SOCIAL WORK ADMINISTERED HYPNOSIS FOR PATIENTS UNDERGOING BONE MARROW PROCEDURES: A RANDOMIZED CONTROLLED TRIAL

by

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A dissertation submitted to the Graduate Faculty in Social Welfare in partial fulfillment of the requirements for the degree of Doctor of Philosophy, The City University of New York

2013

This manuscript has been read and accepted for the Graduate Faculty in Social Welfare in satisfaction of the dissertation requirement for the degree of Doctor of Philosophy.

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ABSTRACT

SOCIAL WORK ADMINISTERED HYPNOSIS FOR PATIENTS UNDERGOING BONE MARROW PROCEDURES: A RANDOMIZED CONTROLLED TRIAL

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This dissertation examines how a social work intervention of brief hypnosis during bone marrow procedures impacts pain and anxiety for adult patients. The study design was a randomized controlled trial with one intervention group and one control group (standard of care). Standard of care (lidocaine injection) was provided to both groups. Adult participants were eligible for participation in this study if they were over eighteen years of age, English speaking, and undergoing bone marrow biopsy and/or aspiration. Study hypotheses predicted that those patients who were randomized to the hypnosis intervention would have significantly lower levels of pain and anxiety. A sample of patients at Mount Sinai Medical Center (n = 80) provided data, which included demographic information. There were 41 patients in the intervention group and 39 in the control group. Results supported the study hypothesis that pain scores would be significantly lower among the experimental group; however, results did not support the hypothesis that hypnosis reduced anxiety associated with the procedure. Pain and anxiety were not significantly associated to demographic variables, such as, gender, ethnicity and age. Participants could not be blinded to the intervention, since the social worker was present during the procedure if the patient received hypnosis. However, the social worker administering the post procedure scales was blinded to what group the patient was randomized to. There were no adverse events or side effects as a result of participation in this study. The unusual role of the

social worker as the direct provider and the researcher will be discussed as well as the implications for practice. Funding was provided by the American Cancer Society: Doctoral Training Grant in Oncology Social Work, DSW-10-096-02-SW

ACKNOWLEDGMENTS

Foremost I would like to acknowledge all the support from my family, friends and classmates that contributed to my completing this dissertation. This is especially true of my husband, John who was a great source of support throughout my doctoral studies.

I would like to formally acknowledge all the work and mentorship of my chair Dr. Irwin Epstein. His constant encouragement throughout the doctoral program and the dissertation process helped me to realize the potential of this dissertation. I would also like to thank the other members of my committee, Dr. Harriet Goodman, and Dr. Mary Cavanaugh, who made great contributions to this work and were a pleasure to work with**.**

Support for this research was provided by a grant from the American Cancer Society (119621-DSW-10-096-01-SW) and I thank them for the opportunity the funding afforded me with.

Additionally, I thank the multidisciplinary team of co-investigators, the oncology social workers, Rachel Warbet, Meredith Cammarata, and Stephanie Eisenman. I also thank the mentoring that Dr. David Dorfman provided to our team and the contributions of Shyamala Navada for her help in carrying out this research. I would also like to acknowledge and thank Emily Sherlock for her patience and grammatical assistance.

Finally, I thank the patients who participated in this research; this study would not have been possible without them and I learned so much from their openness and generosity.

This dissertation is gratefully dedicated to John O. Mascarenhas, whose scientific research and clinical care of this patient population inspires me every day and to Julian Oliver Mascarenhas who helps me to keep things in perspective and maintain balance.

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CHAPTER I: INTRODUCTION

Medical Social Work

Hospital social workers are professionals working within a host setting. They are generally well informed about medical and social implications of a diagnosis. The traditional work of social workers in outpatient oncology settings includes bio-psychosocial assessments; psycho-education; counseling; linking patients to community resources; and evaluating and arranging for concrete services which include home care, hospice, durable medical equipment and transportation. Social workers are the primary psychosocial professionals available to patients receiving medical treatment. Although medical social workers have become more widespread in health care settings, oncology social workers have evolved as a sub-specialty. However, despite their training and expertise, social workers are frequently underutilized in the hospital setting as professionals with training to provide psychosocial support for patients and families (Ross, 1993; Snow & Warbet, 2010). They generally do not provide direct medical care and rarely conduct research in hospitals.

Employees who are not creating revenue, whose efficiency and cost saving value is not easily demonstrated, and whose role is misunderstood are valued least within the hospital environment (Ross, 1993). According to Donnelly (2009), the therapeutic functions of social work are often poorly understood by the interdisciplinary team and by hospital administrators. Therefore, social workers in medical settings are faced with the challenge of not only advocating for their patients, but also advocating for their professional role within the medical setting in which they are often marginalized. Nevertheless, social workers are usually prepared for discussions with physicians, patients and families around diagnosis, prognosis and treatments, and are aware of psychosocial problems encountered at various stages of illness (Ross, 1993).

Despite the numerous organizational challenges, social workers continually seek ways within the interdisciplinary team to assert "the core values of the profession" (Donnelly, 2009, p. 92).

At the same time, professional staff are struggling to identify their distinctiveness relative to other disciplines, such as between social work and nursing (Globerman, 1999). The medical profession is exceptional in that other professions have not been able to achieve the singular degree of economic power and cultural authority (Starr, 1982). Oncologists may not consider that social workers are able to provide clinical treatment for patients with pain and anxiety. While social workers might not recognize their power, Starr (1982) points out that professionals such as social workers often stand between people and benefits they desire or penalties they fear. His description of this gatekeeping illustrates one way that the professional responsibilities of social workers can yield power.

Conducting research on social work interventions is another way that social workers can assert their knowledge and expertise to the multidisciplinary team. The ability to carry out research in a hospital setting provides medical social workers with a universal language that they can utilize to communicate with physicians and nurses. For example, one recent article by Miller et al. (2007) described oncology social work intervention in a multidisciplinary clinical trial investigating quality of life in advanced cancer patients. They reported in their limitations section that "social work has not historically been a part of research-based interventions and continued exploration of these issues may be beneficial for the expansion and substantiation of the social work profession" (p. 116). The current health care climate focuses on market-driven, cost-containment strategies for the provision of medical care. This emphasis has greatly influenced the delivery of services, including the dissolution of many social work departments (Berger, Robbins, Lewis, Mizrahi & Fleit, 2003; Mizrahi & Berger, 2001). In the health care setting,

social work services are often viewed as ancillary and are frequently weighed against the budgetary constraints of a hospital (Ross, 1993). Therefore, utilizing research as a strategy to expand and legitimate the social work profession in the medical setting is not only sensible, it is necessary.

Randomized controlled trials (RCTs) are considered the "gold standard" of scientific evidence when determining the efficacy of practice interventions (Solomon, Cavanaugh & Draine, 2009). Social work borrows heavily from other disciplines with regard to practice knowledge. However, social workers that provide direct practice are in the position to conduct research that captures the needs of the patient population they serve, and they have the responsibility to engage in research (Magill, 2006; Solomon, et al., 2009). Theory development and hypothesis testing are best performed and developed when they are drawn from the experience of the practice world (Palmeri & Tutten, 2005). Psychologists who conduct research involving cancer patients and academic researchers are removed from the patient experience; therefore, they might not design studies in the most beneficial way to meet the needs of the patients. Social work clinicians are positioned to perform their own research with therapeutic interventions to determine the effectiveness of specific interventions. This study sets out to demonstrate the benefit of expanding the role of oncology social workers to include a psychosocial intervention (hypnosis) for physical or psychological symptoms, which are amenable to psychological intervention. In addition it illustrates how social workers can contribute to knowledge building in the medical setting. This dissertation illustrates the example of how an oncology social worker led a research team and carried out research in a hospital setting.

Problem Statement

An estimated 1,638,910 new cases of cancer will be diagnosed in 2012, and approximately 577,190 Americans are expected to die from cancer this year (American Cancer Society, 2012). In the cancer treatment paradigm patients are routinely exposed to treatment regimens and medical procedures in which they are likely to experience both pain and anxiety (Neron & Stephenson, 2006). Moreover, anxiety frequently occurs and fluctuates over time in response to diagnosis, treatment, remission, recurrence, and refractory disease (Deng & Cassileth, 2005; Spiegel & Moore, 1997). Typically, physicians address the pain and anxiety associated with cancer treatment through pharmacological interventions. As complementary and alternative therapies have gained popularity, medical research has expanded to include studies of the effectiveness of various additional treatments (Deng & Cassileth, 2005). However, the search for more effective ways to reduce or eliminate pain and anxiety associated with the cancer experience in order to enhance the patient's quality of life remains a challenge.

Pain and Anxiety

Pain is a subjective experience that cannot be measured with complete accuracy (Syrjala & Chapko, 1995). Physicians classify cancer-related pain into three major categories: pain caused by tumor involvement, pain from diagnostic or therapeutic procedures, and pain as a result of side effects or toxicities of treatment (Deng & Cassileth, 2005; McGuire, 2004). Pain from cancer and subsequent treatments frequently result in anxiety and emotional distress (Otis-Green, Sherman, Perez, & Baird, 2002).

Most patients consider medical procedures as sources of psychological and physiological stress. As a result, they are likely to experience high levels of anxiety and distress prior to and during medical procedures (Pinnell & Covino, 1999). Specifically, needle-related procedures are

a common source of pain and distress for oncology patients (Deng & Cassileth, 2005; Uman, Chambers, McGrath, & Kisely, 2006). For example, bone marrow aspirations and biopsies are considered extremely painful procedures, despite their frequent use over the past several decades (Vanhelleputte, Nijs, Delforge, Evers, & Vanderschueren, 2003; Weisman, Bernstein, & Schechter, 1998). Estimates are that more than 300,000 patients undergo bone marrow aspirates and biopsies for diagnosis and disease monitoring of blood and bone marrow cancers in the United States annually. They play a central role in the diagnosis and follow-up of many blood and bone marrow cancers and related disorders. It is a diagnostic procedure in which a needle is inserted into the bone and marrow is extracted to determine the presence of cancer cells.

The procedure is generally regarded as painful and potentially traumatic for patients (Jay, Ozolins, Elliott & Caldwell, 1983; Vanhalleputte, et al., 2003). Although doctors routinely use local anesthesia to address this pain, it does not prevent the pain experienced during the aspiration or during the application of pressure during the core biopsy, nor does it address the anxiety associated with the procedure. The anxiety produced by the anticipation of these procedures can be severe to the extent that some patients report symptoms such as nausea, vomiting and insomnia days before the procedure (Jay, et al., 1983).

Experiences of pain and anxiety can contribute to anticipatory distress, and they may and have long term psychological consequences (Kwekkeboom, 2003). Anxiety can also amplify pain perception in procedural settings (Deng & Cassileth, 2005). If a patient experiences a painful procedure, the memory of that occurrence may cause anxiety about subsequent procedures. The reactive component to pain can minimize or maximize pain sensations (Spiegel, 1997). Moreover, anxiety may greatly increase the degree of pain that patients feel during later procedures (Kellerman, Zeltzer, Ellenberg & Dash, 1983; Weisman, et al., 1998).

In the last decade, hypnosis gained recognition as a useful and beneficial clinical pain relief and anxiety reduction tool (Pavlek, 2008; Schnur, Kafer, Marcus & Montgomery, 2008). Schnur et al. (2008) conducted a meta-analytic review of hypnosis on emotional distress associated with medical procedures and reported that the data strongly supported hypnosis as an intervention to reduce emotional distress with a large effect size (D= 0.88). In the literature review that follows, studies involving hypnosis in medical and procedural settings will be explored further in relation to pain and anxiety reduction.

Gender differences in the reporting of pain have been cited as well in the literature. Women report higher levels of pain than men, specifically in relation to cancer pain (Cleeland, et al., 1994; Unruh, 1996). Ethnicity, culture and age can also impact the reporting of pain (Brittain, 2004). Cultural variability in the expression of pain and in anxiety levels accompanying pain is well established in the social science and medical literature (Bates, 1987).

The Use of Pharmacological and Non-pharmacological Treatments

Pain management is a major concern for cancer patients and providers alike. In order to treat the pain associated with bone marrow aspirations and biopsies, some patients receive analgesics for pain or anxiolytics for anxiety prior to the biopsy. However, these medications are not prescribed to every patient as a standard of practice. In fact, one study reported that less than 20% of patients undergoing potentially painful procedures received pre-procedure opiates (Puntillo, et al., 2001). Moreover, patients who receive pain or anxiety medication may still report pain and discomfort from the biopsy, largely due to the penetration of the biopsy needle into the bone. For example, a randomized placebo-controlled trial on the effects of oral lorazepam (ativan) before bone marrow biopsy found no difference in pain recalled immediately after the procedure. Despite their intermittent usage, premedication with lorazepam was also

associated with prolonged sedation and amnesia (Milligan, 1987). Pharmacological treatments do not always adequately relieve procedural pain, and some patients have difficulty tolerating their side effects (Deng & Cassileth, 2005; Wild & Espie, 2004).

The pediatric literature proposes non-pharmacological alternatives, such as hypnosis, for controlling pain and anxiety for children with cancer (Liossi & Haitra, 1999); however, these alternative therapies have not been taken into account for adult patients. Yet there are good reasons to consider non-pharmacological alternatives for adults. Although providers may find premedication with anti-anxiety medication inexpensive and easy to employ, these medications may burden patients. For example, the law does not allow patients to drive after receiving these medications, so they may have to find someone to accompany them to and from the procedure. In addition, they cannot engage in work involving machinery for 24 hours (Lang, et al., 2006). Oral premedications for pain also produce unpleasant side effects. Opioids are associated with fatigue, sedation, vomiting, confusion, constipation, urinary retention, sleep disturbances, itching, sexual dysfunction, and dry mouth (National Institute of Health, 2002).

Complementary modalities used before and during procedures can be an effective way to reduce procedural pain and anxiety (Deng and Cassileth, 2005). Hypnotic techniques can be used during procedures and they are safe and carry little risk for adverse events (Flory & Lang, 2008). In addition premedications are not completely efficacious at controlling pain and anxiety. Moreover, it has been reported in some cases that the degree of analgesia was equivalent or greater with hypnosis than morphine (Lynn, Kirsch, Barabasz, Cardena, & Patterson, 1999).

Hypnosis

Although most cancer center staff members are familiar with the procedural-related distress patients endure, the methods of reducing this distress are often inadequate. The lack of

pharmacological efficacy for pain management has led to the exploration of behavioral interventions to manage pain and anxiety during diagnostic and therapeutic procedures. The National Comprehensive Cancer Network (NCCN) pain guidelines recommend consideration of non-pharmacological modalities, such as hypnosis (Bendetti, et al., 2000). Research studies often define hypnosis as a behavioral approach, since it involves focused attention, deep relaxation, imagery and suggestion (Katz, Kellerman, & Ellenberg, 1987). Used either alone or in conjunction with medication, behavioral methods can be effective for treating side effects associated with cancer treatment, especially in procedural settings (Neron & Stephenson, 2007). Furthermore, behavioral interventions have broad appeal because of their positive impact on patient distress and suffering, their ease of application, and the sense of control they provide vulnerable patients (Redd, Montgomery, & DuHamel, 2001).

Researchers cite the benefits of hypnosis among other psychological and behavioral techniques that are available (Syrjala, Cummings & Donaldson, 1992). Hypnosis has been described as a highly effective intervention for managing pain and anxiety in cancer populations (Mansky & Wallerstedt, 2006; Saadat, et al., 2006). Montgomery and colleagues (2000) conducted a meta-analytic review to determine the effectiveness of hypnotic suggestion for pain relief relative to other behavioral interventions. As a result of their positive findings (a moderate to large effect size D=0.67), they recommended broadening the use of hypnosis for pain control and reported that hypnosis could be classified as a well-established treatment for pain.

Hypnosis has been reported to be effective with the acute pain associated with invasive medical procedures (Lang, et al. 2006; Montgomery, et al., 2007; Patterson & Jensen, 2003). Numerous studies have demonstrated the effectiveness of hypnosis in relieving pain and anxiety in pediatric cancer patients undergoing procedures, such as bone marrow aspirations and biopsies

(Hilgard & LeBaron, 1982; Katz, et al., 1987; Kuttner, Bowman & Teasdale 1988; Liossi & Haitra, 1999; Wall & Womack, 1989; Zeltzer & Lebaron, 1982). Although a variety of behavioral methods have demonstrated reduction in treatment related pain, increasing evidence demonstrates that hypnotic methods, involving relaxation, suggestions for reduced pain, and distracting imagery, appear to have the greatest potential for benefit to the patient (Redd, et al., 2001).

Even though a growing body of knowledge demonstrates the effectiveness of hypnosis to control anxiety and pain with children undergoing bone marrow biopsies, there is a significant gap in the literature involving adult cancer patients undergoing the same procedure. The literature review that follows argues for increased research on the potential for hypnosis to reduce pain and anxiety among adult cancer patients undergoing bone marrow aspirations and biopsies.

Study Aims

The primary goal of this dissertation is to examine the impact of a social work administered hypnosis intervention on pain and anxiety related to bone marrow procedures. This dissertation is a randomized controlled trial quantitative data analysis that involves 80 adult hematologic patients undergoing bone marrow procedures at an urban academic medical center. Additionally, information was gathered from debrief interviews conducted with five participants. The debriefing interviews occurred in the weeks or months after the patients had enrolled in the study and undergone the bone marrow procedures. These interviews provided qualitative insight into the patient's experience. In sum, the current study is guided by the following specific aims: The specific aims include:

1. To examine the effectiveness of hypnosis in reducing the pain experienced by patients undergoing bone marrow aspirations and biopsies as measured by the VAS scores.
2. To examine the effectiveness of hypnosis in reducing the anxiety experienced by patients undergoing bone marrow aspirations and biopsies as measured by the VAS scores.
3. To examine the association between pain and anxiety levels with gender, ethnicity, and age.

The following hypotheses will be tested:

1) The intervention group will evidence a statistically significant lower mean score reflecting bone marrow biopsy pain relative to patients receiving standard care;
2) The intervention group will evidence a statistically significant lower mean score reflecting post biopsy anxiety levels relative to patients receiving standard care;
3) The relationship between study group and mean scores reflecting bone marrow biopsy pain and anxiety will be moderated by patient gender, ethnicity, and age.

Chapter II: LITERATURE REVIEW

A review of the literature reveals that although numerous studies address the use of hypnotic interventions in pediatric bone marrow aspirations and biopsies, none of the studies have focused on adults undergoing the same procedure (Katz, et al., 1987; Kuttner, Bowman & Teasdale, 1988; Liossi & Hatira, 1999; Wall & Womack, 1989; Zeltzer & Lebaron, 1982). However, relevant literature points to the effectiveness of hypnosis with the adult population in other procedural settings. Moreover, the use of hypnosis is expanding as complementary and alternative medicine therapies have grown in popularity in conjunction with conventional cancer treatment (Bardia, Barton, Prokop, Bauer, & Moynihan, 2006; Mansky & Wallerstedt, 2006; Schernhammer, Haidinger, Waldor, & Vutuc, 2009). Examining the available research highlights the importance of further research on the effectiveness of hypnosis on pain and anxiety in adult hematology patients.

Background

Hypnosis involves an interaction between two people, in which the patient responds to suggestions by the interventionist. This intervention results in the patient experiencing alterations in perception, memory and voluntary actions (Kihlstrom, 1985). "The intensity of focus allows the hypnotized person to make maximal use of innate abilities to control perception, memory and somatic function" (Spiegal & Moore, 1997, p. 1180). Hypnosis derives from *hypnos*, the Greek word that means, "sleep;" however, hypnosis is a state between wakefulness and sleep (Rajasekaran, Edmonds & Higginson, 2005). The American Society of Clinical Hypnosis defines hypnosis as a state of inner absorption, concentration, and focused attention ("Definition of Hypnosis", 2010). It incorporates the subjective experience and the report of participants (Burrows & Stanley, 2001); it typically involves visual imagery, but always implies

a state of highly focused attention during which time a subject is susceptible to indirect or direct suggestions with the purpose of reaching a particular goal (Hilgard & Hilgard 1975; Syrjala & Abrams, 2002).

Hypnosis has been used in the medical field to treat various conditions since the 1700s, when treatment was more primitive and pharmaceutical, and surgical options were not readily available. Franz Anton Mesmer is credited with being the first to use hypnosis as a psychotherapeutic treatment in the 18th century (Spiegel & Moore, 1997). The usefulness of hypnosis was solidified when combat physicians reported using hypnosis during World War II for the wounded (Waldholz, 2003; Weisberg, 2008). In 1958, as more doctors described their experiences in the war, the American Medical Association (AMA) and Canadian Medical Association reported that hypnosis could be used in medical and dental practice as a valid therapy (Weisberg, 2008). Three years later, the American Psychiatric Association (APA) approved the use of hypnosis in various areas of medicine, and issued a position statement indicating that physicians would be seeking psychiatrists for training in hypnosis (Stewart, 2005). Although these advances were significant, the use of hypnosis by health professionals did not become widespread. The health field struggled in deciding who should deliver hypnosis, especially with so few physicians, psychologists and dentists available to train others in hypnosis (Weisberg, 2008). The lack of professionals trained in hypnosis led to the development of lay hypnosis in the 1960's. Tensions regarding the training and use of hypnosis arose between lay hypnotists and licensed health care professionals certified in hypnosis (Weisgberg, 2008).

Sigmund Freud (1856-1939) utilized hypnosis in psychoanalysis; however, he eventually turned to free association instead. Freud worked with hypnosis in the pre-psychoanalytic period; however, psychoanalysis included his recognition of indirect ways of dealing with unconscious

motivation (Kline, 1972). Milton Erickson (1901-1980) is noted for his significant contributions to the field of hypnotherapy. He was a psychiatrist and he received a Masters in psychology. He specialized in medical hypnosis and influenced practitioners of hypnotherapy; specifically, his work helped to broaden the clinical applications of hypnosis. Not only is he known for his work in hypnosis, he has also been recognized as one of the most influential pioneers in the evolution of family therapy along with Minuchin (Nichols, 2011). Additionally, strategic (problem-centered) therapy derived from Ericksonian hypnotherapy (Nichols, 2011). Erickson's experience as a hypnotherapist convinced him that people can change suddenly; therefore, he believed therapy could be brief. Jay Haley (1993-2007) studied hypnosis with Erickson and utilized brief therapy (a directive form of treatment focused on patient's symptoms) (Nichols, 2011). In 1973, Haley published Uncommon Therapy, which brought Erickson to the attention of those outside the clinical hypnosis community (Matthews, 2000). Today there are a number of Ericksonian Institutes in the United States, Europe and Australia. The Erickson Foundation is part of an international organization that carries on his work and promotes his approach to therapy (Matthews, 2000).

Before 1980, research on the efficacy of hypnosis was largely confined to psychodynamic hypnotherapy (Kirsch, Montgomery & Sapirstein, 1995). The application of behavioral principles in the early 1980s represented a paradigm shift within psychosocial oncology. Cancer adjustment problems were no longer seen as reflecting psychopathology, which required psychoanalysis (Redd, 2010). Some of the first studies involving cognitive behavioral therapy (CBT) with cancer patients focused on control of conditioned aversive symptoms through hypnosis, relaxation training, and cognitive-attentional distraction (Redd,

2010). This problem centered approach was in line with Erickson's view of psychotherapy and reflects a trend in the field towards shorter term approaches, such as CBT.

Since receiving acknowledgement and validation by the AMA and the APA, the acceptance of hypnosis as an intervention gradually increased. In 1996 The National Institutes of Health (NIH) concluded that there is strong evidence for the use of hypnosis in alleviating chronic pain associated with cancer, and NIH is providing funding for various clinical trials involving hypnosis (Pavlek, 2008; Richardson, et al., 2006; Stewart, 2005; Weisberg, 2008). Moreover, the NIH panel recommended that social workers can use hypnosis at a reduced cost as compared to physicians or psychologists (Nugent, 1996). The NIH support along with empirical findings aided the acceptance of hypnosis as a covered therapeutic service by insurance payers (Weisberg, 2008).

Today, many health insurance plans will pay for hypnosis when part of an accepted medical treatment (Waldholz, 2003). Hypnosis is being used increasingly for healthcare applications in hospitals, clinics and psychotherapy practices (Weisberg, 2008). Furthermore, hypnosis can be applied to many conditions, including panic disorders, irritable bowel syndrome, and insomnia (Pinnell & Covino, 1999). In addition, two professional hypnosis societies have become known: The Society for Clinical and Experimental Hypnosis (SCEH) formed in 1949, which emphasizes research in the field; and The American Society of Clinical Hypnosis (ASCH) founded in 1958 by Milton Erickson. ASCH membership requires individuals to have a Masters degree, be a licensed or certified healthcare worker, and to obtain at least 20 hours of ASCH approved training in hypnosis (http://asch.net/genpubinfo.htm). SCEH has similar criteria for membership (http://www.sceh.us/membership). These societies reflect the professional use of

hypnosis and their journals demonstrate ongoing research which further grounds hypnosis in scientific literature.

While the literature supports the use of hypnosis for a wide range of presenting problems, it has not been proven to be effective in all circumstances (Bausell, 2007). A Cochrane review of nine small trials of hypnotherapy did not show a benefit in smoking cessation, because it was difficult to assess the studies under review in the absence of an equivalent procedure which would control for non-specific effects (Barnes, et al., 2010). Determining the effectiveness of a hypnotic intervention when measured against placebo controls is challenging, since it is impossible to determine whether the treatment results are a factor of the hypnotic intervention or cognitive, behavioral, or educational procedures (Alladin, Sabatini & Amundson, 2007).

Clinical Theory

Hypnotic techniques have the ability to alter sensory awareness, perception, and behavior, and provide the potential to influence physiological functioning (Pinnell & Covino, 1999). Some researchers describe hypnosis as an altered conscious state different from the cognitive processes occurring during day to day activities (Patterson & Jensen, 2003). "Hypnosis is the art of securing a patient's attention and then effectively communicating ideas that enhance motivation and change perceptions" (Hammond, 1990, p. 2). According to Nugent (1996), hypnosis can be conceptualized as "an approach to intervention," (p. 362) thereby allowing social workers who employ various theoretical frameworks to utilize it. As previously stated, recent conceptualizations of clinical hypnosis focus on the cognitive-behavioral components, such as, focused attention, relaxation, imagery and suggestions to help patients cope (Katz, et al., 1987; Kirsch, et al., 1995; Schoenberger, 2000; Redd, et al., 2001).

A hypnotic experience often involves absorption, dissociation and suggestibility (Spiegel & Moore, 1997). A hypnotherapy session usually begins with the consent process and an explanation of the session. An induction (i.e., progressive muscle relaxation) is utilized to bring patients into a trance state and is typically followed by a deepening statement that is used to bring the patient into, or deeper into, the trance state (Rajasekaran, et al., 2005). Once the patient is in the trance state the utilization phase follows, in which the therapeutic suggestions are given. Suggestibility is enhanced in hypnosis due to the absorption in the trance experience; instructions are usually accepted uncritically (Spiegel & Moore, 1997). Utilization involves the activation of the patients' cognitive and affective skills as well as their life experiences (Nugent, 1996). The integration phase follows, whereby the patient is given post hypnotic suggestions typically including ego boosting and suggestions for well-being to ratify the new or enhanced ability (Rajasekaran, et al., 2005). Lastly, the patient is gradually brought out of the trance state and re-oriented to the normal waking state. This part of the process is sometimes referred to as re-orientation or termination (Wild & Espie, 2004; Stewart, 2005). (See Figure 1).

Figure 1. The Hypnotic Process

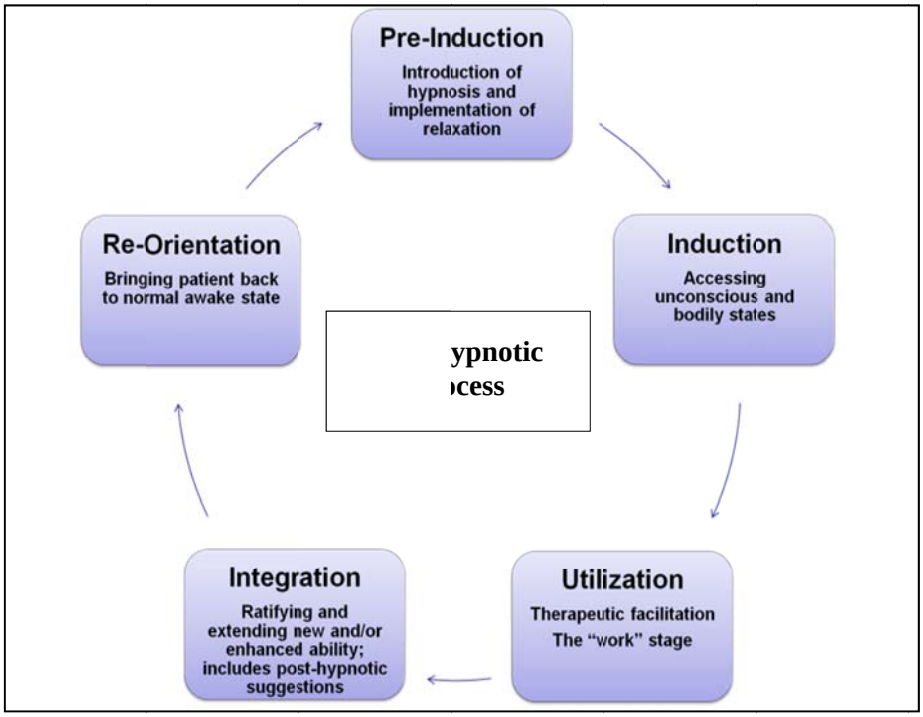


Figure 1**.** Figure depicts the process usually followed when people are brought into a hypnotic trance. Adapted from "Utilizing Hypnosis in the Hospital Setting and Implications for Social Work Practice." By A. Snow & R. Warbet, 2009, Poster presented at the *25th annual Association of Oncology Social Work Conference*.

A hypnotic experience depends on several factors, including openness and cooperation from the patient, and trust in the hypnotherapist (Chaves & Dworkin, 1997; Patterson & Jensen, 2003; Winsor, 1993). Additionally, patients' decisions to try complementary and alternative medicine therapies are often based on trust (Piantadosi, 2005). The success of hypnosis can also be influenced by the skills of the therapist (Filshie, 2005). Furthermore, the medical setting may be an ideal setting for hypnosis, since patients receiving medical care are highly suggestible (Flory and Lang, 2008). According to Spiegel (1997) in the presence of authority figures with

knowledge, such as doctors, a person is more likely to become absorbed in external factors and suspend his or her own critical judgment to accept what is being communicated.

Frequent misperceptions are associated with hypnosis. Despite its growing use and acceptance as a beneficial clinical intervention, misperceptions that hypnosis is "mind control," equivalent to sleep, or only successful on people who are hypnotizable are widespread. Hypnotized individuals are not deprived of their will; rather they have suspended the usual conscious editing function that typically arises when instructions are given (Spiegel & Moore, 1997). Furthermore, hypnosis is not equivalent to sleep, in that the trance state of hypnosis is a period in which one becomes more alert and awake, and enter an intense state of concentration. Moreover, this state can significantly influence the mind and body (Spiegel, 2007). Erickson (1980) believed that resistance could be overcome with hypnotic techniques; therefore, hypnotizability, or the degree of ability to experience images and to respond to suggestions following a hypnotic induction, is not the result of the patient's ability, but rather the hypnotherapist's skill (Matthews, 2000). The efficacy of a hypnotic intervention depends on the imagination of the patient in conjunction with the clinician's skill; these factors complicate the ability to evaluate hypnotic effectiveness (Jay, Elliot & Varni, 1986).

Complementary and Alternative Medicine

Hypnosis is often included in the broad category of complementary and alternative medicine (CAM) which has expanded in the US and abroad, particularly among cancer patients (Bardia, Barton, Prokop, Bauer, & Moynihan, 2006; Mansky & Wallerstedt, 2006; Schernhammer, Haidinger, Waldor, & Vutuc, 2009). The growing use of complementary therapies has resulted in its increasing availability in hospitals and oncology centers (Paltiel, et

al., 2001; Vickers, 2000). Patients are often psychologically accepting of CAM modalities, provided that they appear safe and have sound rationale (Piantadosi, 2005).

The federal government noticed the increasing popularity of alternative modalities and started funding empirical studies. The National Institutes of Health formed the Office of Alternative Medicine, with $50 million annually, after several years this office was titled, the National Center for Complementary and Alternative Medicine (NCCAM) to fund research in this area (Weisberg, 2008). Complementary therapies include acupressure, acupuncture, hypnosis, massage, meditation, relaxation and visualization, and yoga (Barbia, et al., 2006; Deng & Cassileth, 2005). CAM is understood as nonstandard treatments, which have not been validated using the standard methods, have not been taught widely in US medical schools, and have not been officially accepted in clinical cancer care (Schernhammer, et al., 2009).

Some suggest that CAM should be used in conjunction with (complementary to) conventional therapies in an integrative approach, rather than as "alternatives" to standard treatment (Bardia, et al., 2006; Deng & Cassileth, 2005; Wesa & Cassileth, 2009). In order to make the distinction that hypnosis is not an alternative intervention to standard treatment, it is important to change the language to promote an integrative model. Complementary therapies, for the purposes of this review, are those most often used in conjunction with standard treatment, not as a replacement. Complementary therapies are evidence-based, can decrease side effects associated with cancer treatment, and can, therefore, be relied upon to improve the quality of cancer patient's lives (Wesa & Cassileth, 2009).

Financial Considerations

In order for psychosocial interventions to become an integral part of cancer care and delivery, these interventions must maximize effectiveness while minimizing costs. This can be

achieved in a number of ways: decreasing procedure time, utilizing less costly interventions, or decreasing time in administering medications. Hypnosis is a promising cost-saving intervention as an adjunct to pharmacologic treatments (Lang & Rosen, 2002; Lang et al., 2006; Montgomery et al., 2007). Hypnosis is not only effective in decreasing pain and anxiety, it has also been found to decrease procedure time (Lang, et al., 2000; Lang, et al., 2006). Montgomery et al. (2007) concluded from a randomized controlled trial of 200 patients that hypnosis not only reduced pain experienced during excisional breast biopsy or lumpectomy, but also reduced institutional costs because of decreased mean operating time (Attention: 53.97 minutes vs. Hypnosis: 43.47 minutes). Similarly, in a randomized controlled trial conducted by Lang and Rosen (2002), the authors concluded that the addition of hypnosis provided patients with increased comfort and with less need for intravenous drugs, as well as less risk of over-sedation. This is another example of how hypnotherapy as an adjunctive treatment can help reduce costs. These findings have placed hypnosis in a position to expand in the current managed care environment (Lynn, et al., 1999).

Anesthesia is expensive, and most patients do not get bone marrow biopsies under monitored airway control (MAC) anesthesia in an operating room under the supervision of an anesthesiologist. The procedure can be easily performed in an outpatient physician office. However, when patients choose to get MAC, the costs are considerable and include the price of the treatment room, preoperative assessment, use of the room, anesthesia and post procedure recovery (Christensen & Fatchett, 2002). When patients are put under general anesthesia, the institution may also have opportunity costs because physicians are not seeing or billing other patients. Additionally, patients can choose to have intravenous anti-anxiety and/or pain medication. Intravenous pre-medications also add to the cost of the procedure because they

require treatment room utilization and infusion nurse time. The addition of hypnosis as an adjunct to standard care (lidocaine injection) would decrease the costs, risks and side effects for patients, compared to the use of intravenous medication and MAC.

The current health care climate focuses on market-driven, cost containment strategies for the provision of medical care. In the health care setting, social work services are often viewed as ancillary services and are frequently weighed against the budgetary constraints of a hospital. Hospital administrators scrutinize expenditures in terms of necessity, cost and value. Therefore, employees who are not creating revenue, whose efficiency and cost saving value is not easily demonstrated, and whose role is misunderstood, are valued least within the hospital environment (Ross, 1993). If social workers can demonstrate that a psychosocial intervention could benefit the hospital with cost savings, the evidence could have a major impact on their sustainability in health care settings.

Hypnosis for Acute Procedural Pain and Anxiety

"Acute pain is caused by noxious or tissue-damaging stimulation resulting from bodily insult or disease, and is rarely caused by psychological factors, although anxiety often plays a prominent role" (Jay, Elliot, & Varni, 1986, p. 601). Acute procedure-related pain is associated with invasive medical procedures such as bone marrow aspirations and biopsies, and lumbar punctures. Notably, patients with hematological malignancies often require numerous bone marrow aspirates and biopsies for disease monitoring throughout the course of their illness. Although this procedure is considered minimally invasive, patients often report experiencing severe pain during it and anxiety in anticipation of it. Some assert that procedural hypnosis can reduce pain and anxiety. Moreover, hypnotherapy has demonstrated beneficial effects in reducing acute procedural pain and anxiety (Flory & Lang, 2008). Interventions for pain in adult

cancer patients have centered on chronic disease-related pain rather than acute procedural pain (Jay, et al., 1986).

Even though hypnosis is often still associated with theatrical performances, contributing to the suspicions about this intervention, it has been utilized in medical settings for the use of pain reduction for over a century (Hilgard & Hilgard, 1975). Hypnosis has the potential to reduce or in some cases eliminate acute pain (Lynn, et al., 1999). Hypnosis for pain focuses on decreasing the negative qualities of the experience by reducing the intensity or transforming the pain into something less distressing. Clinicians providing hypnotic analgesia usually offer specific suggestions for alterations in how pain is experienced (Jensen & Patterson, 2006; Spiegel & Moore, 1997).

Hypnosis has been theorized to reduce pain through the use of a variety of strategies. These include direct suggestion of pain reduction, shifting the experience of pain by converting it to some other sensation, and directing attention away from the pain and its source (Hilgard & Hilgard, 1975; Syrjala & Abrams, 2002; Spiegel & Spiegel, 2004). The techniques most often used involve physical relaxation combined with imagery that provides a substitute focus of attention for the painful sensation. Since pain is both psychological and physical, the hypnotic technique mobilizes the cognitive experience while simultaneously producing a sense of physical relaxation (Spiegel & Moore, 1997).

Spiegel and Moore (1997) described three general principles that are often utilized during hypnosis for pain control. The first principle teaches patients to transform the pain experience by acknowledging that even though it exists, there is a distinction between the signal itself and the discomfort that the signal causes. The hypnotic metaphor is used to help to transform the signal into one that is less uncomfortable. Second, patients can be taught to expand the perceptual

options available to them. Pain is present but is transformed by the presence of another competing sensation, such as numbness or coolness. Third, patients can be taught not to fight the pain experience. Fighting pain can enhance pain by focusing attention on it. Focusing on pain can intensify anxiety and depression, as well as increase physical tension, which, in turn, can amplify the pain signals generated.

Hypnosis has been studied in adult bone marrow transplant patients and has resulted in an improvement in symptoms, though this study did not include bone marrow aspirates and biopsies (Syrjala, Cummings, & Donaldson, 1992). The study findings suggested that the patients who received hypnosis reported less oral mucositis pain than those who received treatment as usual, therapist contact alone, or cognitive behavioral coping skills (Syrjala, Cummings, & Donaldson, 1992). While this study is not representative of hypnosis decreasing acute pain, it is relevant to include in this literature review, since it highlights the effectiveness of hypnotic interventions in adult hematologic patients.

Pain and anxiety are closely associated with one another in the experiences cancer patients face. Cancer is overwhelming for most patients; therefore, it is likely that anxiety is heightened with each diagnostic procedure. Patients approach procedures concerned about the outcomes. In addition, if previous procedures have been painful, the patient may experience anticipatory anxiety for subsequent ones. Anticipatory anxiety can increase subjective pain experienced during the procedure (Flory & Lang, 2008). A recent study examining pain and anxiety in pediatric cancer patients reported that patients do not become accustomed to painful procedures, such as bone marrow aspirates and biopsies (Dufresne, et al., 2009). Additionally, the children who anticipated pain in this study tended to experience more pain during the needle insertion. If pain can be at least partially relieved by hypnosis, anxiety is lessened not only from

the pain relief, but also through posthypnotic suggestions. In other words, patients can be prompted to feel more relaxed, calm, and comfortable following the hypnosis (Hilgard & Hilgard, 1975). Furthermore, the mind can be an influential in controlling pain; by modifying perception with hypnosis, the brain changes through dopamine pathways, which reduces pain perception (Spiegel, 2007).

One study examined positron emission tomography (PET) scans to differentiate areas of the brain involved in pain affect. With healthy volunteers, the researchers compared hypnosis to a control group and found that hypnosis was effective at decreasing the unpleasantness associated with the painful stimulus (Rainville, et al., 1997). Furthermore, Rainville et al. (1997) identified the anterior cingulate cortex as the area of the brain correlated with unpleasantness. These researchers suggest that hypnosis is modulated by brain structures centrally involved in the regulation of consciousness. A similar study, conducted by Faymonville et al. (2000), examined healthy adults undergoing a painful stimulus and compared hypnosis to control group. The study found that both intensity and unpleasantness were reduced during the hypnotic state. Therefore, there is neurophysiologic reason to believe that hypnosis is an intervention which can effect the perception of pain and related anxiety (Spiegel, 2007).

The biological mechanisms influencing hypnotic analgesia remain uncharacterized. Researchers hypothesize that hypnosis leads to a secretion of an endogenous substance similar to opioids. The substance binds to opioid receptors in the central nervous system, modifying the anesthetic effect of hypnosis (Goldstein & Hilgard, 1975; Moret, et al., 1991). Laboratory studies tested whether the opioid antagonist naloxone reverses the hypnotic analgesia in patients with induced pain, and found that none of the studies demonstrated that naloxone was effective in reducing pain (Goldstein & Hilgard, 1975; Moret, et al., 1991). Small study populations and

lack of methodological rigor prevent drawing firm conclusions from these studies. No matter the mechanism, systematic studies have demonstrated the potential hypnosis has at reducing pain and distress over control conditions in pediatric patients undergoing painful procedures (Accardi & Milling, 2009; Mansky & Wallerstedt, 2006; Zeltzer & LeBaron, 1982).

It has been suggested that hypnosis delivered continuously throughout the pain stimulus provides more relief than when the suggestion is delivered once at the outset of the pain (Accardi & Milling, 2009; Price & Barber, 1987). Accardi and Milling (2009) reviewed ten studies providing hypnotic intervention during an invasive procedure and found only six that performed hypnosis continuously throughout the procedure. In five of the six studies, a significant effect for hypnosis was obtained for pain. Comparatively, two of the four studies did not produce significant effects for hypnosis when the intervention was not provided throughout the procedure (Accardi & Milling, 2009; Katz et al., 1987; Wall & Womack, 1989). This suggests that a hypnosis intervention delivered during the procedure is more effective.

Gender, Ethnicity, and Age Differences

Ethnicity, age, gender, culture, values, and family dynamics can influence pain feelings, attitudes about pain and how people discuss their pain. The perception of pain depends on how it is processed through feelings, thoughts and memories of pain (Brittain, 2004). These factors can influence not only how people perceive pain, but also how they communicate, and even if they are willing to discuss pain with health care professionals. However, concepts such as gender, ethnicity, and race are challenging to reliably assess due to inconsistent definitions (Edwards, Fillingim, & Keefe, 2001).

Gender differences may be the result of biological, psychological, and sociological factors. There may be gender differences in pain sensitivity and tolerance in acute pain

management (Miaskowski, 2004). Men and women differ in their expression of pain. Women are more likely to acknowledge and disclose pain (Klonoff, Landrine, & Brown, 1993). There are biological differences in pain mechanisms which may predispose women to have more pain. For example, menstrual phase and reproductive status can affect pain ratings (Berkley, 1997). Katz et al. (1982) reported that endorphin levels (endogenous opioids produced during pain that resemble opiates in their ability to produce analgesia) in children with two types of leukemia were found to be higher for males compared to females. The higher endorphin level in males was reported as an explanation for the decreased pain in males.

Sex differences in attitudes towards pain exist, which can affect the pain reports (Bendelow, 1993). These differences may also influence emotional responses to pain (Unruh, 1996). Men may be more embarrassed by pain (Klonoff, et al., 1993), which could also contribute to gender differences in pain reports. Male socialization discourages males from being allowed to express physical pain as compared to females (Bendelow, 1993; Brittain, 2004). Additionally, several researchers found that girls have more behavioral distress towards pain from bone marrow biopsies or similar procedures (Katz, et al. 1987; Schecter, Bernstein, Beck, Hart, & Scherzer, 1991). Furthermore, Hilgard and Lebaron (1982) found that females reported more pain than males in their study involving pediatric bone marrow biopsies. Moreover, Walsh, Donnelly and Rybicki (2000) found that females with advanced cancer reported more anxiety than males in their study, though this finding was not related to procedural anxiety.

Sex differences in attitudes might not always impact pain ratings; Fowler-Kerry and Lander (1991) found no sex differences in venipuncture pain. Additionally, Jay et al. (1983) did not find significant sex differences in children's rating of distress associated with bone marrow procedures. Furthermore, Koopman, Eisenthal and Stoeckle (1984) found ethnicity, age and sex

were not significantly associated with patients' emotional distress, although the authors noted a trend that women communicated more often. Moreover, Katz et al. (1987) did not find any support for ethnic differences in acute pediatric pain associated with bone marrow procedures. The willingness to report pain is difficult to resolve because it is challenging to separate the physical insult and the psychological response to it (Berkley, 1997; Fowler-Kerry & Lander, 1991; Spiegel, 1997). Furthermore, in some cultures, the vocalization of pain is considered weak behavior and therefore men may be expected to endure pain without complaining (Brittain, 2004). The experimenter's gender is an additional factor related to this concept and may be influential in pain reports. Levine and De Simone (1991) reported that the gender of the experimenter significantly influenced the report of (cold pressor) pain, and males reported significantly lower pain to a female than to another male.

Age also affects communication about pain: older people are less likely than younger people to acknowledge and discuss their pain. The elderly tend to underestimate the amount of pain they are in and sometimes need prompting to report their pain with an accurate description of severity (Brittain, 2004). Parker, Baile, Moor and Cohen (2003) surveyed a large sample of cancer patients and found that older cancer patients (with social support) reported less anxiety. Moreover, they found demographic variables, such as age and gender, to be associated with measures of adjustment and quality of life. Another study involving advanced cancer patients found that younger patients reported more anxiety and pain than older patients (Walsh et al., 2000). However, these findings were not related to procedural anxiety or pain.

Ethnicity focuses on the distinction between groups of people based on behavior, culture, biology and physical characteristics. Therefore, the term ethnicity is used to describe groups of people with distinctive behaviors, culture, history, experience, ancestry and beliefs. The term

ethnicity can also be used to describe race, as well as cultural, social, psychological and political differences (Edwards, et al., 2001). Pain can also be thought of as a cultural expression which may be influenced by the social characteristics of a person. Thus, pain can be examined from a cultural, biological, psychosocial, economic and spiritual context (Martinelli, 1987).

In many cultures, tradition can influence pain expectations, ways to tolerate pain, and how to act while experiencing pain. Moreover, social scientists assert that an individual's ethnic background regulates how one perceives pain and communicates it to others (Martinelli, 1987). For example, in some cultures discussing pain is not encouraged. Therefore, it can influence how people express and rate pain (Brittain, 2004). One of the complexities of measuring ethnic differences in pain includes the fact that ethnic groups can be quite heterogeneous. For example, the meaning of pain for a recent immigrant from the Caribbean, whose views may be influenced by a spiritual/religious context, may be quite different from a fourth generation acculturated African American (Edwards & Keefe, 2002).

Various ethnic groups differ with regard to their cultural experiences and attitudes as well as in meanings for pain. Bates (1987) suggested these differences may influence the neurophysiological processes of pain perception and tolerance, as well as psychological and behavioral responses to pain. According to Clark et al. (1999) ethnic minorities are prone to chronic levels of stress, which have been found to produce chronically high levels of sympathetic activation and physiological exhaustion. It has been suggested that coping resources may become reduced, thereby making it more difficult to cope with acute pain (Edwards et al., 2001). According to Anderson et al. (2000; 2002) African Americans and Hispanics with cancer-related pain were reluctant to report or complain of pain. Several studies have reported ethnic differences in pain reports. Lipton and Marbach (1984) found statistically significant differences

in the reported pain experience (with participants from a facial pain clinic) for various ethnicities. Faucett et al. (1994) reported that Latino and African-American patients demonstrated greater postoperative pain from a dental extraction compared to Caucasian patients. It is important to note that the aforementioned studies did not utilize cancer patients or bone marrow procedures in their studies. Yet, there have been studies that have reported no ethnic differences in measures of pain sensation among patients with cancer (Greenwald, 1991).

Few researchers have explored ethnic differences in emotional expressiveness and response to pain. Studies that have explored this area utilized healthy samples and reported that Hispanics and African Americans tend to express more pain-related affective distress than Caucasians (Hastie, et al, 2005; Riley, Gilbert, & Heft, 2002). However, a population-based study found nominal ethnic differences in pain-related emotional distress (Portenoy, Ugarte, Fuller & Haas, 2004).

In Accardi and Milling's (2009) recent methodological review of the effectiveness of hypnosis in reducing procedure-related pain, they found that most studies reviewed did not include information on ethnicity. The American Psychological Association Division 12 Task Force for empirically supported treatment emphasized the importance of specifying the ethnicity of participants, so that it is possible to draw conclusions about the efficacy of treatments for ethnic groups (Chambless, et al., 1996).

The impact of gender, age and ethnicity differences is complex, and although these factors are often considered demographic variables, they can also be considered as factors that might significantly impact the clinical pain experience (Brittain, 2004; Unruh, 1996). Since these demographics can also influence the manner in which pain is experienced and communicated, these factors should be examined for potential interactions. As a result of the

literature examining differences across gender, age and ethnicity there is a reason to examine the association between those variables and pain and anxiety levels.

Hypnosis with Pediatric Bone Marrow Aspirates and Biopsies

Current evidence, including numerous randomized controlled trials, supports the effectiveness of hypnosis at reducing pain with children and adolescents undergoing medical procedures. However, the progress toward empirical validation of clinical hypnosis is still in its early stages (Alladin, et al., 2007). Recent critical reviews addressing acute pain concluded that hypnotherapy is a clinically valuable intervention for procedure-related pain and distress (Patterson & Jensen, 2003; Richardson, et al., 2006; Neron & Stephenson, 2007).

Hypnosis is a commonly utilized intervention in pediatric oncology for anxiety and pain, and has been studied as an intervention for children and adolescents undergoing bone marrow aspirates and biopsies. Additionally, some have claimed that hypnosis is the most promising intervention to reduce procedural pain and distress for children and adolescents (Barabasz & Perez, 2007). There are at least five studies that included a hypnosis experimental group and involved children undergoing bone marrow aspirates and biopsies that resulted in decreased pain and anxiety compared to control groups (Katz, et al., 1987; Kuttner, Bowman & Teasdale, 1988; Liossi & Hatira, 1999; Wall & Womack, 1989; Zeltzer & Lebaron, 1982). (See Table 1).

Zeltzer and LeBaron (1982) were the first to publish a randomized study of hypnosis during bone marrow biopsies. They randomized 33 pediatric patients with leukemia, non-hodgkins lymphoma (NHL) and neural tumors ages 6-17 undergoing bone marrow procedures to receive hypnosis during the procedure or to a control group of distraction and deep breathing exercises conducted during the procedure. Measurements of pain and anxiety were taken by both independent observers and the patients on a scale of 1 to 5. The inter-rater reliabilities

between observers and patients during the bone marrow aspirates (n=27 pairs) were .56 for pain (P<.001), and .67 for anxiety (P<.001). The results indicated that pain was reduced by hypnosis ($p<0.001$) and to a smaller, but significant extent by the distraction technique ($p<0.01$). Additionally, they found that anxiety was significantly reduced only by hypnosis ($p<0.001$). The lack of no-treatment/standard of care control group prevents making conclusions on efficacy, since the outcome may have been attributed to therapist attention. Furthermore, Zeltzer and Lebaron (1982) did not use a treatment manual to guide their hypnotic intervention.

Katz, et al. (1987) randomized 36 children (ages 6-11) diagnosed with acute lymphoblastic leukemia (ALL) undergoing bone marrow procedures to receive a 20-minute training in hypnosis and self-hypnosis or to non-directed play sessions. Children in both groups had significant decreases in self-reported measures of pain and fear ($p<0.001$). As previously reported, these authors noted a gender difference, in that girls exhibited more distress behavior than boys. However, this study utilized a small sample with only 8 females and 24 males. This study did not utilize a treatment manual for the hypnosis intervention, nor did they use an active delivery of the intervention during the procedure. The control group was used to control for therapist attention and time, but they did not utilize a no-treatment group/standard of care control group.

Of the published works, Kuttner, et al. (1988) had the largest sample size of 48 children (ages 3-10) diagnosed with lymphoblastic leukemia or acute myeloblastic leukemia (AML) undergoing bone marrow procedures. They utilized two intervention groups, hypnosis and behavioral distraction, as well as a control group that received standard of care. Participants received a 5-20 minute preparation session before the bone marrow procedure and a clinician actively delivered the intervention during the procedure. The results of the first post-treatment

bone marrow procedures demonstrated that for the younger patients (ages 3-6), hypnosis provided a significant reduction in pain and anxiety compared to the distraction and control groups. In the older patients (ages 7 to10), the hypnosis and distraction groups showed significant reductions in observer rated pain and anxiety compared to control groups. At the second post-treatment intervention, all groups showed reductions. Since there was no difference in the effectiveness of the three conditions, the authors contributed this finding to a possible contamination by the staff's knowledge of the two treatments. The limitations of this study include the lack of a treatment manual to guide the interventions and the nurses were inadequately blinded.

Wall and Womack (1989) only had 20 pediatric patients ages 5-18 in their non-randomized sample. Patients received two training sessions in either hypnosis or cognitive coping strategies twice prior to either bone marrow procedures or lumbar punctures. Their results indicated that the hypnosis group showed significant decreases in observational ($p<0.009$) and self-reported ($p<0.03$) pain and observer reported ($p<0.04$) anxiety. They did not find significance in patient reported ($p<0.217$) procedural anxiety compared to control groups. Wall and Womack (1989) utilized a treatment manual; however, this was a small sample size. They also did not deliver the intervention during the medical procedures.

Finally, Liossi and Hatira (1999) conducted a randomized controlled trial of 30 pediatric patients ages 5-15 diagnosed with leukemia. The patients were randomized to one of three groups: hypnosis, cognitive behavioral coping skills training, and standard of care control group. The intervention included two 30-minute sessions of hypnosis, or two 30-minute sessions of cognitive-behavioral (CBT) training in alleviating pain and distress five days before the bone marrow procedure. Patients in the hypnosis and CBT groups reported less pain and anxiety, and

were found to have significantly less distress from observer ratings as compared to the standard of care control group. Additionally, they noted that the children in the CBT group reported more anxiety and exhibited more behavioral distress than the children in the hypnosis group. This study was also limited by a small sample population of 10 patients in each group and they did not utilize a treatment manual. Moreover, the intervention was not delivered during the procedure.

Despite the positive findings in the literature involving children, support for the effectiveness of hypnotic interventions is limited by heterogeneity, small sample size and absence of treatment manuals (Pinnell & Covino, 1999; Neron & Stephenson, 2007). Furthermore, Alladin, et al. (2007) assert that the field of pediatric hypnosis is in an early stage of development with regards to gold standard validation.

Table 1. Hypnosis with Pediatric Cancer Patients Undergoing Bone Marrow Procedures

Table 1

Summary of Studies Using Hypnosis for Pediatric Patients Undergoing Bone Marrow Procedures

Authors	Sample	Study Design	Summary of Findings
Zeltzer & Lebaron 1982	N=33 6-17yrs	2 groups, hypnosis and non-hypnotic behavioral technique BMA	Hypnosis reduced pain more than distraction
Katz et al. (1987)	N=36 6-11yrs	2 groups, hypnosis and non-directed play therapy BMA	Hypnosis no difference from play therapy at reducing pain
Kuttner et al. (1988)	N=48 3-10yrs	3 groups, hypnosis, behavioral distraction, control - RCT BMA	Hypnosis reduced pain more than distraction & stnd care in younger children; hypnosis & distraction reduced pain more than control in older children
Wall & Womack (1989)	N=20 5-18yrs	2 groups, hypnosis and distraction, crossover design LP or BMA	Hypnosis no difference than distraction in reducing pain. Significant reduction in observational & self-reported pain
Liossi & Hatira (1999)	N=30 5-15yrs	3 groups, hypnosis, CBT control-RCT BMA	Hypnosis reduced observer rated pain more than CBT & no Treatment; Hypnosis & CBT reduced self-rated pain more than no treatment

Note. CBT= Cognitive Behavioral Therapy RCT= Randomized Controlled Trial BMA= Study was conducted involving patients undergoing Bone Marrow Aspirate & Biopsy LP= Study was conducted involving patients undergoing Lumbar Punctures

Children are more likely than adults to receive complementary therapies along with traditional cancer treatment. It is possible this is because parents want to do everything possible to decrease pain and anxiety when their children receive these painful treatments (Dufresne, et al., 2009; Wesa & Cassileth, 2009). In addition, children are considered to be more hypnotizable than adults (Spiegel, 2007). Recently, at the American Society of Hematology national conference it was reported that hypnosis might effectively improve symptom control in children with hematologic malignancies (Lechowicz, 2009). Furthermore, a Cochrane systematic review

indicated that hypnotic interventions are the most promising of the psychological interventions reviewed for decreasing pain and distress associated with needle-related procedures for children (Uman, et al., 2006).

Hypnosis with Adult Cancer Patients Undergoing Medical Procedures

Although substantial research has been conducted with hypnosis and adult cancer patients undergoing various medical procedures, the treatment and procedures that have been studied all differ from bone marrow procedures. Several randomized controlled trials have been published in the last decade involving hypnosis with adult cancer patients undergoing various medical procedures. These studies lend support for the use of hypnosis as a beneficial psychosocial intervention for adult cancer patients undergoing medical procedures.

Montgomery and colleagues (2002) randomized 20 women undergoing excisional breast biopsies to a brief pre-surgery hypnosis session versus standard of care and reported that those in the hypnosis group experienced significantly less postsurgical pain ($F(1,18)=15.48$, $p<.0001$) and distress ($F(1,18),=5.97$, $p<.025$) than those who received standard care. Another study conducted by Montgomery et al. (2007) randomly assigned 200 excisional breast biopsy or lumpectomy patients to pre-surgery hypnosis versus standard of care. Their findings indicated that patients in the hypnosis group required less propofol and lidocaine than patients in the control group. Additionally, they found that patients in the hypnosis group reported less pain intensity (means = 22.43 vs. 47.83; difference 25.40; 95% CI = 17.56-33.25), pain unpleasantness, nausea, fatigue, discomfort, and emotional upset (means = 8.67 vs. 33.46; difference= 24.79; 95% CI = 18.56-31.03) compared to the standard of care group.

In 2008, Schnur et al. studied the same patient population. They randomly assigned 90 pre-surgery patients undergoing excisional breast biopsies to receive standard of care or a 15-

minute pre-surgical hypnosis session. The women in the hypnosis group had significantly lower mean values for presurgery VAS emotional upset (16.5 vs. 38.2, *P* 0.0001, *d* =.85), SV-POMS anxiety (10.0 vs. 5.0, *P* =0.0001, *d* = 0.85); and significantly higher levels for VAS relaxation (75.7 vs. 54.2, *P* = 0.001, *d* = -0.76) than attention controls. These findings suggest that hypnosis can be an effective intervention for controlling pre-surgical distress in women awaiting diagnostic breast cancer surgery (Schnur, et al., 2008).

Lang and her colleagues have conducted several trials involving hypnosis and various medical procedures. Lang et al. (2006) randomized 236 large core needle breast biopsy patients to three groups: standard of care, empathetic attention during the procedure, or hypnotic relaxation during the procedure. The researchers found that women in the hypnosis group (logit slope= -0.27, p<.001) experienced a significant reduction in anxiety. Women in the empathy group experienced no change in anxiety levels (logit slope= -.04, p=0.45) and women in the standard group experienced increased anxiety (logit slope= 0.18, p<0.001). All three groups experienced significant increases in pain; (logit slopes: standard care = 0.53, empathy = 0.37, hypnosis = 0.34; all p<0.001); however, the hypnosis and empathy groups were less steep than the standard care group (p=0.024 vs p=0.018).

In a similar study conducted by Lang et al. (2008), they randomized 201 patients undergoing tumor embolization or radiofrequency ablation (procedures used to treat liver cancer, benign tumors, carcinoid tumors) to receive standard of care, empathetic attention during the procedure, or hypnotic relaxation during the procedure. Empathetic attentive behaviors included matching nonverbal communication patterns and listening attentively to patients. Procedural hypnosis recipients had less pain, anxiety and medication use compared to patients in the standard of care group. They reported that the patients in the hypnosis group experienced

significantly less pain and anxiety (mean 2.0; interquartile range (IQR), 1-4) compared to patients in the standard group (mean 3.0; IQR, 1.5-5.0; P= .0147) and empathy group (mean 3.50; IQR, 2.0-5.9; P= .0026). A surprising finding in this study was that the patients in the empathetic attention group had an exceedingly high adverse event rate (48%) prompting the trial to be stopped. Authors concluded that empathetic approaches without hypnosis do not enhance patients' coping, and can result in more adverse events. Since these authors found the comparison group of empathetic attention to produce high adverse events, it remains a challenge to determine an adequate comparison group to control for placebo effects of a hypnosis intervention.

While the findings from the studies involving breast biopsy and lumpectomy patients indicate the effectiveness of hypnosis, the type of pain experienced during the breast biopsy procedure is different than the pain associated with a bone marrow aspiration and biopsy. In excisional breast biopsy the entire suspicious mass, plus a margin of normal tissue, is removed with a scalpel, whereas in a bone marrow aspiration and biopsy the pain component is comparatively minor, since little tissue mass is involved.

Unlike the previous studies, Staplers et al. (2005) did not report significant findings for the benefits of a hypnosis intervention with adult cancer patients undergoing radiation treatment in the Netherlands. This study was conducted on 69 adult cancer patients undergoing curative radiotherapy. Patients were randomized to standard radiotherapy or radiotherapy plus three sessions of hypnosis spread out during the course of daily radiotherapy treatment (radiotherapy treatment is usually given once a day over the course of three to six weeks). The authors reported no statistically significant differences in anxiety or quality of life between the intervention and control groups (p=0.96). However, patients in the hypnotherapy group

indicated an improvement in mental and overall well-being. This study utilized a different treatment modality and as a result, different intervention doses were possible (3 sessions of hypnosis). Consequently it is not comparable to bone marrow procedures. Additionally, another difference between this sample population and hematology patients is that the majority of patients enrolled in this study had breast and prostate cancer; only two patients enrolled had a diagnosis of lymphoma.

The aforementioned studies involve hypnosis with different types of medical procedures for adult cancer patients. Therefore, the type and amount of pain experienced is likely to be different due to tissue damage, duration of the procedure and the type of treatment. Additionally, the anxiety level would likely be impacted by whether or not the procedure is diagnostic or treatment related. The majority of studies conducted involving hypnosis with adult cancer patients undergoing medical procedures demonstrates the effectiveness of hypnosis as a non-pharmacological intervention. Nevertheless, none of the studies examined the effectiveness of hypnosis for adult patients undergoing bone marrow aspirates and biopsies.

Social Work Interventions and Hypnosis Research

Literature involving social work practitioners conducting hypnosis is limited. According to Windsor (1993) clinical hypnosis has been largely overlooked by social workers. Cwikel and Behar (1999) performed a vote count review of the extent of social work involvement with intervention research with adult cancer patients. Not surprisingly, they found that social workers were involved with the delivery of the intervention in less than half of the studies. They also found that social workers publish fewer RCTs and more frequently studied interventions such as social support, counseling and education. Moreover, they reported that the social workers involved in research interventions were less successful at demonstrating efficacy, which the

author's attributed to the social workers not utilizing CBT interventions in their research. They found that psychologists and other health professionals were more often conducting studies utilizing CBT interventions, such as hypnosis (Cwikel & Behar, 1999).

One study utilized a social worker to conduct a self-hypnosis intervention for 72 pediatric pulmonary center patients to assist them with symptoms including: anxiety, asthma, chest pain, dyspnea, habit cough, sighing, hyperventilation, and vocal cord dysfunction (Anbar & Hummell, 2005). The authors of the study concluded that clinical hypnosis can be provided by a team of varied professionals. Furthermore, they reported that the results from their study demonstrated a clear benefit of expanding the social worker's role to include hypnosis for pulmonary symptoms (Anbar & Hummell, 2005). Moreover, Anbar and Hummell (2005) found that the rate of improvement from the hypnosis intervention performed by the social worker was similar to that achieved by the physician (pulmonologist) using hypnosis at the same Center in a previous study (Anbar, 2002).

One well known study in the field of psychosocial oncology research is a study by Spiegel and Bloom (1983). They randomized women with breast cancer to a weekly support group, led by a social worker or psychiatrist, as well as a therapist who was in remission from breast cancer. The intervention involved one of the groups ending with a self-hypnosis exercise (5-10 minute); however, the psychiatrist was the only group facilitator to lead the self-hypnosis intervention. Spiegel and Bloom (1983) reported that those who had self-hypnosis and group therapy fared best in controlling pain sensations ($F= 3.1$, $p< 0.05$). Moreover, in reviewing several of the aforementioned studies, social workers were not utilized to perform the hypnosis intervention. Psychologists and physicians were primarily utilized to conduct the hypnosis interventions (Zeltzer & Lebaron, 1982; Katz et al., 1987; Liossi & Hatira,1999; Lang et al.,

2006; Montgomery et al., 2007). It is not clear why social workers were not selected to perform the intervention in these studies.

Despite, the lack of research involving social workers preforming hypnosis interventions, hypnosis can be used effectively by a variety of health professionals, including medical social workers, as demonstrated by Anbar and Hummell (2005). "As health care has become more complex, there is a growing realization that a multidisciplinary approach to patient care is essential" (Morrow, et al., 1992, p.255). The Anbar and Hummell (2005) study demonstrated that social workers can successfully utilize this intervention in a medical setting**.**

Conceptual Framework

The hypnosis intervention should produce an increase in relaxation among study participants, and in conjunction, there should be a decrease in anxiety and pain associated with the procedure. If the intervention is effective in decreasing anxiety and pain, the results of this study could lead to an increased demand for hospital social workers to perform this intervention for patients undergoing bone marrow procedures.

Figure 2. Conceptual Framework

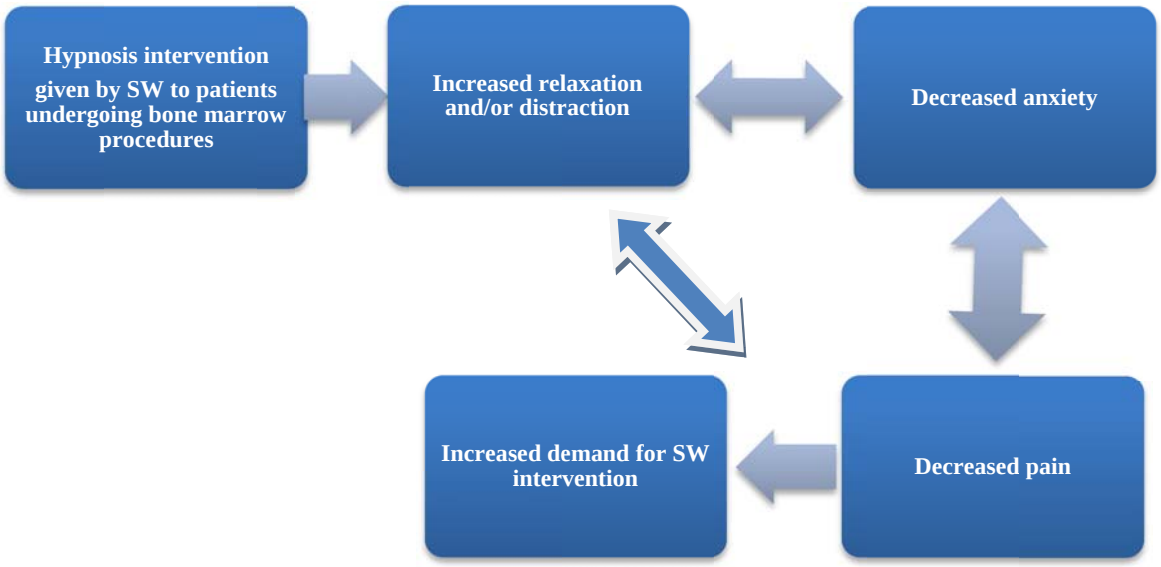


Figure 2. This figure represents the conceptual framework of this research study.

Conclusions

Pain produces suffering for cancer patients; therefore, the management of cancer pain is a major concern for both patients and providers. The common goal of both standard medical care and complementary therapies, such as hypnosis, is to ease patient suffering. Although hypnosis has also been cited as effective in reducing pain and anxiety in procedural settings with adults, it has never been tested empirically with adults undergoing bone marrow aspirates and biopsies, and therefore warrants further investigation. Another reason to test the intervention with this patient population is because they are particularly vulnerable due to the poor prognosis associated with hematologic malignancies, as compared to breast biopsy and lumpectomy patients (American Cancer Society, 2011).

Unfortunately, despite medical and behavioral advances, cancer patients are still experiencing considerable distress. Adult cancer patients continue to require specialized interventions that will address their pain and anxiety associated with bone marrow aspirates and biopsies. An intervention that attempts to reduce distress in cancer patients ought to be a priority, especially since hypnosis is safe, does not produce adverse effects and can provide patients with a sense of control.

CHAPTER III: METHODS

Setting

The traditional social work role in outpatient oncology settings includes bio-psychosocial assessments; psycho-education; counseling; linking patients to community resources; and evaluating and arranging for concrete services which include home care, hospice, durable medical equipment and transportation. Social workers are the primary psychosocial professionals available to patients receiving medical treatment. However, despite their training and expertise, social workers are frequently underutilized in the hospital setting as professionals with training to provide psychosocial support for patients and families (Ross, 1993; Snow & Warbet, 2010). Oncologists may not consider that social workers are able to provide clinical treatment for patients with pain and anxiety. Therefore, this study sets out to demonstrate the benefit of expanding the role of oncology social workers as researchers. Additionally, this dissertation brings attention to the psychosocial intervention (hypnosis) for physical or psychological symptoms, which are amenable to psychological intervention which social workers can provide as the primary psychosocial providers in the hospital setting.

The Social Work Department administration at Mount Sinai Hospital approved the study and provided us with the opportunity to conduct the research. Mount Sinai Hospital's has a history of supporting social work research among its staff (Blumenfield & Epstein, 2002). The department's culture of encouraging practice-based research afforded this author the opportunity to design and conduct this research study, which was performed in addition to the regular and routine job requirements of the hospital social worker. The study was conducted in the Ruttenberg Treatment Center, outpatient hematology/oncology hospital based faculty practice.

Recruitment

Hematologists, oncology nurses and oncology social workers recruited patients at the Mount Sinai Medical Center Ruttenberg Treatment Center in the study.

Sample

Both the Mount Sinai Hospital and Hunter College Institutional Review Boards approved the following study and participants provided informed consent. Participants were 80 adult male and female English speaking cancer patients undergoing bone marrow aspirations and/or biopsies. Researchers excluded from the analysis data from 2 subjects as they received IV medication (Ativan) prior to undergoing bone marrow procedures (see Consort flow diagram; Fig. 3). All were volunteers serving without pay (which was explained in the consent form) (See Appendix II). Subjects were not paid due to the lack of funding for this research study at the time of data collection. Participants were eligible for this study if they met the following inclusion criteria:

Inclusion Criteria:

1) Outpatient male and female subjects of any race or ethnicity 18 years and older.
2) Patients receiving a bone marrow aspirate and/or biopsy.
3) Ability to give informed consent.
4) Physically able to attend hypnotherapy session and evaluation procedures.

Participants were not recruited to this study if they met the following exclusion criteria:

Exclusion Criteria:

1) Non-English speaking patients (adapted this from the study by Lang et al. (2006) where patients were required to give written informed consent as well as hear and understand

English) The oncology social workers that are trained in hypnosis are not bilingual and therefore, would not be able to translate the script effectively into another language.

2) A psychiatric disorder, medical condition, or other life circumstance, which in the opinion of the investigators, would make it difficult for patient to successfully complete the evaluation procedures.
3) Patients receiving any type of intravenous anxiolytics or analgesics as pre-medications before or during the bone marrow aspirate and biopsy. The exclusion of such patients from the primary analyses follows the practice of similar investigations of the effectiveness of hypnosis for managing the acute pain associated with medical procedures (e.g., Lang, et al., 2006). While pre-medication is not part of standard of care at the Mount Sinai Medical Center, these are sometimes given if requested by patients.

Sample Size

This study sample included males and females, 18 years of age and older, of diverse race and ethnic groups who needed to undergo bone marrow procedures. Researchers performed a sample size calculation to estimate the minimum number of participants needed based on a pre-specified alpha level (α), a given power and overall effect size. An alpha (α) level (the probability of wrongly rejecting the null hypothesis) of 5% is generally the cutoff level for statistical inferences in refereed publications and the power level (i.e. 1- β, with beta (β) being the probability of wrongly failing to reject the null hypothesis) is ordinarily set at 80% (Vogt, 2005). The effect size is a measure of the strength of a phenomenon (Kelley, 2012), and is function of the estimated study parameters. Effect sizes can range from 0 to infinity, but are usually categorized into small (<0.1), medium (0.3) and large (≥0.5) (Cohen, 1992). When comparing means of two independent groups an estimate of Cohen's d (mean difference/sample

standard deviation) is required. If these conventions are adopted, the remaining parameters, effect size and sample size can be estimated. The effect size for pain reduction found by Dorfman et al. (2008) expressed as Cohen's d (Cohen, 1988) was 0.53. A two-sample formula with power set at 80% with alpha set at 5% recommended by Murphy and Myors (2004) and Myors (2006) calls for a sample size = $7.85/r^2$ where $r^2=d^2/4 + d^2$. This calculation yields 119.63, indicating a need for a sample of 120 participants. An interim analysis demonstrated that the overall effect of the intervention would not be large enough to demonstrate a significant difference in pain and anxiety between the study groups. Therefore, it was decided by the study team that recruitment would be stopped at 80 participants. The study team made this decision with regard to the ethical consideration of the patient experience. If the intervention was not producing beneficial results, then the study team felt that it would be best to complete accrual at 80. Although this decision was not beneficial statistically, the patients' treatment experience was paramount.

Figure 3. Consort Flow Diagram

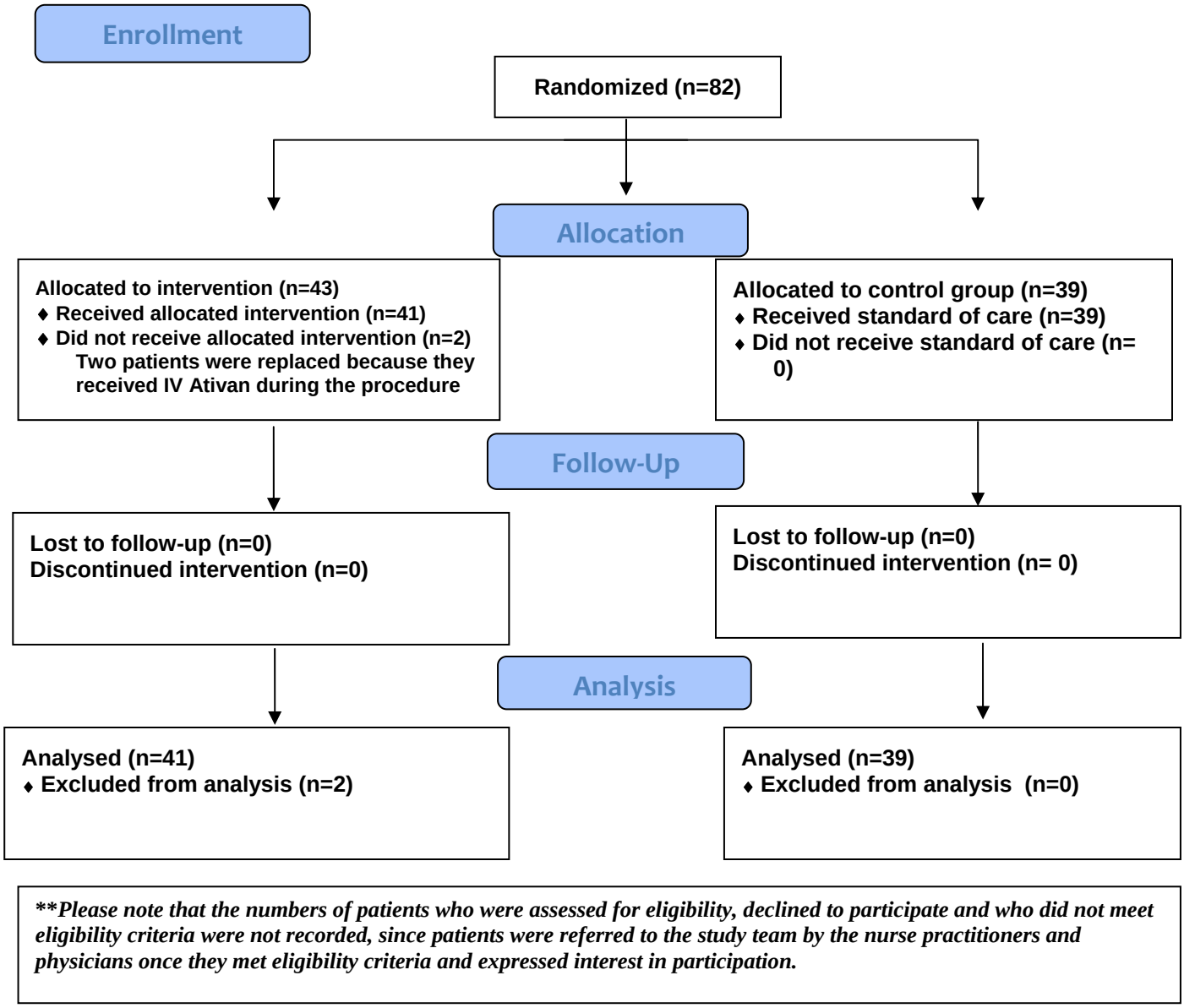


Figure 3. Participant flow chart.

Research Design

Researchers selected a randomized controlled trial (RCT) as the most appropriate method to evaluate whether a social work led hypnotic intervention would improve the management of pain and anxiety associated with a painful procedure, which many patients need to repetitively endure throughout their chronic illnesses. Since RCTs are considered to be the "gold standard" of evidence for practice interventions, researchers selected this method to build upon the evidence base of hypnosis as a psychosocial intervention in the outpatient hospital setting (Solomon, et al., 2009). Critiques of randomized controlled trials with social work populations include that not every patient will receive the intervention, which can be considered unethical when patients are excluded from a known effective treatment (Solomon, et al., 2009). Other critiques of the RCT design among social work researchers include that practitioners may be reluctant to partake in university-based culture of "experimentalist" and "proof-oriented" research if the practitioner feels that patient service may be compromised by this type of design (Blumenfield & Epstein, 2002, p. 2). In this study, however, it was not known whether the intervention would be successful and both groups received standard of care (lidocaine injection). Therefore, the research team did not feel that there was any sacrifice to patient care in the design and implementation of this study.

Pain and anxiety are closely associated with bone marrow aspirates and biopsies. To determine whether hypnosis could ameliorate these morbidities, Researchers randomized a sample of 82 adult cancer patients undergoing bone marrow procedures at Mount Sinai Medical Center to hypnosis plus standard of care (lidocaine injection) or standard of care alone (lidocaine injection). In addition to the 80 patients that participated in the randomized controlled trial, researchers interviewed 5 patients after their participation in the study. The debrief interviews

were one time, semi-structured tape recorded conversations between the principal investigator and 5 patients. Many of the participants enrolled in the study passed away as a result of the severity of hematologic malignancies impeded recruitment for the interviews.

Measures

Social work research staff collected all data by assisting adult patients in completing a series of standardized scales administered using read aloud procedures. All data collection occurred at Mount Sinai Medical Center's Ruttenberg Treatment Center (outpatient cancer center). Data gathering methodologies included self-report measures as well as measurements of physiological parameters (see Table 2). At the time of the consent process, demographic information collected from participants included: age, race, ethnicity, gender, and educational attainment (see Appendices). The researchers collected demographic information in order to define the sample. In the demographic questionnaire, ethnicity is defined as Hispanic vs. Non-Hispanic. Race is categorized by: White, African American, Asian, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, Other, and Multiracial. If patients selected "multiracial" or "other," they were asked to specify with which races they identify. The researcher's categorized ethnicity and race in this way as standard research practice to illustrate that patients can identify as both Hispanic and another race.

Variables

Drawing on a perspective informed by clinical hypnosis theory and prior hypnosis research in medical settings, variables included those identified as salient influences on pain and anxiety, particularly for cancer patients. Please see appendices for study measures. A summary of variables by construct, measurement, and reporter can be found in Table 2.

Table 2. Measures and Reporter

Table 2

Study Measurements and the Primary Reporter

Construct	Instrument	Reporter
Anxiety	Visual Analog Scale	Patient
Pain	Visual Analog Scale	Patient
Chronic Anxiety	State Trait Anxiety Inventory (STAI)	Patient
Demographic Information	Demographic Questionnaire	Patient
Patient Satisfaction	Patient Satisfaction Question	Patient
Physiological Parameters	Blood Pressure & Heart Rate	Patient

Independent Variable

Hypnosis is defined as an interaction between two people, in which the patient responds to suggestions by the interventionist.

The Hypnosis Script (Intervention)

The principal investigator and another oncology social worker on the study team adapted the hypnosis script based on their training in clinical hypnosis as well as from the *Handbook of Hypnotic Suggestions and Metaphors* by Hammond (1990) and Lang et al. (2006). The procedures used were modeled on those used by Dorfman and colleagues (2008) and adapted for use with patients undergoing bone marrow biopsies. It is not dissimilar to the script used by Lang et al. (2006) (see Appendices). The hypnosis script focuses on relaxation as well as on numbing the biopsy site in an effort to decrease pain associated with the procedure. The script begins with an induction (progressive muscle relaxation) and uses a beach scene to create relaxing imagery. For pain management, participants are encouraged to distract themselves, i.e. "in a movie you can become absorbed and distracted so that you do not even notice a headache". There are also suggestions that patients can control the sensations by "dialing down the pain" and "placing their breath in the area that needed it the most." The script also provides

suggestions for "cool, comfortable numbness," and researchers provided imagery suggestions associated with those feelings.

Dependent Variables

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. In order to measure pain, the Visual Analog Scale (VAS) was utilized (Price, McGrath, Rafii & Buckingham, 1983). The VAS was the principal outcome measure used in previous studies evaluating the possible benefits hypnosis in medical procedures (e.g., Lang et al., 2006; Montgomery et al., 2007). This scale consists of a 100 millimeter horizontal line anchored by verbal descriptors at each end of the line. For the pain VAS the anchors were "no pain at the biopsy site" versus "very severe pain at the biopsy site" (see Appendices). This scale took approximately 1 minute to complete. The VAS pain scale has been shown to have high inter-rater reliability in the clinical setting (Gallagher, Bijur & Latimer, 2002). According to Price, McGrath, Rafii and Buckingham (1983) the VAS has been reported as valid and reliable measure for the intensity of pain and the unpleasantness of human pain. The same ruler was used to measure each VAS scale.

Anxiety is defined as a psychological and physiological state characterized by somatic, emotional, cognitive, and behavioral components. The VAS was also utilized to measure anxiety. The VAS anchors for the anxiety scale were "no anxiety" versus "very severe anxiety" (see Appendices). Maxwell (1978) found the VAS scale to be highly reliable when a valid reason is used. The same ruler was used to measure the VAS scores of each participant. The VAS scale takes approximately 1 minute to complete. Additionally, we administered the "Trait" section of the *State Trait Anxiety Inventory (STAI)* (Spielberger, 1981). The purpose of this measure is to assess whether the two groups were equivalent in terms of chronic levels of anxiety. The STAI is

a widely used scale in psychological studies and is very reliable with an alpha coefficient of greater than .90 for the item-remainder correlations (Spielberger, 1981). The STAI is a 20-item measure that is scored on a 4-point Likert scale (1=not at all, 2=somewhat, 3=moderately, 4=very much so) (see Appendices). This scale took approximately 5 minutes to complete.

Patient Satisfaction Rating: We asked each patient to circle a statement that best describes how satisfied they were with the overall treatment, i.e., I am very satisfied, I am pretty unsatisfied. We intended for this question to be used to measure patients' satisfaction with the treatment session (see Appendices). This question took less than 1 minute to complete.

Physiological Parameters: Each patient's blood pressure and heart rate was measured before and after the biopsy by medical assistants. These measurements were utilized to provide a more objective indicator of patients' distress related to the biopsy (see Appendices). This measurement took approximately 2 minutes.

Procedure

Hypnosis Training: Four oncology social workers underwent 40 hours of training and course work in clinical hypnosis in preparation to deliver the hypnotic script to those patients assigned to the hypnosis group. The oncology social workers were all trained from The Center for the Advancement of Clinical Hypnosis (CATCH) in New York City. CATCH instructors are licensed clinical social workers; their curriculum in clinical hypnosis is geared for health practitioners and their courses are all approved by the American Society of Clinical Hypnosis (ASCH). All four social workers took the introductory course in clinical hypnosis (20 hours). The introductory course focused on hypnosis theory, hypnotic phenomena, basic hypnotic techniques, including the use of the Ericksonian approach. Additionally, the four social workers attended the intermediate course in clinical hypnosis at CATCH (20 hours). The intermediate

course focused on clinical applications of hypnosis and on learning advanced theory and techniques. Topics covered included exploratory techniques, use of various types of suggestion and ego state work. The treatment applications covered also included work with anxiety and depression. Two social workers also completed the advanced consultation group at CATCH, which was an additional 20 hours of focused consultation in a small group, in order to advance their knowledge and skills in hypnosis. The focus of the instruction was on practical concerns regarding the application of course material into clinical work.

Patients signed informed consent (see Appendix II) prior to the procedure, or on the same day of the procedure. Although researchers gave consideration to having a placebo control group with empathetic attention, in which patients would have an oncology social worker sit with them during the procedure and provide support, one recent study demonstrated that this is not a beneficial intervention. Lang et al. (2008) reported that having an empathy group (nonspecific support) without providing management of acute pain and anxiety may actually do more harm than good. They found that the patients undergoing tumor embolizations that were randomized to the empathy control group actually experienced more (48%) adverse events than those in the hypnosis (12%) or standard of care group (26%), which prompted them to close the study (Lang et al., 2008).

Intervention (Hypnosis) Procedure: Once a patient entered the examination room for his or her biopsy, the study team completed the following steps:

1) The social worker informed the patient to which group they were randomly assigned (following the completion of consent form)

2) Medical assistants measured physiological parameters

3) The social worker gave the STAI

4) The social worker gave the VAS for anxiety

5) The social worker who completed the pre-procedure scales read the hypnosis script immediately following the injection of lidocaine, and continued until the procedure was over (for hypnosis group only; the script was timed to the procedure and was written to be anywhere from 20-30 minutes)

6)15 minutes after the MD/RN injected lidocaine, the MD began the procedure for all patients enrolled in the study

7) Upon completion of the procedure, the social worker who administered the pre-biopsy scales and read the hypnosis script called another social worker from the study team to administer post-biopsy scales (VAS, patient satisfaction question); this ensured that the social worker administering the scales was blinded to whether or not the patient had received the intervention

8) Upon completion of the biopsy procedure, medical assistants measured physiological parameters again

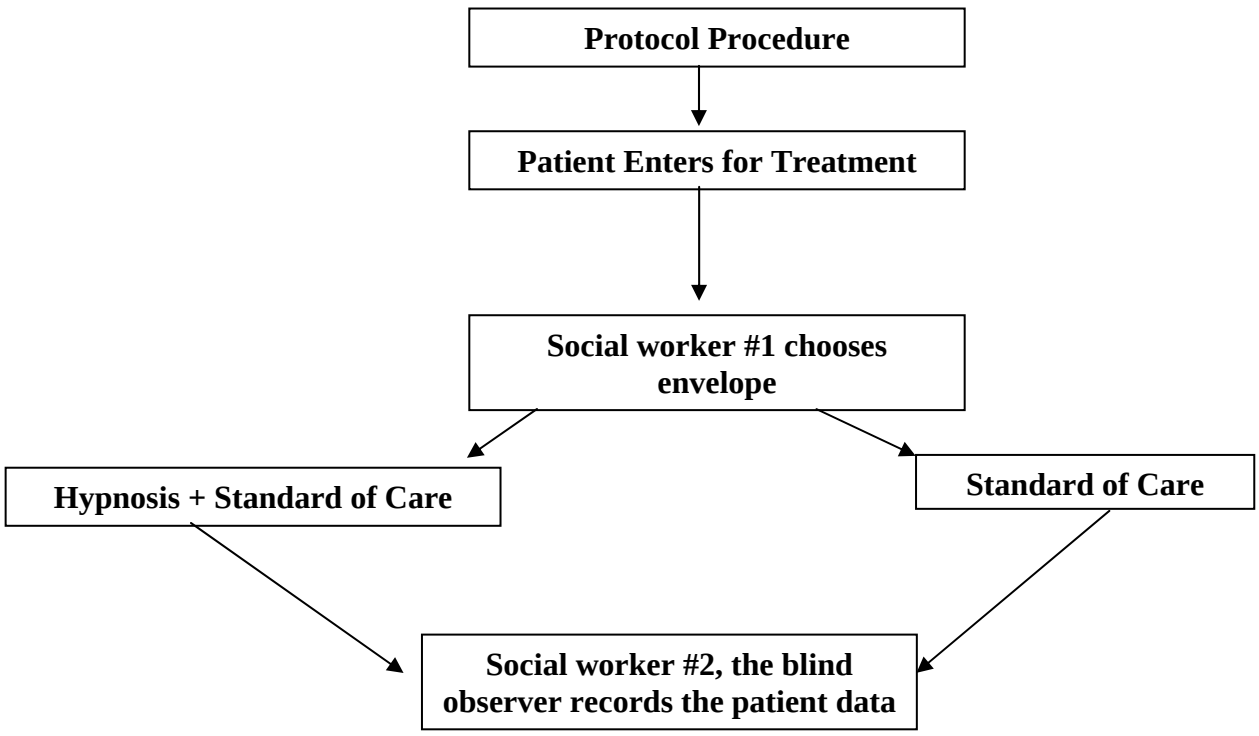
9) The social worker who administered the hypnosis intervention wrote session notes to record what happened during the procedure, i.e. physician had difficulty obtaining sample and needed to go in several times or patient fell asleep and was snoring during procedure.

Standard of Care (Lidocaine Injection) Procedure: Researchers followed steps 1-4 for patients randomized to the standard of care group. For step number 5, if the patient was randomized to the control condition the social worker left the exam room after the measures were gathered (prior to the biopsy). Therefore, no social worker was in the room during the procedure (which is standard for bone marrow biopsy and aspirate procedures). The social worker who obtained the pre-procedure scales waited outside the procedure room to determine when the procedure was

completed, to call another social worker on the study team to collect the post-procedure scales. The researchers followed steps 6-9 as outlined above for the standard of care group as well. The social worker collecting the post procedure scales wrote session notes if the patient reported anything.

It was impossible to blind the physician performing the bone marrow biopsy as to whether the patient is randomized to the intervention, since the social worker read the script during the procedure. The researchers reviewed all study participants' records to determine what medications patients were taking (specifically, if they were taking any pain and/or anxiety medications) (see Appendices). If patients received intravenous pre-medications, these patients would be excluded from the primary analyses and replaced. Social workers took session notes regarding their impressions of the hypnosis session. The social worker who read the hypnosis script took session notes regarding their impressions of the hypnosis session. If anything unusual happened in the standard of care group, the social worker completing the post-procedure measures took session notes (see Appendices). The social worker completing the measures after the procedure also recorded the name of the physician performing the biopsy, the duration of the procedure, which side the procedure was performed on (left or right), as well as the patient's diagnosis (if it was known), whether it was the patient's first bone marrow biopsy, the patient's height and weight, and whether both a biopsy and aspiration were performed (see Appendices). Social workers collected the above information because of their potential to be moderating variables.

Figure 4. Protocol Procedure



Bone Marrow Biopsy Procedure

The site of the bone marrow biopsy was either the right or left posterior iliac crest of the hip bone. Standard of care is 2% lidocaine injected to the skin, subcutaneous tissue and periosteum for local anesthesia followed by a 15 minute interval prior to the start of the procedure (Ruegg, Curran & Lamb, 2009). The physician typically obtains the bone marrow aspirate, or blood first. The physician inserts an aspirate needle through the skin using manual pressure until he reaches the surface of the bone. Subsequently, the physician advances the needle with a twisting motion of the clinician's wrist, through the bony cortex and into the marrow cavity. Once the needle is in the marrow cavity, the physician attaches a syringe to obtain liquid bone marrow. Then, the physician performs the biopsy using a separate, larger

trephine needle. This is anchored in the bony cortex and then advanced with a twisting motion to obtain a small cylindrical solid piece of bone and bone marrow (about 1/16 inch in diameter and ½ inch long) ("Bone Marrow," n.d.). The entire procedure is typically 10-15 minutes in length. The puncture site may also be bruised and tender for a few days after the procedure. All subjects studied received standard of care.

Randomization Procedure

In order to randomize the patients, a statistician prepared 80 packets that included a sealed envelope that was numbered on the outside to correspond to the patient's study number. Researchers generated the randomization order of the envelopes using the website random.org. We selected random.org because it offers a free random number sequence service. The letter on the inside of the envelope indicated the assignment to a C (control group) or an H (hypnosis group). We stored the envelopes in a locked cabinet in Ruttenberg Treatment Center. The social workers alternated providing hypnosis and administering the scales based on their availability.

Debrief Interviews

In addition to the data collected through quantitative measures, the researchers interviewed five adults who received the hypnosis intervention using a semi-structured interview guide created by the research team. Researchers conducted the debrief interviews primarily before or after a medical appointment, and conducted two in the patient's inpatient hospital room. As a result, there was limited time to conduct these interviews. The debrief interview included questions such as, "When you were filling out the pain scale, were you thinking about the pain you were experiencing during the biopsy, or level of pain experiencing after the biopsy?; Since you had hypnosis, can you describe what that experience was like for you?; Did you find that the hypnosis session you had during that biopsy had any benefits beyond that procedure?;

Would you want hypnosis again at a future biopsy?" The goal of the interviews was to try to capture what the subject's experience was like, since the quantitative measurements were not descriptive.

Researchers added the interview guide was added as an addendum to the IRB approved protocol; this addition was approved by the Mount Sinai Hospital IRB as well as the Hunter IRB. The PI tape recorded the interviews and obtained participant consent prior to the start of the interview.

Data Collection, Management and Storage

The researchers obtained approval from Mount Sinai Hospital and Hunter College Institutional Review Board prior to the collection of data (see Appendix II). The four oncology social workers on the study team collected the data. The principal investigator entered the data and an independent reviewer checked the data for accuracy.

A patient identification number identified participants at all times to ensure confidentiality. The researchers assigned participants their patient identification number on the day of their procedure as part of the randomization procedure. We linked their data to their name on a separate piece of paper stored in a locked file cabinet, which only the study team was able to access. Researchers used these coded numbers to complete the computer entry and networking programs. We protected the information contained on the computers by password that was only available to the study team. The linking information will be destroyed at the conclusion of the study. Research data are stored in a locked file cabinet in the social work office of the PI. The linking information will be destroyed at the conclusion of the study. The researchers did not follow patients after they completed their participation in the study, meaning that participation ended after they completed their scales following the aspiration and/or biopsy.

Data Analysis

There are five steps involved in the data analysis plan, which we conducted using the statistical software SPSS version 13.0. First, the researchers examined all study variables descriptively (e.g., means, standard deviations, frequencies, etc.). Second, we assessed for bias among the experimental and control groups. Specifically, the researchers conducted a series of chi-square and *t*-test analyses to determine if the two study groups (hypnosis versus standard of care) differed significantly by all study variables (i.e., demographic, medical, and psychological variables).

Third, the researchers made an examination to determine which demographic and independent variables were significantly related to the study dependent variables (i.e., levels of anxiety (Pretest VAS and biopsy pain) at the bivariate level. Specifically, we conducted a series of chi-square and *t*-test analyses to determine if the dependent variables differed at a statistically significant level as a function of study group (hypnosis versus standard of care), demographic, medical, and psychological variables. We included any factors associated with a dependent variable at a statistically significant level ($p \leq .05$) in the multivariate model examining the respective dependent variable. It is important to note that the researchers measured changes in anxiety levels via a change score that was be computed through subtracting posttest scores from pretest scores on the VAS measure.

Fourth, researchers conducted multivariate tests examining the possible main effects of anxiety and pain (as per the VAS measure) as a function of study group. Specifically, we conducted ordinary least squares (OLS) regression to test the hypothesis that the dependent variables differed significantly by study group.

Lastly, we conducted tests for interaction effects. Specifically, we added an interaction term (study group X gender) to each OLS regression model to assess if the relationship between the study group with anxiety and pain as per the VAS measure was moderated by gender. Additionally, the researchers added an interaction term (study group X race – White/non-White) to each OLS regression model to assess if the relationship between study group with anxiety and pain as per the VAS measure was moderated by racial identity. Furthermore, the researchers added an interaction term (study group X ethnicity – Hispanic/non-Hispanic) to each OLS regression model to assess if the relationship between study group with anxiety and pain as per the VAS measure was moderated by ethnic identity. Lastly, we added an interaction term (study group X age) to each OLS regression model to assess if the relationship between study group with anxiety and pain as per the VAS measure was moderated by age.

Additionally, the researchers transcribed and coded five debrief interviews with study participants, and coded the five session notes for the interviewees. We coded and analyzed the data using grounded theory methods as outlined in Charmaz (2006). Once we assigned codes to the document, we pulled out the statements that matched the code into a separate document, and evaluated to see if the code worked. We organized the codes by categories, codes and subcodes and lastly, we created a code book with the description and examples of each code. As previously stated, the severity of hematologic malignancies limited the amount of patients that were available to participate, since many study participants passed away prior to the IRB addendum to conduct debrief interviews.

Human Subjects

The Institutional Review Boards of Hunter College and Mount Sinai Hospital completed and approved human subject reviews. The consent form for this study outlined matters of

confidentiality, risks and benefits of participation. There are no known risks in the literature to participating in a hypnotherapy procedure. Additionally, the consent form provided study participants with contact information for the principal investigator and a hematologist if they experienced unusual upset associated with participation in the study. The researchers also created a referral resource list with professional mental health providers and agencies to contact for free counseling both at the medical center and in the community in case any problems with participation occurred. The resource list was created to provide to study participants as needed; however, it was not used.

Chapter IV: RESULTS

The research team conducted a randomized controlled trial to evaluate the effectiveness of a brief hypnotic intervention on pain and anxiety during bone marrow procedures. The results of this study will be outlined in this chapter.

Checks for Assumption for Ordinary Least Squares Regression

The research team performed an analysis was performed to examine if the assumption of a normal distribution was violated among continuous explanatory variables. Specifically, we performed an analysis to examine if the values of skewness and/or kurtosis indicated that the distributions of the continuous explanatory variables approximated a normal distribution. Data indicated that skewness and kurtosis values for the explanatory variables Age, Baseline Anxiety, and Trait Anxiety were within in the range of -2.0 to +2.0, which have been identified as being acceptable criteria for assuming that distributions approximate normality (Pallant, 2001). Furthermore, collinearity statistics performed for the OLS regression model examining post pain scores indicated that issues related to multicollinearity would not be a concern (Menard, 1995).

Sample Characteristics

The sample was 51.3% (*n*=41) Male and 48.8% (*n*=39) Female. Ten percent (*n*=8) of the sample was Hispanic, while the remainder was non-Hispanic (90.0%; *n*=72). Almost three quarters of the sample was White (73.8%; *n*=59), while 17.5% (*n*=14) were of a Black, 6.3% (*n*=5) was of an Asian, and 2.5% (*n*=2) was of an "other" racial identity. Regarding highest level of education, 24.1% (*n*=19) reached middle school/high school, 35.4% (*n*=28) graduated college, and 40.5% (*n*=32) earned a post baccalaureate degree. The average study participant was 59.7 (*SD*=13.7) years old (range = 23-84). (See Table 3 for demographic characteristics of study population).

Table 3. Demographic Characteristics of Study Population (n=80)

Table 3

Demographic Characteristics of Study Population (n=80)

Characteristic	Hypnosis (*n* = 41)	Standard of Care (*n* = 39)
Ethnic Composition		
Non-Hispanic White	21(51%)	30 (77%)
Hispanic	5(12%)	3 (8%)
African American	8(20%)	6(15%)
Asian	5(12%)	0
Other	2(5%)	0
Sex		
Female/Male	20/21	18/21
Highest Level of Education		
Secondary School	14(34%)	5(13%)
College	10(24%)	18(46%)
Post Baccalaureate	16(39%)	16(41%)
Unknown	1(2%)	0
Diagnosis		
Leukemia	5(12%)	9(23%)
Lymphoma	10(24%)	2(5%)
Plasma Cell Dyscrasis	6(15%)	5(13%)
Myelodysplastic Syndrome	7(17%)	10(26%)
Myeloproliferative Disorder	9(22%)	9(23%)
Aplastic Anemia	2(5%)	0
Multiple or other disorders	2(5%)	4(10%)
Analgesic or Anxiolytic Medications		
Analgesics	7(17%)	8(21%)
Anxiolytics	4(10%)	3(8%)
None	29(71%)	27(69%)
Unknown	1(2%)	1(2%)
Other Characteristics	Mean(SD)	Mean(SD)
Age in Years	58 (±14)	61(±14)
Body Mass Index	25(±5)	27(±7)
Trait Anxiety Score	38(±11)	34(±10)
Baseline Anxiety Level	48(±28)	36(±27)

Study Variables

About half of the sample was in the experimental group (51.3%; *n*=41), while 48.8% (*n*=39) were in the control group. Mean score values for Post Pain scores were 31.15 (*SD*=23.69) with a minimum and maximum score of 0-98. The mean score on the Trait Anxiety Score was 35.66 (*SD*=10.70; range=3-73). Mean score for anxiety levels at pretest was 42.05 (*SD*=28.12; MIN/MAX=1-98), while mean scores at posttest was 24.16 (*SD*= 27.44; MIN/MAX=1-100). The mean score for pretest to posttest changes was -17.89 (*SD*=29.32; MIN/MAX=-97.00-51.00).

Examination of Bias by Study Group

The researchers conducted an analysis to assess if the two study conditions differed at a statistically significant level by study variables. Data indicated that the two groups do not differ significantly ethnicity, χ^2 (4)= .45, *p*=.50, gender, χ^2 (1) = .21, *p*=.65, highest level of education, χ^2 (4)= 6.87, *p*=.14. Furthermore, the two groups did not differ significantly by age, *t*(78) = .92, *p*=.36, trait anxiety scores, *t*(78) = 1.78, *p*=.08, post pain scores, *t*(78) = .92, *p*=.36, or baseline levels of anxiety, *t*(78) = 1.84, *p*=.07. Analysis did reveal that the two groups differed by race (White vs. Non-White) at a statistically significant level, χ^2 (1)= 4.64, *p*<.05. Specifically, there was a higher percentage of Non-White in the experimental condition (63.4% White vs. 36.6% Non-White), relative to the control condition (84.6% White vs. 15.4% Non-White).

Hypothesis 1

The intervention group will evidence a statistically significant lower mean score reflecting bone marrow biopsy pain relative to patients receiving standard care.

Bivariate Analysis

Table 4 presents a bivariate analysis between categorical explanatory variables by post pain scores. Data indicated that post pain scores were not significantly associated with gender, *t*(78)=-

1.95, p=.06, ethnicity, $t(78)$=-.39, p=.69, race, $F(2,77)$=1.28, p=.28, highest level of education, $F(2,76)$=.70, p=.50, or Study Group, $t(78)$=.92, p=.36. Table 5 presents intercorrelations between post pain scores and explanatory variables. Data indicated that post pain scores were not significantly correlated with age, $r(78)$=-.18, p=.12, but were significantly correlated with trait anxiety score, $r(78)$=.26, $p<.05$, and anxiety levels at pretest, $r(78)$=.31, $p<.01$.

Table 4. Categorical Explanatory Variables by Post Pain Scores

Table 4

Categorical Explanatory Variables (*n*=80)

	n	M (SD)	t(df)	p
Sex			-1.95 (78)	.06
Male	41	26.20 (22.00)		
Female	39	36.36 (24.56)		
Ethnicity			-.39 (78)	.69
Hispanic	8	28.00 (24.21)		
Non-Hispanic	72	31.50 (23.78)		
Race			1.28 (2, 77)	.28
White	59	28.68 (21.93)		
African American	14	36.93 (29.15)		
Asian/Other	7	40.43 (25.75)		
Highest Level of Education			.70 (2, 76)	.50
Middle School	19	26.84 (22.00)		
High School				
College	28	30.64 (26.92)		
Post Baccalaureate	32	34.84 (21.84)		
Study Group			.92 (78)	.36
Hypnosis	41	28.78 (22.88)		
Standard of Care	39	33.64 (24.57)		

Table 5. Intercorrelations Between Post Pain Scores and Explanatory Variables

Table 5

Intercorrelations Between Post Pain Scores and Explanatory Variables (n=80)

Variable	Pain	Age	Trait Anxiety	Pretest Anxiety
1. Pain	--	-.18	.26*	.31**
2. Age in Years		--	.09	-.19
3. Trait Anxiety Score			--	.37**
4. Anxiety Level Pretest				--

Note.* p < .05, **p < .01.

Multivariate Analysis

Table 6 presents an ordinary least squares regression model explaining post pain. Data indicated that the overall model was statistically significant, $F(79) = 3.13$, $p < .01$. Furthermore, the model explained 23% ($R^2 = .23$) of the variance in post pain. Analysis indicated that post pain scores were not significantly associated with age, B=-.11, β=-.06, p=.62, race, B=7.63, β=.21, p=.12, ethnicity, B=5.34, β=.07, p=.55, gender, B=4.73, β=.10, p=.36, or trait anxiety score, B=.42, β=.19, p=.11. Data also indicated that post pain scores were related to pretest anxiety levels, B=.23, β=.28, p<.05, and study condition, B=-12.49, β=-.27, p<.05, at a statistically significant level.

Table 6. Ordinary Least Squares Regression Explaining Post Pain

Table 6

Ordinary Least Squares Regression Explaining Post Pain (N=80)

Variable	*B*	SE B	β	*p*
Age	-.11	.22	-.06	.62
Race	7.63	4.85	.21	.12
Ethnicity	5.34	8.81	.07	.55
Gender	4.73	5.13	.10	.36
Trait Anxiety Score	.42	.26	.19	.11
Anxiety Before	.23	.10	.28	.03
Study Condition	-12.49	5.33	-.27	.02

Note. Model. R^2 = .23, Adj. R^2= .16, df = 79, F = 3.13, p < .01.

Hypothesis 2

The intervention group will evidence a statistically significant lower mean score reflecting post biopsy anxiety levels relative to patients receiving standard care;

Bivariate Analysis

Table 7 presents a bivariate analysis of categorical explanatory variables by anxiety change scores. Data indicate that pretest to posttest anxiety change scores were not significantly associated with gender, $t(78)$=-.09, p=.93, ethnicity, $t(78)$=-.09, p=.93, Race, $F(2, 77)$= 1.05, p=.36, Highest Level of Education, $F(2, 76)$=.52, p=.60, or Study Group, $t(78)$= -1.06, p=.29. Table 8 presents intercorrelations between anxiety change scores and explanatory variables. Data indicated that change scores were not significantly associated with age, r(78)=.10, p=.37, or trait anxiety scores, r(78)=-.09, p=.43.

Table 7. Categorical Explanatory Variables by Anxiety Change Scores

Table 7

Categorical Explanatory Variables by Anxiety Change Scores (n=80)

	n	M (SD)	t(df)	p
Sex			-.09 (78)	.93
Male	41	-18.17 (27.42)		
Female	39	-17.59 (31.56)		
Ethnicity			-.09 (78)	.93
Hispanic	8	-18.75 (25.33)		
Non-Hispanic	72	-17.79 (29.89)		
Race			1.05 (2, 77)	.36
White	59	-20.39 (28.28)		
African American	14	-7.79 (36.23)		
Asian/Other	7	-17.00 (21.15)		
Highest Level of Education			.52 (2, 76)	.60
Middle School	19	-21.42 (35.45)		
High School				
College	28	-13.32 (29.87)		
Post Baccalaureate	32	-19.59 (25.56)		
Study Group			-1.06 (78)	.29
Hypnosis	41	-21.27 (31.29)		
Standard of Care	39	-14.33 (14.33)		

Table 8. Intercorrelations Between Anxiety Change Scores and Explanatory Variables

Table 8

Intercorrelations Between Anxiety Change Scores and Explanatory Variables (n=80)

Variable	1	2	3
1. Pain	--	.10	-.09
2. Age in Years		--	.09
3. Trait Anxiety Score			--

Multivaraite Analysis

Table 9 presents an ordinary least squares regression model explaining pretest to posttest change scores reflecting levels of anxiety. Data indicated that the overall model was not statistically significant, $F(79) = 1.21$, $p = .31$.

Table 9. Ordinary Least Squares Regression Explaining Pretest to Posttest Change Scores Reflecting Levels of Anxiety (N=80)

Table 9

Ordinary Least Squares Regression Explaining Pretest to Posttest Change Scores Reflecting Levels of Anxiety (N=80)

Variable	*B*	SE B	β	*p*
Age	.50	.29	.24	.08
Race	13.18	6.44	.29	.04
Ethnicity	-8.62	11.64	-.09	.46
Gender	1.60	6.64	.03	.81
Study Condition	-11.03	6.93	-.19	.12

Note. Model. $R^2 = .08$, Adj. $R^2 = .01$, df = 79, $F = 1.21$, $p = .31$.

Hypothesis 3

The relationship between study group and mean scores reflecting bone marrow biopsy pain and anxiety will be moderated by patient gender, ethnicity, and age.

The Moderating Effect of Patient Gender, Ethnicity, and Age on the Relationship Between Study Group and Post Pain Scores

Table 10 presents a model examining the moderating effect of age on the relationship between study condition and post pain scores. Data indicated that that the model was statistically significant, $F(79)=2.83$, $p<.01$. However, the interaction term examining study condition by age was not statistically significant, $B=-.36$, $\beta=-.47$, $p=.38$. Table 11 presents the moderating effect of gender on the relationship between study condition and post pain scores. Data indicated that the model was statistically significant, $F(79)= 2.72$, $p < .01$. However, the interaction term examining study condition by gender was not statistically significant, $B=-3.91$, $\beta=-.11$, $p=.76$.

Table 12 presents the moderating effect of ethnicity on the relationship between study condition and post pain scores. Data indicated that the model was statistically significant, $F(79)=4.14$, $p < .001$. Data also indicated that the interaction term examining study condition by ethnicity was statistically significant, $B=-49.88$, $\beta=-2.05$, $p<.01$. Table 13 presents the mean and standard deviation values for post pain scores by ethnicity within each study condition. The mean values for the Hispanic group in the intervention condition ($n=5$) was 38.00 (SD=26.20), while the mean value in the Hispanic group in the control condition ($n=3$) was 11.33 (SD=3.51). The mean value for the non-Hispanic group in the intervention condition ($n=36$) was 27.50 (SD=22.49), while the mean value in the non-Hispanic group in the control condition ($n=36$) was 35.50 (SD=24.66).

Table 10. The Moderating Effect of Age on the Relationship between Study Condition and Post Pain Scores (N=80)

Table 10

The Moderating Effect of Age on the Relationship between Study Condition and Post Pain Scores (N=80)

Variable	*B*	SE B	β	*p*
Age	.07	.30	.04	.23
Race	6.52	5.02	.18	.20
Ethnicity	4.83	8.84	.06	.59
Gender	5.34	5.18	.11	.31
Trait Anxiety Score	.41	.26	.18	.12
Anxiety Before	.26	.11	.31	.02
Study Condition	8.91	24.90	.19	.72
Study Condition by Age	-.36	.41	-.47	.38

Note. Model. $R^2 = .24$, Adj. $R^2 = .16$, df = 79, $F = 2.83$, $p < .01$.

Table 11. The Moderating Effect of Gender on the Relationship between Study Condition and Post Pain Scores

Table 11

The Moderating Effect of Gender on the Relationship between Study Condition and Post Pain Scores (N=80)

Variable	*B*	SE B	β	*p*
Age	-.09	.23	-.06	.68
Race	7.69	4.89	.21	.12
Ethnicity	4.88	8.99	.06	.59
Gender	6.33	6.37	.13	.39
Trait Anxiety Score	.42	.26	.19	.11
Anxiety Before	.23	.10	.28	.03
Study Condition	-7.92	15.94	-.17	.62
Study Condition by Gender	-3.91	10.16	-.11	.76

Note. Model. $R^2 = .23$, Adj. $R^2 = .15$, df = 79, $F = 2.72$, $p < .01$.

Table 12. The Moderating Effect of Ethnicity on the Relationship between Study Condition and Post Pain Scores

Table 12

The Moderating Effect of Ethnicity on the Relationship between Study Condition and Post Pain Scores (N=80)

Variable	B	SE B	β	*p*
Age	-.26	.21	-.15	.24
Race	7.60	4.61	.21	.10
Ethnicity	36.89	13.52	.47	.008
Gender	1.53	4.99	.03	.76
Trait Anxiety Score	.47	.24	.21	.06
Anxiety Before	.26	.10	.31	.009
Study Condition	81.82	32.16	1.74	.01
Study Condition by Ethnicity	-49.88	16.79	-2.05	.004*

Note. Model. $R^2 = .32$, Adj. $R^2 = .24$, df = 79, $F = 4.14$, $p < .001$.

Table 13. Mean and Standard Deviation Values for Post Pain Scores of by Ethnicity Within Each Study Condition (N=80)

Table 13

Mean and Standard Deviation Values for Post Pain Scores of by Ethnicity Within Each Study Condition (N=80)

		Intervention	Control
Domain	n	M (SD)	M (SD)
Ethnicity			
Hispanic	8	38.00 (26.20)	11.33 (3.51)
		n=5	*n*=3
Non-Hispanic	72	27.50 (22.49)	35.50 (24.66)
		n=36	*n*=36

The Moderating Effect of Patient Gender, Ethnicity, and Age on the Relationship Between Study Group and Anxiety Change Scores

Table 14 presents the moderating effect of age on the relationship between study group and pretest to posttest change scores reflecting levels of anxiety. Data indicated that the model was not statistically significant, $F(79)=2.14$, $p=.06$. Table 15 presents the moderating effect of gender on the relationship between study group and pretest to posttest change scores reflecting levels of anxiety. Data indicated that the model was not statistically significant, $F(79)=1.00$, $p=.43$. Table 16 presents the moderating effect of ethnicity on the relationship between study group and pretest to posttest change scores reflecting levels of anxiety. Data indicated that the model was not statistically significant, $F(79)=1.02$, $p=.42$.

Table 14. The Moderating Effect of Age on the Relationship between Study Group and Pretest to Posttest Change Scores Reflecting Levels of Anxiety

Table 14

The Moderating Effect of Age on the Relationship between Study Group and Pretest to Posttest Change Scores Reflecting Levels of Anxiety (N=80)

Variable	*B*	SE B	β	*P*
Age	1.10	.36	.51	.003
Race	8.61	6.48	.19	.19
Ethnicity	-11.72	11.31	-.12	.30
Gender	4.71	6.53	.08	.47
Study Condition	65.78	31.24	1.13	.04
Study Condition by Age	-1.26	.50	-1.33	.014

Note. Model. $R^2 = .15$, Adj. $R^2 = .08$, df = 79, $F = 2.14$, $p = .06$

Table 15. The Moderating Effect of Gender on the Relationship between Study Group and Pretest to Posttest Change Scores Reflecting Levels of Anxiety

Table 15

The Moderating Effect of Gender on the Relationship between Study Group and Pretest to Posttest Change Scores Reflecting Levels of Anxiety (N=80)

Variable	*B*	SE B	β	*p*
Age	.50	.29	.23	.10
Race	13.15	6.49	.29	.05
Ethnicity	-8.33	11.91	-.09	.49
Gender	.64	9.77	.01	.95
Study Condition	-13.75	21.34	-.24	.52
Study Condition by Gender	1.84	13.59	.05	.89

Note. R^2 = .08, Adj. R^2= .00, df = 79, F = 1.00, p =.43.

Table 16. The Moderating Effect of Ethnicity on the Relationship between Study Group and Pretest to Posttest Change Scores Reflecting Levels of Anxiety

Table 16

The Moderating Effect of Ethnicity on the Relationship between Study Group and Pretest to Posttest Change Scores Reflecting Levels of Anxiety (N=80)

Variable	*B*	SE B	β	*p*
Age	.53	.30	.25	.08
Race	13.22	6.48	.29	.05
Ethnicity	-14.20	18.85	-.15	.45
Gender	2.08	6.80	.04	.76
Study Condition	-27.96	45.41	-.48	.54
Study Condition by Ethnicity	8.90	23.59	.30	.71

Note. Model. R^2 = .08, Adj. R^2= -.00, df = 79, F = 1.02, p =.42.

Figure 5. Distribution of VAS Anxiety Score by Study Time Point for Hypnosis (Intervention) and Standard of Care (Control).

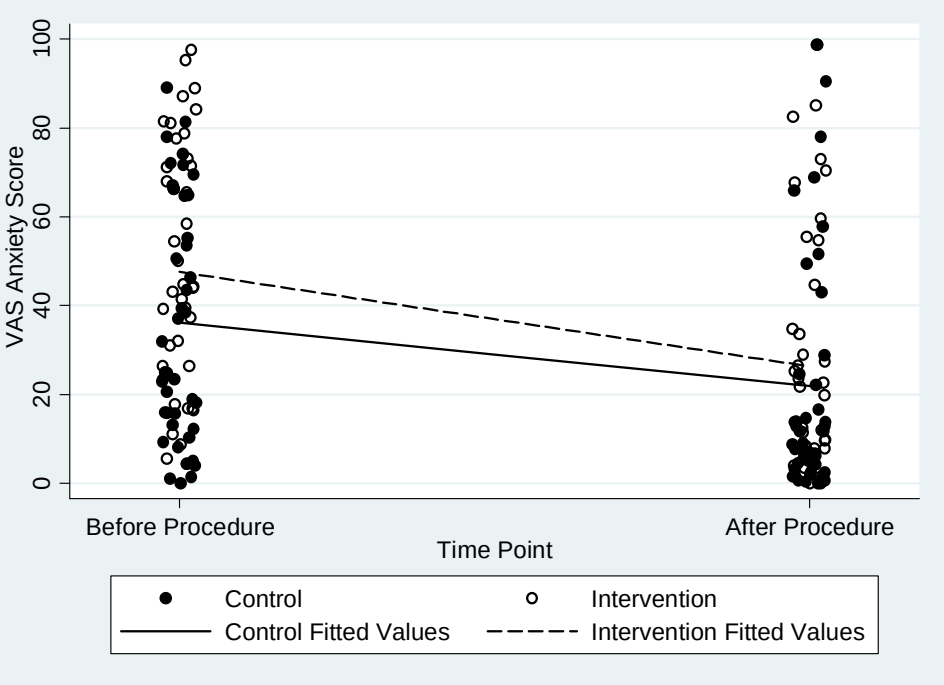
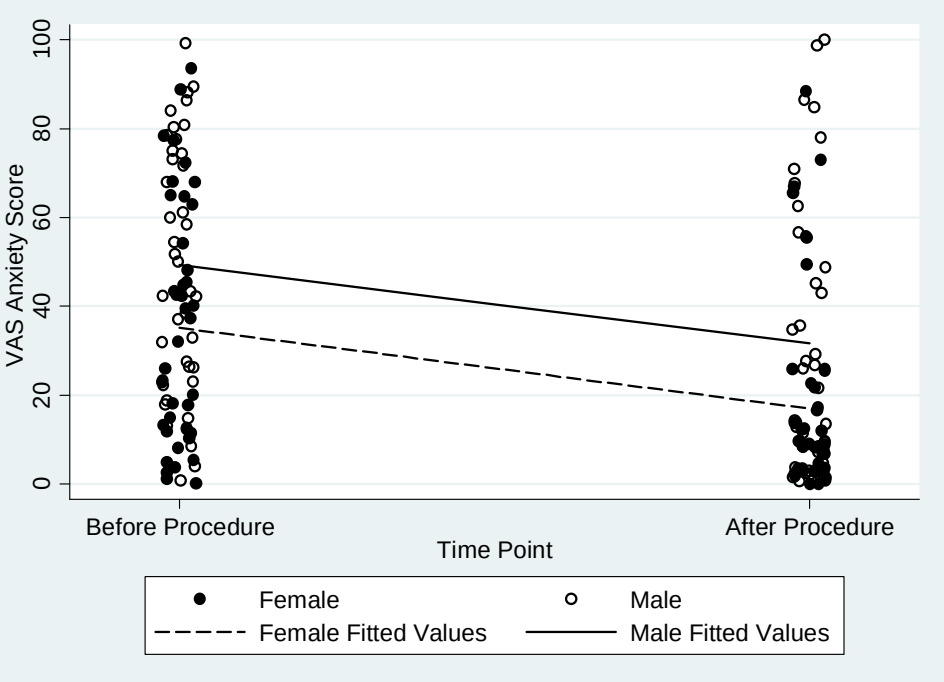


Figure 6. Distribution of VAS Anxiety Score by Study Time Point by Participant Sex



Debrief Interviews

The quantitative measures employed in this study were limited in capturing and understanding the participants' experience with hypnosis. Therefore, several debriefing interviews were conducted in order to obtain a more complete picture of the patient's experience and to develop a better understanding of their perspective on the usefulness of a hypnotic intervention with this particular procedure.

The debrief interview sample included two females, one African American and one Caucasian; and three males, two Caucasian and one African American. They each had different diagnoses, ranging from Myelodysplastic Syndrome, which requires outpatient medication to Acute Lymphoblastic Leukemia, which frequently requires a rigorous bone marrow transplant. The median age of the participants was 63.

The semi-structured questions produced brief responses from the five participants. The debrief interviews revealed that patients considered hypnosis to be a helpful intervention during bone marrow biopsies. One pattern that emerged through examination of the code "helpful," was that participants expressed benefits from their participation in this study.

> …it was very successful the first time absolutely. I was looking forward to it the second time…laughs…I wasn't looking forward to it, but I was thinking that it would be helpful. I was just kind of amazed by how different the experience was. - *Marjorie*
> …just listening to your words was very calming so it helped a lot. It was good.- *Loretta*
> I think it was a very good experience, calming relaxing, taking my mind off of the procedure. -*Michael*
> I found it useful… I remember going to meditation class on Thursdays and reporting to my class what a positive experience it was...- *Paul*

Several patients discussed the presence of someone being useful as a distraction; however, two patients reported that having a relationship with the hypnotherapist made a difference to their experience of hypnosis. The code "relationship" is defined as the interaction

and association between the participant and the hypnotherapist. Examples of the code "relationship" are:

> The first time I found it to be very successful and soothing and the second time (hypnosis off study) not as much. These were both outpatient. It was someone that I did not know, it was two different people. I felt comfortable the first time because I knew the social worker and trusted her and the second time I didn't feel as comfortable with a complete stranger. That's the thing that is going to be tricky, if someone doesn't know the hypnotist but still there are certain people that engender that.-*Marjorie*
> …if I had to have anything major on my bone or amputation or something cut off and I had to be awake, yes you better be there! -*Loretta*

These statements demonstrate that patients felt a connection to the hypnotherapist and suggest the importance of the relationship between the hypnotherapist and the patient. Marjorie was more descriptive, since she had the hypnotic intervention twice with two different hypnotherapists. She described that the intervention was more successful when she had trust and confidence in the therapist. This finding is consistent with the literature. For example, Hammond (1990) discussed the necessity of the patient having confidence in the therapist in order to have a hypnotic experience. Furthermore, Snow and Warbet (2010) discussed how the therapeutic alliance established between the social worker and patients assisted with the patients' willingness to experience hypnosis.

Participants explained their experience with hypnosis in a variety of ways, but the information that they provided only gave a glimpse into what their experiences were like and how the intervention might have been successful.

> you made me relax, you kept talking to me you distracted me whereas I would have been thinking about what the doctor was doing behind me they gave me a local pain killer a local whatever but you were talking to me and you were talking and you kept me distracted talking. Talking about going places…I'm like where am I going I'm like okay just listening to your words was very calming so it helped a lot. It was good -*Loretta*
> I think it was a very good experience, calming relaxing, taking my mind off of the procedure –*Michael*
> It was very pleasant. I was able to get into it. The experience I remember you were talking about a beautiful beach in a tropical island and I remember really feeling

> transposed into the feeling and uh I attributed that to…I meditate also and I thought that having practiced meditation for a number of years since my illness began…um, I found it useful that that was helpful. I remember going to meditation class on Thursdays and reporting to my class what a positive experience it was because I was hypnotized very easily. -*Paul*

Although the participants reported beneficial experiences with hypnosis, they did not experience lasting benefits from the intervention. Participants answered this in a one word response. Marjorie was an exception who stated, "Um, I guess that's a big benefit that I have been able to get through (biopsies) better."

Comparing the session notes demonstrated that there was a match between the participants' description of their experience and the hypnotherapists' description. One example was Loretta who reported that she found the session very helpful, which matched the hypnotherapist's session notes:

> Patient stated that she found the hypnosis helpful and that she was able to imagine herself in a special place. Patient was grateful to have social worker's voice with her during this long procedure. –*Rachel* (hypnotherapist/oncology social worker)
> You made me relax, you kept talking to me you distracted me whereas I would have been thinking about what the doctor was doing behind me they gave me a local pain killer a local whatever but you were talking to me and you were talking and you kept me distracted talking…-*Loretta*

These data offer greater opportunity to discover the complex and subtle dynamics of how the process of hypnosis may influence a biopsy experience. However, the small number of interviewees limits the generalizability of this data.

Chapter V: DISCUSSION

Adult patients undergoing bone marrow procedures are a unique group of patients that may benefit from hypnosis during a bone marrow biopsy and aspiration. This study sought to evaluate whether pain and anxiety would be reduced by a hypnosis intervention led by an oncology social worker during the bone marrow procedure. Previous studies examined hypnotic interventions with children and adolescents undergoing this procedure and found that pain and anxiety were reduced (Katz, et al., 1987; Kuttner, et al., 1988; Liossi & Hatira, 1999; Wall & Womack, 1989; Zeltzer & Lebaron, 1982). Based on the previous studies we expected that patients in the experimental (hypnosis) group would have decreased pain and anxiety. The major finding of this study was a reduction in pain in the hypnosis group; however, we did not find a significant reduction in anxiety. Despite the non-significant reduction in anxiety, this study adds to the literature in that hypnosis can provide physical comfort to individuals with cancer. Moreover, this study makes a significant contribution to the literature, since it is the first study to use a hypnosis intervention targeted to adults undergoing bone marrow procedures. The study builds on previous research conducted with children and adolescents undergoing the same procedure. According to a recent review article on hypnosis with cancer patients, Montgomery et al. (2012) found that the majority of research done with hypnosis and cancer patients, has been done with breast cancer patients and many published studies used case studies and non-randomized samples. The present study utilized a randomized controlled trial design with hematologic malignancy patients.

Hypothesis 1

The intervention group will evidence a statistically significant lower mean score reflecting bone marrow biopsy pain relative to patients receiving standard care. The results of this study support

hypothesis number one, since pain scores were significantly lower among the experimental (hypnosis) group. The patients who received hypnosis reported lower levels of pain on the visual analog scale. Thus, the study hypothesis that the hypnosis group will have lower pain scores compared to patients receiving standard of care was supported by the data. This finding supports other recent evidence that hypnosis is effective for pain reduction (Montgomery, et al., 2007; Lang, et al., 2006).

Unlike the previous studies demonstrating a reduction in pain with a hypnosis intervention, this study involved social workers performing the intervention. Therefore, this study lends support to social workers expanding their professional role by attending to the physical suffering that often accompanies a cancer diagnosis and treatment. Furthermore, the reduction in pain as a result of the social work clinical intervention demonstrates that social workers can achieve similar results as the psychologists and physicians who performed the hypnosis intervention in previous studies (Montgomery, et al., 2007; Lang, et al., 2006). Anbar and Hummell (2005) similarly found that the rate of improvement from the hypnosis intervention performed by the social worker was similar to that achieved by the physician (pulmonologist) using hypnosis.

Hypothesis 2

The intervention group will evidence a statistically significant lower mean score reflecting post biopsy anxiety levels relative to patients receiving standard care. Data did not support the second hypothesis. This finding is not consistent with previous studies on hypnosis with children and adolescents undergoing bone marrow procedures (Katz, et al., 1987; Kuttner, et al., 1988; Liossi & Hatira, 1999; Wall & Womack, 1989; Zeltzer & Lebaron, 1982) or adult cancer patients undergoing medical procedures (Lang, et al., 2006; Lang, et al., 2008). While this

finding was surprising, it could be related to several factors. One factor that might have impacted this finding was the use of the visual analog scale as the only measurement of post procedure anxiety. Since the visual analog scale is a one-dimensional measure, Wewers & Lowe (1990) recommended that it not be used as a single measure of a multidimensional construct, such as anxiety. Additionally, anxiety might have decreased from the baseline visual analog measure to the post visual analog measure, resulting in a beneficial experience for the patients, however the difference might not have been large enough to capture a statistically significant decrease in anxiety in the hypnosis group. Data indicated that post pain scores were significantly correlated with trait anxiety scores and anxiety levels at the pretest, therefore, future research may reveal that reducing anxiety would reduce pain even more.

Lastly, the patients who participated in the debriefing interviews reported that they considered hypnosis to be a helpful intervention during bone marrow procedures, providing examples of how they were relaxed during the hypnosis session. Although there were only five interviews, the participant feedback yielded a deeper understanding of their experiences with the intervention compared to the one-dimensional measure of anxiety.

Hypothesis 3

The relationship between study group and mean scores reflecting bone marrow biopsy pain and anxiety will be moderated by patient gender, ethnicity, and age. Data did not support the third hypothesis. Pain and anxiety were not significantly associated to demographic variables, such as, gender, ethnicity and age. It is likely that these findings were related to low levels of statistical power due to a relatively small sample size. Moreover, as previously discussed in the literature review, several studies did not find demographic differences among pediatric subjects (Fowler-Kerry & Lander, 1991; Jay et al., 1983; Katz, et al., 1987; Koopman, et al., 1984). Although this

is a non-significant finding, the impact of gender, ethnicity, and age differences is multifaceted, and should continue to be considered as factors that might significantly impact the clinical pain experience (Brittain, 2004; Unruh, 1996). Future research should examine these variables, as they are important to help determine who would benefit from a hypnosis intervention.

Implications for Practice and Policy

Based on the results of the present study, several practice implications can be made for the role of the oncology social worker. This study demonstrates that social workers can provide a clinical intervention which adequately reduces pain associated with bone marrow procedures. This is an important finding, especially because Windsor (1993) found that clinical hypnosis has been largely overlooked by social workers. Additionally, social workers who work in medical settings are not limited to performing assessments and addressing the concrete needs of patients; they can also perform practice-based research to evaluate clinical interventions.

The social work role in conducting the intervention in this study allowed the physicians to view the role of the social worker in a broader context. This is essential because the interdisciplinary team often misunderstands the therapeutic functions of social work (Donnelly, 2009). As a result of their participation in this study, the physicians learned that social workers could be called upon to deliver an intervention to treat pain in cancer patients, in addition to their traditional role of discharge planners providing concrete services. Moreover, the physicians who participated in this study regularly requested that the oncology social workers who participated in this study utilize hypnosis for patients undergoing bone marrow procedures in both the inpatient and outpatient hospital setting. This reflects a shift in the referrals and type of work oncology social workers were performing. Therefore, social workers would benefit from

educational opportunities to learn hypnosis in order to be able to use it as an intervention in their clinical practice.

Findings from the current study may also serve to expand the growing body of knowledge in the area of hypnosis and cancer patients and can improve the quality of medical care rendered. The study draws attention to the need to enhance patient care for adult cancer patients, and the results of this study may guide other institutions to adopt similar interventions that address pain and anxiety patients during bone marrow procedures.

Study Limitations

The current dissertation has several limitations. First, the sample size is relatively small and the analyses had a low degree of statistical power. The initial power analysis suggested that 120 subjects were needed to find significant effects from this intervention; however, at a mid-term analysis the intervention group was not showing decreased pain or anxiety and the decision was made to complete subject recruitment at 80. As previously stated, the study team made this decision with regard to the ethical consideration of the patient experience. If the intervention was not producing beneficial results, then the study team felt that it would be best to complete accrual at 80. Although this decision was not beneficial statistically, the patients' treatment experience was paramount. Due to the small sample size, variables that may have been significant influences on pain and anxiety may have been passed over because a low degree of statistical power in the current study precluded their reaching statistical significance. Future research could benefit from a larger and more representative sample from the target population to increase statistical power and generalizability.

Another limitation of this study was that the participants had different doses of the hypnosis intervention due to the variability in physician practice, clinical setting and patient

conditions. For example, patients with strong bones can make obtaining a sample harder for a physician and therefore, the procedure time is impacted. There was also variability introduced by the numerous hematologists who performed the procedure. This variability could have an impact on the study results since some physicians have an easy time doing the biopsy and aspiration and others find it more difficult. For example, one hematologist had a difficult time with the procedure and therefore, it often took her over 30 minutes to obtain the sample. Additionally, there was variability introduced by the four different oncology social workers performing the intervention. We controlled for this confounder by obtaining the same hypnosis training and using a standardized script to guide the intervention. Furthermore, since we did not have a control condition we cannot rule out that the positive finding for reduction in pain was the result of a placebo effect.

Due to the fact that the physicians and nurses assisted with recruitment we could not keep track of the excluded patients. This is important information that we did not have access to, and represents a major limitation in the study.

Hypnosis is experiential and therefore difficult to quantify and measure; as a result, a qualitative component to this type of research is important. An additional challenge with the debriefing interviews was that several interviews took place many months after the biopsy with hypnosis. The time delay in conducting the interviews could impact the participant's ability to recall their experience with the hypnosis intervention. Moreover, as a result of the time delay in interviews, two of the subjects who were interviewed had hypnosis again (off study, by their request) during subsequent biopsies. The fact that the two subjects had hypnosis again reflects that the intervention was successful, since they requested it again; however, it likely influenced their responses to the questions about their experience of hypnosis. Since these respondents

(Marjorie and Michael) had experienced hypnosis more than once, their experience was different than the other three interviewees. Another challenge was finding subjects to interview; since so many patients had passed away, it was difficult to obtain interviews from subjects who had participated, limiting the number of interviews conducted.

Lastly, the principal investigator in this study was one of the four oncology social workers, and therefore was involved in participant recruitment, data collection and conducting the hypnosis intervention. As a result of the dual role of researcher and facilitator, there might have been an impact on the outcome of the study, since the principal investigator is invested in the research outcome.

Future Research

The findings of the current dissertation suggest that pain may be decreased by the addition of hypnosis during the bone marrow procedures. This is an important finding and is consistent with the hypnosis literature involving bone marrow procedures. However, the lack of statistical significance in anxiety reduction raises questions for future research. Future researchers should include more than one measure of post-procedure anxiety. A scale such as the Short Version of the Profile of Mood States (SV-POMS) Tension/Anxiety subscale, which is a six item self-report scale, could be added to determine anxiety level (Shacham, 1983). This scale would provide more information compared to the visual analog scale and has been found to be reliable and valid in breast cancer settings (DiLorenzo, Bovbjerg, Montgomery, Jacobson & Valdimarsdottir, 1999). Using a more precise measure of anxiety might help to clarify if hypnosis would address procedural anxiety in this setting.

The findings in the current dissertation should attempt to be replicated using a larger sample. A larger sample is needed in order to generalize the results to all adult patients who

undergo bone marrow procedures. Furthermore, this study accrued patients at one treatment facility; however, it would be beneficial for future studies to enroll patients in multiple treatment sites. Future researchers should try to control for some of the procedural difficulties, such as the timing of the intervention. In addition, attitudes toward hypnosis have been cited as an important determinant of hypnotic responsiveness (Milling, 2012). Future research could benefit from including a scale, which captures attitudes/beliefs about hypnosis, such as the Attitudes Toward Hypnosis Questionnaire (ATHQ) (Milling, 2012). For example, if a patient has a negative attitude toward hypnosis, the intervention could be significantly less effective. Understanding these attitudes would help researchers to tailor hypnotic interventions. Furthermore, participants were not asked about their income, life stressors, or relationship status. This information could yield helpful information about who would benefit from this type of intervention.

Future researchers should include cost effectiveness analyses on hypnosis interventions in cancer settings. This type of data would be very important to support and justify the role of social workers in medical settings. If social workers can demonstrate that a hypnosis intervention could benefit the hospital with cost savings, (i.e. reduction in procedure time) the evidence could have a major impact on their sustainability in these settings.

In conclusion, the present study supports the use of hypnosis by social workers for decreasing pain associated with bone marrow procedures. The study also demonstrates the importance of addressing the emotional and psychological components of cancer treatment. The social work led hypnosis intervention has the potential to make the difficult procedure easier to tolerate. As a result of their positions within the interdisciplinary team, oncology social workers have an opportunity to make a contribution to enhance patient quality of life. In addition, this study highlights the fact that oncology social workers can participate in research and test their

clinical interventions. As the primary psychosocial professionals working in hospital settings, social workers are in a prime position to move hypnosis into mainstream clinical practice.

APPENDIX I

DEMOGRAPHICS:

Subject's Gender: ☐M ☐F Date of Birth: ____/____/____
MM DD YY

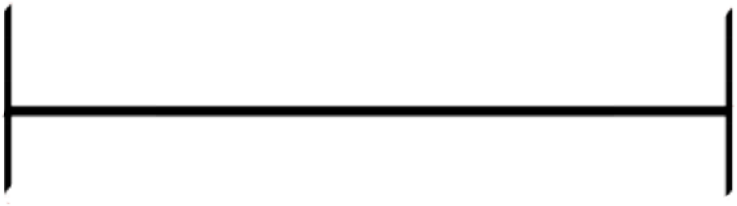
Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino
Race: ☐ American Indian or Alaska Native ☐ Asian ☐ African American
☐ Native Hawaiian or other Pacific Islander ☐ White
☐ Other, specify:_____
☐ Multiracial, specify:_____

Occupation_____Educational Level_____

VISUAL ANALOG SCALES

PAIN

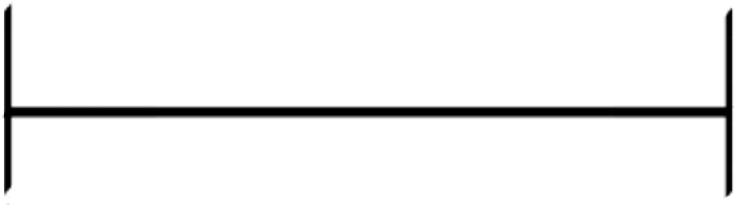
How severe is your pain at the biopsy site today? Place a vertical mark on the line below to indicate how bad you feel your pain at the biopsy site is today.



No pain at the biopsy site **Very severe pain at the biopsy site**

ANXIETY

How severe is your anxiety today? Place a vertical mark on the line below to indicate how bad you feel your anxiety is today.

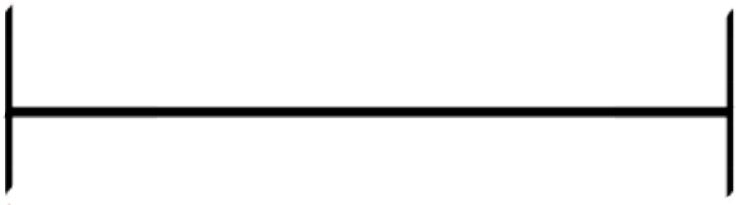


No anxiety **Very severe anxiety**

VISUAL ANALOG SCALE

ANXIETY

How severe is your anxiety today? Place a vertical mark on the line below to indicate how bad you feel your anxiety is today.



No anxiety **Very severe anxiety**

SCALE

STAI – Y2

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

1 = ALMOST NEVER; 2 = SOMETIMES; 3 = OFTEN; 4 = ALMOST ALWAYS

1) I feel pleasant.....1 2 3 4
2) I feel nervous and restless.....1 2 3 4
3) I feel satisfied with myself.....1 2 3 4
4) I wish I could be as happy as others seem to be.....1 2 3 4
5) I feel like a failure.....1 2 3 4
6) I feel rested 1 2 3 4
7) I am "calm, cool, and collected".....1 2 3 4
8) I feel that difficulties are piling up so I can't overcome them.....1 2 3 4
9) I worry too much over something that doesn't really matter 1 2 3 4
10) I am happy 1 2 3 4
11) I have disturbing thoughts 1 2 3 4
12) I lack self-confidence.....1 2 3 4
13) I feel secure.....1 2 3 4
14) I make decisions easily 1 2 3 4
15) I feel inadequate.....1 2 3 4
16) I am content 1 2 3 4
17) Some unimportant thought runs through my mind and bothers me 1 2 3 4
18) I take disappointments so keenly that I can't put them out of my mind.....1 2 3 4
19) I am a steady person 1 2 3 4
20) I get in a state of tension or turmoil as I think over my recent concerns and interests.....1 2 3 4

Patient Satisfaction:

Please circle one statement that best describes how satisfied you are with the overall treatment session:

I am very satisfied.

I feel pretty satisfied.

I am somewhat satisfied.

I feel neutral.

I am somewhat unsatisfied.

I am pretty unsatisfied.

PATIENT DATA COLLECTION PAGE

BEFORE BIOPSY

Blood Pressure_____

Heart Rate_____

AFTER BIOPSY

Blood Pressure_____

Heart Rate_____

Additional Information about Patient & Procedure

Prior BMA (Y/N)_____Site of BMA_____

Indication_____State anxiety –STAI-Y2_____

Bone Marrow Biopsy (Y/N)_____ Duration of Procedure_____

Hematologist (Performing Procedure):_____

Biopsy Result_____

Height_____ Weight_____

Name of Hypnotist (if Relevant)_____

CURRENT MEDICATIONS

List below all medications (whether prescribed or "over the counter") you regularly take as well as their dosage and frequency. Include vitamins, food supplements, herbals, alternative medicines, and the like. Use other side or additional sheet of paper is necessary.

NAME	DOSAGE/FREQUENCY

Was list confirmed with PMD? _____Yes _____No

Session Comments:

Script for Hypnotherapy for Symptom Relief of Anxiety and Pain/Discomfort:

Please make yourself comfortable. Close your eyes and let yourself relax. Take a few slow deep breaths and notice that as you exhale, you can feel yourself becoming more and more relaxed.…very good…now take a long exhale, and as you do, you have all the time you need to breathe out as much tension as you're ready to let go of…for now, that's right…taking all the time you need to breathe as deeply as you wish…. You can continue to relax as I speak to you . . . and each time you exhale, you can feel yourself becoming more and more relaxed . . . more and more relaxed. Soon you will experience hypnosis. I want to assure you that no matter how deeply hypnotized you become; you will remain in complete control. You will stay in control, even when very deeply involved in the experience of hypnosis. I will make suggestions, but it will be up to you to decide whether you want to experience those suggestions. If you don't like the suggestion that I make, you can choose to ignore it and to not have that experience. But if you want to experience a suggestion, you may find it easier to experience than you ever thought possible. So the choice is always yours, and it's safe to enter hypnosis now, as you allow yourself to relax. As I speak, you can feel yourself becoming more and more relaxed. But no matter how relaxed you become, you will hear my voice, and you will be able to respond to my suggestions. If you become at all uncomfortable, you can readjust your body and make yourself comfortable again, and that won't get in the way of your experience of hypnosis. You may hear the sounds in the room, the door open and close, the sounds of voices and the sound of my voice. Just allow the sounds to enter into your experience and bring you into a deeper state of relaxation. If you need to speak to me, you will be able to do so easily, without disrupting your hypnotic experience. Right now, you might want to relax even more, and as you relax, you may feel a slight tingly sensation in your body and if you do, it can comfort you because you will know that it is a feeling of relaxation that some people have, as they begin to experience hypnosis. Let your body relax. Just begin to feel the a spreading sense of calm . . . and peace . . . letting go of all your cares and concerns . . . let them drift away, like clouds in the wind . . . nothing to bother . . . nothing to disturb . . . more and more deeply relaxed, as you enter hypnosis . . . becoming so deeply involved in hypnosis that you can have all of the experiences you want to have . . . deep enough to experience whatever you want to experience . . . but only the experiences you want . . . just your own experiences.

And as you continue to hear my voice, your mind may be drifting with various different ideas, different sorts of experiences and yet the deeper part of your mind can hear whatever it needs to hear and exactly what I am saying as you continue to allow yourself to simply rest comfortably and as you continue to rest there, you probably hadn't noticed the sensation of your head gently laying on the table and yet as I speak about that now you can notice that experience simply by focusing your attention on that….and yet your focused attention may be gradually fading in and out of your awareness as you begin to drift deeper and deeper ….letting yourself know that there are many things to know about the experience of sensation and even about the experience of comfort or discomfort…And as you relax you can you can focus your attention on the top of your head…just let your head relax. And you can let the muscles in your head and in your temples relax….relax completely, and let your forehead relax as you feel so calm and at ease ……and your eyelids may feel heavy……let them completely relax letting go of all of your cares and concerns….and you can relax all of the muscles in your face….your nose…. your cheeks…. And relax your jaw muscles…... Just let them go limp. All the nerves and muscles in your jaw relaxing completely. Would it feel even better to relax the muscles of your neck? . . . . I wonder if you can begin to let go . . . let go and relax. . . loose and limp . . . completely relaxed. Now pay attention to the muscles in your shoulders. And let your shoulders relax, and your back….all the muscles going loose and limp . . .let them become more and more relaxed…. as you can feel so calm and at ease…... And let the relaxation spread down your shoulders and across your back. Let all the nerves and muscles in your back and shoulders relax completely . . . relaxed . . . loose and limp . . .loose and limp…..feel the peace spreading as you feel so at ease . . . so secure . . . your body and mind so relaxed and at peace. And now your chest can relax. Let yourself feel the relaxation across your chest. Notice how it feels. Can you let it feel completely relaxed? . . . Let the relaxation spread through your arms, down into your hands and your fingers. Focus on the feelings in your arms and hands. Do your fingers feel more heavy than light or more light than heavy? Focus on your right upper arm . . . right lower arm . . . your right hand . . . and fingers . . . relaxing completely . . . more and more relaxed . . . completely relaxed. And now your left arm relaxing completely, so relaxed, completely relaxed. I wonder if you can go even deeper now. Deeper and deeper . . .just as you wish . . . just as comfortable and as deep as you would like to go. And the relaxation can spread into your belly. And you can let your pelvis relax . . . relaxing more and more. Relax your stomach. Let your stomach become completely

relaxed. Just let it go loose and limp . . .loose and limp. And you can focus your attention on your thighs . . . your right thigh . . . then you left thigh. Let your legs relax completely….. And let the relaxation spread from your thighs down your legs and into your calves…….and your ankles…..and down into your feet. Just let your legs relax . . . More and more relaxed . . . more and more completely relaxed. You might like to imagine being somewhere peaceful and relaxing…...Perhaps you can imagine lying on a quiet beach on a warm sunny day, with a beautiful blue sky and just a few billowy clouds floating by…..can you imagine the feel of the soft gentle breeze …the smell of the salt sea air….the warmth of the sun beating down on your skin…..but you can imagine being anywhere you like. It might be someplace you've been or someplace you'd like to be. Or just a place in your imagination…it doesn't matter….all that matters is your comfort and your peace. Wherever it is, it is so peaceful and calm…..someplace where you can just be you….where you can feel completely at ease and content. And you can imagine yourself actually being there…..seeing in your minds eye, the things you would feel, hearing the sounds you would hear, smelling the smells. And while you're in this perfect place, I am going to count from one to ten. And with each count you can drift more and more deeply into hypnosis . . .more and more able to experience whatever you want to experience. One . . . drift . . . drift deeper. . . two . . .more and more centered and balanced . . . three . . . four . . . deeper and deeper . . .five . . . halfway there . . . six . . .seven . . . even deeper than before . . . so deep that you can experience whatever you wish to experience . . . eight . . . nine . . . ten . . . very deep now . . .very deep . . . completely at one with yourself . . . completely engrossed. And while you are in this special place, I would like you to experience all the things you would see . . . all the things you would hear . . . all the things you would smell . . . all the things you would touch . . . Focus on all these sensations. It is almost like you are there now enjoying this special place. More and more comfortable . . . more and more relaxed . . . more and more at ease . . . more and more deeply hypnotized. With each breath, you can become more and more deeply hypnotized, so deep that you will be able to do whatever you need to do in hypnosis today . . .deeper and deeper . . . deep enough to experience anything you wish to experience. I would like you now to focus on your special place. Just be there now, and know that you are at peace, calm and relaxed. There is no tension, no anxiety. Concentrate on this feeling, and know that you can take it with you throughout the day. Imagine yourself feeling relaxed and calm. You can feel calm and peace throughout all parts of your day. No stress . . . just peace, contentment, satisfaction . . . well-

being . . . and calm. Nothing can disturb your special place if you don't want to . . . You can choose to be calm and at peace, feeling healthy and relaxed …… Just continuing to experience all that you are experiencing…..seeing in your mind's eye all the things you would see in this place….all the things you would feel…noticing how your body feels to be in this place. You are so comfortable in your special place that noting will disturb you. Your lower back might feel slightly warm or slightly tingly but you won't feel any anxiety or pain. You will be comfortable and relaxed throughout your day not noticing your anxiety and discomfort at all. It is almost like you special place protects you. You will feel calm relaxing sensations . . . peace and comfort . . .healthy and at ease. You are so comfortable in your special place that nothing will disturb you. There is no tension, no anxiety, no physical discomfort. All the parts of your body feel healthy and limber. You might notice very slight physical discomfort from time to time…..but it will just be a minor…. It is almost like your special place protects you from any discomfort. You feel calm sensations, peace and ease . .. You may notice tingling and a numbness on your lower back…now. You may feel a spreading feeling of numbness and tingling on your lower back, like when you get Novocain at the dentist and you can't feel that part of your body…and this may feel cool…like spearmint or peppermint…and it might be the feeling that you have when you go outside in the winter and you forget to bring your gloves and you lose feeling in your fingertips…similar to when you hold an ice cube and feel the cold spreading sensations…tingling and numb…numb and tingling...like pins and needles you feel in your lower back, now…enjoying the numbness you are experiencing in your lower back…similar to how it feels when you make a snowball...and your hand slowly goes numb….as you continue to relax… maybe you associate a color with this feeling…blues and purples…I am curious what color you are associating with this feeling? This coolness and numbness becomes a protective filter between you and the discomfort/pain. As you continue to relax…know that you can access this feeling of numbness today when they do the bone marrow, it will be interesting to think about the cool comfortable numbness right in the area they're working. Wouldn't you be surprised if you could make it numb even before they start? Make it numb before they begin, if you want… and whenever you want…at any point in the future…Isn't it nice to know that you have the ability to make a part of your body feel numb? And that you can use this ability to numb feelings of pain and discomfort whenever you want to….as you continue to relax allow yourself to imagine a situation when this will be helpful to you…and enjoy the relaxation…knowing that

your body has the ability to heal itself…and go numb…whenever it needs to…there is no longer a need to worry about procedures, you'll be able to relax, able to control the sting of needles, to take the hurt right out of it- pressure, but nothing more….you can bring relaxation into the part of your body that needs it most. If you have any discomfort right now imagine that you are applying a hot pack or you are putting ice on it and see what it feels like. Develop the sense of warm or cool tingling numbness to filter the hurt out of the pain.…so that all you can feel is a slight pressure…and you already know that in this special trance state…it is possible for all sorts of things to happen…like the feeling of lightness throughout your body and the sensation of numbness on your lower back…and I don't know if that numbness or lightness will spread up or down, more to one side or the other, or if it will develop slowly or quickly, you can just allow it to happen in its own time…and in its own way… Continuing to focus on your breath….noticing how your body feels to breath in the calm, and the comfort, and to breath out the tension….breathing in all that you need and breathing out what you don't need…. With each breath, breathe deeper and easier, filter the hurt out of the pain…. Imagine brining your breath to your lower back or the place that needs it most…Good…its as if a thousand tiny fingers massaging your lower back now….direct your breath there and release the tension…fiber by fiber…strand by strand…you have the ability to regulate your experience… just like you have the ability to forget about a body ache…while you are watching a movie…you have the ability to become absorbed and distracted…so that the ache fades into the background…and you may be surprised to notice how absorbed you can be….that's right…you can dial the pressure down…dial it down to zero from wherever it is at right now….and as you gradually turn it down…you can feel comforted in knowing that you have the ability to control the amount of pressure you are experiencing….see if you can change the pressure/pain into some other sensation…like a tingling sensation…an itch…a warm sensation…see if you can change it into some other sensation now…. Imagine how the body feels with this new sensation you experiencing…as you experience the sensation….imagine that it is no longer a part of you…you can step back and look at it from a distance…as if it is not happening to you… If you are feeling any sense of discomfort, breathe in and out through that area so that your warm breath can soothe those muscles and allow them to feel soft and warm and relaxed. While you continue to enjoy whatever it is you are experiencing…….

I am going to count backwards from five, and with each count you are going to become more and more alert and energized. At the count of one you can open your eyes. At zero you will be fully alert and wide awake and feeling better than when we began. Five . . . four . . . feeling more and more alert…..three . . . feel the energy flowing into you . . . two . . . more awake…..one . . . open your eyes . . . zero…….wide awake.

APPENDIX II

HUNTER COLLEGE

INSTITUTIONAL REVIEW BOARD
695 PARK AVENUE, ROOM E1426
NEW YORK, NY 10021
PHONE (212) 650-3053 ◆ FAX (212) 650-3055
http://www.hunter.cuny.edu/irb

Committee for the Protection of Human Subjects from Research Risks

To: Alison Snow
Irwin Epstein
Social Work

From: Darrell Wheeler, Chair DW

Date: 12/17/2009

Re: Human Subjects Review **Type of Review:** Full Review

Protocol #: HC-100914257

Federalwide Assurance Number: FWA00003623 **IRB Registration Numbers:** IRB00004471 and IRB00000136

Project: "Brief Hypnosis for Treatment of Pain and Anxiety in Patients Receiving Bone Marrow Biopsies"

The Hunter College Committee for the Protection of Human Subjects has approved your project with the following provisions:

a. This approval is for the period **12/17/2009** through **12/16/2010**. You will receive a renewal notice approximately eight weeks before the expiration of this project's approval. This notice will be sent to the faculty advisor for student projects. However, it is your responsibility to ensure that you have an approved protocol at all times during your research. Please not that if there is a lapse, the work of the protocol must stop, as the protocol is no longer protected by the CUNY-wide assurance of compliance. The IRB will notify you of the lapse by certified mail. Work connected to the protocol may not be resumed until the IRB has given approval.

b. Documents reviewed and approved are:
1 Consent Form(s), HIPAA Research Authorization and Patient Data Collection Page

c. Approved and stamped consent form(s) must be used by all participants. You are responsible for maintaining signed consent form(s) for a period of at least three years.

d. All modifications and/or changes to the approved protocol must be reviewed and approved by the IRB prior to implementation.

e. All adverse events or unanticipated problems as a result of this research, must be reported to the IRB within 10 business days. Please refer to website for the Adverse Event and Unanticipated Problem Form that should be used when reporting.

f. All key personnel must have CITI training certificates on file at the IRB Office. It is your responsibility to submit an updated Key Personnel form should there be a change in the key personnel on this project.

Good luck with your work!

By signing below, I acknowledge that I have received this letter and am aware of and agree to abide by all of its stipulations in order to maintain active approval status, including prompt reporting of adverse events/serious problems and annual continuing review. I am aware that it is my responsibility to be knowledgeable of all federal and state regulations including CUNY's Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).

Signed: _____

Alison Snow
Irwin Epstein
Social Work

PLEASE SIGN AND RETURN ONE COPY OF THIS MEMO TO CAROLYNN JULIEN
INSTITUTIONAL REVIEW BOARD, 695 PARK AVENUE, NEW YORK, NY 10021.

YOUR PROJECT WILL NOT BE APPROVED UNTIL WE RECEIVE THE SIGNED COPY.

Mount Sinai

Program for the Protection of Human Subjects
Mount Sinai Medical Center 108
One Gustave L. Levy Place, Box 1075
Icahn Medical Institute Building 4-78
New York, NY 10029-6754,
Phone (212) 659-8980
Fax (212) 876-6789

Date: March 25, 2009

MSSM Project # **09-0195 0001 01 SW ***
Principal Investigator: **Alison Snow, MSW**
Sponsor: **MSSM**

The project entitled **BRIEF HYPNOSIS FOR TREATMENT OF PAIN AND ANXIETY IN PATIENTS RECEIVING BONE MARROW BIOPSIES** includes research activities that involve human subjects. The new application for this research was last reviewed by the convened IRB at the 3/10/2009 meeting of the Institutional Review Board of the Mount Sinai School of Medicine, in accordance with Mount Sinai's Federal Wide Assurance (#FWA00005656) to the Department of Health and Human Services.

The IRB has determined that this research involves GREATER THAN minimal risk. Minimal risk is defined as the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests (45CFR.46.102.; 21CFR50.3k)

This project received final approval on 3/24/2009 and is approved to be conducted from **3/24/2009** through **3/9/2010.** In order to continue working on this project beyond **3/9/2010**, a continuation application must be received, reviewed, and approved prior to that date. Therefore the IRB recommends submission of a continuation application for this project **8-9 weeks prior to that date** in order to avoid a gap in IRB approval periods. If an application is not submitted in a timely fashion, the research will default into terminated status. Please be aware that material changes to the research (other than to remove immediate hazards to the human subjects) cannot be conducted without prior IRB review and approval. Please consult the IRB's Guidelines and Policies Manual for other Investigator responsibilities.

- The record review activity that was specified in the project application has been approved.

IRB approval does not constitute or imply institutional support for the conduct of this research.

Sincerely yours,

Jeffrey H. Silverstein, MD

Jeffrey H. Silverstein, M.D.
Chair, Institutional Review Board
Program Director, Program for the Protection of Human Subjects
Associate Dean, Research

TITLE OF RESEARCH STUDY:

Brief Hypnosis for Treatment of Pain and Anxiety in Patients Receiving Bone Marrow Biopsies

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND ADDRESS:

Name: Alison Snow
Address and Phone: Ruttenberg Treatment Center, One Gustave L Levy Place Box 1252, NY, NY 10029; 212-241-7805

PURPOSE OF THIS RESEARCH STUDY:

You are being given information about becoming a volunteer in a research study. The purpose of this study is to find out the effectiveness of hypnotherapy (a form of guided relaxation) in relieving the pain and anxiety associated with bone marrow aspirates and biopsies. Bone Marrow biopsies are required procedures in the follow-up of many blood disorders. A bone marrow biopsy is a procedure that removes a small solid piece of tissue for examination. A bone marrow aspiration removes a sample of the fluid (blood), called an aspirate. A common site for a bone marrow biopsy and aspiration is the pelvic bone, which is located in the lower back by the hip.

There is medical literature showing that hypnotherapy is effective in the relief of pain related to problems such as minor surgery, arthritis, and migraine headaches. Hypnotherapy has also been shown to be effective in reducing pain in children receiving bone marrow biopsies. However, it is not known if hypnotherapy can relieve pain and anxiety associated with bone marrow aspirates and biopsies in adults.

You qualify for participation in this study because your hematologist has determined that it is necessary for you to undergo a bone marrow aspirate and biopsy to diagnose and/or further evaluate your current medical condition.

INFORMATION ABOUT VOLUNTEERING:

Participation in this research study is totally voluntary. If you decide not to participate, there will be no penalties involved, and it will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you promptly. A copy of this consent form will be given to you.

Study ID #: 09-0195 Consent Form Version:

EXPECTED LENGTH OF TIME FOR STUDY PARTICIPATION:

Recruitment for this study is expected to last about 12 months. Each individual will spend about 15-30 minutes participating in activities related to the study. There will be no follow up after your participation.

NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

The number of people expected to participate in this study is 160.

DESCRIPTION OF WHAT'S INVOLVED:

Hypnotherapy is a treatment using a form of guided relaxation known as hypnosis. Hypnosis is a state of awareness with an increased ability to be influenced by suggestion. Hypnosis is characterized as a feeling of relaxation or letting go of tension, focusing your attention to one or a few targets, or feeling removed from your normal sense of time, location, or awareness of self. It has been used in medical settings to help patients going through a variety of procedures to cope with their pain. There is evidence that hypnotherapy can relieve various forms of pain, but this method has not been proven to reduce pain or anxiety in patients undergoing bone marrow aspirates and biopsies.

If you agree to participate in this research study, you will be randomized (assigned by chance, like the flip of a coin) to one of two group, either a control group or a hypnotherapy group. In the control group, you will receive the standard of care that is given to all subjects undergoing bone marrow aspirates and biopsies, including a lidocaine injection, which is a numbing medication, to the area of the biopsy. If you are in the hypnotherapy group, you will receive the standard treatment in addition to a 20 minute hypnosis session after receiving the lidocaine injection. During this session the effect of the Lidocaine will not wear off. The hypnotherapy will be administered by an oncology social worker trained and certified in hypnotherapy. One hundred sixty subjects will be enrolled in this study..

Each subject will be asked to fill out anxiety scales prior to the bone marrow aspirate and biopsy and a pain and anxiety scale after the aspirate and biopsy. The anxiety scale will be a questionnaire asking you about your feelings before the bone marrow biopsy. This will take no more than five minutes to complete. The pain and anxiety scales given after the bone marrow biopsy will measure any pain and anxiety that may be experienced as a result of the procedure. These scales will also take no more than five minutes to complete. We will ask you about the medications you are taking. In addition, your blood pressure and heart rate will be measured before and after the procedure. The measuring and recording of your blood pressure and heart rate will take no more than three minutes.

If you agree to participate in this study, you will be allowed to continue the medications and treatments you are currently receiving to manage your pain and anxiety. The use of hypnotherapy will be considered investigational. We will review your medical record to make sure that we have correctly recorded your current medications.

COSTS AND/OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

There will be no costs or payments that will result from participation.

POSSIBLE BENEFITS:

You may experience an improved quality of life as a result of participating in this study, as a result of decreased pain and anxiety from your bone marrow biopsy procedure. You may also learn other aspects of pain management, which may reduce the intake of pain medications. However, it is possible that subjects will receive no benefit from your participation in this study.

POSSIBLE RISKS AND DISCOMFORTS:

There are no known risks in the literature to participating in a hypnotherapy procedure. Some subjects might experience disappointment, frustration, or anxiety if they have difficulty following techniques, or if they do not feel a reduction in pain as a result of participating in this study. Some subjects might experience mild anxiety when they fill out questionnaires.

OTHER POSSIBLE OPTIONS TO CONSIDER:

The alternative to participating is to continue with the standard of care that is given to all subjects undergoing bone marrow aspirates and biopsies. In addition, you might try to join a clinical trial of another experimental treatment for procedural-related pain.

IN CASE OF INJURY DURING THIS STUDY:

In the event of injury resulting from your participation in this research study, the facilities at Mount Sinai Medical Center and professional attention will be made available to you at your expense. Financial compensation from Mount Sinai Medical Center will not be provided. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Alison Snow, LCSW at telephone number 212-241-7805. If you need to speak to a physician you can contact Dr. Isola at 212-241-6021.

Study ID #: 09-0195 Consent Form Version:

ENDING PARTICIPATION IN THE STUDY:

You may stop participating in the study at any time without any penalty. This will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

You may withdraw your permission for the use and disclosure of any of your protected information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from participating in the study.

CONTACT PERSON(S):

If you have any questions, at any time, about this research, or want to discuss any possible study-related injuries please contact Alison Snow at telephone number 212-241-7805 or Dr. Isola at 212-241-6021.

If you still have questions or concerns about the study, or your rights as a research participant, please contact a representative of the Program for Protection of Human Subjects at The Mount Sinai School of Medicine at telephone number 212-659-8980.

DISCLOSURE OF FINANCIAL INTERESTS:

None

CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (Research Record) will be kept confidential to the extent permitted by law. However, this Research Record and your personal Medical Record (if any and if relevant to the study) may be reviewed by government agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, individuals who are involved in, or authorized to monitor or audit, the research, or the Institutional Review Board (the committee that oversees all research in humans at Mount Sinai School of Medicine) if required by applicable laws or regulations.

This Section For IRB Official Use Only

This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)
From: 3/24/09 To: 3/9/2010

PROTOCOL#:
HC- 1009914257

MOUNT SINAI MEDICAL CENTER
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY

Study ID #: 09-0195

Consent Form Version:

DOCUMENTATION OF CONSENT TO PARTICIPATE IN THE RESEARCH

The volunteer (or their representative) and the investigator/delegate must each SIGN, DATE and TIME this consent form.

I have read, or had read to me, this entire consent for research. All blanks or statements or questions that require completion were properly completed before I signed this consent. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction. If I do not choose to participate in this research, or if I choose to withdraw from this research at any time, this will not affect my ability to receive medical care outside of this research study. I hereby volunteer to participate in this research.

Research Subject/Representative(s) Signature: _____

Name(s): _____
Print Name(s)

Date: _____ Time: _____

Relationship(s): _____
If signed by representative

I have fully explained to the potential volunteer (or his/her representative) the nature and purpose of the research study, any possible alternatives to participation which might be advantageous, the benefits (if any) to be reasonably expected, the foreseeable discomforts and risks that may be involved, and the consequences and risks (if any) which might be involved if participation is discontinued. I believe that the potential volunteer (or his/her representative) understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions and have fully and completely answered all such questions.

_____
Signature of Principal Investigator/Delegate (person who obtained consent)

_____
Print Name of person who obtained consent Title

Date: _____ Time: _____

HUNTER COLLEGE OF C.U.N.Y
COMMITTEE FOR THE PROTECTION
OF HUMAN SUBJECTS
APPROVED:
FROM 12/7/09 TO 12/16/10

This Section For IRB Official Use Only

This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)
From: 3/24/09 To: 3/9/2010

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