A Telemedicine-delivered Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) in HIV-positive women in the Deep South

Disclosure

- Relevant Financial Relationship(s):
  None
Women and HIV in the US

- Women represent 25% of HIV infections in the US, with Women of color being disproportionately affected.

- 1.49% of Black Women in the US (18-49yrs old) are HIV positive (22 times the rate of White Women).

- 69% of HIV-positive women evidence prolonged symptoms of depression compared to 45% of men.

Prejean et. al. 2011; Cook et al., 2004; Wisniewski et al., 2005; Yun, Maravi, Kobayashi, Barton, & Davidson, 2005.
Women and HIV in the South

- Seven of the 10 states with the highest case rates among women are located in the South.
- Southern states comprise 67% of all HIV/AIDS cases among rural populations.
- Access to reliable transportation has been identified as one of the main barriers to access and adherence to HIV care.

CDC, HIV Surveillance Reports, 2014; Kempf, 2010
Sweet Home Alabama

- 55 of Alabama’s 67 counties are considered rural
- 7 counties, all rural, have no hospital
- 55% of the population lives in a federally designated mental health professional shortage area
- Average wait time to see a psychiatrist: 3 months

Telemedicine

- Telecommunication used to provide clinical health care at a distance

- Interactive telemedicine provides real-time interactions between provider and patient

- Beneficial for people living in isolated/remote communities

- Patient can be seen by a specialty care health provider without having to travel long distances

Objectives

• To culturally adapt an evidence-based psychotherapy for adherence and depression to HIV-positive African American women residing in rural Alabama

• To assess the feasibility and acceptability of a telemedicine delivered psychotherapy
Methods

- Time-matched Pilot Randomized Controlled Trial (RCT) (CBT-AD vs. supportive psychotherapy) via Telemedicine

- HIV-positive women seeking care at 4 outpatient clinics located in Alabama between 2014-2016

**Inclusion/Exclusion Criteria:**
- Female + ≥19yrs + HIV-positive
- Seeking care at one of the clinics + on ART
- Screened positive on the CES-D + confirmatory dx using the Mini International Neuropsychiatric Inventory (MINI)
- Substance abuse or mental disorder interfering w/ therapy
- No prior cognitive behavioral therapy treatment within the last 12 month
Clinic/Study Sites

- Birmingham (UAB)
- Montgomery
- Dothan
- Selma
- Tuscaloosa
Analysis

• **Main outcomes:**
  - Feasibility of intervention (process evaluation)
  - Acceptability of intervention (quantitative and qualitative assessment)
  - Preliminary effect on depression and ART adherence
    - Depression: CES-D
    - Adherence: Wisepill (real-time adherence monitoring device)
Wisepill

Slide courtesy Jessica Haberer
Feasibility: Enrollment & Retention

- 5 substance abuse or mental disorder
- 14 did not meet MINI criteria

Screened
55

Baseline
41

- 7 CES-D ≤10
- 5 not on ART
- 2 other

CBT
11

3 months
11

6 months
11

SP
11

3 months
9

6 months
10
## Results - Patient Characteristics

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Total (N=22)</th>
<th>CBT (N=11)</th>
<th>SP (N=11)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs), mean (SD)</td>
<td>45.8 (±11.8)</td>
<td>48.6 (±11.3)</td>
<td>43 (±12)</td>
<td>0.278</td>
</tr>
<tr>
<td>Year of HIV dx (yr), mean (SD)</td>
<td>2006 (±6.9)</td>
<td>2005 (±8.2)</td>
<td>2007 (±5.6)</td>
<td>0.476</td>
</tr>
<tr>
<td>ART initiation (yr), mean (SD)</td>
<td>2008 (±5.6)</td>
<td>2008 (±5.6)</td>
<td>2008 (±5.7)</td>
<td>0.824</td>
</tr>
<tr>
<td>CD4 count &lt;200 cells/μl, N (%)</td>
<td>2 (9.1)</td>
<td>1 (9.1)</td>
<td>1 (9.1)</td>
<td>1</td>
</tr>
<tr>
<td>HIV VL &lt;200 copies/ml, N (%)</td>
<td>19 (86.4)</td>
<td>10 (90.9)</td>
<td>9 (81.8)</td>
<td>1</td>
</tr>
<tr>
<td>Ever being dx w/ depression, N (%)</td>
<td>15 (68.2)</td>
<td>9 (81.8)</td>
<td>6 (54.5)</td>
<td>0.362</td>
</tr>
</tbody>
</table>
# Results - Patient Characteristics

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Total (N=22)</th>
<th>CBT (N=11)</th>
<th>SP (N=11)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital Status, N (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>6 (27.3)</td>
<td>5 (45.5)</td>
<td>1 (9.1)</td>
<td>0.051</td>
</tr>
<tr>
<td>Married/w/ partner</td>
<td>7 (31.8)</td>
<td>1 (9.1)</td>
<td>6 (54.5)</td>
<td></td>
</tr>
<tr>
<td>Separated/Divorced/Widowed</td>
<td>9 (40.9)</td>
<td>5 (54.5)</td>
<td>4 (36.4)</td>
<td></td>
</tr>
<tr>
<td>Education, N (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; High School</td>
<td>4 (18.2)</td>
<td>1 (9.1)</td>
<td>3 (27.3)</td>
<td>0.087</td>
</tr>
<tr>
<td>High School</td>
<td>6 (27.3)</td>
<td>3 (27.3)</td>
<td>3 (27.3)</td>
<td></td>
</tr>
<tr>
<td>Graduate/GED</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some college/Technical training</td>
<td>9 (40.9)</td>
<td>6 (63.6)</td>
<td>2 (18.2)</td>
<td></td>
</tr>
<tr>
<td>College Graduate</td>
<td>3 (13.6)</td>
<td>0</td>
<td>3 (27.3)</td>
<td></td>
</tr>
<tr>
<td>Income w/n the last year &lt; $10,000, N (%)</td>
<td>12 (54.5)</td>
<td>6 (54.5)</td>
<td>6 (54.5)</td>
<td>1</td>
</tr>
</tbody>
</table>
## Results - Feasibility and Acceptability

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Total (N=22)</th>
<th>CBT (N=11)</th>
<th>SP (N=11)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td># weeks of intervention, mean (SD)</td>
<td>11.5 (±1)</td>
<td>11.6 (±0.7)</td>
<td>11.3 (±1.2)</td>
<td>0.550</td>
</tr>
<tr>
<td># weeks to complete intervention, mean (SD)</td>
<td>14.7 (±4.3)</td>
<td>13 (±2.7)</td>
<td>16.3 (±5)</td>
<td>0.071</td>
</tr>
<tr>
<td>Client Satisfaction (CSQ-8; 8-32), mean (SD)</td>
<td>30.7 (± 3.8)</td>
<td>29.6 (±5.3)</td>
<td>31.8 (±0.4)</td>
<td>0.829</td>
</tr>
</tbody>
</table>

**Acceptability Ratings (1-100), mean (SD)**

<table>
<thead>
<tr>
<th></th>
<th>Total (N=22)</th>
<th>CBT (N=11)</th>
<th>SP (N=11)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression counseling</td>
<td>97.2 (±5.4)</td>
<td>96.4 (±7)</td>
<td>98 (±3.1)</td>
<td>0.503</td>
</tr>
<tr>
<td>HIV Tx adherence counseling</td>
<td>96.6 (±12.8)</td>
<td>94.7 (±17.6)</td>
<td>98.5 (±5)</td>
<td>0.506</td>
</tr>
<tr>
<td>Telemedicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wisepill</td>
<td>85.1 (±13.5)</td>
<td>83 (±17.3)</td>
<td>90.2</td>
<td>0.261</td>
</tr>
</tbody>
</table>
Results - Acceptability (Quotes)

• “…also, for you guys, if it wasn’t for you, I would be done. I would be lost. Can I do it over again?…”

• “…told a couple friends I liked it and how I enjoyed it already. They felt I was doing better, you know, coming to you and also my family thought so also…”

• ” …it was a great help, to me. It really was, and it brought out in me some things I didn't even know—some things that I was bothered with, I didn't even know I was…”
# Results - Depression and Adherence

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Total (N=22)</th>
<th>CBT (N=11)</th>
<th>P-value</th>
<th>SP (N=11)</th>
<th>P-value</th>
<th>δ P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CES-D (0-60), mean</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>36.4</td>
<td>37.5</td>
<td>.001</td>
<td>35.3</td>
<td>.001</td>
<td>0.543</td>
</tr>
<tr>
<td>Change 13 weeks</td>
<td>-16.2</td>
<td>-17.6</td>
<td>&lt;.0001</td>
<td>-14.8</td>
<td>&lt;.0001</td>
<td>0.542</td>
</tr>
<tr>
<td>Change 24 weeks</td>
<td>-14</td>
<td>-14</td>
<td>&lt;.0001</td>
<td>-14</td>
<td>&lt;.0001</td>
<td>0.997</td>
</tr>
<tr>
<td><strong>Wisepill, % past week adherence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>71.2</td>
<td>89.6</td>
<td>.393</td>
<td>51.3</td>
<td>.478</td>
<td>0.003</td>
</tr>
<tr>
<td>13 weeks</td>
<td>-2.6</td>
<td>-9.2</td>
<td>.053</td>
<td>5.9</td>
<td>.743</td>
<td>0.270</td>
</tr>
<tr>
<td>24 weeks</td>
<td>-21.2</td>
<td>-34.5</td>
<td>.053</td>
<td>-4.3</td>
<td>.743</td>
<td>0.17</td>
</tr>
<tr>
<td><strong>Wisepill, % past week adherence + behavioral corr.</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>89.6</td>
<td>94.8</td>
<td>.584</td>
<td>84.4</td>
<td>.126</td>
<td>0.239</td>
</tr>
<tr>
<td>Change 13 weeks</td>
<td>3.9</td>
<td>-5.2</td>
<td>.150</td>
<td>13</td>
<td>.077</td>
<td>0.156</td>
</tr>
<tr>
<td>Change 24 weeks</td>
<td>2.2</td>
<td>-7.8</td>
<td>.150</td>
<td>12.6</td>
<td>.025</td>
<td>0.025</td>
</tr>
</tbody>
</table>
Conclusions

• The delivery of a Telemedicine-delivered psychotherapy is feasible and acceptable among HIV-positive women living in the rural South.

• The use of Wisepill as an adherence monitoring device within this population needs to be further evaluated.

• The efficacy of the intervention needs to be tested in a large scale clinical trial using ART non-adherence or uncontrolled virus as an entry criteria.
Thanks

UAB
- Andre Azuero
- Karen Cropsey
- Robert Savage
- Corilyn Ott
- Kristi Stringer
- Christina Jagielski

Tuscaloosa
- Deborah Tucker
- Marquetta Campbell

Montgomery
- Laurie Dill

Harvard/Miami
- Steve Safren
- Christina Psaros
- Jessica Haberer
- HIV care providers and staff at participating clinics
- Study Participants

NIMH
- 1 R34 MH097588-01
CBT for Adherence and Depression (CBT-AD) in HIV

- Life-Steps (1 session)
- Psychoeducation/Motivational Interviewing about CBT for Depression (1 session)
- Behavioral Activation/Activity Scheduling (1 session)
- Adaptive thinking (3 sessions)
- Problem Solving (3 sessions)
- Relaxation/Diaphragmatic Breathing (1 session)

*Each session builds on the previous session and each session integrates adherence skills.*
Life-Steps*

- Psychoeducation/Motivation for Adherence
- Getting to Appointments
- Communication with Treatment Team
- Coping with Side Effects
- Obtaining Medications
- Formulating a Daily Medication Schedule
- Storing Medications
- Cue Control Strategies for Taking Medication
- Guided Imagery/Rehearsal
- Handling Slips in Adherence
- Review

Barriers to Telemedicine Use

- Equipment Cost
- Technical Training
- Evaluation Time
- Quality of transmitted records/clinical information
### Telemedicine/Computer Use

<table>
<thead>
<tr>
<th>Patient Characteristics (N=33)</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Telemedicine Use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>Are you comfortable using a computer?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>22</td>
<td>67</td>
</tr>
<tr>
<td>Prior Skype use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Own a cell phone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32</td>
<td>97</td>
</tr>
<tr>
<td>Own a smart phone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>12</td>
</tr>
</tbody>
</table>
Transportation

“The only thing that ever happened to me to where I couldn’t make it was if I didn’t have enough money for gas, that particular time, I would just reschedule my appointments….Or, if I had car trouble.”
R34 - Telemedicine to improve depression and adherence in HIV+ women in the rural South

- To conduct **formative research** among HIV-infected women and HIV care providers to inform the cultural adaptation of the CBT-AD intervention for HIV-infected women in rural areas of Alabama;

- To **systematically adapt the CBT-AD intervention** to HIV-infected depressed women residing in rural Alabama and telemedicine technology, using an iterative open-label – non-randomized process.

- To **assess the feasibility, acceptability and preliminary efficacy** of the adapted CBT-AD in reducing depression and improving ART adherence and retention in care among HIV-infected depressed women via a pilot randomized controlled trial (RCT).
Barriers to retention-in-care among HIV-infected Women

- Work
- Family
- Bad Health
- Organization of Health Care Facility
- Distance to Clinic
- Length of Clinic Appointments
- Transportation
- Finances
- Conflict with Law
- Stigma

Treatment by Healthcare Providers
Conceptual Framework

Fig. 1: Social Ecological Model of Behavior Change, Conceptual Framework for Depression, Adherence and Retention to Care (modified and adapted from Katz, 2008)
Wireless monitoring devices
The technology

- Device components
  - Microchip to record time-date stamp (like a MEMS cap)
  - SIM card and a rechargeable battery
  - Pill container insert (2 or 7 compartments)
The technology

- **Data**
  - Transmission via GPRS with SMS back up
  - Hosted by Wisepill in Cape Town or locally
  - Accessible via the web with customizable reports

- **Functionality**
  - Positive control via early morning “heartbeat”
  - Each transmission includes battery level, signal strength, air time
  - Capacity for SMS reminders
Choice of Wisepill

- Availability of developer
- Flexibility of software
- Portability of the device
- Works in remote settings (e.g. Africa)
Challenges

- Looking for the absence of a signal
- Battery life
- SIM cards
  - Unexpected expiration
  - Registration requirement
- Network availability
  - Delayed transmission resulting in “false interruptions”
  - Need for SMS back-up
- Frozen modem
Challenges

- Data cleaning
- Potential for stigma/unintended disclosure
- Cost

- Importantly, no reported problems with
  - Diversion
  - Med refills
R34 - Telemedicine to improve depression and adherence in HIV+ women in the rural South

- To conduct **formative research** among HIV-infected women and HIV care providers to inform the cultural adaptation of the CBT-AD intervention for HIV-infected women in rural areas of Alabama;

- To **systematically adapt the CBT-AD intervention** to HIV-infected depressed women residing in rural Alabama and telemedicine technology, using an iterative open-label – non-randomized process.

- To **assess the feasibility, acceptability and preliminary efficacy** of the adapted CBT-AD in reducing depression and improving ART adherence and retention in care among HIV-infected depressed women via a pilot randomized controlled trial (RCT).