Consent Form

Title: PROmoting Diabetes Education and Management Through Peer Support and Team Referral

NCT Number: NCT05587348

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 6/1/22
IRB Study # 22-0357
Title of Study: Novel Interventions to Increase Uptake of Diabetes Self-Management Support Training within Primary Care
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CONCISE SUMMARY

The purpose of this study is to see if adding a peer support person to the care time makes a person referred to Diabetes Education classes more likely to attend, and more likely to complete the classes. The peer support person will be someone that has diabetes and has completed the classes and is trained to support people like you.

Participants in this study will be randomized to get the usual support from their provider and care team or be contacted by the peer support person. Participants will answer survey questions at the beginning of the study and 3 months later. Data about your diabetes and class attendance will be obtained from your medical records. All participation will end after the 3-month survey.

There is a potential risk that others may find out you are in this study.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.
Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this study is to see if adding a peer support person to the care time makes a person referred to Diabetes Education classes more likely to attend, and more likely to complete the classes. Diabetes Education has been shown to be effective at improving outcomes for patients with diabetes. Referral to Diabetes Education and attendance at Diabetes Education Classes has been historically low.

The practice you are seen at is participating in one part of the study to improve rates of referral to the Diabetes Education Classes. People who are referred to the classes from those practices are eligible for the study.

People who enroll in the study will be randomized to get a peer support person or receive the usual support from their practice care team. The peer support person will be a patient with diabetes who completed the Diabetes Education Classes and received training in how to best support people like you. You will fill out Surveys at the start of the study and 3 months later.

We will get information about your attendance in classes and results of your A1c that your care team orders from your medical records. We will determine the proportion of participants that attend classes and how many they attend as well as changes in their A1c. We get information from your medical records for 6 months after you enroll

You are being asked to be in the study because you are from one of our study practices and your provider or care team has referred you to Diabetes Education Classes.

Are there any reasons you should not be in this study?

You should not be in this study if you are not eligible to enroll in the Diabetes Education Classes, cannot speak English, or you are moving in the next 6 months.

How many people will take part in this study?

Approximately 90 people seen in UNC-PN clinics will take part in this study.

How long will your part in this study last?

Your active participation in this study will last 3 months and will follow your medical records for a total of 6 months.

What will happen if you take part in the study?

- Consent. You will be asked review and sign this consent for and to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.
- Once you have consented to be in the study you will be randomized to additional peer support or usual support given by your practice. This means you will be assigned to one of the two group by chance, like flipping a coin.
- At that time, you will fill out surveys about your experience as a person living with diabetes. You may choose not to answer a question for any reason
- If you are assigned to peer support, you will be contacted by your peer supporter

- You will decide if you will attend the Diabetes Education Classes and how many you will attend, and when
- At 3 months you will fill out surveys about your experience as a person living with diabetes. You may choose not to answer any question for any reason.
- We will follow your medical records for a total of 6 months.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?
You may feel uncomfortable answering some of the questions about diabetes that you are asked.

Someone could learn you are helping with this study. We will store all the information about this study in a secure office at the Sheps Center in Chapel Hill NC 27599. All study data will be stored with a number rather than your personal information. Even with these precautions there could be a risk of a breach of confidentiality.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Your personal information will be stored in a database on a secure server at the Sheps Center at UNC-Chapel Hill. Only individuals who need to see your identifying information will have access to the database. All study data will be coded with your study number.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.\

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal

Will you receive anything for being in this study?

You will be receiving $30 for taking part in this study. $15 after each completed survey. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

Will it cost you anything to be in this study?

If you enroll in this study, you will have costs which include:

- Costs associated with your usual care including attendance at the Diabetes Education Classes.
- Phone minutes or text message costs associated with communicating with your Peer Supporter.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness