-of-life measure for evaluating patients receiving cancer treatment. Scores range from 0-108, with a higher score indicating better quality of life. Table 2 illustrates mean and standard deviation FACT scores for both the Intervention Group and the Usual Care Group.

Baseline

At baseline, the FACT scores for the Intervention group and Usual Care group scores were relatively similar. The mean FACT score for the Intervention group (n=15) was 77.2 (SD=4.5) and the mean score for the Usual Care group (n=14) was 77.9 (SD=4.1).

Time point 1

At time point 1, both the Intervention group and the Usual Care group illustrated an increase in mean FACT scores. The Intervention group (n=13) had a mean score of 82.7 (SD=3.5) and the Usual Care group (n=13) had a mean score of 82.9 (SD=4.7)

Time point 2

At time point 2, both the Intervention group and the Usual Care group illustrated an increase from baseline and time point 1 in mean FACT scores. The Intervention group (n=12) had a mean score of 84.0 (SD=2.4) and the Usual Care group (n=11) had a mean score of 87.2 (SD=4.3).

Emotional and Physical Distress

Emotional and physical distress is measured using the Distress Thermometer. The Distress Thermometer is a screening tool widely used by health professionals to assess the level of distress that a patient is experiencing in a 0-10 scale. 0 indicates no distress while 10 indicates extreme distress. See Table 3.

Baseline

At baseline, the distress scores for the Intervention group and Usual Care group were relatively similar. The mean distress score for the Intervention group (n=15) was 4.2 (SD=.77) and the mean score for the Usual Care group (n=14) was 3.6 (SD=.66).

Time point 1

At time point 1, the distress scores for the Intervention group (n=13) decreased slightly from what was recorded at baseline to a mean score of 3.3 (SD=.86). The mean score for the Usual Care group (n=13) was 3.8 (SD=.69).

Time point 2

At time point 2, the distress scores for the Intervention group (n=12) decreased slightly from what was recorded at baseline and at time point 1 to a mean score of 2.6 (SD=.62). The mean score for the Usual Care group (n=11) was 2.2 (SD=.86)

Symptom Distress

The McCorkle Symptom Distress scale has been developed and validated as a cancer-specific tool for assessing symptoms. This 13-item scale measures degree of distress on a 1-5 Likert scale. A total summed score of 25 or above indicates moderate distress; scores of 33 or above indicate severe distress that requires immediate intervention. See Table 4.

Baseline

At baseline, the symptom distress scores for the Intervention group and Usual Care group were relatively similar. The mean symptom distress score for the Intervention group (n=15) was 25.4 (SD=1.8) and the mean score for the Usual Care group (n=14) was 23.7 (SD=1.8).

Time point 1

At time point 1, the symptom distress scores for both the Intervention group and the Usual Care group remained relatively unchanged from the recorded baseline scores. The mean score for the Intervention group (n=13) was 24.5 (SD=1.6) and the mean score for the Usual Care group (n=13) was 23.1 (SD=2.1).

Time point 2

At time point 2, the symptom distress scores for both the Intervention group and the Usual Care group decreased from baseline and time point 1. The Intervention group (n=12) had a mean score of 21.5 (SD=1.7) and the Usual Care group (n=11) had a mean score of 21.0 (SD=2.2).

Conclusion

The results to date do not suggest the SEA Intervention has had a measurable impact on the quality of life scores, distress scores and symptom distress scores of the subjects randomized to the Intervention group. From baseline, both the Intervention group and the Usual Care group illustrated similar mean FACT scores that increased moderately at time point 1 and at time point 2.

Similarly, mean distress scores for both the SEA Intervention group and the Usual Care group were relatively similar at baseline and both saw moderate decreases by time point 2. Despite the ability of the SEA Intervention to have a favorable impact on quality of life, distress and symptom distress as measured by instruments, the comments from an open ended survey and Likert-Scale survey assessing the impact of the Intervention's components suggest that the

information provided in the SEA Intervention is important and necessary as women are diagnosed with metastatic breast cancer. See Tables 5 and 6.

Providing all women with the appropriate and reliable information regarding diagnosis and treatment trajectory is essential in helping women achieve the advocacy necessary as well as the information to influence informed health care decision making.

Table 1.

Sociodemographic Information		
	SEA Intervention (n=15)	Usual Care (n=14)
Age (mean)	47.7 SD= 9.4 (range 28-72)	52.4 SD= 12.3 (range 39-63)
Married, % yes	9 (60%)	9 (64%)
Education-High School	15 (100%)	14(100%)
Race- African American	4 (26.6%)	2 (14.2%)

Table 2.

FACT (Higher Scores=Better Quality of Life)		
	SEA Intervention (n=15)	Usual Care (n=14)
Baseline (n=29)	77.2 (mean) 4.5 (SD)	77.9 (mean) 4.1 (SD)
Time point 1 (n=26)	82.7 (mean) 3.5 (SD)	82.9 (mean) 4.7 (SD)
Time point 2 (n=24)	84.0 (SD=2.4)	87.2 (SD=4.3)

Table 3.

Distress Thermometer (Higher Scores=More Distress)		
	SEA Intervention (n=15)	Usual Care (n=14)
Baseline (n=29)	4.2(mean) .77 (SD)	3.6 (mean) .66 (SD)
Time point 1 (n=26)	3.3 (mean) .86 (SD)	3.8 (mean) .69 (SD)
Time point 2 (n=24)	2.6 (mean) .62 (SD)	2.2 (mean) .86 (SD)

Table 4.

McCorkle Symptom Distress (Higher Scores=Higher Symptom Distress)		
	SEA Intervention (n=15)	Usual Care (n=14)
Baseline (n=29)	25.4(mean) 1.8 (SD)	23.7 (mean) 1.8 (SD)
Time point 1 (n=26)	24.5 (mean) 1.6 (SD)	23.1 (mean) 2.1 (SD)
Time point 2 (n=24)	21.5 (mean) 1.7 (SD)	21.0 (mean) 2.2 (SD)

Table 5.

Acceptability of the SEA Intervention: 5-point Likert Scale Assessment (1= Strongly Disagree – 5=Strongly Agree)	
The SEA Intervention was well timed.	3.6 0.3 (SD)
The SEA Intervention was clear.	4.3 0.2 (SD)
The SEA Intervention content is needed information.	4.7 0.2 (SD)
The SEA Intervention was designed for me.	4.0 0.2 (SD)

Table 6.

Open Ended Responses
<p>1.) In recalling what your needs were when you were first told that you had metastatic breast cancer, can you tell me if these materials would meet your needs for information at that time?</p> <ul style="list-style-type: none"> • I don't remember. • It is helpful to answer a lot of questions. • I think that the materials did meet the needs at this time. The materials provided information that was helpful to me. • I was happy with the presentation. • The information met my needs. • The materials met my needs. However, earlier delivery would have been better. • This was the only material that I got for this breast cancer [stage IV] and we [me and my family] had some questions which the books helped with.
<p>2.) Can we specifically look at the 6 modules and comment on the content of method and presentation?</p> <ul style="list-style-type: none"> • I can't think of any one particular thing now, but it was a helpful presentation. • I liked the pamphlets. I liked having the easy access to something for questions. Everything was there, I didn't have to go online and google everything because you don't want to go online when you have advanced breast cancer. • I think it was a good general presentation. Everyone's case is so individual. Each person would have to take that information and do more research on their case. Nonetheless, good overall presentation. • I thought it was good to have the DVD first and then have the materials to take home and use as needed. • I thought the DVD modules were pretty thorough and well addressed. • Perfect, I was able to use the materials at my leisure and go back and read again. I also shared with my family. • The DVD was my favorite. I have watched it more than once, I like to see the women in the video still doing day to day things and doing well. • The video was nice. It was nice to have my own packet to keep and refer to things. Having reference material about holistic treatment was interesting and helpful. • There was a lot in there that helped. For example, "how you feel" and "diet", it was put together well.

3.) What are some things you particularly liked about the materials?

- At the time it was knowing that there were women in my situation. Actually seeing them on the DVD and not just reading about them was helpful. Plus, seeing Dr [Brufsky] made it more relevant for me.
- Easy to understand. The website was concise and clear. I used the website 2-3 times.
- I liked the folder, organization and easy access to materials on as needed basis.
- I liked that I was sought out to get these materials. It was nice to have someone give me these materials and resources that I was able to share with my family.
- I liked the interviews in the DVD with “survivors” and hearing about how they cope. There was also a lot of written material that gave good resources.
- I liked the subject order and organization.
- I thought the materials gave a view of everything you needed. It presented what you were feeling at diagnosis and throughout illness.
- It was informational but I cannot think of anything specifically.
- The DVD went over things that I had previously gone over when talking to the doctor. The DVD made me feel like I could always go back and talk to the doctor about my concerns.

4.) Can you tell me your recommendations for improvement of the modules?

- For me, I would have liked to have gotten it the day the doctor told me how bad it was. Even though I was upset, it would have been helpful to receive it on that day to know that there was hope.
- I thought it would be nice to have a younger face in the DVD because I am only 28.
- I thought the written materials were good, it covered all of my needs.
- I used the written materials as a reference. I didn’t read it all the time, but used it as a reference. Sometimes when something new happened (symptom/side effect), I would reference the written information.
- One thing that has helped me personally is following a nutritional program. More information on nutrition would be helpful.

5.) Do you think the materials were representative for you?

- Yes.
- Yes and no. At the time I didn’t think it was something that I needed to use. Thinking back on it, it was a comforting thing, it was something that was available to use. It is good to know that there are resources that you can use.

6.) Was the language clear enough? Should we “break down” the language any more so that it is more easily understood?

- Everything was easily understood and explained.
- I thought the language was clear enough.
- I understood everything.
- I understood it, but I had already done a lot of research prior to getting the materials. But for someone who had not done their research, it was very clear and helpful.
- Yes, I think the language was done very nicely. Nothing was over your head and it was easy to understand.

7.) Did we accurately discuss the concerns that you had when you first found out that you had advanced or metastatic breast cancer?

- Everything was addressed.
- This covered my questions and concerns.

8.) Do you believe these materials are sensitive and appropriate for your race and economic status?

- yes