Technology Enhanced Nurse Navigation (TENN)℠ Trial

Conducted in collaboration with DHMH

Mercy Medical Center TENN Study Team
Kathy J. Helzlsouer, MD, MHS, Susan Appling, PhD, Susan Scarvalone, MSW, Shannon Manocheh, Ryan MacDonald, PhD, and Arti Varanasi, PhD

November 19, 2013

The Prevention and Research Center, Mercy Medical Center, Baltimore, MD
Advancing Synergy, LLC, Baltimore, MD, and DHMH

Funded in part by Susan G. Komen for the Cure
Technology-Enhanced Navigation: The TENN℠ Trial

Aim: Determine if “virtual” interaction with a patient navigator vs information access alone will improve:

- adherence (relative dose intensity)
- symptom management
- quality of life

among low income breast cancer patients undergoing adjuvant breast cancer treatment
Motivation

• The poor cancer outcomes
  – Multifactorial
    • Adherence
    • Access - treatment, support, navigational support

• Information gap – and information overload

• Disparities
  – race, age, geography

• Social isolation

• Increasing reliance on self-care
Navigation

Physical Interaction

Virtual Interaction
Technology-Enhanced Navigation: The TENN℠ Trial

• Recruitment Goal: 100; currently 90 patients enrolled;
  – Eligibility:
    • Stage I-III; enrolled within 3 months of initiating adjuvant treatment
    • Income $\leq 300\%$ poverty (e.g., family of 4 = $69,150); HUD guidelines
    • English speaking/able to consent
    • Residing within area of wireless access
Intervention v. Control Group

Intervention group is given:
• Netbook with internet access (Wi-Fi)
• Access to portal with vetted internet links + videos to assist with treatment and recovery issues + documents
• Access to a navigator (nurse/social worker) who will virtually (via Skype, phone, email) assist patient during their treatment course

Control group is given:
• Netbook with internet access (Wi-Fi)
• Access to vetted internet links (e.g. NCI, ACS, Komen, etc.) to assist with treatment and recovery issues

Duration of Intervention: 1 year
Welcome Page

Welcome

We are excited that you have decided to join the Technology Enhanced Nurse Navigation (TENN℠) Trial. Through your participation in this trial, we will learn more about the best way to give information to individuals to help them through their breast cancer treatment. The Prevention and Research Center at Mercy Medical Center is leading the study efforts. The mission of the center is to improve the health of individuals through clinical programs and research into the prevention, early detection and treatment and long-term management of diseases. This study is funded by Susan G. Komen for the Cure®. To access the TENN℠ Portal, please click here.

If you have any questions regarding your computer or the TENN℠ Trial, please contact the TENN℠ Trial Research Coordinator by calling 410-332-4945 or a member of our study team at anytime by calling 410-951-7950 from Monday through Friday between 8:00 AM to 4:30 PM. If you call after 4:30 PM or on a weekend or holiday, please leave a message and your call will be returned the next business day. If you have a medical emergency or any medical issues, please call either 911 or your healthcare provider.

Disclaimer: If you have a medical emergency or any medical issues, please call either 911 or your healthcare provider. The privacy of all medical records and other individually identifiable health information will be protected at all times. Information relating to a study participant’s personal information and medical history are considered individually identifiable health information. Confidentiality of this health information is maintained at all times and may only be disclosed in accordance with privacy laws and the Health Insurance Portability and Accountability Act (HIPAA).

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Tips & Resources

TENN Portal

THOUGHT FOR THE DAY -- Happiness often sneaks in through a door you didn’t know you left open. -- John Barrymore

Tips & Resources, Communication, My Information, Questionnaires, My Portal Use

Click on the symbols below to find videos, website links and documents selected to help support you through your breast cancer treatment.

Common Symptoms
Nutrition Corner
Exercise Tips
Relaxation Corner
Coping & Feelings
Work & Family Matters
Practical Resources
Treatment & Beyond

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<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| General Treatment Information | **About Breast Cancer and Treatment**  
Source: National Cancer Institute  
Date last updated: 01/02/2012                                                                                                                                 |
| General Treatment Information | **Overview of Treatment Options**  
Source: National Cancer Institute  
Date last updated: 01/02/2012                                                                                                                                 |
| General Treatment Information | **Adjuvant Breast Cancer Therapy**  
Source: National Cancer Institute  
Date last updated: 01/02/2012                                                                                                                                 |
| Communicating with your doctor | **Talking to Your Healthcare Provider**  
Source: Susan G Komen for the Cure  
Date last updated: 01/02/2012                                                                                                                                 |
| Treatment by Stage             | **Treatment Options by Stage**  
Source: National Cancer Institute  
Date last updated: 01/02/2012                                                                                                                                 |
| Treatment by Stage             | **Breast Cancer Treatment and Stage**  
Source: ACS  
Date last updated: 01/02/2012                                                                                                                                 |
| Screening                      | **Breast MRI**  
Learn about magnetic resonance imaging (MRI), a noninvasive medical test that helps physicians diagnose and treat medical conditions, including breast cancer.  
Source: RadiologyInfo.org  
Date last updated: 01/02/2012                                                                                                                                 |
| Chemotherapy                   | **Chemotherapy: What to Expect**  
Learn what to expect during your chemotherapy treatment and how it will affect your daily routine.  
Source: BreastCancer.org  
Date last updated: 01/02/2012                                                                                                                                 |
My Information
## My Information

Enter information and your breast cancer diagnosis and treatment.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Date of Birth</th>
<th>Age</th>
<th>Gender</th>
</tr>
</thead>
</table>

(*) Denotes mandatory information

### Tumor Information

**Tumor Stage**

**Tumor Size**

1 cm

**Tumor Type (select all that apply)**

- Ductal carcinoma in situ
- Invasive ductal
- Invasive lobular
- Don't Know
- Other, specify

**Tumor Location**

- Left breast

**Estrogen receptor status**

- Positive

**Progesterone receptor status**

- Negative

**HER-2/neu receptor status**

- Negative

**Lymph node involvement**

- Yes

If yes, number of involved nodes:

3

### Treatment

**What type of surgery did you or will you have?**

- Lumpectomy

- Left Breast
### Doctor Contact Information

(*) Denotes mandatory information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Last Name (*)</td>
<td></td>
</tr>
<tr>
<td>Specialty</td>
<td></td>
</tr>
<tr>
<td>Street Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Zipcode</td>
<td></td>
</tr>
<tr>
<td>Provider Email</td>
<td></td>
</tr>
<tr>
<td>Provider Phone</td>
<td></td>
</tr>
<tr>
<td>Provider Fax</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td></td>
</tr>
</tbody>
</table>

Submit  | Cancel
Communication
**Kathy J. Helzlsouer, MD, MHS**
Dr. Kathy Helzlsouer is the principal investigator (director) of the TENN Trial. Dr. Kathy's clinical work and research interests concern both cancer prevention and cancer survivorship. The project developed from her experience and interest in improving the quality of life of cancer survivors through treatment and beyond. She is fortunate to work on this project with a wonderful team who strive to make a difference in the lives of cancer patients.

**FIELD:** Epidemiology, Medical Oncology, Cancer Risk Assessment and Prevention, Women’s Preventive Health  
**POSITION:** Director, The Prevention and Research Center at Mercy  
[Click here to meet Dr. Kathy](#)

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**Susan Appling, PhD, MS, CRNP**
Dr. Susan (Sue) Appling is the nurse navigator for the TENN Trial. At Mercy, Dr. Sue provides clinical care to women at increased risk for cancer and manages the long-term health promotion and disease prevention needs of cancer survivors. As the coordinator for both a clinical program and a research study for breast cancer survivors, Dr. Sue has helped to develop an innovative holistic mind-body medicine program to treat persistent fatigue in women who have been successfully treated for breast cancer.

**FIELD:** Women’s Health and Wellness, Nursing Education  
**POSITION:** Nurse Practitioner, The Prevention and Research Center at Mercy  
[Click here to meet Dr. Sue](#)

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**Susan A. Scarvalone, MSW, LCSW-C**
Ms. Susan is the social worker for the TENN Trial. She is a licensed clinical social worker with many years experience working with cancer patients and their families. Ms. Susan has completed training in Mind-Body Medicine and Motivational Interviewing. Her areas of expertise include counseling, survivorship for cancer patients, including pediatric cancer patients, and fatigue intervention research.

**FIELD:** Cognitive Therapy  
**POSITION:** Clinical Research Therapist, The Prevention and Research Center at Mercy  
[Click here to meet Ms. Susan](#)
Health Questionnaires

<table>
<thead>
<tr>
<th>Phase</th>
<th>Start Date</th>
<th>Completion Date</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>10/7/2012</td>
<td></td>
<td>Active</td>
</tr>
<tr>
<td>6 months</td>
<td>4/7/2013</td>
<td></td>
<td>Not Started</td>
</tr>
<tr>
<td>12 months</td>
<td>10/7/2013</td>
<td></td>
<td>Not Started</td>
</tr>
</tbody>
</table>

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# Characteristics at Enrollment

## TENN Trial Participants N=90

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention N=46</th>
<th>Control N=44</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at baseline (mean (SD))</td>
<td>52.5 (10.3)</td>
<td>48.7 (9.5)</td>
</tr>
<tr>
<td>Race %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>37.0</td>
<td>31.8</td>
</tr>
<tr>
<td>Black</td>
<td>60.9</td>
<td>63.6</td>
</tr>
<tr>
<td>Other</td>
<td>2.2</td>
<td>4.5</td>
</tr>
<tr>
<td>Education %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school or less</td>
<td>56.5</td>
<td>36.4</td>
</tr>
<tr>
<td>Greater than high school</td>
<td>43.5</td>
<td>63.6</td>
</tr>
<tr>
<td>Marital Status %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/Partnered</td>
<td>23.9</td>
<td>27.3</td>
</tr>
<tr>
<td>Single/Divorced/Separated/Widowed</td>
<td>76.1</td>
<td>72.7</td>
</tr>
<tr>
<td>Employment Status %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>23.9</td>
<td>31.8</td>
</tr>
<tr>
<td>Disabled/Medical Leave</td>
<td>13.0</td>
<td>22.7</td>
</tr>
<tr>
<td>Unemployed/Other</td>
<td>63.0</td>
<td>45.5</td>
</tr>
</tbody>
</table>
Characteristics at Enrollment
TENN Trial Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention %</th>
<th>Control %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;30.0</td>
<td>56.5</td>
<td>59.1</td>
</tr>
<tr>
<td><strong>Self-Reported Health</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent/Very Good</td>
<td>30.4</td>
<td>27.3</td>
</tr>
<tr>
<td>Good</td>
<td>47.8</td>
<td>47.7</td>
</tr>
<tr>
<td>Fair/Poor</td>
<td>21.7</td>
<td>25.0</td>
</tr>
<tr>
<td><strong>Current Smoker</strong></td>
<td>21.7</td>
<td>22.7</td>
</tr>
</tbody>
</table>
# Usability Questionnaire Follow-up
3 to 6 months after enrollment

## Usability Questions

<table>
<thead>
<tr>
<th>Usability Questions</th>
<th>Intervention %</th>
<th>Control %</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Computer experience</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable/Very Comfortable</td>
<td>90.6</td>
<td>62.9</td>
<td>0.08</td>
</tr>
<tr>
<td><strong>I use the Portal frequently</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agree/Strongly Agree</td>
<td>59.4%</td>
<td>48.6%</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>I think the Portal is easy to use</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agree/Strongly Agree</td>
<td>84.4%</td>
<td>57.1%</td>
<td>0.08</td>
</tr>
<tr>
<td><strong>I feel very confident using the Portal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agree/Strongly Agree</td>
<td>81.3%</td>
<td>60.0%</td>
<td>0.2</td>
</tr>
</tbody>
</table>
Comments: Navigator

- My navigator answered a lot of questions about breast cancer and what I would be going through and helped me to understand the side effects of drugs.

- Helpful is an understatement. She was excellent. She was helpful in every aspect of my life. She was there to help with my physical and mental needs 100% of the time. If I could put a star on someone it would be there for Susan

- This is a wonderful program and has lots of helpful information to anyone that is going through breast cancer. My nurse Sue is the best
What Have We Learned?

- Technology literacy improves with a brief education
  - My little Tenn portal buddy has been like my sidekick of information so far. I am happy to have something to help me remember appointments...I can go to one place and find all my doctors contact info... (Control)
  - It’s easy to find information on the tenn without having to call the doctor every time you think of something..... (Control)
  - I like that I have everything I need in one place, such as, resources, tips, schedule. It helps keep everything organized, which in turn, takes a lot of stress off of me. (Control)
  - I find the Tenn Portal has extremely good information. It’s easy reading and has been very helpful to me. (Intervention)
  - I like being able to send and receive messages. The messages I received have been very encouraging and informative. (Intervention)
  - It has helped me to have more insight on the things I don't understand. I specifically like the nutrition information- what is good and what is not good. (Intervention)
What Have We Learned?

• Participants are good stewards of the equipment – only 3 computers needed to be replaced

• Connectivity has geographical restrictions

• Biggest expense – connectivity charges; constant monitoring of data use needed (5GB limit)
  – Free Wi-Fi access increasing - sustainability
  – Tablet prices reasonable

• Phone interactions preferred by patients and navigators over Skype®

• Asset to navigate a mobile population – mobility high; follow-up challenging – changing phone numbers. Computers travel with them!
What Have We Learned?

- Social ills often exceed medical ills during treatment
  - Home visits have been enlightening
- Untreated or inadequate treated mental health is prevalent
- Navigator TEAM required – social worker + nurse
- Overcome social isolation:
  - *without this portal i wouldn’t have much communication i live alone and no family or friends that are close to talk with.* (I)
  - *This program was indeed a blessing to me at a time when I [was] left hopeless and [in] despair. The program was added support for me.* (I)
  - *I am lucky to have the access, and opportunity to have "my mini support system" by my side.* (C)
- Adjunct to medical care
  - *This TENN Portal has help me very much. I knew nothing about breast cancer. Now I can easily look up information about breast cancer. I am starting to understand more about my condition and treatments. Thank you all.* (C)
  - Relieves provider burden
Summary

• Computer competence achieved after brief training (~2-3 hours) even among those with no prior computer experience
• Use of portal and confidence in using higher among those with interactive navigator than controls
• Both intervention and control participants report positive experience with accessibility to information
• Health outcomes, quality of life, and adherence (relative dose intensity) will be analyzed when all have completed the 12 month intervention period
• DHMH and BCDDT staff
• Provider referrals
• Participants
• Susan G Komen for the Cure