Acceptance and Commitment Therapy for Adherence to an Erectile Rehabilitation Program After Radical Prostatectomy

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Funding: NCI R21 CA 149536
Disclosure

- No Disclosures
Introduction

• All treatments for prostate cancer impact sexual functioning
  • Only 16% of men get back to their baseline erections

• Effective treatments for erectile dysfunction (ED) are available

• Penile rehabilitation programs post surgery
  − Early intervention
  − Medication assisted erections 2 to 3 times/week

Men Avoid and Drop-out of ED Treatment
Use of ED Treatment

• Many drop out of treatment
  − 50% of PDE5i users\textsuperscript{1}
  − 50% of injection users\textsuperscript{2}

• Self-report injection use\textsuperscript{3}
  − Only 60% continue at 4 months
  − Only 33% at a rate suggested for rehabilitation

• Syringe count injection use\textsuperscript{4}
  − Mean injections/week: 0.9
  − Only 10% at a rate suggested for rehabilitation

\textsuperscript{1}IMS Health, 2001; \textsuperscript{2}Sundaram et al., Urology, 1997;
\textsuperscript{3}Neleson et al., JSM, 2013, \textsuperscript{4}Nelson et al, SMSNA, 2013
Pilot Psychotherapeutic Intervention to Improve Compliance with an Erectile Rehabilitation Program
Phases of Intervention Development

- **Phase I**: Qualitative study to help inform pilot intervention

- **Phase II**: Pilot intervention using concepts of Acceptance and Commitment Therapy (ACT) to improve compliance with penile rehabilitation
  - Aims: Feasibility and Efficacy
ACT-ED Intervention

• Coaching vs. Therapy
• Explore importance of sexuality
• Accept short-term anxiety for long-term goal
  − Listen to patients’ “predictions” about injections
  − Willingness to experience anxiety and frustration
• Defuse anxiety and frustration
  − Cognitive/emotional processing
  − Humor
  − Focus on physical sensations in sexual situation
• Discuss/highlight barriers
• Commitment
  − Set injection target
Pilot Intervention

• Randomized:
  − Injection Training + ACT-ED
  − Injection Training + Nurse Practitioner (NP) Information Phone Calls

• ACT-ED lasts 4 months
  − 4 individual sessions (in person/phone, 30-45min)
  − 3 check-in phone calls (5-10min)

• NP information phone call
  − Enhanced monitoring (EM)
  − 7 phone calls on the same schedule as ACT-ED
Pilot Intervention Design

60 Radical Prostatectomy (RP) Survivors

Baseline Assessment

ACT-ED
N = 30

NP Information Calls
N = 30

4 Month Follow-Up Post Baseline

8 Month Follow-Up Post Baseline
Pilot Intervention

• Inclusion criteria
  − Within 9 months post-RP
  − Had good erectile functioning pre-surgery
    − ≥ 24 IIEF Erectile Function Domain
  − Advised to start penile injections

• Exclusion criteria
  − Specific injection phobia
  − A history of bipolar disorder or psychotic disorder
  − Current major depression
Primary Outcomes

- Feasibility
  - Acceptance rate
  - Completion rate

- Injection Use (syringe count)
  - Objective way to assess use of injections
Secondary Outcomes

• ED treatment satisfaction (EDITS)

• Sexual self-esteem and relationship quality (SEAR)

• Sexual bother (SB)

• Prostate cancer treatment regret
Analytic Strategy

• Descriptive statistics

• ANCOVA

• Reported effect sizes (Cohen’s d)$^1$
  - Small (.20)
  - Medium (.50)
  - Large (.80)

$^1$Cohen, Psych Bull, 1992
## Subject Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Total Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>53</td>
</tr>
<tr>
<td><strong>N by Group</strong></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>26</td>
</tr>
<tr>
<td>Control</td>
<td>27</td>
</tr>
<tr>
<td><strong>Mean age (years)</strong></td>
<td>60 ± 7</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>82%</td>
</tr>
<tr>
<td>Black</td>
<td>18%</td>
</tr>
<tr>
<td><strong>Relationship Status</strong></td>
<td></td>
</tr>
<tr>
<td>Partnered</td>
<td>73%</td>
</tr>
<tr>
<td>Single</td>
<td>37%</td>
</tr>
<tr>
<td><strong>Months Post-Surgery</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 ± 2</td>
</tr>
<tr>
<td><strong>EFD w/Injections</strong></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>24.5 ± 6</td>
</tr>
<tr>
<td>Control</td>
<td>25.8 ± 6</td>
</tr>
</tbody>
</table>
Primary Outcome: Feasibility

- 63 subjects recruited to the study
  - 53 subjects started the study

- Acceptance rate
  - 63% (53 out of 84)

- Completion rate for intervention group
  - 71% (21 out of 26)
  - No difference compared to EM group
Primary Outcome: Injection Use

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control</th>
<th>Intervention</th>
<th>p</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Weekly Injection Use</td>
<td>0.9</td>
<td>1.7</td>
<td>0.001</td>
<td>d = 1.25</td>
</tr>
<tr>
<td>% Adherence</td>
<td>10%</td>
<td>44%</td>
<td>0.04</td>
<td>RR = 4.4</td>
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</tbody>
</table>
### Secondary Outcomes: 4 Months

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention Compared to Control</th>
<th>p</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED Treatment Satisfaction (Range = 0-44)</td>
<td>↑ 6.6 points</td>
<td>0.09</td>
<td>0.71</td>
</tr>
<tr>
<td>Sexual Self-Esteem (Range = 0-100)</td>
<td>↑ 9.5 points</td>
<td>0.03</td>
<td>0.76</td>
</tr>
<tr>
<td>Sexual Bother (Range = 0-15)</td>
<td>↓ 1.2 points</td>
<td>0.20</td>
<td>0.51</td>
</tr>
<tr>
<td>Prostate Cancer Treatment Regret (Range = 0-25)</td>
<td>↓ 4 points</td>
<td>0.01</td>
<td>1.18</td>
</tr>
</tbody>
</table>

Cohen’s d effect size: 0.2 = weak; 0.5 = moderate; 0.8 = strong
Primary Outcome: Injection Use

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<thead>
<tr>
<th>Variable</th>
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<th>Effect</th>
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<tr>
<td>Mean Weekly Injection Use</td>
<td>0.7</td>
<td>1.2</td>
<td>0.03</td>
<td>( d = 1.08 )</td>
</tr>
<tr>
<td>% Adherence</td>
<td>0%</td>
<td>18%</td>
<td>0.18</td>
<td></td>
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</tbody>
</table>
## Secondary Outcomes: 8 Months

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention Compared to Control</th>
<th>p</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED Treatment Satisfaction</td>
<td>↑ 5.4 points</td>
<td>0.15</td>
<td>0.61</td>
</tr>
<tr>
<td>(Range = 0-44)</td>
<td></td>
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</tr>
<tr>
<td>Sexual Self-Esteem</td>
<td>↑ 9.1 points</td>
<td>0.05</td>
<td>0.70</td>
</tr>
<tr>
<td>(Range = 0-100)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Sexual Bother</td>
<td>↓ 0.9 points</td>
<td>0.40</td>
<td>0.39</td>
</tr>
<tr>
<td>(Range = 0-15)</td>
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<td></td>
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</tr>
<tr>
<td>Prostate Cancer Treatment Regret</td>
<td>↓ 3.9 points</td>
<td>0.02</td>
<td>0.93</td>
</tr>
<tr>
<td>(Range = 0-25)</td>
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</tbody>
</table>

Cohen’s d effect size: 0.2 = weak; 0.5 = moderate; 0.8 = strong
Conclusion

• Preliminary pilot data suggests ACT-ED is:
  − Feasible
  − Effective
• Significantly increased:
  − Number of injections per week
  − Adherence to erectile rehabilitation program
• Moderate to large effects on secondary outcomes
• Novel intervention:
  − Proactively helping men regain erections mitigating negative psychosocial implications of chronic ED
  − Integrates psychosocial with medical best practice
• Need to do more than support