Title of Research Study: Journaling and Addiction Recovery

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Supported By:

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Key Information About This Research Study

This is a short summary. It will help you decide if you want to be a part of this research study. More detailed information is listed later in this form.

What is research?

The goal of research is to learn new things to help people in the future. In a research study, groups of people do the same activities and answer the same questions. That is why researchers do not usually make changes to the research plan for individual research participants. You, as an individual, may or may not be helped by being in a research study.

Why am I being invited to be in this research study?

We are inviting you to be in this research study because you are a person getting care at NUWAY.

What should I know about a research study?

- If you are eligible for the study, then being in the study is up to you.
- You can choose to not be in the study
- You can agree to be in the study and later change your mind.
- Your choice will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to study if a specific kind of journaling called "Positive Peer Journaling" (PPJ) might support recovery from substance use disorders, compared to other kinds of check-ins on your emotions and recovery.

How long will the research last?

This study will take about 9 weeks. All of the activities together will take about 20 hours.

What will I need to do to participate?

People in this study will be randomly assigned to one of two groups. Using University of Minnesota school colors, these groups are the Gold and Maroon groups. To participate you would agree to be assigned to one of the groups and the follow the instructions for your group. There are different instructions for the Gold and Maroon groups that are described later in this form.

Is there any way that being in this study could be bad for me?

There are a few risks involved with being in this study. First, it might feel uncomfortable to answer survey questions about your past substance use, your mood, history of trauma, or your satisfaction with your recovery. The questions will ask you to rate the strength of any urges you are feeling to drink or use drugs. The questions will ask you to rate the strength of any negative moods you might be feeling, such as feeling distressed or hostile. These questions will ask you about your outlook on your life right now. These things might be linked with upsetting thoughts.

Whether you are in the Gold or Maroon group, you will be getting a journal from us. In some ways, journaling might be uncomfortable at times. It might feel uncomfortable to journal about the past day if something upsetting happened.

What kinds of questions will I be asked? How long will it take for me to answer the questions? What kinds of questions might be upsetting?

This list describes the kinds of questions you will be asked and how long it should take to answer the questions.

Kinds of Questions and How Long It Will Take to Answer Them

- Things about me such as age, education, in other words, "demographics", 3 minutes
- Worries and sad feelings, 3 minutes
- History of trauma, 1 minute
- Negative consequences of substance use, 5 minutes
- My feelings about sobriety, 2 minutes
- Outlook on life, 2 minutes
- Feeling thankful, 2 minutes

- Alcoholics Anonymous, Narcotics Anonymous, or other self-help affiliation, 2 minutes
- My thoughts and behaviors, 4 minutes
- My mood, 2 minutes
- Confidence in my ability to be abstinent, 1 minute
- Commitment to being sober, 2 minutes
- Urges to drink, ½ minute
- Urges to use drugs, ½ minute
- Satisfaction with my recovery, ½ minute
- Ease, helpfulness, satisfaction, effort of being in this study, 2 minutes
- Your thoughts about study activities, 2 minutes
- Whether you are using MAT (Medication Assisted Treatment) to help with your recovery, ½ minute
- Whether you have legal concerns right now, ½ minute
- Your satisfaction with treatment at NUWAY, 2 minutes
- Exit Interview, in about 5 weeks: "What was it like for you to be in this study?" "What do you think of specific research team members and how they were doing their job?" 30-60 minutes.

How will I be asked these questions?

All study activities will take place via Zoom, email, telephone, or internet. Most questions will be asked of you by way of an electronic survey on a tablet, computer, or your own smartphone. You will use your finger on a touch screen to indicate your answers to the questions or if using a computer, you will use a keyboard. In most cases, different possible answers will be provided, such as "strongly agree" or "strongly disagree."

For the Exit Interview and Follow-Up interviews, research staff will talk with you one-on-one. Research staff will ask you questions about your experiences being in the study.

Even in the Exit Interview and Follow Up interviews, you can freely choose to answer questions, or decide you would like not to answer any questions asked. This will be entirely up to you.

Will being in this study help me in any way?

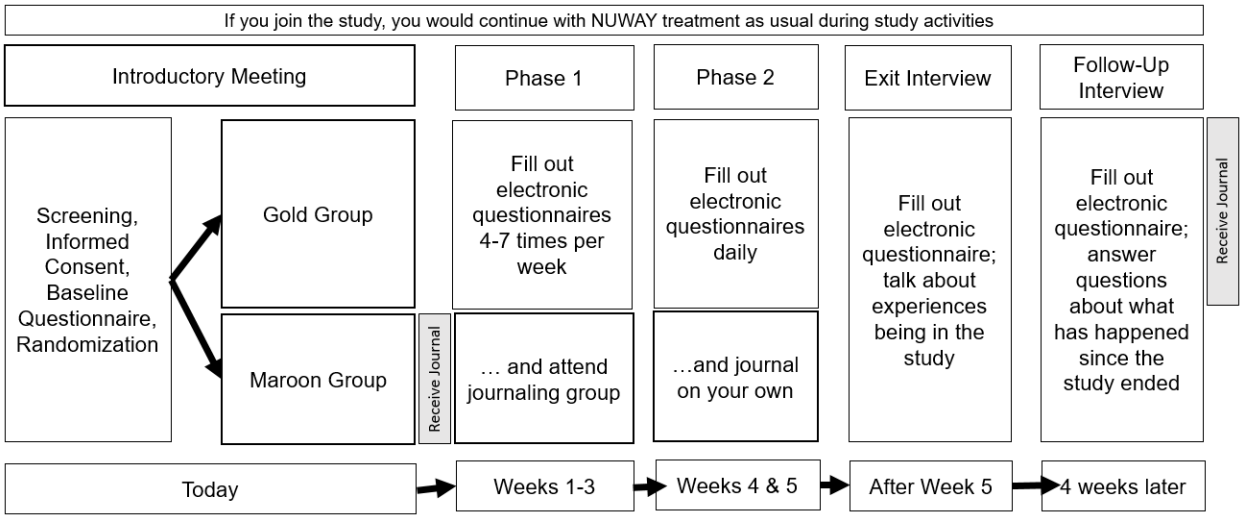
There is a chance you could benefit from being in this study. No matter which group you are assigned to, you will eventually get a journal. But the PPJ journal is only now starting to be tested. Therefore, if you are in the Gold or Maroon group, you might not benefit from being in this study.

What happens if I do not want to be in this research?

You would continue your care at NUWAY if you join this study, and you would continue your care at NUWAY if you do not want to be in this study. You do not have to be in this study.

Detailed Information About This Research Study

The following chart shows the schedule of study activities.



On some days, the electronic questionnaires will be a bit longer. This will happen today, at the end of Phase 1, at the end of Phase 2, and at the Follow-Up interview.

Activities of the Gold Group
People in the Gold group will fill out surveys we will email to you, 4-7 times a week.

Activities of the Maroon Group
People in the Maroon group will attend a journaling group via Zoom. The group will meet for about 8 hours over 2 to 2 and a half weeks. Then, people in the Maroon group will be asked to keep journaling for 2 more weeks. In this group, you will also fill out surveys we will email to you, 4-7 times a week.

For the Gold and Maroon Groups
Both groups will be invited to an Exit Interview and a Follow-Up interview.

What group will I be in?
At the end of our meeting today, we will randomly assign you to either the Gold or Maroon group, then we will go over the instructions in more detail. Like the flip of a coin, you will have 50:50 odds of being in one group or the other. Both groups are equally important and we appreciate your willingness to participate if you choose to.

How many people will be in the study?

Over time, we think about 76 people here at NUWAY will be in this research study. NUWAY is the only place where we will be doing this research now. We will invite 12-24 people at a time

into this study.

What happens if I say "*Yes, I want to be in this research*"?

- By being in the study and by signing this form, you agree to be contacted by us via email or text message. These emails and texts are unsecured, this means that they can be misdirected by us by accident (although we will work hard to avoid this). Unsecured emails and texts can be read by other people. We can't guarantee the confidentiality of texts or emails.
- Groups, the Exit, and Follow-Up interviews will be audio recorded or recorded with live captioning. You must agree to be recorded to be in this study.
- For all people in the study, we will get the following information from your NUWAY treatment record:
    - Whether, why, and when you leave NUWAY
    - Your ratings of satisfaction with NUWAY treatment
    - The results from Urine Analyses (UAs) and other tests for alcohol and drug use and any time you told NUWAY of any substance use
    - If you stop being in the study or you leave NUWAY, we would still get this information from your NUWAY treatment record.
    - Your address, email address, or phone number if it changes.
    - We are asking your permission for information from your NUWAY treatment record because we will look at any substance use and the reason you leave NUWAY as important markers of recovery. Our research study is interested in these markers of recovery.
- If you leave the study or you leave NUWAY before the end of the study, we would also invite you to talk with us about what it was like to be in the study. You can feel free to say yes or no to that invitation. We will reach you by email or text and we might also try to reach you using other contact information that you have provided to NUWAY.
- By signing this form, you give NUWAY permission to share with us your updated contact information so we can contact you to invite you to participate in this meeting.
- We will also ask you if you would be willing to share with us the names and contact information for 1 or 2 people who will always know where you are. If we have trouble reaching you, we would contact that person for your phone number or email address. By signing this form, you give us permission to contact the 1-2 people who will always know where you are.
- If you leave NUWAY and you don't hear from us, feel free to reach out to us also to schedule these meetings.
- You will get a free copy of the journal to keep.
- By being in this study, you agree not to read other people's journals.
- By being in this study, you agree to keep your Zoom camera on during study

meetings.

- We ask everyone in this study not to talk with other NUWAY clients about the study. Of course you can talk with your counselor about the study in any way that you want to.
- We will let your primary counselor know that you are in the study and we will let them know about your participation in the study. We will let them know about your participation in study activities such as your group attendance if that is part of what you will be doing and questionnaire completion.
- In this study there are times when we might want to reach out to you. For example, if we notice that you have missed some study activities, we would like to reach out to you to warmly welcome you back into the study if you want to come back.
- Please note that once you get the journal, there is always a chance someone else might read your journal.
- If you take a picture of your journal entry and save it to your device instead of the electronic survey, a copy of this picture will be retained on your device until you delete it.
- Your information (all kinds) might be used to create products or to deliver services. For example, we might publish the journal or train counselors how to teach the journal. These may be sold and/or make money for others. If this happens, there are no plans to tell you or to give any kind of payment to you or your family.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time. No one will be upset by your choice. If you choose to leave the research study, please contact us or tell a NUWAY staff member. They will tell us so that we can make note of this in our study records.

Your choice not to be in this study will not change any present or future care you receive from NUWAY. It will not change any link you have with the University of Minnesota.

We want to especially emphasize something for NUWAY clients who are furloughed from incarceration or workhouse or who are court mandated or civilly committed. This study is optional and you can feel free to say no to this study and still remain in treatment at NUWAY. Being in this study or not being in this study does not affect your legal status in any way. Return to incarceration is in no way a consequence of either deciding to be in the study or deciding not to be in the study. Please ask us if you have any questions about this.

Will it cost me anything to participate in this research study?

No. Being in this research study will not cost you anything. To avoid some telephone bills based on your plan, you will want to attend Zoom meetings using the wireless internet in the place where you are living.

Will I receive research test results?

The surveys you will take as part of this study are only for research. They have no clear meaning for health care. The researcher(s) will not share your survey responses with you.

However, you might want to know the overall results of this research. If you do, please call or write to Dr. Krentzman one year from now. She will send you any academic reports that she has finished and a summary of study results.

Can I give feedback after the study is over?

The HRPP may ask you to answer a survey that asks about your time as a research participant. You do not have to answer the survey if you do not want to. If you do choose to answer the survey, your answers will not be linked to you.

If you are not asked to answer a survey, but you want to share information, please contact the study team or the HRPP.

- See "Investigator Team Contact Information" on this form for study team contact information or "Whom do I contact if I have questions, concerns or feedback about my experience?" on your screening consent form for HRPP contact information.

Can I be removed from the research?

If you leave NUWAY because you are asked to leave NUWAY or you leave NUWAY against staff advice, you will not be able to continue to participate in this study. If you leave NUWAY on good terms during study activities, and you have access to a tablet or smartphone, you will be able to continue to participate in this study.

Research staff or NUWAY staff can remove you from the research study without your approval. Possible reasons for removal include:

- Displaying offensive images or words in Zoom meetings or other disruptive or inappropriate behavior.
- Other reasons your counselors decide on, such as they feel that being in the study is not helpful for your recovery.
- Any impairment, activity or situation that the research staff feels might prevent us from doing or finishing the study.

Will I be given anything for being in the study?

If you agree to be in this research study, you will get paid.

- Gold group: $5 each day that you complete a survey.
- Maroon group: $5 for each hour of group session that you go to and finish.
- Maroon group: $5 for each PPJ upload that you finish in between group sessions
- Please note, in the Maroon group, PPJ uploads that you do during group or immediately

after group are not paid an additional $5.

- Please note, if you fill out more than one survey a day, you will be compensated only for the first survey that you submit
- If you are invited to complete the baseline questionnaire at the end of this meeting, you will be compensated $15 for your work on the baseline questionnaire.
- $10 for the Exit Interview.
- $10 for the Follow-Up interview.
- $20 bonus if you finish the baseline interview, the Exit Interview including electronic survey, the Follow-Up interview including electronic survey, and at least 90% of all other study activities.
- Total possible payment including the bonus is $160.
- You will be paid in electronic Target gift cards.
- Electronic Target gift cards cannot be replaced if lost or stolen, but you can always contact Target directly to follow up in case of any issues.
- By being in this study, you agree not to use these cards to get alcohol or substances of abuse.

Payment you get for being in the research study is considered taxable income. If payment to one person equals or goes over $600 in any one calendar year, the University of Minnesota must report this information to the Internal Revenue Service (IRS). Research payments to people in the study that equal or go over $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☒ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data when this study is over?

Things about you like your real name will be taken off the information collected from you. Information you provide to us with your name taken off of it could be used for future research studies or given to

another researcher for future research studies without your additional informed consent.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

In general…

- Sharing things with us is just like sharing things with any NUWAY staff member.
- We would let NUWAY staff know if something has us worried about you, if you tell us you committed a crime, used or will use drugs or alcohol, have or intend to hurt yourself or someone else, and similar kinds of things.
- Things you say to us, write to us, and responses to questionnaires all count as information about you that we will study for the purposes of this research.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Signature Block for Witness:

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process