COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Text Messaging to Reduce Alcohol Relapse in Liver Transplant Patients
Principal Investigator: Benjamin Toll, Ph.D.
1 Long Wharf Drive, Box 18, New Haven CT 06511
Funding Source: Yale-New Haven Hospital, Psychological Medicine Service

Invitation to Participate and Description of Project

You are invited to take part in a research study designed to look at the feasibility and acceptability of a text-messaging intervention to reduce alcohol relapse risk in pre-transplant liver transplantation patients. You have been asked to take part because over the age of 18, have consumed alcohol within the past year, and have a diagnosis of alcohol-related liver disease (ALD). If you are eligible to participate, you would be one of 20 participants at the Liver Transplantation Clinic on the 4th floor of the Yale Physician's Building (YPB), part of Yale New-Haven Hospital. YPB is located at 800 Howard Avenue in New Haven.

The main purpose of the study is to evaluate interest and overall acceptability of a text-message based, mobile intervention for alcohol relapse in combination with an assessment of your alcohol use and related behaviors. All participants in the study will receive either standard care at the liver transplantation clinic and some will receive the text-message based intervention. In addition, all participants will receive a brief assessment of their alcohol use and medical history. All of the components will provided by trained and experienced professionals, free of charge.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Duration

Your participation in the treatment phase of the study will last 8 weeks. After the treatment period has ended, there will be one follow-up visit conducted 1-week after the last day of treatment. At 3-months post-treatment, we will review your liver transplant medical record to determine your liver transplant wait-list status. Thus, the total duration of study participation is 5 months.

Description of Procedures

This study has three parts: 1) a screening period, 2) an 8-week study intervention period and a post-study intervention follow-up, and 3) a medical chart review.

Screening Period. If you chose to participate in this study, you will be asked to complete a number of questionnaires that will ask you about your alcohol use, smoking, drug use, personality, and family history. In addition, we will ask for demographic information including age, sex, ethnic/racial identity, sexual orientation, and educational history. We will ask you to complete a brief series of tasks to assess aspects of cognition, including memory and decision-making. You will also be asked to review your medical history and will be asked to provide a urine sample. Urine samples will be used to check on alcohol and drug use. Women who are able to have children will also undergo a pregnancy test, which must be negative in order to participate. A staff member will measure your breath alcohol level. You will be asked to have a Breathalyzer test by blowing into a small tube for five seconds. This test will be repeated at the Week 4 and Week 8 appointments. This visit will take place at the Liver Transplant clinic in YPB, listed above. This part of the study will last about 1 hour and it could take up to 2 weeks for the study staff to determine if you are completely eligible to participate in the study.

Study Intervention Period. If, on the basis of your screening appointment, you are found to be eligible and you wish to participate, then you will be enrolled in the study. You will be randomly assigned (like the flip of a coin) to receive either a text message intervention or standard alcohol relapse prevention treatment in the Liver Transplant Clinic. The text message intervention will be given in conjunction with standard alcohol relapse prevention treatment.

If you are assigned to receive the text message treatment, you will be issued a cell phone, which will have a pre-paid text-messaging plan, for the duration of the study. For the first four weeks of the study, you will receive two text messages per day and will be asked to respond to both messages. After the first 4 weeks of the study, you will then receive 3 messages per week for the next 4 weeks of the study. You will be asked to respond to these messages as well.

All participants will be asked to complete questionnaires in the fourth week of treatment and immediately post-treatment at the end of week 8. We ask that you return the phone to us after the 8 week treatment period. Urine analysis will be given at both appointments to biologically confirm alcohol abstinence. You will be paid $20 for the Week 4 appointment and $30 for the Week 8 appointment. We will do our best to make sure that these appointments are as convenient as possible for you.

Follow-Up Medical Chart Review. Three months after you complete treatment, we will review your Liver Transplantation medical chart to obtain information about any other blood or urine toxicology tests you have completed, to obtain your most current Model for End-Stage Liver Disease (MELD) score, your liver transplant wait-list status, and information about any medical complications that may have occurred since the end of treatment. You will not need to come in to the Liver Transplant clinic for this chart review. This information will be collected to better understand your response to treatment and progress in the Liver Transplantation clinic.

Risks and Inconveniences

Before you decide whether you want to participate, there are some risks and inconveniences that you should know about. These include:

Ratings Scales and Assessments: These are all non-invasive and should add no risk. The major disadvantage is the time it takes to complete these questionnaires. We have done our best to make these questionnaires brief, and our past experience with these measures indicates that they are acceptable to most study participants. Careful efforts aimed at maintaining confidentiality will be made.

Benefits

You will receive a standard treatment to help with alcohol relapse. Specifically, individual psychotherapy has been shown to be an effective treatment for alcohol relapse. We expect that the results of the study will benefit science and others through increasing our knowledge about treatment for alcohol relapse in liver transplant patients.

Economic Considerations

You will receive $20 for completion of study assessments at baseline and $30 at the Week 8 follow-up assessment appointment, for a total of $50.

Treatment Alternatives/Alternatives

You may engage in clinical (i.e., non-study) treatment with the Liver Transplantation Service at Yale-New Haven Hospital. Other treatments include Alcoholics Anonymous or other psychotherapy provided outside the Liver Transplantation clinic. Study staff can advise you of the other treatment options that are available to you.

Confidentiality and Privacy

If you decide to be in this study, the researcher will have information that identifies you and your personal health. This may include information that might directly identify you, such as your name and street number, date of birth, and social security number. This information will be kept for 7 years. After that time, it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator (PI) will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study.

The information about your health that will be collected in this study includes:

Past medical or laboratory records collected by other members of the Liver Transplantation clinical team

Research records
Records about phone calls made as part of this research
Records about your study visits
Information obtained during this research regarding laboratory and other test results, including drug toxicology tests
Information obtained via questionnaires

Information about your or your health which might identify you may be used by or given to:

The U.S. Department of Health and Human Services (DHSS) agencies
Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan
Representatives of Yale University and the Human Investigation Committee, who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
The Principal Investigator (Benjamin Toll, Ph.D.)
Co-Investigators and other investigators
Study Coordinator and Members of the Research Team

If you give permission to let us give your identifiable health information to others as listed above, the information may no longer be protected by law. There is a risk that your information will be further released to others without your permission.

Records that include identifiable information will be kept in a locked research cabinet. Most of the information that is collected will be coded by number and initials and not by name. Number coded records will be stored in a locked room. Number coded records are also stored as data in computer files, and the computers storing these data are password protected and stored in a locked unit. Your name will not be publicly disclosed at any time, and the records will be strictly maintained according to current legal requirements. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Information about your study participation will ***not*** become a part of your Yale-New Haven Hospital (YNHH) medical record, which identifies you. Information about your participation in research will not be entered into your medical record. The clinical and medical treatment team at the Liver Transplantation clinic will not obtain information about the results of your urine toxicology tests or your answers on questionnaires. Kelly DeMartini, Ph.D. is the exception to this rule. As a Co-Investigator and Study Coordinator, Dr. DeMartini, who is a clinical provider of psychotherapy in the Liver Transplantation Clinic, will have access to and knowledge of your questionnaire results and toxicology results. Dr. DeMartini will not inform any medical providers about these results nor will she participate in any UNOS listing decisions for any participants in this study. Your questionnaire results and toxicology results will be strictly kept from the rest of the medical treatment team. As a result, your participation in this study will have ***no effect*** on any UNOS listing decisions made about you nor will your participation impact your treatment in the Liver Transplantation clinic in any way.

We may release identifying information in some circumstances. For example, we will disclose medical information in cases of medical necessity, or take steps (including notifying authorities) to protect you or someone else from suspected or known abuse or neglect of a child or elderly person, a risk of harm to yourself or others, or plans to damage to property.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale-New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential. You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

This authorization to use and disclose your health information collected during your participation in this study *will never expire.*

Voluntary Participation and Withdrawal

You are free to decide whether or not to participate in this study. Should you decide not to participate in this study, or later withdraw from the study, your decision will in no way affect your eligibility for alcohol abstinence services, treatment in the liver transplant clinic or any future treatment. To withdraw, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any appointments in the future. When you withdraw your permission, information that has already been gathered about you may still be used and given to others to complete the study. This may be done when it is necessary for the research to be reliable. To take away, or withdraw, your permission to use and disclose your health information that has been collected during this study, you must also follow up your phone call by sending a written notice to the principal investigator (name and address on page 1 of this form). You can choose not to answer specific questions on the pen and paper questionnaire that we ask you to complete, and this will in no way affect your study participation. The study doctors may stop your participation in the study if they believe that it is in your best interest. In addition, any significant new findings developed during the course of this research study that may relate to your willingness to continue participation will be provided to you.

If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors or with Yale-New Haven Hospital. We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the principal investigator, Benjamin Toll, Ph.D. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that

date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight. You do not waive any of your legal rights by signing this form.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

CONSENT FOR FORWARDING ADDRESS

In the event that the investigators can not contact me at my current address and phone number, I give consent for the following persons to be contacted to obtain my forwarding address and phone number: (I will tell these persons that they may be contacted)

Name:	_____	Name:	_____
Relationship:	_____	Relationship:	_____
Address:	_____	Address:	_____
	_____		_____
Phone:	_____	Phone:	_____

CONSENT TO RECONTACT

The research team may wish to contact you in the future, to clarify questions from the questionnaires or interviews, or to invite you to participate in other studies. Therefore, we ask your permission to contact you in the future. Giving your permission for the research team to contact you does not obligate you to answer any future questions, or to participate in any future research-- you always have the right to decline further participation in research. Please indicate your preference about future contact by writing your initials in one of the spaces below:

Initials: _____I give the research team permission to contact me in the future. Initials:

_____I do not give the research team permission to contact me in the future.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____

Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Benjamin Toll, Ph.D (work: 203-974-5767, cell: 203-376-6113). If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.