An evaluation of tracheostomy care anxiety relief through education and support (t-cares) a pilot study

William Crosby

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AN EVALUATION OF TRACHEOSTOMY CARE ANXIETY RELIEF THROUGH EDUCATION AND SUPPORT (T-CARES): A PILOT STUDY

by

WILLIAM WOODFIN CROSBY

A thesis submitted in partial fulfillment of the requirements for the completion of Honors in the Major in Nursing in the College of Nursing and in the Burnett Honors College at the University of Central Florida Orlando, Florida

Spring Term 2012

Thesis Chairs: Mary Lou Sole, Victoria Loerzel, Kimberly Renk
ABSTRACT

Background: Home care of a patient with a tracheostomy after surgery for head and neck cancer requires the caregiver to be proficient with new equipment and required skills. The responsibility of managing an artificial airway, may lead to an increase in caregiver anxiety. Education of caregivers varies; it is often a 1:1 impromptu instruction provided by the patient’s nurse and/or respiratory therapist. The purpose of this study was to evaluate the effect of the T-CARES course on caregiver anxiety and tracheostomy suctioning competency.

Method: A quasi-experimental non-randomized control group design was used. The independent variable was method of instruction (T-CARES versus standard). Dependent variables were caregiver anxiety and tracheostomy suction competence. Caregivers (n=12) self selected into groups based on availability to attend T-CARES course. The control group was to receive the unit-based standard of education. The experimental group participated in the T-CARES course. Only one person chose to be in the control group; therefore, data were analyzed for the experimental group only (N=11). The T-CARES course, created by the researcher, was standardized and instructor-led; it incorporated media and simulated practice. Caregiver anxiety for both groups was obtained before (State/Trait Anxiety) and after (State Anxiety) tracheostomy care instruction was provided. Tracheostomy suctioning competence was assessed using a standardized checklist for participants in the T-CARES study group only. Demographic data were summarized with frequencies and descriptive statistics. Given the small sample size, non-parametric statistics were used for data analysis.
**Results:** Data were analyzed from the experimental group only (n=11). The majority of caregivers were women (n=7), white/caucasian (n=10), married (n=8), employed full time (n=7), and were high school graduates or higher (n=10). The mean age of participants was 50.8 years. Seven of the participants reported previous caregiver experience. Mean score of caregiver trait anxiety was 36.8. Mean caregiver state anxiety score was 50.5 before, and 34.3 after the T-CARES intervention. A Related-Samples Wilcoxon Signed Rank Test was performed on the pre and post T-CARES intervention state anxiety scores. The T-CARES intervention significantly reduced anxiety (p=.008). Tracheostomy suctioning competency for 9 of the participants was evaluated upon completion of T-CARES. Mean score was10.8 skills performed correctly out of a possible 14. Caregivers’ responses regarding their biggest fear/concern about tracheostomy care included “not doing it right,” “trach coming out or being blocked,” “hurting the patient,” and “not being able to help in an emergency.” Participants’ suggestions for future improvements were creation of a Spanish language course and the addition of supplementary training to include CPR, First Aid, and the management of feeding tubes.

**Discussion:** Research supported the hypothesis that the T-CARES course would be successful in reducing state anxiety. The T-CARES course also had a positive impact on tracheostomy suctioning competency, though without a control group it is difficult to quantify the effect. The continued development and dissemination of T-CARES to all tracheostomy patients and their caregivers may ease their transition home.

The views expressed are those of the author and do not reflect the official policy or position of the US Air Force, Department of Defense or the US Government.
This dissertation is dedicated to my awesome son Finn, my beautiful little girl Tatumn, and my soul mate Jaime.

Finn you are my best friend. People say a parent shouldn’t be their child’s friend…Well, they haven’t met you. Your bravery and positive attitude through the most difficult of times is the definition of courage. You inspire and touch everyone you meet. Son, you are incredibly smart and have taught me more than you will ever know.

Tatumn, your smile is contagious. Watching you explore the world around you with wonderment is a constant reminder to relax and enjoy life. You are the best parts of your mother and me. I can’t wait to see you grow up.

Jaime, you are an amazing mother and wife. Thank you for encouraging and enabling me to pursue my passion. It would not have been possible without your constant support. Fellow students often ask how I was able to perform this research while juggling school and a family. I tell them without you it would not have been possible. Our life together has been an adventure and I know that together we can accomplish anything.

Love always, William.
ACKNOWLEDGMENTS

First I would like to acknowledge the nurses, nurse practitioners, respiratory therapists, and physicians of the Neonatal and Pediatric Intensive Care Units of Florida Hospital. You provided me with my first insight into how to care for a child and family in crisis. Your knowledge and professionalism inspired me to pursue a career in nursing.

I would like to thank my committee members and co-investigator for their involvement in the project. Your guidance was key in the completion of this lofty undertaking. Dr. Mary Lou Sole, your knowledge and love for research is contagious. Your enthusiasm for research will stay with me always. Thank you for all the opportunities that would not have been possible with your guidance. Dr. Victoria Loerzel, you knew my areas of interest and gave me the courage to pursue them. Your door was always open and candy dish always full. You always made time no matter how busy you were. Dr. Kimberly Renk you helped me to identify and properly assess anxiety. Without which this project would have surely floundered. Ellen Reising, without you this project would have never been. You identified the need and opened the doors. I would like to thank all of you for giving me complete ownership of this project. The lessons I have learned from all of you will stay with me for the rest of my career.

The students and faculty of the University of Central Florida College of Nursing, you were my sounding board for new ideas and a constant source of encouragement.

The United States Air Force, for making it possible to devote full attention to my studies and providing me with countless opportunities.
The Office of Undergraduate Research, Student Government Association, and Burnett Honors College provided funding. With these grants, I was able to pay for supplies needed to conduct the research and travel to present my findings.

Lastly my parents, Syd and Beverly Crosby. Thank you for providing a house that was filled with unconditional love. You have made me the man, husband, and father that I am today.
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CHAPTER 1: INTRODUCTION

Statement of the Problem

A study conducted by National Alliance of Caregiving (2009) found that more than 28 million U.S. households reported at least one member of the family had served as a caregiver to an adult in 2009. Only 20% of these caregivers received formal caregiver training, and 83% of the caregivers in high burden situations desired more information regarding the care they provide. Primary caregivers spent on average 18.9 hours a week providing direct patient care (National Alliance of Caregiving).

Early involvements in patient care activities and sufficient education have proven to have a positive effect on caregivers. Caregivers that have received information and support early in patient treatment have demonstrated greater trust and confidence of the health care system, have fewer needs, and cope better in the later stages of the patient’s illness (Kristjanson & White, 2002). The perception of unmet needs has been found to be a causative agent for the anxiety experienced by many caregivers (Friðriksdóttir, Sævarsdóttir, Halfdánardóttir, Jónsdóttir, Magnúsdóttir, Ólafsdóttir, & ... Gunnarsdóttir, 2011; Kim, Kashy, Spillers, & Evans, 2010; Molassiotis, Wilson, Blair, Howe, & Cavet, 2011).

Treatment for some disorders requires a high level of caregiver involvement, knowledge and expertise in technical skills. One such area is surgical treatment for head and neck cancers. Head and neck cancers account for approximately 3 percent of all malignancies in the United States. These include cancers of the larynx, nasal cavity, paranasal sinus, nasopharyngeal, salivary glands, oral and oropharyngeal cavity (United States Department of Health and Human
The American Cancer Society (2011) projected that more than 52,000 men and women will be diagnosed with head and neck cancer in 2011.

After surgical treatment, many patients with head and neck cancer are discharged home with a tracheostomy. Tracheostomy management requires the caregiver to become comfortable and proficient with many new skills and pieces of medical equipment. It is crucial for the caregiver to become comfortable with this new equipment and properly apply these new skills to reduce the rate of complications such as pneumonia, skin breakdown, tracheostomy plugging, tracheal stenosis, development of granulation tissue, accidental decannulation, hypoxemia, and death (Potter & Perry, 2009).

This thesis was undertaken in collaboration with a local cancer center to address identified needs of caregivers. A request was made by the Clinical Nurse Leader at a local cancer center for the development of a course to educate caregivers of tracheostomy patients about procedures for proper care prior to discharge. The standards of care for educating/training caregivers at this location consisted of implementing the Critical Check—Tracheostomy Patient Teaching Plan (Appendix A). The Tracheostomy Patient Teaching Plan is implemented by the nurse and/or respiratory therapist (RT) and included caregiver viewing of an instructional video, demonstration of tracheostomy care at the bedside, and having the caregiver perform tracheostomy care and tracheal suctioning prior to discharge. Informational pamphlets were distributed (Appendices B and C). The staff nurses were responsible for patient/family education, but the process often varied.

Mr. Crosby had firsthand knowledge of the tracheostomy caregiver experience. His son had a tracheostomy for 3 years before a scheduled decannulation. The anxiety experienced by
him and his wife regarding the care for their son was a motivating factor in the creation and evaluation of a standardized tracheostomy caregiver course as part of his Honors in the Major (HIM) project.

Purpose of the Study

The intent of this pilot study was to serve as the evaluation of a standardized tracheostomy caregiver course, Tracheostomy Care Anxiety Relief through Education and Support developed by the investigators (T-CARES [Appendix D]). T-CARES is a comprehensive course that includes basic airway anatomy, tracheostomy tube description and operation, signs and symptoms of respiratory distress, suctioning technique, tracheostomy tube-cleaning and maintenance, stoma-site assessment and cleaning, emergency decannulation and reinsertion procedures, and equipment and supply use.

A group class that covers essential content and also incorporates skill practice using low technology simulation, in addition to the hospital’s standard Tracheostomy Teaching Plan may better prepare caregivers for managing the care of the patient with a new tracheostomy, improve the technical skills needed to provide optimal care, provide them with a support group, and thereby reduce their state anxiety. By participating in the T-CARES course, caregivers may be provided with an environment to increase knowledge and master required skills. Mastery of these skills should reduce state anxiety in regards to caring for the patient with a new tracheostomy.

The primary objective of this study was to evaluate the effect of the T-CARES course on caregiver anxiety. The secondary objective of this study was to evaluate the effect of the T-CARES course on caregiver suctioning competency.
Anxiety

The increased responsibility of managing an artificial airway, may lead to increased state anxiety in the caregiver. State anxiety is conceptualized as a transitory condition of unpleasant, consciously perceived feelings of tension, apprehension, and nervousness that vary in intensity and fluctuate in time as a reaction to circumstances that are perceived as threatening; whereas trait anxiety refers to relatively stable individual differences that are impervious to situational stress (Spielberger, 1983).

Suctioning Competency

Tracheostomy management requires the caregiver to master many new skills and become familiar with medical equipment. Of these skills tracheostomy suctioning was selected for assessment, because of its invasiveness and necessity to master multiple skills. It requires a basic understanding of anatomy, assessment of respiratory status, critical thinking, adherence to sterile technique, familiarity with medical equipment, and manual dexterity.

Low Cost Anatomical Model

The use of life-like models provides the opportunity to receive training and feedback in life-like circumstances. One component of the T-CARES course was the use of a low-cost model for demonstration and return demonstration. This model was available for checkout by the participant upon completion of the course. This may allow the caregiver to become familiar with equipment/materials and master hands on skills.
Research Question and Hypothesis

The following research questions were identified:

1. What is the effect of the T-CARES course on the state anxiety of caregivers who will be providing home care to patients with a new tracheostomy performed as part of head and neck cancer treatment?

2. What is the effect of the T-CARES course on tracheal suction competency of caregivers who will be providing home care to patients with a new tracheostomy performed as part of head and neck cancer treatment?

The following hypothesis was tested:

1. T-CARES participants will demonstrate a reduction in state anxiety upon successful course completion.

Definitions and Terms

Table 1: Definitions and Terms

<table>
<thead>
<tr>
<th>Variable</th>
<th>Conceptual Definition</th>
<th>Operational Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Individual undergoing medical treatment at local cancer hospital.</td>
<td>Individual whom received a tracheostomy as part of the treatment of head and neck cancer at local hospital. Individual must be 18 years of age or older, not require mechanical ventilation upon discharge, and be discharged home under the care of an identified caregiver.</td>
</tr>
<tr>
<td>Caregiver (population)</td>
<td>Individual who will be providing care at home for the patient who has a new tracheostomy</td>
<td>Self-identified caregiver of a patient who undergoes a tracheostomy for treatment of head/neck cancer. Age 18 or older.</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Method of Instruction</td>
<td>Standard of care. Usual education provided to caregivers by nursing or RT staff.</td>
<td>Implementation of education as defined in the Critical Check: Tracheostomy Patient Teaching by MDACCÓ (Appendix A) along with distribution of written materials (Appendix B &amp; C)</td>
</tr>
<tr>
<td></td>
<td>T-CARES Class on management of the tracheostomy patient, to include skill practice in tracheal suctioning; in addition to standard bedside instruction provided by RN and/or RT.</td>
<td>Formal classroom instruction in the management of a patient with a new tracheostomy to include an instructor led video, group discussion, and practice on a low-cost anatomical model. Following Critical Check: T-CARES Teaching Plan (Appendix E). T-CARES content described in Appendix D.</td>
</tr>
<tr>
<td>Anxiety</td>
<td>State Anxiety is an emotion that signifies the presence of danger that cannot be identified, or if identified, is not sufficiently threatening to justify the intensity of the emotion that exists for a particular situation or moment in time and at a particular intensity. Trait anxiety is one’s general predisposition to respond to stress; relatively stable</td>
<td>State anxiety score and trait anxiety score as measured on the Spielberger State-Trait Anxiety (STAI) scale.</td>
</tr>
<tr>
<td>Tracheostomy Suctioning Competence</td>
<td>Ability to perform tracheostomy suctioning.</td>
<td>Skills performed according to a standardized checklist (Appendix F) developed from Cleaning your Tracheostomy Tube: Home Care Instructions (Appendix B)</td>
</tr>
<tr>
<td>Low-Cost Anatomical Model</td>
<td>A three-dimensional model of human anatomy that can be purchased and/or fabricated at minimal cost.</td>
<td>A three dimensional life size model of a male human head with a cutaway that reveals anatomical structures to include the esophagus, trachea, and vocal chords. This model allows for practice and return demonstration of learned skills (Appendix G).</td>
</tr>
</tbody>
</table>
Summary

This chapter introduced the problems encountered by caregivers of patients with a new tracheostomy as part of their cancer treatment. Chapter 2 reviews relevant literature; Chapter 3 describes methods; Chapter 4 lists the findings; and Chapter 5 discusses results.
CHAPTER 2: REVIEW OF LITERATURE

A literature search was performed in using the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and MEDLINE databases. The date range was 1992 to 2011 with the following key words: (Tracheostomy or tracheotomy) & Caregiver* NOT Child or Pediatric. This produced sixty-five results. Of these, no studies were deemed relevant to this study. They were rejected for the following reasons. The subjects of thirty-two of the articles researched mechanically-ventilated patients. Nine of the articles were editorials. Eight defined health care providers as the caregiver. The subjects of five of the articles were infants or children. Four researched end-of-life care. One researched air travel of a patient with a tracheostomy. One discussed emergency placement of a tracheostomy. One recommended education to caregivers of patients with an obstructive hematoma. One researched obese patient wound care and one researched interventions for patients in a vegetative state. Finally one observational study investigated the strain felt by caregivers of patients with a tracheostomy due to chronic obstructive pulmonary disease (COPD), kyphoscoliosis, or phrenic nerve palsy. This study did not investigate the effects of any educational interventions.

As a result of not being able to locate articles that researched the effect of an educational intervention on tracheostomy care competencies or caregiver anxiety, it was necessary to broaden the review of literature to other populations.

Anxiety

After an extensive review of the literature, no studies were located that studied anxiety of the caregiver of an adult with a new tracheostomy prior to discharge. Researchers have studied anxiety experienced by parents of children with a tracheostomy. Parents described anxiety about
mastering newly-acquired skills and being solely responsible for their child once discharged. One parent stated “Learning to change the trach was very scary…knowing that her life depended on my doing it fast and correctly.” Another parent expressed a fear of not thinking she could clean the [tracheostomy stoma] areas and care for her child if he choked or turned blue (Montagnino & Mauricio, 2004).

Studies were also located that identified anxiety in the caregivers of cancer and stroke patients. Seventy-seven percent of cancer caregivers identified feelings of anxiety (Perry & Roades de Meneses, 1989). Caregivers of stroke patients also experienced anxiety. Karla et al. (2004) measured the anxiety of the caregivers of stroke victims twelve months after a pre-discharge course. They compared a comprehensive education program to simply providing educational pamphlets. They found that the education program led to a significant reduction in anxiety, as well as an improved quality of life for the patient. Wellwood, Dennis, and Warlow (1994) found that although stroke victims were satisfied with the amount of information given, their caregivers were not. These findings support the implementation of a more comprehensive approach to education of caregivers.

**Suctioning Competency**

Tracheostomy suctioning is a critical element of tracheostomy care. No studies have assessed the suctioning competency of caregivers. Limited published studies relating to suctioning competencies focus on nurses, and the parents of children with a tracheostomy. Multiple studies have identified that many parents and nurses were unaware of recommended practice and demonstrated unsafe practices during this critical skill (Chau et al., 2007; Day,
Studies on effectiveness of tracheostomy suctioning training of nurses have shown positive results. Pelaes de Carvalho et al. (2009) demonstrated a > 30% increase in identifying correct suctioning pressure, a > 45% increase in identifying correct suctioning sequence, and a > 60% increase in knowledge of appropriate suction duration by educating nursing personnel. Another study substantiated the implementation of nurse education. Endotracheal tube suctioning skills of these nurses improved from 73% to 89% after attending a 45-minute course (Chau, 2007). Self-learning modules have also proven to be effective in educating nurses (Kang, 2002). Caregivers of mechanically ventilated children scored an average of 35.3% before, and 91.1% after, a course in airway management led by respiratory therapists (RT) (Tearl & Hertzog, 2007). Support, camaraderie, and a decrease in anxiety have also been shown among clients who attended classes together (Howard, Daviews, & Roghmann, 1986; Ireys, Chernoff, Stein, DeVet, & Silver, 2001).

Low Cost Anatomical Model

No studies were located that discussed the use of mannequins in caregiver education. The use of mannequins has been shown to be just as effective as using live patients (Roberts et al., 1997). In one study of 67 nursing students, the experimental group of 29 students that participated in simulation training improved their skills and knowledge score by 6.76% (p < 0.05) over the 38 students in the control group that did not participate in simulation training (Alinier, Hunt, & Gordon, 2004). The Institute of Medicine’s 2000 report, To err is human: Building a Safer Health System, advocates the use of simulation whenever possible, especially
for the novice practitioner when new procedures or equipment are used. They recommend the use of life-like models to encourage crisis management and problem solving (Kohn, Janet, & Molla, 2000).

Summary

A review of the literature has identified a significant lack of studies researching the caregivers of an adult with a tracheostomy. The scarcity of studies in this population required the researcher to investigate comparable populations. In these populations an increase in caregiver anxiety was observed and was closely linked to a felt need for further education. The effects of a tracheal suctioning training have shown to be effective for nurses and caregivers of children requiring mechanical ventilation. The use of simulation has also shown to be a useful tool when educating people about new concepts. The pilot nature of this study will serve to build a foundation for future research on this unique population.
CHAPTER 3: METHODS AND PROCEDURES

Design

A quasi-experimental, non-randomized control group design was used for this study. A pre-test post-test design was used to measure and compare anxiety of the control and experimental groups. A post-test only design was used to evaluate suctioning competency of the experimental group.

Subjects

Subjects in this study were adult caregivers that would be responsible for providing tracheostomy care (to include suctioning, stoma care, tie changes, inner cannula changing, and troubleshooting of alterations) of head and neck cancer patients upon discharge.

Inclusion criteria

Criteria for inclusion were as follows: 1) caregiver 18 years of age or older; 2) planning to provide care for an adult patient who had a tracheotomy as part of head and neck cancer treatment, and who is not on mechanical ventilation; and 3) able to speak and read English.

Sample size determination

This study was a pilot study to assess effectiveness of a standardized educational program over approximately 12 to 14 weeks. Based on the average number of patients who undergo tracheostomy, we anticipated being able to recruit at least 28 caregivers, and requested enrollment of 40 individuals. The sample size was based on a large effect size (1 or higher), to have adequate power (.80) for an independent sample t-test at the alpha error probability of .05.
on the primary measure of anxiety. It was noted during the proposal planning that if the effect size were lower, the study would be underpowered. However, due to the pilot nature of the study, it was important to develop a mechanism for evaluating the best way to deliver it and evaluate the T-CARES course.

**Variables**

The independent variable was the method of instruction on care of tracheostomy. The dependent variables were caregiver anxiety and tracheostomy suctioning competence.

**Procedures**

A convenience sample of caregivers of head and neck cancer patients at a local cancer center that were discharged between the dates of 1 December 2011 to 15 March 2012 with a new tracheostomy were the subjects of this study. Upon identification subjects were provided with an Invitation to Participate in a Research Study (Appendix G). Subjects were allowed to self-select into either the control or intervention group.

The control group was educated by the staff members on the nursing unit per the *Critical Check: T-CARES Teaching Plan* (Appendix E). The experimental group attended the T-CARES course, in addition to receiving the standard instruction, constituted the experimental group.

A summary of procedures and measurements is shown in Table 2. Participants in the control group received standard care with current pre-discharge instruction, which includes watching a video, bedside instruction, and written instructional materials. In addition to standard bedside instruction provided by RN and/or RT, participants in the T-CARES group received 1-hour of instructor-led class. The T-CARES class consisted of instruction that included audiovisuals and
written instructional materials, and performed practice and return demonstration of learned skills on the low-cost anatomical model.

Demographic information and both state and trait caregiver anxiety were measured prior to starting the educational process. Skill competence in suctioning was assessed using a standardized checklist for participants in the T-CARES study group only. Suctioning competency was not pretested because we assumed no past experience in performing the procedure. Demographic data were collected from all participants (Appendix H). State anxiety was measured prior to discharge after caregiver education has been provided. The co-Investigator, Ms. Reising, assisted in coordinating data collection with the unit staff.

T-CARES Intervention

Group classes were scheduled approximately once a week when eligible participants were available. Attempts will be made to coordinate class schedules with the surgery schedule. Attendance of caregivers was voluntary. Information was provided to caregivers so that they knew when the classes were scheduled. The T-CARES class was standardized to ensure that all participants received the same experience. It was video based and instructor led. Pauses were interspersed throughout the video after skills were demonstrated. During this pause participants could ask questions, practice, and perform return demonstration. Caregivers were permitted to attend the class but not participate in the research study.

Demonstration was performed on low-cost models (Appendix G). Classes were led by the PI (Mr. Crosby) under the supervision of the other PI or co-I. All content was reviewed by the study team to ensure that the current organization standards and policies/procedures were followed. Approval was received from the cancer center and UCF Institutional Review Board.
Instructor (Mr. Crosby) encouraged an open environment where concerns could be expressed and validated. Participants in both groups were provided written instructional materials that included tracheostomy care quick reference (Appendix B & C). Participants were allowed to practice on low-cost model at their leisure upon completion of course. Participation in T-CARES course did not alter standard bedside instruction or information provided to the caregiver or patient. RNs and RTs were still encouraged to provide instruction and answer questions.

Table 2: Activities and Measurements for the Study

<table>
<thead>
<tr>
<th>Timeline/Activity</th>
<th>Measure</th>
<th>Control Group</th>
<th>T-CARES Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to beginning caregiver instruction (approximately post-op Day 1 per Tracheostomy Patient Teaching Plan)</td>
<td>Demographic Data Spielberger State-Trait Anxiety Scale</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Standard instruction (implementation of Tracheostomy Patient Teaching Plan)</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Estimated post-op days 1-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T-CARE Class held Estimated post-op days 1-4 (scheduled weekly)</td>
<td>Assessment of suctioning competency Evaluation of class</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Prior to discharge when education completed Estimated post-op day 4</td>
<td>Spielberger State Anxiety Scale</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Data Analysis

Statistical Package for the Social Sciences (SPSS) version 19.0 was used for data analysis. Demographic data were summarized with frequencies and descriptive statistics. A decision was made to analyze data only from those who participated in the experimental T-CARES group since only one person participated in the control group. Data were assessed for assumptions, and nonparametric statistics were run rather than parametric ones. The Related-Samples Wilcoxon Signed Rank Test was used to compare pre and post state anxiety scores.

Materials

Materials used for this study included a video, low-cost anatomical models, demographic data collection tool, tracheostomy suctioning evaluation tool, an anxiety measurement tool, and a course evaluation.

Video

One component of the T-CARES course was an 18-minute video. The instructional video was written, produced, and edited by the researcher. The video was shot in the principal investigator’s home using a mannequin provided by the University of Central Florida College of Nursing, and the low-cost anatomical model created by the researcher. By filming the video in a home environment the researcher hoped to emulate the environment that the subjects would be providing care. Video was recorded on a Cannon G12. All video editing was performed on a Lenovo SL510 using Windows Live Movie Maker version 14.
Low-Cost Anatomical Model

Another component of T-CARES was the ability of caregivers to practice new skills on a low-cost anatomical model created by the researcher. While researching tracheostomy education the researcher discovered two different tracheostomy teaching aids created by other nurses. The first created by Pothier (2006), consisted of clear plastic rigid tubing model of the trachea and left and right main-bronchus. While this model allowed users to practice suctioning it did not allow the user to practice changing tracheostomy ties, cleaning the stoma, and did not adequately approximate surrounding anatomy. The second teaching aid created by Zeien (2011) used a foam head typically used for the display of wigs. The creator recommended a hole be placed in the area where a tracheostomy tube would be placed. This allowed the user to practice tracheostomy care activities to include stoma cleaning, tracheostomy tie changes, and tracheostomy tube changes. Another version of the model was cut down the sagittal plane. The two inner halves of each piece were then carved and painted to resemble the internal anatomy of the neck, oropharynx, coral cavity, and nasal cavity. This model allowed for visualization of internal anatomy, but not for practice of tracheostomy care activities.

The low-cost anatomical model (Appendix I) for T-CARES was a compilation of ideas of the models created by Zeien and Prothier with some major revisions. The revisions include a male head, orientation of the right main-stem bronchus to more accurately reflect human anatomy, inclusion of simulated vocal chords in the clear tube, and a cross-section of only the neck region that was secured with magnets. A stand was also made so the model could stand upright.
Demographics

Demographic data were collected using the T-CARES Demographic Tool (Appendix H). Data were collected using a one-page form that was filled out by the participant. Demographic data collected included relationship to patient, education level, employment, previous health care experience, age, race, marital status, previous experience with a tracheostomy, and if caregiver will receive assistance at home by someone with previous tracheostomy care experience. The demographic tool also included one open ended question. This question was “What are your biggest concerns or fears about caring for your family member after discharge?”

Suctioning Competency Evaluation

Suctioning competency was evaluated by use of an observation tool (Appendix F) created by the researchers. The checklist was derived from Cleaning your Tracheostomy Tube: Home Care Instructions (Reising, 2009) (Appendix B) provided to patients prior to discharge. Fourteen key skills were included on the list. Upon completion of evaluation participants were remediated on missed items.

Anxiety Measurement

Goodwin (1986) defined anxiety as “an emotion that signifies the presence of danger that cannot be identified, or if identified, is not sufficiently threatening to justify the intensity of the emotion.” State anxiety exists for a particular situation or moment in time and at a particular intensity; whereas trait anxiety is defined as stable individual differences in anxiety-proneness (Spielberger, 1983). Subjective feelings of apprehension, nervousness, worry, tension, and arousal of the autonomic nervous system are key characteristics of anxiety (Spielberger).
Anxiety was evaluated using the State-Trait Anxiety Inventory (STAI). The pre-instruction questionnaire included all 40 questions of the inventory. The first 20 questions assessed state anxiety regarding the care of the tracheostomy. The second 20 questions assessed the caregivers’ trait anxiety. The post-instruction questionnaire only included the 20 questions from the state portion of the inventory and was used to assess the caregivers’ state anxiety regarding the care of the tracheostomy after attending the T-CARES course.

The STAI was written at the sixth-grade level (Spielberger). Available responses to each of the questions were 1) Almost Never, 2) Sometimes, 3) Often, or 4) Almost Always. Scores can range from 20 to 80 on each of the two sections of the STAI (Spielberger). The instrument has been used extensively in research and has established reliability and validity. During its initial development, validation, and eventual modernization approximately 12,000 subjects were tested (Spielberger). The STAI’s adaptation to 30+ languages has allowed for its use in more than 25,000 cross-cultural research and clinical practice studies worldwide (Spielberger).

Course Evaluation

Course evaluations (Appendix J) were used to assess components of the course and allow for input for future development of the course. Course evaluations were anonymous and were provided upon completion of the course. The first section allowed for the participant to evaluate seven key points of interest as either poor, average, good, or excellent. The second section allowed for summary components.
Maintaining Confidentiality

An informed consent (Appendix M) form was provided when participants signed up for the study. Signing up for the study and completing the questionnaires indicated willingness to participate. All data was entered into a computer that was password protected. Data were stored in a locked office of the investigators (Dr. Sole) on the UCF campus and will be maintained for a minimum of ten years after the completion of the study.

Table 3: Study Duration/Study Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2011</td>
<td>NRC approval</td>
</tr>
<tr>
<td>November 2011</td>
<td>IRB approval (Appendices K &amp; L)</td>
</tr>
<tr>
<td></td>
<td>Submit abstract to Southern Nursing Research Society</td>
</tr>
<tr>
<td>December 2011–</td>
<td>Data collection</td>
</tr>
<tr>
<td>March 2012</td>
<td></td>
</tr>
<tr>
<td>February 2012</td>
<td>Present at the Southern Nursing Research Society 26th Annual Conference</td>
</tr>
<tr>
<td>March 2012</td>
<td>Data analysis</td>
</tr>
<tr>
<td>April 2012</td>
<td>Report and article(s) for publication</td>
</tr>
<tr>
<td></td>
<td>Submit abstracts for presentation</td>
</tr>
<tr>
<td>April 2012</td>
<td>Follow-up to Nursing Research Committee and units/departments</td>
</tr>
<tr>
<td>April 2012</td>
<td>Present results at Sigma Theta Tau annual research meeting and the UCF Showcase for Undergraduate Research</td>
</tr>
</tbody>
</table>
CHAPTER 4: FINDINGS

Upon completion of the last T-CARES course collection, data were analyzed using SPSS. Tables were developed from generated information.

Sample

Head and neck cancer patients with a new tracheostomy who met inclusion criteria were approached about availability of caregivers to participate in the study. Fifteen caregivers were approached. Three caregivers decided not to participate in the study, but attended some portion of the T-CARES course. Of the twelve caregivers that accepted invitation into the study, only one caregiver decided to participate in the control group. This participant completed the pre-test data collection only. Therefore, data were analyzed for the 11 participants that were enrolled into the experimental (T-CARES) group. Demographic data are shown in Table 4. The target sample size was not achieved as a result of a reduced census of patients needing surgical intervention for head and neck cancer.

Table 4: T-CARES Demographic Data

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>T-CARES Participants (n = 11)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relationship to patient</strong></td>
<td></td>
</tr>
<tr>
<td>Spouse</td>
<td>2</td>
</tr>
<tr>
<td>Sibling</td>
<td>4</td>
</tr>
<tr>
<td>Child</td>
<td>1</td>
</tr>
<tr>
<td>Other Family Member</td>
<td>4</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
</tr>
<tr>
<td>Male</td>
<td>4</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>31 - 69</td>
</tr>
<tr>
<td>Mean</td>
<td>50.8</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>10</td>
</tr>
<tr>
<td>Black/African American</td>
<td>1</td>
</tr>
</tbody>
</table>
### Demographic Characteristics

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>T-CARES Participants (n = 11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian</td>
<td>0</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td><strong>Hispanic</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>7</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>1</td>
</tr>
<tr>
<td>Married</td>
<td>8</td>
</tr>
<tr>
<td>Divorced</td>
<td>2</td>
</tr>
<tr>
<td>Widowed</td>
<td>0</td>
</tr>
<tr>
<td><strong>Education Level</strong></td>
<td></td>
</tr>
<tr>
<td>Some High School</td>
<td>1</td>
</tr>
<tr>
<td>High School Graduate</td>
<td>5</td>
</tr>
<tr>
<td>Technical/Trade School</td>
<td>1</td>
</tr>
<tr>
<td>Some College</td>
<td>3</td>
</tr>
<tr>
<td>College Degree or Higher</td>
<td>1</td>
</tr>
<tr>
<td><strong>Employed</strong></td>
<td></td>
</tr>
<tr>
<td>Yes, Full Time</td>
<td>7</td>
</tr>
<tr>
<td>Yes, Part Time</td>
<td>0</td>
</tr>
<tr>
<td>No or Retired</td>
<td>4</td>
</tr>
<tr>
<td><strong>Previous Health Care Experience</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>7</td>
</tr>
<tr>
<td><strong>Previous Caregiver Experience</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
</tr>
<tr>
<td><strong>Previous Experience With a Tracheostomy</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
</tr>
</tbody>
</table>

### Answers to Demographic Tool Narrative Question

An open ended question regarding their concerns about tracheostomy care was presented to the caregiver upon entry into the study in the demographic tool (Appendix H). The objective for this question was to provide insight about caregivers’ fears and/or concerns. The question
was, “What are your biggest concerns or fears about caring for your family member after discharge?” Answers to this question are presented in Table 5.

Table 5: Demographic Tool Open Ended Question Responses

<table>
<thead>
<tr>
<th>Question</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What are your biggest concerns or fears about caring for your family member after discharge?</td>
<td>“Not being able to help him in an emergency”</td>
</tr>
<tr>
<td></td>
<td>“Kinda scared”</td>
</tr>
<tr>
<td></td>
<td>“Not doing something”</td>
</tr>
<tr>
<td></td>
<td>“That I do it right the 1st time”</td>
</tr>
<tr>
<td></td>
<td>“Trach coming out or becoming blocked”</td>
</tr>
<tr>
<td></td>
<td>“doing something wrong / hurting the patient”</td>
</tr>
<tr>
<td></td>
<td>“Not doing the right things”</td>
</tr>
<tr>
<td></td>
<td>“Not to do it right”</td>
</tr>
<tr>
<td></td>
<td>“Hopefully none after training”</td>
</tr>
<tr>
<td></td>
<td>“Doing something wrong / hurting the patient”</td>
</tr>
</tbody>
</table>

Hypothesis One: Reduction in State Anxiety

T-CARES participants will demonstrate a reduction in state anxiety upon successful course completion.

STAI results were evaluated. Mean score for trait anxiety was 36.8. Mean score for state anxiety before the T-CARES intervention (pre-T-CARES) was 50.5. Mean score of state anxiety after the T-CARES intervention (post-T-CARES) was 34.3. A Related-Samples Wilcoxon Signed Rank Test was performed on the pre-T-CARES and post-T-CARES state anxiety scores. The null hypothesis was rejected with a significance of .008. Results from SPSS are included in Figure 1. Trait anxiety, pre-T-CARES state anxiety, and post-T-CARES state anxiety were also compared against normative values of 1,838 “normal adults.” The normal values for adults were provided in the STAI Manual and were based off of a heterogeneous group of 1,838 (1,387 males & 451 females) employees of the Federal Aviation Administration (Spielberger, 1983).
Values displayed in the last three columns of Table 6 represent the participants’ percentile rank against the “normal” population in their corresponding sex and age group.

![Hypothesis Test Summary](image)

Asymptotic significances are displayed. The significance level is .05.

**Figure 1: Hypothesis One Test Summary**

**Table 6: T-CARES Anxiety Compared Against the Norm**

<table>
<thead>
<tr>
<th></th>
<th>Pre-T-CARES Trait Anxiety</th>
<th>Pre-T-CARES State Anxiety</th>
<th>Post-T-CARES Trait Anxiety % Against the Norm</th>
<th>Pre-T-CARES State Anxiety % Against the Norm</th>
<th>Post-T-CARES Trait Anxiety % Against the Norm</th>
<th>Post-T-CARES State Anxiety % Against the Norm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>64</td>
<td>43</td>
<td>62</td>
<td>25</td>
<td>86%</td>
<td>99%</td>
</tr>
<tr>
<td>Male</td>
<td>63</td>
<td>28</td>
<td>42</td>
<td>26</td>
<td>86%</td>
<td>99%</td>
</tr>
<tr>
<td>Female</td>
<td>55</td>
<td>37</td>
<td>60</td>
<td>40</td>
<td>76%</td>
<td>99%</td>
</tr>
<tr>
<td>Male</td>
<td>53</td>
<td>43</td>
<td>53</td>
<td>25</td>
<td>86%</td>
<td>95%</td>
</tr>
<tr>
<td>Male</td>
<td>48</td>
<td>34</td>
<td>36</td>
<td>40</td>
<td>54%</td>
<td>58%</td>
</tr>
<tr>
<td>Female</td>
<td>47</td>
<td>33</td>
<td>41</td>
<td>27</td>
<td>50%</td>
<td>72%</td>
</tr>
<tr>
<td>Female</td>
<td>45</td>
<td>28</td>
<td>57</td>
<td>37</td>
<td>27%</td>
<td>94%</td>
</tr>
<tr>
<td>Female</td>
<td>39</td>
<td>47</td>
<td>70</td>
<td>48</td>
<td>89%</td>
<td>100%</td>
</tr>
<tr>
<td>Female</td>
<td>38</td>
<td>37</td>
<td>36</td>
<td>37</td>
<td>61%</td>
<td>59%</td>
</tr>
<tr>
<td>Female</td>
<td>31</td>
<td>33</td>
<td>38</td>
<td>20</td>
<td>47%</td>
<td>68%</td>
</tr>
</tbody>
</table>
Research Question 2: Tracheostomy Suctioning Competency

What is the effect of the T-CARES course on tracheal suction competency of caregivers who will be providing home care to patients with a new tracheostomy performed as part of head and neck cancer treatment?

Suctioning competency was evaluated by use of an observation tool (Appendix F) created by the researchers. The checklist was derived from *Cleaning your Tracheostomy Tube: Home Care Instructions* (Reising, 2009) (Appendix B). Two of the eleven T-CARES participants chose to not have their suctioning competency evaluated; therefore, suctioning competency of nine participants was evaluated. Of the 14 evaluated skills, two participants performed 9 skills correctly, two performed 10 skills correctly, two performed 11 skills correctly, two performed 12 skills correctly, and one performed 13 skills correctly. The number of caregivers that correctly and incorrectly performed each skill is presented in Table 7.

**Table 7: Tracheostomy Suctioning Individual Item Analysis**

<table>
<thead>
<tr>
<th>Tracheostomy Suctioning Skill</th>
<th>Number Performed Correctly</th>
<th>Number Performed Incorrectly</th>
<th>Percentage Performed Incorrectly</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assess need for suctioning.</td>
<td>8</td>
<td>1</td>
<td>11%</td>
</tr>
<tr>
<td>2. Wash hands.</td>
<td>5</td>
<td>4</td>
<td>44%</td>
</tr>
<tr>
<td>3. Opens kit keeping supplies sterile.</td>
<td>8</td>
<td>1</td>
<td>11%</td>
</tr>
<tr>
<td>4. Fills container with water.</td>
<td>5</td>
<td>4</td>
<td>44%</td>
</tr>
<tr>
<td>5. Puts on gloves (maintaining sterility).</td>
<td>3</td>
<td>6</td>
<td>67%</td>
</tr>
<tr>
<td>6. Attaches tube to suction catheter.</td>
<td>9</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>7. Ensures suction pressure is 80 – 120 mm/Hg.</td>
<td>7</td>
<td>2</td>
<td>22%</td>
</tr>
<tr>
<td>8. Asks patient to take two deep breaths.</td>
<td>6</td>
<td>3</td>
<td>33%</td>
</tr>
<tr>
<td>9. Keeps thumb off of port during insertion.</td>
<td>8</td>
<td>1</td>
<td>11%</td>
</tr>
<tr>
<td>10. Inserts catheter proper depth.</td>
<td>9</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>11. Covers port during removal.</td>
<td>9</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>12. Suctions for no longer than 15 seconds.</td>
<td>9</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>13. Suctions tray to clean line.</td>
<td>5</td>
<td>4</td>
<td>44%</td>
</tr>
<tr>
<td>14. Washes hands.</td>
<td>6</td>
<td>3</td>
<td>33%</td>
</tr>
</tbody>
</table>
Course Evaluation

Course Evaluations (Appendix J) were used to assess components of the course and allow for input for future development of the course. Course evaluations were anonymous and were provided upon completion of the course. Caregivers could rate each of the provide questions as “Poor,” “Average,” “Good,” or “Excellent.” The numbers of caregiver responses to each question are provided in Table 8.

Table 8: Caregivers’ Course Evaluation Responses

<table>
<thead>
<tr>
<th>Questions</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>Excellent</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>How easy was the course to understand?</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Was the content suite to your requirements?</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Were the topics covered in sufficient detail?</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Overall quality of training materials?</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Overall rating of instructor?</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Overall rating of the course?</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Would you recommend this course to others?</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>9</td>
<td>0</td>
</tr>
</tbody>
</table>

Narrative Questions

Three open ended questions regarding future improvements to the course were presented to the caregivers after the T-CARES intervention in the Course Evaluations (Appendix J). Responses to the three questions are listed in Table 9.

Table 9: Course Evaluation Open Ended Question Responses

<table>
<thead>
<tr>
<th>Questions</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What, if anything, would you have improved on the course?</td>
<td>“Maybe a later date”</td>
</tr>
<tr>
<td></td>
<td>“Checking pressure on the machine first, before connecting tubes”</td>
</tr>
<tr>
<td></td>
<td>“Bilingual”</td>
</tr>
<tr>
<td></td>
<td>“To be bilingual”</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>2. What other types of training do you feel should be made available?</td>
<td>“Don’t know as of now”</td>
</tr>
<tr>
<td></td>
<td>“feeding tubes”</td>
</tr>
<tr>
<td></td>
<td>“CPR? (In case he can’t breathe for some reason)”</td>
</tr>
<tr>
<td></td>
<td>“How to control the patient”</td>
</tr>
<tr>
<td></td>
<td>“Same course for other treatment”</td>
</tr>
<tr>
<td></td>
<td>“CPR training/First Aid or what to do in case of patient not breathing”</td>
</tr>
<tr>
<td></td>
<td>“Ways to keep sterile”</td>
</tr>
<tr>
<td>3. Is there anything else you would like to know?</td>
<td>“Just thanks for the education”</td>
</tr>
<tr>
<td></td>
<td>“I think I got it covered”</td>
</tr>
<tr>
<td></td>
<td>“No”</td>
</tr>
<tr>
<td></td>
<td>“No”</td>
</tr>
<tr>
<td></td>
<td>“Any person or number to call for questions”</td>
</tr>
</tbody>
</table>
CHAPTER 5: DISCUSSION

Hypothesis One: Reduction in State Anxiety

T-CARES participants will demonstrate a reduction in state anxiety upon successful course completion.

The null hypothesis was rejected with a .008 significance of using the Related-Samples Wilcoxon Signed Rank Test. Participants demonstrated a 16.2 point reduction in mean state anxiety score from 50.5 to 34.3 after the T-CARES intervention.

State anxiety was also compared against a defined normal. This proved to be a useful benchmark due to the absence of a control group. The results represent the percentage of the “normal” population that scored lower than the participant. Spielberger (1983) states individuals with a score > 90% may have anxiety that is paralyzing their ability to act. For this discussion, participant scores > 90% will be referred to as “highly anxious,” scores from 50% - 90% as “above the norm,” and scores < 50% as “below the norm.” Before the T-CARES intervention six participants were identified as “highly anxious” and five were identified as “above the norm.” After the T-CARES intervention one participant was still “highly anxious,” five were “above the norm,” and five were “below the norm.” Within this experimental group five participants demonstrated a striking (more than 50 percentage points) reduction in state anxiety after the T-CARES course. Of these five, two demonstrated extreme reductions in state anxiety. One participant’s state anxiety level plummeted from the 99% to the 21% and another from the 95% to the 21%. These results support the continued use and development of the T-CARES intervention for the reduction of caregiver state anxiety.
Research Question Two: Tracheostomy Suctioning Competency

What is the effect of the T-CARES course on tracheal suction competency of caregivers who will be providing home care to patients with a new tracheostomy performed as part of head and neck cancer treatment?

The researcher’s assumption that participants had no prior experience in suctioning a tracheostomy was supported through oral questioning and observation of the caregivers. While many participants had observed suctioning while in the patient room, none had witnessed the operation of portable suction equipment that would be used by them at home. Donning gloves (while maintaining sterility), was the one skill that more than 50% of the participants performed incorrectly. This was also the most difficult item. This skill requires planning and manual dexterity. Participants broke sterility multiple ways. Some of the participants picked up the glove by the outside, touched their ungloved hand with their gloved hand, and touched unsterile items with the sterile hand. Some participants identified the break in sterility immediately after it happened and others were remediated after the fact. Hand washing before and after the procedure was the next highest missed skill. Participants were remediated and were able to convey the importance of proper hand hygiene. Filling the container and clearing the line with distilled water were the next highest missed skills. Remediation was performed. The complexity of evaluated skills supported the evaluation of tracheostomy suctioning. A benefit of the group environment was peer assessment. This reinforced the skill in both the individual being assessed and the observers. An evaluation of tracheostomy suctioning on individuals that have not attended T-CARES would provide for a control.
Responses to Narrative Questions

Participants were able to provide narrative responses to four open ended questions.

The responses to the question “What are your biggest concerns or fears about caring for your family member after discharge?” supported the need for T-CARES. Most of the caregivers were concerned about not knowing what to do or doing something wrong.

These concerns were reiterated by the participants during class discussions. Fear of accidental decannulation was another fear expressed by all participants during the course. Most patients are discharged before being able to witness a change of the tracheostomy tube. After practicing removal and reinsertion of the tracheostomy tube on the low cost anatomical model, participants expressed that this was still a concern, but that they felt more prepared.

Narrative questions on the course evaluations served to provide the researcher with data regarding areas for improvement and future development of the T-CARES course. A request for “feeding tube” training was a written suggestion by one of the participants and was also requested by multiple participants during the course. After speaking with the unit CNL, the researcher was able to verify that many of the patients being discharged with a new tracheostomy also have gastrostomy tube. The researcher believes the future addition of a feeding tube component would be worthwhile addition to the T-CARES course. The researcher agrees with the caregivers’ requests for CPR training, but believes that it should not be a component of T-CARES. A request was also made by multiple participants for a bilingual course. The wife of one patient was not able to enroll in the study due to the fact that she did not speak English. She did attend for a portion of the class and translation was provided by a family member enrolled in
the study. Many participants expressed gratitude for the creation of a course that fulfilled this unmet need.

**Course Evaluations**

Course evaluations were positive overall. This tool served to provide participants with a place to rate the course/instructor, provide comments, and express concerns. Modification of this form to allow for participants to rate specific components of the course would identify weaknesses and strengths of the course.

**Limitations of the Study**

Limitations are identified for the study. Time constraints, limited number of participants, absence of a control group, limited number of instructors, unfamiliarity with patient history, and language.

**Time Constraints**

Time constraint was a distinct limitation of this study. The researcher had to identify specific need, research the population, develop the course and low-cost anatomical models, receive IRB approval, and collect/analyze data in less than seven months. This timeline was significantly impacted by a two-month delay in receiving IRB approval.

**Limited Number of Participants**

The hospital had identified that approximately one to two qualified patients a week had historically been available. Unfortunately, during the time this study took place we were only able to identify five patients who required surgical treatment for head and neck cancer. We had
planned for recruiting up to 40 caregivers. The actual number of participants was less than one-quarter of the anticipated qualified caregivers.

Absence of a Control Group

To make T-CARES available to this limited number of caregivers we cast aside the original plan to hold courses only once a week and made courses available based on caregiver availability. This switch in priority eliminated the possibility of a control group. Without a control group, the ability to compare to a similar population was lost. Further study could be performed on caregivers that have not attended T-CARES and a comparison could be made.

Number of Trained Instructors

Upon completion of this study only one person had instructed the T-CARES course. Two of the other researchers have sat in on courses and were available to be instructors if needed.

Unfamiliarity with Patient History

The research had limited knowledge of the patients’ history. During discussion the instructor was unable to answer caregivers’ questions pertaining to their particular situation. The instructor was unable to provide education on issues regarding patients’ outlook and specialized needs. When the instructor was unable to adequately answer questions he was able to contact the unit’s Clinical Nurse Leader. Future instructors from the unit that have been able to communicate with patients’ nurses, physicians, and therapist would allow for a better understanding of the caregivers’ needs.
Language

Spanish is a prominent language in the community surrounding the hospital. All materials and products for this course were developed in English. The instructor only spoke English. The availability of a Spanish speaking course would prove vital in supporting the more than 250,000 Spanish speakers of Orange county of which more than 94,000 reported to speak English less than “very well” in 2010 (U.S. Census Bureau, 2011).

Implications for Further Research

During the literature review, a need for research was identified in the area of caregivers of adult head and neck cancer patients with a tracheostomy. This deficit continued to exist when broadening the scope of the search to caregivers of an adult with a tracheostomy. Further research into identifying the needs of this population is crucial. As the care for this group continues to shift out of the hospital the caregiver population will continue to grow. The research conducted on the outcomes of tracheostomy care educational interventions was also lacking. A literature search located many bundles and tracheostomy care packages, but limited studies on their effectiveness were noted.

Continued research on this topic with inclusion of others adults with a new tracheostomy may prove promising. Serial assessment of caregiver state anxiety and suction competency after discharge may provide further evaluation of longstanding effects of T-CARES and may identify areas where the caregiver needs further instruction or continued support.
Clinical Implications

The T-CARES course was an approximately one hour intervention. One instructor could instruct up to six caregivers. Making this course available to the caregivers of other adults with a tracheostomy could increase course throughput. These aspects would make for an efficient use of hospital resources. The education provided to caregivers would develop a solid knowledge base for nurses and respiratory therapist to build upon. Making T-CARES available to caregivers before a tracheotomy is performed may better prepare them for the upcoming procedure and allow them to provide supervised care in the hospital sooner. T-CARES could also be made available to tracheostomy patients. Continued development and refinement could allow this course to reach a multitude of populations in the hospital.

Summary

State anxiety for all of the caregivers was above the norm before the T-CARES intervention. This supports researcher’s belief that there is a substantial elevation in the state anxiety of this population. This research supported the hypothesis that the T-CARES course would be successful in reducing state anxiety. The T-CARES course also had a positive impact on tracheostomy suctioning competency, though without a control group it is difficult to quantify the affect. At the beginning of each class it was easy to observe how overwhelmed these individuals felt; but participants began to relax as they shared with each other and soon realized they were not alone.
APPENDICES
Appendix A: Critical Check: Tracheostomy Patient Teaching Plan
Critical Check: Tracheostomy Patient Teaching Plan

ORHS Critical Checks

PROBLEM: Tracheostomy Patient Teaching Plan

PURPOSE: To serve as a resource for nurses planning discharge patients with Head & Neck surgery. (For further information, see P & P #3445, and Trach C.A.I. on SWIFT e-learning)

Day of surgery:
☐ Orient patient/significant others to the environment
☐ Evaluate patient’s ability to communicate with writing and providing writing utensils
☐ If patient unable to communicate in writing, provide picture board
☐ Explain each procedure (suctioning, tracheostomy care, wound/drain care) as it is performed
☐ Teach/reinforce coughing and deep breathing

Post-op Day 1:
☐ Assess patient/family learning style, readiness to learn
☐ After assessing readiness to learn, give patient/family written instructions for tracheostomy care, wound care, drain care.
☐ Determine the primary care giver for the patient upon discharge
☐ If possible, discuss teaching plan with patient and primary caregiver and determine care giver’s ability to be present for learning opportunities.
☐ Have pt/family watch video “Tracheostomy care in the Home Setting”
☐ With family/significant other observing, perform tracheostomy care, explaining each step
☐ With family/significant other observing, perform wound/drain care, explaining each step

Post-op Day 2:
☐ Discuss learning needs with patient/family – when possible, set time for learning experience
☐ Demonstrate wound/drain care
☐ Have patient/family do return demonstration of wound/drain care
☐ Demonstrate tracheostomy care, including suctioning
☐ Discuss tracheostomy care with patient/family, answer questions, review key points
☐ Have patient and/or family perform tracheostomy care with supervision
☐ Consult Home Care Coordinator for home care needs, supplies, etc

Post-op Day 3:
☐ Assess patient/family knowledge and comprehension of wound/drain care
☐ Assess patient/family knowledge and comprehension of tracheostomy care
☐ Have patient and/or family perform tracheostomy care, including suctioning
☐ Have patient/family perform wound/drain care
☐ Discuss any problems or concerns
☐ Have patient and/or family perform tracheostomy care, throughout the day

Post-op Day 4:
☐ Verify that all teaching is complete
☐ Complete any return demonstration needed
☐ Discharge home

DOCUMENTATION: Medical Record, computer, Patient Education form.

GOAL: To plan for discharge care of patients with head and neck surgery.

This document serves only as a guide to care of the Adult patient. May require individualization. Please consult with physician, P&P, pharmacist, and other references for more information
Appendix B: Cleaning Your Tracheostomy Tube
Cleaning Your Tracheostomy Tube

You are being sent home with a tracheostomy tube. It helps maintain the size and shape of the opening in your neck called a stoma. It is important to keep the obturator and extra tracheostomy tube where they can be easily reached.

**Supplies**
- Tracheostomy/suction cleaning kit
- Hydrogen peroxide
- Sterile or distilled water
- Cloth, towel or gauze pad to cover table surface
- Disposable gloves (provided in kit)
- Suction kit

**How to deep suction**
- If you are going to do both the suctioning and cleaning at the same time, it is best to do the suctioning first; then you will be able to clean up any secretions.
- Open the tracheostomy cleaning kit as described below and use the suction items provided.
- Gather the suction kit. There may be a suction catheter provided in the cleaning kit mentioned below, if so, open the kit as described and use the suction equipment before cleaning.
- If you are only doing the suctioning, gather the suction kit.
- Wash your hands with warm, soapy water and dry well.
- Open kit.
- Take out the gloves provided, open them on the table surface and dump the catheter from the plastic container onto the gloves surface.
- Fill the plastic container with water. This is used to clean the catheter in between deep suctioning.
- Put on gloves.
- Attach catheter to suction tubing.
- Have the patient take two deep breaths.
- Place the catheter tip into the trachea far enough for the patient to start coughing.
- Put thumb over the suction hole for 2 to 3 second intervals as you pull the catheter back out of the trachea.
- Let the patient take two deep breaths before suctioning a second time.
- Two times should be enough to get up secretions.
- It is expected and encouraged that the patient coughs after suctioning – this will keep the trachea clear.
- Wash hands thoroughly with warm soapy water and dry well.
How to clean

- Gather the supplies.
- Wash your hands thoroughly with soap and water and dry well.
- Cover table surface with cloth provided in tracheostomy cleaning kit.
- Empty contents of kit onto the cloth.
- Pour hydrogen peroxide into the larger section of the kit and mix with water (½ to ½).
- Fill second section with water (this is for rinsing tracheostomy items).
- Remove inner cannula by gently turning.
- Place the inner cannula tube into the larger section with the saline/peroxide mixture.
- Using the brush provided in the kit, clean the tube thoroughly inside and out until there is no mucus on the tube.
- Rinse the tube in the smaller section with water.
- Shake off excess moisture.
- Gently replace the inner cannula into the tracheostomy tube that is still in your neck. Twist to tighten. The green dots should line up. You will hear and feel a click.
- Throw away the gloves and the used portion of the cleaning kit.
- Clean any equipment that can be used again so it is ready for the next time.
- Always wash your hands thoroughly with warm soapy water after every procedure.
Appendix C: Reinsertion of Tracheostomy Tube
Reinsertion of Tracheostomy Tube

1. If trach becomes dislodged or falls out, follow these instructions for reinsertion.

2. If patient has trouble breathing, CALL 9-1-1 FIRST. If airway is stable, use replacement trach supplies.

3. Insert the obturator into the tracheostomy tube. You will know the obturator is in place when you see the round tip protrude out of the cannula.

4. Hold the obturator in place with your thumb and grasp the outer cannula under the faceplate with the index and middle fingers, and insert the new tube following the track of the dislodged tube.

5. Guide tube into trachea gently with tip toward your toes. If you have difficulty inserting the cannula, lift your chin up to better align the stoma with the hole in the trachea.
6. Immediately remove the obturator. This restores airflow through trach tube.

7. Reinsert the inner cannula.

8. Secure the tube with Velcro trach ties.

9. If airway is stable but you are unable to reinsert the trach tube, take replacement items to nearest Emergency Department.

10. If you need to call 9-1-1, try inserting a suction catheter into trach opening to maintain some airway and keep incision open until expert help arrives.

If you would like more information or have questions, please contact The Head & Neck Center at MD Anderson Cancer Center Orlando, 321.841.7171.

Revised materials from:
The Ohio State University. Reinsertion of a Tracheostomy Tube.

Retrieved from:
Appendix D: Outline of T-CARES Video
Outline of T-CARES Video

1. An introduction to airway anatomy: trachea, esophagus, vocal chords, phonation, swallowing
   1.1. Tracheostomy bypasses the patients mouth/nose and allows breathing directly into trachea
   1.2. Since mouth and nose is now bypassed the air is no longer filtered or humidified
   1.3. Why speaking is not possible without covering the tube (or speaking valve)
   1.4. How care must be taken during bathing
   1.5. Distancing themselves from airway irritants such as smoke and powders

2. Components of a tracheostomy tube
   2.1. Outer cannula (including size and type)
   2.2. Inner cannula
   2.3. Obturator/guide

3. Tracheostomy suctioning
   3.1. Developed from Cleaning your tracheostomy tube (Appendix B).

4. Stoma care (Stoma care covered in MDA video; video recommends cleaning stoma with 3% hydrogen peroxide)
   4.1. Gather required supplies (kit or clean bowl w/soapy water, cotton swabs, two clean cloths, and fenestrated [cut] gauze
   4.2. Wash hands with soap and water
   4.3. Put on gloves (if desired)
   4.4. Remove old gauze
   4.5. Clean area around stoma starting nearest to the stoma then moving out
   4.6. Assess the area for any redness or signs of irritation
   4.7. Dry the area
   4.8. Replace gauze
   4.9. Wash hands

5. Changing the ties securing the tracheostomy (MDA video, altered to instruct about use of Velcro ties)
   5.1. Gather new ties or commercial tracheostomy holder
   5.2. Have patient securely hold tracheostomy to neck
   5.3. Remove old ties/holder
   5.4. Clean neck with soap and water
   5.5. Dry neck
   5.6. Replace ties/holder
   5.7. Ensure 1 finger can fit in between ties/holder and neck

6. Cleaning inner cannula
   6.1. Developed from Cleaning your tracheostomy tube (Appendix B).

7. Prepare for the unexpected

8. Reinsertion of tracheostomy tube after accidental decannulation
   8.1. Developed from Reinsertion of tracheostomy tube (Appendix C).

9. What to do if patient develops a mucous plug
   9.1. First remove inner cannula
   9.2. Assess for a change in breathing
   9.3. If breathing has improved replace inner cannula with a new one
   9.4. If not attempt to suction
   9.5. If no improvement call 911 and monitor status

10. If you notice bleeding or signs of infection around the stoma contact your primary care provider (MDA Video)

11. Caregiver must take care of themselves also.
Appendix E: Critical Check: T-CARES Teaching Plan
Critical Check: T-CARES Teaching Plan

Critical Checks During T-CARES STUDY

PROBLEM: Tracheostomy Patient Teaching Plan during T-CARES Study

PURPOSE: To serve as a resource for nurses planning discharge patients with Head & Neck surgery whose caregivers will be asked to participate in T-CARES Study. (For further information see P & P 63445, Trach C.A.I on SWIFT e-learning, and T-CARES Study Folder)

Day of surgery:
☐ Orient patient/significant others to the environment
☐ Evaluate patient’s ability to communicate with writing and providing writing utensils
☐ If patient unable to communicate in writing, provide picture board
☐ Explain each procedure (suctioning, tracheostomy care, wound/drain care) as it is performed
☐ Teach/reinforce coughing and deep breathing

Post-op Day 1:
☐ Assess patient/family learning style, readiness to learn.
☐ After assessing readiness to learn, give patient/family written instructions for tracheostomy care, wound care, drain care.
☐ Determine the primary care giver for the patient upon discharge
☐ If possible, discuss teaching plan with patient and primary caregiver and determine care giver’s ability to be present for learning opportunities.
☐ Provide caregiver(s) with T-CARES flyer.
☐ Fill out T-CARES subject log for each caregiver.
☐ If eligible provide each caregiver with a T-CARES bundle.
☐ Have caregiver(s) complete demographics tool.
☐ Have caregiver(s) complete State-Trait Anxiety Inventory Form.
☐ Schedule caregiver(s) for T-CARES course; if caregiver is willing. (Post-op Day 1–4)
☐ Have pt/family watch video “Tracheostomy care in the Home Setting”
☐ With family/significant other observing, perform tracheostomy care, explaining each step
☐ With family/significant other observing, perform wound/drain care, explaining each step

Post-op Day 2:
☐ Discuss learning needs with patient/family – when possible, set time for learning experience
☐ Demonstrate wound/drain care
☐ Have patient/family do return demonstration of wound/drain care
☐ Demonstrate tracheostomy care, including suctioning
☐ Discuss tracheostomy care with patient/family, answer questions, review key points
☐ Have patient and/or family perform tracheostomy care with supervision
☐ Consult Home Care Coordinator for home care needs, supplies, etc

Post-op Day 3:
☐ Assess patient/family knowledge and comprehension of wound/drain care
☐ Assess patient/family knowledge and comprehension of tracheostomy care
☐ Have patient and/or family perform tracheostomy care, including suctioning
☐ Have patient/family perform wound/drain care
☐ Discuss any problems or concerns
☐ Have patient and/or family perform tracheostomy care, throughout the day

Post-op Day 4:
☐ Verify that all teaching is complete
☐ Complete any return demonstration needed
☐ Have caregiver(s) enrolled in T-CARES study complete State portion of State-Trait Anxiety Inventory Form
☐ Discharge home

DOCUMENTATION: Medical Record, computer, Patient Education form, T-CARES subject log.

GOAL: To plan for discharge care of patients with head and neck surgery and encourage participation in T-CARES study.

This document serves only as a guide to care of the Adult patient. May require individualization. Please consult with physician, P&P, pharmacist, and other references for more information.
Appendix F: Suctioning Skill Competency Checklist
Suctioning Skill Competency Checklist

Subject ID:

Date:

<table>
<thead>
<tr>
<th>Skills</th>
<th>Y</th>
<th>N</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assess need for suctioning.</td>
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<td>2. Wash hands.</td>
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<tr>
<td>3. Opens kit keeping supplies sterile.</td>
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<td>4. Fills container with water.</td>
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<tr>
<td>5. Puts on gloves (maintaining sterility).</td>
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<tr>
<td>6. Attaches tube to suction catheter</td>
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<tr>
<td>7. Ensures suction pressure is 80-120 mm/Hg</td>
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<tr>
<td>8. Asks patient to take two deep breaths.</td>
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<tr>
<td>10. Inserts catheter to proper depth.</td>
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<tr>
<td>12. Suctions for no longer than 15 seconds.</td>
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<td>13. Suctions tray to clean line.</td>
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<tr>
<td>14. Washes hands.</td>
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Totals:

Total items correctly done:

Remediation if not 100% (y/n)
Appendix G: Invitation to Participate in a Research Study
Invitation to Participate in a Research Study

Eligibility

- Are you going to be providing care at home (caregiver) for a patient who has just had a tracheostomy?
- Are you age 18 or older?
- Can you read and write English?

If you answered yes to the questions, we invite you to participate in a study to see how nervous or stressed caregivers are before and after they are taught to care for a patient with a tracheostomy.

What is expected?

- Filling out two short surveys (one before teaching is begun and one before your family member is discharged)
- Option of attending a class on tracheostomy care (T-CARES). The next class will be held _______________

We need your participation whether you attend the optional class or not.

If interested, please let your nurse know so that one of the researchers can meet with you. Or you may contact one of the investigators, Ellen Reising. She can be reached at __________

Investigators

William Crosby, Honors in the Major Nursing Student, UCF
Mary Lou Sole, PhD, RN, Supervising Professor, UCF
Ellen Reising, MSN, RN, Clinical Nurse Leader, Orlando Health
Victoria Loerzel, PhD, RN, Assistant Professor, UCF
Appendix H: Demographics Tool
T-CARES Demographic Tool

ID Code: _____ _____ _____ _____
  First four letters of mother’s maiden name  Your birth month  Your birth day

Your relationship to patient: __________________________

Education:  Up to 8th grade
  Some high school
  High school graduate
  Technical/Trade school
  Some college
  College degree or higher

Employed:  Yes, full-time
  Yes, part-time
  No or retired

What type of work do you do? __________________________

Do you have any previous work experience in healthcare? Yes  No

If yes, describe: __________________________________

Do you have any previous experience in caring for an ill or injured family member? Yes  No

If yes, describe: __________________________________

Age:  ______

Race:  White/Caucasian
  Black/African American
  Asian
  Pacific Islander
  Other: __________________________

Hispanic:  Yes
  No

Marital Status: Single
  Married
  Divorced
  Widowed

Prior to today, what is your experience regarding the care of a person with a tracheostomy:

________________________________________________________________________

What are your biggest concerns or fears about caring for your family member after discharge?

________________________________________________________________________

When your family member goes home, will you have assistance and/or support from someone who has experience caring for a patient with a tracheostomy?  Y  N  If yes, what type of support will you receive?

________________________________________________________________________
Appendix I: Image of Low-Cost Suctioning Mannequin
Image of Low-Cost Suctioning Mannequin

Figure 1. Low cost model anterior view
Figure 2. Low cost model lateral view.
Appendix J: Course Evaluation
Course Evaluation

<table>
<thead>
<tr>
<th>Course: T-CARES</th>
<th>Instructor:</th>
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</thead>
<tbody>
<tr>
<td>Training Location:</td>
<td>Date:</td>
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We welcome your comments about the time you have spent training with us. Please complete the following details so that we can continue to offer the best service possible. Pass them to your instructor at the end of the course.

Please place a check mark in the appropriate box for your answer.

<table>
<thead>
<tr>
<th><strong>Course overall:</strong></th>
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<tr>
<td>How easy was the course to understand?</td>
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<td>Was the content suited to your requirements?</td>
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<td>Were the topics covered in sufficient detail?</td>
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<tr>
<td>Overall quality of training materials?</td>
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<tr>
<td>Overall rating of instructor?</td>
</tr>
<tr>
<td>Overall rating of the course?</td>
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<tr>
<td>Would you recommend this course to others?</td>
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<table>
<thead>
<tr>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>Excellent</th>
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**Summary Comments**

What, if anything, would you have improved on the course?

________________________________________________________________________

________________________________________________________________________

What other types of training do you feel should be made available?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Is there anything else you would like to know?

________________________________________________________________________

________________________________________________________________________
November 9, 2011

Mary Lou Sole, PhD
UCF College of Nursing
12201 Research Parkway #465
Orlando FL 32826-2210

Dear Dr. Sole;

Action has been taken regarding the following study:

Our Study #: 11.067.10
Protocol Title: Tracheostomy Care Anxiety Relief through Education and Support (T-CARES).
Study Documents/Forms being submitted: Expedited Review Request Form; Protocol (Version
dated 10/7/11); Informed Consent (dated 10/27/11) Study Recruitment Flyer.
Reason on Agenda: Initial submission
Action Taken: Expedited approval performed by IRB chair on 11/9/11
Expiration Date: 11/8/12
Condition 1:

If you have any questions regarding the action taken, please contact the Oncology IRB office at
(321)843-1412.

Respectfully yours,

[Signature]

David M. Flory, PhD
Chairman, Oncology IRB
Appendix L: UCF IRB Approval
UCF IRB Approval

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-2246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: UCF Institutional Review Board #1
FWA0000351, IRB00061138

To: William W. Crosby and Mary L. Sole

Date: November 16, 2011

Dear Researcher:

On November 16, 2011, the IRB approved the following human participant research until 11/15/2012 inclusive:

- **Type of Review:** UCF Initial Review Submission Form
- **Expedited Review Category:** #7
- **Project Title:** An Evaluation of Tracheostomy Care Anxiety Relief through Education and Support (T-CARES): A Pilot Study
- **Investigator:** William W. Crosby
- **IRB Number:** SBE-11-08017
- **Funding Agency:** Office of Undergraduate Research (OUR)
- **Grant Title:** N/A
- **Research ID:** N/A

The Continuing Review Application must be submitted 30 days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form cannot be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu.

If continuing review approval is not granted before the expiration date of 11/15/2012, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in IRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., CF IRB Chair, this letter is signed by:

Signature applied by Janice Turchin on 11/16/2011 01:47:10 PM EST

IRB Coordinator
Appendix M: Informed Consent
Informed Consent

Institutional Review Board
Informed Consent Form

IRB #: 11.067.10 TITLE: 11.0673 – Tracheostomy Care Anxiety Relief through Education and Support (T-CARES)

Participant’s Name: ___________________________ Date: ______

Sponsors: The University of Central Florida, Office of Research & Commercialization, and MD Anderson Cancer Center Orlando

Principal Investigators:
William Crosby, Honors in the Major Nursing Student, University of Central Florida
Mary Lou Sole, PhD, RN, CCNS, FAAN, Supervising Professor, University of Central Florida

Sub-Investigators:
Ellen Reising, MSN, RN, OCN®, CNL
Victoria Loerzel, PhD, RN, OCN®

MD Anderson Cancer Center Orlando
1400 South Orange Ave, MP# 780
Orlando, FL 32806

INFORMED CONSENT FOR CLINICAL RESEARCH

You are being asked to take part in a clinical research study at MD Anderson Cancer Center Orlando (MD Anderson-Orlando) because you will be a caregiver of a head and neck cancer patient who is being discharged home with a new breathing tube in the neck called a tracheostomy (tra-kee-OS-to-mee) or trach (rhymes with brake).

Research studies include only people who choose to take part. This consent form explains why the study is being done, what will happen during the study, and what your role will be if you choose to take part. This form also describes the possible risks of taking part in the study. After reviewing this information, you will be asked if you want to take part. Feel free to talk to your friends and loved ones, your personal doctor, and the study doctor before you decide. You will be asked to sign this form only if you choose to take part.

Version Date: 10/27/11
1. **PURPOSE OF THE STUDY**

The overall goals of this study are to:

- Teach caregivers of at-home patients with tracheostomies the proper care and maintenance of the trach.
- Reduce caregiver anxiety about the care and maintenance of the trach.

We plan to do this by:

- Comparing 2 ways of teaching caregivers how to manage the at-home patient with a trach.
- Assessing whether caregiver tracheostomy suctioning skill is improved after the T-CARES class.

2. **EXPERIMENTAL DRUG**

Does not apply.

3. **LENGTH OF PARTICIPATION**

You will be asked to be in the study from the time you complete the first survey until you complete the second survey before discharge of the patient. This will be about 1 to 3 days.

4. **NUMBER OF PARTICIPANTS**

There will be about 30 participants in this study at MD Anderson-Orlando.

5. **STUDY PROCEDURES**

The study will include participants in 2 groups:

One Group will receive standard instruction on managing the trach by the nursing unit staff (control group) and the other group that chooses to attend a formal class on managing the trach (study group). Based on your schedule, you will decide which method of instruction in which you are able to participate.

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If you are in the control group, you will be asked to complete a short survey about your stress and anxiety before you receive instruction from the nursing unit staff. Instruction includes watching a video, receiving written materials, and time for questions and answers. It will take about 15 minutes to complete the survey. You will be asked to complete a shorter version of the survey again before the patient is discharged from MD Anderson-Orlando.

If you are in the study group, you will be enrolled in the T-CARES group class, and attendance is voluntary. Group classes will be held about 1 time a week during evening hours and will last about 1 hour. Session times will be posted on the unit. The course will include an instructor-led presentation, demonstration of skills, practice, and return demonstration. Return demonstration means you will show what you just learned.

Written materials will be provided and time will be available for question and answers. You will be asked to complete a short survey about your stress and anxiety before the class, which will take about 15 minutes. After the class, you will be asked to practice and demonstrate your skills in suctioning the trach on the mannequin, and we will observe and rate your skills. You will be asked to complete a shorter version of the stress/anxiety survey before the patient is discharged from MD Anderson-Orlando.

6. RISKS/SIDE EFFECTS

There are no known risks to you for participating in this research, other than the time to complete the surveys and attend the instruction.

7. RESEARCH RELATED INJURY

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Mary Lou Sole at 407-823-5133 or 407-823-2744 or mary.sole@ucf.edu.
8. INSTITUTIONAL REVIEW BOARD

An institutional review board (IRB) is a diverse group of scientists and non-scientists who assure in advance and by periodic review that appropriate steps are taken to protect the rights, safety, and well-being of all research participants. The IRB does this by reviewing research protocols and related materials.

For more information about your rights as a research participant, you may call the Institutional Review Board manager at 321 843-1412 or 800 648-3818 ext. 8431412.

You may also call the IRB at the University of Central Florida, Office of Research & Commercialization at 407 823-2901. You may talk to them for any of the following reasons:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

9. BENEFIT

There are no known direct benefits of participating in the study. You may find that participating in the study reduces your anxiety about providing trach care for the at-home patient.

10. ALTERNATE PROCEDURES OR TREATMENT

Your other option is not to take part in this study. You may receive the standard instruction on how to do trach care without being in this study.

11. VOLUNTARY PARTICIPATION

Your choice to participate in the study is voluntary. You do not have to take part in this study if you do not want to. The quality of patient care will not change if you choose not to be part of this study, or if you stop being part of the study. Your refusal to participate at any time will not be held against you.
12. **STOPPING THE STUDY EARLY**

Does not apply.

13. **NEW FINDINGS**

Does not apply.

14. **COSTS**

There is no cost to you for taking part in this study.

15. **PAYMENT**

You will not be paid to take part in this study. If any new ways to teach caregivers about trach care or any patents are developed because of this study, there are no plans to pay you for them.

16. **FINANCIAL DISCLOSURE**

Does not apply.

17a. **CONFIDENTIALITY OF RECORDS**

You will be issued an identification number for the study. We will not be recording your name or that of the patient. Data from all participants will be used to report study findings. No study participant or patient will be personally identified.

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17b. AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Federal Privacy Regulations, including the Health Insurance Portability and Accountability Act (HIPAA), provide safeguards for privacy and security of health information that may identify you. You will be given a copy of the Notice of Privacy Practices, which describes the MD Anderson-Orlando privacy practices. In certain circumstances, PHI about you may be used or disclosed for research purposes.

What PHI Is Collected in the Study?
Your PHI is information that could be used to find out who you are. It includes information in your existing medical records and information created or collected during the study.

The following PHI may be collected during your involvement with this study:

- Birth date
- Social Security number
- Race and ethnic background
- E-mail address
- Personal medical history
- Current and past drugs, therapies, surgeries, procedures
- Current and past hospitalizations
- Information from current and past physical exams
- Results of tests noted in the "Procedure" section of the informed consent

Who May Use or Disclose Your PHI?
The following individuals/organizations may use or disclose your PHI for this study:

- Study doctor and the study doctor’s team
- MD Anderson-Orlando Institutional Review Board
- Orlando Health, Inc.

To Whom May Your PHI Be Disclosed?
As part of the study, the study doctor and the investigator’s team may disclose the results of study related tests and procedures that may identify you to the following:

- Researchers at UCF and their representatives
- MD Anderson-Orlando Institutional Review Board
- Orlando Health, Inc.

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18. SIGNATURES

My signature means that I consent and authorize William Crosby and his assistants, including the University of Central Florida, MD Anderson-Orlando, Orlando Health, Inc., their employees, and their agents to enroll me in this study.

I AM MAKING A DECISION TO TAKE PART IN THIS STUDY. I HAVE READ ALL OF THE ABOVE, ASKED QUESTIONS, RECEIVED ANSWERS ABOUT AREAS I DID NOT UNDERSTAND, AND WILLINGLY GIVE MY CONSENT TO TAKE PART IN THIS STUDY. UPON SIGNING THIS FORM, I WILL GET A COPY OF THIS CONSENT.

__________________________
Print Name of Participant or Legal Representative

__________________________
Signature of Participant or Legal Representative

__________________________
Date / Time

For signature by legal representative, please describe below the authority to act on behalf of the participant:

__________________________
Signature of Witness

__________________________
Date

I have defined and fully explained the study as described in this consent form to the participant.

__________________________
Print Name of Study Doctor/Investigator

__________________________
Signature of Study Doctor/Investigator

__________________________
Date

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I have verbally interpreted the informed consent process into ________ for this participant. (Name of Language)

Print Name of Interpreter

Signature of Interpreter Date

Address and Phone Number of Interpreter
REFERENCES


U.S. Census Bureau (2011). Language spoken at home by ability to speak English for the population 5 years and over. Retrieved 1 March 2012 from http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_10_1YR_B16001&prodType=table

