


MORRISTOWN MEDICAL CENTER / ATLANTIC HEALTH SYSTEM

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Session C821

Common Scents: Using a Placebo-Controlled Research Study to Drive Practice

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Disclosure

- There are no disclosures related to this study.
- Beekley Medical™ supplied the aromatherapy tabs. Beekley Medical had no input to the design, conduct or outcome of the study.

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Atlantic Health System



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Carol G. Simon Cancer Center



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Morristown Medical Center Morristown, NJ




6,612 employees: 1800 nurses
1,588 physicians
198 medical residents
687 licensed beds
40,828 admissions
4,317 births
86,385 emergency visits
419,118 outpatient visits
2,066 breast biopsies


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ANCC Magnet Recognition® at Morristown Medical Center



In 1983, MMC was one of 41 original hospitals in the US recognized by the American Academy of Nursing as a top hospital for recruiting and retaining well qualified nurses, a precursor to the Magnet designation.



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Research Team



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Carol W. and Julius A. Rippel Breast Center



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Research Process

- Research Question
- Putting team together
- PICO: Defining the population and intervention to be studied
- Literature Search
- Incorporation of the Nurse Theorist
- Design: objectives, comparison, variables, statistical analyses, sample size
- Recruitment Plan
- Writing the Protocol
 - Develop Forms
 - Create Consent
 - Brochure for Recruitment
- Resources
- IRB Approval
- Initiation
- Statistical consult
- Findings
- Dissemination


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Background

Approximately 232,340 women will be diagnosed with breast cancer in the USA this year.

Breast biopsy is the standard diagnostic procedure for diagnosis.

Biopsies are anxiety provoking for patients!




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Aromatherapy

- For centuries aromatherapy has been used to reduce anxiety.
- This study uses a unique deliver system to measure the reduction of anxiety using aromatherapy.



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Common Scents: Anticipated Aromatherapy Effects


Aroma	Documented effects
Lavender	Calming
Sandalwood	Anti-depressant, calming
Orange	Calming, sedative effect
Peppermint	Relieves nausea, combats fatigue
Placebo	Anticipated benefit may be realized

ACS, 2014; Alankar, 2009; Setzer, 2009

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Research Question




- Biopsies are anxiety provoking for patients
- Culture of Healing
- "How can nurses reduce anxiety for people having breast biopsies?"

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Roy Adaptation Theory



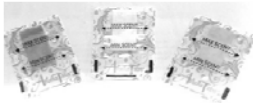
The nursing theory used at MMC.
A systematic and holistic nursing theory.
Incorporates physical, emotional, social and spiritual nature of beings.
Charges nurses with helping patients adapt to stressors.

Focal Stimuli	Contextual Stimuli	Residual Stimuli	Question
Anxiety – related to breast biopsy	Family history of breast cancer	Age, race, insurance, educational level, marital status	Will aromatherapy enhance adaptation to anxiety associated with breast biopsy?
Primary Stressor	Other	factors	

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Aromatabs®



- Small foam-like tab (1 in X 1 ½ inches) on a larger cardboard backing (2 inch X 2 ½ inches)
- Hypo-allergenic adhesive backing
- Tab is placed on the gown, by the shoulder
- MDS information was provided to the IRB
- Beekley Manufacturer provided the tabs and matched placebo. They had no input in the design, conduct or outcome of the study.

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Literature Review

- Librarians: Janina Kaldan, Library Manager
Yi Zhou, Librarian
Kelly Heeney, Library Technician
- Shinn-Lathrope Health Science Library at Morristown Medical Center
- Multiple databases: CINAHL, Pubmed, EBSCO
- Mary Loughran was used as an resource because of her previous research experience with aromatherapy
- Beekley Manufacturer

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Key Findings from Lit Review

- Anxiety is one of the most common problems patients face before an image-guided core biopsy
- Methods to reduce anxiety and enhance adaptation are paramount to nursing care
- Reduced anxiety may improve patient's outpatient hospital experience
- Documented results include reduced anxiety and improved mood with aromatherapy
- Aromatherapy has been shown effective in a variety of clinical settings
- Delivery is challenging
- Aromatabs are easy, convenient delivery system

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PICO Question

Population: Females, 18 – 90 years, no prior personal history of breast cancer, having breast biopsy at the Carol W. and Julius A. Rippel Breast Center of the Carol G. Simon Cancer Center at MMC

Intervention: Aromatherapy Tab using a unique delivery system

Comparison: Three groups of aromatherapy including: Lavender Sandalwood, Orange/Peppermint compared to a Matched Control Delivery System

Outcome: Reduction of Anxiety as measured by the State-Trait Anxiety Inventory for adults Self-Evaluation Questionnaire (Spielberger, 1977)

Adapted from Cincinnati's Children's Hospital
<http://www.cincinnatichildrens.org/assets/0/78/176/4711/4715/1ca30651-b07c-43be-a28a-80e171e7cad.pdf>
 accessed 09/09/2015

WOMEN'S OWN MEDICAL CENTER / ATLANTIC HEALTH SYSTEM

Study Objectives

- To explore the use of aromatherapy, via aromatherapy tabs, to reduce anxiety during image-guided breast biopsy.
- To investigate the effects of lavender/sandalwood (Group A) or the effect of orange/peppermint (Group B) aromatherapy, compared to a matched placebo (Group C), in the reduction of anxiety and related physiological changes in women.
- To evaluate differences in anxiety and vital signs with the aromatherapy tabs verses placebo.

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Outcome

Will aromatherapy enhance adaptation to anxiety associated with breast biopsy?

↓

Anxiety as measured by Spielberger State Trait Inventory

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State Anxiety Inventory (STAI)

- The STAI measures state anxiety
- Difference between state and trait anxiety
- Validity and Reliability of the instrument well established
 - Validity – over 5000 tests
 - Reliability – test/re-test, correlation
- Licensed through Mind Garden™
- The State Anxiety Inventory Scale = 20 questions
- The Trait Anxiety Inventory Scale = 20 questions
- Paper and pencil

SELF-EVALUATION QUESTIONNAIRE Form Y-12

Please provide the following information:

Name _____ Date _____

Age _____ Gender (Circle) M F Y _____

DIRECTIONS:

A number of statements of why people have used sex to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now. That is, are you right or wrong? There are no right or wrong answers. Do your best. Circle only one statement but give the answer with it in pencil.

Do not print here (see back).

	Not at all	Mostly not	Neutral	Mostly yes	Yes, definitely
	1	2	3	4	5
1. I feel proud	1	2	3	4	5
2. I feel horny	1	2	3	4	5
3. I feel ashamed	1	2	3	4	5
4. I feel at ease	1	2	3	4	5
5. I feel upset	1	2	3	4	5
6. I am presently worrying over possible misfortunes	1	2	3	4	5

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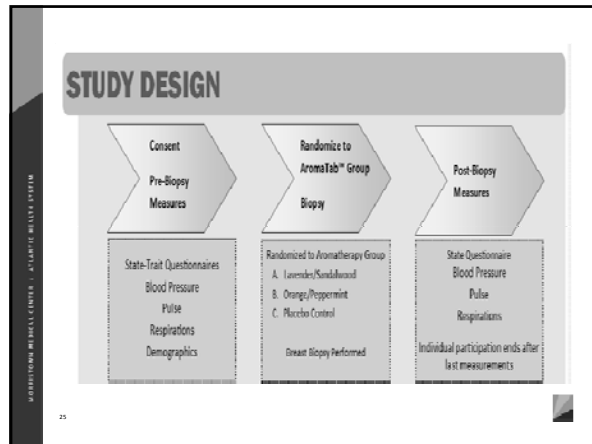
SELF-EVALUATION QUESTIONNAIRE

STA Form Y-2

Name _____	Date _____	
DIRECTIONS		
<p>A number of statements about people have been listed to describe themselves and give below. Read each statement and circle the appropriate number on the right of the statements to indicate how you personally feel. There is no right or wrong answer. Do not spend too much time on one statement but give the answer which seems to describe how you</p>		
1. I am pleasant	1	2 3 4
2. I feel nervous and restless	1	2 3 4
3. I feel satisfied with myself	1	2 3 4
4. I wish I could be as happy as others seem to be	1	2 3

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Sample Size

- N = 87
- Based on alpha level of 0.05, power = 80%, and a medium effect size
- The effect size is estimated from a post-operative study (Fayazi, et al, 2011). Showed an eight point difference in anxiety.

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Feasibility

- Out of 21 counties in NJ, Morris County is 2nd highest annual incidence rate of breast cancer (147.8), second only to Hunterdon County 156.3 (2005-2009 rate period).
- MMC = 1478 breast biopsies/year
 - 673 ultrasound guided core biopsies annually
 - 547 stereotactic guided core biopsies a year
 - 258 MRI guided core biopsies a year
- Recruitment rate of approximately 10 cases/month
- Plan was September 30, 2013 to June 30, 2014
- Actual was September 30, 2013 to June 23, 2014
- Duration of enrollment was 9 months

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3 Essential 2nd Therapy

Studies have shown that a combination of essential fatty acids and antioxidants can significantly reduce the risk of heart disease.

We have now seen that a combination of essential fatty acids and antioxidants can significantly reduce the risk of heart disease.

It is a well known fact that a combination of essential fatty acids and antioxidants can significantly reduce the risk of heart disease.

It is a well known fact that a combination of essential fatty acids and antioxidants can significantly reduce the risk of heart disease.



Muller's Choice of Omega-3

It is a well known fact that a combination of essential fatty acids and antioxidants can significantly reduce the risk of heart disease.

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Omega-3

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4 Essential 3rd Therapy

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Omega-3

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Aromatherapy (use of essential oils) has been used to reduce anxiety in various practice settings in many places around the world.

Purpose
This research study will determine the extent of weight gain in community-dwelling, noninstitutionalized, nonworking adults in relation to their level of physical activity. The study will also determine the extent of weight gain in relation to their level of physical activity.

What's involved?
The study proposes to do a randomised treatment or control assignment, to place women having late or early the risk of abortion.

- Participation is voluntary
- You will need to sign a consent form prior to entering the study
- All research activities are confidential

Keywords:
information; learning; health care; quality; management; patient; physician; doctor; nurse

- The back side of the table is effective that can be placed your screen easily.
- The use of smartphones is



^a Values are cell number per core (n = 30).

[illegible][illegible]

The image shows two handwritten notes on lined paper. The left note contains several math problems and solutions, including a word problem about a car's speed, a problem about a person's age, and a problem about a person's weight. The right note contains a problem about a person's age and a problem about a person's weight. The handwriting is in cursive and somewhat slanted.

[illegible]

Microsoft Word
 Microsoft Office Word 2003
 File Edit Format Tools Window Help

New

Style: Normal

Style type: Paragraph

Name: Normal

Format

- 30

WISCONSIN MEDICAL CENTER / ATLANTIC HEALTH SYSTEM

IRB Approval

- Nursing Research Council approval
- Submit Institutional Review Board Documents: Protocol, Consent Form, Information Forms, STAI Survey Forms, Brochure, MSD Sheets, application, sub-investigator forms, CV, CITI training certification
- Full IRB review – PI present for questions at meeting
- Approved via letter
- Use of Stamped Consent Form

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Data Entry, Coding and Analysis

- Demographic variables collected were: age, marital status, education, insurance type
- Clinical variables: BP, P, R
- Psychosocial: State and trait anxiety inventory (Spielberger)
- Time of procedure, time of tab placement, group, day of week

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Data Collection Form



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Coding

Study ID #	Date	Day of week	Age	Inclusion Criteria met	Insurance	Race/Ethnicity	Education
	YY-MM-DD	M, T, W, T, F	in years	0 = no, 1 = yes	1 = gov 2 = commercial 3 = not insured	1 = white, 2 = AA, 3 = Hispanic/Latino, 4 = American Indian, 5 = other	1 = HS, 2 = coll, 3 = grad school, 4 = post-grad
1	9/10/2013	M	47	1	1	2	3
2	10-Sep-13	M	46	1	2	2	3
3	10-Sep-13	M	85	1	3	3	5
4	2-Oct-13	W	47	1	2	2	2
5	2-Oct-13	W	53	1	2	2	3
6	2-Oct-13	W	52	1	2	2	3
7	9-Oct-13	F	31	1	2	2	3
8	7-Oct-13	M	51	1	2	2	3
9	8-Oct-13	T	40	1	2	2	3
10	10-Oct-13	W	45	1	2	2	3
11	9-Oct-13	W	76	1	2	2	3
12	15-Oct-13	F	44	1	2	2	3
13	16-Oct-13	W	48	1	2	2	3

Statistical Analyses

- Descriptive statistics are provided for the study sample.
 - Continuous variables are summarized using average and standard deviation or median (range)
 - Proportions are used for categorical variables.
- The three groups are compared in terms of baseline demographic and clinical factors using ANOVA/Kruskal-Wallis test or the Chi-square test
- The change in the State score (post – pre) was compared in the three groups using the Kruskal-Wallis test
 - Pairwise comparisons between groups were made using the Mann-Whitney U test
- The three groups were also compared in terms of the change (post-pre) in BP (systolic and diastolic), pulse and respiratory using the Kruskal-Wallis test

Findings

- Demographics
- State Pre and Post
- Physiological Measures Pre and Post
- Compare groups

Demographics N=87

Variable	Lavender	Orange	Placebo	p Value
Age (years) Mean \pm SD	52.4 \pm 10.6	50.3 \pm 10.5	47.5 \pm 8.9	0.21
White Race %	90%	83%	96%	0.26
Private Insurance %	93%	96%	93%	0.83
Education %				0.74
High School	16%	7%	15%	
College	56%	56%	44%	
Graduate or post-graduate	28%	37%	41%	
Type of Biopsy %				0.54
MRI	7%	7%	4%	
Stereotactic	62%	47%	68%	
Ultrasound	31%	47%	29%	

17 Demographic statistics: ANOVA/Kruskal-Wallis test or the Chi-square test

Baseline Measures: Vital Signs and State/Trait Anxiety Scores

Variable	Lavender	Orange	Placebo	p Value
Systolic BP median (range)	118 (99-169)	128 (94-148)	118 (91-146)	0.25
Diastolic BP median (range)	70 (56-101)	76 (60-97)	70 (53-96)	0.20
Pulse median (range)	74 (54-87)	75 (60-100)	73 (55-133)	0.32
Respirations median (range)	16 (12-24)	16 (12-20)	16 (12-20)	0.51
State median (range)	48 (22-66)	43 (22-73)	43 (23-66)	0.34
Trait median (range)	37 (23-61)	32 (20-64)	30 (23-59)	0.30

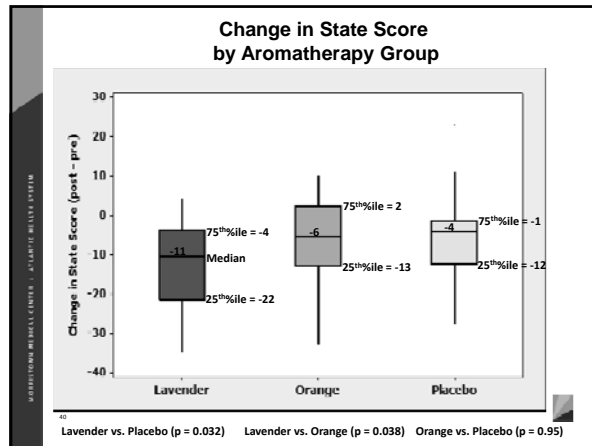
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Outcome Measures: Vital Signs and State Anxiety Scores

Variable	Lavender	Orange	Placebo	p Value
Outcomes				
Change in Systolic median (range)	0 (-32, 6)	0 (-22, 25)	4 (-23, 22)	0.87
Change in Diastolic median (range)	0 (-16, 14)	1 (-20, 18)	1 (-21, 16)	0.98
Change in Pulse median (range)	1 (-13, 13)	-4 (-18, 14)	-2 (-15, 15)	0.066
Change in State median (range)	-11 (-35, 4)	-6 (-33, 10)	-4 (-28, 23)	0.050

19 The change in the State score (post - pre) was compared in the three groups using the Kruskal-Wallis test

Pairwise comparisons between groups were made using the Mann-Whitney U test




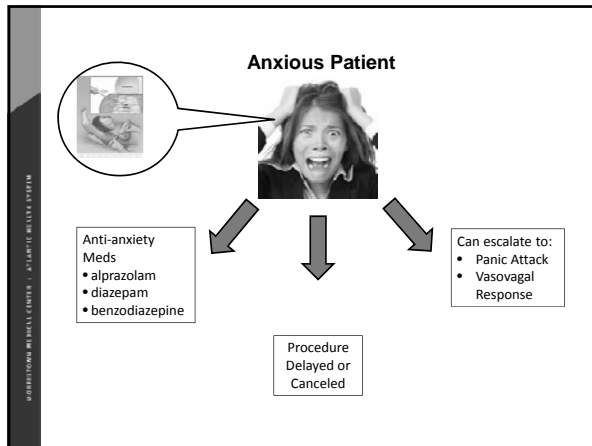
Results

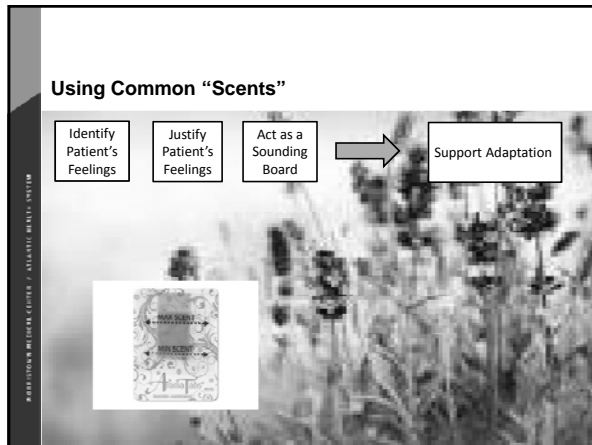
- A reduction in anxiety as measured by the STAI was observed between pre and post biopsy in all groups
- Reduction in anxiety was observed most in Lavender, then Orange, and least in Placebo
- Lavender showed a statistical difference compared to placebo
- Lavender and Orange were statistically different
- Orange did not show a statistical difference compared to placebo

Conclusions

- This study showed that Aromatabs are an effective nursing intervention to reduce anxiety in women having image guided breast biopsies, thus, promoting adaptation.
- Results led to the development of a procedure at MMC for aromatherapy using Aromatabs.
- Patients without a preference for scent should be offered the lavender aroma, based on the findings of this study.
- The Roy Adaptation Theory provided a useful guide for this nursing study.





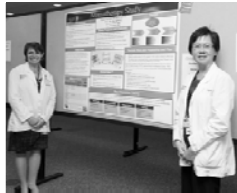


Future implications and research

- A similar study using Aromatabs during breast biopsy is planned at Overlook Medical Center, Summit, NJ.
- Research in areas including the ED and the pain center are being explored.
- Future studies should be expanded to other populations:
 - Women with a personal history of breast cancer
 - Spanish speaking patients
 - Men.

Dissemination

- Poster of concept within the Medical Center
- 2015 Magnet Conference Podium
- Planned Written Publication



Tips for Your Research Journey

1. Think of real issue/problem that will enhance patient experience
2. Find a mentor where you work
3. Be passionate about your research and find others who are like yourself
4. Process is always longer than you think, but worth the effort
5. Realize the changes you make can affect the world in your little corner.
6. Research drives our patient practice

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**KEEP
CALM
AND
USE
"SCENTS"**

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Thank you

- Women's Foundation at Morristown Medical Center
- Beekley Medical for the donation of supplies
- Ms. Stephanie Chiu and Dr. Rami Bustami
- Supportive staff at the Carol W. and Julius A. Rippel Breast Center at Morristown Medical Center
- Special thanks to the women who participated in this study



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