Informed Consent Form

Youth-Led Intervention to Improve Blood Pressure

NCT05029687

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RUTGERS
Robert Wood Johnson
Medical School

Department of Emergency Medicine
Rutgers, The State University of New Jersey
One Robert Wood Johnson Place, MEB 264
New Brunswick, NJ 08903

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: A Youth-Led Digital Education Intervention to Improve Blood Pressure for Hypertensive Adults Who Present to the Emergency Department

Principal Investigator: Sara Heinert, PhD, MPH

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Sara Heinert, PhD, MPH is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Heinert may be reached at (732) 235-7872 or sara.heinert@rutgers.edu.

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: New Jersey Alliance for Clinical and Translational Science (NJ ACTS)

Why is this study being done?
The study is about hypertension, which is another word for high blood pressure. This study is being done to evaluate the effectiveness of a youth-led hypertension education digital intervention on HTN knowledge, confidence in HTN management, and health behavior changes. The digital education intervention is comprised of a series of 6 modules that are completed on a computer or smart phone.

Who may take part in this study and who may not?
Eligible adult participants will be 18 years or older who have an existing relationship with a student at New Brunswick Health Sciences Technology High School. It must be feasible for you and the adult to complete an online module together 1 hour per week for 6 weeks. The eligible youth participants must have access to the internet or data plan and a smart phone or computer.

People who cannot take part in the study are people who are not able to speak fluently in English or Spanish (youth and adult must be able to speak the same language), and youth with no access to the internet or a data plan and a smart phone or computer.

Why have I been asked to take part in this study?
Because you are an adult (18 years or older) who has an existing relationship (family or friend) with a student at New Brunswick Health Sciences Technology High School.

How long will the study take and how many participants will take part?
200 participants will be in the study (100 adults and 100 youth). For adults, participation duration will be 10 weeks (6 weeks for digital badge intervention plus 4 weeks for final follow-up after completion of intervention). Baseline data collection is expected to take approximately 20 minutes. During the 6-week

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digital education module, participants will spend approximately 1 hour per week on the module. Follow-up data collection is expected to take approximately 20 minutes per session (with sessions at the end of the intervention and 1 month later).

What will I be asked to do if I take part in this study?
If you take part in the study, you will be asked to do the following:

1. You will be told about the study, given the opportunity to ask questions, and then will be asked to sign a consent form. You will then complete study assessments including demographics, hypertension knowledge, confidence in HTN management, and health behaviors.

2. For 6 weeks, the youth will implement the digital hypertension education intervention with you at home- completing one module per week (each module will take about one hour). (You will complete feedback assessments at the end of each module.)

3. At the end of the 6-week intervention and then 1 month later, you will again complete the assessments that you completed before the 6-week intervention.

4. Halfway through the 6-week intervention and after the intervention, any participants (youth or adults) who are interested can complete interviews about feedback on the intervention (on Zoom or in person). This is not a required portion of the study, but interview participants will receive an additional $10 gift card per interview. If you participate in the interview, it will be audio recorded.

What are the risks of harm or discomforts I might experience if I take part in this study?
This is a minimal risk study. The only foreseeable risk of harm is a possible loss of confidentiality, however procedures will be in place to minimize risks of harm.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be an improvement in blood pressure or increase in hypertension health knowledge. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take part in this study?
There is no cost to you to take part in this study.

Will I be paid to take part in this study?
If you complete the study, you will receive $80 total for participation. You will receive:

- a $20 gift card after completing the second in-school session,
- a $20 gift card after completing the first 3 weekly modules (halfway through the intervention),
- a $20 gift card after completing all 6 weekly modules (end of intervention) and questionnaires, and

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- a $20 gift card after completing questionnaires 1 month after the end of the intervention.

You will also have the opportunity to participate in an interview halfway through the intervention and one at the end of the intervention. These are not required as part of the study. You will receive $10 per interview if you choose to participate.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Patient confidentiality will be maintained through secured, password protection computerized data collection. All documents and information about this study will be kept confidential in accordance with federal, state, and local laws and regulations. The results of this study will be published. If results are published, no participant will be identified by name.

A description of this clinical trial will be available on 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.

What will happen to my information collected for this research after the study is over?
The information collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Sara Heinert, Department of Emergency Medicine, Rutgers Robert Wood Johnson Medical School, One Robert Wood Johnson Place, MEB 264, New Brunswick, NJ 08903.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Sara Heinert, PhD, MPH, Department of Emergency Medicine, at (732) 235-7872 or sara.heinert@rutgers.edu.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB Office at: (973) 972-3608 or (732) 235-9806 or (732) 235-2866, or email us at IRBOffice@research.rutgers.edu, or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

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AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____