Community-based, client-centered prevention homes to address the rural opioid epidemic

ClinicalTrials.gov registration number: NCT04268173

Informed Consent Documents

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Sponsors: National Institutes of Health: NIDA
Wisconsin Partnership Program

Grant numbers: UG3DA044826
UH3DA044826
WPP 4803

UW-Madison Health Science Institutional Review Board Approval ID: 2017-0866

Consent Form

UNIVERSITY OF WISCONSIN-MADISON

Subject CONSENT to Participate in Research and AUTHORIZATION to Use and/or Disclose Identifiable Health Information for Research

Title of the Study: Community-based, client-centered prevention homes to address the rural opioid epidemic (Prevention Navigation Intervention)

Principal Investigator:
Ryan Westergaard, MD, PhD, MPH
University of Wisconsin - Madison
Departments of Medicine & Population Health Sciences
5223 UW Medical Foundation Centennial Building
1685 Highland Avenue
Madison, WI 53705
608-265-7927
rpw@medicine.wisc.edu

INVITATION
You are invited to participate in this research study to identify health problems that can result from injecting opioid drugs such as heroin, methamphetamine, oxycodone, and other prescription pain killers. You are invited to take part because you have injected drugs in the past, and live in a rural area of Wisconsin. Approximately 540 individuals will take part in this study. If you decide to take part, your participation would last between 60 and 90 minutes during today's visit and will require two additional visits at 3 and 6 months for data collection. You might also be asked to return to this Vivent Health office one or more times in the future to get test results.

Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you by UW Health, or the services you receive from Vivent Health will not be affected in any way.

A. WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this research is to collect information from people who inject drugs in order to know how easy or hard it is for people to access certain health services that are useful for preventing infectious diseases, opioid overdose and other health problems.

B. WHAT WILL MY PARTICIPATION INVOLVE?
If you decide to participate in this research you will take part in a multi-session intervention for clients for the purposes reducing risky behaviors associated with HIV, hepatitis C, and overdoses. We will collect information from you about your medical history, your drug use, and other past behaviors that could indicate you are at risk for

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Consent Form

UNIVERSITY OF WISCONSIN-MADISON

Subject CONSENT to Participate in Research and AUTHORIZATION to Use and/or Disclose Identifiable Health Information for Research

Title of the Study: Community-based, client-centered prevention homes to address the rural opioid epidemic (Non-intervention)

Principal Investigator:
Ryan Westergaard, MD, PhD, MPH
University of Wisconsin - Madison
Departments of Medicine & Population Health Sciences
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INVITATION

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B. WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research we will collect information from you about your medical history, your drug use, and other past behaviors that could indicate you are at risk for infectious diseases. We will also ask you to get tested for HIV, hepatitis C virus (HCV) and syphilis today in this office, and up to two more times. These tests are

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part of the routine services provided by Vivent Health staff, who will also provide counseling related to the testing and discuss your results with you. You are able to have these same tests done whether or not you choose to participate in this study.

The three tests involve finger stick blood samples for rapid testing of HIV, HCV and syphilis. If any of the three rapid tests are positive, then a Vivent Health staff member will draw your blood (about 2-3 tablespoons) to be sent to the Wisconsin State Laboratory of Hygiene (WSLH) for "confirmatory tests." This means additional tests will be done to confirm whether you really have one of these infections. If we are unable to collect blood for confirmatory testing, you may be asked to come back to the office for another attempt to draw blood on a different day. Testing for a fourth infection, hepatitis B virus (HBV) will also be done at WSLH only if your blood is sent for confirmatory testing. Vivent Health staff will collect your contact information to arrange a follow-up visit to review your test results.

Research Questionnaire. As part of today's visit, you will be asked to complete a questionnaire on a tablet computer. Your answers to the questions will be automatically saved on a network computer at the University of Wisconsin in Madison, and then will be erased from the tablet computer. They will ask you questions about your health, your drug use, and types of health care you have received. The questionnaire will take approximately 20-30 minutes. You will be asked to repeat this questionnaire in 3 months and 6 months.

Sharing data and blood specimens with researchers at other institutions. This research study is part of a collaboration with scientists at other institutions, including the U.S. Centers for Disease Control and Prevention (CDC), The University of Washington, and Tulane University. It is possible that the blood collected as part of the testing for HIV and viral hepatitis will be sent to laboratories at other institutions for additional testing. A specialized testing called Global Hepatitis Outbreak and Surveillance Technology (GHOST) will be used to understand hepatitis transmission links and outbreak investigations. Results from the GHOST analysis will inform state and local health departments on how to identify outbreaks or transmission networks. If any specimens or data that we collect from you are sent outside for GHOST analysis, they will be labeled with a unique identification number, specimen type, date of collection, and preliminary test results. Since these results are for research purposes and not to determine whether you have an infectious disease, the results will not be shared with you.

We will collect the following information from you for this research study:
Age, ZIP code, county of residence, ethnicity, education, marital status, alcohol and drug use, prior HIV and Hepatitis C test results, types of health care you have received, how you are feeling, mental health, coping techniques, and other related items. In addition,

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the Wisconsin Department of Health Services requires that Vivent Health collect additional information from people when they get tested for HIV, hepatitis C or syphilis. This information includes your full name, date of birth, address, and whether you have engaged in certain types of drug use and sexual behaviors.

We will also link your information to databases like the Wisconsin Immunization Registry and Medicaid to understand how health services are utilized among people who inject drugs. If you agree to be in the study, we will ask for your permission to use this information for research purposes as well.

Incarceration. If you become incarcerated during the time you are participating in the study, we will not conduct any of the research activities while you are in jail or prison. You can resume participation in the research after you are no longer incarcerated by contacting the staff at Vivent Health or a study coordinator.

C. ARE THERE ANY BENEFITS TO ME?
Your participation may benefit other people in the future by helping us learn how to make prevention services more available to people who inject drugs.

D. WILL I BE PAID FOR MY PARTICIPATION?
You will be paid $20 for completing the survey and blood tests today, plus an additional $20 at 3 and 6 months. If you are asked to return to the office on a different date to collect blood for confirmatory testing, then you will be paid $10 for your time.

E. ARE THERE ANY COSTS?
There are no costs to you to join this study.

F. ARE THERE ANY RISKS TO ME?
The main risk of taking part in this study is that information about you may become known to someone who is not involved in performing or monitoring this study. This study involves asking questions about illegal drug use. There is a chance that someone outside of the study could find out about the answers to your questions. If that happens, this could expose you to legal risks or damage your reputation. Some people may feel uncomfortable answering questions about drug use. A breach of confidentiality could result in damage to you or your reputation, but the chances that this will happen are very small. If one of the tests for HIV, hepatitis C, hepatitis B or syphilis comes back positive, it is possible that you will feel anxious or distressed. If this happens, we will talk with you about what all the results mean and make sure that you are linked to the appropriate care and treatment. Pregnant women who abuse illegal drugs or alcohol may be reported by members of the research team to county social services under Wisconsin state law. Although this rarely happens, pregnant women found abusing drugs or alcohol to a severe degree may be placed in custody to protect the fetus. The decision to place

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someone in custody is made by county social services.

You can stop answering questions at any time of the study. Refusal to answer questions will not negatively affect any relationship you may have with Vivent Health, the University of Wisconsin-Madison, or its affiliates.

G. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

To protect your privacy, the research team will collect and maintain all of your Private Health Information on a secure, encrypted database. No one will know you are in the study except for you and the research team.

The personal health information you give us, including details about your drug use, will be stored in a separate place from any information that directly identifies you like your name, birth date and phone number. When the research team is examining the data, they will see a code number only, so that your responses to the survey cannot be directly linked to you.

If you test positive for human immunodeficiency virus (HIV) hepatitis C, hepatitis B or syphilis the Wisconsin health department will be informed of the results. The health department may contact you with resources for counseling and medical care, if you need them and want them. You may be asked about sex and/or needle-sharing partners. These are all common practices of the health department and apply to all individuals who test positive for HIV and viral hepatitis.

Certificate of Confidentiality. To help us further protect your privacy, a Certificate of Confidentiality has been obtained from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The researchers will use the certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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There are some situations when we WILL NOT keep information confidential. WE WILL report information about you the appropriate authorities 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**

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices

Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research. This research is being done as part of a collaboration with researchers in other areas of the country, and therefore some information about you may be shared with researchers at other institutions. Because the study is federally funded, federal agencies can inspect our study records**.**

- National Institutes of Health
- Centers for Disease Control and Prevention (CDC)
- Researchers at other institutions who are collaborating with the UW-Madison research team

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. When we share information from research studies with others outside the UW-Madison and its affiliates; it is not shared in a way that can directly identify an individual, but may include your Zip code.

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

H. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely remove yourself from the study at any time. You also may choose to stop taking part or skip any questions that you do not feel comfortable answering. You will be told of any new and significant findings which may affect your willingness to continue.

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If you decide not to participate in this study or if you stop while the study is underway, the health care you receive from UW Health and their affiliates will not be affected in any way.

ARE THERE ANY ALTERNATIVES?
You do not have to participate in this study to receive testing for HIV, HCV, or syphilis. The study researchers can discuss your alternatives with you.

I. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. There is no end date for its use for this research study unless you write to the person listed below that you want to stop sharing your health information. You may stop sharing your health information at any time by writing to:

Ryan Westergaard, MD, PhD, MPH
5223 UW Medical Foundation Centennial Building
1685 Highland Avenue
Madison, WI 53705

Beginning on the date you stop sharing your health information, no new information about you will be used. Any information that was shared before you stopped sharing your health information will continue to be used. If you stop sharing your information, you can no longer actively take part in this research study.

J. WHOM SHOULD I CONTACT IF I HAVE QUESTIONS?
Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Ryan P. Westergaard at 608-265-7927.

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team, contact the UW Health Patient Relations Representative at 608-263-8009.

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Informed Consent Comprehension Quiz

Which of the following statements about this research study are TRUE?

A. The topic of the study is preventing health problems and navigating services that are related to injecting drugs.

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 research team includes researchers at the University of Wisconsin-Madison, Tulane University, Massachusetts General Hospital, and University of Washington.

D. People can participate in the study if they live in a rural area and injected drugs in the past month.

E. The study involves a commitment of 6 months that will include 3 research assessments.

F. I can get tested for HIV and Hepatitis C at Vivent Health even if I don't participate in this study.

G. All of the above are true

H. None of the above are true

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AGREEMENT TO PARTICIPATE IN THIS STUDY AND PERMISSION TO USE AND/OR SHARE MY HEALTH INFORMATION

I have read this consent and authorization form. It describes the research study procedures, risks, and benefits of being in the study. It also describes what and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

_____ I do NOT wish to be contacted in the future by members of the research team about participating in future research studies.

Signature of participant for consent and authorization:

_____ _____

Signature of participant Date

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

Signature of person obtaining consent and authorization:

_____ _____

Signature of person obtaining consent and authorization Date

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infectious diseases. We will also ask you to get tested for HIV, hepatitis C virus (HCV) and syphilis today in this office, and up to two more times. These tests are part of the routine services provided by Vivent Health staff, who will also provide counseling related to the testing and discuss your results with you. You are able to have these same tests done whether or not you choose to participate in this study.

The three tests involve finger stick blood samples for rapid testing of HIV, HCV and syphilis. If any of the three rapid tests are positive, then a Vivent Health staff member will draw your blood (about 2-3 tablespoons) to be sent to the Wisconsin State Laboratory of Hygiene (WSLH) for "confirmatory tests." This means additional tests will be done to confirm whether you really have one of these infections. If we are unable to collect blood for confirmatory testing, you may be asked to come back to the office for another attempt to draw blood on a different day. Testing for a fourth infection, hepatitis B virus (HBV) will also be done at WSLH only if your blood is sent for confirmatory testing. Vivent Health staff will collect your contact information to arrange a follow-up visit to review your test results. If you test positive for HIV, HCV, HBV or syphilis infection, a Vivent Health prevention navigator will assist in linking you to a local provider.

Prevention Navigation. Based on our study design you will participate in an intervention geared towards increasing knowledge of people who inject drugs on navigating prevention and treatment services for HIV, hepatitis C, and drug overdose. You will receive these services immediately upon enrollment to the study by scheduling an intake appointment with our prevention navigator in about a week.

Prevention navigation's primary goal is to reduce HIV, hepatitis C, and overdose while addressing other issues you may face. The program offers four one-on-one sessions. The first session will focus on a risk assessment and working with you to develop a risk reduction plan. In the subsequent sessions, we will gather information on your life needs (e.g. housing, employment, substance use, etc). Our staff will work with you to prioritize these needs and develop a plan that will help you reduce risky behaviors. We will reassess needs and goals, update your risk reduction plan, and provide facilitated referrals. You will not be charged for these services, and you may terminate services at any time, in person, or by writing.

Research Questionnaire. As part of today's visit, you will be asked to complete a questionnaire on a tablet computer. Your answers to the questions will be automatically saved on a network computer at the University of Wisconsin in Madison, and then will be erased from the tablet computer. They will ask you questions about your health, your drug use, and types of health care you have received. The questionnaire will take approximately 20-30 minutes. You will be asked to repeat this questionnaire in 3 months and 6 months.

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We will collect the following information from you for this research study:
Age, ZIP code, county of residence, ethnicity, education, marital status, alcohol and drug use, prior HIV and Hepatitis C test results, types of health care you have received, how you are feeling, mental health, coping techniques, and other related items. In addition, the Wisconsin Department of Health Services requires that Vivent Health collect additional information from people when they get tested for HIV, hepatitis C or syphilis. This information includes your full name, date of birth, address, and whether you have engaged in certain types of drug use and sexual behaviors. Vivent Health will collect and store information about your participation in prevention navigation. This will include your name, services you may have received, case notes, and assessments you completed. Vivent Health will keep this information as part of their efforts to evaluate and improve the prevention navigation program in order to expand services in the future.

We will also link your information to databases like the Wisconsin Immunization Registry and Medicaid to understand how health services are utilized among people who inject drugs. If you agree to be in the study, we will ask for your permission to use this information for research purposes as well.

Incarceration. If you become incarcerated during the time you are participating in the study, we will not conduct any of the research activities while you are in jail or prison. You can resume participation in the research after you are no longer incarcerated by contacting the staff at Vivent Health or a study coordinator.

C. ARE THERE ANY BENEFITS TO ME?

Your taking part in this research may benefit you as you will be engaged in the

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intervention. You may receive resources and linkages to care for treatment related to injection drug use. Your participation may also benefit other people in the future by helping us learn how to make prevention services more available to people who inject drugs.

D. WILL I BE PAID FOR MY PARTICIPATION?

You will be paid $20 for completing the survey and blood tests today, plus an additional $20 at 3 and 6 months. If you are asked to return to the office on a different date to collect blood for confirmatory testing, then you will be paid $10 for your time.

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There are no costs to you to join this study.

F. ARE THERE ANY RISKS TO ME?

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You can stop answering questions at any time of the study. Refusal to answer questions will not negatively affect any relationship you may have with Vivent Health, the University of Wisconsin-Madison, or its affiliates.

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Certificate of Confidentiality. To help us further protect your privacy, a Certificate of Confidentiality has been obtained from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The researchers will use the certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

There are some situations when we WILL NOT keep information confidential. WE WILL report information about you the appropriate authorities 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**

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- UW-Madison regulatory and research oversight boards and offices

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study is federally funded, federal agencies can inspect our study records**.**

- National Institutes of Health
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- Researchers at other institutions who are collaborating with the UW-Madison research team

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. When we share information from research studies with others outside the UW-Madison and its affiliates; it is not shared in a way that can directly identify an individual, but may include your Zip code.

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

H. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely remove yourself from the study at any time. You also may choose to stop taking part or skip any questions that you do not feel comfortable answering. You will be told of any new and significant findings which may affect your willingness to continue.

If you decide not to participate in this study or if you stop while the study is underway, the health care you receive from UW Health and their affiliates will not be affected in any way.

ARE THERE ANY ALTERNATIVES?

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Ryan Westergaard, MD, PhD, MPH
5223 UW Medical Foundation Centennial Building
1685 Highland Avenue
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Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Ryan P. Westergaard at 608-265-7927.

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team, contact the UW Health Patient Relations Representative at 608-263-8009.

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Informed Consent Comprehension Quiz

Which of the following statements about this research study are TRUE?

A. The topic of the study is preventing health problems and navigating services that are related to injecting drugs.

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 research team includes researchers at the University of Wisconsin-Madison, Tulane University, Massachusetts General Hospital, and University of Washington.

D. People can participate in the study if they live in a rural area and injected drugs in the past month.

E. The study involves a commitment of 6 months that will include 3 research assessments.

F. I can get tested for HIV and Hepatitis C at Vivent Health even if I don't participate in this study.

G. All of the above are true

H. None of the above are true

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_____ I do NOT wish to be contacted in the future by members of the research team about participating in future research studies.

Signature of participant for consent and authorization:

_____ _____

Signature of participant Date

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

Signature of person obtaining consent and authorization:

_____ _____

Signature of person obtaining consent and authorization Date

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