

PROTOCOL TITLE: Addiction Recovery in a Rural Minnesota Community: Piloting
 “Positive Peer Journaling” PART II
 VERSION DATE: 20 June 2019
 NCT03903159

PROTOCOL COVER PAGE

Protocol Title	Addiction Recovery in a Rural Minnesota Community: Piloting “Positive Peer Journaling” PART II
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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
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 implementation	Yes
5	2.3.19	Revisions to the protocol that clarify research assistant duties and content of treatment group sessions.	No
6	2.12.19	Numerous minor revisions to screening consent, regular consent, screening check sheet, and protocol.	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, to obtain a more accurate count.	Yes
8	3.18.19	Now we are ready to recruit the second set of 5 women. 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	Yes

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		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.	
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. Wayside already screens all clients for trauma, but we will notify Wayside if any participant in the study seems to be having difficulty with study activities because of trauma or any other reason.	

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10	6.3.19	Protocol revised to include an electronic survey to be sent to the staff of the host treatment center (“Wayside”). The purpose of this staff survey is 1) to gather information about the implementation of the study logistics at Wayside 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

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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 wishes for others are listed.

1.0 Objectives

- 1.1 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 2010.¹ Negative consequences from substance use disorders suffered by Minnesotans have included death, arrest, incarceration, homicide, and suicide.² The economic cost of alcohol use in the State was estimated at \$5.06 billion, or \$975 per taxpayer, in 2007.³ However, the citizens of Minnesota residing in the rural parts of the State are likely to be at greater risk.

Sociologists have identified the classic features of rural life. These features include population dispersion, physical distance, absence of services, and “the larger territory over which people travel to meet their needs.”⁴ These features could make recovery more difficult to sustain in rural areas, because successful recovery involves distancing one’s self from former drug using friends, making new non-drug using friends, and initiating recovery-oriented social activities.⁵ These tasks are facilitated by access to a wide range of social connections and multiple options for recreational activity—things that are sparse in rural life.

The current study is the second part of a two-part program of research on recovery from addiction in rural southeast Minnesota. The first part of this program of research is an active study entitled, *Addiction Recovery in a Rural Minnesota Community: Piloting “Positive Peer Journaling,”* IRB ID #1611S99341.

This research protocol describes the second part of the study. In this study, *Addiction Recovery in a Rural Minnesota Community: Piloting “Positive Peer Journaling” Part II* we focus on developing, refining, and enhancing the logistics of 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.⁶ These practices involve conducting a review of the day, spirituality, gratitude, and striving for self-knowledge and self-improvement.⁶ The 10th step of Alcoholics Anonymous (AA) recommends that members conduct such a daily inventory.⁷ While this practice may benefit AA members, not everyone seeking addiction recovery joins AA. Even for those who do, it can take time to work steps 1-9 to reach step 10 and begin deriving benefits from it.

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 10th step which recommends a regular “personal inventory” where the day is reviewed and what went well and what went poorly is identified and acknowledged.⁷ 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....”⁸ The AA 10th 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.

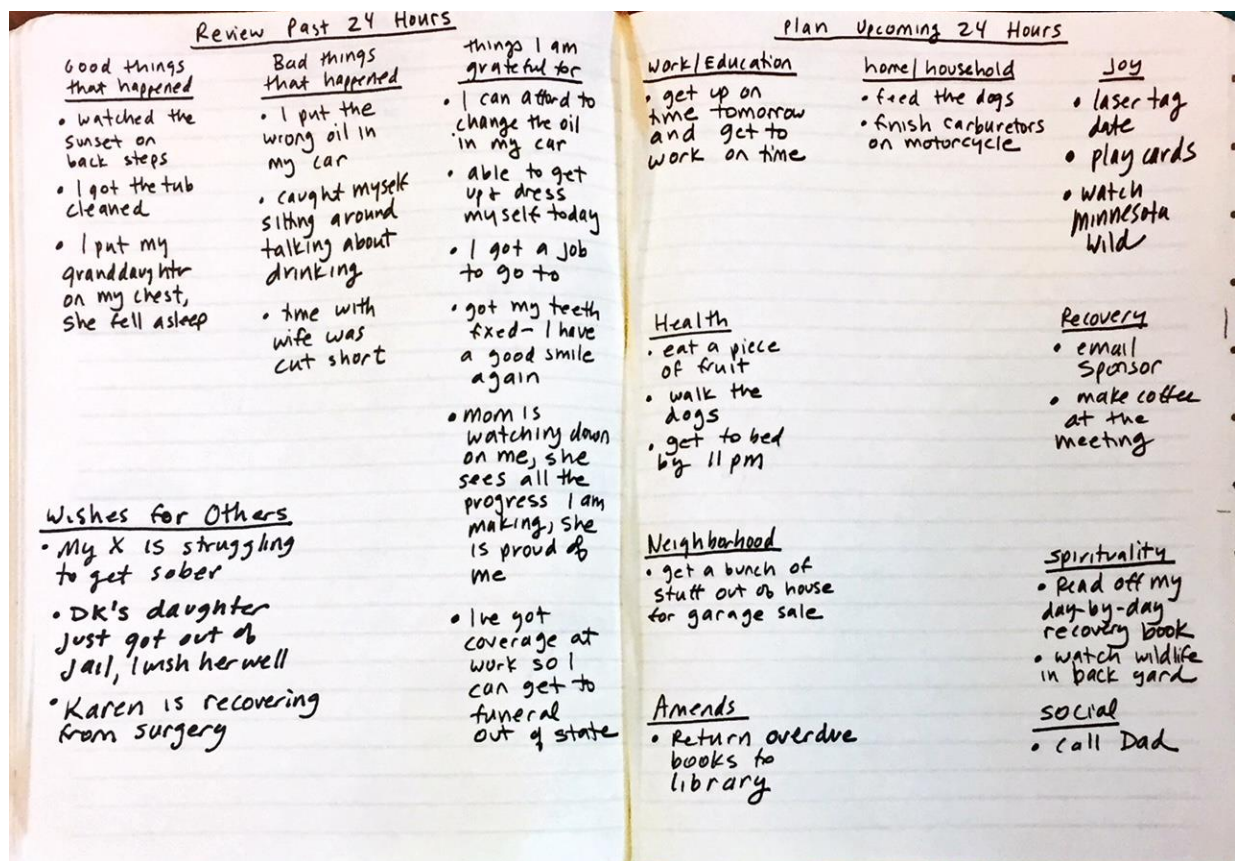


Figure 1. Positive Peer Journaling (PPJ) Example

Objectives. The main objective of this study is development of the PPJ intervention and the feasibility, acceptability, and logistics of treatment delivery.

One primary output of this work is to produce a PPJ treatment manual that specifies number of sessions, content for each session, clinician scripts and instructions, and group activities. This treatment manual can then be used in a future randomized controlled trial.

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.

2.0 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.^{9–12} Many current interventions focus, reasonably and necessarily, on reducing pathology,¹³ i.e., identifying triggers, reducing cravings, managing thoughts about alcohol, and coping with relapse.¹⁴ 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.¹⁵

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 3rd 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.^{16–18} To build confidence and

success, participants would aim to achieve zero tasks per day (planning only) and then one task a day at first.

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.¹⁹ 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.

Our preliminary work has demonstrated 1) high rates of treatment retention for the “Three Good Things” study, 2) high acceptability among AUD patients for the “Three Good Things” exercise and 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 meetings²⁰ and is a prevalent theme in AA literature.²¹ Recent empirical investigations into this phenomenon suggests that trait gratitude correlates positively with recovery supportive factors and negatively with factors that might challenge recovery.²⁰ Research also suggests that gratitude practices are associated with improvement in mood, which should make recovery more positively reinforcing.¹⁹ 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.²² In the only study we are aware of that explored the role of gratitude specifically as it occurs in 12-Step programs, LaBelle and Edelstein²⁰ 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. Charzyńska²³ found that trait gratitude increased among women but not men between baseline and treatment completion, five to seven weeks later. Krentzman²⁴ found that trait gratitude did not change between treatment entry and 6-month follow-up. Charzyńska and colleagues²⁵ built on their earlier study²³ 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.

Krentzman²⁴ 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.²⁶ 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.²⁷ A gratitude intervention, the “Three Good Things” exercise²⁸ 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.¹⁹

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^{29,30} modified for individuals with substance use disorders. Three randomized controlled trials showed that compared to comparison groups, LETS ACT participants demonstrated lower levels of depression¹⁷ and anxiety,¹⁷ greater enjoyment of activities,¹⁷ higher activity levels,¹⁸ decreased dropout from treatment,¹⁸ and increased abstinence at 3-, 6-, and 12-month follow-ups.¹⁶ 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.^{31,32} This association may be causal: in previous research, gratitude has been shown to improve affect^{19,33} which has been shown to encourage more frequent and more diverse types of activity.³⁴ 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.

This study will add to the existing knowledge base because we will be able to determine PPJ’s feasibility and acceptability and we will produce a PPJ treatment manual.

3.0 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. At the end of this study, we will develop a treatment manual to use in a future study to test the intervention in a randomized controlled trial.
- 3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): These include hypothesized mediators of the effect of the intervention on outcomes. These include: environmental reward, mood, satisfaction with life, perceived stress, recovery capital, wellbeing, commitment to sobriety, alcohol and drug craving, anxiety, and depression. For a complete list, see the measures section 5.2.

4.0 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 standard 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

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that happened and things for which one is grateful. 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 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, the image above has been updated in the June 2019 protocol revision. The far left and far right pages have been updated to include some of the kinds of daily life events, goals, and experiences our research participants in cohorts 1 and 2 have written about in their journal entries. For example, on the left flap we added under examples of good things, “had a good meal.” Under examples of things to be grateful for, we added, “good food” and “sunshine.” On the right flap we added, for example, the goal, “look for jobs” under “work/education” and the goal “go outside” under “joy.” The left and right flaps (far left and right panels on the image above and also uploaded to Ethos) offer suggestions for what participants will list in their own daily PPJs (the middle two panels).

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. We have included updates to these documents in ethos.

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^{35,36} and the “Three Good Things” exercise.²⁸ 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 will look like:

<p>Important Life Area:</p> <p>What makes this life area important to you?</p> <p>What makes this life area mean a lot to you?</p> <p>What do you wish for in this area?</p> <p>What do you believe strongly in this area?</p> <p>What are you striving for in this life area?</p> <p>What do you long for in this area?</p> <p>If this life area were going well, what words would you use to describe it?</p> <p>What about this area is important to you, in your heart?</p> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <div style="border: 2px solid black; height: 100px; width: 100%;"></div> <ul style="list-style-type: none"> • • • •
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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" (Gajwani 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.

Please note, for the June 2019 protocol revision, there are two edits to the “Important Life Area” page, above. First, we add the citation. Second,

removed a question that was confusing to participants: “What are the qualities of this life area that are important to you?” has been removed.

Instead of providing a handout with instructions for “each one teach one,” one of the final group exercises, we will include these instructions inside the journal, these journal pages will look like this:

Each One Teach One Script—Page 1	Each One Teach One Script—Page 2
<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>What questions do you have before we begin?</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>	<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>

The reasons we have included these pages (the values exercise pages and the each one teach one pages) is so that the women 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 wishes 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 this ethos modification.

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.¹⁹ Based on participant feedback from previous research, individuals will be coached that items on the gratitude list can include things often taken for granted.¹⁹ Based on published gratitude research, participants will be provided with suggested areas in which to look for gratitude content in their lives, i.e., circumstances, relationships, objects, qualities, events, sensations, opportunities, and capabilities^{37,38} and will be taught different types of gratitude, e.g., micro gratitude (gratitude for small things), macro gratitude (gratitude for large things), gratitude savoring (reflecting on something positive), interpersonal gratitude (grateful for someone), and redemptive gratitude (when something good has come from something stressful).³⁹ Gratitude interventions will be modeled by the therapist and other group members³⁹ until participants are able to produce a minimum of three items for each gratitude intervention each day. In keeping with the 10th 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.⁴⁰ 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 will also have 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 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.⁴¹

In PPJ, the right hand page is devoted to a structured plan for the upcoming 24 hours, and includes activity scheduling.^{17,42} 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.

5.0 Procedures Involved

- 5.1 Study Design: 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 comprises 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 Greene⁴³ and Li, Marquart, and Zercher.⁴⁴ In this integrative process, convergence across different data sources will be documented, and divergence will be examined further to elucidate deeper understandings.^{45,46} 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. 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. Outside of group sessions, Wayside Staff will make the iPads available for this same purpose. During the screening interview, we will provide some information about how to use the iPads. 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.

The study is being conducted at Wayside Women’s Treatment Center in St. Louis Park, MN.

Wayside staff participate in many aspects of study implementation. Wayside staff assist with recruitment, 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. Therefore, in addition to existing study activities, we also wish to survey the Wayside staff. The purpose of the survey will be to ascertain our operations and whether we can do anything to improve study logistics and implementation. We want to make sure Wayside staff feel considered and appreciated.

In addition, Wayside counselors have residents who participate in study activities. These residents likely describe to their counselors how the group is going for them and what it is like to be in the study. We would like to capture the counselor’s perceptions of how the study is going for their clients.

We will administer this survey via email link. The clinical director at Wayside will send the survey out to all staff members using email.

We are requesting waiver of documentation of consent for the staff only. Staff can choose whether or not to answer the questions, but we will not be documenting their consent anywhere. Our rationale for this request is that 1. We will provide information with all elements of consent disclosure, this text will be included in the body of the email sent to staff (the text is included as an ethos attachment), 2. The questions are minimal risk.

We will have a lottery and will give out four \$25 Target gift cards to four people who complete the survey and who choose to provide their email address. Providing the email address is optional but necessary for being in the pool to win a Target gift card.

Attached to ethos, please find the questions we will ask in the survey. The survey is brief and asks 14 questions. Sample questions include: Are you okay with continuing to assist with the Positive Peer Journaling study? What are some things we can do to make this experience better for you? Please share any feedback about the journaling practice that you have received from participants or others.

- 5.2 Study Procedures: The purpose of this study is to further develop PPJ, test its acceptability and feasibility, and write a treatment manual using an iterative process of testing, feedback, and revision. We will focus on the logistics of treatment delivery and research feasibility including recruitment, subject remuneration, instructions for the intervention, therapist scripts, group processes, and data collection. We will focus on feasibility, acceptability, and potential impact. These purposes govern study procedures.

Procedures. There are three phases to this intervention: the Group Phase (2-3 50- to 60-minute groups meeting each week for 3 weeks), the Independent Practice Phase (2 week duration after the group terminates in which participants practice PPJ 2-7 times per week), and 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 participant’s opinion of relevance to recovery in rural communities. Participants continue with treatment as usual during PPJ study activities. We will begin with one set of 3-5 women, make any revisions (including IRB amendments) and then begin again with a second set of 3-5 women. We will repeat that process at least one more time. See Figure 2 below for a description of the three phases which are described further in the text after the diagram.

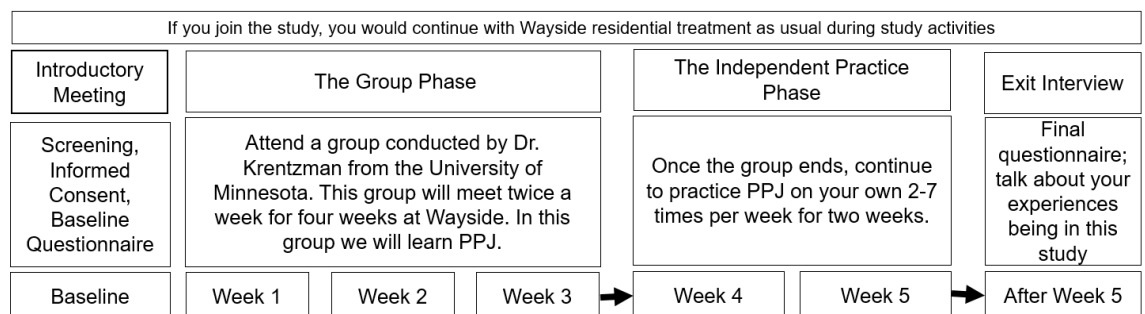


Figure 2. Study Flow Diagram

The Group Phase. Three consecutive small groups of 3-5 residents at a substance use disorder treatment program (specifically, the Wayside Recovery Center Women’s Treatment Center; see section 23.1 below for a detailed description of the study site) will be recruited and will meet for 50- to 60- minute group sessions 2-3 times per week for 3 weeks to learn PPJ.

The optimal number of group meetings needed to teach and learn PPJ will be determined by this intervention development process (e.g., we may ultimately determine that 3 weeks is sufficient for this phase and if so we will make an IRB amendment or we may determine that the groups should meet 3 times per week). PI Krentzman will conduct these intervention therapy groups. The primary aim of the groups is to teach the elements of PPJ. Groups will be audio recorded to aid treatment manual development. Audio recorded sessions also serve as qualitative data for analysis. 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 Wayside 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 Amy Krentzman, primary investigator, who would provide supervision and instruction in such an event. Wayside staff or research staff will also practice PPJ. Please note the study protocol has already stated that Research Assistants RAs will be involved in all aspects of the research. Journals and pens will be provided by the study to the study participants. Notebooks or paper for taking notes may also be provided. Journals will have pre-printed category headings listed on the pages (see the figure, above). 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. An additional journal will be provided if the original journal is lost or stolen during the group sessions. An additional journal will be offered to each participant who attends an Exit Interview.

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 Wayside 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 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 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.*

Also, one objective of the current study is to ascertain how many sessions will be required for this content. For the first group, we will use 2 sessions per week for 4 weeks. For the second group, we will also use 8 sessions but over 3 weeks instead of 4 weeks. 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
Week 1, Session 1	Ice breaker, establish group rules, describe rationale for PPJ 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 Homework: Continue to practice TGT exercise
Week 1, Session 2	Debrief: How did homework go? Practice TGT exercise Introduce gratitude list Provide tips for success Practice gratitude list Sharing about the exercise Introduce “Wishes for Others” list Sharing about the exercise Homework: Continue to practice TGT exercise and gratitude list exercise
Week 2, Session 3	Debrief: How did homework go? Practice TGT exercise, gratitude exercise, and wishes for others (WFO) WFO, “advanced moves”: find someone in your “good things” and “bad things” 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. Provide tips for success Sharing about the exercise Introduction to the right hand side of the page, discussion of each life area. Homework: Continue to practice what we have learned so far.

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Week and Session #	Session Content
Week 2, Session 4	<p>Debrief: How did homework go?</p> <p>Practice TGT, gratitude list, what did not go well, and WFO</p> <p>Provide tips for success</p> <p>Sharing about the exercise</p> <p>Rank order each life area. Write about what makes your top life area valuable and meaningful to you.</p> <p>Write about values for this life area.</p> <p>Teach how to identify a SMART goal for each valued life area</p> <p>Generate a SMART goal for three life areas, one at a time</p> <p>Homework: Continue to practice what we learned so far.</p>
Week 3, Session 5	<p>Debrief: How did homework go?</p> <p>Practice left and right sides of the page</p> <p>Have participants choose other life areas important to them</p> <p>Write about values, develop SMART goals.</p> <p>Homework: Continue to practice left hand and right hand side of the page</p>
Week 3, Session 6	<p>Debrief: How did homework go?</p> <p>Practice left hand and right side of the page</p> <p>Choose more valued life areas</p> <p>Write about values for this life area</p> <p>Generate SMART goals for each valued life area</p> <p>Practice right hand side of the page</p> <p>Homework: Continue to practice left hand and right hand side of the page</p>
Week 4, Session 7	<p>Debrief: How did homework go?</p> <p>Practice left and right hand side of the page</p> <p>Choose more valued life areas</p> <p>Write about values for this life area</p> <p>Generate SMART goals for each valued life area</p> <p>Practice right hand side of the page</p> <p>Homework: Continue to practice left hand and right hand side of the page.</p> <p>Homework: Each One Teach One: Find a person supportive of your recovery. Teach them the journaling practice. Journal alongside them. Share content you wish to with each other.</p>
Week 4, Session 8	<p>Debrief: How did the Each One Teach One and homework go?</p> <p>Practice left hand side of the page and right hand side of the page</p> <p>Sharing about the journaling practice</p> <p>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.</p> <p>Homework: Move on to The Independent Practice portion of the study where PPJ continues 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.

When we talk about recovery as an important life area, we will present to the group the research that has shown that mutual aid (for example, Alcoholics Anonymous) meeting *involvement* has been more strongly associated with abstinence than mutual aid *attendance*. We will describe small action items that can improve mutual aid involvement, such as helping to set up the chairs or greeting the newcomer. In the questionnaires, we will determine whether individuals have enacted these action items (see Hypothesized Mediators in the Measures section, below) if they have attended a mutual aid meeting in the past 24 hours.

If we don't have time to use the iPads to capture journal entries completed during group, participants might be asked to borrow the iPads from Wayside staff later in the day 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.

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.

The 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 2 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 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 and any potential impact or downsides of PPJ. This interview will also involve administration of the final quantitative questionnaire that we are calling the “end of group and independent practice phase” questionnaire, administered via Qualtrics and iPads (see pdf attached to ethos). 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 telephone or in writing through email.

Data Capture. Participants 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 iPads during group and will be able to continue to use study-issued iPads to continue this practice during The Independent Practice Phase. After uploading the image of their journal, participants will answer psychometric questionnaires in Qualtrics (see the question items checked under the column heading, “At Every PPJ Qualtrics Upload,” in Table 2 below.) Study iPads will be physically secured when not at use in a staffed office/supervised cabinet at Wayside. Participants will be asked to complete their journal entries right before they upload them to Qualtrics.

Please note we will thank Wayside staff members by citing Wayside and individual staff names in the acknowledgments section of academic posters and manuscripts that result from these data. We may make periodic presentations to Wayside staff about study observations and findings throughout the study period. When appropriate, we will offer CEUs for Social Workers to Wayside staff for their attendance at these presentations.

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. All surveys, scripts, and participant-facing data collection forms are uploaded to ETHOS. Specifically, three pdfs are uploaded to ETHOS that contain all of the Qualtrics questionnaire items including all Qualtrics items from Table 2: “PPJ_Baseline Survey, PPJ_after_Group_and_Independent_Practice_Phases, and PPJ_After_Each_Upload Survey.

Please note: in the June 2019 protocol change, we are making some small changes to our assessment protocol to reduce response burden on participants as follows: 1) we are removing the Gratitude Adjectives Checklist items from the PANAS. These covary at high levels with the Trait Gratitude measure so they are not necessary; 2) We are removing the Life Orientation Test from the every upload assessment. Updated versions of the three surveys will be uploaded to ethos.

Table 2. Schedule of Assessments.

	How long does it take to complete each of these measures ?	Baseline	At Every PPJ Qualtrics upload	Asked or Tallied after Group Phase Ends	Asked or Tallied after Independent Practice Phase Ends	Final Study Activity
Baseline characteristics						
Sociodemographics	3 minutes	X				
Hospital Anxiety and Depression Scale	3 minutes	X		X	X	
10-item SIP-AD, addiction consequences	5 minutes	X				
Perceived Stress Scale	2 minutes	X		X	X	
World Health Organization Wellbeing Index	1 minute	X		X	X	
Satisfaction with Life	1 minute	X	X	X	X	
Recovery Capital	2 minutes	X		X	X	
Commitment to Sobriety (full scale)	2 minutes	X		X	X	
Life Orientation Test (optimism)	2 minutes	X		X	X	
Trait gratitude	2 minutes	X		X	X	
Reward probability index	2 minutes	X		X	X	
AA Affiliation Scale	2 minutes	X				
Demoralization Scale	2 minutes	X		X	X	
Exposure to trauma	1 minute	X				
Using Medication Assisted Treatment?	½ minute	X				
Legal issues?	½ minute	X				
Satisfaction with treatment	2 minutes			X	X	
Social Desirability Scale	4 minutes	X				
Open ended questions: history living in / plans to return to rural areas/small towns, 12-step experience including experience working the 4, 5, and 10 th steps. What have you already heard about this study?	3 minutes	X				
Hypothesized Mediators						
Positive and Negative Affect Schedule, including three items comprising the serenity subscale (calm, relaxed, at ease)	2 minutes	X	X	X	X	
Abstinence Self Efficacy Question (single item)	1 minute	X	X	X	X	
Commitment to Sobriety (single item)	2 minutes		X			

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	How long does it take to complete each of these measures ?	Baseline	At Every PPJ Qualtrics upload	Asked or Talled after Group Phase Ends	Asked or Talled after Independent Practice Phase Ends	Final Study Activity
Alcohol craving (single item)	½ minute	X	X	X	X	
Drug craving (single item)	½ minute	X	X	X	X	
Satisfaction with Recovery (single item)	½ minute	X	X	X	X	
Individual items to assess specific impact of PPJ journaling practice	3 minutes	X	X	X	X	
Behavioral activation to increase depth of involvement in mutual aid meetings	2 minutes	X	X	X	X	
Effort, Feasibility, and Acceptability						
# of Qualtrics surveys completed				X	X	
Ease, helpfulness, satisfaction, effort	2 minutes		X	X	X	
# group sessions attended				X		
# homework assignments completed				X		
# journal entries completed ¹				X	X	
Eligibility rate and consent rate						X
Open Ended Survey Question						
What are your thoughts about Positive Peer Journaling (PPJ) so far?	2 minutes			X	X	
Outcomes						
Recurrence of Substance Use				X	X	
Treatment Retention at Wayside center				X	X	
Qualitative Exit Interview	30 minutes					X

Baseline characteristics.

- Sociodemographics

Exposure to trauma. Women 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.⁴⁷ 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

¹ The number of journal entries completed will be counted using the iPad entries and it will also be counted by Research Staff examination of the written journals or by asking participants to examine their own journals. We will count the number of journal entries and the dates journal entries will be made. We will do this because participants create a new journal entry for the iPad uploads, but in addition to these, they also make new journal entries that are not captured in the iPad uploads. Therefore, if we or they manually count the paper journal entries, we should get a more accurate count of participation than if we count only the journal entries that are captured using the iPads.

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. Wayside 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 Wayside. 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 Wayside staff.

-
- Legal involvement. Women 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 or criminal court case?”
- Medication Assisted Treatment (MAT). Women with severe addiction histories are often prescribed specific medications to reduce substance use and cravings. Therefore, we will add two items to determine if women in our sample are using MAT to support their recovery. For the specific item, see the baseline questionnaire attached to ethos.
- Symptoms of anxiety and depression will be assessed using the Hospital Anxiety and Depression Scale.⁴⁸
- 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).⁴⁹
- Perception of personal stress will be assessed by the Perceived Stress Scale.⁵⁰
- Participant’s positive feelings and overall sense of well-being will be assessed using the WHO-5 Well-being Index.⁵¹
- Satisfaction in Life will be assessed with the Satisfaction with Life Scale.⁵²
- A participant’s resources related to recovery will be assessed using the Brief Assessment of Recovery Capital.⁵³
- Motivation to remain abstinent will be assessed by the Commitment to Sobriety Scale.⁵⁴
- Participant’s optimism will be assessed using the Life Orientation Test – Revised.^{55,56}
- An individual’s disposition toward gratitude will be assessed with the GQ-6 Gratitude Scale.⁵⁷
- Environmental Reward will be assessed with the Reward Probability Index.⁵⁸

- 12 step affiliation will be assessed via the AA affiliation scale⁵⁹
- Demoralization will be assessed via The Demoralization Scale.⁶⁰ The feeling of demoralization has been shown to decrease with psychotherapy.
- Satisfaction with treatment at Wayside will be assessed via a treatment satisfaction scale.⁶¹ In previous research, participants who received behavioral activation treatment for substance use disorders had higher treatment satisfaction than individuals in the control group. We will include this instrument to pilot test it since the current study has no control group.
- A participant’s concern with social approval will be assessed with the Marlow-Crowne Social Desirability Scale.⁶²
- At baseline we will ask participants about their histories living in rural areas and plans to return to rural communities, if relevant. We will ask them to tell us the places they have lived to determine if they have lived in rural areas or small towns, defined as communities with census of less than 10,500. We will ask about their 12-step participation, especially if they have worked the 4, 5, and 10th steps which are relevant for life review. We will ask if they currently do a 10th step daily life review and if so, what form it takes. We will ask what they already know about this research study (counselors might have mentioned things about the study and the groups subsequent to the first group might have heard about the study). These will be a qualitative open-ended questions.

Hypothesized mediators.

- A participant’s current feelings of gratitude (measured through individual items assessing thankfulness, gratefulness, and appreciativeness) will be assessed with the Gratitude Adjectives Checklist.³⁵
- Affect will be assessed with the Positive and Negative Affect Schedule.⁶³
- Self-confidence in a participant’s ability to abstain from addictive substances will be assessed by the Abstinence Self Efficacy Scale Question: “I am confident in my ability to abstain from drugs and alcohol”.⁶⁴
- Commitment to sobriety (single item) “I am totally committed to staying off of alcohol/drugs”
- 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”
- We developed several single items to assess change that is directly related to the activities of the journaling practice. These items are now included in the updated versions of the Qualtrics surveys uploaded to ethos. We ask, “in the past 24 hours...something good happened to me, I thought about the needs of other people, I took a step towards one of my goals, I took time to do something which made me happy, I expressed gratitude about something in my life, I did something to help another person in recovery, I found good ways to spend my time, I had unpleasant experiences (reverse coded), I felt able to get things done, and I had the opportunity to socialize with people. Some of these items are items from the environmental reward instrument⁵⁸ that we are using, or were inspired by items from this instrument.
- We ask whether the person attended a mutual aid group in the past 24 hours (such as Alcoholics Anonymous).
- If they attended a mutual aid meeting, they would then check all that apply in a list of items designed to capture depth of involvement in mutual aid. Previous research has shown that depth of involvement is a stronger predictor of lower alcohol use than attendance.⁶⁵ Here are the items they would be able to check: “At that mutual aid meeting (that I attended in the past 24 hours), I did the following: put away chairs/set up chairs, spoke at the meeting, spoke to my sponsor (if I have one), read program literature out loud during the meeting, helped make coffee, helped a newcomer, shared during the meeting, reached out to a member for help, reached out to welcome someone new, helped to plan or run the meeting, announced my length of sobriety at the meeting, celebrated my recovery birthday, talked to someone after the meeting, arrived early, arrived on time, stayed after the meeting, sat in the front or towards the front, stayed until the end of the meeting, took steps to get a sponsor (if I don’t already have one), reached out to someone who is struggling, cleaned up after the meeting, helped to set up the meeting, other.”

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 Wayside site
- Consent rate: Number consented/number screened

Open ended survey question.

- What thoughts would you like to share with us about positive peer journaling, if any?

Outcomes.

- Recurrence of substance use.
- Retention of treatment in Wayside treatment center
- Wayside reason for leaving

Recurrence of substance use and treatment retention will be assessed via Wayside treatment record. Research staff will not have direct access to the Wayside treatment record. A Wayside 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 Wayside treatment record. Recurrence of substance use is assessed at Wayside by positive urine analyses (UAs) and other drug screens as well as resident self-report. At this meeting, research staff will have a 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 Wayside staff into a de-identified database (e.g. excel or SPSS or google drive).

Dr. Amy Krentzman, the lead investigator, will keep a log throughout the study, qualitatively recording observations, especially after each class session.

Analysis Plan. The intervention will be repeatedly modified and the sample size too small to conduct quantitative statistical analyses, however, some descriptive data will be summed as follows.

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. We will use this information to inform intervention modifications.

Secondary measures: outcomes and mediators. We will compare rates of treatment retention and recurrence of substance use to the general rates reported by Wayside. 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 designs⁶⁶ 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.¹⁵ Here, the researcher examines transcripts of texts and identify key themes and how themes relate to one another. These data will inform intervention development and study implementation procedures.

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) (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. This will take place in a quiet and private setting after screening and informed consent. 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. During the independent practice phase, study iPads will be kept in a staffed or locked office at the Wayside residence; participants will ask staff for access at appointed hours (there will be appointed hours scheduled every day, 7 days a week) and will photograph their journal pages and answer survey questions using that iPad. The iPad will access the internet via existing Wayside wireless service.

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

- Present PPJ to clinical staff at Wayside to gain setting-based insights and situate the intervention successfully in context.
- Train Wayside 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 meeting with study staff, providing study fliers and the informed consent document to interested persons. Wayside staff will take no further action if the prospect is not interested. Wayside staff will also sit in on group sessions, and lend out the iPads.
- Work with U of M (Office of Measurement Services) Qualtrics survey developer to use Qualtrics to capture data.
- Teach PPJ to a small group of 3-5 clients.
- Assess feasibility, acceptability, and 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 5.1.
- Assess feasibility and acceptability of The Group Phase and The Independent Practice Phase.
- Determine optimal number of group sessions and optimal length of group sessions to adequately teach PPJ.
- Determine script for describing steps of PPJ, e.g., instructions for the “Three Good Things” gratitude practice, instructions for the gratitude list practice, and all other elements of the treatment intervention. See Table 1 for an outline of what will be covered in each session and the attachment to ethos for a more detailed description.

- Conduct qualitative exit interviews to ascertain participants’ subjective experiences of the intervention, logistics of delivery, relevance to recovery in rural communities, and feasibility and acceptability of the intervention. The final quantitative Qualtrics survey will also be administered at this meeting.
- Study and refine recruitment processes, retention ability, functioning of Qualtrics surveys, and feedback about feasibility and acceptability. Create IRB amendments as needed.
- Revise PPJ and study procedures based on data acquired, test PPJ again with a second group of 3-5 clients.
- Repeat process one final time with a small group of 3-5 clients to finalize the treatment manual.
- Repeat process additional times with small groups of 3-5 clients as time and resources permit to capture as much data as possible to answer the research questions.
- Produce the treatment manual which then can be tested in a future randomized controlled trial.

5.3 Follow-Up: After The Group Phase and The Independent Practice Phase participants will be invited to participate in a qualitative exit interview with research staff. There will be no other follow-up after the exit interview. If the resident has moved out of Wayside on good terms during the course of the study, we will reach out to them at their new residence and invite them to an exit interview. We would contact the person at the forwarding information kept by Wayside when women move out and at other contact information they left with Wayside. The participant will have given informed consent for this in the informed consent document. We will meet with participants at Wayside or in their new home or at a local library or other reasonable location that offers privacy. The research study will pay for a taxi for the participant to meet us for the Exit Interview. Participants will also be encouraged to call us to schedule the Exit Interview.

If participants leave Wayside 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 Wayside for the independent practice phase. Any smartphone 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 Wayside.

- 5.4 Individually Identifiable Health Information: Research study staff will meet with Wayside 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 Wayside 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. To facilitate this work, study staff will use a password protected file linking participants’ real names with study IDs (codenames/numbers).

[Please note: we called the IRB to consult on the question of whether this information represents PHI. I was advised that HIPCO will be brought on board as an ancillary reviewer for this study to make the determination of whether this study involves PHI. In the meantime, we have completed the University’s Privacy Office online application and attached the pdf entitled “HIPCO Survey” under “other attachments” under question #3 in ETHOS.]

6.0 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.

Qualitative data will be stored in several formats. Audio recordings of group sessions and of exit interviews will be stored only on the secure U of M School of Social Work Shared Drive server. Uploaded pictures of PPJ entries will be shared on this same server. Transcripts of the audio recorded sessions will also be uploaded here and will be de-identified before qualitative data analysis. 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 (datagain.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.

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 under 5.2 of this protocol. We will also store jpg files representing the snapshots of the uploaded PPJs.

6.3 Release/Sharing: N/A

7.0 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. 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 and will publish study findings in academic journals. We will also make a presentation of findings to Wayside staff when the study is over and throughout the study, as requested by Wayside.

8.0 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: Up to 8 group sessions over 3 weeks, 2 weeks of independent PPJ practice (bringing

participation to 5 weeks), and a qualitative exit interview to take place as soon as possible at the 6 week mark but perhaps up to 4 weeks later depending on scheduling and research staff availability.

- The duration anticipated to enroll all study participants: Enrollment will be rolling during this iterative process, we are planning for this study to last approximately 9 months. Typically, we plan to screen and consent and enroll participants during the week before group starts.
- The duration anticipated to complete all study procedures and data analysis: Including manuscript production and publication, approximately three years.

9.0 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 2 weeks sustained abstinence, 5) completed first 2 weeks of treatment at Wayside (approximately 2 weeks), a residential substance use disorder treatment program and the recruitment site, 6) priority will go to participants who are from or moving back to a rural area or small town defined as a population less than 10,500, 7) agree to be audio recorded in group meetings and in individual meetings with research staff, 8) currently are clients in the Wayside residential program, 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. Priority will go to women who will be residing at Wayside for the duration of the study activities (and not moving out after one week, for example).

The women in treatment at Wayside 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. Wayside on occasion will have a 17 year old resident, 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 judgement of the research staff would prevent satisfactory participation in or completion of the study protocol.

See the attached document “PPJ inclusion exclusion questions.” This document shows how each of the inclusion/exclusion criteria will be assessed during the recruitment and screening phase of the study. This document also shows who will make the determination for each criteria (Wayside staff or Research staff) and how they will make the determination (e.g., chart review, screening activity, screening questions, the GAIN SS instrument,^{67,68} the GAIN cognitive impairment screener,⁶⁹ the UCSD Brief Assessment of Capacity to Consent (UBACC).⁷⁰ Each of these screening instruments and the screening procedures are described in detail below in section 9.3.

9.3 Screening: The screening process will proceed as follows.

1) Wayside staff will conduct chart reviews to determine items 1, 2, 4, 5, 6, 7, 9, 10 of the “PPJ Inclusion and Exclusion Questions” uploaded to Ethos. Prospective participants who meet these criteria (e.g., English speaking, resident at Wayside) will be given a study flyer (see attached), a copy of the regular informed consent document, and will have the opportunity to sign up to have an appointment with Research Staff at Wayside to continue the screening and informed consent process. Prospective participants will be encouraged to read the informed consent document before their scheduled meeting with researchers, and to bring any questions they have.

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,⁷⁰ the HIPAA Authorization form, the GAIN SS^{67,69,69} 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. In

addition, prospective participants will be asked questions about their experience growing up in, living in, or moving to or returning to, small towns or rural areas with census <10,500. 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 10th grade reading level down to 7th 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.

4) The screening interview will take place as follows:

1. Participant will have been given the study main consent form in advance by Wayside staff, ideally, 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. Participants and research staff will review the HIPAA consent document.
4. Research staff will double check the inclusion criteria that Wayside staff determined via treatment records before referral to the research team, using the “Recruitment, screening, consent, and baseline script” document to guide the questions.
5. Please note, that this study seeks to enroll women from rural areas and small towns of census less than 10,500. If women are from towns/cities, or will return to towns/cities, of greater census, then 10,500, then they will be offered the opportunity to be placed on a waiting list for admission into the study, giving women from small towns or rural areas first priority. This is stated in the screening consent form and regular consent form and will be described verbally to participants in the “Recruitment, screening, consent, and baseline script.”
6. Participants may also be placed on the waiting list if: a) they will not be at Wayside 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, Wayside counseling staff are consulted to make sure the participant is eligible (e.g., if the person is adequately stabilized psychiatrically for participation).

7. 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.
8. Research staff will administer the GAIN Cognitive Impairment Screener.⁷⁰ 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 each of the items of the GAIN SS. 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 the modified response format adapted by Wayside. Wayside uses this instrument at baseline to screen participants, so the items will have been asked of the individuals before. Wayside’s response format is 0=never, 1=in lifetime, 2= last year, 3=last month, 4=last week. 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 Wayside.” 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 Wayside 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 Wayside staff before determining final eligibility for the study.

9. The requirement of 2 weeks continuous sobriety before enrollment in the study may be waved based on clinical judgement.
10. Participant would read/review/discuss with study staff the informed consent document. Participant would read/review/discuss with study staff the HIPAA consent document.
11. Research staff would ask the participant the questions from the UBACC quiz to determine capacity to consent.⁷⁰ 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.
12. 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 sign the main informed consent document and the HIPAA consent document. Sign these forms in duplicate, provide one copy for staff, one for participant.
13. If the participant is deemed to meet all study criteria, they would move on to take the baseline assessment instrument. If they are from or going to a rural area or small town of census < 10,500, they will be informed of the day, time, and location for the first group session. They will may be placed on the wait list, depending on their

qualifications for the study and enrollment into the study at that point.

10.0 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:

Perhaps 5% of Wayside residents are furloughed from incarceration. These women are not prisoners while in residential treatment at Wayside, but if they were to leave treatment without approval, a warrant would be issued for them to return to incarceration. There are a larger percentage of Wayside residents who 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 choice 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 Wayside residents who are furloughed from incarceration 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 Wayside. 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 at Wayside, 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, in group, or via journal entries) that you are at risk for hurting yourself or others, we will inform Wayside treatment staff of this information as soon as possible.

In general, if something worries us about what you put in your journals, one on one meetings, groups, your iPad surveys, or any other contact you have with us, we will let Wayside 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 Wayside staff member that you used drugs or alcohol. Wayside 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 Wayside Staff. Telling us that you committed a crime would have the same consequences as if you told a Wayside staff member that you committed a crime. If you are on probation or parole, Wayside 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 at Wayside, we would tell Wayside staff.

Some of these things that you might tell us might have consequences related to your stay at Wayside.

In general, the Wayside Staff will not find out your answers to the iPad surveys.

11.0 Number of Participants

11.1 Number of participants to be consented will be a minimum of 9 and maximum of 35.

12.0 Recruitment Methods

12.1 Recruitment Process: Wayside counselors will inform clients who have completed 2 weeks of treatment of the possibility to participate in this research study by providing them with a study flyer and by discussing the opportunity with them. Counselors will emphasize that participation is entirely optional and that clients may choose to participate or not, and may drop out or continue with the study as they wish. Prospective participants' relationships with Wayside or the University of Minnesota will not be negatively compromised whatever choice they make, and this point will be emphasized.

Wayside staff will approach clients who appear to meet study criteria. Clients will receive the recruitment flyer, which may also be posted on bulletin boards or made available in group rooms or lounge areas. Interested clients will make an appointment with research study staff. At this appointment, prospective participants will be screened by research staff (see screening document attached). Those who meet inclusion criteria will go through the informed consent procedure and take the baseline questionnaire on the iPad. They will then be scheduled to join the first study group. Individuals who meet criteria for the waiting list would also take the baseline screening instrument.

We will recruit participants who are from rural areas of the state or who believe they will return to rural areas after treatment. As 75-100 women are served each year at Wayside from rural areas, Wayside staff anticipate we will have no problem recruiting 15 women from rural areas.

12.2 Source of Participants: All women to be enrolled in the study will be concurrently in residence, receiving SUD treatment at Wayside Women's Treatment Center. PPJ is offered in addition to SUD treatment as usual, but women may miss Wayside groups in order to instead attend PPJ groups. This decision will be made by Wayside staff.

- 12.3 Identification of Potential Participants: Wayside staff will initially make contact with potential participants. Wayside staff will be aware of the inclusion and exclusion criteria and will approach women who appear eligible. Such women, if interested, will make appointments to be screened by research staff. The research study team will not have access to clients’ Wayside treatment records. Some clients of Wayside might self-identify based on the recruitment flyer (see attached). The recruitment flyer will have instructions for the prospective participant to approach a selected staff member to make an appointment with research staff.
- 12.4 Recruitment Materials: Recruitment materials include the screening document and the recruitment flyer (copies are attached).
- 12.5 Payment: Payment will be made in the form of Target gift cards given out at baseline, during each weekly group session, at the end of the independent practice phase, and at the exit interview. 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. Participants will be compensated \$5 each time they upload PPJ using Qualtrics outside of group. This will be practiced once per week during the Group Phase to teach the skills needed for the Independent Practice Phase.

During the two-week Independent Practice Phase, participants are required to upload PPJ a minimum of 2 times per week but can upload a maximum of 7 times per week if they wish to (they will only be compensated up to 5 times). Each time they upload, they will be compensated \$5, assuming all aspects are completed (successful upload of photograph 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 for uploads that take place during group sessions.

Participants will be compensated \$15 for the exit interview. Participants will be paid a \$20 bonus for completing the baseline interview, the exit 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 \$155.

13.0 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 Wayside treatment against staff advice, 2) if the participant leaves Wayside treatment at the request of staff for breaking the rules (for example, if they instigate a physical altercation), or 3) the participant leaves Wayside treatment without discussion with staff and does not return (e.g., does not return from a pass). 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 cards they have earned. If a participant leaves treatment and the study owes the individual Target gift cards, these will be left for the individual at Wayside and/or forwarded to their home address listed in Wayside records.

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 Wayside 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 attending group, we will reach out to them once if they are still in residence in Wayside 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 group, but will then consider them to have left the study if they do not return. If the participant stops recording PPJ entries after the Group Phase, we will also ask them if they would like to leave the study. If they say they would like to leave the process stops and we will pay them any remaining Target gift cards we owe them. If they are uncertain we will warmly encourage them to continue one time. We may also ask Wayside 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 cards they have earned and we will pay out any additional Target gift cards earned upon their exit from the study.

Wayside study participants will be invited to sign a release of information naming research staff, so that if study participants call research staff by telephone, we will be able to call them back and speak to them or leave a message.

14.0 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 resident at Wayside) 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 the iPad until study staff deletes it. In this case, there is a risk that another research participant will see their journal entry. This is described as a risk on the informed consent document.

Although our sample participants will have been in treatment for a minimum of two weeks at Wayside 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 Wayside staff. In such cases, we will refer the patient to appropriate medical/psychiatric/counseling staff at the Wayside treatment center.

More specifically, individuals who indicate suicidal ideation will be referred to the Wayside staff. Wayside 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 separated and kept in a separate locked storage container or drawer. All forms that include identifying information (i.e., consent form) will not include participant codenames or numbers. This information is not available to anyone except the investigators. All data collected 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 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 Wayside staff.

A Wayside staff member will sit in on all group sessions to monitor the session and participant wellbeing, as the groups will be part of participants' overall Wayside experience. If an individual is in an amount of distress that cannot be managed by the group process, then the Wayside staff member can take the person out of group to address the issue. The Wayside 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 Wayside staff member for any reason, and any incident of this kind takes place, research study staff will go down the hall to find a Wayside staff member to assist.

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 Wayside 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 Wayside staff and make sure that reporting

procedures are followed. Wayside 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.

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: N/A. Participants will be informed that this is a test of a journal practice that involves daily life review and planning for the future as a way to support recovery.

16.0 Potential Benefits to Participants

16.1 Potential Benefits: The hypothesized benefit of the proposed study is the potential of improving quality of life 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 Wayside 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.

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.

17.0 Data Management

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

- 17.2 Power Analysis: N/A. No power analysis is needed for this pilot study that will enroll 9-35 participants (see sections 5.2 and 11.0).
- 17.3 Statistical Analysis: N/A. No hypothesis testing will be done in this pilot study designed to develop, refine, and enhance the PPJ intervention. However, descriptive statistics of the quantitative measures will be used to conduct power analyses and sample size calculations for a larger controlled trial.
- 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.

18.0 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.

A copy of the consent form will be placed in the participant’s Wayside hard-copy file. Wayside will make mention in chart notes that the client has participated in the PPJ group.

19.0 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 has been an Assistant Professor of Social Work for five years. PI Krentzman has expertise in positive psychology,^{71,72} gratitude,^{19,24} and spirituality in AUD recovery;^{65,73–75} as well as qualitative data analysis;^{19,76} quantitative data analysis;^{65,73,77} mechanisms of behavior change;⁶⁵ and the conduct of randomized control trials to test novel interventions to support AUD recovery.^{19,78} PI Krentzman will be in ongoing contact with staff at Wayside, specifically Jessie Everts, PhD, Vice President of Clinical Programs at Wayside, who is the study’s primary contact 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; Managing Personnel Data; University Information Security; Assessing Capacity to Consent to Research; Collaborative Institutional Training Initiative (CITI) Program’s Social/Behavioral or Humanist Research Investigators and Key Personnel; and Responsible Conduct of Research Core – Social and Behavioral Sciences. 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 Wayside. The meeting 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. Two copies of the informed consent document will be signed and the participant will keep one copy and study staff the other copy. In addition, participants will complete a “screening consent” document where they will obtain informed consent and give permission to be screened for this study. 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, HIPAA form, and the “codename” form, the participant’s name will not appear anywhere on other collected information which instead will be marked with a codename or number that will be listed on all data forms; 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 Wayside. 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. Now that we have added the Demoralization scale, we will also check responses to this scale and report to Wayside high responses to items #20 or #2, which are: “I would rather not be alive” and “My life seems to be pointless.” If we see scores of 3 or more (3 indicates “often”) on either of these items, we will report this to Wayside.

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

20.0 Provisions to Protect the Privacy Interests of Participants

20.1 Protecting Privacy: The consent documents and codename sheets will be the only documents that contain the participant’s name. 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. 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.

20.2 Access to Participants: The research team will not have access to Wayside records. To determine our key outcomes, recurrence of substance use or discontinuation of treatment, a Wayside staff member will sit 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 Wayside via urine testing or other drug screening. Results of these tests, if positive for substances, will be communicated to research staff at these prescribed meeting times (2, 4, and 6 weeks into the study or at other reasonable periods) and we will code this information into our de-identified data records.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: N/A

21.2 Contract Language: N/A

22.0 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 Wayside house. 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

23.0 Setting

23.1 Research Site: Four factors governed our choice of community partner. 1) Our analyses of existing study data indicated that many rural individuals migrate to more densely populated areas for substance use disorder treatment. 2) An important part of new intervention development is identification of the subpopulation with whom the intervention might be most successful. Our analyses of pilot data indicated that the journaling intervention might be more acceptable among women. 3) The earliest stages of intervention development require repeated and frequent site visits to coordinate logistics, plan, revise, and pilot the intervention. 4) A site that would be feasible given time and cost limitations would be located in the Twin Cities metro. Ideally, it would serve women from rural areas.

Therefore, our partner for the study will be Wayside Women’s Treatment Center, a residential substance use disorder treatment program in St Louis Park, MN, where 25%-33% of clients come from rural areas. Wayside Recovery Center is a private, non-profit organization treating substance use disorders since 1959. Over 300 women each year are treated at the Center for approximately 90 days followed by intensive outpatient care. Treatment elements include education groups and lectures, process group therapy, and individual therapy. The therapeutic model uses relational-cultural therapy, trauma-informed care, cognitive behavioral therapy, and motivational interviewing. PPJ is not redundant with existing aspects of the program.

The research team in coordination with Wayside staff will identify and recruit potential participants from this site. Research procedures including screening, informed consent, baseline assessment, study groups, and exit interviews will be performed on this site. We will work in close collaboration with the staff and management of Wayside Women’s Treatment Center throughout. Specifically, Wayside staff will help us with recruitment by identifying prospective participants, Wayside staff will sit in on group meetings, Wayside staff might help us get messages to participants in between group meetings or study phases. Wayside staff will keep the iPads under lock and key and distribute them to participants during the independent practice stage of this study. We will also solicit input from Wayside staff before the study begins and seek consultation on drafts of the treatment manual after the study ends.

23.2 International Research: N/A

23.3 Community Based Participatory Research: N/A

24.0 Multi-Site Research

N/A

25.0 Resources Available

25.1 Resources Available:

Time. The Agricultural Experiment Station (AES) grant that is funding this study provides PI Krentzman with one course buy out each year for 2018-2019 and 2019-2020 academic years. 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 years one and two of this study (2018-2019 and 2019-2020 when we will be writing up our results and planning next steps). 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.

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 Wayside and will be utilized if necessary via referral of the participant to Wayside 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.

26.0 References

1. Minnesota Department of Human Services. 2010 Minnesota Survey on Adult Substance Use. 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. 2015. 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*. St. Paul, MN: Minnesota Department of Health; 2011.
4. Wilkinson KP. *The Community in Rural America*. New York: Praeger; 1991.
5. McIntosh J, McKeganey N. The recovery from dependent drug use: Addicts' strategies for reducing the risk of relapse. *Drugs Educ Prev Policy*. 2000;7(2).
6. Emmons RA. *Gratitude Works!: A 21-Day Program for Creating Emotional Prosperity*. 1 edition. San Francisco: Jossey-Bass; 2013.
7. AA World Services. *Twelve Steps and Twelve Traditions*. New York: AA World Services; 1953.

8. WA World Services. *The Workaholics Anonymous Book of Recovery*. Second. Menlo Park, CA: Workaholics Anonymous World Service Organization; 2015.
9. DiClemente C. *Addiction and Change: How Addictions Develop and Addicted People Recover*. 1st ed. New York: Guilford; 2003.
10. Hendershot CS, Witkiewitz K, George WH, Marlatt GA. Relapse prevention for addictive behaviors. *Subst Abuse Treat Prev Policy*. 2011;6:17:1-17. doi:10.1186/1747-597X-6-17
11. Marlatt GA, Gordon JR. Determinants of relapse: Implications for the maintenance of behavior change. In: Davidson PO, Davidson SM, eds. *Behavioral Medicine: Changing Health Lifestyles*. New York: Brunner/Mazel; 1980:410-452.
12. Laudet AB. The Case for Considering Quality of Life in Addiction Research and Clinical Practice. *Addict Sci Clin Pract*. 2011;6(1):44-55.
13. 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
14. Kadden R. *Cognitive-Behavioral Coping Skills Therapy Manual: A Clinical Research Guide for Therapists Treating Individuals with Alcohol Abuse and Dependence*. DIANE Publishing; 1995.
15. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101.
16. 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*. 2017. doi:10.1111/add.14049
17. 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.
18. 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
19. Krentzman AR, 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
20. 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
21. AA World Services. *As Bill Sees It: The AA Way of Life*. New York: AA World Services, Inc.; 1967.
22. 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
23. 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
24. Krentzman AR. 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
25. 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
26. Akhtar M, Boniwell I. Applying positive psychology to alcohol-misusing adolescents. *Groupwork*. 2010;20(3):6-31. doi:10.1921/095182410X576831
27. Carrico AW, Gómez W, Siever MD, Discepola 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
28. 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
29. 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.
30. Lejuez CW, Hopko DR, Hopko SD. A brief behavioral activation treatment for depression: Treatment manual. *Behav Modif*. 2001;25(2):255–286.

31. 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
32. 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
33. 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
34. Fredrickson B. Gratitude, like other positive emotions, broadens and builds. In: *The Psychology of Gratitude*. 1 edition. Series in Affective Science. Oxford ; New York: Oxford University Press; 2004:145-166.
35. 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
36. Emmons RA, Stern R. Gratitude as a Psychotherapeutic Intervention. *J Clin Psychol.* 2013;69(8):846–855. doi:10.1002/jclp.22020
37. Frisch MB. Evidence-based well-being/positive psychology assessment and intervention with quality of life therapy and coaching and the Quality of Life Inventory (QOLI). *Soc Indic Res.* 2013;114(2):193–227.
38. Frisch MB, Clark MP, Rouse SV, et al. Predictive and Treatment Validity of Life Satisfaction and the Quality of Life Inventory. *Assessment.* 2005;12(1):66-78. doi:10.1177/1073191104268006
39. 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
40. 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*. Minneapolis, MN; 2018.
41. Sheldon KM, Lyubomirsky S. Achieving sustainable new happiness: Prospects, practices, and prescriptions. In: Linley A, Joseph S, eds. *Positive Psychology in Practice*. Hoboken, NJ: John Wiley & Sons; 2004:127-145.
42. 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

43. Caracelli VJ, Greene JC. Data Analysis Strategies for Mixed-Method Evaluation Designs , Data Analysis Strategies for Mixed-Method Evaluation Designs. *Educ Eval Policy Anal.* 1993;15(2):195-207. doi:10.3102/01623737015002195
44. Li S, Marquart JM, Zercher C. Conceptual Issues and Analytic Strategies in Mixed-Method Studies of Preschool Inclusion , Conceptual Issues and Analytic Strategies in Mixed-Method Studies of Preschool Inclusion. *J Early Interv.* 2000;23(2):116-132. doi:10.1177/105381510002300206
45. 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*. Thousand Oaks, CA: Sage Publications; 1979:68-86.
46. Greene JC. The generative potential of mixed methods inquiry. *Int J Res Method Educ.* 2005;28(2):207-211. doi:10.1080/01406720500256293
47. 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
48. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand.* 1983;67:361-370.
49. 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
50. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. *J Health Soc Behav.* 1983;24(4):385-396. doi:10.2307/2136404
51. Wellbeing measures in primary health care/the DEPCARE project. :45.
52. 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
53. Vilsaint CL, Kelly JF, Bergman BG, Groshkova T, Best D, White W. Development and validation of a Brief Assessment of Recovery Capital (BARC-10) for alcohol and drug use disorder. *Drug Alcohol Depend.* 2017;177:71-76. doi:10.1016/j.drugalcdep.2017.03.022
54. 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

55. Scheier MF, Carver CS. Optimism, Coping, and Health: Assessment and Implications of Generalized Outcome Expectancies. *Health Psychol.* 1985;4(3):219-247.
56. Scheier MF, Carver CS, Bridges MW. Distinguishing Optimism From Neuroticism (and Trait Anxiety, Self-Mastery, and Self-Esteem): A Reevaluation of the Life Orientation Test. :16.
57. 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
58. Carvalho JP, Gawrysiak MJ, Hellmuth JC, et al. The Reward Probability Index: Design and Validation of a Scale Measuring Access to Environmental Reward. *Behav Ther.* 2011;42(2):249-262. doi:10.1016/j.beth.2010.05.004
59. 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.
60. Kissane DW, Wein S, Love A, Lee XQ, Lee PL, Clarke DM. The Demoralization Scale: A Report of Its Development and Preliminary Validation. *J Palliat Care.* 2004;20(4):269-276.
61. 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.
62. 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
63. Watson D, Anna L, Tellegen A. Development and Validation of Brief Measures of Positive and Negative Affect: The PANAS Scales. :8.
64. Shiyko MP, Lanza ST, Tan X, Li R, Shiffman S. Using the Time-Varying Effect Model (TVEM) to Examine Dynamic Associations between Negative Affect and Self Confidence on Smoking Urges: Differences between Successful Quitters and Relapsers. *Prev Sci.* 2012;13(3):288-299. doi:10.1007/s11121-011-0264-z
65. Krentzman AR, 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

66. 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.
67. 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.
68. Dennis ML, Chan Y-F, Funk RR. Development and Validation of the GAIN Short Screener (GSS) for Internalizing, Externalizing and Substance Use Disorders and Crime/Violence Problems Among Adolescents and Adults. *Am J Addict*. 2006;15(s1):80-91. doi:10.1080/10550490601006055
69. Dennis ML, Feeney T, Titus JC. *GAIN-SS, Global Appraisal of Individual Needs--Short Screener (GAIN-SS): Administration and Scoring Manual, Version 3*. Normal, IL: Chestnut Health Systems; 2013.
70. 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
71. Krentzman AR. 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
72. Krentzman AR, Barker SL. Counselors’ perspectives of positive psychology for the treatment of addiction. *Alcohol Treat Q*. 2016;34(4):370-385.
73. Krentzman AR, Webb JR, Jester JM, Harris JI. Longitudinal relationship between forgiveness of self and forgiveness of others among individuals with alcohol use disorders. 2016.
74. Krentzman AR, Strobbe S, Harris JI, Jester JM, Robinson EAR. Decreased Drinking and Alcoholics Anonymous are Associated with Different Dimensions of Spirituality. 2016.
75. 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.
76. 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

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77. 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.
78. 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.