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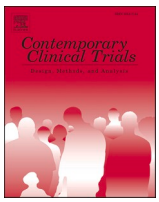

EXpanding Technology-Enabled, Nurse-Delivered Chronic Disease Care (EXTEND): Protocol and Baseline Data for a Randomized Trial

Jashalynn German [a], Qing Yang [b], Daniel Hatch [b], Allison Lewinski [b,c], Hayden B. Bosworth [d,e], Brystana G. Kaufman [c,e,f], Ranee Chatterjee [g], Gina Pennington [b], Doreen Matters [b], Donghwan Lee [b], Diana Urlichich [b], Sarah Kokosa [h], Holly Canupp [h], Patrick Gregory [h], Cindy Leslie Roberson [h], Benjamin Smith [h], Sherry Huber [i], Katheryn Doukellis [i], Tammi Deal [g], Rose Burns [i], Matthew J. Crowley [a,c,1], Ryan J. Shaw [b,*,1]

[a] Division of Endocrinology, Department of Medicine, Duke University School of Medicine, Durham, NC, USA
[b] School of Nursing, Duke University, Durham, NC, USA
[c] Durham Center of Innovation to Accelerate Discovery and Practice Transformation, Durham Veterans Affairs Medical Center, Durham, NC, United States of America
[d] Division of General Internal Medicine, Department of Medicine, Duke University School of Medicine, Durham, NC, USA
[e] Department of Population Health Sciences, Duke University School of Medicine, Durham, NC, USA
[f] Duke-Margolis Center for Health Policy, Duke University, Durham, NC, USA
[g] Division of General Internal Medicine, Department of Medicine, Duke University, Durham, NC 27713, USA
[h] Department of Pharmacy, Duke University, Durham, NC, USA
[i] Duke Office of Clinical Research, Duke University School of Medicine, Durham, NC, USA

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ABSTRACT

Background: Approximately 10–15 % of individuals with type 2 diabetes have persistently poorly-controlled diabetes mellitus (PPDM) despite receiving available care, and frequently have comorbid hypertension. Mobile monitoring-enabled telehealth has the potential to improve outcomes in treatment-resistant chronic disease by supporting self-management and facilitating patient-clinician contact but must be designed in a manner amenable to real-world use.

Methods: Expanding Technology-Enabled, Nurse-Delivered Chronic Disease Care (EXTEND) is an ongoing randomized trial comparing two 12-month interventions for comorbid PPDM and hypertension: 1) EXTEND, a mobile monitoring-enabled self-management intervention; and 2) EXTEND Plus, a comprehensive, nurse-delivered telehealth program incorporating mobile monitoring, self-management support, and pharmacist-supported medication management. Both arms leverage a novel platform that uses existing technological infrastructure to enable transmission of patient-generated health data into the electronic health record. The primary study outcome is difference in HbA1c change from baseline to 12 months. Secondary outcomes include blood pressure, weight, implementation barriers/facilitators, and costs.

Results: Enrollment concluded in June 2023 following randomization of 220 patients. Baseline characteristics are similar between arms; mean age is 54.5 years, and the cohort is predominantly female (63.6 %) and Black (68.2 %), with a baseline HbA1c of 9.81 %.

Conclusion: The EXTEND trial is evaluating two mobile monitoring-enabled telehealth approaches that seek to improve outcomes for patients with PPDM and hypertension. Critically, these approaches are designed around existing infrastructure, so may be amenable to implementation and scaling. This study will promote real-world use of telehealth to maximize benefits for those with high-risk chronic disease.

* Corresponding author.
E-mail address: ryan.shaw@duke.edu (R.J. Shaw).
[1] Co-senior authors.

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1. Introduction

Chronic diseases like diabetes and hypertension require complex self-management, including health data monitoring, diet and activity regulation, adherence to multi-drug regimens, and navigating psychosocial concerns [1–4]. When the demands of self-management exceed patients' capacity, poor disease control results [5]. When available care neither reduces self-management demands nor sufficiently bolsters patient capacity, poor control persists [6–9]. In type 2 diabetes (T2DM), 10–15 % of patients maintain a persistently elevated hemoglobin A1c (HbA1c) despite receiving available care [10,11]; we have defined this group as having 'persistently poorly-controlled diabetes mellitus' (PPDM). Over 85 % of patients with PPDM have comorbid hypertension [11]. Importantly, racial disparities exist in diabetes and hypertension control, with African American patients being less likely to meet glycemic and blood pressure targets compared to non-Hispanic White populations. [11–14]

Comprehensive, mobile monitoring-enabled telehealth may improve management of treatment-resistant chronic diseases like PPDM with uncontrolled hypertension by facilitating frequent patient-provider interactions, addressing drivers of poor control, and providing health insights in daily environments [15]. We previously demonstrated telehealth programs combining telemonitoring, self-management support, and medication management produced clinically significant HbA1c reductions among patients with PPDM [16,17].

Despite this promise, evidence gaps hinder routine implementation of comprehensive, mobile monitoring-enabled telehealth for treatment-resistant chronic diseases in most clinical settings. There remains uncertainty about the availability of necessary infrastructure for delivering comprehensive, mobile monitoring-enabled telehealth in practice, including appropriately trained staff, technical support for monitoring systems, clinical support for remote medication adjustment, automated integration of patient-generated data into the electronic health record (EHR), and transparent reimbursement mechanisms. Evidence is also limited regarding barriers and facilitators to scaling mobile monitoring-enabled telehealth across systems; thus, mobile monitoring-enabled telehealth remains underutilized, even for treatment-resistant chronic diseases where it is most needed.

To support the use of mobile monitoring-enabled telehealth for managing treatment-resistant chronic diseases in real-world practice, we are conducting the Expanding Technology-Enabled, Nurse-Delivered Chronic Disease Care (EXTEND) study. This ongoing randomized trial compares the effectiveness of two mobile monitoring-enabled telehealth programs for patients with comorbid PPDM and hypertension: an intervention designed to facilitate self-management, and a comprehensive, mobile monitoring-enabled intervention. This manuscript describes the interventions, trial protocol, and baseline population characteristics, emphasizing the clinical and scientific importance of this study.

2. Methods

2.1. Study design and research questions

The EXTEND trial (Clinicaltrials.gov NCT05120544) compares two 12-month interventions designed to enhance chronic disease control among patients with PPDM and hypertension: 1) EXTEND, a mobile monitoring-enabled intervention in which participants use multiple monitoring devices to support their self-management; and 2) EXTEND Plus, a comprehensive telehealth intervention that builds upon mobile monitoring-enabled self-management by providing nurse-delivered self-management support and pharmacist-guided medication management. An active comparator trial design was chosen because the target population, patients with PPDM and uncontrolled hypertension, have already demonstrated a suboptimal response to usual care. Patients are followed for a total of 24 months to assess the persistence of intervention effects. This trial aims to address multiple research questions. First, the study examines the effect of the EXTEND and EXTEND Plus interventions on diabetes control (HbA1c) at 12 months; we hypothesized that EXTEND Plus participants would show a greater reduction in HbA1c levels compared to EXTEND comparator participants. Additionally, the study examines the interventions' impact on glycemic control at 18 and 24 months, along with blood pressure, weight, and patient-reported outcomes at 12 months. Finally, the study explores barriers and facilitators to implementing the EXTEND interventions in real-world clinical settings, including intervention costs. This study is overseen by the Duke University Health System (DUHS) Institutional Review Board (protocol Pro00107722) and is monitored by a Data Safety Monitoring Board comprised of independent researchers and statisticians that meet at least annually.

2.2. Community engagement

Given existing racial disparities in diabetes and hypertension control [11–14], we wished to assure that the EXTEND interventions would be appropriate for historically marginalized patient groups. To this end, we used a community-engaged approach to refine our study processes, which included presentation to and discussion with a panel of Black/African American North Carolina residents with diabetes. This panel was convened in October 2021 with support from the Duke University Community Engaged Research Initiative. Community members provided insights that guided refinement of EXTEND trial recruitment materials, trial procedures, and intervention content. Feedback also guided the selection of the four mobile monitoring devices used for the study, which are iOS and Android compatible and are notable for their consumer-friendly interfaces, and accessibility to racially, ethnically, and socioeconomically diverse populations.

2.3. Study population

Participants were recruited from Duke Primary Care and Endocrinology clinics that provide care for a large population with PPDM and hypertension. Inclusion criteria included: (1) T2DM diagnosis based on ICD code (E11.xx) or treatment with glucose-lowering medications; (2) HbA1c $\geq$8.0 % for 6 months (with no values <8.0 %) with $\geq$1 clinic appointment for diabetes over the past year; (3) diagnosis of hypertension based on ICD code (I10-I16), treatment with antihypertensive medications, or documentation of hypertension management in clinical notes; (4) age 30–75 years; (5) ownership of a smartphone; (6) able to speak and read English; and (7) able to provide informed consent. Exclusion criteria included: (1) dementia, psychosis, or life-limiting illness; (2) acute coronary event in past year; (3) hypoglycemic seizure or coma over the past year; (4) nursing home residence; (5) insulin pump use; (6) are or plan to become pregnant during the study period; or (7) unable or unwilling to use necessary mobile monitoring devices.

2.4. Study recruitment and enrollment

Eligible patients were identified through the institution's Epic-based EHR system (Verona, Wisconsin) and contacted via secure EHR-based message (Duke MyChart) with opt-out instructions. A follow-up email was sent to the patient to ensure receipt of the opt-out message. Two weeks after the initial outreach, patients were contacted by phone to assess interest and eligibility. Interested and eligible patients were scheduled for 90-min, in-person baseline appointments.

After informed consent, staff explained study procedures, distributed four remote monitoring devices, downloaded mobile applications ('apps') to participants' smartphones, synced devices to the mobile apps and EHR, and completed baseline assessments (Table 1). Patients whose baseline study HbA1c was <8.0 % were initially excluded prior to randomization; however, this threshold was lowered during the study to

Table 1
Summary and timing of data collection and outcome measures.

Outcome	Method	Baseline	3 mo	6 mo	9 mo	12 mo	18 mo	24 mo
Primary Outcome								
Diabetes Control at 12mo	Hemoglobin A1c	X	X	X	X	X	X	X
Secondary Outcomes								
Blood pressure	Digital BP monitor	X	X	X	X	X	X	X
Weight	Digital Body scale	X	X	X	X	X	X	X
Disease burden								
Perceived Self-management Workload	DDS + H	X		X		X	X	X
Self-management Capacity								
Self-efficacy	PCS	X		X		X	X	X
Knowledge	DKQ, HKM	X		X		X	X	X
Extend Engagement								
Self-management adherence	DSMQ, VMNQ	X		X		X	X	X
Intervention Encounter Completion[a]						X	X	X
Data Transmission	Metrics from mobile devices					X		X
Intervention Cost Outcomes								
Labor costs[b]	EXTEND Plus nurse and clinician time, intervention training time, patient recruitment, and technical support time					X		
Revenue[c]	Assessed based on the number of potentially eligible reimbursable services by the Medicare reimbursement rate					X		
Health utilization costs	Adjusted DUHS hospital and clinic billing charges (EHR based)					X		
	Patient Questionnaire to capture care outside of DUHS					X		
Process Evaluation	Semi- structured interviews (20 patients and 20 health system key informants)					X		

DDS + H = Diabetes Distress Scale plus modified questions for hypertension; PCS = Perceived Competence Scale; DKQ = Diabetes Knowledge Questionnaire; HKM = Hypertension Knowledge Measure; DSMQ = Diabetes Self-Management Questionnaire; VMNQ = Voils Medication Non-Adherence Questionnaire.
[a] For Extend- Plus cohort only.
[b] Hourly wages, along with fringe benefits (based on Duke Human Resources data).
[c] Expected Medicare Fee-for-Service.

<7.5 % to prevent the exclusion of patients that could potentially benefit from HbA1c lowering.

2.5. Randomization and blinding

Participants were randomized using a computer-generated, blocked randomization with block size of four, stratified by clinic (Primary Care or Endocrinology) and HbA1c levels (< or ≥ 10 %) to ensure equal allocation. Randomization was managed by the project coordinator to ensure blinding of research assistants conducting outcome assessments. Participants were informed about both interventions during consent; hence they were not blinded to assignment.

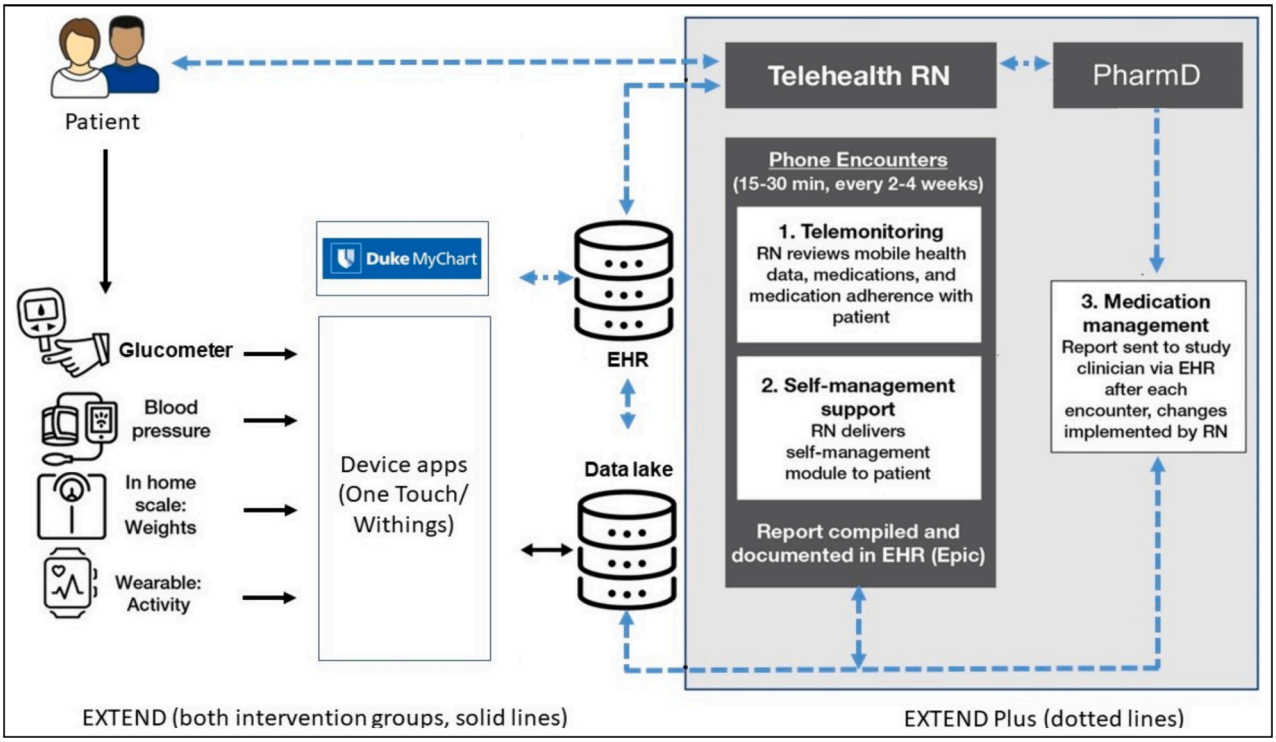


Fig. 1. Overview of EXTEND interventions.

2.6. Mobile monitoring and EHR data management

Participants received an FDA-cleared glucometer from OneTouch® (Milpitas, California) and three devices from Withings® (Issy-les-Moulineaux, France): an FDA-cleared blood pressure (BP) monitor, a Bluetooth-enabled scale, and a wrist-worn activity tracker. Device selection was approached through a health equity lens, prioritizing devices that met necessary technical specifications while remaining practical and easy to use. Utilizing a novel information technology (IT) build, patient-generated data from study devices were integrated into the DUHS data lake (a centralized repository that allows storage of patient-generated data) and EHR, with clinician-facing alerts for abnormal data values (Fig. 1). Data were visualized within the EHR, and telehealth encounters were templated using SmartSets and SmartPhrases to facilitate intervention delivery and documentation [5,18,19]. Participants using continuous glucose monitors (CGM) were encouraged to continue, although these data were not EHR-integrated.

2.7. EXTEND intervention design

EXTEND arm patients were instructed to use the data from study devices, available in mobile apps and Duke MyChart, to facilitate their diabetes and hypertension self-management (Fig. 1). Patients were instructed at baseline to address any chronic disease management questions via their primary clinics' established avenues (as would be the case for any patient using mobile monitoring in practice). Our team provides technical support during the study.

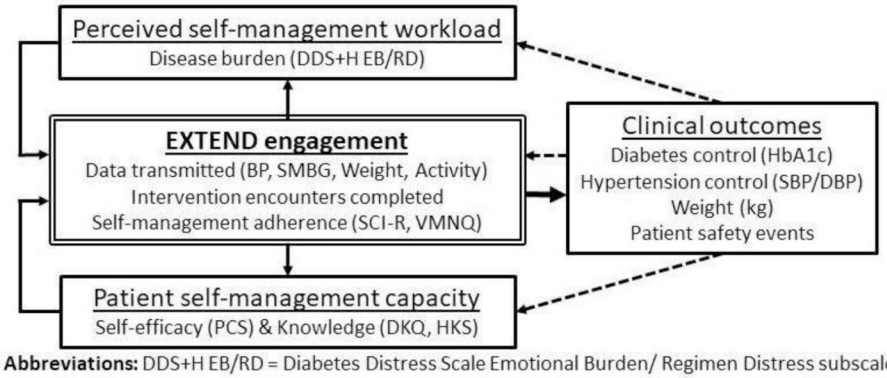
2.8. EXTEND Plus intervention design

The EXTEND Plus intervention design was guided by a Cumulative Complexity Model (CCM)-informed theoretical framework [5,18] (Fig. 2). The intervention components, primarily administered by registered nurses (RNs), consists of mobile monitoring, self-management support, and pharmacist-guided medication management. Participating RNs include a combination of clinic-embedded nurses and nurse interventionists employed by the Duke Office of Clinical Research; we utilized the former when possible, and relied on the latter in cases where clinic-embedded nurse interventionists were unavailable due to shortages in nursing effort. RN training comprised a single session led by the study Principal Investigators, and recruitment deliberately proceeded slowly to ensure RN comfort with intervention procedures. Each participant is followed by a consistent intervention RN throughout their 12-month intervention period. RNs deliver EXTEND Plus during scheduled telephone encounters every two to four weeks, lasting 30–60 min, at the discretion of the intervention team and participants (Fig. 1). Encounter delivery and tracking are managed using REDCap (Research Electronic Data Capture), a secure web-based platform that allows data capture, data storage, and automated notifications to participants and research staff [20,21]. The core research team manages research-specific tasks and technical support but does not deliver intervention components. Participants continue management with existing medical providers throughout the study.

For the EXTEND Plus mobile monitoring component, patient-generated data are received continuously, and values outside preset ranges trigger automated alerts that are reviewed within 24 h by the intervention RN. Patients are instructed to self-monitor blood glucose 1–4 times daily (based on their treatment regimen), monitor weight, activity, and BP daily. During each encounter, the RN reviews interim mobile monitoring data, reconciles medications, and assesses self-reported medication adherence, and then compiles encounter-related information into an EHR-based, templated report. For participants using CGM, intervention RNs do not track these data continuously, but intervention teams can review and utilize CGM data during scheduled encounters to help guide treatment decisions.

The EXTEND Plus self-management support component includes 20 unique modules addressing important self-management topics in PPDM and hypertension, including blood glucose and BP self-monitoring, developing diet plans, medication adherence, and self-managing insulin, hypoglycemia, and hypotension. RNs deliver a self-management module during most intervention encounters based on a schedule; topics central to patient self-management and safety (e.g., self-monitoring of blood glucose, hypoglycemia) are delivered earlier in the program to ensure that all participants receive this content. The modules, written at an 8th-grade reading level, utilize patient-centered strategies and focus on knowledge, self-efficacy, and goal setting. Module content is rooted in social cognitive theory and was developed and refined over the course of our group's prior studies [17,22–26].

The EXTEND Plus medication management component is delivered by an RN in collaboration with a clinic-embedded clinical pharmacist practitioner (CPP; the CPP designation allows pharmacists in North Carolina and other states to provide direct patient care, including prescribing medications/ordering labs under a supervising physician [27]. This component facilitates frequent patient-staff contact and empowers study clinicians to adjust medications [28]. Each participant is followed by a consistent study pharmacist throughout the intervention period. After each scheduled encounter, the RN relays their EHR-based summary report to the pharmacist, who determines whether medication changes are needed based on diabetes and hypertension medication protocols. Per American Diabetes Association guidelines, HbA1c and BP goals are individualized, with a typical HbA1c goal of <7.0 % and BP goal of <130/80 [29,30]. Pharmacists notify RNs of recommendations



Abbreviations: DDS+H EB/RD = Diabetes Distress Scale Emotional Burden/ Regimen Distress subscales + modified hypertension questions; HbA1c = hemoglobin A1c; SMBG = self-monitored blood glucose; PCS = Perceived Competence Scale; SCI-R = Self-Care Inventory – Revised; VMNQ = Voils Medication Nonadherence; DKQ = Diabetes Knowledge Questionnaire; HKS= Hypertension knowledge scale

Fig. 2. EXTEND Conceptual Model.

via an addendum to the EHR report, and the RN implements any changes with the participant by phone. Primary providers are alerted to medication changes via the EHR.

2.9. Intervention fidelity assessment

Tracking data are regularly reviewed by the study team to ensure intervention encounters are delivered as intended. Staff also shadow 5–10 encounters per RN and conduct monthly case review meetings with RN and pharmacist study teams. In the EXTEND Plus arm, RNs perform REDCap-based tracking of all intervention activities (e.g., attempted/completed encounters, encounter duration, modules delivered, medication changes, etc.).

Data transmission is assessed in both study arms at a minimum of every outcome visit, and participants receive a text message reminder to bring their study devices for data connection checks. In cases of disengagement, patients are encouraged to resume using the devices. The study team assists all participants with troubleshooting technical issues. Monthly automated e-mails remind patients to monitor and refresh device apps. EXTEND Plus participants have the opportunity to address issues during their telephone encounters and patients can call the study team to report data collection or transmission problems at any time.

2.10. Measures and outcomes

Baseline measures include demographics, clinical data (e.g., comorbidities, medications, markers of disease control), and psychosocial measures linked to constructs in our conceptual model (Fig. 2, Table 1).

The primary study outcome is between-group difference in HbA1c change from baseline to 12 months. Secondary clinical outcomes include BP, weight, and 18- and 24-month HbA1c change. Additional secondary outcomes are linked to our conceptual model and include disease burden assessed via the Diabetes Distress Scale plus modified questions for hypertension [31,32], self-efficacy assessed via the Perceived Competence Scale [33], self-management quality assessed via the Diabetes Self-Management Questionnaire [34,35], and the Voils Medication Non-Adherence measure [36], and disease knowledge measured using the Diabetes Knowledge Questionnaire and Hypertension Knowledge Measure [37,38]. Participant engagement is examined via data transmission from study devices and EXTEND Plus intervention encounter completion [39].

In both study arms, outcome data collection occurs at parallel time points (3, 6, 9, 12, 18 and 24 months). As per Table 1, each follow-up visit includes measurement of (1) HbA1c (DCA Vantage® Analyzer, Siemens), (2) BP (average of two readings taken one minute apart after patient has been in supine position for 5 min), (3) weight and (4) completion of follow up surveys. Participants receive compensation for time and travel in the form of $75 at baseline and $50 for each completed follow-up assessment, totaling up to $375.

All data are collected and managed in a secure REDCap database and stored on a secure electronic drive for statistical analyses [20,21].

2.11. Adverse events

We assess adverse events through: 1) proactive EHR review; 2) structured self-report at each follow up visit [40]; and 3) continuous review of EHR-generated notifications regarding emergency visits and inpatient hospitalizations within DUHS. Additionally, we will examine hypoglycemia (blood glucose <70) and hypotension (SBP <90) rates from mobile monitoring data in each study arm.

2.12. Statistical analysis

Primary analysis and sample size calculations are based on tests of superiority. Hypothesis testing will be conducted according to the intention-to-treat principle with two-sided p-values at the standard 0.05 level using SAS Version 9.4 (Cary, NC). For the primary outcome (HbA1c change at 12 months), we will build linear mixed models (LMMs) that include fixed effects for linear and/or quadratic time, time-by-group interaction terms, and randomization stratification variables. To account for within-participant correlations over time, a random intercept and slope for time will be included. We will also construct LMMs to examine the durability of any HbA1c effects through 18- and 24-month time points. Effects on secondary outcomes will be examined using similar models. Given that our pilot work identified age, sex, and race/ethnicity as markers for intervention engagement, we will examine whether these markers moderate intervention effects using three-way interaction terms added to the LMM, incorporating each potential moderator, the treatment group, and time.

Should participant follow-up rates prove lower than expected, we will conduct sensitivity analyses that include clinical HbA1c and blood pressure data available in the EHR along with study-collected outcome data in order to assess the robustness of our primary analyses.

2.13. Missing data

All LMMs will employ a full maximum likelihood method using all available data. These models accommodate responses missing at random (MAR), where the missing mechanism may relate to observed covariates or response variables but not to unobserved data.

2.14. Power calculations

Based on prior studies [41,42], we assumed a mean HbA1c reduction at 12 months of 0.5 % in the EXTEND arm and 1.3 % in the EXTEND Plus arm [17], thus predicting a 0.8 % between-arm difference. Based on prior work [17], we assumed 20 % dropout by 12 months, an HbA1c standard deviation (SD) of 1.6, and a within-patient correlation of 0.5 for baseline and 12-month HbA1c. These conservative estimates indicated that 110 patients per arm would provide 90 % power to detect a between-arm difference in HbA1c change of 0.8 % (Cohen's $d = 0.5$) at 5 % alpha level. With the sample size of 220, we will also be able to detect meaningful between-group differences in change in secondary outcomes. For example, assuming a correlation between baseline and a 12 month measurement of 0.8 and 20 % dropout [17], our sample size will allow for detection of differences in SBP of 4.5 mmHg (SD = 10.4) and in weight of 5.4 kg (SD = 12.6) between baseline and 12 months with 80 % power.

2.15. Process evaluation

To guide future scaling and dissemination of the EXTEND interventions, we will conduct a Consolidated Framework for Implementation Research (CFIR)-informed process evaluation [43,44]. Using a rapid analysis approach, we will conduct semi-structured interviews with 20 patients, sampled for maximum variation (10 from each arm, balanced on gender, race, and engagement) [45,46]. Additionally, 20 relevant health system key informants, including 7 clinicians, 7 case managers, and 6 administrators, will be interviewed using purposeful sampling to ensure diverse perspectives [47,48]. Interview guides, mapping to CFIR domains and constructs, will be utilized to elicit impressions of the EXTEND interventions and gather perspectives on implementation barriers and facilitators. To obtain rich data we will use probes and follow-up questions. Interviews will be conducted via phone, last 20–30 min, and be securely recorded with permission [45,46]. We will conduct thematic analysis using the matrix method [49]; patient and key informant transcripts will be analyzed separately but will follow the same process. Development of codes and themes will be guided by a priori CCM concepts (Fig. 2) and CFIR domains.

2.16. Cost evaluation

This study also includes economic analyses that seek to: 1) compare intervention costs by trial arm; 2) simulate the impact of recent and proposed changes in Medicare reimbursement on the business case for the EXTEND interventions; and 3) estimate the budget impact of implementing the EXTEND interventions within an academic health system. We will consider costs and revenues, comparing expected per-patient implementation costs (multiplied by the number of eligible patients) to anticipated potential revenues. We are collecting intervention-related costs and health care utilization associated with the EXTEND interventions from the perspective of a large health care system. Implementation cost will include labor, capital, and equipment components. Labor costs (documented through study task logs) include intervention training time, patient recruitment, EXTEND Plus nurse and clinician time, and technical support time. Hourly wages, along with fringe benefits (based on Duke Human Resources data), will be applied to calculate total labor costs. Expected Medicare Fee-for-Service (FFS) revenues will be estimated by multiplying the number of potentially eligible reimbursable services by the Medicare reimbursement rate. Sensitivity analyses will assess how variations in the length, number, and timing of EXTEND services impact FFS revenue eligibility.

2.17. Data safety monitoring board (DSMB)

A DSMB of members with expertise relative to the EXTEND study convenes at least yearly. The DSMB reviews safety data and trial progress, and provides advice with respect to study continuation, modification, and termination.

3. Results

3.1. Baseline demographic and clinical characteristics

Enrollment occurred from April 2022 to June 2023. Of the 1761 assessed for eligibility, 264 patients were consented and 220 were randomized (Fig. 3); most of the 44 patients who were consented but not randomized were excluded because their HbA1c measured during the baseline encounter fell below inclusion criteria. Each study arm was allocated 110 patients. Table 2 presents baseline characteristics of the study population, which are generally well balanced across arms. Participants had a mean age of 54.5 years (SD = 10.3); 63.6 % were women and 68.2 % African American. Mean baseline HbA1c was 9.81 % (SD = 1.71), and mean SBP and DBP were 134.89 (SD = 20.17) and 81.09 (SD = 9.25), respectively. Baseline HbA1c was ≥10 % in 36.8 % of patients. Final 12-month outcome assessments occur in July 2024, and 24-month assessments in July 2025.

4. Discussion

4.1. Overview

EXTEND is an ongoing trial comparing the effectiveness of two 12-month mobile monitoring-enabled telehealth interventions for patients with high-risk PPDM and hypertension: a self-management facilitation intervention and a comprehensive, nurse-led program with pharmacist-led medication management. The study examines HbA1c reduction and secondary outcomes, including BP, weight, disease burden, self-efficacy, self-management, and disease knowledge. This work will provide insights into scaling and dissemination of the EXTEND interventions through cost analysis and qualitative methodologies to inform future intervention refinement and implementation.

4.2. Importance and relevance of EXTEND

The EXTEND study addresses barriers to practical use of mobile monitoring-enabled telehealth, including lack of implementation using available clinical workforce, infrastructure, and technical capabilities. Current evidence on the effectiveness of mobile technologies as self-management tools in clinic-resistant chronic diseases is limited due to its reliance on clinical staff and integration with EHRs. Moreover, the obstacles and facilitators involved in scaling mobile technology-enabled telehealth interventions within and across healthcare systems remain poorly understood, with a lack of evidence supporting sustainable

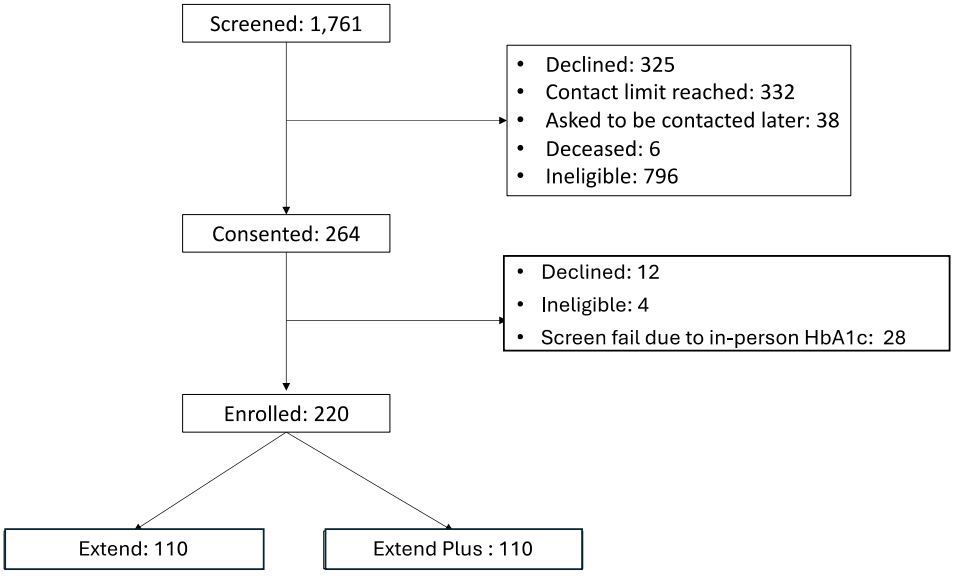


Fig. 3. EXTEND Participant Recruitment Enrollment.
*Patients were classified as "ineligible" after screening if they met any of the following criteria: a) lacked a diagnosis of Type 2 diabetes, b) age outside of target range of 30–75 years, c) did not meet HbA1c inclusion criteria, d) Did not have at least 1 appointment at primary clinic site over the past year, e) did not have hypertension or did not meet blood pressure inclusion criteria, f) did not use a smart phone with an active data plan, g) not able to provide informed consent, h) unable to speak and read English, i) diagnosis of dementia or unstable mental health condition, j) diagnosis of life-limiting illness, k) acute coronary event or hypoglycemic seizure or coma within past year, l) residing in a nursing home, m) use of an insulin pump, n) unable or unwilling to use necessary technology to participate in the study, o) currently pregnant or planning to become pregnant during study period.

Table 2
Baseline characteristics overall and stratified by intervention.

	Overall (n = 220)	Intervention (n = 110)	Control (n = 110)
Demographics			
Age (years), Mean (SD)	54.5 (10.3)	54.1 (10.1)	54.9 (10.5)
Site, n (%)			
DPC	78 (35.5 %)	39 (35.5 %)	39 (35.5 %)
Duke Endocrinology	142 (64.5 %)	71 (64.5 %)	71 (64.5 %)
Gender, n (%)			
Male	79 (35.9 %)	35 (31.8 %)	44 (40.0 %)
Female	140 (63.6 %)	75 (68.2 %)	65 (59.1 %)
Unknown	1 (0.5 %)	0 (0 %)	1 (0.9 %)
Race, n (%)			
American Indian or Alaska Native	2 (0.9 %)	2 (1.8 %)	0 (0.0 %)
Asian	2 (0.9 %)	2 (1.8 %)	0 (0.0 %)
Black or African American	150 (68.2 %)	77 (70.0 %)	73 (66.4 %)
Native Hawaiian or Other Pacific Islander	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
White	47 (21.4 %)	19 (17.3 %)	28 (25.5 %)
More than one race	5 (2.3 %)	2 (1.8 %)	3 (2.7 %)
Unknown	14 (6.4 %)	8 (7.3 %)	6 (5.5 %)
Ethnicity, n (%)			
Not Hispanic/Latino	217 (98.6 %)	109 (99.1 %)	108 (98.2 %)
Hispanic/Latino	2 (0.9 %)	0 (0 %)	2 (1.8 %)
Unknown	1 (0.5 %)	1 (0.9 %)	0 (0 %)
Marital Status, n (%)			
Single	74 (33.6 %)	32 (29.1 %)	42 (38.2 %)
Married	92 (41.8 %)	49 (44.5 %)	43 (39.1 %)
Engaged	3 (1.4 %)	1 (0.9 %)	2 (1.8 %)
Living together in a committed relationship	6 (2.7 %)	3 (2.7 %)	3 (2.7 %)
Separated	10 (4.5 %)	6 (5.5 %)	4 (3.6 %)
Divorced	21 (9.5 %)	10 (9.1 %)	11 (10.0 %)
Widowed	9 (4.1 %)	4 (3.6 %)	5 (4.5 %)
Unknown	5 (2.3 %)	5 (4.5 %)	0 (0 %)
Education, n (%)			
Grade school/ middle school	2 (0.9 %)	1 (0.9 %)	1 (0.9 %)
Some high school	13 (5.9 %)	8 (7.3 %)	5 (4.5 %)
High school graduate or equivalent	40 (18.2 %)	11 (10.0 %)	29 (26.4 %)
Trade/technical/vocational school	17 (7.7 %)	11 (10.0 %)	6 (5.5 %)
Some college credit but no degree	52 (23.6 %)	32 (29.1 %)	20 (18.2 %)
Associate's degree (AA or AS)	18 (8.2 %)	7 (6.4 %)	11 (10.0 %)
Bachelor's degree (BA or BS)	37 (16.8 %)	18 (16.4 %)	19 (17.3 %)
Post graduate work or graduate degree	37 (16.8 %)	18 (16.4 %)	19 (17.3 %)
Unknown	4 (1.8 %)	4 (3.6 %)	0 (0 %)
Income, n (%)			
Less than $10,000	37 (16.8 %)	22 (20.0 %)	15 (13.6 %)
$10,000- 19,999	27 (12.3 %)	14 (12.7 %)	13 (11.8 %)
$20,000- 29,999	22 (10.0 %)	11 (10.0 %)	11 (10.0 %)
$30,000- 39,999	31 (14.1 %)	12 (10.9 %)	19 (17.3 %)
$40,000- 49,999	20 (9.1 %)	11 (10.0 %)	9 (8.2 %)
$50,000- 59,999	17 (7.7 %)	6 (5.5 %)	11 (10.0 %)
$60,000- 79,999	16 (7.3 %)	9 (8.2 %)	7 (6.4 %)
$80,000 or more	22 (10.0 %)	6 (5.5 %)	16 (14.5 %)
Unknown	28 (12.7 %)	19 (17.3 %)	9 (8.2 %)
Patient Centered Measures, Mean (SD)			
Diabetes Distress Scale: Total Score	2.45 (1.04)	2.44 (1.09)	2.46 (0.99)
Diabetes Distress Scale: Emotional Burden	2.97 (1.40)	2.92 (1.45)	3.01 (1.35)
Diabetes Distress Scale: Regimen-Related Distress	2.89 (1.27)	2.81 (1.28)	2.97 (1.26)
Diabetes Distress Scale: Interpersonal Distress	1.93 (1.27)	2.00 (1.31)	1.86 (1.22)
Diabetes Distress Scale: Physician-Related Distress	1.61 (1.05)	1.65 (1.11)	1.58 (0.98)
Diabetes Self-Management: Total Score	6.15 (1.51)	6.09 (1.45)	6.22 (1.57)
Diabetes Self-Management: Glucose Management	6.51 (2.23)	6.33 (2.26)	6.69 (2.19)
Diabetes Self-Management: Dietary Control	4.60 (2.07)	4.64 (2.14)	4.56 (2.00)
Diabetes Self-Management: Physical Activity	6.02 (2.38)	5.96 (2.31)	6.07 (2.45)
Diabetes Self-Management: Health-Care Use	7.94 (2.04)	7.97 (2.08)	7.92 (2.00)
Voils Medication Non-Adherence	1.93 (0.86)	2.04 (0.93)	1.81 (0.78)
Diabetes Knowledge Questionnaire	16.30 (3.80)	16.26 (3.79)	16.34 (3.83)
Godin Leisure Time Exercise: total score	33.20 (65.33)	32.60 (67.91)	33.79 (63.03)
Godin Leisure Time Exercise: total score categories			
Insufficiently Active/Sedentary: <14	111 (52.11 %)	56 (53.33 %)	55 (50.93 %)
Moderately Active: 14–23	31 (14.55 %)	17 (16.19 %)	14 (12.96 %)
Active: ≥ 24	71 (33.33 %)	32 (30.48 %)	39 (36.11 %)
New Vital Sign	3.12 (1.96)	2.93 (2.00)	3.30 (1.90)
Digital Health Literacy Scale	7.84 (3.83)	7.43 (4.17)	8.23 (3.49)
Perceived Competence	4.80 (1.50)	4.86 (1.53)	4.74 (1.48)
Clinical Variables			
Medication use, n (%)			

(*continued on next page*)

Table 2 (*continued*)

	Overall ($n = 220$)	Intervention ($n = 110$)	Control (n = 110)
No insulin	29 (13.30 %)	12 (11.11 %)	17 (15.45 %)
Basal insulin	126 (57.80 %)	69 (63.89 %)	57 (51.82 %)
Mixed insulin	21 (9.63 %)	9 (8.33 %)	12 (10.91 %)
Prandial insulin	96 (44.04 %)	49 (45.37 %)	47 (42.73 %)
Metformin	113 (51.83 %)	54 (50.00 %)	59 (53.64 %)
Thiazolidinediones	5 (2.29 %)	4 (3.70 %)	1 (0.91 %)
DPP4 inhibitors	7 (3.21 %)	4 (3.70 %)	3 (2.73 %)
SGLT2 inhibitors	48 (22.02 %)	19 (17.59 %)	29 (26.36 %)
Sulfonylureas	33 (15.14 %)	17 (15.74 %)	16 (14.55 %)
GLP 1 receptor agonist	82 (37.61 %)	33 (30.56 %)	49 (44.55 %)
Tirzepatide	6 (2.75 %)	3 (2.78 %)	3 (2.73 %)
Pramlintide	0 (0 %)	0 (0 %)	0 (0 %)
Systolic blood pressure, average (SD)	134.89 (20.17)	136.21 (21.65)	133.57 (18.59)
Diastolic blood pressure, average (SD)	81.09 (9.25)	81.36 (9.84)	80.81 (8.66)
HbA1c, n (%)			
$<$ 10 %	139 (63.2 %)	70 (63.6 %)	69 (62.7 %)
$\geq$ 10 %	81 (36.8 %)	40 (36.4 %)	41 (37.3 %)
HbA1c, mean (SD)	9.81 (1.71)	9.80 (1.74)	9.82 (1.70)
Weight, mean (SD)	234.96 (56.30)	232.56 (57.13)	237.37 (55.62)
Weight, median (IQR)	231.40 (191.15–265.90)	223.84 (191.40–264.60)	238.20 (190.90–267.20)
Height, mean (SD)	67.12 (7.46)	66.38 (3.88)	67.86 (9.76)
Height, median (IQR)	66.50 (64.00–69.50)	65.80 (63.50–69.00)	67.00 (64.20–69.50)

reimbursement models. Addressing these barriers is particularly urgent in diseases like PPDM and uncontrolled hypertension because continued standard care leaves patients at high risk for complications and costs. The EXTEND study aims to overcome these barriers by aligning with the capabilities of the current clinical workforce and existing EHR infrastructure to the greatest extent possible, while also incorporating consumer-friendly mobile monitoring technologies.

Prior studies show nurse and clinical pharmacist participation in remote chronic disease management can improve outcomes [50–52]. However, comprehensive, mobile monitoring-enabled telehealth delivered by nurses and pharmacists has seldom been accomplished in real-world practice. EXTEND's explicit use of existing clinical staffing to the greatest possible extent may facilitate implementation and scaling, while allowing participating nurses and pharmacists to operate at their full scope of practice in the context of EXTEND Plus. Critically, our implementation analyses will identify barriers and facilitators of delivering a mobile monitoring-enabled telehealth intervention, which will facilitate refinement of the studied programs. Similarly, our cost analyses will help assure the delivery of a mobile monitoring-enabled telehealth in a sustainable manner.

Effective real-world implementation of mobile monitoring-enabled telehealth relies on automating patient-generated health data integration into the EHR. However, such integration is challenging due to barriers including digital equity, health literacy, lack of interoperability, data management, and workflow barriers, among others [53,54]. Our team successfully integrated several mobile monitoring technologies (glucometer, scale, activity tracker, and BP monitor) using both Apple Inc. and Android platforms, to aid in chronic disease self-management, allowing for longitudinal collection of health data from diverse populations [39,55–60]. The innovative IT system created for EXTEND leverages clinical infrastructure to enable within-EHR ordering of mobile monitoring devices, incorporation of patient-generated data into the EHR, generation of EHR-integrated alerts for abnormal values, and data visualization for clinical encounters [19]. This work provides a foundation for mobile monitoring-enabled telehealth delivery in real-world practice and should be amenable to dissemination across US healthcare systems with similar EHR infrastructure.

Our work also highlights the need for continued expansion of infrastructure to support future mobile monitoring advancements, such as integration of CGM data into EHR systems. Additionally, incorporation of multiple mobile monitoring technologies into telehealth-based care will require ample patient-facing technical support to ensure equitable utilization across populations with varying digital literacy. For example, older African American individuals may be less likely to use technology for health-related purposes [61].

Nevertheless, with over 90 % of the US population owning a smartphone, including populations with higher rates of PPDM (low-income, racial/ethnic minority individuals), [62], our ability to gather mobile monitoring data from broad, generalizable populations is growing. The EXTEND trial thus presents an opportunity to address disparities in chronic disease care. Our consideration of inclusivity in device selection and requirement of a smartphone data plan (rather than in-home internet) may help mitigate disparities in technology adoption. Leveraging participant-owned smartphones and readily accessible consumer mobile monitoring devices, likewise enhances the EXTEND interventions' translational potential. This work is further strengthened by our community engaged approach.

4.3. Limitations

The EXTEND trial cohort may not reflect all populations with PPDM and uncontrolled hypertension, so findings from this study may not fully generalize to all clinical settings. For example, participants are required to own a smartphone and use multiple monitoring devices, which might limit applicability to patients with low digital literacy. Furthermore, delivering the EXTEND Plus intervention may not be feasible in clinical settings where the availability of nurse interventionists and CPPs is limited. Of note, the EXTEND Plus intervention has several components, but the study does not explore whether a simpler approach could be equally effective. The trial was launched during the COVID-19 pandemic, which presented various challenges, including recruiting nurses amid a national shortage, dealing with rapid inflation (e.g., increased patient travel costs), and social drivers of health that disproportionately affect our patient population.

5. Conclusions

The EXTEND trial will generate data that may help make mobile-monitoring enabled telehealth a feasible, real-world option for PPDM and uncontrolled hypertension. Should the EXTEND and/or EXTEND Plus programs prove effective, we will leverage our process and cost evaluation data to partner with key shareholders in implementing the interventions within our system and other healthcare systems. We will also explore adapting the EXTEND approaches for other chronic diseases

that would benefit from mobile monitoring-enabled telehealth (e.g., heart failure, chronic obstructive lung disease). Because the EXTEND interventions were specifically designed for feasible implementation, this work may help reshape current paradigms in chronic disease care by addressing fundamental barriers to practical use of telehealth.

CRediT authorship contribution statement

Jashalynn German: Writing – review & editing, Writing – original draft, Investigation. **Qing Yang:** Writing – review & editing, Formal analysis, Data curation. **Daniel Hatch:** Writing – review & editing, Formal analysis, Data curation. **Allison Lewinski:** Writing – review & editing, Writing – original draft, Investigation, Conceptualization. **Hayden B. Bosworth:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Brystana G. Kaufman:** Writing – review & editing, Writing – original draft, Methodology. **Ranee Chatterjee:** Writing – review & editing, Investigation, Conceptualization. **Gina Pennington:** Writing – review & editing, Writing – original draft, Project administration, Methodology. **Doreen Matters:** Writing – review & editing, Writing – original draft, Project administration, Methodology. **Donghwan Lee:** Writing – review & editing, Investigation. **Diana Urlichich:** Writing – review & editing, Investigation. **Sarah Kokosa:** Writing – review & editing, Methodology, Investigation. **Holly Canupp:** Writing – review & editing, Methodology, Investigation. **Patrick Gregory:** Writing – review & editing, Methodology, Investigation. **Cindy Leslie Roberson:** Writing – review & editing, Methodology, Investigation. **Benjamin Smith:** Writing – review & editing, Methodology, Investigation. **Sherry Huber:** Writing – review & editing, Methodology, Investigation. **Katheryn Doukellis:** Writing – review & editing, Methodology. **Tammi Deal:** Writing – review & editing, Methodology. **Rose Burns:** Writing – review & editing, Methodology. **Matthew J. Crowley:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Ryan J. Shaw:** Writing – review & editing, Writing – original draft, Supervision, Software, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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