A Randomized Trial Evaluating a Web-Based Decision Aid To Support Decisions About Cancer Clinical Trials

Mary C. Politi, Ph.D.

Department of Surgery
Division of Public Health Sciences
Acknowledgements/Disclosures

• Kimberly A. Kaphingst, ScD
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Cancer Clinical Trials (CCTs)

- Vital to advance evidence-based cancer treatment
- ~3% of adult cancer patients participate in a CCT
- Recent decline in enrollment of minority groups
- Meta-analysis of 103 studies: > 25% did not understand the nature of the study or voluntary participation
- ~ 50% of participants understood central trial concepts such as the use of placebos or randomization
Why Don’t People Participate in CCTs?

- Fear-based barriers
  - Randomization
  - Placebos
  - Possible side effects
  - Possible impact on relationship with physician

- Misconceptions
  - “Last resort” after standard treatment
Informed Consent for CCTs: Key Elements

1) Disclose information necessary for informed choice

2) Facilitate understanding of the disclosed information

3) Promote the voluntariness of the decision

http://answers.hhs.gov/ohrp/categories/1566
Key Elements Often Missing from IC Process

• Patients often do not carefully read forms
  • Written at very high reading levels
  • Long, cumbersome forms
  • Information appears irrelevant for participation

• Few participants ask questions or engage in discussions with clinicians about trials

  “Tell me what you would do”
CHOICES Development: Overview

- Web-based DA
- Patient stories
- Supplement to existing consent procedures
Making a choice about joining a cancer treatment research study

“When my doctor asked if I would join a research study trying new ways of treating my cancer, I didn’t understand. I didn’t know what would happen in a study or how it could affect my treatment. I trusted my doctor, but this was a big decision for me and my family. I learned all I could and then I made my choice. This website can help you learn and make your choice.”

“When I was asked to join a cancer research study, I got worried. I thought maybe there was no hope for me. Or, maybe they wanted to try some new treatment that wouldn’t work. I didn’t want to be a guinea pig. My worries went away as I learned more about research studies. You can learn more on this website and make the right choice for you.”

This website is about cancer clinical trials.

Cancer clinical trials help doctors learn if new drugs or treatments help cure or slow the growth of cancer. Other clinical trials may focus on how to prevent cancer or find it early. But, this website is about just treatment trials.

A cancer clinical trial may also be called a cancer treatment research study.

If you have been asked to join a clinical trial, this is the same as a cancer treatment research study. On this website, we will call cancer treatment research studies just cancer research studies or research studies.

Cancer research studies may be a choice for treatment when you have cancer. On this site we will be sharing general information about your choice to participate in cancer research studies and not information on any one research study in particular.

Click here to learn how to use this site
This page shows what matters to you when thinking about joining a study. Look it over and make sure you feel that the answers are right for you. Change any answers you want. If you change an answer, that statement may move up or down the list to show how important it is to you.

Once you feel like all the answers are right for you:
- print this page if you want
- use it to help you think about
  - what's important to you
  - how you feel about joining a study

### Reasons to be in a study

- I believe being in a study might possibly improve my health.
  - disagree
  - agree

- It is important to me to help others with this disease in the future.
  - disagree
  - agree

- It is important to me to have more than the usual treatment.
  - disagree
  - agree

### Concerns about being in a study

- I am worried about side effects.
  - disagree
  - agree

- I am worried about the time commitment required.
  - disagree
  - agree

- I would feel like a guinea pig if I were to participate.
  - disagree
  - agree

- I am worried about the procedures that I might have to go through.
  - disagree
  - agree
Some studies divide patients into 2 groups

- In Phase 3 studies, patients are put into groups at random, this is also called randomization.

- Half the patients get the standard treatment or drug. Half get the new treatment or drug. Which group you are in is decided by chance, like the flip of a coin.

Standard treatment
- A computer, not the doctor, decides which treatment you get. You may get the new treatment or you may get the standard treatment.
- You will likely not know which treatment you are getting until the study is over.
- Placebos or sugar pills are almost never used in cancer research studies.
- Putting people in groups at random means that both groups end up with a similar mix of patients. This means that if one group gets better results, it is probably because of the treatment, not who is in the group.
CHOICES Modification: Stakeholder Feedback

• High acceptability among those who develop and deliver informed consent

“I think this tool will be very beneficial to patients as well as staff. Sometimes explaining trials to patients is hard because we have the knowledge that they may not have. This will help staff with communicating with patients.”

 “[I like that it] reassures patients about their choice.”
Randomized Trial: CHOICES vs. Usual Care

- Adults (18+)
- Cancer diagnosis in the past 6 months
- No previous CCT participation

- 200 total enrolled; 100 randomized to each group
- 87 (87%) complete in CHOICES group
- 90 (90%) complete in enhanced usual care (UC) group
CLINICAL TRIALS

The Siteman Cancer Center offers many different types of clinical trials - research studies that test whether new ways to prevent, diagnose and treat cancer are safe and effective. These clinical trials, also called clinical studies or research protocols, are conducted by doctors with people who volunteer to take part. They often give patients access to potentially helpful therapies not widely available elsewhere. At any given time, Siteman has more than 250 trials under way.

To search for clinical trials offered at Siteman, click here. You may search for trials by disease type, keyword, principal investigator and protocol number.

For more information about clinical trials in general or any trials listed on this site, call 314-747-7222 or 800-660-3606 toll free or e-mail info@ccadmin.wustl.edu.

+ What is a Clinical Trial?
+ Types of Clinical Trials
  + Eligibility
  + Signing Up for a Clinical Trial
  + Frequently Asked Questions
  + Search for a Clinical Trial

+ Podcast: Phase I Clinical Trials: Advancing Cancer Treatment
+ Clinical Trial Increases Patient's Odds
PATIENT STORIES

Beverly Sodemann's desire to participate in a clinical study led her to the Siteman Cancer Center for her pancreatic cancer treatment. 
more...

Kathy Ferrara fought colon cancer with the help of a clinical trial at the Siteman Cancer Center. 
more...
No Statistically Significant Differences Between Groups

<table>
<thead>
<tr>
<th></th>
<th>UC N=90</th>
<th>CHOICES N=87</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>54.03</td>
<td>56.02</td>
<td>0.28</td>
</tr>
<tr>
<td>SD</td>
<td>12.07</td>
<td>12.35</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>26.80</td>
<td>30.83</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22 (24.4)</td>
<td>23 (26.4)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>68 (75.6)</td>
<td>64 (73.6)</td>
<td>0.76</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>35 (38.9)</td>
<td>27 (31.0)</td>
<td>0.27</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>2 (2.2)</td>
<td>7 (8.1)</td>
<td>0.08</td>
</tr>
<tr>
<td>Gynecological</td>
<td>18 (20.0)</td>
<td>17 (19.5)</td>
<td>0.94</td>
</tr>
<tr>
<td>Lung</td>
<td>7 (7.8)</td>
<td>5 (5.8)</td>
<td>0.59</td>
</tr>
<tr>
<td>Skin Cancer (melanoma and non)</td>
<td>16 (17.8)</td>
<td>22 (25.3)</td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td>6 (6.7)</td>
<td>7 (8.1)</td>
<td>0.73</td>
</tr>
<tr>
<td>Other</td>
<td>15 (16.7)</td>
<td>16 (18.4)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ High School Degree</td>
<td>22 (24.4)</td>
<td>26 (29.9)</td>
<td></td>
</tr>
<tr>
<td>Some College</td>
<td>21 (23.3)</td>
<td>26 (29.9)</td>
<td></td>
</tr>
<tr>
<td>≥ College Degree</td>
<td>47 (52.2)</td>
<td>35 (40.2)</td>
<td>0.28</td>
</tr>
<tr>
<td>Annual Household Income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; $30,000</td>
<td>25 (31.3)</td>
<td>20 (26.3)</td>
<td></td>
</tr>
<tr>
<td>$30,000 - $60,000</td>
<td>16 (20.0)</td>
<td>16 (21.1)</td>
<td></td>
</tr>
<tr>
<td>$60,000 - $75,000</td>
<td>11 (13.8)</td>
<td>6 (7.9)</td>
<td></td>
</tr>
<tr>
<td>&gt; $75,000</td>
<td>28 (35.0)</td>
<td>34 (44.7)</td>
<td>0.47</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>18 (20.0)</td>
<td>18 (20.7)</td>
<td>0.91</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (1.1)</td>
<td>1 (1.2)</td>
<td>0.98</td>
</tr>
<tr>
<td>Caucasian</td>
<td>70 (77.8)</td>
<td>66 (75.9)</td>
<td>0.76</td>
</tr>
<tr>
<td>Native Am/Alaskan</td>
<td>3 (3.3)</td>
<td>2 (2.3)</td>
<td>0.68</td>
</tr>
<tr>
<td>Native</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (1.1)</td>
<td>2 (2.3)</td>
<td>0.54</td>
</tr>
<tr>
<td>Ever heard of trials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>23 (25.6)</td>
<td>30 (34.5)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>67 (74.4)</td>
<td>57 (65.5)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Results are presented as n (%) for all characteristics except age. UC = Usual Care. CHOICES= Decision Aid.
## CHOICES group: higher overall knowledge compared to enhanced UC

<table>
<thead>
<tr>
<th>% Items Correct</th>
<th>CHOICES n=87</th>
<th>UC N=90</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Items Correct</td>
<td>73.7 (SD 2.3)</td>
<td>61.5 (SD 2.0)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### Selected Individual Items

<table>
<thead>
<tr>
<th>Item</th>
<th>CHOICES</th>
<th>UC</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A patient can choose to stop being in a cancer research study at any time, even after he or she has signed the consent form and the study has started</td>
<td>93.0</td>
<td>83.1</td>
<td>.04</td>
</tr>
<tr>
<td>A patient can only be in a research study if his or her doctor recommends it.</td>
<td>60.5</td>
<td>30.3</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>A cancer research study could not be offered to a patient unless the new drug has been tested for safety in animals.</td>
<td>58.1</td>
<td>41.6</td>
<td>.028</td>
</tr>
<tr>
<td>Cancer research studies almost never involve the use of a placebo or sugar pill alone.</td>
<td>47.7</td>
<td>20.2</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>A phase III cancer research study focuses on finding the safety of new treatments.</td>
<td>36.1</td>
<td>23.6</td>
<td>NS</td>
</tr>
<tr>
<td>Cancer research studies follow strict guidelines that are described in the study protocol.</td>
<td>91.9</td>
<td>84.3</td>
<td>NS</td>
</tr>
<tr>
<td>Cancer research studies are only offered when the doctor thinks there are no other treatment options for a patient.</td>
<td>81.4</td>
<td>73.0</td>
<td>NS</td>
</tr>
</tbody>
</table>
# Self-Reported Outcomes by Study Group

<table>
<thead>
<tr>
<th></th>
<th>UC n=90</th>
<th>CHOICES n=87</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-Perceived Knowledge About CCTs</td>
<td>3.09 (0.11)</td>
<td>3.57 (0.12)</td>
<td>0.003</td>
</tr>
<tr>
<td>Self-Efficacy for Finding Information About CCTs</td>
<td>3.5 (0.11)</td>
<td>4.06 (0.11)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Clear Opinions About CCTs</td>
<td>3.49 (0.11)</td>
<td>3.90 (0.12)</td>
<td>0.01</td>
</tr>
<tr>
<td>Intent to Participate in a CCT</td>
<td>3.78 (0.11)</td>
<td>3.78 (0.11)</td>
<td>0.98</td>
</tr>
<tr>
<td>Intent to Encourage Others to Participate in a CCT</td>
<td>3.72 (0.11)</td>
<td>3.71 (0.12)</td>
<td>0.95</td>
</tr>
<tr>
<td>Decision Readiness</td>
<td>3.63 (0.11)</td>
<td>3.90 (0.12)</td>
<td>0.11</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>36.52 (3.8)</td>
<td>24.13 (3.6)</td>
<td>0.02</td>
</tr>
<tr>
<td>Unclear Values</td>
<td>31.46 (3.9)</td>
<td>16.67 (3.1)</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Relation Between Group (CHOICES vs. UC) and Outcomes, Controlling for Whether or Not Patients Had Heard of CCTs and Education (n=177)

CHOICES group had:

Higher Knowledge (LS-Mean=69.8 vs 55.8, SD 2.9, p<0.001)

Clearer Values (LS-Mean=15.8 vs 32.3, SD 4.5, p<0.001)

More Certainty about Choice (LS-Mean=24.3 vs 36.4, SD 5.4, p<0.02)
Correlations of Intentions and Decision Outcomes with Objective Knowledge (N=177)

<table>
<thead>
<tr>
<th>Objective Knowledge (PropKCorrect)</th>
<th>ρ (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent to Participate in a CCT</td>
<td>0.08 (p=0.32)</td>
</tr>
<tr>
<td>Intent to Encourage Others to Participate</td>
<td>0.04 (p=0.59)</td>
</tr>
<tr>
<td>Decision Readiness</td>
<td>0.25 (p&lt;0.001)</td>
</tr>
<tr>
<td>Self-Perceived CCT Knowledge</td>
<td>0.39 (p&lt;0.001)</td>
</tr>
<tr>
<td>Self-Efficacy for Finding CCT Information</td>
<td>0.51 (p&lt;0.001)</td>
</tr>
<tr>
<td>Clear Opinions About CCT</td>
<td>0.46 (p&lt;0.001)</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>-0.31 (p&lt;0.001)</td>
</tr>
<tr>
<td>Unclear Values</td>
<td>-0.46 (p&lt;0.001)</td>
</tr>
</tbody>
</table>
Implementation Outcomes

• Well-received by patients & institutional stakeholders
  • 94 unique visits to the DA
  • 1.4 visits per participant on average
  • 20.1 minutes to view it on average
# Implementation Outcomes

## Flexibility in completing tool and survey

<table>
<thead>
<tr>
<th></th>
<th>Overall N=177</th>
<th>UC N=90</th>
<th>CHOICES N=87</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td>107 (60.5)</td>
<td>56 (62.2)</td>
<td>51 (58.6)</td>
</tr>
<tr>
<td>Mail</td>
<td>44 (24.9)</td>
<td>22 (24.4)</td>
<td>22 (25.3)</td>
</tr>
<tr>
<td>Clinic</td>
<td>15 (8.5)</td>
<td>8 (8.9)</td>
<td>7 (8.0)</td>
</tr>
<tr>
<td>Phone</td>
<td>11 (6.2)</td>
<td>4 (4.4)</td>
<td>7 (8.0)</td>
</tr>
</tbody>
</table>
Implications: Decision Quality

- Improvement in key decision quality outcomes

- Clear presentation of ideas necessary for consent
  - Voluntary nature of trials
  - Potential risks and benefits

- High acceptability (stakeholders & patients)

- Delivery of information outside of clinics
Implications: Participant Recruitment

• Lack of quantitative difference in intent:
  • Diversity of patients
  • Not specific to a trial
  • Aim of DAs is not to persuade

• Qualitative data

  “This really has changed my mind about clinical trials. When I was first diagnosed, my husband said no trials, we are doing what they know works. Now I would have no objections [to participating].”
Implications: Participant Retention

- Could improve if participants are making more preference-consistent choices
- Future studies could explore enrollment & retention rates
I'm bringing you into the decision-making process, Ruggles. Here - flip this coin.
Questions

Email: mpoliti@wustl.edu

Faculty pages:

http://publichealthsciences.wustl.edu/Faculty/PolitiMary

http://politilab.wustl.edu
Assessed for eligibility (n=234)

Excluded (n=34)
- Did not meet inclusion criteria (n=4)
- Declined to participate (n=30)

Randomized (n=200)

CHOICES Group
Allocated to intervention (n=100)
- Received allocated intervention (n=99)
- Did not receive (already enrolled and completed study) (n=1)

Lost to follow-up (n=6)
- Deceased prior to completion (n=3)
- Did not complete survey prior to end of study period (n=3)

Discontinued intervention (n=6)
- No reason provided (n=5)

UC Group
Allocated to intervention (n=100)

Lost to follow-up (n=5)
- Deceased prior to completion (n=4)
- Did not complete survey prior to end of study period (n=1)

Discontinued intervention (n=5)
- No reason provided (n=5)

Analysis

Analyzed (n=87)

Analyzed (n=90)