Colon Cancer Vaccine Study: Development of a Decision Support Intervention for Study Recruitment

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COLON CANCER VACCINE STUDY: DEVELOPMENT OF A DECISION SUPPORT INTERVENTION FOR STUDY RECRUITMENT

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Summer Training Program in Cancer Immunotherapy
Thomas Jefferson University
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Colorectal Cancer

- 3rd leading cause of cancer and 2nd leading cause of cancer related deaths in the United States\(^1\)
- African Americans have higher rates of recurrence\(^1\)
- Guanylyl cyclase C (GCC) is a protein that is over expressed by metastatic colorectal tumors
- Cancer clinical trials \(^2,^3\)
  - Participation is 3-5%
  - Recruitment (communication challenges)
  - Lower rates in African Americans

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1. Center for Disease Control, 2012
2. Cox & Mcgarry, European Journal of Cancer Care, 2003
Cancer Mucosa Antigens as Novel Vaccine Targets to Eliminate Stage-Specific Racial Disparities in Colorectal Cancer (CCV STUDY)
Health Services Research

• Addresses patient access to health care and health care services as well as patient outcomes and effectiveness of health care
• Addressing racial barriers in participating in cancer vaccine trials
• Develop a decision support intervention to improve informed participation

Identify factors that may influence trial participation
Figure 1. The PHM and AHP in Mediated Decision Support

- Perceived Susceptibility
- Salience and Coherence
- Worries and Concerns
- Response Efficacy
- Social Support
- Decision Stage

Representations

Decision Making, Planning, and Performance

Preference Clarification

Planning

Decision

Action

Likelihood Assessment

Experience

* PHM = Preventive Health Model, AHP = Analytic Hierarchy Process

Phases of The CCV Study

Phase I
Materials & Methods Development
- Conduct literature review
- Develop and pretest trial informational booklet
- Adapt web-based decision counseling program
- Prepare questionnaire for Phase 2 survey

Phase II
Pre-test and Feasibility Assessment
- Pilot test informational booklet
- Administer Survey
  ✓ Measure intention to participate in trial
  ✓ Identify patient factors associated with intention to participate in trial

Phase III
In-Person Decision Counseling
- Identify patients interested in trial participation
  ✓ Determine preference for trial participation
- Refer interested patients to study coordinator for enrollment

Center of Excellence in Cancer Immunotherapy
Phase I: Conclusions

- Perceived effectiveness of the informational booklet varied by age
  - Older patients found the booklet more challenging

- **Modifications to the booklet**
  - Large print
  - Subheadings
  - Reducing reading level from 11th grade to an 8th grade level
  - Additional information
    - clarify side effects and safety
    - participation requirements
Colon Cancer Vaccine Study

About this booklet

Goals of the study
This booklet includes information about a research study on a new vaccine that may help prevent colon cancer from coming back (recurrence) for people who have been treated for early stage (stage I or II) colon cancer.

The study, referred to here as the Colon Cancer Vaccine Study, aims to:
1. Make sure the vaccine is safe, and
2. Find out if the vaccine is likely to work.

Information in the booklet is for people who may be interested in joining the study.
To help you decide if you want to be a part of the Colon Cancer Vaccine Study, we encourage you to take the following steps:
• Read. Review information in this booklet.
• Ask questions. Speak with a research staff member and your doctor to learn more about the study and get your questions answered.

Medical terms and abbreviations
Some words in the booklet might not be familiar to you. These words are printed in orange and are defined in the Glossary.

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Developed and pre-tested the Informational Booklet
Phase II

Identify factors that may influence trial participation

• Began my research during the middle of phase II
  – Recruitment at 21 patients (19 Whites and 2 Blacks)
  – Goal is 25 Blacks and 25 Whites

• Literature review
• Data entry
• Preliminary Analyses
Literature Review

• Search databases were RefWorks, Scopus, and PubMed
• Annotated 42 articles
• Identified factors that influence trial participation:
  – Decision-Making Process (9)
  – Participant – provider communication (12)
  – Decision Aids (11)
  – Recruitment Strategies (10)
Literature Review

• Decision Making Process
  – Shared decision making is ideal for increasing trial participation

• Patient – Provider Communication
  – Important to ensure participants have complete understanding of the research study
    • Test/feedback mechanisms

• Recruitment Strategies
  – Specific to culture and socio-demographics will increase trial participation

• Decision Aids
  – Enhanced informed consent, audiovisuals, and in-person interactions seem to influence trial participation
Phase II

• **Independent Variables**
  – Background Characteristics
  – Knowledge about the CCV Study
  – Thoughts about joining the CCV Study
  – Perceptions about Religion and Health
  – Perceptions about Health Care Research
  – Thoughts about the CCV Informational Booklet

• **Dependent Variable**
  – Intention to join the CCV Study if it were available today
    (hypothetical scenario)

• **Goal of recruitment**
  – 25 Whites and 25 Blacks
Intention to Join CCV Study

Introduction
Colon cancer can come back (recurrence) among some people who have had early (Stage I or II) colon cancer. Currently, there is no known treatment that prevents colon cancer recurrence. This problem is the focus of a study, the Colon Cancer Vaccine Study.

In the Colon Cancer Vaccine Study, work is now underway to develop a new vaccine that may help to prevent colon cancer recurrence. When the vaccine is ready, it must be evaluated to make sure it is safe and is effective in activating the body's defense (immune system). At that time, we will ask eligible patients to join a research study intended to evaluate the vaccine.

Summary of Steps in the Colon Cancer Vaccine Study
- Sign a consent form, complete blood studies, provide their medical history information, and have a physical exam.
- Visit the clinic, receive the vaccine injection in the upper arm, and remain for at least 30 minutes to make sure there are no reactions to the vaccine. (Mild flu-like symptoms are an example of a potential side effect of the vaccine)
- Receive follow up telephone calls to assess well-being
- Visit the clinic at one, three, and six months to evaluate response to the vaccine and have blood studies.
Phase II: Participant Accrual

Eligible Participants
(n=40)

Excluded (n=19)
- Unable to contact initially (n=4)
- Received surveys, but no response (n=4)
- Did not complete survey (n=11)
  - Comorbidities (n=2)
  - Not interested (n=6)
  - Other (n=3)

Completed Surveys
(n=21)
19 Whites, 2 Blacks

Figure 2: Participant Accrual for Phase II
### Phase II: Participant Characteristics

**Table 1: Summary of Participant Characteristics for Phase II, n=21 participants**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Site</strong></td>
<td></td>
</tr>
<tr>
<td>Thomas Jefferson University</td>
<td>14 (67)</td>
</tr>
<tr>
<td>University of Pittsburgh</td>
<td>7 (33)</td>
</tr>
<tr>
<td>Fox Chase Cancer Center</td>
<td>-------</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>≤ 65</td>
<td>11 (52)</td>
</tr>
<tr>
<td>&gt; 65</td>
<td>10 (48)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9 (43)</td>
</tr>
<tr>
<td>Female</td>
<td>12 (57)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>19 (90)</td>
</tr>
<tr>
<td>Black</td>
<td>2 (10)</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>11 (52)</td>
</tr>
<tr>
<td>Not Married</td>
<td>10 (48)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>≤ High School</td>
<td>8 (38)</td>
</tr>
<tr>
<td>&gt; High School</td>
<td>13 (62)</td>
</tr>
</tbody>
</table>

*Note: Recruitment is not complete for Phase II*
Intention to Join CCV Study

If the vaccine were available today and you were asked to join the Colon Cancer Vaccine Study, what do you think you would do?

- 6 I would join
- 11 I am unsure what I would do
- 4 I would not join
Background Characteristics of Participants by Joining the CCV Study if the Vaccine Were Available Today

Table 2: Summary of Background Characteristics of Participants by Joining the CCV Study

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Would Not Join/Unsure</th>
<th>Would Join</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n ( % )</td>
<td>n ( % )</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 65</td>
<td>10 (90.91)</td>
<td>1 (9.09)</td>
<td>0.0635</td>
</tr>
<tr>
<td>&gt; 65</td>
<td>5 (50.00)</td>
<td>5 (50.00)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5 (55.56)</td>
<td>4 (44.44)</td>
<td>0.3310</td>
</tr>
<tr>
<td>Female</td>
<td>10 (83.33)</td>
<td>2 (16.67)</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>14 (73.68)</td>
<td>5 (26.32)</td>
<td>0.5000</td>
</tr>
<tr>
<td>Black</td>
<td>1 (50.00)</td>
<td>1 (50.00)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>8 (72.73)</td>
<td>3 (27.27)</td>
<td>1.0000</td>
</tr>
<tr>
<td>Not Married</td>
<td>7 (70.00)</td>
<td>3 (30.00)</td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ High School</td>
<td>5 (62.50)</td>
<td>3 (37.50)</td>
<td>0.6311</td>
</tr>
<tr>
<td>&gt; High School</td>
<td>10 (76.92)</td>
<td>3 (23.08)</td>
<td></td>
</tr>
</tbody>
</table>

Fisher’s Exact Test, n=21
Summary of Survey Responses: Joining the CCV Study if Vaccine Were Available Today by Thoughts about Joining the CCV Study

Table 3: Summary of Joining the CCV Study If Vaccine Were Available Today by Thoughts about Joining the CCV Study

<table>
<thead>
<tr>
<th>Survey Items</th>
<th>Would Not Join/Unsure</th>
<th>Would Join</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Important thing for me to do</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>10 (66.67%)</td>
<td>0 (0.00%)</td>
<td>0.0124</td>
</tr>
<tr>
<td>Agree</td>
<td>5 (33.33%)</td>
<td>6 (100.00%)</td>
<td></td>
</tr>
<tr>
<td><strong>Could help protect my health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>7 (46.67%)</td>
<td>0 (0.00%)</td>
<td>0.0609</td>
</tr>
<tr>
<td>Agree</td>
<td>8 (53.33%)</td>
<td>6 (100.00%)</td>
<td></td>
</tr>
<tr>
<td><strong>Could help prevent a recurrence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>10 (66.67%)</td>
<td>1 (16.67%)</td>
<td>0.0635</td>
</tr>
<tr>
<td>Agree</td>
<td>5 (33.33%)</td>
<td>5 (83.33%)</td>
<td></td>
</tr>
<tr>
<td><strong>Family thinks I should join</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>13 (86.67%)</td>
<td>2 (33.33%)</td>
<td>0.0307</td>
</tr>
<tr>
<td>Agree</td>
<td>2 (13.33%)</td>
<td>4 (66.67%)</td>
<td></td>
</tr>
<tr>
<td><strong>My doctor thinks I should join</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>13 (86.67%)</td>
<td>2 (33.33%)</td>
<td>0.0307</td>
</tr>
<tr>
<td>Agree</td>
<td>2 (13.33%)</td>
<td>4 (66.67%)</td>
<td></td>
</tr>
</tbody>
</table>

Fisher’s Exact Test, n=21
Phase II: Implications

- **Representations of Theoretical Model**
  - **Salience and Coherence**
    - Those patients who agreed that joining is important and want to join, may be more likely to follow through with the requirements of participation
    - Time and effort of research staff is not wasted
  - **Response Efficacy**
    - Protect my health (67%)
    - Prevent a recurrence (48%)
    - False hope or false reassurance (therapeutic fallacy)
  - **Social Influences (i.e. doctor and/or family)**
    - 13 participants (61%) disagreed with believing their family thinks they should join and 13 participants (61%) disagreed with believing their doctor thinks they should join
    - Provide more information to the providers and/or encourage participants to talk with family members about the vaccine and invite them to read the informational booklet and/or in the future attend the in-person decision counseling session
• **Age** has a tendency to be associated with intention to join the CCV study

• **Attitudinal Factors**
  – Important thing for me to do
  – Could help protect my health (marginally significant)
  – Could help prevent a recurrence (marginally significant)
  – Family thinks I should join
  – Doctor thinks I should join

• **Preliminary analyses, all these factors may change!**
Future of Health Services Research

• Phase III
  – Identify patients interested in trial participation
  – Determine preference for trial participation
    • Combine informational booklet and web-based decision counseling
    • Refer interested patients to study coordinator for vaccine trial enrollment

Table 4: Summary of participants that would like to be notified when the vaccine trial is ready to enroll by participants who would join if vaccine were available today

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>Would Not Join</th>
<th>Unsure</th>
<th>Would Join</th>
</tr>
</thead>
<tbody>
<tr>
<td>Would you like to be notified when</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the vaccine trial is ready to enroll?</td>
<td>No 2 (9.52)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td></td>
<td>Yes 2 (9.52)</td>
<td>11 (52.38)</td>
<td>6 (28.57)</td>
</tr>
</tbody>
</table>
Lessons Learned

• **Important to participate in clinical research**
  – *The Immortal Cells of Henrietta Lacks*” by Rebecca Skloot
  – Understand the trial
  – Make an informed decision

• **Importance of a statistician**

• **The value of reading literature**
Acknowledgements

- Dr. Scott Waldman
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- Ms. Carol Sims and Ms. Joan Faust
- Family and Friends for their continued support
References


References


References


Thank You!

Are There Any Questions?