RCT of iTAB Plus Motivational Interviewing for PrEP Adherence in Transgender Individuals

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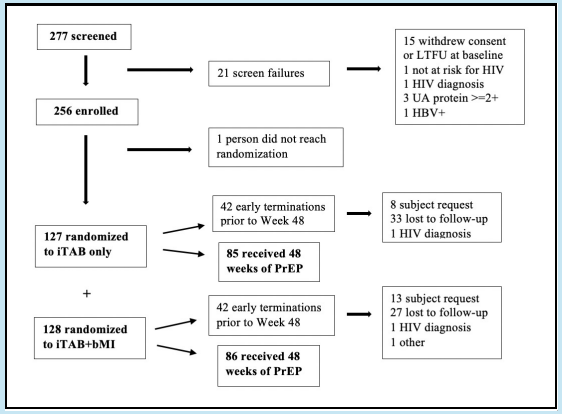
Sheldon Morris[1], Sonia Jain[1], Jill Blumenthal[1], Robert Bolan[2], Michael Dubé[3], Philip Henderson[4], Katya Corado[5], Feng He[1], Leah Burke[1], Peter Anderson[6], David Moore[1]
[1]University of California San Diego, La Jolla, CA, USA, [2]Los Angeles LGBT Center, Los Angeles, CA, USA, [3]University of Southern California, Los Angeles, CA, USA, [4]Family Health Centers of San Diego, San Diego, CA, USA, [5]Los Angeles Biomedical Research Institute at Harbor–UCLA Medical Center, Torrance, CA, USA, [6]University of Colorado Anschutz Medical Campus, Aurora, CO, USA

BACKGROUND

Transgender individuals are at risk for HIV, with transgender women having some of the highest HIV incident rates. Use of pre-exposure prophylaxis (PrEP) for HIV prevention is highly dependent on adequate adherence that can be measured by TFV-DP in dried blood spots. This study aimed to support transgender individuals in taking PrEP with a customized adherence intervention.

METHODS

This 48-week study was a parallel two arm 1:1 randomized controlled trial of a tailored texting intervention for PrEP adherence in transgender individuals; participants received individualized Texting for Adherence Building (iTAB) with or without brief motivational interviewing (bMI) via telephone for 3 sequential days of not reporting dose taking by text. Between June 2017 and September 2020, 255 transgender individuals were randomized to iTAB or iTAB+bMI.



The primary endpoint was a binary composite outcome derived from dried blood spot (DBS) tenofovir (TFV-DP) concentrations at both week 12 and week 48 (or the last on-drug visit) of ≥1246 fmol/punch consistent with ≥7 doses per week (i.e., near perfect adherence). Secondary outcomes included i) DBS TFV-DP concentrations of ≥719 fmol/punch consistent with 4 doses per week (i.e., adequate adherence) and ii) the mean self-reported adherence by daily text message response.

Transgender women in the iTAB-bMI arm showed an increase in self-reported adherence when compared to iTAB only with FTC/TDF for 48 weeks of follow-up.

Table 2: Adherence Outcomes in the iM-PrEPT Study

	iTAB	iTAB+bMI	
	N (%)	N (%)	*p* value
≥ 1246 fmol/punch at week 12 and the last DBS visit at week 24, 36, or 48 (near perfect adherence)			
Entire cohort (N=255,N1=127,N2=128)	44 (34.7)	49 (38.3)	0.603
Transgender man (N=57,N1=27,N2=30)	14 (51.9)	14 (46.7)	0.793
Transgender woman(N=145,N1=70,N2=75)	18 (25.7)	27 (36.0)	0.211
Non-binary (N=53,N1=30,N2=23)	12 (40.0)	8 (34.8)	0.779
≥ 719 fmol/punch at week 12 and the last DBS visit at week 24, 36, or 48 (adequate adherence)			
Entire Cohort (N=255,N1=127,N2=128)	55 (43.3)	67 (52.3)	0.169
Transgender man (N=57,N1=27,N2=30)	16 (59.3)	17 (56.7)	>0.999
Transgender woman(N=145,N1=70,N2=75)	25 (35.7)	39 (52.0)	0.065
Non-binary (N=53,N1=30,N2=23)	14 (46.7)	11 (47.8)	>0.999
Mean (SD) percentage of 'Yes' responses received out of text received			
All receiving iTAB (N=251, N1=124, N2=127)	46.4 (33.6)	57.9 (32.3)	**0.009**
Transgender man (N=56, N1=26, N2=30)	62.0 (29.1)	60.7 (34.1)	0.895
Transgender woman (N=144, N1=69,N2=75)	37.3 (34.1)	58.5 (32.0)	**<0.001**
Non-binary(N=51, N1=29, N2=22)	54.0 (29.7)	52.0 (31.4)	0.742

N: overall sample size; N1: iTAB sample size; N2: iTAB+bMI sample size

RESULTS

- Adherence for the primary outcome (≥ 1246 fmol/punch) was 49.1% for 57 transgender men, 37.3% for 19 nonbinary individuals and 31.0% for 145 transgender women.
- Adherence for the secondary outcome f(≥ 719 fmol/punch) was 57.9% for transgender men, 47.1% for nonbinary individuals and 44.1% for transgender women.
- Adherence was not statistically different between iTAB+bMI and iTAB alone for ≥ 1246 fmol/punch or ≥ 719 fmol/punch
- Those in the iTAB-bMI arm reported taking their daily dose a mean of 59.8% of days versus 48.7% of those in the iTAB alone arm (**p=0.011**).

- Stratification by gender found the improved self-reported adherence was primarily in transgender women with the mean percent of daily reported dose taking of 60.1% in the iTAB-bMI compared to 40.8% in the iTAB alone arm (**p=0.002**).
- Among transgender women, there was adequate adherence (≥719 fmol/punch consistent with 4 doses per week) in 39/75 (52%) in the iTAB+bMI arm compared to 25/70 (35.7%) in the iTAB alone arm (p=0.065).

CONCLUSIONS

iTAB daily texting with brief MI compared to iTAB only arm improved self-reported adherence, and helped transgender women achieve adequate adherence to TFV/FTC through 48 weeks of follow-up. Transgender women many benefit from personalized adherence support where there is a person-to-person contact in addition to automated methods (texting and mobile applications).

ADDITIONAL KEY INFORMATION

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