THE EFFECTS OF AROMATHERAPY ON THE PATIENT OUTCOMES OF ANXIETY AND SLEEP QUALITY IN CORONARY CARE UNIT PATIENTS

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ANNABELLE R. BORROMEO, B.S.N., M.S.N.

DENTON, TEXAS

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TEXAS WOMAN'S UNIVERSITY
DENTON, TEXAS

May 12, 1998
Date

To the Associate Vice President for Research and Dean of the Graduate School:

I am submitting herewith a dissertation by Annabelle R. Borromeo entitled " The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Unit Patients." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Nursing.

Anne Young
Anne Young, Major Professor

We have read this dissertation
and recommend its acceptance:

K. Lynn Kieck
Donette Kennicki

Accepted
Linda M Thompson
Associate Vice President for Research
and Dean of the Graduate School

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THE EFFECTS OF AROMATHERAPY ON THE PATIENT OUTCOMES OF ANXIETY AND SLEEP QUALITY IN CORONARY CARE UNIT PATIENTS

Annabelle R. Borromeo

August 1998

Anxiety and poor sleep quality in the Coronary Care Unit (CCU) population are well documented. Traditionally, these problems are treated with drugs that are expensive and have harmful side effects. Complementary therapies are gaining acceptance because they provide cost-effective and safe alternatives to achieve the desired outcomes.

Aromatherapy, the controlled use of essential oils to enhance health, is one example of a complementary therapy. It utilizes the healing properties of the oils and their odor. Aromatherapy appears to be most useful in achieving positive effects on such problems as anxiety, and insomnia.

A repeated measures design was used to examine the effects of a passively-diffused 9-hour lavender aromatherapy treatment compared with a control on anxiety and sleep quality in CCU patients. A systematic random sampling technique was used to select 25 subjects admitted to the CCU of a large tertiary care hospital located in Southeast Texas. The State-Trait Anxiety Inventory (STAI), a 20-item instrument, was used to measure anxiety immediately before treatment, thirty to sixty minutes after treatment start, and upon awakening the next day. The Richards-Campbell Sleep Questionnaire (RCSQ), a 5-item instrument with a visual analogue scale design, was used to measure sleep quality. Investigator-designed instruments were used to record demographic data and medications for anxiety, sleep and pain used during the study.

The first three hypotheses, there will be a significant difference in anxiety scores between treatments, in anxiety scores over time, and there will be a significant difference in treatment and time interaction effect on anxiety, were examined using a multivariate approach to analysis of variance for repeated measures. An analysis of covariance was not performed because there were no significant correlations between variables. The fourth hypothesis, there will be a significant difference in sleep scores between the two treatments (aromatherapy vs. control), was examined using a t-test for dependent samples. None of the hypotheses were supported.

Passively diffused aromatherapy using lavender on cotton ball did not significantly affect anxiety levels and sleep quality in CCU patients. These findings must be viewed with caution, because power analysis revealed low effect sizes and an inadequate sample size.

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CHAPTER 1

INTRODUCTION

The problems of anxiety and poor sleep quality in the Coronary Care Unit (CCU) population are well documented in the literature (Broughton & Baron, 1978; Cassem & Hackett, 1971; Hackett, Cassem, & Wishnie, 1978; Litrell & Schumann, 1989; Richards & Bairnsfather, 1988). Traditionally, these problems are treated with drugs that are often expensive and have harmful side effects. The emphasis on holistic, cost-effective, and safe strategies to achieve patient outcomes has encouraged the proliferation of alternative, or complementary, modalities that are not included within the realm of conventional Western medicine. Many of these complementary healing modalities are natural, as opposed to drug-based therapies.

The growing interest in complementary healing modalities is client-driven. A study published in the New England Journal of Medicine found that over one-third of those surveyed chose alternative or complementary medicine over conventional methods, because of the emphasis of allopathic practitioners on diagnostic testing and treating with drugs without focusing on the patient as a whole (Eisenberg et al., 1993). In addition, insurers are beginning to reimburse practitioners of complementary healing modalities (Paulson, 1995). One complementary healing modality that is gaining popularity is aromatherapy (Buckle, 1997). Aromatherapy is the controlled use of essential oils to restore or enhance mental, emotional, physical or spiritual health (Valnet, 1990; Wise, 1989). This therapeutic modality works through a combination of the healing properties

of the oils and their smell. The essential oils are believed to exert a benefit because of their different properties. Some are relaxing; others are uplifting. It appears that aromatherapy is most useful in achieving psychotherapeutic effects on such problems as anxiety, depression and insomnia (Tisserand, 1988b; Valnet, 1990; Worwood, 1996).

There are two kinds of aromatherapy according to application: fragrance aromatherapy (also known as aromatology) and massage aromatherapy (Price & Price, 1995). Fragrance aromatherapy entails inhaling the essential oils while massage aromatherapy consists of cutaneous penetration of the oils (Tisserand, 1977). Fragrance aromatherapy will be used in this study.

The use of plants in medicine has a long history, and oils distilled from them are known to have been prepared as far back as 3000 BC in the Indus Valley (presently Pakistan). The oils are believed to enhance well being, relieve stress, and help in the rejuvenation of the human body. Since the oils that are used are organic in nature, they are believed to be safe, with minimal or no side effects. They are also more cost-effective than pharmacological interventions.

The therapeutic properties of the essential oils have been investigated, although much of the research has occurred in the laboratory using animal subjects. Evaluations of aromatherapy as a therapy, however, are more tenuous. A limited number of small studies using actual patients were reported in the literature (Dunn, Sleep & Collett, 1995; Hewitt, 1995; Stevensen, 1992; Passant, 1990).

Lavender (*Lavandula augustifolia*) is one of the most commonly used essential oils (Price & Price, 1995). Its origin is in the Mediterranean region but it is now grown at

altitudes of nearly 6,000 feet in the mountains of southern France, Italy, Spain, North Africa, India, Australia, and the United States (Lawless, 1994). It is a favorite essential oil in many cultures not only for its fine fragrance but also its valuable medicinal properties. Lavender is believed to be the most useful and versatile essential oil used in aromatherapy today (Lawless, 1994; Tisserand & Junemann, 1994). It is also considered to be a very safe oil which can be used easily for first-aid purposes as well as for a wide variety of common physiologic problems such as burns, and problems with a psychological component such as anxiety, depression and insomnia (Davis, 1996; Tisserand, 1988a; Worwood, 1996). Practitioners of aromatherapy believe that lavender has analgesic, antispasmodic, sedative, anxiolytic, antidepressive, and other healing properties (Buckle, 1997; Price, & Price, 1995; Tisserand & Junemann, 1994; Valnet, 1990).

Precisely how lavender works to promote healing, decrease anxiety and increase sleep quality remains unknown, but it is believed that when lavender is inhaled, droplets of the essential oil reach the nasal mucous membranes and numerous olfactory neuron receptors that are attached to the mucous membranes. These neurons are intimately connected with the central nervous system. The scent stimulates the limbic system, which is the emotional center of the brain. The effect of lavender is suppression or relaxation of the central nervous system (Price & Price, 1995; Tisserand & Junneman, 1994); thus it is believed to achieve positive results in decreasing anxiety and increasing sleep quality.

Problem of Study

The present study examined the effects of aromatherapy, the diffusion of an essential oil into the atmosphere, on two patient outcomes relevant to the CCU population. Patient outcomes examined were level of anxiety and perceived quality of sleep.

Rationale for Study

The problems of anxiety and poor sleep quality are found frequently in the Coronary Care population (Broughton & Baron, 1978; Jensen & Herr, 1993; Lueders-Bolwerk, 1990; MacWilliams, 1923; Zimmerman, Pierson, & Marker, 1988). The phenomena of anxiety and poor sleep quality have great biologic and clinical importance.

Anxiety can stimulate sympathetic nervous system activity that leads to increased workload of the heart. Anxiety has also been linked to physiological changes such as increases in heart rate and blood pressure, palpitations, tightness in the chest, and peripheral vasoconstriction (Zimmerman, Pierson, & Marker, 1988). As a result, the stimulation of the sympathetic nervous system generally leads to an increased workload of the heart. All these effects are detrimental to the patient who has had a myocardial infarction or exhibits chest pain as a result of compromised myocardial circulation. On the other hand, when anxiety is controlled and when the patient is in a relaxed state, sympathetic activity is decreased resulting in decreased cardiac workload and oxygen consumption (Benson, 1977). Several factors may contribute to increasing anxiety in the Coronary Care patient. These factors, identified since the first Coronary Care Unit

opened, include admission to and transfer from the Coronary Care Unit, nature of the condition or illness, environmental factors (e.g. visiting regulations, interrupted sleep, noise), and interactions with staff (Cassem & Hackett, 1971; Davis, 1972). The continuing identification of anxiety in the Coronary Care population supports the need for further clinical nursing investigation of the phenomenon of anxiety and interventions that may reduce it.

MacWilliams (1923) first reported the presence of "disturbed sleep" in patients with angina and myocardial infarction. Subsequent studies confirm the presence of this problem in patients confined to a critical care environment such as a Coronary Care Unit (Broughton & Barron, 1978; Jensen & Herr, 1993; Karacan et al., 1974; Wood, 1992). Many factors are thought to contribute to poor sleep quality in these patients. Anxiety, pain, the strangeness of the critical care environment (e.g. monitors, alarms, lights), the routine of staff (e.g. sleep interruption for assessment and medication administration), and even drugs, have all been identified as contributing to sleep pattern disturbances in the critically ill patient (Jensen & Herr, 1993, Schwab, 1994).

Although sleep is an essential physiologic need required for healing, critically ill patients, including coronary care patients, share the problem of sleep deficit (Broughton & Barron, 1978; Jensen & Herr, 1993; Karacan, et al., 1974; MacWilliams, 1923; Wood, 1992). Lack of sleep or poor sleep quality may negatively affect the chances of survival and recovery (Carola, Harley, & Noback, 1990; Hackett, Cassem, & Wishnie, 1978). There is a continuing need to test nursing interventions that facilitate sleep and improve sleep quality.

Traditionally, anxiety reduction and sleep quality enhancement have been promoted through pharmacological means. In their seminal work, Cassem and Hackett (1971) recommended the use of daytime tranquilizers and nighttime sedation for all patients unless there were strong contraindications for not doing so. Today, pharmacological interventions, including the use of anxiolytics to help patients deal with moderate to high anxiety levels are still recommended (Burns & Shelly, 1992; Schwab, 1994; Spear, 1996). The ideal agent would have a short half-life, few drug interactions, exert minimal effects on the respiratory and cardiovascular system and preserve normal sleep patterns. Benzodiazepenes, like lorazepam and alprazolam, are short acting tranquilizers that suppress the central nervous system without adversely affecting cardiovascular function (Schwab, 1994). Unfortunately, benzodiazepenes have significant deleterious effects on respiratory function and sleep patterns (Schwab, 1994). They have little effect on rapid eye movement (REM) sleep and they also suppress stages 3 and 4 sleep, which are the two deepest stages of sleep (Borbely, Mattmann, & Loepfe, 1985; Robinson & Zwillich, 1994; Roth, Roehrs, & Zorick, 1985). Additionally, in patients where loss of control is an issue, the use of pharmacological intervention may add to their sense of loss of control because of the need for a foreign substance to gain control (Spear, 1996). The increasing cost of pharmacological interventions is also an issue (Wild, 1993).

The disadvantages of using conventional drug therapy to allay anxiety and enhance sleep quality described above have prompted practitioners to investigate nonpharmacological interventions such as music, white noise, guided imagery, and

therapeutic touch (Lueders-Bolwerk, 1990; Williamson, 1992; Zimmerman, Pierson, & Marker, 1988). In general, data demonstrating a relationship between specific interventions and anxiety reduction or sleep improvement in the critical care environment are tenuous (Schwab, 1994). The need to continue exploring nonpharmacologic interventions and psychologically supportive environments to achieve the goals of anxiety reduction and sleep quality enhancement in the Coronary Care population is imperative.

There is a growing public demand to have hospital environments that are psychologically supportive (Ruga, 1989). Psychologically supportive environments are environments that facilitate patient healing and recovery (Ulrich, 1992). Therefore, psychologically supportive environments, or healing health care environments, may be linked to dollar savings in health care costs.

Aromatherapy is an emerging healing modality that may contribute to a healing health care environment, which, in turn, has the potential to decrease anxiety and promote sleep quality. While the use of aromatherapy has been documented since the time of the ancient Egyptians, there is a lack of scientific studies with rigorous methodology (Tisserand, 1977). Anecdotal and small sample studies have revealed aromatherapy to be useful in such patient problems as anxiety and poor sleep quality (Passant, 1990; Tattum, 1992; Wise, 1989).

Despite care protocols and advances in pharmacological interventions for treatment of anxiety and poor sleep quality, these problems continue to affect the CCU

population. The purpose of this study was to test a more homeopathic and less costly intervention for these problems.

Theoretical Framework

The Science of Unitary Human Beings (Rogers, 1970; 1980; 1987) provides a framework for examining the effects of aromatherapy on the patient outcomes of anxiety and sleep quality. This section will present the theory, its concepts and principles, the application of the study to the theory and a proposition that will be tested by the study.

The role that the environment plays and its influence on the well being of people is an important concept in the Science of Unitary Human Beings. The human being and the environment are perceived as irreducible energy fields integral with one another and continuously creative in their evolution. Energy fields are units of the universe that manifest as pattern and organization.

A unitary human being is a homeodynamic being and is not homeostatic (Rogers, 1987). Rogers offered no definition for the concept of homeodynamics but grounded her principles of homeodynamics in five basic assumptions about human beings.

First, the human being is a unified whole possessing an individual integrity and manifesting characteristics that are more than and different from the sum of the parts. The second statement assumes that the human being and the environment are continuously exchanging matter and energy with each other. Environment is defined as the patterned wholeness of all that is external to a given human being. This constant

interchange of material and energy between the human being and the environment characterizes each of them as open systems.

The third assumption holds that the life process of the human being evolves irreversibly and unidirectionally along a space-time continuum. At any given time, the human being is the expression of the totality of events present at that given time (Rogers, 1980). The fourth assumption is that pattern and organization identify the human being and reflect wholeness. The fifth statement assumes that the human being is characterized by the capacity for abstraction and imagery, language and thought, sensation and emotion. Of all the earth's life forms, only the human being is a sentient, thinking being, with the capacity to experience the environment through all of the senses and to promote change in the person by aligning the human and environment energy fields to create a sense of harmony and healing.

Rogers (1980) also postulated three principles to describe the patterns of human being and environment interaction and change. To understand the nature of the interaction between the human being and the environment, one has to consider motion and changes in energy fields through the principles of resonancy, helicy, and integrality.

Resonancy describes the direction of change from lower to higher wave patterns. The principle of helicy postulates that change manifested in increasing diversity and nonrepeating rhythmicity is continuous. Integrality describes the nature and the process of the relationship between the human and environment energy fields, which is a continuous and mutual process. There is a constant mutual exchange between the two entities whereby simultaneous molding is taking place in both at the same time.

Rogers (1987) dealt with the concept of time in her theory of accelerating evolution. In this theory, she postulates that each nurse-patient interaction is a human being-environment, space-time unit that leads to repatterning of the individual patient over time and many interactions. With each new interaction, new knowledge, feelings, and ideas blend in the life-space of each person so that each will never be the same. The repatterning that occurs is unidirectional. Pattern is an abstraction that cannot be observed, but the manifestations of pattern are observable. The pattern is in the form of a single wave and is always changing and accelerating with time. The field patterns are, therefore, unpredictable, dynamic, creative, and continuously innovative. In humans, patterns are abstractions that display themselves as nonrepeating rhythms in human behavior, such as sleep and waking, and perceptions of time and motion (Rogers, 1990). Rogers views human bodies as manifestations of field pattern. The view of humans as energy fields, with manifestations of pattern in human bodies, is unique to Rogers.

In conceptualizing a unitary human being, Rogers (1970, 1987, 1990) viewed the person as an energy field experiencing the environmental field beyond the five senses. The theory leaves the door open for complementary healing modalities, and opens up the possibility that certain aspects of non-traditional, non-Western therapeutic modalities may be worth exploring.

The validity of research engaged in the study of non-Western therapeutic modalities has been seriously handicapped by a paucity of theories to explain these practices. The nature of Rogers' paradigm provides a framework for studying such modalities. Specifically, the present study proposed to test Rogers' principle of

integrality. The proposition that was tested in this present study was, patterning change in the environmental energy field (aromatherapy) will manifest as a repatterning change in the human energy field (anxiety level and sleep quality). The statement does not imply direction because Rogers states explicitly that the nature of change is unpredictable and probabilistic. The statement also does not imply cause-and-effect because acausality is a fundamental tenet of Rogers' SUHB (Rogers, 1980).

The present study tested the patterning manifestations in the human energy field when an environmental repatterning strategy was employed. The repatterning strategy used in the study was aromatherapy, the diffusion of low frequency waves (lavender oil) in the environment. The low energy waves of aromatherapy was thought to exert an influence on the individual's anxiety level and sleep quality. The human energy field patterning manifestations would be apparent in the changes that occurred over time in the patient's anxiety level and sleep quality. Anxiety and sleep quality are holistic manifestations of the human energy field. It is theoretically not congruent to use the word "effect" in any study using Rogers' views as framework. It would be more appropriate to use the term "interaction" when describing the patterning changes in both environmental and human energy fields. "Interaction" more accurately depicts the mutual changes that occur in both the environmental and human energy fields. The investigator has, however, chosen to keep the term "effect" in the title of the study because it is more readily understood and less cumbersome than the more accurate title, "The Interaction between the Repatterning Strategy of Aromatherapy and Repatterning

Manifestations in the Patient Outcomes of Anxiety and Sleep Quality in the Coronary Care Population."

Assumptions

Two assumptions underlying the proposed study are derived from the Science of Unitary Human Beings (Rogers, 1970, 1980, 1987, 1990):

1. There is mutual interaction between the human (e.g. CCU patient) and environmental (e.g. introduction of aromatherapy into the environment) energy fields resulting in repatterning (e.g. changes in patterns of anxiety and sleep quality) in both energy fields over time.

2. The human energy field experiences the environmental energy field through and beyond the five senses.

Hypotheses

The following hypotheses were examined in this study:

1. There will be a significant difference in anxiety scores between aromatherapy and control treatments in coronary care unit patients (main effect: treatment).

2. There will be a significant difference in anxiety scores over time in coronary care unit patients receiving aromatherapy or control treatments (main effect: time).

3. There will be a significant treatment and time interaction effect on anxiety in coronary care unit patients receiving aromatherapy (interaction effect).

4. Coronary care unit patients will have a significant difference in sleep scores between aromatherapy and control treatments.

Definitions of Terms

The following terms were conceptually and operationally defined for this study:

Aromatherapy was conceptually defined as environmental repatterning through the introduction of low frequency wave patterns in the environmental energy field (Rogers, 1970, 1987). Operationally, aromatherapy was defined as the passive diffusion of one drop of lavender oil (believed to relieve anxiety and enhance sleep) applied to a cotton ball and fastened to the underside of the upper right hand corner of the pillow case with a safety pin between the hours of 9:00 P.M. and 6:00 A.M. the next day.

Patient outcomes were conceptually defined as a repatterning of the human energy field that results in harmony (Rogers, 1987). For this study, two patient outcomes were operationalized as follows:

Anxiety was operationalized as a score in the State portion of the State-Trait Anxiety Inventory (Spielberger, 1983) (Appendix A).

Sleep quality was operationalized as a score on the Richards-Campbell Sleep Questionnaire (RCSQ) (Richards, 1985) (Appendix B).

Limitations

Limitations of the study were:

1. Participants for the study were selected from patients in the CCU with a diagnosis of rule out (R/O) myocardial infarction, unstable angina or chest pain; thus, the findings from the study is limited to these patient populations.

2. There was no attempt to control the environment, except to introduce the independent variable of aromatherapy.

3. Medications taken by the subjects may affect their responses to the instruments. Experimental control of the confounding variable of intake of medication for anxiety and sleep was not feasible and would seriously deplete the sampling frame and limit generalizability. Therefore, statistical control over the confounding variable of medication intake was performed.

Summary

Complementary healing modalities and their effects on human well being have emerged as research priorities. This increased interest in complementary healing modalities is partly due to the disappointment of patients with the fragmented approach to disease prevention and treatment, and partly due to the scarcity of health care dollars (Goldberg, 1994). The move to discover non-traditional treatment modalities that might potentially impact patient outcomes in a cost-effective manner is underway. There is also a growing body of research that suggests that treating the human's body is not as effective as treating the whole person. Rogers' (1970, 1980, 1987, 1990) Science of Unitary Human Beings provides a framework for studying the interaction between the complementary healing modality of aromatherapy and the patient outcomes of anxiety and sleep quality.

CHAPTER 2

REVIEW OF LITERATURE

The purpose of this review is to provide a historical context of aromatherapy and aromatherapy research, and to critically examine the body of research pertaining to aromatherapy, anxiety and sleep in the coronary care population. The latter part of this section will deal with the anatomy and physiology of the sense of smell and current beliefs about how what is perceived through the sense of smell can affect the mind. This review will be divided into the following subsections: the history of herbals and fragrance, history of aromatherapy, aromatherapy, aromatherapy research, the limbic system, and anxiety and sleep in the critically ill patient.

History of Herbals and Fragrance

Although the word "aromatherapy" was first used in the present century, the principles on which the practice is based are very old. The spread of aromatherapy has followed the westward course of civilization, beginning in the ancient cultures of Egypt, China, India, and Persia.

According to the orthodox view of history, civilization began with the ancient Egyptians, some 5300 years ago (Tisserand, 1988b). The oldest pyramid in Egypt, the Step Pyramid, was built in the third dynasty, around 3,000 BC, by King Zoser. Zoser had extensive medical knowledge, but his chief architect, a man named Imhotep, was also a

famous physician. Imhotep is thought to be the grandfather of aromatherapy as he infused oils and aromatic unguents in the course of treating his patients.

The ancient Egyptians made pills, powders, suppositories, ointments, and pastes from trees, plants, animal, and mineral substances (Damian & Damian, 1995; Davis, 1996; Lavabre, 1990). One of the few surviving medical papyri is the Papyrus Ebers. The papyrus is full of recipes and remedies for all kinds of ailments, and the methods of application used are not very different from those used in herbal medicine and aromatherapy today (Tisserand, 1988b). Aromatics were often used, although there is much debate about whether the Egyptians knew how to distill essential oils from plants. Probably, the very earliest use of aromatics was as incense. There is no mention of distillation in the earliest documents, but there is evidence that by the third century BC, the Egyptians had a primitive form of distillation (Davis, 1996).

A little further East, the Babylonian doctors recorded detailed prescriptions and formulae of common herbs on clay tablets. Unlike the Egyptians who described the quantity of the herb to be used, the Babylonians carefully described when the remedy must be prepared and taken.

The Greeks learned much from the Egyptians, but made further discoveries of their own. They further developed the use of aromatic oils and ointments and employed them in medicinal and aesthetic ways (Tisserand, 1988b). They found that odors of certain flowers were stimulating and refreshing while that of others were relaxing and sedating (Davis, 1996). They used olive oil to absorb the odors of the flower petals, and found medicinal and cosmetic purposes for the perfumed oil. Greek soldiers went to

battle with an ointment made from myrrh that was used for the treatment of wounds. Hippocrates, a Greek and the father of medicine, used poultices and fumigations regularly as part of his treatments.

The works of Hippocrates, Galen, and Dioscorides, all Greek physicians, were translated into Arabic languages, and after the fall of Rome, surviving Roman physicians fled to Constantinople with their books. The Arab world then came to know and practice the remedies discovered by the Greeks and the Romans.

The Arab physicians put their knowledge of herbal medicine to use and many of them wrote books on herbal formulae (Davis, 1996). The greatest of these Arab physicians was Abu Ali al-Hysayn ibn Abd Allah ibn Sina who lived between 980 AD and 1037 AD and who is known to the Western world as Avicenna. He left valuable written records describing over 800 plants and their effects on the body. He described plants that are used in modern aromatherapy including lavender, chamomile, and rose. His greatest contribution, however, was perfecting the process of distillation. This method is, to this day, the preferred method for producing essential oils. Small pieces of plant material and water are put into a container. The content is heated and the oil droplets are carried by steam into a tube cooled by cold water, which carries the content into a receptacle. The receptacle is filled with water, which allows the lighter oil to float on top. The oil that is collected represents the essential oil of the particular plant (Fischer-Rizzi, 1990).

Essential oils, or essences as they are often called, are the odoriferous, volatile liquid components of aromatic plants (Wildwood, 1991). They accumulate in specialized

cells or in specific parts of the plant. They may be found in the petals, leaves, wood, fruit, seeds, roots, rhizomes, resins, and gums of plants and flowers, and sometimes in more than one part of the plant. Lavender, for instance, yields an essential oil from the flowers and the leaves.

By the 12th century, essential oils were used all over Europe. Crusading knights brought back both the essential oils and the knowledge of how to distill and use them. The invention of printing made it possible to disseminate this knowledge of herbals. Women made all the remedies for home use, including pomanders, lavender bags, and other herbal sachets. Apothecaries or pharmacies sold more complex remedies. Little bouquets of aromatic herbs were carried in public places to ward off infection.

In the 13th and 14th centuries, Italy monopolized the thriving Eastern trade established during the Crusades. The guilds, composed of grocers, spicers, apothecaries, perfumers, and glovers, controlled the import of large quantities of spices and essential oils used to disinfect cities against the Plague and other illnesses (Keville & Green, 1995). An indication of the antiseptic properties of essential oils came from the apparent immunity of many perfumers to the Plague and cholera that swept Europe during the Middle Ages.

The number of plants distilled expanded in the 16th century, and many references on herbals and the art of distillation appeared. In 1732, an Italian perfumer based in Cologne produced aqua admirabilis, a blend of neroli, bergamot, lavender, and rosemary. French soldiers stationed there named it eau de Cologne. The blend was splashed on the skin and used for treating sore gums and indigestion (Keville & Green, 1995).

By the 17th century, chemists started to research the active ingredients of the plants, and they identified many substances, including morphine, quinine, and atropine. This search for active ingredients was leading away from the use of whole substances in a natural way. Essential oils continued to be used, but were not as popular, as the medical practitioners began to use the drugs that had the active ingredient. Gradually, essential oils began to be replaced by synthetic chemical equivalents.

In the East, however, there is an unbroken tradition of the use of plants for healing, especially in India and China. It is possible that the ancient civilizations of India and China were practicing some form of aromatherapy at the same period as the Egyptians (Tisserand, 1988b). In India, the use of plants reflects the religious and philosophic view of human beings as part of the changing process of nature (Davis, 1996). The medicinal plants of India eventually found their way into Western medicinal practice. Ayurvedic medicine, which is the traditional form of Indian medicine that emphasizes the use of essential oils of plants, is growing in popularity in the West.

The Chinese have used plants for thousands of years, the earliest records found in the Yellow Emperor's Book of Internal Medicine, dating from more than 2000 years BC (Keville & Green, 1995). This reference describes the various uses of aromatic herbs.

In the 19th century, two important changes occurred in the Western world that affected the future of fragrance and scents. The 1867 Paris International Exhibition displayed perfumes and soaps apart from the pharmacy section, and the branch of "cosmetics" was formed. Even more significant was the introduction of the first synthetic

fragrance, coumarin, in 1868. Other synthetic fragrances followed, like musk, vanilla, and violet. These were the first perfumes that were unsuitable for medicinal use.

Practitioners of allopathic medicine began to rely on drugs, which are laboratory formulations of the plants' active ingredients. The use of essential oils for therapeutic purposes was slowly replaced by the use of synthetic drugs.

History of Aromatherapy

France became the leader in rediscovering the therapeutic uses of fragrance. Rene-Maurice Gattefosse first coined the term "aromatherapie". His interest in therapeutic oils began by accident. He was working in his family's perfumery laboratory when an explosion occurred, which severely burned his hand. He plunged his injured hand into a container of lavender oil and the hand healed quickly with very minimal scarring (Keville & Green, 1995). Gattefosse also found that many of the essential oils used in his family's business were better antiseptics than the chemical antiseptics being added to the same products. He performed numerous research studies on the various essential oils, published a scientific paper in 1928, and a book on the subject in 1937 (Gattefosse, 1990).

By the 1960s, Gattefosse's work influenced the French doctor, Jean Valnet and the Austrian-born biochemist, Madame Marguerite Maury. As an Army surgeon in World War II, Dr. Valnet used essential oils such as thyme, clove, lemon, and chamomile on wounds and burns, and later found fragrances successful in treating psychiatric disorders, despite the skepticism of the hospital staff (Davis, 1996; Keville & Green, 1995; Valnet, 1990). Largely as a result of the work of Dr. Valnet, there are today,

approximately 1,500 physicians who routinely prescribe essential oils in France (Damian & Damian, 1995).

One of Dr. Valnet's students, a French biochemist, Marguerite Maury, contributed a more personalized approach to aromatherapy. She emphasized the external use of essential oils in massage and proposed the concept of "individualized prescription," that is, a blend of essential oils that would harmonize the physical, psychological, and spiritual nature of the patient, thereby balancing the whole person (Maury, 1964).

Today, aromatherapy research continues to flourish and the practice of aromatherapy is considered "traditional" or "conventional" in France. Other countries, like England, are following suit.

Aromatherapy Research

The body of research on aromatherapy is limited, considering that it has a history that can be traced back to the ancient Egyptians. There is widespread belief that aromatherapy enhances well being, relieves stress, promotes sleep and is effective in diseases such as migraines, digestive disorders, moderate anxiety or depression, minor aches and pains, skin problems, and minor infections such as thrush and cystitis (Trevelyan, 1993). Much of the research in support of such belief is anecdotal (Passant, 1990; Tattum, 1992; Wise, 1989). There have been few objective studies to evaluate the effects of aromatherapy.

Research on aromatherapy is concentrated on two aspects: (a) the physiology of smell and aromatherapy (Hines, 1977; Smith, Van Toller, & Dodd, 1983), and

(b) clinical applications of selected essential oils to specific diseases like vaginal infections, systemic infections, and common foot problems (Belaiche, 1985; Blackwell, 1991; Kabara, 1984; Maruzella & Henry, 1958; Pena, 1962; Walker, 1972). The therapeutic properties of essential oils were investigated on a limited scale in England, Italy and France, but much of the research has not been translated into English.

References to aromatherapy studies made under standardized conditions are rarely found in the literature. This review will focus on aromatherapy research studies that address the independent variables of anxiety and sleep quality and the use of lavender, which is the essential oil selected for this study.

Aromatherapy and Anxiety

Dunn, Sleep, and Collett (1995) compared the differences in physiologic stress indicator scores (systolic blood pressure, heart rate and respiratory rate) and behavior scores (anxiety, mood and coping) among three treatment groups. The study involved randomly assigning 122 intensive care unit (ICU) patients to receive either massage (light effleurage strokes with grapeseed oil as lubricating medium), aromatherapy massage (light effleurage strokes with essential oil of lavender as lubricating medium), or a period of undisturbed rest of at least 30 minutes. Patients received a minimum of one and a maximum of three sessions of the assigned therapy. The researchers found that patients who received aromatherapy massage reported significantly greater improvement in their mood and perceived levels of anxiety ($F = 5.73$, $df = 2$, $p = .05$), but there was no difference between groups in the physiologic stress indicators. They also found that the patients in the aromatherapy group reported feeling more positive immediately following

the therapy; although they reported that this effect was neither sustained nor cumulative. Limitations of the study include the use of apparently inappropriate statistical analysis (e.g. multiple t-tests and chi square) and failure to perform Bonferroni adjustment to control the experiment-wise error rate. Split-plot factorial would have been more appropriate to examine differences in the physiologic stress indicator and behavioral scores among the three groups over time.

Stevensen (1992) conducted a study in the intensive care unit to examine the effects of aromatherapy foot massage on physiological variables such as systolic, diastolic and mean blood pressure, heart rate, and respiratory rate; and level of anxiety as measured by a score on a modified Spielberger questionnaire. The trial involved 100 patients randomly assigned to one of four groups: a control group with no intervention for a 20-minute period, a control group where patients received a 20-minute chat without tactile input, an experimental group where patients received a 20-minute plain vegetable oil foot massage, and an experimental group where patients received a 20-minute neroli essential oil foot massage. Each group was assessed on the physiologic variables and the psychological variable, level of anxiety, before and after the 20-minute intervention and at controlled intervals over the next several hours. On the fifth post-operative day, a follow-up questionnaire was given to patients assigned to the two massage groups asking patients about perceived benefits of the massage and duration of the benefits, if any.

The researcher found significantly better short-term psychological results in the two massage groups, than the two control groups, but no significant differences were

found between the plain vegetable oil group and the essential oil group. There were no significant differences in the physiological variables between any of the groups.

On the fifth day, however, there was a significant reduction in anxiety in patients who received the neroli oil foot massage compared to the plain oil group. The patients who received the aromatherapy foot massage found the effects more relaxing, calming, and restful and more sustained than the plain oil group. No statistics, including probability values, were reported in this study. The study was published in the "Short Reports" section of the Nursing Times (Stevensen, 1992).

Aromatherapy and Sleep

In a small (N=4) preliminary study testing the effect of lavender on sleep in the elderly, Hardy, Kirk-Smith, and Stretch (1995) measured the hours of sleep of each of four psychogeriatric patients for six week. The study consisted of three phases. Phase 1 monitored the effects of common sleep medications like Temazepam, Promazine, and Chlormethiazole on the dependent variable of hours of sleep. The researchers did not clarify how the variable, hours of sleep, was determined. After two weeks of measurement, medication was withdrawn and the middle two weeks of testing commenced (Phase 2). For the final two weeks (Phase 3), ambient lavender oil was diffused into the ward with an odor diffuser. Measurements of the dependent variable were again performed. The study revealed that the amount of time spent asleep was significantly reduced when the medications were withdrawn, but the amount of time asleep returned to the same level when the ambient odor was introduced. The researchers performed statistical comparisons between the scores of the four patients over the three

phases and found significant results (Patient 1 $p < 0.005$, Patient 2 $p < 0.010$, Patient 3 $p < 0.005$, Patient 4 $p < 0.025$). However, posthoc comparisons indicated that pairwise differences between Phases 1 and 3 were not significant. The amount of time spent asleep during lavender inhalation was not significantly different from the amount of time spent asleep on sleep medication. They also reported that the patients were less restless during sleep induced by the lavender oil. The results were preliminary, being based on only four patients. No statistics or significance values for the posthoc differences were reported.

Studies on Lavender

There are three species and one hybrid of the essential oil lavender: *Lavandula augustifolia*, *Lavandula burnatii*, *Lavandula latifolia*, and *Lavandula stoechas*. *Lavandula augustifolia* is the most commonly used oil and is known to be one of the safest (Maury, 1964; Tisserand, 1988a). There is no record of any adverse reaction to *Lavandula augustifolia* (Tisserand, 1964). This species is safe to use on babies, pregnant women, and critically ill patients (Blackwell, 1991; Buckle, 1993).

Lavandula latifolia is known to be a stimulant and expectorant. This species has traditionally been used in veterinary medicine. *Lavandula burnatii* is a hybrid, a cross between augustifolia and latifolia. This hybrid is used primarily in the perfume industry, but it is chemically very similar to augustifolia. *Lavandula stoechas* has no known therapeutic or practical application.

Buckle (1993) was interested in disproving the hypothesis that aromatherapy using topical application of oils is effective purely because of the touch, massage, or

placebo factor. The study design was a randomized double blind trial of two essential oils (*Lavandula augustifolia and Lavandula burnatii*) topically applied to 28 post-bypass patients. Measures for physiologic parameters (BP, heart rate, and respiratory rate), memory, coping and anxiety were obtained before and after treatment with one of the two essential oils. Treatment consisted of massaging one of the two oils on the second and third post-operative days on the patient's feet, legs, hands, arms, and forehead. Treatment took 20 minutes and measurements were done after 10 minutes to allow the essential oils to reach the brain.

Using chi square analysis, *Lavandula burnatii* was found to be more effective than *Lavandula augustifolia* in alleviating anxiety ($p<.10$). The author posits that *Lavandula burnatii* was found to be more effective because it contains a higher percentage of camphor, which is highly volatile. Contamination of results due to the inhalation of the essential oil could not be ruled out.

The results, as reported, are to be viewed with caution, as the data were interpreted using a high level of significance which could lead to the possibility of making a Type I error (e.g. use of $p < .10$ rather than .05 or .01). No corrections were made for one of the cells having less than five subjects. In addition, the author, in an effort to control variability in technique, performed the intervention on all the patients. A repeated measures ANCOVA approach to statistical analysis may have yielded more reliable results.

Research on aromatherapy is largely composed of studies that have small sample sizes and unreported power. There is a need for studies that have sound methodology.

How Aromatherapy Works

The exact mechanism by which aromatherapy works is as yet unknown. The outcomes attributed to aromatherapy are believed to be affected by different factors: the purity of the essential oil, method of extraction and intactness of the olfactory and neurological systems (Damian & Damian, 1995; Lavabre, 1990; Worwood, 1996).

A pure essential oil is the condensation of a plant's vital essence. This essential oil is what gives the plant its fragrance. The vital essences of plants are converted into pure essential oils and aromatic hydrosols by the process of steam distillation (Damian & Damian, 1995) (See Figure 1).

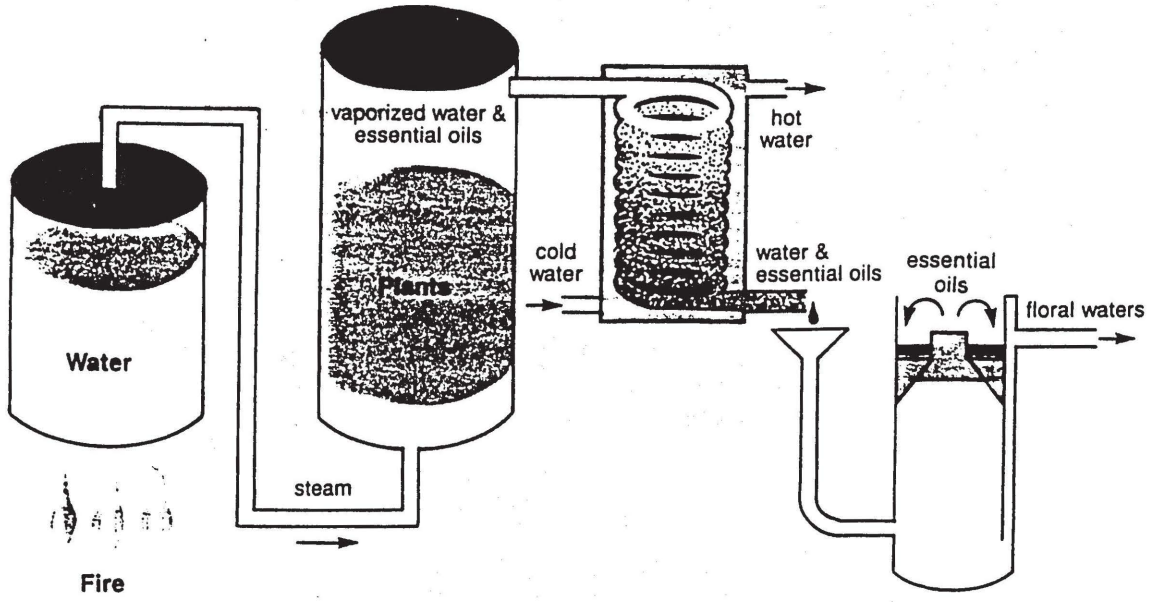


Figure 1. The Steam Distillation Process
Note. From Aromatherapy Workbook (p. 18), by M. Lavabre, 1990, Rochester, Vermont: Healing Arts Press. Copyright 1990 by Marcel Lavabre. Reprinted with permission.

Most essential oils are colorless or pale yellow; some are highly pigmented. Essential oils are highly concentrated but are not oily. They are fat soluble, rather than water soluble, thus allowing for easier cutaneous penetration. Essential oils are highly volatile . Essential oils can be absorbed orally, through ingestion to the stomach; cutaneously, through massage; and through inhalation by the nose and the lungs. The physiological and psychological pathways of aromatherapy are illustrated in Figure 2.

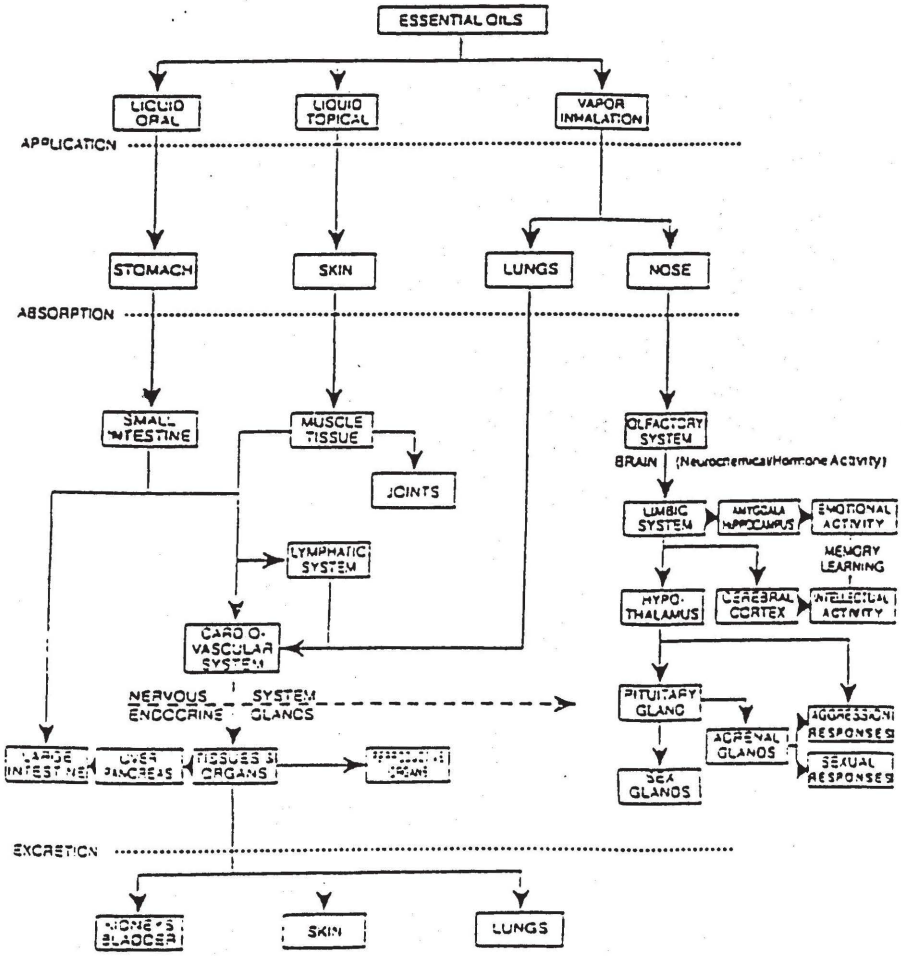


Figure 2. Physiological and Psychological Pathways of Aromatherapy
Note. From Aromatherapy: Scent and Psyche (p. 55), by P. Damian & K. Damian, 1995. Rochester, Vermont: Healing Arts Press. Copyright 1995 by Peter and Kate Damian. Reprinted with permission.

Anatomy and Physiology of Smell

The nose is the primary organ of smell (See Figure 3). The nose contains the olfactory epithelium, an area of special mucous membrane located at the roof of the inner nasal cavity. Olfactory nerves, neurons connected to the olfactory bulb located above the epithelium, protrude into the epithelium and project clusters of olfactory cilia. Olfactory cilia are microscopic hair endings found at the tip of each tiny nerve that are designed to detect incoming odorant stimuli.

There are three stages in the process of smelling. The process begins with the *reception* of the odor molecules. Odorant stimuli entering the nose penetrate and dissolve into mucus and are detected by the olfactory cilia. Odor *transmission* occurs when the message is fired to the right and left olfactory bulbs, located above and behind the nose at the base of the brain. The neurons respond to the odorant and trigger electric nerve transmissions to the olfactory bulb. The nerve signal entering the bulb then travels along the olfactory tract into the brain. At this point, a variety of cells and neurons interpret, amplify, and transmit the message to the limbic system. Perception takes place when the message is received by the hypothalamus. The hypothalamus then sends the information to other parts of the brain including the olfactory cortex, the thalamus, and the neocortex (Keville & Green, 1995).

Until very recently, the exact mechanism of how olfactory cells are stimulated or fired by a specific odorant or how an odorant molecule is recognized remained unknown. Two mechanisms to explain odor encoding or recognition, the ability to recognize certain odors, are found in the literature.

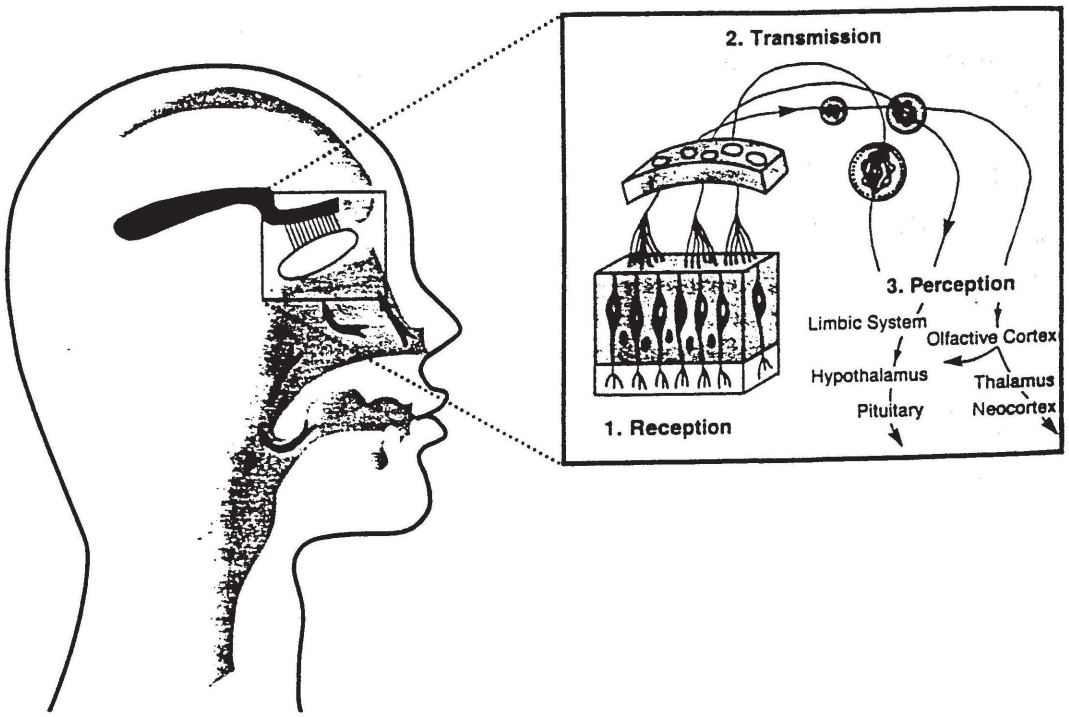


Figure 3. The Anatomy of Olfaction

Note. From Aromatherapy Workbook (p. 10), by M. Lavabre, 1990, Rochester, Vermont: Healing Arts Press. Copyright 1990 by Marcel Lavabre. Reprinted with permission.

The first theory of odor recognition involves odorant-specific receptors, that is, specific receptors within each olfactory neuron respond to specific odorant molecules (Damian & Damian, 1995). Several proteins have been found in the olfactory cilia, hairlike projections along the respiratory tract, which contain specific receptors that react to specific odors. After entering the body through the nose, the odorant stimulus is bound to its specific receptor. After the odorant is bound to its receptor, the receptor activates a protein that sequentially activates the release of thousands of odor-specific enzymes. These enzymes, in turn, stimulate sensory neuron cells to transmit signals to the brain via the olfactory bulb and tract. The brain interprets the transmission signals originating from the specific sensory cell as evidence that a particular odorant has been encountered.

The simplified process described above is an abbreviated version of the more involved biochemical process that occurs. Complex odors may activate various sensory cells simultaneously, sending the brain numerous signals in combination that it processes and identifies.

A second, more popular theory about odor recognition arose from research on locusts. The locust brain is considered ideal for olfactory research because the olfactory antennal lobe of the locust has approximately 800 projection neurons that respond to specific odorant stimuli through oscillating and dynamic neural patterns. Recent research focusing on the locust brain reveal that specific odorant molecules evoke stimulus-specific activity in dynamic ensembles of transiently synchronized neurons (Wehr & Laurent, 1996). Odor recognition is thought to be due to deterministic and stimulus-specific sequential activation of groups of neurons. Wehr and Laurent also propose that the brain assigns meaning to the pattern, which aids in reliable and rapid identification of the odorant stimulus.

Smell is the only sense that has a direct access and route to the brain; taste, touch, sight, and hearing arrive at the limbic system of the brain through indirect pathways. The path of an odor stimulus leads into the nose, the olfactory bulb, the olfactory tract and then directly into the limbic system of the brain. The limbic system is that part of the brain that is believed to interpret the odor stimulus. It is also thought to be the center for anxiety and sleep.

The Limbic System

The limbic system was originally called the rhinencephalon, the "smell brain." In the late nineteenth century, it was renamed "le grand lobe limbique" by the French anatomist Broca (Damian & Damian, 1995). The limbic system is a complex ring of brain structures and interconnected pathways arranged into fifty-three regions and thirty-five associated tracts (See Figure 4). The limbic system and hippocampus act as central switchboards that coordinate all sensory inputs, including the sense of smell, into a whole.

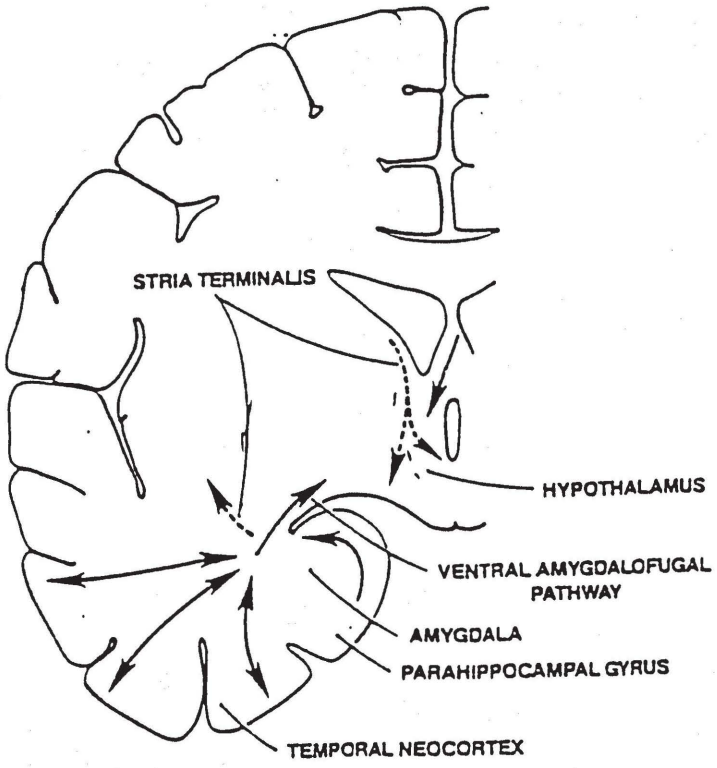


Figure 4. The Limbic System
Note. From Essentials of Clinical Neuroanatomy and Neurophysiology (p. 209), by S. Gilman and S. Winans Newman, 1996, Philadelphia: F.A. Davis Company. Copyright 1996 by F.A. Davis Company. Reprinted with permission.

How sensation is perceived is a matter of much debate. There are two schools of thought as to how a sensation, such as smell, is perceived and acted upon by the person. The two views about sensory perception are the Standard view and the New view (Cytowic, 1993). A review of the Standard view is useful to differentiate it from the New view, which is still not widely accepted.

The Standard View of Brain Function

The three primary concepts underlying the standard view of brain function are that information flow is linear, physical and mental functions can be localized into a specific part in the cortex of the brain, and the cortex is the organ functioning at the highest level, dominating everything else below it (Cytowic, 1993). According to the Standard view of brain function that originated in the nineteenth century, the flow of nervous impulses, including the flow of energy emitted by stimulation of a sense organ, is thought to be linear. The flow of incoming sensory impulses is in a hierarchical direction. At each step in the hierarchy, the stimulus is interpreted, eventually ending in interpretation at the cortical level. To be able to sense something, the first step is to transform different types of energy, either electromagnetic (vision), mechanical (hearing and touch), or chemical (taste or smell) into nervous impulses (Cytowic, 1993). These impulses travel to different stations in the brainstem and thalamus and from there to progressively more complex relay stations of the cortex. The cortex pulls external stimuli from the stream of nerve impulses in a sequential manner. The patterns are then

assembled in the cortex as a conscious experience and the sensation is perceived and identified as a specific stimulus in the external world that has affected the sense organ.

Localization of the function is the second major assumption of the Standard view (Cytowic, 1993). The brain is thought to be divided into different lobes according to function reflecting one-to-one mapping. For example, the occipital lobe is the structure in the brain that is solely concerned with perception of the sense of sight. This view asserts that the different brain structures are "control centers" for specific functions. For example, the cortex is believed to be the control center for intelligence and rational thought. The cortex is the largest of all brain components and architecturally the most complex structure; however, in terms of evolution, it is the youngest structure of the brain. The cortex is large, cellularly complex, accessible, and far more highly developed in humans than in animals. Because of these reasons, proponents of the Standard view have identified the cortex as that which differentiates humans from animals (Cytowic, 1993).

The concept of a triune brain or three-in-one brain was proposed by MacLean (1990). He theorized that the brain is composed of three systems, all different in age of evolution, and each responsible for a different category of behavior. The oldest is the reptilian brain that is concerned with self-preservation. The reptilian brain includes the brainstem and basal ganglia. The paleo-mammalian brain then evolved later and is concerned with preservation of the species. These species-protecting activities include sex, procreation, socialization, parenting, audiovocal communication, and play (Cytowic,

1993). The structures comprising the paleo-mammalian brain are collectively known as the limbic system. In humans, the limbic system represents the emotional brain.

The third structure, the newest of the three brains, is the neo-mammalian brain, which is composed mostly of the cortex, which, in turn, is viewed as the dominating force in the brain. The triune brain concepts fit the framework of the standard view of brain function in that the cortex is given primary importance.

The third tenet of the standard view is the assumption that the cortex is the seat of reason and the mind, and that reasoning and sentience are human qualities (Cytowic, 1993). The cortex is believed to be the brain's most important part because it is the seat of consciousness, mind, reason, and reality. Anything located below the cortex is believed to be literally subservient or unimportant.

The three tenets described above are the hallmarks of the Standard view of brain function. However, the Standard view of how the brain works is no longer adequate in explaining certain phenomena, including how the sensory stimuli of smell and taste occur. Smell and taste sensations are not processed in the cortex. Instead of addressing this flaw, proponents of the Standard view dismissed smell and taste as less important than sight, hearing, and touch (Cytowic, 1993). The New view of brain function evolved from the need to explain phenomena that could not be accounted for by the Standard view.

The New View of Brain Function

The New view of brain function has five major tenets (Cytowic, 1993):

1. The flow of neural impulses is not linear, but parallel and multi-modal, including transfer of information outside of nerve pathways.

In contrast with the Standard view, there is no such thing as a hierarchy of pathways as would be if the transfer of information were strictly linear. Stimuli are processed simultaneously and over many hormonal, peptide and enzyme circuitries in addition to nerves and synapses (Agnati, Bjelke, & Fuxe, 1992). This method of stimuli transfer is called "volume transmission." Volume transmission means that information can be transmitted through the entire body not only by neurons, axons, and synapses, but through the extracellular fluid that surrounds the whole system itself. The multi-modal or "multiplex" nature of the circuitry denotes the abundance of alternate routes. The multiplex ways of transmitting information in the brain are parallel, moving forward, and moving back (Cytowic, 1993).

In the human brain, the limbic system is the regulating system that organizes all the different means of information transfer. This fundamental deviation from the standard view of brain function is supported by new anatomic techniques that permit neurotransmitter molecules to be tagged with special dyes and followed through the circuitry at the cellular level. These anatomic studies support the new view of brain function in that the findings indicate that every single division of the nervous system, from the frontal lobes to the spinal cord, contains some component of the limbic system. The limbic system forms the emotional core of the nervous system (Armstrong, 1986).

2. Localization does not mean one-to-one mapping; that is, one organ is in charge of processing a specific sensory stimulus. Localization is now taken to imply one-to-many

mapping, which means that specific lobes in the brain serve many functions and that a given function is not localized in one area, but is distributed over many areas. The idea that multiple circuits or pathways rather than "control centers" support brain function such as emotion, was first suggested by James Papez in 1937 (Cytowic, 1993). The major structures that comprise the limbic system were linked by the Papez circuit, through which all aspects of emotion were manifest. This discovery led to the realization that emotion was not localized in a discrete control center but was spread out over many circuits or pathways. The linear idea of separate work stations gave way to the concept of multiple mapping in which a brain with multiplex communication channels can process information in many locations at once (Cytowic, 1993).

3. While the cortex organizes the model of reality and what exists outside of the person's body, it is the limbic brain that determines whether that information is salient or relevant.

For centuries, emotion was viewed as unimportant and primitive; and reason as significant and advanced. Emotions were considered subservient to rational thought. Proof of this assertion was the presence of the developed cortex that makes humans unique and superior to other mammals. But exhaustive anatomic studies (Armstrong, 1986; Gilling & Brightwell, 1982) showed that the cortical and limbic circuits have co-evolved, and that reason and emotion evolved in tandem. The two circuits, however, perform different functions. The cortical circuit grounds the stimulus in reality while the limbic circuit determines salience and importance of the stimulus (Cytowic, 1993). The limbic system is found in all mammals, but is fully developed only in humans, making

the human emotional system more powerful than that of other mammals. Determination of salience, relevance or meaning, not reason, is what makes humans unique (Cytowic, 1993). The reason is human behavior is determined by an interpretation of the salience of the stimulus, not the rationality of the stimulus.

4. Human behavior is ultimately controlled by an emotional evaluation of the stimulus, not a reasoned one. The role of the cortex is to analyze the external world and compare the experience or the sensation being perceived to what is known as reality. The role of the limbic brain, on the other hand, is to decide whether what is being perceived is both relevant and salient and in so doing, determines behavior or action. What moves humans to action is an emotional assessment, not a logical one (Cytowic, 1993).

5. Emotion plays a greater role than reason in differentiating humans from animals. The cortex and limbic system are interdependently connected and one system affects the other. In addition, the hippocampus, which is a large part of the limbic system, has been identified as a point in the brain where all information converges. All stimuli, whether they be sensory, visceral, or internal, must be filtered through the emotional limbic brain before being redistributed to the cortex for analysis. After the cortex has analyzed the stimulus, the limbic system determines whether the input is salient or not. If the input is determined to be salient, then the person will likely act; if not, the information will be ignored (Cytowic, 1993). In determining salience, the limbic system decides whether the information is relevant to the person's present and future condition. This ability to act on the salience or relevance of the input is what eventually differentiates humans from lower forms of mammals.

In addition to the finding that the cortex and limbic systems are connected in a reciprocal fashion, neuroanatomists, through advanced mapping techniques, have also determined that the cortex has more inputs from the limbic system than the limbic system from the cortex (Cytowic, 1993). The number and nature of the feedback circuits ensure that the influence of the limbic system is greater on the cortex than the cortex on the limbic system. Emotion, rather than reason, is primary.

A clinical example is given by Cytowic (1993) to illustrate this point. Patients in coma manifest the automatic or involuntary movements first, then voluntary movements and speech that is childlike and emotionally childish follow. If they continue to recover, they will eventually exhibit behavior that is more rational. To be able to achieve full recovery, they will need to exhibit emotional control because the intellect cannot be reclaimed unless the emotion recovers first (Cytowic, 1993).

The New view of brain function evolved as a result of advanced techniques in neuroanatomical mapping that made it possible to identify the direction, flow and scope of neurological connections and circuits. The advanced mapping techniques revealed that flow of information is non-linear, function is not strictly localized, the limbic system determines salience or relevance, behavior is ultimately determined by emotion, and that emotion, more than reason, determines a person's humanity (Cytowic, 1993).

Anxiety

May (1950) described anxiety as a feeling of uncertainty and helplessness in the face of danger, vague and objectless fear, and diffuse apprehension. Kolb (1968) viewed anxiety as a state of tension signaling potential or impending disaster, a warning of

danger from the presence of unacceptable internal attitudes that erupt into consciousness or action.

Anxiety has been conceptualized as having both stable and variable attributes. State anxiety may be transitory yet recurrent when evoked by certain stimuli. State anxiety is an attribute that is conceptualized as dynamic and changeable over relatively short periods of time and from one situation to another (Spielberger, Gorsuch, & Luchene, 1983).

Trait attributes, on the other hand, can be conceptualized and ingrained in the person, and can recur with some amount of predictability. These traits, as defined by Campbell (1963), refer to acquired behavioral dispositions. Trait anxiety refers to an attribute that is conceptualized as being stable with little variability.

Anxiety can produce an increase in sympathetic nervous system activity leading to an increase in cardiac workload (Zimmerman, Pierson, & Marker, 1988). In CCU patients, this increase in cardiac activity has a negative impact on patient condition. Anxiety may have subjective and physiologic manifestations (Clark, Fontaine, & Simpson, 1994). Subjective responses include a sense or unrealness, difficulty concentrating and remembering, and cognitive distortions, all of which can cause fear (Spear, 1996). Physical responses typically include increased pulse rate, blood pressure, and respiratory rate, a heightened startle response, abdominal distress and urinary frequency (Spear, 1996).

Anxiety is protective, and in small amounts, can sharpen mental capacities and increase productivity. Moderate to high levels of anxiety, however, have just the opposite effect. As anxiety levels increase, the patients become angry, confused, or highly distressed, and have difficulty concentrating, relaxing, and even coping (Spear, 1996).

In their seminal work on coronary care unit (CCU) patients, Cassem and Hackett (1971) followed 441 patients admitted to a CCU and found that the three most frequent reasons for referral for psychiatric consultation were anxiety, depression, and management of behavior. The earliest and most common psychological response to a myocardial infarction is anxiety (Vetter, Cay, Philip, & Strange, 1977). The anxiety response is usually focused on two issues: the feeling of impending doom, or sudden death, and the symptoms of impending death such as breathlessness, severe chest pain or complications such as dysrhythmias, and the need for cardioversion or pacemaker insertion (Cassem & Hackett, 1971). Weakness, which is a less obvious symptom, and one which is frequently overlooked, is a symptom that evokes much anxiety in the CCU population. Weakness usually marks the beginning of loss of control and is interpreted by patients to be proof of the gravity of their condition and irreversibility of damage to their hearts (Cassem & Hackett, 1971).

Several other factors may also contribute to increasing the anxiety of patients in critical care units, including admission to and transfer out of the unit, nature of the illness, environment, and the unit and staff routines (Cassem & Hackett, 1971; Davis, 1972). Visiting regulations, interrupted sleep, and noise all contribute to patients' anxiety (Hoffman, Donckers, & Hauser, 1978). Recurrence of symptoms such as pain or dyspnea may also increase anxiety in the CCU population (Froese, Hackett, Cassem, & Silverberg, 1974).

The average CCU patient is anxious on admission and that anxiety, on an average, persists through the first 48 hours of CCU stay (Cassem & Hackett, 1971; Thompson,

Webster, Crodle, & Sutton, 1987). The anxious CCU patient is at risk for autonomic arousal and long-term stress effects, which place additional stress on an already compromised heart. Emotional factors, such as anxiety, have been associated with increased incidence of cardiac complications and increased mortality rates (Hackett, Cassem, & Wishnie, 1968; Vetter, Cay, Phillip, & Strange, 1977).

The use of minor tranquilizers and hypnotics early in the hospital stay is standard treatment of anxiety in the CCU population (Zimmerman et al., 1988). Such medications are administered to reduce anxiety, but may produce undesirable side effects such as lethargy, confusion, or agitation (Niven, 1976).

Over the past five years, alternative and safe non-pharmacological treatments and their effects on anxiety in the CCU population have been explored, notably psychological interventions such as relaxation training and stress reduction techniques and music therapy (Hase & Douglas, 1987; Lueders-Bolwerk, 1990; Zimmerman, Pierson, & Marker, 1988). Hase and Douglas (1987) tested progressive muscle relaxation training (PMR) as a means to decrease the anxiety response in patients with myocardial infarctions. A convenience sample of forty adults admitted to a CCU with a first diagnosed episode of uncomplicated acute myocardial infarction were assigned to either a treatment group or a "no treatment" group. Subjects assigned to the treatment group received two cassette tapes, a cassette recorder, and headphones and were asked to listen to the tapes once a day. The Spielberger State-Trait Anxiety Inventory was completed on three occasions by and for all subjects: at the first meeting to obtain baseline data, on the day of discharge from the hospital, and between four and five weeks post-discharge.

The researchers reported significantly greater decrease in anxiety scores in the experimental group compared to the control group over time ($F = 3.924$, $df = 2, 56$, $p = .025$), using the multivariate repeated measures analysis of variance technique. The researchers noted that the experimental group had a decrease in state anxiety scores at discharge and at home but did not perform post-hocs to determine if there were significant differences between the three administration times. Limitations of this study include the relatively small sample size that severely limits power and the relatively uncomplicated nature of the subjects' condition that limits generalizability of findings. The convenience method of sampling used is also a limitation of the study.

Zimmerman, Pierson, and Marker (1988) examined the effects of listening to music on self-reported anxiety of patients admitted with suspected myocardial infarction to a CCU. Seventy-five patients were randomly assigned to one of three groups : listening to music, to "white noise," (e.g. repetitive sounds such as ocean sound) and to a control group. Subjects in the two experimental groups (self-selected music and "white noise") listened to the stimulus via headphones. Subjects in the control group were allowed 30 minutes of quiet and uninterrupted bedrest. The Spielberger State Anxiety Inventory was administered before and after each testing session. Physiologic parameters of anxiety including blood pressure, heart rate, and digital skin temperature, were also measured at baseline and at 10-minute intervals for the 30-minute session.

Using analysis of covariance (ANCOVA) with pre-test state anxiety scores as the covariate, the researchers found no significant differences between groups in anxiety scores. No statistically significant differences were found among the three groups in

systolic or diastolic blood pressure, heart rate, or skin temperature, using repeated measures ANOVA. No statistics were reported for the physiologic parameters, only a statement referring to the lack of significant differences was noted. Because no statistical differences were found in the physiologic parameters, the researchers then performed repeated measures ANOVA analyses on total scores (combined group scores) for the four time intervals on the physiologic parameters. They found statistically significant differences for systolic blood pressure ($F = 3.25$, $df = 3,72$, $p < 0.05$), diastolic blood pressure ($F = 2.78$, $df = 3.72$, $p < 0.05$), heart rate ($F = 3.84$, $df = 3,72$, $p < 0.05$), and skin temperature ($F = 9.58$, $df = 3,72$, $p < 0.001$). The above significant findings on the physiologic parameters over time, regardless of group, were interpreted by the researchers as an indication of the value of uninterrupted rest for patients in critical care units. The researchers failed to use appropriate statistical analysis and to determine power analysis to address the issue of adequacy of sample size. Split-plot factorial would have been more appropriate to examine the differences in physiological parameters between groups over time. The researchers also noted that the majority of subjects in all three groups had low baseline anxiety scores at the time of testing. They posit that the low anxiety score could be a reflection of the use of denial as a defense mechanism employed by CCU patients.

Lueders-Bolwerk (1990), in a study to investigate the effects of relaxing music on state anxiety in myocardial infarction patients, addressed the issue of low baseline anxiety scores by only including patients with anxiety scores of 40 or above on the State Trait Anxiety Inventory (STAI). Forty adult patients with confirmed diagnosis of

myocardial infarction were randomly distributed into two equal groups of 20: music group and nonmusic group. Subjects in the nonmusic group completed the STAI twice; once during the first 48 hours of admission and then upon the third or fourth day of hospitalization. The music group completed the STAI prior to the music intervention during the first 48 hours of admission, and after the final music session. The music group listened to three selected classical pieces at each session; each session lasting approximately 22 minutes. They listened to the music once during the day for three consecutive days. The subjects completed the STAI after the third session.

A significant difference was found between the posttreatment anxiety scores of subjects in the music group and the nonmusic group using a t test for independent samples ($t = -2.87$, $p = .007$). No significant difference was found in the pretreatment anxiety scores between groups. Significant differences were found between the pretreatment and posttreatment anxiety scores in both the music ($t = 10.26$, $p = .001$) and nonmusic ($t = 3.78$, $p = .001$) groups, using t-tests for dependent samples. State anxiety decreasing in both groups, the researchers note, may be due to improvement in the patient's condition, the effect of sedative medications, therapeutic interventions, and coping mechanisms. As with the previous study, the more appropriate test would have been the split plot factorial ANOVA to determine differences between the two groups over time.

Relaxation training and therapeutic music have yielded positive results although the results would have to be interpreted with caution due to inadequate sample sizes and inappropriate statistical tests. The identification of anxiety as a major factor in the care of

the CCU patient supports the continuing search for interventions that might reduce it (Lueders-Bolwerk, 1990).

Sleep

Sleep is a period of natural suspension of consciousness during which restorative processes occur within the body (Hodgson, 1991). It is considered a necessary factor in recovery from illness (Sanford, 1983). Sleep deprivation can lead to aggressiveness, irritability, disorientation, hallucinations, impaired respiratory muscle function, and possibly decreased immune response (Chen & Tang, 1989; Hartmann, 1973; Palmblad, Petrini, Wasserman, & Akerstedt, 1979).

Sleep is known to be an active process, although it appears passive. The modern conceptualization of sleep as an active and functional process stemmed from a study by Loomis, Harvey, and Hobart (1937). These researchers discovered different states of sleep (wakefulness, non-REM sleep and REM sleep) based on the amplitude and activity of the brain during sleep. The first state of sleep, non-rapid eye movement (N-REM) is a period of relative inactivity. N-REM can be further subdivided into four stages, each stage increasingly deep. Stage 1 is the period of lightest sleep and is characterized by low voltage, desynchronized electroencephalogram (EEG), and a suppression of the autonomic responses of heart rate, blood pressure and sweating. Stage 2 is characterized by 12 to 14 sleep spindles and high voltage K complexes appear. Stage 3 is when delta waves, characterized by slow and deep waveforms, become apparent and there is a decline in physiologic response to external stimuli. Slow respiratory and pulse rates are accompanied by a decrease in temperature and blood pressure. Stage 4 is the deepest

stage where delta waves predominate. There is a considerable decline in physiologic reactivity to stimuli and the sleeper is difficult to arouse. While the first state of sleep is a period of relative inactivity, the sleeper is active in the second state of sleep.

The second state of sleep is rapid eye movement (REM) sleep or paradoxical sleep. It occurs during entry to each new sleep cycle. The eyes move rapidly, the rest of the body is relaxed, and dreaming occurs. During this state, the sleeper is difficult to arouse and has bursts of accelerated heart rate and rapid breathing.

Following Stage 4 of NREM sleep, sleepers start to reverse through the stages of sleep. The sleep cycle is illustrated in Figure 5. A normal sleep cycle is completed every 60 to 120 minutes, averaging 90 minutes for adults, four or five times a night (Closs, 1988; Williams, R., Karacan, I., & Hursch, 1974).

The two stages of sleep, NREM and REM, have different functions. NREM sleep is believed to be necessary for physiological restoration, tissue replenishment and protein synthesis. REM sleep is needed for psychological restoration, maintenance of orientation, and emotional stability (Beck, 1992; Chuman, 1983).

Many bodily functions, including sleep, are regulated by an innate 24-hour cycle called the circadian rhythm (Thelan, Dain, & Urden, 1990). The circadian rhythm is controlled by an area in the hypothalamus called the "body clock" (Dorociak, 1990).

Hospitalization leads to sleep pattern disturbance as normal sleep/wakefulness patterns are disrupted by the physical and emotional responses to illness, drugs and treatments and changes in the environment (Beck, 1992). These sleep pattern disturbances have been associated with intensive care unit syndrome, mood changes,

irritability, aggressiveness, anxiety and decreased pain tolerance (Gerner, Post, Gillen, & Bunney, 1979; Kollar, Namerow, Pasnow, & Naitoh, 1968; Ross, 1965).

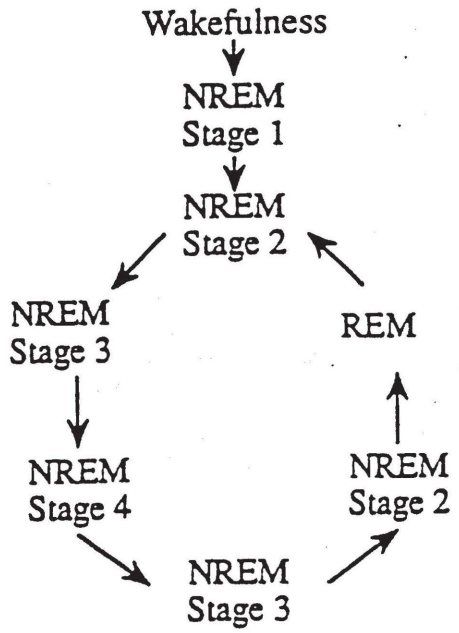


Figure 5. The Cyclical Nature of Sleep

Note. From Textbook of Critical Care Nursing: Diagnosis and Management (p. 129), by L. Thelan, J. Dain, & L. Urden, 1990, St. Louis, C.V. Mosby. Copyright 1990 by C.V. Mosby. Reprinted with permission.

Several researchers have examined the sleep patterns of patients in the intensive care unit, focusing on surgical patients or patients with respiratory disorders rather than coronary care patients (Helton, Gordon, & Nunnery, 1980; Jensen & Herr, 1993, Morath & Lynch, 1989; Schwab, 1994; Walker, 1972; Wood, 1993). These researchers found that patients in the intensive care unit were disturbed at least once, and sometimes as often as 14 times per hour. In an 8-hour sleep period, patients were interrupted between

five to 59 times (Woods, 1972). No complete sleep cycles were seen in any of the patients. Davidson (1990) reported that as little as 2.6 hours of sleep was common in critically ill patients. Frequently interrupted sleep leads to decreased quantity and quality of sleep. Since one sleep cycle usually takes 90 minutes to complete, patients are deprived of sleep stages 3 and 4, and REM sleep. It is believed that Stages 3 and 4 offer the most restorative value for the patient, therefore, interruptions in the sleep cycle exert a detrimental effect on health and recovery (Carola, Harley, & Noback, 1990).

Many factors are thought to contribute to poor sleep quality in these patients. Anxiety, pain, the strangeness of the critical care environment (e.g. monitors, alarms, lights, noise), the routine of staff (e.g. sleep interruption for assessment and medication administration), and even drugs, have all been identified as contributing to sleep pattern disturbances in the critically ill patient (Jensen & Herr, 1993, Schwab, 1994).

Only two studies were found in the literature describing sleep patterns of CCU patients (Broughton & Baron, 1978; Karacan et al., 1974). Both studies had similar results and found that nocturnal sleep in this patient population was significantly disturbed within the first 48 hours following myocardial infarction. There was increased wakefulness, low REM sleep percent, long REM latency, decrease in the number of REM periods, increased awakenings, increased stage shifts, and decreased sleep efficiency. Broughton and Baron (1978) concluded that the total biological and psychological stress associated with the myocardial infarction was the major cause of sleep disturbance, and not the highly unusual environment, the drug regimen, or bed rest as evidenced by no

differences noted in the sleep patterns of the patients when they transferred out of the critical care unit and were subsequently admitted to the floor.

Most of the studies used polysomnography to measure sleep quantity and quality. Although polysomnography strengthens the research design and is considered the gold standard in sleep measurement, nursing's focus is the human response and as such, it is essential that nurses continue to monitor sleep quantity and quality from the patient's perspective (Jensen & Herr, 1993). Snyder-Halpern and Verran (1987) defined terms associated with the subjective measurement of sleep. These terms include sleep depth, falling asleep, awakenings, return to sleep, and overall quality of sleep. Sleep depth refers to soundness of sleep, and correlates with Stages 3 and 4 NREM sleep. Falling asleep, or latency to sleep onset, is the time from the patient becomes still and the onset of the first sleep, and strongly correlates with Stage 1 NREM sleep. Awakenings imply returning from any sleep stage to the waking stage. Return to sleep is the total amount of time in minutes from awakening to returning to sleep. Sleep quality is the estimate of sleep along the dimensions of satisfaction, or disturbance, and correlates with Stage 2 NREM sleep.

All these studies note that sleep can be extremely difficult to achieve in the critical care setting and sleep deprivation can be a major problem in patients confined to these settings. Pharmacologic interventions, specifically hypnotics, are frequently prescribed to promote sleep in the critical care patient. Benzodiazepenes are the hypnotic agents most commonly administered to patients. They induce sedation and muscle relaxation. Unfortunately, benzodiazepenes exert a deleterious effect on the sleep cycle

(Schwab, 1994). Benzodiazepenes are unable to promote REM sleep and they suppress Stages 3 and 4 sleep while increasing Stage 2 sleep (Schwab, 1994).

Although pharmacological interventions are part of the standard treatment for sleeplessness, nonpharmacological options to enhance sleep should be considered and explored. Only one sleep-enhancement interventional study was found (Williamson, 1992).

Williamson (1992) investigated the effect of ocean sound (white noise) on the night sleep pattern of postoperative coronary artery bypass graft (CABG) patients after transfer from an intensive care unit. Night sleep pattern was measured as a score on a sleep quality self-report measure, the Richards-Campbell Sleep Questionnaire (RCSQ). A consecutive sample of 60 first time CABG patients was systematically assigned to one of two groups: the experimental group (receiving ocean sounds) and a control group (no exposure to ocean sounds). Subjects in the experimental group listened to ocean sounds for three consecutive nights posttransfer from the intensive care unit (ICU). Using ANCOVA with pretest scores as the covariate, the researcher found significant differences in five of six sleep variables between the experimental and control groups: sleep depth ($\underline{F} = 12.05$, $\underline{p} = .001$), awakening ($\underline{F} = 5.19$, $\underline{p} = .026$), return to sleep ($\underline{F} = 7.24$, $\underline{p} = .009$), quality of sleep ($\underline{F} = 9.50$, $\underline{p} = .003$), and total sleep score ($\underline{F} = 10.98$, $\underline{p} = .002$). Limitations of the study include inability to generalize to the population of CABG patients and absence of power analysis.

Many strategies for promoting sleep have been suggested. These include acoustic modifications in the structure of the unit, abandoning the routine practice of measuring

vital signs throughout the night or obtaining early morning chest x-rays or phlebotomy, planning nursing interventions to maximize uninterrupted sleep time (Schwab, 1994). In general, data demonstrating a relationship between specific interventions and sleep quality improvement in the critical care environment are lacking.

Summary

In summary, research on aromatherapy, anxiety and sleep in the CCU population has been limited. Sample sizes for many of the studies were small, thus limiting the usefulness of findings. The lack of interventional studies to alleviate the problems of anxiety and sleep in the CCU population was noted. There was a need to test interventions aimed at promoting anxiety and sleep, two recurring problems facing the CCU patient. Aromatherapy, a nonpharmacologic intervention, is a holistic strategy that has the potential to help alleviate these problems.

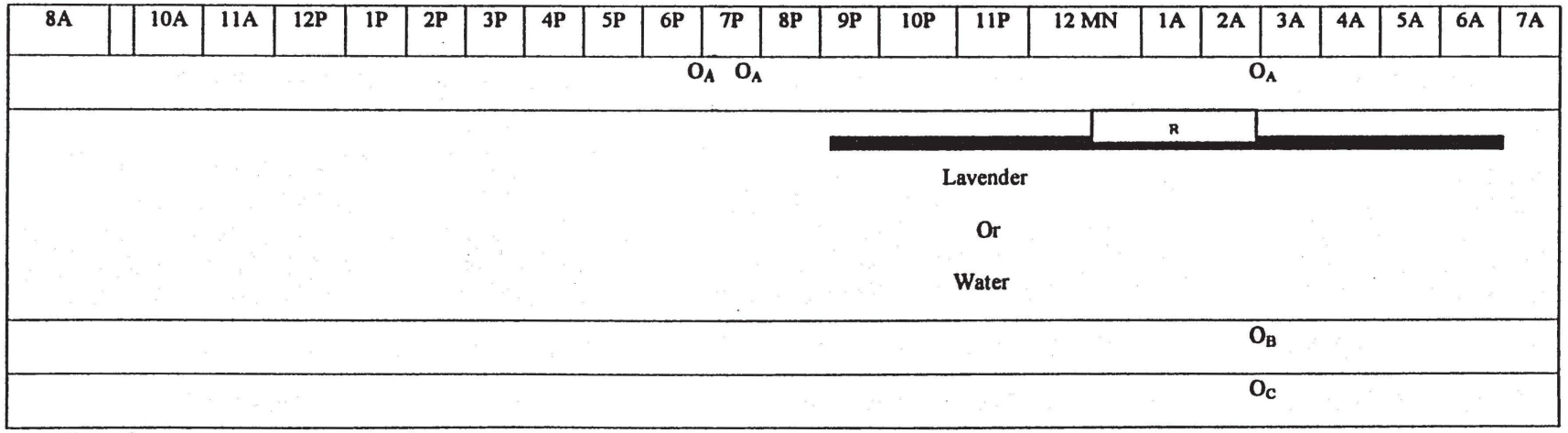
CHAPTER 3

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

A repeated measures intervention study design using the subjects as their own control was used for the present study to determine the interaction between the repatterning strategy of aromatherapy (independent variable) and the patient outcomes of anxiety and sleep quality (dependent variables). With this design, each subject serves as his/her own control during sequential treatments and control periods. This means that innate characteristics such as age, gender and genetic factors are not merely balanced, but actually eliminated as confounding variables (Hulley & Cummings, 1988). The repeated measures design is shown in Figure 6. The dependent variable, anxiety, was measured before the intervention, one hour and nine hours after the introduction of the intervention. The dependent variable, sleep quality, was measured nine hours after the introduction of the intervention.

Clinical studies such as the present study are fraught with methodological difficulties because so much of the environment cannot be controlled. Residual effects of the aromatherapy were controlled by the study design which allowed for 15 hours between interventions although six (6) hours is sufficient to totally disseminate the vapors (Tisserand, 1977). An extension of nine (9) hours was built into the design to ensure that cross-contamination does not occur.

A. Daily Intervention



Legend:

O_A = Spielberger State Anxiety Scale
O_B = Richards Campbell Sleep Questionnaire
O_C = Total Daily Anxiety and Sleep Medication Data Tool

R = Random assignment of treatment plans
R_x1 = Lavender at night
R_x2 = Water at night

B. Total Intervention

Subject	Day 1	Day 2
1	R_x1	R_x2
2	R_x2	R_x1

Figure 6. Repeated measures design for each day and total days intervention

There was one treatment with the essential oil of lavender (*Lavandula augustifolia*). Control treatment consisted of the use of water instead of lavender. Patients were randomly assigned to one of two Treatment Groups. The patients in the two Treatment Groups received the same treatments. Only the order in which the treatments were received by the patient, differed. Treatment Groups were designed to exert control over the variable of cross-contamination. The Treatment Groups are described in Table 1.

Table 1

Treatment Groups for Aromatherapy Study in CCU Patients

Night	Treatment Group 1	Treatment Group 2
First Night	one drop of lavender oil was applied to a cotton ball and fastened to the underside of the upper right hand corner of the patient's pillow case and kept there from 9:00 P.M. to 6:00 A.M. the following morning	one drop of water was applied to a cotton ball and fastened to the underside of the upper right hand corner of the patient's pillow case and kept there from 9:00 P.M. to 6:00 A.M. the following morning
Second Night	one drop of water was applied to a cotton ball and fastened to the patient's pillow as described above	one drop of lavender oil was applied to a cotton ball and fastened to the patient's pillow as described above

Each subject was tested for 2 consecutive nights. Each subject was asked to complete the Spielberger State-Trait Anxiety Inventory (STAI) (See Appendix A) three times within a 24-hour period. These tools were completed immediately before the treatment at 9:00 P.M., 30 minutes to an hour after the treatment between 9:30 P.M. and 10:00 P.M., and nine hours after the treatment at 6:00 A.M. the following day, for a total of six times over the two-day test period. All of the subjects completed the STAI (See Appendix A) over the three administration times. Each subject was asked to complete the Richards-Campbell Sleep Questionnaire (RCSQ) (See Appendix B) once daily, immediately upon arising in the morning, for a total of two times during the two-day test period. The RCSQ takes approximately three minutes to complete. Additional data were collected from the patient's medical record to determine patterns of medication use for anxiety and sleep.

Experimental control of the confounding variable of intake of medication for anxiety and sleep was not feasible and was believed to seriously deplete the sampling frame. The investigator also did not wish to limit generalizability of the findings only to patients who either have, or have not received medication for anxiety and/or sleep. Therefore, statistical control over the variable in question was planned to be performed through the use of analysis of covariance (ANCOVA) where the covariance is the amount and type of anxiety or sleep medication that the patient has received. This information was recorded and monitored on a daily basis for the two treatment days.

Setting

The study was conducted in the Coronary Care Unit (CCU) of a large 950-bed tertiary care hospital in Southeast Texas. The CCU consists of two separate but adjacent units of 10 beds each. Each bed is enclosed by fixed walls on three sides and a sliding glass door on the fourth side that opens up to the nurses' station. The sliding glass doors are usually kept open for ready access by CCU personnel; however, between the hours of 9:00 P.M. and 6:00 A.M., the glass doors of subjects' rooms remained closed during the course of the study except when health care personnel entered these rooms to deliver care. Patients are connected by leads to cardiac and hemodynamic monitors that emit audible warning signals in response to changes in patient condition. There is unrestricted airflow between patient rooms and the CCU nurses' station within each unit. The ventilation system within each unit is centralized but separate from other units.

Population and Sample

The population consisted of all CCU patients with a diagnosis of Rule/Out (R/O) myocardial infarction (MI), unstable angina, angina, or chest pain. A review of admission data during the three months preceding the study revealed that a monthly average of 30 patients were admitted to the CCU with these diagnoses.

Subjects were considered for inclusion in the study if they met the following criteria:

1. admitted to the CCU with any of the following diagnosis: R/O MI, unstable angina, angina or chest pain,
2. 21 years of age or older,

3. willing to participate in the study as evidenced by signing the informed consent,
4. able to speak, read, and understand English, and
5. have an intact olfactory sense tested by the Smell Test.

Subjects were excluded if they had chronic sleep problems (sleep apnea); any condition that has been reported to affect the sense of smell like Parkinson's, sinusitis, allergic rhinitis, nasal polyps, and diabetes; reported to be day sleepers, or declined to participate in the study.

Twenty-five patients were included in the study. The sample size for this study was based on power calculations of pilot study data using the Statistical Package for the Social Sciences (SPSS) (1990) for analysis of variance (ANOVA) for repeated measures using the multivariate approach. Estimated effect size, based on pilot study data, was moderate (0.4) ($\alpha = .05$). The sampling technique was systematic random sampling of patients meeting the study criteria. This method of probability sampling uses a random process to guarantee that each unit of the population has a specified chance of selection (Hulley & Cummings, 1988). The researcher at 7:00 P.M., reviewed a list of the patients admitted for the day. Every other patient who met the criteria was approached for inclusion in the study. If the patient agreed to participate in the study, the patient was randomly assigned to one of two Treatment Groups described in Table 1. Approximately ten patients per month fit eligibility criteria. Time of data collection was eight weeks.

Protection of Human Subjects

Permission to conduct the study was obtained from the Human Subjects Review Committee of Texas Woman's University. Agency permission for the study was

obtained from the Nursing Research Committee and the Institutional Review Board of the selected hospital (Appendix C). A written consent was obtained from the subjects that addressed potential risks and steps that will be taken to reduce the risks (Appendix D).

Potential risks to the subjects participating in the study include:

1. loss of privacy from intermittent presence at the bedside of the investigator,
2. loss of confidentiality,
3. allergic, noxious, uncomfortable or unpleasant response to lavender oil

The following measures were used to reduce potential risks to subjects participating in the study:

1. The investigator is an employee of the institution in which the study was conducted and works directly with unit staff; thus loss of privacy is minimized. The investigator only stayed in the patient's room when obtaining consent and when setting up the treatment.
2. Multiple intermittent and continuous caregivers are at the bedside. One additional intermittent person's presence was not likely to disturb the subjects.
3. Patient name and hospital identification number were recorded on a master roster of subjects for tracking purposes. Because the study extended over a two-day period, the ability to locate patients in the event of bed or unit transfer is essential. The master roster was kept in a locked place and destroyed upon study completion. All data collection instruments used the patient's assigned study code number; no names or personal identifiers were recorded.
4. Research materials were kept confidential and accessible only to the investigator.

5. Results were reported as aggregate data.

6. The study was terminated immediately if the subject reported an allergic, noxious, uncomfortable or unpleasant response to the aromatherapy treatment.

7. The patient was given the opportunity to withdraw from the study at any time without jeopardy to patient care from the institution.

Instruments

The instruments that were used for data collection in this study were the following:

1. STAI or S-Anxiety scale (Spielberger et al., 1983) (Appendix A),
2. RCSQ (Richards, 1985) (Appendix B),
3. Demographic Data Sheet (Appendix E),
4. Total Daily Anxiety, Sleep and Pain Medication Data Logs (Appendix F).

The instruments were used to collect demographic data, measure the dependent variables of anxiety and perceived sleep quality and to determine the amount and type of anxiety and sleep medication used by the subjects participating in the study.

The State Portion of the State-Trait Anxiety Inventory (STAI) or S-Anxiety Scale

The purpose of the STAI or S-Anxiety scale (Appendix A), designed for adolescents and adults, is to evaluate anxiety levels at the present moment, or state anxiety. The instrument is a 20-item test that may be completed in six to ten minutes. Each item is given a weighted score of one to four (1 - 4). A rating of four (4) indicates the presence of a high level of anxiety for ten items; a high rating indicates the absence of

anxiety in the remaining ten items. The scoring weights for anxiety-present items are the same as the numbers on the test form that are circled by the subject, and the scoring for the anxiety-absent items is reversed. The weighted scores for the 20 items are then added to obtain a total score. Scores can vary from a minimum of 20 (low anxiety) to a maximum of 80 (high anxiety).

According to Dreger (1978) and Chaplin (1984), the STAI is among the best of the standardized anxiety measures. More than 5,000 subjects were tested in the construction and standardization of Form Y. Spielberger and his colleagues began with an initial item test pool of 177 items taken from three existing anxiety scales: the Taylor Manifest Anxiety Scale, the Welsh Anxiety Scale, and the Institute for Personality and Ability Testing, Inc. (IPAT) Anxiety Scale. They subjected these items to a combination of rational, internal, and external test development procedures to insure that the content, consistency and correlates of the items were all acceptable (Spielberger et al., 1983). Dreger (1978) reports alpha reliability coefficients of 0.83 to 0.92 for state anxiety scores for the normative samples. Correlations with the IPAT Anxiety Scale (0.75), the Manifest Anxiety Scale (0.80), and the Adjective Check List (0.52) provide estimates of validity.

Test-retest correlations were based on testing done on high school graduates, adults, neuropsychiatric patients, and critical care patients. The STAI showed stability coefficients that were relatively low ranging from 0.16 to .62, with a median of .33. A reliable measure of state anxiety should reflect the influence of situational factors that

may be present at the time of testing, and because of this, low stability coefficients were expected for the scale (Spielberger et al., 1983).

Measures of internal consistency provide a more meaningful index of the reliability of the STAI than test-retest correlations because of the transitory nature of state anxiety. Overall, alpha reliability coefficients of .86 to .95 have been reported for the S-Anxiety scale (Spielberger et al., 1983). Psychometric testing of the instrument was done on the S-Anxiety scale by the researcher on CCU patients. Cronbach's alpha during psychometric testing was between .86 to .95 for the three administration times ($\underline{n} = 8$). During the pilot study, Cronbach's alpha for the three administration times was between .92 and .96. These alpha coefficients demonstrate adequate internal consistency as they are above .80 (Corcoran & Fisher, 1987; Nunnally, 1967).

In summary, the STAI has been found to be a valid and reliable tool to measure state anxiety in the coronary care population. Because of its excellent psychometric properties, the STAI was used in the present study.

The Richards-Campbell Sleep Questionnaire (RCSQ)

The purpose of the RCSQ (Appendix B) is to measure both qualitative and quantitative characteristics of sleep. Richards (1985) described the tool as a five-item instrument that uses a visual analogue scaling (VAS) design to measure sleep quality. The horizontal line measures 100 mm in length, with anchors at each end to indicate the measurement extremes. The patient was instructed to mark a point on the horizontal line that best describes the previous night's sleep experience. Scores for each question range from 0 (indicating optimal sleep) to 100 (indicating poor sleep). Scores were determined

by measuring the distance between the "0" end of the line to the patient's mark. The total sleep score was obtained by adding the individual scores for each of the five questions and dividing the sum by five.

Content validity for the RCSQ (Richards, 1985) was established using a panel of experts that included doctorally prepared nurses with medical-surgical, critical care, neurophysiology, gerontology, and sleep disorder expertise. Items on the sleep questionnaire correlated with electroencephalography (EEG) data for 14 nights of observation of nine patients in a medical-surgical unit (Richards, 1985). Criterion related validity of the RCSQ was established through comparison with EEG. In a study by Gragert (1990) on the effects of a masking signal of sleep in patients in a critical care environment, both patients and nurses were instructed to use the tool. Patients used the tool as a self-report; nurses used the RCSQ as an observation tool. Convergent validity for the tool was supported. The RCSQ and nurse observations were highly positively correlated ($\underline{r} = .86$). Campbell (1986) tested the instrument in an ICU. Internal consistency (Cronbach's alpha) was .92 indicating adequate reliability. Evidence of adequate stability reliability ($\underline{r} > .80$), as measured by the correlation of scores on two (horizontal and vertical) administrations of the RCSQ, was analyzed by the researcher in the coronary care population. The analysis showed high ($\underline{r} = .99$, $\underline{p} < .0001$) positive correlation between the horizontal and vertical versions of the RCSQ over time, suggesting adequate evidence of stability and equivalence reliability of the RCSQ in the coronary care population.

Demographic Data Sheet

A demographic data sheet (Appendix E) developed by this investigator was used to record descriptive data. The demographic data sheet consisted of the following information: date, time, research subject number, room number, age, race, gender, admitting diagnosis, and night in CCU.

Total Daily Anxiety and Sleep Medication Data Log

The purpose of the Total Daily Anxiety and Sleep Medication Data Log (Appendix F) was to record the daily amount in milligrams of anxiety and sleep medication over a 24-hour period. This data log was used to tally the amount of anxiety and sleep medication used from 7:00 A.M. the previous day to 7:00 A.M. on the day of measurement. All medications for anxiety were converted to the equivalent dose for the drug Xanax. All sleep medications were converted to the equivalent dose for the drug Ambien. The log was drafted to facilitate tallying of total count of anxiety and sleep medication and to possibly track down the time of day of high or low anxiety and sleep medication usage to establish trends of when aromatherapy may be most useful. Evidence of equivalence reliability was measured by interrater agreement ($\underline{r} = .85$) in the psychometric study conducted by the researcher on CCU patients.

Total Daily Pain Medication Data Log

The purpose of the Total Daily Pain Medication Data Log (Appendix F) was to record the daily amount in milligrams of narcotic analgesic used over a 24-hour period. This data log was used to tally the amount of pain medication used from 7:00 A.M. the

previous day to 7:00 A.M. on the day of measurement. All narcotic dosages were transformed to equianalgesic doses of the drug morphine sulfate, which is commonly used in the CCU population for the treatment of chest pain. Evidence of equivalence reliability of this tool was measured by interrater agreement ($\underline{r} = .85$) in the psychometric study conducted by the researcher on CCU patients.

In summary, the instruments used in the study all exhibited evidence of reliability and validity. All five instruments were easy to use, required very minimal language and manual dexterity, had adequate psychometric properties, and all were easily administered and scored.

Data Collection

Permission to conduct the study was obtained from the Human Subjects Review Committee of the Texas Woman's University (Appendix C) and the Nursing Research Committee and Institutional Review Board of the participating institution (Appendix C). The sampling technique was systematic random sampling of patients meeting the study criteria. The researcher at 7:00 P.M, reviewed a list of the patients admitted for the day. Every other patient who met the criteria was approached for inclusion in the study. A written consent was obtained from all of the subjects and the mechanics, process, risks of participation in the study fully explained. If the patient agreed to participate in the study and met inclusion criteria, the patient was randomly assigned to one of two Treatment Groups to receive aromatherapy on the first night or the second night following enrollment in the study.

The repeated measures design is shown in Figure 6. The subjects were asked to complete the STAI, after which the patient was exposed to either lavender oil or water. After 30 minutes, the patient was again asked to complete the STAI. After 9 hours of exposure to either the lavender oil or water, the patient was asked to complete the STAI and the RCSQ. The Total Daily Anxiety, Sleep and Pain Medication Data Logs were used to record daily anxiety, sleep and pain medication usage from 7:00 A.M. the day before to 6:59 A.M. the day after the treatment. These forms were completed by the investigator on research days number two and the day after the second research day, for a total of two times during the course of the study.

The study was conducted over two days for each subject. All subjects were exposed to the two possible treatment combinations. The order of treatment was randomly assigned to each subject.

The step-by-step protocol is detailed in Appendix G. After the patients were screened for fit with eligibility criteria, they underwent a smell test to rule out anosmia. Random assignment and intervention were then performed as previously described.

Pilot Study

A pilot study was conducted by the investigator prior to the present study to test the research design and methodology to identify problems, and to test the instruments to be used in the major study. A repeated measures design using subjects as their own controls was used for the pilot study to determine the effects of aromatherapy on anxiety and perceived sleep quality. The methodology of the pilot study was designed to occur over a four-day period and entailed the diffusion of the essential oil of chamomile in

addition to lavender oil with an electric diffuser. The subjects were asked to fill out two instruments immediately upon awakening between 7:00 A.M. and 9:00 A.M.: the STAI and the RCSQ. The subjects were then exposed to either chamomile or no aroma between 9:00 A.M. to 12 noon. Between 12 noon and 2 P.M., the subjects were requested to fill out another STAI for the second administration. The third administration occurred between 7 P.M. and 9:00 P.M., after which lavender was or was not diffused between 9:00 P.M. and 12 midnight. The RCSQ was not administered on the first research day as the subjects were not exposed to any treatments prior to research day one. The last RCSQ was administered the morning after the fourth research day. The STAI was administered a total of 12 times over four days. The RCSQ was administered a total of four times over four days.

The study was conducted over four days for each subject. All subjects were exposed to the four possible combinations of treatments: (1) chamomile in the morning and lavender at night, (2) lavender only at night, (3) chamomile only in the morning, and (4) no treatment in the morning or at night. The order of treatment was randomly assigned to each subject. The convenience sampling technique was used.

The pilot study sample included eight CCU patients between the ages of 48 to 68 with a mean age of 61. All of the subjects were Caucasian. Six subjects were males and two females. Five subjects were admitted with the diagnosis of unstable angina and three subjects with chest pain.

Data screening of anxiety scores and sleep scores for each administration of the instruments was done to determine if the scores were normally distributed. The skewness

of the STAI scores during the three administration times ranged from -1.52 to -2.34, which showed slight skewness to the left. However, when Fisher's measure of skewness (Fisher, 1971) was calculated, all the distributions were grossly skewed to the left. The distribution is also more peaked than normal with kurtosis values ranging from 2.74 to 6.47. A curve with the right bell shape will result in a value of zero (Munro & Page, 1993). Two outlier scores (39 and 41) were identified and dropped. Skewness approached a more normal distribution but kurtosis was still abnormal (skewness range .64 to -.87, kurtosis range .622 to 2.744). Skewness and kurtosis values for the sleep scores were normal. The means, standard deviations, medians, and ranges of the three anxiety administrations and the sleep scores are found in Table 2.

Table 2

Measures of Central Tendency and Variability for Anxiety and Sleep Scores for the Aromatherapy Pilot Study in CCU Patients (N=8)

Score	Mean (S.D.)	Median	Range
Anxiety 1	72 (5.8)	73	60 - 80
Anxiety 2	75 (7.3)	75	55 - 80
Anxiety 3	73 (4.9)	72	63 - 80
Sleep	26 (11.3)	26	4 - 44

The following hypotheses were tested in the pilot study with Repeated Measures ANOVA using the Multivariate Analysis of variance (MANOVA) command:

1. There will be a significant difference in the anxiety scores over the three administration times (within group effect).

2. There will be a significant between group and interaction effect on anxiety.

The hypothesis, there will be significant effects on sleep scores between groups, was tested using one-way ANOVA. The assumptions underlying ANOVA are: (a) normal distribution, (b) homogeneity of variance, (c) compound symmetry, and (d) sphericity. The assumption of normal distribution was violated. The raw scores were converted to z scores to achieve normally distributed measures. This procedure uses a nonlinear transformation that yields normally distributed standard scores (Roscoe, 1975). When the raw scores were transformed to z scores, no significant improvement in skewness and kurtosis was evident. The assumption of normal distribution, therefore, was violated. This violation can be corrected with an increase in sample size; therefore, the sample size was increased to 25 in the present study.

Homogeneity of variance was tested using the BoxM (SPSS-X, 1988). All the scores met the assumption of homogeneity of variance. The third and fourth assumptions, compound symmetry and sphericity, are accounted for by the multivariate approach to repeated measures ANOVA. These assumptions, therefore, were irrelevant for the first and second hypotheses. Homogeneity of variance was tested and met for the third hypothesis.

The first hypothesis, there will be significant differences in anxiety scores across the three administration times, was not supported (F=.88, df = 16, p = .53). The second hypothesis, there will be a significant difference in anxiety scores among the four treatment groups, was not supported (F=1.62, df = 8, p = .27). Effect sizes of .08 (power = .13) for between subjects, .27 (power = .24) for interaction, and .40 (power = .27) for within-subjects are low. These low effect sizes and power are consistent with the non-significant findings. The third hypothesis, there will be a significant effect on sleep, was not supported (F=3.87, df = 8, p = .052). In summary, the pilot study results revealed no significant within or between-groups effects on anxiety. No significant between-groups effect on sleep quality were found.

Several revisions in methodology based on the pilot study were incorporated in the major study. Problems were identified in the initial phase of the study due to the inability of the researcher to recruit subjects. This problem arose due to two major reasons: the apprehension of the patients to participate in the study and the inability of the patients to complete the study. The apprehension of the patients to participate in the study centered around three factors: the unfamiliarity with the treatment of aromatherapy, the presence of the spouse, and the negative reactions to the smell of chamomile oil, which is not a floral-based aroma. The problem of spousal effect on consents was handled by waiting to approach the patient when the spouse was not in the room. In several cases, the patient could make up his/her own mind, but some patients still wanted to wait for their spouse's approval to participate in the study.

The problem related to the inability of the patients to complete the study was due to patients' discharge from the CCU before study completion. Average length of stay for CCU patients was 2.3 days. The original research protocol was designed for four days. This problem led the researcher to decrease the number of days to complete the research protocol. The problem with the aroma of chamomile was corrected by exposure of the patient to only one essential oil, lavender, which is a floral-based aroma.

Another problem contributing to poor enrollment was the refusal of some doctors to have their patients participate in the study. This problem was solved by presenting the study to the CCU Committee, which unanimously approved the study. Physicians were then approached individually by the investigator to explain the study. Two physicians did not wish their patients to participate in the study. Another problem concerning the physicians involved their concerns about the use of the electric diffuser which was thought to contaminate the air so that even the non-participants would be affected. The decision was made to use passive diffusion through application of the oil to a cotton ball in the major study.

The small sample size contributed to the abnormal distribution of scores, which subsequently led to a problem with data analysis. The researcher anticipated correction of this problem by use of a larger sample size for the present study.

The STAI and the RCSQ were found to be reliable for the CCU patients in the pilot study. Cronbach's alpha for the STAI ranged from .92 - .96 among the three administration times. Cronbach's alpha for the RCSQ ranged from .86 - .95.

Summary

The purpose of this study was to examine the patterning manifestations of anxiety and sleep quality when a repatterning strategy, aromatherapy, was introduced in the environment of the CCU population. The study utilized a repeated measures interventional design. The sampling technique was systematic random sampling of patients meeting the study criteria. The STAI was used to measure anxiety; the RCSQ to assess sleep quality.

CHAPTER 4

ANALYSIS OF DATA

The purpose of this study was to examine the effects of aromatherapy on two patient outcomes relevant to the CCU population: level of anxiety and perceived quality of sleep. A Demographic Data Sheet was used to record descriptive data, medication logs were used to document medication usage, the State Portion of the Spielberger State-Trait Anxiety Inventory (STAI) or S-Anxiety Scale was used to record level of anxiety, and the Richards-Campbell Sleep Questionnaire (RCSQ) was used to record perceived sleep quality.

Descriptive statistics were used to summarize the sample demographic data. Data related to level of anxiety were analyzed using a multivariate approach to repeated measures analysis of variance (ANOVA). To determine whether an analysis of covariance (ANCOVA) would be necessary, correlations between 1) anxiety scores and use of pain and anxiety medication, and 2) sleep scores and use of pain and sleep medication were examined.

Description of Sample

Twenty-seven subjects agreed to participate in the study , but two subjects failed the Smell Test. The remaining 25 patients all met inclusion criteria. All were patients in the CCU with one of the following diagnoses: rule out (R/O) MI, chest pain, angina or unstable angina (USA) ; at least 21 years of age; hemodynamically stable; and able to complete the STAI and RCSQ.

Sample subjects ranged in age from 38 to 82 (M = 62, SD = 3). The sample consisted primarily of white (n = 18, 72%) males (n = 18, 72%). The most common admitting diagnosis was USA (n = 11, 44%). Table 3 further describes the demographic characteristics of age, race, gender, and admitting diagnosis. Table 4 describes the means for anxiety, sleep, and pain medication use for the lavender and the control groups. No significant differences in medication use were found between the two groups.

Table 3

Frequencies and Percentages of Demographic Information of CCU Patients Participating in Aromatherapy Study (N = 25)

Variable	n (%)
Age (years)	
38 – 49	6 (24)
50 – 59	4 (16)
60 – 69	8 (32)
70 – 82	7 (28)
Race	
Caucasian	18 (72)
African-American	3 (12)
Hispanic	4 (16)
Gender	
Male	18 (72)
Female	7 (28)
Admitting Diagnosis	
Chest Pain	7 (28)
Unstable Angina	11 (44)
R/O MI	7 (28)

Table 4

Means of Anxiety, Sleep, and Pain Medication Use of CCU Patients Participating in Aromatherapy Study (N = 25)

Variable	Mean
Lavender Treatment	
Anxiety Medication	.33 mg.
Sleep Medication	5.00 mg.
Pain Medication	12.00 mg.
Control Treatment	
Anxiety Medication	.35 mg.
Sleep Medication	7.00 mg.
Pain Medication	13.00 mg.

Findings

The STAI was used to assess the level of anxiety in this study. The STAI was administered at 9:00 P.M. prior to the treatment (lavender oil or water), thirty minutes to an hour into the treatment, and immediately upon waking up the next morning. The STAI is a 20-item test. Each item is given a weighted score of one to four (1-4). A rating of four (4) indicates the presence of a high level of anxiety for ten items; a high rating indicates the absence of anxiety in the remaining 10 items. The scoring weights for anxiety-present items are the same as the numbers on the test form that are circled by the subject, and the scoring for the anxiety-absent items are reversed. The weighted scores

for the 20 items were added to obtain a total score. Scores can vary from a minimum of 20 (low anxiety) to a maximum of 80 (high anxiety).

The RCSQ was used to measure the perceived quality of sleep. This instrument is a five-item instrument that uses a visual analogue tool to indicate sleep quality. The horizontal line measures 100 mm in length, with anchors at each end to indicate the measurement extremes. The subjects were instructed to mark a point on the horizontal line that best described the previous night's sleep. Scores for each item range from 0 (indicating optimal sleep) to 100 (indicating poor sleep). Scores were determined by measuring the distance between the "0" end of the line to the subject's mark. The total sleep score was obtained by adding the individual scores for each of the five questions and dividing the sum by five.

Data screening of anxiety scores and sleep scores for each administration of the instruments showed that the scores were normally distributed. The means, standard deviations and ranges of the three anxiety administrations and the sleep scores are found in Table 5.

Correlations

The relationships between the dependent variables (anxiety and sleep scores) and the covariates (amount of anxiety, pain, and sleep medications) were examined to determine whether an analysis of covariance (ANCOVA) was necessary. Pearson product-moment correlation coefficients were calculated. None of the correlation coefficients met the .05 level of significance, therefore, an ANCOVA was not indicated. Table 6 presents the correlation coefficients obtained for the relationships.

Table 5

Measures of Central Tendency and Variability for Anxiety and Sleep Scores (N = 25)

Score	Mean (S.D.)	Range
Control Anxiety 1	51.76 (2.55)	30 - 65
Lavender Anxiety 1	51.40 (2.14)	20 -67
Control Anxiety 2	52.76 (1.88)	32 - 64
Lavender Anxiety 2	50.16 (2.18)	22 -68
Control Anxiety 3	52.96 (2.32)	35 - 78
Lavender Anxiety 3	50.92 (2.31)	18 - 70
Control Sleep	63.28 (2.48)	29 - 83
Lavender Sleep	59.84 (2.91)	26 - 69

Hypotheses

The data were tested to determine whether the assumptions of equality of variance and compound symmetry required for use of the repeated measures ANOVA were met. Levene's Tests of Equality of Error Variances were performed for each of the repeated measures (anxiety and sleep scores). No significant differences between the three administration times for the anxiety scores and the two administration times for the sleep scores were found ($p > .05$). Therefore, the groups did not significantly differ in terms of variance. The assumption of compound symmetry was tested using the Mauchly

Sphericity Test. The assumption was not met ($W = .63$, $p < .05$); therefore, the multivariate results, rather than the univariate, were reported and examined (Munro, 1997). Another approach to decreasing the probability of making a Type I error when the sphericity assumption is not met is to use a smaller pair of df values to determine the critical F value used to evaluate the calculated F value. This adjustment results in a larger critical value, which increases the likelihood of making a fail-to-reject decision when evaluating the null hypothesis (Huck & Cormier, 1996). One of the ways to adjust the df values is to use the Greenhouse-Geisser approach. This approach involves basing the critical F value on the df values that would have been appropriate if there had been just two levels of the repeated measures factor (Huck & Cormier, 1996). This approach was especially useful when examining the data on the main effect of time, which has three levels.

The first hypothesis, there will be a significant difference in anxiety scores between aromatherapy and control treatments in coronary care unit patients (main effect: treatment), was examined using a multivariate approach to ANOVA for repeated measures. The results showed no significant differences between the aromatherapy and control anxiety scores (Table 7).

The second hypothesis, there will be a significant difference in anxiety scores over time in coronary care unit patients receiving aromatherapy or control treatments (main effect: time), was examined using a multivariate approach to ANOVA for repeated measures. The results showed no significant differences in anxiety scores between the three administration times (Table 7).

Table 6

Correlations Between Anxiety and Sleep Scores and Anxiety, Pain, and Sleep Medication Usage (N = 25)

Variables	Anxiety Medication	Pain Medication	Sleep Medication
Control Anxiety 1	.04	.02	-
Lavender Anxiety 1	.10	.03	-
Control Anxiety 2	-.02	.19	-
Lavender Anxiety 2	.22	.11	-
Control Anxiety 3	.02	.20	-
Lavender Anxiety 3	.19	-.11	-
Control Sleep	-	.12	.11
Lavender Sleep	-	-.07	.08

The third hypothesis, there will be a significant treatment and time interaction effect on anxiety in coronary care patients receiving aromatherapy (interaction effect), was examined using a multivariate approach to ANOVA for repeated measures. The results showed no significant interaction between type of treatment and time in the aromatherapy and control anxiety scores (Table 7). Effect sizes of .03 (power = .16), .01 (power = .07), and .16 (power = .39) for treatment, time, and treatment by time within-subjects effects respectively, are low. These low effect sizes and power are consistent with non-significant findings.

Table 7

ANOVA Summary Table for the Aromatherapy Study on Anxiety

Source	df	SS	MS	F
Subjects	24	10928.75	496.76	
Treatment	1	104.17	104.17	.74
Treatment x Subjects	24	3370.00	140.42	
Time (Greenhouse-Geisser)	1.46	6.24	3.12	.21
Time x Subjects (Greenhouse-Geisser)	35.16	704.09	14.67	
Treatment x Time	2	33.97	16.99	1.54
Treatment x Time x Subjects	48	530.36	11.05	
Total	135.62	15677.58		

The fourth hypothesis, there will be a significant difference in sleep scores between aromatherapy and control treatments in coronary care unit patients, was examined using a t-test for dependent or paired samples. The hypothesis was not supported ($t = -1.12$, $df = 24$, $p = .28$). The effect size of .25 (power = .20) is consistent with non-significant findings.

Reliability of the Instruments

Although reliability of the instruments used in this study was previously established during the pilot study, internal consistency was assessed in this study during the three administration times for the STAI and the two administration times for the RCSQ. Cronbach's alpha for the three STAI administrations ranged from .84 - .99. Cronbach's alpha for the two RCSQ administrations was .92. These values are consistent with reliability studies already published in the literature on the two instruments.

Summary of Findings

A total of 25 subjects participated in this quasi-experimental, interventional, repeated measures study to determine the effects of aromatherapy on two patient outcomes relevant to the CCU population: level of anxiety and perceived quality of sleep. A Demographic Data Sheet was used to record descriptive data, the STAI was used to record anxiety scores over three administration times, the RCSQ was used to record sleep quality scores over two administration times, and the Total Daily Anxiety, Sleep, and Pain Medication Data Logs were used to record the anxiety, sleep, and pain medications received by the subject during the study period.

Four hypotheses were tested. The first hypothesis, there will be a significant difference in anxiety scores between aromatherapy and control treatments in coronary care unit patients (main effect: treatment), was not supported. The second hypothesis, there will be a significant difference in anxiety scores over time in coronary care unit patients receiving aromatherapy or control treatments (main effect: time), was not supported. The third hypothesis, there will be a significant treatment and time interaction

effect on anxiety in coronary care unit patients receiving aromatherapy (interaction effect), was not supported. The fourth hypothesis, coronary care unit patients will have a significant difference in sleep scores between aromatherapy and control treatments, was also not supported. The reported effect sizes and power of the tests were small and consistent with the nonsignificant findings.

CHAPTER 5

SUMMARY OF THE STUDY

The problems of anxiety and poor sleep quality continue to affect Coronary Care Unit (CCU) patients. Pharmacologic interventions have traditionally been used to address these problems. However, drugs are costly and they have been known to cause harmful side effects. Complementary healing modalities, such as aromatherapy, are being examined as adjuncts to traditional treatments. Aromatherapy, as defined in this study, is the passive diffusion of essential oils in the atmosphere. The essential oils are plant and flower extracts that are relatively harmless and cheaper than drugs.

The purpose of the study was to examine the effect of aromatherapy on two CCU patient outcomes: anxiety level and sleep quality. The theoretical framework utilized in this study was the Science of Unitary Human Beings (Rogers, 1970; 1980; 1987). In conceptualizing a unitary human being, Rogers viewed a person as an energy field interacting with the environmental energy field. The treatment of aromatherapy is the patterning change in the environmental energy field while the outcomes of anxiety level and sleep quality are patterning manifestations of a person's energy field. The study proposed to test Rogers' principle of integrality which states, patterning change of increasing diversity in the environmental energy field will manifest as a repatterning change in the human energy field. This chapter includes a summary of the study, discussion of the study findings, conclusions, and implications for nursing. The chapter concludes with recommendations for further study.

Summary

A quasi-experimental, interventional, repeated measures design was used to examine the effects of aromatherapy on the anxiety level and sleep quality of patients in the CCU over time. Subjects were selected using systematic random sampling of patients, who were admitted to the CCU of a large tertiary care hospital in Southeast Texas, and who met the study criteria.

Protection of human subjects were ensured by obtaining permission to conduct the study from the Texas Woman's University Human Subjects Review Committee and the institution's Institutional Review Board. In addition, the investigator gave the subjects a full explanation of the intent, protocol, and nature of participation in the study of all potential subjects. Procedures to safeguard confidentiality were explained and observed throughout the course of the study and after the study was completed. A written consent form was obtained from all of the subjects that addressed potential risks and steps that will be taken to reduce the risks.

The State Portion of the Spielberger State-Trait Anxiety Inventory (STAI), a 20-item test, was used to assess level of anxiety in this study. The weighted scores for the 20 items were added to obtain a total score. Scores can vary from a minimum of 20 (low anxiety) to a maximum of 80 (high anxiety). Subjects were asked to complete the STAI three times during the course of a 24-hour time period: at 9:00 P.M. before the diffusion of either the aromatherapy or the control treatment, thirty minutes to an hour after the start of diffusion, and immediately upon waking up the next day. Subjects were asked to complete the STAI six times during the course of the study.

Sleep quality was assessed using the Richards-Campbell Sleep Questionnaire (RCSQ). The instrument is a five-item instrument that uses a visual analogue tool to indicate sleep quality. Scores for each item range from 0 (indicating optimal sleep) to 100 (indicating poor sleep). Scores were determined by measuring the distance between the "0" end of the line to the subject's mark. The total sleep score was obtained by adding the individual scores for each of the five questions and dividing the sum by five. The Demographic Data Sheet was used to collect demographic information and the Total Daily Anxiety, Sleep, and Pain Medication Logs were used to record the anxiety, sleep, and pain medications received by the subject during the study period.

The first three hypotheses of this study, there will be a significant difference in anxiety scores between aromatherapy control treatments in the coronary care unit, there will be a significant difference in anxiety scores over time in coronary care unit patients receiving aromatherapy or control treatments, and there will be a significant treatment and time interaction effect on anxiety in coronary care unit patients receiving aromatherapy, were examined using a multivariate approach to ANOVA for repeated measures. The fourth hypothesis, coronary care unit patients will have a significant difference in sleep scores between aromatherapy and control treatments, was examined using a dependent or paired sample t-test.

Discussion of Findings

The final sample size for this study was 25, after two subjects failed to pass the Smell Test. All of the 25 subjects completed the tools over three administration times over a two-day study period. There was no attrition over the 8-week study period. This

attrition rate is consistent with the study design, which allowed for the study to be held over a period of only two days. This rate may also be attributed to the fact that the institution's CCU Committee gave the investigator permission to collect data only over the weekend. The members of the CCU Committee decided that it might potentially be disruptive for the treatments to be diffused during the week when most of the diagnostic tests and therapeutic procedures are ordered.

The sample consisted primarily of white (n = 18, 72%) males (n = 18, 72%). The greater number of males recruited for this study is consistent with reports in the literature that men are treated more aggressively for heart disease than women (Altman, 1991; Schwartz et al., 1997). The racial distribution of this study sample is not consistent with the 1:1:1 ratio reported for angina treatment (American Heart Association, 1996). The under-representation of African-American and Hispanic patients may be related to the study setting. A more representative sample might be obtained if the study were conducted in a community or county facility.

Hypotheses

The first hypothesis, there will be a significant difference in anxiety scores between aromatherapy and control treatments in coronary care unit patients (main effect: treatment), was examined using a multivariate approach to ANOVA for repeated measures. The results showed no significant differences between the aromatherapy and control anxiety scores ($F = .74$, $df = 1,24$, $p = .39$).

The second hypothesis, there will be a significant difference in anxiety scores over time in coronary care unit patients receiving aromatherapy or control treatments

(main effect: time), was examined using a multivariate approach to ANOVA for repeated measures. The results showed no significant differences in the anxiety scores over time in coronary care unit patients receiving aromatherapy or control treatments ($F = 1.54$, $df = 35$, $p = .21$).

The third hypothesis, there will be a significant treatment and time interaction effect on anxiety in coronary care unit patients receiving aromatherapy (interaction effect), was not supported ($F = 1.54$, $df = 2,48$, $p = 1.54$). The aromatherapy anxiety scores were consistently lower than the control anxiety scores, but no significant differences could be found between the two scores over the three administration times. Effect sizes of .03 (power = .16), .01 (power = .07), and .16 (power = .39) for treatment, time, and treatment by time within subjects effects respectively, were low. These low effect sizes and power are consistent with non-significant findings.

The low effect size may be due to the method of essential oil diffusion used in the present study. In this study, one drop of the essential oil was applied to a cotton ball using a dropper and allowed to passively diffuse to the atmosphere. The cotton ball was then attached to the patient's pillow. The quantity and method of diffusion of essential use for the present study were the result of several factors. First, only one drop of the essential oil lavender (*lavandula augustifolia*) was used from recommendations made in the literature that suggest that lavender in low doses is sedative, but may cause insomnia in high doses (Price & Price, 1996; Worwood, 1996). Second, potential problems with air contamination were raised by some physicians with the electric diffusion method used during the pilot study. The method of diffusion was changed from electric diffusion to

the cotton ball technique in response to the physicians' concerns that the electric diffusion might contaminate the air breathed by non-participants. However, there is no assurance of consistency and concentration when the cotton ball technique is used, as vaporization occurs at a variable rate. This variability may have contributed to the low effect sizes obtained in this study.

The number of subjects needed for the study ($\underline{N} = 25$) was projected from a power analysis performed on the pilot study data in which the effect size was .40 and data obtained from studies reported in the literature (effect size range .25 - .40). The possibility of a lower effect size in the present study due to the change in the method of diffusion from the pilot study was not anticipated. According to Maxwell and Delaney (1990), the minimum sample size needed to achieve power of .80 with $\alpha = .05$, using the statistics from the present study (minimum $\underline{r} = .02$, effect size = .06) is 254.

Massage aromatherapy was the treatment utilized for all of the studies found in the literature regarding aromatherapy and its effects on anxiety (Dunn, Sleep & Collett, 1995; Stevensen, 1992). The effect of the massage along with the aromatherapy may have inflated the effect size reported in these studies. Buckle (1993), in an effort to disprove that touch or massage exerted an influence on patients' anxiety levels, conducted a study that involved the use of two types of lavender essential oils, one more volatile than the other. Chi square analysis was used to examine the differences in physiologic parameters and memory, coping, and anxiety levels. A significant decrease in anxiety levels was found when the more volatile essential oil was used, leading to her

conclusion that the fragrance exerted an influence over and above that exerted by the massage portion of the therapy ($p < .10$).

The results of the present study are not congruent with the results of the study by Buckle. The significant results in Buckle's study must be viewed with caution, however, due to problems in the statistical analysis employed to analyze the data. Buckle's data were interpreted using a high level of significance which could lead to the possibility of making a Type I error (e.g. use of $p < .10$ rather than .05 or .01). The author also opted to use the chi square method of data analysis instead of the more appropriate repeated measures ANCOVA approach since intervention using both types of oils were used in all of the subjects and the level of data obtained were continuous, rather than categorical, data.

The fourth hypothesis, coronary care unit patients will have a significant difference in sleep scores between aromatherapy and control treatments, was examined using a t-test for dependent or paired samples. The hypothesis was not supported ($t = -1.12$, $df = 24$, $p = .28$). The study findings of no significance is not congruent with the results of the study conducted by Hardy, Kirk-Smith, and Stretch (1995) on a limited number of patients ($N = 4$). The difference in the findings may be the result of the method of diffusion of aromatherapy which resulted in a small effect size in the present study (.25, power = .20). In the Hardy, Kirk-Smith, and Stretch study, the essential oil lavender, was diffused through an electric diffuser in a geriatric ward. The authors did not specify how sleep quality was measured in their study, but they reported less

restlessness during sleep induced by the diffused lavender oil compared to sleep where no essential oil was diffused at all.

The findings of the present study, on the surface, do not support the theoretical discussions proposed by Rogers in the Science of Unitary Human Beings, 1970; 1980; 1987). However, an analysis of the principles of the Science of Unitary Human Beings may serve to explain the limitations of the study that could account for the nonsignificant findings. The Unitary Human Being is conceptualized as an energy field interacting with the environmental energy field. Rogers referred to this constant and mutual interaction between the human and environmental energy fields as the principle of integrality. This principle was what the present study proposed to test. Rogers, however, posited that two other principles, helicy and resonancy, must be considered to describe the patterns of human being and environment interaction and change.

Resonancy describes the direction of change from lower to higher wave patterns. The principle of resonancy was not applied in the present study. A single drop of lavender essential oil was passively allowed to evaporate over a 9-hour period in the present study. The intensity of treatment over a period of time, which would allow for the movement of human and environmental energy field change from lower to higher wave patterns, was not present.

Helicy describes the structural nature (simple vs. complex) of the repatterning change which is believed to occur in continuous, non-repeating cycles. This principle states that when there is change of increasing diversity in both the environment and the human energy fields, change becomes continuous and cyclical, but non-repeating. The

human energy field is constantly evolving and changing while it interacts with the environmental energy field and thus, one can never be what one was five minutes ago. In aromatherapy, the principle of helicy can be applied through the use of "blends" or combinations of essential oils that are believed to act synergistically, thus exerting a more intense effect. Practitioners of aromatherapy have intuitively known that single oils are not as effective as combinations of oils (Damian & Damian,1995; Tisserand, 1988a; Worwood, 1996).

Rogers did not specify that changes in the patterns of human and environmental energy fields are dependent on the three principles acting on an energy field simultaneously. However, if it is true that the three principles must be in effect for the energy fields to be repatterned, then testing and controlling for only one of the three principles will not exert the desired repatterning change. It may be possible, using this line of thought, that the small effect sizes obtained in the present study could be due to the lack of attention to the principles of helicy and resonancy.

Conclusions and Implications

Anxiety and sleep problems continue to affect patients in the CCU. Conclusions derived from the findings of this study and implications for nursing practice are presented in this section.

Conclusions

The following conclusions were drawn based on the findings of this study:

1. Anxiety levels in CCU patients are not significantly different between aromatherapy and control treatments using the cotton ball diffusion method.

2. Anxiety levels in CCU patients are not significantly different over time when receiving either the aromatherapy or control treatment using the cotton ball diffusion method.

3. Anxiety levels in CCU patients are not significantly decreased over time with the use of passively diffused aromatherapy using the cotton ball diffusion method.

4. Sleep quality in CCU patients is not significantly improved with the use of passively diffused aromatherapy using the cotton ball diffusion method.

Implications

The following implications for nursing practice were derived from the study conclusions:

1. The use of cotton balls does not appear to be an effective medium for diffusing essential oils to decrease anxiety levels and improve sleep quality in CCU patients. The use of electric diffusers may be preferred.

2. The use of single oils does not appear to be an effective strategy for decreasing anxiety levels and improving sleep quality in CCU patients. The use of "blended" or combination oils may be preferred.

Recommendations for Further Study

Recommendations for future research concerning the use of aromatherapy to affect anxiety levels and sleep quality in CCU patients were generated from this study:

1. Replication of this study, using the electric diffusion method, should be undertaken to increase the intensity and concentration of the treatment of aromatherapy on a larger sample size.

2. Because of the difficulties encountered in obtaining permission to use the electric diffuser in the CCU, replication of the study using subjects with similar diagnoses in different settings such as general medical units or in patients' homes should be explored. Other populations and settings which may be affected by high anxiety and which may potentially benefit from aromatherapy are offices where Type A personalities abound, emergency rooms, operating rooms, and waiting areas in hospitals.

3. To maximize effectiveness of the aromatherapy treatment, a combination of different oils is recommended.

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APPENDIX A

State Portion of the Spielberger State-Trait Anxiety Inventory

SELF-EVALUATION QUESTIONNAIRE

Developed by Charles D. Spielberger

Date:_____ Time: _____ AM PM
Study Code #: _____ Room #: _____
Hospital Day #: _____ CCU Day #: _____ Research Day #: _____

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 feel RIGHT NOW, that is, AT THIS MOMENT. 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 your present feelings best.

1 – Not at all
2 – Somewhat
3 – Moderately so
4 – Very much so

1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I feel tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am worrying about possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

APPENDIX B

Richards Campbell Sleep Questionnaire

RICHARDS CAMPBELL SLEEP QUESTIONNAIRE

Date:_____ Time: _____ AM PM
Study Code #: _____ Room #: _____
Hospital Day #: _____ CCU Day #: _____ Research Day #: _____

Directions: Place an "X" anywhere on the answer line that you feel BEST describes your sleep last night.

1. My sleep last night was:

Deep Sleep	_____	Light Sleep

2. Last night, the first time I got to sleep, I:

Fell Asleep Almost Immediately	_____	Just Never Could Fall Asleep

3. Last night I was:

Awake Very Little	_____	Awake All Night Long

4. Last night, when I woke up or was awakened, I:

Got Back To Sleep Immediately	_____	Couldn't Get Back To Sleep

5. I could describe my sleep last night as:

A Good Night's Sleep	_____	A Bad Night's Sleep

APPENDIX C

Permission to Conduct Research

Institutional Review Board
Mail Code 3-288
(713) 791-3347

ST. LUKE'S ®
EPISCOPAL HOSPITAL

March 16, 1998

Annabelle R. Borromeo, R.N.
St. Luke's Episcopal Hospital
6720 Bertner Avenue, MC 4-278
Houston, Texas 77030

Project #1889
"The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Patients"

Dear Ms. Borromeo:

Thank you for your response to the request by the St. Luke's Episcopal Hospital Institutional Review Board at their February 4, 1998 meeting. Recommendations of the committee have been satisfied by your response and I am pleased to inform you that your protocol and informed consent are approved according to institutional guidelines.

Continued review will be required as follows:

a. Annually
b. Prior to any change in protocol
c. Promptly after unanticipated problems (adverse events)
d. After any other unusual occurrence

The method of review will be by written summary.

A dated copy of the approved informed consent is attached for use as the "master" for copying for research subjects' signatures.

THE NEXT REVIEW DATE FOR THIS STUDY IS FEBRUARY 3, 1999. IRB APPROVAL OF THIS STUDY TERMINATES FEBRUARY 4, 1999.

Sincerely,

W H Moore

Warren H. Moore, M.D.
Chairman
Institutional Review Board

WHM/jrs

Enclosure

cc: Rosemary Luquire

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

HSRC APPROVAL FORM

Name of Investigator(s): Annabelle R. Borromeo, RN, MSN

[redacted]

Name of Research Advisor(s): Dr. Anne Young

Address: 2626 Holly Hall #311

Houston, Texas 77054

Dear: Annabelle Borromeo

Your study entitled: The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Patients

(The applicant must complete the top portion of this form)

has been reviewed by the Human Subjects Review Committee - Houston Center and it appears to meet our requirements in regard to protection of the individual's rights

Please be reminded that both the University and the Department of Health and Human Services regulations typically require that signatures indicating informed consent be obtained from all human subjects in your study. These are to be filed with the Human Subjects Review Committee Chairman. Any exception to this requirement is noted below. Furthermore, according to HHS regulations, **another review by the HSRC is required if your project changes or if it extends beyond one year from this date of approval.**

Any special provisions pertaining to your study are noted below:

_____ The filing of signatures of subjects with the Human Subjects Review Committee is not required.

_____ Other: see attached sheet.

__✓__ No special provisions apply.

Sincerely,

Gayle Hersch

Gayle Hersch, Ph D
Co-Chairperson, HSRC - Houston Center

12-8-97
Date

HSRC 1997

APPENDIX D

Consent to Act as a Subject for Research and Investigation

1889

Consent to Act as a Subject for Research and Investigation

THE EFFECTS OF AROMATHERAPY ON PATIENT OUTCOMES

I am being asked to participate in a research study called, "The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Patients." This study is being done by Annabelle R. Borromeo, RN, MSN, a Texas Woman's University doctoral student. The purpose of the study is to find out the effects of a treatment called aromatherapy on anxiety levels and sleep quality.

1. I understand that AROMATHERAPY is a treatment that involves exposure to subtle aromas. Lavender oil will be released in my room by application to a cotton ball and diffused over a nine (9)-hour period.
2. I understand that my exposure to the aroma will be determined by chance. During the two (2) days that I will participate in the study, I may be exposed to lavender aroma only or to no aromas at all.
3. I also understand that I will be asked to fill out the Spielberger Self-Evaluation Questionnaire. This is a twenty (20)-item questionnaire that will take about seven (7) minutes to complete. I understand that I will be asked to complete this questionnaire three (3) times daily: at or around 9:00 P.M., at or around 10:00 P.M., and immediately upon arising the next day. I understand that I will be asked to fill out this questionnaire six (6) times during the course of this study.

Consent to Act as a Subject for Research and Investigation
The Effects of Aromatherapy on Patient Outcomes
(Page 2/5)

4. I understand that I will be asked to fill out the Richards-Campbell Sleep Questionnaire. This questionnaire consists of five (5) items and takes about three (3) minutes to complete. I understand that I will be asked to complete this questionnaire once daily, immediately upon arising in the morning, making a total of two (2) times during the course of this study.
5. I also understand that the investigator will have access to my medical records to see how much pain, anxiety, and sleep medicine I use.
6. I understand that the total time needed to complete all of the questionnaires for this study is 24 minutes over a 24-hour period, or 48 minutes over a 2 day period.
7. The procedures listed in paragraphs 1 through 5 have been explained to me by Annabelle R. Borromeo, RN, MSN.
8. I understand that potential benefits of the study include decreased anxiety levels and improved sleep quality.
9. I understand that I risk losing some of my privacy during the study due to the occasional presence of the researcher. I also understand that the researcher is on staff at St. Luke's Episcopal Hospital.
10. I understand that there is a risk that I may be identified through my participation in this study. This risk will be reduced by identifying me only by a code number instead of my name. The study results will be reported for all patients who participate as group results rather than individual results. I understand that the researcher will keep the research forms and a master list with my name and code number under lock, and

Consent to Act as a Subject for Research and Investigation
The Effects of Aromatherapy on Patient Outcomes
(Page 3/5)

when the study is over, the forms and the master list will be destroyed.

11. As far as I know, I am not allergic to lavender oil. However, I understand that there is a risk that I may have allergic or unpleasant reactions to lavender oil like headache, nausea, or sneezing. I understand that if these reactions occur, I may signal the researcher or my nurse to stop the aromatherapy.

12. I understand that there is a risk that I may feel uncomfortable with or inconvenienced by answering the questionnaires. I also understand that I may refuse to participate in the study or withdraw from the study at any time and that my care in the Coronary Care Unit will not be affected in any way should I refuse to participate or withdraw from the study.

13. In the event of injury resulting from this research, Texas Woman's University and St. Luke's Episcopal Hospital will not offer financial compensation nor absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to research subjects just as they are to the community generally. My signature below acknowledges my voluntary participation in this research project, but in no way releases the investigator(s), sponsor(s), institution(s), or granting agency(ies) from their professional and ethical responsibility to me. In the event of a research-related injury, I must contact Annabelle R. Borromeo, the researcher, at Beeper (713) 284-9225. For questions about my rights as a research subject, I may contact the St. Luke's Episcopal

Consent to Act as a Subject for Research and Investigation
The Effects of Aromatherapy on Patient Outcomes
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Hospital Institutional Review Board at (713) 791-3347 and the TWU Office of Research and Grant Administration at (940) 898-3375.

14. I understand that I can contact Annabelle R. Borromeo, the researcher, through her beeper by following the procedure described below:

    14.1. Dial (713) 284-9225.

    14.2. Wait for long beep after voice message.

    14.3. Dial my number and then the "#" sign.

    1.4. Hang up.

15. I understand that there will be no extra cost to me for the aromatherapy done for research purposes.

16. I understand that the study results will be available after completion of the study, and I may receive a copy of the group results by contacting Annabelle R. Borromeo through Beeper (713) 284-9225.

17. My questions have been answered to my satisfaction by the researcher. If I have further questions about this study, I may contact Annabelle R. Borromeo at Beeper (713) 284-9225.

18. I understand the confidentiality of my records insofar as they identify me will be maintained in accordance with applicable state and federal laws and regulations. I understand that my records may be reviewed by the St. Luke's Episcopal Hospital Institutional Review Board.

Consent to Act as a Subject for Research and Investigation
The Effects of Aromatherapy on Patient Outcomes
(Page 5/5)

I voluntarily agree to participate in this research study with the understanding that I may withdraw my consent or discontinue my participation at any time and that my decision will not affect the care I receive in the Coronary Care Unit. I understand that this study has been approved by the Human Subjects Review Committee of Texas Woman's University and the Nursing Research Committee and Institutional Review Board of St. Luke's Episcopal Hospital.

I acknowledge that I have received a copy of my signed consent form.

Patient Signature	Date
Witness Signature	Date
Signature of Individual Obtaining Informed Consent	Date

Revised Informed Consent
Approved by IRB

Date 3-16-98
Signature J. Scott

APPENDIX E

Demographic Data Sheet

DEMOGRAPHIC DATA SHEET
(To be filled by researcher)

The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Unit Patients

Date: _____ Time: _____ A.M. P.M.

Study Code Number: _____ Room Number: _____

1. Age: _____

2. Race: _____

3. Gender: _____

4. Admitting Diagnosis: _____

APPENDIX F

Total Daily Anxiety, Sleep and Pain Medication Data Logs

TOTAL DAILY ANXIETY AND SLEEP MEDICATION DATA LOG
(To cover medications from 7:00 A.M. yesterday to 6:59 A.M. today)
(To be filled by researcher)

Date: _____ Time:_____ A.M. P.M.

Study Code No.: _____ Room No.: _____

Hospital Day No.: _____ CCU Day No. :_____ Research Day No.: _____

TIME (Military)	ANXIETY MEDICATION	ROUTE OF ADMINIS-TRATION	AMOUNT RECEIVED (in mg)
Total Anxiety Medication Received in 24-hours			

TIME (Military)	SLEEP MEDICATION	ROUTE OF ADMINIS-TRATION	AMOUNT RECEIVED (in mg)
Total Sleep Medication Received in 24-hours			

TOTAL DAILY PAIN MEDICATION DATA TOOL
(To cover medications from 7:00 A.M. yesterday to 6:59 A.M. today)
(To be filled by researcher)

Date: _____ Time:_____ A.M. P.M.

Study Code No.: _____ Room No.: _____

Hospital Day No.: _____ CCU Day No. :_____ Research Day No.: _____

TIME (Military)	NARCOTIC	ROUTE OF ADMINIS-TRATION	AMOUNT RECEIVED (MS Equianalgesic Dose) (in mg)
		Total Pain Medication Received in 24 Hours	

APPENDIX G

Step-by-step Protocol

The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Patients

Step-by-step Protocol

Sample Selection, Recruitment and Consent

1. Review the census records of Coronary Care Unit (CCU) patients and identify every third patient who meets the following criteria:
    - 1.1. Admitted to the CCU with the following diagnosis: r/o myocardial infarction, chest pain, angina, or unstable angina
    - 1.2. At least 21 years of age
    - 1.3. Absence of an acute cardiac condition or hemodynamic instability, impairing ability to complete the questionnaires
2. Call attending physician and request permission to approach patient for entry into the study.
3. Approach patient and assess for:
    - 3.1. Inability to speak, read, and understand English
    - 3.2. Presence of any physical or mental problem(s) that would hinder participation (e.g. blindness, retardation)
    - 3.3. Self-report of having chronic sleep problems (sleep apnea, insomnia) and report to be a day sleeper
    - 3.4 History of Parkinson's, sinusitis, allergic rhinitis, nasal polyps, and

diabetes

4. If any of the above criteria are met, exclude the patient from the study.

5. In none of the above criteria are met, explain the study to the patient.

6. If the patient wishes to participate, administer the Smell Test (Appendix H).

   6.1. Subject and researcher should wash their hands prior to test administration.

   6.2. Avoid the use of cosmetics, perfumes, after-shave lotion, and scented soap for 15 minutes prior to testing, avoid smoking, food, drink, candy, or chewing gum.

   6.3. Flip open the pair of bottles in the test kit and squeeze each bottle twice to condition the bottles to the current test environment. Air from a different source may be in each bottle; by exchanging the head-space air with the current environment, an increased accuracy will result. Close the bottle caps.

   6.4. Explain the blank: Tell the subject that a selection will be made between the pair of bottles; one bottle having an odor and other a blank. Tell the subject that the object of the test is to identify which bottle has an odor, and which bottle is odor-free. Look at the bottom of the bottles. Choose bottles marked "B" and "25 ds."

   6.5. Demonstrating the test: Flip open the bottle caps and demonstrate

procedure to the patient using the researcher as subject. Hold the orifice of one bottle about an inch from the nostril and squeeze the bottle three times while sniffing, then try the same bottle on the other nostril (the nose tends to breathe through one nostril preferentially for a time and then switches over). Repeat the procedure with the other bottle.

Hand the bottles to the subject to practice the test procedure. After selecting the bottle having an odor, the subject should hand the researcher that bottle. Check the label on the base of the bottle. If the choice is wrong, or if the subjects says no odor is distinguishable, offer the "55 ds" bottle to replace the "25 ds" bottle. Repeated sniffs are permitted before making the choice. Detection only is required, not recognition of the odor.

6.6. Beginning the test: Once the subject feels comfortable with the test, take the bottles back and rotate or randomize both bottles out of sight of subject. Hand the two bottles back to the subject to select the bottle having the stronger odor. Enter the results at the appropriate dcismel level in the first column of the score sheet . Check the appropriate box "Correct" or "Wrong.". Do not comment on the selections, as this may influence the test result. Take the bottles back, and randomize both bottles out of sight of the subject; hand them back and repeat the

procedure three times. Enter the results in the second and third columns of the score sheet. In order for the subject to pass, the correct selection must be made all three times (no errors permitted). Note that the subject has to make a choice (forced choice); a mere statement that he or she cannot detect any difference is not acceptable.

6.7. If the subject fails the test, thank him/her for his/her time, and exclude the subject from the study.

7. If the patient passes the Smell Test, ask the patient if he/she is allergic to lavender oil. If the patient reports an allergic reaction to lavender oil, exclude the patient from the study.
8. If the patient does not report an allergic reaction to lavender, apply one drop of lavender oil to a cotton ball and allow the patient to smell. If the patient identifies the smell as noxious or unpleasant, exclude the patient from the study.
9. If the patient does not identify the smells as noxious or unpleasant, obtain signature on consent form.
10. Stamp right upper corner of consent form with the patient's addressograph.
11. Make two copies of the consent form.
12. Give one copy to the patient.
13. Place the other copy in the patient's medical record.

14. Place original in a brown envelope marked "Signed Consent Form" and keep in the mailbox designated for Consent Forms in Nurses' Lounge.
15. Obtain bright pink research sticker from envelope marked "Chart Research Sticker" and put on the right upper corner of the patient's chart.
16. Obtain a bright pink research sticker from envelope marked "Room Research Sticker" and put on the glass panel directly above the handle on the patient's door. The room research sticker states, "Aromatherapy research in progress. Please keep door closed at all times."

Random Assignment

1. Get Master Research Roster (Appendix I) and write patient's name, bed number, and medical records number beside Research Subject Number.
2. Get Random Assignment Sheet (Appendix J) and assign patient to the next available treatment plan. Fill out Research Subject Number and Dates.

Patient and Equipment Preparation and Intervention Procedure

1. Knock on the patient's door.
2. Open patient's door and step inside room.
3. Re-introduce self to patient and review protocol.
4. Explain the procedure to the patient.

5. Give the patient three copies of the STAI and one copy of the RCSQ on a clipboard with a pen attached to it. Explain the procedure for completing the questionnaires. Encourage questions. Instruct the patient to put completed questionnaires in brown envelope provided. Clip brown envelope to clipboard.
6. Get one cotton ball from the clear plastic bag and, with a medicine dropper, put one drop of lavender oil or water.
7. Fasten the cotton ball to the underside of the upper right hand corner of the pillow case with a safety pin. Instruct the patient that you will come back after thirty minutes to administer the second STAI.
8. Leave the room and close the door. Instruct the patient's nurse to leave the door closed at all times.
9. At 6:00 A.M. the next day, unfasten the cotton ball and throw in a garbage container outside of the patient unit.

Procedures for Data Collection

For the Demographic Data Sheet (Appendix E)

1. The researcher will complete the following items on the Demographic Data Sheet at the time the consent is obtained: date, time, study code number, room number, and items 1 through 4.

For Treatment Plan 1: Lavender on first night, water on second night

Day of Treatment:

7:00 P.M. - 9:00 P.M.	Patient will fill out STAI.
9:00 P.M. - 6:00 A.M.	Diffuse lavender. See procedure - Patient and Equipment Preparation and Intervention Procedure
9:30 P.M.	Patient will fill out STAI.

Day after the Treatment:

7:00 A.M. - 9:00 A.M.	Patient will fill out STAI scale and RCSQ.

For Treatment Plan 2: Water on first night, lavender on second night

Day of Treatment:

7:00 P.M. - 9:00 P.M.	Patient will fill out STAI.
9:00 P.M. - 6:00 A.M.	Diffuse water. See procedure - Patient and Equipment Preparation and Intervention Procedure
9:30 P.M.	Patient will fill out STAI.

Day after the Treatment:

7:00 A.M. - 9:00 A.M.	Patient will fill out STAI scale and RCSQ.

For Total Daily Anxiety, Sleep, and Pain Medication Data Logs

1. At 7:00 A.M., review the PRN medication column of the patient flow sheet.
2. Obtain a copy of the Total Daily Anxiety, Sleep, and Pain Medication Logs
3. Review the PRN Medication sheet and transcribe all anxiety, sleep, and pain medications on to the tool, including time, A.M. or P.M., name of medicine, route of administration, and amount received in milligrams. Record equivalent doses for Xanax (for anxiety medications), Ambien (for sleep medications), and morphine (for pain medications).
2. The Medication Data Logs will be used for all anxiety, sleep, and pain medications given from 7:00 A.M. the previous day to 6:59 A.M. on the day of the assessment. The researcher completes the Medication Data Logs.

Note: This protocol conforms with the OSHA/HHS Guidelines for HIV/HBV Occupational Safety.

APPENDIX H

Smell Test Decismell Score Sheet

SMELL TEST

Study Code No.:_____ Date: _____

Conditions (Check if present.)

- ☐ No smoking?
- ☐ No eating?
- ☐ No perfume?
- ☐ No rhinitis?
- ☐ No work odor?
- ☐ No odor here?

SMELL TEST

Trial 1		Trial 2		Trial 3	
☐ Correct	☐ Wrong	☐ Correct	☐ Wrong	☐ Correct	☐ Wrong

Evaluation (Please check.)

- ☐ **Anosmia**
- ☐ **Normal**

APPENDIX I

Master Research Roster

MASTER RESEARCH ROSTER

The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Unit Patients

No.	Research Study No.	Date	Patient's Name	Bed No.	Medical Records No.

APPENDIX J

Random Assignment Sheet

RANDOM ASSIGNMENT SHEET

The Effects of Aromatherapy on the Patient Outcomes of Anxiety and Sleep Quality in Coronary Care Patients

Treatment Plans: *R_x1 = Day 1 (Lavender) Day 2 (Water)*

R_x2 = Day 1 (Water) Day 2 (Lavender)

Research Subject No.	Treatment Plan	Research Subject No.	Treatment Plan