

Cover Page for ClinicalTrials.gov

Official Study Title:	A Pilot Trial of a Network Intervention for Youth After Incarceration
NCT Number:	NCT03556618
Document:	Statistical Design
Document Date:	February 27, 2020

UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH (TAY 18-24 Exiting Jail)

“UCLA Whole Person Care (WPC) Transition Age Youth (TAY) Reentry Study”

You have been selected to be invited to participate in a research study conducted by Dr. Liz Barnert from the UCLA Department of Pediatrics. You were selected as a possible participant in this study because you are eligible for the Whole Person Care Program offered by LA County.

Your participation is voluntary. Your decision about whether or not to participate in this study will not affect your relationship with the Los Angeles (LA) County Jail, Parole, Probation, Sheriff's Department, or UCLA.

Why is this study being done?

The purpose of the project is to describe the social supports of young people involved in the justice system and to understand the impact of the Whole Person Care (WPC) program in improving outcomes. Participation in the WPC program is independent of the study. We hope to use this information to better understand how the WPC program works and learn more about young people involved in the justice system, so that we can find ways to improve the transition home for young people who are detained.

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to:

1) Surveys and Focus Group:

- Complete 3 surveys. The first survey will be done while you are detained. The other 2 will be completed 3 and 9 months after your release.
 - During the survey, you will answer questions about your health, drug or alcohol or “substance” use, and relationships with people around you.
 - You may refuse to answer any questions that you do not want to answer and still remain in the study.
- You may also be invited to participate in an audio-recorded focus group interview. The focus groups will also ask about your health, any drug/alcohol use, and your relationships with people around you. You would not be allowed to review, edit, or erase the audio recordings; they would be used for study purposes only.
-

2) Contact Information:

- Contact the study team after you are released.
- Provide your contact information, such as a telephone number and mailing address, so we may contact you for follow-up surveys.
- Provide your permission for the research team to ask Probation or the WPC team for a telephone number for you if we become unable to reach you.

3) Medical Record Access:

- Provide your permission so that we can review some of your health records related to your incarceration as well as health services, such as hospitalization and treatment you've received from LA Department of Health Services.

- Provide your permission to be contacted by the research team in the future for possible participation in a new study – if you are interested in volunteering. You can say “yes” or “no”.

How long will I be in the research study?

You will be in the study over the course of approximately 10 months. Your participation in this project will take up to 3 hours in total. There are a total of 3 surveys – today and again about 3 and 9 months after you are released; each survey will last about 30 minutes. If you participate in a focus group, it will be about one hour long and would take place after the 9 month survey.

Will information about me and my participation be kept confidential?

- This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that Dr. Barnert and her team are not allowed to share or use information that may identify you. Information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a law that requires it. Some examples of these laws are to report child abuse or neglect, harm to self or others, or communicable diseases, like chlamydia or gonorrhea.
- The Certificate cannot be used to refuse a request for information from personnel of the U.S. government agency sponsoring the project that is needed for auditing or program evaluation by the NIH, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal FDA. These federal agencies may review records to see how the researchers are conducting the study.
- A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.
- For focus groups, all participants will be asked to keep what is said during the discussion between participants only. However, the research team cannot guarantee complete privacy (confidentiality). Focus group interviews will be audio recorded, so all participants will have their voices recorded.
- If you check the box stating, “Please check this box if you do not want your data saved for other research,” we will not use your data beyond this research project.
- If you check the box stating, “Please check this box if you do not want to be contacted for other research,” we will not contact you to participate in future research projects.

Are there any potential risks or discomforts that I can expect from this study?

The researchers do not expect that volunteers will experience risks or discomfort. If any questions make you feel uncomfortable, you can skip the question or stop the survey at any time.

Are there any potential benefits if I participate?

There is no direct benefit to you if you volunteer to take part in the study. However, the results of the research may help to improve services offered to other youth who are involved in the justice system.

Will I be paid for participating?

You will receive up to \$200 for participating. Specifically, you will receive \$50 (cash or gift card) for connecting with us after release, \$50 for completing each of the two follow-up surveys once in the community, and an additional \$50 if you participate in the focus group.

What are my rights if I take part in this study?

You can choose to take part in this study, or not. If you volunteer to be in this study, you may leave the study at any time without consequences of any kind. This does not affect any County services you may receive. You are not waiving your legal rights if you choose to be in this research study.

Who can I contact if I have questions about this study?

If you have any questions or concerns about the research, you can talk to one of the researchers. Please contact: Principal Investigator: Dr. Liz Barnert at (310) 825-3496, via email at ebarnert@mednet.ucla.edu, or by mail at 10833 Le Conte Ave 12-467 MDCC, LA, CA 90095.

If you have questions about your rights as a research subject, or you have concerns and you want to talk to someone other than the researchers, you may contact UCLA OHRPP by phone at: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, LA, CA 90095.



Please check this box if you do not want your data (the answers to your questions) saved for other research



Please check this box if you do not want to be contacted for other research. If contacted, you can say “yes” or “no” at that time

SIGNATURE OF STUDY PARTICIPANT

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Name of Participant

Date

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

In my judgment, the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Name and Signature of Researcher

Date