

iThrive WI – A smartphone intervention for overdose and risk and  
COVID-19 among people who use drugs

NCT05518461

8/24/2022

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

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### **Study Title for Participants:** iThrive WI

**Formal Study Title:** iThrive WI – A smartphone intervention for overdose and COVID-19 among people who use drugs

### **Lead Researchers:**

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### **Key Information**

The information in this form is to help you decide whether or not to be a part of this study. Ask questions about anything that is not clear. This research is being conducted by the University of Wisconsin-Madison in partnership with Vivent Health.

### **Why are researchers doing this study?**

This research study will examine the use of a smartphone application called Thrive4Life Connect. We want to learn if this app can help people who use drugs lower their risk of overdose and learn more about COVID-19 vaccines. The purpose of this study is to find out how well the Thrive4Life Connect app works. We invite you to take part in this study because you have injected drugs in the past.

You may find participating in this research and using Thrive4Life Connect to be beneficial for you. Thrive4Life Connect provides a way to get support from other people who use drugs. Additionally, Thrive4Life Connect has information about local resources and harm reduction strategies.

The study may also benefit other people in the future by helping us learn more about how a smartphone app can lower overdose risk for people who use drugs.

### **What will I need to do in this study?**

The research team will ask you to engage in using the Thrive4Life Connect app and complete various surveys on the app over the course of 6 months. Today's visit will last between 60 and 90 minutes. In this study, you will be provided with an iPhone SE that will be yours to keep. Phone service (unlimited data plan) will be provided during the 6 months of the study. You will complete weekly surveys for 12 weeks using your study iPhone. You will also be asked to complete additional surveys at 3 and 6 months. We expect that you will be in this research study for 6 months.

You can find more detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

### **What are some reasons I might – or might not – want to be in this study?**

<b>You may want to be in this study if you are:</b>	<b>You may NOT want to be in this study if you:</b>
<ul style="list-style-type: none"><li>• Interested in lowering your overdose risk.</li><li>• Interested in learning more about COVID-19 vaccines.</li><li>• Comfortable answering questions about drug and alcohol use, mental health, and other related topics.</li><li>• Willing to visit a participating Vivent Health location (Appleton, Eau Claire, or Milwaukee) to engage in study appointments.</li><li>• Willing to complete surveys and participate in the study for 6 months.</li><li>• Interested in contributing to scientific knowledge.</li></ul>	<ul style="list-style-type: none"><li>• Are NOT interested in lowering your overdose risk</li><li>• Are NOT interested in learning more about the COVID-19 vaccines.</li><li>• Are nervous about sharing information about drug and alcohol use, mental health, and other related topics.</li><li>• May not have time to complete study surveys for 6 months.</li></ul>

### **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. You can ask all the questions you want before you decide.

Instead of being in this research study, your choices may include:

- Getting the regular care offered to you at UW Health or Vivent Health

- Taking part in a different study, if one is available

## **Detailed Information**

The following is more detailed information about this study.

### **How is research different from health care?**

When you take part in a research study, you are helping to answer a research question. Study activities and procedures are not for your health care.

### **Who can I talk to about this study?**

Please take as much time as you need to think about if you want to participate in this study or not. If you have any questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at (608-294-7446). If you have any questions about your rights as a research subject or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

### **If I take part in the study, what will I do?**

**If you decide to participate in this research study, here are the required activities:**

Today, you will set-up your study iPhone and Thrive4Life Connect account and begin your first surveys. You will complete most study activities and surveys on your own time using your study iPhone for the next 6 months. The location where you decide to complete surveys on your own time is up to you.

***Thrive4Life Connect:*** Thrive4Life Connect is a smartphone and computer app that we will use in this research study. We will ask you to download the Thrive4Life Connect app on your study-provided iPhone and login using your pre-created account. We will ask that you use this app to respond to surveys delivered to your phone.

***Surveys:*** We will ask you to complete multiple surveys using the Thrive4Life Connect app. Surveys will collect information directly from you in the app. Surveys will be used to collect information about sensitive and potentially distressing topics such as drug and alcohol use, mental health, health care usage, and other related areas. All questions are voluntary. You are free to not answer questions you are uncomfortable with.

### ***Survey Schedule:***

- **Today:** 45-minute baseline survey and your first 10-minute daily check-in, which will ask about the most recent time you used drugs.
- **This week:** Two more daily check-ins will be available later this week.
- **Next 12 weeks:** You will be asked to do 12 weekly check-ins that involve setting goals to lower your overdose risk and learn about COVID-19 vaccines.
- **After 3 months:** 45-minute survey and three 10-minute daily check-ins.
- **After 6 months:** 45-minute survey and three 10-minute daily check-ins.

**We will collect the following information from you in this study:** Name, age, gender identity, 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.

**Private Messaging:** The study staff will send you messages in the Thrive4Life Connect app to contact you. Study staff will use these private messages to remind you when surveys open and need to be completed, send you personalized resources, and help answer any questions you may have.

**Database Linkage:** As part of the study, the research team will also link your information to databases like the Wisconsin Immunization Registry, Medicaid, and Wisconsin hospitalization, emergency medical services, and infectious disease surveillance registries. By “link your information to databases,” we mean that we will use the information collected in this study to identify and access your health care records to understand how people who inject drugs use health care resources.

## **Optional study activities**

This part of the consent form is about additional research activities that you can choose to take part in. You can still be in the study if you do not participate in these activities.

- Interactive modules about COVID-19 vaccines.
- You can share your thoughts by posting on discussion boards or using private messaging in Thrive4Life Connect. These are ways to talk with other study participants without sharing your name or seeing them. You can also use the private messaging function to talk to study team members.
- A list of online and local community resources and their contact information (E.g., Vivent Health, emergency numbers, harm reduction services, etc.).
- Logs for motivation and thoughts of gratitude.
- UW-Madison study team contact information.

The purpose of these optional activities is to provide you with access to more information and support resources to lower your overdose risk and learn more about COVID-19 vaccines. Data from these optional activities will be collected directly from your answers to surveys in Thrive4Life Connect and indirectly in the app based on your engagement with these supplemental activities.

## **Anticipated or Unanticipated Events**

If you decide to take part in this study, certain situations may occur during the 6-month study period. Below are some common scenarios and the process that would be followed if you are in one of these situations.

- If you are no longer visiting your usual Vivent Health location or if you move, you may continue to participate in the study and use Thrive4Life Connect. Contact our study team (608-294-7446) to provide your new contact information.

- If you are incarcerated, no research activities will occur during the time of incarceration. You can contact the study team (608-294-7446) 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.

### **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. In this study, we will use the following kinds of PHI:

- Results of activities completed as part of the study.
- Things you report in the surveys about your health.
- We will also ask for your contact information and the contact information of people you know in case we have trouble reaching you.
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history; your health care usage; or billing records. We will get this information from databases like the Wisconsin Immunization Registry, Medicaid, and Wisconsin hospitalization, emergency medical services, and infectious disease surveillance registries.

### **Who at UW-Madison can use my information?**

- Members of the research team
- Offices and committees responsible for the oversight and funding of this research, such as the Human Research Protection Program

### **Who outside the UW-Madison may receive my information?**

- Vivent Health staff who are part of the study team

### **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 health care 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. We will tell you about any new information that may affect your choice to stay in the research.

If you decide to leave the study, data collected prior to you fully withdrawing will still be used and shared with others, but the researchers will no longer be able to collect NEW information about you. However, if you partially withdraw (E.g., Do not complete the 12 weekly check-ins) data may continue to be collected if you begin using the Thrive4Life Connect app again and if you decide to still complete the 3-month and 6-month surveys.

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, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- 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, Rachel Gicquelais, PhD, MPH, at 701 Highland Avenue, Signe Skott Cooper Hall, Room 4257, Madison, WI 53705 or at gicquelais@wisc.edu.

### What are the study risks?

1. Information you enter into Thrive4Life Connect can be viewed by UW and Vivent Health research team members. They may monitor discussion boards and post information there. Study staff will also reach out to you via private messaging or other contact methods (texts, phone calls, social media, etc.). Information you enter into Thrive4Life Connect is not stored on the phone, but this information is stored on the Thrive4Life Connect app.
2. When you set up your Thrive4Life Connect account, you will be asked to create an account username. This username will be listed on discussion board posts and included in a list of participants that can receive private messages. To reduce the risk of being identified, we will require you to **choose a username that will NOT include any identifiable information such as your first name, last name, date of birth, address, etc.**
3. Other participants can see what you post to the discussion boards. There is a risk that other participants could identify you based on the information you provide in your discussion board posts.
4. 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.
5. The Thrive4Life Connect app allows you to share your views, opinions, photos, and personal experiences. However, you are NOT allowed to post content on the Thrive4Life Connect app that promotes racism, bigotry, hatred, nudity, or physical harm of any kind against any group or individual. If you use the app in an inappropriate or illegal manner, the research staff will delete the inappropriate content and follow up with you. If the behavior continues, the research staff may withdraw you from the study.
6. There is a risk that other study participants may send you private messages including unwanted or inappropriate content. If this happens, we ask that you report this information to the study team (608-294-7446).
7. Information from the internet and/or Thrive4Life Connect discussion boards could be wrong. However, a panel of UW staff review all information on the

app, so this risk is unlikely. We will provide tips to help you figure out whether you can trust the information you receive from these sources.

8. 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.
9. The study team may discover behavior that raises concern about harm to yourself or others. If we see anything that suggests that you or others face imminent risk of harm, we will contact appropriate parties to intervene (e.g., your care team and/or police).

### **What happens to the information collected for the research?**

We have strict rules to protect your personal information and protected health information (PHI). We limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securely on HIPAA compliant servers at the UW-Madison School of Nursing and School of Medicine and Public Health. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

This study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study.

While we have a Certificate of Confidentiality for all study data on the Thrive4Life Connect app, other activities you do on the study iPhone may NOT be covered. Therefore, we strongly recommend that you secure your iPhone with a password and fingerprint ID.

We cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program and U.S. Department of Health and Human Services.

We may also 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. WE WILL report information in the following circumstances:

- If you tell us that you are planning to harm yourself or another person.
- If you tell us something that causes us to believe that a child or vulnerable adult is being abused.



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 your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, 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.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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. The researchers are not required to release health information to you if it is not part of your medical record.

**Will I receive the results of research activities?**

Most activities done as part of a research study are only for research and have no clear meaning for health care. You will not be informed of any results or unexpected findings. The surveys in this study will ask about sensitive issues (like drug and alcohol use, mental health, etc.), which may cause anxiety, distress, embarrassment, or feelings of sadness. We are using the surveys only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider.

**Can I be removed from the research without my agreement?**

The study team can remove you from the research study without your approval.

Possible reasons for removal include:

- If you use the Thrive4Life Connect app in an inappropriate or illegal manner.
- Your health changes, and the study is no longer in your best interest.
- The study is stopped by the researchers.

**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. Please note that payment depends on the successful completion of specific Thrive4Life Connect surveys at different time points during the 6-month study period.

- You will be paid up to \$30 for completing the baseline survey and first daily check-in today.
- There is an additional \$20 available for completing two more daily check-ins during this first week.
- You can also get up to \$50 for completing the 3-month survey and three more daily check-ins.

- Another \$50 is available for completing the 6-month survey and three additional daily check-ins.

You can pick up your compensation payments at the Vivent Health location where you are today. Alternative ways to get your cash compensation may also be available depending on your situation.

We will also provide a phone and an unlimited data plan throughout the study period of 6 months, but you must complete weekly check-ins during the first 12 weeks to keep your phone service turned on. If you do not complete the 12 weekly check-ins, this situation will be considered a partial withdrawal. If your phone service is turned off, you can contact the study team at (608-294-7446) to discuss participation and turning the service back on. All surveys can be completed without phone service using Wi-Fi.

### **Permission to communicate about the study by email**

We are requesting your email address so we can help you set up an Apple ID and account on your study iPhone. If you already have an Apple ID, you may use that login information instead. If you do not have an email, study staff will help you make one. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately about a health issue, you should call 911 or contact your health care provider.

### **How many people will be in this study?**

We expect about 60 people will be in this research study nationally.

### **What will happen to my data after my participation ends?**

The UW-Madison research team will keep your data for an indefinite period of time, meaning we have no plans of ever destroying your data. Keeping data for future research is called “banking.” The banked data will be kept on HIPAA compliant secure servers at the School of Nursing and School of Medicine and Public Health at UW-Madison for use by researchers.

#### **This is what will happen with your banked data:**

- The banked data will be labeled in a way so that no one can identify which data came from you. This means that if you decide later that you do not want your data used, we will not be able to remove your data from the bank.
- We may use the data in future research projects about harm reduction, substance use, overdose prevention, or other related areas.
- Deidentified data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- Banked data will NOT be shared with you or your health care providers.

- Because the data will not include any information that can identify you, we cannot withdraw them from the bank once they have been added.

### **Informed consent comprehension quiz**

Which ONE of the following statements about this research study is TRUE?

- A. The topics of the study are overdose and COVID-19.
- B. If I choose to participate, the research team will keep all the information that I share confidential, EXCEPT if I tell them I am planning to harm myself or someone else, or that a child or elderly person is being abused.
- C. The study involves a commitment of 6 months total.
- D. All of the above are true

### **Agreement to participate in the research study**

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?**

- ☐ **Yes, I agree to take part in this study**
- ☐ **No, I do not agree**