Individualizing Disease Prevention for Middle-Aged Adults

ClinicalTrials.gov Identifier: NCT03023813

Patient Study Information Sheet: 9/11/2019
Employee Study Information Sheet: 1/29/2018

Patient Study Information Sheet

Project Title: Individualizing Disease Prevention for Middle-Aged Adults
Principal Investigator: Glen Taksler, PhD (216-445-7499)

Your health care provider is participating in a research study about different ways to discuss health with patients. At your visit, your provider may show you some written materials and discuss them with you. If so, the written materials were created *just for you* based on your health needs and risk factors. No other patient will receive the same materials.

If you don't see anything new, that's ok. About half of patients will get their usual care.

Please be aware that we are only evaluating **the way** in which your health care provider discusses health with you. The specific recommendations that your health care provider makes are **not** part of the study.

We would like to invite you to participate in the research study as well. If you agree, we will ask you to complete a 10-15 minute survey after your visit. You may answer the questions before you leave, or within 3 days. We will give you a $25 gift card for your time.

If you choose to participate, we will also review your medical record to see what health care services you receive within 1 year after today's visit. This will help us find out whether different ways to discuss health care eventually change patients' health.

If you are interested in participating, this information sheet gives you information about the study. The study staff can review this information with you. The study staff will explain the purpose of the study, any risks to you and what is expected of you. You are free to ask questions about the study at any time. This study has been approved by Cleveland Clinic's Institutional Review Board. Before you learn more about the study, it is important for you to know that your participation in this study is entirely voluntary. You may decide not to take part in, or to withdraw from, the study at any time.

Why are you being asked to participate in this study?
You are being asked to participate because your health care provider is also participating in a research study.

What is the purpose of this study?
The primary objective of this study is to help patients compare the benefits of various preventive care services (things you can do to prevent future health care problems). We are asking health care providers to try discussing the information in different ways, to see what works best.

What are the requirements and time commitment to participate?
There are **no requirements** for you. However, if you would like to participate, you will be asked to participate in a survey. The survey will take about 10-15 minutes. You may complete the survey immediately after your visit today or later on your own computer (using the internet). Or, if you prefer, we can ask you the questions over the phone. If you complete the survey on your own computer or by phone, you will need to do so within 3 days.

Also, we will review your medical record to see what health care services you receive within 1 year after today's visit. This will help us find out whether different ways to discuss health care eventually change patients' health.

You may also be asked to participate in an optional interview asking about your opinions on the written materials and discussion with your doctor. We only plan to interview a small number of patients, so please don't be surprised you are not asked to participate in this part of the study. The main purpose of the interview is to help the research team improve the study in the future, for other patients and doctors who may participate. If you agree to an interview, it may take place over the phone or in person, up to 1 year after your appointment with your doctor. The interview will take about 15 to 30 minutes and may be audio recorded.

What are the benefits to taking part in the study?
There is no direct benefit to you. Participating in this study may help researchers gain further knowledge about the best ways to discuss preventive care services with patients.

Are there any risks to you in participating in the study?
There are no physical risks associated with the study. Some of the questions asked as part of the survey or the optional interview may make you feel uncomfortable. You may refuse to answer any of the questions. There is also the possibility that the survey or optional interview questions could cause psychological stress or fatigue to you. You may stop the survey or optional interview at any time.

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of the following safeguards: All data will be stored in password-protected and encrypted storage facilities accessible only by the research team. Participant names will be replaced by a study number so that individuals who do not need to know your name will not be able to connect your name with the research data.

If you participate in an interview, it may be audio recorded for purposes of transcription (writing) which is needed for research analysis. Your audio recording will not be sent outside of Cleveland Clinic; the transcription (or written copy of the interview) will be made by a member of the Cleveland Clinic research team. Only de-identified (anonymous) text quotes will appear in manuscripts or publications; your audio recording (voice) will not be presented publicly.
The study team may include quotations from your interview in research publications and presentations, but the quotations will not include any information that could identify you.

Do I have to participate in the survey or interview?

Your participation is strictly voluntary. Your decision to participate in the survey or interview will not impact your current or future medical care at Cleveland Clinic. You may choose not to take part or may stop the survey or interview at any time. Stopping the survey or interview will not result in any penalty. You may also choose to participate in the survey but not the interview.

What other options are there?
Your participation is strictly voluntary. The alternative is to not participate in the survey.

What are the costs?
There are no costs for you to participate. If you choose to participate, you will receive a $25 gift card after completing the survey.

If you participate in the in-person or phone interview, you will receive an additional $25 gift card, for a total of $50. If you complete the interview by phone, we will mail this gift card to you.

Who do I contact if I have questions about the study?
If you have questions about the study after you have agreed, you may ask the study coordinator Jackie Fox, RN for assistance at any time (216-444-4590) or you can contact Glen Taksler, PhD (principal investigator) at 216-445-7499. If you have any questions about your rights as a research subject, you may contact the Institutional Review Board at (216) 444-2924.

Version 9/11/19

Employee Study Information Sheet

Project Title: Individualizing Disease Prevention for Middle-Aged Adults
Principal Investigator: Glen Taksler, PhD (216-445-7499)

Thank you for taking the time to review this information.

This information sheet gives you information about the study which the study staff will then review with you. The study staff will explain the purpose of the study, any risks to you and what is expected of you. You are free to ask questions about the study at any time. This study has been approved by Cleveland Clinic's Institutional Review Board. Before you learn more about the study, it is important for you to know that your participation in this study is entirely voluntary. You may decide not to take part in, or to withdraw from, the study at any time.

Why are you being asked to participate in this study?
You are being asked to participate in this study because you are a health care provider at Cleveland Clinic in adult primary care services.

What is the purpose of this study?
The primary objective of this study is to better understand how health care providers can help adults to make an informed decision about services that are likely to help them live longer, healthier lives, based on their individual needs and risk factors.

What are the requirements and time commitment to participate?
We will randomize select patient appointments to "intervention" or "usual care". For intervention appointments, we will provide you with written materials that describe various preventive care services for patients. The written materials are *different for each patient* based on their disease risk factors. We ask you to discuss the written materials with patients and engage in shared-decision making. For usual care appointments, we will not provide you with any information.

After each intervention appointment, we will ask you to provide feedback to the research team. You may provide feedback in any format that is convenient for you (oral, written, email, Epic™ staff message, etc.). Additionally, at the end of the study, we may ask to interview you regarding topics such as: your overall perceptions, feasibility, shared decision-making with patients, thoughts about the written materials and future implementation. The interview is optional; you do not have to complete an interview. We anticipate that your time commitment will be as follows: about 10 minutes per patient during office visits, about 2 minutes per patient for after-visit feedback, and about 30 minutes for the end-of-study interview (if you choose to do so).

If you choose to provide oral feedback or participate in an end-of-study interview, we would like to audio record it, to ensure that we accurately capture your perspectives.

For both intervention and control appointments, your patients may be told that you are participating in a research study. We may also ask your patients (both intervention and usual care) to participate, in 2 ways. First, we may ask for feedback to help improve the study. We will only share aggregate feedback with you (no individual patient feedback). Second, we may review patient medical records, to see which health care services they receive within 1 year after their appointment. This will help us find out whether different ways to discuss health care eventually change patients' health.

What are the benefits to taking part in this study?
You may be able to help improve patient adherence to preventive care recommendations. Participating in this study may help researchers to gain further knowledge about what patients think about different things they can do to improve their health.

Are there any risks to you in participating in this study?
There are no physical risks associated with this study. If discussion of the written materials takes longer than anticipated, you may be late for other patient appointments. Some of the interview questions may make you feel uncomfortable or cause psychological stress or fatigue. You may refuse to answer any of the questions.

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the following safeguards: All data will be stored in password-protected and encrypted storage facilities accessible only by the research team. No one with direct supervisory responsibilities for your work will have access to your individual responses. Participant names will be replaced by a study number so that individuals who do not need to know your name will not be able to connect your name with the research data. Only unique study identification numbers will identify participants in research databases. All data will be reported in aggregate and will not be linked to specific providers. Identifying information will be removed during the analysis and your responses will only be identified using an ID code.

Do I have to participate in the research?
Your participation is strictly voluntary. Your decision to participate will not impact your current or future employment a Cleveland Clinic or your performance reviews. The decision to participate or not to participate in our study will not affect your employment status in any way.

You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty.

What other options are there?
Your participation is strictly voluntary. The alternative is to not participate.

What are the costs?
There is no cost for participation. You will not be compensated for participation in the study. Please be aware that, if your patients choose to provide feedback, they will be compensated $25.

Who do I contact if I have questions about the research?

If you have questions about the study after you have agreed, you may ask the study coordinator Jackie Fox, RN for assistance at any time (216-444-4590) or you can contact Glen Taksler, PhD (principal investigator) at 216-445-7499. If you have any questions about your rights as a research subject, you can contact the Institutional Review Board at (216) 444-2924.

Providing the study's written materials to a patient, discussing the written materials with a patient, providing after-visit feedback to the research team, and/or completion of the study interview will indicate your agreement to participate in the research.

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