University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

---

Study Title for Participants: The ENHANCE Connect Toolkit
Formal Study Title: Mobile health strategies to support longitudinal engagement in comprehensive, community-based prevention services for people who use drugs - ENHANCE (Aim 3)
Institution: University of Wisconsin - Madison
Lead Researchers:

Co-lead Researcher: Rachel Gicquelais, PhD, MPH
Departments of Medicine and Population Health Sciences
(608) 890-1837, gicquelais@wisc.edu
610 Walnut St, Madison, WI 53726

Co-lead Researcher: Ryan Westergaard, MD, PhD, MPH
Department of Medicine
(608) 265-7927, rwestergaard@wisc.edu
610 Walnut St, Madison, WI 53726

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

People who use drugs are at risk for overdose. This project is trying to learn more about the ways phone and internet harm reduction tools can help reduce risk of overdose for people who struggle to access in-person harm reduction services. Harm reduction services include naloxone, safer drug use supplies, and other services provided by programs like syringe services programs (also called a needle exchange). We invite you to take part in this research study because you use drugs but have not recently used in-person harm reduction services. This means you may benefit from this project by gaining access to a smart phone and online tools for overdose risk reduction.

What will I need to do in this study?

The research team will ask you to try using several phone-based and online harm reduction tools. This includes access to the Vivent Health Online Depot, where you can order free safer use supplies, an overdose response hotline called SafeSpot, and an app called Connections. The Connections app includes discussion boards, educational content, goal setting, journaling, and resource guides about substance use. You will be provided with a smart phone and asked to learn about and try using these tools, and then you will be asked about your experiences on a

monthly basis. In total, you will be asked to complete seven surveys and may also be invited to complete an interview after completing the intervention.

We expect that you will be in this research study for at least six months but up to nine

For Peer Mentor Participants Only: In addition to standard research activities listed above, Peer Mentors will provide additional social support on the Connections App. Peer mentors will curate educational and supportive posts for the discussion boards, attend Peer Meetings, and support Pilot Participants in their goal setting activities.

What are some reasons I might – or might not – want to be in this study?
You may want to be in this study if you are:

- Comfortable having researchers ask questions about your mental health, drug use, and harm reduction strategies.
- Interested in phone apps and internet tools to reduce overdose risk
- Willing to participate in the study for at least six months
- Interested in contributing to scientific knowledge

You may NOT want to be in this study if you:

- Are not interested in using phone apps or hotlines for overdose prevention
- Are uncomfortable about sharing information related to illicit activities like drug use
- May not have time to complete study activities or continue participation for several months.

Do I have to be in the study?
No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights as a patient or client. You can ask all the questions you want before you decide.

Instead of being in this research study, your choices may include going to a syringe services program in person, attending public support groups, or entering a treatment program.

<u>Detailed Information</u>
The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?
When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at 608-572-3514.
If you have concerns about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. UW Staff who are not part of the study team will work with you to address concerns and assist in resolving any complaints.

If I take part in the study, what will I do?
If you decide to enroll in the study you will be asked to use several phone and app based harm reduction tools over the next 6 - 9 months and then answer questions each month about your experiences.

Required activities for participants:

- Complete one baseline survey before starting the intervention
- Attend one Study Orientation visit, either virtually or in person
- Complete a survey about your substance use, overdose risk behaviors, and experiences with the harm reduction tools once a month
- If selected, complete one in-depth interview

Optional Activities for participants:

- Download and use an app called Connections
    - Engage with peers using app discussion boards
    - Complete weekly check ins about goals you have for yourself
    - Complete journals about your progress toward your goals
    - Review resources relevant to your goals
    - Connect with peers for additional support
- Call the SafeSpot hotline while using drugs alone
- Use the Vivent Health Online Depot to order free safer use supplies like sterile syringes, naloxone, and test strips shipped to your doorstep

Interviews. You may be offered an opportunity to complete an in-depth interview with the research team. Not all participants will be invited to do the interview. If you are selected and agree to complete an exit interview, we will collect audio recordings of you during the interview procedures to better understand your experiences, preferences, and opinions of the phone and online harm reduction tools. Recordings will not be used for purposes outside of the study or in any papers or publications. A written copy of the recordings will be made for use in the research. Written copies made from the recordings will remove any information that could identify you.

What data will be collected from me and how will it be used?

Name, age, gender identity, address, zip code, race and ethnicity, education, marital status, alcohol and drug use, types of health care you have received, mental health, and other related items will be collected as part of this study.

Database Linkage: As part of the study, the research team will also link your information to administrative databases like the Wisconsin Medicaid claims data and hospitalization registry. By "link your information to databases," we mean that we will use the information collected in this study to identify health care services you have received. The reason for doing this is to understand how people in your community use health care services and identify ways to improve the health care system for people who use drugs.

Future Research: All information that could identify you (for example, your name, date of birth, and contact information) will be removed from the research record for this study at the end of the study. After we remove all identifiers, the information you provide during the study may be used for future research, analysis, or shared with other researchers without your additional informed consent.

Collaborating with other research sites: The information collected from this study will be stored on secure servers at the other research sites and the data coordinating center at RTI International during the study. We plan to keep your data indefinitely. Your name and other contact information that would identify you will not be part of that dataset, but some elements of sensitive information may be shared (this is called a limited dataset). Having information collected from many people helps researchers identify trends and discover better ways to work with communities to improve harm reduction services. Researchers can use the stored information to research additional scientific questions.

Public access data repositories: as part of a federally funded research project, the National Institute of Health requires funded research projects to follow open access data sharing policies. The data collected as part of this research project will be made publicly available on a data repository called the National Addiction and Health Data Archive Program (NAHDAP). The data that is shared in NAHDAP will not include any personally identifying or sensitive health information (PHI).

Anticipated or Unanticipated Events

If you decide to take part in this study, certain situations may occur during the study period. Below are some common scenarios and the process that would be followed if you are in one of these situations.

- If you move, you may continue to participate in the study. Contact our study team at (608) 572-3514 to provide your new contact information.
- If you are incarcerated, no research activities can occur during the time of incarceration. You can contact the study team at (608) 572-3514 when you are released to discuss participating in the study. If you are under criminal justice supervision and are prohibited

from using internet-enabled devices, it is your responsibility to ensure that your study participation is allowable under the terms of your supervision.
- If you experience an overdose or other health emergency during the study, please seek immediate medical attention. You may continue to participate in the study if you would like.

Protected Health Information (PHI) used in this study
Protected Health Information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:
- Things you tell the researchers about your health such as a mental health diagnosis, treatment, substance use, overdose experiences, etc.
- We will also ask for your contact information and the contact information of people you know in case we have trouble reaching you.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights as a patient or client.

If you decide to leave the study, data collected prior to you withdrawing will still be used and shared with others, but the researchers will no longer be able to collect NEW information about you. Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:
- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher at rpw@medicine.wisc.edu or mailing address:

  MPI: Rachel Gicquelais, PhD, MPH
  Departments of Medicine and Population Health Sciences
  610 Walnut St., 5th Floor
  Madison, WI 53726

Will being in this study help me in any way?
Being in this study may benefit you by learning new information, gaining access to risk reduction tools you may not have otherwise had, and potentially helping you avoid overdose; however, we cannot promise this will happen. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about phone and internet harm reduction tools and their impact on people who use drugs.

What are the study risks?

- Answering questions on sensitive issues (like drug and alcohol use, mental health, etc.) in surveys may cause anxiety, distress, embarrassment, or feelings of sadness. You do not have to answer any questions that you do not want to.

- There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

- This study will enroll a small number of people. It is possible that your identity may become known to other people who are enrolled in the study. We will take steps to promote anonymity on the app and between participants, however sharing certain types of information may make it easier to identify you.

Who has access to the information collected for the research?

We have strict rules to protect your personal information and Protected Health Information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, as described in this consent form. However, we cannot promise complete confidentiality.

We will share information with individuals or organizations identified in this consent form. This includes University of Wisconsin and its representatives and affiliates, including those responsible for ensuring compliance, such as:

- Members of the research team
- Federal or state laws may also permit or require us to show information to offices and committees responsible for the oversight and funding of this research, such as the Human Research Protection Program, the National Institutes of Health, or the Food and Drug Administration
- UW-Madison Institute of Research on Poverty, who may use your information to link your Medicaid records

The study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means we will not share any information that would identify you as a participant in the study, even if the police or courts ask to look at the data we have collected. We may have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once we share your identifiable health information outside UW-Madison, the HIPAA Privacy Rule may no longer

protect it. However, we try to make sure that everyone who sees your health information keeps it confidential.

We will share information collected for this study with researchers or organizations outside UW-Madison to help us conduct the research project, including:

- Vivent Health staff who are part of the study team (Vivent Health operates a syringe services program [also called needle exchange] in Wisconsin)
- RTI International (the project's Data Coordinating Center)
- CHESS Health (the company that created and operates the Connections App)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will information from this study go in my medical record?
None of the information we collect for this study will go in your medical record.

Will my information be used in other research?
With appropriate confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you.

Participating in this study means you agree to share your information. You can change your mind later, but researchers might still use your information if they have already been shared or have been de-identified and can't be removed. If you do not want your information used for other research studies, you should not participate in this study.

We may share transcripts of interviews and survey responses with researchers at other institutions. We will remove direct identifiers about you, such as your name, date of birth and other information we think could be used to identify you. However, we cannot guarantee there is no risk you could be identified. Information in free text fields such as those in transcripts of interviews or survey responses may contain details that could be used with other available information to identify you (such as an employer name, job title or rare diagnosis).

We will share the data from this study in a database that collects information from research studies and is publicly available on a website. Anyone can use the data for any purpose in the future. This is called "open access." We will remove any personal information that could identify you (like name, birthdate, age, gender, address, and medical record number). This is called de-identified data. We believe there is a low risk that de-identified study data could be used to re-identify you. However, it's possible that data that cannot be used to identify you today could be used to identify you in the future.

Can I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- The study is stopped by the sponsor or researchers
- You do not complete the enrollment activities and we are unable to reach you for a certain period of time
- Your conduct in the study becomes inappropriate or threatening to other participants or research team members

What else do I need to know?

Will I receive anything for participating?
If you agree to take part in this research study, we will pay you for your time and effort. Activities are paid upon completion of each individual activity, which means if you do not complete the activity you will not be compensated. Not all participants will be able to complete all activities.

Study Activity	**Amount**	**# of times you can earn**	**Total Amount**
Redeemed recruitment coupons	$10 each	*Redeem up to 5 coupons if selected*	Up to $50
Baseline Survey	$50	Once	$50
Monthly Survey	$20 each	Complete 5 monthly surveys	$100 if all are completed.
Six Month Survey	$40	Once	$40
In-depth Interview	$50	*Once, if selected*	*$50, if selected*
		Total	Up to $290

You will also be provided with a smart phone with a cellular and data service plan as part of your participation in this study.

Permission to communicate by phone, text, email, or other preferred social platforms (such as Facebook Messenger).
We are requesting your email address, phone number, and other alternate methods of contact so we can reach you about your study activities. We know that the best way to reach you might change often, so we need to ask for multiple methods and use any options possible. Generally, email, text, and social media are not secure ways to communicate about your health or identifiable information. There are many ways for unauthorized users to access your information. Entering or saving any sensitive information in your phone texts or social apps can

be accessed, used, and shared by cell phone providers and third party platforms like Facebook. We discourage sending any information you want to keep private over these channels, however, by enrolling in this study you authorize the research team to use these methods of communication for exchanging study related information, which may include identifiable information or sensitive topics like drug use.

Use of Mosio
Mosio is a text service the project will use to send you information about the study, reminders for and links to research surveys, and educational content about harm reduction or substance use. Mosio and the university have an agreement that Mosio will keep your information protected, however similar to regular text messages the information exchanged this way may become available to unauthorized users like your phone company. By enrolling in this study, you authorize the research team to use Mosio for the reasons outlined above.

These channels should also never be used for emergency purposes. If you need to talk to someone immediately, please contact the research team at 608-572-3514. By agreeing to participate in this study, you are agreeing to allow us to communicate with you in your preferred method and accept the potential risks explained above.

How many people will be in this study?
We expect about 40 people will be in this research study.

Who is funding/supporting this study?
This research is being funded by the National Institutes of Health.

Agreement to participate in the research study
Please answer true or false to the following statements to assess your understanding of the study.

- My participation in this research is voluntary. If I decide not to participate, my relationship with UW Madison and Vivent Health will not be affected.
- If I choose to participate in this study, my personal health information collected as a part of the study will be shared with researchers at UW-Madison, the NIH, RTI International, and Vivent Health.
- My involvement in this study will consist of using phone and internet based harm reduction tools over the next six to nine months and answering survey questions about my experiences.
- All Vivent Health and research staff will protect my personal information as best they can, and my name will never be published with my data.

You do not have to agree to this form. If you refuse to agree, however, you cannot take part in this research study.

If you say “Yes, I agree to take part in this study” it means that:

- You have read this consent form.
- You have been told about the study procedures, risks, and benefits.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You give authorization for your protected health information to be used and shared as described in this form.
- You want to be in this study.

Do you agree to be in this study? Please click yes or no.

□ Yes, I agree to take part in this study
□ No, I do not agree