INDIVIDUALS MOTIVATING TO PARTICIPATE IN ADHERENCE, CARE AND TREATMENT

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A collaboration between UNC, TCU and NIDA
Background

- Treatment as prevention (TasP) is advocated to improve personal and public health.
- In prisons, HIV prevalence is 3-5 times that of the general US population.¹
- Many HIV-infected prison releasees do not link to community medical care or maintain viral suppression.²
- At community re-entry, a return to risk behaviors and viral rebound can create a ‘perfect storm’ for transmission.

¹ Maruschak LM, BOJ 2012.
² Baillargeon J, et al., 2013; Springer S et. al., CID 2004; Stephenson B, et al., PHR
Background

Effective programs to help maintain the health benefits experienced during incarceration are essential to prevention.

Incarceration

Undetectable

Link to HIV Care
Adhere to ART

Freedom

Undetectable
Study Objectives

- To create Project imPACT, a multi-component intervention for HIV-infected prisoners facing re-entry.

- To compare with standard of care the effect of Project imPACT on viral suppression after release.
imPACT Intervention Development

- Targets motivation and self-efficacy to access care and adhere to ART (Social Cognitive Theory).

- Linkage to community HIV clinics for ongoing care and services.

- Adapted from multipronged interventions previously designed:
  - Project CONNECT
  - Participating and Communicating Together (PACT)
  - CETOP (Cognitive Enhancements for the Treatment of Probationers)

- Formative qualitative studies of formerly incarcerated HIV-infected patients and community providers.

1 Mugavero, Top HIV Med, 2008; Golin, et al., JAIDS 2006; Lehman et al., 2015.
Three main components of Project imPACT

Motivational Interviewing (MI) sessions with accompanying videos

Brief Link

Coordination

Text Message Adherence Reminders
imPACT Intervention

- **Motivational Interviewing Sessions**
  - 2 face-to-face sessions in prison with preparatory videos
    - (8 weeks pre-release)
  - 6 phone sessions after release over 12 weeks

- **Brief Link Coordination**
  - Needs assessment → Clinic
  - Schedules HIV care appointment
  - Initiates ADAP and PAP paperwork

- **Tailored text message reminders** before each dose of ART (for 12 weeks via cell phones provided at release)
imPACT Intervention

Link Coordinator Needs Assessment

Connect to Clinic

Study week

-12
-4
0
2
4
6
8
10
12
14
16
18
20
22

= Prison Release

= Face to Face MI with Cognitive Mapping

= Telephone MI

= daily text reminders
imPACT Video 1 Minute Clip
Setting

- NC and Texas
- 90+% of inmates tested at prison entry
- HIV care/ART provided for free.
- Routine discharge planning.
- 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)
Design and Methods

- 1:1 randomized controlled trial stratified by state
  - Standard of Care Arm
  - Project imPACT Arm (+ SOC)
- Audio computer assisted self-interviews (ACASI).
- Follow-up Assessments at weeks 2, 6, 14, 24
  - Blood draw for HIV viral load
  - ACASI for health services use (time line follow back)
Primary and Secondary Outcomes

• **Primary Outcome**: VL level < 50 copies/mL at 24 weeks.

• **Secondary Outcomes**:
  - VL level < 50 copies/ml at 2, 6, 14 weeks
  - Viremia copy-years over 24 weeks
  - Non-emergency medical care appointment attendance

• **Additional Outcomes (future analyses)**
  - Adherence to ART
  - Emergence of ART resistance mutations
  - Transmission risk behaviors and STIs
  - Predicted HIV transmission events
Statistical Methods

• Primary Outcome Analyses
  • Intent to treat analysis
  • Logistic Regression Models to estimate Odds Ratios (OR) and 95% Confidence Intervals
  • Multiple imputation employed
  • Complete case secondary analysis

• Sensitivity analyses
  • Simple imputation of missing outcome data
  • Alternate HIV-1 endpoints, including earlier time points and viremnia copy-years
  • Survival Analysis (Kaplan Meier) of time to first medical visit
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
*Includes 3 participants who completed week 24 but for whom plasma HIV RNA was unable to be performed.
## Results: Participant Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (N = 195)</th>
<th>SOC (N = 186)</th>
<th>All (N = 381)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – year Median (IQR)</td>
<td>44 (35 – 49)</td>
<td>43 (34 -50)</td>
<td>44 ( 35 – 49)</td>
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<tr>
<td>Male sex - no. (%)</td>
<td>79%</td>
<td>77%</td>
<td>78%</td>
</tr>
<tr>
<td>Race - no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>24%</td>
<td>21%</td>
<td>22%</td>
</tr>
<tr>
<td>Black</td>
<td>62%</td>
<td>69%</td>
<td>65%</td>
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<tr>
<td>Other</td>
<td>14%</td>
<td>10%</td>
<td>12%</td>
</tr>
<tr>
<td>Hispanic - (%)</td>
<td>6%</td>
<td>9%</td>
<td>7%</td>
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<tr>
<td>Education - no (%)</td>
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<tr>
<td>Some high school</td>
<td>39%</td>
<td>43%</td>
<td>41%</td>
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<tr>
<td>High school / GED</td>
<td>37%</td>
<td>33%</td>
<td>35%</td>
</tr>
<tr>
<td>Some college / trade school</td>
<td>24%</td>
<td>24%</td>
<td>24%</td>
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<tr>
<td>CD4 cell count/mm(^3) ^†</td>
<td>Median (IQR)</td>
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<td></td>
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<tr>
<td></td>
<td>490 (339 – 709)</td>
<td>511 (300 –743)</td>
<td>505 (328 – 724)</td>
</tr>
<tr>
<td>Incarceration length – year-</td>
<td>Median (IQR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.77 (0.49 - 1.82)</td>
<td>0.84 (0.50 - 1.92)</td>
<td>0.81 (0.49 - 1.88)</td>
</tr>
</tbody>
</table>
Main Outcome (24 Week HIV RNA)

Results: Primary, Secondary & Sensitivity Analyses

- Viremia-copy-years (number of copies of HIV RNA per mL over time), cumulative VL measure (P value = 0.36)
  - Intervention = median $3.6 \log_{10}$ copy x year/ml (IQR, 3.4 to 4.8)
  - Standard of care = median $3.7 \log_{10}$ copy x year/ml (IQR, 3.4 to 5.7)
Results: Viral Suppression over Time

A) Multiple Imputation

Proportion of participants with HIV RNA <50 copies/ml (for baseline [-12 weeks] <75 copies/ml)

<table>
<thead>
<tr>
<th>Study week (prison release=0)</th>
<th>Intervention</th>
<th>Standard Care</th>
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<tr>
<td>-12</td>
<td>0.93</td>
<td>0.85</td>
</tr>
<tr>
<td>-24</td>
<td>0.81</td>
<td>0.74</td>
</tr>
<tr>
<td>0</td>
<td>0.78</td>
<td>0.68</td>
</tr>
<tr>
<td>2</td>
<td>0.71</td>
<td>0.63</td>
</tr>
<tr>
<td>6</td>
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<tr>
<td>12</td>
<td></td>
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<tr>
<td>24</td>
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Number of participants contributing data

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Control</th>
<th>P-value</th>
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<tbody>
<tr>
<td>195</td>
<td>186</td>
<td>0.21</td>
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<td></td>
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<td>0.12</td>
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<tr>
<td></td>
<td></td>
<td>0.05</td>
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<td></td>
<td></td>
<td>0.18</td>
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<tr>
<td></td>
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<td>0.84</td>
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</table>
Results: Week 6 Clinic Visits and Time to First Appointment

**NOTE:** The median time to first medical clinic appointment following release was 10 days for imPACT versus 13 days for controls ($P = 0.03$).
Limitations

- Participant loss to follow-up, largely driven by re-incarceration was 33%, though similar in each arm.

- Cellphones provided to participants in both arms to minimize risk of an imbalance in study retention could have facilitated clinical care access in the control arm.

- Conducted in only two state prison systems.
Despite a fairly intensive, theory-based, multi-pronged intervention, both groups experienced a similar steady loss of pre-release viral suppression.

About 60% had undetectable viral loads at 24 weeks in both the imputed and complete case analyses.

More imPACT participants (10%) did access medical care within 6 weeks than controls.
Implications

- Linkage to care alone is insufficient when the objective is sustained suppression of HIV viremia for released prisoners.

- More distal steps of the cascade, which we sought to address, are also critical.

- Addressing chaotic social and economic environments to which prisoners return may be needed to surmount structural barriers to retention and adherence.
Acknowledgements (aka “THE VILLAGE”)

Thank you to the imPACT Participants!

- **Co-Principal Investigators**
  - Carol Golin, MD (UNC)
  - David Wohl, MD (UNC)
  - Patrick Flynn, PhD (TCU)
  - Kevin Knight (TCU)

- **Project Managers**
  - Jessica Cardo-Auten, MPH (UNC)
  - Michele Gould, MPH (TCU)

- **Data Manager**
  - Jennifer Groves, MBA (UNC)

- **Intervention Staff**
  - Kemi Amola, PhD
  - Roxanne Muiruri (TCU)
  - Lisa McKeithan, BA (UNC)
  - Steve Bradley-Bull, MS (NC)
  - Scott Edmiston (TDCJ)

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  - Michael Mugavero, MD (UAB)
  - Brian Pence, PhD (UNC)

- **Statisticians**
  - Sonia Napravnik and Steve Cole

- **Research Assistants**
  - Elizabeth Larios (TCU)
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  - Amy Neevel (UNC)
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- NICHD: K24-DA037101
- NIHD: K24-HD06920
Questions
Additional slides
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<th>All (N = 381)</th>
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<tbody>
<tr>
<td>Psychological distress - no (%)</td>
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<tr>
<td>&lt; High</td>
<td>129 (66)</td>
<td>133 (72)</td>
<td>262 (69)</td>
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<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>Marital Status - no (%)</td>
<td></td>
<td></td>
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</tr>
<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>Functional health literacy - no (%)†</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 (66)</td>
<td>122 (90)</td>
<td>243 (88)</td>
</tr>
<tr>
<td>HIV RNA copies/ml - (%)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>38%</td>
<td>32%</td>
<td>35%</td>
</tr>
<tr>
<td>50 - &lt; 75</td>
<td>54%</td>
<td>53%</td>
<td>54%</td>
</tr>
</tbody>
</table>
Results: Care Engagement by Week 6

- 260 participants had at least one visit by week 6
- 438 total non-emergency clinical visits
- 71% of medical visits were at an HIV clinic
Results: Effect on Viral Suppression

*Adjusted for age, sex, race/ethnicity, CD4+ cell count, length of incarceration, marriage status, education, substance abuse, measures of health and well-being and psychological distress - all measured at baseline.
Results: Effect on Viral Suppression

*Adjusted for age, sex, race/ethnicity, CD4+ cell count, length of incarceration, marriage status, education, substance abuse, measures of health and well-being and psychological distress - all measured at baseline.
Cell phone

- Used to deliver intervention and to augment retention
- Provided to participant and activated within <48 h after release

- **Intervention Arm**
  - Phone-based MI, SMS ART reminders prior to each dose, clinic appt reminders
  - Plan: Verizon 10 Friends & Family including #s for clinic, case manager, and others selected by participant; unlimited SMS

- **Control Arm**
  - Plan: Verizon 10 Friends & Family (TX) or limited service to study staff #s programmed into phone (NC); unlimited SMS

- **All Participants**
  - Unannounced pill counts
  - Study visit scheduling and reminders
  - Unlimited calls and SMS to research staff
- Secondary analyses
  - Adherence data
- Cost effectiveness analysis*
- Qualitative studies of:
  - Factors associated with suppressed VL*
  - Factors associated with linkage into care**
- Aim 3 – modeling of secondary outcomes to follow complete data collection

* Awarded K24 (Golin: NICHD)
**Awarded K24 (Wohl: NIDA)
A Back Up Cognitive Mapping Slide