INFORMED CONSENT

NC Works4Health

NCT Number: NCT04815278

June/1/2022

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
CDPP Adult Participants

Consent Form Version Date: June 2022
IRB Study # 21-0859
Title of Study: NCWorks4Health: Phase 2 Intervention
Principal Investigator: Dr. Shawn Kneipp
Principal Investigator Department: School of Nursing
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Funding Source and/or Sponsor: NIH National Institute on Minority Health and Health Disparities (NIMHD)

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Study Contact Email: ncworks4health@email.unc.edu

The purpose of this study is to test the effectiveness of a Chronic Disease Prevention Program (CDPP) on weight, psychological distress, blood pressure, and health habits of individuals experiencing unemployment.

If you consent to this study, you may take part in an 11-week online lifestyle coaching curriculum and 9 lifestyle coach sessions over a 40-week period. During this time, you will complete web-based learning modules that teach healthy habits for those entering the workforce including food, exercise and stress. You will also be asked to complete self-report questionnaires at baseline (0 months), 3, 6, and 12 months. In addition, you may be given a Fitbit to track step count, a scale to track weight and a food log to track diet intake. You may directly benefit from participation in this study through improving your health habits and reducing your risk for chronic disease.

Potential risks involved in participation are minimal. There are no physical risks associated with study involvement.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-

Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this study is to test the effectiveness of a Chronic Disease Prevention Program (CDPP) on weight, psychological distress, blood pressure, and health habits of people who are unemployed and have received employment services in any of the following participating study counties:

Orange, Chatham, Durham, Caswell, Person, Alamance, Wake, and Guilford.

Are there any reasons you should not be in this study?
There are no reasons you should not be in this study if you meet the below eligibility criteria.

You are eligible to be in this study if you:

- Are unemployed
- Have less than a 4-year college education/degree; OR

  Have received any form of public assistance in the prior two years (this includes rental/housing assistance, heat or utility assistance, SNAP benefits, TANF benefits, or accessing a food pantry); AND

  Accessed any resources in the target counties available through the Department of Social Services or the NC Works Career Centers to facilitate job search or job placement activities in the past year; this includes community-wide job fair events held within these counties.

- Are between the age of 18 and 64 years old;
- Are able to speak and read English fluently;
- Are not receiving or applied for disability benefits;
- Are not pregnant (however, women may join the study immediately after delivery if they want to);
- Do not have a gastrointestinal condition that requires following strict dietary guidelines or another health condition that significantly limits your routine physical activities (like walking);
- Do not have any of the following chronic conditions:
    - Severe high blood pressure (with a reading of 180/110 or higher in the past 6 months)
    - A health condition or injury that has left you unsteady, or unbalanced when you walk
    - A history of falling in the past 6 months
    - Cancer that is actively being treated with chemotherapy of radiation to your chest or abdomen (stomach area)

- Inflammatory bowel disease (such as Crohn's disease, or ulcerative colitis)
- An implanted cardiac defibrillator (a small device placed under the skin on your chest to help your heart function

How many people will take part in this study?
We expect 600 people will take part in this study.

How long will your part in this study last?
Your participation in this study will last for a total of 12 months.

What will happen if you take part in the study?
All study participants: If you participate in this study, you will be asked to complete self-report questionnaires at baseline (0 months), again in 3 months, 6 months, and 12 months after enrolling.

The data collection will be in-person at a public facility of convenience to you (ex. local library, DSS, career center, etc.). The visit will last approximately 30 - 45 minutes. The appointment will consist of taking your weight and blood pressure and filling out an online food log to track dietary intake over 3 days. You will also be asked to wear a wrist device to measure your physical activity. A follow up appointment will be scheduled one week later to retrieve the wrist device. You will be provided an incentive at each data collection time as a thank you for completing data collection tasks (more on that below).

Periodic fidelity checks will be performed during data collections to ensure that staff are performing the responsibilities correctly. The fidelity checks will be conducted by either the PI or lead Data Collector. The session may be recorded and presented to the PI or lead Data Collector if they are unable to attend in-person. Each data collector staff will have an data collection visit observed. The purpose of the fidelity check is to maintain proper safety and research protocol during the collection of the data.

If your data collection is taped, the video will be recorded via Zoom on the data collectors iPad. The video will be stored in a secured file in the UNC Teams account and deleted after no more than 7 days.

If you choose to participate, you will be randomized to one of two groups. Being 'randomized' works like tossing a coin to decide which group you will be in. All participants will be randomized to either the CDPP intervention group or a control group.

If you are randomized to the CDPP intervention group: You will be asked to complete 8 online modules which are designed to help people develop healthy habits in the areas of stress, diet, and being more physically active. Each Module takes about 20-30 minutes to complete. The 8 modules are completed over a 12-week period of time. You will also be given a Bluetooth Scale (for you to keep) and weigh yourself daily, will be given a Fitbit (for you to keep) and asked to track your daily steps, and asked to track your stress level and food intake on a daily or other regular basis during the 12 months you are in the CDPP. Finally, you will receive 10 regularly scheduled visits with a Lifestyle Coach to help guide you in building healthier habits into your daily life. These visits will be in-person and by phone and will last 30-45 minutes. They are scheduled to start just after you are enrolled in the study, with the 10th visit occurring 40 weeks after you enroll in the study. In addition, you may have access to what we call "Stepped

Care" Lifestyle Coach visits between the regular times you meet with your Coach. These visits can provide extra support for you to build healthier habits if you need it.

If you are randomized to the control group: You will do nothing different in your everyday life while in the study for 12 months other than completing the tasks asked of you during the data collection visit (see above, under "All study participants"). At the end of a 12-month period, you will be given access to the same CDPP modules to complete and healthy habit building resources online that the CDPP intervention group participants receive. If in the control group, you will not receive a scale, Fitbit, or visits from the Lifestyle Coach.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may include learning more about how to manage your stress and weight, improve your health-related habits, and reduce your risk for developing or worsening chronic disease.

What are the possible risks or discomforts involved from being in this study?
There are potential risks involved in participation. Some survey questions may cause you to feel stressed or sad and may cause discomfort. You are not required to answer any questions that make you uncomfortable when completing the survey questions. In addition, study staff will reach out to you if your responses to questions suggest you might benefit from additional assessment or resources.
There is an infrequent chance that intervention participants may experience mild skin irritation while wearing the Fitbit.
There is a potential risk of breach of confidentiality. Every precaution will be taken to protect personal identifiable information. The steps taken to secure participant data are outlined in the following sections.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. A study ID will be assigned to each participant to protect their identity. All records will be securely stored in electronic files that are password protected by the UNC system, and that only members of the research team can look at.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or ensuring public safety. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information.

We may use de-identified data from this study in future research without additional consent.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you 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.

What steps are the study team and UNC taking to prevent the spread of COVID?
Physical distancing and mask-wearing is the primary strategy used to prevent the spread of the virus. When possible, meetings will be conducted virtually to avoid in-person contact. The majority of study activities and appointments will take place virtually with the exception of four data collection points at baseline, 3 months, 6 months, and 12 months. During these visits, a data collector will follow strict guidelines to avoid contact and transmission by:

- wearing a mask of at least 2 layers of material
- remaining 6 feet away
- sanitize equipment both before and after the appointment
- performing hand hygiene before and after face-to-face interaction
- When possible, interacting in an outdoor setting

In addition, prior to a face-to-face visit, research personnel must confirm your appointment and perform telephone wellness screenings no more than 24 hours prior to the scheduled visit. If the individual is found to have any of the below symptoms, the appointment will be postponed.

People with COVID-19 have had a wide range of reported symptoms – ranging from mild symptoms to severe illness which may lead to death. Symptoms may appear 2-14 days after exposure to the virus. People with these symptoms may have COVID-19:

- Cough
- Shortness of breath or difficulty breathing
- Fever
- Chills especially repeated shaking chills
- Muscle pain

- Sore throat
- New loss of taste or smell
- Vomiting and diarrhea

This list is from the CDC but may not include all possible symptoms. People experience the virus in many different ways. Please contact your medical provider if you are experiencing symptoms that are concerning to you.

If you feel as though the above precautions are not being followed please either talk with the study staff, submit an anonymous request through Ethics Point by calling 1-866-294-8688, or reach out to the UNC OHRE IRB at 919-966-3113.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
This study could not take place without your participation, and we truly appreciate your time and commitment. You will receive the compensation as detailed below upon completion of all data collection at each time point. “All data collection” means that the survey is completed, and that you meet with the data collector in person to provide (1) blood pressure and weight during the data collection visit, and (2) movement data (wearing an actigraph wrist watch device for 1 week) and 3 days of food log data (online or mobile reporting).

- $35 gift card at enrollment (visit 1)
- $40 at month 3 (visit 2)
- $50 at month 6 (visit 3)
- $60 at month 12 (visit 4)

Gift cards will be sent by Tango Rewards. The redemption link will be sent by email to the email address you provided us within 2 business days of completing all data collection requirements at baseline. All additional incentives provided after 3 month, 6 month, and 12 month data collection is completed will be sent via Tango Rewards within 48 hours.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on 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.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____	_____
Signature of Research Participant	Date
_____	
Printed Name of Research Participant	
_____	_____
Signature of Legally Authorized Representative	Date
_____	
Printed Name of Legally Authorized Representative	

_____	_____
Signature of Research Team Member Obtaining Consent	Date
_____	
Printed Name of Research Team Member Obtaining Consent	

_____	
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)	_____ Date
_____	
Printed Name of Witness	

Video recording consent:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to be video recorded during data collection visits as a part of this research study.

Select one:

___ Yes, I agree to be video recorded.

___ No, I do not agree to be video recorded.