THE EFFECTS OF AMA DEUS HEALING ON ANXIETY AND DEPRESSION IN WOMEN WITH STAGE III AND IV OVARIAN CANCER

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Dissertation submitted to the Faculty of Holos University Graduate Seminary in partial fulfillment of the requirements for the degree of

DOCTOR OF THEOLOGY
The work reported in this thesis is original and carried out by me solely, except for the acknowledged direction and assistance gratefully received from colleagues and mentors.

______________________________
Elizabeth Helen Cosmos
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ABSTRACT

**Background:** A review of clinical studies investigating hand mediated healing methods reveals a lack of independent replication that demonstrates adequate blinding, randomization and reliability of outcomes. This randomized research project is an evaluation of the effects of Ama-Deus (AD) hands-on energy healing on anxiety and depression in women with stage III or IV ovarian cancer.

**Method:** A randomized cross-over design was conducted with fourteen women diagnosed with stage III ovarian cancer at a Midwestern hospital using the AD method as the intervention. Group I received twenty minutes of Ama Deus hands on energy healing 2 times a week for three weeks, with one week of rest, then crossed over to the control of twenty minutes 2 times a week of relaxation sessions for three weeks. Group II received twenty minutes of relaxation 2 times a week for three weeks, with one week of rest, and then crossed over to Ama Deus for twenty minutes 2 times a week for three weeks.

**Results:** The statistical analysis revealed that Ama Deus Group I had significant reduction in state anxiety. Group II demonstrated significant reduction in Trait anxiety. Significant findings in depression reduction were revealed among Group II participants. These findings provide support that AD energy healing and relaxation sessions help reduce anxiety and depression in ovarian cancer patients.

**Conclusion:** Energy healing is widely used in conjunction with western allopathic treatment in the U.S. and Europe for a variety of health conditions. This research supports the efficacy of Ama Deus in reducing anxiety and depression. Widespread use of energy healing, coupled with the findings of the research, indicates the need for additional research that evaluates the effectiveness of energy healing in clinical settings to support the healing process and help improve quality of life.

**Key Words**
Ama Deus, anxiety and depression, energy healing, general relaxation, quality of life, ovarian cancer, stress management.
TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>iv</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>vi</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>vii</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>x</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>xi</td>
</tr>
<tr>
<td>CHAPTER 1: Introduction</td>
<td>1</td>
</tr>
<tr>
<td>1. Background of Problem</td>
<td>1</td>
</tr>
<tr>
<td>1.1 Purpose of the Study</td>
<td>4</td>
</tr>
<tr>
<td>1.2 Background to Ama Deus Healing</td>
<td>10</td>
</tr>
<tr>
<td>1.2.1 Alberto Aguas: The Link to Preserving an Indigenous Healing Technique</td>
<td>10</td>
</tr>
<tr>
<td>1.2.2 A Brief Historical Perspective on the Guarani Indians</td>
<td>12</td>
</tr>
<tr>
<td>1.2.3 Ama Deus – An Energy Healing</td>
<td>14</td>
</tr>
<tr>
<td>1.3 Research Question and Hypotheses</td>
<td>18</td>
</tr>
<tr>
<td>1.4 Importance of the Study</td>
<td>18</td>
</tr>
<tr>
<td>1.5 Definition of Terms As Used in this Work</td>
<td>19</td>
</tr>
<tr>
<td>CHAPTER 2: Review of Literature</td>
<td>25</td>
</tr>
<tr>
<td>2.1 One Global Community</td>
<td>25</td>
</tr>
<tr>
<td>2.2 Spiritual Dimensions of Healing</td>
<td>26</td>
</tr>
<tr>
<td>2.3 Conventional Practice for Ovarian Cancer</td>
<td>29</td>
</tr>
<tr>
<td>2.4 Stress, Cancer and Quality of Life</td>
<td>30</td>
</tr>
<tr>
<td>2.5 Quality of Life in Ovarian Cancer Patients</td>
<td>32</td>
</tr>
<tr>
<td>2.5.1 Anxiety and Depression in Cancer Patients</td>
<td>34</td>
</tr>
<tr>
<td>2.5.1.1 Anxiety</td>
<td>35</td>
</tr>
<tr>
<td>2.5.1.2 Treatments for Anxiety</td>
<td>36</td>
</tr>
<tr>
<td>2.5.1.3 Depression</td>
<td>39</td>
</tr>
<tr>
<td>2.5.1.4 Treatments for Depression</td>
<td>40</td>
</tr>
<tr>
<td>2.5.2 CAM Usage with Cancer Patients</td>
<td>41</td>
</tr>
<tr>
<td>2.5.3 Prevalence of Energy Healing</td>
<td>42</td>
</tr>
<tr>
<td>2.5.4 Ama Deus as Compared to Other Energy Healing Techniques</td>
<td>47</td>
</tr>
<tr>
<td>2.5.4.1 Reiki</td>
<td>48</td>
</tr>
<tr>
<td>2.5.4.2 Therapeutic Touch™ (TT)</td>
<td>49</td>
</tr>
<tr>
<td>2.5.4.3 Healing Touch International™ (HT)</td>
<td>50</td>
</tr>
<tr>
<td>2.5.4.4 Some Distinctions in Energy Healing</td>
<td>50</td>
</tr>
<tr>
<td>2.5.4.5 Qigong</td>
<td>52</td>
</tr>
<tr>
<td>2.5.4.6 Comparison Summary</td>
<td>53</td>
</tr>
<tr>
<td>2.5.4.7 Ama Deus: The Scientific Connection</td>
<td>53</td>
</tr>
<tr>
<td>2.5.4.8 Measuring Biological Energy Fields of the Hands</td>
<td>56</td>
</tr>
<tr>
<td>2.5.4.9 Conclusion</td>
<td>57</td>
</tr>
<tr>
<td>CHAPTER 3: Research Methods</td>
<td>64</td>
</tr>
<tr>
<td>3.1 Methodology</td>
<td>64</td>
</tr>
<tr>
<td>3.1.1 Process and Procedures for Conducting Research in a Clinical Setting</td>
<td>64</td>
</tr>
<tr>
<td>3.1.2 Study Design</td>
<td>69</td>
</tr>
</tbody>
</table>

vii
APPENDIX O Practitioners Preparation ................................................................. 156
APPENDIX P Participant Encounter Form ............................................................. 157
APPENDIX Q In-service Notification ...................................................................... 159
APPENDIX R State-Trait Anxiety Inventory ............................................................ 160
APPENDIX S Beck Depression Inventory II ............................................................ 161
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1.</td>
<td>Within Group I Difference in Anxiety Trait 2 and Trait 1 (n=14) .......... 86</td>
</tr>
<tr>
<td>Figure 2.</td>
<td>Within Group I Difference in Anxiety Trait 3 and Trait 2 (n=14) .......... 86</td>
</tr>
<tr>
<td>Figure 3.</td>
<td>Within Group I Difference in Anxiety Trait 3 and Trait 1 (n=14) .......... 87</td>
</tr>
<tr>
<td>Figure 4.</td>
<td>Within Group I Difference in Anxiety State 2 and State 1 (n=14) .......... 87</td>
</tr>
<tr>
<td>Figure 5.</td>
<td>Within Group I Difference in Anxiety State 3 and State 2 (n=14) .......... 88</td>
</tr>
<tr>
<td>Figure 6.</td>
<td>Within Group I Difference in Anxiety State 3 and State 1 (n=14) .......... 88</td>
</tr>
<tr>
<td>Figure 7.</td>
<td>Within Group I Difference in Depression 2 and Depression 1 (n=14) .... 89</td>
</tr>
<tr>
<td>Figure 8.</td>
<td>Within Group I Difference in Depression 3 and Depression 2 (n=14) .... 89</td>
</tr>
<tr>
<td>Figure 9.</td>
<td>Within Group I Difference in Depression 3 and Depression 1 (n=14) .... 90</td>
</tr>
<tr>
<td>Figure 10.</td>
<td>Within Group II Difference in Anxiety Trait 2 and Trait 1 (n=14) .... 90</td>
</tr>
<tr>
<td>Figure 11.</td>
<td>Within Group II Difference in Anxiety Trait 3 and Trait 2 (n=14) .... 91</td>
</tr>
<tr>
<td>Figure 12.</td>
<td>Within Group II Difference in Depression 3 and Depression 2 (n=14) .... 91</td>
</tr>
<tr>
<td>Figure 13.</td>
<td>Within Group II Difference in Anxiety State 2 and State 1 (n=14) .... 91</td>
</tr>
<tr>
<td>Figure 14.</td>
<td>Within Group II Difference in Anxiety State 3 and State 2 (n=14) .... 92</td>
</tr>
<tr>
<td>Figure 15.</td>
<td>Within Group II Difference in Anxiety State 3 and State 1 (n=14) .... 92</td>
</tr>
<tr>
<td>Figure 16.</td>
<td>Within Group II Difference in Depression 2 and Depression 1 (n=14) .... 93</td>
</tr>
<tr>
<td>Figure 17.</td>
<td>Within Group II Difference in Depression 3 and Depression 2 (n=14) .... 93</td>
</tr>
<tr>
<td>Figure 18.</td>
<td>Within Group I Difference in Depression 3 and Depression 1 (n=14) .... 94</td>
</tr>
<tr>
<td>Figure 19.</td>
<td>Between Group Difference: Group II – Trait 1 and Group I – Trait 1 .... 95</td>
</tr>
<tr>
<td>Figure 20.</td>
<td>Between Group Difference: Group II – State 1 and Group I – State 1 .... 95</td>
</tr>
<tr>
<td>Figure 21.</td>
<td>Between Group Difference: G II Depression 1 and GI Depression 1 .... 96</td>
</tr>
</tbody>
</table>
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1. Participant Sample of Marital Status.</td>
<td>81</td>
</tr>
<tr>
<td>Table 2. Participant Sample of Education Level.</td>
<td>81</td>
</tr>
<tr>
<td>Table 3. Participant Sample of Income.</td>
<td>82</td>
</tr>
<tr>
<td>Table 4. Participant Sample of Occupation.</td>
<td>82</td>
</tr>
<tr>
<td>Table 5. Key to Abbreviations used in the Quantitative Analysis.</td>
<td>85</td>
</tr>
<tr>
<td>Table 6. Overview of Means for Group I and Group II.</td>
<td>96</td>
</tr>
</tbody>
</table>
CHAPTER 1: INTRODUCTION

Integrative care combines the best of conventional medical approaches and holistic energy medicine to offer the maximal benefits to patients and therapists. When practiced holistically, this is whole-person caring.

― Daniel Benor

Background of Problem

Cancer is a disease that threatens well-being on multiple levels. People with cancer experience various physiological symptoms of distress, such as pain, fatigue and nausea, as well as emotional and mental distress. In addition, the diagnosis and treatment of cancer has extensive psychosocial repercussions for individuals and their families.

According to the American Cancer Society, ovarian cancer is ranked as the fifth leading cause of death for women and is second among women with gynecologic cancer. The five-year survival rate—meaning the percentage of patients who live five years after diagnosis of the disease—for early stage ovarian cancer is approximately 80 percent. The early stages are I and II; staging is determined by the size of the tumor. The five-year survival rate for patients with stage III ovarian cancer drops to approximately 35 percent; stage IV ovarian cancer has less than a 10 percent five-year survival rate. Ovarian cancer causes more deaths than any other cancer of the female reproductive system.

The American Cancer Society estimated that 20,000 new cases of ovarian cancer would be diagnosed in the United States in 2006, with an estimated increase to 22,430 for 2007. More than 15,000 women per year will die from this disease. These cancer patients have to deal with not only the physical effects of the disease, but emotional

1 People with cancer experience various physiological symptoms of distress, such as pain, fatigue and nausea, as well as emotional and mental distress. In addition, the diagnosis and treatment of cancer has extensive psychosocial repercussions for individuals and their families.
2 According to the American Cancer Society, ovarian cancer is ranked as the fifth leading cause of death for women and is second among women with gynecologic cancer. The five-year survival rate—for early stage ovarian cancer is approximately 80 percent. The early stages are I and II; staging is determined by the size of the tumor. The five-year survival rate for patients with stage III ovarian cancer drops to approximately 35 percent; stage IV ovarian cancer has less than a 10 percent five-year survival rate.
3 Ovarian cancer causes more deaths than any other cancer of the female reproductive system.
4 The American Cancer Society estimated that 20,000 new cases of ovarian cancer would be diagnosed in the United States in 2006, with an estimated increase to 22,430 for 2007.
5 More than 15,000 women per year will die from this disease.
distress as well; the diagnosis of ovarian cancer elicits a predictable response of emotional distress, with a primary fear of painful death. The principal investigator of this study suggests that more attention should be focused on the psychosocial issues for stage III or IV diagnoses until early detection becomes more effective and a higher survival rate is achieved with advanced treatment.

In ovarian cancer patients, symptoms of anxiety often coexist with symptoms of depression. Anxiety and depression significantly impede the healing process of cancer patients, as indicated in two studies conducted by Susan Lutgendorf and her colleagues: “Quality of Life and Mood in Women with Gynecologic Cancer: A One Year Prospective Study” and “Quality of Life and Mood in Women Receiving Extensive Chemotherapy for Gynecologic Cancer.” The psychosocial measure Lutgendorf used to obtain a comprehensive assessment of mood was the Profile of Mood States (POMS); anxiety and depression are two of the six items measured in the POMS scale. Lutgendorf’s studies suggest patients who use coping strategies tend to feel better and the coping strategies appear to play an important role in influencing patient perception of well-being. Patients using avoidance to cope with the challenges they were facing experienced poorer emotional well-being and greater anxiety and depression, even when their prognosis was relatively good.

Numerous studies on anxiety and depression in cancer patients have been conducted in the fields of allopathic and Complementary and Alternative Medicine (CAM). A survey investigating the use of CAM therapies in women with breast cancer indicates that 91 percent of participants in the Midwest region ranked prayer, exercise and energy healing as the most commonly used CAM therapies. Eisenberg et al., in
their study “Trends in Alternative Medicine Use in the United States, 1990–1997: Results of a follow-up national survey,” found that among the 16 alternative therapies they investigated, the demand for energy healing is growing the most rapidly.\textsuperscript{14} Energy healing, as defined for the purpose of this research, is a system of purposeful intention by a person or persons to catalyze the healing process for another living system using the hands without using any known physical means of intervention.\textsuperscript{15}

Ama Deus\textsuperscript{®} is an energy healing technique developed by Alberto Aguas. After mastering the technique over the course of many encounters with a tribe of Guarani Indians in the Amazon, Aguas, a Brazilian healer, began teaching this energy healing system in the United States and Canada in 1985. Under the direct tutelage of Aguas, this principal investigator studied Ama Deus for three years; after his death in 1992, she accepted the responsibility to carry on Aguas’s teachings and began traveling worldwide to do so. The principal investigator has used the Ama Deus technique on patients in a Midwest hospital for ten years and observed its positive effects on the cancer patient population there—effects that include reduced feelings of anxiety and depression.

Other practitioners have made similar observations of reduced feelings of anxiety, depression and pain when conducting sessions using Ama Deus for self-healing and for healing others. The principal investigator advocates that validating these observations would increase the understanding and promote the use of energy healing therapies in a clinical setting.
Purpose of the Study

We are witnessing a revolution in medical practice. David Eisenburg’s well-known study “Unconventional Medicine in the United States,” published in *The New England Journal of Medicine* in 1990, clearly indicated that a third of the population used alternative healthcare providers rather than conventional medical practitioners, spending nearly $14 billion out of pocket on alternative therapies. Along with Eisenburg, other credible sources such as Herbert Benson, Larry Dossey, Deepak Chopra, Richard Gerber, Mehmet Oz, Bernie Siegel and Andrew Weil have indicated the importance of body, mind and spirit relationships in medical practice.

This increasing awareness of patients as multi-dimensional beings has triggered an integrative healthcare movement concerned with exploring holistic, relationship-centered care and techniques for healing in clinical settings. In his extensive analysis of energy healing research in *Consciousness, Bioenergy and Healing*, Daniel Benor states, “Integrative care combines the best of conventional medical approaches and holistic energy medicine to offer the maximal benefits to patients and therapists. When practiced holistically, this is whole-person caring.”

As the interest in people’s innate capacity to heal emerges in Western medicine, health professionals are becoming more aware of the crucial role the individual plays in his or her own healing process, and are supporting that role by exploring the mind-body connection and employing holistic practices. As noted in the introduction, in a 1998 follow-up survey investigating trends in CAM therapies, Eisenburg and colleagues showed that energy healing was among the fastest growing therapies in terms of demand.
Energy healing has been practiced in many cultures for thousands of years. Chinese medicine, the Ayurvedic system from India, and Native American healing are a few traditional systems that have ancient roots; healing is practiced in most religions today, in the form of prayers and rituals. More than 150 studies have validated the efficacy of energy healing in alleviating anxiety and pain, and increasing well-being. However, energy healing, as yet unexplained by existing scientific theories, remains a mystery to Western science. Though little is known about the underlying mechanism or mechanisms of energy healing, evidence-based research exists to suggest its clinical value in supporting and improving health while easing the discomfort of some medical illnesses.

In 2004, another study suggesting CAM trends, “Complementary and Alternative Medicine Use by Women after Completion of Allopathic Treatment for Breast Cancer,” was completed. The study, conducted by Henderson and Donatelle, further supports Eisenburg’s findings. Henderson and Donatelle’s study explored the degree to which CAM therapies were used by women diagnosed with breast cancer; the women in the study ranked diet and energy healing as the most important contributors to their healing. These studies indicate a high consumer demand for energy healing as an option in concert with medical treatment. Furthermore, Benor’s review of more than 150 controlled trials related to energy healing reveals that more than half the studies demonstrated significant results in “Healers and a Changing Medical Paradigm.” The sheer number of studies indicates a high interest in investigating energy healing, and the significant results suggest a potential role for energy healing in clinical settings.
What effects might the use of energy healing have on real-life clinical situations? To best answer this question, the term clinical setting must first be defined. Dorland’s *Illustrated Medical Dictionary* defines “clinical setting” as “pertaining to a clinic or to the bedside; pertaining to or founded on actual observation and treatment of patients, as distinguished from theoretical or basic sciences…Clinician: an expert clinical physician and teacher.”31 According to Mosby’s *Medical Nursing & Allied Health*, clinical medicine is “a system of health maintenance based on direct observation of and communication with a patient.”32 Based on these definitions, the term clinical refers to healthcare delivered by medically trained staff operating in a clinical setting, where they observe and treat patients by means of direct communication.

The question of what impact energy healing has in real-life clinical situations is one of three that Wayne Jonas and Cindy Crawford investigated in their book *Healing, Intention and Energy Medicine: Science, Research Methods and Clinical Implications*.33 Jonas and Crawford’s summary of findings offers critical reviews of healing practices in six categories, of which energy healing is one. More than half of the findings in the studies of energy healing under review proved efficacious, and 11 of the 19 randomized controlled trials reported positive significance.

One of these controlled trials reviewed by Jonas and Crawford, investigated by Michael Dixon specifically addressed energy healing in a clinical setting. Dixon’s controlled study, conducted in 1998, consisted of a quasi-randomized trial in general practice.34 Chronically ill patients were offered ten weekly 40-minute energy healing sessions for three months; further assessments at six months were done for everyone receiving the intervention and for half of the control patients. Approximately 60 percent
of the 87 patients involved with these studies experienced improved well-being and relief from symptoms (chronic symptom of six months or longer in duration, identified by the patient and doctor). Furthermore, this study noted a positive impact on the attitudes of physicians in attendance.

Tim Harlow examines this observation of the positive impact of healing in a clinical setting from Dixon’s investigation in his paper “The Impact of Healing in a Clinical Setting.” Harlow discusses Dixon’s results and methods of the two studies performed at College Surgery, a general medical practice. Physicians in this practice combined CAM therapies including acupuncture, homeopathy, and hypnotherapy for the studies; though some physicians were skeptical of CAM, none voiced outright opposition. All physicians remained open-minded about the possibility of helping their patients and researching energy healing, as they thought it to be a poorly understood therapy.

Harlow details five “effects” or “impacts” experienced by the medical staff through their involvement with the energy healing studies conducted at College Surgery. The first impact was derived from the positive results of Dixon’s controlled study in this practice. As physicians became confident in the use of energy healing, they realized it gave them more options for treatment of patients who were not responding to conventional therapies. The second impact was related to the physicians’ positive attitudes toward CAM therapies as observed by the patients; patients were less hesitant to discuss their use of CAM therapies when the clinical practice included the use of energy healing and the presence of energy healers. Of this effect, Harlow observes that
“paradoxically, our being ready to accept complementary treatments seems to make patients readier to accept our offer of conventional therapy.”

The third impact, which is pointedly relevant to the question discussed in this research, demonstrated the effects of research on the efficacy of energy healing in clinical settings. Harlow maintains that physicians are often so accustomed to the everyday methods of their practices that they are blinded to alternative approaches; conversely, research does not always address the real world of clinical settings and the important issues of everyday practice. Thus, having the physicians involved in the research ensures that the research is pertinent to clinical practice.

The fourth impact Harlow reported demonstrates how conventional practice does not have a foundation of understanding for referring to the use of CAM therapies for specific diagnoses. Based on their research and their experience, the physicians in the clinic were able to determine which medical conditions responded best to energy healing. The research and direct experience in the clinical setting made it clear that conditions, such as impaired immunity, skin conditions, anxiety and depression responded well to energy healing; however, other conditions, such as chronic fatigue syndrome, responded poorly. It is important to note that the patients’ overall responses to energy healing were generally positive, even when it seemed not to have had much effect on their symptoms.

The fifth impact, which Harlow determined as the most surprising of the study, revealed that having energy healing in the clinical practice changed the attitudes and practice of some of the physicians. According to Harlow, the trials changed the doctors’ view of themselves as they became aware of the need to “relearn the power of healing”
within themselves in order to maximize their patients’ benefits. Harlow’s “five impact” summary of the clinical trials and the interface with conventional practice clearly demonstrates the ways energy healing can be complementary to conventional methods in a clinical setting. The most important aspect, according to Harlow’s observations, was the change in the physicians’ mind-set regarding complementary therapies.

In *Healing Research, Volume I*, Daniel Benor reviewed a substantial body of published research on energy healing, dealing with both clinical and laboratory studies. The 59 clinical controlled studies Benor reviewed concluded that more than half the studies indicated significant effects.

Another recent critical review, “‘Energy’ healing research,” conducted by Warber, Kile and Gillespie was carried out in two phases. The results from this review revealed 82 reports related to energy healing; of these reports, 20 were published randomized controlled trials. In summary, a critical review of these trials reported a general positive effect of energy healing across all primary outcomes, such as well-being, anxiety and pain.

The critical reviews by Benor, Jonas and Crawford, and Warber and colleagues clearly indicate that a large body of studies and literature investigating energy healing already exists. Within their critical reviews, a substantial number of randomized controlled studies suggested significant positive outcomes. Even though randomized controlled trials have been viewed as the “gold standard” of research, it is important to note that the National Academy of Science Institute of Medicine on CAM strongly recommends the need for more appropriate research designs that will capture the complex processes of some CAM modalities. With the increased use of CAM therapies,
additional and improved studies will substantiate their impact on healthcare. If patients are increasingly demanding energy healing, as indicated in Eisenburg’s and Henderson and Donatelle’s studies, it is important to continue to examine its efficacy with appropriate research methods. In this way, healthcare providers can render knowledgeable counseling on the topic of energy healing with confidence and build respect for its use in healthcare communities.

The purpose of this research is to investigate the effects of the use of Ama Deus energy healing on anxiety and depression in women with stage III and IV ovarian cancer using a randomized crossover research design.

**Background to Ama Deus Healing**

*You cannot heal until you first Love. Love is in all healing no matter what technique you use, without the Love it is impossible to heal.*

— Alberto Aguas

**Alberto Aguas: The Link to Preserving an Indigenous Healing Technique**

Who was Alberto Aguas and how did he come to teach this energy healing technique named Ama Deus? Very little literature on Aguas exists. His good friend, author David St. Clair, gives us a picture of Aguas in St.Clair’s book *Psychic Healers*.51

Born in Brazil in 1942, Aguas had a reputation as a gifted healer from a young age; he first manifested his natural healing abilities at age six, when he cured a woman plagued for several years with headaches. His mother was a spiritual healer, and his grandfather a physician;52 through their influences, Aguas learned to value both the Western medical model and energy healing.

Though his early years brought him distinction as an actor in Brazil, Aguas came to feel that his future lay elsewhere. In the early 1970s he traveled to the United States,
to extend his career as a healer and lecturer world-wide into his later years. It is known through his lectures that in the last ten years of Aguas’s life, he encountered a specific Guarani Indian tribe in the Amazon and became involved with their Paje (shaman).

Aguas worked alongside the Paje and the village people for many years. The Guarani recognized Aguas’s healing ability but, more importantly, they recognized his capacity for love. The Guarani believe that love is the essential component of healing. The tribe openly shared their holistic approach to healing with him; over the years, he learned how they used herbs, watched their massage techniques and observed auricular acupuncture using bamboo shoots. The technique that became most important to Aguas was the Guarani energy healing system. The Guarani chose to initiate Aguas into their energy healing system because he demonstrated sensitivity to their perspective on life and shared their views on the principles of healing.

Like most indigenous communities, the Guarani have an oral tradition for transmitting their history and sacred healing techniques. The Paje granted Aguas permission to translate the Guarani energy healing system into a form that would be understood in Western classrooms. Aguas named this reshaping of the Guarani energy healing system Ama Deus and he taught that the translation of the Latin words *ama deus* meant “to love God.” According to Cassell’s Latin Dictionary, “amare” translates to the verb “to love,” and “ama” is a verb form of amare; “Deus” means “God.” Thus Ama Deus can be translated as: “to love God.” Like the Guarani Indians, Aguas believed that without the component of love there could be no healing.

Aguas taught in his Ama Deus workshop no matter what healing technique is used, love is the foundation. History abounds with reference to love being the foundation
for healing. In Baird T. Spalding’s book *Life and Teachings of the Masters of the Far East* the explanation given for love is:

The Universe is the sum total of all things visible and invisible that fills infinite space. The Universe is the great whole, composed of all its parts. It might be said that the Universe is another name for God...It is the sum of all life, all substance, all intelligence, all power...It is all Love for it is bound together in a single system and operates as a single unit. Love is the integrity principle or the binding principle which maintains the universe as a unity and keeps all its operations moving in perfect harmony and regularity.⁵⁴

Current recognized leaders in the field of medicine, such as Dr. Andrew Weil, suggest that “love is the one source of sustaining comfort in life and it is of such force that it has miraculous powers of healing in the physical, mental, and spiritual realms. We must try to cultivate that force and to experience it as habitually as possible.”⁵⁵ Bernie Siegel, another medical doctor, answers the question why love is so important in healing with, “Simply because it is the most significant thing in human life.”⁵⁶ A recognized leader in the business field, Stephen Covey, looks “upon love as the supreme activity of life. You need to draw upon the divine energy from God so that you have the power to manifest or express this kind of love.”⁵⁷ And the spiritual leader His Holiness the Dalai Lama reminds us that “the essence of all religions is Love, compassion, and tolerance.”⁵⁸

Aguas spoke of his international travels witnessing many different techniques of healing, but like the Guarani, he observed and believed that the essential ingredient or common thread in all healing was love.

**A Brief Historical Perspective on the Guarani Indians**

The Guarani are one of the oldest indigenous peoples in the world. Aguas estimated their history as spanning more than 6,000 years.⁵⁹ The Guarani of Brazil and Paraguay live in some of the largest subtropical forests in the world. In spite of invasions
by Portuguese and Spanish explorers, missionaries and twentieth-century merchants, the Guarani culture has managed to survive to the present day.

Like many indigenous peoples, the Guarani are a deeply spiritual community. They believe that everyone has the ability to access universal energy for healing and maintaining balanced health. All of the Guarani Aguas encountered, children as well as adults, knew how to work with healing energy. Both the film “The Mission” and Bradford Keeny’s book *Guarani Shamans of the Forest* thoughtfully depict the Guarani’s profoundly spiritual nature.

The Guarani do not believe in illness. They see everything as spirit and believe that outside forces cause imbalance. If the outside force, unwanted spirit, or energy is removed, the physical, emotional and mental bodies are thus restored, and balance and spiritual harmony is maintained. This healing process is done through the use of the energy healing system that Aguas named Ama Deus.

According to Aguas, the Guarani house of prayer served as the spiritual center for the village and the people’s center of focus. The tribe would meet every night without fail to pray, meditate and perform healings. The Paje lit his pipe, sang, danced and chanted while the rest sang sacred songs. To the Guarani, the singing of sacred songs creates a sense of closeness to the spirit world. While conceding that he was not a scientist, Aguas noted that when the songs were sung, an unmistakable vibration could be physically felt, some unexplained sensation beyond “usual” hearing that was palpable in the body. When the sense of connection was felt or physically perceived and a vibration was established, the Paje began his healing. Aguas had the honor of being at the side of the Paje watching the healing. The Paje would say or pray the word Ñhandeva.
repeatedly as he worked: Ñhandeva is a Guarani word for the love aspect of God, the essential ingredient in the Guarani healing process.

**Ama Deus – An Energy Healing Technique**

*No one has a copyright on God’s Love.*

— Alberto Aguas

Now practiced worldwide, Ama Deus is both a hands-on and a distance healing system. As a hands-on healing system, Ama Deus uses techniques common to many indigenous cultures. Energy healing itself has ancient roots. Daniel Benor, probably the most widely read expert on research in healing, argues that such healing practices have been handed down through history by oral transmission via shamans and medicine men, in every known culture. Cindy Crawford, investigator at the Samueli Institute for Information Biology at the University of the Health Sciences, Bethesda, Maryland, states: “Cultures that practice these methods of healing claim that spiritual healing recruits forces beyond belief and expectation.” Because belief is not necessary, it is reasonable to posit that the healing effects of universal energy can be isolated and investigated using good research design.

The Ama Deus Teaching Manual, designed for instructors of this system, provides further explanation of this energy healing technique including the purpose of healing, and the historical background of Ama Deus. The manual is comprised of Aguas’s direct verbal communications and teachings as well as the author’s personal experiences in teaching Ama Deus with Aguas. The purpose of this teaching manual is to ensure and maintain the integrity of the energy healing system. The manual is used for teaching by all instructors of The International Association of Ama-Deus® LLC (IAAD), delivering the same information in a consistent manner to practitioners. There
are several certified instructors of this organization in North America, Central America, South America and Europe. The PI is available to assist in inquiries related to class instructions, and the above mentioned IAAD website contains further information about classes.

Instructors explain in the first session of class, that Ama Deus, as an energy healing system, allows practitioners to tap into a source of energy. This occurs with the learning of a specific invocation, which sets the intention of accessing unconditional love. With Ama Deus, practitioners tap into an energy flow that is connected to love. They access a stream of consciousness, an originally created energy that is enhanced and expanded by all who have ever used it. After invoking the energy, the practitioner is able to use this source of energy for self-healing or to transmit to others, through the hands or via distance healing treatment. This very gentle and subtle energy adapts to circumstances and offers what is needed, as Ama Deus primarily helps to smooth, stabilize, balance and bring tranquility. Its purpose is to support the healing process. The Ama Deus energy healing system can be easily taught to both children and adults. No known dangers or side effects exist in working with Ama Deus.

Ama Deus employs geometric symbols in its application. The universal symbolic language of geometric figures gives purposeful attention to achieving a specific goal during energy healing. There are two levels of training in Ama Deus and different symbols are taught at each level. However, all symbols are used to focus intent toward healing at the immaterial essence of an individual or soul level. For example, instructors of Ama Deus entrust persons initiated into the first level with nine sacred symbols. One of the symbols in the first level addresses the intention of enhancing and expanding the
heart center; another assists in the dying process. In the second level, participants learn additional symbols including one which addresses the intention of accessing the subconscious through the dream state.

The use of symbols with assigned intention allows a practitioner to become a conduit for the healing energy, allowing their mind to be empty, with less personal intention involved with the healing, and offering the recipient the potential for a transpersonal experience. Each symbol has a specific intention and so offers aid in a particular situation—sending healing energy to a person over a distance, for example, or dealing with an emergency situation. These symbols aid the practitioner by offering a concrete focus centered on the intention for invoking the energy.

In keeping with the integrity of the oral tradition of the Guarani and Aguas’s system of structured classes, the sacred symbols are not to be shared with others. In this way, the sacred meaning and intentions of the symbols are preserved. In keeping with the oral tradition of the Guarani, all information is transmitted orally by certified instructors. By maintaining an oral tradition the information passed on does not become a book learning exercise, but rather becomes a way of knowing that is internalized through experience.

Both Aguas and the Guarani stressed the importance of the breath when connecting to and using Ama Deus healing energy. Aguas lectured at length about the importance of the breath. He shared how the Guarani Indians began with deep abdominal breathing when invoking energy for healing purposes. The breath, along with intention centered from the heart in unconditional love, are the most important components for energy healing as demonstrated by Aguas during class and in his lectures of Guarani
healing practices. Aguas said repeatedly, “No matter what energy healing technique you use, without ‘love’ you are not healing.” He shared not only how the pajé indicated that love was the healing agent, but also that the cacique (chief) would use his finger and tap Alberto’s physical body over his heart and say, “always move from here.” In the experience of the principal investigator assisting Aguas as he taught class, along with the emphasis on the breath and unconditional love, he stressed the importance of establishing a relationship with the energy. The practitioner is not a healer, but rather a conduit or channel for the love of God. Many times Aguas would repeat in class, “let go and let God. No healer chooses the way they heal; it comes through the way God wishes. Do not structure it to your needs. You are a channel, an instrument of peace and light: know the Source, be clear about the Source and use it with integrity.” As a practitioner of energy healing, it is important to realize that the healing process occurs between the Universe and the soul of the one receiving the healing.

Direct observation, experience in teaching and years of practicing this technique have demonstrated to the principal investigator Ama Deus’ strong potential as a tool for transpersonal or soul-level healing. This system provides support throughout the healing process, aids in personal growth and invites transformation of consciousness. Ama Deus has strong potential for integration into medical practice, where it could help relieve negative symptoms associated with side effects of allopathic medical treatments. By using the intention of love, an ill person may experience a changed perception of the meaning of illness and gain a sense of control and empowerment. In short, Ama Deus emphasizes healing, and could prove to be a strong foundational block in holistic care and relationship-centered medical practice.
Research Question and Hypotheses

The purpose of this research is to conduct an investigation into the effects of Ama Deus energy healing on anxiety and depression in women in the advanced stages (III and IV) of ovarian cancer. Does Ama Deus energy healing have a positive effect on anxiety and depression in these women, as compared to a general relaxation session? Based on clinical observations, Ama Deus as an intervention appears to be of benefit in the clinical setting as an adjunct to traditional treatments with cancer patients. Thus, the following hypotheses were stated for the purposes of this research:

1. Exposure to Ama Deus energy healing reduces symptoms of anxiety more than a general relaxation session in women with stage III and IV ovarian cancer, as measured by the State-Trait Anxiety Inventory.

2. Exposure to Ama Deus energy healing reduces symptoms of depression more than a general relaxation session in women with stage III and IV ovarian cancer, as measured by the Beck Depression Inventory.

Importance of the Study

This investigation is original to the field of energy healing and energy medicine because, to the knowledge of the principal investigator, no other studies using Ama Deus as an intervention have been conducted. Several energy healing studies have focused on oncology and cancer patient populations; however, no published studies have been found that speak to the use of energy healing in patients with ovarian cancer. Lutgendorf has acknowledged to the principal investigator that a study is in progress using Healing Touch (HT) as an intervention to measure its impact on the Quality of Life for women with cervical cancer. In addition, it is known through personal
communication with faculty members at the University of Michigan that a proposal has been submitted by the department of Complementary and Alternative Medicine at the University of Michigan for funding of research that will investigate the effects of the Barbara Brennan energy healing method on ovarian cancer patients.

Using Ama Deus energy healing to relieve anxiety and depression in patients with stage III and IV ovarian cancer offers a non-pharmacologic adjunct to conventional approaches to treatment.

**Definition of Terms As Used in this Work**

**Ama Deus:** Latin for: To love God, is used as the title to an energy healing technique. Ama Deus is a healing system that uses the intention to tap a higher Source of energy, with Ama Deus one taps into an energy flow that is connected to a particular thought, and that thought is Love. 73

**Chakra:** a Sanskrit word describing whirling foci points of energy in the body that coordinate with various physical and mental functions.74

**Consciousness:** a state of awareness. It is the ability to be aware of self and others; it is the capacity to react to, and attend to, all categories of experience, whether it be through perception, cognition, intuition, or instinct. “Conscious” is contrasted with “nonconscious” or “unconscious,” a state of being below the threshold of consciousness in any category of perception, cognition intuition or instinct.75

**Energy healing:** Energy healing is a system of purposeful intention by a person or persons to catalyze the healing process for another living system using the hands without using any known physical means of intervention.76
**Fourth World:** The fourth world encompasses indigenous populations. The World Council of Indigenous Peoples has chosen to stand apart from the other three worlds—with this designation of “fourth world”—because the first, second and third worlds believe that the land belongs to the people; the fourth world believes that the people belong to the land.  

**Healing:** involves moving in a self-directed way toward wholeness; moving toward acceptance of oneself and others, to a state of balance and harmony with ourselves and our environment. Healing involves self-examination and emotional release.

**HT:** Healing Touch.

**Higher Source of Energy:** God, Universe, Source of All that Is.

**Intention:** consciously holding a thought to act in a specific manner.

**Love:** God, the Universe, Source of All that Is.

**Qi, (Chi) or Ki:** is defined as vital life energy that is constantly transforming with multiple functions in a systemic interdependent network. Qi refers to the perceived Almighty (the original and interconnected energy system).

**Spirit:** Great Principle, God, Source of All that Is, Universe, Absolute.

**Soul:** the spiritual, energetic essence of an individual.

**Spiritual:** an understanding of, and a sense of the interconnectedness to, something larger than oneself, beyond the normal realities of life, a connection to a transcendental force; any feelings, thoughts, experience, and behaviors that arise from a search for that which is generally considered sacred or holy. Spirituality is usually, though not universally, considered to involve a sense of connection with an absolute, imminent, or
transcendent spiritual force, however named, as well as the conviction that meaning, value, direction, and purpose are valid aspects of the universe.\textsuperscript{82}

**TT**: Therapeutic Touch.

**Transpersonal**: beyond the individual ego, mind, and body.\textsuperscript{83}
Chapter 1 Endnotes:


5. Ibid., 1364.

6. American Cancer Society.


10. Ibid., 1410.


28 Cook, Guerrerio, and Slater, “Healing Touch and Quality of Life in Women Receiving Radiation Treatment for Cancer,” 34.
35 Tim Harlow, “The Impact of Healing in a Clinical Setting” in Healing, Intention, and Energy Medicine, 175.
36 Ibid., 179.
37 Ibid., 180.
38 Ibid., 179.
39 Ibid.
40 Ibid., 180.
41 Ibid.
42 Ibid.
43 Ibid.
44 Ibid., 181.
46 Daniel J. Benor, Spiritual Healing.
47 Ibid., 50.
49 Ibid., 97.
52 Ibid.
53 Ibid., 276.
59 Elizabeth Cosmos, Ama Deus Teaching Manual (Grand Rapids, MI: 2004), 16.
61 Ibid.
64 Cosmos, Ama Deus Teaching Manual, 16.
The International Association of Ama-Deus, LLC. http://www.ama-deus-international.com/

Cosmos, 20

Ibid., 26.

Ibid., 15

Ibid., 26.

Shore, “Long-Term Effects of Energetic Healing on Symptoms of Psychological Depression and Self-Perceived Stress.”


Cosmos, Ama Deus Teaching Manual, 20


Ibid.


Douglas Chung, Qigong Therapies: A Self-Care Approach (Grand Rapids, MI: Chung Institute, 2000), 1.

Ibid.

Ibid.
CHAPTER 2:
Review of Literature

Every part of this land is sacred to my people... whatever befalls the earth befalls the sons of the earth. Man did not weave the web of life; he is merely a strand in it. Whatever he does to the strand he does to himself... One thing we know, which the white man may one day discover—our God is the same God. You may think now that you own Him as you wish to own our land. But you cannot... this earth is precious to Him... with all your mind, with all your heart, preserve it for your children and love it... even white man cannot be exempt from the common destiny. We may be brothers after all. We shall see...

— Chief Settle

Though of questionable historical accuracy, this passage captures the essence of the indigenous perception.¹

One Global Community

Fundamental to this research is an understanding of the indigenous perspective of life: the understanding that all life is interconnected to the Universe and the perspective that the earth is home. Conventionally non-indigenous people tend to consider home the four walls of their house, whereas the indigenous view the plants, trees, birds, animals, rocks, mountains, rivers, oceans all as their home. This view of interconnectedness is really their understanding of the interdependence with all life. In Julian Burger’s *The Gaia Atlas of First Peoples: A Future for the Indigenous World* definitions for global communities has been categorized into four sections or worlds and provide a support to begin understanding the indigenous perspective.² We are most likely familiar with three of these worlds: the First World encompasses the industrialized countries; the Second World, what used to be socialist blocs in the former U.S.S.R., which are now an array of various governmental forms; and the Third World, developing countries.
The fourth world encompasses indigenous populations. The World Council of Indigenous Peoples has chosen to stand apart from the other three worlds—with this designation of “fourth world”—because the first, second and third worlds believe that the land belongs to the people; the fourth world believes that the people belong to the land. Understanding this fourth world distinction is the beginning of understanding a true wisdom inherently preserved through the ages by indigenous peoples. Historically, they are not the fourth world; they are the primal world, which is not necessarily a primitive world.

Indigenous peoples have been pushed out of their habitats through the widespread economic expansion of colonialism, past and present. In this ousting and exposure of indigenous ways, we are slowly recognizing that perhaps these peoples are not in such a primitive developmental stage after all. In fact, they present an extensive oral library of lessons on how to live in harmony with the environment and with the world. The fourth world or primal world of the indigenous people is a spiritual world, a world that brings the sacred into everyday life. Healing is a natural component of this sacred life.

**Spiritual Dimensions of Healing**

Our culture has forgotten the sacredness, wholeness, or holiness of health and well-being. The words “whole,” “health,” and “holiness” share a common linguistic root. The modern world is coming to grips with the idea of the interconnectedness of wholeness, a connection that is deeply spiritual.

The Merriam-Webster Dictionary’s definition of “spiritual” is “relating to, consisting of, or affecting the spirit; of, or relating to spiritual matters”; the definition of “spirit” is: “breath, a life-giving force; soul.” Spirituality is not synonymous with any
one religion; it has no doctrine. Being spiritual means cultivating and developing a stronger sense of interconnectedness with and developing a greater awareness of something that is larger than oneself, something beyond the normal realities of life. This “something larger than oneself, something beyond the normal realities of life” may be labeled God, Love or Higher Source of Energy.⁶

Indigenous peoples make connection to “something beyond the normal realities of life” by seeking spiritual experience for healing and maintaining balance and wholeness; they are intimately aware of life’s interconnectedness.⁷ This interconnectedness also applies within their community during healings. Even though the shaman will lead the healing process for an individual, the presence and involvement through singing and meditating by the community plays an important role. “The mere presence of community combats the isolation and demoralization that accompanies illness,” says Ken Cohen in his book Honoring the Medicine: the Essential Guide to Native American Healing.⁸ What can we learn from their experience of sacredness, wholeness, healing, interconnectedness and harmony? How can we use that wisdom to help heal the suffering in the world?

Indigenous healing methods do not focus on symptoms. Holger Kalweit, in her book Shamans, Healers and Medicine Men, observes that indigenous methods are not based on symptoms but rather [they revive] life and heal our relationship with the world—for is illness not the clogging of our spiritual pores, a blockage of a global perception of the world…our bureaucratized and materialistic medicine—this mechanical model with an active therapist and a passive patient… this kind of healing belongs to the mechanical age. Today, however we are already daring to make the transition to “organic” medicine, “spiritual healing” through personal transformation, through the transformation of consciousness on all levels…If we are seeking classical models for this kind of healing, they exist:
the masters of basic health—shamans, primeval healers, primal physicians, wise men and women.\textsuperscript{9}

An understanding of indigenous energy healing is also shared by Malidoma Somé, a wise man of the Dagara tribe from Africa. In his book \textit{Of Water and the Spirit},\textsuperscript{10} Somé claims that his elders are convinced that the West is as endangered as indigenous cultures. “There is no doubt that, at this time in history, Western civilization is suffering from a great sickness of the soul. The West’s progressive turning away from functioning spiritual values, its total disregard for the environment and the protection of natural resources…In the face of all this global chaos, the only possible hope is self-transformation.”\textsuperscript{11} Self-transformation is concerned with healing oneself to regain the loss of interconnectedness and make whole for the self and the good of the community. This research incorporates an indigenous healing practice (Ama Deus) into allopathic medical care.

As stated previously, Ama Deus is an energy healing method based on the healing practices of a specific tribe of Guaraní Indians, indigenous peoples of the Amazon. Bradford Keeney has captured the Guaraní approach to healing in these statements: “We regard health as being in harmony with one another and with nature. Health means to understand and to love all of Creation. This brings inner peace and quiet.”\textsuperscript{12} Energy healing, as understood by the Guaraní, is used for personal transformation. The proposed study seeks to evaluate Ama Deus as a healing method for the purpose of helping to ease anxiety and depression in women with stage III and IV ovarian cancer. The greater goal of the study is to demonstrate and substantiate the strong potential for integrating the indigenous spiritual model with the Western model of medicine.
**Conventional Practice for Ovarian Cancer**

The general public considers ovarian cancer a lethal diagnosis. “Any woman diagnosed with ovarian cancer faces both a true medical challenge and a clear awareness that when she shares her diagnosis with anyone she changes dramatically how she is perceived,” says Sarah Auchincloss, department of Psychiatry at Sloan-Kettering Cancer Center. Ovarian cancer is an aggressive tumor. The prognosis is generally poor, as ovarian cancer is difficult to detect in the early stages; the presenting symptoms are hard to recognize, and women will often see a variety of specialists before seeing the ovarian oncologist. As a result, patients are generally in stage III before they receive proper treatment. In 70 percent of ovarian cancer cases, the disease is diagnosed in stage III or IV. Thus, women diagnosed with ovarian cancer face the very real possibility of early death given that diagnosis at advanced stages results in low survival rates.

The standard treatments for patients diagnosed with stage III ovarian cancer are surgical debulking and chemotherapy. Debulking in ovarian cancer is a major surgical procedure, but its success improves the outcome of chemotherapy. The risk of reoccurrence decreases if all or nearly all of the tumor tissue is removed. (One centimeter or less in size remaining is considered optimal debulking.) Chemotherapy sessions are administered for removing the remainder of the tumor, commonly using taxol or carboplatin, and are scheduled once every three weeks for six treatments. Side effects of chemotherapy include fatigue, nausea, hair loss (including eyelashes and eyebrows) and neuropathy in the hands and feet. After surgery and chemotherapy, a recurrence of the tumor is generally taken as an indication that the cancer is incurable.
The diagnosis of ovarian cancer carries the threat of death and causes significant levels of stress in women both physically and psychologically. Physical stresses are manifested in surgery, cycles of chemotherapy, and the removal of reproductive organs. The psychological impacts on the female patient include a perceived loss of femininity, an altered role with family and friends, and fear for herself and her family, especially for her children. The negative influences of psychological, behavioral, and social variables on the immune system are increasingly recognized by the biomedical research community, healthcare providers, and the lay public,” conclude D. Bovbjerg and H. Valdimarsdottir creating a significantly stressful environment which results in a diminished quality of life for patients diagnosed with ovarian cancer.

**Stress, Cancer and Quality of Life**

Books, articles and research about how stress impacts the immune system abound. W. H. Redd and associates discuss the psychological factors informing the general public’s belief that stress can affect cancer in their study “Physiologic and Psychobehavioral Research in Oncology.” Hans Selye, a pioneer in stress research, identified stress as a major cause of disease. General Adaptation Syndrome (GAS), identified by Selye, presents three stages: stress or alarm reaction of the body; resistance with new adaptation at an increased level of pituitary/adrenal activity; and exhaustion that consumes the body because of the inability to maintain homeostasis. Selye maintained that “resistance and adaptation depend on a proper balance of these three factors.” Our reaction to stress has more impact on the immune system than the stress itself: While stress may predispose to illness, the significant factor still seems to be how the individual copes with it.
In their paper “Implications for Psycho-oncology” D. Bovbjerg and H. Valdimarsdottir state:

The immune system, once widely viewed as operating as an autonomous bodily defense mechanism, is increasingly recognized to be subject to regulatory control by the central nervous system. Interdisciplinary research efforts in “psychoneuroimmunology” have provided compelling evidence of intimate connections between the brain and the immune system, as well as hints of the potential impact of such links for health and disease.\textsuperscript{25}

Michael Winkelman, in his “Neural Ecology of Consciousness and Healing,” explains that the physiology of stress is a complex interaction between the central nervous system, the endocrine system, and the immune system. Psychoneuroimmunology studies the interactions of three systems and identifies stress mechanisms that affect the response of the immune system.\textsuperscript{26} There is much literature concerned with the study of the immune defenses with respect to slowing or preventing the progression of cancer. The complex interaction of stress from illness and the diagnosis of cancer impacts the immune system; directly impacting a person’s quality of life.

Studies have shown that treatment for gynecologic malignancies involving surgery, radiation therapy and chemotherapy can have a significant impact on health-related Quality of Life (QOL).\textsuperscript{27} While several studies purport to measure the QOL—meaning comfort, enjoyment, and ability to pursue daily activities—in newly diagnosed cancer patients, fewer studies have been carried out on patients in advanced stages of the disease, particularly on the QOL for women with ovarian cancer, according to Susan Lutgendorf and colleagues.\textsuperscript{28} In the one-year prospective study, Lutgendorf et al. again found that coping patterns emerged as significant predictors of QOL.\textsuperscript{29} These findings are supported by other studies demonstrating that coping patterns can influence distress in cancer patients. A. Stanton and P. R. Snider investigated coping behavior with breast
cancer diagnosis, as did C. S. Carver et al. in “How Coping Mediates the Effect of Optimism on Distress: A Study of Women with Early Stage Breast Cancer.” The analysis by Carver et al. suggests strongly that several coping mechanisms played a role in the effects of optimism on distress. Acceptance, positive reframing, humor and religion were the most common coping mechanisms in the study. The study involved 59 breast cancer patients and reported coping responses and distress levels at three intervals: pre-surgery; ten days post-surgery; and then at three-, six, and twelve-month follow-ups. The outcomes demonstrate positive correlation, indicating that optimism is effective in active coping. The analysis suggests that acceptance, positive reframing, and practice of religion are the most commonly used coping mechanisms, which support feelings of optimism that lessen distress. Denial and disengagement predicted more distress.

Payne studied 53 women with breast or ovarian cancer in advanced stages for six months. Those patients with extensive treatment, such as hospital-administered chemotherapy, and poorer prognoses were reported to have elevated anxiety and depression. Furthermore, anxiety and depression accounted for most of the variance in QOL.

**Quality of Life in Ovarian Cancer Patients**

A review of the following studies supports research that combines the symptoms of both anxiety and depression in cancer patients for the reason that, in this population, symptoms of anxiety often coexist with symptoms of depression. In a study by B. Cassileth investigating depression and anxiety in patients with cancer, the scores between the State-Trait Anxiety Inventory and the Beck Depression Inventory in patients with
malignancies indicated a high correlation (r = 0.81), supporting the coexistence of depression and anxiety.\textsuperscript{34}

Anxiety and depression significantly impede positive coping which negatively affects the healing process of cancer patients, as indicated in two studies,\textsuperscript{35} one of which is a one-year prospective study\textsuperscript{36} by Susan Lutgendorf et al. These researchers concluded that the data indicated gynecologic patients had “substantial decrements to physical, emotional, and functional well-being and that avoidant coping behavior was associated with poorer Quality of Life and greater distress, whereas active coping was associated with less overall stress and better social well-being.”\textsuperscript{37}

In a study titled “Fatigue in Ovarian Carcinoma Patients,” Bernhard Holzner confirmed that fatigue is a widespread and highly significant symptom in ovarian cancer patients.\textsuperscript{38} Using the Hospital Anxiety and Depression Scale (HADS), the impact of fatigue was found in this study to increase significantly the anxiety and depression scores, along with helpless coping behavior. Holzner indicates that further investigation is needed to understand completely the relationship of fatigue with anxiety and depression.\textsuperscript{39} Holzner notes that behavioral disruptions and emotional distress were prevalent in this patient population; this finding is further supported by F. Guidozzi’s “Living with Ovarian Cancer.”\textsuperscript{40} Guidozzi studied 32 patients, of whom 27 were in advanced-stage treatment. Behavioral disruption and emotional distress was reported as lasting two years after beginning treatment. Similarly, Bordurka-Bevers et al. conclude in their study “Depression, Anxiety, and Quality of Life in Patients with Epithelial Ovarian Cancer” of which 181 patients, or 74 percent, were in advanced stages, that
significant clinical anxiety and depression in ovarian cancer patients may be more prevalent than previously reported.\textsuperscript{41} These studies strongly indicate that psychological support addressing emotional distress is one of the most important ways of improving coping and QOL in cancer patients, and in ovarian cancer patients specifically. Hilary Jefferies, in her study “Ovarian Cancer Patients: Are Their Informational and Emotional Needs Being Met?” begins her introduction by stating, “Emotional and social support is of paramount importance to oncology patients as it can have a positive effect on physical health, mental well being and social functioning.”\textsuperscript{42} Given the steady rise in highly aggressive treatment plans, which have increased survival time,\textsuperscript{43} QOL becomes very important in view of the psychological effects of cancer: “A growing literature is suggesting that the development and progression of cancer and other medical illness is affected by psychological and social factors, such as coping style, stress, and marital status,” according to W. H. Redd and colleagues.\textsuperscript{44} The empirical evidence discussed suggests that QOL and symptoms of anxiety and depression are prevalent in individuals diagnosed with cancer and are important factors in coping with cancer treatment. The empirical research cited supports the need to improve and make available interventions that positively sustain behavioral and emotional needs, and elevate QOL and decrease anxiety and depression.

\textbf{Anxiety and Depression in Cancer Patients}

As reported, many studies show that anxiety and depression lower QOL for cancer patients. The diagnosis of ovarian cancer elicits a predictable response of emotional distress, with a primary fear of painful death.\textsuperscript{45} Jimmie Holland shares a
similar opinion: “Individuals who receive a diagnosis of cancer, learn that relapse has occurred, or that treatment has failed show a characteristic emotional response: a period of initial shock and disbelief, followed by a period of turmoil with mixed symptoms of anxiety and depression, irritability and disruption of appetite and sleep.”

A closer look at anxiety and depression in relation to cancer clarifies how these symptoms of stress significantly impede the healing process.

**Anxiety**

Anxiety is prevalent in patients diagnosed with cancer. The definition of “anxiety” from *Psychiatric Nursing* reads: “A diffuse apprehension vague in nature and associated feelings of uncertainty and helplessness. It is an emotion without a specific object, is subjectively experienced by the individual, and is communicated interpersonally. It occurs as a result of a threat to the person’s being, self-esteem, or identity.”

According to the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revised (DSM-IV-TR)*

The essential feature of Generalized Anxiety Disorder is excessive anxiety and worry, occurring more days than not for a period of at least six months, about a number of events or activities. The individual finds it difficult to control the worry. The anxiety and worry are accompanied by at least three additional symptoms from a list that includes restlessness, being easily fatigued, difficulty concentrating, irritability, muscle tension, and disturbed sleep.

Anxiety arises in cancer patients at the time of diagnosis, while waiting for treatment, and throughout advanced or terminal stages. Cancer patients who experience anxiety exhibit symptoms of irritability, loss of appetite, and difficulty sleeping. The State-Trait Anxiety Inventory (STAI), developed by Charles Spielberger, divides anxiety into two categories: State and Trait. State anxiety is transitory, occurring with appropriate stimuli; it is characterized by feelings of tension, apprehension, nervousness,
and worry, and by activation or arousal of the autonomic nervous system. Trait anxiety refers to personality or acquired behaviors of how individuals perceive the world.  

Treatments for Anxiety

Pharmacological treatments for anxiety are widely prescribed for cancer patients. Surveys show that between one-quarter and one-third receive anti-anxiety drugs; benzodiazepines are the most frequently prescribed. In addition to reducing anxiety, these drugs also reduce the side effects of nausea and vomiting associated with chemotherapy. Clinical trials have studied the effectiveness of benzodiazepines, and indicate a significant reduction in the anticipatory nausea, vomiting, and phobic anxiety accompanying the treatment of chemotherapy. A double-blind crossover study using lorazepam, a benzodiazepine, assessed its effectiveness as compared to a placebo in controlling nausea and vomiting in 107 patients undergoing chemotherapy. The study showed a significant reduction in severity of nausea (p<0.002) and duration of vomiting (p<0.0016). Anxiety was reduced, but not significantly, and there was significantly more sedation (p< 0.0001). In using benzodiazepines, patients benefit from a reduction in nausea and vomiting. These studies demonstrate the limited effectiveness of pharmaceutical intervention in reducing anxiety.

Two physicians, Mary Jane Massie and Elisabeth Shakin, discuss the management of depression and anxiety in cancer patients in a chapter from Psychiatric Aspects of Symptom Management in Cancer Patients. They used a combination of relaxation techniques and anxiolytic medications for decreasing daytime anxiety and relieving insomnia at bedtime. According to their summary, a multidisciplinary approach is an effective means to help patients through the stressful process of cancer treatment.
Other than medication, treatments for anxiety include emotional support, adequate information about their disease and treatment plan, relaxation techniques, distraction, and cognitive reframing. A study by Holland et al. compared treatment using alprazolam, a benzodiazepine, to treatment with progressive muscle relaxation, and found both significantly reduced symptoms of anxiety; however, patients using the drug showed a more rapid decrease. In an un-blinded, randomized ten-day study, alprazolam was compared with progressive muscle relaxation in reducing the symptoms of anxiety and depression in 147 cancer patients. Significant reduction for anxiety and depression (p<.001) was seen in both groups. Approximately two-thirds of all participants showed significant improvement; however, the margin was greater on certain measures with alprazolam versus the behavioral intervention.

Fawcy, Fawcy, Arndt and Pasnau, reviewed studies related to psychological treatment for anxiety in cancer care. This review noted the four most commonly used psychological treatments: education, behavioral training, individual psychotherapy and group interventions. The use of education is intended to reduce the feeling of helplessness; however, behavioral techniques have proven to be a stronger intervention. Noyes Jr., Holt, and Massie report that “behavioral training methods have been used along with many cancer interventions to reduce physical as well as psychological distress, and these methods have, in general, yielded more robust responses than education. Behavioral techniques have included progressive muscle relaxation, hypnosis, deep breathing, meditation, biofeedback and guided imagery.” All of these techniques were used in the studies that Fawcy and colleagues reviewed, either in combinations or
alone. The most frequently reported techniques used in the studies were progressive muscle relaxation (PMR) and guided imagery (GI).

One study, by Morrow and Morrell, looked at the effects of systematic desensitization with PMR in reducing anticipatory nausea and vomiting. Sixty patients were randomly assigned to three groups: no treatment; counseling; or desensitization with PMR. Morrow et al state: “Significantly more patients receiving desensitization reported no anticipatory nausea before their fifth and sixth chemotherapy treatments than patients given counseling (p<0.05) or no treatment (p<0.01). Desensitized patients also reported significantly less severe anticipatory nausea (p <0.01) and vomiting (p <0.05) and a shorter duration of anticipatory nausea (p <0.01).”

A drug-free, natural approach to anxiety is another option for treatment. Some behavioral techniques, such as deep breathing, meditation, and muscle relaxation can be seen to fall into this category. Most natural approaches to anxiety have not been documented by empirical research. They are rooted in a holistic model that differs from the traditional Western model in that it addresses the whole person. In his “Natural Relief for Anxiety,” Ed Bourne plots out holistic strategies for easing fear, panic, and worry by combining practices such as exercise, nutrition, meditation, and spirituality.

Recent studies of CAM therapies in reducing anxiety in cancer patients have found significant decreases in anxiety using massage as the intervention. *Outcomes of Therapeutic Massage for Hospitalized Cancer Patients* by Smith et al. examines the effects of massage on the patient’s perception of pain, symptom distress, and anxiety. Using the Spielberger State-Trait Anxiety Inventory, Smith’s findings showed statistically significant improvement in subjects who received massage. Pain, symptom
distress, and anxiety improved for the participants who received massage; only anxiety improved for participants in the comparison group. Another study by Stevenson et al. suggests that foot reflexology as a self-care approach may decrease anxiety in breast and lung cancer patients. This pre-test/post-test designed study demonstrated a significant decrease in anxiety in breast and lung cancer patients, following the intervention of foot reflexology. One of the three pain measures used in this study indicated breast cancer patients experienced a significant decrease in pain.

Other CAM therapies, such as acupuncture and music therapy, are being used to help ease anxiety in hospitalized cancer patients. The studies associated with these therapies as interventions demonstrate improvements in anxiety and other symptoms of distress.

**Depression**

Depression in cancer patients presents the following psychological symptoms: hopelessness, feelings of helplessness, loss of self-esteem, feelings of worthlessness, and thoughts of death.

“Depression” is defined in *Psychiatric Nursing* as “an abnormal extension or over-elaboration of sadness and grief. The word depression can denote a variety of phenomenon (e.g., a sign, symptom, syndrome, emotional state, reaction, disease, or clinical disorder).” The *DSM-IV-TR* provides the following description for depression:

The essential feature of Major Depressive Disorder is a clinical course that is characterized by one or more Major Depressive Episodes: depressed mood most of the day… markedly diminished interest or pleasure in all, or almost all, activities… significant weight loss, insomnia or hypersomnia most of the day, psychomotor agitation or retardation…, fatigue or loss of energy nearly every day, feelings of worthlessness or excessive or inappropriate guilt nearly every day…, recurrent thoughts of death…
In relation to cancer, depression is considered a normal response to an initial diagnosis, to learning that a relapse has occurred, or when treatment has failed.\textsuperscript{70}

**Treatments for Depression**

The standard treatment for depression in cancer patients is a combination of supportive psychotherapy and pharmacological treatment.\textsuperscript{71} The standard pharmacological treatment is the use of antidepressants such as selective serotonin reuptake inhibitors (SSRIs).

The side effects of drugs and the patient’s drug history are relevant variables that support the need to increase management of treatment for depression in cancer patients. Nancy Lovejoy shares this concern in her study of mood-altering drugs with cancer patients: “Undertreatment of depression in patients with cancer is a clinical problem requiring prompt action. Although responsive to cognitive and behavioral interventions, unipolar depression in patients with cancer often requires pharmacologic management. Because of pathologies associated with cancer and its treatment, pharmacologic outcomes are often unpredictable, necessitating careful assessment of risk factors for over and undermedication.”\textsuperscript{72}

Some patients who have contraindications to pharmacologic treatments have been treated with Electroconvulsive Therapy (ECT). Those cancer patients who exhibit suicidal or psychotic tendencies are also considered candidates for ECT. Present data demonstrate ECT may be more effective than pharmacotherapy.\textsuperscript{73}

Psychological treatment for management of depression is often requested by cancer patients when in times of crisis, such as first hearing of the diagnosis, a recurrence of the diagnosis, or the perceived threat of death. The goal of psychotherapy
is to support the patient through educational, emotional, and social interventions, along with cognitive coping techniques.\textsuperscript{74} Psychological interventions support the patient with coping strategies that provide a sense of control over the illness.

CAM interventions are showing themselves to be effective treatments for coping with anxiety and depression. Michael Speca’s study illustrates this. He employed a randomized, wait-list controlled design to research the effects of mindfulness and meditation on mood disturbance and symptoms of stress in cancer patients. Using both the Profile of Mood States and the Symptoms of Stress Inventory to evaluate his subjects before and after the intervention, Speca found the treatment group showed more vigor, and had significant reduction in total mood disturbance and in the subgroups of anxiety, depression, anger, and confusion.\textsuperscript{75} Another randomized study, undertaken in an Australian hospital by Rodney Petersen, demonstrated significant effects using relaxation and counseling as interventions.\textsuperscript{76} A statistically significant reduction was seen in both anxiety and moderate depression.

Given the current interest in research and the findings for CAM interventions, frequently referred to as Integrative Medicine in clinical settings, validated options are beginning to open for supporting cancer patients with anxiety and depression.

**CAM Usage with Cancer Patients**

As noted earlier, Eisenburg’s study indicates that CAM is a growing area of study due to increasing public interest in holistic therapies.\textsuperscript{77} Henderson and Donatelle claim that CAM’s growing popularity reflects the changing needs and values in modern society in general. Their study “Complementary and Alternative Medicine use by Women after Completion of Allopathic Treatment for Breast Cancer”\textsuperscript{78} shows that when cancer
patients use CAM, they are more likely to take an active role in the treatment of their cancer and its symptoms; they maintain general health and well-being; and their immune functions improve, as does their QOL. The nature of this study was to determine how frequently CAM therapies were used and their degree of importance to women diagnosed with breast cancer. The majority of participants felt the use of CAM was moderately important; diet and spiritual healing were the most commonly used forms of CAM. The study also found that more than 40 percent of participants used CAM as a treatment because the single most important expectation was increased QOL. CAM enabled patients to reduce stress, feel in control, and boost their immune systems—positive effects supported by other studies.

Henderson and Donatelle’s study also shows energy healing to be one of the women’s top choices among CAM therapies. This corresponds with the principal investigator’s literature review on energy healing and cancer, a search that revealed more than 200 peer-reviewed studies, some of them dating back to the early 1980s. In 1990, Benor reported 114 studies on energy healing, of which 61 reported significant therapeutic effects. Eisenberg and colleagues found that, among 16 CAM therapies investigated—including approaches such as Reiki, Therapeutic Touch™ (TT), Healing Touch™ (HT), and Qigong, all of which use energy to heal and involve a practitioner and a recipient—the demand for energy healing is fastest growing.

Prevalence of Energy Healing

The rapidly growing demand for energy healing in the United States has generated a strong interest in researching the efficacy of this therapy. Sara Warber, Director of Complementary and Alternative Medicine at the University of Michigan, and
her colleagues have performed two systematic reviews concerning the quality of research involving energy healing.\textsuperscript{83}

The discussion from Warber’s review results in several observations. First, Therapeutic Touch (TT) dominates the field of study on energy healing; this is not surprising, as there are a large number of nurses who practice TT and, as they work in clinical settings, have relatively easy access to study participants. Second, of the many published investigations and unpublished dissertations, twenty are randomized controlled clinical trials.\textsuperscript{84} This confirms an interest in using energy healing in clinical settings.

Warber’s systematic review reveals a large interest in validating the efficacy of energy healing and the need for replication of scientifically rigorous investigations. In the majority of studies on the use of TT, anxiety was one of the variables; two of the studies involved cancer patients. While investigating TT, Marie Giasson and Louise Bouchard studied a patient population with terminal cancer, focusing the outcome on the sense of well-being. The results showed a significant difference in the mean progression of sensation of well-being between the experimental group and the control group, ($t= -3.73; p=.0015$). The experimental group showed a mean increase of 1.70 and the control group showed a decrease of 0.31, supporting Giasson and Bouchard’s hypothesis that TT increases the sensation of well-being in terminally ill cancer patients.\textsuperscript{85}

As previously discussed, according to Lutgendorf and S. A. Payne, very few studies regarding QOL in cancer patients have focused on patients with ovarian cancer. No known published research uses energy healing as an intervention with ovarian cancer.

Daniel Benor, also discussed in the introduction, has reviewed a substantial body of published research on energy healing in both clinical and laboratory studies. His
review reveals that more than half the studies indicate that energy healing has significant effects. Of the 61 studies with human participation, TT was the most commonly used intervention (specifically, 28 studies used TT, five used Reiki, one used HT). Benor listed one study on cancer, thirteen on anxiety (State), three on depression, and two that combined anxiety and depression.

Across the three systematic reviews, two studies on energy healing and cancer met the quality controls standards for reviewing clinical trials. Giasson and Bouchard’s study “The Effect of Therapeutic Touch on the Well Being of Persons with Terminal Cancer,” previously discussed in Warber’s review, showed positive results; however, the principal investigator was the healer used for the study, which could create a level of bias if it was deemed that this person had advanced or unusual abilities and the sample size was small.

The second study of Samarel et al. on the “Effects of Dialogue and Therapeutic Touch on Preoperative and Postoperative Experiences of Breast Cancer: An Exploratory Study” with thirty-one participants showed a positive result in the experimental group (n=14) versus the control group (n=17). Univariate analysis revealed that women in the experimental group had lower State anxiety than women in the control group (p=0.008), a statistically significant rate. These conclusions indicate that a large-scale study is warranted.

As well, in the systematic reviews seven key research studies measured anxiety, which included Samarel’s study noted above. All seven of these studies were also listed in Cindy Crawford and Wayne Jonas’s annotated bibliography of controlled clinical trials with quality scores. In Kathryn Lafreniere’s study, the experimental
group showed significant reduction in anxiety (p<0.01), demonstrating that TT is effective in reducing anxiety. Participants were randomized to either the experimental group, who received TT, or a control group who did not receive TT.

Janet Quinn’s two investigations, “Therapeutic Touch as Energy Exchange: Testing the Theory” and “Therapeutic Touch as Energy Exchange: Replication and Extension,” demonstrated positive results in reducing anxiety with TT. The objective of the first study was to determine the effect of TT without physical contact on State anxiety in cardiovascular patients. The non-contact group scored a significantly greater decrease in State anxiety (p<0.0005) compared to the control group (p<0.082). The second study by Quinn was an investigation to determine the effect of having no facial or eye contact between the TT practitioner and the participant. A total of 153 preoperative patients, scheduled for open heart surgery, were randomized to three treatment groups: TT, mock TT, or no intervention. As hypothesized, the TT group showed the largest difference; the mock TT group showed the second largest; and the no-intervention group showed the least change.

A 1993 study by Simington and Laing suggests that TT reduces anxiety in the institutionalized elderly. The study’s method demonstrated the effects of TT combined with a back rub; 105 patients were randomized to either a group who received a back rub and TT or a group who received a back rub with no TT. Anxiety scores of the group who received the back rub and TT were found to decrease significantly from those who received a back rub without TT.

D. Gagne and R. Toye conducted a small, randomized control study in which TT was used with psychiatric inpatients at a Veteran’s Administration hospital. A total of
31 participants were randomly assigned to three treatment groups: TT, mock TT and relaxation therapy. Both the TT group (23%) and the relaxation group (26%) reported significant reduction in anxiety in the STAI scores. The mock TT (7.7%) demonstrated small but not statistically significant reduction (p<0.05). 99

M. Ireland studied the effects of TT on children with HIV and measured their levels of State anxiety. Twenty children participating in a pilot study were randomized to either TT or mock TT treatment groups; the TT group showed significant decrease in anxiety (p<0.01) compared to the control group (p<0.20) which showed no significant decrease. 100

All seven of these studies used the State-Trait Anxiety Inventory (STAI) 101 as a single psychometric measure or in combination with another measure. All seven demonstrated the potential for positive outcomes by using energy healing in clinical settings.

A 2003 study by Janice Post-White demonstrated a reduction in anxiety with cancer patients using CAM therapies. This randomized crossover study tested the effects of massage and Healing Touch (HT) on 230 participants, as compared to standard care or simple presence of a caring professional. Massage was the only intervention that produced significant decreases in anxiety. There was a non-significant decrease in anxiety with HT; however, HT demonstrated significant results in reducing fatigue, as measured by the Profile of Mood States (POMS). 102 Thus, indicating an improvement in the QOL. Additionally, Greyson’s study using depression as a variable found no significant improvement in a small trial using the LeShan meditation technique and distance healing on patients being treated for psychiatric disorders. 103
Of all these studies, two previously discussed measured both anxiety and depression while using a form of healing intervention: one measured the effects of prayer,\textsuperscript{104} and the other measured the effects of energy healing.\textsuperscript{105} S. O’Laoire conducted an experimental study to determine the effects of distance prayer (which consisted primarily of intention and visualizing the patient as healed) on anxiety and depression; no significant differences were found between the experimental and control groups. Michael Dixon’s study on energy healing—employing a technique that consisted of a healing practitioner applying a sweeping movement with the hands over the entire body while visualizing white light running through the practitioner into the patient—revealed it to be an effective intervention by significantly reducing anxiety and depression in chronically ill patients.

Altogether, these studies, which have similar outcome measures and population as this research indicate a large interest in demonstrating the effectiveness of energy healing in clinical settings, and indicate an overall moderate positive outcome. Such research provides further validation for the importance of this research.

\textbf{Ama Deus as Compared to Other Energy Healing Techniques}

Ama Deus is both a hands-on and distance healing technique that accesses universal energy for purposes of healing. It is practiced worldwide, yet it is not among the most widely known or widely used energy healing technique in North America. The most well known techniques practiced include Reiki, TT, HT, and Qigong. Ama Deus shows similarities as well as differences when compared to these other hands-on healing techniques which are explored in the following sections.
Reiki

Reiki is widely used in the Western world and many thousands practice this technique around the world. Reiki as developed by Dr. Mikao Usui, taps into “ki,” the universal life energy, for purposes of healing oneself or others. Reiki is similar to Ama Deus in its approach to accessing energy. Some of the standard works discussing the history and use of Reiki are Reiki Fire by Frank Arjava Petter and Empowerment through Reiki by Paula Horan. Reiki Energy Medicine by Libby Barnett and Maggie Chambers elaborates not only on the history of Reiki but also on its comprehensive use in hospitals and hospice care.

There are many similarities between Reiki and Ama Deus. Both tap into higher energy sources; both have specific mantras or prayers used to invoke or tap into this energy source. Both use symbols to give definition to the intention of their use, and both were introduced to the world by gifted healers: Reiki by Usui and Ama Deus by Alberto Aguas.

As hands-on and distance healing techniques, Reiki and Ama Deus are easy to use in everyday situations to benefit oneself or others, as appropriate. They both possess the kind of simplicity and adaptability that allows them to integrate more easily into health-care settings. Barnett and Chambers, demonstrate this adaptability in their book Reiki Energy Medicine.

Because the practice of Reiki does not require complicated techniques, practitioners of many and varied disciplines are able to incorporate it easily into their specialties. By virtue of the fact that it enhances their healing skills and is also a rejuvenating practice of self-care, Reiki is becoming an important bridge of communication among a wide range of health-care providers.

Reiki has been used in observational and non-randomized studies. The significant outcomes from the preliminary trial “Using Reiki to Manage Pain: A Preliminary
Report,” by Karen Olson and John Hanson,\textsuperscript{113} led to the full investigation “A Phase II Trial of Reiki for the Management of Pain in Advanced Cancer Patients,” by Olson, Hanson and Mary Michaud.\textsuperscript{114} Twenty-four participants were randomized to either an intervention group receiving Reiki or a control group receiving a rest period. The purpose of the study was to determine whether Reiki was an effective adjunct to the standard treatment for cancer pain with opioids, which are synthetic narcotics. Measures of pain showed a highly significant improvement following Reiki treatment (p<0.0001) compared to the rest period.\textsuperscript{115}

Another randomized control study similar to this research using Ama Deus is “Long-Term effects of Energetic Healing on Symptoms of Psychological Depression and Self-Perceived Stress,” by Adina Goldman Shore.\textsuperscript{116} In her study, Shore demonstrated a significant reduction in symptoms of psychological distress in treatment groups as compared with the control (p<0.05) using Reiki as the intervention. These studies validate the use and prevalence of Reiki as an adjunct in the health-care setting.

\textbf{Therapeutic Touch\textsuperscript{TM} (TT)}

Dolores Krieger, a registered nurse and the founder of TT, developed this system with the gifted healer Dora van Kunz by studying natural healers from other cultures.\textsuperscript{117} Krieger conducted investigations centering on the idea that healing is a natural human potential that can be taught. There are two primary factors in the practice of TT: focused intention and a transfer of energy from the environment through the healer’s hands to the subject.\textsuperscript{118}

As reported above, in reviewing the literature on energy healing research, the largest number of studies exists on TT; this is probably because between 20,000 and
30,000 healthcare practitioners use this therapy.\textsuperscript{119} Olson and Sneed designed a small randomized trial investigating the effectiveness of TT in reducing State anxiety in 40 healthy professional caregivers.\textsuperscript{120} The correlations between the three self-reported measures of anxiety were highly significant; however, the small sample size prevented differences between treatment and control groups to reach statistical significance. Despite this, the study did demonstrate that the high-anxiety group who received TT had a reduction in anxiety as compared to those who did not receive TT.\textsuperscript{121}

**Healing Touch International\textsuperscript{TM} (HT)**

Developed by Janet Mentgen, Healing Touch is similar to TT in practice; however, it encompasses additional healing practices such as chakra treatment, meditation and the use of pendulums.\textsuperscript{122} A randomized study using HT was published in 2004 by Cynthia Loveland Cook, Joanne Guerrerio, and Victoria Slater.\textsuperscript{123} Their study investigated the effects of HT on QOL for women receiving radiation treatment for cancer. Participants were randomized to groups receiving either HT (n=44) or a mock treatment (MT) (n=34). HT significantly demonstrated improving conditions of pain, physical functioning and vitality over MT. The study results suggest HT is beneficial in improving QOL in women with gynecological or breast cancer who are undergoing radiation treatment.\textsuperscript{124}

**Some Distinctions in Energy Healing**

In her article “What are the Distinctions between Reiki and Therapeutic Touch?”\textsuperscript{125} Pamela Potter discusses her sense of difference. Potter had been practicing TT for more than ten years when she trained in Reiki. Her overall opinion is that the outcomes are the same for both techniques; however, the journey to the outcomes is
Potter described some of the differences in Reiki and TT as follows: TT is generally described as a non-contact intervention, whereas Reiki practitioners place their hands on the recipient predominantly in a structured format. Therapeutic Touch is a process of directing energy through intention, whereas Reiki is facilitated by a practitioner who is open to energy and enables the flow of universal energy to reach the recipient. These descriptors of Reiki compare directly to how Ama Deus is used. In Reiki, an attunement process opens practitioners up to the flow of energy. Similarly, Ama Deus has an initiation process that connects the practitioner to the flow of energy.

Potter describes her first experience of Reiki as follows, and, in the experience of the principal investigator, this happening is shared by many people who have participated in Ama Deus initiations:

After more than ten years of practicing TT and healing touch, I added Reiki to my healing repertoire. The attunement process was palpable. Although I did not expect it, I could feel the movement of energy within me unlike any I felt from receiving energy field treatments. The technique for passing on the attunement reminded me of a shamanic healing ritual. Does a difference exist for people attuned to Reiki who practice TT? For me, the quality of my ability to assess and treat people changed and became less directive, more intuitive, and more like prayer. The effort involved in staying centered, grounded, and clear was no longer a concern: hands-on, centering-on, Reiki-on. Rand (1991) told a story of experienced healers who were amazed to find their healing energies raised to a higher vibration with Reiki attunement.

Potter’s experience is not unlike the personal experience of this principal investigator using Ama Deus. One possible explanation for these experiences is explored by Michael Winkleman, who delivers a fascinating perspective on shamanic healing in his book *Shamanism: The Neural Ecology of Consciousness and Healing.* Winkleman’s physiological and psychological presentation of the processes at work in shamanic healing depicts ancient traditions as a foundation for understanding.
consciousness and human development—then and now. This informative work provides a rationale for the reemergence of traditional techniques in contemporary practices, and is instructive, for example, in understanding Potter’s experience of her Reiki attunement and her sensing of a higher vibration. Ancient traditions, like shamanism with their understanding of multiple dimensions of reality, offer help in understanding the therapeutic alteration of consciousness.

**Qigong**

Qigong, another healing energy therapy, has been used for roughly 8,000 years and is practiced in more than 3,000 variations. Traditionally, these variations have been divided into four categories: health for maintenance, medical for healing; martial for fighting; and spiritual for enlightenment. Qigong is a practice used to cultivate one’s “chi.” Practicing Qigong awakens chi that lies dormant and accesses energy in the environment to store or to revitalize oneself.

Wayne Jonas and Cindy Crawford critically reviewed laboratory and clinical research with Qigong in their 2003 article “Science and Spiritual Healing” published in the journal *Alternative Therapies*. The evaluation, conducted by Michael Mayer involving 33 controlled studies, examined the effects of Qigong on hypertension. Evidence suggests that practicing Qigong has positive effects on hypertension.

Qigong is a healing practice for oneself and in advanced practice, for aiding others. This practice depends on individual discipline in performing the exercises and enhancing one’s own chi level. This technique appears to be a very beneficial system for health and longevity. Ama Deus, however, does not require one to develop innate chi in order to begin using the technique for healing or personal growth. However, practicing
Qigong could aid an Ama Deus practitioner in being more attuned. Again, this can be seen as very similar to Potter’s experience of her Reiki attunement enhancing her TT practice.

**Comparison Summary**

Each of these energy healing therapies draws information either from oral teachings, such as Reiki and Qigong, or from observing healers, as in the case of TT and HT. As well, each technique discussed thus far shares some similarities with Ama Deus. Reiki is the most similar to Ama Deus in principles and methods; TT, HT, and Qigong reach similar outcomes through different pathways. All of these energy healing techniques have had some level of scientific investigation—except for Ama Deus. The benefits of researching Ama Deus includes not only a structured test of its efficacy, but also adds to the growing body of research on energy healing suggesting that this field of therapy is beneficial and supportive with conventional medical practice.

**Ama Deus: The Scientific Connection**

Cultures that practice healing methods claim that energy healing recruits forces beyond belief and expectation.\(^{135}\) Ama Deus involves directing or channeling a “biofield,” or healing energy, through an individual toward a patient or self with the goal of improved health outcomes. Warber gives the definition of “energetic biofield” from the National Institutes of Health Office of Alternative Medicine as “a massless field, not necessarily electromagnetic, that surrounds and permeates living bodies and is postulated to affect the body.”\(^{136}\) The principal investigator has learned, through direct experience with Reiki and Ama Deus, that energy healing is the laying of hands on or near a person with the intention of opening to and transferring universal energy for the purpose of
healing in a spiritual frame of mind or presence. Crawford maintains that if there is more to energy healing than belief, then such effects should be able to be isolated by appropriate methods, which she feels are randomization, blinding, and control conditions.\textsuperscript{137}

A recently published book, titled \textit{The Scientific Basis of Integrative Medicine} by Leonard Wisneski and Lucy Anderson, includes a comprehensive listing of and references to research in energy healing. Of particular interest to this research is the discussion of Dr. William Tiller and Russel Targ’s work. Tiller, a scientist, researched the structure of matter in the department of Material Science and Engineering at Stanford University. He demonstrated a very specific exchange of electrical current that occurs as healers perform their work.\textsuperscript{138} Targ, a physicist from Stanford Research Institute, conducted investigations funded by the Central Intelligence Agency (CIA), providing a theoretical basis for the transfer of energy from person to person. Targ’s work confirmed how information is acquired psychically, or what he termed remote viewing. He maintains that spiritual healers are in touch with their interconnected and nonlocal minds in facilitating healing.\textsuperscript{139} When Aguas described how Ama Deus was used in the Guaraní community, he specifically observed that the Paje would not begin healing until a certain vibration was sensed, a vibration created by a grouping of people; this suggests a scientifically observable phenomenon. Such a phenomenon gives rise to the possibility of an explanation for how energy healing works that lies in the realm of quantum physics—a possibility that sparks thought and fuel for further study.

In \textit{The Field: The Quest for the Secret Force of the Universe}, Lynne McTaggart brilliantly describes a scientific perspective on energy that indigenous societies and
spiritual masters have understood for several thousand years. In the chapter “Beings of Light,” McTaggart discusses the historical progression of scientific investigation into the interaction of electromagnetic radiation on biological fields. This broadly documented chapter can perhaps explain Aguas’s experience of the vibration that was created before any healing took place in the Guaraní village. The chapter is filled with the contributions of biologists and physicists such as Fritz-Albert Popp, Rupert Sheldrake, Alexander Gurwitsch, Harold Burr, Elmer Lund, Robert Becker, and Albert Szent-Győrgyi, who were advancing the idea of electrical waves and radiation and oscillating waves as being responsible for living processes, such as synchronizing cell division and sending chromosomal instructions around the body. These contributions to science seem to provide a convincing bridge to a closer understanding of indigenous healing methods.

Yet another example of the encouraging potential in researching energy healing to support our understanding of energy consciousness can be found in the work of Herbert Frohlich, a physicist and the recipient of the annual Max Planck Medal for his outstanding career as a physicist. McTaggart reports that Frohlich is one of the first to introduce the idea that some sort of collective vibration was responsible for getting proteins to cooperate with each other and carry out instructions of DNA and cellular proteins. Frohlich even predicted that certain frequencies (now termed ‘Frohlich frequencies’) just beneath the membranes of the cell could be generated by vibrations in these proteins...Frohlich had shown that once energy reaches a certain threshold, molecules begin to vibrate in unison, until they reach a high level of coherence. The moment molecules reach this state of coherence, they take on certain qualities of Quantum mechanics, including nonlocality. They get to the point where they can operate in tandem.

Explorations such as Winkelman’s and Frohlich’s contribute to expanding the understanding of energy healing by bridging indigenous traditions and science.
Measuring Biological Energy Fields of the Hands

An interesting parallel in this literature discussion with regard to energy healing is the technological advances and investigative research that support the measurement of energy in the human energy field. Technological advancement has opened the opportunity to study these more subtle fields. New technologies can detect the effects of energy emitted from practitioners’ hands during energy healing; laboratory equipment can now detect the effects of “healing hands” even when the healer has no direct contact with a patient’s body. As this subject could be a research investigation in itself, it is worth mentioning as the hands are widely used in energy healing and give support to the cultures that insist that belief is not a factor as mentioned earlier. Perhaps the inquiry of science can help to explain the biological factors involved.

James Oschman, in his book *Energy Medicine*, summarizes key scientific advances in measuring biological energy fields:

- In the early 20th century, it was discovered that various organs in the body produced electrical fields that can be detected on the skin.
- In the 1950s, instruments were developed to detect the electric currents that flow through tissue. The SQUID (an acronym for superconducting quantum interference device), used around the world in medical research laboratories, led to new clinical tools such as magnetocardiography and magnetoencephalography.
- Medical researchers have explored the application of electric and magnetic fields to stimulate healing; sensitive photometers and thermographic imaging techniques have enabled scientists to map the patterns of light and heat emitted from cells, tissues, organs, and the entire body.
- Cell biologists are recognizing that regulations involve more than nerve impulses and hormones, and that nuclear, cytoplasmic, and extracellular matrices form a continuous and interconnected communication system. Tensegrity concepts explain how the various forms of energy are absorbed and conducted throughout the framework of the body affecting all cells. Vibrations of living matrix molecules are affected by cellular activities, growth factors, carcinogenesis, and emotional states.
These brief historic points of scientific advancement indicate the study of the interactions between biological energy fields and their functions. The growing use of energy therapy has piqued the interest of science enough to engage in research to understand the benefits. The documentation of huge biomagnetic fields emitted from the hands of therapists of various kinds is an exciting discovery\textsuperscript{146} and has been shown to be repeatable, as demonstrated by Zimmerman in “New Technologies Detect Effects of Healing Hands”\textsuperscript{147} and Seto et al “Detection of Extraordinary Large Bio-Magnetic Field Strength from Human Hand during External Qi Emission.”\textsuperscript{148}

As the numerous investigations testing the effectiveness of energy healing grow, so too does the interest in understanding, biologically, how the hands are an efficient tool in conducting an energy healing session.

**Conclusion**

Understandably, patients diagnosed with ovarian cancer have clinically significant levels of anxiety and depression, as seen in the literature review. The possibility of death, pain, disrupted relationships and disfigurement are all fears and concerns that ovarian cancer patients face; therefore, it is not surprising that anxiety and depression are prevalent. The empirical evidence discussed not only suggests that anxiety and depression are prevalent in individuals diagnosed with cancer, but also demonstrates that CAM therapies can benefit cancer patients with anxiety and depression. It appears these therapies should play an important role in the treatment of the side effects of cancer and its treatment. The scientific evidence validates energy healing as an effective therapy in reducing anxiety and depression. This review of the literature provides a strong rationale
for the investigation of Ama Deus energy healing as an intervention in improving QOL by decreasing anxiety and depression in women with stage III and IV ovarian cancer.
Chapter 2 Endnotes:

3 Ibid.
8 Ibid., 137.
9 Kalweit, 2.
11 Ibid., 1.
16 Auchincloss and McCartney, 366.
19 Dana H. Bovbjerg and Heiddis B. Valdimarsdotir, “Psychoneuroimmunology: Implications for Psycho-oncology” in Psycho-oncology, 125.
23 Ibid.
25 Bovbjerg and Valdimarsdotir, 125.
29 Ibid.


Lutgendorf et al., “Quality of Life and Mood in Women Receiving Extensive Chemotherapy for Gynecologic Cancer,” 1402-1411.


Lutgendorf et al., “Quality of Life and Mood in Women Receiving Extensive Chemotherapy for Gynecologic Cancer,” 1402-1411.

Ibid., 1410.


Ibid., 1570.


Ibid., 42.

Redd, Silberfarb, Anderson, et al., 813.


Ibid.


Noyes Jr., Holt, and Massie, 548.

Ibid.


Ibid., 4.

Noyes Jr., Holt, and Massie, 557.


Noyes Jr., Holt, and Massie, 557.


Noyes Jr., Holt, and Massie, 557.


Noyes Jr., Holt, and Massie, 558.


Massie and Popkin, 531.

Stuart and Laraia, *Principles and Practice of Psychiatric Nursing*, 861.


Massie and Popkin, 518.

Ibid., 534.


Massie and Popkin, 537.

Ibid., 534.


Ibid., 53.

Ibid., 56.


Ibid., 321.


Giasson and Bouchard, 383.


Jonas and Crawford, 309.


Quinn, “Therapeutic Touch as Energy Exchange: Replication and Extension.”


Ibid., 444.

Ibid., 186.


Horan, 18.


Ibid., 85.

Ibid., 3.


Ibid., 990.


Ibid., 36.


Ibid., 99.

Benor, *Consciousness, Bioenergy and Healing*, 252.


Ibid., 40.


Ibid., 91.

Ibid., 89.

Ibid., 91.

Winkelman,


Ibid., 3.

Ibid., 63.

Ibid., 58.


137 Crawford, Sparber, and Jonas, A96.


141 Ibid., 37.

142 Ibid., 48.

143 Ibid.


146 Ibid., 219.

147 Zimmerman, 3.

CHAPTER 3: 
RESEARCH METHODS

Those who fear that scientific medicine will be compromised by spiritually based approaches need not worry. We have entered an era in which it is becoming unscientific not to address spiritual concerns in medical care.

— Larry Dossey

Methodology

Process and Procedures for Conducting Research in a Clinical Setting

For the duration of this research, the investigator was employed as coordinator of holistic services at Saint Mary’s Health Care, a Midwest hospital. Prior to filing an application to perform research at the hospital, the investigator sought and was granted approval from her immediate supervisor. A meeting was arranged by the investigator with the physician whose patients would be involved with the research; in this meeting the investigator outlined the proposal for a research. The physician granted verbal permission and requested the involvement of his nurse. The investigator was designated as the principal investigator (PI) and the nurse would be considered the secondary investigator. The two departments within the hospital involved with the research were the Wege Institute: Mind Body Spirit for the PI and The Lacks Cancer Center for the secondary investigator.

The process of filing an application to conduct research at Saint Mary’s Health Care began with the Grand Rapids Medical Education and Research Center for Health Professionals (MERC). MERC is a medical, health education and research consortium whose mission is to enhance the health of the Grand Rapids community through a variety of programs, services, education initiatives and research activities. As a research
institute, MERC serves as the central vehicle for clinical studies in Grand Rapids’ community hospitals.

An intermediary at MERC processes all research requests and coordinates these requests with the appropriate hospital. Requests must include an original application along with nine copies prepared for submittal to MERC (see Appendix A). Upon receipt, MERC reviews the application and forwards nine copies to the hospital research committee members. MERC contacts the requesting applicant with a date, time and location for attendance at a Research Committee meeting. The Research Committee is the first stage in the approval process at Saint Mary’s Health Care. The Research Committee reviews the design and nature of a given study and determines whether the goals of the research align with the mission and strategic advancement of the hospital.

For this research, the Research Committee required the presence of the PI and the secondary investigator at the meeting. To open the meeting, the PI was asked to give a short overview of the research. The Committee suggested that the PI record any medications patients were currently taking; record other treatments patients received or were receiving (e.g., radiation) and include a protocol for managing severely depressed participants at any point in the research. The Research Committee gave unanimous approval (see Appendix B), and the Committee’s suggestions were documented in the approval letter. The approval and suggestions were forwarded to the hospital’s Institutional Review Board (IRB) and a date was set for an IRB review.

Research Committee suggestions for additional intake of information concerning medications and other treatments were incorporated into the Participant Enrollment form (see Appendix C). The protocol for managing severely depressed participants would be
to refer the participant back to the hospital’s cancer resource specialist. This process was verbally authorized by the cancer center psychologist. The cancer resource specialist is an employee of the hospital who is a case worker with the responsibility of supporting cancer patients and their families through their care as an inpatient. Indicators for severe depression in any participant would be expressing suicidal thoughts, indicating thoughts of suicide on the Beck Depression Inventory (BDI) or scoring between 29 and 63 on the BDI.

Every patient entering The Lacks Cancer Center is assigned a cancer resource specialist. In the case of a severely depressed patient, the cancer resource specialist would coordinate a referral to a psychologist. With approval from the Research Committee in place, the PI drafted a letter to the medical director of The Lacks Cancer Center, indicating the intent to process a research study with the IRB (see Appendix D). This communication also served to alert the manager and medical staff in the oncology department about the pending research.

Preparations for the IRB consisted of filling out the Saint Mary’s Health Care consent form (see Appendix E), preparing a research flow chart (see Appendix F), incorporating the results of the Research Committee meeting into the IRB application, and incorporating the Authorization To Use and Disclose Personal Health Information for Research (HIPPA) (see Appendix G) as well as a letter of approval from the Gynecologic Oncologist for the hospital, Kevin Brader, MD, from whose patient population research participants would be recruited (see Appendix H). All preparations were reviewed and supported by the secondary investigator.
The result of the IRB meeting on March 27, 2006 was to postpone making a decision of approval due to concerns regarding energy healing. The committee was concerned with how to best protect a participant from a spiritual perspective. The chair and the assistant to the chair requested a meeting with the PI to determine how to address these issues before the resubmission of the protocol for the next IRB meeting. In preparation for the meeting with the chair and assistant to the chair, the PI prepared an informative document that detailed the history of energy healing in society as well as in a clinical setting (see Appendix I) in order to educate members of the IRB and help address their concerns. The chair and the assistant to the chair of the IRB helped the PI rework the consent form using language better suited to the sensitivities of members of the IRB related to spiritual issues. Along with reworking the document, the PI changed the title of the research from “The Effects of Ama Deus Healing on Depression and Anxiety in Women with Stage III or IV Ovarian Cancer” to “The Effects of Ama Deus Healing Compared to a Standard Relaxation Exercise on Depression and Anxiety in Women with Stage III and IV Ovarian Cancer.” At the subsequent IRB meeting, held one month later, the research protocol was approved (see Appendix J) with a request for one minor revision in wording. The chair’s verbal reminder to “be vigilant about this matter during the consent process” underlined the importance of sensitivity to the religious beliefs of the potential participants. An Institutional Review Board Progress Report was also included in the approval letter from the IRB (see Appendix K).

To conclude the approval process for this research, the PI met with the secondary investigator to refine the research methodology. The IRB revisions and concerns were shared and noted. In keeping with the intentions set forth by the IRB, the PI composed
an additional ‘Frequently asked Questions’ form to supplement the consent form and be included with the recruitment package (see Appendix L). This document, based on a question-and-answer format, was submitted to the chair of the IRB for approval, which was granted without the need for an additional IRB meeting, as all documentation reflected the actual consent form. Upon approval for the research, a letter of gratitude from the PI was sent to the chair of the IRB and the Research Committee (see Appendix M).

In June of 2006, the approved consent form, HIPPA document and signed copies of the IRB and Research committee approval papers were submitted to Holos University Graduate Seminary (Holos University). Via an electronic communication by the investigator’s chair, it was deemed by the Holos University IRB that the hospital IRB approval process met the IRB requirements for Holos University and a second process with the graduate school was not necessary.

In the course of the research, revisions and progress reports occurred and were implemented according to the hospital IRB requirements. The progress report came one year from the granting of approval (see Appendix K). This progress report was executed through electronic process and approved through a letter of approval (see Appendix N). The revision was also an electronic communication alerting the IRB that participants were coming from outside the hospital patient base. A verbal authorization was given for this revision by the chair of the IRB who also suggested writing a letter, with permission from the participants, to their physician regarding their enrollment in the research. As a result of outside interest direct communication in person to three sources of potential recruitment occurred with: the support group for ovarian cancer at Gilda’s Club of Grand
Rapids, Michigan, the research committee for Gynecologic Oncology of West Michigan, Grand Rapids, Michigan and the director of research and education with the West Michigan Cancer Center, Kalamazoo, Michigan (forty miles south of principal research site). Gilda’s Club sent an electronic email to all members registered with ovarian cancer informing of the research project and providing phone numbers for further inquiry. The two physician offices reviewed their patient files for eligibility and either mailed or hand delivered recruitment packages.

**Study Design**

Studies that compare effectiveness of various interventions have the goal of measuring the comparative performance of treatments. Outcomes from measurable comparatives demonstrate benefits which assist in answering practical questions associated with health care delivery, ‘How well does it work in practice?’ A cross over design was used in this study to measure the effectiveness of the treatments used in the hypothesis: Does Ama Deus energy healing have a greater positive effect on anxiety and depression in women with stage III and IV ovarian cancer, as compared to a general relaxation practice? In a cross-over design the participant experiences both treatments in different order, switching over at the midpoint of the study with a one week ‘rest’ period between techniques.

**Setting and Sample**

For the study, adult female patients, ranging in age from forty-eight to sixty-nine, and diagnosed with stage III and IV ovarian cancer within the past 18 months, were recruited from The Lacks Cancer Center at Saint Mary’s Health Care in Grand Rapids, Michigan and the organizations listed above. There are approximately seven newly
diagnosed ovarian cancer cases at The Lacks Cancer Center per year. Grand Rapids is a large city and the hospital network serves an expansive metropolitan area.

Only patients who met the criteria were eligible for the research. Inclusion criteria were as follows: adult female patients; 18 years or older; a diagnosis of stage III or IV ovarian cancer; post-surgical. Exclusion criteria were: those patients who are actively dying, meaning apnea modeling, tachycardia, hypotension, decrease in urinary output, in a coma or unresponsive. Eligible participants were given a recruitment package that included the Saint Mary’s consent form appendix, HIPPA form appendix, FAQ appendix and letter appendix. A follow up phone call, by either the PI or secondary investigator to each eligible participant, inquired if they would like to partake in the research. Participants were expected to sign the consent and HIPPA form and return to the secondary investigator during a regular doctor’s office visit if they agreed to participate. At this time the first set of quantitative measures were given and the PI met with the participants and confirmed dates and times for the initial session.

This research was conducted in the departments of the Wege Institute for Mind, Body and Spirit and The Lacks Cancer Center, both at Saint Mary’s Health Care. The Wege Institute is an outpatient clinic, providing privacy and a quiet, relaxed atmosphere. The facility offers private 10’ x 10’ rooms that comfortably hold a massage table as well as a chair and side table. In these rooms the lights can be dimmed and soft music can be played. The Lacks Cancer Center offers private rooms as well, with the same features as the Wege Institute. In both facilities, the rooms are decorated with soft paintings that create a tranquil atmosphere. The same rooms were used both for the experimental and
control groups. Rooms will continue to be available for subsequent energy healing sessions after completion of the research.

**Investigative Design**

This research, as indicated earlier, employed a Crossover Design. When participants agreed to and signed the consent form, they were assigned randomly to one of two groups (see Appendix F), by way of a random number generator. Participants in Group One (I) received the study intervention: an Ama Deus session which lasted twenty minutes as described below, twice a week. Participants in Group Two (II) represented the control treatment and received structured relaxation sessions twice a week lasting twenty minutes as described below. After three consecutive weeks of sessions, neither group received any treatment for one week. At the end of the weeklong wait period, the sessions were reversed: Group I received structured relaxation sessions (20-minute sessions, twice a week for three weeks) and Group II received Ama Deus sessions (twenty-minute sessions, twice a week for three weeks).

**Description of Intervention**

At the start of each Ama Deus session, participants were asked to remove only their shoes and to lie flat on their backs on a padded, adjustable massage table. The room was dimly lit or lit by soft, natural light, with gentle music playing (specifically, Steven Halpern’s *Inner Peace*). A practitioner greeted each participant, explained the session with a scripted message (see Appendix 0) and stayed with the participant throughout the 20-minutes. The practitioner lightly placed one hand on the participant’s forehead and the other hand on the participant’s abdomen above the belly button – the practitioner’s
hands stayed in this position throughout the session. At the conclusion of the session, the practitioner set or confirmed the date and time for the next session with the participant.

**Description of Control**

At the start of each structured relaxation session, participants were asked to remove only their shoes and to lie flat on their back on a padded massage table. The room was dimly lit or lit by soft, natural light, with gentle music playing (again, Steven Halpern’s *Inner Peace*). A practitioner greeted each participant, explained and then guided the participant in the relaxation exercise from a scripted message (see Appendix 0) and stayed seated in the room with the participant throughout the 20-minute session. At the conclusion of the session the practitioner set or confirmed the date and time for the next meeting with the participant.

**Practitioners**

Practitioners for this research had to have completed two levels of Ama Deus instruction and have a minimum of two years actively practicing energy healing. Apart from the PI, two health care professionals employed by Saint Mary’s Health Care met the requirements to become practitioners for this research. One managed the critical care unit in the hospital and received permission to be involved with this research from the Vice President of Nursing Services; the second practiced massage therapy for the department of the Wege Institute. No practitioner involved with this research was at the instructor level, except for the PI. Two other practitioners from outside the organization were also available on an “on-call” basis. Prior to the research, all practitioners participated in a review of both levels of Ama Deus training that was conducted by the PI. The PI also held a two-hour meeting with practitioners to discuss the research
protocol (including the scripted messages for the research sessions) and answer any
questions about the investigation and their roles in the project (see Appendix O).

The PI supplied each practitioner with a CD copy of Steven Halpern’s *Inner Peace*, a copy of the scripted message, a door sign that indicated research was in session, and an intake form. The intake form was used to collect additional data for each session, record observations and to monitor quality issues (see Appendix P). At the end of a participant’s involvement with the research, practitioners sent a letter thanking the participant for her involvement and noting that she would be informed of the results in a subsequent letter.

The first research session was conducted by the PI and secondary investigator together to ensure all details of the study design were in place, before the other two practitioners became involved. The recruitment package was given to the first participant in the hospital, as the first step, within a week of her surgery. The PI and the secondary investigator met with the patient and the patient’s husband to explain the research. The recruitment package was left with the patient for her review. The patient was informed that her decision would be discussed at the one-week post-operative clinical check-up. At the check-up, the patient agreed to be a participant and, at that time, filled out the enrollment form, a form to gather additional personal history (see Appendix C) and signed the consent form and HIPAA release.

The secondary investigator administered psychometric measures at the participants’ first office visit after the hospital stay. All data were entered into a private computer application and all papers filed in a locked file cabinet. This participant was
then randomly assigned to one of the two groups, and a practitioner was notified and given the phone number of the participant to set up session dates and times.

Through experience with this first participant, the PI and secondary investigator saw the need to conduct a brief meeting with staff in the oncology unit, to give information about the research. A hospital staff in-service was scheduled and conducted to inform and educate the medical staff about the research and answer any questions concerning the research (see Appendix Q).

**Quantitative Measure**

Participants completed the research survey of their feelings of depression and anxiety three times during the seven-week study period. This information was collected at the first meeting after enrollment (pre-test, Time 1), after the completion of the first three weeks (mid-test, Time 2) and after the last session of the second three weeks (post-test, Time 3). The survey takes approximately 15 to 20 minutes to complete.
The measures selected for use in this study were the State-Trait Anxiety Inventory (STAI)\(^3\) (see Appendix R) and the Beck Depression Inventory (BDI)\(^4\) (see Appendix S). Both of these measures have been assessed for reliability and internal validity and they are well established as psychometrically sound tools for measuring anxiety (STAI)\(^5\) and depression (BDI)\(^6\) as demonstrated in the following literature review.

**State-Trait Anxiety Inventory**

The STAI is a self-report instrument that establishes and measures two distinct anxiety states: State anxiety (STAIS) and Trait anxiety (STAIT)\(^7\). According to Spielberger, “The STAI clearly differentiates between the temporary condition of “state anxiety” and the more general and long-standing quality of “trait-anxiety.” The essential qualities evaluated by the STAIS – Anxiety scale are feelings of apprehension, tension, nervousness, and worry. Scores on the STAIS – Anxiety scale increase in response to physical danger and psychological stress, and decrease as a result of relaxation training. On the STAIT-Anxiety scale, consistent with the trait anxiety construct, psychoneurotic and depressed patients generally have high scores.”\(^8\) The STAIS scale consists of twenty statements to which subjects respond in order to rate how they feel at a particular moment, whereas on the STAIT scale, the twenty statements refer to how subjects feel generally\(^9\).

The STAIS Y-1 and the STAIT- Y-2 are printed on opposite sides of a single test form. The STAI instrument is designed to be used either individually or in a group, and takes less then 15 minutes in total to complete. The STAI requires a fifth or sixth grade reading level, which makes it applicable to most adult populations.\(^10\) The STAI uses a weighted Likert score between 1–4, whereby 4 indicates the highest level of anxiety and
1 the lowest, with a range of possible total scores from 20 to 80. The four response categories for STAIS are: (1) Not at all; (2) Somewhat; (3) Moderately so; and (4) Very much so. The four responses for STAIT are: (1) Almost never; (2) Sometimes; (3) Often; and (4) Almost always.

**Reliability:** The test-retest correlations for STAIT was .73 to .86 for college students and .65 to .75 for high school students. The mean reliability coefficient for the two groups is .765 and .695, respectively. The STAIS stability coefficients were low, ranging .16 to .62 college students and high school students. This was to be expected as the STAIS measure reflects unique situations at the time of testing.

**Concurrent Validity:** Evidence illustrating validity is the correlation of the STAIT scale with the Taylor Manifest Anxiety Scale (TMAS) .80 for college females, .79 for college males; and with the IPAT Anxiety Scale .75 for the females, .76 for the males. At the time that the STAIT was being developed, the TMAS and the IPAT were the most commonly used anxiety scales. Evidence illustrating validity with STAIS is illustrated in a study with 197 undergraduate students under four different experimental conditions, with alpha coefficients reported as high as .94 with the exam/stressful movie and .89 normal/relax period for males; and .93 with the exam/stressful movie and .91 normal/relax period for females.

The rationale for using the STAI measurement in this particular research lies in its high use as the psychometric measure in energy healing studies. The annotated bibliography in *Healing Intention and Energy Medicine,* by Cindy Crawford and Wayne Jonas, showed that the STAI was the most frequently used anxiety scale in controlled clinical trials using energy healing.
Beck Depression Inventory

The BDI is a 21-item inventory instrument that is designed to screen for depression. The design corresponds to the criteria for diagnosing a Major Depressive Disorder (MDD) as defined in the *Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV)*. The BDI is a self-administered instrument that takes approximately ten minutes to complete. As with the STAI, subjects require a fifth-to sixth-grade reading level to understand the questions. The 21 questions are assessed on a four-point scale; and the scoring runs from 0 to a possible 63, with 0 indicating no depression and above 40 indicating significant depression.

The original version was created in 1961, revised in 1971 and then copyrighted in 1978. The BDI is designed to assess the intensity or depth of depression in patients with psychiatric diagnoses as well as in normal patients. It has been employed in more than 1,000 different research studies.

**Reliability:** Internal consistency for the BDI ranges from .73 to .92, with a mean of .86, and demonstrates high internal consistency with alpha coefficients of .86 and .81 for psychiatric and non-psychiatric populations, respectively.

**Concurrent validity:** Clinical ratings for psychiatric patients are reported as high to moderate ranging from .55 to .96 Man $r=.72$. Moderate correlations are also found in other scales measuring depression, such as the Hamilton Psychiatric Rating Scale for Depression (.73) and the Zung Self Reported Depression Scale (.76) and the MMPI Depression Scale (.76). The BDI is also able to differentiate between psychiatric patients and those from nonpsychiatric population. A nonpsychiatric population refers to persons who were lonely, self-reporting anxiety, and reporting general stress.
Advantages of this measure include its high internal consistency, abundance of validity evidence, and widespread use in a variety of populations. A recent investigation by Adina Shore in 45 adults in need of treatment for symptoms of stress and depression is a good demonstration of the use of the BDI for measuring depression. Shore’s investigation, “Long Term Effects of Energetic Healing on Symptoms of Psychological Depression and Self-perceived Stress,” was chosen for this discussion for two reasons: the intervention of Reiki was used in Shore’s investigation; and the variable of depression correlates well to this research. Catherine Leb studied “The Effects of Healing Touch on Depression” for her master’s thesis where results suggest a significant decrease in depression on the BDI inventory after intervention.

Conclusion for Justification of Use

Charles Spielberger and R. L. Gorsuch developed the STAI in the early 1960s, roughly the same period during which Aaron Beck and associates created the original BDI. The long history of use of these inventories attests to their strength as instruments: they have been utilized for professional assessment of anxiety and depression for more than forty years. The STAI’s high frequency of use in measuring anxiety and demonstration of positive outcomes in recent investigations with energy healing as the intervention is yet another encouraging indicator that substantiates reliability for continued assessments. Given the reliability and the validity of the STAI and the BDI, they were chosen for this research to demonstrate the effect of Ama Deus energy healing on anxiety and depression.
Chapter 3 Endnotes:


2 Steven Halpern, *Inner Peace* (San Anselmo, California: Open Channel Sound Co. 1994).


5 Spielberger, Gorsuch and Lushane, 9.

6 G. Groth-Marnat, 125.

7 Charles Spielberger, *State-Trait Anxiety Inventory for Adults* (Redwood City, California: Mind Garden, 1983), 6.


9 Spielberger, 3.

10 Ibid., 5.

11 Ibid., 5.

12 Ibid., 5.

13 Ibid., 30.

14 Ibid., 35.

15 Ibid., 35.

16 Spielberger, Gorsuch and Lushane, 11.

17 Spielberger, 6.


19 Ibid., 309.

20 G. Groth-Marnot, 125


22 Ibid.

23 G. Groth-Marnot, 126.

24 Ibid., 124.

25 Ibid.

26 Ibid.

27 Ibid., 125.

28 Ibid.

29 Ibid.


CHAPTER 4: RESEARCH FINDINGS

This chapter is a summary of findings for the research, which includes a characteristic of the sample, the statistical analysis, discussion of means, anecdotal findings and an overall discussion of the results.

Summary of Findings

Background

This research was conducted with women with a diagnosis of stage III ovarian cancer at a 324-bed community hospital with a specialized 42 bed state-of-the-art cancer hospital. The hospital system also supports a regional Institute for Mind, Body, and Spirit, see Process and Procedures for Conducting Research in a Clinical Setting.

Situated in the Great Lakes region of the U.S., the metropolitan community is the second largest in the state and is generally characterized as relatively conservative.¹

A simple cross over design was used in this study to measure the effectiveness of the treatments used in the hypotheses: Does Ama Deus energy healing (treatment) have a greater positive effect on anxiety and depression in women with stage III and IV ovarian cancer, as compared to a general relaxation (control)? The design consisted of a seven week intervention, three weeks of treatment or control, a one week wait period, followed by another three weeks of treatment or control (see Appendix F).

Characteristics of the Sample

The research sample consisted of fourteen women all diagnosed in stage III ovarian cancer between the ages of 48 and 69. Of the 14 participants, thirteen identified as Caucasian and one as African American. The research interventions took place at various stages of
medical treatment within eighteen months of being diagnosed. Five patients were diagnosed and still hospitalized at time of enrollment in the study and first intervention; four were undergoing chemotherapy; and five had completed treatment at the time of the interventions. Seventy nine percent were married, fourteen percent were divorced and seven percent had never married. The figures are shown in table 1.

### Table 1. Participant Sample of Marital Status.

<table>
<thead>
<tr>
<th>MARITAL STATUS</th>
<th>FREQUENCY</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEVER MARRIED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MARRIED OR LIVING WITH PARTNER</td>
<td>11</td>
<td>78.6</td>
</tr>
<tr>
<td>DIVORCED/SEPARATED</td>
<td>2</td>
<td>14.3</td>
</tr>
<tr>
<td>WIDOWED</td>
<td>1</td>
<td>7.1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>14</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Twenty-nine percent of participants had a high school education, nearly forty-three percent (42.9%) had some college education, twenty-one percent had a college degree and seven percent had post-graduate education. The figures are shown in table 2.

### Table 2. Participant Sample of Education Level.

<table>
<thead>
<tr>
<th>LEVEL OF EDUCATION</th>
<th>FREQUENCY</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH SCHOOL</td>
<td>4</td>
<td>28.6</td>
</tr>
<tr>
<td>SOME COLLEGE</td>
<td>6</td>
<td>42.9</td>
</tr>
<tr>
<td>COLLEGE</td>
<td>3</td>
<td>21.4</td>
</tr>
<tr>
<td>POST GRADUATE</td>
<td>1</td>
<td>7.1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>14</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
Twenty-three percent of participants reported an income of less than $20,000; nearly thirty-eight percent (38.5%) reported incomes between $20,000 and $40,000 and thirty-eight percent reported incomes between $40,000 and $80,000. The average income among participants was $40,000. One participant chose not to include income information. The figures are shown in table 3.

**Table 3. Participant Sample of Income.**

<table>
<thead>
<tr>
<th>INCOME</th>
<th>FREQUENCY</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>LESS THAN $20,000.00</td>
<td>3</td>
<td>23.1</td>
</tr>
<tr>
<td>$20-40,000.00</td>
<td>5</td>
<td>38.5</td>
</tr>
<tr>
<td>$40-80,000.00</td>
<td>5</td>
<td>38.5</td>
</tr>
<tr>
<td>$80,000.00 AND ABOVE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>13</td>
<td>100</td>
</tr>
</tbody>
</table>

Fifty percent of the participants were employed full-time, seven percent worked part-time, fourteen percent were retired, seven percent were classified as disabled and twenty-one percent identified themselves as homemakers. The figures are shown in table 3.

**Table 4. Participant Sample of Occupation.**

<table>
<thead>
<tr>
<th>OCCUPATION</th>
<th>FREQUENCY</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULL-TIME</td>
<td>7</td>
<td>50.0</td>
</tr>
<tr>
<td>PART-TIME</td>
<td>1</td>
<td>7.1</td>
</tr>
<tr>
<td>NOT EMPLOYED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RETIRED</td>
<td>2</td>
<td>14.3</td>
</tr>
<tr>
<td>DISABLED</td>
<td>1</td>
<td>7.1</td>
</tr>
<tr>
<td>HOMEMAKER</td>
<td>3</td>
<td>21.4</td>
</tr>
<tr>
<td>TOTAL</td>
<td>14</td>
<td>100</td>
</tr>
</tbody>
</table>
When asked if they had ever been diagnosed with or treated for depression or anxiety, one respondent reported being in therapy for depression and one was on medication for depression.

When asked about their spiritual preference, fifteen percent reported none; seventy-seven percent reported a church association and eight percent identified the self as their spiritual preference. When asked how often they participate in their spiritual preference activities, fifteen percent reported never, twenty-three percent reported hardly ever, thirty-one percent reported sporadically and twenty-three percent reported weekly engagement in some spiritual activity.

This research began in June of 2006 with eight participants and with six added in 2007. Even though three more participants indicated the desire to be involved with the research, they had to drop out before starting the sessions due to extreme illness. Two participants who had completed the study in 2006 died in 2007.

Participants were randomized into two groups. Group I, was identified as the treatment group and consisted of nine participants; Group II, consisting of five participants, was identified as the control group (see Appendix F).

In summary, the majority of participants was married, had full-time occupations, was predominately Caucasian, had at least some college education, and identified themselves as middle class and Christian. Sixty-four percent of participants received the Ama Deus intervention during the first three weeks of the research and thirty-six percent of participants received the relaxation intervention during the first three weeks of their participation in the research. After a one week break in intervention, all participants crossed over to receive either an Ama Deus or relaxation intervention. Each participant acted as her own control to determine the effects of each treatment intervention.
The following findings of this quantitative research are based on data collected from the above described sample (n=14). The STAI and BDI were the psychometric measures used for this investigation. To recap, the aim of this research was to examine the effects of Ama Deus energy healing and general relaxation in reducing symptoms of anxiety and depression in women with Stage III ovarian cancer. All participants for this research were diagnosed at stage III. As this research progresses participation of women with stage IV ovarian cancer may occur. This researcher posited that exposure to Ama Deus energy healing would reduce symptoms of anxiety and depression more than exposure to general relaxation sessions.

Findings

Due to the small sample size, both parametric and non-parametric tests of significance were used. All tests for significance were expected to meet the standard 95 percent confidence level or achieve .05 percent or less probability that effects were achieved by chance. Before examining for differences among and between groups on anxiety and depression test scores, each group was tested for normality based on the normal curve. If test scores in both groups achieved normality, paired sample t-tests were used to compare means at Time 1 (pre-test), Time 2 (mid-test) and Time 3 (post-test, after completion of both interventions). Paired sample t-tests are appropriate as each data piece, pre-test, mid-test, and post-test is associated with a distinct individual. If normality was not achieved, the non-parametric Mann-Whitney test to compare medians at Time 1, Time 2 and Time 3 was used to investigate significance. In this case, the data were not paired as the Mann-Whitney test does not provide such a scenario. Summary of steps for determining parametric and non-parametric use is as follows:
1. Test of normality:
   - The data is normally distributed
   - The data is not normally distributed
2. Paired t-test of difference of means: used for data normally distributed - parametric
3. Mann-Whitney test: used for data not normally distributed – non-parametric

Discussion of results will initially report findings of Group I (received Ama Deus first) on both Trait and State levels of anxiety and on depression at Times 1, 2 and 3. Results for Group II (received relaxation first) on all measures will immediately follow. This findings section will conclude with a discussion comparing Groups I and II. A key to the abbreviations referenced in the findings is shown in table 5.

**Table 5. Key to Abbreviations used in the Quantitative Analysis.**

<table>
<thead>
<tr>
<th>Randomized Group I and Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI - Group receiving Ama Deus treatment first then crossing over to Relaxation session</td>
</tr>
<tr>
<td>GII - Group receiving Relaxation session first then crossing over to Ama Deus treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Psychometric Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tr - Trait anxiety</td>
</tr>
<tr>
<td>St - State anxiety</td>
</tr>
<tr>
<td>Dp - Depression</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time Distribution for Psychometric Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 1 - STAI and BDI pre-test - administered at the time of consent before any treatment</td>
</tr>
<tr>
<td>Time 2 - STAI and BDI mid-test - administered at the last treatment session of the first intervention (first week).</td>
</tr>
<tr>
<td>Time 3 - STAI and BDI post-test - administered at the last treatment session of the intervention (second week).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI, Tr1 - Group I Trait anxiety at Time 1.</td>
</tr>
<tr>
<td>GII, St3 - Group II, State anxiety at Time 3</td>
</tr>
</tbody>
</table>

**Group I Anxiety - Trait**

The following discussion examines within group differences in levels of Trait anxiety.

When examining Group I on Trait anxiety at Time 1 (pre-test) with Time 2 (mid-test), the paired t-test was used because both data sets were normally distributed. Analysis revealed that
participants reported less anxiety at Time 2 (p<0.045). Visually, participants are grouped toward the low - mid-point of the scale (range 20-80) indicating low to medium levels of Trait anxiety. However, this finding should be considered marginal in that if the t-test had tested for “not equal” rather than “less than,” the p-value would have been p<0.09, hence, not significant as shown in figure 1.

Figure 1. Within Group I Difference in Anxiety Trait 2 and Trait 1 (n=14).

Comparing Group I in Figure 2, on Trait anxiety at Time 2 and Time 3, revealed very little difference between the two times. A paired value t-test (p<0.825) strongly indicated no significant difference.

Figure 2. Within Group I Difference in Anxiety Trait 3 and Trait 2 (n=14).
Similarly, when comparing Group I on Trait anxiety between Time 1 and Time 3 (after the completion of both interventions), the paired t-test ($p<0.144$) revealed no significant difference as seen in figure 3.

**Figure 3.** Within Group I Difference in Anxiety Trait 3 and Trait 1 (n=14).

*Group I Anxiety - State*

When examining Group I for differences in State anxiety levels, the Mann-Whitney test of difference was used because the distribution was slightly skewed to the left not meeting the requirements of a normal curve. In Group I, this researcher found statistical significant differences in levels of State anxiety between Time 1 and Time 2 ($p<0.019$) as shown in figure 4. This strongly suggests that the Ama Deus intervention significantly reduced State levels of anxiety.

**Figure 4.** Within Group I Difference in Anxiety State 2 and State 1 (n=14).
However, when examining Group I for State anxiety between Times 2 and 3, the Mann-Whitney test revealed no statistical difference (p<0.479) suggesting that perhaps the effects of Ama Deus energy healing were mitigated by the effects of general relaxation indicated in figure 5.

Figure 5. Within Group I Difference in Anxiety State 3 and State 2 (n=14).

When comparing Group I between Times 1 and 3 on State anxiety using the Mann-Whitney test (see figure 6), there appears to be a marginal reduction in anxiety between Time 1 and Time 3 (p<0.056). While this finding does not reveal statistical difference, it does suggest movement and that statistical difference may be achieved using a larger sample.

Figure 6. Within Group I Difference in Anxiety State 3 and State 1 (n=14).


**Group I Depression**

Visually, there appears to be a difference in levels of depression (see figure 7) between Time 1 and Time 2, with more participants clustering on the lower end of the scale and with all respondents below the cutting point of 40 which indicates significant depression. Statistically, the Mann-Whitney test of differences revealed no statistical differences between Time 1 and Time 2 ($p<0.268$).

![Figure 7. Within Group I Difference in Depression 2 and Depression 1 (n=14).](image)

When comparing Time 2 and Time 3 on depression levels, visually Time 3 appears to be slightly better but the outliers in each group overlap. The Mann-Whitney test found that depression at Time 3 is not significantly less than depression at Time 2 ($p<0.189$) as shown in figure 8.

![Figure 8. Within Group I Difference in Depression 3 and Depression 2 (n=14).](image)
As expected based on depression levels between Time 1 and Time 2, no significant differences were found when comparing depression at Times 1 and 3 as shown in figure 9. The p value of the Mann-Whitney test is \(p<0.145\).

**Figure 9.** Within Group I Difference in Depression 3 and Depression 1 (n=14).

**Group II Anxiety - Trait**

The paired t-test was used for all statistical analysis, because a normal distribution was found in Group II. Examination of Group II (figure 10) in levels of Trait anxiety at Time 1 and Time 2 achieved statistical difference \(p<0.049\). This suggests that the general relaxation intervention was successful in reducing levels of Trait anxiety.

**Figure 10.** Within Group II Difference in Anxiety Trait 2 and Trait 1 (n=14).

When comparing Group II at Time 2 and Time 3 (see figure 11), even greater significance was achieved \(p<0.027\) suggesting that the addition of Ama Deus energy healing helped to decrease Trait anxiety.
Figure 11. Within Group II Difference in Anxiety Trait 3 and Trait 2 (n=14).

Moreover, when comparing Group II between Time 1 and Time 3, statistical significance was maintained (p<0.034) revealing that levels of Trait anxiety decreased over the course of both interventions (see figure 12).

Figure 12. Within Group II Difference in Depression 3 and Depression 2 (n=14).

Group II Anxiety - State

When examining levels of State anxiety between Time 1 and Time 2, no difference was found (p<0.199) as shown in figure 13.

Figure 13. Within Group II Difference in Anxiety State 2 and State 1 (n=14).
Comparing levels of State anxiety at Time 2 and Time 3 also revealed no significant differences (p<0.145) as seen below in figure 14.

![Figure 14. Within Group II Difference in Anxiety State 3 and State 2 (n=14).](image)

However, as shown in figure 15, when examining State anxiety differences between Time 1 and Time 3, statistical significance was achieved (p<0.027).

![Figure 15. Within Group II Difference in Anxiety State 3 and State 1 (n=14).](image)

While levels of State anxiety decreased between Time 1 and Time 2, statistical significance was achieved only after the addition of the Ama Deus intervention at Time 3. This suggests that perhaps a cumulative effect is occurring. That is, the effects of reducing State anxiety using general relaxation are enhanced when Ama Deus energy healing is added.
Group II Depression

Tests for normality revealed that participants in Group II were normally distributed, thus, paired t-tests were used for all data sets. Comparing Group II for depression at Time 1 and Time 2 revealed decreases but only marginal significance (p<0.06). However, based on the standard confidence level of p<0.05, this was not a statistically significant finding (See figure 16).

![Figure 16. Within Group II Difference in Depression 2 and Depression 1 (n=14).](image)

When examining differences in depression levels between Time 2 and Time 3, no differences were found (p<0.082) as visually depicted in figure 17. The depression findings suggest that a larger sample might achieve statistically significant differences.

![Figure 17. Within Group II Difference in Depression 3 and Depression 2 (n=14).](image)

Visually, when comparing depression levels between Time 1 and Time 3 as shown in figure 18, there is a strong indication that depression at Time 3 is lower than
depression at Time 1. With a t-test p value of p < 0.009) we can unequivocally conclude that depression decreased over the course of the two interventions for Group II.

![Figure 18. Within Group I Difference in Depression 3 and Depression 1 (n=14).](image)

This finding is interesting in that no significant differences in levels of depression were found in Group I. One can speculate that the order of the intervention affected the outcomes. Receiving general relaxation sessions prior to receiving Ama Deus energy healing may have prepared participants for a deeper level of relaxation, resulting in a decrease in depression.

**Between Groups**

The following discussion first examines the differences in levels of Trait and State anxiety between Groups I and II. Because of randomization (see Appendix F), we can assume that the groups are statistically equivalent, thus, the t-test (non-paired) has been used to test for between group differences. A discussion comparing Groups I and II on depression immediately follows the anxiety discussion.

T-tests comparing Group I and Group II on Trait anxiety (see figure 19) and State anxiety (see figure 20) revealed that the groups are statistically equivalent with p values of .484 and .352 respectively, thus we can assume there is no difference between Groups I and II on either Trait or State anxiety.
Because there is no statistical difference between Groups I and II at Time 1, differences in Trait and State anxiety revealed in subsequent analysis are likely due to interventions.

When comparing Group I with Group II at Time 2 on Trait anxiety, the t-test revealed no difference between groups (p<0.62). Likewise, when comparing the two groups on State anxiety at Time 2, no statistical difference was found (p<0.505). At Time 3 (post-test), no statistical differences were found between groups on either Trait (p<0.219) or State anxiety (p<0.096).

Comparison of Group I and Group II on depression levels indicates no difference as shown in figure 21 between the groups at Time 1 (p<0.943). Visually it appears there may be a difference in depression levels between groups at Time 2; however, the Mann-Whitney test for
statistical significance revealed no difference (p<0.641). It is possible the outliers in Group I are skewing the results. A larger sample size may find significant differences.

Figure 21. Between Group Difference: G II Depression 1 and GI Depression 1.

At Time 3, the Mann-Whitney test found no statistical difference between groups (p<0.698). Again, the outliers in Group I may be skewing the results.

Discussion of Means
While the statistical analysis to determine if there were differences between the groups revealed no difference (or group equivalence), we can conclude that through the randomization process the groups began as equal, thus all significant findings can be attributed to the interventions of this research project. An overview of the means of each group at each time help to visually reveal trends that may not have been captured in the paired t-test or the Mann-Whitney test for significance are shown in table 6.

Table 6. Overview of Means for Group I and Group II.

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-test</th>
<th>Mid-test</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety-Trait</td>
<td>34.67</td>
<td>30.67</td>
<td>32.89</td>
</tr>
<tr>
<td>Anxiety-State</td>
<td>41.67</td>
<td>28.33</td>
<td>31.33</td>
</tr>
<tr>
<td>Depression</td>
<td>12.33</td>
<td>8.67</td>
<td>7.44</td>
</tr>
<tr>
<td>Group II</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety-Trait</td>
<td>39.2</td>
<td>32.6</td>
<td>26.8</td>
</tr>
<tr>
<td>Anxiety-State</td>
<td>35.2</td>
<td>28.8</td>
<td>23.4</td>
</tr>
<tr>
<td>Depression</td>
<td>12.6</td>
<td>7.6</td>
<td>4</td>
</tr>
</tbody>
</table>
When compared to the normative data reported by Spielberger on Trait and State anxiety, participants in Group I of this research were within normal limits on Trait anxiety at all Times 1. When comparing means for State anxiety with normative data, participants in Group I reported higher means at Time 1, yet within the normal standard deviation. At Time 2 and Time 3, State anxiety means were below normative mean but within standard deviation limits.

Means for Group II on Trait anxiety at Time 1, Time 2 and Time 3 were within the normal range and standard deviation reported by Spielberger. State anxiety means for Group II were within normal limits at all stages of the experiment, except at Time 3 when means fell below normal standard deviation.

When comparing depression means to the normative data reported by Beck on a comparative normal group of college students, participant means on depression were lower in both groups but within limits of standard deviation.

In Group I Trait means reveal little change and State means trended downward significantly from the beginning of the experiment to achieve statistical significance at the midpoint. While a decrease in State anxiety means was maintained between Time 1 and Time 3, statistical analysis revealed that this was a marginally significant finding. The slight rise in State at the end of the experiment in Group I may be due to chance or reflects the uncertainty associated with a cancer diagnosis. This finding merits further investigation with a larger sample.

In both Groups I and II depression means trended downward during the course of the experiment, however, no statistical differences in depression means were found for Group I.
When comparing depression means for Group II, marginal decreases were reported at Time 2
with a statistically significant decrease in depression means at Time 3.

In Group II, all means trended downward and all of this data was normally distributed.
A marginally significant decrease was found in Trait anxiety means between Time 1 and Time
2, yet not statistically significant decreases were revealed for State anxiety means. When
comparing Trait means between Time 2 and Time 3, statistically significant decreases were
achieved; however no significant decrease in State anxiety were revealed. When comparing
Trait means of Time 1 and Time 3, a strongly significant decrease in Trait anxiety was revealed.
Comparing depression means at Time 2 to Time 1 indicated marginal significance. Yet a
decrease in depression means between Time 1 and Time 3 achieved statistical significance.
Because no differences were found in between group analysis, this finding suggests that the
ordering of the interventions may be affecting depression means. We can state with some
confidence that these consistent downward trends are not due to chance only.

**Anecdotal Findings**

The anecdotal findings were taken from practitioners’ hand written session notes of the
practitioners on the Participant Encounter Forms (see Appendix P). In reviewing the notes, we
found that all participants reported positive feelings associated with the sessions.
Observationally, several participants slept during the Ama Deus treatment session and many
participants reported using the relaxation exercise as a self-empowerment tool to overcome
anxious moments at home, to help sleep at night and to cope with their medical treatments. All
participants but one expressed verbally how they looked forward to the sessions as it helped
them cope with everyday life issues and the anxiety of medical treatments. Additional
comments and reporting are as follows:
Four different participants fell asleep during their Ama Deus treatment session.

One participant had shaky leg problems at night. She was anxious because she feared that the trembling would begin during the Ama Deus treatment session, and was very hesitant to begin the treatment. However, she found that relief came during the treatment session. She was very surprised and was very happy.

One participant and her spouse requested to attend a class to learn how to do Ama Deus energy healing for themselves as they witnessed personally how effective it was for anxiety and physical relaxation. (This took place after all research-related sessions were complete.)

Three participants asked to set up appointments for family members and a friend to receive Ama Deus sessions.

Three participants had deep relaxation and experienced peaceful images during Ama Deus sessions.

One participant reported, “I think everyone needs this support. At first I didn’t think I wanted to come two times a week. This has been the best medicine. I wish it was not ending.”

Three participants indicated that they used the relaxation session as a general sleep aid.

Twelve participants verbally shared after Ama Deus treatment that at more than one time, they felt less anxious and looked forward to the next session.

No one expressed discontent with any of the sessions.

One participant said, “I had a stressful event with my family; however, I knew I could cope because I was coming in for a healing session and I held on to that thought. That is what got me through without breaking down. I knew I would feel better after the healing session.”

**Overall Results**

The statistical analysis coupled with anecdotal observations and comments indicates an overall reduction in anxiety and/or depression suggesting that the use of holistic practices are useful in ameliorating symptoms of anxiety and depression in women with stage III ovarian cancer.

The data supports the hypothesis that exposure to Ama Deus energy healing reduces symptoms of State-anxiety more than a general relaxation session in women with stage III
ovarian cancer assigned to Group I, as measured by the State-Trait Anxiety Inventory. No State anxiety decreases were found in women assigned to Group II until Time 3; however, significant Trait anxiety differences were found throughout the experiment. This is an interesting finding in light of Spielberger's discussion of Trait and State anxiety, whereby Trait anxiety is posited to refer to relatively stable individual differences in anxiety proneness.²

While no statistically significant differences were found in the between group analysis at the outset of the experiment, means for Trait anxiety in Group II were at higher levels at Time 1 and Time 2 than means for participants in Group I, but were significantly less at Time 3. Concomitantly and in accordance with Spielberger's discussion of Trait and State anxiety,³ State anxiety levels were significantly lower at Time 3. This finding suggests that contrary to Spielberger’s discussion, interventions such as the ones used in this research affect Trait anxiety levels.

The data does not support the second hypothesis that exposure to Ama Deus energy healing reduces symptoms of depression more than a general relaxation session in women with stage III ovarian cancer, as measured by the Beck Depression Inventory. However, after the completion of both interventions, depression levels in Group II achieved a statistically significant decrease. The unexpected demonstration of significant findings in Group II Trait and State anxiety and depression suggests a possible cumulative effect when using both interventions and reveals opportunities beyond the hypothesis testing of this research to include hypothesis generating ideas for future research. The following is a summation of the data analysis.

As indicated earlier, statistical significance was achieved in both the STAI and BDI measures and in both groups; however, the statistical significance varied greatly between groups
in what the interventions accomplished. Analysis revealed a marginal decrease in Trait and significant decrease in State anxiety, Group I, the group receiving Ama Deus first. However, the findings were not consistent. Between Time 1 and Time 2, a marginal decrease in Trait anxiety was revealed. Yet, no significant or marginal indication of decrease in Trait anxiety was revealed when comparing Trait anxiety between Time 2 and Time 3, nor was a difference found when comparing Trait anxiety at Time 1 and Time 3. When comparing group means, Group I began with lower Trait anxiety scores which might explain why a decrease was not as dramatic as in Group II over the course of the research interventions. A larger sample size is needed to conclusively interpret this data.

After the Ama Deus intervention, statistical analysis revealed that Group I reported significantly less State anxiety at Time 2 when compared to Time 1 indicating that the Ama Deus energy healing intervention was effective in reducing State anxiety. When examining State anxiety between Time 1 and Time 3, statistically significant decreases remained; however, the statistical significance was marginal at p<0.056. Understanding the reason for this finding can only be speculative at this point. For instance, it is possible that participants felt that after receiving the Ama Deus intervention, the general relaxation sessions failed to meet their expectations. This marginal finding may be explained with a large sample. Further research is needed to explore these differences. The significant finding supports hypothesis one which states: Exposure to Ama Deus energy healing reduces symptoms of anxiety more than a general relaxation session in women with stage III and IV ovarian cancer, as measured by the State-Trait Anxiety Inventory.

Despite achieving statistical equivalence at the onset of the interventions, significant differences in effects between the groups occurred during the course of the research.
In Group II, both Trait and State anxiety decreased over the course of both interventions. Statistical analysis revealed that Trait anxiety decreased marginally between Time 1 and Time 2 after the general relaxation sessions (p<0.049). Strong significance was found in decreased Trait anxiety between Time 2 and Time 3 after the crossover to Ama Deus (p<0.037). When comparing Group II for difference between Time 1 and Time 3, the decrease in Trait anxiety remained relatively consistent and significant (p<0.034). From this, this researcher posits that the general relaxation intervention was effective in decreasing Trait anxiety initially and effects were enhanced when adding the Ama Deus intervention. The decrease in Trait was sustained throughout the seven-week course of the research and suggests that stronger decreases in Trait anxiety were found when general relaxation sessions preceded the Ama Deus sessions. Because of the short duration of the interventions, we cannot state that the decreases in Trait anxiety would be sustained long-term. A longitudinal research study may be needed to investigate the long-term effects of this researcher’s intervention in decreasing Trait anxiety in women with stage III ovarian cancer.

Within Group II, no significant differences in State anxiety between Time 1 and Time 2, nor were differences found in State anxiety between Time 2 and Time 3. However, when comparing the differences in State anxiety in Group II at Time 1 and Time 3, a very strong decrease in State anxiety was found (p<0.027).

Based on these Trait and State statistical findings, we can state with some confidence that general relaxation sessions decreased Trait anxiety when administered before Ama Deus sessions but was ineffective in decreasing State anxiety. Interestingly, after the crossover to Ama Deus energy healing no State anxiety differences were found between Time 2 and Time 3, yet when examining the succession of the two interventions, a strong decrease in State anxiety
occurred at the end of the interventions. This suggests that the order of the intervention is fundamental in effecting decreases in State anxiety, that is, the general relaxation session may set the stage for participants to be more receptive to the Ama Deus healing sessions and the ordering of the interventions may produce a cumulative effect. Again, a longitudinal study would indicate if the decrease in State anxiety could be sustained over a longer period of time.

Statistical analysis of depression in Group I revealed no differences between pre-test, midpoint-test and post-test. However, for Group II, marginal, but not statistically significant decreases in depression occurred between Time 1 and Time 2 as well as between Time 2 and Time 3 indicating that both the general relaxation intervention and the Ama Deus intervention affected levels of depression. A strong decrease in depression occurred between Time 1 and Time 3 (p<0.009) again suggesting a cumulative effect of both treatments when the general relaxation session precedes the Ama Deus intervention.

These findings for depression do not support the hypothesis that Ama Deus decreases levels of depression more than general relaxation in women with stage III ovarian cancer but Ama Deus clearly has some effect on depression among Group II participants in that stronger statistical significance was achieved at the end of the study after participants received both interventions.

With a sample of this size, it is difficult to explain why no decreases in depression levels were found among Group I participants, yet differences in depression levels were found in Group II despite the fact that beginning analysis found the groups to be statistically equivalent. Only two scores in depression at Time 1 were in the moderate range. Of the two moderate scores, one occurred in Group I and the other in Group II. All others at Time 1 scored between minimal and mild levels of depression. To speculate on this finding in Group II, perhaps non-
significantly higher levels of Trait anxiety at Time 1 account for the difference. Conversely, Group II reported lower levels of State anxiety at Time 1 and Time 3 which may have impacted perception of self-reported depression. Again, the sequence of the interventions seems to indicate an effect on outcomes. A larger sample and a longitudinal study may answer these questions.

The significant results found with the statistical analysis lend support to hypothesis 1. A detailed discussion of this research’s findings follows in the next chapter.
Chapter 4 Endnotes:

3 Ibid.
CHAPTER 5:
DISCUSSION AND SUGGESTIONS

“What we observe is not nature itself, but nature exposed to our method of questioning”
-Werner Heisenberg

This final chapter discusses the findings of Chapter 4 and provides suggestions for future research.

Discussions

This research investigation, despite its small sample size, demonstrated significant findings and provides justification to support the continuation of this research. As previously stated, statistical significance was achieved in both the STAI and BDI measures and in both groups; however, the statistical significance varied greatly between groups in what the interventions accomplished. Group I demonstrated significance for decreasing anxiety as stated in hypothesis one. Of particular interest is Group II where both Trait and State anxiety decreased and was sustained over the course of the interventions along with a strong decrease in depression occurring between Time 1 and Time 3.

Out of all the studies cited in this literature review, one study recorded significance in reducing Trait anxiety. In Sean O’Laoire’s study, “An Experimental Study of the Effects of Distant, Intercessory Prayer on Self-esteem, Anxiety and Depression”,¹ Trait anxiety reduction occurred in people praying; however, not in the subjects who were being prayed for. With the Trait anxiety reduction being marginal in Group I, after the Ama Deus intervention (p< 0.45) at Time 2 and significant in Group II after both the relaxation and Ama Deus interventions at Time 3 (p<0.034) the possibility
of deep healing effects is strongly suggested. When viewed from the perspective of the Guarani who regard health as being in harmony and energy healing as being utilized for personal transformation in “bringing inner peace and quiet,”\(^2\) this data may provide a glimpse of this transformation at a deep level of one's being. With the addition of significance found in Group II’s level of depression between Time 1 and Time 3 (\(p<0.009\)) we can posit that combined with the significant reduction in Trait anxiety that deeper levels of healing may be occurring. Most assuredly, this is of great interest and is viewed by the Principal Investigator as hypothesis generating.

Other studies on stress using STAI have suggested that perhaps Trait is not as ‘fixed’ as Spielberger believes. One study by Nancy Calloway, “A Comparative Study on the Effects of Photostimulation and Autogenic Training in reducing Stress, Anxiety and Depression”\(^3\) discusses “the possibility that trait is not immutable and can actually change in a short period of time.”\(^4\) In search of studies with indication that Trait is not fixed in State-Trait Anxiety index, several investigations were revealed. One Study by Richard Hussian and P. Scott Lawrence in “The reduction of Test, State, and Trait Anxiety by test-specific and generalized stress inoculation training,” found that test-specific training reduced trait anxiety relative to the two control groups in forty-eight highly test-anxious students.\(^5\) A theoretical and review article in the Journal of Anxiety Disorders titled “Trait anxiety: it’s not what you think it is” by Steven Reiss praises Spielberger’s efforts while simultaneously discussing the limitations to the concept of trait anxiety in STAI measures.\(^6\)

Speculating on why the observance of a trend in decreasing Trait anxiety scores may be occurring may be reflective in the number of holistic interventions focused on
reducing anxiety related to stressful lifestyles. The growing number of self-help and self-awareness education and holistic practices, along with the advancement of psychoneuroimmunology, are all possible strong contributors affecting trait anxiety. Trait anxiety not being ‘fixed’ could be viewed as an indication of significant progress – an indicator that suggests that deeper levels of change are taking place, change that is empowering persons to achieve a more ‘whole’ state of being.

Several of the studies in the literature search for this investigation reported significant findings with State anxiety. The significant findings in State anxiety in Group I clearly indicate that the Ama Deus intervention was an effective intervention. Gaisson and Bouchard’s study “The Effect of Therapeutic Touch on the Well Being of Persons with Terminal Cancer” also reported significant findings with a small sample size. This Ama Deus research however, was different in that three practitioners were used; whereas in the Gaisson and Bouchard research, the principal investigator was the only practitioner. Based on the findings in this Ama Deus research which use three different practitioners, we can with some assurance state that no researcher bias existed. Of the seven studies reported in the literature search using STAI as the psychometric measure and having significant outcomes using energy healing in clinical settings only one study was with cancer patients, specifically breast cancer. This research adds to the literature by reporting positive outcomes for use with ovarian cancer patients. To this research’s knowledge, this is the first research documenting the efficacy of energy healing, as a positive intervention for women with ovarian cancer.

The Reiki study “Long-Term Effects of Energetic Healing on Symptoms of Psychological Depression and Self-Perceived Stress” by Shore had three arms to the
The results indicated that both hands-on and distance healing achieved significance in reducing depression using the BDI; however the distance healing had greater significance than hands on. Given that this study had some indications of decrease in depression with the combined treatments perhaps along with a larger sample size, an additional arm of distance healing would add to the present investigative findings.

This research also had observable positive indications of an impact on medical staff as reported earlier in Harlow’s paper “The Impact of Healing in Clinical Settings.” All staff at the hospital of this research remained open-minded, asking questions, observing positive behavior from patients and even requesting experience in receiving a treatment session.

Further, the cumulative effect of the interventions found in Group II is of especial importance for use in clinical settings. Patients are often initially overwhelmed with their diagnoses, and then are bombarded with information and decisions about treatment modalities. Such stimuli may be too intense for some patients and contribute to feelings of powerlessness. Perhaps when introducing something new, such as energy healing and education in the form of a relaxation session, they might feel empowered. This speculation is supported by Henderson and Donetelle’s study cited earlier in the literature review, whereby women who use CAM are more likely to take an active role in the treatment of their cancer, exhibiting improved immune functions and QOL. This personal empowerment may allow them to become more in touch with their inner selves and strengths that enhance coping. It seems that any activity that leads to empowerment, also directs a way to greater levels of self-awareness and identification of inner strengths.
that contribute to either self love or a stronger belief in a higher power that loves. This could set the environment for not only a more productive healing session, but also the more active participation of the participant in practicing relaxation sessions between healing sessions, which in turn offers a greater healing opportunity.

Because this research will continue beyond the dissertation, weaknesses and strengths are reviewed to give further power to the present design and future researchers.

**Weakness of the Design and Study**

- The small sample size was probably the most significant limitation to this research. Small sample size requires using caution in interpreting data, however the statistics used in this research are well-suited to small sample size and offer a high degree of assurance that similar significant findings would occur in a larger sample size as well. A larger sample would allow additional statistical measures to be used to identify between group differences and differences for other variables such as age, race, educational level, etc. A larger sample would allow for the application of more robust measures of significance.

- Incorporating a randomization process that forms equal groups, thereby increasing statistical approaches.

- The varied time in stage of medical treatment among the participants could also be seen as a strong limitation to this research. It became evident that those participants who were very sick because of chemotherapy treatment were in a different emotional and mental framework than those who were not in treatment and/or had resumed normal life activities.
The Hawthorne effect could have been a contributor to the positive outcome. Strong precautions were made to avoid intended positive outcome by the practitioners, as this patient population usually has compromised physical, emotional and mental health resulting from diagnosis and medical procedures. All three practitioners have strongly integrated energy healing into their lives and their belief in the benefits of energy healing may have had a halo effect on the participants. Each participant acknowledged that they were happy to be involved with the research. Participants were not asked if the practitioner providing the intervention affected their perception of positive change.

There was no blind arm to this study.

Presence of a practitioner during the relaxation sessions could have impacted the participants positively. Even though the practitioner was instructed to perform mental exercises and not to engage in relaxing or meditative states, the simple presence of another person could have fostered a sense of well-being. Further, the presence of a practitioner supports the indigenous model of community involvement as a necessary component to healing.

Time and travel issues contributed to lack of recruitment because many of the participants were too sick. One participant who had started and completed the first session of treatment attempted to come three times to start the relaxation session; however, each time she became too ill to complete the journey.

The length of study was a draw back to recruiting, again due to the level of illness acuity. If a participant was in medical treatment, the first road block to recruiting was the amount of time (seven weeks) involved for participation in the sessions.
Participant attitude and belief toward energy healing could have negatively biased the findings. All participants indicated a sense of unknown in approaching the research, as no one had ever experienced energy healing and most had not experienced a formal relaxation session. It would interesting to conduct similar research with women who had previously reported been exposed to energy healing or formal relaxation.

As with all self-report inventories such as the STAI and the BDI, response bias may occur. That is, some participants may report more symptoms than they actually have, resulting in spuriously high scores while others may under-report symptoms, resulting in spuriously low scores. However, numerous reliability and validity tests of both measures suggest high reliability of results.

**Strengths of the Design and Study**

The cross over design reduces the statistical variability between participants as each participant acts as her own control, which strengthens internal validity and allows for fewer participants to conduct the investigation. This is demonstrated with the findings in this investigation. While the small sample size of fourteen limited the statistical analysis, this study design was able to demonstrate significant differences in levels of depression and anxiety at the pre-set intervals of questionnaire completion.

This research increased clinical staff education as to the benefits of energy healing and demonstrated to them how it might help their patients. Energy healing is the least known of the holistic services offered in this clinical setting. Furthermore, many of the medical practitioners have inquired about energy healing for their
family and other patients. Many of their first questions asked were: “What is it?” “Will it interfere with my religion?” and many were surprised the doctor supported this intervention. The great response to the patients was, “The doctor specifically requested this study for his patient population.” This research activity has resulted in staff taking Ama Deus workshops.

- The experience with the IRB demonstrated the need for more education to raise the understanding of energy healing and its place in a clinical setting. The concern of the IRB in regard to this study was how to protect a patient’s spirituality. This study has demonstrated to the IRB through progress reports that all participants have been positively supportive.

- Given the positive support by the physician, the physician’s nurse (secondary investigator) and spouse a sense of community support was created, thereby, replicating and demonstrating the importance of community involvement for healing as viewed by indigenous societies. Oral traditions by their very nature create community. During this research oral communication between the above mentioned persons created an interconnectedness offering a healing environment.

- Participant education about the effects of energy healing coupled with a deeper understanding of the importance of relaxation in lowering stress levels for optimum healing has certainly been an enhancement for both participants and their caregivers. One participant shared her difficulty in sleeping one night. Her husband suggested that she do the relaxation session. Another participant and spouse attended a workshop. These are some of the indications of greater awareness in the experience of energy healing and relaxation sessions.
Participants felt empowered by the relaxation session and realized the potential benefit in understanding their emotional and mental body.

- This research encouraged many participants to look deeper than the physical disease for healing. Many times participants shared deep insights after experiencing a healing session. This experience allowed the participant access to different aspects of their selves, thus providing a newer, deeper understanding of their lives.

- The setting of the research may be considered a strength in that all interventions were conducted in surroundings familiar to the participants. Because all services for cancer patients, including integrative and complementary services, are delivered from one central location, participation in the research did not involve traveling to an unfamiliar location.

- Having three practitioners administrate the treatment and control sessions helped to control internal validity and may have mitigated the Rosenthal effect.

- Grant funding facilitated payment for gas to those participants who had to drive great distances and for taxis for those participants who had no mode of transportation. This benefited the recruitment process.

**Suggestions for Future Research**

Adequate sample size is essential for clinical significance. Perhaps most importantly, a larger sample size is important in reducing the possibility of statistical type II errors and to determine if significance could have been achieved with the findings that were marginally significant.
Future researchers would be well-advised to standardize recruitment criteria as it relates to entry into the research study and stage of medical treatment. A specific timing for entry to the study should be determined and maintained. Rather than viewing all participants as homogeneous as it relates to their stage of medical treatment, more definitive findings would result if groups were matched by stage of medical treatment. Such matching would eliminate the possible variance among those who are very ill because of their medical treatment and those participants who have completed their medical treatment and have resumed normal activity and/or had not yet begun treatment.

It would be difficult to suggest a blind arm to this patient population; however, it may be interesting to use a design that incorporates a control group that initially receives no intervention beyond standard medical care for comparison to the intervention groups.

As evidenced by the findings in Group II with the strong overall reduction in anxiety and depression, a study examining the effects of Ama Deus energy healing after an introduction to general relaxation may produce more definitive findings.

Given that so many participants indicated how they looked forward to the next sessions, a suggestion for future research is to add a question regarding a participants' belief in energy healing to the demographic intake form. Participant attitude and belief toward energy healing could have supported a positive outcome setting up bias and weakening internal validity. A question such as, “Do you believe that energy healing will help your situation?” would allow for data to examine the effect of the participants' beliefs on outcomes.

With so much interest in investigating energy healing for clinical justification, future recommendations include a longitudinal study aimed at determining a general rule
for the longevity of effectiveness received from an energy healing session. Another recommendation would be to design a study examining if the length and quantity of energy healing session affects outcomes and longevity of effects.

**Summary**

Outcomes from the measurable comparatives demonstrate significance and help to answer the practical question of how well energy healing works for making good health care better. Moreover, the Principal Investigator experienced first hand the medical challenge that ovarian cancer patients face. The significant level of psychological and physical stress this patient population faces is tremendous. The small contribution of this study to validate Ama Deus energy healing as a non-pharmacological support for patients in their healing process is promising, not only from the point of view for use in a clinical setting; but just as importantly, it demonstrates how can we aid in the empowerment of patients in what often is seen as a hopeless journey.

Based on the findings in this research and the review of the literature cited in this research examining stress and quality of life, we can state with some assurance that stress was decreased and quality of life was increased for the research participants as evidenced by the reduction in anxiety and depression which accounts for most of the variance in quality of life.

Perhaps as a result of this research, participants may have gained more active coping skills to help them cope with life’s uncertainties and experience an increased perception of overall well-being.

This research adds to the growing number of investigations as to the efficacy of energy healing in health care. With the hypothesis generating indications of this
investigation perhaps our attention should turn from validating the worth of such interventions to investigating how to enhance the service and routinely incorporate its use within a clinical setting. The effects of Ama Deus on anxiety and depression in women with stage III ovarian cancer has contributed to the growing evidence of energy healing as a positive adjunct in healthcare.

____________________

For the Guarani -

The only request the Guarani made after sharing their knowledge of healing with Alberto Aguas so that he could share it with the outside world, was the preservation of their land. May we honor their gift of Ama Deus by continuing to open ourselves in a loving way to the rich heritage they have preserved and to begin to view all the earth as home and her inhabitants as precious.
Chapter 5 Endnotes:


REFERENCES AND BIBLIOGRAPHY


Oliff, M. “Stress, Depression and Immunity, the Role of Defense and Coping Styles.” *Psychiatry Research* 85, no. 7 (1999): 15.


APPENDIX A
Research Application to Saint Mary’s Health Care

Research Application
Dear Clinical Investigator,

Thank you for your interest in engaging in research activity at Saint Mary’s Health Care (SMHC). As a teaching institution, SMHC is committed to creating an environment that fosters scholarly activity and academic inquiry.

The attached Research Packet has been prepared to assist you in submitting your research proposal/protocol to the SMHC Research Committee and Institutional Review Board (IRB). In this packet you will find the Research Application for Approval and/or Funding, Guidelines for the Development of a Research Proposal, the Key Elements of Informed Consent, and a sample Informed Consent Document.

All research that takes place at SMHC must be sponsored by a SMHC Medical Staff member or employee and be in accord with the organization’s Mission, Values and Philosophy and the Religious and Ethical Directives for Catholic Health Facilities. Proposed research protocols must go through a two-step review process. The initial review is performed by the Research Committee. The Research Committee is a sub-committee of the IRB and is charged with the task of verifying the scientific validity and merit of the proposal. Once approved at this level, the research is submitted to the IRB for review of the protection of human rights and to assure compliance with established federal guidelines for informed consent. No research may take place at SMHC or its affiliates without prior SMHC IRB approval. The Research Committee and IRB meet monthly.

In the event that the Research Committee or IRB finds cause for concern with the submitted protocol/proposal the principle investigator will be contacted and provided with an opportunity to address these concerns and make any required modifications to the study.

It is our goal to make the research approval process a user friendly, prompt, and educational one. Please review the enclosed materials carefully and feel free to contact Jan Nowicki in the Office of Research Education & Support, Grand Rapids Medical Education & Research Center at 732-6230 with any questions or concerns.

Sincerely,

David Baumgartner, M.D.    Sr. Myra Bergman
Chair, Research Committee   Chair, Institutional Review Board
Saint Mary’s Health Care   Saint Mary’s Health Care

SAINT MARY’S HEALTH CARE
RESEARCH APPLICATION
1. **Protocol/Project Title:**

   The Effects of Ama Deus Healing on Depression and Anxiety in Women With Stage III or IV Ovarian Cancer

2. **Study Medication:** *(if applicable)*

   not applicable

3. **Study Phase:** *(if applicable)*

4. **Date of Application:**

   February 21, 2006

5. **Principal Investigator:**

   Name: Elizabeth Cosmos
   Institutional Affiliation: Manager for Wege Institute: Mind Body Spirit
   Mailing Address: 300 Lafayette, Grand Rapids, MI 49503
   Telephone Number: (616) 732-8967  Fax Number: (616) 732-8973
   Pager Number: (       )

6. **Co-Investigator/Institutional Affiliation:** *(if applicable)*

   Name: Michelle Weller, RN, OCN
   Institutional Affiliation: Gynecologic Oncology nurse at Lacks Cancer Center
   Mailing Address: 250 Cherry SE Grand Rapids, MI 495034502
   Telephone Number: (616) 752-5830  Fax Number: (616) 752-5260

7. **Saint Mary’s Health Care Faculty Sponsor:** *(required for Non-SMHC employees, Physicians without SMHC privileges, Resident, or Student proposals)*

   Name:
   Department:
   Affiliation:
   Title:

7A. **Other Institutions or Sponsors Involved:** *(if applicable)*

8. **Anticipated Dates of Project:** From April 15, 2006 Through June 1, 2006

9. **Human Subjects:** *(if yes, please enclose informed consent form)*

   YES

9A. **Number of Human Subjects Involved:**

   Minimum of 30

10.1 **Vertebrate Animals:** *(if yes, please include animal use form)*

   NO

11. **Risks Posed to Subject:**

   no risks to participants, however there is the potential of no decrease in depression and anxiety

12. **Do you have any funding pending for this project?** *(if yes, disclose source(s) and amount)*

   NO

12A. **Attach Anticipated Budget:** *(if applicable)*

13. **Protocol Summary:**

   A. **Study Objective(s):**
   The purpose of this study is to examine measurable changes over time that demonstrates Ama Deus spiritual energy healing is an effective
The intervention for anxiety and depression in stage III and IV ovarian cancer patients. (See Appendix A for literature review).

The Statement of the Problem is The efficacy of Ama Deus spiritual healing energy has not been scientifically documented and the quality of life for women diagnosed with ovarian cancer is significantly impacted. The treatments for this disease evoke anxiety and emotional distress. The resulting depression is often under diagnosed. The conventional, pharmacological treatments for anxiousness and depression often have side effects, and do not always relieve the symptoms.

B. Study Design:

The study design is a Cross Over Design. A minimum of 30 participants who choose to partake in this study will be randomized to either the intervention group (Ama Deus spiritual energy healing) or to the control group (relaxation session). Each participant will receive six treatments two times a week of 30 minute sessions of either the intervention or the control. One week for wash out and then all participants will cross over into the opposite treatment, those who had the intervention would now experience the control treatment or relaxation session; and the control group would then experience the intervention or Ama Deus spiritual energy healing.

All participants will be given a pretest assessment, mid point (after wash out) and post test assessment for anxiety and depression Psychometric Measures used are The Beck Depression Inventory II (BDI II) and the Stait Trait Anxiety Scale (STAI) (see Appendix B).

The intervention will be delivered by designated practitioners who meet the requirements (see Appendix C), and who are screened by the principal investigator. All practitioners will be scripted to the procedure in delivering the intervention. The control group will be given a scripted message prior to the relaxation session by the principal investigator.

Upon completion, the participants will be mailed the results and an opportunity to receive the intervention gratis will be offered for two more treatments.

C. Study Population:

Source of subjects: Lacks Cancer Center Saint Mary’s Health Care.

Inclusion Criteria: Adult female patients, eighteen years and older, with a histologically documented stage III and IV ovarian cancer, and a rating of more than 10 on the Beck Depression scale and on the Stait Trait anxiety Scale.

Exclusion Criteria: Those patients who are actively dying.

Gynecologic nurse (co-investigator) will pre phone all eligible participants informing them of the study and of the mailing of information requesting their participation in the study with a scripted message. (see Appendix C).

Number of subjects required to meet protocol needs:

Minimum of thirty participants

Number of subjects needed from Saint Mary’s:

Minimum of thirty participants

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2 Ibid pg.109
D. Duration of subject participation in research:  
   Two months  
E. Study medication(s): Not applicable  

Dosage and regimen:  

Route of administration  
F. Date data collection will begin: April 15, 2006  
G. Anticipated date of completion: June 15, 2006  
H. Identification of other study centers:  
   Wege Institute: Mind Body Spirit  

14. Informed Consent:  
   A. Describe the process for obtaining informed consent:  
      The principal investigator will mail pre-appointment packages to the participants, which  
      will include the consent form (see Appendix D), a map, appointment instructions, and the two  
      psychometric inventories. The pre-appointment packages will include a self addressed stamped envelope  
      for return of the two inventories and consent form. Reminder phone calls will be placed a day before the  
      first session.  
   B. If applicable, how will you ensure informed consent from non-English speaking subjects?  
      Consent forms will be provided in English and Spanish as well as  
      translators that will be at hand to answer any questions.  
   C. Describe any potential issues related to confidentiality:  
      Only the principal investigator and the co-investigator will have access to patients  
      identifying patient information, as well as Saint Mary’s Health Care. All  
      participant identifying information will be kept separate from the data collection.  

15. Implementation Processes:  
   A. Identify method of obtaining primary care physician consent. Include copies of written  
      materials.  
      Dr. Kevin Brader, Medical Director of Gynecologic Oncology Department  
   B. List below all participating departments of Saint Mary’s, how they will be informed about the  
      research, and how their consent to participate will be obtained.  
      Lacks Cancer Center consent is delivered through Dr. Brader’s head nurse and co-  
      investigator for the study, Michelle Weller  
      Wege Institute: Mind Body Spirit, consent has been approved through the Wege  
      Administration and reported at the Wege Executive meeting.  

16. Investigator Assurance:  
   I agree to accept full responsibility for the ethical conduct of the scientific project and to provide  
   the required progress reports if funding is approved.  

   Signature of Principal Investigator     Date  

17. Co-Investigator Assurance:  
   I have been involved in the preparation of this proposal and have agreed to actively participate in the  
   described research.  
   Signature of Co-Investigator     Date
18. **Faculty Assurance:**

I have read the proposal, believe that the topic of research is worthwhile, that the approach of the research is valid, and agree that I will support the resident(s) in the performance of this research project.

Signature of Faculty Sponsor   Date

Signature of Program Director   Date

19. **Person Completing Application:**

Signature:  

Type or Print Name: Elizabeth Cosmos  

Title: Manager Wege Institute: Mind Body Spirit  

Mailing Address: 300 Layfayette, Grand Rapids, MI 49503

Telephone Number: (616) 732-8967  Fax Number: (616) 732-8973  
Date: February 14, 2006

20. **Complete Protocol/Proposal**

Please provide one (1) copy of the complete study for Research Committee and IRB review.

Submit to the address below:

Cindy Johnston  
IRB Assistant to Myra Bergman  
Chairperson  
Saint Mary’s Health Care  
200 Jefferson Ave. SE  
Grand Rapids, MI 49503  
Telephone: (616) 752-6198  
Fax: (616) 752-6151

21. **Complete Protocol/Proposal**

Please provide nine (9) copies of the complete study for Research Committee and IRB review.

Submit to the address below:

Jan Nowicki  
Office of Research Education & Support  
Grand Rapids Medical Education & Research Center  
1000 Monroe Ave NW  
Grand Rapids, MI 49503  
Telephone: (616) 732-6230  
Fax: (616) 732-6257
APPENDIX B

Research Committee Approval Letter

March 20, 2006

Ms. Elizabeth Cosmos
Wege Center: Mind, Body, Spirit
300 Lafayette SE
Grand Rapide, MI 40603

Dear Ms. Cosmos:

This is to inform you that the Saint Mary’s Health Care Research Committee has completed its review of your protocol entitled, “The Effects of Ama Deus Healing on Depression and Anxiety in Women with Stage III or IV Ovarian Cancer.”

The Committee gave unanimous approval to your study, with these suggested additions to your data sheet & protocol:

1. Addition of any medications the patient is currently taking;
2. Other treatments the patient has had (i.e., radiation, surgery, etc.);
3. Include information in protocol on managing the severely depressed patient at any point in the study.

It will now be forwarded on to the Saint Mary’s Health Care Institutional Review Board. The meeting will be held in Wege 1,2,3 from 12:00 noon until 1:30 pm. on March 27, 2006. For questions regarding your IRB presentation, please phone Cindy Johnston at (616) 752-6198.

Should you have any questions or concerns, please feel free to contact Jan Nowicki at (616) 732-6230.

Sincerely,

Jeffrey Van Houten, PharmD
Acting Chairman, Saint Mary’s Health Care Research Committee

cc: Michelle Weller, RN, OCN
Sr. Myra Bergman/Cindy Johnston
File
APPENDIX C
Participant Enrollment Form

Name:__________________________________ Birth Date________

Marital Status: 1.□ Never Married, 2.□ Married or Living with Partner, 3.□ Divorced/Separated
4. □ Widowed
6. □ Homemaker
5. □ Native American, 6. □ Other.
Income: 1. □ Less than $20,000, 2. □ $20-40,000, 3. □ $40-80,000, 4. □ $80,000 and above
Have you ever been diagnosed or treated for either 1. □ Depression or 2. □ Anxiety

office use only

Medical Record #_________ Randomized G.____ ID #_________

Inclusion/Exclusion criteria

Inclusion Criteria: Exclusion Criteria:
- Stage III or IV Ovarian Cancer - Regular use of Energy Healing

Current Treatment

Stage: III □ IV □

Type of Treatment: □ Radiation, □ Chemotherapy

Currently on Medication for: □ Depression, if so what _______________________
□ Anxiety, if so what _______________________

INVENTORY SCORES

Date: 1.) ________ 2.) ________ 3.) ________
Depression: 1.) ________ 2.) ________ 3.) ________
Anxiety: 1.) ________ 2.) ________ 3.) ________

Number of Sessions completed _____
APPENDIX D
Letter to Medical Director of Richard J Lacks Cancer Center at Saint Mary’s Health Care

March 21, 2006

Dr. Tom Gribbin
Medical Director for the
Lacks Cancer Center
250 Cherry
Grand Rapids, MI 49503

Dear Dr. Gribbin;

This letter is to inform you of the details of my research as required for my doctorate program with Holos University Graduate Seminary. My thesis is: “The Effects of Ama Deus Energy Healing on Depression and Anxiety in Women with Stage III and IV Ovarian Cancer.”

Dr. Brader has approved this pilot study. The application for research at Saint Mary’s was submitted to the Research Committee on February 28, 2006 and was approved to move the IRB committee meeting of March 27, 2006.

Ama Deus energy healing is a non-invasive therapy that is being taught and practiced around the world. My personal experience of more than ten years in treating people showing symptoms of depression or anxiety is noticeable improvement. I believe there may be potential for improvement in depression and anxiety for this patient population.

The goal of this study is to test a complementary therapy intervention that will assist in improving the quality of life for women with stage III or IV ovarian cancer. This project has the potential of demonstrating an enhanced system of care through integration of scientifically based complementary therapies.

I will inform you of the results from the IRB. Thank you for your continued openness to Integrative Medicine and the department of Mind, Body, Spirit. If you have any further questions about this project, please contact me at 732-8967 or cosmosb@trinity-health.org.

Sincerely

Elizabeth Cosmos
Manager for Wege Institute: MBS
cosmosb@trinity-health.org
APPENDIX E
Saint Mary’s Health Care Consent Form

INFORMED CONSENT    page 1 of 2

The Effects of Ama Deus Healing compared to a Standard Relaxation Exercise
on Depression and Anxiety in Women
with Stage III or IV Ovarian Cancer

Investigators: Elizabeth (Beth) Cosmos, Principal Investigator
               Michelle Weller, Secondary Investigator

INTRODUCTION:
You are being asked to participate in a pilot study entitled, “The Effects of Ama Deus Healing compared to a Standard Relaxation Exercise on Depression and Anxiety in Women with Stage III or IV Ovarian Cancer”. The purpose of this research study is to conduct an investigation on the effects of the use of Ama Deus Energy Healing on depression and anxiety. Ama Deus Energy Healing is a method of using hands to direct healing energies to promote wellness. Medical based practices are focused on curing the disease, whereas holistic practices focus on supporting an individual to move in a self directed way or self-examination and emotional release. Healing involves moving toward wholeness, moving us toward acceptance of ourselves and others, to a state of balance and harmony with ourselves and our environment.

Ama Deus is similar to other energy healing techniques such as Reiki, Therapeutic Touch, and Healing Touch. The National Institute of Health recognizes and classifies these therapies as non-invasive techniques that clear, energize, and balance the human and environmental energy fields. These energy techniques are not affiliated with nor do they draw upon any formal religion (Christianity, Buddhism, Hinduism, Islamic, Judaism) and are respectful of all religions and cultures. The investigator, Beth Cosmos, an experienced and trained graduate student in energy healing, is employed at Saint Mary’s Health Care and is the manager for the Wege Institute: Mind Body Spirit. Michelle Weller, the co-investigator, is also employed at Saint Mary’s Health Care as an oncology nurse at Lacks Cancer Center.

DESCRIPTION OF PROCEDURES:
When individuals agree to participate in this study, they will be assigned by random to one of two groups. In Group One, participants will receive Ama Deus sessions that last from 15 or 20 minutes, two times a week. In Group Two, participants will receive structured relaxation sessions that last from 15 or 20 minutes, two times a week. After three consecutive weeks, both groups will not receive any sessions for one week. At the end of that one-week wait period, Group One will then receive structured relaxation sessions (15 to 20 minute sessions, twice a week for three weeks) and Group Two will receive Ama Deus sessions (15 to 20 minute sessions, twice a week for three weeks).

In a typical Ama Deus session, participants will be asked to lie flat on a padded table after being asked to remove only their shoes. The room will be dimly lit and gentle music will be playing. A practitioner will greet, explain the healing session, and stay with participants throughout the session. The practitioner will lightly place one hand on participants’ forehead and the other hand on participant’s abdomen above the belly button. Practitioner hands will stay in this position throughout the session.

In a typical structured relaxation session, participants will be asked to lie flat on a padded table after being asked to remove only their shoes. The room will be dimly lit and gentle music will be playing. A
The practitioner will be greet, explain the relaxation exercise, and stay with participants throughout the session. The practitioner will be seated in the room.

Participants will be asked to complete a survey of their feelings of depression and anxiety 3 times during the 7-week study period. This information will be collected before the first session, during the fourth week, and after the last session. The survey takes about 15 to 20 minutes to complete.

**RISKS & BENEFITS:**
This procedure is a non-invasive, relaxation session. There are no known medical risks to you as a participant. The potential benefit may be your ability to relax, which may relieve stress related to your diagnosis and treatment. Knowledge gained from this pilot study could help determine the efficacy of Ama Deus energy healing on depression and anxiety in patients with stage III or IV ovarian cancer.

**STUDY PARTICIPATION:**
Your participation in this study is strictly voluntary and there is no charge. Should you decide to not participate or would like to drop out of the study after participating; you will continue to receive the standard medical care for ovarian cancer.

**ALTERNATIVE:**
If you choose not to participate in this study, consult with your physician or your cancer resource specialist for other available treatments for anxiety and depression.

**CONFIDENTIALITY and PRIVACY:**
Your confidentiality will be protected to the extent permitted by law. All information will be recorded on a data sheet and labeled with a subject code. Your name or other identifying information will not be reported publicly. For example, date of birth will be recorded but only age will be used in reporting results of the study. The master log with your identifying information will be kept separate from collected data and stored in a locked file in a locked office at Lacks Cancer Center. The principal investigator and the secondary investigator are the only persons who will have access to your identifying information. The investigators, IRB, and/or governmental regulatory agencies, may look at your medical records when needed and necessary.

**QUESTIONS and PARTICIPANT’S RIGHTS:**
If you have any concerns or questions regarding this study you may contact Beth Cosmos at 616-732-8967 or Michelle Weller at 616-752-5830. If you have any questions or concerns regarding your rights as a research participant you may contact Sister Myra Bergman, Chairperson of the Saint Mary’s Health Care Institutional Review Board (IRB) at 616-752-6567. The IRB is a group that makes sure that study participants have their rights of privacy and safety protected.

**STATEMENT OF CONSENT:**
I have read the information in this consent form and have had the opportunity to have my questions answered. By signing this form, I voluntarily consent to participate in this research study. I also understand that by signing this form I have not waived any of my legal rights.

____________________________    ___________________ __________ _____/_____/_____
Study Participant’s Name (Print)  Signature     Date

________/_____/_____
Witness Name (Print)    Signature
APPENDIX F
Flowchart Depicting Steps for Recruitment

Nurse recruiter will determine eligibility from post surgical diagnosis

Nurse will describe study to eligible women post operatively before leaving hospital

Eligible participants will receive a packet from recruiter nurse that includes the a letter of introduction, consent form, and HIPAA.

One week post-operative follow-up clinical visit participant will return recruitment packet with obtained signed consent to the nurse recruiter.

Inclusion

Exclusion

Participant will be given the BDI and the State-Trait Inventories to complete during this clinical office visit by the primary or secondary investigator

Participant will be randomized to Group I or Group II by the primary or secondary investigator through a random number generator

GROUP I
Randomized to Ama Deus session 2 times a week for three weeks

GROUP II
Randomized to Relaxation session 2 times a week for three weeks
GROUP I
One week wait period, mid assesment taken after last Ama Deus session

GROUP II
One week wait period, mid assesment after last relaxation session

GROUP I
Crosses over to the Relaxation session 2 times a week for three weeks

GROUP II
Crosses over to the Ama Deus sessions 2 times a week for three weeks

GROUP I
Final inventory is taken at the last session

GROUP II
Final Inventory is taken at the last session

GROUP I
Discontinued sessions:
- 
- 

GROUP II
Discontinued sessions:
- 
- 

GROUP I
Analysis

GROUP II
Analysis
APPENDIX G

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Name of Research Study: “The Effects of Ama Deus Healing Compared to a Standard Relaxation Exercise on Depression and Anxiety in Women with Stage III or IV Ovarian Cancer”

Protocol #: 06-0424-03
Sponsor: Holos University Graduate Seminary
Principal Investigator: Elizabeth (Beth) Cosmos
Research Site: Wege Institute for Mind, Body and Spirit
Daytime telephone: 616-732-8967

The United States government has issued a new privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an “Authorization” describes your rights and explains how your health information will be used and disclosed (shared).

In working with the sponsor, the study doctor, Elizabeth Cosmos, will use and share personal health information about you. This is information about your health that also includes your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam and laboratory test results. Some of these tests may have been done as part of your regular care. The study doctor will use this information about you to complete this research.

In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representative may review or copy your personal health information at the study site. Regulatory authorities and the Saint Mary’s Health Care Institutional Review Board may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

By signing this Authorization, you allow the study doctor to use your personal health information to carry out and evaluate this study. You also allow the study doctor to share your personal health information with:
• the sponsor and its representatives
• the Saint Mary’s Health Care Institutional Review Board
• the U.S. Food and Drug Administration (FDA)
• Other regulatory agencies

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health confidential.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to Elizabeth Cosmos – Wege Institute for Mind, Body and Spirit – 300 Lafayette SE – Grand Rapids, MI 49503. If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical records may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event to the study, will be sent to the study sponsor.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years.

If you do not sign this Authorization, you cannot participate in this research study or receive study-related treatment. If you withdraw this Authorization in the future, your will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

I authorize the release of my medical records and personal health information related to this study to the sponsor and its representatives, the Saint Mary’s Health Care Institutional Review Board, the FDA, and other regulatory agencies as described as below. I have been told that I will receive a signed and dated copy of this Authorization for my records.

___________________________________
Printed Name of Subject

___________________________________   _____________ ______
Signature of Subject      Date

___________________________________
Printed name of person obtaining Authorization

___________________________________   ____________________
Signature of person obtaining Authorization    Date

OPTIONAL

I certify that under state law I am the legally authorized representative of the Subject named above. I am the responsible person legally permitted to sign this Authorization to release the Subject’s medical records and health information as described above.

___________________________________
Printed name of legal representative

___________________________________   ____________________
Signature of legal representative      Date
(Relationship to the subject)
APPENDIX H
Letter of Authorization from Participating Physician

February 17, 2006

To Whom It May Concern:

This is to inform you that Dr. Kevin Brader, Gynecologic Oncologist, and Michelle Weller, RN OCN, of the Lacks Cancer Center in Grand Rapids, Michigan; have agreed to participate in Elizabeth Cosmos’ study in, “The Effects of Ama Deus Healing in Depression and Anxiety in Women in Stage III and IV Ovarian Cancer”.

This study is part of Ms. Cosmos’ dissertation. We acknowledge that she will be gathering her information from our ovarian cancer patients with their consent. If you have any questions or concerns, please, feel free to contact us at (616) 752-5600.

Thank you

Dr. Kevin Brader, MD
St. Mary’s Health Services department of Mind, Body, Spirit began nearly a decade ago with one person. The Administration and senior leadership team initiated and supported this endeavor. They established a complementary task force to develop the foundation services for the department.

Massage was the first therapy introduced. At first, massage was considered “New Age.” A lot of education and thoughtful consideration went into the introduction of this therapy. Once the medical staff observed its significant benefits, referrals resulted from every department as well as employee engagement for themselves.

Over the subsequent years, music therapy, acupuncture and energy healing were slowly introduced. As staff came to understand these therapies, they learned how to identify the patient population who would best benefit from them. Today, more than 20 practitioners work in the department of Mind, Body, Spirit. Each therapy provided is research-based; and a high standard of credentialing for the practitioner has been installed.

This type of growth is not new news. Since the 1960s, Americans have been turning to alternative and complementary medicine to balance the limitations and side effects of conventional medicine. In 1991, the White House Commission on Complementary and Alternative Medicine was established with a $2 million budget that has recently risen to $10 million. “The job of the commission was to set guidelines for scientifically exploring approaches that have come from other cultures and practices that have flourished outside of conventional care; to gather information about and describe models that can successfully integrate the most effective and safe of these practices into conventional care; to make this information available to all Americans; and to recommend legislative initiatives that will make the best of these therapies, and training in them an integral part of medical and other professional education.” (J. Gordon 2005).

The National Institute of Health NIH has defined energy healing as "bioenergy" that contains a group of standardized, noninvasive techniques that clear, energize, and balance the human and environmental fields."

Therapeutic Touch, Healing Touch, Reiki and Ama Deus are not associated with any religious dogma. They are techniques or therapies that align one’s intention. The foundation of all energy healing techniques is intention. Proven in the 1920s, the Hawthorn effect has demonstrated that the observer can affect the observation. The Hawthorn effect study demonstrated improvements in productivity or quality resulting from the mere fact that workers were being studied or observed. Further, in research, one is always contending with the possibility of the placebo effect.

Over the past 40 years, these phenomena have led investigators to look closer at what could be the possible driving mechanism. We seem to be in a time when many different fields of study are converging to conceptualize the understanding of intention, energy and consciousness. Psychology is moving into transpersonal psychology; quantum physics is describing quantum fields as exchanges of energy, which constantly remixes in dynamic patterns--leading scientist to deduce the existence of an inexhaustible energy source.

Many of these scientists have become more spiritual from their experience in these investigations. Gary Zukov, a quantum physicist, has since left his field to write two books. His Seat of the Soul was on Schulers’ best selling list for almost a year. After his trip to the moon, Edgar Mitchell left NASA to scientifically investigate his experience in space.
Our current model (classical Newtonian view and Cartesian view) is being replaced by an emerging view that sees the human as more than machinery. This view sees the human from an energy perspective, as well. Many “New Age” exercises are energy-based practices with roots in the ancient, e.g. acupuncture.

When Lister taught that washing hands and wearing white clean clothing would help decrease death rates, he was chastised and ridiculed—until the microscope was discovered. Now we can see the culprits.

A parallel is happening today. Scientists are detecting and measuring subtle energy fields. Two wonderful pieces of work documenting the existence of this energy are:

- James Oschman’s *Energy Medicine: The Scientific Basis*, 2000. Providing a historical background to energy fields and medicine, this book tells about the measuring of such fields as heart magnetism; the electric circuitry of the cells; how acupuncture and therapeutic touch work; and how other related methods affect the healing process.
- Wisneski’s and Anderson’s *The Scientific Basis for Integrative Medicine*, 2005, demonstrates the growing scientific literature supporting energy based practices. It is available in our cancer center library.

Energy-based practices view the world from a holistic philosophy. Therefore, when conducting research, much thought is needed for best positioning them in a research model that takes things apart and attempts to view only the part. Interestingly enough, it has been managed. For instance, acupuncture is viewed from a holistic perspective. Only a part of the practice when studied in research is considered, stripping away, so to say, part of its essence, and yet there is still significant results, when subjected and confined to western research models. RCTs are recent designs for research investigation. These new holistic practices are challenging the existing models of scientific design. They bring to light the idea of providing more adequate research designs. This is a good thing.

The National Academies reported last spring “The integration of CAM therapies with conventional medicine requires that practitioners and researchers be open to diverse interpretations of health and healing, to finding innovative ways of obtaining evidence, and to expanding the medical knowledge base.” (Institute of Medicine of the National Academies, Washington DC 2005)

If the question is “How do we protect a person’s spirituality?” we first must define spirituality. The dictionary defines spiritual as: “relating to, consisting of, or affecting the spirit; of, or relating to spiritual matters.” The definition for spirit is: “breath, a life giving force; soul” (Merriam, Webster Dictionary. 1999). Spirituality is not synonymous with any one religion. It has no doctrine. Spirituality is cultivating a stronger sense of interconnectedness and developing a greater awareness of something that is larger than oneself, something beyond the normal realities of life. This something larger than oneself may be labeled God, Love or the Universe.

Our culture overlooks the sacred, wholeness, or holiness of health and wellbeing. The words “whole,” “health,” and “holiness” share a common linguistic root. The modern world is coming to grips with the idea of the interconnectedness of wellness and wholeness, a connection that is really spiritual.

The ancient practices that bring us back to principles of wholeness and interconnectedness have been termed “New Age.” Perhaps this is a good thing. The Americas were called the “New World” when an explorer landed on their shores, thinking he discovered something new. More important, it proved the earth was not flat—a startling discovery for the European. Even though most of the world at that time did not hold to the concept of a flat world, nor did they believe the earth had ever been the center of the Universe.

The practice of energy healing is ancient. Over the past few decades, science has been able to adequately measure the subtle fields of energy that surround the human body, which was previously not measurable by western science. Observations are being made in a wide area of study. As science, medicine and religion come together to better understand this great mystery of healing, we have the opportunity to heal our differences and grow together for the betterment of all.
The foundation of energy healing is intention. Therapeutic Touch, Healing Touch, Reiki and Ama Deus are techniques or therapies that align one’s intention. Each technique is colored by its cultural background. However, the focus of each technique brings the practitioner into alignment for the highest good, for themselves or for others. Ama Deus sets the intention of opening to unconditional love. Ama Deus is Latin for “God loves.” There is no intention to cure, to force, or to suggest anything else.

Every person has experienced the power of love. One small gesture from one person can bring the greatest joy to another; that joy aligns that soul to spirituality. Energy healing when performed on others, is the act of giving to another to empower and uplift.

Knowing an energy healing practitioner’s background is of the utmost importance. If a concern for protection exists, let’s focus on the important issue. Most of these practices are not under any form of uniform credentialing. This story may give clarity to this situation.

Early in my practice, about 17 years ago, I was working at East Hills Athletic Club. Then, people did not even discuss massage in this community. A gentleman came because his neck was sore. My first assessment of his neck immediately told me there was more to his problem than routine soreness so I refused to work on his neck. I shared my assessment and strongly suggested he see his physician. A few days later, he thanked me profusely. He was wearing a neck brace and he did indeed have a serious condition. He introduced himself as a physician! Whether I am doing energy work or massage, I have been trained to see signs of conditions outside of my scope of practice.

This experience was a building block for me and a learning experience for this person. He was educated about massage therapy and he learned to trust. This later became significant when I was hired by Saint Mary’s, as this man was an Advantage Health physician.

All of the Mind, Body, Spirit practitioners are screened for the highest credentials. Furthermore, energy healers are trained to see not only the spiritual aspect of the person but also the mental, emotional and physical aspects so referral to a specialist can be made when needed.

I have set the standards for this research project with the same stringent structures as Healing Touch and Therapeutic Touch. These organizations are predominantly nursing practices and they have established good policies and procedures in clinical settings for the use of energy healing. With more than 30,000 nurses in Healing Touch alone, structure was needed for the practice of this therapy and to conduct numerous research projects.

At the time of my interview more than ten years ago, the administration shared their hope that one day energy healing would be taught here at Saint Mary’s Health Care. It seemed a natural fit. Did not Jesus show us the power of touch when he reached out and touched the lepers? He demonstrated, over and over again, to love all without judgment. He reminded us constantly, in words and actions, that we are to love and to realize this for ourselves. “Physician heal thyself…greater things ye shall do.”

When I was first hired, I refused to do energy healing. I felt strongly the first way to overcome the concern over “New Age” practices could best be demonstrated through the most tangible practice of massage. Education and patience has led to a very successful program that paved the way, through trust, to introduce additional modalities and practices.

In the past three years, a policy and procedure for energy healing has been established in our hospital; it has also gone through the process of mission discernment. It is important to have these P&Ps, not only for the Mind, Body, Spirit practitioners, but also for the nurses trained in these techniques. Here is where the need to establish a policy and procedure was necessary to uphold high standards of care when delivering these therapies. Our hospital was not the first; we have sisters in the Trinity Health Care system that are on staff to do energy healing in the other hospitals.

We will not force any one into this research. We have established protocols that indicate people’s comfort zones with these practices. We will certainly bring our trained and experienced sensitivity when recruiting participants for trials.
This study presents many positive possibilities to our practice and our patients. In studies by Henderson and Donatelle (attached for your viewing), energy healing is highly sought after in women with breast cancer. Please note the choices for the Midwest as indicated in the survey from Ohio; prayer and spiritual healing were two of the three highest choices.

With patients in our hospital, we have observed calming and relaxing effects occur with energy healing. When a person is in a relaxed, less anxious or less depressed state, they are able to better cope with their situation. This relaxed state of being comforts and empowers the individual.

Energy healing helps without adding more drugs to an already complicated situation. The possibility of reducing anxiety and depression for this patient population with a non-complicated method demands investigation, if not only to substantiate what so many consumers are seeking.

Without citing more literature, studies indicate that a person is more receptive at the delta levels to healing through positive imagery, thought, and intentions. Thus a relaxation response, or level, is a positive approach to helping a person achieve their own innate healing powers. This research is designed to compare the intervention to a different relaxation technique.
APPENDIX J
Institutional Review Board Approval

April 25, 2006

Elizabeth Cosmos, principal investigator
Wege Institute for Mind, Body & Spirit
300 Lafayette SE
Grand Rapids, MI  49503

Re:  Review of tabled protocol:  “The Effects of Ama Deus Healing compared to a Standard Relaxation Exercise on Depression and Anxiety in Women with Stage III or IV Ovarian Cancer”
– Assigned IRB File #06-0424-03

Dear Investigators:

Saint Mary’s IRB reviewed your revised consent document associated with the aforementioned study at our April 24, 2006 meeting. Members found this revised statement to be much clearer and effective in helping potential study participants to give informed consent. There is one change that the IRB requests you make in the consent document—page 2, “Risks and Benefits” section, last sentence. Replace the last sentence with the following: “Knowledge gained from this pilot study could help determine the efficacy of Ama Deus energy healing on depression and anxiety in patients with stage III or IV ovarian cancer.” Send a revised statement with this language to the IRB chair within 5 days of your receipt of this letter.

With this change in the consent document, the IRB approves this study protocol and the latest revision of the consent document for a period of one year, beginning April 24, 2006 and ending April 24, 2007.

Any other changes in the study protocol and/or consent document must be submitted to the IRB before they are implemented. Additionally, if any adverse safety events occur with study participants, these must be submitted to the IRB within ten days of your knowledge of them.

A completed progress report will be due to the IRB no later than March 1, 2007. It is the investigator’s responsibility to submit this report in the timeframe indicated.

IRB members are grateful for your cooperation with addressing our previous issues. While there is much greater comfort with the changes you have made in the consent process and document, there remains some concern about sensitivity to potential study participant’s religious beliefs. The IRB urges the investigators to be vigilant about this matter during the consent processes.

Sincerely,

Sister Myra Bergman
IRB Chair
cc:  Michelle Weller, RN, OCN, co-investigator
      Notice of Approval
To: Elizabeth Cosmos, Principal Investigator  
Wege Institute for Mind, Body & Spirit  
300 Lafayette SE  
Grand Rapids, MI 49503

Re: IRB File #06-0424-03 “The Effects of Ama Deus Healing compared to a Standard Relaxation Exercise on Depression and Anxiety in Women with Stage III or IV Ovarian Cancer”

Date: March 27, 2007

This is to inform you the Saint Mary’s Health Care IRB has renewed its approval of the above research study.

The approval period is from 03/26/2007 to 03/26/2008. Your study number is #06-0424-03. Please be sure to reference either this number and/or the study title in any correspondence with the IRB.

All conditions for continued approval during the prior approval period remain in effect. These include, but are not necessarily limited to the following requirements:

• A copy of the Informed Consent Document, approved as of 03/26/2007 is enclosed. No other consent form should be used. It must be signed by each subject prior to initiation of any protocol procedures. In addition, each subject must be given a copy of the signed consent form.

• All protocol amendments and changes to approved research must be submitted to the IRB and not be implemented until approved by the IRB except where necessary to eliminate apparent immediate hazards to the study subjects.

• Significant changes to the study site and significant deviations from the research protocol must be reported.

• Please complete and submit reports to the IRB as follows: Renewal of the study - complete and return the Progress Report/Request for Renewal by 02/01/2008. The study cannot continue after 03/26/2008 until re-approved by the IRB. Completion, termination, or if not renewing the project - send the report upon completion of the study.

Please call me if you have any questions about the terms of this approval.

Sheryl Veurink-Balicki, RN, MSN, CEN  
IRB Chairperson

Copy: File
Enclosures: Informed Consent Document dated 03/26/07  
Progress Report form
Please take part in a complementary therapy project at Saint Mary’s Health Care involving the Lacks Cancer Center and the Wege Institute: Mind Body Spirit.

The goal of this pilot study is to find ways to enhance the quality of life for patients with ovarian cancer. **Are you eligible?** If you are newly diagnosed with III or IV ovarian cancer, you may be eligible.

**What is involved?** Energy healing is a form of complementary therapy. It involves a method of using hands to direct healing energies to promote wellness. It may help you to relax and have less feelings of anxiousness.

First, the oncology nurse from Lack Cancer Center will obtain your consent.

Second, you will complete a survey of your feelings of depression and anxiety. Then be assigned by random to one of two relaxation groups:

- **Group I** - participants will receive Ama Deus sessions that last from 15 or 20 minutes, two times a week.
- **Group II** - participants will receive structured relaxation sessions that last from 15 or 20 minutes, two times a week.

After three weeks of the above sessions there will be a one week rest period. Then you will begin the sessions again. Note: group one now has the relaxation sessions and Group Two has the Ama Deus sessions.

**How do you start?** You need to sign a consent form agreeing that:
- The study was explained to you,
- You volunteer to participate,
- You are free to change your mind
- There is no cost to you.
Frequently asked questions are:

Q. **What is the purpose of this study?**
A. The purpose of this study is to gain knowledge that could help determine the efficacy of Ama Deus energy healing and to learn if there is potential benefit for relaxation that could improve the quality of life for women with ovarian cancer.

Q. **What do you expect to get out of the study?**
A. We hope to get scientific data that will show that Ama Deus energy healing results in a higher quality of life.

Q. **I really cannot afford to pay for a therapist. What will the cost be?**
A. There is absolutely no cost to you. This is a pilot study for a dissertation and is funded by the student and Saint Mary’s Health Care.

Q. **If I am chosen for a particular group will I miss out on care I would otherwise receive?**
A. All women in this study will continue to receive standard medical care from their doctor. And this study is designed for the participant to experience both the intervention and the control group session.

Q. **Is there any risk in participating in this study?**
A. This procedure is a non-invasive, relaxation session. There are no known medical risks to you as a participant. The potential benefit may be your ability to relax, which may relieve stress related to your diagnosis and treatment.

Q. **What if I agree, and then after I sign the consent I decide I do not want to participate?**
A. You may stop participating in this pilot study at any time.
Thank you Letter

April 30, 2006

Sister Myra Bergman, IRB Chair
Jeffrey Van Houten, Acting Chair Research Committee
200 Jefferson Avenue SE
Grand Rapids, Michigan 49503

Re: IRB File #06-0424-03 “The Effects of Ama Deus Healing compared to a Standard Relaxation Exercise on Depression and Anxiety in Women with Stage III and IV Ovarian Cancer”

Dear Sister and Jeffrey;

Please extend this letter of thankfulness and appreciation to all who sit on the IRB and Research Committees. The careful analysis and consideration toward this pilot study by all members of both committees has greatly enhanced my learning, and certainly helped to position this study for the best possible outcome.

All suggestions by the Research Committee were included in the methodology. Sensitivity will be thoughtfully administered during the consent process in keeping with the concerns addressed by the IRB.

With the numerous requests and the growing interest of the public in using the “holistic therapies,” there is the need not only to merge and integrate but to also investigate. Hopefully more studies will continue in order to provide the validity and efficacy of CAM therapies as adjunct to our medical services to better serve our community.

Respectfully

Elizabeth Cosmos
Principal Investigator

cc: Dr. Kevin Brader, MD Gynecologic Oncologist, Lacks Cancer Center
    Michelle Weller, RN OCN, Lacks Cancer Center: co-investigator
APPENDIX N
Institutional Review Board One Year Progress Report

Federal regulations require a protocol review within one year of previous approval/review (unless a more frequent review has been designated by our IRB). This report is essential to permit continued human subject involvement. Although actual study approval is for one year from the date of initial review or from the date of renewal, you must return this form and requested information at least one month prior to the approval expiration date to ensure compliance with the regulations. If the report is not complete or is not returned, the IRB will conclude that the project is terminated and approval will expire. If your approved study concludes before the approval expiration date, you must send a progress report covering the appropriate period of time with your written notification that the study has ended. A full report covering study’s findings must be included when study closes.

<table>
<thead>
<tr>
<th>Protocol #</th>
<th>Project Title</th>
<th>Date of Initial Approval</th>
<th>Most Recent Approval Date</th>
<th>Progress Due Date</th>
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<td>06-0424-03</td>
<td>“The Effects of Ama Deus Healing Compared to a Standard Relaxation”</td>
<td>04/24/06</td>
<td>04/24/06</td>
<td>03/01/07</td>
</tr>
</tbody>
</table>

Principal Investigator: Elizabeth Cosmos

Address
Wege Institute for Mind, Body & Spirit
300 Lafayette SE

City Grand Rapids
State IL
Zip Code 49503

Phone: 616-732-8967
FAX: 616-732-8973
E-mail: cosmosl@trinity-health.org

Co-Investigators (Please list):
Michelle Weller, RN, OCN

Study Coordinator:
Phone:
Fax:
E-mail:

Number of Revision(s): ___

Project Status: ☑ Active  Renewal is requested for (state length of time up to one year) 1 year

☑ Closed  Date of Closure: ___

Protocol Consent (check one):

☑ Protocol and consent form use continues as most recently approved. (Attach most recently approved consent document. NOTE: Please update consent document to reflect Saint Mary’s contact as Sheryl Vearink-Balicki, Saint Mary’s Health Care Institutional Review Board (IRB) Chair at 616-752-6798.)

☑ Changes are requested at this time (attach request with changes listed and a copy of the revised form)
APPENDIX O

Practitioners Preparation

It is not how much we do, but how much love we put in the doing.
It is not how much we give, but how much love we put in the giving.
--Mother Teresa

Steps for informing and preparing practitioners

1. Refresher course offered in both levels of Ama Deus.
   a. Practitioners attend actual classes and participate with other attendees.
2. One hour briefing of procedures for working with consenting participants.
   a. Discussion regarding the research took place and questions concerning procedures were answered.
   b. Scheduling was done according to the practitioners availability
   c. Appropriate rooms for the sessions were discussed and defined for consistency of use whether the room used was in the department of Mind Body Spirit or Lacks Cancer Center
   d. Scripted messages for the intervention and the control were passed out (see A and B below).
   e. Music for session is *Inner Peace* by Steven Halpern, each practitioner received a personal copy.
   f. Encounter forms were distributed for use and all charting or extra documentation was to be applied on the back of the encounter form.
   g. A copy of the flow chart was given to each practitioner (see Appendix VII).
   h. Grounding and clearing meditation was before any energy session.
   i. Intention set prior to each A.D, session was to help at a soul level the symptoms of anxiety and depression. No intention during relaxation session, only to perform mental exercise.
   j. Practitioners held mentally a color of either pink a color associated with love or repeated the words love
   k. Agreed on a definition of energy healing...
3. First run of the investigation was shared with practitioners.
   a. The principal and the secondary investigator together used the first consenting participant to ensure that all procedures had smooth interactions and that the investigative forms for data entry were sufficient.
   b. Entered Data was sent to the statistician for review.

Scripted Message

A) The intervention group
   • Hello, please lie down on your back on the massage table.
   • Do you need a blanket for warmth and comfort?
   • Please close your eyes, take a couple of deep cleansing breathes relax and simply listen to the music. Closing your eyes helps to maintain a state of relaxation.
   • You need to do nothing but relax sink into the table and listen to the music.
   • I will gently rest one of my hands on your tummy area and one on your forehead.
   • When the session is complete I will gently pat your hand that is nearest to me.
   • Thank you and I will see you next………………………

B) The control group
   • Hello, please lie down on your back on the massage table.
   • Do you need a blanket for warmth and comfort?
   • Please close your eyes, take a couple of deep cleansing breathes relax and simply listen to the music. Closing your eyes helps to maintain a state of relaxation.
   • You need to do nothing but relax sink into the table and listen the music.
   • When the session is complete I will gently pat your hand that is nearest to me.
   • Thank you and I will see you next …………………………….
APPENDIX P

Participant Encounter Form

ID #________

Participant Encounter Form
Group A

Participant Name:________________________________________________________

Date:_____/_____/_______                Encounter 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

Day of the Week:_____Sun.____Mon._____Tues._____Thurs._____Fri.

Time of the Day: ___am, ___pm

Unable to do the session:
__Too tired
__No transportation
__Other ______________

General concerns reported to:
Principal Investigator Date: ___/____/_____    Time:____________

ID #________

Participant Encounter Form
Group A

Participant Name:________________________________________________________

Date:_____/_____/_______                Encounter 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

Day of the Week:_____Sun.____Mon._____Tues._____Thurs._____Fri.

Time of the Day: ___am, ___pm

Unable to do the session:
__Too tired
__No transportation
__Other ______________

General concerns reported to:
Principal Investigator Date: ___/____/_____    Time:____________
Participant Encounter Form
Group B

Participant Name:__________________________________

Date:_____/_____/_______  Encounter 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

Day of the Week:___Sun.____Mon. ___Tues. ____Thurs. ____Fri.

Time of the Day: ___am, ___pm

Unable to do the session:
__ Too tired
__ No transportation
__ Other ______________

General concerns reported to:
Principal Investigator Date: ___/___/_____ Time:____________

ID #_________

Participant Encounter Form
Group B

Participant Name:__________________________________

Date:_____/_____/_______  Encounter 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

Day of the Week:___Sun.____Mon. ___Tues. ____Thurs. ____Fri.

Time of the Day: ___am, ___pm

Unable to do the session:
__ Too tired
__ No transportation
__ Other ______________

General concerns reported to:
APPENDIX Q

In-service Notification

RESEARCH INSERVICE FOR MEDICAL STAFF

ON WEDNESDAY 18TH AND THURSDAY 20ST 4:30

The Effects of Ama Deus Healing Compared to a Standard Relaxation Exercise on Depression and Anxiety in Women with Stage III and IV Ovarian Cancer

Principal investigator: Beth Cosmos
Secondary investigator: Michelle Weller
APPENDIX R
State-Trait Anxiety Inventory

STAI Form Y-1
STAI Form Y-2
(One two-sided sheet with Y-1 on one side and Y-2 on the other side)

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APPENDIX S
Beck Depression Inventory II

Beck Depression Inventory – II
(a two-sided sheet)

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