Enhanced Care Planning and Clinical-Community Linkages to Comprehensively Address the Basic Needs of Patients with Multiple Chronic Conditions

(HM20015553)

Version 12.3.2020, Approved by the IRB 6.9.21

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Enhanced Care Planning and Clinical-Community Linkages to Comprehensively Address the Basic Needs of Patients with Multiple Chronic Conditions

VCU INVESTIGATOR: Alex Krist, MD, MPH (804) 828-9626

INOVA SITE INVESTIGATOR: Marc Childress, MD (703) 391-2020

SPONSOR: Agency for Healthcare Research and Quality

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. It is important that you carefully think about whether being in this study is right for you and your situation.

This consent form is meant to assist you in thinking about whether you want to be in this study. Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to test whether helping patients to create care plans to address unhealthy behaviors, mental health needs, and social risks will improve health better than current care. Often primary care practices have difficulties with helping patients address these complex needs. The care planning intervention will include identifying a patient navigator to guide patients and creating linkages to community programs to help patients achieve their goals. In addition to learning about whether the care planning process helps patients, we hope to learn which unhealthy behaviors, mental health needs, and social risks patients want to address and the type of help they need to make changes.

What will happen if I participate?

If you agree to participate, you will be asked to help us identify your patients with chronic conditions so we can mail them a survey. Of survey respondents, 10 patients with uncontrolled

conditions will be randomly selected for study participation. Then you will be randomized (like the flip of a coin) to either (a) continue the current care you provide your patients or (b) continue the current care you provide, plus receive supported enhanced care planning for your patients. You have an equal chance of being assigned to either group. At the start of the study, you will also be asked to provide basic demographic information about yourself and your practice and to complete a brief questionnaire about the climate of your practice.

Care planning means that in addition to continuing the current care that you provide your patients, your patients will be asked to do the following things:

1. Get help from a patient navigator (a nurse or medical assistant in your office, or a member of our research team if no one in your office can do this). The patient navigator will help your patients in creating a care plan, check in on the patient each week, and make sure your patient gets the help they need.
2. Use an online tool to create a care plan. The tool is called My Own Health Report and it…
    a. Asks patients about health behaviors, mental health needs, and social risks;
    b. Let's the patient select which needs they would like to change;
    c. Helps the patient make personal goals about their needs; and
    d. Walks the patient through creating a care plan to achieve their goals.
3. After patients create their care plan, they will log in to My Own Health Report weekly to…
    a. See messages from their patient navigator;
    b. Report on their progress with achieving goals; and
    c. Ask for help from their care team if having trouble.
4. If appropriate, get help from a community health worker to direct patients to community programs to assist their doctor and patient navigator better to help patients achieve their goals.

At the end of the study, we will ask you to participate in a 30-minute exit interview about your experiences with the study. Your participation in this study will last up to 1 year. We plan to recruit 60 to 120 doctors and 600 patients to participate in this study (10 patients from each doctor).

What alternative treatments or procedures are available?

If you decide not to participate in this study, you can continue providing current care to your patients.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no guarantee that you will receive any benefits from being in this study. However, possible benefits include:

- Support to better manage your patients with unhealthy behaviors, mental health, and social risks
- A better understanding about your patients' goals and how they want to achieve them
- A baseline and one-year assessment on how your practice does with managing chronic disease
- Use of an enhanced care planning tool
- Staff training for a member of your team to function as a patientnavigator
- Increased support from a community health worker and/or community programs
- Earn MOC Part IV, AAFP CMEs or Nursing CEUs

We hope that the information learned from this study will provide information about ways to better help patients, doctors, and practices with unhealthy behaviors, mental health needs, and social risks. This information will be shared with other physicians and practices.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

There are minimal risks to your privacy in participating in this study. We will save the demographic information and survey responses you provide. We will store all information with a numerical identifier and not your name. You may refuse to answer any question that makes you feel uncomfortable. We will not share your information with your employer, other researchers, of others.

WHAT ARE THE COSTS?

There are no costs for participating in this study.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

CAN I STOP BEING IN THE STUDY?

You can stop being in this study at any time. Leaving the study will not affect the current medical care you provide to your patients. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study, we will consider your patients' care plan "complete." We will not mail subsequent surveys to your patients or conduct further chart reviews, unless you give us permission. Unless you request otherwise, data that has already been collected about you/your practice will remain part of the study database.

HOW WILL INFORMATION ABOUT YOU BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information will be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside the research team. The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed. Results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed. Once the study has been completed, we will send you a summary of aggregate study results and what they mean.

CONFIDENTIALITY STATUTE

To help us protect your privacy, this study has a confidentiality statute supported by the Agency for Healthcare Research and Quality (AHRQ). A confidentiality statute helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Alex Krist, MD, MPH
alexander.krist@vcuhealth.org
(804) 828-9626

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research

800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be

entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

_____	
Participant Name (Printed)	
_____	_____
Participant's Signature	Date
_____	
Name of Person Conducting Consent Discussion (Printed)	
_____	_____
Signature of Person Conducting Consent Discussion	Date
_____	_____
Principal Investigator Signature (if different from above)	Date

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AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to test whether helping patients to create care plans to address unhealthy behaviors, mental health needs, and social risks will improve health better than current care. Often primary care practices have difficulties with helping patients address these complex needs. The care planning intervention will include identifying a patient navigator to guide patients and creating linkages to community programs to help patients achieve their goals. In addition to learning about whether the care planning process helps patients, we hope to learn which unhealthy behaviors, mental health needs, and social risks patients want to address and the type of help they need to make changes.

What will happen if I participate?

If you agree to participate, you will be randomized (like the flip of a coin) to receive either (a) continued current care with your doctor or (b) continued current care with your doctor plus care planning. You have an equal chance of being assigned to either group. Continued current care means that you and your doctor continue to do what you are currently doing to maintain your health.

Care planning means that in addition to continuing your current care with your doctor, you will be asked to do the following things:

1. Get help from a patient navigator (nurse or medical assistant in your doctor's office). The patient navigator will help you create your care plan, check in on you each week, and make sure you get the help you need.
2. Use an online tool to create a care plan. The tool is called My Own Health Report and it…
    a. Asks you about health behaviors, mental health needs, and social risks;
    b. Let's you select which needs you would like to change;
    c. Helps you make personal goals about your needs; and
    d. Walks you through creating a care plan to achieve your goals.
3. After you create your care plan, log in to My Own Health Report weekly to…
    a. See messages from your patient navigator;
    b. Report on your progress with achieving your goals; and
    c. And ask for help from your care team if you are having any troubles.
4. If appropriate, get help from a community health worker to direct you to community programs to assist your doctor and patient navigator better help you achieve your goals.

Everyone (both patients getting continued current care and patients getting care planning), will be asked to do the following things:

1. Complete an online questionnaire about health behavior, mental health, and social needs now, in 6 months, and in 1 year.
2. Complete the paper survey that you already completed about the help your doctor's office gives you and your quality of life in 6 months and 1 year.
3. Allow our research team to look at your medical record to see if you have received recommended care and how well your chronic conditions are controlled.

At the end of the study, we will ask 60 patients to participate in a one-hour interview about their experience with getting help addressing health behaviors, mental health needs, and social risks.

Your participation in this study will last up to 1 year. We plan to recruit 60 to 120 doctors and 600 patients to participate in this study (10 patients from each doctor). You are being asked to participate because your doctor has already agreed to be in the study.

What alternative treatments or procedures are available?
If you decide not to participate in this study, you can continue to receive your current care.

If you participate you do have the option to take a paper survey instead of the electronic one. You also have the option of the patient navigator helping you to complete your care plan rather than using the tool online.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no guarantee that you will receive any benefits from being in this study. However, possible benefits include:

- Identifying health behavior, mental health, and social needs that may be impacting your health;
- Helping your doctor to better know your goals and needs; and
- Getting additional help from a patient navigator, community health worker, and/or community programs.

We hope that the information learned from this study will provide information about ways to better help patients with unhealthy behaviors, mental health needs, and social risks. This can help your doctor and will be shared with other doctors and practices.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Your health may not get better or may become worse while you are in this study.

There is minimal risk to your privacy in participating in this study. We do save your My Own Health Report information, survey responses, and basic health information from the chart review. You may refuse to answer any question that makes you feel uncomfortable.
Furthermore, to protect your privacy, we will store all information with a numerical identifier, not your name. My Own Health Report uses secure communication protocols (e.g. https). All information on My Own Health Report is encrypted and password protected. We will never disclose information about individual patients. We will only publish results about aggregate or all combined patients.

WHAT ARE THE COSTS?

There are no costs for participating in this study.

You and/or your insurance plan will need to pay for the costs of your medical care from your doctor, as you have been. This includes insurance co-pays and deductibles.

While the patient navigator and community health worker will try to help you find community programs with no cost, some community resources may have fees. If you choose to use these programs to achieve your goals, you will be responsible for those costs.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

Participants will receive a $10.00 Visa, Amazon, or Target gift card after completing the baseline, 6-month, and 12-month paper and online survey for a total of $30.00. Patients who participate in the end of study interview will also receive a $50 Visa, Amazon, or Target gift card after completing the interview. If you complete all the surveys and participate in the interview, you will have received a total of $80.

CAN I STOP BEING IN THE STUDY?

You can stop being in this study at any time. Leaving the study will not affect your medical care. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study, we will consider your care plan “complete.” You will continue to receive current care from your doctor. We will not mail you subsequent surveys. We will ask you if it is still acceptable for us to review your medical chart for inclusion in our final results. Unless you request otherwise, data that has already been collected about you will remain part of the study database.

HOW WILL INFORMATION ABOUT YOU BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information will be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside your care team and the research team. The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed. Results of this research may be

presented at meetings or in publications, identifiable personal information about participants will not be disclosed. Once the study has been completed, we will send you a summary of aggregate study results and what they mean.

CONFIDENTIALITY STATUTE

To help us protect your privacy, the study has a confidentiality statute supported by the Agency for Healthcare Research and Quality (AHRQ). A confidentiality statute helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited.

HOW WILL YOUR HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and permit us to access existing information from your healthcare records. New health information will also be created from your answers on My Own Health Report and the surveys. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information will be used for the conduct of this research:

- ☒ Complete health record
- ☒ History and physical exam
- ☒ Laboratory test results
- ☒ Diagnosis & treatment codes
- ☒ Information about mental health
- ☒ Information about drug or alcohol abuse

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Sponsor
- Data Coordinators
- Research Collaborators
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use your protected health information expire? This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at:

Alex Krist, MD, MPH
Virginia Commonwealth University School
of Medicine
Department of Family Medicine and Population Health One
Capitol Square, sixth floor
830 E Main Street Richmond, VA
23298-0101
alexander.krist@vcuhealth.org

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_____ Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date