Antiretroviral Adherence over Six Months Following Prison Release in a Randomized Trial of the imPACT Intervention to Maintain Suppression of HIV Viremia

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Background

• Treatment as Prevention (TasP) improves personal and public health.

• HIV prevalence among prisoners is 3-5x that of the general US population.

• Many HIV+ prisoners do not engage or remain in care following release from prison.

• Low adherence to ART and lack of engagement leads to loss of viral suppression following release from prison.
Study Objectives

• Project imPACT (individuals motivating to participate in adherence, care and treatment)
  • A randomized trial to test the effectiveness of a comprehensive linkage to care and adherence intervention on maintaining viral suppression following prison release.
  • Project imPACT primary outcome: viral suppression

• This study’s primary outcome: adherence to antiretroviral therapy following release from prison.
Three main components of Project imPACT

Motivational Interviewing (MI) sessions with accompanying videos

Brief Link Coordination

Text Messages (SMS)
Setting

- NC and Texas
- 90+% of inmates tested at prison entry.
- HIV care/ART provided for free during incarceration.
- Routine discharge planning prior to release.
- Supply of ART given at release
  - TX: 10 days
  - NC: 30 days
Study Eligibility

• At least 18 years old, English-speaking

• Incarcerated in a prison in:
  • Texas Department of Criminal Justice (TDCJ)
  • North Carolina Department of Public Safety (NCDPS)

• Documented HIV+, ART, viral load < 400 copies/mL

• Within 12 weeks of prison release

• Not convicted of violent offenses
  (i.e. involving serious injury, sexual assault, or death)
Methods

• Examined the effect of the intervention post-release on ART adherence.
  • Measured at unannounced telephone pill counts, conducted monthly for 6 months.

• Adherence: ratio of observed pills taken to expected pills taken at each telephone count.

• Intent to treat analysis

• Complete case
Study Participation

1,802 Screened

- 1,324 Ineligible
- 73 Declined

405 Randomized

206 Intervention

- 11 Ineligible
  - 6 sentence extended
  - 4 high threat risk
  - 1 post-release location

- 195 Intervention
  - 32 incarcerated
  - 22 LTFU
  - 10 withdrew; 3 died

199 Standard care

- 13 Ineligible
  - 9 sentence extended
  - 3 high threat risk
  - 1 detained by ICE

- 186 Standard care
  - 31 incarcerated
  - 21 LTFU
  - 5 withdrew; 1 died

128 Completed

128 Completed
## Participant Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (N = 195)</th>
<th>Standard Care (N = 186)</th>
<th>All Patients (N = 381)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age - year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>44</td>
<td>43</td>
<td>44</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>35 - 49</td>
<td>34 - 50</td>
<td>35 - 49</td>
</tr>
<tr>
<td>Male sex - no. (%)</td>
<td>147 (79)</td>
<td>150 (77)</td>
<td>297 (78)</td>
</tr>
<tr>
<td>Race - no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>46 (24)</td>
<td>39 (21)</td>
<td>85 (22)</td>
</tr>
<tr>
<td>Black</td>
<td>121 (62)</td>
<td>128 (69)</td>
<td>249 (65)</td>
</tr>
<tr>
<td>Other</td>
<td>28 (14)</td>
<td>19 (10)</td>
<td>47 (12)</td>
</tr>
<tr>
<td>Hispanic - no. (%)</td>
<td>7 (6)</td>
<td>12 (9)</td>
<td>27 (7)</td>
</tr>
<tr>
<td>CD4 cell count/mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>490</td>
<td>511</td>
<td>505</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>339 - 709</td>
<td>300 - 734</td>
<td>328 - 724</td>
</tr>
<tr>
<td>HIV RNA copies/ml - no (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;400</td>
<td>194 (99)</td>
<td>186 (100)</td>
<td>380 (&gt;99)</td>
</tr>
<tr>
<td>&gt;=400</td>
<td>1 (&lt;1)</td>
<td>0</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>History of substance use – no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inactive</td>
<td>127 (68)</td>
<td>116 (66)</td>
<td>243 (67)</td>
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<tr>
<td>Incarceration length - year</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>0.77</td>
<td>0.84</td>
<td>0.81</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>0.49 - 1.82</td>
<td>0.50 - 1.92</td>
<td>0.49 - 1.88</td>
</tr>
</tbody>
</table>
### Participant Characteristics

<table>
<thead>
<tr>
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<th>Standard Care (N = 186)</th>
<th>All Patients (N = 381)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health and wellbeing - no (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>58 (30)</td>
<td>53 (28)</td>
<td>111 (29)</td>
</tr>
<tr>
<td>Very good / good</td>
<td>101 (52)</td>
<td>93 (50)</td>
<td>194 (51)</td>
</tr>
<tr>
<td>Fair / poor</td>
<td>36 (18)</td>
<td>40 (22)</td>
<td>76 (20)</td>
</tr>
<tr>
<td><strong>Psychological distress - no (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; High</td>
<td>129 (66)</td>
<td>133 (72)</td>
<td>262 (69)</td>
</tr>
<tr>
<td>High</td>
<td>22 (11)</td>
<td>24 (13)</td>
<td>46 (12)</td>
</tr>
<tr>
<td>Very high</td>
<td>44 (23)</td>
<td>29 (16)</td>
<td>73 (19)</td>
</tr>
<tr>
<td><strong>Education - no (%)</strong></td>
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<td></td>
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<tr>
<td>Some high school</td>
<td>76 (39)</td>
<td>80 (43)</td>
<td>156 (41)</td>
</tr>
<tr>
<td>High school / GED</td>
<td>73 (37)</td>
<td>61 (33)</td>
<td>134 (35)</td>
</tr>
<tr>
<td>Some college / trade school</td>
<td>46 (24)</td>
<td>45 (24)</td>
<td>91 (24)</td>
</tr>
<tr>
<td><strong>Marital Status - no (%)</strong></td>
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<tr>
<td>Married</td>
<td>33 (17)</td>
<td>24 (13)</td>
<td>57 (15)</td>
</tr>
<tr>
<td>Formerly married</td>
<td>47 (24)</td>
<td>35 (19)</td>
<td>82 (22)</td>
</tr>
<tr>
<td>Never married</td>
<td>115 (59)</td>
<td>127 (68)</td>
<td>242 (64)</td>
</tr>
<tr>
<td><strong>Functional health literacy - no (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inadequate</td>
<td>7 (3)</td>
<td>5 (4)</td>
<td>12 (4)</td>
</tr>
<tr>
<td>Adequate</td>
<td>13 (9)</td>
<td>8 (6)</td>
<td>21 (8)</td>
</tr>
<tr>
<td>Functional</td>
<td>121 (86)</td>
<td>122 (90)</td>
<td>243 (88)</td>
</tr>
</tbody>
</table>
Rates of pill count completion

• 302 (79%) participants completed at least 1 pill count over 6 months
  • Median: 3
  • IQR: 2-5

• 63 (17%) re-incarcerated

• Those LTFU were less adherent before being lost
  • No difference between arms
Results: Adherence

Overall adherence:  
- imPACT - 80.3% (SD 2.4)  
- Control - 81.0% (SD 2.5)
Limitations

• Missing Data - Loss to follow up
  • Re-incarceration - balanced between arms
  • Missed contacts
  • Next steps: Apply multiple imputation

• Two state prison systems

• Imperfect measure of adherence
Conclusions

- ART adherence averaged >80% in both arms through 6 months after release from prison among those who completed pill counts.

- No difference between study arms, consistent with primary outcome of the trial.

- Factors independent of intervention influence ART adherence.

- Future targeted interventions needed.
Acknowledgements

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Kim Powers (UNC)

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Michele Gould (UNC)

imPACT Data Manager:
Jennifer Groves

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Questions?

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