

# 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.<sup>1</sup>
- Many HIV-infected prison releasees do not link to community medical care or maintain viral suppression.<sup>2</sup>
- At community re-entry, a return to risk behaviors and viral rebound can create a 'perfect storm' for transmission.

<sup>1</sup> Maruschak LM, BOJ 2012.

<sup>2</sup> 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

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- 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 <sup>1</sup>
  - Participating and Communicating Together (PACT) <sup>2</sup>
  - CETOP (Cognitive Enhancements for the Treatment of Probationers) <sup>1</sup>
- Formative qualitative studies of formerly incarcerated HIV-infected patients and community providers.

<sup>1</sup> Mugaletch, et al. *Journal of the American Academy of HIV Medicine*, 2015.



# Three main components of Project imPACT

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

**Brief Link**

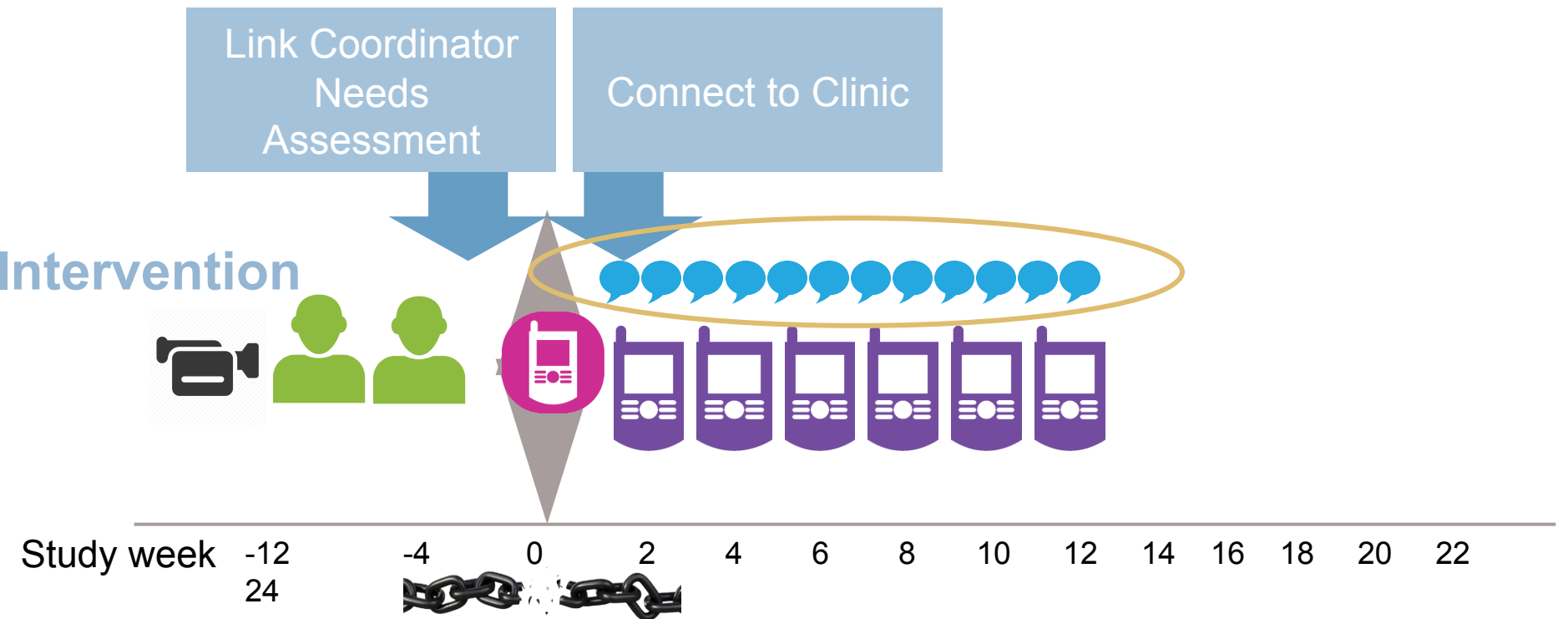
**Coordination**

**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



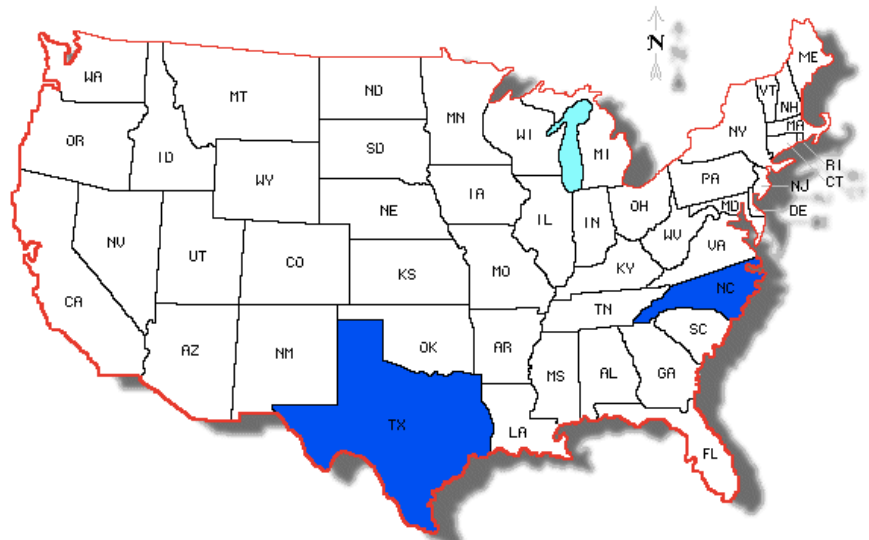


# imPACT Video 1 Minute Clip



# 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)

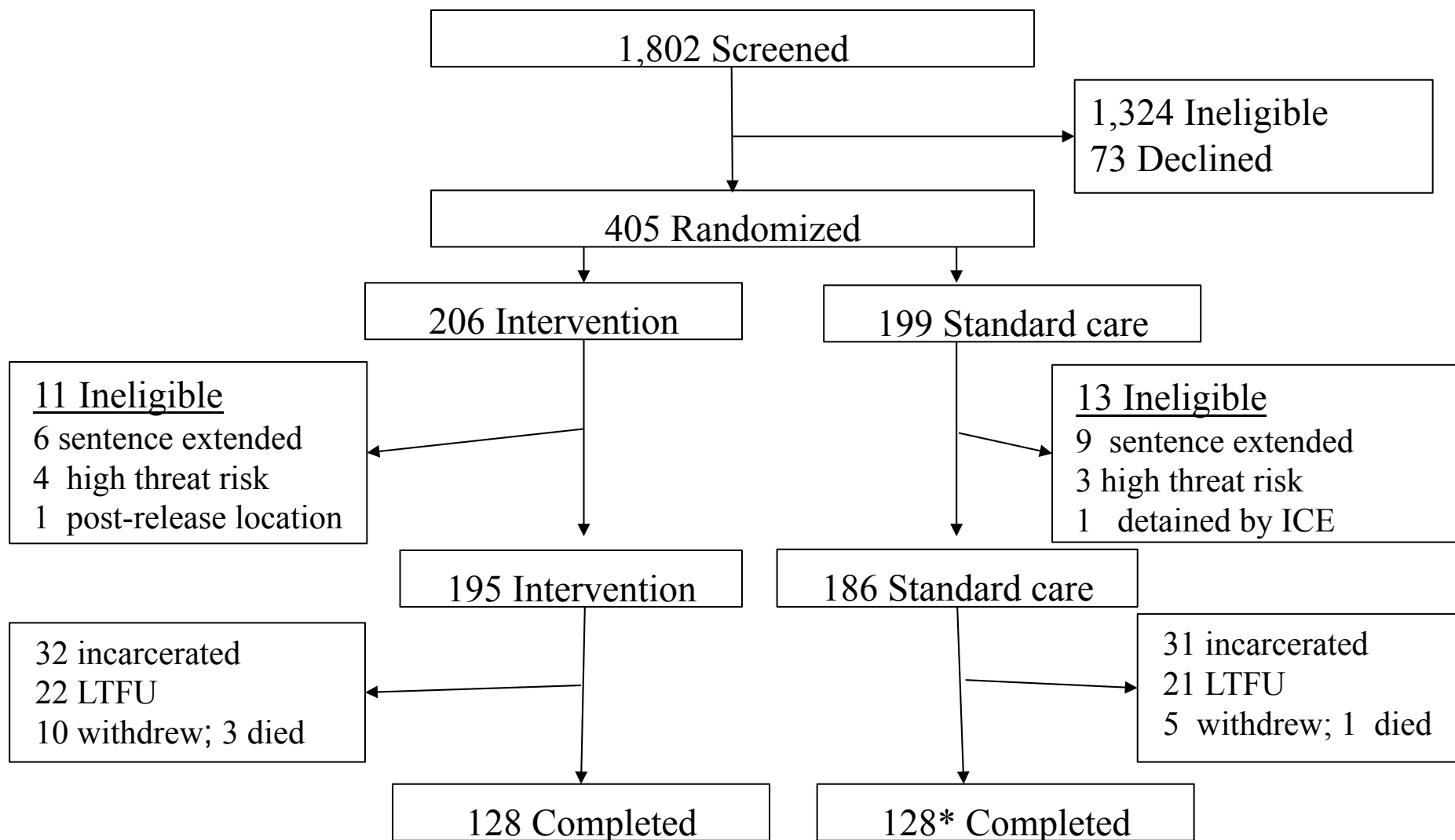
# Primary and Secondary Outcomes

- **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.

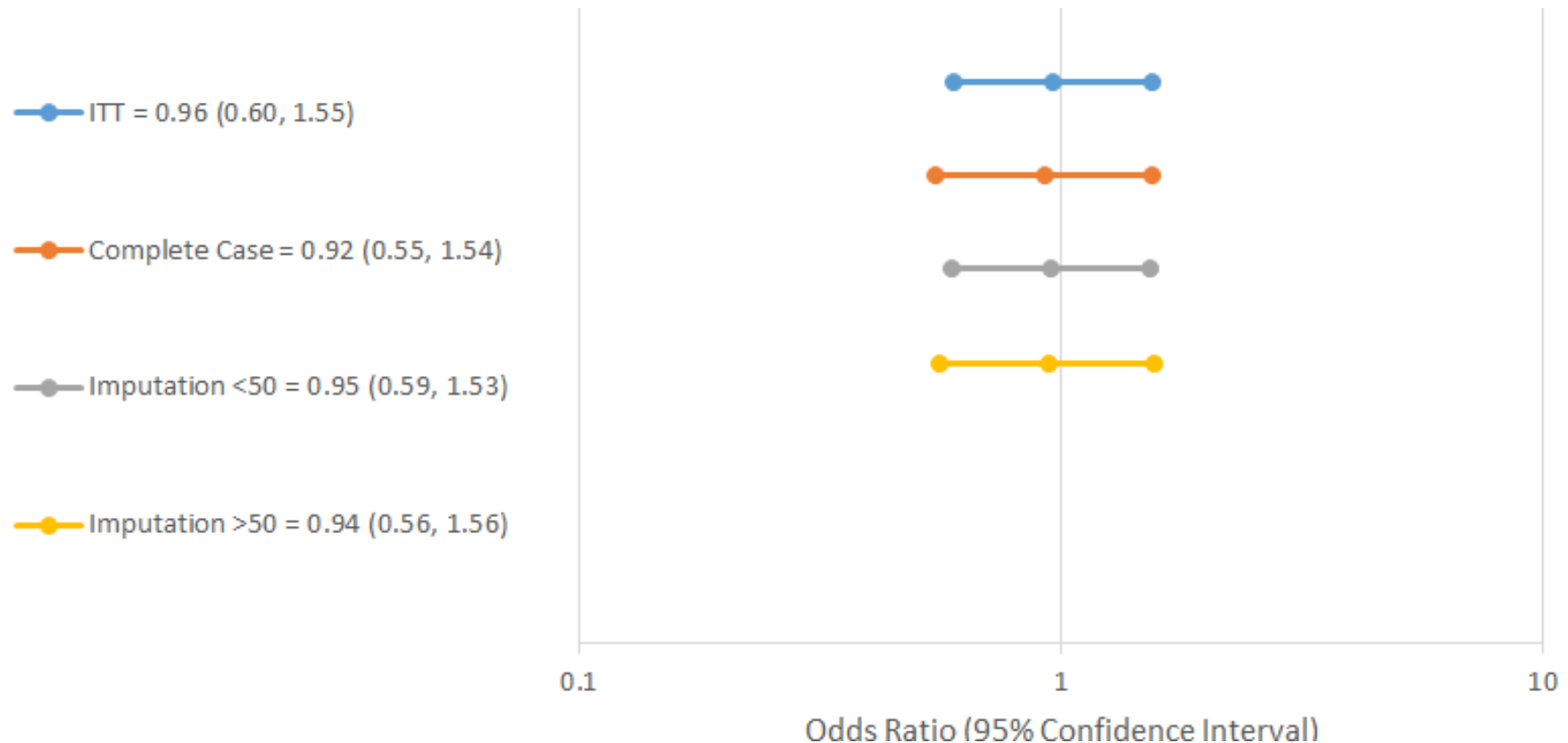
# Results: Participant Characteristics

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 <sup>3</sup> †      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

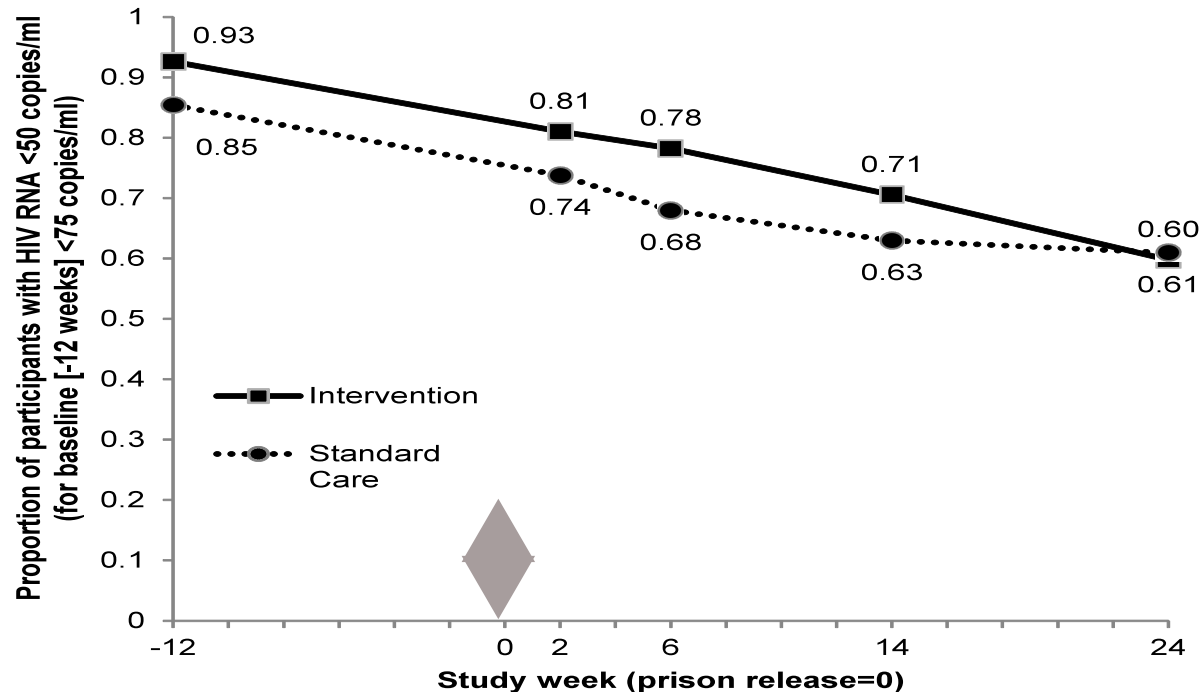


□ **Viremia-copy-years (number of copies of HIV RNA per mL over time), cumulative VL measure (P value = 0.36)**

- Intervention = median 3.6 log<sub>10</sub> copy x year/mL (IQR, 3.4 to 4.8)
- Standard of care = median 3.7 log<sub>10</sub> copy x year/mL (IQR, 3.4 to 5.7)

# Results: Viral Suppression over Time

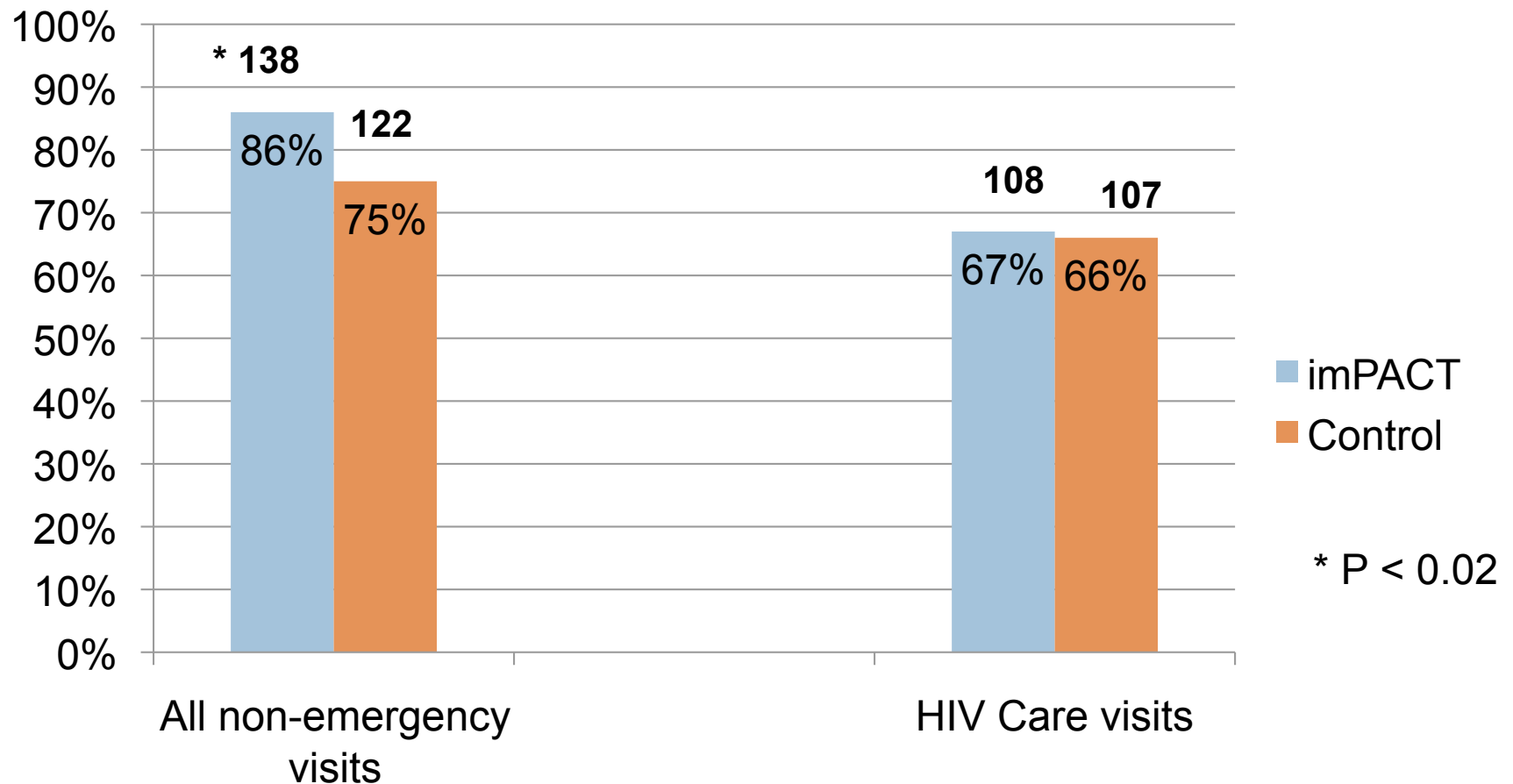
## A) Multiple Imputation



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 (TDCI)

- **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 McFatrach (TCU)
- Lynn Tillery (UNC)
- Makisha Ruffin (UNC)
- Angela Edwards (UNC)
- Katesha Peele (UNC)
- Amy Neevel (UNC)
- Laurence Misedah (TCU)

# Questions

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# Additional slides



# Participant Characteristics

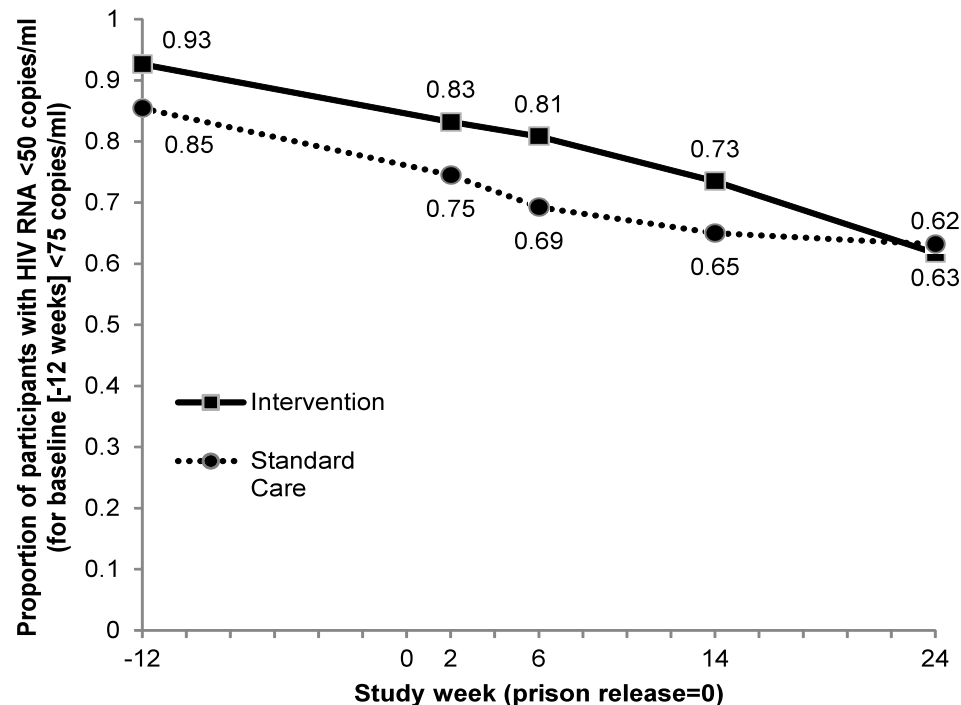
Characteristic	Intervention (N = 195)	SOC (N = 186)	All (N = 381)
Psychological distress - no (%)			
< High	129 (66)	133 (72)	262 (69)
High	22 (11)	24 (13)	46 (12)
Very high	44 (23)	29 (16)	73 (19)
Marital Status - no (%)			
Married	33 (17)	24 (13)	57 (15)
Formerly married	47 (24)	35 (19)	82 (22)
Never married	115 (59)	127 (68)	242 (64)
Functional health literacy - no (%) <sup>†</sup>			
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 - (%) <sup>*</sup>			
<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



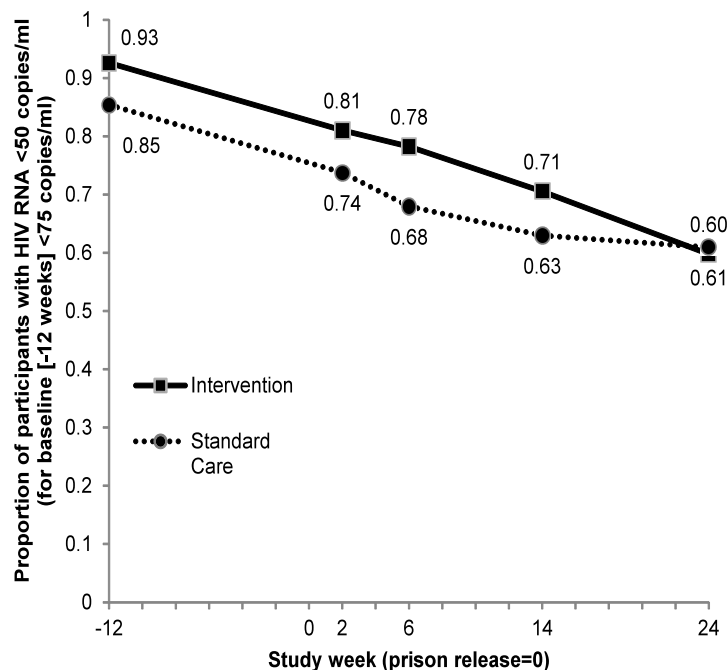
Number of participants contributing data

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.

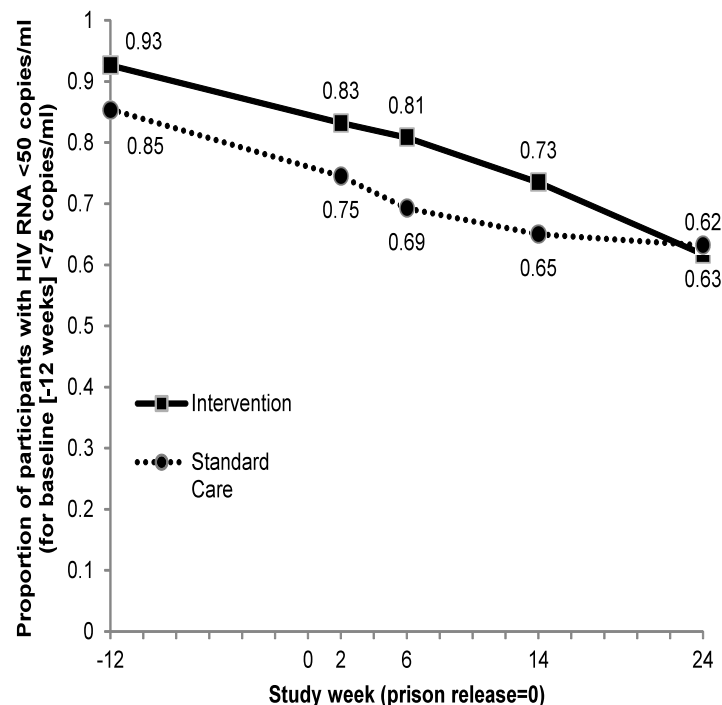
# Results: Effect on Viral Suppression

A) Multiple Imputation



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# Cell phone

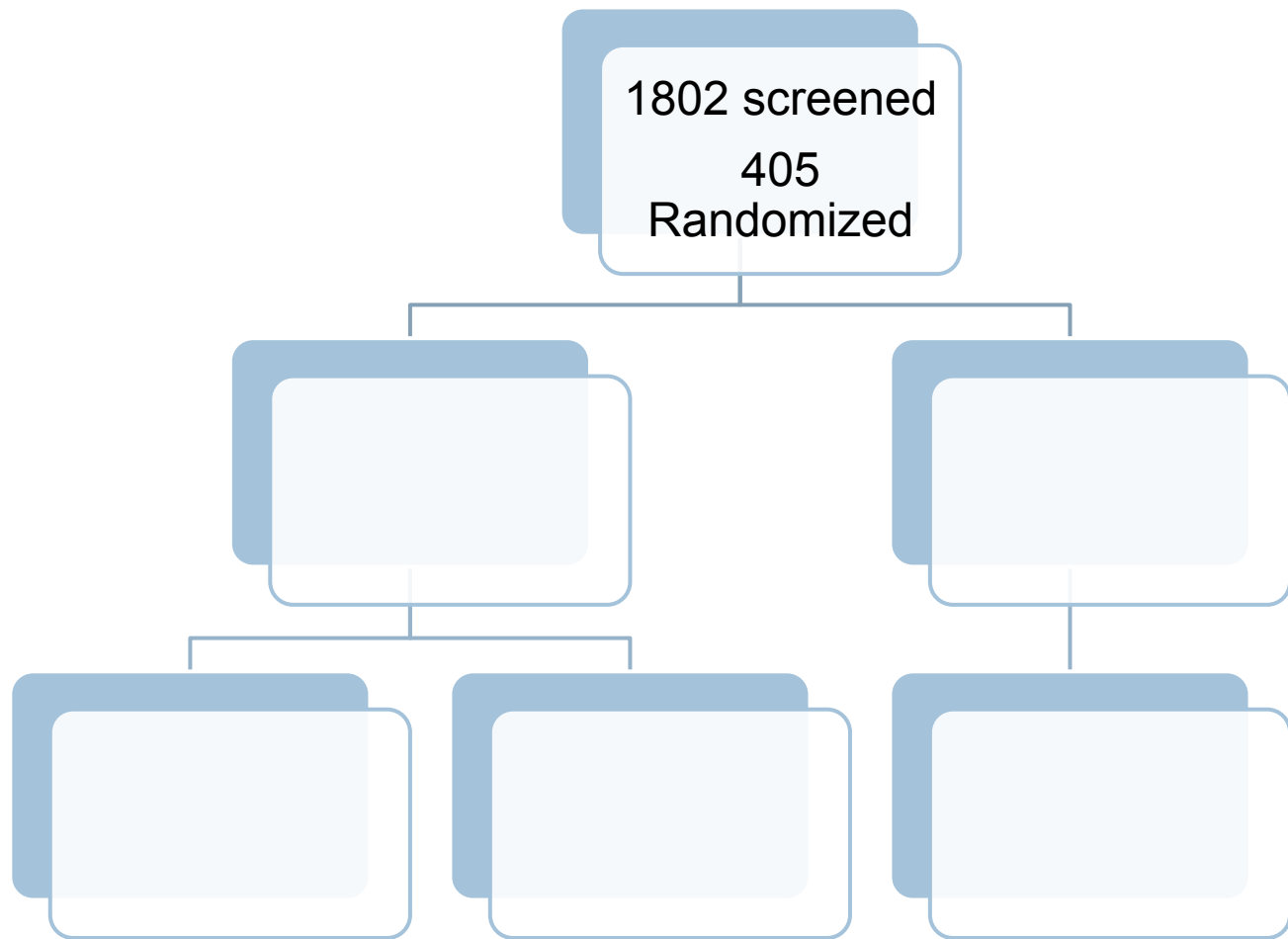
- Used to deliver intervention and to augment retention
- Provided to participant and activated within <48 h after release
  - ▣ Intervention Arm
    - Phone-based MI, SMS ART reminders prior to each dose, clinic appt reminders
    - Plan: Verizon 10 Friends & Family including #s for clinic, case manager, 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)





# A Back Up Cognitive Mapping Slide

