The TENDAI Study: Treatment for depression and adherence to ART in people living with HIV in Harare, Zimbabwe

Melanie Abas, Dixon Chibanda (on behalf of TENDAI team)
Overview

• HIV, depression, and non-adherence in sub-Saharan Africa

• Cognitive-behavioral interventions for ART adherence and depression

• Methods and preliminary results of a feasibility study in Harare
• Infections in Sub-Saharan Africa account for 2/3 of the world’s total (WHO 2014)
• Average rate of reporting =>90% adherence is 67% in low income countries (Ortego 2011)
• Lifetime prevalence of common mental disorders, including depression, is 22% in low income countries (Steel et al 2014). Depression significantly associated with non-adherence in LIC (Chibanda et al 2014)
• Cognitive-behavioral interventions can improve both adherence & mental health for people on ART with co-morbid depression
• But, lack of research on adapting such interventions for use in Sub-Saharan Africa. Any innovation must have potential for scale-up
Interventions for ART adherence (WHO, 2013)

- Program level approaches: decentralise care to community-based delivery models, reduce costs for patients, simplify regimens and ensure drug supply.

- Individual level approaches: SMS, real time monitoring, peer support, treating comorbid mental disorders, psychosocial support,

- Nothing on motivational and PST interventions
AIMS OF THE STUDY

• Select and adapt an evidence-based intervention for adherence and depression in people living with HIV (PLWH) at risk of treatment failure

• Test the feasibility and acceptability of the intervention
The Intervention: New Direction ("Nzira Itsva")

- Used Life-Steps, evidenced-based cognitive behavioral intervention (CBI) to improve ART adherence (Safren et al 2001, 2009).

- Adapted for local Zimbabwean adult population:
  - Qualitative work to understand barriers to adherence; included cultural factors that influence access to HIV care & adherence; added locally relevant phrases, metaphors, visual aids & illustrations
  - Main barriers identified: getting to clinic, talking to doctor, coping with side effects, getting & storing medication, financial constraints, marital problems, forgetting, depressive rumination, nature of job, stigma, comprehension
New Direction Structure

• Set the agenda
• Identify motivation for taking medication
• Review 2-week adherence
• Identify goal for adherence
• Psycho-education, information on HIV and ART using video
• Problem solving
  - Identify barriers to adherence
  - Identify a plan to overcome barriers
• 5 minutes on other issues e.g. unprotected sex
• Sessions 2 – 4 boosters
Differences from Life-Steps approach

- Language
- Greater number of sessions
- Use of an educational video
- Cadre of the interventionist
- Culturally-competent probes
- Integrated with stepped care for depression based on problem-solving therapy (not CBT)
Feasibility study

Inclusion Criteria:

• 18 years of age or above
• On antiretroviral therapy for at least 4 months – pharmacy records
• Score above cut-point for depression on a locally validated scale for depression
• Indicator of poor adherence via any one of: 1) missed clinic appointments; 2) falling CD4 count; 3) self-reported adherence problems; 4) detectable viral load
Some preliminary results

Recruitment & randomisation

• Various methods were used to recruit patients
  - referrals from doctors and other clinical staff most effective

• Out of 105 participants screened, 44% were eligible for the trial, 91% of which consented to take part.
  - recruitment took place over a period of 29 weeks

• The process of randomisation appeared to be highly acceptable to patients, as all eligible patients were willing to be randomised.
Number of Patients Screened according to Inclusion Criteria: **105**
(female = 65/105)

Number excluded due to not meeting inclusion criteria: **59**
(female = 35/59)

Number who were eligible but declined to take part: **4**
(*2 lived too far away, 2 busy with exams*)

Number Recruited: **42**
(female = 26/42)

Number in intervention arm: **22**

Number lost to follow up: **2**

Number entering the analysis: **20**
(male/female = 8/12)

Number in comparison arm: **20**

Number lost to follow up: **3**

Number entering the analysis: **17**
(male/female = 4/13)
## Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
<th>mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td>39.2 (11.2)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>female</td>
<td>13 (59.1)</td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>9 (40.9)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>married</td>
<td>11 (50.0)</td>
<td></td>
</tr>
<tr>
<td>single</td>
<td>6 (27.3)</td>
<td></td>
</tr>
<tr>
<td>widowed</td>
<td>5 (22.7)</td>
<td></td>
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<tr>
<td><strong>Highest Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pre-primary</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>primary school</td>
<td>5 (22.7)</td>
<td></td>
</tr>
<tr>
<td>secondary school</td>
<td>16 (72.7)</td>
<td></td>
</tr>
<tr>
<td>high school</td>
<td>1 (4.6)</td>
<td></td>
</tr>
<tr>
<td>tertiary</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Time on ART (years)</strong></td>
<td></td>
<td>5.0 (2.9)</td>
</tr>
<tr>
<td><strong>ART regimen</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>first line</td>
<td>18 (81.8)</td>
<td></td>
</tr>
<tr>
<td>second line</td>
<td>4 (18.2)</td>
<td></td>
</tr>
</tbody>
</table>
Counsellor fidelity

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean fidelity rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>4</td>
<td>8/18</td>
</tr>
<tr>
<td>After additional 2 days training in Shona</td>
<td>4</td>
<td>14/18</td>
</tr>
<tr>
<td>After supervised practice on 6 cases</td>
<td>4</td>
<td>17/18</td>
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*Spot checks found scores remained at a mean of 17/18 across 6-month period

Session Attendance

<table>
<thead>
<tr>
<th>Number of sessions completed</th>
<th>N (%)</th>
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<tbody>
<tr>
<td>1</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>5</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>6</td>
<td>18 (81.8)</td>
</tr>
</tbody>
</table>

* Of those who attended 5 or 6 sessions, took a mean of 8.3 weeks (mean) after baseline visit to complete
Outcomes

Depression

<table>
<thead>
<tr>
<th>Measure</th>
<th>N</th>
<th>Number of participants scoring above cut-point (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>Depression Scale (PHQ-9)</td>
<td>13</td>
<td>13 (100)</td>
</tr>
<tr>
<td>Local Scale for common mental disorders (SSQ)</td>
<td>20</td>
<td>13 (65)</td>
</tr>
</tbody>
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Electronic Adherence (n=18)

<table>
<thead>
<tr>
<th>Measure</th>
<th>N (%)</th>
<th>Number of participants with good adherence (&gt;=90%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up</td>
</tr>
<tr>
<td>Electronic adherence (corrected)</td>
<td>13 (72.2)</td>
<td>16 (88.9)</td>
</tr>
</tbody>
</table>

Self-report adherence: Fall in reporting a missed dose in the last month from 6/20 (30%) to 2/20 (10%).

‘Depression’: Mean PHQ-9 fell from 13.5 (SD 2.6) to 3.4 (SD 3.3).
Conclusion

• CBI intervention appears to be feasible and acceptable
• Promising impact on pill-taking and depression in those with adherence problems.
• Robust evaluation is needed to evaluate efficacy in public ART facilities in Zimbabwe.

Key Tendai references
• Kidia, K et al (2015). “I was thinking too much”: Experiences of HIV-positive adults with common mental disorders and poor adherence to antiretroviral therapy in Zimbabwe. *Tropical Medicine & International Health*, 20(7).
• Bere, T et al (under review) Cultural adaptation of a cognitive-behavioural intervention to improve adherence to antiretroviral therapy among people living with HIV/AIDS in Zimbabwe: “Nzira Itsva”.
Points for discussion

• Distress or depression/ measurement?

• How best to measure of adherence?

• Efficacy or effectiveness trial? – or both?
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