

INTRODUCTION

- Opioid use disorder (OUD) is associated with significant health and societal consequences in the U.S. (Clausen et al., 2009; Gomes et al., 2018; Scholl et al., 2019).
- While opioid agonist treatment with methadone or buprenorphine is efficacious in reducing illicit opioid use, IV drug use, overdose, criminal activity, and infectious disease, demand for treatment exceeds available capacity in many areas of the country.
- We recently completed a randomized 12-week pilot study (n=50) demonstrating the initial efficacy of a novel, technology-assisted IBT intervention vs. continued waitlist control (WLC) for reducing illicit opioid use and other risk behaviors during waitlist delays (Sigmon et al., *NEJM*, 2016).
- Our current ongoing, larger scale trial expands upon the pilot in several key ways:
 - Extends duration over longer, 6-month period
 - Delivered among individuals residing in rural, medically-underserved geographic areas
 - Includes an additional educational intervention to address opioid overdose risk

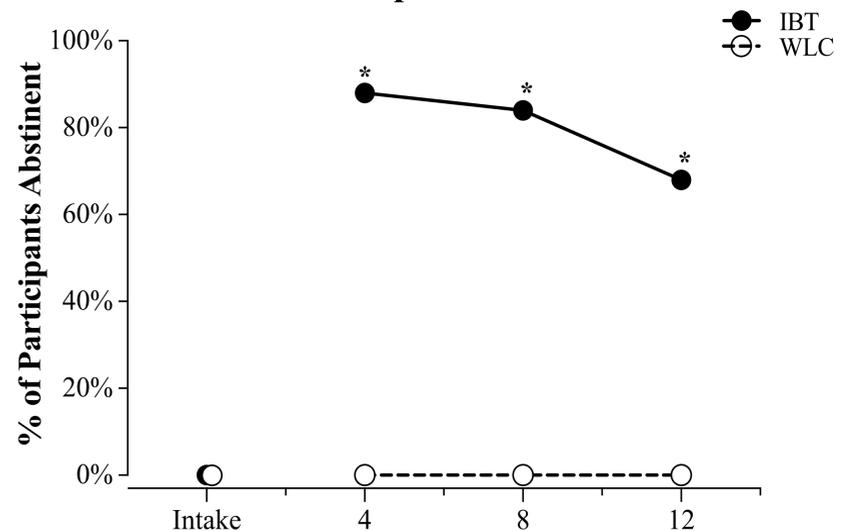
METHODS

- **Adults with OUD not currently receiving treatment are randomized to 1 of 2 groups:**
 - **IBT (n=30):** After stabilization, IBT participants:
 - Visit clinic every 2 weeks to ingest dose, provide urine specimen, and receive remaining doses via computerized Med-O-Wheel device.
 - Complete daily, automated Interactive Voice Response (IVR) System phone calls to assess recent drug use, craving, and withdrawal
 - IVR-generated random call-backs (~2x/month)
 - Mobile health HIV+Hepatitis C and opioid overdose (OD) educational interventions.
 - **Waitlist Control (n=31):** WLC participants remain awaiting comprehensive treatment.
 - Both groups complete monthly follow-ups at Study Weeks 4, 8, 12, 16, 20, and 24.

Participant Characteristics	IBT	WLC
Age, yrs	38.3±11.4	39.1±12.4
Male, %	57%	43%
Education, yrs	12.6±1.8	12.4±1.2
Employed full time, %	60%	39%
Primary past year opioid of abuse, %		
- Heroin	13%	18%
- Prescription opioids	87%	82%
Primary past year route, %		
- Oral/sublingual	57%	52%
- Intranasal	33%	21%
- Intravenous	10%	24%
- Inhalation	0%	3%
Duration of regular use, yrs	9.7±6.1	9.6±7.3
Past-month cocaine use, %	43%	36%
Ever used IV, %	50%	61%
Ever used heroin, %	70%	67%
Ever overdosed on opioids, %	18%	37%

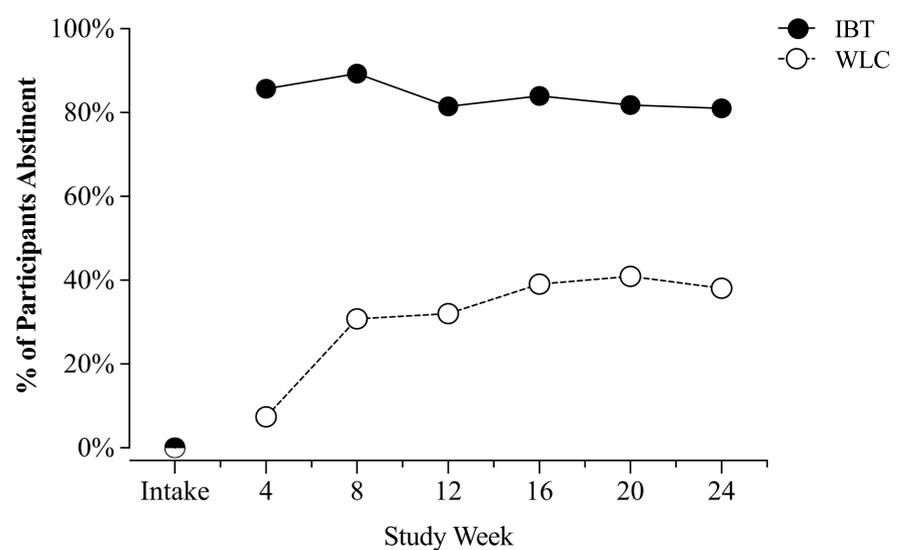
RESULTS

Illicit Opioid Abstinence



- **Figure 1.** In our 3-month duration IBT pilot (Sigmon et al., 2016), participants randomized to IBT achieved significantly greater abstinence from illicit opioids, with 88%, 84%, and 68% of IBT vs. 0% of WLC participants abstinent at Study Weeks 4, 8, and 12 ($p < .001$).

Illicit Opioid Abstinence: IBT vs. WLC



- **Figure 2.** In our ongoing RCT, those randomized to the IBT group are achieving greater illicit opioid abstinence compared to WLC throughout the extended, 6-month duration.
- Participants are also demonstrating favorable adherence to IVR daily monitoring calls (94%) and random call-backs (88%).

DISCUSSION

- Demand for opioid treatment far exceeds available capacity, particularly in rural geographic areas.
- Thus far, this larger-scale, expanded randomized trial is showing promising effects of IBT in reducing illicit opioid use among individuals living in rural areas with limited treatment options.
- IBT-associated illicit opioid abstinence is being maintained throughout the 6-month study.

ACKNOWLEDGEMENTS

This work was supported in part by NIDA (R01DA042790, R34DA037385, T32 DA007242), the Health Resources & Services Administration (UD9RH33633) and the Laura and John Arnold Foundation. The authors have no known conflicts of interest to report.