Study Title: *Peer i-Coaching for Activated Self-Management Optimization (PiCASO) in AYAs and Young Adults with Chronic Conditions*

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Peer i-Coaching for Activated Self-Management Optimization (PiCASO) in AYAs and Young Adults with Chronic Conditions

CONCISE SUMMARY

The purpose of this research study is to determine the effectiveness of a peer coaching intervention for adolescents and young adults (AYA) with chronic conditions. AYAs will be randomized to the Peer Coach Transition Program or the Transition Education Program, both for improving chronic illness self-management. AYAs in the Peer Coach Program will be matched with a young adult coach with a similar chronic condition and will interact using a mobile app (phone and text) once a week for the first 3 months (6-12 calls), followed by once a week to twice a month for the next 3 months (6-12 calls), followed by monthly communication (6-12 calls) for the final 6 months of the study. Each call will last 20-30 minutes and will focus on a goal chosen elected by the AYA. AYAs in the Transition Education Program will receive an electronic newsletter every two weeks with educational content about chronic illness management as well as a monthly phone call from study staff for the first six months to ensure receipt of the newsletter and to answer questions regarding content, and an opportunity to link them to other resources. After the first six months, text messages will be sent through the PeerMentor app to continue to check in. AYAs in both groups will complete an electronic survey at the beginning of the study, after 3 months, 6 months, 9 months and 12 months of study. It will take approximately 30-35 minutes to complete the survey. AYAs in both groups will be paid each time they complete the electronic survey. There are no physical risks associated with this study. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

You are being asked to take part in this research study because you have a chronic medical condition and expressed interest in the Peer Coach Transition Program. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Gary Maslow and Dr. Sharron Docherty will conduct the study and it is funded by the National Institutes of Health: National Institute of Nursing Research. The sponsor of this study, the National Institute of Nursing Research, will pay Duke University to perform this research, and these funds may reimburse part of Dr. Maslow's and Dr. Docherty's salary.

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WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Maslow will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to evaluate the effectiveness of the Peer Coach Program for improving self-management skills in AYAs and young adults with a chronic condition who are transitioning to adult based care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 225 people will take part in this study at Duke University.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will be randomly assigned (like drawing numbers from a hat) to receive either the Peer Coach Transition Self-Management Program (PiCASO) or Transition Education Program (control group). You will have a 2 out of 3 chance of being in the PiCASO group. If you are in the PiCASO program group, you will be asked to download the mobile application "PeerMentor" and complete an electronic survey which will take approximately 30-35 minutes. While in the program you will speak by phone and text with a trained, young adult Peer Transition Coach about your health-related goals once a week (6-12 calls) for months 1 through 3, then once a week to twice a month (6-12 calls) for months 4 through 6, then monthly (6-12 calls) for months 7 through 12. Each call will last approximately 20 minutes in length and you can schedule these calls at a time most convenient for you and the Transition Coach.

All peer coaching interactions will occur using the mobile application from InquisitHealth called Mentor 1:1™. This mobile app and web-based platform was designed by InquisitHealth and is being used commercially across multiple settings in which peer support is used. It facilitates interactions between you and your assigned peer coach using telephone and a web-based peer-support interface. InquistHealth uses two-way line-bridging technology and text messaging to facilitate peer mentoring relationships via smartphones (Android or iPhone). The coach hits the 'Call Now' button, and the system first calls the coach with a generic phone number and then calls you separately with that same generic phone number and bridges the line together. Phone numbers are not exchanged between you and coach, and thus calls are not possible during non-scheduled times. The application is compatible with IOS and Android and can be downloaded in the App Store or Google Play Store.

During the first call, you and your coach will have the opportunity to learn about each other's experiences with living with a chronic condition. During subsequent calls, your coach will focus on a specific goal elected by you from a predefined list. As goal progress is made over the calls, you and your coach will work to identify a new goal, or in the case of no progress, discuss barriers and strategies, with an option to move on to another goal. Between sessions you and your coach can exchange text messages

including an update on progress towards a goal. At the end of the intervention the final call involves an opportunity for closure and for you and your coach to review progress on goals and future steps.

If you choose not to download the mobile application, you can still participate in the study via phone calls with a coach. If you decide not to use the application, text messages will not be possible and phone calls will not be encrypted. Additionally, phone calls will still be exchanged and the same two-way line bridging technology will be utilized, but there will be no text messaging component, as messaging is only made secure via the mobile application.

You will be asked to complete an electronic survey at 5 points in time across the 12 month study (At the beginning of the study, after 3 months, 6 months, 9 months and 12 months of study). It will take approximately 30-35 minutes to complete the survey and you will be paid each time you complete the survey: $30 per data collection session (5) for a total of $150 over the course of the study. A subset of participants in the PiCASO group will asked to participate in a brief interview upon completion of the 12-month study. Those chosen for an interview will receive an additional $30 for the interview.

Data will be collected from the "PeerMentor" application used to connect you and your coach, which includes progress on key health behaviors discussed and notes the coaches submit after each session. Also, we will review your medical records to ensure study eligibility and assess relevant health history information and measure the progress your coach reports.

If you are randomized to the Transition Education program, you will receive an electronic newsletter every two weeks with educational content about chronic illness management and the differences between pediatric and adult health care systems, as well as a monthly phone call from study staff for the first six months to ensure receipt of the newsletter and to answer questions regarding content, and an opportunity to link them to other resources. After the first six months, text messages will be sent through the PeerMentor app to continue to check in. If you report any health concerns, you will be directed to contact your health care team. Participants in the Transition Education program will also be asked to complete an electronic survey at 5 points in time across the 12-month study (At the beginning of the study, after 3 months, 6 months, 9 months and 12 months of study). It will take approximately 30-35 minutes to complete the survey and you will be paid each time you complete a survey: $30 per data collection session (5) for a total of $150 over the course of the study.

We will record clinical information from your medical record for up to ten years after you complete the study in order to assess the effects of the transition clinic on transition outcomes.

HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for 12 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

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WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. This study involves sending your data, including goal progress and coaches' meeting notes, to some commercial entities, including InquistHealth, Audacity, Amazon Cloud Services, and Firebase. These companies may further share information from data in the application, about you. Disclosures by InquisitHealth and their business partners are not covered under the privacy policies described in this document. Any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. As you use the application, it will ask for specific permissions, which you can choose whether to allow. These permissions can be revoked by you at any time. You are encouraged to limit personal identifiers entered into the mobile application (particularly name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. Data from the application will be stored on the Amazon Cloud but may also be stored, at least temporarily, on your device. Mobile applications may have unanticipated impact on the operations of your device (such as battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the end of the study, you may remove the mobile application from your device. We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

Participant interview recordings will be transcribed by a vendor outside of Duke (SureTypesALot, Inc). If your information is further disclosed by the vendor, it may not be covered by federal privacy regulations. The audio recordings will be destroyed after checking the transcriptions for accuracy.

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop participation in this study at any time.

You will receive a signed copy of this consent form via the email address you provide. The use of email is not secure and is a potential risk of loss of confidentiality.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to participate in this study, there will be no direct medical benefit to you. However, information gained from this study may help to improve the Peer Coach Transition Program which serves AYAs and young adults with chronic illness.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people

including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. As a part of this study, you will provide identifying information such as your phone number. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS).

You will be assigned a unique study code number for your responses to the survey. The key which links your personal information and unique study code number will be stored in a secured database that is password-protected and only accessible by study team personnel. Similarly, electronic study records will be stored in the Amazon Cloud, which is encrypted. Paper study records such as the demographic form will be stored in a locked filing cabinet in Dr. Docherty's research office.

Participant interview recordings will be transcribed by a vendor outside of Duke (SureTypesALot, Inc). If your information is further disclosed by the vendor, it may not be covered by federal privacy regulations. The audio recordings will be destroyed after checking the transcriptions for accuracy. While the information resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. The study results will be retained in your research record forever.

Your medical records may be reviewed in order to meet federal or state regulations. Reviewers may include the DUHS Institutional Review Board. Any study-related research information logged in your medical record will be kept indefinitely.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report AYA abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

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Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

Dr. Ashwin Patel of InquisitHealth is working closely with the Duke investigators on this study. He has developed the technology that is being used in the study and will be involved with customization of the platform and deployment to assist in the delivery of peer-to-peer mentoring. If the technology is commercially successful, the developers may benefit financially.

Nonparticipation or withdrawal from this study will not affect your grades if you are a Duke student.

WHAT ARE THE COSTS TO YOU?
There are no costs to you or your insurance associated with participation in this study.

WHAT ABOUT COMPENSATION?
You will be paid $30 per data collection session (5) for a total of $150 over the course of the study. A subset of participants will be asked to participate in a brief interview upon completion of the 12-month study. These participants will each receive an addition $30 for the interview.

WHAT ABOUT RESEARCH RELATED INJURIES?
We do not expect that you will be hurt by taking part in this research study. However, in the event that you are injured as a result of your participation in this research study, immediate necessary medical care is available at Duke University Medical Center. At the same time, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

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For questions about the study or research-related injury, contact Gary Maslow, MD, MPH during regular business hours at (919) 668-0080 (after-hours 919-797-5363) or Sharron Docherty, PhD, PNP during regular business hours at (919) 668-3836 (after-hours 919-423-2179. Coaches have the mobile phone number for Dr. Gary Maslow in case of emergency.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Gary Maslow or Dr. Sharron Docherty in writing and let them know that you are withdrawing from the study. Their mailing address is:
Dr. Gary Maslow, MD: Address: 4020 N Roxboro St., 3675 DUMC, Durham, NC 27704; Phone: (919) 620-5333
Dr. Sharron Docherty, PhD, PNP: Address: 307 Trent Drive, 3322 DUMC, Durham, NC, 27710; Phone (919) 668-3836.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ as required by U.S. Law. 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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you or your AYA have problems, concerns, questions or suggestions about the research, contact Dr. Gary Maslow at (919) 620-5333 during regular business hours and at (919) 620-5333 after hours and on weekends and holidays or Dr. Sharron Docherty at (919) 668-3836 during regular business hours and at (919) 423-2179 after hours and on weekends and holidays.

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For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time