

PROTOCOL TITLE: Journaling and Addiction Recovery  
VERSION DATE: 13 April 2021

<b>Protocol Title</b>	Journaling and Addiction Recovery
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**PROTOCOL COVER PAGE**

**REVISION HISTORY**

<b>Revision #</b>	<b>Version Date</b>	<b>Summary of Changes</b>	<b>Consent Change?</b>
2	10.11.18	Miscellaneous small changes required as part of pre-review process	Yes
3	11.12.18	7 changes itemized in 10/30/18 letter from the IRB.	Yes
4	12.20.18	Numerous revisions to screening consent, consent form, flyer, and protocol that adapt the study to the treatment center setting and finalize the details of study	Yes
5	2.3.19	Revisions to the protocol that clarify research assistant duties and content of treatment group	No
6	2.12.19	Numerous minor revisions to screening consent, regular consent, screening check sheet, and	Yes
7	2.26.19	Minor revisions to informed consent document, HIPAA Authorization form, and a footnote describing that in addition to counting the journal entries uploaded to Qualtrics we will additionally manually count the journal entries in the paper journal,	Yes

Revision #	Version Date	Summary of Changes	Consent Change?
8	3.18.19	<p>Now we are ready to recruit the second set of 5 participants. Therefore, we submit changes to various study documents. We will offer the group sessions over three weeks instead of over four weeks. Minor changes to informed consent and screening consent documents. Minor changes to protocol. Now that we have finished the first 8-session group, we upload a detailed list of contents for all 8 sessions and submit the handouts we used during group. During screening we will have participants sign a release of information with the host setting, so we can return their phone calls. We will also teach them a few iPad basics during screening, to spend more time in group on the therapy and not on teaching the technology. We added three standardized measurement instruments and some single-item assessment instruments. We will revise the actual journal. Now, we include the content of handouts that we have used in group in the journal pages (see attachments). Details are described herein.</p>	Yes

Revision #	Version Date	Summary of Changes	Consent Change?
9	3.25.19	Responding to required modifications from the IRB. Regarding our use of a trauma assessment instrument at baseline: in this revision, we clarify that we use the first item of the trauma instrument only to assess trauma exposure and not trauma symptoms, we ask this question to enable us to describe the characteristics sample. NUWAY Inc. already screens all clients for trauma, but we will notify NUWAY Inc. if any participant in the study seems to be having difficulty with study activities because of trauma	
10	6.3.19	Protocol revised to include an electronic survey to be sent to the staff of the host treatment center ("NUWAY Inc."). The purpose of this staff survey is 1) to gather information about the implementation of the study logistics at NUWAY Inc. to optimize logistics before we recruit for the third cohort and 2) to gather staff perspectives of client experiences of study participation.	No
11	6.20.19	Miscellaneous changes to protocol as we prepare to recruit for the third and final cohort: changes to exit interview questions; minor changes to protocol; minor changes to questionnaires.	No

Revision #	Version Date	Summary of Changes	Consent Change?
12	10.10.19	<p>As the current phase of this study concludes and the next phase begins, there are several changes to the protocol:</p> <ol style="list-style-type: none"> <li>1. Changes in research staff (Ms. Staab and Ms. Tillman are no longer on the project; Rebecca Donaldson has been added)</li> <li>2. Changes in funding source</li> <li>3. Change in research setting from Wayside to NUWAY (including a new letter of agreement from NUWAY, attached)</li> <li>4. No longer a focus on rural populations (although we will retain one question in the exit interview about the intervention's application in rural communities)</li> <li>5. Revisions to screening consent, now version 8 (information about being on the wait list is retained here)</li> <li>6. Revisions to informed consent, now version 12 (information about being on the wait list is deleted here, covered in #5, above)</li> <li>7. Journals to be distributed for informal feedback</li> <li>8. Keeping counselors informed of study participant activity</li> <li>9. New study will use a certificate of confidentiality.</li> <li>10. Changes to screening check sheet, now version 5</li> <li>11. Miscellaneous small changes and correction of typos</li> <li>12. There will be no staff survey at the new site, so staff survey information has been removed from protocol and from ethos attached documents</li> </ol>	Yes

Revision #	Version Date	Summary of Changes	Consent Change?
13	11/18/19	<ol style="list-style-type: none"> <li>1. Miscellaneous minor updates related to the host setting.</li> <li>2. The addition of a control group and the modification of study documents to reflect addition of a control group (informed consent documents, screening documents, study flyer, questionnaires, etc.).</li> <li>3. Change of name of the study</li> <li>4. For this next phase, clinicaltrials.gov is not required, therefore, we remove that number from the ethos system and our informed consent documents</li> <li>5. Fix miscellaneous typos</li> <li>6. Minor modifications to HIPCO survey.</li> </ol>	Yes

Revision #	Version Date	Summary of Changes	Consent Change?
14	5/1/20	Modifications to convert the study to online delivery so that it can proceed during safe practices for social distancing during the covid19 pandemic. Language for face-to-face administration is retained in case social distancing laws are changed in time, but the plan as of this writing is to conduct this study remotely. This set of modifications also includes: updates and improvements to informed consent documents. Changes in research staffing. Modifications to the text within the journals. Fixing typos. Addition of “quick start” journaling instructions. Changing main study site collaborator. Addition of treatment site prescreening checklist, to be used by treatment staff. Addition of email or text reminders to treatment and control groups. Use of REDCap to collect and organize study data including information formerly collected on our screening check list, recruitment and enrollment and retention data, informed consent signatures, group attendance, study participation, exit interview, and follow up interview data. Changes to measurement instruments. We moved the detailed instructions for the treatment and control groups out of the informed consent document into a separate instructions document “instructions for gold and maroon groups v2” and kept basic information about the two groups in the informed consent document. We used the	Yes

Revision #	Version Date	Summary of Changes	Consent Change?
15	7/22/20	Miscellaneous updates based on current round of recruitment, screening, and intervention: control group will also get a copy of the quick start guide, research staff might also conduct the pre-screenings during recruitment phase, participants will be encouraged to do their last journal entry (if applicable) and complete their Qualtrics questionnaire before the exit interview (instead of during the exit interview). Participants will be encouraged to complete their Qualtrics questionnaire before the follow up interview. We will continue to send emails with survey links until the end date of study activities, in case someone who has been inactive wishes to resume study activities. Change of inclusion criteria to <i>approximately</i> 2 weeks of abstinence. Minor edits to exactly what is covered in each group session. Change in our use of Zoom video recordings. We have revised exit interview and follow up questions and also have used PowerPoint slides during intervention groups that we have attached to this set of modifications. Our screening checklist has been slightly updated and administered via REDCap, so we include this update.	No



Revision #	Version Date	Summary of Changes	Consent Change?
16	8/7/20	We will add two questions that we will administer halfway through the journaling groups (on approximately group #4): “what is working for me in this journaling group is...” and “what is not working for me in this journaling group is...”	Yes but the informed consent changes are not related to this change mentioned on the left. The informed consent modifications eliminate redundancies to our previous version and make the electronic versions easier to sign for remote signatures.
17	8/25/20	We will now be recruiting from an additional “branch” or site under the host-setting umbrella. The host setting is NUWAY. The current recruitment site is “3Rs.” We will now also be recruiting from “NUWAYIII.”	No
18	9/18/20	Minor changes to study flyer. Addition of new “branch” or site under host setting (NUWAY) umbrella from which we will recruit. Updated “quick start guide.” Ability to send additional journal to Maroon group participants who request it at the 1 month follow up interview. Research staff will create short video recorded group session “recaps” which will be useful for anyone who misses a group or wants to review content. The recaps have the same content as group sessions. Updates to exit interview scripts. Other minor	No

Revision #	Version Date	Summary of Changes	Consent Change?
19	10/25/20	<p>Minor updates to informed consent documents (to fix typos and add clarity), minor changes to exit interview scripts, submission of the text of and links to the short video-recorded group session “recaps” (same content as the group sessions, made available to participants as review or if they missed all or a part of a session). Updates and clarification added to recruitment approach: in addition to our usual recruitment procedures, we will now make presentations in client treatment groups (via zoom) and when able, will use the “journaling study recruitment presentation” PowerPoint slides to do so (which are based strongly on the content of our recruitment flyers and are attached to this modification in ethos). Modification to 30 day follow up interview script: we will not invite the participant to look at a calendar if that would be helpful, and to report to us the number of days they used any addictive substances (in addition to alcohol) because frequency of use is</p>	Yes

Revision #	Version Date	Summary of Changes	Consent Change?
20	12/8/20	Minor edits to exit interview scripts, submission of updated slides used to teach the journaling groups, updated inventory of emails the study has sent to participants, new combined exit and follow up interview script for treatment and control groups, protocol if a participant is having technological difficulties that we cannot rectify during group sessions. We fixed one typo in the protocol: participants are eligible if they have been at the treatment center one week, not	
21	2/27/21	Minor typos corrected to protocol. Changes to recruitment strategy. Minor changes to exit interview scripts. Offer of \$40 in gift cards to counselors who agree to review, comment on, and propose edits to our draft treatment manual. All former participants can request a new journal at any time, and we will provide one as supplies last. Change in number of total participants we hope to enroll, increased to 100 participants.	

Revision #	Version Date	Summary of Changes	Consent Change?
22	3/11/21	Previous versions of this protocol stated that when the control group members finish the 1 month follow up check-in, they get a copy of the journal with written instructions for how to use it. We now want to additionally provide to control group members access to the study YouTube channel that features short videos that show how to use the journal. This is an additional way for the control group to gain any benefit from learning how to do the journaling that the treatment group receives. The videos have already been approved by the IRB and are currently in use by the treatment group. Also included in this IRB modification is the cover letter we will mail to control group members explaining how to access the videos. This letter is included as an attachment to ethos.	
23	4/13/21	We are adding the University of Minnesota Box Secure Storage as a place where we share and store research files. When we collect data from the treatment provider, we will enter that information in to	No

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## **ABBREVIATIONS/DEFINITIONS**

- 12-step programs = Community-based mutual-aid groups (such as Alcoholics Anonymous) comprised of individuals in recovery from a SUD and/or AUD that follow the 12 suggested steps of recovery.
- AA = Alcoholics Anonymous
- AUD = Alcohol Use Disorder
- In recovery = Maintaining abstinence from addictive substances in order to address an AUD and/or SUD and place the AUD and/or SUD into remission.
- PPJ = “Positive Peer Journaling”
- SMART goals = Goals that are Specific, Measurable, Achievable, Realistic, and Timely.
- Sponsor = A member of a 12-step program who often has more experience with recovery than another member who is selected by the less experienced member to serve as that person’s guide and to take a special interest and spend additional time with that member.
- SUD = Substance Use Disorder
- TGT = The gratitude practice called the “Three Good Things” exercise.
- WFO = The daily practice where good wishes for others are listed.
- NUWAY=NUWAY, Inc., the host setting for the study.
- COVID19 = coronavirus pandemic/pandemic of coronavirus disease 2019.
- Zoom = Video teleconferencing service.

## 1. Objectives

Purpose: Citizens across Minnesota suffer from substance use disorders and their consequences. Nearly 9% of Minnesotans met diagnostic criteria for a substance use disorder (SUD) in 2010.<sup>1</sup> Negative consequences from substance use disorders suffered by Minnesotans have included death, arrest, incarceration, homicide, and suicide.<sup>2</sup> The economic cost of alcohol use in the State was estimated at \$5.06 billion, or \$975 per taxpayer, in 2007.<sup>3</sup> In this study we pilot test an intervention we developed (called Positive Peer Journaling, "PPJ"). All aspects of PPJ are described in detail in this protocol (specifically in section 4.1, below). However, in order to clarify the sections of this protocol that precede 4.1, a brief description of PPJ is provided here.

**Brief description of PPJ.** Many spiritual and religious traditions involve the practice of moral inventory or moral self-examination.<sup>4</sup> These practices involve conducting a review of the day, spirituality, gratitude, and striving for self-knowledge and self-improvement.<sup>4</sup> The 10<sup>th</sup> step of Alcoholics Anonymous (AA) recommends that members conduct such a daily inventory.<sup>5</sup> While this practice may benefit AA members, not everyone seeking addiction recovery joins AA. Even for those who do, it can take time to reach step 10 and begin deriving benefits from it.

Review Past 24 Hours		Plan Upcoming 24 Hours		
Date: <u>05/20/2019</u>		Codename: <u>Sunshine</u>		
Good things that happened	Bad things that happened	Work/Education	Home/Housing	Joy
<ul style="list-style-type: none"> <li>• I stayed sober</li> <li>• I met with my counselor</li> <li>• I painted my nails</li> <li>• It's a nice day outside</li> <li>• I talked to peers about NA meetings</li> <li>• A peer made taco dip and shared it with me</li> </ul>	<ul style="list-style-type: none"> <li>• I got into an argument with a peer</li> <li>• I got lost riding the bus</li> <li>• I took my meds late</li> </ul>	<ul style="list-style-type: none"> <li>• Talk to my job counselor</li> </ul>	<ul style="list-style-type: none"> <li>• Do my house support job by 11:30 AM</li> </ul>	<ul style="list-style-type: none"> <li>• color a picture</li> <li>• get coffee creamer</li> </ul>
Things that I am grateful for	Wishes for others	Health	Recovery	Spirituality
<ul style="list-style-type: none"> <li>• My daughters</li> <li>• My dad and stepmom</li> <li>• Treatment center staff and peers</li> <li>• My recovery</li> <li>• Nice weather</li> <li>• My sober support</li> <li>• My sisters</li> </ul>	<ul style="list-style-type: none"> <li>• My daughters</li> <li>• Everyone in treatment</li> <li>• The addict still suffering</li> <li>• My grandpa</li> <li>• My daughter's father</li> <li>• A peer here at treatment</li> </ul>	<ul style="list-style-type: none"> <li>• Take my meds in the morning and before bed</li> </ul>	<ul style="list-style-type: none"> <li>• Go to an AA meeting tonight</li> <li>• Read my NA book</li> </ul>	<ul style="list-style-type: none"> <li>• Find a church near the treatment center</li> </ul>
		Community	Social	Financial
			<ul style="list-style-type: none"> <li>• Family night</li> </ul>	<ul style="list-style-type: none"> <li>• Figure out how to pay my phone bill</li> </ul>
		Amends/Repair		
		<ul style="list-style-type: none"> <li>• My daughter</li> </ul>		

We developed PPJ as a simple 10-minute daily practice which reviews the past 24 hours on the left hand side of an open-page spread and plans the

upcoming 24 hours on the right hand side of the open-page spread of any standard journal.

Two primary sources inspired PPJ. The first is AA's 10<sup>th</sup> step which recommends a regular "personal inventory" where the day is reviewed and what went well and what went poorly is identified and acknowledged.<sup>5</sup> The second source of inspiration for PPJ is the daily action plan recommended in some 12-step programs where the upcoming day is planned with health and balance in mind, including activities related to "recovery, recreation, and relationships in addition to work...."<sup>6</sup> The AA 10<sup>th</sup> step practiced on the left hand page and the action plan practiced on the right hand page together affirm the value of each sober day and strengthen the odds of learning from the day's events and planning a successful, balanced, and healthy upcoming 24 hours, which should strengthen quality of life in recovery.

While each element of PPJ is explained in detail in this protocol (in section 4.1), we provide a visual snapshot of what a completed daily PPJ entry might look like in Figure 1 below.

*Figure 1. Positive Peer Journaling (PPJ) Example*

**Objectives.** The main objective of this study is to pilot test the PPJ intervention and to examine the feasibility, acceptability, and logistics of treatment delivery.

A second objective is to observe whether PPJ is associated with improvement in hypothesized outcomes. The primary outcomes we will examine are enhanced treatment retention and reduced recurrence of substance use. We will also explore the association between the intervention and a set of hypothesized mediators of the effect of the intervention on outcomes, e.g., satisfaction with recovery and improved mood. A complete list of hypothesized mediators is outlined in the measures section 5.2 of this protocol. While our sample sizes will limit quantitative analysis, we will also employ qualitative exit interviews as will be described below to meet these research objectives.

## **2. Background**

- 2.1. Significance of Research Question/Purpose: Many scholars in the addiction field have made the case that clients with alcohol use disorders (AUD) and substance use disorders (SUD) should be helped to build an abstinent lifestyle that is positively reinforcing and more appealing than active addiction.<sup>7-10</sup> Many current interventions focus, reasonably and necessarily,



on reducing pathology,<sup>11</sup> i.e., identifying triggers, reducing cravings, managing thoughts about alcohol, and coping with relapse.<sup>12</sup> Pathology-based treatments by themselves miss an opportunity to aid clients in building a positively reinforcing life in recovery that will make the hard work of abstinence worth the effort.

PPJ is designed to support the construction of a positive, affirming sober lifestyle. PPJ emphasizes expressing gratitude and savoring what is positive about sober life and making plans to support recovery based on each person's prized values. If satisfaction with recovery is increased, risk of relapse should decrease.

- 2.2. Preliminary Data: **Relevant Study #1.** We conducted a qualitative study in which we gathered opinions of PPJ from 33 individuals residing in rural southeast Minnesota who have knowledge of SUD and AUD treatment and recovery. The sample was comprised of 61% people in recovery, 15% treatment providers, and 24% treatment providers in recovery. We conducted in-depth semi-structured interviews with participants to ascertain their perspectives of PPJ. PPJ was presented and practiced one time by participants. We asked, "What are your observations and thoughts about this journaling practice?" "How can this practice be helpful to individuals in recovery, if at all?" and "What might be a downside to this practice, if any?" Interviews were audio recorded, transcribed, and analyzed for themes.<sup>13</sup>

Overall, PPJ was perceived to be feasible and acceptable. The majority (79%) stated the practice was feasible, e.g., "nothing too difficult," "faster than I thought it would be," and "a really easy way to journal." The majority (82%) offered favorable impressions, e.g., "This is just a marvelous piece" and "I love it." A quarter (27%) initially had objections to "journaling" but liked the practice after thorough introduction where they learned that PPJ involves bullet-pointed lists and not lengthy written narratives. One participant said: "That's my kind of journaling. Just a phrase." A fifth (21%) were ready to get started with the practice right away, e.g., "I'm so pumped, I'm going to buy a notebook after this." A fifth (18%) expressed more moderate positive intentions, e.g., "I should show this [to the sober house manager]," "I could see using this [for my treatment group]," and "I can talk to my sponsor...and see how we could put it in play."

Participants stated that the practice would aid recovery by increasing awareness of "what is," e.g., it might aid becoming "more aware of themselves, and more aware of what's going on in their life day to day." The practice would help them to focus their attention on both the positive and the negative in a day of recovery, which was identified as helpful. Tracking the positive would draw attention to what is going well and help give one's

self credit for things going right. It would increase awareness of positive changes and provide an opportunity to express gratitude. Tracking the negative would help identify issues that need attention, put negative things into perspective, and inspire improvement.

There were two exceptions where people interviewed were hesitant about PPJ and in the current study we will take steps to address both of these concerns.

First, people had concerns about a practice that involved writing. Some felt writing was beneficial, e.g., “get it out of your head” and “write it down, you’ve released it.” Some stated they felt they were not good at “writing and all that kind of stuff.” Others said they had “a hard time concentrating.” A practitioner recognized that clients often have low levels of education, stating, “some of my clients only made it to 3<sup>rd</sup> grade so they get embarrassed to write stuff.” To address this concern, we will explain that the practice involves short bullet-pointed lists and not long pages of writing. We will explain that grammar and spelling are not relevant for this practice. We will explain that while the researchers will review a snapshot of a daily entry in the course of research activities, and participants will be invited to verbally share aspects of their entries, no other person will be shown their entries and no one will critique them.

Second, some participants of our pilot study expressed concern about activity scheduling and planning. Many had positive things to say about planning, e.g., it would help them to prioritize tasks and it would provide reminders of important tasks. However, for others, planning might engender burdensome thoughts, e.g., “I hate remembering what I have to do in my home” or could cause feelings of disappointment, “my fear would be, I’d start it and then wouldn’t follow through... it would feed into my negative thoughts.” To address this concern, we will invite participants first to identify sober aspects of life that align with their values, and then identify tasks that flow from these values, as is recommended in the behavioral activation therapy LETS ACT.<sup>14–16</sup> To build confidence and success, participants would aim to achieve zero tasks per day (planning only) and then one task a day at first. Also, participants are encouraged to plan the smallest next step of a task, so it will be achievable and not overwhelming.

**Relevant Study #2.** A component of the left side of the page in PPJ is the “Three Good Things” gratitude exercise to aid the review of the past 24 hours. PI Krentzman conducted a randomized controlled pilot test of the “Three Good Things” gratitude intervention among AUD patients.<sup>17</sup> In the study, adult AUD outpatients were randomized to a gratitude intervention or active control group. All who were assigned to the treatment group

completed the 14-day gratitude intervention. The majority (91%) of participants completed the gratitude intervention each day and, on average, 91% of participants completed all gratitude interventions over 14 days. The gratitude group rated the exercise as highly satisfying, pleasant, helpful, and moderately easy (averages of 8, 8, 8, and 6, respectively, on a scale of 0 “not at all” to 10 “extremely”). In multi-level models to detect change in the slope of affect over the 14-day treatment, unactivated positive affect increased and negative affect decreased. Qualitative results depicted that the exercise became easier over time. On days when things did not go well for individuals, participants found it harder to name three good things; however, they reported that with effort they could do so and that the practice helped disrupt negative thoughts and feelings. Participants found that the exercise affirmed recovery. On day 14, the majority of participants (82%) reported they would continue the practice but at 14-week follow-up, few had continued the practice and only one continued written recording. Improvements in mood were not sustained at 14-week follow-up, presumably because individuals did not continue with the practice. To address this concern, we will take steps to improve teaching and learning of PPJ which we believe will foster success and encouragement. We will provide small group sessions that involve coaching and modeling to help people with all PPJ activities including the “Three Good Things” activity. The later stages of learning PPJ includes an exercise (“each one teach one”) where each participant will teach PPJ to another person in recovery, to cement learning and improve success and confidence.

**Relevant Study #3. PPJ Development Study (This is phase 1 of the current study).** In this one-armed (no control group) study, we administered PPJ to 15 women. While we are currently analyzing these data, we do have preliminary information on the demographics of the sample and PPJ feasibility, acceptability, and impact.

The women’s ages ranged from 25-59, average age was 37. Most (67%) were white and the rest were black or African American, Native American or Alaskan Native, Asian or Pacific Islander, and multiracial. They had an average of 14 years of education. Three quarters of the sample earned less than \$15,000 last year. They had an average of 2 children. Most (70%) were involved in a legal case and most (90%) had a history of trauma.

Roughly half (47%) had been addicted to amphetamines, one quarter (27%) to alcohol. A fifth had been addicted to opiates and 7% to cannabis. Length of sobriety at baseline was 48 days (SD=32 days). The women had had 6 previous treatment episodes (SD=3). On a 0-10 point scale with high numbers indicating high levels, the women had high commitment to

sobriety (10, SD=1), moderate happiness with recovery (7, SD=2), and moderate confidence in their ability to remain sober (6, SD=2). On a scale that could range from 5-35, their average satisfaction with life was 15 (SD=6). Craving for drugs or alcohol was moderate on a 0-10 point scale: 5 (SD=3).

This study provided preliminary evidence for acceptability and feasibility of PPJ. On a scale of 0-10, with 10 representing high levels, participants gave PPJ high ratings for being easy (8.6), satisfying (8.0), pleasant (7.9), and helpful (8.0) and low ratings for being difficult (1.6).

In the sample overall, there were significant increases in satisfaction with life, happiness with recovery, and confidence in the ability to remain abstinent. Commitment to sobriety did not increase perhaps because baseline average levels were at the top of the scale (9.5/10 points).

In the qualitative data, participants emphasized two main benefits from PPJ: 1) PPJ helped them to realize that more good things than bad things happened in a day and 2) PPJ's right-hand side served as a simple planner which reminded the participants to do things that were important and meaningful to them. When they were reminded in this way, the participants acted to accomplish a wide range of recovery-supportive behaviors.

The majority (73.3%) were discharged from the treatment host setting on good terms (with staff approval) and 73.3% did not use substances on or after the onset of PPJ therapy (one person used substances after intake but not again during treatment). Two thirds (66.7%) did not use substances and left on good terms. One used substances and left on good terms. One did not use substances but left against staff advice. Three used substances and left at staff request. Our preliminary work has demonstrated 1) high rates of treatment retention for the "Three Good Things" study, 2) high acceptability and feasibility among AUD patients for the "Three Good Things" exercise and among SUD patients for PPJ, 3) significant impact of the "Three Good Things" exercise on improvement in mood, and 4) revelation of important considerations to address as we implement the intervention moving forward.

- 2.3. Existing Literature: PPJ is a novel intervention, but it draws most strongly from two bodies of research: 1) the research on gratitude and its relationship to addiction recovery (PPJ includes two gratitude exercises on the left hand side of the page) and 2) the research on activity scheduling and behavioral activation to support addiction recovery (featured on PPJ's right hand side page).

**Research on Gratitude and Addiction Recovery.** Anecdotally we know that gratitude is a strong component of addiction recovery in 12-step programs

such as Alcoholics Anonymous. It is a common theme in AA meetings<sup>18</sup> and is a prevalent theme in AA literature.<sup>19</sup> Recent empirical investigations into this phenomenon suggests that trait gratitude correlates positively with recovery supportive factors and negatively with factors that might challenge recovery.<sup>18</sup> Research also suggests that gratitude practices are associated with improvement in mood, which should make recovery more positively reinforcing.<sup>17</sup> Supporting recovery and improving mood should reduce relapse risk. In the paragraphs that follow, this body of research is described in detail.

In a cross sectional study of 105 men in treatment for substance use disorders while incarcerated, frequency of drug use in the 12 months before incarceration was negatively correlated with trait gratitude during treatment.<sup>20</sup> In the only study we are aware of that explored the role of gratitude specifically as it occurs in 12-Step programs, LaBelle and Edelstein<sup>18</sup> surveyed 184 members of Alcoholics Anonymous and Narcotics Anonymous in a cross sectional study. The authors found that trait gratitude was positively associated with wellbeing outcomes (post-traumatic growth and social support) and 12-step factors (12-step practices and AA promises). Trait gratitude was negatively associated with number of physical health symptoms.

Three studies explored change in trait gratitude before and after SUD treatment. Charzyńska<sup>21</sup> found that trait gratitude increased among women but not men between baseline and treatment completion, five to seven weeks later. Krentzman<sup>22</sup> found that trait gratitude did not change between treatment entry and 6-month follow-up. Charzyńska and colleagues<sup>23</sup> built on their earlier study<sup>21</sup> by increasing the number of participants from 112 to 358 and using latent class growth analysis and three time waves to form latent class trajectories of gratitude from pre-treatment to 6-month follow-up. They found four heterogeneous classes. Individuals with high gratitude at baseline maintained high gratitude, two classes of individuals with low gratitude at baseline showed increases in gratitude, and a class with moderate gratitude at baseline showed decreases in gratitude. These classes were different by baseline education, religiosity, and age, but not by gender.

Krentzman<sup>22</sup> found a significant interaction between current drinking status and trait gratitude on future abstinence. Trait gratitude was positively associated with abstinence among those abstinent at 6 months, and negatively associated with abstinence among those drinking frequently at 6 months.

Studies of gratitude as an intervention to improve mood have been conducted among individuals with substance use concerns. An 8-week

positive-psychology intervention was constructed to include gratitude and other interventions to boost positive emotion and supportive behaviors and tested among adolescents with substance use problems. The intervention showed increases in happiness, optimism, and positive affect relative to a comparison group.<sup>24</sup> A 5-session positive-affect intervention was conducted with men who were methamphetamine users and who had sex with men. The intervention included gratitude exercises as well as other strategies to induce positive affect such as noticing positive events, mindfulness, positive reappraisal, strengths, and altruism. Individuals randomized to this treatment showed a trend toward increases in positive affect. Qualitative data indicated that participants found the intervention to support their recovery. However, the comparison condition showed significant reductions in negative affect, compared to the treatment group.<sup>25</sup> A gratitude intervention, the “Three Good Things” exercise<sup>26</sup> was piloted in a small sample of adults in treatment for alcohol use disorders. The gratitude intervention increased feelings of ease and calm and decreased negative affect.<sup>17</sup>

**Research on Activity Scheduling and Behavioral Activation to Support Recovery.** Behavioral activation therapy is another powerful strategy for making abstinence more positively reinforcing, and activity scheduling is a key component of behavioral activation. Activity planning comprises the right hand side of the page in PPJ. The Life Enhancement Treatment for Substance Use (LETS ACT) is behavioral activation treatment<sup>27,28</sup> modified for individuals with substance use disorders. Three randomized controlled trials showed that compared to comparison groups, LETS ACT participants demonstrated lower levels of depression<sup>15</sup> and anxiety,<sup>15</sup> greater enjoyment of activities,<sup>15</sup> higher activity levels,<sup>16</sup> decreased dropout from treatment,<sup>16</sup> and increased abstinence at 3-, 6-, and 12-month follow-ups.<sup>14</sup> This work is similar to what we are proposing herein, i.e., daily activity scheduling that is aligned with an individual’s values for a sober life. We hypothesize that the benefits of PPJ will approximate the similar benefits found from LETS ACT therapy.

**Rationale for PPJ.** *Why combine daily life review (including gratitude interventions) with planning for the future (activity scheduling) in a daily exercise?* Gratitude interventions and activity scheduling should reinforce and extend each other’s impact. A positive correlation between higher levels of gratitude and greater behavioral activity have been reported.<sup>29,30</sup> This association may be causal: in previous research, gratitude has been shown to improve affect<sup>17,31</sup> which has been shown to encourage more frequent and more diverse types of activity.<sup>32</sup> Therefore, gratitude intervention should encourage positive, abstinent behavior. Conversely, activity scheduling will enhance gratitude by guiding individuals to shape

their own positive experiences rather than to passively notice them. Positive behaviors will produce content to populate the next day's gratitude inventory.

**3. The next phase of this study will add to the existing knowledge base because we will collect more information about PPJ's feasibility, acceptability and impact with a larger sample size. Our development study included only women; this phase of the study will include women and men. We will also have a control group in this next phase of the study. We will also modify the protocol so we can conduct the study on Zoom to comply with shelter-in-place orders and COVID19 best practices**

**Study Endpoints/Events/Outcomes**

- 3.1. Primary Endpoint/Event/Outcome: The primary outcome is empirical data on the feasibility and acceptability of PPJ. We will also assess rates of substance use and treatment retention as primary outcomes.
- 3.2. Secondary Endpoint(s)/Event(s)/Outcome(s): These include hypothesized mediators of the effect of the intervention on outcomes. These include: mood, satisfaction with life, commitment to sobriety, alcohol and drug craving, anxiety, and depression. For a complete list, see the measures section 5.2.

**4. Study Intervention(s)/Interaction(s)**

- 4.1. Description: **In-Depth Description of PPJ Intervention.** PPJ encourages past 24-hour review and upcoming 24 hour planning to improve quality of life in recovery and reduce relapse. PPJ uses lined journals with column headings under which individuals make bullet-pointed lists. On the left hand page, past 24 hours is recalled, itemizing "good" and "bad" things that happened and things for which one is grateful. Good wishes for others are also expressed on this page. On the right hand page, activities for the upcoming 24 hours are planned via headings representing valued life domains, such as "recovery," "work/school," "spirituality," "home and household," and "health."

PPJ invites participants to open to a page in a journal we developed which has column headings representing the different categories on the left and right of the fold. See the figure below, which is a snapshot of the journal. The pages (or "flaps") on the far left and far right fold in and serve as bookmarks. The far left and right pages provide helpful hints for what to include under each column heading. Please note, minor changes have been

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made to the wording that appears in this example. New wording has been uploaded to ethos, see file “PPJ Journal Text for IRB May 2020.”

Left hand flap with suggestions	Left hand page	Right hand page	Right hand flap with suggestions
<p><b>Review Past 24 Hours</b></p> <p>Good things that happened</p> <p>Small things that happened</p> <p>Anything fun or enjoyable</p> <p>Anything that surprised you</p> <p>State or heard something beautiful</p> <p>Feeling relief about something</p> <p>A problem was solved</p> <p>A moment with nature</p> <p>Feeling rested, sleeping well</p> <p>Self-care activities</p> <p>Had a good conversation</p> <p>Completed a good project</p> <p>Spent time with a loved one</p> <p>Had a good meal</p> <p>Things that I am grateful for</p> <p>People I want to take care of</p> <p>Gratitude</p> <p>Family members</p> <p>Friends</p> <p>My recovery program</p> <p>Higher power</p> <p>Good experiences I have had in life</p> <p>Good qualities of my loved ones</p> <p>Good food</p> <p>Sunshine</p>	<p>Date: _____</p> <p><b>Review Past 24 Hours</b></p> <p>Good things that happened</p> <p>Bad things that happened</p> <p>Things I am grateful for</p> <p>Wishes for others</p>	<p>Codename: _____</p> <p><b>Plan Upcoming 24 Hours</b></p> <p>Work/Education</p> <p>Home/Housing</p> <p>Health</p> <p>Recovery</p> <p>Spirituality</p> <p>Community</p> <p>Social</p> <p>Financial</p> <p>Personal/Physical</p>	<p><b>Plan Upcoming 24 Hours</b></p> <p>Work/Education</p> <p>Home/Housing</p> <p>Health</p> <p>Recovery</p> <p>Spirituality</p> <p>Community</p> <p>Social</p> <p>Financial</p> <p>Personal/Physical</p> <p>Blank Category</p> <p>Blank Category</p> <p>Blank Category</p>

On the bottom of the third panel “plan upcoming 24 hours” we added along the footer the following words: “observable measurable (where, when, how often, how long, how much) smallest pieces possible” to help participants to articulate tasks that are small and achievable.

The left hand page is devoted to a structured review of the past 24 hours, and includes evidence-based gratitude interventions including making a gratitude list<sup>33,34</sup> and the “Three Good Things” exercise.<sup>26</sup> The “Three Good Things” exercise involves past 24 hour recall, identification, and recording of three positive events that occurred that day (e.g., “warm exchange with cashier at dollar store”). The “gratitude list” involves listing items for which one feels thankful (e.g., “roof over my head”). Gratitude list items are more global in nature. These two exercises approach gratitude content via different prompts to expand access to good things in life. The two exercises are distinct, but it is acceptable if they overlap (e.g., a “good thing” is listed on the “gratitude list.”)

The journal will also feature pages on which the participants will write about their values for important life areas and identify small, actionable items to move toward their values. Here is what that page looks like (please note we might make minor changes to the wording):



<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <b>Important Life Area:</b> </div> <p style="text-align: center;">What makes this life area important to you?</p> <p style="text-align: center;">What makes this life area mean a lot to you?</p> <p style="text-align: center;">What do you wish for in this area?</p> <p style="text-align: center;">What do you believe strongly in this area?</p> <p style="text-align: center;">What are you striving for in this life area?</p> <p style="text-align: center;">What do you long for in this area?</p> <p style="text-align: center;">If this life area were going well, what words would you use to describe it?</p> <p style="text-align: center;">What about this area is important to you, in your heart?</p> <div style="border: 1px solid black; height: 100px; margin-top: 10px;"></div>	<div style="border: 1px solid black; height: 100px; margin-bottom: 10px;"></div> <div style="border: 1px solid black; height: 30px; margin-bottom: 10px;"></div> <ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul>
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The life area questions and the upcoming 24 hour prompts (observable, measurable, smallest pieces) are quoted from, inspired by, or paraphrased from the "Ten Year Revision of the Brief Behavioral Activation Treatment for Depression: Revised Treatment Manual" (Lewin et al., 2011) and the "Life Enhancement Treatment for Substance Use (ACT): Outpatient 6-Session Therapist Manual Paper Group," University of North Carolina, Chapel Hill.

Also printed in the journal are instructions for the “each one teach one” exercise, where participants teach PPJ to another person. That page looks like this (please note we might make minor changes to the wording):

<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;"> <b>Each One Teach One Script—Page 1</b> </div> <p>[Find someone to explain Positive Peer Journaling to. The person can be a person who is in or even not in recovery.]</p> <p>I'm in a research study conducted by the University of Minnesota. In the study, we learned a journaling practice. My homework is to teach this journaling practice to someone else. Would you like to be the person I teach it to? It will take about a half an hour.</p> <p>[Go ahead and tell them some good things about the practice, for example, "I have found this practice to help support my recovery" or any other statement that is true for you.]</p> <p><b>What questions do you have before we begin?</b></p> <p>This journaling practice uses the left and the right hand sides of the page. The center represents the present moment. On the left side, we review the past 24 hours. On the right side, we plan the upcoming 24 hours.</p> <p>Here is an example, take a moment to read it. [show them the example]</p> <p>[Next show them the blank journal page.] We will use this sheet where the categories are already listed. Make short bullet pointed lists under every category on the left side, and as many categories as you want on the right side. If you are not sure what to write, please use the explanation page. [Show them the explanation page]</p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;"> <b>Each One Teach One Script—Page 2</b> </div> <p>Let's practice this together now. Would that be okay with you? [if yes] While you are filling this out, I'm going to do the same thing, in my journal. Stop me if you have any questions.</p> <p>[Sit with the person and fill in the journal. This should take about 10 minutes]</p> <p>Would you be willing to share with me some of what you wrote? [if yes] Please only share what you feel comfortable sharing. What did you put for good things? [hear what they say, read what you put] Bad things? [hear what they say, read what you put] Gratitude? [hear what they say, read what you put] Wishes? [hear what they say, read what you put]. Upcoming 24 hours? [have them share all on this page, then you share all on this page.]</p> <p>[Pay them some compliments, like, "you did a really good job!"]</p> <p>What did you think of this practice? Thank you so much for your help.</p>
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The reasons we have included these pages (the values exercise pages and the each one teach one pages) is so that the participants will have access to this information within their journal, instead of miscellaneous pieces of notebook pages or handouts that can be separated from the journal itself. These materials might have lasting value as reference material for the participant.

Based on participant feedback, we added approximately 10 pages of the journal that are lined pages with the word “notes” in the upper left corner of the double page spread. Participants told us they wished the journals had space to capture additional thoughts and observations. It will also be a good place to take notes during journaling group. The notes page is uploaded to ethos.

1. We will engage in several strategies to enhance participants’ success with gratitude interventions. Based on feedback from participants in our previous gratitude research, individuals will be coached that items on the “Three Good Things” list need not be monumental in scope but that small things count.<sup>17</sup> Based on participant feedback from previous research, individuals will be coached that items on the gratitude list can include things often taken for granted.<sup>17</sup> Based on published gratitude research, participants will be provided with suggested areas in which to look for gratitude content in their lives.<sup>35</sup> In this way, gratitude interventions will be modeled by the therapist and other group members.<sup>35</sup> In keeping with the 10<sup>th</sup> step from AA, the past 24 hour review will also include a bullet-pointed list of what did not go well in the past 24 hours. In our pilot qualitative work, we learned that participants with expert knowledge of addiction recovery described that listing what did not go well in a day was useful.<sup>36</sup> Listing what did not go well should be useful in forming plans for the upcoming 24 hours to address the negative circumstances from the previous day. For example, one category heading on the right hand page in PPJ is “repair/amends” which offers a venue for setting things right and can reference items from the left hand page. The left hand page also has a column wherein participants can express well-wishes for someone else that they know is suffering or struggling. We will refer to this component as good wishes for others (WFO). This too can inform plans for the upcoming 24 hours, e.g., it might prompt reaching out to that person to express support and thereby strengthen interpersonal bonds. Expressing well wishes for others is an act of kindness, and acts of kindness interventions have been studied as positive psychology interventions to improve mood.<sup>37</sup>

In PPJ, the right hand page is devoted to a structured plan for the upcoming 24 hours, and includes activity scheduling.<sup>15,38</sup> Activity scheduling prompts action toward work-related and personal goals, positive activities, and self-care behaviors each day. This work will focus on identifying important life areas, values, and activities. First, participants will be guided to select areas in life that are of most value to them (choosing from, e.g., mental health, physical health, education/work, hobbies/recreation, relationships, and

spirituality). Next, participants will be guided to articulate their values and activities for chosen life areas. For example, in the life area “physical health” a value could be “feel good in my body” and a corresponding activity could be “walk outside for 20 minutes.” Participants will start with zero items each day (planning only) and build to achieving one item a day to avoid feeling overwhelmed and build a track record of success. Participants will be encouraged to share their goals with their primary counselors at the host session in order to obtain support and help.

## **5. Procedures Involved**

5.1. Study Design: This study is a randomized control trial with a one-month follow up. In this mixed-methods study we will collect quantitative and qualitative data. Questions related to feasibility and acceptability as well as hypothesized outcomes (increased treatment retention and decreased recurrence of substance use) and hypothesized mediators will be assessed quantitatively via self-report questionnaire instruments and participant treatment record, as described below. Qualitative data will focus on subjective experiences of PPJ and logistics of study implementation. The spoken words of participants during group and the written content of their journals also comprise qualitative data that we will study. This has been outlined for the participant in the informed consent document. Qualitative and quantitative data will be combined using integrative strategies recommended by Caracelli and Greene<sup>39</sup> and Li, Marquart, and Zercher.<sup>40</sup> In this integrative process, convergence across different data sources will be documented, and divergence will be examined further to elucidate deeper understandings.<sup>41,42</sup> Who will administer these measures? The quantitative measures will be assessed via electronic Qualtrics survey that the research participants will access and complete themselves. (In the event there are technological difficulties, we might administer these surveys as paper questionnaires). At baseline, research staff will hand the participant the iPad (a computer can be used as back up) to complete the electronic Qualtrics survey. (For the electronic administration of this study, we will screen participants on Zoom and send them the link to the survey in the Zoom chat or via text or email, or we will provide them with the url.) During group, the research staff conducting the group will hand out the iPads and participants will use them to upload a picture of their journal entry and answer Qualtrics questions. (For the electronic administration of this study, we will send the link to the survey to participants electronically or give them the URL to navigate there themselves). Participants will use their own smart phones or tablets. Outside of group sessions, NUWAY Staff will make the iPads available for this same purpose (for electronic administration, we might retain a couple of iPads at the treatment center for clients to use

during face to face visits for drug screening or other purposes, following all COVID19 best practices including social distancing). During the screening interview, we will provide some information about how to use the tablets/smart phones to access the surveys and take a picture of journal entries (for electronic administration, we will only provide this information to the treatment group). When will these measures be administered? Please see Table 2 “Schedule of Assessments” below for the timeframe indicating when these measures will be assessed. Please note we might make minor changes to the wording of the Qualtrics survey, for example, to improve the wording of some instructions to aid clarity or to correct typos and other small errors.

2.The study is being conducted in collaboration with our community partners for this study, NUWAY Inc. treatment center in Minneapolis, Minnesota. NUWAY has been providing substance use disorder treatment remotely via Zoom groups and individual sessions shortly after the COVID19 crisis began.

3.

4.NUWAY staff participate in many aspects of study implementation. NUWAY staff assist with recruitment, they will complete a pre-screening check list for each client referred to us, they provide us access to the treatment rooms and offices, they help us locate participants and prospective participants who have appointments with us, and they disseminate the iPads among other duties. For electronic administration, we will not use NUWAY treatment rooms or offices.

The counselors at the treatment center will review their caseloads and identify prospective participants who meet all the criteria on the check sheet (attached). Counselors will inform eligible clients of the opportunity to participate. Counselors will provide potential participants with study contact information and instruct them to reach out to study staff to ask questions and/or indicate their interest. If potential participants prefer, they may give permission for the counselor to share their contact information with study staff. Study staff will be responsible for final screening and obtaining consent from interested families. Study staff might also pre-screen participants using the counselor check sheet.

We will use REDCap software to collect and organize study data including information collected on the screening check list, recruitment and enrollment and retention data, group attendance, study participation, exit interview, and follow up interview data. We will also obtain consent signatures electronically using REDCap.

Please note that the wording described in all participant-facing documents and questionnaires may be modified slightly to improve word choice or correct typos or other errors.

We will use Zoom features such as sharing our screen, white board, polls, and waiting room to enhance learning and protect integrity of group sessions.

We will teach basic Zoom skills (how to raise your hand, how to use the chat box, etc.).

5.

- 5.2. **Procedures.** This study will be advertised to be a study of “journaling in recovery from addiction.” All those interested in the study will be screened first by NUWAY staff to see if they meet basic criteria (see “prescreening guide for NUWAY staff,” attached) and then by research staff (using Zoom for electronic administration, see screening procedures, below). After screening and administration of the baseline assessment battery, individuals will be randomized into treatment and control groups using randomly generated pairs of numbers or using REDCap’s randomization procedure.

**Activities of the control group.** The control group will receive emails from the study team 3-7 times per week for 5 weeks (to mimic the assessment schedule of the treatment group). The control group, like the treatment group, will get a reminder email if they do not respond to our first email after several hours. Each email will contain a link to a Qualtrics survey. Control group participants will complete the Qualtrics surveys and earn \$5Target gift cards for doing so. Gift cards will be distributed electronically for electronic administration of this study. The control group will be able to accumulate the same number of gift cards as the treatment group. After 5 weeks, control group participants will be invited to participate in a qualitative exit interview to ascertain their experiences with the study. At approximately one month after the exit interview, control group participants will be invited to participate in a follow-up interview. At this interview, research staff will ask participants about any substance use and any journaling behavior. After the 30-day follow up, control group participants will be given (or will be mailed using social distancing best practices) a copy of the PPJ journal along with written instructions for how to use the journal (see “PPJ quick start guide,” attached). Please note, small changes to the quick start guide might be made such as small wording changes, fixing of typos, changing examples to make them gender neutral, changing examples so that the language used matched the terminology used at the host setting. In addition, control group members will also be

given access to the study YouTube channel, which features short videos explaining how to use the journal. The rationale is that this will help the control group learn how to use the journal in more detail than the written instructions, so they have a better chance of getting any benefit from the journals. We will include a new cover letter when we mail them the journal and the written instructions. This cover letter will give them the URL for accessing the YouTube channel. A copy of this letter has been uploaded to ethos. Treatment group participants will be emailed or regular-mailed the PPJ quick start guide also, at the end of the group phase.

**Activities of the treatment group.** The treatment group will be assigned to attend 8 hours of group sessions (for electronic administration, these sessions will be delivered via Zoom) in which PPJ journaling is taught in groups (which takes place over 2.5 weeks, and can be offered in alternative arrangements, for example, 4 2-hour sessions or other configuration acceptable to the treatment host setting) followed by 2 weeks of independent journaling practice, as described in detail below. They will earn \$5 Target gift cards for their participation, administered electronically. After 5 weeks, treatment group participants will be invited to participate in a qualitative exit interview to ascertain their experiences of the study and of journaling. At approximately one month after the exit interview, treatment group participants will be invited to a follow-up interview in which research staff will ask participants about any substance use and any journaling behavior. Exit and follow-up interviews will take place via Zoom for electronic administration. The treatment group will also receive emails from the study team reminding them to do the journaling and fill out the Qualtrics questionnaire. The treatment group, like the control group, will get a reminder email if they do not respond to our first email after several hours.

Emails to the treatment and control groups will contain encouraging statements such as, “well done” “thank you for your participation in this research study” “we really appreciate your participation in this research study” and other similar encouraging messages. We will also use structuring statements, such as “this is the first email of the research study” or “this is the final email of the research study” or “you are halfway through” or other similar structuring statements. We will also use statements to increase the validity of responses, such as “please answer as honestly as you are able” or “please put down the response that best matches how you really feel.”

Before any Zoom meetings, group or one-on-one, we will send out a reminder with the Zoom link to email or text ahead of time. We will send out reminders the day before and 10 minutes ahead of the meeting.

To aid the treatment group in accessing the correct URL for uploading the photo of their journal and completing the Qualtrics questionnaire, the QR Code and the URL to the Qualtrics survey will be printed on a front page of the journal.

Please note, if any participant has technological difficulties with Zoom or with study procedures that we cannot adequately address during group sessions, we might place the participant with a research assistant in a Zoom break out room or make an appointment to meet with that participant by Zoom or telephone to help solve the difficulty.

See the table below for a summary of study activities by arm.

*Study Activities by Arm*

Baseline: All participants	Randomization	Phase 1. First 2.5 weeks	Phase 2. Following 2 weeks	Exit interview, immediately following Phase 2	Follow-up interview, approximately 1 month later
Screening and assessment battery	Control Group	Complete Qualtrics surveys 3-4 times a week, Earn gift cards	Complete Qualtrics surveys daily. Earn gift cards.	Interview with research staff, Qualtrics survey.	Interview with research staff, Qualtrics survey. After this interview, control group is mailed copy of journal with instructions for
All participants continue with treatment as usual at the host setting throughout this study	Treatment Group	This is the "group phase." Attend approximately 8 hours of journaling groups. Complete Qualtrics surveys 3-4 times a week. Earn gift cards.	This is the "independent practice phase." Journal daily. Complete Qualtrics surveys daily. Earn gift cards.	Interview with research staff, Qualtrics survey.	Telephone interview with research staff, Qualtrics survey.

**Detailed description of the activities of the treatment group.** There are three phases to this intervention: the Group Phase (8 hours of content), the Independent Practice Phase (2 week duration after the group terminates in which participants practice PPJ 3-7 times per week), the Qualitative Exit Interview, which features the final quantitative Qualtrics questionnaire and an in-depth semi-structured exit interview to ascertain satisfaction with and criticism of PPJ, study logistics and the Follow-Up interview 30 days later which is a brief interview and final Qualtrics survey. We will encourage completion of the quantitative Qualtrics questionnaire before the exit interview facilitated by research staff for all research participants. Participants continue with treatment as usual during PPJ study activities.

**The Treatment Group's Group Phase.** Participants will meet for 8 hours of group content 2-3 times per week for 3 weeks to learn PPJ. For electronic administration, these groups take place via Zoom.

PI Krentzman or another trained research staff member will conduct these intervention therapy groups. The primary aim of the groups is to teach the elements of PPJ. Groups and other Zoom meetings will be audio recorded or Zoom's instant audio transcription tool will be used to aid treatment manual development and to collect qualitative data. Zoom meetings will be video recorded (this happens automatically in Zoom), but client images will be edited out so as to completely remove them from the video recordings. These videos will be used by research staff to learn how to lead the treatment groups. The videos will include the audio track and only images of our PowerPoint slides and research study staff images. PPJ is taught by a counselor or group facilitator who themselves uses PPJ on a daily or near daily basis and the facilitator will practice PPJ along with participants in the group setting.

A NUWAY Inc. staff member will sit in on all group sessions. Study staff (research assistants) may also sit in on group sessions and may lead group sessions in the unlikely event of any absence of the primary group leader. Amy Krentzman, primary investigator, would provide supervision and instruction in such an event. NUWAY Inc. staff or research staff will also practice PPJ. Journals will be provided by the study to the study participants. For electronic administration, journals will be mailed or delivered to the participants and to the NUWAY staff member. A set of journals will also be delivered to the NUWAY office as a backup. Clients can pick up a journal on a usual face-to-face visit to NUWAY for drug screening. Journals will have pre-printed category headings listed on the pages (see the figure, above) and other PPJ elements such as note pages, worksheets for describing values and instructions for teaching PPJ to others. The study



will provide lap desks for participants to use to lean on when writing their journal entries unless we use a room with a table to lean on (this is not relevant to electronic administration). One additional journal will be provided if the original journal is lost or stolen during the group sessions.

Participants will complete PPJ during group and will be invited to share some aspects of PPJ in a group process that will include modeling and coaching to support learning. During the sharing part of group, the facilitator and the NUWAY staff member and the Research Assistant will also (judiciously) share their own PPJ entries. In between group sessions, participants will be given homework to continue to practice and therefore learn the elements of PPJ. Group participants are also encouraged to share journal content judiciously as some content may feel private. Group participants are also encouraged to protect their privacy by writing some journal items using brief words, codes, or initials that would not be meaningful to another person.

See Table 1 below for a detailed plan for each group session.

**Table 1. PPJ Treatment Group's Group Phase Daily Session Content.** *Please note: this represents a general idea of content for each session. We will follow this general plan but the details (activities, PowerPoint slides, topics, exercises) might be modified week by week. Preparation of detailed group session plans, handouts and PowerPoint slides (if used) might be conducted the day before or the morning of group sessions. Therefore, there would not be time to gain approval for these details from the IRB in advance of the group session. However, we will submit detailed group session plans, PowerPoints and handouts to the IRB as soon as they are ready and we are able to submit them in a modification to the study.*

*Please note: some of these sessions might be conflated based on host setting, for example, we might cover content of sessions 1 and 2 in a 2-hour session versus 2 1-hour sessions.*

*Exactly what is covered in each session may vary based on pacing of different groups but this sequence will be followed approximately.*

Week and Session #	Session Content
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<p>Week 1, Session 1</p>	<p>Ice breaker, establish group rules, describe rationale for PPJ Recommendations to protect privacy of journal contents Recommendations for Zoom privacy A few words about writing (no need to worry about spelling, grammar, etc.) Group schedule Duties of the research team About your gift cards Introduction to the journal Introduce “Three Good Things” exercise (TGT) Provide tips for success Practice TGT exercise Sharing about the exercise Introduce listing of what did not go well in the past day (i.e., “Bad Things”) Homework: Continue to practice TGT exercise</p>
<p>Week 1, Session 2</p>	<p>Debrief: How did homework go? Practice TGT exercise and Bad Things Introduce gratitude list Provide tips for success Practice gratitude list Sharing about the exercise Introduce “Good Wishes for Others” list Tips for journaling on your own Power moves: look through your “good things” and “bad things” and “gratitude” lists and add their name to send them well wishes. For the right hand page: think of any of the people on your wishes list who you would like to reach out to extend your kind wishes. Sharing about the exercise Homework: Continue to practice TGT exercise and gratitude list exercise</p>
<p>Week 1, Session 3</p>	<p>Debrief: How did homework go?  Teach back: invite a group member to describe what they have learned so far. More about the “bad things” list. Why do we treat it differently? Lecture on negativity bias, hedonic treadmill, changes to the brain during addiction that make it harder to feel positive emotion and easier to feel stress. Provide tips for success Sharing about the exercise Homework: Continue to practice what we have learned so far.</p>

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<p>Week 2, Session 4</p>	<p>Debrief: How did homework go? Practice TGT, gratitude list, what did not go well, and WFO Provide tips for success Sharing about the exercise More about the “bad things” list, some days in life will be challenging and the “bad things” list will be longer than the “good things list.” This is part of being human. Learning the right hand page. Rank order each life area. Write about what makes your top life area valuable and meaningful to you. Write about values for this life area. Teach how to write goals so that they are observable, measurable, and represent the next small step. Provide examples. Homework: Continue to practice what we learned so far.</p>
<p>Week 2, Session 5</p>	<p>Debrief: How did homework go? Practice left and right sides of the page Have participants choose other life areas important to them Write about values, develop goals that are observable, measurable, and represent the next small step. Homework: Continue to practice left hand and right hand side of the page</p>
<p>Week 2, Session 6</p>	<p>Debrief: How did homework go? Practice left hand and right side of the page Choose more valued life areas (address the second important life area) Write about values for this life area Generate goals for each valued life area Practice right hand side of the page Reminder not to discuss study activities with other clients. Homework: Continue to practice left hand and right hand side of the page</p>
<p>Week 3, Session 7</p>	<p>Debrief: How did homework go? Practice left and right hand side of the page Learn the Each One Teach One exercise. Practice the Each One Teach One exercise, which involves how to teach someone else the journaling practice. Homework: Continue to practice left hand and right hand side of the page. Homework: Each One Teach One: Find a person supportive of your recovery who is not enrolled in the study. Teach them PPJ. Journal alongside them. Share content you wish to with each other.</p>
<p>Week 3, Session 8</p>	<p>Debrief: How did the Each One Teach One and homework go? Practice left hand side of the page and right hand side of the page Sharing about the journaling practice Group closure exercise, such as, the “What you got and what you brought” activity where each group member writes down what they got out of the group and all other group members write down what each other member “brought” or contributed or other similar closing exercise. Homework: Move on to The Independent Practice portion of the study where PPJ continues independently over the next 14 days.</p>

When we address values, we will pay special attention to the life areas selected by participants and will help them identify small, action steps that are measurable and observable that they can take toward their goals in every life area.

If we don't have time to capture journal entries completed during group, participants might be asked to upload journal entries later in the day or use their own smartphones or tablets to complete the survey questionnaires for that day.

If a group member misses group, we will ask for a volunteer from group to fill that person in on what we did in group that day (this is likely to be irrelevant with electronic administration).

From October 2020 forward, we will be creating short video-recorded recaps of each group session that will be made available to study participants 1) if they missed group and want to catch up on what we learned before returning to group the next session or 2) if they attended group but want a review of the content covered. We feel these recaps might aid retention because members who miss one group session might not want to return to group unless they learn the content they missed. Only the PI's voice and image and PowerPoint slides will be included in these videos. These videos are optional for participants to watch. The content on the videos is the same as the content of the group sessions and the PowerPoint materials are the same or very similar. No client faces, handwriting, or voices, or any identifying information about clients at all will be included in these video recaps. When the final text and PowerPoints and links to these videos are available we will submit them to the IRB.

Individuals in the Maroon group who request an additional journal at the one month follow up will be mailed an additional journal. Based on availability, we might provide an older (but very similar) version of the journal. Individuals in the Gold group are mailed their first journal at the one month follow up. If these journals are filled up, or any other similar reason, and the former participant would like yet another copy of the journal, they can always request one from us and we will mail them an additional journal as long as supplies last.

**For the control group and the treatment group:**

NUWAY counselors are responsible for the overall wellbeing of their clients. Therefore, NUWAY counselors will be informed of their client's study

participation. NUWAY counselors will be informed of group attendance after each group session to learn whether their client attended or not. Similarly, NUWAY counselors will be informed of the control group's participation in taking the Qualtrics surveys.

If someone misses group or other study activity for 2 days or 2 sessions in a row, we will reach out to them and gently encourage continued participation, or inquire whether they wish to drop out of the study.

At the screening meeting, we will also ask participants how they would like to be contacted. By being in the study, they will agree to have us contact them by email since the questionnaires will be administered via email message. However, we will ask about a secondary way to reach the participant such as text, telephone, snail mail, or other method) and if we need to reach the participant for any reason, including to invite them to return to the study, we will use their preferred method. After reaching out a maximum of 2 times, we will not pursue the participant further. We will continue to send them Qualtrics surveys, which they can feel free to ignore, in case they wish to resume study participation. We will also invite participants who have dropped out to an abbreviated exit interview (see Maroon group exit interview script). To send the person a journal, we will need their home address and will collect this information at the screening interview. Participants will also agree to using Zoom for study participation.

If a participant misses the exit interview but presents for the 1-month follow up interview, we will use a new combination interview script to conduct that interview, and that interview will be audio recorded. If a participant misses the exit interview and the 1-month follow up interview but presents at a more distal date, we will also use the new combination interview script and that interview will be audio recorded. The new combined script is attached to ethos.

In general, counselors will be informed of their clients' participation. We will inform counselors of their clients' participation in study activities. If there is a lapse in study activities, we will let counselors know that their client is warmly welcomed to continue with study activities.

We will be certain to clearly communicate with counselors that they are not to put any pressure whatsoever on client participation, participation or lack thereof is entirely the choice of the research participant and no negative consequences will result from participation or lack thereof.

**The Treatment Group's Independent Practice Phase.** This phase begins when The Group Phase ends. During this phase, participants will continue the journal practice on their own over the next 14 days. Participants are encouraged to complete PPJ a minimum of 3 times a week during this phase but they can feel free to complete PPJ daily if they would like to (they are compensated for up to 5 entries each week).

**Qualitative Exit Interview.** At the end of the Independent Practice Phase, participants in the control and treatment groups will be invited to participate in an individual (one-on-one) semi-structured qualitative exit interview to ascertain their experience of being in the study. For electronic administration, these meetings will take place on Zoom. Treatment group participants will also be asked about any potential impact or downsides of PPJ. Before the interview, participants will be encouraged to complete the quantitative questionnaire that we are calling the "end of group and independent practice phase" questionnaire, administered via Qualtrics. Ideally, these interviews will not be conducted by PI Krentzman but will be conducted by research staff or perhaps by the University of Minnesota Office of Measurement Services in order to diminish socially desirable responses.

Every effort will be made to conduct the exit interviews in person, but when that is not possible, we will offer the opportunity to complete the exit interview via Zoom, telephone or in writing through email. For electronic administration, first choice delivery will be Zoom followed by telephone or writing through email.

**Follow-Up Interview.** This takes place for treatment and control groups 30 days after the exit interviews. Here, participants answer a few questions about substance use and journaling since we met with them last. Before this interview, participants will be asked to complete their final Qualtrics questionnaire.

**Data Capture.** Participants in the treatment group will take a snapshot of their journal entries and upload this image to a Qualtrics survey to affirm that assignments are completed; this skill will be taught and practiced during the screening meeting and Group Phase and practiced during the Independent Practice Phase. Participants will learn how to do this using Qualtrics and smartphones or tablets during group and will be able to continue to use their own smartphones or tablets to continue this practice during The Independent Practice Phase. After uploading the image of their journal, participants will answer psychometric questionnaires in Qualtrics. Study iPads will be physically secured when not at use in a staffed office/

supervised storage space (e.g., cabinet or drawer) at NUWAY. Participants will be asked to complete their journal entries right before they upload them to Qualtrics. Individuals in the control group will simply fill out the Qualtrics surveys at the same schedule as the treatment group.

Participants' written entries into their journals is also data of interest to us, including what they write and how many items they write under each category. NUWAY is outpatient versus our previous host site which was residential so we suspect there will be greater incidence of people arriving to group without their journals (having left them at home for example). Participants will have the option to leave their journals on site at NUWAY with staff in a supervised storage space (e.g., cabinet or drawer). Forgetting one's journal is less of a worry during stay-at-home electronic administration.

Please note we will thank NUWAY staff members by citing NUWAY and perhaps individual staff names in the acknowledgments section of academic presentations, posters, and manuscripts that result from these data. We may make periodic presentations to NUWAY staff about study observations and findings throughout the study period and afterward. When appropriate, we will offer CEUs for Social Workers to NUWAY staff for their attendance at these presentations and host inexpensive lunches or coffee hours for NUWAY staff (who are still working from the office during COVID19 at this time). When we are able, we will present NUWAY staff with honoraria as a gesture of thanks for their help with recruitment.

Data capture will also take place using REDCap. We will use REDCap to keep track of our screening procedures and study participation activities.

**Measures.** Sociodemographic factors will be assessed at the initial baseline measurement (e.g., age, sex, marital status, years of education, race/ethnicity, employment status, and annual household income). A variety of psychometric scales will be used at baseline and throughout the study. Please see Table 2 for the Schedule of Assessments and the text following after Table 2 for more detail about each assessment approach.

Contents of Qualtrics survey and REDCap survey are described herein in full.

#### **Table 2. Schedule of Assessments.**

PROTOCOL TITLE: Journaling and Addiction Recovery  
 VERSION DATE: 13 April 2021

	How long does it take to complete each of these measures	Baseline	At Every PPJ Qualtrics upload	Asked or Tallied after Group Phase Ends (Phase 1)	Asked or Tallied after Independent Practice Phase Ends (Phase 2)	Final Study Activities including 1 Month Follow-up
<b>Baseline characteristics</b>						
Sociodemographics, including current housing situation, i.e., “are you now living in sober living?”	3 minutes	X				
Hospital Anxiety and Depression Scale	3 minutes	X		X	X	X
10-item SIP-AD, addiction consequences	5 minutes	X				
Commitment to Sobriety (full scale)	2 minutes	X		X	X	X
Trait gratitude	2 minutes	X		X	X	X
AA Affiliation Scale	2 minutes	X				
Exposure to trauma	1 minute	X				
Using Medication Assisted Treatment?	½ minute	X				
Legal issues: current involvement in civil legal case and current involvement in criminal court case	½ minute	X				
Satisfaction with treatment	2 minutes			X	X	X
Social Desirability Scale	4 minutes	X				
Open ended questions: Experience with 10 <sup>th</sup> step, journaling, gratitude practices, and using a planner.	4 minutes	Verbally administered using REDCap			Verbally administered using REDCap	Verbally administered using REDCap
What have you already heard about the study?	1 minute	Verbally administered using REDCap				
<b>Hypothesized Mediators</b>						
Positive and Negative Affect Schedule, including three items comprising the serenity subscale (calm, relaxed, at ease)	2 minutes	X	X	X	X	X
Abstinence Self Efficacy Question (single item)	1 minute	X	X	X	X	X
Commitment to Sobriety (single item)	2 minutes		X	X	X	X
Alcohol craving (single item)	½ minute	X	X	X	X	X
Drug craving (single item)	½ minute	X	X	X	X	X
Happiness with Recovery (single item)	½ minute	X	X	X	X	X



PROTOCOL TITLE: Journaling and Addiction Recovery

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Individual items to assess specific impact of PPJ journaling practice <sup>1</sup> (attached as “single items to assess change”)	3 minutes	X	X	X	X	X
Satisfaction with Life	1 minute	X	X	X	X	X
Quality of life scale, modified to compare quality of life during recovery (“now”) to quality of life during active addiction (“then”) <sup>1</sup>	3 minutes	X	Global quality of life item only	X	X	X
Flourishing scale	2 minutes	X		X	X	X
<b>Treatment Group Only</b>						
# of Qualtrics surveys completed				X	X	X
Ease, helpfulness, satisfaction, effort of PPJ (for control group, ease, helpfulness, satisfaction, effort of filling out the survey questionnaires)	2 minutes		X	X	X	
# group sessions attended				X		
# homework assignments completed				X		
# journal entries completed				X	X	
Count of # of items entered into PPJ		X	X	X	X	
Eligibility rate and consent rate (treatment and control group)						X
On approximately the fourth session of group (halfway through the total # of sessions) ask: “what is working for me in this journaling group is....” And “what is not working for me in this journaling group is....”						
<b>Open Ended Survey Question</b>						
Treatment group: What are your thoughts about Positive Peer Journaling (PPJ) so far?	2 minutes			X	X	
<b>Outcomes</b>						
Recurrence of Substance Use				X	X	X
Treatment Retention at NUWAY (successfully exiting treatment with staff approval versus against staff advice or at staff request)				X	X	X
<b>Qualitative Exit Interview</b>	45 minutes					X
<b>1 month follow up interview</b>	25 minutes					X

Baseline characteristics.

- Sociodemographics

*Exposure to trauma.* Participants who have experienced addiction have high rates of exposure to trauma. We will ask about exposure to trauma in order

to describe the sample, that is, to report what percentage of the sample has been exposed to trauma. To determine exposure to trauma, we will use the first question from The Posttraumatic Diagnostic Scale.<sup>43</sup> The first question of this instrument asks if the participant has ever experienced life threatening illness, physical assault, sexual assault, military combat, child abuse, accident, natural disaster, or other trauma. Participants will be informed that we will be asking about this in the informed consent document. Please note, we will not assess for symptoms or effects of trauma since our objective is to use the single item to describe the sample. NUWAY regularly screens all residents for trauma. However, if any participant has difficulty with study activities because of trauma or any other reason, we will inform NUWAY. If participants experience distress related to this trauma question or any other element of the baseline questionnaire or screening interview, we will refer them to NUWAY staff.

- Legal involvement. Participants with severe addiction histories such as those in our study have greater rates of involvement with the legal system. Therefore, to better define our population, we will ask, “Are you currently involved in a civil legal case? Are you currently involved in a criminal court case?”
- Medication Assisted Treatment (MAT). Participants with severe addiction histories are often prescribed specific medications to reduce substance use and cravings. Therefore, we will add two items to determine if participants in our sample are using MAT to support their recovery. We ask if they are using MAT and if so, for what substance. For the specific items, see the baseline questionnaire attached to ethos.
- Symptoms of anxiety and depression will be assessed using the Hospital Anxiety and Depression Scale.<sup>44</sup>
- Severity of addiction consequences will be assessed using the 10-item version of the Short Inventory of Problems-Alcohol and Drugs scale (10-item SIP-AD).<sup>45</sup>
- Motivation to remain abstinent will be assessed by the Commitment to Sobriety Scale.<sup>46</sup>
- An individual’s disposition toward gratitude will be assessed with the GQ-6 Gratitude Scale.<sup>47</sup>
- 12 step affiliation will be assessed via the AA affiliation scale<sup>48</sup>
- Satisfaction with treatment at NUWAY will be assessed via a treatment satisfaction scale.<sup>49</sup> In previous research, participants who received behavioral activation treatment for substance use disorders had higher treatment satisfaction than individuals in the control group.

- A participant's concern with social approval will be assessed with the Marlow-Crowne Social Desirability Scale.<sup>50</sup>
- We will ask what they already know about this research study (counselors or other clients at the treatment center might have mentioned things about the study). These will be a qualitative open-ended questions.
- Quality of life "now" in recovery compared with "then" in active addiction will be assessed by a modified version of the EUROHIS Quality of Life instrument.<sup>51</sup>

Hypothesized mediators.

- Affect will be assessed with the Positive and Negative Affect Schedule and the Serenity subscale of this instrument.<sup>52</sup>
- Self-confidence in a participant's ability to abstain from addictive substances will be assessed by the Abstinence Self Efficacy Scale Question: "How confident are you that you will be able to stay clean and sober in the next 90 days, or 3 months?".<sup>53</sup>
- Commitment to sobriety (single item) "I will do whatever it takes to recover from my addiction."
- Alcohol craving (single item) "Rate the strongest urge to drink you have experienced in the past 7 days"
- Drug craving (single item) "Rate the strongest urge to use drugs you have experienced in the past 7 days"
- Satisfaction with recovery (single item) "In general, I am happy with my recovery"
- Satisfaction in Life will be assessed with the Satisfaction with Life Scale.<sup>54</sup>
- Flourishing will be assessed with Diener's Flourishing Scale.<sup>55</sup>
- We developed several single items to assess change that is directly related to the activities of the journaling practice. These items are uploaded to ethos as "single items to assess change".
- We ask whether the person attended a mutual aid group in the past 24 hours (such as Alcoholics Anonymous).
- It will be important to know whether participants are already doing aspects of the journaling practice. Therefore, at baseline, at the exit interview, and at the 3 month follow up, we will ask participants these questions verbally and we will record answers in REDCap or we will ask these questions in Qualtrics:
  - What kind of journals or diaries do you keep, if any? (If in the treatment group, what kinds in addition to PPJ?) Tell me about your use of journals or diaries over the past month.

- Tell us about any gratitude practices you have been doing over the past month, if any. (For treatment group, ask about any gratitude practices in addition to PPJ).
- Tell us what the 10th step means to you. What kind of 10th step have you been doing, if any, over the past month? (For the treatment group, ask if they have been doing any 10<sup>th</sup> step in addition to PPJ).
- What kind of planner or calendar do you keep, if any? What has your use of this planner been like over the past month? (for the treatment group, what have they been doing in addition to PPJ, if anything?)
- (at exit interview and follow up interview) Tell us about any times that you talked about your experience being in this study with other people, such as family members, housemates, your counselors, or others, if at all.

Effort, Feasibility, and Acceptability.

- # of Qualtrics surveys completed
- Effort, Ease, helpfulness, satisfaction (one item to assess each: “For this PPJ, I would say I put forth this much effort...” Degree to which PPJ was difficult, helpful, satisfying, easy, rated on a 0-10 point scale)
- # of group sessions attended
- # homework assignments completed
- # journal entries completed
- Eligibility rate: Number eligible/total at NUWAY site
- Consent rate: Number consented/number screened
- Group completion rates
- Independent practice phase completion rates
- # PPJs uploaded
- # PPJs completed
- % of PPJs completed out of total # of possibilities to complete PPJ
- # of items entered under each category
- Qualitative data from group discussion and exit interviews

Open-ended survey question.

- What thoughts would you like to share with us about being in this research study, if any?

Outcomes.

- Recurrence of substance use.
- Retention of treatment in NUWAY
- NUWAY reason for leaving
- Qualitative data from group discussion or exit interviews

Recurrence of substance use and treatment retention will be assessed via NUWAY treatment record. Research staff will not have direct access to the NUWAY treatment record. A NUWAY staff member will meet with research staff at reasonable intervals to report information about treatment retention and recurrence of substance use for study participants from the NUWAY treatment record (for electronic administration, these meetings will be via Zoom or telephone). Recurrence of substance use is assessed at NUWAY by positive urine analyses (UAs) and other drug screens as well as resident self-report. At or after this meeting, research staff will use the password protected electronic document which links participants' real names with their study codenames/numbers. Research staff will use this key to record the information from NUWAY staff into a de-identified database (e.g. excel or SPSS or Google drive) or into REDCap.

Dr. Amy Krentzman, the lead investigator, will keep a log/personal notes throughout the study, qualitatively recording observations, especially during recruitment and after each class session.

A de-identified participant tracker will be maintained on Google drive using only participant codenames to track group attendance, independent practice phase activity and other study activities.

### **Analysis Plan.**

Sample characteristics. We will aggregate information about the demographics and baseline characteristics of the study to be able to describe the psychosocial, demographic, and clinical profile of study participants. We will calculate means and standard deviations for continuous measures (e.g., age) and calculate percentages for categorical measures (e.g., marital status).

Primary feasibility and acceptability measures. We will aggregate information designed to assess feasibility and accessibility such as number of Qualtrics surveys completed, group sessions attended, journal entries completed, as well as participant assessment of the difficulty, ease, helpfulness, satisfaction, and effort expended on PPJ. We will sum these items and calculate means and standard deviations.

Secondary measures: outcomes and mediators. We will compare rates of treatment retention and recurrence of substance use to the general rates reported by NUWAY. We will also examine pre-post treatment means and standard deviations of hypothesized mediators (affect, satisfaction with recovery, individual items theoretically related to PPJ) to determine if change is in the expected direction. We will also study these constructs to determine if there is reasonable variability in the data we collect or if floor or ceiling effects are present. We may also use single-subject designs<sup>56</sup> to depict change over time in key constructs by study participant. Qualitative data will be thematically analyzed using the techniques recommended by Braun and Clarke.<sup>13</sup> Here, the researcher examines transcripts of texts and identifies key themes and how themes relate to one another. These data will inform intervention development and study implementation procedures.

Data analytic techniques to compare treatment and control groups. While this pilot study will not be adequately powered to detect significant effects between treatment and control groups, we will compare differences between the treatment and control groups at baseline and over time using either t-tests or multi-level modeling. T-tests will reveal significant differences between groups and multi-level modeling will show whether rate of change is significantly different between groups.

**Data Collection Methods.** The University of Minnesota allows faculty and researchers access to Qualtrics software. Qualtrics is an online software survey program which collects survey data. We, along with the University of Minnesota Office of Measurement Services, will program Qualtrics to administer the self-report measurements discussed in the Measures section at baseline, throughout group, during the independent phase, and at the exit interview. At baseline, we will provide participants with an electronic tablet (iPad or smartphone) (if necessary we will use a computer at baseline or at other measurement occasions) so they can access the baseline assessment via Qualtrics. Study staff will sit unobtrusively in the same room with participants as they complete the baseline assessment (for electronic administration, we will stay on the Zoom meeting while the participant fills out the Qualtrics Survey). Participants will be invited to ask questions of study staff as they complete the survey. Once the Group Phase begins, participants will take a snapshot of their PPJ entries and upload them to Qualtrics during group and independently during the Independent Practice Phase. Study therapists will teach participants how to do this during The Group Phase.

The specific procedural steps that we will take to conduct this study include:

- Present the study to clinical staff / leadership at NUWAY to gain setting-based insights and situate the intervention successfully in context.
- Train NUWAY staff on their participation in the study, that is, identification of prospective participants. This includes reviewing the study with the prospect to determine interest, having the prospect sign up for a screening meeting with study staff, providing study fliers (electronically) to interested persons. NUWAY staff will take no further action if the prospect is not interested. NUWAY staff might also sit in on group sessions, and lend out the iPads (during electronic administration, using the study iPads at NUWAY will be rare). NUWAY counselors will receive emails informing them of participant activity in the study, such as group attendance.
- Work with U of M (Office of Measurement Services) Qualtrics survey developer to use Qualtrics to capture data.
- Recruitment and randomization.
- Assess hypothesized treatment outcomes such as increased treatment retention and decreased recurrence of substance use. Assess hypothesized mediators such as satisfaction with recovery and improved mood. For a complete list, see the measures section.
- Assess feasibility and acceptability of The Group Phase and The Independent Practice Phase for the treatment group.
- Conduct qualitative exit interviews to ascertain participants' subjective experiences of the intervention (treatment group), study logistics, relevance to recovery in rural communities (treatment group), and feasibility and acceptability of the intervention (treatment group). A quantitative Qualtrics survey will also be administered at this meeting.
- Conduct one-month follow up interviews. Ask about substance use and journaling behavior. Participants can participate in follow up interview even if they skip the exit interview for whatever reason. Participants complete the final questionnaire at this time.
- Study and refine recruitment processes, retention ability, functioning of Qualtrics surveys, and feedback about feasibility and acceptability. Create IRB amendments as needed.

5.3. Exit Interview: After the first 5 weeks of the study (for those in the treatment group, this 5 week period aligns to The Group Phase and The

Independent Practice Phase) participants will be invited to participate in a qualitative exit interview with research staff. If the resident has been discharged from NUWAY on good terms during the course of the study, we will reach out to them and invite them to an exit interview. We would contact the person at the forwarding information on file at NUWAY. The participant will have given informed consent for this in the informed consent document. We will meet with participants at NUWAY or in their home or at a local library or other reasonable location that offers privacy (during electronic administration, we will meet with them over Zoom). The research study will pay round trip for a taxi or Uber or similar ride program for the participant to meet us for the Exit Interview (we will not use this option during electronic administration). Participants will also be encouraged to call us to schedule the Exit Interview.

If participants leave NUWAY on good terms during the study period, they may still be able to continue to be in the study because it is possible to continue study activities from outside of NUWAY for the independent practice phase. Any smartphone or tablet can be used to continue to participate in the independent practice phase. We may reach out to participants who continue to participate in this way to encourage them to continue in the study or ask if they wish to remain in the study using the contact information they provide to use through NUWAY Inc.

**Follow up Interview:** At approximately 30 days after the exit interview, we will follow up with participants. Zoom is the first choice but a telephone interview is acceptable for this procedure. We will ask participants about any substance use and journaling in the past 30 days. We will ask a few additional qualitative questions such as what was most memorable about being in the research study, and other similar questions. Participants will be encouraged to complete their final Qualtrics survey before this interview.

- 5.4. Individually Identifiable Health Information: Research study staff will meet with NUWAY staff at reasonable intervals to collect data on our primary outcomes: 1) treatment retention and 2) recurrence of substance use. At these occasions we will go through our list of study participants and ask NUWAY staff if: 1) that person has left treatment or been asked to leave; 2) that person has had a positive urine analysis screening indicating recurrence of substance use. We will mark down the replies in our deidentified data file. If the participant cannot remember date of entry into NUWAY, we will also gain this information from NUWAY staff and the treatment record. To facilitate this work, study staff will use a password-protected file linking participants' real names with study IDs (codenames/numbers).



6. This study therefore includes PHI and therefore we have combined our informed consent document with the appropriate text from a HIPAA authorization form.

We have been informed that we do not need to complete a University's Health Information Privacy & Compliance Office (HIPCO) online application for data privacy and security review as the PI, Dr. Krentzman, is not within the University of Minnesota Academic Health Center. For this same reason, we were also informed that Dr. Krentzman can use her University of Minnesota Zoom account and need not use the Academic Health Center version of Zoom. The Zoom accounts we will use for this study belong to the University of Minnesota, Dr. Krentzman and/or study staff.

- 5.5. **Additional procedure for obtaining feedback on the PPJ journal.** I will provide copies of the PPJ hard-copy journal and how-to instructions to colleagues, students, and members of the community during lectures I give, meetings I have, and in other contexts. I will invite individuals to use the journal and provide feedback to me about their experiences using it. The feedback I receive would be useful in optimizing the journal. I would invite users to provide feedback to me via email, regular mail, or telephone calls/voice messages. I would keep de-identified notes on this information and use the feedback to improve the journal.

## 6. Data Banking

- 6.1. **Storage and Access:** Quantitative data will be stored in a spreadsheet or data analytic software file and this data will be de-identified. Qualtrics will be used to collect data prior to download. Qualtrics is HIPAA compliant. Cases will be identified by code name or number only. Using a successful strategy we have used in the past, at baseline, participants will be asked to provide a "codename or number" that does not contain identifiers such as real name or birthday. Examples from the past have included "Rusty" or "007." An electronic key linking participants' real names with codenames/numbers will be held on the PI's and research staffs' laptops in a password-protected file. This file will be deleted one year after the manuscripts based on this research are accepted for publication. Only the PI and research team will have access to the data. Codenames and real names are also listed on the "codename" sheet that individuals fill out at baseline when choosing their codename. These pages are kept in a locked file box or filing cabinet. We will also store certain kinds of data in University of Minnesota Box Secure Storage. Box Secure Storage is HIPAA compliant and is used for sharing confidential files. See <https://it.umn.edu/services-technologies/box-secure-storage>. We will use Box in two primary ways. First, we will

share research files with research team members whose computers cannot join VPN to access the secure drive. Second, we will use Box to share signed participant informed consent documents with the host treatment provider, NUWAY, if they would like to file these documents in their clients' treatment records. Other similar uses of Box Secure Storage might be employed for quantitative and qualitative data and other research files.

Qualitative data will be stored in several formats. Audio recordings of group sessions and of exit interviews and video recordings that feature the audio track and video images only of study stuff will be stored only on the secure U of M School of Social Work Shared Drive server. We might alternatively use Zoom's automatic electronic transcription service. Uploaded pictures of PPJ entries will be shared on this same Shared Drive server. Transcripts of the audio recorded sessions will also be uploaded here and will be de-identified before qualitative data analysis. Once the transcriptions have been de-identified, then de-identified transcriptions and qualitative data software can be saved outside of the shared drive. The Shared Drive Server at the School of Social Work is an access control list (ACL) controlled file server. This means that each user has different access depending on which Active Directory Groups they are in. The folder on the drive where the data would be saved would have its own Active Directory group, and only research team members (and the server administrators) would have access to the files in the folder. We have been advised by Information Technology professionals at the School of Social Work that these security provisions are in line with the University of Minnesota data security provisions including the storage of research study data. De-identified transcripts of these sessions will be kept on the U of M server and/or the PI's and research teams' laptops. Transcripts are created by an outside vendor, Datagain (datagainservices.com). Datagain is a transcription service for research. Datagain offers data encryption on all stored data, secured data transfers, compliance with ISO 9001 and HIPAA standards, and regular security audits. If needed, we will use a different company than Datagain but one with all of the same protections and security provisions. We might use Zoom's automatic electronic transcription service instead of Datagain.

6.2. Data: The data elements to be collected and banked for future use in a de-identified data set include all those listed in the measures section of this protocol. We will also store jpg files representing the snapshots of the uploaded PPJs.

6.3. Release/Sharing: N/A

## **7. Sharing of Results with Participants**

- 7.1. Participants will be encouraged to email or call the PI in about a year's time to obtain study results in the form of academic posters or academic manuscripts or other products. Upon such requests, the PI will email or send via regular mail these products as well as an easy-to-understand fact sheet summarizing the results to date, to improve accessibility to study findings for lay readers. This opportunity is mentioned in the informed consent document. In general, the PI will share research findings at community-based, local, regional, and international conferences, during class or other lectures, and will publish study findings in academic journals. We will also make a presentation of findings to NUWAY staff when the study is over and throughout the study, as requested by NUWAY.

## **8. Study Duration**

### **8.1.**

- The duration for an individual participant's participation in the study is anticipated to be five to nine weeks as follows: Phase 1: 2.5 weeks, Phase 2: 2 weeks, a qualitative exit interview to take place as soon as possible at the 5 week mark, and a follow-up interview approximately 30 days after the exit interview.
- The duration anticipated to enroll all study participants: Enrollment will be rolling. We will recruit 10-20 individuals at a time to populate 1-2 treatment groups and corresponding individuals for the control groups. This study will last approximately 2 years. Typically, we will screen and consent and enroll participants during the week before groups start.
- The duration anticipated to complete all study procedures and data analysis: Including manuscript production and publication, approximately four years.

## **9. Study Population**

- 9.1. Inclusion Criteria: 1) minimum 18 years of age, 2) meet DSM-V criteria for past-year SUD as primary or secondary diagnosis, 3) English literacy sufficient to make short written lists needed to complete PPJ and homework assessments, 4) minimum approximately 2 weeks sustained abstinence (ideally > 10 days), 5) completed first 2 weeks of treatment at NUWAY (approximately 2 weeks), 6) agree to be audio recorded / transcription recorded in group meetings and in individual meetings with research staff, 8) currently are clients at NUWAY, 9) participants must be English speaking and literacy must be strong enough to write short lists and to understand the questions asked in the Qualtrics survey, 10) have an email address and are willing to check it regularly and use it to receive study communications, 11) have a device that has a camera for Zoom

participation and to take pictures and is connected to the internet, such as a smartphone or tablet, 12) has access to high speed internet. Many NUWAY participants live in Sober Living Housing with internet provided. Priority will go to participants who will be in treatment at NUWAY for the duration of the study activities (and not discharging after one week, for example).

The participants in treatment at NUWAY are individuals with low or no income and histories of severe substance use disorder. Therefore in the list below we checked that they are “disadvantaged in the distribution of social goods and services such as income, housing, or healthcare” and, as individuals with addictive disorders, we also checked that they are from an “undervalued or disenfranchised social group.”

All participants will be 18 or over. NUWAY on occasion will have a client younger than 18, but they will not be eligible for this study.

- 9.2. Exclusion Criteria: 1) presence of a psychotic disorder, psychiatric condition (e.g., suicidal ideation), or cognitive impairment (e.g., severe dementia, traumatic brain injury) limiting ability to give consent and/or participate in the study; 2) severe psychiatric illness (current schizophrenia, major depression with suicidal ideation); 3) personality disorders that would interfere with satisfactory participation in or completion of the study protocol, 4) inability to give informed, voluntary consent to participate, 5) lack of sufficient English literacy to participate, defined as inability to make a list of 5 things they did yesterday and inability to understand Qualtrics survey questions, 6) any impairment, activity, or situation that in the judgment of the research staff would prevent satisfactory participation in or completion of the study protocol, 7) the unlikely event that the participant is already doing something very similar on a daily basis such as a written 10<sup>th</sup> step and a daily action plan, 8) no access to a phone/tablet or internet connection.

7. See the attached document “Recruitment, Screening, Consent, and Baseline Script.” This document shows how each of the inclusion/exclusion criteria will be assessed during the recruitment and screening phase of the study.

- 9.3. Screening: The screening process will proceed as follows.

1) NUWAY staff will identify clients who might be eligible. NUWAY staff will complete the “pre screening guide” to make sure that a client meets basic study criteria. Prospective participants who meet these criteria will be

given a study flyer (see attached, an electronic version of the flyer will be sent to clients), and will have the opportunity to sign up to have an appointment with Research Staff at NUWAY to continue the screening and informed consent process, or call research staff to ask questions.

2) When prospective participants meet with Research Staff, Research Staff will follow the recruitment, screening, consent, and baseline script (uploaded to Ethos). During this interview, prospective participants will complete a set of questionnaires and consent forms, specifically: the Screening Consent Form, Informed Consent Form, UBACC quiz to determine capacity to consent,<sup>57</sup> the HIPAA Authorization form, the GAIN SS<sup>58,58,59</sup> instrument to determine presence of a psychotic disorder, psychiatric condition (e.g., suicidal ideation), severe psychiatric illness, and personality disorders, the GAIN Cognitive Impairment Questionnaire. See “Recruitment, screening, consent, and baseline script” document uploaded to Ethos for details. All of these instruments and documents are attached. Please note, the Screening Consent Form and Informed Consent Form were created using University of Minnesota templates, but some of the language was modified to reduce the reading grade level of the documents from approximately 10<sup>th</sup> grade reading level down to 7<sup>th</sup> grade reading level, which is more appropriate for this research sample.

3) When prospective participants meet with Research Staff, they will also do one activity: they will be asked to write a list of 5 things that happened yesterday. Research staff will examine this list to determine if the individual has adequate literacy and writing skills to be part of the study since PPJ requires writing of short lists. This criteria will also apply to the control group so that inclusion criteria are equivalent for the two groups.

4) The screening interview will take place as follows:

1. Participant will have been given the study main consent form in advance by NUWAY staff, ideally (this is unlikely to occur during remote delivery), and will have been asked to read it. They will have the chance to ask any questions.
2. Screening consent form will be read, described, and signed.
3. Research staff will double check the inclusion and exclusion criteria, including whether the participant has a working email address they would be willing to use to receive study communications. Participants will also be asked if they have a smartphone/tablet they are willing to use for the study and internet connection.
4. Participants will be asked about current journaling practices, if any.

5. Participants may also be placed on the waiting list if: a) they will not be at NUWAY for the duration of the study, b) research staff is not sure if the person is eligible based on results of screening tests. In this case, NUWAY counseling staff are consulted to make sure the participant is eligible (e.g., if the person is adequately stabilized psychiatrically for participation).
6. Participant will be asked to write a list of 5 things that happened yesterday, research staff will evaluate this list and determine whether or not it is adequate for study inclusion. If not adequate, screening procedure will stop.
7. Research staff will administer the GAIN Cognitive Impairment Screener.<sup>57</sup> This instrument uses 6 items to determine cognitive impairment. It uses questions such as “What year is it now?” and “Please count backwards from 20 to 1.” Participants earn points for correct answers. Cognitive impairment is considered to be present if the total score is greater than 10. If the participant scores 14 or greater, they will be excluded from the study. Screening procedure will stop.

Research staff will ask participants items derived from the GAIN SS instrument. The GAIN SS is a short instrument designed to determine whether individuals should be assessed more comprehensively for internalizing disorders (6 items), externalizing disorders (7 items), and criminal or violent behavior (5 items). The instrument also asks 5 items about substance use, but since all of the individuals in this study will have met criteria for a substance use disorder, we will not ask these questions. The response format determines how recently the individual had the symptoms or the behavior. We will use a modified response format: 0=never, 1=in lifetime, 2= last year, 3=last month, 4=last week. This response format has been revised from the original GAIN SS in order to capture whether any of the behaviors were more recent, that is, in the last 2 weeks versus the past 1-month. Knowledge of more recent behavior is needed to effectively screen participants for this study. We would change all the questions and prompts that say “when was the last time that you did the following things two or more times” to “when was the last time that you did the following things” so that even one instance would count. We would modify any question that asks about behavior at “school, work or home” so that it reads “school, work, home, or here at NUWAY.” We would add this phrase to the instructions: “I will now ask you some questions about your experiences. Please answer “as of today” so

“in the last week” would mean in the week that ends today. Please know I will not be asking you any follow up questions for any of these next questions. Depending on some of your answers, I might need to let NUWAY staff know of your replies.” We would consider a high score to be two or more past-week symptoms for each subscale: internalizing disorder, externalizing disorder, or criminal/violent behavior. Exclusion from the study based on these items would include endorsing “last week” for certain items such as: “thinking about ending your life or committing suicide,” “lied or conned to get things you wanted or to avoid having to do something,” having a hard time “paying attention at school/work/home” in combination with having a hard time “listening to instructions at school/work/home,” “were a bully or threatened other people,” “started physical fights with other people,” “had a disagreement in which you pushed, grabbed, or shoved someone,” and “purposely damaged or destroyed property that did not belong to you.” In the event of high scores in any of the three subscales or a single score of “last week” for any of these selected items, the person would not be eligible for the study. However, in each of these cases, we would discuss the results with NUWAY staff before determining final eligibility for the study.

8. The requirement of 2 weeks continuous sobriety before enrollment in the study may be waved based on clinical judgment.
9. Participant would read/review/discuss with study staff the informed consent/HIPAA consent combined document. Participant would read/review/discuss with study staff the HIPAA consent document.
10. Research staff would ask the participant the questions from the UBACC quiz to determine capacity to consent.<sup>57</sup> A score of 15 or higher is needed for inclusion in the study. The prospective participant can review the study details and return to re-do the quiz another day if this is possible given the study timeline.
11. If they score over 15 on the UBACC and meet all other study inclusion/exclusion criteria, or if they are eligible for the wait list, they will they sign the main informed consent document (electronically if electronic administration). These forms will be signed in duplicate, providing one copy for research staff and one for participant (duplication unnecessary for electronic administration).
12. If the participant is deemed to meet all study criteria, they would move on to take the baseline assessment instrument.

13. Participants will be asked to provide the names and contact numbers/email addresses for 2 people who will always know where they are. This information will be collected via the screening check sheet (information from the screening check sheet will now be administered via Redcap with data captured in Redcap rather than on paper) and will be used to help invite the participant to the exit interview/follow up interview. At the end of the exit interview, participants will be asked how best to reach them for the follow up interview 30 days later. Final Target gift cards will be disseminated electronically. (At the follow up interview, the control group will be mailed a copy of the journal and journal instructions and so we will make sure to obtain their mailing address).
14. Before randomization, participants will be asked, “In this study you will be assigned to either the Gold or Maroon groups. How do you feel about the fact that you would be helping us either by the Gold group activities or the Maroon group activities? How willing would you be to do your best whether you end up in the Gold or Maroon group? Are you willing to participate even though you might not get the group of your first choice? For our research it is important to get a good response rate. This means participating in study activities as much as possible. Do you agree to help the project in this way?” Responses will be recorded on the screening check sheet. (information from the screening check sheet will now be administered via Redcap with data captured in Redcap rather than on paper)
15. If admitted into the study, participants will be randomized into treatment and control groups. The treatment group is the “maroon” group the control group is the “gold” group (University of Minnesota school colors).
16. If participants decide not to participate when they hear their group assignment, we will ask them why and record their answers on the screening check sheet. (information from the screening check sheet will now be administered via Redcap with data captured in Redcap rather than on paper)
17. Each group will receive instructions for their arm of the study (See “instructions for Maroon and Gold Groups v2,” attached).

## **10. Vulnerable Populations**

### **10.1. Vulnerable Populations:**

☐ Children



- ☐ Pregnant women/Fetuses/Neonates
- ☒ Prisoners
- ☐ Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders
- ☐ Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.
- ☒ Disadvantaged in the distribution of social goods and services such as income, housing, or healthcare
- ☐ Serious health condition for which there are no satisfactory standard treatments
- ☐ Fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)
- ☐ Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research
- ☒ Undervalued or disenfranchised social group
- ☐ Members of the military
- ☐ Non-English speakers
- ☐ Those unable to read (illiterate)
- ☐ Employees of the researcher
- ☐ Students of the researcher
- ☐ None of the above

#### 10.2. Additional Safeguards:

Why we checked the “prisoner” box:

Infrequently, NUWAY clients are furloughed from incarceration or workhouse. Some NUWAY clients are court mandated: they are civilly committed. We would include both groups of individuals in this study. To ensure that such individuals are especially reassured that they are free to choose to be in the study or decline to be in the study without legal consequence, we added this language to the informed consent document:

“We want to especially emphasize something for NUWAY clients who are furloughed from incarceration or workhouse or who are court mandated or civilly committed. This study is optional and you can feel free to say no to this study and still remain in treatment at NUWAY. Being in this study or not being in this study does not affect your legal status in any way. Return to incarceration is in no way a

consequence of either deciding to be in the study or deciding not to be in the study. Please ask us if you have any questions about this.”

We also include special language in the informed consent document to clarify the consequences of certain kinds of disclosures to research staff, including telling research staff about substance use, intent to hurt someone else, and about crimes committed. Here is the language we added, under the category, “What happens to the information collected for the research?”

“We will not ask you about child or vulnerable adult abuse. If you tell us about child or vulnerable adult abuse or neglect, we may have to report it to authorities because of law or policy. This is true if you tell us in group, one on one meetings, or in journal entries. Also, if we learn (in person or in any other contact you have with us) that you are at risk for hurting yourself or others, we will inform NUWAY treatment staff of this information as soon as possible.

“In general, if something worries us about what you share with us in any way, we will let NUWAY staff know. This includes any time you tell us that you have used drugs or alcohol. Telling us that you have used drugs or alcohol will have the same consequences as if you told a NUWAY staff member that you used drugs or alcohol. NUWAY staff would work with you to make sure that you have the support you need to get back on track related to your recovery.

“If you tell us that you committed a crime, we would tell NUWAY Staff. Telling us that you committed a crime would have the same consequences as if you told a NUWAY staff member that you committed a crime. If you are on probation or parole, NUWAY staff would need to report this to your probation or parole officer.

“If you tell us that you intend to hurt yourself or someone else, we would tell NUWAY staff.

“Some of these things that you might tell us might have consequences related to your treatment status at NUWAY.

“In general, the NUWAY Staff will not find out your answers to the iPad surveys.”

## **11. Number of Participants**

11.1. Number of participants to be consented will be approximately 100.

## **12. Recruitment Methods**

- 12.1. Recruitment process. Recruitment will take place one of four ways. 1) NUWAY staff will reach out to clients who appear to meet study criteria. Clients might receive the electronic or hard copy recruitment flyer from their counselor. Clients then will be encouraged to contact study staff. 2) NUWAY staff will complete a release of information form with their clients allowing communication between NUWAY and the research team. NUWAY staff will inform research staff of client contact information, and study staff will reach out to clients (only if the release of information has been signed, unless the counselor is facilitating an introduction based on the in-group recruitment presentation, see #3, for example, a counselor might provide contact information for a client attending the recruitment presentation who needed assistance emailing or texting us directly ). 3) Study staff will make presentations in NUWAY treatment groups (currently only to take place via Zoom), making the basic points from the recruitment flyer (see recruitment PowerPoint, attached). Clients then will be encouraged to contact study staff. 4) The recruitment flyer might be posted on bulletin boards or made available in group rooms or lounge areas on site (now that more clients are coming into the site in person) and clients can reach out to study staff based on information from the flyer. 5) When clients are scheduled for a screening by research staff, we will let the counselor know to begin the Release of Information procedure and we will let the counselor know of the date and time of the screening appointment. The purpose of this is to have the counselor help the client to follow through with attending the screening appointment (currently our rate of cancellations and no-shows for screenings is 51%) . Counselors, when helping with recruitment, will be advised by us that they must emphasize that participation is entirely optional and that clients may choose to participate or not, and may drop out, cancel the screening appointment, reschedule the screening appointment, or continue with the study as they wish. Prospective participants' relationships with NUWAY or the University of Minnesota will not be negatively compromised whatever choice they make, and this point will be emphasized.

Interested clients will contact research study staff by phone, email, or text. Whenever possible, study staff will conduct a preliminary screening and if the participant appears eligible, make an appointment for the screening interview. When a preliminary screening is not possible, the preliminary screening questions will be the first questions asked at the screening interview. The preliminary screening questions are designed to determine as quickly as possible when a person might be eligible for the study and will be conducted via a brief telephone call. The preliminary screening questions are as follows: 1. Are you now a client at NUWAY? 2. How long have you been a client at NUWAY? (6 day minimum is required). 3. What is

your latest date of sobriety? (6 day minimum is required). 4. Are you at least 18 years old? 5. Who is your counselor and what NUWAY facility are you attending? 6. If you are part of this study, you might be asked to join a zoom group that meets from [insert time of group, e.g., 12 to 1 pm] on 8 weekdays, starting [insert start date]. Would that work for your schedule? 7. If you are part of this study, we'll be contacting you by email regularly. Would you be willing to check your email daily? 8. How is your ability to read and write in English? 9. Do you have a device (smartphone/tablet) that has a camera in it, and can connect to the internet? Would you be willing to use this device for the research study? 10. Are you able to attend Zoom meetings for the research study? 11. Are you able to fill out electronic questionnaires that we will send to you? 12. What questions can we answer about the research study?

At the screening interview, research staff will guide prospective participants through the screening informed consent, regular informed consent procedure, take the baseline questionnaire, and be randomized into the treatment (maroon) or control (gold) groups. Individuals who meet criteria for the waiting list would also have the opportunity to take the baseline screening instrument.

- 12.2. Source of Participants: All participants to be enrolled in the study will be concurrently receiving SUD treatment at NUWAY Inc. Study participation is offered in addition to SUD treatment as usual, but participants may miss NUWAY groups in order to instead attend PPJ groups. This decision will be made by NUWAY staff. During COVID19, our groups will be offered at times other than NUWAY core remote treatment groups whenever possible.
- 12.3. Identification of Potential Participants: See 12.1, above.
- 12.4. Recruitment Materials: Recruitment materials include the recruitment flyer, recruitment PowerPoint (if a presentation is made in client treatment groups), screening informed consent, and regular informed consent documents (copies are attached).
- 12.5. Payment to research participants: Payment will be made in the form of Target gift cards given out electronically. Target gift cards cannot be replaced if lost or stolen, this is stated on the regular consent form. Values of the Target gift cards will be based on participation as follows:

Participants will be compensated \$15 for the baseline assessment instrument and \$5 for attending each group session during the 3-week Group Phase (treatment group) or for completing 8 Qualtrics surveys (control group). Participants will be compensated \$5 each time they upload PPJ using Qualtrics in addition to the 8 group opportunities.

During the two-week Independent Practice Phase, participants are required to upload PPJ a minimum of 3 times per week but can upload a maximum of 7 times per week if they wish to but they will only be compensated up to 5 times (treatment group). During this same period, the control group will have equivalent opportunities to complete Qualtrics surveys. Each time they upload, they will be compensated \$5, assuming all aspects are completed (successful upload of photograph (for treatment group only) and answering study questionnaire items). Participants can feel free to upload more than 5 times a week (maximum would be daily) but would not be compensated for more than 5 times per week. Participants are not compensated additionally for uploads that take place during group sessions (treatment group individuals will already be compensated for attending group).

Participants will be compensated \$10 for the exit interview and \$10 for the 30 day follow up interview. Participants will be paid a \$20 bonus for completing the baseline interview, the exit interview, follow up interview, and at least 90% of all other study activities (group participation, homework, and the minimum number of independent PPJ uploads).

Total possible compensation including the bonus is \$160.

Payment to addiction treatment providers/administrators: We will offer \$40 in gift cards to treatment providers / administrators for reading, critiquing, and offering edits and comments to our draft PPJ treatment manual.

### **13. Withdrawal of Participants**

13.1. Withdrawal Circumstances: Participants will be withdrawn from the research without their consent for three reasons: 1) if the participant leaves NUWAY treatment against staff advice, 2) if the participant leaves NUWAY treatment at the request of staff for breaking the rules (for example, if they instigate a physical altercation), or 3) the participant leaves NUWAY treatment without discussion with staff and does not return. In these three situations, we would retain the person's data to date and code them as having discontinued treatment, since treatment retention is one of our primary outcomes. Participants of course can keep any Target gift card credits they have earned. If a participant leaves treatment and the study owes the individual Target gift cards, these will be distributed electronically.

13.2. Withdrawal Procedures: Participants can elect to leave the study at any time. This is emphasized in the informed consent document. If participants leave the study, we will still consult NUWAY records to determine relapse or

treatment departure for all study participants. We will include this information in the informed consent document.

Termination Procedures: If a participant stops participating in study activities, we will reach out to them up to 2 times and ask them if they would like to leave the study. If they say no then the process will stop and we will pay them any Target gift cards we owe them. If they are uncertain, we will warmly invite them to return to study activities, but will then consider them to have left the study if they do not return. We may also ask NUWAY staff to help us find out this information. If a person wishes to leave the study, we will note this in our study records. For individuals who leave the study prematurely, we will use data already collected and follow up data on relapse and treatment departure in our data analyses. Participants of course can keep any Target gift card credits they have earned and we will pay out any additional Target gift cards earned upon their exit from the study.

NUWAY study participants will be required to sign a release of information naming research staff, so that research staff and NUWAY staff can communicate with each other. If study participants call research staff by telephone, we will be able to call them back at NUWAY and speak to them or leave a message.

## **14. Risks to Participants**

- 14.1. Foreseeable Risks: The potential risks in this study include those related to confidentiality, alcohol and illicit drug abstinence, and uncomfortable emotions when completing PPJ and Qualtrics questionnaires, which will ask about substance use, affect, trauma history, satisfaction with recovery, and other wellbeing and health indicators.

Although the PPJ is hypothesized to be supportive, affirming, and encouraging, uncomfortable emotions may also arise when looking back over the past 24 hours or planning the upcoming 24 hours when completing PPJ.

One risk to confidentiality will be if a third party (such as another person residing with them ) reads the participant's journal. We will advise participants to use codenames and symbols to code material that is especially private to them in case their journal is viewed by other people. We will also advise participants to keep journals stored in a safe place. Some participants may accidentally take a picture of their journals outside of the Qualtrics survey which would then be saved on their phone or tablet unless deleted. This is described as a risk on the informed consent

document. We will ask participants to make sure they are in a quiet, private place when they are on any Zoom calls with us and are encouraged to use headphones to reduce risk that anyone will overhear what is being discussed.

Although our sample participants will have been in treatment for a minimum of one week at NUWAY and should no longer be experiencing the acute physical withdrawal effects associated with drug and alcohol abstinence, continued abstinence from drugs and alcohol is often associated with irritability, restlessness, anxiety, depressed mood, sleep disturbance, increased appetite, and decreased concentration. Abstinence may also exacerbate pre-existing mental health conditions. Although these symptoms may be effectively treated with appropriate intervention, we will monitor these symptoms at each session.

Individuals reporting extreme mental health issues either in the treatment group or in their PPJ Qualtrics entries will be referred to NUWAY staff. In such cases, we will refer the patient to appropriate medical/psychiatric/counseling staff at the NUWAY. More specifically, individuals who indicate suicidal ideation will be referred to the NUWAY staff. NUWAY staff would then follow their usual procedures and refer patients with life threatening conditions to inpatient psychiatric programs in the Minneapolis metro area.

**Procedures to be performed to lessen the probability, magnitude, duration, or reversibility of those risks.** All of the information obtained from subjects is entirely for research purposes and will be referenced by codename or number versus participant name and kept in locked confidential files at the University of Minnesota School of Social Work or on password protected University of Minnesota computers or servers. At baseline, participants will be invited to select a codename or number that they can easily remember but one that is not an identifier (e.g., real name, birthdate). They will use this codename or number on all study materials except for the informed consent document including study homework and PPJ entries. Their codename and real name are also listed on paper forms but these are always kept in a locked file cabinet or locked file box.

The original PPJ entries will remain in the hard-copy paper journal which we will provide to participants. The research team will see electronic snapshots of journal entries uploaded to Qualtrics. These snapshots will not contain identifying information (participant name, date of birth, etc.). It is important to see these snapshots to make sure the participant is authentically completing PPJ that day.

Consent forms will be collected and saved securely using REDCap. All data collected via Qualtrics are solely identified by codename or number and are not identifiable by any other subject information. The exit interviews and parts of group sessions will be transcribed. Transcriptions will be fully de-identified.

We will maintain an electronic document with a password that links subject number or codename to participant names, and we will delete this document after data analyses are complete, approximately one year after the last data are collected from study participants. We will also destroy any paper forms linking real name to codename at this same time.

There may be some discomfort associated with completing questionnaires that ask about affect, which may be poor in early recovery, satisfaction with life in recovery, which may be low in early recovery, and history of substance use and trauma. There may be some discomfort with looking back over the past 24 hours and planning the upcoming 24 hours. We expect that any such discomfort would be temporary. We will alert participants to this in the informed consent document and in group. We will also address emotions related to past 24 hour review and planning the upcoming 24 hours to provide support and understanding for any uncomfortable feelings that may arise during the group sessions. Any emotions of extreme intensity or duration will cause study staff to refer the participant to NUWAY staff.

A NUWAY staff member may or may not sit in on group sessions to monitor the session and participant wellbeing, as the groups will be part of participants' overall NUWAY experience (having a staff member sit in on groups has been less necessary during remote delivery). If an individual is in an amount of distress that cannot be managed by the group process, then the NUWAY staff member can take the person out of group to address the issue. The NUWAY staff member will also help maintain group norms, group rules, and appropriate group behavior which will foster an environment conducive to learning. If there should be a group meeting conducted without a NUWAY staff member for any reason, and any incident of this kind takes place, research study staff will go down the hall to find a NUWAY staff member to assist. During electronic administration, we would excuse the NUWAY participant from the group and contact NUWAY staff or 911 immediately in the case of a medical emergency.



Another risk is the privacy of journal contents. The journaling practice is meant to capture the person's lived experience over the past 24 hours. Some of this content will be private and personal and not meant to be shared with anyone, which is entirely acceptable and even encouraged. However, to keep such information private in a written journal, we will encourage participants to use code names or code initials for very personal information, e.g., "I was upset and mad at DB" where DB are code initials for the individual referenced. This will protect the individual in case a third party (e.g., other NUWAY resident) reads the person's journal. We will ask all participants to respect the privacy of other people's journals. We will discuss this in the group sessions.

We will monitor journal entries submitted in the Group and Independent Practice Phases for any information about feelings about participants hurting themselves or others or cases of abuse of a vulnerable adult or child neglect or abuse. We are mandated reporters in such cases and will share what we see with NUWAY staff and make sure that reporting procedures are followed. NUWAY will provide us with an emergency staff number that we can dial 24/7 if we see something worrisome in a PPJ journal entry uploaded to Qualtrics. We will describe this limitation to confidentiality in the informed consent document and in group sessions.

14.2. Reproduction Risks: N/A

14.3. Risks to Others: One group exercise we will employ is "each one teach one." In this exercise, group members are invited to choose someone in their supportive network to teach the journaling practice to. This secondary person would be invited by the participant to try PPJ, and then the "teacher" and the friend will share contents of PPJ with each other. We do not expect that the secondary participant would face any risks beyond mild and temporary feelings of discomfort that might arise when reviewing the past 24 hours or planning the upcoming 24 hours.

**15. Incomplete Disclosure or Deception**

15.1. Incomplete Disclosure or Deception: N/A. Participants will be informed that this is a study of journaling in recovery.

**16. Potential Benefits to Participants**

16.1. Potential Benefits: The hypothesized benefit of the proposed study is the potential of improving satisfaction with life in recovery and increasing other wellbeing factors (e.g., positive emotion), which we hypothesize will support sustained abstinence from alcohol and other illicit drugs and sustained enrollment in the NUWAY treatment center. However, while there

is evidence that gratitude practices and activity planning may yield such benefits, there is no evidence for the benefits of the combined elements that comprise PPJ. The control group will receive the journal and brief instructions for using it and access to the YouTube videos that describe how to use the journals at the exit interview and therefore they may experience some of these benefits. However, in our previous research, participants told us that they felt that the completion of the PANAS instrument to assess mood felt therapeutic.<sup>60</sup>

Although potential risks include frustration, existing psychological withdrawal effects from alcohol and substance use abstinence, mild discomfort when filling out questionnaires, and adjusting to a new lifestyle, these are not life threatening and will subside as treatment progresses.

Finally, issues of confidentiality are a high priority and will be closely monitored throughout the treatment study. Consequently, the risk to benefit ratio in the proposed study appears to be acceptable.

## **17. Data Management**

17.1. Data Analysis Plan: Please see “Analysis Plan” under 5.2, above.

17.2. Power Analysis: Preliminary data from existing behavioral activation (BA) research was used to determine power for the original proposal with N=76. For the outcome of abstinence (yes/no), previous work found outcomes for this variable of 41.5% for the BA group and 24.8% in the control group.<sup>14</sup> For a 1-tailed test with  $p < .10$ , our power to detect a significant effect for abstinence (yes/no) in the proposed study would be .61 (for a 2-tailed test with  $p < .05$ , power would be .34). For the outcome of treatment retention (yes/no), previous work showed 96.6% for the BA group and 75.9% in the control group.<sup>16</sup> For a 1-tailed test with  $p < .10$ , our power to detect a significant effect for treatment retention (yes/no) in the current study would be 94% (for a 2-tailed test with  $p < .05$ , power would be .82). Therefore, we should be adequately powered to detect statistically significant differences for the outcome of treatment retention in the current study using a 2-tailed test. R was used to conduct these power analyses.<sup>61</sup>

17.3. Statistical Analysis: This pilot study will not be adequately powered to detect an effect. Still we will compare the treatment and control groups using t tests and multi-level models to determine differences in means and in slopes between the groups, respectively. Descriptive statistics of the quantitative measures will be used to conduct power analyses and sample size calculations for a larger controlled trial. Also, multi-level analyses will

be conducted to determine significant change over time in factors of interest. We will also be able to examine whether change over time varied by certain subgroups (e.g., those with lower versus higher levels of the factor of interest at baseline).

- 17.4. Data Integrity: The use of Qualtrics to collect survey data will improve data accuracy because this allows us to avoid keystroke and other errors involved with manual data entry from written questionnaires. We will scrutinize the data produced by Qualtrics to ensure its integrity; whether values are within scale ranges and whether missing data is coded correctly. We will carefully examine and clean the data to ensure accuracy. For standardized instruments, we will be very careful to follow the directions for summing or taking the mean of scale items and reverse code any items as per the instructions.

## **18. Confidentiality**

- 18.1. Data Security: We will safeguard against breaches of confidentiality by coding participant data by codename or number rather than by name and by keeping information linking these codenames or numbers to research staff via password protected electronic file. Further, no individuals will be identified by name nor will any identifying information be offered when presenting data in lectures, seminars, professional presentations, or papers. When qualitative data are transcribed, whether from exit interviews or recorded group sessions, they will be de-identified to replace any spoken names or identifiers with brackets, e.g., “Joan” will be replaced with “[Participant’s Daughter].”

The Office of Measurement Services (OMS) of the University of Minnesota will be assisting the study by designing the Qualtrics mechanism that we will use for data collection. OMS has many years of experience in collecting, maintaining, and storing data in accordance with FERPA and HIPAA regulations. OMS’s internal security and safeguards go beyond the minimum levels established for the University of Minnesota. OMS provides data security and privacy protection by using a dedicated server to store data, by performing daily data back-ups, and by using Secure Sockets Layer (SSL), the industry-standard means for safeguarding web communications. OMS also utilizes encryption protocols for the storage and transmission of data which further ensures data security. Additionally, OMS recently completed IT risk assessments from Berry Dunn and Deloitte to verify that our data handling and storage procedures are up to date and effective.

NUWAY will make mention in chart notes if and when clients have participated in PPJ groups.

Since this research is being funded by the National Institutes of Health, it is automatically issued a Certificate of Confidentiality (CoC). The CoC protects the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in the following situations: (1) The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA). (2) The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

## **19. Provisions to Monitor the Data to Ensure the Safety of Participants**

### **19.1. Data Integrity Monitoring:**

The job of data integrity monitoring will be conducted by PI Krentzman. She will oversee all study progress and ensure that the study is conducted, recorded, and reported in accordance with the protocol and standard operating procedures. In the event that changes to the protocol are needed, PI Krentzman will make modifications using standard IRB procedures. PI Krentzman is an Associate Professor of Social Work and has been employed by the University of Minnesota since 2013. PI Krentzman has expertise in positive psychology,<sup>62,63</sup> gratitude,<sup>17,22</sup> and spirituality in AUD recovery;<sup>64-67</sup> as well as qualitative data analysis;<sup>17,60</sup> quantitative data analysis;<sup>64,65,68</sup> mechanisms of behavior change;<sup>64</sup> and the conduct of randomized control trials to test novel interventions to support AUD recovery.<sup>17,69</sup> PI Krentzman will be in ongoing contact with staff at NUWAY, specifically Ken Roberts, Chief Clinical Officer of NUWAY, and the NUWAY site supervisor, who will be the study's primary contacts at the host agency. PI Krentzman will supervise study staff including all Research Assistants. Supervision will involve face to face meetings at a minimum of once every two weeks. Study reports will be provided to the IRB according to the regularly scheduled requirements of such reporting. In these reports we will describe recruitment progress and study findings as they unfold.

### **19.2. Data Safety Monitoring:**

All research staff will complete the online training modules which cover HIPAA, ethical research with human subjects, accuracy, record keeping, and confidentiality. These modules are offered by the University of Minnesota and include HIPAA Training and the Collaborative Institutional Training Initiative (CITI) Program's Social/Behavioral or Humanist Research

Investigators and Key Personnel curriculum. PI Krentzman will model and extensively review this content with all staff.

**Safety.**

As noted in the human subjects section of this application, we will protect against physical and emotional symptoms resulting from substance use abstinence and any other relevant psychological symptoms. Further, we are acutely aware of the importance of protecting participant confidentiality and in abiding by HIPAA guidelines.

The baseline session will take place in a private and quiet setting at NUWAY, or, with electronic administration, on a Zoom call but we will make sure the participant is in a quiet, private place and will encourage them to use headphones. The meeting will begin with screening informed consent, screening, and then informed consent, which will include a detailed description of the purpose and procedure of the study, emphasizing our policy regarding privacy and confidentiality, and an opportunity for the individual to ask any questions or voice any concerns. A screening informed consent document will be signed before screening activities take place. A regular informed consent document will be reviewed and a quiz on its contents passed before any study data are collected. Documents will be signed electronically. We will invite and answer any questions about the study. We will make sure the participant understands the information and does not feel pressured to make a decision. Participants will understand that their participation is entirely voluntary.

Aside from signing the consent forms, and the “codename” form, The participants’ name will be retained in REDCap but all other data (from the Qualtrics surveys for example) will be separated from the participant’s name; only research staff will have access to a document(s) that links participant number/codename and name. All of the information obtained from subjects is entirely for research purposes and quoted by codename or number and kept in locked confidential files at our offices at the University of Minnesota or on password protected laptops or university servers. This information is not available to anyone except the investigators.

Although our sample participants will have been in treatment a minimum of 2 weeks and no longer suffering from the acute physical withdrawal effects of alcohol or drug abstinence, continued abstinence from drugs and alcohol is often associated with irritability, restlessness, anxiety, depressed mood, sleep disturbance, increased appetite, and decreased concentration. Abstinence also may exacerbate pre-existing conditions. Although these symptoms may be effectively treated with appropriate intervention, we will monitor these symptoms at each session. Individuals reporting moderate or persistent concerns or problems will be referred by study staff to appropriate medical/psychiatric staff at NUWAY. We will periodically

evaluate the data collected regarding both harms and benefits to determine whether participants remain safe.

Study Research Assistants or PI Krentzman will review the data, especially the pictures of the journal entries, as soon as possible after submission but no later than 72 hours after submission to examine the data for any safety concerns.

If participants experience distress related to the baseline questionnaire, including the question that asks about history of trauma, we will refer them to NUWAY staff.

We will use the Zoom waiting room feature and we will only admit group members into the Zoom room. If a group member behaves inappropriately (e.g., shares inappropriate words or images, i.e., Zoom bombing) we will remove them from the Zoom room.

## **20. Provisions to Protect the Privacy Interests of Participants**

20.1. Protecting Privacy: REDCap information will contain the participant's name but all other documents in paper or electronic format will include the person's codename or number only. An electronic file matching participant name to codename or number will be kept on a password protected computers and the file itself will be password protected and erased one year after the conclusion of data analysis. Any paper copies of this information will also be destroyed at this time.

We will go to great lengths to make sure participants understand the nature of the research study and our concern about their privacy. This will be made clear in the content of the informed consent document. We will review this information with participants in depth as we go over all elements of the informed consent process. We will assure the participant that we will do everything we can to ensure their privacy, including using a codename or number associated with their data and putting a password on the electronic file that matches their codename or number to their name. Limitations to confidentiality will also be described, such as whether the participant describes the desire to harm themselves or others, or whether a minor or vulnerable adult is at risk of abuse or neglect. We will ask that participants use a quiet, private room for Zoom meetings and use headphones if at all possible during our Zoom class with them.

20.2. Access to Participants: The research team will not have access to NUWAY records. To determine our key outcomes, recurrence of substance use or discontinuation of treatment, a NUWAY staff member will meet with a member of the research team at reasonable time intervals to share whether participants have left treatment or whether they have resumed

substance use. Resumption of substance use is confirmed at NUWAY via urine testing or other drug screening or client self-report. Results of these tests, if positive for substances, will be communicated to research staff at reasonable periods and we will code this information into our de-identified data records. We will also have staff check the NUWAY record if the individual does not remember the date they started at NUWAY.

## **21. Compensation for Research-Related Injury**

21.1. Compensation for Research-Related Injury: N/A

21.2. Contract Language: N/A

## **22. Consent Process**

22.1. Consent Process (when consent will be obtained): Our consent process is informed by the instructions provided in HRP-090 and HRP-091. The consent process will take place on site at NUWAY (for electronic administration, it will take place via Zoom). Research staff will meet with prospective participants. First, participants will complete a screening informed consent document then they will be screened using our screening document (attached to ETHOS). If the participant meets eligibility, we will offer the participant the choice of reading the informed consent document and we will verbally summarize it for them in detail. Participants will be administered the UBACC quiz to determine that they have understood the study and their role in the study. A score of 15 or higher is needed for inclusion in the study. An impartial witness will be used if necessary, for example, if the prospective participant has a visual impairment and cannot read the informed consent document. If an impartial witness is used we will follow the guidelines described in HRP-090 for that procedure.

22.2. Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): N/A

22.3. Non-English Speaking Participants: N/A

22.4. Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

22.5. Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: N/A

22.6. Adults Unable to Consent:

- Permission: N/A
- Assent: N/A

## **23. Setting**

23.1 Research Site: **NUWAY House, Inc.** NUWAY is the host partner for the proposed study. NUWAY is a private, not-for-profit substance-use disorder treatment facility serving men and women with addictions since 1966. NUWAY operates five treatment centers which serve over 700 clients in the Twin Cities. The proposed work will recruit from NUWAY's 3R's Counseling Center, 1404 Central Avenue NE, Minneapolis, MN which currently serves 288 intensive outpatient clients for individualized treatment durations generally ranging from 90-120 days. This is a 17,000 square foot facility featuring 13 group rooms, 21 offices assigned to counseling staff, eight therapy offices with standard office furniture that are open to any staff member or clinician for client interviewing (which we have been permitted to use to screen and consent clients), several client lounges, a cafeteria for clients, a lecture hall that seats 150 people, a smoking area, and an outdoor green space. There is high-speed wireless internet throughout the facility that can be accessed by research staff and clients to upload their journals and complete daily assessments. 3R's has 18 full-time licensed clinicians, two program managers, one program director, four admissions staff, 14 interns from various counseling programs throughout the Twin Cities, and 7 floating therapists who fill in as needed. Clients at 3R's receive 20 hours of licensed substance-use disorder treatment per week, 4 hours per day, Monday through Friday. Treatment elements include educational lectures, process group therapy, and individual therapy. PPJ is not redundant with current services offered. The facility is 4.5 miles from the PI's office at the School of Social Work, a 13 minute drive. During COVID19, NUWAY staff are providing groups and individual sessions to clients on Zoom.

As of August 2020, we will also be recruiting from a second NUWAY site, "NUWAY III." NUWAY III is located at 2104 Stevens Avenue South, Minneapolis, MN 55404. NUWAY III is a medium-intensity residential treatment program for women and transgender people. The program provides comprehensive treatment for substance use and mental health disorders and has the capacity for 31 women and transgender people. NUWAY III offers gender-informed curriculum, treats trauma, and offers individual and group therapy.

As of September 2020, we will also be recruiting from a third NUWAY site, "2118." Nuway's 2118 Blaisdell Avenue South location in Minneapolis, MN, serves over 220 outpatients each year. Nuway is an extended care outpatient facility where clients attend treatment 4 hours per day, Monday through Friday, for 90-120 days. "2118" is a 20,000 square foot facility featuring 10 group rooms, 16 offices assigned to counseling staff, five therapy offices, several client lounges including five designated as quiet



areas, a cafeteria for clients, a lecture hall that seats 135 people, a smoking area, and an outdoor green space. “2118” has 15 full-time licensed clinicians, two clinical supervisors, one program director, one executive program director, three admissions staff, three information technology support staff, 6-10 interns from various counseling programs throughout the Twin Cities, and 2-4 floating therapists who fill in as needed.

All study procedures are the same for all NUWAY sites.

2. International Research: N/A
3. Community Based Participatory Research: N/A

## 2. Multi-Site Research

N/A

## 3. Resources Available

### 3.2. Resources Available:

**Time.** The Agricultural Experiment Station (AES) grant that is funding this study provides PI Krentzman with one course buy out for the academic year 2019-2020. PI Krentzman will use this time and additional time to conducting and completing this research.

**Research Assistant(s) (RA).** The AES grant that is funding this study allows for two 25% RAs for the 2019-2020 school year and two 25% RAs for the 2020-2022 school year. One RA will be dedicated to this study. The CTSI grant will also provide a second RA. The RAs will be involved in all aspects of the research including screening and informed consent, data management, data cleaning, literature reviews, exit interviews, attending group sessions, and general research activities.

**Facilities.** The School of Social Work is home to five research and training centers that serve local and national educators, researchers, and professional social workers. The School is located at 1404 Gortner Avenue in St. Paul, MN. Faculty members at the School of Social Work are among the most productive in the nation, conducting research on a wide range of topics. The School produces a wide range of high-quality research relevant to social welfare including work in health, mental health, disability, aging, and methods and methodology (<http://www.cehd.umn.edu/ssw>). The School of Social Work’s research committee hosts monthly research

colloquia to showcase the current research of University of Minnesota faculty.

**Offices.** A 118 square foot office for PI Krentzman is permanently available in Peters Hall. The office features a desk, credenza, attached table with two guest chairs, two lockable large two-drawer filing cabinets, one lockable three-drawer filing cabinet, and high-speed internet access hardwired to a laptop docking station. The University's wireless network is also accessible throughout Peters Hall. Project staff will be equipped with additional office space in Peters Hall similarly equipped with desks, chairs, filing cabinets, computers, and internet service. During COVID19 Dr. Krentzman is working remotely.

**Computers.** The PI has a Dell PC laptop (Windows 10) and two monitors. All research staff will have Dell PC workstations in their offices. The University provides SPSS Statistics Software and the PI has perpetual licenses for two copies of NVivo software for qualitative data analysis. Annual NVivo licenses have been purchased for additional research staff members.

**Availability of medical or psychological resources.** These currently exist at NUWAY and will be utilized if necessary via referral of the participant to NUWAY staff in the event of medical or psychological concerns beyond the scope of this study.

**Trained research staff.** PI Krentzman takes responsibility to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions. Research assistants will be trained in data collection, data cleaning, and data management including recruitment activities, informed consent, and administration of self-report, interview, and electronic measures. All research staff will complete University of Minnesota training modules which cover HIPAA, ethical research with human subjects, accuracy, record keeping, and confidentiality. PI Krentzman will model and extensively review this content with staff. Research assistants will develop skills (e.g., informed consent procedures) via role-play exercises with PI. Krentzman. PI Krentzman will provide ongoing supervision for research staff.

#### 4. References

1. Minnesota Department of Human Services. 2010 Minnesota Survey on Adult Substance Use. Published online 2012. <https://edocs.dhs.state.mn.us/lfserver/Public/DHS-6423B-ENG>

2. Minnesota Department of Human Services, Alcohol and Drug Abuse Division. Substance Abuse in Minnesota: A State Epidemiological Profile. Published online 2015. [http://www.sumn.org/~media/403/2015\\_Minnesota\\_EpiProfile.pdf](http://www.sumn.org/~media/403/2015_Minnesota_EpiProfile.pdf)
3. Minnesota Institute of Public Health. *The Human and Economic Cost of Alcohol Use in Minnesota*. Minnesota Department of Health; 2011.
4. Emmons RA. *Gratitude Works!: A 21-Day Program for Creating Emotional Prosperity*. 1 edition. Jossey-Bass; 2013.
5. AA World Services. *Twelve Steps and Twelve Traditions*. AA World Services; 1953.
6. WA World Services. *The Workaholics Anonymous Book of Recovery*. Second. Workaholics Anonymous World Service Organization; 2015.
7. DiClemente C. *Addiction and Change: How Addictions Develop and Addicted People Recover*. 2nd ed. Guilford; 2018.
8. Hendershot CS, Witkiewitz K, George WH, Marlatt G. Relapse prevention for addictive behaviors. *Subst Abuse Treat Prev Policy*. 2011;6:17:1-17. doi:10.1186/1747-597X-6-17
9. Marlatt G, Gordon JR. Determinants of relapse: Implications for the maintenance of behavior change. In: Davidson PO, Davidson SM, eds. *Behavioral Medicine: Changing Health Lifestyles*. Brunner/Mazel; 1980:410-452.
10. Laudet AB. The Case for Considering Quality of Life in Addiction Research and Clinical Practice. *Addict Sci Clin Pract*. 2011;6(1):44-55.
11. McKay JR. Making the hard work of recovery more attractive for those with substance use disorders: Making recovery more attractive. *Addiction*. 2017;112(5):751-757. doi:10.1111/add.13502
12. Kadden R. *Cognitive-Behavioral Coping Skills Therapy Manual: A Clinical Research Guide for Therapists Treating Individuals with Alcohol Abuse and Dependence*. DIANE Publishing; 1995.
13. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101.
14. Daughters SB, Magidson JF, Anand D, Seitz-Brown CJ, Chen Y, Baker S. The effect of a behavioral activation treatment for substance use on post-treatment abstinence: a randomized controlled trial: Behavioral activation for substance use. *Addiction*. Published online 2017. doi:10.1111/add.14049

15. Daughters S, Braun A, Sargeant M, et al. Effectiveness of a brief behavioral treatment for inner-city illicit drug users with elevated depressive symptoms: The Life Enhancement Treatment for Substance Use (LETS Act!). *J Clin Psychiatry*. 2008;69:122-129.
16. Magidson JF, Gorka SM, MacPherson L, et al. Examining the effect of the Life Enhancement Treatment for Substance Use (LETS ACT) on residential substance abuse treatment retention. *Addict Behav*. 2011;36(6):615-623. doi:10.1016/j.addbeh.2011.01.016
17. Krentzman A, Mannella KA, Hassett AL, et al. Feasibility, acceptability, and impact of a web-based gratitude exercise among individuals in outpatient treatment for alcohol use disorder. *J Posit Psychol*. 2015;10(6):477-488. doi:10.1080/17439760.2015.1015158
18. LaBelle OP, Edelstein RS. Gratitude, insecure attachment, and positive outcomes among 12-step recovery program participants. *Addict Res Theory*. 2018;26(2):123-132. doi:10.1080/16066359.2017.1333111
19. AA World Services. *As Bill Sees It: The AA Way of Life*. AA World Services, Inc.; 1967.
20. Leung C-C, Tong EMW. Gratitude and Drug Misuse: Role of Coping as Mediator. *Subst Use Misuse*. 2017;52(14):1832-1839. doi:10.1080/10826084.2017.1312449
21. Charzyńska E. Sex Differences in Spiritual Coping, Forgiveness, and Gratitude Before and After a Basic Alcohol Addiction Treatment Program. *J Relig Health*. 2015;54(5):1931-1949. doi:10.1007/s10943-015-0002-0
22. Krentzman A. Gratitude, abstinence, and alcohol use disorders: Report of a preliminary finding. *J Subst Abuse Treat*. 2017;78:30-36. doi:10.1016/j.jsat.2017.04.013
23. Charzyńska E, Gruszczyńska E, Heszen I. Forgiveness and gratitude trajectories among persons undergoing alcohol addiction therapy. *Addict Res Theory*. 2018;26(4):282-293. doi:10.1080/16066359.2018.1429595
24. Akhtar M, Boniwell I. Applying positive psychology to alcohol-misusing adolescents. *Groupwork*. 2010;20(3):6-31. doi:10.1921/095182410X576831
25. Carrico AW, Gómez W, Siever MD, Discepolo MV, Dilworth SE, Moskowitz JT. Pilot Randomized Controlled Trial of an Integrative Intervention with Methamphetamine-Using Men Who Have Sex with Men. *Arch Sex Behav*. 2015;44(7):1861-1867. doi:10.1007/s10508-015-0505-5

26. Seligman MEP, Steen TA, Park N, Peterson C. Positive Psychology Progress: Empirical Validation of Interventions. *Am Psychol*. 2005;60(5):410-421. doi:10.1037/0003-066X.60.5.410
27. Lejuez CW, Hopko DR, Acierno R, Daughters SB, Pagoto SL. Ten year revision of the brief behavioral activation treatment for depression: revised treatment manual. *Behav Modif*. 2011;35(2):111–161.
28. Lejuez CW, Hopko DR, Hopko SD. A brief behavioral activation treatment for depression: Treatment manual. *Behav Modif*. 2001;25(2):255–286.
29. Wood AM, Joseph S, Maltby J. Gratitude uniquely predicts satisfaction with life: Incremental validity above the domains and facets of the five factor model. *Personal Individ Differ*. 2008;45(1):49-54. doi:10.1016/j.paid.2008.02.019
30. Wood AM, Joseph S, Maltby J. Gratitude predicts psychological well-being above the Big Five facets. *Personal Individ Differ*. 2009;46(4):443-447. doi:10.1016/j.paid.2008.11.012
31. Dickens LR. Using gratitude to promote positive change: A series of meta-analyses investigating the effectiveness of gratitude interventions. *Basic Appl Soc Psychol*. 2017;39(4):193-208. doi:10.1080/01973533.2017.1323638
32. Fredrickson B. Gratitude, like other positive emotions, broadens and builds. In: *The Psychology of Gratitude*. 1 edition. Series in Affective Science. Oxford University Press; 2004:145-166.
33. Emmons RA, McCullough ME. Counting blessings versus burdens: An experimental investigation of gratitude and subjective well-being in daily life. *J Pers Soc Psychol*. 2003;84(2):377-389. doi:10.1037/0022-3514.84.2.377
34. Emmons RA, Stern R. Gratitude as a Psychotherapeutic Intervention. *J Clin Psychol*. 2013;69(8):846–855. doi:10.1002/jclp.22020
35. Wong YJ, McKean Blackwell N, Goodrich Mitts N, Gabana NT, Li Y. Giving thanks together: A preliminary evaluation of the Gratitude Group Program. *Pract Innov*. 2017;2(4):243-257. doi:10.1037/pri0000058
36. Krentzman A, Goodenough K, Banerjee R, Daughters S. Gratitude and positive activity planning to support recovery from alcohol and substance use disorders. Poster. In: *University of Minnesota Research Day*. ; 2018.
37. Sheldon KM, Lyubomirsky S. Achieving sustainable new happiness: Prospects, practices, and prescriptions. In: Linley A, Joseph S, eds. *Positive Psychology in Practice*. John Wiley & Sons; 2004:127-145.

38. Kanter JW, Manos RC, Bowe WM, Baruch DE, Busch AM, Rusch LC. What is behavioral activation? A review of the empirical literature. *Clin Psychol Rev.* 2010;30(6):608-620. doi:10.1016/j.cpr.2010.04.001
39. Caracelli VJ, Greene JC. Data Analysis Strategies for Mixed-Method Evaluation Designs. *Educ Eval Policy Anal.* 1993;15(2):195-207. doi:10.3102/01623737015002195
40. Li S, Marquart JM, Zercher C. Conceptual Issues and Analytic Strategies in Mixed-Method Studies of Preschool Inclusion. *J Early Interv.* 2000;23(2):116-132. doi:10.1177/105381510002300206
41. Trend M. On the reconciliation of qualitative and quantitative analyses: A case study. In: Cook TD, Reichardt CS, eds. *Qualitative & Quantitative Methods in Program Evaluation.* Sage Publications; 1979:68-86.
42. Greene JC. The generative potential of mixed methods inquiry. *Int J Res Method Educ.* 2005;28(2):207-211. doi:10.1080/01406720500256293
43. Foa EB, McLean CP, Zang Y, et al. Psychometric properties of the Posttraumatic Diagnostic Scale for DSM-5 (PDS-5). *Psychol Assess.* 2016;28(10):1166-1171. doi:10.1037/pas0000258
44. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand.* 1983;67:361-370.
45. Hagman BT, Kuerbis AN, Morgenstern J, Bux DA, Parsons JT, Heidinger BE. An Item Response Theory (IRT) analysis of the Short Inventory of Problems-Alcohol and Drugs (SIP-AD) among non-treatment seeking men-who-have-sex-with-men: Evidence for a shortened 10-item SIP-AD. *Addict Behav.* 2009;34(11):948-954. doi:10.1016/j.addbeh.2009.06.004
46. Kelly J, Greene MC. Beyond motivation: Initial validation of the commitment to sobriety scale. *J Subst Abuse Treat.* 2014;46(2):257-263. doi:10.1016/j.jsat.2013.06.010
47. McCullough ME, Emmons RA, Tsang J-A. The grateful disposition: A conceptual and empirical topography. *J Pers Soc Psychol.* 2002;82(1):112-127. doi:10.1037//0022-3514.82.1.112

48. Humphreys K, Kaskutas LA, Weisner C. The Alcoholics Anonymous Affiliation Scale: development, reliability, and norms for diverse treated and untreated populations. *Alcohol Clin Exp Res*. 1998;22(5):974-978.
49. Larsen D, Attkisson C, Hargreaves W, Nguyen T. Assessment of client/patient satisfaction: Development of a general scale. *Eval Program Plann*. 1979;2:197-207.
50. Strahan R, Gerbasi KC. Short, homogeneous versions of the Marlow-Crowne Social Desirability Scale. *J Clin Psychol*. 1972;28(2):191-193.  
doi:10.1002/1097-4679(197204)28:2<191::AID-JCLP2270280220>3.0.CO;2-G
51. Schmidt S, Mühlan H, Power M. The EUROHIS-QOL 8-item index: psychometric results of a cross-cultural field study. *Eur J Public Health*. 2006;16(4):420-428.  
doi:10.1093/eurpub/cki155
52. Watson D, Anna L, Tellegen A. Development and Validation of Brief Measures of Positive and Negative Affect: The PANAS Scales. :8.
53. Hoepfner BB, Kelly JF, Urbanoski KA, Slaymaker V. Comparative utility of a single-item versus multiple-item measure of self-efficacy in predicting relapse among young adults. *J Subst Abuse Treat*. 2011;41(3):305-312. doi:10.1016/j.jsat.2011.04.005
54. Diener E, Emmons RA, Larsen RJ, Griffin S. The Satisfaction With Life Scale. *J Pers Assess*. 1985;49(1):71-75. doi:10.1207/s15327752jpa4901\_13
55. Diener E, Wirtz D, Tov W, et al. New Well-being Measures: Short Scales to Assess Flourishing and Positive and Negative Feelings. *Soc Indic Res*. 2010;97(2):143-156.  
doi:10.1007/s11205-009-9493-y
56. Horner RH, Carr EG, Halle J, McGee G, Odom S, Wolery M. The use of single-subject research to identify evidence-based practice in special education. *Except Child*. 2005;71(2):165–179.
57. Jeste DV, Palmer BW, Appelbaum PS, et al. A New Brief Instrument for Assessing Decisional Capacity for Clinical Research. *Arch Gen Psychiatry*. 2007;64(8):966-974. doi:10.1001/archpsyc.64.8.966
58. Dennis ML, Feeney T, Titus JC. *GAIN-SS, Global Appraisal of Individual Needs--Short Screener (GAIN-SS): Administration and Scoring Manual, Version 3*. Chestnut Health Systems; 2013.
59. Dennis M, Feeney T, Stevens L, Bedoya L. Test Review: Global Appraisal of Individual Needs–Short Screener (GAIN-SS). *Rehabil Couns Bull*. 2017;60(2):121–124.

60. Krentzman AR, Higgins MM, Staller KM, Klatt ES. Alexithymia, emotional dysregulation, and recovery from alcoholism: therapeutic response to assessment of mood. *Qual Health Res.* 2015;25(6):794-805. doi:10.1177/1049732315577608
61. Faul F, Erdfelder E, Buchner A, Lang A-G. Statistical power analyses using G\*Power 3.1: Tests for correlation and regression analyses. *Behav Res Methods.* 2009;41(4):1149-1160. doi:10.3758/BRM.41.4.1149
62. Krentzman A. Review of the application of positive psychology to substance use, addiction, and recovery research. *Psychol Addict Behav J Soc Psychol Addict Behav.* 2013;27(1):151-165. doi:10.1037/a0029897
63. Krentzman AR, Barker SL. Counselors' perspectives of positive psychology for the treatment of addiction. *Alcohol Treat Q.* 2016;34(4):370-385.
64. Krentzman A, Cranford JA, Robinson EAR. Multiple dimensions of spirituality in recovery: A lagged mediational analysis of Alcoholics Anonymous' principal theoretical mechanism of behavior change. *Subst Abuse.* 2013;34(1):20-32. doi:10.1080/08897077.2012.691449
65. Krentzman AR, Webb JR, Jester JM, Harris JI. Longitudinal relationship between forgiveness of self and forgiveness of others among individuals with alcohol use disorders. Published online 2016.
66. Krentzman AR, Strobbe S, Harris JI, Jester JM, Robinson EAR. Decreased Drinking and Alcoholics Anonymous are Associated with Different Dimensions of Spirituality. Published online 2016.
67. Krentzman AR. Longitudinal Differences in Spirituality and Religiousness between Men and Women in Treatment for Alcohol Use Disorders. *Psychol Relig Spiritual.* 2016;Advance online publication.
68. Krentzman AR, Brower KJ, Cranford JA, Bradley JC, Robinson EA. Gender and extroversion as moderators of the association between alcoholics anonymous and sobriety. *J Stud Alcohol Drugs.* 2012;73(1):44.
69. Krentzman A, Westlund J, Tinetti T. Pilot Test of a Communication-Skills Intervention among Individuals in Recovery from Severe Substance-Use Disorders. *Alcohol Clin Exp Res Spec Issue 40th Annu Sci Meet Res Soc Alcohol June 24–28 — Denver Colo.* 2017;41(S1):255A.