Participant Centered Adherence Counseling for MTN-017

Ivan C. Balán, Ph.D. & Behavioral Working Group

Columbia University
Overview: MTN-017 Adherence Counseling

- **Goal**
  - Help participants adhere to product use regimen as specified in study protocol
  - To reach a more accurate estimate of product use

- **Contacts**
  - Weeks 0, 4, and 8 of each Study period
  - A total of 9 contacts per participant

- **Elements**
  - Convergence Interview
  - Adherence Counseling
    - Client Centered + Problem solving approaches
Training

- Counselors
  - Counselors
  - Nurses
- Received 2 days of onsite training
- Completed 2 practice sessions with colleague
  - Rated for fidelity
  - 1 of two sessions needed to meet competency
- Monthly coaching calls
- Review first 10 sessions of each counselor, then randomly select 1 of 5 sessions.
SESSION CONTENT
Initial Visit

**STEP 1:** Welcome participant; present overview of client centered adherence counseling

**STEP 2:** Set structure for session

**STEP 3:** Assess understanding of product use regimen

**STEP 4:** Assess confidence of using product as indicated

**STEP 5:** Identify plan for using product as indicated

**STEP 6:** Identify & problem-solve potential obstacles to using the product as indicated

**STEP 7:** Close session
Mid-Period Visit

**STEP 1:** Welcome participant; set structure for session
**STEP 2:** Conduct DATA convergence interview
**STEP 3:** Conduct PK convergence interview (Visit 6 & 9)
**STEP 4:** Explore what helped participant’s adherence
**STEP 5:** Explore participant’s thoughts on their adherence
**STEP 6:** Explore ways to improve adherence
**STEP 7:** Close the session
Period End Visit

**STEP 1:** Welcome participant; set structure for session

**STEP 2:** Conduct DATA convergence interview

**STEP 3:** Conduct PK convergence interview

**STEP 4:** Explore what helped participant adhere to product

**STEP 5:** Close the session
The Convergence Interview
What is it like?
Fidelity Ratings
Fidelity ratings: Intervention steps

Poor 1 2 3 4 5 6 7 Excellent

Average rating of 5+ = Competence
Fidelity ratings: Global Scales

1 2 3 4 5

- Collaboration
- Respect for autonomy
- Evocation
- Direction
- Empathy

Average rating of 4.0+ = Competence

Adapted from MITI (Moyers, et al.,)
Fidelity: Practice sessions

Session 1
Session 2
## Fidelity: Study Sessions

<table>
<thead>
<tr>
<th>Session Type</th>
<th>Duration Minutes (M)</th>
<th>Steps (M)</th>
<th>Globals (M)</th>
<th>Pass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid-Period (n=19)</td>
<td>17:05 [8:49 - 32:41]</td>
<td>5.54 [4.1 - 6.67]</td>
<td>4.45 [3.4 - 5.0]</td>
<td>60%</td>
</tr>
<tr>
<td>End-Period (n=10)</td>
<td>11:40 [6:56 – 20:05]</td>
<td>5.50 [4.6 - 6.75]</td>
<td>4.38 [3.6 - 5.0]</td>
<td>70%</td>
</tr>
</tbody>
</table>
## Fidelity: Initial Period Session (n=27)

<table>
<thead>
<tr>
<th>SESSION STEP</th>
<th>DESCRIPTION</th>
<th>M</th>
<th>RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1:</strong></td>
<td>Welcome participant; present overview of client centered adherence counseling</td>
<td>5.9</td>
<td>2.0 – 7.0</td>
</tr>
<tr>
<td><strong>2:</strong></td>
<td>Set structure for session</td>
<td>5.6</td>
<td>1.0 – 7.0</td>
</tr>
<tr>
<td><strong>3:</strong></td>
<td>Assess understanding of product use regimen</td>
<td>5.4</td>
<td>1.0 – 7.0</td>
</tr>
<tr>
<td><strong>4:</strong></td>
<td>Assess confidence of using product as indicated</td>
<td>5.7</td>
<td>3.0 – 7.0</td>
</tr>
<tr>
<td><strong>5:</strong></td>
<td>Identify &amp; problem-solve potential obstacles to using the product as indicated</td>
<td>5.2</td>
<td>1.0 – 7.0</td>
</tr>
<tr>
<td><strong>6:</strong></td>
<td>Close session</td>
<td>5.6</td>
<td>1.0 – 7.0</td>
</tr>
</tbody>
</table>
# Fidelity: Mid-Period Session (n=20)

<table>
<thead>
<tr>
<th>SESSION STEP</th>
<th>M</th>
<th>RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Welcome participant; set structure for session</td>
<td>6.1</td>
<td>4.0 - 7.0</td>
</tr>
<tr>
<td>2: Conduct DATA convergence interview</td>
<td>5.9</td>
<td>3.0 - 7.0</td>
</tr>
<tr>
<td>3: Conduct PK convergence interview (Visit 6 &amp; 9)</td>
<td>4.5</td>
<td>4.0 - 5.0*</td>
</tr>
<tr>
<td>4: Explore what helped participant’s adherence</td>
<td>5.5</td>
<td>1.0 - 7.0</td>
</tr>
<tr>
<td>5: Explore participant’s thoughts on their adherence</td>
<td>5.3</td>
<td>1.0 - 6.0</td>
</tr>
<tr>
<td>6: Explore ways to improve adherence</td>
<td>4.6</td>
<td>2.0 - 7.0</td>
</tr>
<tr>
<td>7: Close the session</td>
<td>6.1</td>
<td>4.0 - 7.0</td>
</tr>
</tbody>
</table>
### Fidelity: End-Period Session (n=10)

<table>
<thead>
<tr>
<th>SESSION STEP</th>
<th>M</th>
<th>RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Welcome participant; set structure for session</td>
<td>6.0</td>
<td>3.0 -7.0</td>
</tr>
<tr>
<td>2: Conduct DATA convergence interview</td>
<td>5.3</td>
<td>1.0 - 7.0</td>
</tr>
<tr>
<td>3: Conduct PK convergence interview</td>
<td>4.8</td>
<td>1.0 - 7.0</td>
</tr>
<tr>
<td>4: Explore what helped participant’s adherence</td>
<td>6.0</td>
<td>5.0 - 7.0</td>
</tr>
<tr>
<td>5: Close the session</td>
<td>5.6</td>
<td>4.0 - 7.0</td>
</tr>
</tbody>
</table>
Challenges identified

- Insufficient use of manual
  - Skipped steps in session
  - Important alterations in wording

- PK convergence
  - Not confrontational, which is great!
  - With “Detectable” results
    - Less exploration of positive results
    - Tendency to use as check on participant’s product use.

- Plans/Problem solving obstacles
  - When adherence is poor, this tends to be done well
  - When adherence is good, less focus on reviewing plan and planning for future obstacles
Summary: Training

- Initial Training
  - All counselors met to criteria for using the intervention
    - Yet, they varied in their ease of learning and using this approach
    - There is a clear need for continuing coaching and fidelity monitoring to ensure the quality and consistency of counseling provided

- Coaching
  - Counselors welcome coaching sessions
    - Used sessions to discuss challenges in counseling
    - Were comfortable reviewing recordings together
Summary: Fidelity to Intervention

- Majority of sessions “passed” criteria
  - Challenges remain and must be overcome
  - Few patterns established
    - Skipping steps in sessions
    - Missed opportunities with “good” participants

- All counselors had excellent sessions
  - Challenge is not ability, but consistency
Next Steps

- Continue coaching and monitoring of sessions
- Assess for “drift”
  - Limited data available, but is becoming apparent
- Counselors with low fidelity ratings
  - More intensive coaching
  - Red flagging
Thank you.