Interim Buprenorphine Treatment (IBT): Preliminary outcomes over a longer duration

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INTRODUCTION

- America's opioid epidemic continues to exact a devastating toll on individuals and communities, driving increasing rates of overdose and premature death and imposing an estimated $78.5 billion economic burden (Florence et al., 2016; Gomes et al., 2018; Scholl et al., 2019).
- These consequences are often especially pronounced in rural geographic regions (Palombi et al., 2018).
- While maintenance treatment with methadone or buprenorphine is efficacious in reducing illicit opioid use, IV drug use, overdose, criminal activity, and infectious disease, demand for treatment can far exceed available capacity in many areas of the country, particularly rural regions (Sigmon, 2014, 2016).
- We recently completed a randomized 12-week pilot study (n=50) demonstrating the initial efficacy of a novel, technology-assisted Interim Buprenorphine Treatment (IBT) intervention vs. continued waitlist control (WLC) for reducing illicit opioid use and other risk behaviors during waitlist delays (Figure 1; Sigmon et al., 2016).
- Our current ongoing, larger-scale trial expands upon the pilot in several key ways:
  - Increases duration from 3 to 6 months
  - Extends to individuals residing in rural, medically-underserved geographic areas
  - Includes a new component to address opioid overdose risk
- Here we present preliminary primary outcomes on illicit opioid abstinence from this ongoing randomized clinical trial.

METHODS

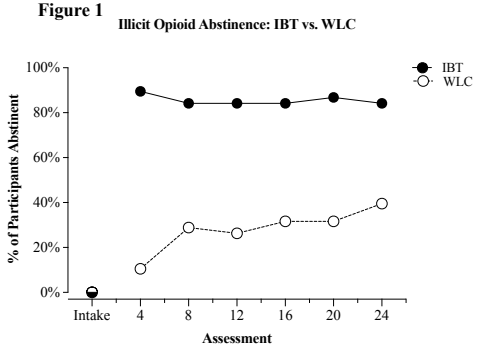
- **Adults with OUD not currently receiving treatment are randomized to 1 of 2 groups:**
  - **IBT (n=38):** Following buprenorphine stabilization, IBT participants visit clinic every 2 weeks to ingest dose, provide observed urine sample, and receive their remaining doses via a computerized Med-O-Wheel device. They also complete daily, automated Interactive Voice Response (IVR) System phone calls to assess recent drug use, craving, and withdrawal and IVR-generated random call-backs (~2x/month). Finally, participants complete mobile health HIV+Hepatitis C and opioid overdose educational interventions.
  - **Waitlist Control (n=38):** WLC participants remain on the waitlist.
  - Both groups complete monthly follow-ups at Study Weeks 4, 8, 12, 16, 20, and 24.
- Based on their residence, participants complete study visits either at a non-rural or one of three rural sites.

Table 1. Participant Characteristics	IBT (n=38)	WLC (n=38)	*p*-value
Age, yrs	37.9 ± 10.5	39.8 ± 12.4	*p*= .47
Female, %	40%	58%	*p*= .11
Non-Hispanic white, %	90%	82%	*p*= .33
Education, yrs	12.7 ± 1.8	12.4 ± 1.2	*p*= .42
Employed full time, %	61%	37%	***p*= .04**
Rural, %	50%	47%	*p*= .82
Primary past year opioid of abuse, %			*p*= .99
- Heroin	16%	16%	
- Prescription opioids	84%	84%	
Primary past year route, %			*p*= .52
- Oral/sublingual	61%	58%	
- Intranasal	26%	18%	
- Inhalation	0%	3%	
- Intravenous	13%	22%	
Duration of regular use, yrs	9.8 ± 6.4	8.9 ± 7.1	*p*= .58
Past-month cocaine use, %	37%	35%	*p*= .30
Ever used IV, %	53%	53%	*p*= .99
Ever used heroin, %	74%	61%	*p*= .22
Ever overdosed on opiates, %	21%	32%	*p*= .30
Addiction Severity Index (ASI)[a]			
Alcohol	.087 ± .12	.059 ± .10	*p*= .28
Drug	.309 ± .12	.328 ± .10	*p*= .49
Employment	.493 ± .34	.575 ± .31	*p*= .28
Family	.111 ± .17	.125 ± .19	*p*= .74
Psychiatric	.236 ± .19	.306 ± .21	*p*= .14
Medical	.301 ± .38	.356 ± .41	*p*= .55
Legal	.036 ± .10	.061 ± .13	*p*= .34

Note: Values represent mean ± SD; [a]ASI composite scale scores range from 0-1

RESULTS

Figure 1



- **Figure 1.** Participants randomized to the IBT group are achieving significantly greater illicit opioid abstinence, with 89%, 84%, 84%, 84%, 87%, and 84% abstinent vs. WLC, with 11%, 29%, 26%, 32%, 32%, and 39% abstinent throughout the 6-month study (*p's*<.001).

Figure 2

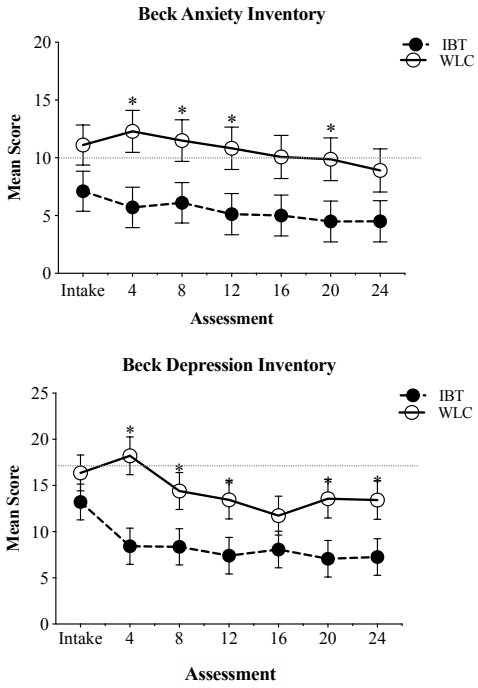
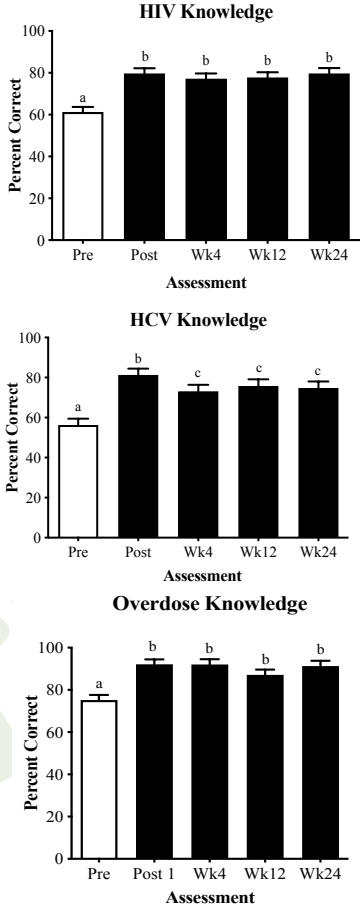


Figure 2. Participants randomized to IBT are reporting significantly lower levels of anxiety (*p*=.02) and depression (*p*<.01) from intake to study's end.

Figure 3



- **Figure 3.** HIV, HCV and opioid overdose knowledge are significantly increasing as a function of the single iPad delivered educational interventions, with improvements generally persisting throughout the 6-month study (*p's*<.01).

DISCUSSION

- Despite the efficacy of opioid agonist therapy in reducing health and societal consequences of OUD, the demand for treatment far exceeds available capacity, particularly in rural geographic areas.
- In an initial feasibility study with a limited sample size and duration, we observed that individuals randomized to the IBT group achieved significantly greater sustained illicit opioid abstinence as compared with WLC counterparts.
- Thus far in our efforts to replicate and further build upon those initial promising results, we are observing similarly high levels of illicit opioid abstinence that are generally sustained over the longer 6-month duration.
- Upon completion of this randomized trial, we hope to contribute additional empirical evidence that low-barrier, technology-assisted buprenorphine dosing can promote sustained illicit opioid abstinence and reduce drug-related harms over extended periods and diverse settings.

REFERENCES

- Florence, C., Luo, F., Xu, L., & Zhou, C. (2016). The economic burden of prescription opioid overdose, abuse and dependence in the United States, 2013. *Medical Care*, *54*(10), 901.
- Gomes, T., Tadrous, M., Mamdani, M. M., Paterson, J. M., & Juurlink, D. N. (2018). The burden of opioid-related mortality in the United States. *JAMA Network Open*, *1*(2), e180217.
- Palombi, L. C., St Hill, C. A., Lipsky, M. S., Swanoski, M. T., & Lutfiyya, M. N. (2018). A scoping review of opioid misuse in the rural United States. *Annals of epidemiology*, *28*(9), 641-652.
- Scholl, L., Seth, P., Kariisa, M., Wilson, N., & Baldwin, G. (2019). Drug and opioid-involved overdose deaths — United States, 2013–2017. *Morbidity and Mortality Weekly Report*, *67*(51 & 52), 1419–1427.
- Sigmon, S. C. (2014). Access to Treatment for Opioid Dependence in Rural America: Challenges and Future Directions. *JAMA Psychiatry*, *71*(4), 359.
- Sigmon, S. C., Ochalek, T. A., Meyer, A. C., Hruska, B., & Heil, S. H. (2016). Interim buprenorphine vs. waiting list for opioid dependence. *New England Journal of Medicine*, *375*(25).

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