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UNIVERSITY OF SAN DIEGO

Hahn School of Nursing and Health Science

DOCTOR OF PHILOSOPHY IN NURSING

DYSPNEA: EFFECT OF AURICULAR ACUPRESSURE IN END STAGE LUNG CANCER PATIENTS, A PILOT FEASIBILITY STUDY

Ву

Roger Alan Strong

A dissertation presented to the

FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE

UNIVERSITY OF SAN DIEGO

In partial fulfillment of the

requirements for the degree

DOCTOR OF PHILOSOPHY IN NURSING

April 2008

Dissertation Committee

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Abstract

<u>D</u>YSPNEA: EFFECT OF AURICULAR ACUPRESSURE IN END STAGE LUNG CANCER PATIENTS, A PILOT FEASIBILITY STUDY

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Introduction: Dyspnea is a debilitating symptom, common in advanced lung cancer patients, and poorly controlled. The National Institutes of Health has promoted the need for research regarding end of life care symptom control.

Purpose: Conduct a feasibility study evaluating auricular acupressure effects on dyspnea in hospice lung cancer patients.

Theoretical Framework: The UCSF School of Nursing Symptom Management Faculty Group's Model for Symptom Management was used for the conceptual framework. The model includes three dimensions: symptom experience, symptom management strategies, and symptom outcomes. The Human Energy Field Theory provided context for using auricular acupressure.

Aim: Conduct a pilot study evaluating feasibility and effects of auricular acupressure on dyspnea. Hypotheses: auricular-acupressure seed adhesive use on appropriate points plus standard care (SC) would be more effective than usual care or usual care plus placebo in (1) reducing dyspnea and (2) increasing oxygen saturation.

Methods: Both quantitative and qualitative methods. <u>Sample</u> –11 hospice patients with lung cancer and dyspnea. <u>Procedure</u> – 8 times (Day 1 baseline and post intervention, Days 2 early-late, 3 early-late, 4 early-late follow-ups) dyspnea was measured by the Cancer Dyspnea Scale and oxygen saturation was measured by pulse-oximeter.

Qualitative questions were asked on Days 1 and 4. A trained professional administered the acupressure intervention after baseline assessments. <u>Design</u> – The experimental design included 3 conditions with eight measurement points in time. Patients were randomly assigned to one of three treatment conditions: (1) Standard Care; (2) Standard Care with seed adhesive on inappropriate points (placebo); (3) Standard Care with seed adhesive Auricular acupressure on appropriate points. The results were analyzed using analysis of variance (ANOVA).

Results: Both quantitative and qualitative analyses supported the presence of acupressure effects with medium to large effects and a significant effect for dyspnea effort.

Conclusions: Although difficult to recruit patients to a trial of alternative therapy in advanced disease, it is possible to test such treatments that potentially can improve symptoms in palliative care. Auricular acupressure may help ameliorate dyspnea. There is a continued need for symptom control at end of the life. The role of nursing is central to end of life care.

Dedication

I dedicate this work to those who have played pivotal roles in my life and to those who continue to do so.

I am grateful to you all.

There is no way that anyone can manage the path that I have chosen without such people as you to guide, counsel, and encourage me.

Chief Phil Crazy Bull, Spiritual Man, Medicine Man, and Sundancer

Chief Shellbone Williams and Laurie Williams

My Family: Jeffrey Smith, Gabriel Scott Smith-Gilardi, Sue Smith, Walt Smith, Chad Smith

San Diego Hospice and Palliative Care patients and their families who graciously volunteered precious time to this study and who have served as my teachers for 22 years.

George Beck

My Parents, James and Joan Strong, the foundation of my life.

Mitakaye Oyasin

Preface

Dame Cecily Saunders stated her purpose in life was to "help the dying to live until they die and their families to live on"

Dame Cecily Saunders

June 22, 1918 – July 14, 2005

Cecily Saunders died at St. Christopher's Hospice, a Hospice that she founded

What is life?
It is the flash of a firefly in the night.
It is the breath of a buffalo in the wintertime.
It is the little shadow which runs across the grass and loses itself in the sunset.

Crowfoot, Blackfoot warrior and orator 1830-1890

Acknowledgements

A work of this size and scope can not be completed without the direct help and support of many people. Here is a list of those to whom I am greatly indebted. It would be impossible to list here all of your contributions. You each know what you did.

My Dissertation Committee: Dr. Jane Georges, Dr. Patricia Roth, Dr. Betty Ferrell

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San Diego Hospice and Palliative Care Staff

Jennifer Mitch, RN, BSN

Carol Carotenuti and Helen Grove with whom I started at Southwestern College

TABLE OF CONTENTS

ABSTRACT										
COPYRIGHT										
DEDICATION	•	•	•	•	•	•	•	•	•	ii
PREFACE .	•	•	•		•	•	•		•	iii
ACKNOWLEDGEM	IENTS	•	•	•		•			•	iv
LIST OF TABLES	•	•	•	•	•	•	•		•	ix
LIST OF FIGURES	• .	•	•	•	•	•	•	•	•	x
LIST OF APPENDIC	CIES	•	•	•	•	•	•	•	•	хi
CHAPTER										
1. INTR	ODUCT	ION A	ND SIC	NIFIC.	ANCE	•	•	•		1
	Dyspn	ea and	Context		•	•	•	•		1
		Dyspn	ea Defi	nition a	nd Prev	alence	•	•		1
		Nursin	ng Mand	late to S	Study D	yspnea	•	•		1
	Theore	etical M	lodels	•	•	•	•	•	•	3
			ded Reg	_	End-of-	Life				6
	• -		essment		•	•	•	0	•	8
			Palliativ		•	•	•	9	•	10
					e, Acupi	· uncture	•	•	•	10
		cupressi		·	·	•	•		•	11
	Resear	ch Purp	ose and	l Hypot	heses	•	•	•	•	11
2. BACK	KGROU	ND AN	D·LITE	ERATU	RE REV	VIEW	•	•	•	14
•	Theore	etical Fr	amewo	rk	•		•	•		14

Symptom Management Model (RSMC) .	•	14
Dyspnea as Symptom	•	15
RSMC Model and Dyspnea	•	21
Early Organizational Models of Dyspnea	•	23
Carrieri-Kohlman Dyspnea Variables Model.	•	24
Gift Five Elements Model	•	25
Later Dynamic Models of Dyspnea	•	26
Steele and Shaver Person-Environment Model		26
Breslin, Roy, and Robinson's Physiological Model	•	27
McCord and Cronin-Stubbs Mediation Model	•	27
West and Popkess-Vawter Modified Zelechowski Action Model		28
Campbell Antecedent-Response Model for Terminal Diseases	•	29
McCarley Chronic Dyspnea Model	•	30
Theory of Unpleasant Symptoms Model .	•	31
Conceptual Models and Measurement	•	34
Assessment Instruments	•	35
The Cancer Dyspnea Scale	•	36
Other Dyspnea Measuring Instruments .	•	39
Issues of Hospice and Palliative Care Research	•	50
Chinese Medicine and Acupuncture Treatment .		58
Complimentary and Alternative Medicine and Human Energy Field Theory	•	58
Principles and Theories of TCM		59

			Auricu	ılar Acu	punctu	re	•	•	•	•	61
				ng Rese		aluating •	g Effects	S .			62
		Summ	ary Syn	-							71
3.	METH		ary Oyn	inosos	•	•	•	•	•	•	
5.	MEIN		•	•	•	•	•	•	•	•	73
			ch Desi	gn	•	•	•	•	•	•	73
		Sample	e .	•	•	•	•	•	•	•	76
		Data C	ollectio	n Proce	edures	•	•	•	•	•	77
		Measu	res	•	•	•	•	•	•		78
		Experi	mental	Procedi	ıre	•	•	•	•		80
		Data A	nalysis	•	•	•	•	•	•	•	85
4.	RESU	LTS	•	•	•	•	•	•	•	•	89
•		Sample	e .	•	•	•	•	•	•	•	89
		Hypoth	nesis Te	sting	•	•	•	•	•		91
			Hypoth	nesis 1:	Dyspne	a Chan	ge	•		•	92
				Dyspn	ea Tota	l .	•	•	•	•	92
				Dyspn	ea Effoi	rt	•		•	•	94
				Dyspn	ea Anxi	ety	•			•	96
				Dyspn	ea Disc	omfort	•	•	•		97
				Demor	nstrating	g use of	covaria	tes	•	•	98
			Hypoth	nesis 2:	Oxyger	a Satura	tion	•	•	. 1	100
				Oxyge	n Satura	ation Pe	rcent V	alues.	•	. 1	101
				Oxyge		ation Ar	csin Tr	ansform	ed	1	102

				n Dysp	nea Asse	essment	and		
	Oxygei	n Satur	ation	•	•	•	•	•	. 103
	Evalua	tion of	Parame	etric A	ssumptio	ons.	•	•	. 106
	Qualita	tive A	nalysis	of The	mes	•	•		. 110
		Breath	lessnes	SS.	•	•	•		. 110
		Suffer	ing	•	•	•	•	•	. 111
		Qualit	y of Li	fe.	•	•	•		. 112
		Experi	ence of	f Acup	ressure [Гheraру	•		. 113
		Aware	ness of	f Morta	lity	•	•	•	. 115
		Recon	ımenda	itions c	of Acupr	essure fe	or Other	rs.	
			ung Ca			•	•	•	. 115
		Global	Them	e: Help	oing Oth	ers and	Meaning	g.	. 116
5. DISC	USSION	•	•	•	•	•	•	•	. 117
	Purpos	e of the	Study	and Pi	relimina	ry Overv	view of	Results	. 117
	Testing	of Hy	pothese	es and	Estimati	ng Effec	et Sizes	• .	. 118
	Qualita	tive Re	esults	•		•	•	•	. 120
	Study I	Limitat	ions		•	•		•	. 122
	Nursing	g Profe	ssion I	mplica	tions	•		9	. 123
	Future	Resear	ch Imp	licatio	ns.	•		•	. 125
	Conclu	sions	•	•	•	•	•	•	. 128
REFERENCES			•	•	•	•	•	•	. 130

LIST OF TABLES

TABLE

1.	ALPHABETICAL LISTING OF DYSNPEA MEASURING INSTRUMENTS	. 40
2.	3 (CONDITION/GROUP) BY 8 (TIME) ANOVA WITH TIME AS THE REPEATED MEASURE	. 74
3.	AURICULAR ACUPRESSURE POINTS USED	. 83
4.	AURICULAR ACUPRESSURE POINTS NOT USED	. 84
5.	SUBJECT CHARACTERISTICS ACROSS 3 EXPERIMENTAL CONDITIONS	. 90
6.	EXPERIMENTAL CONDITIONS: CANCER DYSPNEA SCALE TOTAL [MEAN (SD)]	. 93
7.	EXPERIMENTAL CONDITIONS: CANCER DYSPNEA SCALE EFFORT [MEAN (SD)]	. 93
8.	EXPERIMENTAL CONDITIONS: CANCER DYSPNEA SCALE ANXIETY [MEAN (SD)]	. 93
9.	EXPERIMENTAL CONDITIONS: CANCER DYSPNEA SCALE DISCOMFORT [MEAN (SD)]	. 93
10.	EXPERIMENTAL CONDITDIONS: OXYGEN SATURATION, PERCENT [MEAN (SD)]	. 101
11.	EXPERIMENTAL CONDITDIONS: OXYGEN SATURATION, ARCSIN TRANSFORMED [MEAN (SD)]	. 102
12.	CORRELATIONS OF CANCER DYSPNEA SCALE WITH PERCENT OXYGEN SATURATION	. 104
13.	CORRELATIONS OF CANCER DYSPNEA SCALE WITH ARCSIN TRANSFORMED OXYGEN SATURATION	. 104
14.	SPEARMAN RHO COEFFICIENTS OF CANCER DYSPNEA	105

LIST OF FIGURES

1	CT	TT	
HI	Gl	112	н

1.	REVISED SYMPTOM MANAGEMENT CONCEPTUAL MODEL (RMSC MODEL)	•	4
2.	PLOT OF CONDITION BY TIME FOR DYSPNEA TOTAL .	•	94
3.	PLOT OF CONDITION BY TIME FOR DYSPNEA EFFORT.	•	95
4.	PLOT OF CONDITION BY TIME FOR DYSPNEA ANXIETY	•	96
5.	PLOT OF CONDITION BY TIME FOR DYSPNEA DISCOMFORT	•	97
6.	PLOT OF CONDITION BY TIME FOR DYSPNEA EFFORT WITH AGE AS COVARIATE	•	99
7.	PLOT OF CONDITION BY TIME FOR DYSPNEA EFFORT WITH SUPPORT AS COVARIATE	•	100
8.	PLOT OF CONDITION BY TIME FOR OXYGEN SATURATION AS PERCENT	. 1	02
9.	PLOT OF CONDITION BY TIME FOR OXYGEN SATURATION AS ARCSIN TRANSFORMATION	. 1	03
10.	SCATTER PLOT OF RELATIONSHIP BETWEEN TIME 2 DYSPNEA ANXIETY AND ARCSIN TRANSFORMED OXYGEN SATURATION	. 1	06
11.	HISTOGRAM EVALUATING NORMALITY ASSUMPTION FOR DYSPNEA EFFORT TIME 1	. 1	08
12.	HISTOGRAM EVALUATING NORMALITY ASSUMPTION FOR ARCSIN TRANSFORMED OXYGEN SATURATION TIME 1	1	09

APPENDICES

A.	REVISED SYMPTOM MANAGEMENT CONCEPTUAL MODEL	•	. 159
B.	BACKGROUND INFORMATION FORM		. 161
C.	THE CANCER DYSPNEA SCALE	•	. 162
D.	HUMAN SUBJECTS RESEARCH	•	. 165
E.	HUMAN SUBJECTS TRAINING DOUCMENTS .	•	. 172
F.	AURICULAR ACUPRESSURE POINTS	•	. 177
G.	INFORMED CONSENT	•	. 179
H.	UNIVERSITY OF SAN DIEGO IRB APPROVAL .	•	. 191
I.	SAN DIEGO HOSPICE AND PALLIATIVE CARE IRB APPROVAL	•	. 194
J.	PLEDGES OF CONFIDENTIALITY	•	. 213
K.	NON-ENROLLED SUBJECT CHARACTERISTICS.	•	. 218
L.	TIME TO DEATH OF SUBJECTS ENROLLED		. 220
M.	PUBLICATION PERMISSIONS	_	. 222

Chapter 1 Introduction and Significance

Dyspnea & Context

Dyspnea Definition and Prevalence

Dyspnea as a word is derived from ancient Greek; "dys," means disordered or abnormal and "pnoia" means breath. Hence, dyspnea is literally translated as meaning disordered breathing. Dyspnea, also often called breathlessness or shortness of breath, is a common and debilitating symptom of advanced lung cancer patients (Thomas & von Gunten, 2006; Bruera, Sweeney, Ripamonti, 2002; Ahmedzai, 1993; Cowcher & Hanks, 1990).

In advanced lung cancer patients, reports give a range of dyspnea occurrence of 21% to 79% (Ripamonti, 1999) and Yoder (2006) reports on research showing that 60% of lung cancer patients develop dyspnea early and that about 65% experience dyspnea sometime during their illness. These prevalence estimates are also in line with Bruera, Schmitz, Pither, Neumann, and Hanson's (2000) report of a 55% incidence of dyspnea in ambulatory terminally ill cancer patients (not all of whom had lung cancer). Additional reports on dyspnea incidence rates are presented below in the section, 'Research Needed Regarding End-of-Life Symptom Management.'

Nursing Mandate to Study Dyspnea

A symptom of cardiopulmonary disorder, dyspnea is assessed and managed by nurses in both as an acute and a chronic problem. In a classic review of the sensation of dyspnea, Carrieri-Kohlman, Janson-Bjerklie, and Jacobs (1984) wrote: "In the recent social policy statement by American Nurses' Association [ANS, 1980], nursing was

defined as the diagnosis and treatment of human responses to health problems. Subsequently, the symptom of ineffective breathing patterns has been listed as an accepted nursing diagnosis at the Fifth National Conference on Nursing Diagnosis, April 1982, St. Louis. [Kim & Moritz DA, 1982]. These documents provide a mandate for nurses to study the measurement and management of symptoms and responses to illness, dyspnea being an example."

In her overview article on terminal dyspnea, LaDuke (2001) maintains, even in her title, "Patient deaths are inevitable. 'Bad deaths' – those accompanied by severe suffering -- are not." She notes that dyspnea is characterized by subjective awareness of uncomfortable and difficult breathing. Many patients describe the experience as agonizing and even worse than pain. Terminal dyspnea, sometimes described as "air hunger" (Tarzian, 2000), is present in as many as 75% of those who are dying (Rousseau, 1997). In fact, dyspnea should probably be expected in most dying patients (Berry, 2002). Even though dyspnea is often thought of as characteristic of chronic obstructive pulmonary disease (COPD), pneumonia, heart failure, and pulmonary system malignances, it can and does appear in the absence of any cardiopulmonary pathology (Rousseau, 1999). Nursing professionals are those who most often respond to dyspnea's appearance. Inzeo and Tyson (2003) specifically identify the key role of nursing in the assessment and management of dyspneic patients with lung cancer and Indelicato (2007) provides both an overview of and 72 references for "The advanced practice nurse's role in palliative are and the management of dyspnea."

Dyspnea is not always well assessed or well managed. Three nurses, Webb, Moody, and Mason (2000) note this and describe dyspnea assessment and management in

72 hospice patients using a retrospective, descriptive design with chart audits as the source of data. They conclude that dyspnea assessment needs to be frequently done employing standardized instruments to evaluate intensity of dyspnea and accompanying distress. Additionally, they recommend that these types of instruments be used in clinical trials to determine treatment effectiveness.

Theoretical Models

How does one begin to understand the phenomenon that is labeled dyspnea? Beyond attempting to develop some way to organize the information about dyspnea, Lenz, Suppe, Gift, Pugh, and Milligan (1995) make the case that use of middle-range theories as oppose to grand theories or broad-scope conceptual frameworks will enhance the generation of new knowledge. They argue that placing greater emphasis on such middle-range theories will more efficiently and quickly advance theory-research and theory-practice linkages. These authors cite Merton (1968) as describing middle-range theories as those falling between working hypotheses, an essential part of carrying out research and "the all-inclusive systematic efforts to develop a unified theory [of the discipline]." (p 39)

Lenz et al. (1995) list some middle-range theories that have been developed by nurses and point out that these middle-range theories are now being used in an increasing number of clinical and research settings. These include such middle-range theories as Mishel's (1988, 1990) theory of uncertainty in illness, Cox's (1982) interaction model of client health behavior, Morse and Johnson's (1991) illness constellation model, and Pender's (1987) model of health promotion and illness prevention.

Prominent among those in nursing scholarship that support the importance of middle-range theories is the UCSF School of Nursing Symptom Management Faculty Group (Dodd, Janson, Facioine, Faucett, Froelicher, Humphreys, Lee, Miaskowski, Puntillo, Rankin, & Taylor, 2001). They state, "The UCSF faculty members are committed to developing symptom management knowledge and middle range theories are useful for this purpose" (p 675). This UCSF group themselves have proposed a Symptom Management Conceptual Model (SMCM, Dodd, et al. 2001) updated and revised from their earlier model (Larson, Carrieri-Kohlman, Dodd, Douglas, Faucett, Froelicher, Gortner, Halliburton, Janson, Lee, Miaskowski, Savedra, Stotts, Taylor, Underwood, 1994a, 1994b). See figure 1 for a schematic presentation of the Revised Symptom Management Conceptual Model (RSMC Model).

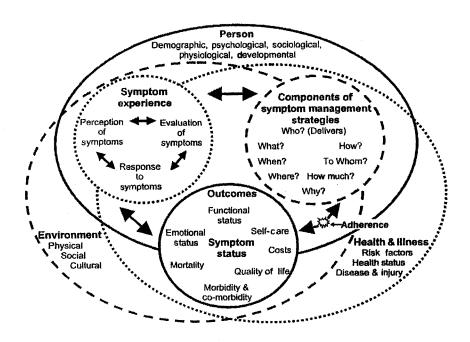


Figure 1. Revised Symptom Management Conceptual Model (RSMC Model).

This is an evidence-based conceptual model for symptom management that has three basic dimensions: symptom experience, symptom management strategies, and

outcomes. Within the model, "a symptom is defined as a subjective experience reflecting changes in the biopsychosocial functioning, sensations, or cognition of an individual" (Dodd et al. 2001, p. 669). The model describes the interrelatedness of the three dimensions within three domains of nursing science (person domain, health & illness domain, and environmental domain). Within the symptom experience dimension, there are three sub-dimensions of perception of symptoms, evaluation of symptoms, and response to symptoms. It is based on five assumptions: (1) the gold standard for understanding and studying symptoms is the perception of the individual experiencing the symptom and the individual's report of the experience; (2) the symptom need not be experienced by an individual in order for the symptom management model to be applied since the individual can be at risk for symptom development from the impact of a context variable such as a work hazard and intervention strategies can be initiated before the symptom is experienced by the individual; (3) nonverbal patients such as infants or poststroke aphasic individuals may experience symptoms where the interpretation by a parent or caregiver is accepted as accurate for intervention purposes since all troublesome symptoms need to be managed; (4) the target of management strategy can be the level of the individual, group, family, or work environment; (5) symptom management is a dynamic process in that it is modified by individual outcomes and the influences of the three nursing domains of person, health/illness, and environment. Note should be made that the authors' statement of six assumptions in their 2000 article is incorrect. There are only five listed in that article and, indeed, Elfreida O'Neil reported to this researcher that the assumptions do number only five (O'Neil, personal communication, 2004).

Research Needed Regarding End-of-Life Symptom Management

The National Institutes of Health has identified a need for research regarding symptom management and end of life care (Grady, 2005; National Institutes of Health, 2005). In setting research priorities specifically in respiratory nursing, the American Thoracic Society (1998) included the need for research on specific interventions for ameliorating dyspnea. A common end of life diagnosis that comes with panoply of difficult to manage symptoms is lung cancer. More people die of lung cancer than of colon, breast, and prostate cancers combined. The American Cancer Society estimates that there were 170,000 people in 2006 that had lung cancer with an estimated 162,000 deaths. For 2008, there are an estimated 215,020 cases of lung cancer in the United States (American Cancer Society, 2008). The numbers simply keep climbing.

There are two major types of lung cancer: non-small cell and small cell. Non-small cell lung cancer (NSCLC) is the most common type (Shepherd, 1994). Cooley (1998) reported that for both men and women in North American, lung cancer is the number one cause of cancer mortality (Parker, Tong, Bolden, & Wingo, 1997). In 2007 this is apparently still the case and Arenberg (2007) points out that though lung cancer leads in cancer causing deaths, it does not lead in the amount of research funds.

Many advanced cancer patients avail themselves of the services of hospices.

Weitzner, Moody, and McMillan (1997) report that a retrospective review of charts from a large hospice in west-central Florida identified the most common physical problem among cancer patients was pain (87%), with dyspnea being the second most common physical problem (56%). These percentages are higher than those reported by Vainio and Auvinen (1996), although it should be noted that Vainio and Auvinen collected data on

admission to hospice care, while Witzner et al. collected data from patients closer to death. In a sample of ambulatory patients with advanced lung cancer, Tanaka, Akechi, Okuyama, Nishiwaki, & Uchitomi (2002) found that over half (55%) the sample experienced clinical dyspnea as measured by the Cancer Dyspnea Scale (CDS) and the Dyspnea Numeric Scale (DNS). Also, Dudgeon, Kristjanson, Sloan, Lertzman, and Clement (2001) found a similar prevalence (46%) in a very large (over 900) sample of ambulatory lung cancer patients. More agreement on this general prevalence rate finding is found in the Skaug, Eide, and Gulsvik (2007) Norwegian community study looking at lung cancer diagnosed cases within a defined hospital area from 1990 to 1996. Here, dyspnea was found in 54% of the cases. Finally, Doorenbos, Given, Given, and Verbitsky (2006) reported that, in their study of symptom experience in the last year of life for individuals with cancer, dyspnea was in the top five most prevalent symptoms. They also note that in their last year of life, patients with lung cancer experienced more symptoms than those with other solid tumor cancers.

The World Health Organization (1990) defines palliative care as the provision of relief from pain and other distressing symptoms. Management of symptoms is a crucial part of the role of nursing in the hospice setting. Besides pain, a critically important symptom for those with impaired breathing is dyspnea. Yet research reveals that dyspnea is frequently inadequately assessed and reported (Moody, McCormick, & Williams, 1990). Good symptom control is important generally, especially for common symptoms such as dyspnea (Vignaroli and Bruera, 2006), and is achieved for dyspnea less frequently than for other symptoms including pain and nausea (Higginson & McCarthy,

1989; Kazanowski, 2001). This may be due to dyspnea not being adequately assessed near end of life (Escalante, Martin, Eltin, Cantor, Harle, Price, and Kish, 1996).

Manzullo, E.F. & Rubenstein, E.B. (1996).). Witzner et al. (1997) note: "Few intervention studies exist that have demonstrated which methods of treating dyspnea work best. Clinical guidelines for dyspnea are needed such as those developed for pain. Interestingly, the historical model of assessment of the experience of dyspnea is the assessment of pain (Matzo et al. 2001).

This research addressed the symptom of dyspnea within advanced lung cancer patients in a hospice setting. For hospice care patients, symptom management is a central goal of treatment. Sadly, as noted above dyspnea is inadequately assessed at end of life and is less frequently controlled well than other symptoms including the symptom of pain (Higginson & McCarthy, 1989; Kazanowski, 2001). One option for ameliorating the experience of dyspnea in this patient population would be auricular acupressure, a complementary alternative intervention.

Dyspnea Assessment

In nursing science, theoretical models are utilized as a basis for the development of new instruments. Conversely, it is also the case that the new instruments of measurement lead to revised or new theoretical models. The following, then, is a brief description of the development of current dyspnea measures.

Earlier definitions of dyspnea were based on objective symptoms, sometimes referred to as signs, such as "difficult or disordered breathing" (Williams, 1845). A hundred years later, there were still some confusing of symptoms and signs, e.g., Wright

and Branscomb's (1954) "difficult, labored, uncomfortable breathing." Today, the general consensus is that the dyspnea is a subjective symptom, experienced by the patient only, and reported by the patient (American Thoracic Society, 1999). Even in the 1950s and 60s when the research on dyspnea primarily dealt with the impact of mechanical loads on respiratory symptoms (Howell & Campbell, 1966), there was an awareness that dyspnea may come with several different qualities (hence, as experienced by the patient), and that the sense of effort (again, something experienced by the patient) was the primary component of breathing discomfort (American Thoracic Society, 1999). In their article on symptom control in palliative care, Fabbro, Dalal, and Bruera (2006) were careful to point out both that dyspnea is a subjective symptom and that objective assessments (e.g., tachypnea and oxygenation saturation levels) "may not adequately reflect the distress experience by patients with dyspnea." (p 423).

There is an astonishing array of instruments for measuring dyspnea. Table 1 provides an alphabetical listing of most of them. Researchers aiming at the development of dyspnea assessment tools have addressed the many different aspects of the phenomenon. These range from in-depth interviews to simple visual analogue scales, and include retrospective reports of impact of breathlessness, current descriptions of a symptom being immediately experienced, descriptors of breathlessness, psychophysiological magnitude estimation, and single factor and multi-factor scales. The range of attempts to describe dyspnea is immense. As with dyspnea itself, some approach to organizing the assessments of dyspnea is needed. In Chapter Two, four general schemes for accomplishing this are presented. McCord and Cronin-Stubb (1992) use four domains within a model of dyspnea: culture, environment, perception, and

psychological status. Carrieri-Kohlman and Janson (1999) use four descriptive categories for classification of degrees of dyspnea (qualitative descriptions, intensity, affective components, and activities of daily living). Sorenson (2000) presents three content groupings of dyspnea (activities of daily living, exercise, and health-related quality of life), while Cullen and Rodak (2002) use six clinical utility categories for grouping (exercise, activities of daily living, benchmark, outcome, responsiveness, and clinical trials) and two dimensions of assessment in evaluating the clinical utility of interventions (the discriminative versus the evaluative instruments). The choice of dyspnea measurement should be made keeping in mind the purpose of the study and populations of the studies within which a measurement was developed.

Hospice and Palliative Care

The unique population that seeks hospice and palliative care and the nature of the services in this area being prevention and relief of suffering are the sources of concerns and issues regarding research in this area (Ferrell and Grant, 2001; Addington-Hall, 2007). Terminally ill patients are a vulnerable group, research participation can be burdensome, and the methods that best address the questions need to be carefully evaluated. Hence, there are both ethical and research methodological issues involved. A number of research approaches to the challenges involved have been proposed. In the current study, efforts were made to lessen the participation burden as much as possible, clear consent procedures were developed, and both quantitative and qualitative methods were used as part of the research design. Indeed, in spite of challenges in hospice and palliative care, research must be conducted in order to build an evolving knowledge base

that allows for the delivery of quality hospice and palliative care. As Ferrell (2004) asserts, "Improved care will not happen without inquiry." (p. 408)

Traditional Chinese Medicine, Acupuncture, and Acupressure

Acupuncture is an ancient Chinese procedure for alleviating many different types of medical complaints. It involves the use of needles that are inserted in specified points of the body. Such insertion is assumed to change the flow of energy along meridians in the human body. Acupressure is assumed to produce similar effects, but by applying pressure to specified points of the body.

Some reviews of treatment for dyspnea already include sections on acupuncture and acupressure. Manning (2000), writing in the journal *Respiratory Care*, included these two procedures in his section on alternative medicine. His review concluded that traditional acupuncture produced greater improvement in breathlessness ratings and the 6-min walk distance than did a placebo acupuncture procedure. Also, in a study that did not use a control condition, acupuncture generated "prompt and significant improvements in dyspnea, relaxation, and anxiety." (p 1348) Manning also reported that patients using auricular acupressure, a procedure related to Auricular acupressure, demonstrated significantly lower visual analog scale (VAS) ratings of breathlessness for real versus sham acupoints. See Chapter Two for details of these and other studies.

Research Purpose and Hypotheses

The focus of this research was on those individuals in a hospice program who have the diagnosis of lung cancer, a prognosis of less than six months, and the specific symptom of dyspnea.

The <u>overall purpose</u> of this research was to function as a pilot feasibility study on evaluating the effects of Auricular acupressure on dyspnea (shortness of breath) in terminal lung cancer patients. The <u>general research question</u> was to determine whether the dependent variable, dyspnea, would be differentially decreased in hospice lung cancer patients across three levels of the independent variable, treatment condition. The three levels of the independent variable consisted of Auricular acupressure plus standard of care, sham Auricular acupressure plus standard of care, and standard of care.

Additionally, a simple thematic analysis qualitative method was used to place the quantitative results in a broader and richer context [Braun and Clarke, 2008].

It is important to collect qualitative data in symptom and palliative care research. Such data provide a source of richness regarding the experience of those individuals with the symptoms of interest and this information may not be captured by quantitative methods only. Additionally, qualitative data can compliment and reinforce the quantitative results.

To address this specific aim and the general question, there were <u>three basic</u> <u>hypotheses</u>:

Hypothesis 1. Over four days there would be a decrease in dyspnea for the standard care plus seed adhesive Auricular acupressure group compared to a standard care group and a standard care non-appropriate seed point adhesive placebo group.

Hypothesis 2. Over four days there would be an increase in the levels of oxygen saturation for standard care plus seed adhesive Auricular acupressure group compared to a standard care group and a standard care non-appropriate seed point adhesive placebo group.

Chapter Two, the background and literature, presents detail regarding the theoretical framework, models of dyspnea, issues of dyspnea assessment, and a brief background on traditional Chinese medicine, acupuncture, and acupressure. Chapter Three, the methods section, presents the research design, the sample, data collection procedures, measurement, the experimental procedure, and data analysis.

Chapter 2 Background and Literature Review

The purpose of this research was to conduct a pilot feasibility study regarding evaluating the effects of Auricular acupressure on dyspnea in hospice lung cancer patients. This literature review will provide a critique and synthesis of the current knowledge regarding dyspnea. The theoretical framework guiding this study will be described and critiqued along with a presentation of efforts to describe and understand dyspnea, followed by an analysis of alternative models of dyspnea. The instrument that was used to assess dyspnea in this study will be presented and placed within the context of a description of critiques of alternative instruments for measuring dyspnea. Finally, a description of the basis for Chinese medicine will be presented along with acupuncture and acupressure as medical treatments.

Theoretical Framework

Symptom Management Model (RSMC)

The UCSF School of Nursing Symptom Management Faculty Group's Model for Symptom Management was used as the conceptual framework for this study (Larson, et al.1994a, 1994b; Dodd et al, 2001). Interestingly, after this model was proposed in 2005 for this research, the researcher found that later another doctoral student adopted this same model for her study of dyspnea in patients with lung cancer under palliative care (I. Henoch, personal communication, February 11, 2008; Henoch, 2007). The model's broad perspective of symptom management includes three dimensions: symptom experience, symptom management strategies, and symptom outcomes. See Figure 1 for a schematic diagram of the RSCM Model (Dodd et al, 2001). As Dodd et. al. (2001) state,

"Healthcare providers have difficulty developing symptom management strategies that can be applied across acute and home-care settings because few models of symptom management have been tested empirically" (p 669). The RSCM model is a generic symptom management model that can provide direction for "selecting clinical interventions, informing research, and bridging an array of symptoms associated with a variety of disease and conditions" (p. 669). The model also has as its base, the nature of the individual's experience of the symptom.

Dyspnea as Symptom

Many advanced cancer patients avail themselves of hospice services. For hospice care patients, symptom management is one of the central goals of treatment. Dyspnea is one of the most important symptoms. Dyspnea is also less frequently controlled well than other symptoms including the symptom of pain (Higginson & McCarthy, 1989). Interestingly the model of assessment of dyspnea is the assessment of pain (Matzo et al. 2001).

When asked what his experience of breathlessness was like, one patient reported that the dyspnea sensation was like "being at the bottom of a swimming pool, struggling but unable to reach the top to breathe" (Dudgeon & Rosenthal, 1996). Asking the patient what he or she experiences is crucial in evaluating dyspnea, since dyspnea is a sensory experience perceived and interpreted by the patient (Widimsky, 1979; Carriere-Kohlman, Janson-Bjerklie, & Jacobs, 1984; American Thoracic Society, 1999; Dodd et al., 2001). Indeed, symptom experience is one of the three dimensions in the RSMC Model (Dodd et al., 2001). Within the model, the person is viewed as central, with the person's symptom

experience itself having three components: (1) perception of the symptom (a change in sensation); (2) evaluation of the symptom (interpretation); (3) response to symptom.

Researchers and clinicians have attempted to define dyspnea through various metaphors (American Thoracic Society, 1999). These include such descriptions as "an uncomfortable sensation of breathing" (Mahler & Schwartzstein, 1995); "the sensation of feeling breathless or experiencing air hunger" (Simon, Schwartzstein, Weiss, LaHive, Fencl, Teghtsoonian, & Weinberger, 1989); "difficult, labored, uncomfortable breathing" (Wright & Branscomb, 1954); and "awareness of respiratory distress" (Wasserman & Cassaburi, 1988). These attempts at descriptive definition mix symptoms (what patients report they are feeling) and physical signs (what a physician or nurse observes about the patient such as the patient exhibiting labored breathing). It is important to remember that only the person who is experiencing a symptom can describe it.

Even though it is the patient who describes a symptom that is experienced, it is possible to generate a more general definition of dyspnea while preserving the necessary attribute of it being a subjective experience. The American Thoracic Society offered this broad definition (1999): "[W]e suggest that dyspnea is a term used to characterize a subjective experience of breathing discomfort that consists of qualitatively distinct sensations that vary in intensity. The experience derives from interactions among multiple physiological, psychological, social, and environmental factors, and may induce secondary physiological and behavioral responses." An examination of the Figure 1 RSMC Model reveals how well the general model of symptom management and this broad definition of the specific symptom dyspnea agree regarding the symptom

experience. Both identify three components of the symptom experience: perception of, evaluation of, and response to symptoms.

Given that the literature consistently presents dyspnea as a subjective symptom (Carrieri-Kohlman, Janson-Bjerklie, & Jacobs, 1984; Gift, 1987; Cockcroft, Adams, & Guz, 1989; Lenz et al, 1995; American Thoracic Society, 1999; Wilcock, Crosby, Hughs, Fielding, Corcoran, Tattersfield, 2002) and that it is detected only by the patient who reports the sensation of difficult or labored breathing, it may be helpful to examine the language of breathlessness. That is, how do patients describe breathlessness; what descriptors do they use? Importantly, in the development phase of their instrument, the Cancer Dyspnea Scale, Tanaka, Akechi, Okuyama, Nishiwaki, & Uchitomi (2000) interviewed dyspneic patients in a thoracic oncology division and palliative care unit. Additionally, they brainstormed with the staff of the same unit and reviewed papers on dyspnea. Eventually, the developmental and validation processes reduced an initial set of 179 terms to 24 (see Appendix for these CDS items).

There were earlier attempts to examine the language of breathlessness often using qualitative methods. Simon, Schwartzstein, Weiss, LaHive, Fencl, Teghtsoonian, & Weinberger (1989) interviewed patients with a variety of cardiac and pulmonary diseases, compiling a list of 19 descriptors of breathlessness. Interestingly, when the researchers used eight different stimuli to induce breathlessness in 30 subjects who then chose descriptors from the list best capturing how they felt, separate groups of descriptors emerged for varying stimuli. The authors surmised that the label breathlessness might actually apply to many different sensations. Indeed, in a follow-up study, Simon, Schwartzstein, Weiss, LaHive, Fencl, Teghtsoonian, & Weinberger (1990) found patients

were able to distinguish different sensations of breathlessness. Additionally, there was some association between the underlying disease and the qualitative descriptors selected.

Elliot, Adams, Cockcroft, Macrae, Murphy, & Guz (1991) conducted a study of hospital staff, beginning with 18 qualitative descriptors of breathlessness discomfort from the Simon et al. (1989) study. They circulated the 18 descriptors among hospital staff, and asked for additional descriptors of the staff's respiratory sensations during exercise. Twelve respiratory physicians on the staff were asked to contribute descriptors used by patients. This generated 45 descriptors. These were then given to five senior nurses who recommended changes of the descriptors for greater ease of understanding by patients. Patients (N=208) who described breathing troubles during walking, running, or climbing stairs were then given the list of descriptors and asked to rate them for agreement with their own sensations on two separate occasions, using response options of yes, no, or don't know. Some items were more consistent over time than others, but the descriptors did group into 12 clusters and 169 of the 208 patients were considered reliable in their responses over the two administrations. Again, there was an association between descriptors endorsed and underlying disorders. For example, chronic obstruction airway disease (COAD) patients were more likely to endorse distress, asthma patients to endorse wheeziness, restrictive airway disease patients to endorse rapid breathing, and cardiac patients to choose a need to sigh. A more recent study (Wilcock, Crosby, Hughs, Fielding, Corcoran, Tattersfield, 2002) using only 15 descriptors of breathlessness also found that patients with different diagnoses (six sub-groups of lung cancer diagnosis four sub-groups of nonmalignant cardiorespiratory disease diagnosis) were differentially likely to endorse the descriptors. Such relationships would support the RSMC Model in

that the Health and Illness domain (e.g., disease) would impact the perception of a symptom within the symptom experience dimension.

It would appear that Sorenson (2001) was correct in stating, "Since this symptom manifests differently in each patient, it would be impossible to design a one-size-fits all instrument to assess dyspnea or serve as an outcome measure in dyspnea control" (p1331). This is echoed by Cullen & Rodak (2002) in their article assessing the clinical utility of breathlessness measures, which they state may have different clinical utility for different diagnoses. Additionally, the American Thoracic Society Consensus Guideline on Dyspnea (1999) directs that dyspnea assessments should be applied as related to the purpose for which they were designed: "Any assessment of dyspnea must take into consideration the question being asked. Are we trying to measure the intensity or quality of the sensation of respiratory discomfort or the emotional or behavioral response to the discomfort?" (p 322)

An interesting qualitative methods study by Bailey (2004) was designed to understand the affective component of dyspnea. Their focus was on the dyspnea-anxiety-dyspnea cycle in COPD patients' stories of breathlessness. Using 10 patient-family-nurse units and an ethnographic research design with in-depth interviews and narrative analysis, Bailey found that anxiety as manifested in a dyspnea-anxiety-dyspnea cycle for acute episodes was an important component of the dyspnea experience. She maintains that this component needs to be recognized by healthcare providers and she states that it is potentially measurable. Presence of anxiety related to dyspnea was also found by Bruera et al. (2000) who reported a correlation of .31 between dyspnea intensity and the level of anxiety in 135 ambulatory terminally ill patients with cancer, of whom 55% manifested

dyspnea. As noted below, Tanaka et al.'s (2000) Cancer Dyspnea Scale has three dimensions, one of which is anxiety. Also, Chiu, Hu, Lue, Yao, Chen, and Wakai (2004) found in their quantitative study of correlates of dyspnea in Taiwanese patients that anxiety again makes an appearance. This appears to be a type of convergence of findings between qualitative and quantitative research methods.

Joyce (M. Joyce, personal communication, February 19, 2008; Joyce, 2006), at the 2006 UICC World Cancer Congress, reported her work reviewing qualitative research on dyspnea in search for themes regarding the experience of dyspnea beyond the simple description of the experience itself. She conducted a search using bibliographic computerized databases between 1990 and 2005. This identified nine English language citations for patients' experience of dyspnea being evaluated using qualitative methods.

Joyce has not yet published this work, but she did respond to an inquiry and send the power point presentation that she used (M. Joyce, personal communication, February 19, 2008) wherein she stated, "Qualitative research method is primary source of exploring symptom experience." (2nd slide) The power point presentation also included the references for the nine articles (Brown, Carrieri, Janson-Bjerklie, and Dodd, 1986; DeVito, 1990; Roberts, Thorne, and Pearson, 1993; O'Driscoll, Corner, and Bailey, 1999; Shih and Chu, 1999; Bailey, 2001; Bailey and Tilley, 2002; Hately, Laurence, Scott, Baker, and Thomas, 2003; Heinzer, Bish, and Detwiler, 2003). Using Forchuk and Roberts' guidelines (1993) for critiquing qualitative research, Joyce found among these nine articles the three qualitative methods of phenomenology, triangulation, and narrative ethnography. Common across these nine studies were the three themes of profound fear, loss of vitality, and the need to legitimize dyspnea distress.

RSMC Model and Dyspnea

The use of the RSMC Model as the conceptual framework for this research is supported by the conceptualization of dyspnea in the research literature. The consensus now is that manifestations of subjective symptoms such as dyspnea are not simple reflections of the intensity of the mechano- and chemo-receptor level (Tanaka et al 2002b; Ripamonti & Bruera, 1997; Bruera & Ripamonti, 1999). Moderators are thought to amplify or decrease perceived dyspnea intensity at the cortical level and include such as psychological state, cultural background, environment, and life experiences (Ripamonti & Bruera, 1997; Bruera & Ripamonti, 1998). These assertions are supported by studies that demonstrated significant relationships of dyspnea with such psychological states as anxiety and depression in non-cancer samples (Dales, Spitzer, Schechter, et al., 1989; O'Connor, Rablin, & Morgan, 1996) and anxiety in cancer patients (Bruera & Ripamonti, 1998; Dudgeon & Lertzman, 1998). Dyspnea has also correlated with such demographic factors as sex and age in non-cancer patients (O'Connor, Rablin, & Morgan, 1996; Gijsbers Van Wijk & Kolk, 1997; Metlay, Schulz, Li YH, et al., 1997). Environmental factors such as exposure to asbestos, coal dust, cotton dust or grain dust were also related to presence of dyspnea (Dudgeon et al. 2001).

Dyspnea is a complex symptom, from its lack of systematic reflection of underlying causes, to its multi-dimensionality, to its manifestation being related to the individual, the environment, and the health or illness status of the person. One way to organize this complexity and to generate strategies or guidelines for research and clinical practice would be to conceptualize dyspnea within the RSMC Model.

This RSMC model for symptom management is an evidence-based conceptual model that has the three basic dimensions of (1) symptom experience, (2) symptom management strategies, and (3) outcomes. Within the model, consistent with the literature on dyspnea, "a symptom is defined as a subjective experience reflecting changes in the biopsychosocial functioning, sensations, or cognition of an individual" (Dodd et al. 2001, p. 669). The model describes the interrelatedness of the three basic dimensions within the three domains of nursing science (1) person domain, (2) health & illness domain, and (3) environmental domain. Again, consistent with dyspnea literature, within the symptom experience dimension, there are three sub-dimensions of (1) perception of symptoms, (2) evaluation of symptoms, and (3) response to symptoms. See Figure 1 above or Appendix A for a graphic schematic of this model.

The RSMC Model is based on five assumptions: (1) the gold standard for understanding and studying symptoms is the perception of the individual experiencing the symptom and the individual's report of the experience; (2) the symptom need not be experienced by an individual in order for the symptom management model to be applied, since the individual can be at risk for symptom development from the impact of a context variable such as a work hazard, and intervention strategies can be initiated before the symptom is experienced by the individual; (3) nonverbal patients such as infants or post-stroke aphasic individuals may experience symptoms where the interpretation by a parent or caregiver is accepted as accurate for intervention purposes; (4) the target of management strategy can be the level of the individual, group, family, or work environment; (5) symptom management is a dynamic process in that it is modified by

individual outcomes and the influences of the three nursing domains of person, health/illness, and environment.

Congruent with the RSMC Model and the dyspnea literature, Bruera and Ripamonti (1998) and Ripamonti (1998) recommended that a scale to measure dyspnea for investigating etiology and establishing therapeutic strategies should have six characteristics: (1) be multidimensional; (2) be self-rating since dyspnea is subjective; (3) be easy and simple enough to be completed by patients with dyspnea; (4) be evaluated not by physical effort evoking dyspnea, but by perceived dyspnea itself so that even bedridden patients can complete it; (5) have its reliability and validity in cancer patients confirmed; (6) be sensitive to clinical changes due to treatment or progression of the disease over time.

Early Organizational Models of Dyspnea

Review of dyspnea models other than the RSMC Model not only provides an historical perspective of the field, but also identifies the common components of a set of models. In addition, this review will assist the reader in understanding the RMSC Model itself, since it is the inheritor and improver of models developed over the last two decades.

Interestingly, the first and second researcher names attached to models of dyspnea are names that reappear and are associated with more than one model. The first name is Virginia Carrieri-Kohlman, D.N.Sc., R.N. The second name is Audrey G. Gift, Ph.D., R.N. The field of nursing can thus lay claim to the first models of dyspnea.

Carrieri-Kohlman Dyspnea Variables Model

The model by Carrieri-Kohlman and colleagues (Carrieri-Kohlman, Janson-Bjerklie, & Jacobs, 1984) was intended as a means to begin organizing the broad range of phenomena related to the complex construct of dyspnea. It was thus more a listing of categories of dyspnea phenomena than the more dynamic models that would emerge over time. Still, anyone who has attempted to grasp the literature surrounding any concept, including those of different clinical symptoms, can appreciate the immense step it is to present a way of organizing that material. The only name these researchers gave to their model was "Variables Related To Dyspnea" (Carrieri-Kohlman et al. 1984, p 443).

Importantly, dimensions and components of later models can already be seen in this heuristic organizing of variables related to dyspnea. The three general domains of variable listing echo through later models: personal, health status, and situational. These domains were conceptualized as being related to two groupings of amelioration strategies: patient coping strategies and self-care behaviors, and therapeutic management strategies. Finally, these two strategies were organized as related to dyspnea itself with three areas: description, mechanisms, and measurement. The model, as do all other models, assumes dyspnea, like pain, to be a sensory experience of the individual.

Although providing direction for studying dyspnea risk factors, the model is limited to the description and measurement of dyspnea. The grouping of some of the factors could be differently conceptualized. For example, some of the variables such as health status could be considered outcomes or consequences of dyspnea, and a bidirectional causal path between dyspnea and such variables would better capture what probably does take place. Still, although dynamics were not presented in this listing of

phenomena, the authors were cognizant of the complex relationships among these variables. They ended their paper with this statement: "The obviously complex, multivariate relationships of all these factors and dyspnea need to be acknowledged in systematic study of this significant clinical symptom" (p. 443.)

Gift Five Elements Model

The next major model of dyspnea was that of Gift (1987, 1990a). This model, like that of Carrieri-Kohlman's was still a template for organizing dyspnea related phenomena. It was a framework with five components (Gift, 1990a), that McCarley (1999) has described as a kind of pie chart of elements. The five components were: (1) the sensation of dyspnea (physiological component), mediated or activated by sensory receptors and the central nervous system; (2) the perception of dyspnea (cognitive component) with interpretation of the sensation and affected by past experience and present expectation; (3) the distress of dyspnea (psychological component) characterized in psychoemotional terms and include the psychological correlates of dyspnea; (4) the response to dyspnea encompassing coping style and strategies used by the individual; (5) the reporting of dyspnea (social component), including the descriptors used and the decision to report the experience or not.

The Gift model incorporated dimensions or domains that will be reflected later in more complex, dynamic models. These included such dimensions as the physiological, the psychological, the person (cognitive), behavioral, and social. Gift's model presented a holistic representation of the dyspnea experience. The model is limited in that it does not address risk factors for dyspnea, precipitating factors, or consequences for the

individual. Nonetheless, as with the organizing model of Carrieri-Kohlman, one can see the precursors of important elements of the later, more complex, dynamic models.

Later Dynamic Models of Dyspnea

Following Carrieri-Kohlman and Gift, there were a series of models focused on different aspects of dyspnea, although the aspects are usually placed within a larger conceptual framework. These larger frameworks were all quite similar in being multi-dimensional, having psychological and physiological components, placing the person in some setting (environment, social, life context), and delineating some relationships among model components.

Steele and Shaver Person-Environment Model

For example, Steele and Shaver (1992) offered a person-environment ecological framework wherein they conceptualized dyspnea as a nociceptive (body part damage) phenomenon, and took into account biopsychosocial factors that affect dyspnea. This has also be labeled an ecologic model of dyspnea because the authors presented dyspnea as a biopsychosocial phenomenon. Although these researchers had a multi-domain model and they did have dynamic relationships among elements of the model (i.e., feedback loops), the schema and the relationships among model elements are often difficult to track or interpret. Also, their focus was on perceptual sensitivity, defined using magnitude estimation procedures. They did provide a quantifiable estimate of sensitivity to dyspnea generating stimluli [Mathler, Rosiello, Harver, Lentine, McGovern, & Daubenspeck, 1987).

Breslin, Roy, and Robinson's Physiological Model

Breslin, Roy, and Robinson (1992) also presented a large framework, but their focus was on the role of the respiratory pump and respiratory muscle function as the basic process contributing to dyspnea. Still, their integrated metaparadigm conceptualized basic nursing science as the understanding of the life processes and clinical science as diagnosis and treatment. This Breslin et al. metaparadigm is similar to the Carrieri-Kohlman, Lindsey, and West (1993) general framework of selected biological and psychosocial life processes along with use of pathophysiological concepts. In both of these models, dyspnea is understood as an alteration in the normal life process of sensation. Indeed, Carrieri-Kohlman, Lindsey, & West (1993) used these general frameworks to propose a treatment of dyspnea distress based on the idea of desensitization, a concept also found in the model of Steele and Shaver (1992) discussed above. Hence, such models can lead to development of treatment possibilities.

McCord and Cronin-Stubbs Mediation Model

McCord and Cronin-Stubbs (1992) also presented a larger model of dyspnea with domains of antecedents, mediators, reactions, and consequences or outcomes. Dyspnea was seen as a multi-dimensional disorder where physiologic and psychogenic antecedents were mediated by culture, environment, perception, and psychological status to yield the reaction of dyspnea sensation. This model presented three areas of consequences: resolution (patient takes action that resolves the dyspnea sensation); adaptation (patient takes action that mediates dyspnea but does not completely resolve it); and no response

(where the action has no effect on dyspnea, either the intensity or duration). Hence, within this framework, coping strategies and management were seen as changing the degree of dyspnea instead of affecting the consequences of dyspnea on quality of life of the person. Most of the models developed up to when this model was presented did not address the impact on quality of life.

The particular focus of the McCord and Cronin-Stubbs (1992) model was actually on measurement. Indeed, the authors grouped a variety of assessments of dyspnea and dyspnea related phenomena under the four domains of their model: antecedents, mediators, reactions, and consequences of dyspnea. Hence, McCord and Cronin-Stubbs (1992) and their model will be re-visited below in the sub-section on dyspnea assessment.

West and Popkess-Vawter Modified Zelechowski Action Model

The next model of interest is that of West and Popkess-Vawter (1994), which was an adaptation of an earlier Zelechowski (1977) model of breathlessness that had physiological and psychological dimensions. The focus of the Zelechowski model was on the response or reaction to dyspnea, the actions taken in the presence of dyspnea. Individuals were conceptualized as having different actions such as anxiety, anger, and exercise, or having or non-action such as sleep, depression, or apathy. These actions in the presence of dyspnea were hypothesized to, in turn, influence dyspnea. Hence, there is a dynamic aspect to the Zelechowski model, the presence of feedback loops. Although the focus of the model was on reactions to dyspnea, the model did also include dyspnea antecedent conditions such as degree of perceived threat and/or physiological changes.

In their modification of the Zelechowski model, West and Popkess-Vawter (1994) expanded the list of antecedent conditions. They also added positive and negative adaptive responses as outcomes. The focus of the adapted model was still on the type of actions taken in the presence of dyspnea.

Campbell Antecedent-Response Model for Terminal Diseases

Campbell (1996) developed a model focused on dyspnea in patients with terminal diseases and offered schema for describing the relationships between antecedents of and response to dyspnea. Even more specifically, the focus was on those patients who refused intubation or ventilation. Still, even with such specific focus for a model, it had some of the same general features found in nearly all models developed to describe dyspnea. These included the elements of antecedents and reactions to dyspnea. There were also physiologic versus psychogenic categories for grouping dyspnea both antecedents and reactions. Physiologic antecedents were those conditions likely to increase the work or breathing (including cardiac, pulmonary, and neuromuscular disease) and physiologic reactions included tachypnea, tachycardia, use of accessory muscles, and tidal volume changes. Psychogenic antecedents included those that Campbell identified as having no physiologic source (including anxiety, anger, and depression) and psychogenic reactions included panic, fear, frustration, anger, and anxiety. Hence, some possible emotional states were also among possible antecedents. Interestingly, research has not supported the relationship between the either the physiologic antecedents or some of the physiologic reactions identified in the model and

dyspnea in patients with COPD (McCarley, 1999). Also depression is not likely to be an antecedent for dyspnea and is more likely a consequence.

McCarley Chronic Dyspnea Model

Although temporally McCarley's (1999) model of chronic dyspnea came after that of either the model of unpleasant symptoms described below or the initial version of the symptom management model (Larson et al, 1994a, 1994b) described above in its revised form (Dodd et al, 2001), it is basically an add on for these more general models. In her review of what had come before her own model, McCarley did cite and describe the unpleasant symptom theory, but she did not present a description of the initial version of the symptom management.

As the title clearly states, McCarley's (1999) model focused on chronic dyspnea as opposed to acute dyspnea, and given the nature of chronic versus acute dyspnea, the primary focus of her model was on the <u>consequences</u> of chronic dyspnea. Her primary criticism of other models was that they did not differentiate between acute and chronic dyspnea. Gift (1987), who has been involved in the development of models, did at least differentiate between acute dyspnea as having rapid onset, and chronic dyspnea as being persistent over time but with the intensity changing. McCarley did point out that within a model, one would want to identify differences for acute versus chronic dyspnea. For example, the emotional responses to chronic as opposed to chronic dyspnea might be expected to be quite different.

Although McCarley states that her purpose was to propose a new model of chronic dyspnea to guide care and evaluation of chronic dyspnea in patients living with

COPD, she did place her own model within the then developing concept of dyspnea as multi-factorial. She also delineated three components of a model of chronic dyspnea (physiologic, the symptom dyspnea, and consequences). Although her model did have three components, her interest here in chronic dyspnea led to an emphasis of the consequences of dyspnea rather than its antecedents. The structure of her model was is similar to that of Campbell's (1996), but she noted that there was only a minor focus on dyspnea antecedents. Also she did not use psychogenic stimuli as antecedents in her model but rather as sequelae of living with the persistent distress of chronic dyspnea. Finally, McCarley described consequences as also multi-factorial and having dimensions of the physical, psychological, and socio-cultural. She noted that, unlike other models of dyspnea McCarley did not place the sensations of fear and panic as consequences of acute dyspnea. Here, one can see how particular models will lead to different emphasis and, hence, guidelines for research and clinical practice.

Theory of Unpleasant Symptoms Model

Lenz, Suppe, Gift, Pugh, and Milligan (1997) offered a model that attempted to describe unpleasant symptoms generally. This model was briefly presented above as an exemplar of a middle-range theory. Labeled the "Theory of Unpleasant Symptoms," this model was developed from research on dyspnea in populations of COPD and asthma patients, and research of fatigue during intrapartum and postpartum periods. As many researchers of dyspnea have done, pain was used as a general analogue. Dyspnea was presented as having both physiological or sensory and psychological or cognitive dimensions. The psychological or cognitive attributes of dyspnea were seen as similar to

the distress components of pain. Importantly, as part of the process of identifying fundamental features of dyspnea, the same individuals were evaluated at times when they and did not have dyspnea. In a series of studies (Gift, 1990b, 1991; Gift, Plaut, & Jacox, 1986), psychological (cognitive) or distress attributes of dyspnea were demonstrated to be similar to pain. These attributes of dyspnea were also found in these studies to be related to anxiety, somatization, and depression).

Consistent with the emerging basic understanding of dyspnea and unpleasant symptoms, the Theory of Unpleasant Symptoms included three dimensions of antecedents of unpleasant symptoms affecting an individual's predisposition to or manifestation of the symptom. These three familiar dimensions were physiological, psychological, and situational. They were also understood to affect the characteristics of the symptom as well as performance variables (physical performance, functional status, and cognitive functioning) affected by the symptom.

Specific to dyspnea and consistent with all other theorists, researchers and the general literature, Lenz et al (1996) conceived of dyspnea as a subjective symptom rather than an object sign. They pointed out that dyspnea could be detected only in the patient who reported the sensation of labored or difficult breathing. Through observation others could identify labored breathing, but only the patient experienced the sensation of labored breathing. Hence, these authors clearly stated that dyspnea must not be confused with rapid respiratory rate, deep breathing, or other signs of respiratory distress. Supporting the conceptualization of dyspnea as a sensation, Wolcove, Dajcxman, Colocone, and Kriesman (1989) demonstrated the lack of a consistent relationship between pulmonary function and dyspnea.

In summarizing their own synthesis of the literature and their basic concept of dyspnea, Lenz et al (1995) presented dyspnea as an unpleasant symptom having five components. These were the same five components of dyspnea explicated in Gift's (1990a) pie chart model for organizing dyspnea phenomena presented in more extended description above. In brief, these five components are: (1) the sensation of dyspnea; (2) the perception of dyspnea; (3) the distress of dyspnea; (4) the response to dyspnea; (5) the reporting of dyspnea. Lenz et al (1995) noted that one could consider these components as the domains of the concept of dyspnea. They also concluded that dimensions of the dyspnea variable would include duration, strength or intensity, degree of distress, and quality.

Here, then, is a middle range theory or model of dyspnea, and unpleasant symptoms generally, that is based on research and a synthesis of the literature, uses dyspnea as one of the two unpleasant symptoms evaluated in leading to the model, incorporates the basic domains and dimensions identified in the literature as part of the concept of dyspnea, and can be heuristic in providing guidelines for research and clinical practice.

It is interesting that this middle-range theory of unpleasant symptoms with its summary of the field, use of dyspnea as an primary example of an unpleasant symptom, capturing of the multi-factorial nature of symptoms including dyspnea, and ability to guide research and practice emerged at about the same time as the RSMC Model that also used literature on dyspnea as a source of information for model development. There are different foci within these two models that are captured by their titles. The unpleasant symptoms model is focused on describing unpleasant symptoms while the RSMC Model

is focused on general symptom management. Still, although the two models also use some different labels for elements of the models and use some element labels differently, both are evidence based, both see dyspnea as a symptom as subjective and multi-dimensional, with antecedents and outcomes that are also multi-dimensional, and both identify the issue of the operationalization or assessment of a symptom as being of primary importance.

Conceptual Models and Measurement

Conceptual models are touted as guiding researchers to, among other things, develop better assessments. It is also true that the development of measurements led to modification of models or the development of new models (Scott, 2004). This happens in all areas of science. If you can now measure something that you could not earlier, then you will learn new things about that which is measured. An example in the field of dyspnea would be the use of visual analogue scales to capture a subjective experience (Hayes & Patterson, 1921) and later measure "feelings" (Aitken, 1969) and pain (McDowell & Newell, 1996), and later still to measure dyspnea (Adams, Chronos, Lane, & Gjuz, 1985; Gift, 1989; Wilson & Jones, 1989; Muza, Silverman, Gilmore, Hellerstein, & Kelsen, 1990). Eventually, such scales were used to demonstrate that patients could differentiate between their experience of shortness of breath and their anxiety regarding that shortness of breath (Carrieri-Kohlman, Gormley, Douglas, Paul, Stulbarg, 1996).

One could, as does Scott (2004), consider this effort of Carrieri-Kohlman et al.

(1996) as presenting a model for management of dyspnea that considers the fear and panic involved and suggesting that desensitization would be an appropriate intervention.

Indeed, exactly this is recommended in a later Carrieri-Kohlman article (Carrieri-Kohlman, Gormley, Eiser, Demir-Deviren, Nguyen, Paul, and Stulbarg, 2001). The development of tools affects the development of our perception of the phenomena that we find of interest. Partially because there were instruments that allowed the differential and independent measurement of patients' experiences of the sensation of dyspnea as opposed to their experiences of the affective components of dyspnea, these authors could hypothesize that and test whether patients <u>could</u> differentiate between the experience of the sensation versus that of the affect. This work then led to a recommended intervention for dyspnea, desensitization.

It seems appropriate that this general review of models of dyspnea ends where it began, with the researcher and nurse, Virginia Carrieri-Kohlman.

Assessment Instruments

There are many instruments for measuring dyspnea. However and importantly, Spector and Klein (2001) state the necessity of more sensitive instruments for assessing dyspnea in critically and terminally ill patients. Also Bruera and Ripamonti (1998) and Ripamonti (1998) provided recommendations for any scale measuring dyspnea for investigating etiology and establishing therapeutic strategies: (1) be multidimensional; (2) be self-rating since dyspnea is subjective; (3) be easy and simple enough to be completed by patients with dyspnea; (4) be evaluated not by physical effort evoking dyspnea, but by perceived dyspnea itself so that even bedridden patients can complete it; (5) have its reliability and validity in cancer patients confirmed; (6) be sensitive to clinical changes due to treatment or progression of the disease over time.

The Cancer Dyspnea Scale

In this research, the scale for assessing dyspnea was the Cancer Dyspnea Scale (CDS). It was developed using patients with cancer, has been used in studies with advanced lung cancer patients (Tanaka et al. 2002b), and, because of its simplicity, is feasible for use with hospice lung cancer patients. The CDS also meets the six criteria of Bruera and Ripamonti (1998) and Ripamonti (1998) stated above. In the text above, it was mentioned that I. Henoch (personal communication, February 11, 2008) had adopted the same theoretical framework for her doctoral work as was here. Additionally, she also chose to use the CDS in her research.

The CDS (Tanaka et al. 2000) is a brief, self-reporting scale designed to measure dyspnea's multidimensional nature. It assesses three dimensions: sense of effort (Dyspnea Effort), sense of anxiety (Dyspnea Anxiety), and sense of discomfort (Dyspnea Discomfort). Although the authors note that the CDS can also yield a total score (Dyspnea Total), the three factors are correlated with each other at only moderate levels (.27, .30, and .55). Hence, the factors can be interpreted as reflecting the multidimensional nature of dyspnea. There is no evaluation of physical function evoking dyspnea since the authors did not want to limit the sensitivity of the instrument when it is used with bedridden patients. The items can be read aloud and the patient can respond with a number from the 5-point scale, if the terminally ill patient cannot read the items or use a pencil to respond to them.

The CDS reflects well the RSMC Model in that it is a multi-dimensional assessment of symptom experience. The three factors of the CDS can be conceptualized

as capturing the RSMC Model's three dimensions of symptom experience. Sense of effort is recognition or perception of the presence of the symptom of dyspnea. Sense of discomfort is the evaluation of the symptom, including an evaluation of threat. Sense of anxiety is a response to the symptom. Additionally, Tanaka, Akechi, Okuyama, Nishiwaki, & Uchitomi (2002b) state, "The manifestations of subjective symptoms have recently come to be interpreted as resulting from the interaction of production, perception, and expression, not as a direct representative of the intensity of the production of the dyspnea at the mechano- and chemo-receptor level" (p 491). This is certainly consistent with the RMSC Model, as the study of these researchers described below.

Tanaka et al. (2002b), a study looking at the correlates of dyspnea in advanced lung cancer patients, used the CDS to measure dyspnea. Congruent with the RMSC model, they not only conceptualized and measured dyspnea as a multi-dimensional construct, but they evaluated how dyspnea was related to a broad range of medicopsycho-social factors. The medical factors included clinical stage, performance status, oxygen saturation levels, organic causes of dyspnea, and other symptoms such as cough and pain. The psychological factors included anxiety and depression, while the social factors included education, marital status, and existence of confidents. Multiple regression analysis demonstrated that psychological distress, presence of organic causes, cough, and pain were significantly related to dyspnea ($R^2 = .30$, p < .05). The study confirmed that dyspnea is multi-dimensional and that the intervention for psychological distress and pain could be a beneficial therapeutic strategy.

Other researchers are now also using the CDS, including versions that are being translated into other languages. For example, Henoch, Bergman, and Gaston-Johansson (2006) translated the CDS into Swedish and evaluated its psychometric properties on a Swedish sample of 99 patients with advanced lung cancer. Using Cronbach's alpha, they reported that the CDS internal consistency was excellent with a coefficient range of .81 to .90. Convergent validity was evaluated through correlations of the CDS with measures of discomfort and both physical and emotional function (r = .34 to .57) as well as with other measures of dyspnea (r = .63 to .68). Interestingly, the researchers reported that the CDS was better at assessing dyspnea's psychological dimension than was the VAS-D (Visual Analog Scale for Dyspnea). Finally, the researchers report that factor analysis of the CDS items yielded the expected three dimensions of effort, anxiety and discomfort. Further they report that these CDS factors correlated as expected with specific other instruments as well as related-factors from other instruments.

For evaluating effects of therapeutic interventions, an important attribute of an assessment of dyspnea would be responsiveness. That is, is the instrument capable of detecting expected changes? The CDS was used as part of a study of the effect of nebulized furosemide on dyspnea in end of life cancer patients. The CDS was given before and 60 minutes after inhalation. The researchers found that the CDS demonstrated a significant change in the total dyspnea score from before to after inhalation as well as significant changes in both sense of effort and sense of anxiety (Kohara, Ueoka, Aoe, Maeda, Takeyama, Saito, Shima, and Uchitomi, 2003).

Other Dyspnea Measuring Instruments

At the end of the section on dyspnea models above, the relationship between theory and measurement was briefly discussed. This relationship is also illustrated by the area of work that could be labeled the language of breathlessness. This area of thought and research was described above in the section on models of dyspnea. It could as easily have been placed here under assessment. It will again be described more briefly below.

There are four categories of mechanisms of dyspnea (Carrieri-Kohlman, Janson-Bjerklie, & Jacobs, 1984): (1) stimulation of afferent intrapulmonary receptors; (2) increased sensitivity to changes in ventilation perceived via central nervous system mechanisms; (3) reduced ventilatory capacity or breathing reserved; (4) stimulation of neural receptors in the musculature of the intercostals and diaphragm and of receptors in skeletal joints. However, the mechanisms are not well understood and there is no general theory explaining dyspnea's physiologic basis completely (Carrieri-Kohlman, Janson-Bjerklie, & Jacobs, 1984; Sassi-Dambron, Eakin, Ries, & Kaplan, 1995).

There is also no general agreement about the appropriate method for measuring dyspnea (Sassi-Dambron, Eakin, Ries, & Kaplan, 1995; Eakin, Kaplan, & Ries, 1993). The lack of a complete understanding of the underlying causes of dyspnea and the lack of a consistent and systematic relationship between the assumed physiological substratum of dyspnea and patient reporting of dyspnea as well as the lack of consistent, observable signs and the subjective experience of dyspnea do raise the question of how one would go about measuring dyspnea. As with everything else connected to dyspnea, the attempts to measure it have been multi-factorial. This is not to maintain that all measurements assumed a multi-dimensional nature of dyspnea, but that the efforts at measurement have

addressed many different aspects of the phenomenon. Additionally, the aspect chosen for assessment depended upon the research question at the time ranging from assessing the breath effects of exercise in normal subjects to evaluating the multi-dimensional nature of dyspnea in cancer patients.

Efforts to develop measurements for dyspnea and its different aspects have employed different techniques of assessment. These ranged from in-depth interviews to simple visual analogue scales, from retrospective reports of impact of breathlessness to current descriptions of a symptom being immediately experience, from listing or checking off descriptors of breathlessness to the use of psychophysiological magnitude estimation, from signal factor to multi-dimensional scales, the history of the assessment of dyspnea is a complex one, the number and range of attempts is enough to take one's breath away. Table 1 presents an alphabetic listing of instruments for measuring dyspnea. Such simple listings are helpful but not a complete answer. As models for dyspnea itself, some approach to organizing the assessments of dyspnea is needed.

Table 1. Alphabetical listing of dyspnea measurement instruments*

Tool & Reference	Brief Description	Psychometrics & Appraisal
ATS-DLD-78 Comstock et al. 1979	Extensive information on antecedents and mediators, including respiratory symptoms	Lacking documented psychometric rigor; does not assess changes over short time periods
ATS/SOB Moody et al. 1990	0-4 scale ADL, also called 5-level SOB or GBS [see below]; similar to the MRC	Psychometric properties not well established; reliability not documented-
ATT Lareau 1986	85-item self-report on 1 to 7 point scale from as active as ever to have omitted entirely with 4 sub-scales	No published data on reliability or validity
BDI/TDI Mahler et al. 1984; Mahler et al. 1987	Interviewer scored 0-12 for BDI related to magnitude of work, activities, effort related to breathlessness. TDI assesses change scored –9 to +9 ADL	Good reliability and validity with psychometrics well established for range of pulmonary and cardiac

<u></u>		
		patients
BESC	89 item self-report checklist with	Acceptable to high internal
Kinsman et	dyspnea one of 11 categories	consistency reliability for 10
al. 1983	·	categories, but <u>not</u> for
		dyspnea.
Borg	0-10 scale [no dyspnea to maximal	Reasonable test-retest
Borg 1970;	dyspnea]; was modified from earlier	reliability and concurrent
Burdon et al	15-point rating version. Used to assess	validity, but needs to be
1982;	reactions during exercise.	tested with larger samples;
Silverman et		can discriminate between
al. 1988		patients' perceived shortness
		of breath
BPQ	33 items & 13 domains such as waking,	Good test-retest reliability
Hyland et al.	bending, bathing. 27 items for	and construct validity;
1994	'problem score.'	developed for clinical trials
CDAT	A general assessment tool that includes	Good content & concurrent
Moody et al.	evaluation of dyspnea	validity; good internal
1990		consistency; needs testing
		applicability for clinical
		practice & research
CDS	Self-report 12-item, 3 factor (effort,	Good reliability, concurrent
Tanaka et al.	discomfort, anxiety), scale using 5-	validity, and construct
2000; Tanaka	point scale from not at all to very much	validity; good for clinical
et al 2002a,	1	trials and sensitive to
2002ь		change; can discriminate
	,	between patients' perceived
		shortness of breath
CRQ	20 items, 4 domains of dyspnea,	Good test-retest & internal
Guyatt et al.	fatigue, mastery, emotion with each	consistency reliability and
1987	scored 1-7 for severity of dyspnea	concurrent validity; needs be
		evaluated on larger samples
DIS	Comprehensive & qualitative	No documentation of
Carrieri &	information on experience with living	psychometric properties;
Janson-	with dyspnea, 48 items & 2 sections:	long & not practical for large
Bjerklie 1986	Shortness of breath (SOB) & impact of	samples or for routine use
	SOB on ADL	
DNS	0 ["no dyspnea"] to 10 ["as bad as can	Good test-retest reliability
Tanaka et al	be imagined"] numeric scale of global	and convergent validity with
2002a	dyspnea; the DNS is very similar to the	the CDS
	NRS, but Tanaka et al 2002a do not	
	reference the NRS	
DOB	19-item self-report questionnaire	Good test-retest reliability
Simon et al.	developed on pulmonary and cardiac	and construct validity; needs
1989	patients with breathlessness and	testing to determine if list of
· ·	healthy college students with induced	symptoms represents larger
	breathlessness	samples

GBS	Same as ATS/SOB [see above]	
MDI	Interview guide with 5-point raring	Reasonable validity but
Stoller et al.	scale and 3 subscales (based on &	reliability is not documented
1986	similar to BDI)	-
ME	Psychophysiologic technique based on	Like the VAS this is more a
Mahler et al.	Steven's power law measuring subject	technique for assessment
1987; Nield	magnitude of a sensation produced by	rather than a particular
et al. 1989;	range of physical stimulus intensities	content assessment; reliable
McCord &		and valid but some
Cronin-		questions; construct validity
Stubbs 1992		established
MRC	5-point scale grading breathlessness	Interrater reliability &
Mahler et al.	from activities that induce dyspnea to	concurrent/construct
1987	severe impairment ADL	validity acceptable; can
		discriminate between
		patients' perceived shortness of breath
NRS	11 numbers from 0 to 10 with end	Good concurrent (with VAS)
Gift &	anchors of "no shortness of breath" and	and construct validity; in
Narsavage	"as bad as it can be"	studies of pain NRS easier
1998		for patients than VAS;
		however, no reliability data
		presented in primary NRS
		article
OCD	VAS 10 cm line with activities such as	Reliability and validity
McGavin et	sleeping to brisk uphill walking along	acceptable; can discriminate
al. 1978;	the line ADL	between patients' perceived
Mahler et al.		shortness of breath
1987	164	
PFSDQ	164-item, intensity-related for ADLs	Good internal reliability and
Lareau et al.		construct validity
1994 PFSS	33 items, self-report with 11 sections	Good internal consistency,
Weaver &	regarding impact on ADL [also	test-retest, and concurrent
Narsavage	reported as being a 64 items with 11	validity; sensitive to change
1989, 1992	sections (McCord & Cronin-Stubbs,	, and the second
	1992).	
PRUS	Interview or self-report 5-point rating	Very little psychometric
Fletcher	scale from patient breath good as	properties information
1952; Stoller	similar others to breathless on talking	available
et al. 1986	or undressing	
RDOS	7-variable observation scale assessing	Good internal consistency
Campbell	respiratory distress	and good convergent and
2008		discriminant validity
I CUTS A CITS	Salf report 2 gention tool: [1] 6 general	Good concurrent validity,
SBAT Lareau et al.	Self-report 2 section tool: [1] 6 general questions & a number of VAS	but no published reliability

1986	measuring shortness of breath at	information.
	different times and for different	
	activities; [2] 85 activities in 4 areas	
SGRQ	Activities are related to dyspnea for 76	Good test-retest reliability
Jones et al.	items. Measures HRQL in 3 domains:	and criterion validity;
1992;	symptoms, activity, impact	developed to compare
Ketelaars et al. 1996		interventions
SOBQ	Same as UCSD/SOBQ [see below]	
SOLQ	29 items, 4 dimensions	Reasonable psychometrics;
Jones 1998		developed to compare
		interventions
UCSD/SOBQ	Self-reported 24-item ADL related to	Good internal consistency
Eakin et al	breathlessness	and construct validity
1998		
VAS	Horizontal or vertical 100 mm line with	The VAS is really more an
Scott &	descriptive anchors at the ends [no	assessment technique than a
Huskisson	breathlessness to greatest	content specific
1979; Gift et	breathlessness]. NOTE: VAS can be	measurement; good
al. 1986; Gift	used to assess different dimensions of	reliability & validity and
1989	dyspnea, e.g., intensity or affect	demonstrated in diverse
		samples of pulmonary
		patients; can discriminate
	·	between patients' perceived
		shortness of breath

*Description of Acronyms

ATS-DLD-78 = American Thoracic Society Standardized Questionnaire

ATS/SOB = American Thoracic Society Shortness of Breath Scale

ATT = Activity Assessment Tool

BDI/TDI = Baseline Dyspnea Index/Transition Dyspnea Index

BESC = Bronchitis-Emphysema Symptom Checklist

BPQ = Breathing Problems Questionnaire

BORG = Borg scale

CDAT = Chronic Disease Assessment Tool

CDS = Cancer Dyspnea (Dyspnoea) Scale

CRQ = Chronic Respiratory Questionnaire

DIS = Dyspnea Interview Schedule

DNS = Dyspnea Numeric Scale

DOB = Descriptors of Breathlessness

GBS = Grades of Breathlessness Scale from American Thoracic Society

MDI = Modified Baseline Dyspnea Index

ME = Magnitude Estimation

MRC = Medical Research Council Breathlessness Scale

NRS = Numeric Rating Scale

OCD = Oxygen Cost Diagram

PFSDQ = Pulmonary Function Status and Dyspnea Questionnaire

PFSS = Pulmonary Function Status Scale

PRUS = Pnemoconiosis Research Unit Score

RDOS = Respiratory Distress Observation Scale

SBAT = Shortness of Breath Assessment Tool

SGRQ = St George's Respiratory Questionnaire

SOBQ = same as UCSD/SOBQ

SOLQ = Seattle Obstructive Lung Disease Questionnaire

UCSD/SOBQ = UCSD Shortness of Breath Questionnaire

VAS = Visual Analog Scale

One impressive attempt to organize dyspnea assessment is found in the previously described model offered by McCord and Cronin-Stubbs (1992). They presented an overview of dyspnea assessment and used a model with the four domains of antecedents, mediators, reactions, and consequences or outcomes for grouping measurements. Nonetheless, some of the classifying was difficult to follow, although this is more due to the nature of the dyspnea and the instruments than any fault of the authors. For example, the antecedent assessments included the American Thoracic Society Standardized Questionnaire (ATS-DLD-78). But the ATS-DLD is an extensive questionnaire providing information regarding both antecedents and mediators of dyspnea. It could be included within both categories, and the authors so included it in both their diagram and text. Similarly, the Chronic Disease Assessment Test (CDAT) is an instrument based on a number of other tools including the Chronic Respiratory Disease Questionnaire, Arthritis Impact Measurement Survey, the Dyspnea Visual Analog Scale, and the ATS Grade of Breathlessness Scale. Hence, it winds up in all four categories of antecedents, mediators, reactions, and consequences. This is not to say that the McCord and Cronin-Stubbs (1992) attempt at organizing dyspnea measures is without value. Indeed, it is an

excellent catalogue of measures and it helps the reader to understand what aspect or aspects of dyspnea each instrument assesses.

Another approach at organizing information about dyspnea instruments is that of our now familiar researcher, Virginia Carrieri-Kohlman, and a colleague (Carrieri-Kohlman & Janson, 1999). These authors did not use a model of dyspnea, and did not attempt to relate the many instruments to components of a model as McCord and Stubbs (1992) did. Instead, they simply provided four descriptive, non-dynamic categories of measurements of dyspnea: qualitative descriptions, intensity, affective components, and activities of daily living. Under qualitative descriptions, they placed much of the research described earlier about the language of breathlessness. This included verbal descriptors that may indicate types of sensations of respiration across disease states, but that probably reflected the pathophysiological mechanism involved (Schwartzstein & Cristiano, 1996). As noted earlier, different descriptors seemed to be reliably used by patients (Elliott et al, 1991) and used with different frequencies by patients with different disorders (Wilcock et al, 2002).

Under measurement of dyspnea intensity, Carrieri-Kohlman and Janson noted the development of instruments that allow for the evaluation of interventions for dyspnea.

They singled out the Visual Analogue Scale (VAS) for special consideration here.

Originally developed for assessing subjective experiences generally (Hayes & Patterson, 1921) and for measuring feelings (Aitken, 1969) and pain (McDowell & Newell, 1996), nurse researchers have validated the VAS for measuring dyspnea in chronic COPD and asthma patients (Gift, 1989) as well as in critically ill ventilated patients (Bouley,

Froman, & Shah, 1999; Knebel, Janson-Bjerklie, Malley, Wilson, & Marini, 1994; Lush, Janson-Bjerklie, Carrieri, & Lovejoy, 1988).

The VAS is presented as a line that varies in length with the study from 100 to 300 mm (Carrieri-Kohlman et al, 1996; Reardon, Awad, Normandi, Vale, Clark, ZuWalack, 1994). The scale can be horizontal or vertical and is anchored on each end by descriptors. The VAS is described has having good validity and reliability (Carrieri-Kohlman & Janson, 1999; Cullen & Rodak, 2001). It can be used to assess different dimensions of the same construct.

In this grouping of intensity measures, the authors also could have included the modified Borg scale (1970) that was initially used to measure effects of perceived exertion rather than dyspnea itself. Nonetheless, the Borg scale is used to measure breathlessness clinically (McCord & Cronin-Stubbs, 1992). Instead of a line like the VAS, the modified Borg scale uses a 0 to 10 ordinal scale. Also, rather than anchor only the ends of the scale like the VAS does, the modified Borg scale uses verbal expressions of severity anchored to the numbers. The modified Borg was considered psychometrically superior to the original Borg since it had ratio properties and non-linear spacing of the descriptors (Borg, 1982). This instrument was also based on psychophysical principles and so was considered applicable to other areas. Hence, it is also used to evaluate breathlessness as well as exertion (Cullen & Rodak, 2002). Another scale that could be place in this same intensity category would be the Numeric Rating Scale (NRS) of Gift and Narsavage (1998). As reflected in its name, this scale has numbers (eleven of them, 0 to 10). But like the VAS, it has anchors only at the ends of the scale (0 = not shortness of breath and 10 = shortness of breath as bad as can be).

Under their category of measuring affective components of dyspnea, Carrieri-Kohlman and Janson (1999), reported the work of Steele and colleagues (Steele, Shaver, Hildebrandt, Schoene, Tyler, Betrus, 1991). Steele et al (1991) used the VAS for assessing two dimensions of dyspnea: a sensory dimension or the perceptual sensitivity to breathing effort and an affective dimension or the perceptual sensitivity to breathing discomfort. Note that these two dyspnea dimensions are among the three assessed by the CDS. Another study (Carrieri-Kohlman, et all, 1996) also evaluated whether patients can differentiate distress and anxiety associated with dyspnea. Both studies demonstrated that dyspnea has more than one dimension and that patients can indeed distinguish between them.

The earliest clinical scale for measuring dyspnea is that Fletcher (1952) and it involved assessing dyspnea on a 5-point scale of grades as a function of its impact activities for patients with lung disease compared to age-comparable individuals without lung disease. A revised version of this assessment (Schilling, Hughes, & Dingwall-Fordyce, 1955) called the Medical Research Council (MRC) scale (Fletcher CM, Elmes PC, & Wook CH, 1959) measured reports of dyspnea when patients were walking distances or climbing stairs. Although Carrieri-Kohlman and Janson (1999) do not report these earlier attempts, they would fall into these authors last category of dyspnea assessment, measuring dyspnea with activities of daily living. They do explicitly include in this category early work by Janson-Bjerklie, Ruma, Stolberg, and Carrieri-Kohlman (1987). These researchers developed the Dyspnea Interview, an open-ended questionnaire that included seven dimensions of dyspnea, the symptom pattern, management strategies used with dyspnea, family support, and education received about

breathlessness. The focus was on activities of daily living. Other instruments that measure dyspnea as a function of daily activities include the University of California San Diego (UCSD), Shortness of Breath Scale (SOB) (Sassi_Dambron, Eakin, Ries, & Kaplan, 1995), the Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ) (Lareau, Carrieri-Kohlman, Janons-Bjerklie, & Roos, 1994), and the Pulmonary Functional Status Scale (PFSS) (Weaver & Narsavage, 1992).

Another attempt at organizing assessments of dyspnea is that of Sorenson (2000). She ordered dyspnea instruments into three groupings: (1) activities of daily living, (2) exercise, and (3) health-related quality of life. She placed the MRC, UCSD/SOBQ, and ATS/SOB in the activities of daily living group, the Borg and VAS for the exercise group, and the PFSDQ for health related quality of life. Of course, including the VAS only under exercise, probably because that area of research was where it was initially developed, can be misleading. The VAS can be and is used in research that does not involve induction of dyspnea via exercise.

A review of dyspnea instruments specifically regarding this use for patients with advanced cancer was undertaken by van der Molen (1995) and included only dyspnea assessment instruments covered here. She concludes that the instrument one chooses to use would depend on what the question is. Also, van der Molen notes that dyspnea has many components and is a multi-dimensional sensation, suggesting that indeed more than one instrument might be needed. It would also seem that the development and use of multi-dimensional assessments might be required.

The last attempt to organize dyspnea assessments that will be briefly looked at here is that of Cullen & Rodak (2002). These authors were interested specifically in the

clinical utility of breathlessness measures. Cullen and Rodak pointed out that dyspnea assessments were developed to measure breathlessness under different conditions and various circumstances. The choice of which instrument to use should, in part, be a function of the conditions and circumstances being studied. These authors grouped instruments under six clinical utility groupings of exercise, activities of daily living, benchmark, outcome, responsiveness, and clinical trials. They presented two broad classification dimensions of dyspnea assessments that cut across the clinical utility groupings, the discriminative versus the evaluative instruments. A discriminative instrument is one whose measures differentiate between patients, assessing individual differences between those who have some characteristic and those who do not. An evaluative instrument is one that measures change within an individual, perhaps for assessing change in an individual's health status or circumstances. Such instruments as the Borg scale and VAS are identified as discriminative while the UCSD/SOBQ and the PFSDQ are identified as evaluative.

Cullen & Rodak (2002) offer an excellent overview of the issues of measurement, and their listing of 11 instruments is also a good resource. Additionally, the use of clinical utility groupings would be helpful to a researcher deciding which instrument to use to measure dyspnea. However, although the authors classify the VAS as a discriminative instrument, there is no inherent reason that the VAS could not be used for evaluative research purposes. Importantly, the authors report that all 11 scales have good validity and reliability.

The presence of a symptom reminds us of the presence of a person. If we keep in mind that every time we hear of a symptom, someone, some person is telling us about

their experience of illness. As Tenner (1996) pointed out in his book, "Whereas drugs and procedures target specific local problems, individual symptoms are often vague: headaches, fatigue, pain, digestive problems. And while X-ray and magnetic resonance devices at first seemed to have revealed the body's innermost secrets, now scans and tests all too often reveal nothing unusual. [The health care professionals] must come to grips with the very conception it thought it could do without: the patient as a whole system" (pp 47-48).

Issues of Hospice and Palliative Care Research

Hospice and palliative care research begins with a consideration of the unique patient population (Ferrell and Grant, 2001) and that, as noted by Addington-Hall (2007), "Palliative care is concerned with the prevention and relief of suffering . . . [and] is therefore by definition concerned with a sick patient group who are going to be sicker. . . [raising] concerns about whether palliative care research can ever be ethical and, if it can, how to conduct ethically sensitive studies." (p. 3) Terminally ill patients constitute a vulnerable group and research participation may be more difficult for them due to the presence of multi-symptoms and severe problems.

Bruera (1994) wrote that initially palliative care programs were designed with only service and some teaching in mind. With the emergence of palliative care research has come issues of the above mentioned patient vulnerability as well as concerns about unstable mental status, ability to consent, response burden, measurement intrusiveness, dependence on health care providers, patients' limited time, use of placebos, nature of research design, nature of the data, subject recruitment and retention, heterogeneity of the

palliative care population, and involving others (hospice personnel, patients themselves, family caregivers) in the development of research proposals (Ferrell and Grant, 2001; Buss and Arnold, 2004; Ferrell, 2004; Penrod and Morrison, 2004; Storey, 2004; Wallen and Berger, 2004; Aoun and Kristjanson, 2005; Kaasa, Hjermstad, and Loge, 2006; Addington-Hall, Bruera, Higginson, and Payne, 2007). In fact, it is just such difficulties, particularly regarding subject recruitment (Storey, 2004) and general logistics (Buss and Arnold, 2004) that led, in part, to the development of this current pilot feasibility study.

Even in the face of such concerns and challenges, both ethical and practical, palliative care research must be done. Indeed, given the goals of palliative care, not conducting research would itself be unethical. Ferrell (2004) writes, "There is no option to avoid research within the field of palliative care, as like all disease areas, there is a critical need to conduct research to advance the field. Improved care will not happen without inquiry." (p. 408)

In 2007, Twaddle, Maxwell, Cassel, Liao, Coyne, Usher, Amin, and Cuny, reported their study on palliative care benchmarks from academic medical centers and noted that in the U.S., although palliative care is growing, little is still known about the quality of care in this area. In 1994, Bruera framed this issue as follows: "... one of the major ethical issues we must confront during the coming decade is whether we can afford not to make a major commitment to research in palliative care." (p 7) The coming decade to which Bruera referred ended in 2004, three years before the Twaddle et al. (2007) article. The issue of research in palliative care medicine and what forms it should take are still with us.

Although the issues in this area are still with us, there have been many calls for more research and a number of research approaches and responses to the challenges of palliative care research have been proposed and conducted. These range from the need for a multidisciplinary approach (Kaasa and Hjermstad, and Loge, 2006; Addington-Hall, 2007) and the necessity of using mixed methods (Ferrell and Grant, 2001; Penrod and Morrison, 2004; Wallen and Berger, 2004; Aoun and Kristjanson, 2005) to designing studies in ways that address palliative care specific issues (e.g., use of placebos: Ferrell, 2004; Aoun and Kristjanson, 2005; and use of skilled nurses instead of general research assistants: Ferrell, 2004) and close scrutiny of proposed instruments (Penrod and Morrison, 2004; Wallen and Berger, 2004). Regarding the recommendation for using skilled nurses as research assistances, Ferrell and Grant (2001) have a specific cautionary note about the potential conflict that nurses may have in managing their dual clinician-researcher roles. This potential conflict should be acknowledged and the nurses helped with managing it. Indeed, this might be the source of productive questions for future research.

It does seem that there is one area where more respect might be demonstrated from each side of the issue to the other side. This is the question of research methods, most particularly quantitative versus qualitative methodology regarding the evaluation of the credibility of evidence. It is unlikely that quantitative randomized control trials or qualitative research separately will be able to tell us all that we wish to know about palliative care. Krishnasamy, Corner, Bredin, Plant, and Bailey (2001), in describing their earlier state, "Despite including a diverse range of instruments to measure the effects of the intervention, the uniqueness of individuals' experiences of breathlessness

were often hidden by a requirement to frame the study within a reductionist research approach." (p 103) Perhaps each side could become more conversant with the other side's frameworks and methodologies as well as recognize what each side contributes to the process of evaluating and understanding how we can best pursue the goals of palliative care.

Regarding the general points of view in the area about appropriate methodologies, three studies might serve as examples of how these apparently conflicting positions can benefit from accepting that others might have something of value to offer as well as actually helping more to move the field forward. Aoun and Kristjanson (2005) make a strong case for the necessity of methods other than evidence-based medicine and randomized controlled trials. Yet they do manage to include a few straw men from the evidence-based side such as the studies being focused on questions that are too simple and using samples that are too restricted. These charges are not in and of themselves reasons to use other methods, since evidence-based studies should be able to ask more complex questions and use either a series of differentially homogenous samples or larger heterogeneous samples.

Kaasa, Hjermstad, and Loge (2006) reported on their evaluation of the status of palliative care research in Europe over the last twenty years. Among the attributes of the literature that they evaluated, they listed types of methodology. They note that the vast majority of the studies used surveys and descriptive/observational methods and that only a "small fraction" of studies used randomized designs. Their response to this was to state that although they judged that palliative care needed to "move forward," become more evidence-based, and use "larger, randomized, clinical, multi-center studies on treatment,

treatment procedures, effects and side effects." (p. 733), they also state, "We do not mean, however, that other methodologies in respect to study design are of little value. On the contrary, we believe that palliative medicine is ideally suited for multi-disciplinary research with methodologies that complement each other, provided that the studies are conducted in a scientifically valid way." (p. 733)

The third study here is a step in the process of addressing this last point. Bailey, Froggatt, Field, and Krishnasamy (2002) report on the 10-year (1990-1999) contribution of nursing to qualitative research in palliative care. They noted the important role that qualitative research plays in generating evidence for nursing practices. They also state that within medicine qualitative research methodologies are gaining more acceptance, although there are still questions about how to evaluate such research. Interestingly, the authors used a rigorous qualitative methodology to evaluate qualitative research. As part of a follow up to their large study of 138 papers from 50 journals, they used thematic analyses to evaluate 67 nursing papers and 29 comparison papers from areas such as death studies, sociology, and medical anthropology journals. In the larger earlier study, the authors used a procedure to assess content and quality of the papers where reviewers provided open-ended comments about each paper's strengths and weaknesses. These constituted the text that was subjected to thematic analyses in this later paper.

The results of this study showed that 30% to 40% of the papers received positive comments on such dimensions as topic, quality of writing, contribution to understanding, and practical value. However, on the relationship between data, analysis, and findings as well as other methodological attributes along with theoretical and conceptual issues, the papers received less than 20% positive comments. Importantly, the authors compared the

positive comment rates for the nursing papers to those of the comparison group. The comparison group papers received a higher proportion of positive comments than did the nursing papers: for theoretical and conceptual content the respective proportions were 23.9% compared to 79.3%, and for contribution to understanding the respective proportions were 29.9% compared to 51.7%. Although these results may in part reflect the smaller sample for the comparison group (one is more likely to obtain larger effects in smaller samples), it may be that the comparison group papers were more sophisticated than then nursing papers. What is important here is that these authors, all nurses, were willing to evaluate their field and its methods in this way.

It should be emphasized that not only is there no inherent reason not to use both qualitative and quantitative methods within studies, but that there have been calls for just this approach. This was already noted above regarding calls for mix methods (Begley, 1996; Ferrell and Grant, 2001; Penrod and Morrison, 2004; Wallen and Berger, 2004; Aoun and Kristjanson, 2005; Williamson, 2005). Both Begley (1996) and Williamson (2005) provide overviews, summaries of the methods debates, and details about how to actually proceed as well as listing additional resources and literature; both are also directed at nursing research. Williamson (2005) also presents a specific illustration for guidance that is specific to nursing research. There is even a study using mixed methods evaluating acupuncture for people with chronic illnesses where the authors that either method alone would have missed information captured by the other method (Paterson and Britten, 2003). There seems little rationale for operating within the frame of one category of methods versus another category.

To this point, Giacomini (2001) writes in his short, but excellent article, that regarding qualitative and quantitative methods, "[c]ontary to popular misunderstandings, both rely on systematic empirical observation, and both generate empirical evidence." (p 5) He notes that the two approaches complement each other rather than compete with each other since each addresses essentially different questions. "These 2 health research traditions are distinctive in what they look at, how they see it, and what they can learn." (p 5) He maintains that biomedical or natural causation questions are best addressed by quantitative methods and that questions about social meanings or behavior and experience to be understood as symbolically mediated social phenomena are best addressed by qualitative methods since these later methods are better suited for understanding why people do what they do. Which method one chooses depends on what question one wants to ask, what it is that one wants to do. These issues are further presented and evaluated by Mays and Pope (1995), Pope and Mays (1995), Green and Britten (1998), and Newman, Thompson, and Roberts (2006).

One approach to coordinating different types of research methods, i.e., qualitative and quantitative methods, is that of methodological triangulation, one of four types of triangulation delineated by Denzin (1970). The goal of this type of research method combination is to better capture the phenomenon under investigation. The intent is that both approaches are used so that each may address the weaknesses in the other, perhaps producing a more accurate representation and understanding of the research results.

Bradley (1995) offers a useable overview of the use of methodological triangulation in healthcare research and Murray (1999) presents an overview while he reports on the results of methodological triangulation analyses including qualitative secondary data

from an earlier study of his (Murray, 1995). The specific triangulation methods the Murray used were based on those used by Connelly, Bott, Hoffart, and Taunton (1997). The Bradley (1995), Murray (1999), and Connelly et al. (1997) articles, and particularly the one by Murray, would be a good introduction to this area for any student. Importantly, Murray points out that methodological triangulation should be used when there is reason to expect that, given the nature of the research question, no one method would "provide a satisfactory explanation of the issue being studied," (p 196) and cites the Bradely 1995 article as well as Denzin and Lincoln (1994) as support for this position.

As an important final comment, in spite of the potential difficulties in palliative care research, research participation can allow those receiving palliative care to experience contributing to others. Ferrell and Grant (2001) write, "Research participation often provides an opportunity to derive meaning from illness and to feel that one's suffering will provide benefit to others." (p. 702) Others have noted this as well (Fine, 2003). Also, there has been both qualitative and quantitative research showing that many hospice patients want to participate in research. Indeed Addington-Hall (2007) reported on two such studies using hypothetically presented research projects. One study was a qualitative study in Australia that found that all hospice inpatients wanted to be a part of research with there most frequent reasons given being altruism, an increased feeling of personal value, continuing to feel a sense of autonomy, and the importance of research efforts to improve palliative care (Terry, Olson, Ravenscroft, Wilss, and Boulton-Lewis, 2006). Another study was a quantitative study in the U.S. where close to half of the hospice patients were willing to be a part of interview, survey, or therapeutic research

(Williams, Shuster, Clay, and Burgio, 2006). Another study in the U.S. found that patients who had actually participated in interview research reported their experience as positive (Emanuel, Fairclough, Wolfe, and Emanuel, 2004).

Chinese Medicine and Acupuncture Treatment

Complimentary and Alternative Medicine and Human Energy Field Theory

The National Center for Complimentary and Alternative Medicine presents a great deal of information about human energy field theory (NCCAM website, 2004a) as well as a general overview of what are termed "whole medical systems" that include traditional Chinese medicine (TCM), Ayurvedic medicine, naturopathy, and homeopathy (NCCAM website, 2004b).

A major difference between Western medicine and TCM is that Western medicine takes a structural view of the human system while TCM adopts a functional approach. The TCM view of human physiology is based on the central concept of energy fields. The central tenet is that matter and energy cannot really be separated. Matter and energy, inner and outer, physical and mental are the same phenomena. They appear different only because we view them from different perspectives. Human energy theory frames the view of human systems through this position and its focus is on the perspective of energy field interpretation. Also, TCM has at its center the concept of Qi, life energy that flows through the body on the meridian grid that all living beings have (Xinnong, 1999; Freeman & Lawlis, 2001).

Complementary and alternative medicine (CAM) has five classifications of CAM therapies: alternative medical systems, mind-body interventions, biologically based

therapies, manipulative and body-based methods, and energy therapies (Hawks and Moyad, 2003; Hospice Palliative Nurse Association, 2003). Although acupuncture is generally classified within the alternative medical systems group, it is nonetheless based on a basic concept of life energy and problems related to the flow of that energy through the body.

Indeed, acupuncture has been singled out as an area of special interest at the National Institute of Health Consensus Panel (NCCMA, 2004c), and NCCAM (2004a) places acupuncture under the heading of "energy medicine involving putative energy fields." Noting that acupuncture is the "most prominent therapy to promote Qi [life energy] flow among meridians," NCCAM reports that acupuncture has been extensively studied and that it has been demonstrated as effective in ameliorating some conditions including some forms of pain (Berman & Straus, 2004). Bringing together TCM and energy field theories in the application of acupuncture, Kloppenburg (1998) reviewed the anatomy of acupuncture points in the human energy field in the body and the acupuncture points' therapeutic consequences.

Principles and Theories of TCM

Chinese medicine has long and complex history that has been dated as far back as 3,000 years. The knowledge of Chinese medicine has been organized and compiled in texts that go back to the first century BC. The various texts have been instrumental in the integration an understanding of all natural phenomena, not just health. There is a religious foundation in traditional Chinese medicine, which comes from Taoism and Confucianism (Herring & Roberts, 2002). Eastern Asian medicine has a very different

paradigm of thinking than Western Medicine. It places an emphasis on the holistic patterns, relationships, cycles and processes. In Chinese medicine the healthy individual is "in harmony" and displays a balance among the mental, physical, and spiritual aspects. The goal of Chinese medicine is to change the disharmony in the mind, emotion, body, or behavior to a state of balance, state of harmony, and well-being. The Western paradigm places an emphasis on linear thinking, causality and reductionist explanations. This may be part of why traditional Chinese medicine has not been easily accepted in this country.

Fundamental to Chinese medicine is the concept of Qi. However, as with Tao, there is no single English word that captures it meaning. All of the universe and everything in the universe is defined by and composed of Qi. The unobstructed flow of qi is essential to physical, emotional, and mental harmony. Qi is the life force, the vital energy of every cell in the body. "One can think of qi as matter on the verge of becoming energy or energy on the point of materializing." (Bennett, 1978, cited by Freeman & Lawlis, 2001).

Another important concept is that of meridians. Meridians are of fundamental importance to acupuncture. Meridians are an invisible network, an energy grid, responsible for the circulation of the Qi, blood, and bodily fluids. They are distributed both on the right and left sides of the body, anterior and posterior, as well as located interiorly and exteriorly. They are linked to one another in a specific order. A cyclical flow of Qi is maintained by the meridians of the hand and foot, yin and yang, and the interior and exterior. There are also two main channels that are located in the center of the body in the anterior and posterior aspects. The twelve meridians share the following

features according to Xinnong (1999): (1) Its own fixed acupuncture points on fixed portion of the body surface; (2) Each pertains to a specific organ; (3) The meridians have an exterior and interior relation of mutual connection; (4) Each meridian has its own pathological manifestations if the Qi does not have a smooth flow.

Auricular Acupuncture.

Both body and auricular acupuncture originated in ancient China, but, while body acupuncture has not changed much over the years, auricular acupuncture changed as a function of work done in Europe. These changes in auricular acupuncture where initiated by Dr. Paul Nogier in France (Oleson, 1998). While body acupuncture assumes that energy lines (meridians) along the body have no obvious anatomical relationship to body organs represented by particular meridians, auricular acupuncture assumes a structured relationship between the anatomical positions of points and an inverted body image of a fetus on the external ear (Oleson, 1998). "A large number of sites have been identified on the ear which become spontaneously tender or otherwise react to the presence of disease or injury elsewhere in the body. Stimulation of these ear points in the turn exerts certain therapeutic effects on those parts of the body with which they are associated. . . . [auricular acupuncture] is relatively simple and economical, and there are few side effects." (O'Connor and Bensky, 1981, p. 472).

Oleson (1998) offered a clarification of the concept of the relationship between points on the ears and body parts and organs labeling these relationships "somatotopic inversion." (p. 6) Regarding somatotopic inversion, Oleson (1998) writes, "The head areas are represented toward the bottom of the ear, the feet toward the top, and the body

in between. As with the somatotopic map in the brain, the auricular homunculus devotes a proportionally larger area to the head and hand than to the body. The size of a somatotopic area is related to the functional importance rather than its size." (p. 6) A caution here is noted by O'Connor and Bensky (1981). They emphasize that the locations of points can differ from person to person because of ear shape variation among individuals.

This section has presented information regarding auricular acupuncture. It should be noted that one of the developments in this area is the use of auricular acupressure. The only difference between auricular acupuncture and acupressure is that acupressure uses external pressure methods instead of acupuncture needles to stimulate the designated points.

Existing research evaluating effects of acupuncture

There is evidence for the positive effect of acupuncture procedures (Manning, 2000; Berman, 2001). However, the empirical research literature does not find clear, consistent support for these effects (Berman, 2001). As with much of the research done within CAM, there are problems of lack of use of control groups, lack of randomized assignment of subjects to conditions, and sample sizes that might not yield sufficient statistical power thus increasing the probability of Type II error (Linde, 2000; Harlan, 2001; Berman, 2001).

Berman (2001) presented a very good overview of research on the effects of acupuncture, including a set of meta-analyses publications. Meta-analysis is the procedure where a search of literature generates a list of qualified studies and then the

results of these studies are themselves subjected to an analysis that uses their effect size results to combine the studies and evaluate their implications for the research area being examined. Most acupuncture research as been on the alleviation of pain.

For chronic pain, three have been three systematic reviews. Patel, Gutzwiller, Paccaud, and Marazzi (1989) did a meta-analysis of 14 studies, ter Reit, Kleijnen, and Knipschild (1990) conducted a meta-analysis of 51 studies, and Ezzo, Berman, Hadhazy, Jadad, Lao, and Singh (2000) also conducted a meta-analysis of 51 studies The first meta-analysis on chronic pain (Patel et al., 1989) found few significant effects among the 14 studies included. Pooling results via meta-analysis did yield results favoring acupuncture, but this was only for the non-blinded effects. Similar results were found by the ter Reit et al. group (1990).

In their meta-analysis for effects of acupuncture on chronic pain, Ezzo et al. (2000) identified four categories of control groups (waiting list, inert placebos, sham acupuncture, and standard care). Of the 51 studies included in this systematic review 21 favored acupuncture. Other treatments were favored in four studies. The remaining 26 studies had no significant findings and most of these were designs using sham acupuncture as the control group. Berman (2001) maintained that the risk of Type II error or false-negative conclusion is high. Although low quality studies were significantly more likely to yield positive results for acupuncture, there was still limited support for acupuncture being more effective than waiting lists or inert, non-acupuncture placebos. Importantly, the evidence for acupuncture being more effective than sham acupuncture or standard medical care was insufficient. Similarly, a meta-analysis of 12 studies on back pain found that acupuncture was better than various control interventions

but that there was insufficient evidence to demonstrate that acupuncture was superior to placebo (Ernst & White, 1998). An earlier meta-analysis by Ernst (1997) on 13 studies found seven positive for acupuncture and six with non-significant results. However, an examination of these 13 studies reveals design flaws including lack of randomization and failure to use placebos as a control condition.

There have been two larger studies reporting positive results since these earlier reviews. Molsberger, Bowing, Jensen, and Lorek (1994; Molsberger & Bowing, 1997) conducted a clinical trial in Germany with 97 patients. They used real versus shamcontrol conditions and found significant pain relief at a three-month follow up assessment. Berman and Ezzo (2000) used an acupuncture versus standard care design in 73 patients and found both pain relief and improved functioning for standard outcome measures at a three month follow up. It may be that many of the earlier studies had samples too small to provide necessary statistical power, thus generating a higher likelihood of Type II error.

Berman and colleagues (Berman, Ezzo, Hadhazy, & Swyers 1999) published a systematic review of acupuncture treatment of fibromyalgia pain. The review included seven studies with three using randomized control designs and four using cohort designs. Two of the randomized control designs demonstrated that real acupuncture was more effective than sham acupuncture for ameliorating pain (Deluze, Bosia, Zirbs, Chantraine, & Vischer, 1992; Cassisi, Roncaglione, Ceccherelli, Donolato, Gagliardi, & Todesco, 1995).

Although some of the studies of acupuncture treatment of pain reported above used randomized control designs, a review article by Pan and colleagues examined

complementary and alternative medicine in the management of 3 symptoms, one of which was pain (Pan, Morrison, Ness, Fugh-Berman, and Leipzia, 2000) and noted, "Acupuncture as a treatment for pain in seriously ill cancer patients has been evaluated only in uncontrolled studies" (p. 379). Hence, in generalizing results of acupuncture treatment of pain, care should be taken to note the nature of the populations studied and the type of designs used. Pan et al. (2000) do cite two case series studies demonstrating alleviation of pain in severely ill cancer patients. One such study reported acupuncture pain control management for at least 1 month in 72% of patients with severe abdominal pain resulting from locally invasive or metastatic cancer following daily treatment for one to two weeks (Xu, S., Lui, A., & Li, Y., 1995). Those patients with such severe pain were a subset of 92 patients with pain ranging from mild to moderate to severe.

The second case series study involved cancer pain clinic patients with a sample size of 183 with 142 of these having pain related either directly to cancer or as a side-effect of treatment (Filshie, J. & Redman, D., 1985). With one to four weekly manual acupuncture sessions of 5-15 minute duration, 70 patients (48%) reported pain relief and/or greater mobility for more than three days.

Interestingly, Pan et al. (2000) also reported in their survey what they labeled a single-blind random controlled trial study examining acupuncture treatment (actual acupuncture sites versus sham acupuncture sites) for painful peripheral neuropathy in 239 HIV-positive patients from multiple centers (Shlay, Chaloner, Max, Flaws, Reichelderfer, Wentworth, Hillman, Brizz, & Cohn, 1998). First, this study was not included in the Pan et al. (2000) review as one done with severely ill cancer patients because here the patients were HIV-positive patients with peripheral neuropathy. Second, although this is a

controlled study and described by the authors as a modified double-blind study, Pan et al, were justified in labeling the study as single-blind one because, regarding the acupuncture conditions, the acupuncturist knew the condition assignment of the patients. Apparently Shlay et al. called their study double-blind because neither the researchers nor the patients knew the experimental conditions. However, they appear to have also labeled the study as "modified" double-blind because the acupuncturist knew the conditions. In any case, the study was thus open to experimenter effects from the acupuncturist. Nonetheless, the results showed no difference between actual versus sham acupuncture treatment in alleviation of pain in the patients.

Some studies have examined the use of acupuncture with breathlessness. Jobst, Chen, McPherson, Arrowsmith, Brown, Efthimiou, Fletcher, Maciocia, Mole, Shifrin, and Lane (1986) reported a controlled study comparing actual versus placebo acupuncture in 24 patients with COPD and disabling breathlessness. They stated that the actual acupuncture group reported greater improvement in symptoms and walked a greater distance in six minutes. Filshie, Penn, Ashley, and Davis (1996) published a study regarding the effects of acupuncture on 20 patients, median age 60, with cancer-related breathlessness. Using VAS analogue scales, the patients reported significant improvements in dyspnea, relaxation, and anxiety and these changes lasted up to at least six hours. However, this study was uncontrolled and not done blind. Hence, the results may have been a function of either experimenter expectations and/or a patient placebo effect. Still, this study was cited in the Pan et al. 2000 a review article as supporting the use of complementary and alternative medicine in managing dyspnea in near the end of life patients.

A well-designed study by Vickers, Feinstein, Deng, and Cassileth (2005) evaluated acupuncture treatment for dyspnea in advanced lung and breast cancer patients at Memorial Sloan-Kettering Cancer Center. They used a randomized placebo-controlled design for a pilot study beginning with 47 patients and 45 patients completing the study. They implanted acupuncture "studs" in either true or placebo acupuncture points. The patients self-applied pressure to these studs twice daily. Patients rated their dyspnea sensation on a numerical scale with a 0 to 10 point range right before and after acupuncture treatment daily for a week. No results were statistically significant, although the placebo acupuncture patients did report a small absolute improvement that was a little greater than that reported by the true acupuncture patients. The author concluded, "The acupuncture technique used in this trial is unlikely to have effects on dyspnea importantly larger than placebo for patients with advanced cancer." (p 1)

Davis, Lewith, Broomfield, and Prescott (2001) conducted a pilot project examining methodological issues when evaluating acupuncture as a treatment for disabling breathlessness. Theirs was a randomized, controlled trial with three treatments: real acupuncture, dummy acupuncture, and mock trans-electrical nerve stimulation. The results showed a small, but statistically non-significant effect for acupuncture. As a pilot project, this study had only 12 subjects, and its statistical power was too low. The researchers had as one of their goals the calculation of an adequate sample size for necessary power. They report that their analyses indicated that 25 patients would be needed for power of .80 with alpha of .05.

These same researchers then ran a larger study with 24 patients completing both arms of a single-blind, placebo-controlled crossover study. Still, the researchers found no

difference between an actual acupuncture procedure and a mock one (Lewith, Prescott, and Davis, 2004). Although this study had twice the number of subjects as that of Davis et al. (2001), again statistical power was probably insufficient.

There have been studies examining the effects of acupressure on dyspnea. For example, Maa, Gauthier, & Turner (1997) evaluated the use of acupressure in decreasing dyspnea in COPD patients and this study was positively evaluated in the Pan et al. (2000) survey of research on complementary and alternative medicine in managing pain, dyspnea, and nausea and vomiting near the end of life. Maa's and co-authors' study had 31 severe COPD patients daily self-administer at home acupressure for 6 weeks alternative with sham acupressure for 6 weeks in a single-blind, randomized crossover study. When patients were using acupressure as opposed to using sham acupressure, they reported significantly less dyspnea as assessed via VAS. A problem with the study may be that there was little compliance control available since the patients were self-administering at home. Still, the results were positive. Nonetheless, a limitation of the study should be noted that with a single-blind design it is possible that experimenter effects were operating.

Another, more recent, study by Maa evaluated the use of acupressure as well as acupuncture in addressing breathing difficulties evaluated relief among patients with chronic obstructive asthma (Maa, Sun, Hsu, Hung, Chen, Yu, Wang, & Lin, 2003). This was a prospective, randomized study with three conditions: eight weeks of daily self-administered acupressure and standard care (17 patients), 20 acupuncture treatments and standard care (11 patients), and standard care alone (13 patients). Both acupressure and acupuncture conditions showed improvement on the St George's Respiratory

Questionnaire. The acupressure condition demonstrated improvement in irritability measured by the Bronchitis Emphysema Symptom Checklist.

A still more recent study by Wu, Lin, Wu, Lin (2007) evaluated acupressure with COPD patients in Taiwan employing a randomized, block experimental design, randomly assigning 44 patients to either a true acupressure condition using points for relaxation and dyspnea or a sham acupressure condition using other unrelated points. The two groups were also matched on a variety of characteristics including sex, age, pulmonary function, steroid use, and smoking. Using the Dyspnea Visual Analogue Scale, the Geriatric Depression Scale, as well as oxygen saturation, the study found that the true acupressure group statistically improved more than the sham group on all assessments.

An interesting study evaluated the effects of acupressure for patients with prolonged mechanical ventilation support (Tsay, Wang, Lin, and Chung, 2005). This study in Taiwan compared acupressure and massage with massage and handholding for 52 randomly assigned patients with COPD. Hence, there was no blinding to conditions. Still, acupressure produced statistically significantly better results for dyspnea, anxiety, and object physiological indicators for both heart rate and respiratory rate.

Interestingly, as a side note, acupuncture has been demonstrated to significantly reduce exercise-induced asthma. Fung, Chow, and So (1986) studied breathing problems not in cancer patients, nor in end of life patients, not those with COPD. Rather, they induced asthma symptoms through motor-driven treadmill exercise in children, ages 9 to 13.5, who had mild to moderately severe perennial bronchial asthma. Asthma symptoms were assessed using forced expiratory flow in the first second, forced vital capacity, and peak expiratory flow rate. The study used a single-blind, cross-over design where

children were given real and sham acupuncture in random order. The results that exercise-induce asthma symptoms in asthmatic children were significantly attenuated by real acupuncture as compared to placebo (sham) acupuncture.

A case study (Fillmore, 1999) used acupuncture on a 45-year old male with reactive airway disease comparing the effects of acupuncture versus medication (albuterol aerosol). The outcome was assessed objectively using a simple peak flow meter measuring peak flow before and after each treatment. The acupuncture provided greater increase in peak flow than did the medication. Limitations of this study included neither the physician nor patient being blinded to the conditions. Although the measure used was an objective one, it is still possible that the patient made greater effort following acupuncture. The author does report that the patient appeared to make a best effort for each peak flow assessment.

As discussed in earlier sections, anxiety and distress are important dimensions of the symptom of dyspnea. There is some research that supports acupuncture procedures as interventions that can reduce anxiety, including Tsay et al. (2005) reported above. Another blinded study treated anxiety in the mothers of children being prepared for surgery. Subjects were randomized to two groups: auricular acupuncture at the relaxation points (n = 34) versus sham acupuncture at the shoulder, wrist, and extraneous auricular points (n = 33) (Wang, Maranets, Weinberg, & Caldwell-Andrews, 2004). This was a repeated measures design where anxiety was measured by the State-Trait Anxiety Inventory at the three points of time: baseline, 30 minutes after the intervention, and on completion of the child's anesthesia induction. Analyses revealed that the group by time

interaction was significant for the change in mother's anxiety with the actual acupuncture group reporting less anxiety.

A study that used auricular acupressure for treatment of anxiety also found support for such intervention (Kober, Scheck, Schubert, Strasser, Gustorff, Bertalanffy, Wang, Kain, & Hoerauf, 2003). Subjects in the study were patients who needed ambulance transport secondary to medical conditions. This was a blinded randomized control study. Subjects were randomized to two conditions: auricular acupressure at the relaxation point (n = 17) versus auricular acupressure at a sham point (n = 19). State anxiety and pain were assessed using visual analog scales before and after transport. The actual auricular acupressure group demonstrated significantly less anxiety and pain than did the sham auricular acupressure group.

Studies of acupuncture and acupressure need to be done using samples and procedures that generate sufficient statistical power. Repeated measures designs with more than two time points should be used since this both allows for assessment of change over time and benefits from the increased power generated by multiple time points. Such studies should also be randomized control trials when ethical and practical with as much blinding to condition as possible.

Summary Syntheses

Dyspnea is a common and debilitating symptom that is not well understood or controlled even though many patients describe the experience as agonizing and worse than pain. Carrieri-Kohlman, Janson-Bjerklie, and Jacobs (1984) maintain that the documents from the 1980 policy statement by American Nurses' Association and the

1982 Fifth National Conference on Nursing Diagnosis "provide a mandate for nurses to study the measurement and management of symptoms and responses to illness, dyspnea being an example." Although there has been research on dyspnea over the last 25 years, the emphasis of this research has been on chronic diseases and there has been very little research on dyspnea in end-of-life patients. The National Institute of Health State-of-the-Science Conference Statement, 2004, has among its recommended future directions for improving end-of-life care: "Develop and test new interventions, including complementary and alternative medicines, to improve symptom management in diverse patient groups. (p. 10)"

This proposed research will evaluate an auricular acupressure intervention for amelioration of dyspnea in end-of-life patients with lung cancer. This research will place the dyspnea construct within the theoretical framework of the Revised Symptom Management Conceptual Model (RSMC Model) that has three basic dimensions of (1) symptom experience, (2) symptom management strategies, and (3) outcomes. The RSMC Model also has three sub-dimensions of the symptom experience consisting on (1) perception of symptoms, (2) evaluation of symptoms, and (3) response to symptoms. These three sub-dimensions will be captured by the multi-dimensional assessment instrument, the Cancer Dyspnea Scale, which was developed on lung cancer patients. Finally, another important contribution of this research will be the use of a true experimental design with random assignment of subjects to experimental conditions in the testing of a complementary alternative intervention.

Chapter 3. Methods

Research Design

This study used both quantitative and qualitative methodologies. Hence, in addition to the quantitative methods described below, this study also employed qualitative questions and analysis. Following the quantitative analyses, the qualitative results are presented. In the Discussion section, the quantitative analyses are reviewed within the context of the qualitative results. This approach extended the researcher's understanding of the phenomenon under investigation.

For the quantitative methodology, this feasibility study employed a true experimental design where group membership was determined through random assignment. Although the sample was essentially one of convenience, an experimental design is not a function of the source of a sample. A true experiment is defined by the subjects being randomly assigned to condition and by the condition or the independent variable being under the control of the researcher. The basic research design for this study was a 3 (group: standard care [SC], standard care plus acupressure placebo [SC + AP] with use of seed adhesive not on lung or anxiety points, standard care plus experimental auricular acupressure using seed adhesive on lung and anxiety points [SC + AE]) by 8 (time: 2 assessments for each of 4 days -- day 1 baseline, day 2, day 3, day4) mixed design analysis of variance (ANOVA) with time as the repeated measure (see Table 2). The auricular acupressure treatment was administered on the morning of Day 2 following the Day 1 baseline assessments. All early and late assessments took place at the same time each day.

These three conditions were designed to help differentiate between different sources of effects. For example, SC versus SC + AP and SC + AE would enable the determination of any effect due to simple change in procedure, additional attention to the patient, and general placebo effects. Also, SC + AP versus SC + AE allowed for the differentiation between effects due to placebo auricular procedures versus those due to actual auricular therapy. Additionally, a baseline assessment allowed for evaluation of any differences between the subjects in the three conditions before any treatment begins.

Table 2. 3 (Condition/Group) by 8 (Time) ANOVA with Time as the repeated measure

		·· · · · · · · · · · · · · · · · · · ·			TIME		· · · · · · · · · · · · · · · · · · ·		·
	Day base			Day 2 p	ost-tx	Day 3 p	ost-tx	Day 4 p	ost-tx
Condition*	Early	Late	ST#	Early	Late	Early	Late	Early	Late
SC			21						
SC + AP									
SC + AE									

^{*}SC = standard care

The major advantage of the basic research design is that it is a true experimental design that allows for direct manipulation of the primary independent variable. In turn, this allows for greater confidence in interpretation of results and for making causal inferences. An additional advantage of a mixed design ANOVA is that with repeated measures statistical power is increased in that each time a subject is assessed, the power increases as if an additional subject had been enrolled in the study. The major disadvantage of this type of design in this study is that each research participant had to be individually run including repeated follow up assessments rather than subjects being run

SC + AP = SC & seed adhesive not on lung or anxiety points (placebo condition)

SC + AE = SC with seed adhesive auricular acupressure on lung and anxiety (experimental condition)

[#]ST = Start Treatment of Auricular acupressure or Placebo Auricular acupressure

in groups. A limitation of this design because of the source of this sample is that of generalizability.

The quantitative independent variable in this study was an experimentally manipulated one, and consisted of treatment condition (SC group versus SC with inappropriate seed point adhesive placebo group versus SC plus acupuncture with appropriate seed adhesive experimental group). The quantitative dependent variables were self-reported dyspnea (total score as well as three subscales), oxygen saturation, and use of respiratory treatments.

The two non-SC conditions (SC with seed adhesive placebo group and the SC plus acupressure with seed adhesive experimental group) were blinded for both the subjects and the research assistants administering the dyspnea and pulse-oximeter assessments. Subjects in both conditions had adhesive on their ears.

Additionally, although there was random assignment to condition, there were still two issues regarding individual differences among subjects. First, even random assignment does not guarantee lack of differences between the subjects in different conditions. This is particularly the case with relatively small samples. Second, even if there were no differences between subjects in different conditions, individual differences within conditions still contribute to the error terms in statistical analyses. Hence, statistically controlling for such individual differences can reduce the error terms and, hence, increase the effect size. Of course, repeated analyses does control for such individual differences within each condition over time since the same subjects are used over time. Still, analysis of covariance (ANCOVA) was used in order to ensure control of differences between conditions because of the relatively small sample in this study.

For the qualitative data, five questions were asked of the subjects. Three questions were asked on Day 1 baseline. On Day 4, these three questions were asked again, but specifically regarding the subject's experienced at that time only, along with two additional questions.

Finally, subjects were told that at the end of their research participation they would have the opportunity to make a decision about any continued treatment. They were told that they would be able to continue receiving acupressure if they were in the experimental group or to begin receiving acupressure if they were in either of the two other groups.

Sample

The 11 research participants consisted of lung cancer inpatients and homecare patients at a Southern California hospice. Inclusion criteria consisted of a primary diagnosis of end stage lung cancer, dyspnea, no lesions in the ears, no allergies to adhesive materials, at least 45 years old, English speaking, ability to comprehend and understand consent, and ability to communicate with the researcher. Research participants were assigned randomly to one of three groups. The first group received current standard of care. The second group received current standard of care plus sham Auricular acupressure. The third group received current standard of care plus Auricular acupressure.

The target sample consisted of 15 subjects in each of the three groups for a total of 45 research participants. Since this research was being conducted on end-of-life stage hospice patients, it was expected that some patients might die during the study. Hence,

the plan was that subjects would continue to be recruited until the sample size of 45 was achieved. This target sample size was chosen as a function of formal statistical power analyses for quantitative data with power set to at least .80, the conventional cut off level for sufficient power (Cohen, 1988, 1992). The power analyses were conducted using the SOLO Power Analysis software (Hintze, 1992). For both research and clinical purposes, the decision was to be able to detect down to at least a medium effect size (f = .25, Cohen 1988, 1992) if the full sample were recruited for this feasibility study. For detecting such medium effects, power analysis demonstrated that originally planned total sample size of 45, there would be more than sufficient power for both the main effect of time (power = .90) and for the interaction of group by time (power = .81). It is the group by time interaction that would be used to determine the presence of group effects. That is, the focus here was on whether the change over time depends on group membership. Although there would have been insufficient power to detect such an effect size for the main effect of group (power = .28), the group main effects were neither the focus of this research nor necessary to demonstrate the efficacy of acupressure in these patients.

For this feasibility study, the target sample of 45 participants was not achieved. The sample size at the time of data analyses was 11 with two subjects in the control condition, five in the placebo condition, and four in the experimental condition. Issues and difficulties regarding participant recruitment are covered in the Discussion Section.

Data collection procedures

There were three general methods of quantitative data collection. First, selfreport was used for both demographic information and for rating of dyspnea. Second, a medical assessment of oxygen saturation was conducted. Third, patient charts were used for determining use of respiratory treatment as well as a source of other data, e.g., diagnosis of small cell versus non-small cell lung cancer. Self-report of demographic data is a frequently used procedure for assessing such data. The self-report scales for dyspnea are commonly used in treatment facilities and appear to provide both reliable and valid information. Patient charts are another frequently used source for research data. As mentioned above, for qualitative data collection five questions were asked of the subjects: Three questions on Day 1 repeated on Day 4 but asked regarding current experience and also on Day 4 two additional questions.

Measures

A short demographic questionnaire was used that asked for self-report of sex, age, marital status, number of children, and support which is the number of family or close friends within a 50-mile radius. Although much of this information could have been obtained from medical records, the taking of such information can also help establish a research rapport with the patient and research participant.

The CDS (Tanaka et al, 2000) was used to measure dyspnea. This 12-item scale assesses three dimensions of dyspnea: sense of effort [Dyspnea Effort], sense of anxiety [Dyspnea Anxiety], and sense of discomfort [Dyspnea Discomfort] using a 5-point Likert scale for responding to each item from 'not at all' to 'very much'. Also, a total score can be used. Bruera and Ripamonti (1998) recommended that a scale to measure dyspnea for investigating etiology and establishing therapeutic strategies should have six characteristics: (1) be multidimensional, (2) be self-rating since dyspnea is subjective, (3) be easy and simple enough to be completed by patients with dyspnea, (4) be evaluated

not by physical effort evoking dyspnea, but by perceived dyspnea itself so that even bedridden patients can complete it, (5) have its reliability and validity in cancer patients confirmed, and (6) be sensitive to clinical changes due to treatment or progression of the disease over time. Tanaka and colleagues stated that they had followed these requirements in their development of the CDS. Additionally, the Oncology Nursing Society (2008) formally listed this scale on their web site.

The CDS is best suited for use in this study because its average time required for completion was 140 seconds. Also if terminally ill patients cannot read the items and/or use a pencil to respond to them, the items can be read aloud and the patient can respond with a number from the five-point scale. Construct validity was confirmed through the use of repeated factor analysis, once in the developmental phase of the research and once in the validation phase. Both factor analyses yielded the expected three factors.

Convergent validity with both the Visual Analogue Scale and a modified Borg scale was good (average r = .57 and .52 respectively with both having p < .001). Reliability as assessed by internal consistency was also good (average Cronbach's alpha = .86). Also test-retest reliability was good (r = .66, p < .005). It is important to keep in mind that one might expect dyspnea itself to change over time in a patient. Hence, this level of obtained test-retest reliability is quite good. Pulse-oximeters are well established, reliable, and valid medical instruments (Tanaka et al., 2002a, 2002b).

Oxygen saturation was assessed with the Welch-Allyn Sure-Temp Pulse

Oximeter. The pulse-oximeter in this study is manufactured by Welch-Allyn Sure-Temp

Technology and is already available at the research site. The use of patient charts is also
a well-established procedure.

For the qualitative data, the three questions on Day 1 were as follows: (1)

Describe what the experience of breathlessness has been for you; (2) Describe how the experience of breathlessness has affected your quality of life; and (3) Describe any suffering that you associate with breathlessness. On Day 4, the 5 questions were as follows: (1) Describe what the experience of breathlessness has been for you at this time; (2) Describe how the experience of breathlessness has affected your quality of life at this time; (3) Describe any suffering that you associate with breathlessness at this time; (4) Describe your experiences of receiving auricular acupressure; and (5) Would you recommend acupressure to other people with breathlessness? If so, what would you tell them? If not, why not?

Experimental Procedure

Each new admission to the inpatient hospice center or homecare that had a primary diagnosis of lung cancer was approached and asked whether the researcher could give them an overview of the research participation opportunity. If permission was given, then the subject was provided with such an overview while clearly emphasizing that the research participation was completely voluntary and that declining participation or withdrawing from participation once enrolled in the study would have no effect on the course of the subject's treatment while at the inpatient hospice center or in homecare.

Once the overview was provided and if the potential subject wished to participate, he or she was given a copy of the Experimental Human Subjects Bill of Rights and asked to sign a consent form.

Before allowing the subject to sign the consent form, the researcher asked whether the subject understood the research, knew what would happen if he or she consented, understood that he or she could decline or withdraw at any time, and understood the nature of any risks of participation. After the subject signed the consent form, he or she was asked to complete the brief demographic form. For each subject, the same individual researcher followed the patient through to the end of the study.

On **Day 1**, once in the morning (about 9 AM ± 1.5 hour) and once in the evening (about 6 PM ± 1.5 hour), the subject was administered the Cancer Dyspnea Scale and had oxygen saturation assessed. Both of these assessments were conducted one-on-one. The Cancer Dyspnea Scale and the oximeter were used twice a day (morning and evening) for the next three days (Day 2, Day 3, Day 4). The first three qualitative questions were asked during the early Day 1 assessment period and the subject responses were tape recorded.

On the morning of **Day 2** and before the early Day 2 assessments, the treatment intervention began. Application of acupressure seed adhesives were carried out by a licensed acupuncturist. The experimental acupressure condition (SC + AE) consisted of placing small seeds (botanical name: vaccaria segetalis; English name: vaccaria seeds obtained from the company Heilo) with an adhesive material that allowed the seed to be held in place over the appropriate acupressure point on both ears. The placebo acupressure condition (SC + AP) also included the use of seed adhesive but not placed on lung or anxiety points. Before the adhesive with seeds was put in place, the auricular points were mildly stimulated for 3 seconds with a surface, non-invasive probe, making a slight indentation on the points, then cleansed with an alcohol applicator stick. Subjects

were asked whether they had any known allergies for adhesives or tape. Additionally, the site of the adhesive used was monitored for any allergic reaction. Skin integrity was monitored during both the application and removal of the adhesive to prevent and ameliorate skin tear. Fatigue was monitored during the subjects' participation in the four-day protocol. The subject was both directly asked about experience of fatigue and observed for any evidence of increasing fatigue over the course of the protocol. The seed adhesives were placed on the ears of the subject the morning of Day 2. Then, within two hours before each morning and evening assessment, research personnel visited the subject, asked how he or she were doing, and reminded the subject that assessments would happen at a specified time. For those subjects in the two-acupressure conditions, pressure was applied to the seeds.

Day 3 and Day 4 involved the morning and evening pre-visits and, for the acupressure groups pressure being applied to the seeds followed two hours later by the assessments. On Day 4, the 5 qualitative questions were asked and the subject responses were tape recorded. On this last day, the subjects were also engaged in conversation where they were asked whether they had any questions regarding the study. Subjects were told that if they had not received the auricular acupressure treatment, they would be offered the treatment when the study was completed. The subjects were thanked for their participation, told that the researcher greatly appreciated their help, and that this research may help others.

The site of this research, the San Diego Hospice Inpatient Care Center, is also a clinical site for the Pacific College of Qriental Medicine. The acupuncturist was licensed

in California. As covered in the Human Subjects Research section below, all research personnel were trained in the ethics and procedures of human subjects research.

Table 3. Auricular Acupressure Points Used (Oleson, 1998)*

Point/Representation	Rationale for Selection
Placebo-Sham Points:	
1) Ankle	Chosen for ease of access, similar physical location as
2) Prolapse	experimental points, but very little likelihood of impacting
3) Shoulder	patients' respiration.
4) Occiput	1
5) Internal ear	-
E	
Experimental Points:	One of most commonly used symioulan naints, colons the
1) ShenMen	One of most commonly used auricular points; calms the spirit, promoting sense of relaxation, helps with coughing.
2) Kidney	Role in respiration. In TMC, the 'Kidney' (TCM organ)
2) Kidiley	assists the 'Lung' (TCM organ) in grasping the clear 'Air
	Qi' that the Lungs send downward to the absorbed by the
	Kidney. If inhalation is difficult, it indicates deficiency in
V.	the 'Kidney.'
3) Lung Lower	Role in respiration. In TCM, the 'Lung' Governs Qi,
	manages respiration, regulates the water pathways,
	Governs diffusions of Qi and body fluids. When there is a
	pathology in the body and phlegm is accumulating it can
	sometimes it can sometimes be stored in the "Lung."
4) Chest	This point as two purposes: (1) The Lung and Kidney's
	relationship in TCM goes beyond simple respiration. The
	use of this point focuses the action of these two organ
	systems directly on breathing. (2) The intention of this
	point is to keep the Qui moving in the chest. Hence,
	breathlessness is not created by the congestion of Qi in the
5 \ D 1	chest.
5) Relaxation	Anxiety seems to be a significant component of dyspnea.
AKA St Jerome point,	This point along with the Shenmen point above (#1) can
Jerome point,	work synergistically to promote a sense of relaxation. This
sexual compulsion	point also helps with insomnia. Also ease of placement.

^{*}Jeffrey Smith, LAc, the Licensed Acupuncturist who conducted the acupressure procedures in this study, helped prepare this information.

The acupuncturist performed the customary pre-assessment procedures for auricular acupressure for the condition of breathlessness. This was done the morning of the second day of the protocol. The placebo or sham acupressure points were chosen for ease of access, similar physical location as experimental points, but very little likelihood of impacting patients' respiration. The experimental acupressure points were chosen for relationships to dyspnea and respiratory distress based upon the Chinese Diagnosis and disease concept of "breathlessness." (See Table 3 for details. Note that Table 4 describes possible points that were not used.) This concept is based on rapid difficult continuous

Table 4. Auricular Acupressure Points Not Used (Oleson, 1998; Bensky, xxxx)*

Point/Representation	Rationale for Non-Selection
1) Stop wheezing	Very close to border of antitragus and other points.
	Concern about loss of seed through poor adhesion and also
	seed could migrate to another point.
2) Adrenal	While easy to activate with a needle, it still had the same
	issues as above, but on the traqus.
3) Allergy point	Just hard to get to.
4) Master Cerebral	Could be issue with hair growth.
5) Wheezing	Too close to ShenMen and not as well rounded for the
	treatment
Emphysema	Too hare to get for good seed placement

^{*}Jeffrey Smith, LAc, the Licensed Acupuncturist who conducted the acupressure procedures in this study, helped prepare this information.

breathing with the mouth open and an inability to lie down because of breathing difficulties. With dyspnea, one of the main problems for the patient is anxiety due to drowning feelings. Hence, points were chosen so as to focus on anxiety. If anxiety is controlled then maybe the breathing will become more even and more efficient. So the points were chosen using three criteria: breathlessness treatment, anxiety reducing, ease and retention of seed placement. All placements also followed three axis lines in the ear:

ShenMen, Kidney and Lower Lung. For detail graphic illustration of these points, see Appendix F.

As mentioned earlier, the SC versus the SC + AP versus SC + AE conditions used SC with no adhesive, SC with seed adhesive not on lung or anxiety points, and Auricular acupressure seed adhesive on lung and anxiety points, respectively. The placement of the seeds on or not on lung or anxiety points was not easily discernable without very close inspection by a knowledgeable acupuncturist of the ears. Hence, the subjects and those who conduct the dependent variable assessments were blind to the SC + AP versus SC + AE conditions.

While blind to subject assigned condition, the researcher asked the qualitative questions at the two designated times and administered the CDS and the pulse-oximeter testing. These quantitative assessments were carried at the eight time points of the protocol.

Data Analysis

Although as a feasibility study this research enrolled only 11 subjects, generally the data were analyzed as if the target sample of 45 had been obtained. The analyses were carried out as part of determining feasibility in that both the researcher tested his ability in this area and the analyses yielded estimated effect sizes that can be used in power analyses for planning continued and future research in this area.

The distributional properties of the dependent variables were evaluated to determine whether they met the assumptions for parametric statistics other than the assumption of independence. The presence of independence was supported by random

assignment and by running subjects one at a time in this study. Other than independence, there are two other assumptions: normality and homogeneity of variance (Keppel, 1991). The initial plan was that in the case where there were violations of these assumptions, data transformations would be used, e.g., logarithmic transformations for highly right-skewed data. Additionally, for repeated measures designs such as this one, there is the assumption of sphericity, which can be thought of as the dependent variable having a similar correlation between any two time points. The original plan was that if this assumption were violated in the data set, Geisser-Greenhouse corrections for the level of violation would be used (Keppel, 1991). A final assumption would apply when analyses of covariance (ANCOVA) were run. That assumption is that the relationship between covariates and the dependent variable is a linear one. However, since the sample size that was generated consisted of only 11 participants, such evaluation of these last two assumptions was not warranted.

Even though random assignment was used, it was always possible for research participant characteristics to differ between conditions. That is the subjects in the three conditions could still have been different on important variables at baseline. This was especially the case with the relatively small target sample size of 45. Since there was the even smaller sample size of 11 generated in this study, evaluations of such differences across groups would not be meaningful. Still, for the sake of the protocol, some tests were run on baseline differences between groups using ANOVA for continuous variables such as age and chi-squares for categorical variables such as sex. In the case of such differences in variables central to the study being present, the original plan called for the basic design to be modified as an ANCOVA where variables that differ between the two

groups at baseline would have been used as covariates in order to take such differences into account. Although there were no such statistically significant differences that could be used here, two such analyses were run as demonstrations of the procedure.

The primary quantitative data analysis that was used in this study was ANOVA for the 3 (group) by 8 (time) mixed ANOVA design. Additionally, besides the demonstration ANCOVA used for taking into account a baseline difference between the groups, a demonstration ANCOVA was also used to test for the effects of controlling sources of individual differences, thus reducing the error term and increasing statistical power. Such potential variables included sex, age, ethnicity, marital status, number of relatives and close friends within a 50-mile radius, number of complementary treatments used, and medications,. For demonstration purposes some of these possible differences among groups at baseline were tested using one-way ANOVA for continuous variables and chi-square for categorical variables. Part of the original plan include considering some variables such as sex as an additional factor in a 2 (sex) by 3 (group) by 8 (time) mixed design ANOVA. Because of the final sample size, this was not done.

The relationships among the dependent variables were evaluated. Pearson product moment correlations were used for these evaluations.

Alpha was set at .05 for evaluating statistical significance. In the original plan, an alpha of .05 was to be used even though there were a number of tests being run in this study. The greater concern for error here was for a Type II error (saying that an effect is not present when it is) than for a Type I error (saying that an effect is present when it is not). It should be kept in mind that replication would be the best way to control for error. Although the original plan was that the significance of the group by time interaction term

for each of the primary dependent variables (dyspnea ratings and oxygen saturation) would be used to evaluate whether each of the three hypotheses was supported, in this pilot feasibility analyses, these tests were used to generate estimates of effect size for each hypothesis.

For the qualitative data, the subjects' tape-recorded responses were transcribed. The qualitative method employed in this study was Simple Thematic Analysis [Braun and Clarke, 2008]. The process here was similar to that used by Jackson, Melvin, and Downe (2007). The procedure was conducted by two people, the author and by a consultant trained in qualitative research and nursing. The interactive procedure was conducted through debate and consensus. The initially identified themes were then reevaluated with an examination for disconfirming data. Thus the transcriptions were evaluated for the presence of themes, there was an agreement on the final themes, and the results were used to inform the understanding of the quantitative results.

Chapter 4 Results

Sample

The data analyzed here came from a sample of 11 subjects enrolled and randomly assigned among three conditions: two in Control, five in Placebo, and four in Experimental. Subjects all had a primary diagnosis of lung cancer and were drawn from the San Diego Hospice and Palliative Care Center with four (36.4%) coming from the Inpatient Care Center (ICC) and seven (63.6%) from Home Care (HC). These 11 were enrolled from a total of 74 approached from July 2007 through March 2008; 11 were in the ICC and 63 were in HC. Of those approached, two in the ICC and 10 in HC died before they could be enrolled in the study. One subject in HC was discharged from San Diego Hospice and Palliative Care Services because he was doing better and began looking for curative interventions. The most common reasons provided for not enrolling were time involvement, appointments for doctors and treatments, and fatigue. For characteristics of those eligible subjects who were approached but did not enroll in the study can be found in Appendix K.

Characteristics of the sample included 54.5% female, 72.7% Caucasian, 63.6% married, and 45.5% with a high school degree. The average age was 68.7 (14.21) with a range from 49 to 89. Support, the mean number of friends and family living within 50 miles of either the San Diego Hospice and Palliative Care Center or the place of Home Care on whom the individual could count, was 3.6 (3.59) with a range from 1 to 13. A little over a third (36.4%) of the subjects had only one person on whom they could count. The average number of eight different types of complementary medical treatments that the individual had had was 1.5 (1.51) with a range from 0 to 4. Those who had had at

least one type of complementary treatment comprised 54.5% of the sample. Also, the time between eight of the subjects' enrolling in the study and death averaged 64.6 days with a standard deviation of 47.39 and a range from 6 to 141 days. Three subjects had not died as of May 9, 2008. See Appendix L for details.

Table 5 presents the sample characteristics with more detail and compares the attributes of the subjects across the three conditions. Because of the small sample it was Table 5. Subject Characteristics Across 3 Experimental Conditions

			Condition]
					X^2
					or F-
Variables	All Subjects	Control	Placebo	Experimental	test
Age mean (sd)	68.7 (14.21)	66.0 (18.38)	68.2 (16.45)	70.8 (13.72)	0.07
Sex N (%)					
Female	6 (54.5)	2 (100.0)	3 (60.0)	1 (25.0)	
Male	5 (45.5)	0(0.0)	2 (40.0)	3 (75.0)	3.13
Ethnicity N (%)					
Caucasian	8 (72.7)	1 (50.0)	3 (60.0)	4 (100.0)	
Hispanic	2 (18.2)	1 (50.0)	1 (20.0)	0 (0.0)	
Native	1 (9.1)	0 (0.0)	1 (20.0)	0 (0.0)	
American					3.71
Marital N (%)					
Single	1 (9.1)	1 (50.0)	0 (0.0)	0 (0.0)	
Married	7 (63.6)	1 (50.0)	4 (80.0)	2 (50.0)	
Divorced	1 (9.1)	0 (0.0)	0 (0.0)	1 (25.0)	
Widowed	2 (18.2)	0 (0.0)	1 (20.0)	1 (25.0)	7.11
Education Degree					
None					
High School	3 (27.3)	1 (50.0)	2 (40.0)	0(0.0)	
Bachelor	5 (45.5)	1 (50.0)	2 (40.0)	2 (50.0)	
Doctorate	2 (18.2)	0 (0.0)	0 (0.0)	2 (50.0)	
(M.D.)	1 (9.1)	0 (0.0)	1 (20.0)	0 (0.0)	6.53
Support # mean					
(sd)	3.6 (3.59)	1.0 (0.00)	5.0 (4.74)	3.2 (2.22)	0.91
# complementary					
tx mean (sd)	1.5 (1.51)	3.5 (0.71)	1.4 (1.34)	0.5 (1.00)	4.50*
Location N (%)					
Inpatient Care	4 (36.4)	1 (50.0)	1 (20.0)	2 (50.0)	
Home Care	7 (63.6)	1 (50.0)	4 (80.0)	2 (50.0)	1.06

p < .05

not expected that the conditions would be statistically significantly different on sample characteristics. Still, the statistics were run as part of the feasibility study, using chi-square for nominal variables and one-way ANOVA for continuous (interval or ratio) variables. In general the differences across the three conditions were not significant. The one exception was for the number of the eight types of complementary medical treatment. Here the difference across the three conditions was significant (F(2,10) = 4.50, p < .05), with Control subjects reporting an average of 3.5 (0.71) types of treatments, Placebo subjects reporting 1.4 (1.34), and Experimental subjects reporting 0.5 (1.00). Even with a small sample size, it is possible to obtain significant results if the estimated effect size is large. For the ANOVA analyses in this study, partial eta square (η_p^2) was used to represent effect sizes. This effect size estimate is available as part of the ANOVA programs within SPSS. For η_p^2 , effect sizes are as follows: small ~ .01, medium ~ .06, large ~ .20 (Cohen, 1988). For the significant result for number of complementary treatments across the three conditions, the η_p^2 = .53, a very large effect.

Hypotheses Testing

A 3 (condition) by 8 (time) mixed design ANOVA with time as the repeated measure was used for testing the two hypotheses predicting change in dyspnea and oxygen saturation as a function of assigned experimental condition (Control, Placebo, Experimental).

Hypothesis 1: Dyspnea Change

Four statistical analyses were conducted to test this hypothesis about the change in dyspnea being a function of the experimental condition. These analyses were run for four different dependent variables: Dyspnea Total, Dyspnea Effort, Dyspnea Anxiety, and Dyspnea Discomfort. The means and standard deviations for these dependent variables over eight time points within each of the three experimental conditions are presented in Tables 6 through 9. The effect that was of interest for each of these analyses was that of the condition by time interaction. Condition by time interactions are reported below for the general overall effect and for the type of interaction: linear where the change is generally in the same direction over time or quadratic where the change shifts directions at least once over time. The type or form of interaction tests have more statistical power since they test for a specific shape of a change rather than testing for whether there is any type of change present. The results of these analyses are presented below and the plots of the results of the changes over time in dyspnea for the three conditions are presented in Figures 2 through 5. Figures 6 and 7 are presented for demonstration purposes to show how possible covariates would be used in an ANCOVA.

Dyspnea Total. For Dyspnea Total, there appears to be a general change in alleviation of dyspnea over time for all subjects, as can be seen in Table 6 and Figure 2. This is reflected in the significant ANOVA main effect for time (F(7,56) = 2.33, p < .04) with a large effect size $(\eta_p^2 = .23)$. The form of this time effect appears to be a simple linear one (F(2,8) = 9.22, p < .02) with a very large effect size $(\eta_p^2 = .54)$. It should be noted that main effects are best not interpreted if there is a disordinal interaction effect present, and the effect interest here is that of the condition by time interaction.

Table 6. Experimental Conditions: Cancer Dyspnea Scale Total [Mean (SD)].

	Time								
Condition	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8	
Control	9.0	10.5	13.0	11.0	4.0	4.5	6.0	3.5	
	(12.73)	(14.85)	(18.38)	(15.56)	(5.66)	(6.35)	(8.49)	(5.00)	
Placebo	8.4	7.0	7.4	11.8	6.4	4.4	7.6	9.2	
	(6.84)	(7.11)	(7.34)	(12.93)	(8.14)	(4.56)	(7.57)	(6.76)	
Experimental	11.5	11.0	9.5	9.0	6.8	2.75	8.2	5.0	
	(5.74)	(6.88)	(5.92)	(5.48)	(3.95)	(3.10)	(5.91)	(4.24)	

Table 7. Experimental Conditions: Cancer Dyspnea Scale Effort [Mean (SD)].

	Time							
Condition	Time	Time	Time	Time		Time	Time	Time
	1	2	3	4	Time 5	6	7	8
Control	4.5	3.5	4.0	3.0	1.5	2.5	2.0	1.5
	(6.36)	(5.00)	(5.66)	(4.24)	(2.12)	(3.54)	(2.83)	(2.12)
Placebo	3.6	2.2	3.0	4.4		2.2	3.4	3.2
	(1.82)	(1.92)	(2.34)	(5.60)	2.8(3.27)	(1.64)	(3.13)	(2.95)
Experimental	6.5	5.2	4.8	4.2	1.8	0.50	3.0	2.0
	(3.32)	(2.87)	(3.20)	(2.06)	(1.50)	(0.58)	(2.45)	(1.41)

Table 8. Experimental Conditions: Cancer Dyspnea Scale Anxiety [Mean (SD)].

	Time								
Condition	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8	
Control	2.5	5.0	5.5	4.5	0.5	0.5	0.0	0.5	
1	(3.54)	(7.07)	(7.78)	(6.36)	(0.71)	(0.71)	(0.00)	(0.71)	
Placebo	1.4	1.0	0.8	4.4	0.4	0.2	1.0	1.4	
	(1.67)	(2.34)	(1.30)	(6.19)	(0.89)	(0.45)	(1.41)	(1.67)	
Experimental	0.8	1.2	0.5	0.8	0.2	0.0	0.0	0.0	
	(0.96)	(1.50)	(1.00)	(0.96)	(0.50)	(0.00)	(0.00)	(0.00)	

Table 9. Experimental Conditions: Cancer Dyspnea Scale Discomfort [Mean (SD)].

	Time							
Condition	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8
Control	2.0	2.0	3.5	3.5	2.0	1.5	4.0	1.5
	(2.83)	(2.83)	(5.00)	(5.00)	(2.83)	(2.12)	(5.66)	(2.12)
Placebo	3.4	3.8	3.6	3.0	3.2	2.0	3.2	4.6
	(4.67)	(4.09)	(4.51)	(3.08)	(4.38)	(3.08)	(3.63)	(3.13)
Experimental	4.2	4.5	4.2	4.0	4.8	2.2	5.3	3.0
	(2.87)	(3.00)	(2.06)	(3.16)	(3.40)	(2.87)	(3.86	(3.56)

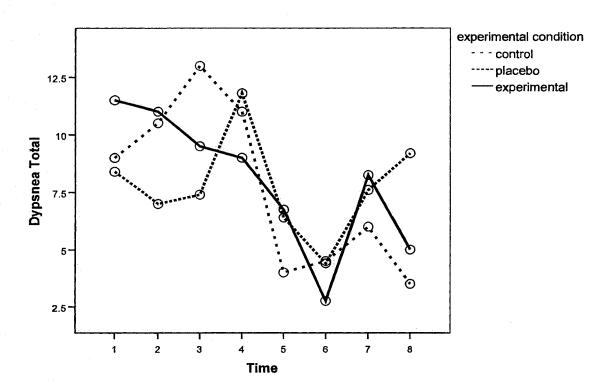
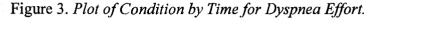


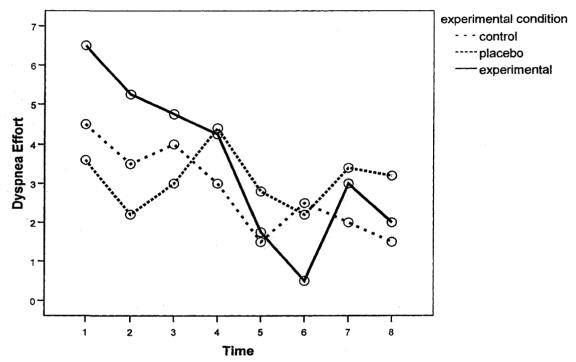
Figure 2. Plot of Condition by Time for Dyspnea Total.

Regarding this interaction effect, the plot in Figure 2 suggests that the Experimental condition has a general overall trend of improvement through time point 6 while the other two conditions bounce around a bit, thus reflecting an interaction. However, the ANOVA is not significant for the overall test of condition by time interaction (F(14,56) = 0.62, p = .84), although it does have a large size effect (η_p^2 = .23). A better result is reflected by the test for a linear condition by time interaction with an F-value at least greater than 1, a p-value that is much better than the overall interaction test (F(2,8) = 2.34, p = .16), and a fairly large effect size (η_p^2 = .37).

Dyspnea Effort. For the dependent variable Dyspnea Effort, the results are a little clearer (see Figure 3). Here, neither the overall main effect for time (F(7,56) = 2.15, p = .053) nor condition by time effect (F(14,56) = 0.86, p = .62) were significant. However, the effects were of reasonable sizes for both the time main effect and the condition by interaction

effect (large with η_p^2 = .21 and medium with η_p^2 = .17 respectively). Importantly, the tests for the form of the changes were significant with large effects for both the main effect of

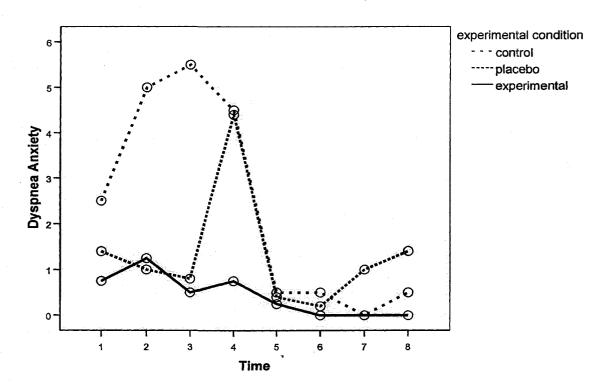




time (F(1,8) = 11.63, p < .01; large η_p^2 = .59) and the condition by time interaction (F(2,8) = 4.69, p < .05, η_p^2 = .54). It appears that the Experimental condition changes more over time, more steeply, will the other two conditions are flatter over time as well as becoming worse and better at different time points. Because of concerns regarding the use of such parametric statistics as ANOVA with a small sample size, these data for Dyspnea Effort were re-run via the nonparametric statistic Friedman two-way ANOVA by ranks (Siegel and Castellan, 1988). The nature of the Friedman is such that the three conditions could not be simultaneously run. Hence, the Friedman was run once for each of the three conditions. The only condition that resulted in a statistically significant change over time was auricular

acupressure experimental condition (control condition: $\chi^2_{df=7} = 7.0$, p = .43; placebo: $\chi^2_{df=7} = 3.3$, p = .86; experimental: $\chi^2_{df=7} = 21.4$, p < .01). These nonparametric results support those generated by the parametric test. A final step here was an example exploration of possible confounding effects using the dependent variable Dyspnea Effort. These results are presented below following the results for Dyspnea Anxiety and Dyspnea Discomfort.

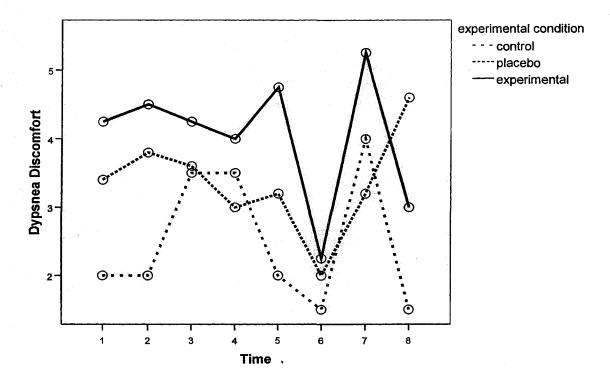
Dyspnea Anxiety. The dependent variable Dyspnea Anxiety has dramatic plots (see Figure 4) that look like they would yield a significant condition by time effect. However, although both the overall main effect for time and the overall condition by time interaction are large effects ($\eta_p^2 = .26$ and $\eta_p^2 = .22$, respectively), the main effect for time is significant (F(7,56) = 2.82, p < .02) while the condition by time interaction is not (F(14,56) = 1.10, p = .38). The same pattern was found for the test of the linear form of the effects with a Figure 4. Plot of Condition by Time for Dyspnea Anxiety.



significant time main effect (F(1,8) = 5.64, p < .05, η_p^2 = .41) and a non-significant condition by time interaction (F(2,8) = 1.81, p = .23, η_p^2 = .31).

Dyspnea Discomfort. The dependent variable Dyspnea Discomfort yielded neither significant effects nor any easily discernable patterns (see Figure 5). For the time main effect, neither the overall test (F(7,56) = 1.15, p = .35) nor the test for linear form (F(1,8) = 0.16) were significant and the effects were medium for the overall test (η_p^2 = .13) and small for the test for linear form (η_p^2 = .02). As well, for the condition by time interaction, neither the overall test (F(14,56) = 0.59, p = .86) nor the test for linear form (F(2,8) = 0.20) were significant and the effects were medium for the overall test (η_p^2 = .13) and small to medium for the test for linear form (η_p^2 = .05).

Figure 5. Plot of Condition by Time for Dyspnea Discomfort.



Demonstrating Use of Covariates. To present a demonstration regarding the issue of possible confounding variables, the dependent variable Dyspnea Effort is revisited here. For examples of possible confounding variables, age and the number of family and friends living within 50 miles of the subject's location on whom the subject could count were chosen. The problem with using other possible confounding variables can be seen in Table 5. Note that sex is completely confounded for the Control condition with only females in this intervention and hence 0.00% males. Also, the variables ethnicity, marital status, and education degree have some cells with 0.00%, indicating some complete confounding. If confounding is complete, then the separate effects for the experimental independent variable and the complete confounding variable are impossible to parse. With a larger sample, it would be expected that these 0.00% cells would have some entries and, thus, no variable would be completely confounded with condition interventions.

The first example used age as the possibly confounding variable, where the potential confounding effects were evaluated through the use of age as a covariate. Figure 6 presents the plots for Dyspnea Effort across the three conditions. If Figure 6 is compared to Figure 3, where it is obvious that age as a covariate had little effect. This lack of effect was also reflected in the statistical results. The overall age by time interaction was not significant (F(7,49) = 2.68, p = .14) although it was nearly a large effect $(\eta_p^2 = .19)$. Neither was the test of the linear form of the age by time interaction significant (F(1,7) = 1.37, p = .28) and this effect size was medium to large $(\eta_p^2 = .26)$. On the other hand, the overall condition by time interaction was still large $(\eta_p^2 = .22)$, although, as it was without age as a covariate, not significant (F(14,49) = 0.98, p = .49); and the test of the linear form of the condition by time

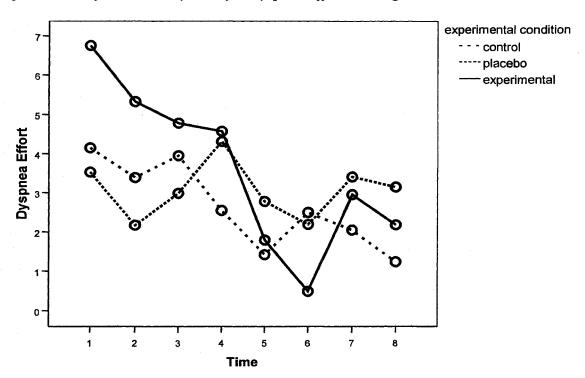


Figure 6. Plot of Condition by Time for Dyspnea Effort with Age as Covariate.

interaction was still significant (F(2,7) = 5.15, p < .05) and the effect size was still large (η_p^2 = .59), as was the case when this analysis was run without age as a covariate.

In the example of testing for possible confounding variables using as the potential covariate support which is the number of family or close friends living within 50 miles and on whom the subject can depend (see Figure 7 for plots). In this case, for the overall support by time interaction, the covariate did have a significant large effect (F(7,49) = 6.79, p < .001, η_p^2 = .49). For the test of the form of the interaction, support did have a significant large effect that was not linear, but rather was for a high order shape that is not easily interpreted (F(1,7) = 8.26, p < .03, η_p^2 = .54). Importantly, even with such large effects, and significant in the case of the overall interaction, the condition by time interaction effect was still large (η_p^2 = .32), although still, as it was initially, not significant (F(14,49) = 1.61, p = .11). Also importantly, the test of the linear form of the condition by time interaction was still large and about the same size as in the initial analysis (η_p^2 = .52) and, although not significant as it was

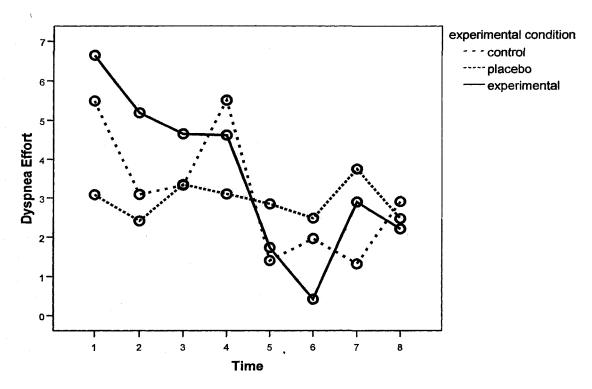


Figure 7. Plot of Condition by Time for Dyspnea Effort with Support as Covariate.

initially the significance level is still notable (F(2,7) = 3.86, p = .074). If Figure 7 is compared with the original Figure 3, the effects of controlling for support can be identified, although the general patterns of the plots remain quite similar reflecting the near significant condition by time interaction.

Hypothesis 2: Oxygen Saturation Change

Two statistical analyses were conducted to test this hypothesis about the change in oxygen saturation being a function of the experimental condition. The first analysis uses as the dependent variable simple percent oxygen saturation. However, as Winer, Brown, and Michels (1991) point out, conducting ANOVAs with a dependent variable using percent or proportion metrics is a problem. The problem is that given the nature of upper and lower limits of such metrics, having values close to the upper or lower limits makes it difficult to

detect the presence of interactions. A remedy for this problem is to use an arcsin data transformation on the percentages or proportions. Given that interaction effects are the effects of interest in this study, a second analysis was run on oxygen saturation using an arcsin data transformation. Tables 10 and 11 present the oxygen saturation means and standard deviations for the eight time points across the three conditions. Table 10 presents the raw percentage values and Table 11 presents the arcsin transformed variables.

Oxygen Saturation Percent Values. See Figure 8 for plotting of the condition by time interaction effect. The ANOVA for the dependent variable using percent values yielded no significant effects for either the overall time main effect (F(7,56) = 0.19, p = .99) or the overall condition by time interaction (F(14,56) = 0.66, p = .81). The effect size for the overall time main effect was small (η_p^2 = .02), while that for the condition by time interaction was medium (η_p^2 = .14). The testing of the linear form of the main effect for time yielded non-significant results (F(1,8) = 0.13, p = .73) for a small effect (η_p^2 = .02). Testing for the linear form of the condition by time interaction also yielded non-significant results (F(2,8) = 1.33, p = .32), but it did have a large effect size ((η_p^2 = .25).

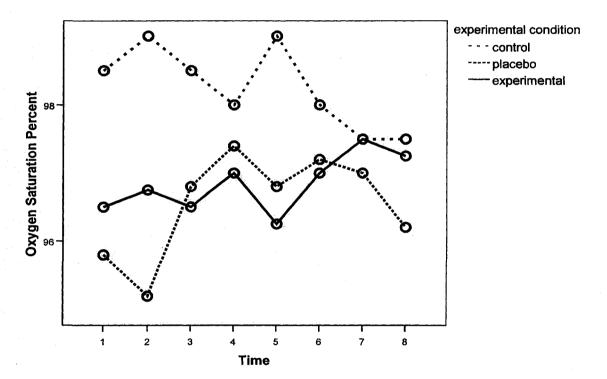
Table 10. Experimental Conditions: Oxygen Saturation, Percent [Mean (SD)].

	Time								
Condition	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8	
Control	98.5	99.0	98.5	98.0	99.0	98.0	97.5	97.5	
	(2.12)	(1.41)	(2.12)	(2.83)	(1.41)	(2.83)	(2.12)	(0.71)	
Placebo	95.8	95.2	96.8	97.4	96.8	97.2	97.0	96.2	
	(2.49)	(0.84)	(2.28)	(1.52)	(2.28)	(1.30)	(1.41)	(2.78)	
Experimental	96.5	96.7	96.5	97.0	96.2	97.0	97.5	97.2	
-	(1.73)	(0.96)	(0.58)	(1.41)	(1.71	(0.82)	(1.92)	(0.96)	

	Time								
Condition	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8	
Control	1.4 (0.17)	1.5 (0.14)	1.4 (0.17)	1.4 (0.20)	1.5 (0.14)	1.4 (0.20)	1.4	1.3 (0.03)	
Placebo	1.3	1.3	1.3	1.3	1.3	1.3	(0.10)	1.3	
	(0.15)	(0.03)	(0.10)	(0.07)	(0.09)	(0.06)	(0.06)	(0.10)	
Experimental	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.3	

Table 11. Experimental Conditions: Oxygen Saturation, Arcsin Transformed [Mean (SD)].

Figure 8. Plot of Condition by Time for Oxygen Saturation as Percent.

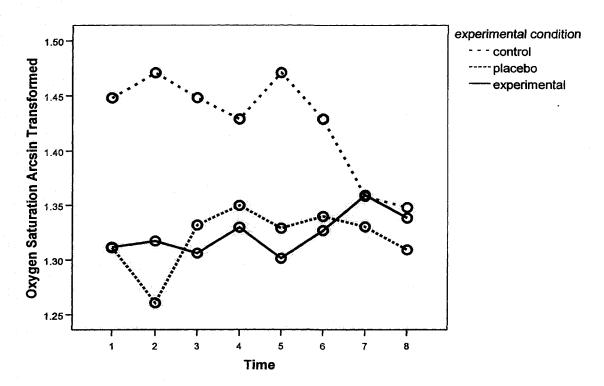


Oxygen Saturation Arcsin Transformed Values. See Figure 9 for plotting of the condition by time interaction effect. The results here were essentially the same as for the oxygen saturation percent values dependent variable.

The ANOVA for the dependent variable using arsin transformed values did not have significant effects for the overall time main effect (F(7,56) = 0.32, p = .94) nor for the overall condition by time interaction (F(14,56) = 0.86, p = .61). The effect size for the overall time

main effect was small $(\eta_p^2 = .04)$, while that for the condition by time interaction was medium $(\eta_p^2 = .18)$. The analysis regarding the linear form of the main effect for time also yielded non-significant results (F(1,8) = 0.24, p = .64) for a small effect $(\eta_p^2 = .03)$. As well, the testing for the linear form of the condition by time interaction yielded non-significant results (F(2,8) = 1.95, p = .21), although it did have a large effect size $(\eta_p^2 = .33)$. It is interesting that although the results of both of the oxygen saturation analyses were similar, the arcsin transformation did result in larger F-values, smaller p-values, and large effect sizes.

Figure 9. Plot of Condition by Time for Oxygen Saturation as Arcsin Transformation.



Correlations Between Dyspnea Assessments and Oxygen Saturation

The correlations between the four measures of dyspnea over the eight time points and the two variables used to assess oxygen saturation were evaluated. See Tables 12 and 13.

Although there is reported in the literature some disconnect between a patient's report of dyspnea and physical measures of functioning, the correlation here suggested that there might be some relationship between the four dyspnea measures and the two oxygen saturation variables. This relationship was not consistent across time or measures. However, some of the correlations were quite large. Effect sizes for correlations are as follows: small = .10, medium = .30, and large = .50. Some correlations here exceeded .80. This may have been due to the small sample and, hence unreliable estimations of effect size. As an example of testing for this, the correlation of Dyspnea Anxiety and arcsin transformed oxygen

Table 12. Correlations of Cancer Dyspnea Scale with Percent Oxygen Saturation.

	Time									
CDS Scale	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8		
Total	.21	.44	.01	.62ª	20	.53	.37	.36		
Effort	.39	.49	11	.52	12	.54	.25	.41		
Anxiety	.25	.72ª	.37	.61ª	.29	.82 ^b	15	.30		
Discomfort	09	10	23	.40	30	.31	.51	.25		

p-values a = .05, b = .01 c = .001

Table 13. Correlations of Cancer Dyspnea Scale with Arcsin Transformed Oxygen Saturation.

	Time								
CDS Scale	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8	
Total	.16	.50	.23	.64 ^a	14	.56	.41	.46	
Effort	.33	.48	.05	.49	07	.62ª	.29	.50	
Anxiety	.29	.83 ^b	.62ª	.65ª	.31	.86°	16	.39	
Discomfort	13	05	09	.43	23	.30	.54	.32	

p-values a = .05, b = .01 c = .001

Table 14. Spearman Rho Coefficients of Cancer Dyspnea Scale with Percent Oxygen Saturation.*

	Time								
CDS Scale	Time 1	Time 2	Time 3	Time 4	Time 5	Time 6	Time 7	Time 8	
Total	.30	.41	19	.62ª	37	.42	.32	.49	
Effort	.39	.46	01	.57	21	.48	.39	.45	
Anxiety	.11	.62ª	06	.63ª	.34	.70 ^b	23	.37	
Discomfort	09	10	26	.41	41	.22	.57	.48	

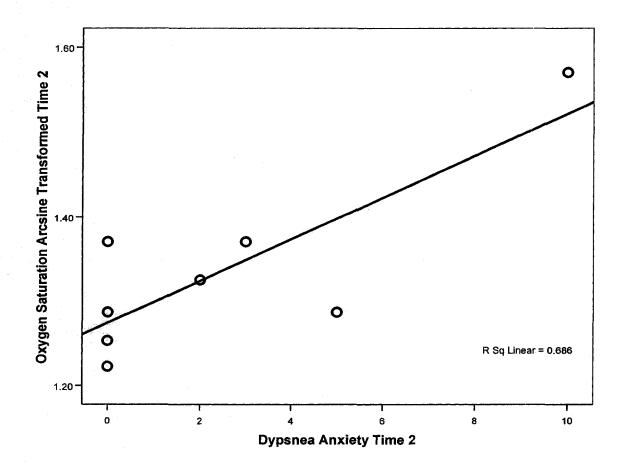
p-values a = .05, b = .01 c = .001

saturation (See Table 13, r = .83, p < .01) was evaluated further via the use of a scatter plot (see Figure 10). A visual examination of the scatter plot identified one outlying subject with a Dyspnea Anxiety score of 10 and an arcsin transformed oxygen saturation level of 1.57 (corresponding to 100 percent oxygen saturation). When this subject was removed from the analysis, the correlation dropped to .33 (p = .36). If there are relationships between dyspnea scores and oxygen saturation, the effects may be more medium than large.

Again, because of the small sample size, a nonparametric statistic was also used to check the parametric results. Here, Spearman rho coefficients (Table 14) were used to compare with the results of the Pearson product moment correlations (Tables 12 and 13). The general pattern of results was remarkably the same. Only the relationships within Time 3 appeared to be much at variance.

^{*}Note: Because of the nature of Spearman rho coefficients, they are the same for both oxygen saturation variables. Hence, only a single table needs to be presented.

Figure 10. Scatter Plot of Relationship Between Time 2 Dyspnea Anxiety and Arcsin Transformed Oxygen Saturation.



Evaluation of Parametric Assumptions

As stated in the Methods Section, the assumption of independence is likely to have been met here since random assignment was used and by subjects were run one at a time. The assumption of homogeneity of variance could not be tested within the 3 (condition) by 8 (time) mixed design ANOVA due to the small sample size. The SPSS general linear model program use to run the ANOVAs was unable to compute Box's Test of Equality of Covariance Matrices because of sample size. Also, as stated in the Methods Section, due to the small sample size, evaluating the assumption of sphericity and ANCOVA linearity

assumption of the relationship between covariates and dependent variables across conditions was not warranted.

Regarding the assumption of normality, again the small sample size limits the usefulness of evaluation this assumption. However, for illustrative purposes, the evaluations of the normality assumption for two dependent variables are presented here. The Dyspnea Effort score at Time 1 had z-scores of less than 1 for both the test of skewness (z = 0.20) and kurtosis (z = -0.82) strongly supporting the assumption of normality. Yet, an examination of the histogram for this variable strongly suggests that the distribution was not actually normal (see Figure 11). The second dependent variable used as an example here was that of arcsin transformed oxygen saturation at time 1. Again, neither of the z-scores for skewness (z = 1.58) and kurtosis (z = 1.22) were significant and thus provided support for the assumption of normality. And, again, however, a visual examination of the histogram for this variable suggests that the distribution was not actually normal (see Figure 12).

Figure 11. Histogram Evaluating Normality Assumption for Dyspnea Effort Time 1

Histogram

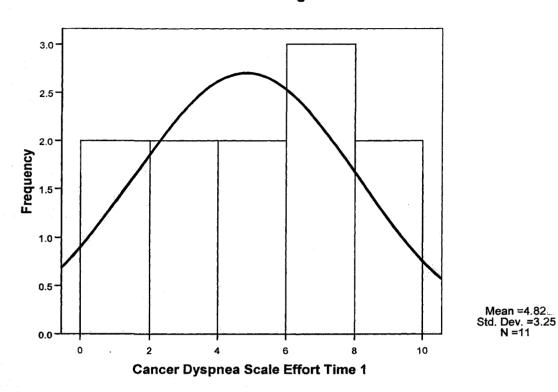
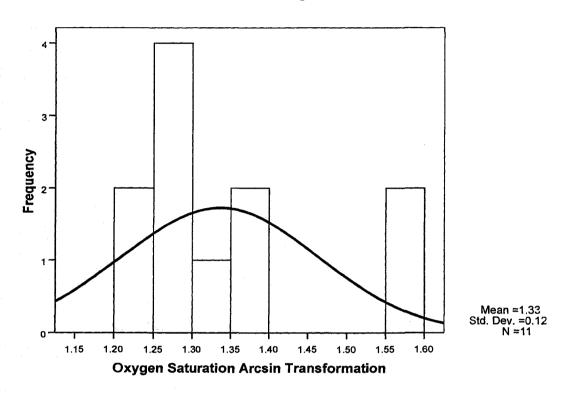


Figure 12. Histogram Evaluating Normality Assumption for Arcsin Transformed Oxygen Saturation Time 1

Histogram



Qualitative Analysis of Themes

Qualitative data were collected, transcribed, and analyzed for themes. Subjects all had a primary diagnosis of end-stage lung cancer. They received palliative care in a hospice setting at the time of data collection. Subjects were interviewed twice, pre-treatment and post-treatment. All subjects were willing to give answers to qualitative questions but at times struggled to communicate due to medical problems, medication effects, and fatigue. Some subjects declined to answer the first three questions of the post interview questions because they had no additional information to share. Simple thematic analysis was performed with the goal of identifying cogent themes that were pertinent to most subjects. There was little if any change in themes from pre-treatment to post-treatment. The following is a discussion of the six themes that emerged along with one global theme most frequently present outside of the formal taping sessions.

Breathlessness

Subjects were asked to describe their experience of breathlessness. All subjects had at least mild or intermittent bouts of breathlessness and were able to describe these experiences vividly. Some descriptions included smothering, drowning, or being buried alive. Subjects noted "It was horrible, sheer fright, that is it", and "Terrible, because you feel like your gonna die." One description characterized it as "Breathlessness is not panting. It is just short breaths without the speed."

Breathlessness was noted to be associated with fatigue and was seen as a part of everyday life: "I am worn out. I still keep trying to walk." and "It's kinda wrapped around everything else, I am worn out." Some subjects injected humor into their discussion: "It's an

interesting experience. I wouldn't wish it on anybody," "It is like being one of those puffer fish," and "I am enjoying the breath I'm getting." Finally, subjects felt that it was a symptom that evidenced a great mortality: It's a consequence of something that's life-threatening. It's a reminder of how close the end is."

Suffering

Most subjects denied that they experienced suffering even with repeated questions related to the concept of suffering. Subjects were prompted with possible aspects of suffering that included physical, spiritual, and psychological suffering. One subject stated "I can't relate to that at all." Another gave the vague response "I can't live my life normal."

Several subjects gave responses that indicated discomfort at being cared for by others to the questions about suffering. Some examples of these responses were: "It is watching what my wife has to go through just to take care of me...waiting on me hand and feet and this hurts me deeply." And "Suffering is irritating. Irritating is having people being bothered, paying too much attention to me."

Finally, several subjects reported anger and sadness at the loss of ability to work and the need to accept help from others. One noted also that the future was a "wait and see game" of unknown further changes.

These responses may indicate that suffering was a difficult concept for subjects to understand within the context of dyspnea; possibly they associated suffering with extreme pain only. Alternately, subjects who self-selected for this study may have experienced less suffering. Most subjects seemed to be accentuating the positives in their lives and minimizing the negatives. This may have inhibited their discussion of suffering.

Quality of Life

Quality of life questions elicited the biggest response from subjects. These responses fell into two general subcategories: loss of abilities and changes in relationships.

Loss of abilities encompassed the areas of loss of power and energy, loss of ability to work, and loss of ability to care for themselves. Subjects spoke about the process of adapting to these losses while accepting some loss in the pursuit of maintaining their independence.

Losses included inability to work outside of home, accomplish activities of daily living, or travel.

Subjects shared their experiences of loss of ability: "I can't do anything. If I could do something I know I'd feel better, but I can't do it today." and "(activities) they are very curtailed. The center of your life seems to be on breathing rather than on enjoying the things in life," and "It's very much slowed me down, my ability to do normal activities has changed incredibly."

They also shared ideas about how they adapted: "I know how to equip myself and I go." and "I'm not doing a lot of things I used to, but you can adapt." They accepted some losses: "It prevents me from traveling so my family has to travel without me. So it's harder for them and not as much fun for me," and "I can't visit like I used to, talk on the phone or any of that (for long periods)."

Changes in relationships were profound. Subjects reported the discomfort of having their wives/partners waiting on them, of having other caring for them, the loss of socializing, role-reversal, and loss of sex life. "I do have a babysitter...my daughter, she is my caretaker

now," "Independence, it's everything, everything," "All of my independence has been taken away," and "It seems like day by day, its using up your energy and your intelligence."

One subject spoke of changes in her relationship with her husband and said, "We have no sex life. That's sad. God, I could cry. It's because I have no desire, that's the main thing, I'm done with that."

Other subjects reported positive changes in their relationships due to illness: "It has brought us closer together in a way that is almost impossible to imagine, a really deep way," and "I am more (emotionally) mature than I was when I came into the ICC (in-patient center)."

Experience of Acupressure Therapy

All subjects found the experience to be pleasant, not noticeable, or minimally uncomfortable at times. None experienced significant discomfort or stopped treatment early. Subjects were happy with their decision to participate, even without noticeable benefits. Two subjects noticed a significant result, one in the reduction of breathlessness and another in the reduction of pain and use of pain medication. The subject who reported a decrease in breathlessness was in the placebo acupressure group. Still, his qualitative reports of breathing more easily are also reflected in his CDS ratings for dyspnea effort across the eight time points. His eight dyspnea effort scores for the eight time points were 3, 3, 5, 5, 0, 0, 3, 4, 1. For the subject who reported less breathlessness, this was also noted by interviewer and family members. However, the subject did not attribute this change to the acupressure. The subject who reported using less pain medication said, "It's beneficial. I think that it might have me not needing my Dilaudid." It should be noted this subject was in the placebo

condition and that, although the subject attributes the lower pain and less use of medications to the acupressure, she stopped taking the medication on the baseline day. Hence, per experimental protocol, she did not receive placebo intervention before she stopped taking pain medication.

Some subjects described the experience as pleasant. "Interesting and curious. It felt very pleasant," "It's been fun, I enjoyed it," "It works out fine," "Very easy," and "I found the whole thing interesting and I was very skeptical". Others noticed nothing during the treatment: "It was sort of not an experience," and "It was nothing." Many subjects noted their satisfaction in deciding to participate even if they did not notice a benefit: "I'm glad that I participated," and "I was hopeful last time but didn't derive much benefit."

The subject who described the experience as fun and enjoyable was in the experimental acupressure condition and on his CDS dyspnea ratings went from 10 to 3 on effort and 15 to 8 for the total score. He is also the subject who stated that he would recommend the treatment to others: as reported below, "Of course I would, I would recommend it 100%." The subject who reported that the experience as being "Interesting and curious. It felt very pleasant" was in the placebo acupressure condition and rated dyspnea effort and total as quite high across all eight time points. The subject who reported "It was sort of not an experience," was in the placebo acupressure group and gave very low ratings (0 and 1's) on the CDS for all eight time points across the four days. Given his low ratings from the first time point, he could not have shown improvement on the scales.

Awareness of Mortality

Subjects spoke indirectly about the process of death and about fears of discomfort during the dying process. They had an awareness that time was limited. Many mentioned similar thoughts, of time being short, making the day count, and making the best of your time and energy. A few subjects' comments included: "I'm half afraid of something happening," "I don't know what will happen at the next stage," "Things mean a lot more and I notice things," and "I was too far gone for immediate help."

Recommendation of Acupressure for Others with Lung Cancer

Subjects generally were positive in recommending it to others in similar situations. Some noted that it was not clearly proven to work. Others noted that it would do no harm and there was little risk associated with trying it. Others noted that cancer put them in a precarious position and that they would try almost anything.

The positive comments included, "Of course I would, I would recommend it 100%" and "Absolutely, I would recommend it highly." More cautious comments included, "I haven't seen any advantage and I haven't seen any disadvantage," and "I don't know, I really don't know." Harm was a big component in recommending acupressure for others with lung cancer, as evidenced by the comments such as "It didn't do me any harm " and "It didn't hurt me any." Cancer-related comments included, "When you are in my position, you really try anything as long as it doesn't interfere with your traditional treatment."

Finally, there was a sense of hopefulness in one subject who said, "I would recommend anybody try it. It is something new and different, and that is where the promise is, in something new and different I think, so yes, I would recommend it." Another subject

said "I hope if it don't help me, it will help others with their breathing and their quality of life." Other subjects also spoke of the possibility that the treatment might help someone else more that it helped them.

Global Theme: Helping Others and Meaning

Subjects spoke outside of actual taping about their desire to help others with similar health challenges and to leave something positive behind. They were looking beyond themselves with a positive view of life, wanting to be involved with something bigger than themselves. Many had hopeful attitudes about their own illness, and positive attitudes about growing and maintaining relationships. They chose freely to participate in the study even though they were experiencing fatigue and breathlessness at times during the study, and were at the end of life. These comments and behaviors point to a desire for connection with others and a wish to contribute to the well being of others and continuing to have meaning in their own lives.

Chapter 5 Discussion

Purpose of the Study and Preliminary Overview of Results

The primary purpose of this research was to conduct a pilot feasibility study for evaluation of the effects of auricular acupressure on dyspnea in hospice patients with a primary lung cancer diagnosis. The general conclusion regarding feasibility is that this type of study can be done, although it is quite difficult, as has been previously reported (Storey, 2004). Of the 74 patients approached, 11 (14.9%) were enrolled as subjects. Twelve additional patients did accept the invitation to be in the study, but before they could be enrolled, their condition quickly deteriorated and they began the active dying process. This emphasized the general fragility of this population. Had these 12 additional patients lived to participate in the study, the enrollment rate would have been 31.1%. Storey (2004) reported that, in the hospice where he was conducting the research, there was a steadily decreasing average length of stay that, "By the time patients were admitted they were usually too ill to participate." (p. 393)

Importantly and similar to what is found in the literature (Ferrell and Grant, 2001; Fine, 2003; Emanuel, et al., 2004), the subjects in this study generally stated that they liked and valued participating in this study. It has also been reported in the literature that from half (Williams et al., 2006) to all (Terry, et al., 2006) hospice patients said that they would like to be in some research. As is discussed below in the sub-section on implications for future research, it might be helpful in the initial recruitment stage to tell potential subjects that most patients find attractive the idea of participating in research and those who have actually been in such research state that they liked the experience.

As part of the feasibility assessment, the planed quantitative and qualitative analyses were carried out. The statistical analyses were used to determine whether effects were present and to estimate effect sizes that might be used in planning future research. There was a statistically significant effect for the auricular acupressure with the general effect sizes being from medium to large. Even the non-significant results generally had the expected pattern of changes over time as a function of experimental condition. The qualitative results yielded six themes and one global theme.

Testing of Hypotheses and Estimating Effect Sizes

The experimental effects of primary interest in this study were those of treatment condition by time interactions with the expectation that the interaction effects would be linear in form. Linear in form means that the changes over time would have the general shape of change in one direction. In general, estimation of these effect sizes yielded medium to large effects with the larger effects being for linear shapes. For the dependent variable of Dyspnea Effort, this interaction was statistically significant and linear with the effects of actual auricular acupressure being greater than those of either the control or the placebo acupressure conditions. It is surprising that the Dyspnea Effort was significant given the small sample size, but it was carried by the very large effect size. Dyspnea Anxiety and Dyspnea Total both had large condition by time interaction effects as well, although they were not significant. Dyspnea Discomfort had much smaller effect sizes and no overall linear pattern.

ANCOVA was used to test for the effects of possible covariates when the dependent variable was Dyspnea Effort. Dyspnea Effort was used in these examples because it had the

only statistically significant condition by time interaction. Age and support were used as example covariates.

Age was not related to the dependent variable and the ANCOVA results reflected this in that the condition by time interaction was still significant and large. Given the absence of any substantial relationship between age and the dependent variable, this was expected. For the second example, the level of support was used because it was related to Dyspnea Effort. Here the ANCOVA still yielded a large condition by time interaction effect, but the effect was not significant, neither for the overall interaction nor the test of the linear form (although the p-value for linear form was .074).

This same pattern of change was also found for the dependent variable oxygen saturation. Here for both the raw percent and arcsin transformed variables, the condition by time interaction effects were large ones, although neither was statistically significant. That the same pattern of change over time was present for oxygen saturation as for dyspnea was also reflected in the presence of some correlations between oxygen saturation and self-reported dyspnea. This is interesting because often the experience of dyspnea is not directly related to physical assessments. Even with oxygen therapy as a treatment for dyspnea, there is some lack of clarity as to its effectiveness.

Some research has been shown oxygen therapy to be helpful in ameliorating dyspnea (Bruera, Stoutz, Velasco-Leiva, Schoeller, and Hanson, 1993). Other research has shown that oxygen is not more helpful than administration of air, although both do help (Booth, Kelly, Cox, Adams, and Guz, 1996). Sadly, a recent review of literature on oxygen and airflow effects for treatment of dyspnea found that there were no earlier systematic reviews of this literature and that most published studies, both case studies and case control studies,

had small samples without matched or cohort controls (Gallagher and Roberts, 2004). These authors concluded that there is little solid high-grade scientific evidence for oxygen or airflow improving dyspnea.

Statistical assumptions were evaluated and were technically met. However, for example, the distributions did not look normal. Still, lack of their both not looking normal and not being found different from normality may itself be due to the small sample size.

Larger sample sizes may indeed yield data distributions that both look reasonable and meet assumptions. The perils of small a sample size was also apparent in the example of scatter plots that was run (see Figure 10). Arcsin transformed oxygen saturation was highly correlated with Dyspnea Anxiety at Time 2. However, this relationship was carried by a single subject. When that subject was removed from the analysis, the correlation became much smaller.

Qualitative Results

For the simple thematic analysis of qualitative data, six themes emerged along with one global theme. The presence of six themes was surely partly due to the questions that were asked. The six themes were breathlessness, suffering, quality of life, experience of acupressure therapy, awareness of mortality, and recommendation of acupressure to others with lung cancer. Strikingly, the content across these six themes was similar to that listed by Ferrell and Coyle (2001). These included the four dimensions of quality of life: physical, psychological, social, and spiritual, although there was not much regarding the latter (see below). Some specific content areas listed by these authors were also found here: social

relationships, sexual intimacy, visiting family and friends, being a burden to others, concern about the suffering of others because of oneself, and working and employment.

The global theme that emerged was that the subjects enjoyed and/or valued their participation in the study. They spoke of the experience as being one of still being useful, potentially helping others, and providing a sense of continued purpose. It may be that the process of gathering the qualitative data was itself part of why every subject communicated that they enjoyed and/or valued being a part of this research. The qualitative process allowed a specific opportunity for the subjects and researcher to engage in a conversation. It is also of note that there were some relationships between what an individual said during the qualitative assessments and what he or she reported on the CDS.

It is also interesting that only one subject mentioned much about spirituality, and her comment was that she did not feel that she was being punished by God. This general lack of response may have been a function of how the question was asked or that the qualitative questions specifically addressed the experience of dyspnea. Even the quality of life question was focused on dyspnea. There is research that supports the important role of spirituality in the well-being of patients with lung cancer (Meraviglia, 2004).

Regarding changes over time, many subjects reported no such major changes. This is reflected in many subjects also not responding much to the first three qualitative questions at the end of the study what were asked at the beginning. Notably there were some relationships between the qualitative and quantitative analyses. For example, the one subject who spoke of her experiences of general anxiety was also the subject who scored the highest on Dyspnea Anxiety.

Study Limitations

Although as a feasibility study, it was expected that the sample size would not be large, the sample size of 11 that was gathered did pose problems not only of issues of statistical power, but for the confidence that one could have in the reliability of the estimates of effect size. For example, this can be clearly seen in the scatter plot of Figure 10 were a single subject can be understood as having a disproportionate affect on the estimation of the effect size of the relationship between Dyspnea Anxiety and the arcsin transformed oxygen saturation.

Beside sample size there is the issue of sample recruitment not reflecting characteristics and attributes of the population being sampled. For example, there is little ethnic or racial diversity. This means that any generalizations one might wish to make, even based on such a small sample, would necessarily be limited. Of course, even if the sample were large and representative of those at San Diego Hospice and Palliative Care, the population at the San Diego Hospice and Palliative Care may not be the same as other hospice and palliative care centers elsewhere in the country.

The researcher read the CDS out loud for nine of the 11 subjects. It is unknown what effects this may have had on the responses of the subjects. In future research, having the instrument read to the subjects versus the subjects being able to read the instrument themselves would need to be evaluated. Since in this study it was the subject who determined whether to have the researcher read the CDS, those who were having more difficulty may have made such a request. Regarding the issue of reading effects, see the discussion in the future research implications above.

Although the CDS is a multi-dimensional, it is still a single instrument. Results using other assessments may be different. This is one reason to use more than a single instrument, even with the increase in subject research burden.

An important limitation and a possible explanation for the effects that were found in this study is that not all personnel were blind to the experimental conditions. Although the primary researcher and the subjects in the two acupressure conditions were blind to their treatment, the acupuncturist was not. This could have produced a form of experimenter expectation effect. However, the presence of such an effect here is not supported by the pattern of results across the dependent variables. Why would such an effect affect Dyspnea Effort, Dyspnea Anxiety, and oxygen saturation while not affecting Dyspnea Discomfort? Nonetheless, the general issue of blindness in such research needs careful consideration.

Nursing Profession Implications

Dyspnea, a leading symptom among lung cancer patients as well as among end-of-life patients, can create a feeling of suffocation. Further, Ferrell and Coyle (2001) report, "Studies tell us that most people fear a protracted, painful death; unfortunately, this is what many experience. Palliative nursing care seeks to change this" (p. 26). Ferrell and Coyle (2001) also note, "Nurses spend more time with patients and families facing advanced illness than do any other health care professionals and are intimately involved in all aspects of end-of-life care" (p. 29). Hence, it is important that nurses understand dyspnea, its treatment, and treatment alternatives.

It is important to keep in mind that a person can have high oxygen saturation and still be experiencing extreme dyspnea. It is the patient's experience, not the observation of others that is central. Additionally, dyspnea does appear to be multi-dimensional. In this study, using a multi-dimensional assessment of dyspnea, dyspnea related effort and anxiety appeared to change over time due to auricular acupressure while discomfort did not. Also, total dyspnea did not significantly change over time as a function of condition, although some of its sub-scales did. This general point is reinforced by the previously cited research by Carrieri-Kohlman et al. (1996) who used a visual analog scale that subjects employed to rate components of dyspnea. The four components of dyspnea were effort in breathing, shortness of breath, distress associated with dyspnea, and dyspnea associated anxiety. They found that the subjects could and did differentiate among these four components. These four components are quite similar to the three sub-scales of the CDS: effort, anxiety, discomfort.

If such procedures as auricular acupressure are shown to be helpful with symptoms like dyspnea, it may be possible to incorporate them into the hospice and palliative care settings. For example, Johnstone, Polston, Niemtzow, and Martin (2002) report on the integration of acupuncture into the oncology clinic of the Naval Medical Center in San Diego, California.

Other implications for nursing would include the education of nurses, nursing staff faculty, and hospice staff regarding CAM and regarding research generally. Specifically, it might be reasonable to provide information on how to complement Western Medicine with the use of CAM in symptom management. Additionally, it might be beneficial to both end of life patients and to the field to educate nurses regarding the potential experience of end of life patients when they participate in research. Specifically, as reflected in this study, end of life patient participants expressed that this experience added purpose to their lives through potentially helping others. This might lead to nurses being appropriately less protective of

such patients when being approached by researchers seeking end of life patient participation in research.

Future Research Implications

This feasibility study certainly demonstrated that researchers should expect such research to take long periods of time to complete if designed as this study was. One way of shortening the time required would be to have more than one experimenter and more than one source of potential subjects. A possible positive implication of this study is that the effects involved may be quite large. If so, then the required sample sizes would be smaller than if the effects generally medium or even small. However, see the limitations of the study section above regarding concerns about the estimation of effect sizes in this study.

Related to issues of time for recruitment and low recruitment rates, reducing subject research burden might help. One way of reducing some potential subject burden might be to use ratings by nursing staff and/or caregivers. Moody and McMillian (2003) found, "Patients' and caregivers' ratings of the patient's dyspnea intensity revealed no significant differences in ratings thus verifying that caregivers can assess dyspnea severity accurately" (p. 1). However, if such an approach is used, there should be careful consideration of the general issue that dyspnea is a symptom experienced by the patient. In the Moody and McMillan (2003) study, the measurement of dyspnea was done using the Memorial Symptom Assessment Scale (MSAS). Perhaps the results of this study are specific to this instrument.

Perhaps involvement of hospice patients, their caregivers, and hospice nurses would be helpful in the development of research protocols that would lead to better recruitment of subjects and a better experience for all involved, including the identification of other ways to lessen as much as possible subject research burden. Moody, Webb, Cheung, and Lowell (2004) report on the use of a focus group of caregivers of hospice patients with severe dyspnea to gather information that might help in research and treatment.

Although it may add to subject research burden, thought should be given using another dyspnea instrument in addition to the CDS. Because of its general utility, its use in a great deal of successful previous research, its psychometric properties, and its low subject research burden, the visual analogue scale might be considered. It was a set of such scales that was used by Carrieri-Kohlman et al. (1996) cited above. It might be interesting and of value to use four such scales, one for each the scores that can be derived from the CDS: effort, anxiety, discomfort, and total.

An important design addition to future research would be not only larger samples, but more diverse samples. Although the sample in this study was too small and had too little diversity regarding ethnicity and race to evaluate the effects of such variables, still it would be important in future research to assess the effects of such variables as age, sex, ethnicity, race, education, etc., since such characteristics may be related to response to auricular acupressure as well as to the experience of dyspnea. This would be the case for both quantitative and qualitative methodologies. For example, Hardie, Janson, Gold, Carrieri-Kohlman, and Boushey (2000) found that African-Americans as compared to white patients with asthma were different in their perception of breathlessness and in the words that they used to describe their breathlessness during induced airflow obstruction.

Generally, it appears that the best type of research approach would seem to involve both quantitative and qualitative methodologies. Not only for the arguments made in the earlier section on issue of hospice and palliative care research, but because use of at least some qualitative methodology may be helpful in ensuring that the subjects value more being in research and are more willing to continue in a project. It is also an opportunity for the subjects and researchers to have conversations and exchanges that are not limited to structured instruments. Additionally, even if there were no benefits to the researcher and the study, use of such methodology could be considered part of what the researcher does for the subjects and their end-of-life experience.

In the current study, most subjects requested that the researcher read the CDS to them. Having the instrument read to a subject versus the subject reading the instrument may have effects on subject responses. This is particularly the case since those subjects who are having more difficulty may be more likely make such a request. For future research to evaluate possible effects here, researchers might take all those subjects who can read the instrument themselves and randomly assign them to one of two conditions: being read to versus reading themselves.

Regarding qualitative open-ended questions, it is interesting to note that the dyspnea measures showed an increase in dyspnea assessments at time 7. This was the morning of the last day of the study. The subjects were aware that the study was then ending. It may be that this increase in dyspnea experience reflected a more general distress response to the end of the study, the loss of twice daily visits from the acupuncturist and the researcher, and the loss of any perceived benefit of the acupressure. Future research might include a question about the subjects' response to the study ending, their interest in the study continuing, their interest in continuing acupressure, and any distress that they are experiencing at study's ending.

In the current study, the researcher was blind to the placebo versus experimental auricular acupressure, but the acupuncturist was not. This could have allowed for some

experimental expectation effect (see limitations of study section below). This is a common problem for such complementary treatment studies as those involving acupuncture or acupressure. Still, in future research, since auricular acupressure points are specific to individuals and are thus individually placed, it may be possible to have an acupuncturist place the seeds, but have the patient, a caregiver, a nurse, or a research assistant do the stimulation of the seeded areas. This might be one way to reduce the opportunities for an experimenter expectancy effect.

Finally, this study did find medium to large effect sizes for the impact of one form of CAM on one important symptom, dyspnea. It might be reasonable for future research to exam different CAM approaches and/or the effects of CAM on other important symptoms.

More generally, it might be of interest to evaluate the impact on general quality of life when a patient participates in CAM approaches to the management of symptoms.

Conclusions

The primary conclusion here is that such a study is feasible. It may take longer than initially expected, but it can be done. The experience with this study highlighted the importance of paying attention to and attempting to improve subject recruitment.

Another conclusion would be that the results of this study suggest that there may be medium to large effects of auricular acupressure on the experience of dyspnea. The likeliest outcome is that the effects are probably medium, since any confidence placed in these results should be made with caution because of the small sample size.

The CDS performed well and the importance of the multi-dimensionality of the CDS was highlighted by the differential pattern of results across the CDS sub-scales. Still other

instruments should also be used in future research so that the results will be more generalizable. Also, other instruments may define additional components of dyspnea.

Using both qualitative and quantitative methodology was important. In fact, the use of both qualitative and quantitative methods might be the best way to advance the field. Within quantitative methods, the use of both randomized control trials and quasi-experimental designs may be helpful given the difficulties of developing reasonable control or sham conditions. Even in the face of important concerns and challenges, both ethical and practical, palliative care research must continue to be carried out. Such research should include compliments to Western medicine such as auricular acupressure. As stated earlier, given the goals of palliative care, not conducting research would itself be unethical. Ferrell (2004) writes, "There is no option to avoid research within the field of palliative care, as like all disease areas, there is a critical need to conduct research to advance the field. Improved care will not happen without inquiry." (p. 408)

In the end, there are two basic points. One, there is a continued need for symptom control at end of the life (National Institutes of Health, 2005). Two, the role of nursing is central to end of life care.

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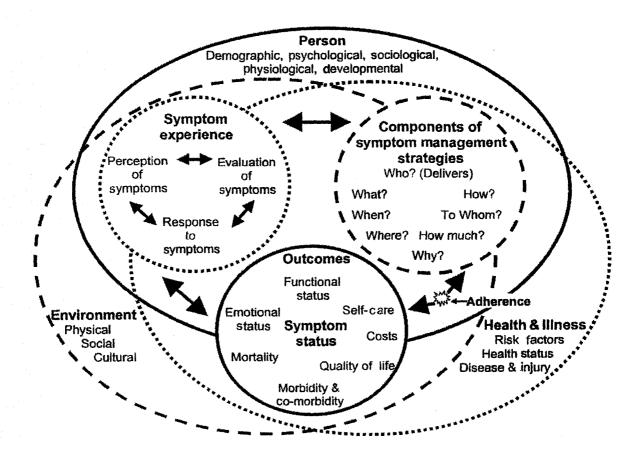
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APPENDIX A

REVISED SYMPTOM MANAGEMENT CONCEPTUAL MODEL (RSMC MODEL)



Revised Symptom Management Conceptual Model (RSMC Model)

APPENDIX B BACKGROUND INFORMATION FORM

BACKGROUND INFORMATION

Instructions:

Please check or provide the most accurate response in each question. Please answer every question.

The information that you give will be held in the strictest confidence and your questionnaires will be identified only by a code.

1.	What is your sex?
	1 Female
	2 Male
2.	What is your age?
3.	What is your marital status?
- '	1. single
	2 married
	3living as married
	4 separated
	5divorced
	6 widowed
4	What is your ethnic/racial background?
•	This has two parts. Please answer both.
	A.
	1. Not Hispanic or Latino
	2. Hispanic or Latino
	В.
	1 White
	2 Native Hawaiian or Other Pacific Islander
	3 Black or African American
	4 Asian
	5 American Indian or Alaska Native
5.	What is the highest educational degree you obtained?
	1. none
	2 high school diploma
	3associate degree
	4 bachelor
	5 masters
	6doctorate
	7 other If other, please specify
5.	What is your approximate current yearly salary?
7.	How many family members and friends do you have that you can count on and tha
	live within 50 miles of the inpatient care center?

APPENDIX C

THE CANCER DYSPNEA SCALE

The Cancer Dyspnea Scale (Tanaka, et al. 2000)

We would like to ask you about your breathlessness or difficulty in breathing. Please answer each question by <u>circling</u> only the numbers that best describe the breathing difficulty that you felt *during the past few days*.* Base your response on your first impressions.

```
Use the scale of
1 = Not at all
2 = A little
3 = Somewhat
4 = Considerably
5 = Very much
1 2 3 4 5 1. Can you inhale easily?
1 2 3 4 5 2. Can you exhale easily?
1 2 3 4 5 3. Can you breathe easily?
  2 3 4 5 4. Do you feel short of breath?
  2 3 4 5 5. Do you feel breathing difficulty accompanied by palpitations and
                sweating?
1 2 3 4 5 6. Do you feel as if you are panting?
  2 3 4 5 7. Do you feel such breathing difficulty that you don't know what to do
                about it?
1 2 3 4 5 8. Do you feel your breath is shallow?
  2 3 4 5 9. Do you feel your breathing may stop?
  2 3 4 5 10. Do you feel your airway has become narrower?
1 2 3 4 5 11. Do you feel as if you are drowning?
```

*For this research, on the first administration these instructions will read, "that you felt in the last 12 hours," and on subsequent administration will read, "that you felt since the last time you completed this scale."

Computation of three factors [subtractions adjust for 0 as state of absence of dyspnea]:

```
Factor 1 [sense of effort] = (items 4 + 6 + 8 + 10 + 12) - 5

Factor 2 [sense of anxiety] = (items 5 + 7 + 9 + 11) - 4

Factor 3 [sense of discomfort] = 15 - (items 1 + 2 + 3)
```

1 2 3 4 5 12. Do you feel as if something is sticking in your airway?

For total scores add the three factors together.

APPENDIX D HUMAN SUBJECTS RESEARCH

Human Subjects Research

An Overview of Subject Selection and Characteristics.

The composition of the sample being studied was established by the requirements of subject selection per the purpose, aims, and hypotheses of the study. Subjects were recruited over the course of 2007 to 2008. These volunteer subjects were end stage lung cancer patients hospitalized in a free-standing inpatient care center that was within a hospice. Inclusion criteria consisted of lung cancer diagnosis, English speaking, and ability to communicate with the researcher. There were no sex or ethnicity criteria for enrollment, although there was an age inclusion criteria of 45 or older. It is also important to note that none of these subjects were selected because of any present mental illness, and there were no subpopulations chosen because of pregnancy, prisoner status, institutionalization, or for any specific characteristic other than their being lung cancer patients enrolled in a hospice program.

<u>Inclusion of Women</u>. Given the nature of the populations within hospice settings, there were women as well as men enrolled in the study. Therefore, we believe that this investigation adequately gathered information relevant to females and males.

<u>Inclusion of Minorities</u>. Minorities were present in the current study population. These groups could have include Latino, Native American, African American, Asian (South East, Chinese, Korean, Japanese), and Ethiopian, but only Latino and Native American enrolled. <u>Inclusion of Children</u>. Due to the nature of the research question, there were no children in the study's sample.

Sources of Research Material.

The materials gathered were generated from patient charts, questionnaires, a pulse-oximeter, and up to five open-ended questions for qualitative data that were tape recorded and then transcribed. There were two questionnaires: a demographic survey asking for basic descriptive information and the Cancer Dyspnea Scale (CDS). All materials were limited to specific research purposes that were outlined in the proposal.

Potential Risks.

There were no significant risks known to be associated with the protocol. As described in the proposal, the subjects responded to a brief demographic questionnaire, one psychometrically sound instrument used to assess dyspnea (the CDS), and up to five openended questions that were tape recorded and transcribed. Subjects were free not to participate and free to refuse any questions or testing they would like. No medications or similar materials were administered to subjects, and no blood draws or invasive procedures were included in this protocol. The treatment intervention consisted of a non-invasive auricular acupressure procedure that involved the use of small seeds with an adhesive backing that were applied to the ear at designated breath and anxiety related points. A placebo condition consisted of non-invasive use of small seeds with an adhesive backing that were applied to the ear at points other than those designated for breath and anxiety. There were no needles used and the skin was not broken. However, there was some risk regarding any allergic reaction to the adhesive used for the auricular acupuncture, although no were present Additionally, given the age and medical conditions of these research participants, it

was possible that skin tears could take place, although, this did not happen. Finally, participating in this protocol could have produced fatigue in the subjects over and above that which would be found in this population generally. However, there was no more fatigue present than they would normally have.

There was a minimal risk for <u>psychological harm</u> through responding to the CDS. Again however, this scale had been used in previous research with similar populations without reports of such harm and no such harm was reported here.

The pulse-oximeter was simply placed on the finger of the patient. This procedure was also non-invasive involving no broken skin.

Procedures for Protecting Subjects and Minimizing Risks.

In this study, the protection of human subjects was an important consideration. The following briefly describes the steps taken:

Informed Consent. Consent was obtained from each subject using IRB approved consent forms. The consent form was presented to the subject along with a written description of the study and a copy of the Medical Research Patient's Bill of Rights. The consent process, the use of demographic questionnaire, the CDS, the pulse-oximeter, and the protocols for managing the data were evaluated by two IRBs. One IRB was from USD and the other was from San Diego Hospice and Palliative Care. An additional consideration for this informed consent in this research was the enrollment of hospice patients. The National Hospice and Palliative Care Organization (NHPCO) (Casarett, Ferrell, Kirschling, Leveton, Merriman, Ramey, & Silverman 2001) procedures regarding the ethics of hospice participation in research were used.

<u>Procedures to Protect Confidentiality</u>. Careful procedures were instituted to protect confidentiality. These included having all research material identified only by code numbers, keeping any information that connects codes with specific names in a locked file cabinet with access limited only to the research personnel working on this protocol, and keeping access to the computer storage of information only to those individuals directly involved in this study.

Special considerations were taken regarding maintaining security of computerized data. These include using complex passwords for access; avoiding any easily guessed password for any of the datasets; working with computer experts; data were stored and analyzed on a computer system isolated from the internet; and with steps taken to build a wall against Trojan-horse-like programs. All data will be kept for 4 years before being destroyed.

Pledges of Confidentiality were signed by the acupuncturist, statistical consultant, transcriber, and qualitative data analyst expert. Copies of these signed Pledges of Confidentiality can be found in Appendix H.

Risk Reduction. Subjects were asked whether they have any known allergies for adhesives or tape. Additionally, the site of the adhesive use was monitored for any allergic reaction. Skin integrity was monitored during both the application and removal of the adhesive to prevent and ameliorate skin tear. Regarding fatigue, this too was monitored during the subjects' participation in the four-day protocol. The subject were both directly asked about experience of fatigue and observed for any evidence of increasing fatigue over the course of the protocol.

All Personnel Were Well Trained and Were Monitored Regarding Maintenance of
Confidentiality and Other Human Subjects Protection Issues.

The person administering auricular acupuncture was an acupuncturist (LAc) licensed by the state of California. This individual was trained at and a graduate of the Pacific College of Oriental Medicine.

All research staff was trained regarding confidentiality procedures. All consent forms were in accordance with HIPAA regulations and were reviewed by two IRBs. All project staff working on the study complied with HIPAA regulations by taking online training, including: 1) Research Aspects of HIPAA Tutorial, 2) Basic principles of Human Research Subjects Protection, and 3) Basic HIPAA 1021: Workforce Training. All individuals working on the study also complied with HIPAA regulations by signing a Healthcare Confidentiality Agreement [see Pledges of Confidentiality in Appendix H). Part of this training and ongoing supervision involved reminders regarding the need to never put identifying information inappropriately into the computer or onto any of the research instruments. Once the demographic questionnaire and the CDS had been completed, no identifying information was kept in the same database as the completed forms. Identifying data were kept in a locked file cabinet with access limited to the doctoral student and the specific research assistants for whom such information was essential. Furthermore, a series of safety measures were developed and limited access to information stored in passwordprotected computers.

<u>Use of Control Groups with Option for Treatment Procedure</u>. Although a control group and a placebo group were used in this study, the control group was a standard care condition and the placebo group was a standard care condition and were also administered the same non-

invasive auricular acupressure seed adhesives but not on breath or anxiety points. Subjects who were randomly assigned to these conditions were given the option of receiving the auricular acupressure seed adhesive procedure immediately following completing their participation in the study.

Potential Benefits of the Proposed Research and the Safety Ratio.

This research helped evaluate the effectiveness of auricular acupressure in reducing dyspnea in end of life hospice patients with lung cancer. This is a common symptom and one that is not generally well managed. Also, the results supported the relevance of the UCSF School of Nursing Symptom Management Faculty Group's Model for Symptom Management to the symptom of dyspnea.

Benefits to the individual subject included the possibility of having some relief from the experience of dyspnea. Benefits also included the possibility of having a sense of purpose, the ability to contribute to helping other individuals who are or will be facing the same problem. Such a sense of being useful and of value has been anecdotally reported by end of life patients even for participating in rounds and teaching of medical students. Indeed this experience of meaning and purpose has been reported in research literature (see Chapter 1, section Hospice and Palliative Care) and it was also reported by all but one subject in this research study.

When one considered the low level of risk involved in this research that used only non-invasive procedures, the careful steps to optimize confidentiality, and the potential benefits of the research including that to the participating subjects, the ratio of risks to potential benefits appeared to be extremely low.

APPENDIX E

HUMAN SUBJECTS TRAINING DOCUMENTS

Human Participant Protection Jucation for Research Teams

Page



Human Participant Protections Education for Resear

Completion Certificate

This is to certify that

Roger Strong

has completed the Human Participants Protection Education for Research Teams online course, sponsored by the National Institutes of Health (NIH), on 06/18/2005.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protecthuman participants at various stage in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a validconsent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

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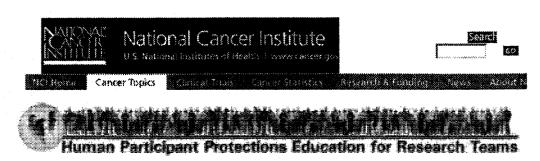




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Human Participant Protections Education for Research Teams

Page 1



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- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- · a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

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CITI Course in The Protection of Human Research Subjects

Human Research Curriculum Completion Report Printed on Thursday, February 1, 2007

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9326 Twin Trails Dr. #205 San Diego, CA 92129 USA

Department: Psychiatry Research

Phone: 858-642-3883 Email: dtomr@aol.com

2006 VA PRIDE Curriculum:

Stage 2. Refresher 1 Course Passed on 02/01/07 (Ref # 873056)

Required Modules	Date completed
101 Refresher Course - History and Ethics	02/01/07
101 Refresher Course - Regulations and Process	02/01/07
101 Refresher Course - Informed Consent	02/01/07
101 Refresher Course - Social and Behavioral Research	02/01/07
101 Refresher Course - Records Based Research	02/01/07
101 Refresher Course - Genetics Research	02/01/07
101 Refresher Course - An Overview of Research with Vulnerable Subjects	02/01/07
101 Refresher Course - FDA Regulated Research and Conference on Harmonization	02/01/07
101 Refresher Course - Conducting human subjects Reserch at the VA	02/01/07
GCP Update Course: Module 1, Good Clinical Practices for VA Staff	02/01/07
GCP Update Course: Module 2, Accountability	02/01/07
GCP Update Course: Module 3, Informed Consent	02/01/07
GCP Update Course: Module 4, Safety Reporting	02/01/07
GCP Update Course: Module 5, Documentation	02/01/07
GCP Update Course: Module 6, Privacy and Confidentiality	02/01/07
GCP Update Course: Module 7, Application of GCP Concepts	02/01/07

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Certificate: VA Research Data Security And Privacy

Pa



Certificate of Completion

This is to certify that
Thomas Smith
has completed the course entitled
VA Research Data Security And Privacy

The Employee Education System has presented this Continuing Education Activity for 1 contact hour(s)

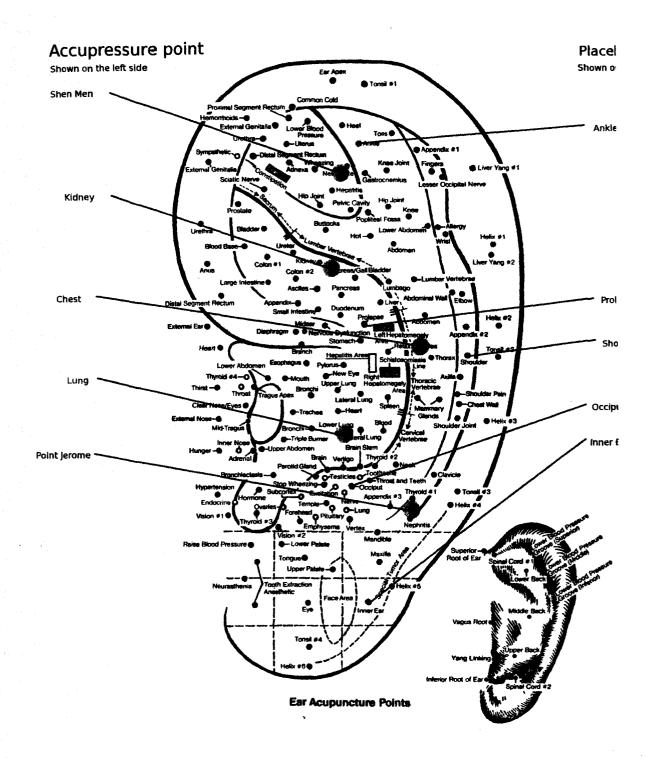
The Employee Education System maintains responsibility for the program.

This On-Line Course was completed on Tue May 15 11:23:32 PDT 2007



Joy W. Hunter Dean, VA Learning University

APPENDIX F AURICULAR ACUPRESSURE POINTS



APPENDIX G INFORMED CONSENT



San Diego Hospice IRB
Center for Palliative Studies
Human Subjects Committee
Approved by:
Exp. Date: 07-10-2008

CPS STUDY #: 03-01(

SPONSOR STUDY #

CENTER FOR PALLIATIVE STUDIES PATIENT INFORMATION AND CONSENT FORM

PROTOCOL TITLE:

Dyspnea: Effect of Auricular Acupressure in End Stage Lur

Cancer Patients

CPS SUTUDY NUMBER:

CPS Study: 03-010-ED

SPONSOR PROTCOL NO.:

Not Applicable

SPONSOR:

Not Applicable

INVESTIGATOR:

Roger Strong, APRN, BC-PCM San Diego Hospice & Palliative Care

4311 Third Avenue San Diego, CA 92103

This consent form may contain words you do not know. Please ask the study nurse the study staff to explain any words or procedures that are not clear to you.

INTRODUCTION

We are asking you to take part in a research study. The nurse in charge of the study has for that you meet what is required to take part in this study. Please read this consent form before you agree to take part in this study.

This consent form contains facts to help you decide if it is in your best interest to take part i study. Study staff members will help with any questions that are not answered for you in th consent form.

The Principal Investigator is a student in the Doctoral Program in the School of Nursing at t University of San Diego. San Diego Hospice in combination with University of San Diego happroved this study.

PURPOSE OF THE STUDY

The purpose of this research study is to evaluate the use of pressure on parts of the exterr ear in helping control the experience of shortness of breath in lung cancer patients.

DESCRIPTION OF THE RESEARCH STUDY

This study will involve about 45 patients at one center in the United States.

Your participation will last 5 days.

Version Date: 03/18/2007	Dago 1 of 0	Dationt's Initials:
Approval Date: 07/11/2007	Page 1 of 9	Patient's Initials:

Screening:

- Researchers will explain the study to you and obtain informed consent.
- You will be asked to be part of the formal study for 5 days.
- If you agree, you will complete one brief background information form at the beginni (takes about 3 minutes).
- If you participate, you will agree that the researchers can look at your medical record record your receiving oxygen, respiratory treatments, or medications for pain or to h you breath.
- If you participate, you will be assigned to 1 of 3 usual care groups.

Randomization:

If, based upon the results of the screening tests, you continue to qualify for the study; you ν randomly assigned by chance (like a flip of a coin) into one of three treatment groups:

- Standard care (SC).
- Standard care plus auricular acupressure with points for lung and anxiety (SC + AE
- Standard care plus auricular acupressure with placebo points (SC + AP).

You will have a 33-1/3% chance of receiving standard care, standard care plus auricular acupressure with points for lung and anxiety, or standard care plus auricular acupressure valuebo points.

The statistician will randomly assign you into one of three groups. Neither you nor your stunurse will know which of the treatments you are receiving. The acupuncturist, student inte and statistician only will be aware of who is receiving the auricular acupressure (SC +AE), auricular acupressure (SC +AP).

Audiotape Recording:

At two times you will be asked for verbal responses to some short questions. We will audi record what you tell us. You may ask us not to record certain things, and we'll turn off the recorder for that part. Anything you tell the researcher or assistant will be kept confidentia the extent permitted by law. We are required by state law to report any abuse and the ide of the alleged offender if you should tell us that information. Everything you tell us on tape be typed without using your name. The actual tape recording of your voice will not be her anyone other than the investigator, research assistant, and the person typing the informat from the tape. Following the completion of the study the tape will be erased. All of the typ information will only use a number to identify you. Even this typed information will be destinated 5 years. During the study the tape, and any coded information will be kept in a locked accessible only to the researcher or assistant. You are protected by federal regulations we require a subpoena from a court for the release of information from research studies.

Version Date: 03/18/2007	Page 2 of 9	Patient's Initials:
Approval Date: 07/11/2007	rage 2 01 9	raucites titudis:

If you agree to be in this study the following will occur:

Day 1

 Once in the morning (between 7:30 and 10:30 AM) and once in the evening (betwe 4:30 and 7:30 PM), you will be administered the Cancer Dyspnea Scale, will have oxygen level in your body assessed, and be asked a series of questions. It may bε necessary to wake you up.

(

- Oxygen level in your body will be assessed with a small finger device that will place over the tip of your finger This device reads your oxygen level without going throu the skin.
- Both of these will be conducted one-on-one.
- All three groups will receive standard care on this day that has been ordered by the physician.
- Each visit will take from 5 to 10 minutes.

Day 2

- On the morning of Day 2 and before the early Day 2 assessments, the treatment intervention will begin. Application of acupressure seed adhesives will be carried a student intern under the supervision of a licensed acupuncturist. It may be nece to wake you up.
- You will be asked whether you have any known allergies for adhesives or tape.
- The experimental acupressure condition consists of placing small seeds with an adhesive material that allows the seed to be held in place over the appropriate acupressure point on both ears.
- Before the adhesive with seeds is put in place, the auricular points are mildly stim for 3 seconds with a surface, non-invasive probe, making a slight indentation on the points, then cleansed with an alcohol applicator stick.
- Additionally, the site of the adhesive use will be monitored for any allergic reactior condition will be monitored during both the application and removal of the adhesiv prevent and treat skin tear.
- Fatigue will be monitored during your participation in the four-day protocol. You we both directly asked about experience of fatigue and observed for any evidence of increasing fatigue over the course of the protocol.
- Then, within two hours before each morning and evening assessment, research
 personnel will visit you, ask a series of questions, and remind you that assessment
 happen at a specified time. If you are in one of the two-acupressure conditions,
 pressure will be applied to the seeds.
- Once in the morning (between 7:30 and 10:30 AM) and once in the evening (betw 4:30 and 7:30 PM), you will be administered the Cancer Dyspnea Scale and will I oxygen levels in your body assessed.
- Oxygen level in your body will be assessed with a small finger device that will be over the tip of your finger. This device reads your oxygen level without going thro the skin.
- · Each visit will take from 5 to 10 minutes.

Version Date: 03/18/2007	Page 3 of 9	Patient's Initials:
Approval Date: 07/11/2007	raye 3 01 9	radent's findals.

Day 3 and 4

- Then, about two hours before each morning and evening, research personnel will visit
 you, ask you a series of questions, and remind you that assessments will happen at a
 specified time. If you are in one of the two-acupressure conditions, pressure will be
 applied to the seeds. It may be necessary to wake you up.
- Fatigue will be monitored during your participation in the four-day protocol. You will be both directly asked about experience of fatigue and observed for any evidence of increasing fatigue over the course of the protocol.
- Additionally, the site of the adhesive use will be monitored for any allergic reaction. Skir integrity will be monitored during both the application and removal of the adhesive to prevent and ameliorate skin tear.
- Once in the morning (between 7:30 and 10:30 AM) and once in the evening (between 4:30 and 7:30 PM), you will be administered the Cancer Dyspnea Scale and will have oxygen levels in your body assessed.
- Oxygen level in your body will be assessed with a small finger device that will placed over the tip of your finger. This device reads your oxygen level without going through the skin.
- Each visit will take from 5 to 10 minutes.

Day 5

• You will be approached and told that you have finished your participation in the study. You will be asked a series of questions, a short debriefing will take place and the researcher will express his or her appreciation for your participation.

RISKS / DISCOMFORTS

As with all studies there are some added risks (or discomforts) to you. There may be other risk or discomforts we do not now know about besides those listed here.

- If you have adhesive (tape) placed on your ear, it is like a small band-aid, you may hav
 an allergic reaction to the adhesive or your skin may tear like when you take off a band
 aid
- Some mild discomfort when mild pressure is applied to the seeds
- Participation in this study may lead to some fatigue
- Some people may feel anxious when being part of a study, when they know that
 research personnel are looking at some of their medical records or when they are filling
 out forms asking about their background information or how they are doing

Some people may find that this added amount of time and energy required during their participation in a study to be a burden. However, it is also true, that some people find t extra time and attention provided to them through additional appointments and attentic from the research team to be a real benefit to them.

Version Date: 03/18/2007	Page 4 of 0	Patient's Initials:
Approval Date: 07/11/2007	Page 4 of 9	Padent's initials.

NEW FINDINGS

Your research nurse will tell you in a timely manner of any new facts he or she learns that mig cause you to change your mind about taking part in the study. We may be able to give you th final study results. We will tell you how to learn more about the results at the end of the study

POSSIBLE BENEFITS

You may get no direct benefit from being a part of this study. We hope you may be helped by

- · Being able to breathe more easily
- Feeling less anxious
- Feel good about helping with research that aims to help those in similar situations to yours

Also, information that we learn from this study may help future patients. It is possible, howev that you may not be helped during or after this study.

PAYMENT FOR PARTICIPATION

We will not be giving you any payment for taking part in this research study. This is not a wa or release of any of your legal rights.

ALTERNATIVE TREATMENTS

If you decide not to take part in this study, there are other treatments that you may discuss we the study doctor or your Primary Care Physician. These other treatments are already available to you here at the inpatient care center and you are eligible to receive whether you are in the study or not. These would consist of receiving oxygen, respiratory treatments, and medication for pain or difficulty in breathing.

CONFIDENTIALITY AND RELEASE OF MEDICAL RECORDS

What we talk about in this study will be kept private to the extent allowed by law. We will keep the records under a code number rather than by name to protect your privacy. We will keep records in locked files. Only study staff will be allowed to look at them. Your name and othe facts that might point to you will not appear when we present this study or publish its results. Certain persons or institutions may sometimes look at your study records and those of other like you who take part in the study. They include:

- Your study nurse and study staff
- Your Primary Care Physician
- San Diego Hospice & Palliative Care
- San Diego Hospice Institutional Review Board (IRB)

The tape recorded and transcribed short questions will be identified by a code number, not y name. The tape and transcription will be stored in a locked file cabinet. The results of this research may be presented at meetings or in published articles. However, your name will b kept private. You have already signed a separate authorization form. This form explained wl will have access to your protected health information.

Version Date: 03/18/2007	Dago E of O	Dationto Taitino
Approval Date: 07/11/2007	Page 5 of 9	Patient's Initials:

A court of law could order study records shown to other people, but this is unlikely.

COMPENSATION FOR RESEARCH RELATED INJURY

Mishaps can occur in any study. We may or may not expect them. They may be no one's fa San Diego Hospice will provide any medical and supportive care for any harm that happens t you from being in the study. San Diego Hospice has not set aside funds to pay you for other costs if you are injured. You may call the San Diego Hospice, Center for Palliative Studies at 1-619-278-6296 to learn more about this or to report problems you have with being the study.

LEGAL RIGHTS

The above section does not restrict your right to seek legal assistance.

RISK MANAGEMENT

Report any unusual symptoms or side effects at once to your study nurse. If you have any question regarding:

- Your adhesives and seeds attached to your ear
- · Your reaction to adhesives and seeds attached to your ear
- Any possible study related injury
- Your participation in the study

Contact your study nurse, Roger Strong, at his work number [619-688-1600 x6280], voice n number [619-688-1600 x6913], or cell number [619-922-4058].

CONTACT FOR QUESTIONS

If you have general questions or questions about your rights as a research subject you may contact:

Eugene Grimshaw Coordinator, Research Programs San Diego Hospice San Diego, CA 92103 Telephone: 1-619-278-6296

If you would like to speak to someone not associated with the study about your rights as a participant, or any other matter related to the study contact:

Vice President/CIO/Compliance Officer San Diego Hospice San Diego, CA 92103 Telephone: 1-619-278-6309

Version Date: 03/18/2007	Page 6 of 0	Patient's Initials:
Approval Date: 07/11/2007	Page 6 of 9	Patient's Initials.

VOLUNTARY NATURE OF PARTICIPATION

You are free to join the study or not. You are also free to join the study and later decide to lefter any reason. Please tell your study nurse if you wish to leave. This will allow the nurse to you of any medical risk to your decision to leave.

WITHDRAWAL

Your study nurse has the right to stop the study at any time. He or she can stop the study wi or without your consent for any of the following reasons:

- If you have an adverse effect from the study treatment
- If you need a treatment not allowed in this study
- If you do not take keep the treatment adhesive on your ear.

Please note that the San Diego Hospice Institutional Review Board (IRB) has signified by the Committee's stamp that it has approved this consent form. The IRB will review the consent form each year. The form expires on the date that is on the stamp.

An IRB is a group of doctors and nurses and laypersons that review a research aim of protecting each study's subjects from harm.	plan with the

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Version Date: 03/18/2007	Dogo 7 of 0	Dationt/s Initials	•
Approval Date: 07/11/2007	Page 7 of 9	Patient's Initials: _	

SUBJECT CONSENT

I know that if I qualify and would like to take part in this research study, the study nurse ma enroll me in the study. I know that my taking part in this research study is my choice. I knot that I may decide not to take part or to withdraw from the study at any time. I know that I c this without penalty or loss of benefits or treatment to which I am entitled. I also know that study nurse or the study Sponsor may stop the study without my consent.

I have had a chance to ask the study nurse and study staff member's questions about this study. They have answered those questions to my satisfaction.

- I state by my signature below that I have read the information above
- I know the conditions and procedures of the study
- I know what the possible risks and benefits are from taking part in this research stu
- I know that I do not give up my legal rights by signing this form
- I know that I will receive a signed and dated copy of this consent form as well as a signed and dated copy of "The Patient's Bill of Rights"

Printed Subject's Name		
Subject's Signature		Date/Time
Printed Name of Legally Authorize (If applicable)	d Representative	
Signature of Legally Authorized Re (If applicable)	epresentative	Date/Time
Printed Name of Person Obtaining	Consent	
Signature of Person Obtaining Cor	nsent	Date/Time
		IRB APPROVAL/EXPIF
	,	
Version Date: 03/18/2007 Approval Date: 07/11/2007	Page 8 of 9	Patient's Initials:



CPS STUDY #: 03-01
SPONSOR STUDY #

Medical Research Patient's Bill of Rights

California law and our policy requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participal on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

- 1. Be informed of the nature and purpose of the research.
- Be given an explanation of the procedures to be followed in the medical experiment any drug or device to be used.
- 3. Be given a description of any attendant discomforts and risks reasonably to be experiment.
- 4. Be given an explanation of any benefits to the subject reasonably to be expected fr the experiment, if applicable.
- 5. Be given a disclosure of any appropriate alternatives procedures, drugs or devices might be advantageous to the subject, and their relative risks and benefits.
- 6. Be informed of the avenues of medical treatment, if any, available to the subject af experiment if complications should arise.
- Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- 8. Be instructed that consent to participate in the medical experiment may be withdra any time and the subject may discontinue participation in the experiment without prejudice.
- 9. Be given a copy of the signed and dated written consent form.
- Be given the opportunity to decide to consent or not to consent to a medical exper without the intervention of any element of force, fraud, deceit, duress, coercion or influence on your decision.

Signature of Subject		Date/Time
Signature of Witness		Date/Time
Version Date: 03/18/2007 Approval Date: 07/11/2007	Page 9 of 9	Patient's Initials:



IRB APPROV

SAN DIEGO HOSPICE II
CENTER FOR PAILIATIVE ST
HUMAN SUBJECTS COMM
APPROVED BY:
END: DATE:

CENTER FOR PALLIATIVE STUDIES AUTHORIZATION TO USE YOUR PRIVATE HEALTH INFORMATION

PROTOCOL TITLE:

Dyspnea: Effect of Auricular Acupressure in End Stage Lung Canc

CPS STUDY NUMBER:

03-010-ED

SPONSOR PROTCOL NO.:

Not applicable

SPONSOR:

Not Applicable

INVESTIGATOR:

Roger Strong, APRN, BC-PCM

San Diego Hospice & Palliative Care

4311 Third Avenue San Diego, CA 92103

What is private health information? Private health information is any information that can be to you. We need your authorization (permission) to use your private health information in this reserved the private health information that we will use and share for this study includes:

- ✓ Your past and present health information,
- ✓ Information that can be used to contact you,
- ✓ Results of your medical tests

Who else will see my information? This information may be shared with:

- ✓ Your study nurse and study staff,
- ✓ Your primary care physician.
- ✓ Institutional committees that review research to help protect people who join research studi

Once we have shared your information, we cannot be sure that it will stay private. If **you share** y information with people outside the research team, it will no longer be private. Your name will not any report that is written.

How long will the institution use and share my information? Your information will be used a until the research is completed. If you are participating in a clinical drug study, your records will be maintained at the institution for no more than two (2) years after FDA approval/decline of the study your study is **not** a clinical drug study, any records will be retained for up to but no more than four **You may not participate in this study unless you sign this approval.**

What if I change my mind about sharing my research information? If you decide not to st information anymore:

- ✓ The research team may continue to use the private information that they have already colle
- ✓ You will no longer be a part of the research study,
- ✓ You will still get the same medical care that you've always had at San Diego Hospice & Pall
- You must write to the study doctor and tell him or her that you no longer want to share yo information. Write to the study nurse at:

Principal Investigator:
Complete mailing address:
Street Address
City/State/Zip

Roger Strong, APRN, BC-PCM
San Diego Hospice & Palliative Care
4311 Third Avenue
San Diego, CA 92103

✓ If you do not withdraw your consent, this form will expire 25 years after the date of study of

Do I have the right to see and copy my research information? No, you may not see your r information unless it is also being used for your health care.

If you agree to share your information you should sign this form below. You will be given a copy c

I agree to share my information as described in this form	1:
Printed Subject's Name	
Subject's Signature	Date/Time
Printed Name of Legally Authorized Representative (If applicable)	
Signature of Legally Authorized Representative (If applicable)	Date/Time
Printed Name of Person Obtaining Consent	
Signature of Person Obtaining Consent	Date/Time

Version Date:

Page 2 of 2

Patient Initials:

APPENDIX H UNIVERSITY OF SAN DIEGO IRB APPROVAL

Roger Strong

From:

Thomas Herrinton [herrinton@sandiego.edu] Thursday, May 11, 2006 10:44 AM

Sent: To: Cc:

Roger Strong; Jane Georges Bernadette Maldonado; Sally Hardin

Subject:

IRB approval of your human subjects research proposal



2006-05-068pas-tr h.doc

Dear Mr. Strong and Dr. Georges,

Your request for IRB authorization of your human subjects research proposal entitled "Dyspnea: Effect of Auricular Acupressure in End Stage Lung Cancer Patients" has been approved. Please see the attached Project Action Summary form for your project number and action date.

Sincerely, Dr. Thomas H

Dr. Thomas R. Herrinton

IRB Administrator

Associate Provost University of San Diego

*** eSafe scanned this email for malicious content ***

*** IMPORTANT: Do not open attachments from unrecognized senders ***

APPENDIX I

SAN DIEGO HOSPICE AND PALLIATIVE CARE IRB APPROVAL



CENTER FOR PALLIATIVE STUDIES

AT SAN DIEGO HOSPICE

& PALLIATIVE CARE
CHARLES VON GUNTEN, MO, PhD
MEDICAL DIRECTOR
LINDA STRAUSE, PhD
CHARR, IRB

BARBARA BALLEY, MS RN SENIOR FACULTY MAY BULL, RN SENIOR FACULTY

GAIL RENER, MS, RN, FNP ASSOC DRECTOR, EDUCATION ANN STURLEY, BBN, DIPH ASSOC DRECTOR, RESEARCH

> PROJECT MANAGER JENNIFER HALECKI, MS COORDINATOR

TARA HICKSON COORDINATOR AIMEE DAVIS, BA

KELLY CARTER COORDINATOR IGENE GRIMSHAW, E COORDINATOR

DAVID HAMLEY ASSISTANT DIANE MUNSON, MPH GRANTS & DEVELOPMENT ROSYN HUFFMAN

FELLOWS
MANA DAMILYCHEV, MO
MANA DAMILYCHEV, MO
RANDY FEDORCHUK, MO
ROBERT FRIED, MO
STEVE GRABOWSKI, MO
SUZANAN MAKOWSKI, MO
SUZANAN MAKOWSKI, MO
MULLAM MITCHELL MO
ANDY PROBOCIUS, MO
ISAAC VIELMA, MO
HOLLY YANG, MO
FACULTY

ROSLYN ALLMA, MEWAMGRILCHW
JERRY BOLTZ, BA, RN FNP
MOREEN CARRINGTON, MA LMFT
LYNETTE CEDEROLIST, MD
DESORAH DUNNE, MSN, MBA
FFANK FERRIS, MD
SHLYA GARCIA, MD
SHLYA GARCIA, MD
SHEYL HARNI, DO
SHERYL HERBIT, MD
CHARLES LEWIS, MD
CONNELES LEWIS, MD
CONNELES LEWIS, MD

CONNIE LESLE, MSWALCSW
BEN MARCANTONIO, ME EL MS
GALBERT MACO, MO
SHARON OTMARY, MSN
STEVEN OPPENNEIM, MO
JULE PRAZICH, MO
RENEE SMILDE, MO
JEFF STONEBERA, DO
ANY THOMAS, MO PRO
LAY THOMAS, MO PRO

ROFESSOR DORIS HOWELL, MD DIRECTOR EMERITA TRUE RYNDES, AMP MPH FOUNDING DIRECTOR

A TEACHING

SO RESEARCH AFFILIATE

THE SCHOOL OF MEDICINE

ואפספיטאר פי באניפספאר פי

14 November 2005

Roger Strong, APRN, BC-PCM San Diego Hospice & Palliative Care 4311 Third Avenue San Diego, CA 92103

RE: <u>CPS Study 03-010-ED</u>: "Dyspnea: Effects of Auricular Acupressure in End Stage Lung Cancer Patients."

Dear Mr. Strong:

The Chair of the San Diego Hospice IRB has reviewed the changes as requested in our letter dated, **July 21, 2005**:

Your protocol dated 28-June-2005 is approved.

Your consent form dated **28-June-2005** is approved. Please find enclosed an original, stamped, and approved consent. Please use this copy to generate copies for consenting subjects.

Approval for this study expires on 13-July-2006

As a reminder, any modifications to the protocol or consent forms must be approved by the IRB prior to their implementation. Any forms, except Case Report Forms, to be used during the study, or any advertisements must be approved by the IRB prior to their implementation. If you are unsure as to what needs review contact this office directly at 619-278-6296.

All Serious or Unexpected Adverse Events must be reported in a timely manner. If you are unsure as to what constitutes a Serious or Unexpected Adverse Event please contact this office directly at 619-278-6296.

You will be required to complete a quarterly report indicating the status of your research. This office utilizes the following as its quarterly reporting requirement (January/February/March — 1st Quarter), (April/May/Jurie — 2nd Quarter), (July/August/September — 3rd Quarter), (October/November/December — 4th Quarter).

Along with quarterly reporting, federal regulations state, "An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year." [Title 21 Part 56, Section 56.109(f)]

14 November 2005 Page 2

When your study has completed you will be required to complete a Study Summary.

The San Diego Hospice is in compliance with Good Clinical Practices, the Common Rule [Title 45 CFR Part 46], the Declaration of Helsinki, the Belmont Report and the regulations set fort by the Food and Drug Administration and all amendments thereto, contained in Title 21 of the Code of Federal Regulations, Parts 50,56 and 312.

Please contact this office for any matters that you are unsure of by calling direct at 619-278-6296.

Sincerely,

Linda G. Strause, Ph.D. IRB Chair

Enclosure LGS/eag



Caring for Our Community Since 1977

July 14, 2006

Roger Strong, APRN, BC-PCM San Diego Hospice & Palliative Care 4311 Third Avenue San Diego, CA 92103

RE: CPS Study 03-010-CM: Dyspnea: Effect of Auricular Acupressure in End Stage

Dyspnea

Dear Mr. Strong:

Your application for Continuing Review was addressed at the San Diego Hospice IRB meeting held on July 13, 2006.

The protocol dated June 28, 2005 is approved. Your consent form dated June 28, 2005 is also approved. Your HIPAA Consent remains in effect unless amended. As a reminder, if your consent form has been modified at this review or at any time during the study duration you are required to re-consent all subject currently enrolled or in follow-up.

Approval for this site expires on July 12, 2007.

As a reminder, any modifications to the protocol or consent forms must be approved by the IRB prior to their implementation. All forms to be used during the study, or any advertisements must be approved by the IRB prior to their implementation. Contact this office at 619-278-6296 should you have any questions.

All Serious or Unexpected Adverse Events must be reported in a timely manner. If you are unsure as to what constitutes a Serious or Unexpected Adverse Event please contact this office directly at 619-278-6296.

All protocol deviations or exceptions should be reported to the IRB in a timely manner:

<u>Deviation is defined as</u>: An incident involving noncompliance with the protocol, but one that typically does not have a significant effect on the subject's rights, safety, welfare, and/or integrity of the resultant data. Deviations may result from the action of the participant, Investigator, or staff.

<u>Exception is defined as</u>: Accidental or unintentional changes to the !RB approved protocol procedures without prior sponsor or !RB approval. Violations generally affect the subject's rights, safety, welfare, and/or the integrity of the resultant data.

4311 Third Avenue • San Diego, CA 92103-1407

619-688-1600 • 866-686-1600 (toil free) • www.sd hospice.org

July 24, 2006 Continuing Review Approval Page 2

Per federal regulations, "An IRB shall conduct continuing review of research covered by the regulations at intervals appropriate to the degree of risk, but not less than once per year." [T 21 Part 56, Section 56.109(f)]

When you have completed your study, you will be required to complete a Final Report Summary.

The San Diego Hospice is in compliance with the regulations Food and Drug Administration all amendments thereto, contained in Title 21 of the Code of Federal Regulations, Parts 50, and 312. The IRB is also compliant with ICH guidelines.

Please contact this office for any matters that you are unsure of by calling direct at 619-278-6296.

Thank you.

Sincerely,

Linda G. Strause, Ph.D. IRB Chair

Enclosure

LGS/eag

San Diego Hospice & Palliative Care

APPLICATION FOR AMENDMENT REVIEW

Investigator Name: Roger Strong APRN, BC	-PCM IRB #: 03-010-ED		
Pl Phone: 619-922-4058	PI Fax: 619-688-6599		
PI Email Address: rstrong@sdhospice.org			
Sponsor Name: NA	Sponsor ID #:		
Protocol Title Dyspnea: Effect of Auricular A Patients	Acupressure in End Stage Lung Cancer		
REVISION OR ADDITIONS:			
1. Revision or Addition Description [check all that apply]			
Revision to currently approved protocol: Original Version Date: New Version Date:	06-28-05		
Revision to currently approved consent: Current Version Date: New Version Date:			
2. Check all that apply:			
This revision involves minor changes only. [Administrative or having no direct impact or intervention pertaining to research subject]			
This revision does not increase risks to participants enrolled in the study.			
This revision does increase risks to participants enrolled in the study. [Include explanation in revision desciription.]			
3. Protocol: Submit a strikeout copy or a summary of changes to the protocol electronically.			
SA. Consent From: Submit a strikeout version electronically.			
I. If requesting Expedited Review, complete Application.	te the IRB Request for Expedited Revie		

Certification and Assurances:

- I certify that this form is complete and is correct.
- I accept ultimate responsibility for the conduct of this study, the ethical performance the project, and the protection of the rights and welfare of the human subjects who directly or indirectly involved in this project.
- I will comply with all SHD IRB policies and procedures as well as with all applicable federal, state and local laws regarding this project.
- I acknowledge that if this activity changes or extends beyond the expiration date, the certificate is voided.
- In the event of any legal action the applicant will hold SDH IRB harmless.

APPROVAL STATUS					
Not Approved Rejected					
4/2/07					
Date Care IRB					
]					

San Diego Hospice & Palliative Care

REQUEST FOR EXPEDITED REVIEW

	Roger Strong APRN, BC-PCM		IRB#: 03-010-ED
PI Phone: 619	922-4058	Pi Fax:	619-688-6599
PI Email Address:	rstrong@sdhospice.org		
Sponsor Name:	NA	Sponsor	ID #:
Protocol Title [Dyspnea: Effect of Auricular Acupre	ssure in End Stag	e Lung Cancer Patients
JUSTIFICATION FOR	R EXPEDITED REVIEW: (Also choo	se one of the crit	eria below)
Title 21 CFR Part 56 kinds of research invo changes in approved		Sec. 46.110 - Explasse give a brief de	edited review procedures for certain escription for your request and for mino
regarding the to the four q be informed a taped part or transcripts o	first qualitative ques ualitative questions w	stion and n ill be audi that they s, that the curely stor	may choose to not have audiotapes and ed, and that the
	•		
			•
f in your judgment you	or research project falls in one of the c	ategories below, p	olease check the appropriate box:
CATEGORY 1: Cli for which an investigat for which (i) an investig	nical studies of drugs and devices onli ional new drug application (21 CFR P jational device exemption application roved for marketing and the medical of	y when condition (art 312) is not req (21 CFR Part 812	a) or (b) is met. (a) Research on druge uired. (b) Research on medical device) is not require; or (ii) the medical

other adults and children, considering the age, weight, and health of the subjects, the collection proceduly amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the drawn may not exceed the lesser of 50 ml or 2 ml per kg in an 8 week period and collection may not occ frequently than 2 times per week.
□ CATEGORY 3: Prospective collection of biological specimens for research purposes by non-invasive Examples: (a) Hair and nail clippings in a non-disfiguring manner; (b) Deciduous teeth at time of exfoliati routine patient care indicates a need for extraction; (c) Permanent teeth if routine patient care indicates a extraction; (d) Excreta and external secretions (including sweat); and (e) uncannulated saliva collected e unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the Placenta removal at delivery; (g) Amniotic fluid obtained at the time of rupture of the membrane prior to abor; (h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not muthan routine prophylactic scaling of the teeth and the process is accomplished in accordance with accept prophylactic techniques; (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mashings; (j) Sputum collected after saline mist nebulization.
☐ CATEGORY 4: Collection of data through noninvasive procedures (not including general anesthesia routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where mere are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety are effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared devices for new indications.) Examples: (a) physical sensors that are applied either to the surfactor at a distance and do not involve input of significant amounts of energy into the subject or an invasion of subject's privacy. (b) weighing or testing sensory aculty, (c) magnetic resonance imaging; (d) electrocare electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinoraphy, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular testing, body composition assessment, and flexibility testing where appropriate given the age, weight and the individual.
CATEGORY 5: Research involving materials (data, documents, records, or specimens) that have befor any reason or will be collected solely for nonresearch purposes (such as medical treatment or diagno
CATEGORY 6: Collection of data from voice, video, digital or image recordings made for research pu
CATEGORY 7: Research on group characteristics or behavior (including, but not limited to, research perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and sor or research employing survey, interview, oral history, focus group, program evaluation, human factors ev quality assurance methodologies.
☐ CATEGORY 8: Continuing review of research previously approved by a convened IRB as follows: (a) research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all reseinterventions; and (iii) the research remains active only for the long term follow-up of subjects; or (b) when subjects have been enrolled and no additional risks have been identified or (c) where the remaining research titles are limited to data analysis.
CATEGORY 9: Continuing review of research not conducted under an investigational new drug applic investigational drug exemption where categories 2 through 8 do not apply but the IRB has determined an documented at a convened meeting that the research involves not greater than minimal risk and no addit have been identified.

Certification and Assurances:

these projects.

- I certify that this form is complete and is correct.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, protection of the rights and welfare of the human subjects who are directly or indirectly involved in

Expedited review is NOT allowed for research involving persons under the age of 18 years except collections, which are part of the usual diagnostic or therapeutic regimen of children. A full review is requ

- I will comply with all SHD IRB policies and procedures as well as with all applicable federal, state a laws regarding this project.
- I acknowledge that if this activity changes or extends beyond the expiration date, the certificate is \u00b1

Signature of Principal Investigator				
APPROVAL ST	TATUS			
Approved	Conditionally Approved	☐ Not Approved	Rejected	
IRB Signature:	Steve Oppenheim, MD Chair, San Diego Hospic	e & Palliative Care IRE	3	1/2, Date

• In the event of any legal action the applicant will hold SDH IRB harmless.

San Diego Hospice & Palliative Care

REQUEST FOR EXPEDITED REVIEW

Investigator Name:	Roger Strong APRN, BO	C-PCM	IRB #: 03-010-ED
Pi Phone: 619	9-922-4058	_ PI Fax:	619-688-6599
Pl Email Address:	rstrong@sdhospice.org		
Sponsor Name:	NA	Sponsor	· ID #:
Protocol Title	Dyspnea: Effect of Auricular A	Acupressure in End Stag	ge Lung Cancer Patients
JUSTIFICATION FO	OR EXPEDITED REVIEW: (Also	choose one of the cri	teria below)
	volving no more than minimal ri		edited review procedures for conscription for your request and f
change in the		consent form co	e minimal. The only onsists expanding the include those in the
	•		
lf in your judgment yo	our research project falls in one	of the categories below,	please check the appropriate bo
for which an investigation for which (i) an investigation	ational new drug application (21 tigational device exemption appl proved for marketing and the m	CFR Part 312) is not red lication (21 CFR Part 813	(a) or (b) is met. (a) Research c quired. (b) Research on medical 2) is not require; or (ii) the medic sed in accordance with its
from healthy, non-pre exceed 550 ml in an other adults and child	egnant adults who weigh at least 8 week period and collection ma dren, considering the age, weigh	t 110 pounds. For these ay not occur more freque t, and health of the subje	stick, or venipuncture as follows subjects, the amounts drawn mently than 2 times per week; or (bects, the collection procedure, the ted. For these subjects, the amounts

Certification and Assurances:
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Signature of Principal Investigator				Date	
APPROVAL ST	TATUS				
Approved	☐ Conditionally Approved	☐ Not Approved	Rejected		
IRB Signature	Linda G. Strause, PhD Chair, San Diego Hospic Steven Oppenhe	e IRB ETM, MD		乙	



Caring for Our Community Since 1977

July 10, 2007

Roger Strong, APRN, BC-PCM San Diego Hospice & Palliative Care 4311 Third Avenue San Diego, CA 92103

RE: CPS Study: 03-010-ED

Study Title: Dyspnea: effect of Auricular Acupressure in End Stage Lung

Patients.

Dear Mr. Strong:

The IRB Chair has had the opportunity to review your request for Expedited review on 0'

1. The protocol dated 06/23/07 is approved.

Approval for this site expires on 07/12/07.

As a reminder, any modifications to the protocol or consent forms must be approved by a prior to their implementation. All forms to be used during the study or any advertisement be approved by the IRB prior to their implementation. Contact this office at 619-278-629 you have any questions.

All Serious or Unexpected Adverse Events must be reported in a timely manner. Should unsure as to what constitutes a Serious or Unexpected Adverse Event, please contact the directly at 619-278-6296.

All protocol deviations or exceptions should be reported to the IRB in a timely manner:

<u>Deviation is defined as</u>: An incident involving noncompliance with the protocol, but hat typically does not have a significant effect on the subject's rights, safety, well and/or integrity of the resultant data. Deviations may result from the action of the participant, Investigator, or staff.

Exception is defined as: Accidental or unintentional changes to the IRB approved protocol procedures without prior sponsor or IRB approval. Violations generally a the subject's rights, safety, welfare, and/or the integrity of the resultant data.

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July 10, 2007] Continuing Review Approval Page 2

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When you have completed your study, you will be required to submit a close-out letter a complete a Final Summary Report.

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Thank you.

Sincerely,

Steve Oppenheim, MD IRB Chair

Enclosure

SO/eag



Caring for Our Community Since 1977

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Roger Strong, APRN, BC-PCM San Diego Hospice & Palliative Care 4311 Third Avenue San Diego, CA 92103

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Study Title: Dyspnea: Effect of Auricular Acupressure in End Stage Lung Canc

Patients

Dear Mr. Strong:

Your application for Continuing Review was addressed at the San Diego Hospice IRB n held on **July 11, 2007.**

1. The protocol dated 06/23/07 is approved.

2. Your consent form dated 03/18/07 is approved.

3. Your HIPAA Consent meets the requirements as set forth in Privacy Rule and st

If your consent was modified, you are required to re-consent those subjects currently or or in follow-up.

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July 11, 2007 Continuing Review Approval Page 2

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Enclosure

SO/eag



Caring for Our Community Since 1977

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July 11, 2007 Continuing Review Approval Page 2

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Please contact this office for any matters that you are unsure of by calling direct at 619 6296.

Thank you.

Sincerely,

Steve Oppenheim, MD IRB Chair

Enclosure

SO/eag

APPENDIX J PLEDEGES OF CONFIDENTIALITY

Acupuncturist's Pledge of Confidentiality

I will be participating in this research project as a licensed Acupuncturist administering

auricular acupressure. Although I will know the names of the participants, I will not

purposefully acquire other identifying information. In any case, I agree to maintain the

confidentiality of the participants. I will maintain confidentiality by not discussing anything

that I learn about the participants with anyone for any reason and by not identifying the

participants to others in any way. I understand that if I do not maintain confidentiality that

the participants' right to privacy will be seriously violated and that this will constitute

unethical behavior that will jeopardize this research project.

Jeffery S. Smith, L.Ac., MSTOM, National Diplomat of OM

Name of Acupuncturist

Segnature of Acupuncturist

Date: 4-2-07

Transcriber's Pledge of Confidentiality

I will be participating in the transcription of audio taped research interviews to typed the will not purposively know the names of the participants being interviewed. However, inadvertently obtain information that would give me clues to participants' identity. It is maintain the confidentiality of the participants. I will maintain confidentiality by not discussing the information that I transcribe with anyone for any reason and by not ide the participants to others in any way. I understand that if I do not maintain confidential that the participants' right to privacy will be seriously violated and that this will const unethical behavior that will jeopardize this research project.

<u>Jennifer Mitch, RN, BSN</u> Name of transcriber

Signature of transcriber

Date: 2/10/

216

Statistical Consultant's Pledge of Confidentiality

I will be participating in this research project as a statistical consultant. I will not know th

names of the participants. I will not purposefully acquire other identifying information. It

any case, I agree to maintain the confidentiality of the participants. I will maintain

confidentiality by not discussing anything that I learn about the participants with anyone for

any reason and by not identifying the participants to others in any way. I understand that i

do not maintain confidentiality that the participants' right to privacy will be seriously

violated and that this will constitute unethical behavior that will jeopardize this research

project.

Tom L. Smith, Ph.D.
Name of statistical consultant

Signature of statistical consultant

Date: 5-01-0

Qualitative Data Analyst Expert's Pledge of Confidentiality

I will assist in the qualitative analysis of transcribed audio taped research interviews. not purposively know the names of the participants being interviewed. However, I m inadvertently obtain information that would give me clues to participants' identity. I maintain the confidentiality of the participants. I will maintain confidentiality by not discussing the information that I help analyze with anyone for any reason and by not identifying the participants to others in any way. I understand that if I do not maintain confidentiality that the participants' right to privacy will be seriously violated and tha

will constitute unethical behavior that will jeopardize this research project.

Rhoberta J. Haley, Ph.D., RN
Name of Qualitative Data Analyst Expert

Signature of Qualitativ Data Analyst Z

Date: 3//08

APPENDIX K NON-ENROLLED SUBJECT CHARACTERISTICS

Characteristics: Approached Eligible Subjects Who Did Not Participate

Variable	N = 54 Me	an (SD) or N (%)
Sex	male	24 (44.3)
	female	30 (55.6)
Age		72.8 (9.83)
Location	Home Care	51 (94.4)
	ICC	3 (5.6)
Reason	Died	13 (24.1)
	SNF*	2 (3.7)
	Declined no specific reason	n 17 (31.5)
	Declined fatigue	14 (25.9)
	Declined fatigue/appointme	ents 2 (3.7)
	Declined by family/spouse	3 (5.6)
	Declined study length	1 (1.9)
	Declined anxiety	1 (1.9)
	Declined appointments	1 (1.9)

^{*}moved to Skilled Nursing Facility

APPENDIX L

TIME TO DEATH OF SUBJECTS ENROLLED

Enrolled Subjects: Characteristics and Number of Days Between End of Study Participation and Subjects' Death as of 5-08-09

			End Date of			
Ss			Study	Date of	No. Days	
Number	Sex	Age	Participation	Death	Until Death	Death Location*
001	F	75	7/12/07	9/10/07	60	SNF
002	F	80	7/27/07	**	**	
003	M	89	8/2/07	**	**	
004	M	64	8/1/07	11/21/07	112	HC
005	M	80	9/24/07	10/29/07	35	SNF
006	F	85	9/27/07	12/8/07	72	B/C
007	M	54	11/2/07	**	**	
008	F	49	12/18/07	5/7/08	141	ICC
009	F	75	1/14/08	3/21/08	81	HC
010	F	53	2/19/08	2/25/08	6	ICC
011	M	55	2/23/08	3/4/08	10	HC

*SNF = skilled nursing facility

HC = homecare

B/C = board & care

ICC = inpatient care center

^{**}Still alive as of 5-08-08

APPEDENDIX M PUBLICATION PERMISSIONS

Roger Strong

From: Sent: To: Keiko TANAKA [k.tanaka@scchr.jp] Thursday, July 07, 2005 4:18 AM

To: Roger Strong,
Subject: Cancer Dyspnea Scale

Dear Strong

I'm Dr. Tanaka, a physician in Palliative Care Unit, who developed the Cancer Dyspnea Scale. Dr. Uchitomi sent your mail to me.

It is our pleasure that you are planing the study using the CDS.

Acupuncture and accupressure are used to alleviate symptoms also in cancer patients. But they are not regarded as "medicine". They are delivered not in Mospital nor even in PCU. There is few reports showing how it works, and few or no scientific studies on it.

I suppose CAM like acupuncture and accupressure is perhaps more widely applied to patients in USA than in Japan.

Sincerely,

Keiko TANAKA M.D., Ph.D.
Division of Palliative Medicine,
Shizuoka Cancer Center Hospital
Naga-izumi, 411-8777, JAPAN
Tel: +81-55-989-5222
Fax:+ 81-55-989-5634

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Apr 14, 200

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multidimensional, brief, self-rating scale.

Licensed content author

Tanaka K, Akechi T, Okuyama T, Nishiwaki Y, Uchitomi Y.

Volume number

82

Issue number

Pages

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Year of publication

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Thank you,

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Thank you for your help, Roger A. Strong, PhD(c), RN