

Connect2BWell: An Evidence-Based Screening, Brief Intervention, and Referral to
Treatment (SBIRT) Program

Consent Form

NCT04745065

Sept. 16, 2021

INFORMED CONSENT FORM

Title of Research: *Connect2BWell Research Study*

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DESCRIPTION OF THE RESEARCH AND THE RIGHTS OF PARTICIPANTS

Key Information:

- Your CHC health care provider has invited you to take part in this study.
- The purpose of the study is to test *Connect2BWell*, a new program designed to help you lead a better, healthier life by lowering your health risks related to the use of alcohol and/or other drugs.
- If you choose to take part, you may be asked to use the *Connect2BWell* online program, complete surveys, and meet with a nurse care manager.
- This will take between 1-3 hours over the next 9 months.
- Risks from this research include possible discomfort answering some questions. Also, some people who stop or cut back on their alcohol or drug use may also experience withdrawal, which can be dangerous.
- The study will have no direct benefits to you. The results of this study may help us develop programs that can help patients improve their lives and well-being.
- You will be paid up to \$110 in gift cards, over the next 9 months, for taking part in this study.
- You will be provided a copy of this consent form on the study website: connect2bwell.prochange.com.
- Taking part in this research project is up to you. You don't have to participate, and you can stop it at any time.

More details are provided below. If you have any questions about this study, please contact Maddie at connect2bwell@chc1.com, or call 860-968-7272.

- 1) **Purpose of Study:** The purpose of this research is to test *Connect2BWell*, a new program designed to help you lead a better, healthier life. The program focuses on lowering your health risks related to the use of alcohol and/or other drugs. To take part, **you must able and willing to get text messages**. You must also **have access to the Internet** using a smart phone, iPad, tablet, or computer.
- 2) **What You Are Being Asked to Do:** A total of 336 patients from Community Health Center, Inc. (CHC) will take part. You've just completed a survey that shows that you qualify for the study. You will be asked to complete four online surveys during the next 9 months. You'll be linked to the first one today, and the next ones will come in 3, 6, and 9 months from now. Those online surveys should take about 10 minutes each. You may or may not also be asked to:
 - a. Use an online program, which has 3 online sessions lasting about 15 minutes each. You'll be linked to the first session today, and the next two sessions will happen in 1 and 3 months from now. The sessions will ask questions and give you ideas and guidance matched to your needs today and again 1 and 3 months from now.
 - b. Meet with a CHC nurse care manager to talk about the results from your first online session, as well as the sessions you will be asked to complete 1 and 3 months from now. The meeting will be via telephone or video chat.
 - c. Read motivational text messages and other information the program will send you during the next 6 months

You will receive an Amazon gift card for each assessment you complete: \$20 for the survey today, \$25 at 3 months, \$30 at 6 months, and \$35 at 9 months. If you are asked to receive text messages, you will receive a \$15 gift card to cover the cost of those messages.

We will also ask you for the contact information of 2 people who would know how to reach out to you if your email address or phone number were to change. Because the study lasts for 9 months, we ask for this information in case we are unable to get in contact with you.

- 3) **Risks:** You may find that some of the questions make you uneasy and that you don't want to answer them. That's OK. You are free to stop answering questions at any time. Also, some people who stop or cut back on their alcohol or drug use may experience withdrawal, which can be dangerous. If you want to talk to someone about these issues or have questions or concerns later, please talk to your health care provider or call CHC at 860-347-6971 and ask to speak to Behavioral Health.
- 4) **Benefits:** The information gathered in this research will help us test the *Connect2BWell* program, to see if it helps lower people's health risks related to alcohol and drug use. Some patients find that taking part in this project is interesting and personally helpful.
- 5) **Costs/Payment:** There is no cost to you. This project is funded by the National Institute on Drug Abuse. Costs of all services and materials will be covered by a grant awarded to Pro-Change Behavior Systems, Inc. You will have the chance to receive up to \$110 in gift cards for participating in this study over the course of 9 months.

- 6) **Confidentiality**: Information from the survey you already completed will be shared with your CHC care team and will become a part of your medical record. Also, notes from any medical visits to discuss the results could become a part of your medical record.

However, the researchers have received a Certificate of Confidentiality from the Federal Government to protect the information collected in the follow-up surveys. This Certificate means that researchers cannot be forced to share any information without your written permission. There is one exception to the promise of confidentiality: if we see or are told that a child is being abused or neglected or that someone is planning to harm themselves or someone else, we may disclose this information to the proper authorities.

Your data from the surveys will be sent to researchers outside of CHC and Pro-Change for data analysis. Any personal information that could identify you will be removed before the data are shared.

- 7) **Injury**: In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. CHC will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at 860-347-6971 x3429

- 8) **Right to Refuse to Participate**: Taking part in this research project is voluntary and up to you. You have the right to refuse to take part in this research, and to stop taking part at any time. Your choice about taking part in this research will in no way impact your relationship with your health care provider, CHC, or Pro-Change.

- 9) **Questions/Concerns**: This research study is being conducted by CHC and Pro-Change Behavior Systems. If you have any questions or concerns about this research, please contact Lauren Bifulco, MPH at CHC at 860-968-7272, or Dr. Kerry Evers at Pro-Change at (888)-399-2117 (toll free). You can also reach out to the study's Project Manager, Maddie Dellert, at connect2bwell@chc1.com or 860-968-7272.

If you have questions or concerns about your rights as a research participant, if this study causes you any harm, or if you feel you are receiving pressure to continue in this research against your wishes, please contact the CHC Institutional Review Board at 860-347-6971 x3429.

By clicking “I give my consent” below, I acknowledge that I have read the consent form and have no further questions about taking part in this project at this time. I understand that I may ask any other questions later, that taking part is voluntary, and that I may withdraw from this project at any time.

[I give my consent]

[I do not give consent.]