Northwell Health

Campus: Zucker Hillside Hospital

Behavioral Intervention Consent for Participation in a Research Study

Title: Project ReDUCE (Collaborative Care for Alcohol Use Disorders in the Patient-Centered Medical Home: Phase I & Phase II)

Principal Investigator: Jon Morgenstern, PhD

Sponsor: National Institute on Alcohol Abuse and Alcoholism

Introduction

You already agreed to participate in a research study and have chosen to receive a behavioral intervention.

This consent form will explain:

- the purpose of the overall study
- the purpose of behavioral interventions in the study
- information about the behavioral interventions available to you in this study
- what you will be asked to do if you decide to receive a behavioral intervention as part of this study
- the potential risks and benefits of the behavioral interventions available in this study

It will also explain that you do not have to be in this study to receive a behavioral intervention. You do not have to agree to receive a behavioral intervention to participate in the study. You should ask questions before you decide if you want to receive a behavioral intervention as part of this study. You can also ask questions at any time during the study.

Why is this research study being done?

The purpose of this research study is to develop and test a care model to treat problem drinking and alcohol use disorders in the primary care setting. You are being asked to participate in this study because routine screening and assessment conducted at your primary care clinic indicates that you have recently exceeded healthy drinking limits as outlined by the National on Alcohol Abuse and Alcoholism. A behavioral intervention is available as one treatment option for you, and this consent form will review this option so that you can determine whether you would like to pursue this option. Whether or not you choose to receive a behavioral intervention will not affect your participation in the overall study.

How many people will take part in this study?

The overall research study hopes to enroll 85 individuals.

How long will you be in this study?
The study will last for 12 weeks. All of the procedures described in the main study consent form will apply to you. If you choose to receive a behavioral intervention in this study, you will undergo an assessment at your initial appointment to evaluate your level of need for treatment. Depending on this assessment, you may be offered any of the behavioral interventions (described in the next section) that will occur either for four sessions over the 12 weeks of the study or weekly. These behavioral intervention sessions will occur in addition to the research assessments you have already agreed to in the main study consent.

What will happen in this research study?
You have already provided verbal consent to be screened for risky alcohol use as a standard of care at the 865 Northern Boulevard General Internal Medicine site, and you received a brief counseling session based on your screening results. After that counseling session, you were asked to participate in the overall research study.

If you chose to participate in the study by signing the main study consent form, you were further assessed and provided medication and behavioral treatment options based on your need. At that time, you chose to receive a behavioral intervention, and, therefore, undergoing this consent process to learn more there interventions available to you and the associated risks and benefits. If you choose to consent, a Behavioral Health Specialist (BHS; which is a licensed mental health professional) will begin the first session of the behavioral intervention you are offered.

You will be offered ONE of the below behavioral treatment options based on your level of need:

> *Motivational Enhancement Therapy* includes four, 45-minute sessions with a BHS, occurring at weeks 1, 2, 4 and 8 of the study. During this treatment, you will discuss potential reasons and ways to reduce your drinking to safe levels.
>
> OR
>
> *Modified Behavioral Self-Control Therapy* includes twelve, 45-minute session with a BHS, occurring weekly since week 1. During this treatment, you will discuss potential reasons to reduce your drinking as well as ways and skills you can use in order to do so.

At week 4, your progress in treatment will be assessed by your BHS and your health coach. You may be offered medication treatment, if it appears that an alternative may be more suitable than the behavioral intervention you have been receiving for the first 4 weeks. This treatment would involve taking naltrexone (50mg) daily. If you agree to receive medication, a medical professional (i.e., a Registered Nurse, a Nurse Practitioner, or a Medical Doctor) will meet with you separately to perform the consenting process for the medication. During that time, you will learn about the medication, including possible side effects and risks and benefits to taking it. Then, you will be able to decide if you want to consent to take the medication.

Decisions regarding additional treatment options will be made by your BHS, who is part of this study, in consultation with you and this study staff and the primary care clinical team.

What are the risks of the research study? What could go wrong?
All the risks reviewed in the main study consent form still apply to you. There are some risks associated with this study. It is possible that your condition may worsen while receiving the behavioral intervention and being in this study. If this occurs, your BHS will discuss this with you and review other treatment options. Also, the topics discussed in the therapy sessions are of a sensitive nature. You may feel uncomfortable in answering some questions or discussing issues that are distressing. If you feel uncomfortable, you may choose to refuse to discuss topics that may be difficult for you. You may refuse to any answer questions that you find hard to talk about.

What are the benefits of this research study?
The possible benefits you may experience from the procedures described in this study include a reduction in problem drinking; however, this cannot be guaranteed. We expect that the findings of this research will help your primary care team recognize and treat excessive drinking and alcohol use disorders in primary care settings in the future.

If you do not want to take part in this research study, what are your other choices?
If you do not choose to participate in the behavioral interventions of this study, you will still be able to participate in the main study. Your alternative treatment options would include medication or referral to treatment elsewhere. If you choose to receive medication, a Registered Nurse, Nurse Practitioner, or a Medical Doctor will meet with you to undergo a separate consent for medication where you will learn about the important risks and benefits associated with that treatment.

Are there any costs for being in this research study?
This research study is funded by the National Institute on Alcohol Abuse and Alcoholism. All study related visits will be given to you at no additional cost to you. If you choose to receive a behavioral intervention as a part of this study, your insurance company will not be billed, and your treatment sessions will occur at no cost to you.

Will you receive any payments for participating in this research study?
You will receive $20 for each study interview you complete, as discussed in the general consent for the study. Therefore, if you participate in all study sessions, you will be paid up to a total of $80 for your time. Payment will be made at the end of each study assessment or when you end your participation. The behavioral interventions sessions are not compensated.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

What are your rights as a research participant?
Your participation in this project as well as in receiving a behavioral intervention as part of your treatment is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study or to receive a behavioral intervention.

If you do not join the study or do not wish to receive a behavioral intervention, you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time or discontinue the behavioral treatment without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in the behavioral intervention may end without your consent. This decision may be made by a researcher, study sponsor, or the Institutional Review Board (IRB—the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue the behavioral intervention, or
- the study is stopped.

If you are withdrawn from being able to receive a behavioral intervention, any data already collected will continue to be used, and you will be offered alternative treatment in the study or referred to treatment outside of the study. You will still be monitored in the research assessment portion of the study, unless you choose to withdraw, which you are free to do at any time without any effect on your care at Northwell Health.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect information about your health and your alcohol use. We may collect the results of questionnaires and interviews. This information may include questions about the amount of alcohol you drink, how often you drink, any problems you have experienced because of drinking, and any reasons why you may have trouble accessing treatment services. If you drop out of treatment, we may ask you why so that we can learn from your experiences. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside the Northwell Health System, except as detailed below.

Investigators will share de-identified information collected from this research study with:

- study sponsor and/or its agents,
- data safety monitoring board,
- clinical staff not involved in the study who may be involved in the participant's treatment

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies, such as National Institutes of Health, US Department of Health and Human Services (DHHS), or the New York State Department of Health. If these representatives request study records, identifiers will be redacted from the documents prior to release.
- Representatives from the Northwell Health System Human Research Protection Program (a group of people that oversee research at this institution)

We will do our best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form that it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-321-2100.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study or about receiving the behavioral intervention, you may withdraw at any time or discuss alternative treatment options with study staff. If you

want us to stop collecting your health information, you can send a letter to the researcher at the following address:

Dr. Jon Morgenstern.
1010 Northern Blvd. Suite 311
Great Neck, N.Y., 11021

Your letter needs say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
We may write about this study and publish it in a scientific journal; however, you will not be named and all participants' data will be combined such that no one participant is written about. Also, a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most the website will include a summary of the results. You can search this website at any time.

Does the investigator of this study receive money if you take part?
Funding for this research study is provided by the National Institute on Alcohol Abuse and Alcoholism. The investigators on this study receive money to conduct the study but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Jon Morgenstern at (516) 837-1694. If you have questions about side effects or injury caused by research you should call Dr. Jon Morgenstern at (516) 837-1694. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 321-2100.

A signed copy of this consent form will be given to you.

REVIEW QUESTIONNAIRE TO FOLLOW

Research Review Questionnaire

After reviewing the consent form for this study please answer the following questions by circling "True" or "False". The researchers doing this study want to be sure that you know what is involved in being in this research study. This questionnaire will help them make that decision. You may ask questions of the researcher and review the consent form again at any time.

You do not have to be in this study or receive the behavioral interventions in the study in order to receive treatment for drinking.

True False

If I decide to receive a behavioral intervention, I will choose from two different options.

True False

I can withdraw from participating in this study at any time. True False

There are no risks to me from participation in this study. True False

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name