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Living With Multimorbidity CO-ORDINATE Program

11/22/2022

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Living with Multimorbidity

Application No.: IRB00244792

Sponsor/Supporter/Funded By: National Institute of Nursing Research

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

This study is being done to determine if the Care cO-ORDInatioN And sympTom managEment (CO-ORDINATE) program we developed for patients living with multimorbidity help decrease symptom burden and improve quality of life.

You being asked to take part in this study for about a 5 month period. If you agree to participate the nurse-led symptom management activities will start pre-discharge with telephone follow-up at 48 hours, 1 week, 4 weeks, 6 weeks and 3 months. The symptom burden will be evaluated at each contact with the patient. To understand if this program is effective, we will collect data throughout the study at the beginning, at 6 weeks and 3 months after the program is complete. Participants at these 3 times are expected complete a survey with questions related to symptom burden, quality of life, pain, fatigue, social support and resilience. Additional clinical data on your diagnosis and healthcare utilization will be collected from your medical chart review. Further at 6 weeks we will be asking you about your feedback and satisfaction with the care coordination and symptom management program to improve for next time.

There are no significant risks associated with participating at any step of this study and you will not incur any costs associated with participation.

2. Why is this research being done?

This research is being done to pilot test the effectiveness of nurse-driven care coordination and symptom management program to decrease the symptom burden and increase the quality of life of patients living with multimorbidity.

Multimorbidity is the coexistence of two or more chronic disease conditions in the same individual. People with multimorbidity might suffer from a high symptom burden such as pain, fatigue, difficulty in breathing, difficulty sleeping, lack of energy and such symptoms directly affect quality of life and increase caregiver burden. Hence, nurse researchers in this study plan to work with patients and family caregivers to identify symptom burden and engage in care coordination and symptom management activities.

Additionally, we would like to implement this nurse-led care coordination and symptom management program to determine if the program is effective in decreasing pain, fatigue, and health care utilization and improving social support and resilience of patients living with multimorbidity.

Who can join this study?

People with multimorbidity, aged 55 years and above, who were admitted to or are eligible to admitted to the Intermediate Care Unit of Johns Hopkins Hospital before discharge from the hospital may join.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

1. Complete a survey. To complete a survey, we will need an access to your medical chart and your self-report. The self-report survey takes about 10-20 minutes to complete. Your approval in this consent also includes approval to access your medical record.

   This will be done at the start of the study, at the end of the symptom management program (6 weeks) and 3 months after the program is complete.
   a. Self-report survey will consist of items related to socio-demographic characteristics, symptom burden, quality of life, pain, fatigue, social support, self-efficacy, fear of COVID-19 and resilience. At 6 weeks survey also consists of items related to your feedback and satisfaction with the program.
   b. Medical chart review will include data related to your sociodemographic and clinical profile such as diagnosis and healthcare utilization (no. of emergency visits, hospitalizations and critical care admissions).

2. Participate in a care coordination and symptom management program which starts pre-discharge with telephone follow-up at 48 hours, 1 week, 4 weeks and 6 weeks after discharge. The predischarge and telephone follow-ups will focus on your needs, question prompt list to help support interaction with care providers, goal settings for symptom management priorities and symptom burden.

Audio recordings:

As part of this research, we are requesting your permission to create and use audio recordings to help answer the research question. Any recordings will not be used for advertising or non-study related purposes. The data collection and symptom-management program activities will be audio-taped for

training and quality assurance purposes. The data collection from you during taping will be destroyed when the study and planned analysis is complete.

You should know that:

- You may request that the audio recording be stopped at any time.
- If you agree to allow the audio recording and then change your mind, you may ask us to destroy that recording. If the recording has had all identifiers removed, we may not be able to do this.
- We will only use these audio recording for the purposes of this research.

Please indicate your decision below by checking the appropriate statement:

_____I **agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use audio recordings of me for the purpose of this study.

_____I **do not agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use audio recordings of me for the purpose of this study.

_____ _____

Participant Signature Date

How long will you be in the study?

You will be in this study for about 5 months.

4. What happens to data that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data we collect about you are important to this effort.

If you join this study, you should understand that you will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

How will your data be shared now and in the future?

Sharing data is part of research and may increase what we can learn from each study.

Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) no further review and approval by an Institutional Review Board (IRB) is needed. If data are shared with identifiers, further IRB review and approval may be needed. The IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

5. What are the risks or discomforts of the study?

Survey and care coordination and symptom-management program

- You may get tired or feel emotional and distressed while answering the questions or being part of the program. You do not have to answer any question you do not want to answer. You are free to take a break or stop the survey at point if you wish to. You may refuse to answer any question that makes you feel uncomfortable or upsets you. If you become distressed or uncomfortable during the study, the researcher will stop the study and the experienced registered nurse will take steps to reduce discomfort. Researcher including data collectors and principle investigator are also nurses and are experienced caring for patients living with chronic and complex disease conditions. You will be allowed to withdraw from the study at any time.

Identifiable private information

- There is the risk that information about you may become known to people outside this study.

6. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. If you take part in this study, you may help others in the future who are living with multimorbidity.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care and/or employment at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

You will be acknowledged for your time and input in the study as follows:

- After complete survey at baseline, you will receive $25 gift card.
- After complete survey at 6 weeks, you will receive $25 gift card.
- After complete survey at 3 months, you will receive $25 gift card.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service, and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
All of the information that we collect from you will be kept private. The only people who have access to the information will be the research team members. All the information you give us will be kept secure in a locked filing cabinet. We will use a study ID number instead of your name on all of the information that we get from you.

13. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

14. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study?
Call the principal investigator, Dr. Binu Koirala at 707-225-2166. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

15. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

<u>Future Contact</u>
We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES _____ _____
Signature of Participant Date

NO _____ _____
Signature of Participant Date

16. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).