Smartphone Help for DWI Offenders and Their Families: A B-SMART App

AA022850

Informed Consent Form

July 2020

Research Subject Information Sheet
Randomized Trial

Sponsor: National Institute on Alcohol Abuse and Alcoholism

Protocol Title: Smartphone Help for DWI Offenders and Their Families: A B-SMART App

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Protocol No.: R44 AA022850
WIRB® Protocol #20182791

Study-Related Phone Number(s): Gill Woodall, PhD
303-565-4321

You are being asked to be in a research study. The study's goal is to test a mobile web application designed for concerned family members of DWI offenders and the offenders themselves. The application may help family members and offenders cope with the DWI experience and the Ignition Interlock Device.

Your participation will involve answering three web-based surveys. The first survey will be completed today and is called the Baseline Assessment. The survey will contain questions about your experience with the Ignition Interlock Device, alcohol consumption, and family communication. You will be asked to complete similar surveys again three months and nine months from now. After you complete today's survey, you will be assigned to either the B-SMART app or the Ignition Interlock Device (IID) information website. We ask that you use the materials provided to you, regardless of which group you are assigned to. Your information on frequency of alcohol-positive IID tests (termed "lockout events) will be acquired by the project from the New Mexico Department of Transportation at the 9-month assessment point for each DWI offender. In addition, information on any DWI re-arrest or conviction in New Mexico will be acquired by the project from the New Mexico Department of Transportation.

Although the study involves minimal risks, some of the survey questions may make you feel uncomfortable. There also is a slight risk that your confidentiality may be compromised. Project staff will take all possible precautions against accidental disclosure of your participation in this study by retaining all project information in secure and locked locations and using only secure websites.

You will be told about any new information that might change your decision to be in this study.

You may not receive a direct benefit if you agree to participate. However, people in the future may benefit from the information obtained from this research.

Your alternative is to not participate in this study.

Contact Gill Woodall, PhD at 303-565-4321 for questions, concerns or complaints about the research or if you think you have been harmed as a result of joining this research. Contact the Western Institutional Review Board (WIRB) if you have questions about your rights as a research subject, concerns, complaints or input: 1-800-562-4789. WIRB is a group of people who perform independent review of research.

The study staff may share the records generated from this research with the sponsor, regulatory agencies such as Department of Health and Human Services (DHHS) and the IRB. This information is shared so the research can be conducted and properly monitored. The people receiving this information may not be required to protect it and your information may be redisclosed without your permission. If you do not provide permission to use your information you cannot be in the study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

This consent will not end unless you decide to withdraw from the study. To withdraw, you may send written notice to the Principal Investigator at gwoodall@kleinbuendel.com or contact the Principal Investigator at 303-565-4321. Any information collected before you withdraw may still be used.

You will receive an electronic gift card equivalent to $100 for completion of the baseline survey. For completion of the 3-month follow-up survey, you will receive a $75 electronic gift card, and $50 electronic gift card for completion of the 9-month follow-up survey. If you decide not to complete any survey, you will not receive compensation for that survey.

Your decision to be in this study is voluntary. You will not be penalized or lose benefits if you decide not to participate or if you decide to stop participating. Your participation in this study will have no effect on your DWI conviction or other related legal matters.

Your part in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to changes made in the study plan;
- or for any other reason.

_____ I agree to participate in this study

_____ I do not agree to participate in this study

Clicking "I Agree" above indicates that you have read this form (or the form was read to you) and that all questions have been answered to your satisfaction, and that you are consenting to participate in this study.

Enrollment

Your Enrollment Information:

First Name: _____
Middle Initial: _____
Last Name: _____
Cell Phone Number: (___) ___-____
Email Address: _____
Driver's License Number: ___-__-___
Date of Birth: __/__/____

Are you:
Male _____
Female_____
Prefer not to answer_____

Family Member Enrollment Information:

First Name: _____
Last Name: _____
Cell Phone Number: (___) ___-____
Email Address: _____