**Title:** Disclosure Intervention for People in Recovery From Opioid Use Disorder

**NCT Number:** NCT04836247

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## 1. OBJECTIVES

*Disclosing Recovery: A Decision Aid and Toolkit* is a patient decision aid that was developed to help people in treatment for OUD make key decisions regarding disclosure and build skills to disclose.

- Primary aims of the current pilot randomized controlled trial are to examine the implementation of the intervention to inform a future efficacy trial. More specifically, participants' perceptions of the intervention's acceptability and feasibility will be assessed. Additionally, the intervention's impact on decision-making quality will be assessed.
- Secondary aims are to explore the intervention's impact on relationship characteristics, including social support and enacted stigma, and commitment to sobriety.

## 2. DESIGN

This is a pilot, parallel randomized controlled trial. Data will be collected from participants at two time points, spaced one month apart, by a research assistant. All participants will be recruited from the waiting room at Brandywine Counseling & Community Services. The research assistant will **screen** interested individuals for eligibility in person (recruitment strategy described below) and schedule study appointments, which may be coordinated with treatment appointments. All study screening and appointments will be conducted in private spaces (i.e., otherwise empty conference room and/or offices) at Brandywine Counseling & Community Services. Participants will receive $50 gift certificates for completing each time point, and a $10 bonus gift card for completing both time points within 1 week of when it was scheduled.

At the **first study appointment**, the research assistant will introduce the study, check for questions, and obtain consent for the study procedures, and follow up procedures. Participants will be assured that study data will be kept confidential (including from clinic staff). Participants will be randomly assigned to receive either the disclosure intervention (n=25) or a control intervention (i.e., an evidence-based mindfulness intervention, n=25).

- Disclosure Condition: Participants will be guided through a workbook and accompanying worksheet designed to help them: (1) decide whether or not they want to share information about their substance use with others, and (2) build skills for disclosing (e.g., planning what to say). Importantly, the intervention is not designed to encourage participants to disclose or not disclose (please see intervention booklet included with this protocol submission), but rather to help participants decide whether they want to disclose based on their own goals and values. Our intervention is an adaptation of a previously published disclosure intervention (i.e., the CORAL), which is associated with reduced decisional conflict surrounding disclosure and greater job retention (Henderson et al., 2013).

- Control Condition: Participants will be able to choose from several guided meditations offered by Headspace. Headspace offers a series of introductory videos on mindfulness. Evidence suggests that usage of the Headspace app over time is associated with decreases in perceived stress and increases in general well-being (Flett et al., 2019; Mani et al., 2015; Yang et al., 2018). Although the videos have yet to be evaluated in terms of their effects on stress and well-being, they review the same content as the app in a more interactive format and therefore may yield similar effects.

Along with completing the disclosure or control condition activity, participants will be asked to respond to several survey and interview questions to gauge the acceptability, feasibility, and

preliminary efficacy of the intervention materials. The first appointment is expected to last less than one hour.

At the **second study appointment,** participants will again be asked to respond to survey and interview questions designed to further evaluate the acceptability, feasibility, and preliminary efficacy of the intervention. The second appointment is expected to last up to 30 minutes. In particular, we will investigate whether participants who completed our disclosure intervention report better disclosure experiences than participants who completed the control condition. Participants will be able to complete the second study appointment by phone or in person at Brandywine Counseling & Community Services.

## 3. METHODS

We aim to recruit 50 adults receiving SUD treatment. People in recovery will be eligible if they are:

- 18 years or older,
- currently receiving outpatient treatment at Brandywine Counseling & Community Services,
- are considering disclosing their SUD recovery status to at least one person in the next month;
- have access to a phone that can receive text messages and phone calls;
- and have no current diagnosis of severe mental illness.

Participants will be recruited from Brandywine Counseling and Community Services. Brandywine Counseling and Community Services serves approximately 3,000 clients per year. The study will be advertised via recruitment flyers that will be available in waiting rooms and distributed to clients. Participants will be instructed to contact a research assistant, who will be available in waiting rooms, if they are interested in participating in the study. Participants will also have the opportunity to email or call the study team to express interest in the study. Individuals who indicate interest in the study will be asked to fill out an electronic screener in a private room. After answering several questions on an iPad, individuals will be notified whether or not they are eligible to participate. The research assistant will not have access to individuals' individual answers – they will only be able to access information regarding whether individuals are eligible or not.

When eligible individuals sign up for the study, we will ask for permission to send them a reminder text the day before their scheduled appointment. A reminder text will only be sent to participants who agree to be contacted.

People with self-reported bipolar I disorder and schizophrenia will not be eligible to participate in the sample of people in recovery given that relational processes for these individuals may not generalize to others in recovery from SUDs. People with mood and anxiety disorders will be eligible.

## 4. STATISTICAL ANALYSIS PLAN

Participant characteristics will be explored using descriptive statistics. Primary and secondary outcomes will be evaluated with t-test and chi-square tests comparing participants in the *Disclosing Recovery* versus comparator conditions. Because opioid use is hypothesized to impact interpersonal interactions, we will additionally explore whether baseline opioid use moderates associations between intervention assignment with relationship outcomes with two-

way analyses of variance (ANOVA). Statistically significant associations will be further explored. Primary analyses will include the full sample of participants, and secondary analyses will include the full sample of participants for preliminary efficacy analyses or participants who completed the second appointment only for relationship outcome analyses.