Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

CONCISE SUMMARY

The purpose of this study is to investigate whether the self-management of diabetes and hypertension can be improved with the use of mobile monitoring devices and nursing support.

In this research study, eligible participants are randomly assigned to one of two groups: the EXTEND Group or the EXTEND Plus Group.

- Participants assigned to the EXTEND Group will receive monitoring devices to help diabetes and hypertension self-management, including a glucose meter and test strips, a blood pressure cuff, a home scale, and a wrist-worn activity tracker. Participants will also be asked to install apps on their smartphone. Over the course of two years, data and trends collected from the monitoring devices will be displayed on the apps so that participants can adjust their self-management practices.
- Participants assigned to the EXTEND Plus Group will receive the same devices as the EXTEND Group, but for the first 12 months of participation will also receive additional support from a Registered Nurse (RN) and diabetes and hypertension medication management from a Clinical Pharmacist.

Risks of partaking in this study include: abnormal blood sugars, abnormal blood pressures, loss of confidentiality; finger stick blood sampling risks; and errors in information transmission from devices.

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

You are being asked to take part in this research study because you have type 2 diabetes and hypertension that have been hard to control with clinic care. 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 them 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. Matthew Crowley, MD and Ryan Shaw, PhD, RN will conduct the study and a grant from the National Institutes of Health (NIH) will sponsor this study. Portions of ***Dr. Crowley and Dr. Shaw's*** and their research team's salaries will be paid by this grant.

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, ***Dr. Matthew Crowley*** will be your doctor for the study. He and his team 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 investigate whether control of diabetes and hypertension can be improved with the use of mobile monitoring devices with or without nursing support.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 220 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

Procedures related to the study:

1. If you agree to be in this study, you will be asked to sign and date this consent form.

2. We will ask you questions and review your medical records for information about you (age, race, etc.) and your health (medical history, lab values, etc.).

3. Although this study involves few risks beyond those that are part of routine diabetes and hypertension care, the changes your body goes through during pregnancy may affect your diabetes treatment plan. Therefore, women who are pregnant or planning a pregnancy are not allowed to participate in this study.

4. This study will last approximately 24 months (2 years) and will include a total of 7 in-person study visits (including the baseline/enrollment visit to determine eligibility). These visits will occur approximately every 3 months during the first 12 months of the study, and then every 6 months for the final 12 months. See Table 1 for a summary of the EXTEND study follow-up visits.

   a. Enrollment visit: This visit should take approximately 60 minutes. We will ask you to review and sign the consent forms for study participation, if you haven't already. We will ask you to complete a series of questionnaires, which can be done remotely or in-person. We will then measure your height (Ht), weight (Wt), and blood pressure (BP). Finally, we may measure your hemoglobin A1c (HbA1c) level using a point-of-care test. The point-of-care HbA1c test requires collection of a non-fasting finger stick sample. In lieu of a point-of-care test, we may use a lab-based HbA1c test, which could already be available from the day of enrollment (i.e.,

Table 1. EXTEND study follow-up visit timing.

Assessment type	3	6	9	12	18	24
BP, Weight, and HbA1c (done in-person, ~30 min.)	X	X	X	X	X	X
Survey (done remotely ~30 min.)		X		X	X	X

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

from a clinic visit) or ordered by our study team. Lab-based HbA1c tests require the collection of a small tube of blood. If you are eligible for the study, we will then help you download the device apps, if you haven't already, on your smartphone and provide and teach you about the devices you will use during the study (described below).

i. Once your enrollment visit is complete, we will use a procedure like flipping a coin to randomly assign you to receive either the EXTEND or EXTEND Plus intervention. You will have a 50/50 chance of being assigned to either of these 2 groups.
    1. During your baseline visit, the study coordinator will let you know which intervention (EXTEND or EXTEND Plus) you will be receiving.
    2. The research assistants that conduct your follow-up visits will not know which program (EXTEND or EXTEND Plus) you are receiving.
ii. Both EXTEND and EXTEND Plus groups will receive the same monitoring devices to help track their blood sugar, blood pressure, weight, and activity (see below).
iii. Both groups will continue to receive their typical care from their existing primary and specialty care providers.

b. 6-month, 12-month, 18-month, and 24-month follow-ups: These in-person visits should take approximately 30 minutes. The study team member will measure your Wt, BP, HbA1c, and administer short questionnaires. Prior to these visits, you will receive an email with a series of questionnaires, which can be done remotely or in-person. These include, for example, questions about how you self-manage your diabetes and hypertension.
c. 3-month and 9-month follow-ups: These in-person visits should take approximately 30 minutes. The study team member will measure your Wt, BP, and HbA1c, and administer short questionnaires.
d. Qualitative interviews: Throughout the study, we will be conducting telephone interviews to inquire about your participation with the EXTEND programs. These interviews are optional and are not required for study participation (see below). Each interview will take approximately 30-45 minutes. Participants will receive $50 for each completed interview.

Optional Qualitative Interview
Are you willing to be contacted for telephone interviews? We will be asking questions related to your participation with your assigned EXTEND program so that we can evaluate what is and is not working for participants and obtain your feedback to make improvements in our offerings and materials. We will audio record the telephone interviews in a secure database at Duke so that we can later write down the conversation for research use. Recordings will be made using Duke-approved software and equipment. Your name and other identifying information will not be linked to the audio recording. We will transcribe the recordings and store the transcriptions in a secure database at Duke. All recordings will be destroyed following completion of transcription. Please initial:

I agree to participate in the qualitative interview: ___Yes ___ No

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

5. **EXTEND group:** If you are assigned to the EXTEND group, you receive multiple mobile monitoring devices to help with your diabetes and hypertension self-management. These consumer devices include a glucose meter and test strips, a BP cuff, a home scale, and a wrist worn activity tracker. The specific devices that are provided are shown in Table 2. Unless advised differently by your primary providers, participants are encouraged to check their blood glucose 1-4 times daily (based on how often you take diabetes medications), measure BP daily, weigh daily, and monitor activity daily. Information from these devices is sent to the associated app and is then sent to these companies. You will be able to review this information on the apps for self-management. This information is then retrieved by Duke and stored in a secure database for access by the study team. Importantly, no study staff monitor your data in real time – so you should address any clinical questions or concerns with your Primary Care or Endocrinology clinic team, just like you would if you were using these devices outside of the study. However, the EXTEND study team does provide technical support (including helping with problems with the devices or study apps) during the study. The EXTEND intervention lasts a total of 24 months. **NOTE:** Participants who use a continuous glucose monitor may continue using it as directed by their primary providers**;** at study outcome visits, we will ask for permission to access the continuous glucose monitor data using standard Duke clinic approaches, which entails a clinic health care provider account within the respective continuous glucose monitor platforms. We will analyze these data for study purposes.

6. **EXTEND Plus group:** If you are assigned to the EXTEND Plus group, you will receive the same devices and study app as participants in the EXTEND group (Table 2). In addition to this, you work with EXTEND study nurses and pharmacists during the first 12 months of the study. Of note, the EXTEND nurses and pharmacists you work with are connected with your Primary Care or Endocrinology clinic. The EXTEND study nurse calls you for a scheduled telephone encounter every 2 weeks during this 12-month period (for about 26 total phone calls). There are 3 EXTEND Plus intervention components, which are described below:

Table 2. Monitoring devices for EXTEND participants.

Data type	Device	Description
Glucose	OneTouch Verio Reflect	Tracks blood glucose readings: FDA cleared
BP	Withings BPM Connect	Tracks blood pressure: FDA cleared
Weight	Withings Body	Tracks weight
Activity	Withings Pulse HR	Tracks the frequency and timing of steps and movement

a. Mobile monitoring. Participants in the EXTEND Plus group receive mobile monitoring devices as per Table 2. As described in the EXTEND section, information from these devices is sent to the associated app and is then sent to these companies. You will be able to review this information on the apps for self-management. This information is then retrieved by Duke and stored in a secure database for access by the study team. For the EXTEND Plus group, information from the devices is also pulled into the Duke electronic health record for viewing by the EXTEND nurse during the phone call. At each every-2-week intervention phone call, this study nurse contacts you by phone to review new data and medications. Participants are encouraged to check their blood glucose 1-4 times daily (based on how often you take diabetes

medications), measure BP daily, weigh daily, and monitor activity daily. **NOTE:** although the EXTEND Plus team will receive notifications about abnormal blood glucose, BP, weight, and activity readings at least once every business day, data will not be monitored 24/7. For any concerns about abnormal blood glucose, BP, weight, or activity readings, or any other urgent concerns, participants should reach out to the EXTEND Plus team and/or their primary clinic team. Also, participants who use a continuous glucose monitor may continue using it as directed by their primary providers; the EXTEND Plus team can use continuous glucose monitor data to help with diabetes management. At study outcome visits, we will also ask for permission to access the continuous glucose monitor data using standard Duke clinic approaches, which entails a clinic health care provider account within the respective continuous glucose monitor platforms. We will analyze these data for study purposes.

b. Self-management support. During most of the every-2-week telephone calls, the EXTEND nurse delivers a brief education session for diabetes or hypertension (about 20 unique topics).
c. Medication management. Following each every-2-week phone call, the EXTEND study nurse creates a report summarizing information from the call, and forwards this report through the Duke electronic health record to an EXTEND study pharmacist. The pharmacist reviews this information, decides whether diabetes or hypertension medication changes are needed, and then recommends any necessary changes to the EXTEND study nurse. The nurse then contacts you to pass on the recommended changes. Your primary providers are alerted to changes through the Duke electronic health record. After 12 months of receiving the EXTEND Plus intervention, you will continue to receive the EXTEND intervention (self-management) for an additional 12 months (total of 24 months).

7. We will use your contact information to share the study results with you.

8. Participating in this study is voluntary, and your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you do not sign this consent form, you will continue to receive care from your primary doctors, but not as a part of this study.

9. Procedures unrelated to the study:
You will continue to receive care for your diabetes, hypertension, and other conditions with your current providers throughout the study period. Your current providers will be updated about any changes made to your medications by the study team.

HOW LONG WILL I BE IN THIS STUDY?
No matter which group you may be assigned to, participating in this study lasts for approximately 24 months, or two years. 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.

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

WHAT ARE THE RISKS OF THE STUDY?

- We expect that the physical risks and discomforts of this study will not be any different than usual care of diabetes and hypertension. A risk of any diabetes medication is causing a low blood sugar, and a risk of any hypertension medication is causing a low blood pressure.
- Symptoms of a low blood sugar can include sweating, confusion, and nausea, and rarely loss of consciousness or seizure.
- Symptoms of a low blood pressure can include lightheadedness, fainting, sweating, confusion, and nausea, and rarely loss of consciousness.
- You will receive a finger stick without fasting to check your HbA1c on 7 occasions for the study. Risks associated with a finger stick include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.
- If your baseline or outcome visit is conducted at your clinic, then your HbA1c test may be conducted via venipuncture (i.e., by taking blood from a vein in your arm by needle stick). Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.
- If you are of childbearing potential and become pregnant, the study treatment might involve unknown risks to the embryo or fetus. We ask that you avoid becoming pregnant during study participation and let us know immediately should you become pregnant.
- We anticipate participating in this study during pregnancy imparts no more risk than standard of care for diabetes and hypertension treatment. However, the changes your body goes through during pregnancy may affect some of the things we are measuring in this study. Therefore, women who are pregnant or planning a pregnancy are not allowed to participate in this study.
- We will be collecting private health information from you during this study, which will be kept confidential. 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.
- Some patients may experience discomfort from being asked questions about their well-being as it relates to their diabetes and hypertension. You may refuse to answer any of the questions and you may take a break at any time during the study. Study staff will be sensitive when asking questions and will allow you to recover before proceeding with further questions.
- Some questions we ask during the survey may be considered sensitive to some people; if you do not wish to answer any question, we can proceed to the next question upon your request.
- All surveys are completed using encrypted software and are kept confidential.
- If you experience discomfort that you think may be related to the research, you can call the study team.

There may be risks, discomforts, drug interactions or side effects with study participation that are not yet known.

Risks specific to mobile apps:

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your 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. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. Though we anticipate data use with these devices will be small. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps 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 as needed.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Data from Withings (blood pressure, weight, activity) and Lifescan (blood sugar) mobile applications may be sent to and permanently kept by these companies and their business associates.
You can choose to make any of your personal data available to the device companies and you will be able to see it in the Lifscan and Withings website dashboards. We will encourage you not to share additional personal data with these companies. Our study team will help you with you these steps and decisions.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, your diabetes and hypertension control may improve; however, this cannot be guaranteed. We hope that in the future the information learned from this study will also benefit other people with your conditions.

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

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.

As part of the study, results of your study-related procedures may be reported to Duke and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the Duke University Health System Institutional Review Board and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

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 child 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.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or 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.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. If you have questions, please discuss the costs of the study with Dr. Matthew Crowley and the EXTEND team. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?
You will be compensated $75 for completing the baseline assessment and $50 for completing each follow-up assessment, for a possible total of $375. Additionally, participants will be able to keep all of the mobile monitoring devices provided for the study as per Table 2 (glucometer, blood pressure cuff, scale, and activity tracker) after the 12-month intervention (approximate value $288). Finally, participants will receive glucose test strips at the baseline screening visit. Further glucose test strip distribution at the 3-, 6-, and 9-month assessments will be based upon use during the prior 3 months and frequency of glucose data transmission to the study team.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, 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.

For questions about the study or research-related injury, contact:

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

- ***Dr. Matthew Crowley*** at ***(919-599-8865)*** during regular business hours, after hours, or on weekends and holidays.
- ***Dr. Ryan Shaw*** at ***(919-684-9434)*** during regular business hours, after hours, or on weekends and holidays.

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 unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

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 and will not affect your job status if you are a Duke employee. If you do decide to withdraw, we ask that you contact Dr. Shaw in writing and let him know that you are withdrawing from the study. His mailing address is:

Ryan Shaw
307 Trent Dr., DUMC 3322.
Durham, NC 27710

You can also contact him at ryan.shaw@duke.edu or you may call him at 919-684-9434. You will be asked to return the mobile monitoring devices. Our study staff will work with you on collecting the devices.

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 and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them. The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

Duke University Health System

Consent to Participate in a Research Study
ADULT
Expanding Technology-Enabled Nurse Delivered Chronic Disease Care (EXTEND)

A description of this clinical trial is available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact*:*

- ***Dr. Matthew Crowley*** at ***(919-599-8865)*** during regular business hours, after hours, or on weekends and holidays.
- ***Dr. Ryan Shaw*** at ***(919-684-9434)*** during regular business hours, after hours, or on weekends and holidays.

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