

PROJECT imPACT

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

Freedom

Undetectable

Link to HIV Care

Adhere to ART

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 on going care and services.
- Adapted from multipronged interventions previously designed:
 - Project CONNECT ¹
 - Participating and Communicating Together (PACT) ²
 - CETOP (Cognitive Enhancements for the Treatment of Probationers) ¹
- Formative qualitative studies of formerly incarcerated HIV-infected patients and community providers.

¹Muganyizi, et al. *Journal of the American Academy of HIV/AIDS*, 2015.



Three main components of Project imPACT

**Motivational Interviewing (MI)
sessions with accompanying
videos**

Brief Link

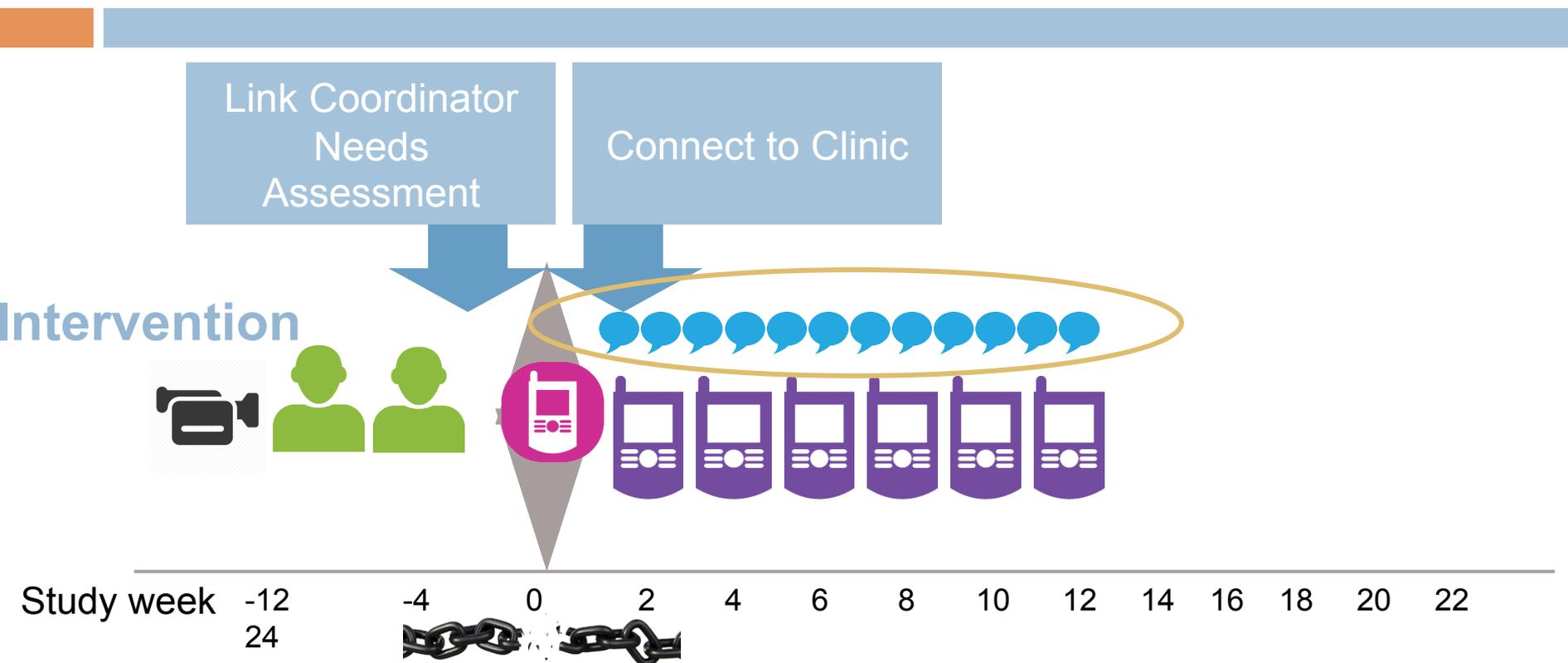
Coordination

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



 = Prison Release

 = Face to Face MI with Cognitive Mapping

 = Telephone MI

 = daily text reminders

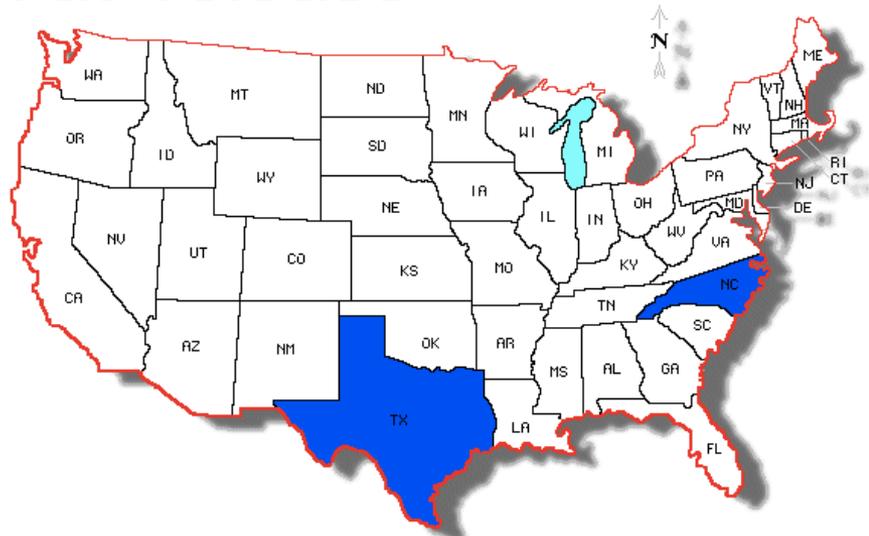


imPACT Video 1 Minute Clip



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)

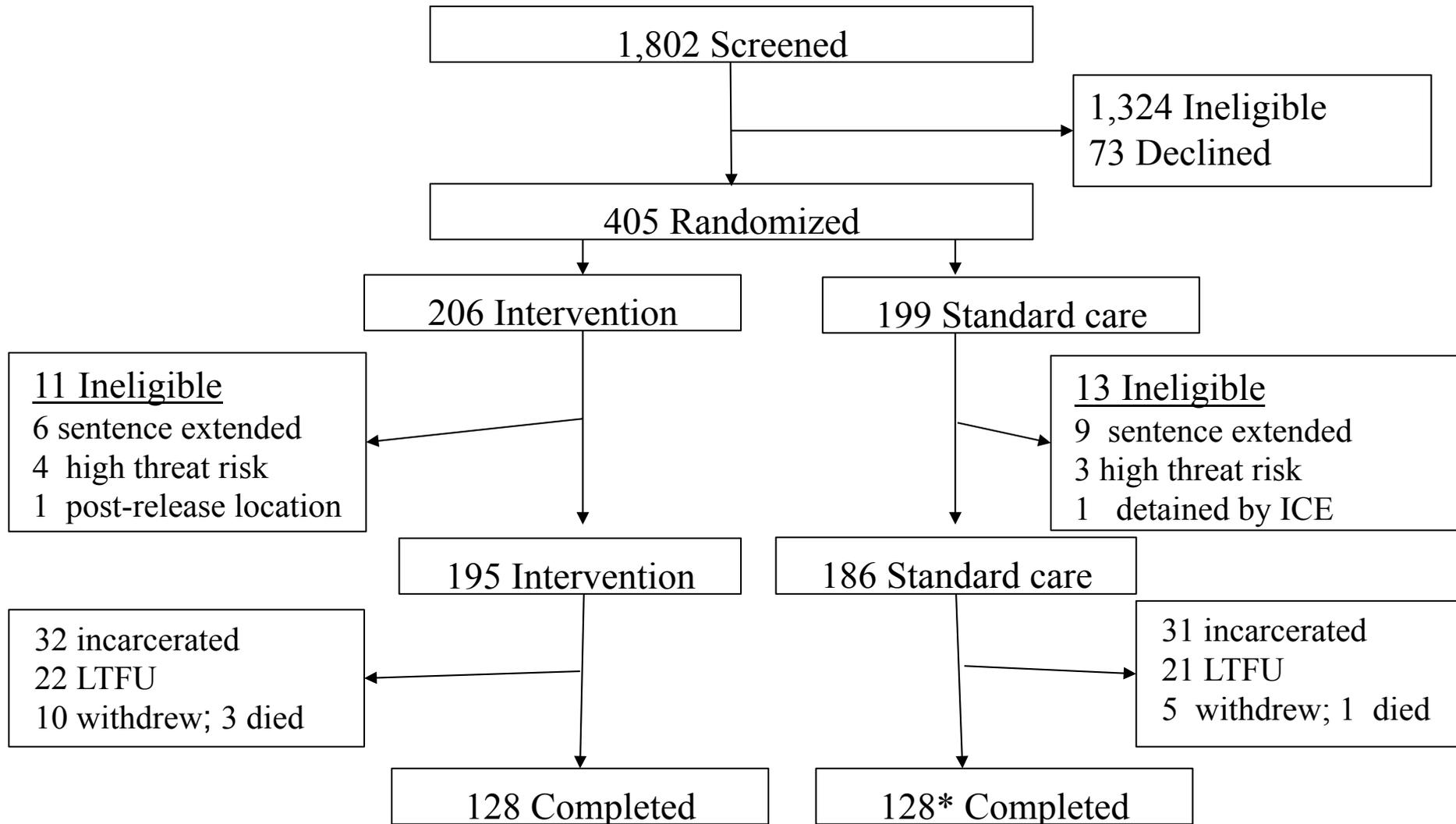
Primary and Secondary Outcomes

- **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 viremia copy-years
 - **Survival Analysis** (Kaplan Meier) of time to first medical visit

Study Participation



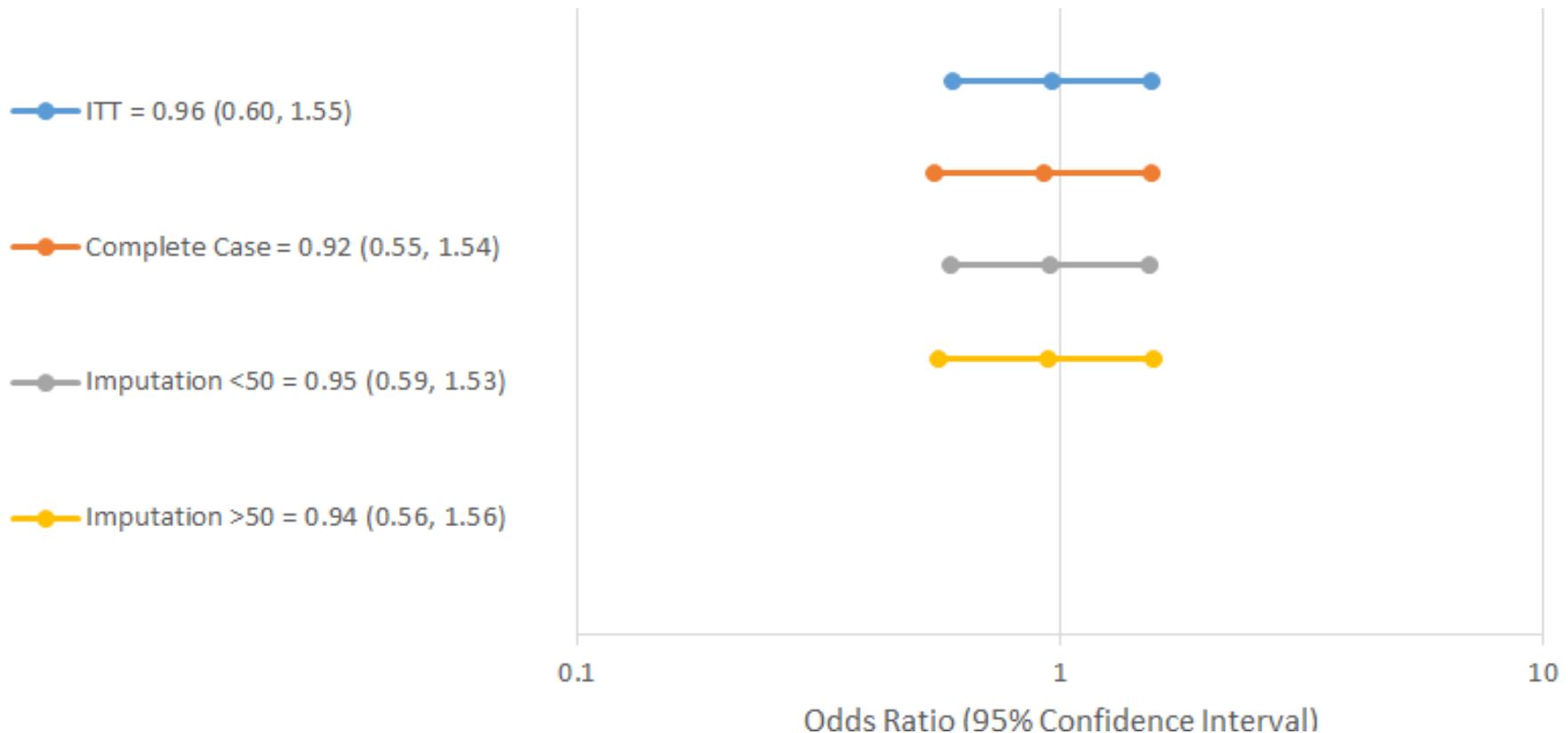
*Includes 3 participants who completed week 24 but for whom plasma HIV RNA was unable to be performed.

Results: Participant Characteristics

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

Main Outcome (24 Week HIV RNA)

Results: Primary, Secondary & Sensitivity Analyses

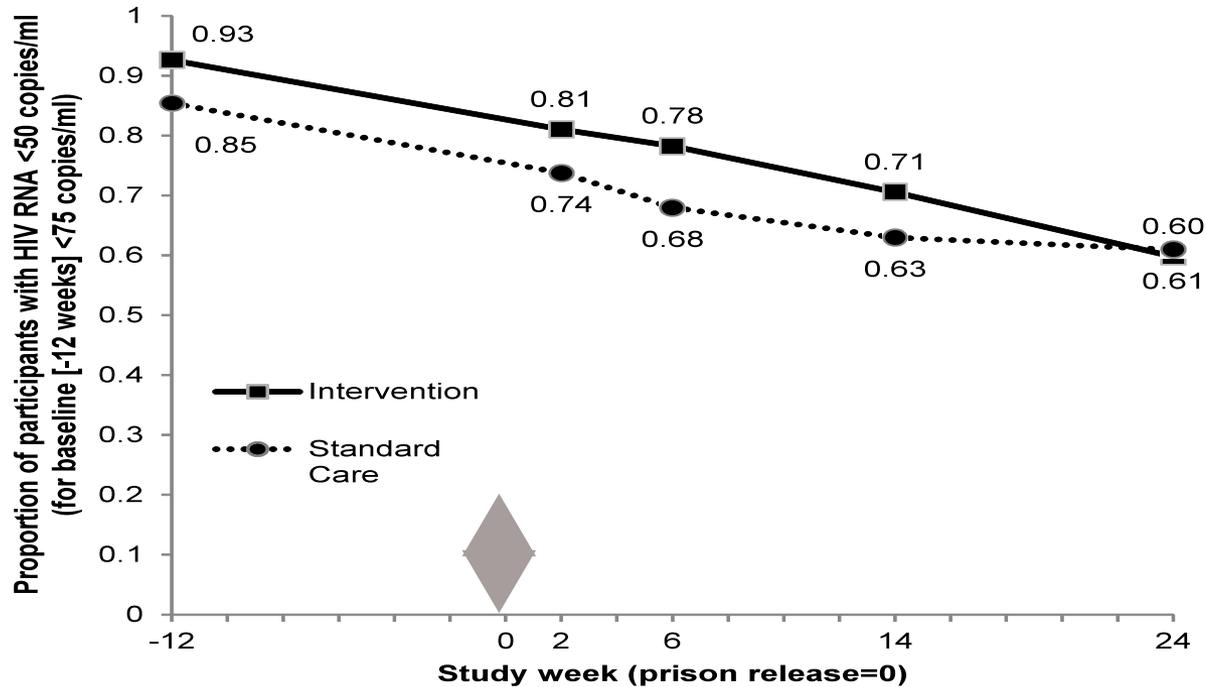


□ **Viremia-copy-years (number of copies of HIV RNA per mL over time), cumulative VL measure (P value = 0.36)**

- Intervention = median 3.6 log₁₀ copy x year/ml (IQR, 3.4 to 4.8)
- Standard of care = median 3.7 log₁₀ copy x year/ml (IQR, 3.4 to 5.7)

Results: Viral Suppression over Time

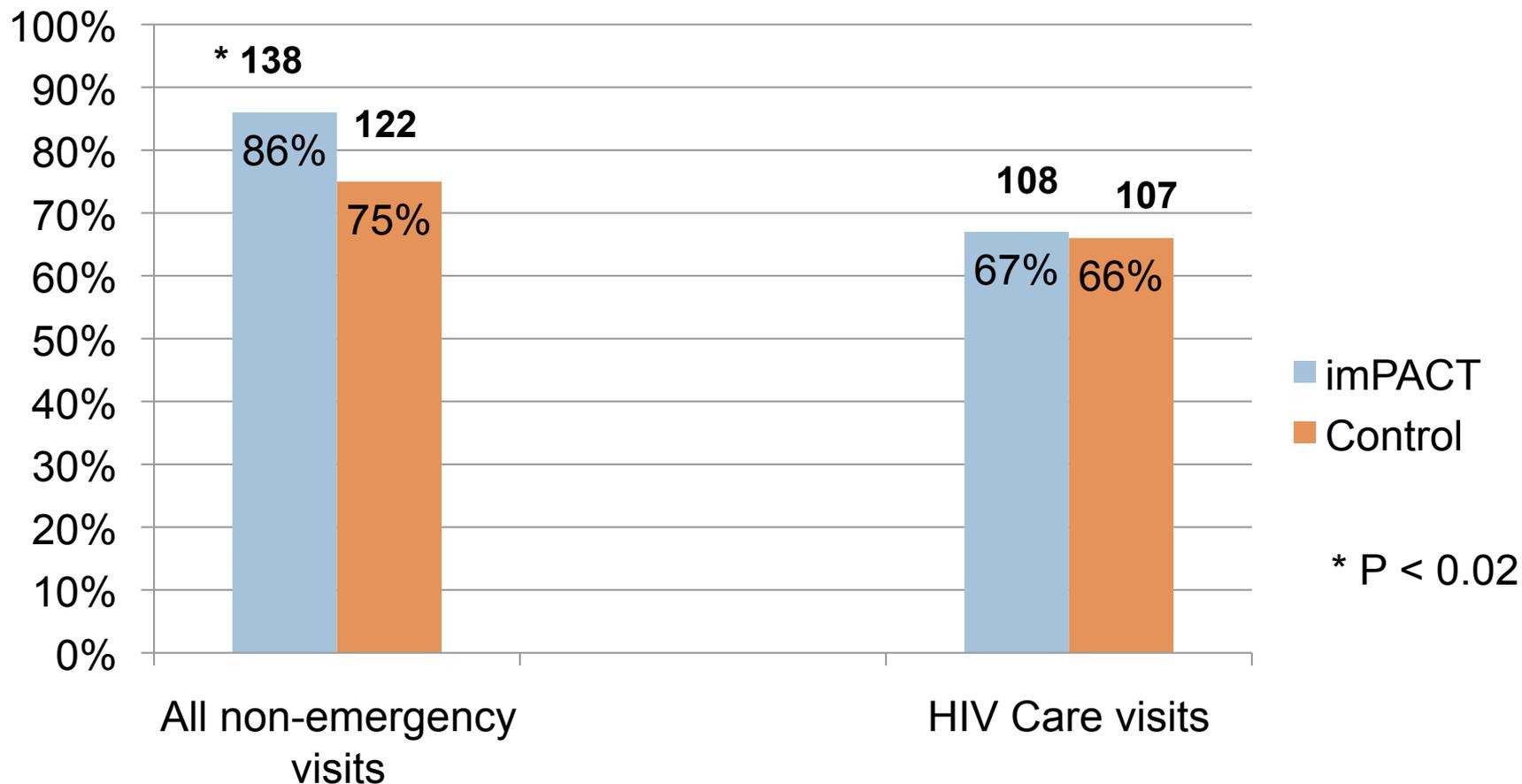
A) Multiple Imputation



Number of participants contributing data

Intervention	195	195	195	195	195
Control	186	186	186	186	186
P-value	0.21	0.12	0.05	0.18	0.84

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.

Summary

- 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.

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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 (TDC I)

• **Consultants**

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

• **Statisticians**

- Sonia Napravnik and Steve Cole

• **Research Assistants**

- Elizabeth Larios (TCU)
- Julie Gray (TCU)
- Bethany Evans (TCU)
- Molly McFatrigh (TCU)
- Lynn Tillery (UNC)
- Makisha Ruffin (UNC)
- Angela Edwards (UNC)
- Katesha Peele (UNC)
- Amy Neevel (UNC)
- Laurence Misedah (TCU)

Questions



Additional slides



Participant Characteristics

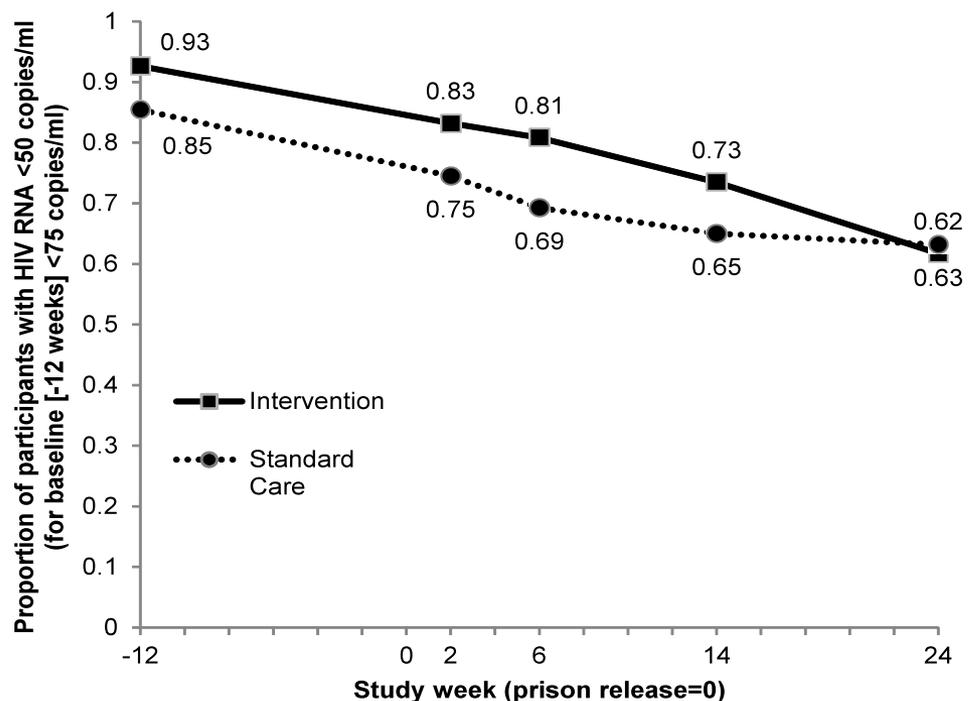
Characteristic	Intervention n (N = 195)	SOC (N = 186)	All (N = 381)
Psychological distress - no (%)			
< High	129 (66)	133 (72)	262 (69)
High	22 (11)	24 (13)	46 (12)
Very high	44 (23)	29 (16)	73 (19)
Marital Status - no (%)			
Married	33 (17)	24 (13)	57 (15)
Formerly married	47 (24)	35 (19)	82 (22)
Never married	115 (59)	127 (68)	242 (64)
Functional health literacy - no (%)[†]			
Inadequate	7 (3)	5 (4)	12 (4)
Adequate	13 (9)	8 (6)	21 (8)
Functional	121 (86)	122 (90)	243 (88)
HIV RNA copies/ml - (%)[*]			
<50	38%	32%	35%
50 - < 75	54%	53%	54%

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

B) Complete Case



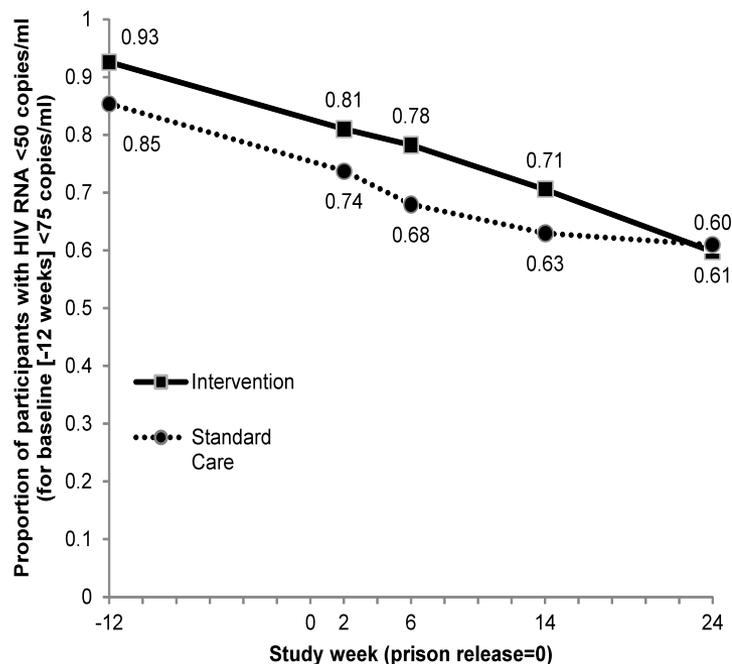
Number of participants contributing data

Intervention	195	155	146	132	128
Control	186	153	143	140	125
P-value	0.21	0.06	0.02	0.13	0.81

*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.

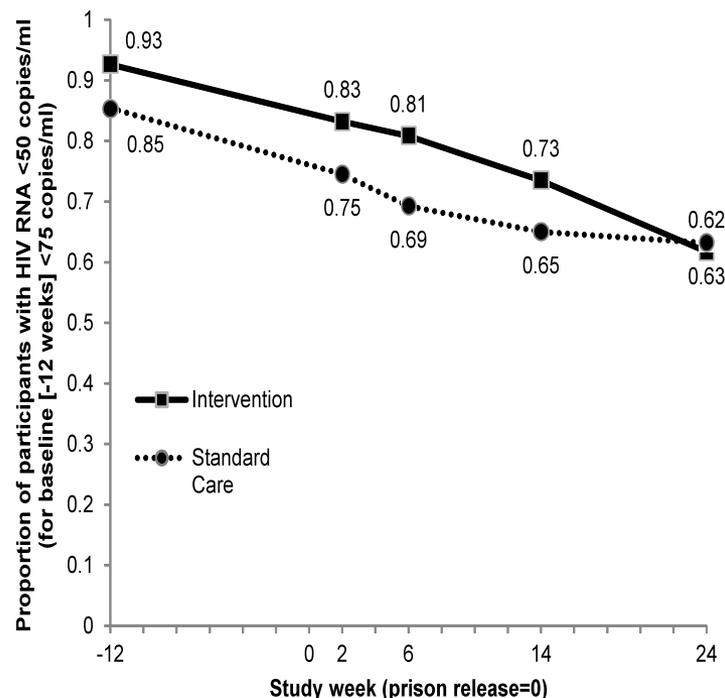
Results: Effect on Viral Suppression

A) Multiple Imputation



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Intervention	195	195	195	195	195
Control	186	186	186	186	186
P-value	0.21	0.12	0.05	0.18	0.84

B) Complete Case



	0	2	6	14	24
Intervention	195	155	146	132	128
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P-value	0.21	0.06	0.02	0.13	0.81

*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

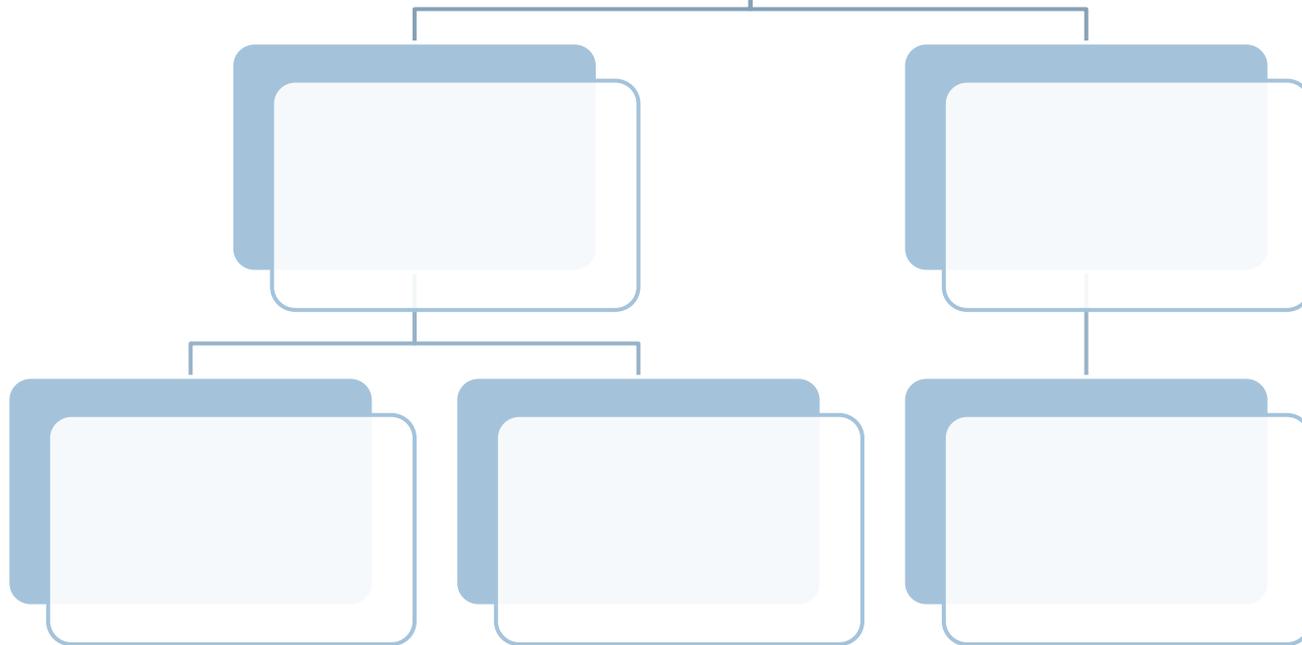
NEXT

- 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)

1802 screened
405
Randomized



A Back Up Cognitive Mapping Slide

