Baseline Characteristics by Randomization Status in NIDA-CTN-0051, Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT)

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Introduction

NIDA-CTN-0051 is a multi-center, two-arm, 6-month (24-week), parallel-group, open-label, randomized controlled trial to examine the comparative effectiveness and safety of Extended-Release Naltrexone (XR-NTX) versus Buprenorphine + Naloxone (BUP-NX). This study is intended to develop an evidence-base to help patients and providers make informed choices and to foster wider adoption of relapse-prevention pharmacotherapies.[1]

Objectives

- Define the study participant enrollment process from consent to the point of randomization.
- To compare randomized vs. not randomized participants in a NIDA sponsored comparative effectiveness study of agonist versus antagonist treatment for opioid use disorder. Comparisons were assessed for:
  - Baseline Demographics
  - Motivations for Participating in the study
  - Attitudes about Study Medication

Methods

- Participants were recruited from detoxification or short-term residential treatment settings. Candidates were consented, screened, and randomized at the time of admission, during detoxification or during early abstinence. Participants meeting all eligibility criteria were randomized to one of two treatment conditions, XR-NTX or BUP-NX.
- Motivation for participating and attitudes regarding study medication were assessed prior to randomization
- The comparison of demographics, motivations to participate in the study and attitudes regarding study medications were assessed between randomized and not randomized participants.
- The analyses are based on baseline data as of December 20, 2016.

Results

- Seven-hundred seventy-two participants were consented; 570 were randomized and 202 were not. Most of those not randomized (181/202; 90%) did not complete screening.
- Among the top reasons for not completing screening were that the participant left the treatment program (82/181; 45%) before completing screening, and not meeting eligibility criteria (62/181; 34%).
- One of the most frequent eligibility criteria not met was the participant was no longer seeking treatment for opioid dependence or not willing to accept agonist-based or antagonist-based therapy (22/202; 11%).

Figure 1. Participant Flow Chart

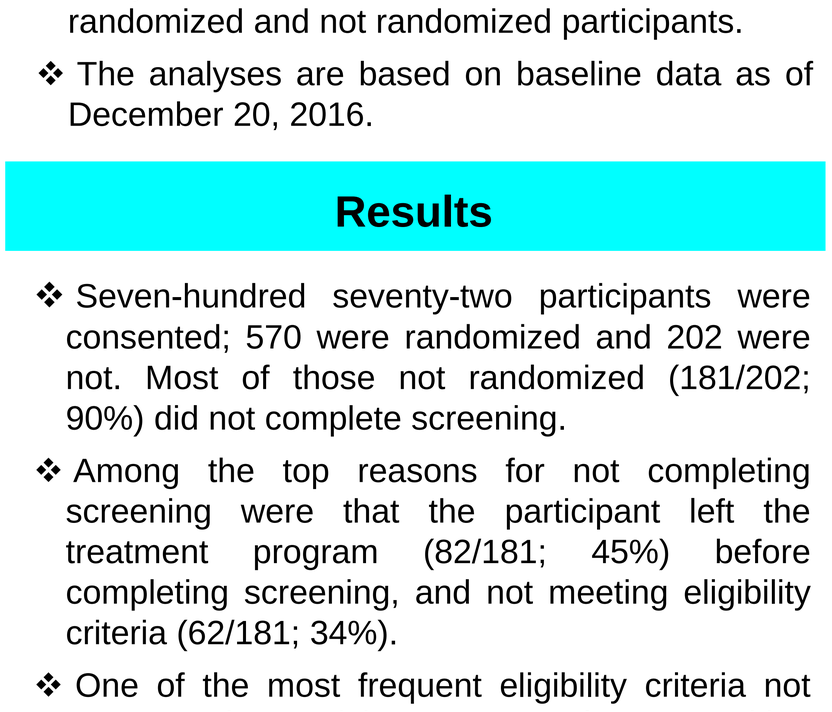

Table 1. Baseline Demographics by Randomization Status

Characteristic	Randomization Status: Not Randomized (N=202)	Randomization Status: Randomized (N=570)
Sex		
Male	143 (71%)	401 (70%)
Female	59 (29%)	169 (30%)
Race		
White	145 (72%)	421 (74%)
Non-White	57 (28%)	149 (26%)
Ethnicity		
Non-Hispanic	166 (82%)	471 (83%)
Hispanic	36 (18%)	99 (17%)
Education		
High school or less	134 (66%)	322 (56%)
More than high school	68 (34%)	248 (44%)
Employment Status		
Unemployed	129 (64%)	360 (63%)
Not unemployed	73 (36%)	210 (37%)
Marital Status		
Never married	139 (69%)	376 (66%)
Ever married, living with partner, or unknown	63 (31%)	194 (34%)

- In the randomized group, most participants were male (70%), white (74%), non-Hispanic (83%), with high school or less education (56%), unemployed (63%), and never married (66%). Similar distributions were noted for the not randomized group.

Table 2. Motivations and Attitudes about Treatment by Randomization Status

	Randomization Status: Not Randomized (N=127)	Randomization Status: Randomized (N=570)
Preference for BUP-NX		
Strongly Disagree/ Disagree	28 (22%)	141 (25%)
Neutral	45 (35%)	239 (42%)
Strongly Agree/ Agree	54 (43%)	189 (33%)
Preference to XR-NTX		
Strongly Disagree/ Disagree	40 (32%)	129 (23%)
Neutral	61 (48%)	273 (48%)
Strongly Agree/ Agree	26 (20%)	167 (29%)
Access to Medication as Motivating Factor		
Strongly Disagree/ Disagree	48 (38%)	366 (64%)
Neutral	30 (24%)	114 (20%)
Strongly Agree/ Agree	49 (39%)	89 (16%)

- Although all motivations and attitudes towards treatment were collected and compared, Table 2 only includes preference for BUP-NX, preference to XR-NTX and access to medication as these were where the biggest differences between randomized and not randomized participants were seen.

Discussion

- Overall the randomized and not randomized groups were quite similar.
- The greatest difference between groups was the role of access to medication as a motivating factor endorsed by 39% of the not randomized group vs. only 16% of the randomized group.
- The not randomized group preferred BUP-NX (43%) over XR-NTX (20%), whereas preference was roughly equivalent amongst the randomized group (33% vs. 29%).
- Access to medication (more often endorsed as a motivating factor in the not randomized group) did not preclude pre-randomization dropout.
- Preference for BUP-NX (greater in the not randomized group) may have contributed to pre-randomization dropout.
- The treatment options available (unknown randomization to either the agonist or antagonist study medication) in the study could have contributed to the differences between the randomized and not randomized participants.
- Participants' willingness to accept agonist-based or antagonist-based therapy likely had a role in their participation in this study.

<u>Limitations:</u>

- Motivations and attitudes towards treatment were not collected for all of the not randomized participants (before they dropped out of the treatment setting or screening). Conclusions about motivations for the not randomized group may not be generalizable.

<u>Future exploratory analyses:</u>

- Assess response to assigned treatment with respect to treatment preference based on these motivation questions within randomization groups.

Conclusions

- The reasons for participants not advancing to randomization were primarily related to leaving the treatment program or not meeting eligibility criteria.
  - Dropout associated with loss of motivation, prior to completing detoxification, is a typical failure mode for this population.
  - This may have implications for mitigating the difficult experience of detoxification and managing the transition to outpatient treatment for patients seeking treatment. Better detoxification strategies are needed.
- Overall the two groups were similar in demographic characteristics.
- After assessing the motivations and attitudes about treatment, it appears that the preference for BUP-NX was stronger than the preference for XR-NTX.

References

- NIDA Clinical Trials Network CTN-0051, Extended Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT): Study design and rationale Contemporary Clinical Trials. 2016 Sep; 50:253-264

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