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

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This clinical trial evaluated *Connect2BWell*, a theoretically-grounded, mobile-optimized substance use risk intervention. *Connect2BWell* is a computer-tailored intervention (CTI) for adult primary care patients who misuse alcohol or other drugs. This program is tailored to each patient in the following ways:

1. Their most problematic drug (i.e., the drug with the highest risk score)
2. Their risk severity (i.e., moderate or high) for their most problematic drug
3. Their readiness to quit their most problematic drug or, for prescription drugs, to use as prescribed
4. Their readiness to seek treatment if their risk severity score is in the "high" range

The *Connect2BWell* program has many different components including:

1. A CTI that delivers three online sessions with assessments, feedback, and guidance matched to each patient on the dimensions above
2. Three one-on-one SBIRT brief intervention sessions delivered in person or via telehealth by a healthcare provider trained in SBIRT and the *Connect2BWell* program
3. Clinical Dashboard that presents the patients' results and responses from the CTI, to guide "change talk" and the collaborative selection of action steps during the one-on-one intervention sessions
4. Patient Portal that allows the patient to view and track their action steps, and that presents online information and activities designed to increase key skills for reducing substance use (e.g., dealing with cravings) and increase well-being
5. Daily text messages with stage and drug-matched messages to patients, to facilitate change and increase well-being
6. PDFs with SBIRT screening and intervention session results that are sent to the patient's electronic health record (EHR)

ProChange collaborated with our partner the Community Health Center (CHC), the leading independent, non-profit healthcare provider in the state of Connecticut, providing comprehensive primary care services in medicine, dentistry, and behavioral health to more than 145,000 people. Two approaches were used to recruit patients to participate in the clinical trial: a "Universal Approach" and a "Targeted Approach," as described below.

Universal Approach: At the same time each day, the CHC Business Intelligence Department (BI) ran an automated query on CHC's electronic data warehouse to identify patients who meet specified criteria. This list of patients and corresponding information was transmitted to a Pro-Change system that automatically sent each patient an email invitation in their preferred language. Patients who did not click on the link to start the study receive additional invitations at 1, 2, and 3 days' follow-up, with a telephone call on day 4 from the CHC Project Manager to a random sample of non-respondents. After clicking on the email link and registering, patients saw a description of the study that presented many elements of informed consent and had the option to: 1) decline participation, 2) continue to the online screener, or 3) simply close out of the program. Patients who begin the online screener but did not complete it received up to five automatic reminders via email at 1, 2, 3, 5, and 6 days to return to their session to complete it.

Targeted Approach. This approach targeted individuals who hadn't completed the Connect2BWell-administered ASSIST measure before their scheduled medical appointment, and instead complete—and screened positive—on CHC's standard care SBIRT screening administered during medical visits by a medical assistant. Each weekday, the CHC BI ran an automated query on CHC's electronic data warehouse to identify patients who meet the study inclusion criteria, listed above, for the Universal Recruitment Approach AND who completed the DAST and AUDIT-C on the previous weekday and scored in the moderate- or high-risk range on either measure. The Project Manager took the list, removed any patients who declined participation in response to the original email and called the remaining at-risk patients to introduce the study and ask permission to send an email invitation with a link to the study website. The Project Manager confirmed the email address of the participants who agreed to be contacted. Each day the Project Manager sent Pro-Change a list of patients who agreed to be invited, and Pro-Change sent out the email invitations.

Patients who complete the ASSIST via Connect2BWell fell into one of six groups

- Group 1 – Screened negative for Substance Use Disorder (SUD) on the ASSIST. A report of the ASSIST results was assigned to their Primary Care Provider (PCP) through the Electronic Medical Record (EMR).
- Group 2 – Screened positive for SUD on the ASSIST but not enrolled in the study due to screening out, not completing baseline, or not consenting. A report of the patient's ASSIST results was provided to the patient's PCP through the EMR. The patient's PCP's nurse contacted the patient to deliver a brief intervention and referred them to behavioral health or specialty treatment if indicated.
- Group 3 – Screened positive for SUD on the ASSIST and assigned to the Comparison Condition. As in Group 2, a report of the patient's ASSIST results was provided to their PCP in the EMR. The PCP's nurse contacted the patient to deliver a brief intervention and referral to behavioral health or specialty treatment if indicated. These patients received an initial email notification—with up to 9 email and text reminders, 5 calls, a mailed flyer, and calls to collateral contacts—to complete additional study assessments.
- Group 4 – Screened positive for SUD on the ASSIST and assigned to the *Connect2BWell* Condition. The patient was transitioned seamlessly from the online *Connect2BWell* screening questions and consent form to the intervention portion of the session. After the session, a report of the patient's ASSIST results was assigned to the study's Nurse Care Manager (NCM) in the EMR. The study's NCM contacted the patient to deliver a brief intervention guided by the *Connect2BWell* Clinical Dashboard and made a referral to behavioral health or specialty treatment if indicated. The patient received additional *Connect2BWell* online sessions at 1 and 3 months follow-up. Each online session was followed by a Clinical Dashboard-guided one-on-one session with the study's NCM. The patient also received 6 months' of stage-matched text messages and access to a patient portal with tools and activities to support and facilitate change. These patients received an initial email notification and the same schedule of reminders as the Comparison group to complete additional study assessments.
- Group 5 – Recruited via the Targeted Approach and assigned to the Comparison Condition. These patients had already completed CHC's standard SBIRT screening and brief intervention.

- Group 6 – Recruited via the Targeted Approach and assigned to the *Connect2BWell* Condition. While these patients had already completed CHC's standard SBIRT screening and brief intervention, their ASSIST results were assigned to the study NCM in the EMR and they received the study intervention.
- Groups 3 and 5 comprise the Comparison group and groups 4 and 6 comprise the *Connect2BWell* treatment group. Both groups are prompted to complete follow-up online assessments 3, 6, and 9 months. Non-respondents received up to 9 email and text reminders, 5 calls, a mailed flyer, and calls to collateral contacts.

Analysis Plan

The analysis will use mixed effects models that account for repeated measures within participants through a random intercept for participants. Fixed effects will include group (treatment vs control), time, and time-by-group interaction. Analyses will be conducted for the primary outcome measure of change from baseline in days of use of the most problematic drug in the previous 30 days at 9 Months. Secondary outcome measures include the change from baseline in ASSIST score for most problematic drug at 9 months and the change from baseline in ASSIST score for total substance involvement at 9 months as well as the change from baseline in depression at 9 months.