Patient Preference and Adherence

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ORIGINAL RESEARCH

Feasibility of a Randomized Controlled Mixed Methods Trial to Address Health Literacy, Beliefs, Medication Adherence, and Self-Efficacy (ADHERE) in a Clinical Pharmacist-Led Clinic

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Purpose: To assess the feasibility and acceptability of a health literacy-psychosocial support intervention – ADHERE and explore changes in glycemic values and medication adherence.

Patients and Methods: Thirty-one participants with hemoglobin A1c (HbA1c) ≥ 8% were randomly allocated to control (usual care) or intervention groups (receiving usual care plus a 6-session pharmacist-led intervention focusing on the modifiable psychosocial factors that may influence medication adherence). Feasibility metrics evaluated recruitment, retention, and intervention adherence. Questionnaires were administered to collect psychosocial factors and self-reported medication adherence at baseline, the end of the intervention, 3 months, and 6 months post intervention. HbA1c values were extracted from electronic medical records. Repeated measures analysis of variance was used to compare differences in mean outcomes between the control and intervention groups. To assess intervention acceptability, eleven individuals participated in semi-structured interviews about their intervention experiences. Qualitative content analysis was used for analyzing the interviews.

Results: Thirty participants completed the study. Overall, the findings support the feasibility of the intervention. There were significant differences in HbA1c values. Participants in the intervention group had lower A1C (8.3 ± 1.4) than in the control group (9.2 ± 1.3) at the time of 6-month follow-up ($p = 0.003$). In addition, the participants in the intervention group showed improved HbA1c at 6-month follow-up (8.3 ± 1.4), compared to baseline (9.4 ± 1.5, $p = 0.011$) and after 6-session intervention (8.9 ± 1.6, $p = 0.046$). However, there were no significant differences in medication adherence between groups over time. Qualitative themes suggest participants liked the intervention and perceived the additional support from the pharmacist as beneficial.

Conclusion: A pharmacist-led intervention to provide additional health literacy-psychosocial support may contribute to long-term improvements in HbA1c. Equipping pharmacists with patient-specific diabetes medication adherence information and building in additional follow-up support for patients may improve patient health outcomes.

Keywords: type 2 diabetes, medication adherence, health literacy, hemoglobin A1c, self-efficacy

Introduction

Diabetes remains one of the most prevalent health conditions in the US. In 2018, 34.2 million Americans had diabetes, and in 2017, diabetes was ranked the seventh leading cause of death with the total costs of diabetes as $327 billion.[1] Diabetes medication adherence rates are reported as low as 36%.[2] According to the World Health Organization, improving medication adherence may have a larger influence on patient outcomes and socioeconomic burden than

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addressing treatment improvements.[3] Improving medication adherence (henceforth called "adherence") is also important for self-management of diabetes.[4,5]

A systematic review summarizing pharmacist-led activities to manage type 2 diabetes (T2D) reported that involving a pharmacist resulted in improved economic, health, and humanistic outcomes.[6] Pharmacists have the capability to positively influence medication adherence in patients with diabetes in a variety of ways, including providing patient education, enhancing positive reinforcement for support in medication adherence, helping patients formulate a medication treatment plan; initiating or modifying medication therapy; monitoring patient response to therapy; and identifying, resolving, and preventing adverse events and other medication-related problems.[6] Patient-related factors have been recognized as playing a large role in adherence, including psychosocial and behavioral factors.[7] Patients with chronic health conditions often appear asymptomatic and sometimes beliefs, concerns, or perceptions about their condition and/or treatment affect their medication-taking. Clinical pharmacists caring for these patients may provide information addressing these factors to improve adherence.[7]

While adherence has been associated with better outcomes in patients with T2D, it is still unclear which interventions are most effective.[8] Approaches to improve adherence include sharing patient-friendly self-care materials or one-on-one teaching focused on diabetes-related knowledge;[9] however, enhancing patients' knowledge alone does not necessarily lead to behavior changes.[10,11] Alternatively, behavior changes tend to occur when education, motivation, and behavioral skills are all emphasized. Increasing patients' motivations to adopt a positive behavior like adherence can best be addressed through reframing negative medication beliefs and illness perceptions.[12] Developing behavioral skills is associated with increasing patients' perception of self-confidence in diabetes self-management.[12] Previous studies have identified an association between health literacy and improved diabetes outcomes. Health literacy may enhance the engagement between patients and their healthcare provider regarding medications.[12] However, improving health literacy alone does not improve diabetes-related outcomes.[13] Interventions need to increase self-efficacy and confidence in making behavior changes.[13–15]

Our previous studies identified medication self-efficacy, illness perceptions, and medication beliefs as important contributors to adherence among patients with T2D.[16–18] Hence, we designed a comprehensive intervention which addressed health literacy, beliefs, medication adherence, and self-efficacy (ADHERE). In the ADHERE intervention, clinical pharmacists addressed health literacy, provided psychosocial support via addressing beliefs about diabetes and medications, and incorporated self-efficacy discussions into tailored diabetes care for patients. The strategy used in ADHERE was to build patients' capacity to be motivated in their self-management.[15,18,19]

This study aimed to assess the intervention feasibility and acceptability, and evaluate its effect on medication adherence and HbA1c. We compared adherence and glycemic values of patients receiving usual care only (eg, traditional pharmacist-led patient education and medication counseling) to those receiving usual care augmented with health literacy- psychosocial support.

Materials and Methods

Study Design

ADHERE was a prospective longitudinal randomized controlled feasibility trial (RCT) with two arms. Using an explanatory sequential mixed methods design, the intervention was piloted in Phase 1 to examine its feasibility and acceptability and explore the intervention effects on patient outcomes. Phase 2 utilized qualitative interviews to explore participants' experiences and explain the changes in outcomes due to the intervention. By collecting both quantitative and qualitative data sequentially, and then integrating these data, it allowed us to fully assess the acceptability and outcomes of the intervention.[20] The Health Sciences Institutional Review Board of the University of Wisconsin-Madison and the Veterans Administration (VA) Research and Development Committee approved the study procedures (2017–0951). The study is registered on ClinicalTrials.gov [NCT03406923] and was completed from January 2018 to February 2021. This study complies with the Declaration of Helsinki.

Study Site

This study was conducted at a Veterans Affairs primary care clinic and a pharmacist led diabetes clinic in a Midwestern city.[21] Patients with poor glycemic control are referred to these clinics by their primary care providers for consultation with clinical pharmacists. Clinical pharmacists conduct one-on-one visits with patients and optimize therapy by changing, initiating, or discontinuing diabetes-related medications.

Participants

Thirty-one participants were enrolled. The eligibility criteria included being English speaking, aged 18–80 years old with diagnosed diabetes, currently taking at least one diabetes medication, being nonadherent to medications and having poor glycemic control (ie, HbA1c $\geq$ 8% in the past 18 months). For phase 2, 11 of the 31 participants who completed the intervention participated in interviews.

Recruitment

Convenience sampling was used for patient recruitment. Study team queried the VA electronic health record database to identify eligible patients at the diabetes and primary care clinics who were diagnosed with diabetes and had an HbA1c $\geq$ 8% in the past 18 months. Subsequently, the pharmacists reviewed diabetes clinic notes from this subset of patients to identify those who were nonadherent to taking diabetes medications. For example, patients were classified as nonadherent if they reported missing two or more insulin doses in the two weeks prior. Researchers mailed study invitation letters and informed consent documents to eligible patients. Three weeks prior to their next clinic appointment, a research team member followed up by phone to answer questions and inquire about study participation. Informed consent was obtained from the study participants prior to study commencement. Participants arrived one hour prior to their scheduled appointment with the pharmacist and met with researchers to complete the informed consent and baseline questionnaires. Participants who completed the intervention were invited to participate in interviews. Informed consent included publication of anonymized responses.

Randomization

Upon enrollment, participants were randomly assigned using concealed allocation to either usual care (n=15) or the intervention group (n=16).[22] Figure 1 describes the randomization process.

Study Arms

Participants were assigned to either of two arms.

Usual Care

Usual care from the clinical pharmacist included checking medication use understanding, adjusting diabetes medication doses, monitoring HbA1c values, screening and monitoring for diabetes-related complications, and making referrals for additional care if needed.

Intervention (ADHERE)

Prior to initiating the intervention, the research assistant provided the pharmacist the baseline survey results that identified participants' specific barriers to medication taking and concerns about diabetes self-management. The 6-session intervention involved the pharmacist collaboratively working with the participant to: (1) address concerns about medications, (2) discuss medication taking barriers and self-management focusing on self-efficacy, beliefs about medicines, and illness perceptions, (3) collaborate with the participants to target specific goals related to increasing their self-efficacy for medication use, addressing their beliefs about diabetes and medications and providing individualized plans based on the participant's goals. Table 1 summarizes the intervention procedures.

Three clinical pharmacists engaged in delivering the intervention separately. Each pharmacist was trained by the Principal Investigator and study coordinator on how to implement the intervention. The 60-minute training involved familiarizing the pharmacist with the form summarizing the participant's survey scores, reviewing how to utilize the

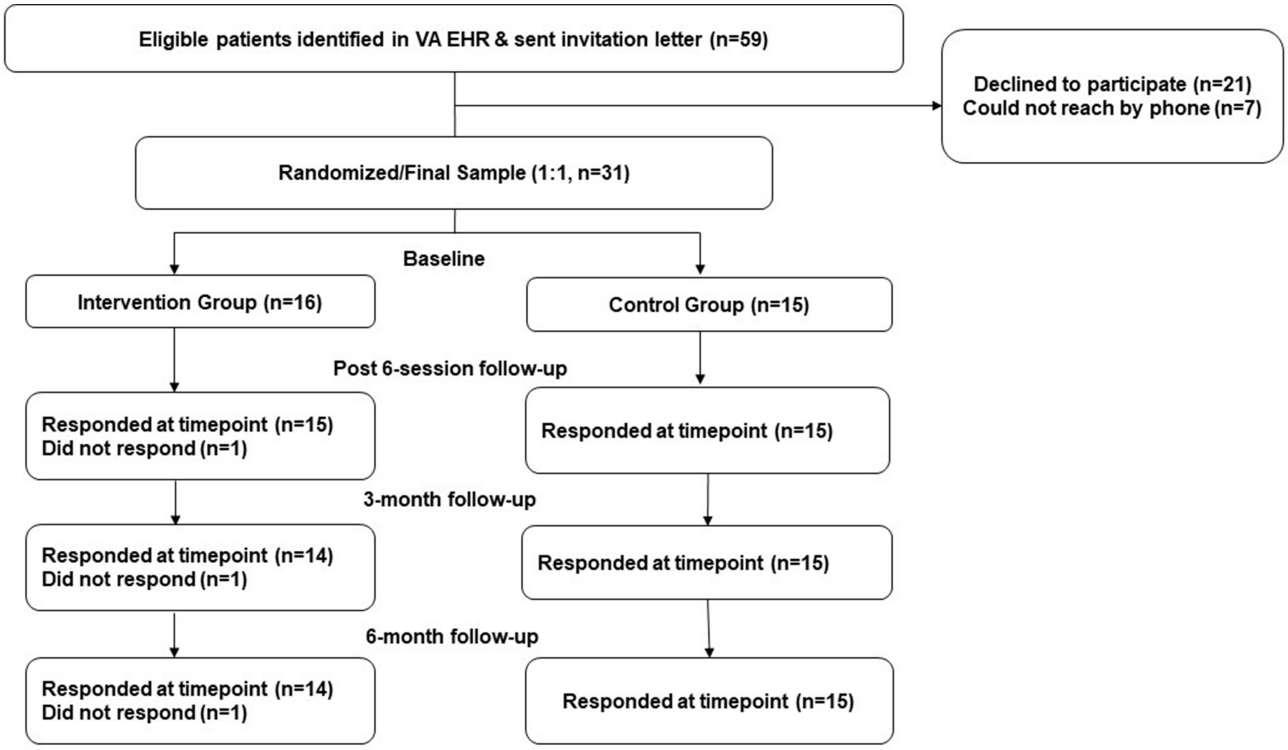

Figure 1 Overview of the study recruitment process.

intervention manual to address the identified psychosocial concerns and having the pharmacist role play the intervention with a mock participant.

Data Collection

Phase 1

To assess feasibility, we examined recruitment, retention rates, and intervention adherence. Recruitment rate was the number of invited patients who agreed to enroll in the study relative to our recruitment goal. Related to retention, we recorded the number of participants who completed outcome assessments at both baseline and 6-month follow-up, with

Table 1 Details of the 6-Session Intervention

	Details of the Intervention
Prior to Session 1	Collected baseline information related to participants' psychosocial factors, scored the survey items, and flagged the items that indicated concerns or challenges. The information was provided to the pharmacist for review before they met with the participant.
Session 1	The initial 45-minute face-to-face session between the participant and pharmacist occurred during a regularly scheduled clinic appointment. The pharmacist discussed participants' self-management goals, self-efficacy and details of the intervention based on the baseline evaluation of their psychosocial factors. The pharmacist provided the patient an educational handout tailored to address the participant's specific area of concern.
Session 2–5	The pharmacist followed-up during 10-minute phone calls with participants every 2–3 weeks to discuss the participant's agreed upon goals and action plans, progress and any concerns about diabetes and medications. Phone calls also reinforced participants' psychosocial factors to improve their medication adherence and self-management skills.
Session 6	The final 45-minute face-to-face session with the pharmacist occurred during their regularly scheduled clinic appointment. The goal was for the pharmacist to reexamine the participant's goals related to diabetes management and psychosocial factors. Due to COVID-19, some of these final follow-up visits occurred over the phone.

the goal of 80% of participants completing baseline assessments. Intervention adherence was assessed by participant's completion of the face-to-face (or virtual during COVID) and telephone appointments with the pharmacist.

A secondary goal was to assess the feasibility of gathering and assessing intervention outcomes. A brief 20-minute questionnaire was administered to participants to collect baseline information including sociodemographic, psychosocial factors (beliefs in medications, illness perception, and medication self-efficacy), and self-reported adherence. HbA1c values were extracted from electronic medical records. Questionnaires were administered at four different time points: baseline, the end of the 6-sessions, 3 months, and 6 months post intervention. Data collection occurred either in-person or over the phone (due to COVID-19 restrictions). All participants received a US $150 incentive for study completion.

Phase 2

We conducted 60-minute, semi-structured interviews with 11 participants. Interviews were held in a private room at the VA clinic or over the phone. All interviews were audio-recorded and transcribed verbatim. Individuals who completed an interview received an additional US $25.

Outcome Measures

Phase 1

Table 2 summarizes the Phase 1 feasibility outcome measures. Table 3 details the intervention outcome measures for primary and secondary outcomes, indicating the timing of assessments. Participant sociodemographic information was collected as well as clinical information.

Phase 2

The semi-structured interviews explored participant intervention experiences, acceptability, and impact on taking diabetes medications. Table 4 shows the sample interview questions.

Data Analysis

Phase 1: Quantitative Analysis

Descriptive statistics summarized the participants' characteristics and intervention feasibility. Repeated measures analysis of variance (ANOVA) was used to compare differences in mean scores of outcome variables over the intervention time points. Separate repeated measures ANOVA were used to compare the mean scores of these outcome variables between the intervention and control groups over 4 time points, except health literacy (2 time points) and medication adherence (3 time points). All statistical analyses were performed using SPSS version 26.

Phase 2: Qualitative Analysis

All transcribed interviews were verified against the audio recordings by a research assistant. We conducted content analysis, organized, and categorized the themes using NVivo 12 (QSR International-Melbourne). The analytical strategy included an initial immersion in the data by reading all the transcripts, creating labels and codes, and organizing and categorizing the themes.[31] Inductive open coding was used for this process, and the themes were compared across participants' responses to

Table 2 Phase 1 Feasibility Outcome Measures and Timing of Assessment

Outcome	Measure	Baseline	After 6-Session Intervention	3-Month Post-Intervention	6-Month Post-Intervention
Feasibility of recruitment	Recruitment rate: number enrolled/number of eligible individuals invited to participate	X			
Feasibility of retaining participants	Number of participants who completed outcome assessments at 6-month/number of participants who completed baseline	X			X
Intervention adherence	Proportion of pharmacist appointments and follow-up phone calls completed		X		

Table 3 Phase I Intervention Outcome Measures and Timing of Assessment

Outcome	Measure	Description	Baseline	After 6-Session Intervention	3-Month Post-Intervention	6-Month Post-Intervention
Primary outcomes						
Medication adherence	ARMS-D[23]	Self-reported medication adherence;[23,24] lower scores indicate fewer problems with medication adherence.	X		X	X
	MAR-Scale[25]	Reasons for medication nonadherence; higher scores mean more barriers to taking medications.	X	X	X	X
Glycemic Control	HbA1c	Abstracted from electronic medication records. Lower HbA1c values, ≤ 8.0%, represented better glycemic control.[26]	X	X	X	X
Secondary outcomes						
Health literacy	NVS[27]	6-item assessment; higher scores indicate better health literacy	X			X
Beliefs in medicine	BMQ[28]	Assesses patient concerns about medicines and perceived necessity of taking medicines; Higher scores indicate stronger concern or necessity beliefs about medicines	X	X	X	X
Illness perceptions	BIPQ[29]	Assesses beliefs about diabetes; Higher scores represent a more threatening perception of diabetes	X	X	X	X
Self-efficacy	SEAMS[30]	Measure medication self-efficacy in taking diabetes medications correctly; higher scores represent more self-efficacy in adhering to medication use	X	X	X	X

Abbreviations: ARMS-D, adherence and refills to medication survey – diabetes; MAR-Scale, medication to adherence rating scale; HbA1c, hemoglobin A1C; NVS, newest vital sign; BMQ, belief about medicines questionnaire; BIPQ, Brief illness perception questionnaire; SEAMS, self-efficacy for appropriate medication use scale.

explore similarities, differences, and connections across other codes. Memos and emerging relationships between themes were documented throughout the analysis. Data saturation occurred when no new dimensions could be identified within the data.[31–33] Two individuals with experience in qualitative research initially coded the transcripts independently, then met to

Table 4 Sample Interview Questions with Intervention Participants

Item	Questions
1.	What was useful about the first face-to-face session with the pharmacist?
2.	What did you find useful about the educational handout that the pharmacist gave to you during the first face-to-face session?
3.	What was unclear about the educational handout?
4.	In what ways did the follow-up phone appointments with the pharmacist address the goals that you had set in the first face-to-face session?
5.	What was helpful about the second face-to-face session/final in-person appointment with the pharmacist?
6.	How has the additional support (ie, the intervention as a whole: first in-person discussion with the pharmacist, the follow-up phone appointments, the second in-person discussion) made a difference to you?
7.	How did receiving the additional support from the whole intervention affect how you take your diabetes medicines?
8.	How did receiving the additional support from the pharmacist affect the concerns that you had about your diabetes medicines?
9.	How did receiving the additional support from the pharmacist change your perception of how diabetes affects your life?

Table 5 Demographic and Clinical Characteristics of the Participants (n=31)

Variables	Control (n = 15)	Intervention (n = 16)
	n (%)	
Age (Mean ± S.D.)	59.9 (9.6)	59.1 (13.0)
Gender		
Male	15 (100)	16 (100)
Race		
Non-Hispanic White	13 (100)	12 (75.0)
Black or African American	1 (6.7)	2 (12.5)
American Indian or Alaska Native	1 (6.7)	1 (6.3)
Others	0 (0.0)	1 (6.2)
Education		
High school graduate or GED	6 (40.0)	4 (25.0)
Trade School	0 (0.0)	3 (18.8)
Some college	7 (46.7)	3 (18.8)
Associate degree or a 2-year college degree	0 (0.0)	3 (18.8)
Bachelor's degree or a 4-year college degree	2 (13.3)	2 (12.5)
Missing	0 (0.0)	1 (6.3)
Annual household income		
Less than 20,000	5 (33.3)	1 (6.3)
Equal or more than 20,000	9 (60.0)	13 (81.3)
Missing	1 (6.7)	2 (12.5)
Types of diabetes		
Type 1 diabetes	2 (13.3)	3 (18.8)
Type 2 diabetes	13 (86.7)	12 (75.0)
Missing	0 (0.0)	1 (6.3)
Number of chronic illnesses (Mean ± S.D.)	4.3 (1.3)	4.5 (1.1)
Number of diabetes medications (Mean ± S.D.)	2.4 (1.2)	2.9 (0.9)
Insulin use		
Yes	9 (60.0)	10 (62.5)
No	6 (40.0)	5 (31.3)
Missing	0 (0.0)	1 (6.3)
Years of diabetes diagnosed (Mean ± S.D.)	17.6 (8.9)	14.1 (9.8)
Baseline HbA1c level (%) (Mean ± S.D.)	9.5 (1.6)	9.4 (1.5)
Self-reported health status		
Poor	1 (6.7)	0 (0.0)
Fair	3 (20.0)	5 (31.3)
Good	9 (60.0)	8 (50.0)
Very good	2 (13.3)	2 (12.5)
Excellent	0 (0.0)	1 (6.7)

Abbreviation: S.D, standard deviation.

discuss similarities and differences. Finally, a meeting to discuss, identify, and agree on the final themes occurred. For the result interpretation, the data were discussed in the context of the intervention and outcomes.[33]

Results

Demographic and Clinical Characteristics

All participants were male with a mean age of 59 years old and most were non-Hispanic White (Table 5). More than 80% had type 2 diabetes and took at least 2 medications for diabetes. Mean HbA1c at the baseline was about 9.5%.

Feasibility Outcomes

Recruitment

Thirty-one participants were enrolled, 16 participants were allocated to the intervention group and 15 participants were allocated to the control group. One participant was lost to follow-up and 30 participants completed the study. Our initial recruitment goal was to enroll 50 participants; however, we encountered recruitment challenges, allowing us to recruit 30 participants. Though we did not meet our initial recruitment goal, we exceeded our revised goal, with 31/30 recruited and enrolled.

Retention

Twenty-nine (94%) and 27 (87%) of participants completed assessment for the primary outcomes, medication adherence and HbA1c, respectively at the 6-month follow up assessment. This surpasses our a priori retention goal of 80%.

Intervention Adherence

We report high rates of intervention adherence, with participants having a mean attendance of 97% for the two appointments with the pharmacist (sessions 1 and 6) and pharmacists completing 52 of 64 (81%) of the overall follow-up intervention phone calls with participants and 88% of participants completing 3 or 4 calls with the pharmacist.

Phase I Exploratory Outcomes

Comparison of HbA1c and Medication Adherence Between Groups

There were significant differences in HbA1c values between the two groups over time. Time had a significant moderator effect on the relationship between the group and HbA1c values (p = 0.029) (Figure 2). When the moderator effect was examined based on the groups that participants were assigned, there was a significant negative association between follow-up time and HbA1c in the intervention group, but in the control group there was no association between follow-up

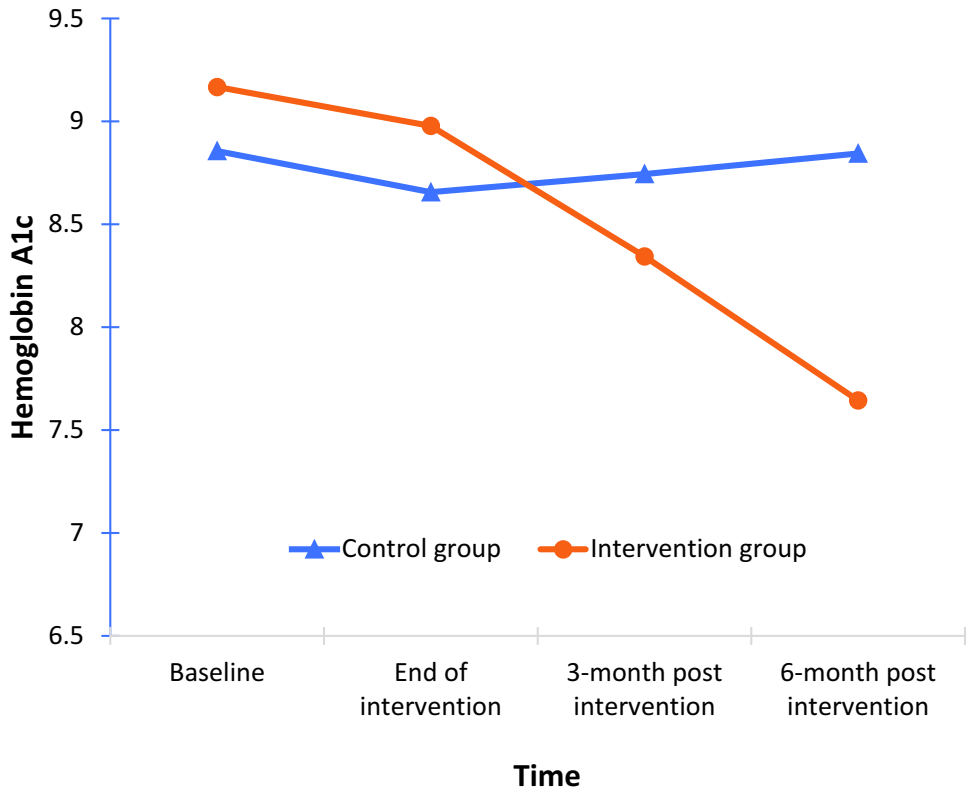

Figure 2 The trends in the change in HbA1c values and time between the control and intervention groups.

Table 6 Comparison of Outcome Variables Between Groups Over Time (n = 31)

	Baseline		6-Sessions After Enrollment		3-Month Follow-Up (Post Intervention)		6-Month Follow-Up (Post Intervention)	
Variables	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
Health literacy	4.1 ± 1.5	4.3 ± 2.1					4.9 ± 0.9	4.0 ± 0.8
Beliefs in medicines – Necessity	21.3 ± 3.2	20.3 ± 4.1	19.8 ± 6.2	19.6 ± 3.9	20.8 ± 3.6	20.9 ± 3.9	22.1 ± 2.2	20.0 ± 4.5
Beliefs in medicines – Concern	12.3 ± 5.8	12.7 ± 5.0	11.9 ± 5.2	13.1 ± 4.0	11.6 ± 3.3	12.3 ± 4.1	13.0 ± 3.7	12.4 ± 4.8
Illness perception*	44.5 ± 7.0 [a, b]	39.9 ± 11.7	38.2 ± 6.5	40.4 ± 8.6	37.5 ± 9.7 [a]	39.6 ± 10.9	37.0 ± 7.8 [b]	36.8 ± 12.4
Self-efficacy for medication use	33.5 ± 5.5	33.5 ± 3.8	34.9 ± 5.6	32.9 ± 5.5	36.5 ± 3.9	36.9 ± 1.7	36.8 ± 3.4	35.8 ± 5.0
Adherence – Medication-taking	24.7 ± 2.4	24.9 ± 1.7			26.2 ± 1.7	25.4 ± 1.7	26.8 ± 1.3	26.4 ± 1.7
Adherence – Medication-refill	12.9 ± 2.2	13.1 ± 1.6			12.9 ± 0.6	12.9 ± 0.9	13.2 ± 0.9	12.9 ± 0.9
Barriers to medication adherence								
Logistic	20%	6.7%	14.3%	64.3%	13.3%	21.4%	13.3%	21.4%
Belief	13.3%	7.1%	20%	7.1%	13.3%	7.1%	0	0
Remembering	20%	53.3%	40%	64.3%	20%	50%	13.3%	28.6%
Concern	13.3%	6.7%	0	0	0	0	0	0
HbA1c level (%)**	9.5 ± 1.6	9.4 ± 1.5 [c]	9.2 ± 1.5	8.9 ± 1.6 [d]	8.7 ± 1.4	8.6 ± 1.5	9.2 ± 1.3 [e]	8.3 ± 1.4 [c, d, e]

Notes: The barriers to medication adherence are presented as the percentage of patients who were non-adherent to medications corresponding to each subdomain. [a–e]Significant differences based on the post-hoc analysis. *$p < 0.05$, **$p < 0.01$.

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time and HbA1c. Intervention participants had reduced HbA1c (8.3 ± 1.4) compared with the control group (9.2 ± 1.3) at the 6-month follow-up (p = 0.003). In addition, the participants in the intervention group showed a change in HbA1c at 6-month follow-up (8.3 ± 1.4), compared to the corresponding HbA1c at baseline (9.4 ± 1.5, p = 0.011) and after the 6-session intervention (8.9 ± 1.6, p = 0.046). There were no significant differences in adherence of medication-taking (p = 0.440) and refill (p = 0.914) between groups over time (Table 6).

Comparison of Health Literacy and Psychosocial Factors Between Groups

Participants in the control group reported a less threatening view of their health condition at the 3-month follow-up (37.5 ± 9.7; p = 0.019) and 6-month follow-up (37.0 ± 7.8; p = 0.009) than baseline (44.5 ± 7.0) (Table 6). However, there were no significant differences in health literacy or self-reported psychosocial factors between groups over time (Table 6).

Phase 2 Qualitative Results

Representative quotes for each theme and sub-theme are provided in Table 7.

Acceptability of the Intervention

Overall, participants reported that they found the components of the intervention and the procedures to be acceptable They shared that the intervention phone calls from the pharmacist were helpful and convenient and their frequency was appropriate.

Perceived Benefits of the Intervention

Participants shared their perceptions of the benefits of the intervention in improving medication adherence and other diabetes outcomes.

Structured Step-by-Step Approach to Shared Decision Making

Participants indicated that the pharmacists used a structured approach to help them think about diabetes and its impact on their life and facilitated a process to set goals and make decisions. Sub-themes included pharmacists: (1) considered participants' health literacy and psychosocial factors to inform goal setting, (2) motivated participants to set and maintain goals, (3) assessed participant's progress and addressed concerns, and (4) continually tailored the care plan based on participant preferences.

Enhanced Understanding of Diabetes Medications and Self-Management

Participants mentioned that they had more understanding about how diabetes medications work and an increased awareness of diabetes self-management, such as diet adjustment, blood glucose monitoring, and exercise.

Helped Reframe Beliefs About Diabetes Medications

Participants reflected on how the additional health-literacy psychosocial support helped them to reframe their beliefs about diabetes, such as beliefs about how much control they have over their health condition and coming to the realization that their condition is life-long.

Enhanced Motivation for Medication Adherence

Participants highlighted how their adherence to diabetes medications improved because of the pharmacist support to problem-solving logistics related to diabetes medications or increase their activation towards taking medications.

Enhanced Social Support

Participants experienced enhanced social support through the intervention provided by the pharmacist. The following subthemes emerged related to social support.

Informational Support from Pharmacist (Enhancing Health Literacy)

Participants viewed the pharmacist as a trusted and reliable resource for diabetes information and were comfortable knowing they could ask the pharmacist questions and get answers. Specifically, they valued the information about specific medications or problem-solving ways of improving medication adherence. One participant discussed difficulty in

Table 7 Themes and Representative Quotes from Qualitative Interviews

Theme	Representative Quotes
Acceptability of ADHERE intervention	
(1)Phone calls with pharmacist were helpful	"Well, it [phone calls with pharmacist] helped as far as within a certain interval, she would contact me and kind of keep the, you know, keep in contact. Whereas, if I, you know, I somewhat make me accountable, I guess. That would be, you know, by talking to me about it." (P100) "Well, those phone appointments [with pharmacist], they actually did well for me. … We also discussed if there was anything I could do to avoid missing my medication on days I do when I'm running late." (P106) "So I think, all in all, these kind of phone calls with her [pharmacist] have been productive. I mean, they have made me take my diabetes more seriously and be more aware and proactive for taking my medications." (P106)
(2)Phone calls with pharmacist were convenient	"I think they are [phone calls w/ pharmacist] fine. I think it's, you know, it's, helps her and helps me. You know, because, well, she does not have, I mean, she only has to take a certain block every day out to, you know, to be able to do that. And it saves me a little bit on driving up here and that sort of thing." (P100) "You know, some days, it's nice just having a phone call, because we are all busy, and it's hard to get into another VA to get a teleconference. … Where, … sometimes it's like I'd rather keep moving on my stuff and take the phone call and talk to somebody as I am, you know, walking through and checking something, or, you know, step away from the lawnmower for a couple minutes, take a breather, talk to that person and then get right, you know, back and go." (P101) "Like I said, I do not feel the in-person visit was any more or less productive than the phone visit. So as far as that goes, I mean, I think the phone visit is, was, I mean, that bad, since I do not have to drive over and do it. Phone visit is actually probably more advantageous for me." (P106)
(3)Frequency of phone calls was acceptable	"A month [between pharmacist phone calls] was a nice enough amount of time just for me personally, just so that way, you know … hopefully you can show a pattern was I guess what I was trying to say. And if you are on track with your pattern, then it's good, and you can still see where you are at and tweak it. But if you are not on track with your pattern, then it's, you know, hey, you know, you need to do something, because we do not have enough information to adjust this either way to see if you are doing better or worse … worse, but you have got to follow the plan." (P107) "Well, for me, that worked out about right. You know, I thought that [frequency of pharmacist phone calls] was good." (P108)
Perceived benefits of the intervention	
(1)Educational handout was helpful	"It's, we talked about it [educational handout] at the meeting, and then she gave me the paper and explained it [educational handout] and then told me take it home and read it over. So that's … yeah, but I thought it was very informational. It was very helpful too." (P110)
(2)Structured and step-by-step approach to shared decision-making	
• Considering participants background information to inform goal setting	"Well, she, she and I maybe set some goals for … she actually gave me parameters to what I could set them at as to where my blood sugar and … at that time, my blood sugar was through the roof. And then, so we set the goals and all that." (P110) "Just, you know, going over the purpose of it, going over, I guess, her forming a baseline on me and determining what I know and what I don't know about diabetes, to some degree." (P108)
• Motivating participants to execute the goal as planned	"But I know that she's thorough, and she tries to get, you know, to get you to think about diabetes and how it will affect you in your future" (P100) "She do not come across as in you have to do this and you have to do that. She, what about, you know, maybe trying this, or what about this, or, I mean, how can we get this done? … Again, it's one of those things where you get more by sucking us in and letting us make that choice compared to rebelling and when somebody tells you you have got to do something." (P101) "So that gave me some motivation. And then after that, now it's you have to. She covered everything … she did." (P110)

(*Continued*)

Table 7 (Continued).

Theme	Representative Quotes
• Assessing participants progress and addressing their concerns	"It's, really, to me, I personally do look forward to those phone calls, because … It's the fact that somebody's, you know, and maybe there, you know, couple times there were some strong questions of, you know, what med, what's going on with the meds? This is happening. We have, you know, we are having some other health issues. And it's like is meds causing this?" (P101) "So it's, so, I mean, me and the phone calls and asking about the medications, and if you're taking them, I never thought I would have to say it, was a lifesaver." (P101) "she would go through the blood sugars, and she explains to me, or she'd ask me what I was eating, what my diet was, and all that. And then she explains why this one is so high and why this one was, I never had a real low one, but. And then she actually coached me how to do stuff is what she did, so, yeah, that was good." (P110)
• Reminding participants to engage in diabetes management	"Well, it helped as far as within a certain interval, she would contact me and kind of keep the, you know, keep in contact. Whereas, if I, you know, I somewhat make me accountable, I guess. That would be, you know, by talking to me about it." (P100) "You know, hey, that friendly kick me in the butt and keep, you know, reminding me we've got to make this change, and we've got to keep doing it, you know. I mean, you can lead a horse to water, but you can't force it to drink." (P101)
• Tracking patient outcomes and tailoring advice /goals	"Give me that sense of doing something. And then it was like if I had a real good blood sugar readings after that month and it was great, and she'd tell me or we'd discuss what I was doing, and then we'd continue on into the next month. And then if something happened during that month, then we discussed that, and." (P110) "I mean, you are like at the cream of the crops. I mean, that is just, I mean, the way she does her goal setting and does everything, it's not really her setting the goals. It's asking us what do we want to give up to make this happen, to make a healthier choice?" (P101)
(3)Increased awareness of diabetes medications and self-management	"Number one is my weight loss, but number two, when my blood sugars were over 500, and my A1C was over 11, I do not drink or smoke, okay, and I think that's probably what kept me alive. But I never felt bad. Well, once I started taking the meds, I still do not feel bad if my blood sugars are low, which is … or high. But I know what the ramifications are if I do not take my meds, so it made me a lot smarter as far as what diabetes will do to the body." (P105) "Well, I think once a month was great, because before that, I did not really think about the blood sugar readings. I probably did not take them often as I should have too. But and then she [pharmacist] gave me, she pushed me a little bit to take them more often, because you can get a better history of your blood sugars and stuff and how the insulin is working and stuff." (P110) "So I think, all in all, these kind of phone calls with her [pharmacist] have been productive. I mean, they have made me take my diabetes more seriously and be more aware and proactive for taking my medications." (P106) "And like I say, I am pretty good at taking it [diabetes medications] when I have it. But, you know, anyway, we problem-solved in terms of, you know, two weeks in, order the meds. Do not wait until, you know, like my last week or … which is crazy. But, anyway, never mind. It's only logistical stuff to try to be consistent with receiving, I mean, I do not have a problem taking it, but having it and being able to take it." (P107) "And I did find that the ones about forgetting my medication, back before I was motivated to do some things, I did miss meds. I do not know whether I want to use the word often, but often enough where I suppose it breaks, you know, if you miss a dose, it may break the effectiveness of it, and I would miss it maybe once every two weeks or once a week, one dose, you know. And I have not been doing that lately, so I have been more cognizant of being careful with it and making sure I do not miss any." (P108)
(4)Reframed beliefs about diabetes	" …. [additional support] lowered like my A1C, and it's made me think about it [diabetes] more. I guess, before, I always thought that it would just go away … They [pharmacist] just kind of opened my eyes. Like I said, that I always thought it [diabetes] would just go away, and then she told me it's not." (P104) "So in the conversations with the pharmacist and stuff, that's what made that decision. So, I mean, that was helpful. And then, like I said, having it pointed out, the fact that I am at the, you know, pretty much maximum dose of medications was the realization that has made me, although I have not done anything about it, it has made me look at the disease more seriously." (P106) " … It [additional support] gave me a sense of trying to control it [diabetes], I think, or help control it." (P110)

(*Continued*)

Table 7 (Continued).

Theme	Representative Quotes
(5)Enhanced social support	
• Informational support from pharmacist	" … I cannot get the rest of the stuff I need, but. with her [pharmacist], it's face to face. It's any question I ask she will give me an answer to if she can. If she cannot, she will find somebody that can, so that's the way I feel about that." (P102) "She [pharmacist] was very nice, and she explained everything and I could understand … even when my son is sitting here, he might have had a question or so, and she answered for him and stuff, you know, and how I can take it, you know, so far … " (P103) "You know, she [pharmacist] would go through the blood sugars, and she explains to me, or she'd ask me what I was eating, what my diet was, and all that. And then she explains why this one is so high and why this one was, I never had a real low one, but. And then she [pharmacist] actually coached me how to do stuff is what she did, so, yeah, that was good." (P110)
• Emotional support from pharmacist	"Like I said, I can't iterate it hard enough that this [intervention] is a positive step, you know. This is a program that, you know, really, you know, does help. Makes the person sort of stop and realize I'm not doing this alone." (P101) "It's that loving smack in the face. You know, I mean, no, I say it that way, because it's like, okay, somebody [pharmacist] cares enough to pick up the phone and call you even though she's getting paid and that's, you know, that's the thing. But yet, you know, it's just the, it's a general smack in the face to say, hey, you know, really keep with this [diabetes management]." (P101) "Well, in a way, it [additional support from pharmacist] gives me the feeling that somebody else cares, you know. You know, I know my wife cares for something like that. A lot of doctors do not give a darn one way or the other. Like mine I feel, you know, he's always on a computer doing this, whatever, but he does not answer questions, so I do not know, but I have to go see him. Otherwise, I cannot get the rest of the stuff I need, but, with her [pharmacist], it's face to face. …. I take my medicine whenever I take my medicine, but she [pharmacist] gave me, she seemed to care about when I took my medicines and did not and that we could work better by doing things at certain times." (P102) "She [pharmacist] was a good supporter. She helped me through a lot of stuff. And we can talk quite a bit, and she helps me out. Now I understand it [diabetes]. It doesn't bother me anymore." (P103)
• Enhanced self-efficacy	"Well … what she [pharmacist] did was she looked at my, my health before she was thinking of letting me take that new medicine because I have several health problems. And so I appreciated the fact that she did not just put me on it, you know, she wanted to make sure that it was not going to interfere with anything. And she also just, you know, gave me the confidence that it would be worth trying. … And so as long as she thought that, I thought that, you know, yes, I would try it. And I did. And it seems to be working so far, you know." (P100)
(6)Patient-centered approach from pharmacist	"I mean, that is just, I mean, the way she [pharmacist] does her goal setting and does everything, it's not really her setting the goals. It's asking us what do we want to give up to make this happen, to make a healthier choice? You know, and it's okay, you know, maybe it's not a healthy choice, but it's a change. So, you know, and so, I mean, that's what [Pharmacist], you know, she lets us sort of, at least I got the feeling of setting, you know, our own goals without being, oh, you are going to have to give up smoking, or you have got to give this … Again, it's one of those things where you get more by sucking us in and letting us make that choice compared to rebelling and when somebody tells you you have got to do something." (P101) "I think she [pharmacist] sticks her neck out a lot of times to help us by, you know, let us try to get you in a different med and stuff like that. So, I mean, that's one nice thing too is she, you know, she gives us the options. It's not like, well, you have to do this and this, you know. Here's your choices, and I'd like to, you know, for you to push to this direction, but you, you know, you make your choice." (P101) "We [patient and pharmacist] usually talk everything out and find out, well, you know, where we are at and what I can and cannot do, you know. Like every person is different in their ways, so I explain mine, and she tells me if I am going wrong. And if I am going wrong, then I will listen, and I will try to follow her way. And somewhere along the line we will meet in the middle." (P102)

(*Continued*)

Table 7 (Continued).

Theme	Representative Quotes
(7)Enhanced accountability to refocus on diabetes self-management goals	"Well, it [phone calls with pharmacist] helped as far as within a certain interval, she would contact me and kind of keep the, you know, keep in contact. Whereas, if I, you know, I somewhat make me accountable, I guess. That would be, you know, by talking to me about it." (P100) "Well, it's good to let me know or for me to let her [pharmacist] know whether I am slipping up or not, you know, and if we are doing something wrong in between here, like she can give me advice to adjust it, which she has and which I did and, but I am hardheaded too sometimes, and sometimes there's just too many birthdays too close together." (P102) "It [pharmacist phone calls] helped me refocus, but I do not know if losing focus is the, is an accurate description as much as it is just getting caught up in doing everything in everyday life, and then trying to have a schedule, which trying to have a schedule to do all this. And then, like I said, if the schedule changes or if anything happens, then I am just, then that just gets lost in the shuffle." (P107)

the comprehension of printed handouts. Conversations between pharmacists and patients could be tailored based on patients' health literacy levels as they get a better understanding of how to integrate recommendations into their life routine. The pharmacist used various approaches to facilitate information delivery, including pharmacist-patient conversation, printed handouts, and hand-writing personalized information about goals and care plan. Pharmacists used plain language to explain how to take action for better diabetes management, and participants used handouts as reminders to encourage them to stay on track.

Emotional Support

Participants were motivated to improve their diabetes self-management and medication use because they felt the pharmacist genuinely cared about their health. Participants reported more confidence as the pharmacist addressed their medication concerns and provided clear information.

Patient-Centered Approach

Participants appreciated that the pharmacist would provide information and recommendations but allow them to make decisions about their own diabetes care, such as when switching medications or modifying dosages.

Enhanced Accountability to Refocus on Diabetes Self-Management Goals

Participants believed that more frequent phone calls with the pharmacist provided more opportunities to refocus on their diabetes self-management progress in between face-to-face appointments and helped enhance their accountability to maintain goals.

Integration

The qualitative data further explains the quantitative data in some areas. For example, there was reduced HbA1c in the intervention group after the 6-session intervention and at 6-month follow-up. Themes showed that after the intervention, participants believed that they had control over their health condition, realizing that diabetes is lifelong. A perception of diabetes control and an increased understanding of diabetes as a chronic condition that requires self-management may have led to better diabetes self-management and improved HbA1c. As well, though there were no significant changes in psychosocial factors over time, the themes indicated that participants valued the enhanced social support from the pharmacist, appreciated the pharmacist recommendations on medications, and answered questions. Increased motivation for self-management may increase self-efficacy for self-management, leading to improved HbA1c. Though the quantitative data showed no significant differences in medication adherence over time, the qualitative data showed that participants believed that their adherence improved because of the pharmacist support including problem-solving logistics related to diabetes medications, and medication use reminders.

Discussion

In this pilot longitudinal RCT, we assessed the feasibility and acceptability of the ADHERE intervention, which aimed to enhance patients' medication adherence and diabetes outcomes by addressing various psychosocial factors including health literacy simultaneously. As well, we conducted exploratory analyses to assess for clinically meaningful changes in HbA1c and medication adherence.

Despite challenges with recruitment, overall, our findings suggest that the ADHERE protocol was feasible. Soon after initiating the study, we encountered challenges recruiting participants and realized early on that we should change our recruitment strategy. Because the intervention was pharmacist-led and embedded into clinical care, our pool of potential participants was limited to patients who were currently being cared for by the study pharmacist and who met the eligibility criteria. To address this, we trained two additional pharmacists to deliver the intervention, thereby expanding our pool of potential participants. Ultimately, we exceeded our revised recruitment goal. We exceeded our retention goal with a rate of ~90% of baseline participants who provided data for the final assessment at 6-months post intervention. Likewise, we had high rates of intervention adherence related to completion of the two sessions with the pharmacist, as well as the follow-up phone calls.

This pilot was not powered to detect statistically significant effects, so we did not anticipate finding statistically significant outcomes. Rather, we aimed to assess for a signal of change in HbA1c and medication adherence, which was detected in the primary outcomes as well as secondary outcomes of beliefs about medicines and diabetes, self-efficacy, and social support. A future adequately powered efficacy trial is needed to show statistically significant improvements in HbA1c and medication adherence. Our results suggest that the intervention may have contributed to sustained improvements in HbA1c values 6 months after the intervention for the participants who received the additional support from the clinical pharmacist. We did not find an effect of the intervention on self-reported medication adherence, health literacy or psychosocial factors throughout the 9-month study. This study calls attention to the role that clinical pharmacists play in providing psychosocial support to patients with diabetes that ultimately lead to long-term improvements of HbA1c.[34]

Our exploratory findings are consistent with similar studies that focused on improving medication adherence through pharmacist-led approaches. A RCT comparing usual care with a pharmacist-delivered educational intervention that incorporated information about diabetes medications and adherence found that the HbA1c of the patients in the intervention group decreased significantly compared to control group, but medication adherence was not improved.[35] A systematic review of 39 RCTs assessed the effectiveness of pharmacist-led interventions for people with type 2 diabetes compared with usual care. Results suggest improvements in various clinical outcomes including HbA1c.[6]

The qualitative results support the quantitative results in demonstrating acceptability of the intervention. For example, participants' perceived benefit of the intervention because of the knowledge gained about diabetes, clarification of misbeliefs about diabetes and diabetes medication, as well as development of self-efficacy to communicate with pharmacists.

In contrast with usual care, the intervention involved the clinical pharmacist spending additional time with the participants during face-to-face appointments and tailoring sessions to focus on the concerns identified from participants' survey responses. This tailored approach assessed the psychosocial and behavior factors impacting each participant. Clinical pharmacists are an underused resource for clinical support in patients with uncontrolled diabetes,[36] as qualitative themes suggest that the additional follow-up phone calls between the clinical pharmacist and the participant were opportunities for the clinical pharmacist to encourage positive behavioral changes and for participants to be reminded of their goals.

Though not statistically significant, some findings indicate improvements in self-efficacy and medication adherence, as well as decreased illness concerns and barriers to medication-taking among the intervention group. Themes supported perceived improvements in adherence to diabetes medications because of pharmacist support and changes in beliefs about diabetes. Many participants characterized their medication adherence improvements as being a work in progress, acknowledging that they had not yet reached their goals, suggesting that they may not be recognizing the full extent of

their actual improvements. This offers a potential explanation for the seeming paradox between finding improvements in HbA1c, but also a lack of significant findings on self-reported medication adherence.

Notably, most participants had high baseline scores on many of the measures, indicating that they did not have many serious concerns or challenges related to diabetes before the intervention. This suggests that there may be a ceiling effect on the potential for improvement. This is not surprising considering that these participants had all been previously referred to this specialist clinical pharmacy service and some had been receiving care from the clinical pharmacist prior to enrolling in the study. Future research should target patients who are new referrals or newly diagnosed with diabetes to assess whether the intervention has a greater effect on patients who had not yet received intensive care from a clinical pharmacist.

Additionally, although we examined medical records for information about poor medication adherence to determine eligibility, we did not use a standardized tool to assess medication adherence prior to enrollment in the study. Therefore, participants may have met the HbA1c eligibility criteria, but not necessarily had challenges with medication adherence. This might explain the high baseline scores and lack of a significant improvement in medication adherence.

As expected, health literacy did not change in the short period of time, though pharmacists tailored their communication, in consideration of participants' level of health literacy. One prior study noted that significant improvements in health literacy for older adults with diabetes occurred after a 24-month intervention, suggesting longer timeframes are needed to make meaningful changes in health literacy.[37] Through understanding the patient's capacity of understanding health-related concepts, pharmacists are better able to individualize their care to meet their needs. Our creation of new patient education handouts that were written in plain language is an example of enhancing health literacy.

The study had some limitations. We had a small sample size for the intervention which might have limited our ability to see a bigger impact. While there are no rigid rules of a sample size for qualitative interview, a 15–30 is considered sufficient for a content analysis approach.[32] We only interviewed 11 individuals in phase 2 of the study. Data saturation was however achieved with the study sample. Our sample was comprised of only males, the majority of whom were white. However, this was somewhat expected as our sampling pool, veterans with T2D, is comprised largely of white males.[38] This limits the generalizability of our findings to women and minorities. Patients were classified as nonadherent if they reported missing two or more insulin doses in the weeks prior, which is not standard for identifying nonadherence. Finally, due to COVID-19 restrictions, some data collection occurred over the phone versus face-to-face as originally planned.

Conclusion

Our findings suggest that future research should conduct interventions over a longer timeframe, to better assess the long-term effects of pharmacist-led interventions on self-reported medication adherence, health literacy or psychosocial factors. Our study may be replicated with more diverse patient populations to understand the impact of the intervention amongst women and racial/ethnic minority groups. Lastly, our findings highlight the need to develop and test a better mechanism to measure medication adherence and identify the reasons for poor adherence in a way that it is embedded it into clinic workflow and can inform patient care in real-time.

Practice Implications

Our findings are relevant for practice and behavior change in three ways: (1) Our intervention was integrated into existing clinic schedules and work flow, suggesting that implementing it within other clinic settings may be feasible, (2) Equipping clinical pharmacists with real-time patient-specific information about health literacy and psychosocial challenges with managing diabetes can enhance pharmacists' ability to tailor treatment recommendations and provide patient-centered care and (3) building in scheduled follow-up phone calls between clinic visits provided opportunities for the clinical pharmacist to encourage positive behavioral changes in patients and for participants to be reminded of their goals and commitment for planned change.

Data Sharing Statement

Data may be shared upon request. We will not share individual deidentified participant data.

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