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The use of patient navigation to transition detoxification patients to substance use treatment in the Alaska Interior

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ABSTRACT

Objectives: Detoxification clinics manage acute intoxication and withdrawal from alcohol and other drugs. At discharge, patients are referred to treatment, yet many are readmitted to detoxification, creating a "revolving door" of discharges and admissions. This pattern disproportionately affects some groups such as Alaska Native and American Indian (AN/AI) people. The primary goals of this study are to: 1) test the effectiveness of a patient navigation intervention to increase rates of transition to alcohol treatment following detoxification, and 2) prevent readmission to detoxification within 12-months. The secondary goal is a cost-effectiveness and cost-benefit evaluation of patient navigation.

Study design: This randomized controlled comparative effectiveness trial plans to recruit 440 patients (~70% AN/AI) admitted to alcohol detoxification. We collaborated with Fairbanks Native Association (FNA) to select an appropriate intervention, control condition, and other study-related decisions. Here, we describe intervention development, study design, challenges encountered during implementation, and collaborative processes to identify solutions.

Methods: Participants are equally randomized to the control (one motivational interviewing session) or intervention (one motivational interviewing session plus up to four weeks of patient navigation). The primary outcomes are successful transition to alcohol treatment within 30-days after discharge and detoxification readmission within 12-months. The secondary outcome is health-related quality of life.

Conclusion: Patient navigation is successful in other settings and for other health conditions. It may assist in overcoming barriers to successful transition to substance use treatment and may augment interventions, such as motivational interviewing, that are less resource-intensive but may not be optimally effective by themselves.

ClinicalTrials.gov Identifier: NCT03737864.

1. Introduction

Detoxification offers medical management of acute intoxication and withdrawal from alcohol or drugs [1]. Patients are typically admitted for three to five days [2], after which they are discharged and referred to substance use treatment (SUT), often with little to no follow-up [3]. A successful transition to SUT can delay or prevent readmission to detoxification [4–6]. However, many patients return to their daily lives without treatment or support, resulting in a "revolving door" of repeated detoxification admissions [7–10]. Certain populations are in greater need of support to transition to post-detoxification SUT [11–13]. Our previous work in Alaska found 75% of Alaska Native/American Indian

Abbreviations: SUT, Substance Use Treatment; AN/AI, Alaska Native/American Indian; MI, Motivational Interviewing; PN, Patient Navigation; TTR, Transition to Recovery; FNA, Fairbanks Native Association; GTR, Gateway to Recovery; EHR, Electronic Health Record; PNs, Patient Navigators; AKAIMS, Alaska's Automated Information Management System; HRQL, Health Related Quality of Life.

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(AN/AI) patients completed inpatient detoxification, yet only 21% entered SUT [14]. This is lower than transition rates of 49%–64% in the general population [7,12,13,15]. Additionally, 42% of AN/AI detoxification patients were readmitted within one-year [16], compared to 26% for the US overall [4].

Motivational Interviewing (MI) may be effective for promoting transition to longer-term SUT in which patients articulate post-discharge goals and strategies [17–19]. The magnitude of benefit for this purpose is not well established [14,19], and it is unclear whether MI alone is sufficient to overcome barriers of transitioning to SUT following detoxification. Patient navigation (PN) is an evidence-based, patient--centered strategy that may be an effective adjunct to MI [20]. Trained navigators work one-on-one with patients to facilitate progress through the SUT continuum, matching needs to community resources [20]. PN has been studied for other health outcomes [21–24] but has not been rigorously evaluated as an intervention to promote transition to SUT in any population.

The primary purpose of our study is to test the effectiveness of "Transition to Recovery" (TTR), an intervention comprising PN plus MI, compared with MI alone, to increase transition to SUT following detoxification among patients in the Alaska Interior. We also aim to prevent readmission to detoxification over 12-months. Our secondary goal is an economic evaluation. Here, we describe the intervention development, study design, challenges encountered during implementation, and collaborative processes to identify solutions.

2. Methods

2.1. Setting and community engagement

Fairbanks Native Association (FNA) is a non-profit tribal organization located in Fairbanks, Alaska. FNA's Behavioral Health Services offer a continuum of care for SUT including inpatient detoxification, short-term residential treatment, long-term residential treatment for women with children, and varying levels of outpatient treatment [25]. Education and social services are also provided [25]. Owned and operated by FNA, Gateway to Recovery (GTR) is a 16-bed inpatient detoxification facility providing medically managed alcohol and opioid withdrawal treatment for adults 18 and older [25]. AN/AI people account for two-thirds of alcohol and one-third of opioid admissions, respectively [26].

TTR's development leveraged our long-standing relationship in which GTR is equitably involved in key decisions, including intervention design. GTR staff recognized in-house case-management helped patients transition to post-discharge SUT and felt PN could be effective to overcome post-discharge barriers to coordinated care resulting from patients no longer being actively in their system. GTR required all patients have an opportunity to benefit from study participation; consequently, a traditional usual care control condition was not acceptable. MI was adopted as the control due to GTR's interest in offering it as routine care and its sustainability at low cost [27]. Equally important is the cost to sustain PN long-term; therefore, conducting cost analyses was enthusiastically supported by GTR.

Rented space allowed integration of TTR staff into the detoxification unit, consistent with a pragmatic study design [28]. GTR felt compensation for baseline data collection may support underlying substance use problems and increase risk of relapse or readmission. Therefore, we only offer compensation for 6-month follow-up, as a compromise to maximize study retention [29]. GTR had concerns for overburdening patients with lengthy study procedures when they experience lingering withdrawal symptoms, psychological and cognitive challenges, and need longer-term care [30]. This necessitated drawing heavily on electronic health record (EHR) data routinely collected by GTR.

2.2. Randomized controlled trial

2.2.1. study design

The study period is 12-months (Fig. 1). Originally, we included self-reported follow-up at 6- and 12-months; we eliminated the latter but still extract relevant EHR data. If it occurs, transition to treatment is most likely within 6- months post-detoxification. This observation combined with staff burden, associated costs, and outcomes not requiring 12-month self-reported data led to this design revision. Staff time and resources were reallocated to focus on recruitment, which slowed dramatically during the pandemic. Budget cuts and original overestimates of the number of participants agreeing to join the study required a reduction of enrollment targets from 700 to 440. We adopted conservative assumptions in original power calculations to buffer against unanticipated contingencies; our minimum detectable effect size remains acceptable.

Table 1 displays study changes noted throughout the paper, date of change, reason, and study impacts.

2.2.2. Eligibility

Inclusion criteria are age 18+; complete or near complete detoxification regimen; ability to provide written informed consent and complete study procedures. Exclusion criteria include comorbid physical or mental health conditions that prevent transition to SUT (e.g., cancer, severe suicidality); current enrollment in SUT; and current incarceration/discharge to an incarceration facility.

2.2.3. Recruitment and enrollment

Collaborative processes ensure patient safety and optimize study enrollment. Nursing staff notify patient navigators (PNs) when a patient can engage in the enrollment process, which differs by patient but typically occurs after the most difficult aspects of detoxifying are complete prior to discharge. PNs meet with patients in private offices to explain the study and obtain consent. Participants authorize use of EHR data, self-report data, and provide contact information for follow-up. Since detoxification patients often feel physically unwell and overwhelmed, enrollment takes place over several shorter conversations rather than one long session.

There are fewer unique eligible patients available each month than originally expected. Over half of the patients admitted monthly are ineligible due to exclusion criteria noted above. Of those eligible, many experience chronic substance use problems with frequent admissions to detoxification. This group rarely seeks long-term SUT; many repeatedly decline participation in the study due to significant personal barriers. This, coupled with subsequent reductions in treatment capacity in 2020 due to COVID-19, complicate progress toward original enrollment targets. Additionally, we experienced pandemic-related PN turnover that created hiring and training delays. However, turnover allowed us to shift position requirements to recruit PNs who work flexible hours, including weekends and evenings, which assist in addressing slow recruitment.

2.2.4. Baseline data collection/EHR extraction

Substantial baseline data is extracted from Alaska's Automated Information Management System (AKAIMS), a performance management system. Clinical facilities funded by the State of Alaska—including GTR—collect and enter standardized data elements into the system which guide local policy and decision-making [31]. We supplement AKAIMS data with a small battery of self-reported measures that provide additional information (Table 2).

Data extraction barriers are multifaceted. In March 2020, the COVID-19 pandemic forced most GTR staff to work off-site, limiting ability to enter data into AKAIMS. The ability to obtain timely AKAIMS data was impacted for some participants but did not permanently compromise the study's database or impede the study's aims. Toward the end of 2021, AKAIMS experienced a cyber-attack halting access for seven months. FNA adopted alternative procedures to enter data, giving us access.

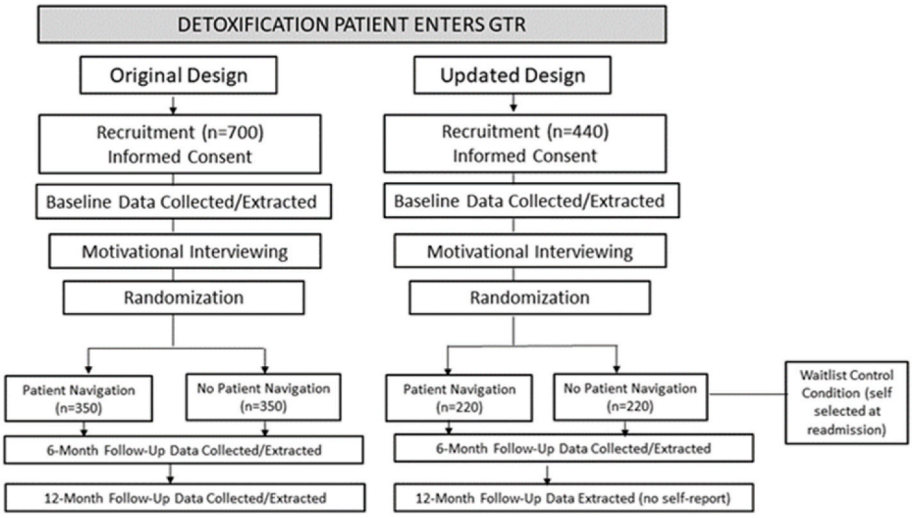

Fig. 1. Study design.

Table 1
Study changes, dates, reasons, and impact.

Change	Date	Reason for Change	Impact on TTR
Follow-up with incarcerated participants	July 2019	Unanticipated study need	More complete follow-up
Reduced enrollment targets	January 2020 & April 2021	Overestimation of eligible and willing participants; resource constraints	Minor effect on MDE and power
Ad hoc PN for study, PN group only	February 2020	GTR request	No change to primary outcomes, additional PN is offered only after first readmission and does not change outcome for transition within 1 month of index admission
Remote enrollment	March 2020	GTR pandemic-related closure to non-essential personnel	Ability to recruit during pandemic
AKAIMS data access	March 2020	No data entry & access due to pandemic-related closure; cyber-attack on AKAIMS	Delayed data extraction, no impact on study aims
Waitlist control group added	June 2021	GTR request	No change to primary outcomes analyses
Elimination of 12-month self-report data collection	June 2021	Outcomes do not require 12-month self-report data	Ability to reallocate resources to recruitment
Transition to treatment outcome variable	June 2021	Limited SUT options, exacerbated by the pandemic	Includes those who would transition if not for limited treatment options
FNA EHR migration	Ongoing	FNA upgrade	Delayed access to data, no impact on study aims

TTR = Transition to Recovery; MDE = minimal detectable effect; PN = patient navigation; GTR=Gateway to Recovery; AKAIMS=Alaska's Automated Information Management System; FNA=Fairbanks Native Association; EHR = Electronic Health Record.

Additionally, we were unable to access GTR patient records for approximately one year while FNA implemented an unanticipated migration to a new EHR. This required reconciling uniformity of data elements across systems.

Table 2
Source of measures and timing of data collection for the randomized controlled trial.

Measure	Source[a]	Timeframe
Transition to treatment	EHR, ROI	30-days after discharge
Readmission to detox	EHR	12-months
Non-study resources form	SS	Baseline, 6-months
EuroQol 5D	SS	6-months
Client Status Review (1 scale)	SS	Baseline, 6-months
Substance withdrawal scales	AKIAMS	Baseline
Substance use before admission	AKAIMS	Baseline
Alaska Screening Tool	AKAIMS	Baseline
Demographic characteristics	AKAIMS	Baseline
Mortality	EHR, public records, personal communication<	12-months
Social connectedness	SS	Baseline, 6-months
Readiness to change	SS	Baseline, 6-months
Medication-assisted treatment	SS	6-months

[a] EHR = Electronic Health Record; ROI=Release of Information; SS=Self-report, AKAIMS=Alaska's Automated Information Management System.

2.2.5. *Motivational interviewing (control condition)*

The control condition is usual care as currently implemented at GTR plus a 45–60-minute one-on-one MI session after completing baseline data collection. MI is offered prior to discharge from detoxification by trained PNs following a standardized protocol monitored for quality control. Participants are guided to articulate goals and strategies to transition to SUT post-discharge but do not receive active support to facilitate transition beyond the MI conversation.

2.2.6. *Randomization*

Randomization occurs within the Research Electronic Data Capture platform [32]. Participants are randomized 1:1 to the study arms.

2.2.7. *Patient navigation (intervention condition)*

In addition to usual care and MI described above, participants

randomized to MI plus PN receive PN immediately before discharge or shortly after. In-person or phone contact is maintained at least once per week for 30-days or until the patient successfully enrolls into SUT, whichever occurs first. Approximately 15% of GTR patients are homeless; PN requires innovative approaches such as meeting in private rooms at local libraries, churches, and shelters. The number of sessions depends upon the complexity of enrollment planning. PNs consult with GTR providers to identify needs and appropriate level of care [3,16]. PNs provide tailored support and active guidance on enrollment steps and address barriers including, but not limited to, transportation, treatment costs, paperwork, and medical appointment and assessment scheduling [20,22,33,34].

2.2.8. Waitlist control

Responding to GTR preferences, we amended the study design in June 2021 to include a waitlist control, allowing MI-only participants to receive the MI and PN intervention if readmitted after their 6-month self-report data collection. The change respects GTR's priorities and preserves the ability to test transition to SUT within 30-days of discharge and prevent readmission to detoxification within 12-months.

2.2.9. Self-report 6-Month Follow-up

A subset of measures is collected through patient self-report at 6-month follow-up. Measures assess cost of care, social connectedness, readiness to change, and medication-assisted treatment. Participants unreachable by phone are contacted through email, outreach to self-nominated contacts, or publicly available methods. Follow-up is also completed at GTR during readmission or at FNA during SUT. Participants receive a $20 gift card.

We developed a protocol for incarcerated participants that complies with strict human subject's regulations overseen by the Colorado Multiple Institutional Review Board. Since participants are enrolled in the study prior to incarceration, we are able to complete follow-up interviews with those willing to continue participation. Interviews mirror non-incarcerated participants, except the team works with officials to coordinate follow-up by phone or in person. Six-month follow-up is impacted by challenges described in the baseline data collection section.

2.2.10. 12-Month follow-up EHR

We query the EHR annually to document readmission to detoxification and mortality for participants whose enrollment period concluded. For participants who fail to complete the 6-month follow-up interview, EHR data is extracted as specified in the informed consent unless it is revoked.

2.3. Measures

Study measures, sources, and collection timeframes are summarized in Table 2.

2.3.1. Transition to treatment

The primary outcome was originally binary, defined as a physical admission to SUT within 30-days of discharge. However, COVID-related mitigation limited availability at SUT treatment facilities in Alaska, causing lengthy delays for patients who would otherwise transition within 30-day. Therefore, the outcome now encompasses three categories: successful transition within 30-days, attempted transition/waitlisted, and no attempt to transition/no transition. Treatment waitlist status is confirmed through FNA EHR or Release of Information for external admissions.

2.3.2. Readmission to detoxification

Time to readmission to detoxification within 12-months is calculated as the number of days from discharge to first readmission to GTR. Days at risk for readmission are adjusted for periods of incarceration or deaths within the study period. Participants are censored from follow-up after their first readmission for primary analyses; however, readmissions within 12-months are documented.

2.3.3. Health economics

Administrative records and self-reported data allow us to calculate the average cost of the intervention, reflecting treatment-related labor, supply, administrative, and space requirements. A standardized form details use of non-study medical resources [35,36]. The Client Status Review and EuroQol 5D measure self-reported health-related quality-of-life (HRQOL) [37–39].

2.3.4. Other measures

AKAIMS includes severity of withdrawal using the 10-item Clinical Institute Withdrawal Assessment for Alcohol [40] or the 11-item Clinical Withdrawal Scale for Opioid Detoxification [41]. Substance use before admission includes frequency of use, days abstinent in the past month, and age at first use. The Alaska Screening Tool measures depression, anxiety, adverse life experiences, and major life changes in the past 12-months [39]. Demographic data comprises age, sex, race, education, marital status, employment, income, living situation, and history of military service. Mortality surveillance is completed using publicly available records, communication with participant contacts, and the EHR.

Other self-report measures include social connectedness, assessed through Inclusion of Community-in-Self scale, and a similar item for family connectedness [42]. The Readiness to Change scale administered during the MI session assesses readiness to transition to SUT within 30-days [43]. Medication-assisted treatment for substance use disorders is also collected.

2.4. Data analysis

2.4.1. Power and sample size

We anticipated 85% retention for SUT transition and 100% retention for readmission to detoxification, as readmission does not rely on self-report. We assumed 10% of MI participants would transition to SUT and 40% would be readmitted within 12-months. Original calculations for $n = 700$ estimated 80% power to detect an 8% increase in transition to SUT and an 11% decrease in readmission. Updated calculations ($n = 440$) estimate 80% power to detect a minimum increase in transition to SUT of 10% and a 13% decrease in readmission.

2.4.2. Statistical analysis

We will examine descriptive statistics by study arm for all variables. Inferential analysis will follow the intent-to-treat principle. We will employ generalized linear models with canonical links as appropriate for the type of distribution and outcome. Models will be specified to reflect periods when participants were not at risk for the outcomes, due to incarceration or mortality. If study variables are unbalanced by chance at baseline, sensitivity analyses will include those variables in the regression analysis to account for potential confounding. We will use Tobit regression to test whether TTR delays time between discharge and first readmission, or whether readmission was prevented entirely over 12-months.

2.4.3. Health economics

We will use cost-benefit and cost-effectiveness analyses for the economics evaluation. Successful transition within 30-days after discharge and fewer detoxification readmissions within 12-months will extrapolate to downstream cost-savings resulting in reduced substance use consumption, substance use-related consequences, and healthcare utilization. The primary economic outcome is the incremental cost-effectiveness ratio, measured as improvements demonstrated by the intervention relative to the control, divided by the incremental cost of treatment. Analyses will be conducted from the perspectives of the payer of healthcare services, given their role in sustaining the intervention,

and society, given the interest of social efficiency related to resource allocation [44]. We will model the person period by 6-month intervals. Separate multivariable generalized-linear models will be estimated to predict the mean value of each resource category, as well as the number of binge drinking episodes and the HRQL preference weights, at each time point [45]. Recycled predictions will be used to obtain the final predicted mean values for each study group and resource/outcome, which will be summed and tested according to relevant perspectives [45]. To account for sampling uncertainty in point estimates, p-values, standard errors, and confidence intervals for the incremental cost-effective ratio will be estimated using nonparametric bootstrapping techniques within the multivariable framework. Sensitivity analyses will account for uncertain precision in assumptions and parameter estimates applied in the analysis [44].

3. Preliminary data

From the beginning of active recruitment in June 2019 to the pandemic-related shutdown nine months later, 598 individuals were screened, 352 were eligible, and 110 enrolled. The protocol was revised to allow for remote study implementation during the pandemic, but GTR staff shortages required full stoppage of new recruitment from March 2020 to July 2020, with an additional 2-week shutdown in mid-November 2020 due to a COVID-19 spike. Currently, due to staff shortages and reduced bed capacity, admissions to GTR are half the pre-pandemic rate. To date we screened 1,847 patients, 819 were eligible, and 206 enrolled.

Retention is currently 83% at 6-month follow-up which is 2% lower than anticipated. Our retention rate is impressive given challenges of conducting research with detoxification patients, patient homelessness, and pandemic-related issues.

4. Discussion

Patients at GTR have complex issues related to their physical and mental health, housing, employment, and socioeconomic status, which contribute to their frequent admissions to detoxification [6,11,30]. These factors impact ability and willingness to participate in the study. Some may not see the potential long-term benefits of PN because they tend to live in the present moment, addressing the most critical issues affecting their current well-being. Research burden and phases of data collection may hinder participation. These barriers may not exist if PN were offered at GTR as usual care without research requirements.

Few studies examine transition to SUT following detoxification [17,18,46,47], underscoring the need to identify a more complete array of successful interventions. Our study addresses the pervasive problem of cyclical discharges and readmissions and bridges the treatment gap immediately after detoxification. Our patient-centered navigation approach contrasts with past transition-to-treatment studies that focus on behavioral therapies [18,27,47].

This study has limitations. It relies greatly on EHR data not designed for health research and is subject to issues described above. However, FNA invests immensely in data managers who oversee the EHR, implement quality assurance, and train all employees in use. We found over 95% complete data in pre-study assessments and are confident the EHR data will adequately address our scientific aims. Some participants may seek detoxification outside the FNA Behavioral Health system; these individuals will be misclassified as not readmitted. Such misclassifications may be rare, given the very limited treatment options in Alaska, and the limited resources and mobility of the population. The control group received one session of MI, which may attenuate differences between groups that would occur if TTR were compared with usual care only. However, FNA requires all participants receive study support. Our study is conducted in a facility located in the Alaska Interior, potentially limiting generalizability. Nevertheless, FNA is a State-supported unit that operates similarly to other detoxification facilities across the US; we expect findings to generalize to other settings [20]. Lastly, multiple issues with recruitment and annual budget cuts resulted in a reduced sample size. However, this did not dramatically increase our minimum detectable effect sizes. We are well powered to detect meaningful benefits of TTR.

5. Conclusion

The detoxification "revolving door," identified more than four decades ago, still persists today [9,48]. PN may bridge the continuum of care for detoxification patients and close the revolving door of discharges and readmissions. Our study is the first such effectiveness trial conducted in partnership with an AN/AI-serving treatment facility. Close collaboration between the investigators and GTR staff is essential to resolving frequently occurring challenges while simultaneously evolving close, mutually supportive relationships that facilitate study implementation and lay the foundation for continued research. The economic evaluation will determine cost-effectiveness and long-term sustainability, often overlooked when conducting intervention research with resource-constrained communities.

Ethical approval

Institutional review board approvals were obtained from the Colorado Multiple Institutional Review Board, #18-2421 and Washington State University Institutional Review Board, #17626.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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