Multimedia Psychoeducation for Cancer Patients Eligible for Clinical Trials: A Randomized Clinical Trial

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USA
## Faculty Disclosure

<table>
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<th>No, nothing to disclose</th>
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<tr>
<td>Yes, please specify:</td>
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</table>
Significance

- 3% of cancer patients in the United States enroll in a clinical trial
- Low rates of participation cause up to 20% of registered trials to close prematurely
- Attitudinal barriers influence patients’ willingness to participate in clinical trials
- Attitudes are modifiable, but require theory-based interventions

Ottawa Decision Support Framework

Decisional Needs
- Decisional conflict (uncertainty)
- Knowledge and expectations
- Values
- Support and resources
- Decision: type, timing, stage, leaning
- Personal/clinical characteristics

Decision Support
- Clarify decision and needs
- Provide facts, probabilities
- Clarify values
- Guide/coach/support skills
- Monitor/facilitate progress

Decisional Quality
- Informed
- Values-based

Actions
- Delay, continuance

Impact
- Values-based health outcomes
- Regret and blame
- Appropriate use and costs of services

Theory of Planned Behavior

- Attitude
- Subjective Norm
- Perceived Behavioral Control
- Intention
- Behavior

Ajzen I. 1991
Aims

• To test whether a theory-based, multimedia education program could improve decision support and attitudes

• To describe the impact of education on rates of clinical trial enrollment

• To examine the mediating relationship of attitudes on trial enrollment
Interventions

- Multimedia psychoeducation (MP)
  - DVD and booklet, *Clinical Trials: Are They Right for You?*

- Print education (PE)
  - NCI booklet, *Taking Part in Cancer Treatment Studies*

- Both arms
  - Research study coordinator, orientation to materials, question and answer
SUCCESSFUL DRUGS
Usually move on to a Phase 2 trial. The goal is to
come up with a promising drug that can be tested
towards market.

WITHOUT
And people like you, there wouldn’t be the standard of care.

WELL-INFORMED PATIENTS ARE CRITICAL
TO ADVANCING CLINICAL RESEARCH

Taking Part in Cancer Treatment Research Studies

NIH NATIONAL CANCER INSTITUTE

2018
28-30 JUNE
VIENNA, AUSTRIA
SUPPORTIVE CARE MAKES EXCELLENT CANCER CARE POSSIBLE

U.S. Department of Health & Human Services | National Institutes of Health

www.mascc.org/meeting
NCI Community Oncology Research Program (NCORP) Trial Network

- Accruals
  - 694 = 2015
  - 1098 = 2016

Aurora NCORP
Cancer Research Consortium of West Michigan
Columbus NCORP
Dayton Clinical Oncology Program
Delaware/Christiana Care NCORP
Geisinger Cancer Institute NCORP
Greenville NCORP of the Carolinas
Gulf South MU NCORP
Hawaii MU NCORP
Heartland Cancer Research NCORP
Kansas City NCORP
Metro-Minnesota NCORP
Michigan Cancer Research Consortium
Nevada Cancer Research Foundation NCORP
Northwell NCORP
SCOR NCORP
Wichita NCORP
Wisconsin NCORP
Pacific Cancer Research Consortium
Eligibility

Inclusion:
• diagnosed with cancer
• eligible for a specific phase II or III therapeutic clinical trial
• informed of eligibility for a therapeutic clinical trial
• > 18 years of age
• able to speak and read English
• capable of providing written informed consent

Exclusion:
• been asked previously to participate in a trial
• already made a decision to participate in a trial
• had visual, auditory, psychiatric/neurological disorders (e.g., blindness, deafness, psychosis, or dementia)
• been eligible only for a phase I trial
Measures

• Demographics
• Preparation for Decision Making Scale
• Clinical Trials Attitudes Scale
• Self-reported trial participation:
  – Had the patient been provided a written informed consent form?
  – Did the patient sign the consent form?
• Chart review to confirm participation

Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. 2010
Statistical Analyses

• MP = better decision support, attitudes
  – Linear mixed models
  – Intervention arm (PE vs. MP)
  – Demographic and clinical covariates at p<0.15

• Intervention effect on participation
  – 2 (arm: MP or PE) × 2 (clinical trial participation: Yes or No/Still Deciding) contingency tables using chi-square tests

• Trial participation mediated by attitudes
  – path coefficients, bootstrap confidence intervals
<table>
<thead>
<tr>
<th>Patient Demographics</th>
<th>Total N=418</th>
<th>MP n=199</th>
<th>PE n=219</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years*</td>
<td>61.5 (11.9)</td>
<td>61.5 (12.6)</td>
<td>61.6 (11.2)</td>
<td>p=0.971</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p=0.262</td>
</tr>
<tr>
<td>Never Married</td>
<td>39 (9.4)</td>
<td>20 (10.0)</td>
<td>19 (8.8)</td>
<td></td>
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<tr>
<td>Currently Married</td>
<td>246 (59.1)</td>
<td>113 (56.8)</td>
<td>133 (61.3)</td>
<td></td>
</tr>
<tr>
<td>Separated/Divorced</td>
<td>85 (20.4)</td>
<td>38 (19.1)</td>
<td>47 (21.6)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>46 (11.1)</td>
<td>28 (14.1)</td>
<td>18 (8.3)</td>
<td></td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>255 (61.0)</td>
<td>121 (60.8)</td>
<td>134 (61.2)</td>
<td>p=0.942</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p=0.663</td>
</tr>
<tr>
<td>White</td>
<td>372 (89.0)</td>
<td>177 (88.9)</td>
<td>195 (89.0)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>37 (8.9)</td>
<td>19 (9.6)</td>
<td>18 (8.2)</td>
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<tr>
<td>Asian/Pacific Islander</td>
<td>5 (1.2)</td>
<td>1 (0.5)</td>
<td>4 (1.9)</td>
<td></td>
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<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p=0.273</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>8 (1.9)</td>
<td>5 (2.5)</td>
<td>3 (1.4)</td>
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</tr>
<tr>
<td>Not Hispanic</td>
<td>406 (97.1)</td>
<td>192 (96.5)</td>
<td>214 (97.7)</td>
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<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p=0.072</td>
</tr>
<tr>
<td>High School or Less</td>
<td>151 (36.2)</td>
<td>67 (33.6)</td>
<td>84 (38.8)</td>
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<tr>
<td>Partial College</td>
<td>136 (32.7)</td>
<td>76 (38.2)</td>
<td>60 (27.6)</td>
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<tr>
<td>College or More</td>
<td>129 (31.1)</td>
<td>56 (28.2)</td>
<td>73 (33.7)</td>
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<tr>
<td>Yearly household income, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p=0.522</td>
</tr>
<tr>
<td>&lt; $20,000</td>
<td>61 (14.8)</td>
<td>23 (11.7)</td>
<td>38 (17.7)</td>
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<tr>
<td>$20,000 - $39,999</td>
<td>64 (15.6)</td>
<td>32 (16.3)</td>
<td>32 (14.9)</td>
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<tr>
<td>$40,000 - $59,999</td>
<td>62 (15.1)</td>
<td>29 (14.8)</td>
<td>33 (15.3)</td>
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<tr>
<td>$60,000 - $100,000</td>
<td>81 (19.7)</td>
<td>37 (18.9)</td>
<td>44 (20.5)</td>
<td></td>
</tr>
<tr>
<td>&gt; $100,000</td>
<td>44 (10.7)</td>
<td>22 (11.2)</td>
<td>22 (10.2)</td>
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</tr>
<tr>
<td>Cancer type (top 4), n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p=0.202</td>
</tr>
<tr>
<td>Breast</td>
<td>122 (29.9)</td>
<td>69 (34.7)</td>
<td>53 (24.2)</td>
<td></td>
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<tr>
<td>Lung</td>
<td>53 (12.7)</td>
<td>26 (13.1)</td>
<td>27 (12.3)</td>
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<tr>
<td>Colon</td>
<td>33 (7.9)</td>
<td>16 (8.0)</td>
<td>17 (7.8)</td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td>31 (7.4)</td>
<td>11 (5.5)</td>
<td>20 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Months since diagnosis*</td>
<td>10.6 (28.5)</td>
<td>7.3 (17.5)</td>
<td>13.6 (35.4)</td>
<td>p=0.021</td>
</tr>
</tbody>
</table>
## Outcomes by Intervention Arm

<table>
<thead>
<tr>
<th></th>
<th>MP n=199 (47.6%)</th>
<th>PE n=219 (52.4%)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preparedness for Decision Making</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Post-intervention (3-7 days)</td>
<td>71.16 (21.49)</td>
<td>71.26 (19.53)</td>
<td>p=0.961</td>
</tr>
<tr>
<td><strong>Decisional Conflict</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up (49-56 days)</td>
<td>17.94 (14.03)</td>
<td>17.99 (12.79)</td>
<td>p=0.971</td>
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<tr>
<td><strong>Decision Regret</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up (49-56 days)</td>
<td>18.26 (15.10)</td>
<td>18.07 (14.91)</td>
<td>p=0.911</td>
</tr>
<tr>
<td><strong>Attitudes about Clinical Trials</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.63 (0.50)</td>
<td>3.66 (0.44)</td>
<td></td>
</tr>
<tr>
<td>Post-intervention (3-7 days)</td>
<td>3.80 (0.46)</td>
<td>3.71 (0.46)</td>
<td>p=0.004³</td>
</tr>
<tr>
<td><strong>Clinical Trial Participation</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Follow-up (49-56 days)</td>
<td></td>
<td></td>
<td>p=0.01²</td>
</tr>
<tr>
<td>No</td>
<td>42 (24.7)</td>
<td>69 (36.0)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>117 (68.8)</td>
<td>119 (62.0)</td>
<td></td>
</tr>
<tr>
<td>Undecided</td>
<td>11 (6.5)</td>
<td>4 (2.0)</td>
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</tr>
</tbody>
</table>
Mediation by Attitudes

Intervention assignment (MP or PE) → 0.34 (0.09-0.59)∗ → Clinical trial participation

Intervention assignment (MP or PE) → 0.04 (0.01-0.10)∗ → Attitudes about clinical trials

Attitudes about clinical trials → 0.11 (0.04-0.19)∗ → Clinical trial participation

Clinical trial participation → 0.35 (0.07-0.63)∗ → Intervention assignment (MP or PE)
Limitations

- Small sample size for racial and ethnic minorities.
- Participants who consented to this study may have been more likely by default to participate in a clinical trial.
Conclusions

• The MP intervention was able to improve patient attitudes toward clinical trials when compared with PE.

• This improvement led to increased rates of participation in trials.

• The MP intervention is easy to deliver and disseminate.
Thank you!

Patients
NCORP Staff
Paul Jacobsen, PhD
The study team
URCC NCORP Research Base members

Any questions?