



## Research paper

# Barriers and solutions to implementing a pragmatic diabetes education trial in rural primary care clinics

Kristie B. Hadden<sup>a,\*</sup>, Connie L. Arnold<sup>b</sup>, Laura M. Curtis<sup>c</sup>, Terry C. Davis<sup>b</sup>, Jennifer M. Gan<sup>a</sup>, Scott I. Hur<sup>c</sup>, Jean C. McSweeney<sup>a</sup>, Brandie L. Mikesell<sup>a</sup>, Michael S. Wolf<sup>d</sup>

<sup>a</sup> University of Arkansas for Medical Sciences, 4301 W. Markham Street, Little Rock, AR, 72205-7199, USA

<sup>b</sup> Louisiana State University Health Sciences Center - Shreveport, 1501 Kings Highway, Shreveport, LA, 71130-3932, USA

<sup>c</sup> Northwestern University, Division of General Internal Medicine and Geriatrics, 750 N. Lake Shore Drive, 10th Floor, Chicago, IL, 60611, USA

<sup>d</sup> Northwestern University, Department of Preventive Medicine, 680 N. Lake Shore Drive, Chicago, IL, 60611, USA



## ARTICLE INFO

## Keywords:

Health literacy  
Diabetes  
Patient-centered medical home  
Rural  
Pragmatic trial  
Pragmatic trial optimization

## ABSTRACT

**Introduction:** The purpose of this report is to describe barriers and solutions to the implementation and optimization of a pragmatic trial that tests an evidence-based, patient-centered, low literacy intervention promoting diabetes self-care in rural primary care clinics.

**Methods:** The two-arm pragmatic trial has been implemented in six rural family medicine clinics in Arkansas. It tests a self-management education and counseling intervention for patients with type 2 diabetes compared to enhanced usual care. Barriers and solutions were identified as issues arose and through interviews with clinic directors and clinic administrators and a focus group, interviews, and tracking reports with clinic health coaches who delivered the intervention.

**Results:** Barriers to optimizing enrollment, intervention delivery, and data collection were addressed through targeted education of and relationship building with leadership, changing enrollment oversight, and ongoing training of health coaches.

**Conclusions:** Successful implementation and optimization of this pragmatic clinical trial in rural primary care clinics was achieved through establishing common goals with clinic leadership, minimizing demands on clinic staff and administration, frequent contact and ongoing support of health coaches, and collaborative troubleshooting of issues with delivering the intervention.

## 1. Introduction

Diabetes mellitus affects 9.4% of the United States population with rates consistently rising [1], and it contributes to lowering life expectancy by as much as 15 years, doubles the risk of heart disease and is the leading cause of kidney failure, lower limb amputation and adult onset blindness [2–4]. Diabetes affects special populations differently, and is one of the top health concerns in rural areas, ranking number two among southern states [5,6]. Rural areas have a 17% higher rate of diabetes compared to urban areas; rural patients tend to be diagnosed later, have more limited access to medical and specialist care, have minimal exposure to diabetes education and experience greater transportation

challenges compared to urban counter parts [7,8]. Additionally, rural patients are also more likely to experience higher rates of poverty and limited literacy [9].

A review of practices and interventions that address diabetes found most improved knowledge, self-efficacy and self-care practices and some improved HbA1c and low density lipoprotein levels, but all had significant limitations, particularly in cost, staffing, fidelity and sustainability [10]. None of the programs designed specifically for rural areas that were evaluated in those studies were clinic-based, and none addressed the prevalent problem of patient limited literacy, which can be a significant barrier to understanding diabetes mellitus self-management and behavior change [10].

\* Corresponding author. University of Arkansas for Medical Sciences, Center for Health Literacy, 4301 W. Markham Street, Slot 599A, Little Rock, AR, 72205-7199, USA

E-mail addresses: [khadden@uams.edu](mailto:khadden@uams.edu) (K.B. Hadden), [carnol@lsuhsc.edu](mailto:carnol@lsuhsc.edu) (C.L. Arnold), [lcurtis@northwestern.edu](mailto:lcurtis@northwestern.edu) (L.M. Curtis), [tdavis1@lsuhsc.edu](mailto:tdavis1@lsuhsc.edu) (T.C. Davis), [JGan@uams.edu](mailto:JGan@uams.edu) (J.M. Gan), [scott.hur@northwestern.edu](mailto:scott.hur@northwestern.edu) (S.I. Hur), [McSweeneyJeanC@uams.edu](mailto:McSweeneyJeanC@uams.edu) (J.C. McSweeney), [BLMikesell@uams.edu](mailto:BLMikesell@uams.edu) (B.L. Mikesell), [mswolf@northwestern.edu](mailto:mswolf@northwestern.edu) (M.S. Wolf).

<https://doi.org/10.1016/j.conctc.2020.100550>

Received 8 September 2019; Received in revised form 20 February 2020; Accepted 23 February 2020

Available online 3 March 2020

2451-8654/© 2020 The Author(s).

Published by Elsevier Inc.

This is an open access article under the CC BY-NC-ND license

(<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Patient education and self-management support are cornerstones of diabetes care, but access to these services in primary care clinics varies broadly [11]. Approximately half of patients with diabetes report not having ever received diabetes education and self-management support, with rates lowest in rural areas [4,12]. Proper self-management requires engagement, considerable knowledge, a range of skills, and ability to sustain multiple health behaviors [13]. While some approaches to promoting self-management have been evaluated with promising results, questions remain on how best to implement them in the most effective, efficient, and sustainable manner.

Implementing and sustaining diabetes education and self-management strategies in rural primary care settings is difficult due to limited resources and vulnerable patient populations (lower socioeconomic status, limited health literacy, greater disease burden) [14]. Pragmatic trials can improve our understanding of how such strategies will perform in clinical practice while also examining effectiveness. We conducted a patient randomized pragmatic clinical trial in rural primary care clinics, addressing the health literacy needs of patients in those clinics. The purpose of this report is to describe barriers and solutions to the implementation and optimization of that trial.

## 2. Pragmatic trial methods

This trial engaged six regional family medicine clinics in underserved regions of a rural southern state that are Patient Centered Medical Homes (PCMH) as part of an National Institute of Health (NIH) funded trial (1R01DK107572-01A1). The trial was approved by the study sites' Institutional Review Board and the protocol has been published [15].

The majority of patients served by the study clinics have low income and there is a high rate of chronic disease in each clinic's patient population. The target population and sample were clinic patients with HbA1c greater than 7.5% and less than 10%, which indicated that an individual may not have achieved tight glycemic control and therefore may be at elevated risk for diabetes-related complications. Patients identified through the Electronic Health Record (EHR) and met inclusion criteria for the pragmatic trial were called by a scheduler. If the patient expressed interest in participating, they were randomized and scheduled for their next quarterly diabetes follow up visit as part of standard care. To minimize the number of clinic visits and due to health coach's limited schedules, randomization occurred prior to baseline visit. At their baseline clinic visit, a site research assistant provided an overview of the study, conducted the informed consent process and administered the survey; participants were followed for one year. Surveys were completed at baseline, three month, and six month regularly scheduled clinic visits, or over the phone, and included knowledge and health behavior questions. Our primary outcome, HbA1c and intermediary biomarkers are extracted from the EHR following the 3, 6, 9, and 12 month clinic visits.

Participants who were randomly assigned to the "enhanced usual care" arm received PCMH standard care, care coordination, and diabetes education in the form of the American Diabetes Association "Living Well with Diabetes" book, given to them by their nurse at their first clinic visit after enrollment. Variability in additional diabetes education for the usual care participants was noted by researchers and inconsistent across sites or time; occasional and sporadic counseling from clinical pharmacists and community-based diabetes education classes and support groups were considered in the pragmatic trial design.

Participants randomized to the intervention arm began with a brief in-person meeting with a health coach in the clinic following their regularly scheduled quarterly diabetes clinic care visit. Health coaches are certified health educators, nurses, or diabetes educators who have been trained by the investigators to deliver the intervention using motivational interviewing, the American College of Physicians (ACP) guide as a health literacy tool, and intervention touchpoint schedule. The health coach oriented the participant to the ACP guide content and used motivational interviewing [16] to help the participant identify one

or two small, but achievable, behavior change goals to work on as part of the guide's "action plan." The goal was documented in the guide and sent home with the participant, as well as recorded in their electronic health record. The health coach called intervention participants two weeks after the initial meeting to check on goal progress and used motivational interviewing to identify barriers and facilitators to achieving the goal. Health coaches made similar follow-up phone calls using a schedule developed from pilot testing. The health coaching touchpoint schedule was front loaded with telephone follow-ups at two, four, and eight weeks, then monthly in between their in-person quarterly scheduled clinical visits with the health coach and their provider (3, 6, 9, 12 month) (See Fig. 1).

## 3. Trial management and optimization evaluation

Because all participants in our trial received diabetes education through either their nurse as part of standard care, or through a health coach, the onus of diabetes education for study participants was taken off physicians and residents. For this reason, ongoing contact with physicians revealed that they did not have opinions about barriers, as they did not perceive any. We therefore collected implementation evaluation data from clinic directors, clinic administrators, health coaches and clinic staff in the form of tracking reports, focus groups, and interviews. We conducted focus groups and individual interviews with health coaches to identify barriers and facilitators to implementing the intervention effectively with the target population. We also conducted telephone interviews with individual clinic staff and administrators to identify barriers and facilitators to implementing the trial effectively in the clinics.

## 4. Results

Over the course of this trial's implementation, we have identified barriers and solutions at many levels. First, because the trial sites are rural family medical clinics that are training sites for Family Medicine Residents, their primary focus is medical care and resident training; none had experience implementing an NIH funded multisite clinical trial. While these clinics are all part of the same network, scheduling, charting, and other processes were not standardized across all clinics, which proved to be a challenge in implementation. Additionally, since the application process, the award notice, and the implementation of the trial activities, the clinic network has experienced significant disruption in the form of leadership change, organizational change, and changes in their electronic health record system (EHR). These issues created barriers to smooth adoption and maintenance for processes in the clinics that were necessary for trial implementation. We identified barriers and addressed them with solutions at the following levels to optimize enrollment, data collection, and implementation activities: clinic directors, clinic administration, and health coach (see Table 1).

The barriers that were identified and addressed at the leadership level had an impact on enrollment and trial implementation. Between the time of the trial launch and completion of data collection, the clinic network experienced three key leadership changes. Personnel were transitioned in the top executive position, the medical director position, and for one clinic director position. With each change, one-on-one onboarding meetings with the principal investigator that focused on shared goals were essential to securing necessary buy-in at the top levels of the clinic network. The shared goals that were identified included improving quality metrics on diabetes patient outcomes for the clinic network and streamlining health coaching at the clinics. Supportive leadership facilitated the solutions to many other barriers that were realized at lower levels of the organization that related to staffing and project time allocations, replacing staff due to turnover, and troubleshooting EHR and reporting errors.

Barriers at the clinic administrative level affected enrollment, data collection, and trial implementation. These barriers included a decline

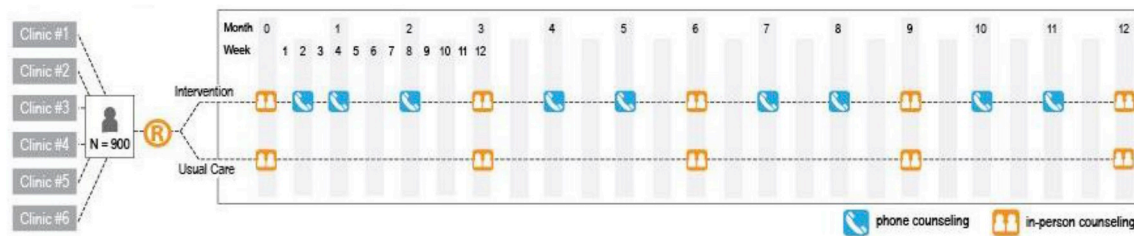


Fig. 1. Study flow chart.

in overall patient population across the network, clinic scheduling inconsistencies, EHR reporting errors, Medicaid visit/lab restrictions, high no-show rates, and a major change in the EHR system at each clinic. The solutions were targeted and effective; we determined a smaller sample size was sufficient by updating our original assumptions mid-study using real-time data; worked with information technology specialists to address EHR reporting errors; worked with clinic administrators and leadership to troubleshoot participant scheduling limitations; employed a new scheduling process to ensure that participants did not exceed lab or visit limits for their insurance coverage; adjusted protocol to allow for clinic visit to be scheduled separately from research visit; and implemented routine reminder calls for participants scheduled for research visits. These solutions collectively resulted in doubling enrollment in year 3 (40/month) relative to years 1 and 2 (20/month).

At the health coach level, barriers were related to turnover in the health coach position at clinics, elimination of the health coach position at two clinics, and inability to reach participants by phone. Additionally, health coaches were occasionally getting referrals to provide education to participants in the enhanced usual care group who were receiving the American Diabetes Association guide and nurse counseling, creating opportunities for contamination of study arms. We addressed turnover issues and loss of health coaches at clinics by hiring a central research health coach to fill gaps across multiple sites during temporary transitions, and on an ongoing basis for clinics who lost the health coach position permanently. Health coaches added follow up calls at the beginning of the following month for participants whose cell phones were likely deactivated due to depletion of paid minutes. Finally, meetings with physicians to refresh their knowledge about the study design and randomization remedied the referral issue for enhanced usual care participants. Physicians were reassured when reminded that all study participants were receiving diabetes education, regardless of study arm, and that clinical pharmacists (where available) could and should continue to counsel their patients on diabetes medication management education.

#### 4.1. Intervention feedback

The health coaches perceived that that the intervention was highly effective at motivating participants to achieve their own self-selected action plan/behavior change goals, and that the easy-to-read-and-understand ACP guides played a key role in affecting those changes. Participants' relationships with their health coaches, which developed over time, created accountability and continuity that also supported behavior change. The health coaches suggested that monthly phone calls for one year may be "too much" for some participants, as the rate of completed calls dropped over time, and some participants' motivation began to wane. Motivation was a challenge for participants with mental health issues, which were common in the rural clinic populations.

## 5. Discussion

We have learned many lessons over the three years of our implementation of this trial. At the top level of organization, identifying barriers with leadership led to important conversations with key leaders

about how clinic disruption could be minimized, and benefit to clinics, patients and providers could be optimized. Annual clinic in-services that included project updates and Question/Answer sessions, along with quarterly update meetings with leadership proved to be critical in overcoming barriers at the top levels of the network organization. Identifying the top drivers of enrollment barriers and addressing them through appropriate staff oversight and unlinking clinic visits to accommodate scheduling limitations resulted in a doubling of our enrollment rate in years 2–3. Other noted successes in implementation resulted from ensuring that health coaches had the right tools to track their interactions with participants.

We also had to overcome many challenges in identifying patients using EHR reports in order to reach the target population. The solution resided outside the clinic through collaborating with informaticists. These stakeholders were essential to creating usable reports that identified eligible patients to contact about enrolling in the intervention.

The trained health coaches in our intervention had different backgrounds and credentials, but had similar scopes of practice in working with patients; some were Registered Nurses (RNs), some were Certified Health Education Specialists (CHES), and some were Certified Diabetes Educators (CDE). All coaches effectively delivered the intervention, but at the clinic level, we were challenged by organizational changes that developed over time. Specifically, when we launched the trial each clinic had one full-time Certified Health Education Specialist who was embedded in the clinic and worked with patients in a variety of capacities, all related to patient education. In the following years, as health coaches left due to normal attrition, their positions were not back-filled with new personnel with the same credentials. Instead, two clinics assigned existing nurses or diabetes educators to the role of health coach for this intervention. While this model also proved to be effective from an implementation standpoint, the turnover caused temporary disruptions and coverage from health coaches at other clinics was needed to ensure fidelity. Interestingly, while health coaches stated that they thought that engaging the physicians in the intervention would have had a positive impact on participants and outcomes, leadership (including physicians) noted that taking the onus of education off the physicians was important for the trial's successful implementation.

Clinic administrators who participated in follow-up interviews stated that full-time, permanent health coach positions in the clinic would be beneficial to replicating and sustaining the intervention at other clinics in the future. They suggested that primary care clinics without the financial resources to hire these fulltime positions consider including Medicare "wellness visits" to the health coach role. These visits are typically within the scope of practice of credentialed health coaches (RNs, CHES, CDE), and are reimbursed by Medicare. The reimbursement can be used to offset the salary costs to clinics and the health coach can see both intervention participants and Medicare wellness patients in their fulltime position.

In order to successfully implement a diabetes education clinical trial in rural PCMH clinics, it is essential that the intervention be truly embedded in the clinic workflows, and that there is buy-in from all levels of clinic personnel. The more value that the trial brings in the form of improved patient outcomes and quality metrics, the more satisfaction and cooperation we found with clinic staff, providers, and

**Table 1**  
Barriers and solutions to trial optimization.

	Enrollment		Data collection		Trial implementation process	
	Barriers	Solutions	Barriers	Solutions	Barriers	Solutions
Clinic Director level	<ul style="list-style-type: none"> <li>Lack of general support for the trial</li> </ul>	<ul style="list-style-type: none"> <li>Quarterly meetings with leadership, established shared goals</li> </ul>	N/A	N/A	<ul style="list-style-type: none"> <li>3 Senior leadership changes</li> </ul>	<ul style="list-style-type: none"> <li>Separate meetings with new leaders prior to quarterly meetings with all leaders</li> </ul>
Clinic administration level	<ul style="list-style-type: none"> <li>Overall patient population decline</li> <li>Low number of participants recruited per week</li> <li>EHR reports not showing all eligible patients</li> <li>EHR clinic schedule slots not created in advance for enrollment appointments</li> <li>Limited scheduling slots for research and clinic visits when combined</li> <li>No show rate within clinical network 25% (higher at some sites)</li> </ul>	<ul style="list-style-type: none"> <li>Adjusted sample size calculation</li> <li>Increased recruitment staffing</li> <li>Troubleshoot and fixed query with multiple stakeholders (IT, clinical, research)</li> <li>Enlisted leadership support to get scheduling slots in advance</li> <li>Separated research and clinic visits; if needed, research visit scheduled separately from clinic visits</li> </ul>	<ul style="list-style-type: none"> <li>Major EHR transformation</li> <li>HbA1c lab fees</li> <li>Follow-up appointments not scheduled because clinic schedules not created</li> <li>Medicaid recipients were only covered for a limited # of clinic visits</li> <li>No show rate within clinical network 25% (higher at some sites)</li> </ul>	<ul style="list-style-type: none"> <li>Met with IT teams to proactively prepare templates/backups and test system</li> <li>Only scheduled HbA1c labs if due, to ensure participants not charged</li> <li>Adjusted visit windows prior to trial to accommodate HbA1c schedule</li> <li>Separated research and clinic visits in system so not charged for research only visits. Scheduled with PCP when due</li> <li>Reminder phone calls made by site and rescheduled visits; tracking of no shows for follow up</li> </ul>	N/A	N/A
Health coach level	<ul style="list-style-type: none"> <li>Staff turnover at sites (2 sites had 2 turnovers, 2 sites had 1 turnover)</li> <li>Loss of health coaching position with no replacement at 2 sites</li> </ul>	<ul style="list-style-type: none"> <li>Replacements were hired by site if health coach position remained</li> <li>Hired one central research health coach to fill gaps at multiple sites</li> <li>Closed enrollment at other site due to loss of health coach</li> </ul>	<ul style="list-style-type: none"> <li>Unable to reach participant because phone disconnected (many have plans with limited minutes per month)</li> <li>Participants not answering phone calls, especially during business hours</li> </ul>	<ul style="list-style-type: none"> <li>Called participant at beginning of month to increase chances of reaching patient</li> <li>Health coaches made 3 attempts to reach participant</li> <li>Left generic voicemail messages for participant to return phone calls</li> </ul>	<ul style="list-style-type: none"> <li>Physicians referring enhanced usual care arm participants to health coach</li> <li>Physician and PharmD awareness about intervention was low</li> </ul>	<ul style="list-style-type: none"> <li>Met with Physicians and PharmDs to refresh knowledge about study design, benefits, and randomization</li> </ul>

administrators. Additionally, the most successful clinics were those who had the least amount of turnover and maintained the same health coach and clinic staff throughout the implementation.

These findings were derived from the trial's implementation evaluation and are qualitative in nature; results were not intended to be quantified, over-generalized or analyzed with statistical significance.

## Funding

Research reported in this publication was supported by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health under Award Number R01DK107572. REDCap is supported at the Feinberg School of Medicine by the Northwestern University Clinical and Translational Science (NUCATS) Institute and by the National Institutes of Health's National Center for Advancing Translational Sciences, Grant Number UL1TR001422. Drs. Davis and Arnold are also supported by 2 U 54 GM 10490, The National Institute of General Medical Sciences of the National Institutes of Health which funds the Louisiana Clinical and Translational Sciences Center. The content is solely the responsibility of the authors and does not necessarily represent the office views of the National Institutes of Health.

## Acknowledgements

The authors acknowledge the University of Arkansas for Medical Sciences Regional Programs network of Family Medicine Clinics that are participating in this trial. Their dedication and service to their patients is the foundation of the success of this project.

## References

- [1] American Diabetes Association, Statistics about diabetes. <http://www.diabetes.org/diabetes-basics/statistics/>, 2018 March 22.
- [2] C.C. Cowie, K.F. Rust, D.D. Byrd-Holt, et al., Prevalence of diabetes and high risk for diabetes using A1C criteria in the U.S. population in 1988-2006, *Diabetes Care* 33 (3) (2010) 562-568.
- [3] Centers for Disease Control and Prevention, Age-adjusted Rate Per 100 of Civilian, Noninstitutionalized Population with Diagnosed Diabetes, by Race, United States, 1980-2011, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, 2014. <http://www.cdc.gov/diabetes/statistics/prev/national/figbyrace.htm>.
- [4] U.S. Department of Health and Human Services, Office of Disease Prevention and Promotion, Healthy people 2020: diabetes. <https://www.healthypeople.gov/2020/topics-objectives/topic/diabetes>, 2014.
- [5] K.G. Keppel, J.N. Pearcey, R.J. Klein, Measuring progress in Healthy People 2010, *Healthy People 2010 Statistical Notes: from the Centers for Disease Control and Prevention, National Center For Health Statistics*, 2004, pp. 1-16 (25).
- [6] L. Gamm, L. Hutchison, G. Bellamy, B.J. Dabney, Rural healthy people 2010: identifying rural health priorities and models for practice, *J. Rural Health: Off. J. Am. Rural Health Assoc. Natl. Rural Health Care Assoc.* 18 (1) (2002) 9-14.
- [7] M.G. Lepard, A.L. Joseph, A.A. Agne, A.L. Cherrington, Diabetes self-management interventions for adults with type 2 diabetes living in rural areas: a systematic literature review, *Curr. Diabetes Rep.* 15 (6) (2015) 608.
- [8] N.L. Hale, K.J. Bennett, J.C. Probst, Diabetes care and outcomes: disparities across rural America, *J. Community Health* 35 (4) (2010) 365-374.
- [9] Arkansas Department of Health, Arkansas' Big Health Problems and How We Plan to Solve Them: State Health Assessment and Improvement Plan, 2013.
- [10] C.N. Massey, S.J. Appel, K.L. Buchanan, A.L. Cherrington, Improving diabetes care in rural communities: an overview of current initiatives and a call for renewed efforts, *Clin. Diabetes* 28 (1) (2010) 20-27.
- [11] American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, American Osteopathic Association, Joint principles of the patient-centered medical home. Patient-Centered Primary Care Collaborative. [http://www.aafp.org/dam/AAFP/documents/practice\\_management/pcmh/initiatives/PCMHJoint.pdf](http://www.aafp.org/dam/AAFP/documents/practice_management/pcmh/initiatives/PCMHJoint.pdf), 2007.
- [12] American Association of Diabetes Educators, Diabetes Education Fact Sheet, American Association of Diabetes Educators, 2010. [https://www.diabeteseducator.org/export/sites/aade/\\_resources/pdf/research/Diabetes\\_Education\\_Fact\\_Sheet\\_09-10.pdf](https://www.diabeteseducator.org/export/sites/aade/_resources/pdf/research/Diabetes_Education_Fact_Sheet_09-10.pdf).
- [13] M.M. Funnell, T.L. Brown, B.P. Childs, et al., National standards for diabetes self-management education, *Diabetes Care* 35 (Suppl 1) (2012) S101-S108.
- [14] B.J. Weiner, C.D. Helfrich, L.A. Savitz, K.D. Swiger, Adoption and implementation of strategies for diabetes management in primary care practices, *Am. J. Prev. Med.* 33 (1,Suppl) (2007) S35-S49.
- [15] Hadden KB, Arnold CL, Curtis LM et al. Rationale and development of a randomized pragmatic trial to improve diabetes outcomes in patient-centered medical homes serving rural patients. *Contemp. Clin. Trials* 73, 152-157. doi: 10.1016/j.cct.2018.09.007..
- [16] C.M. Swoboda, C.K. Miller, C.E. Wills, Impact of a goal setting and decision support telephone coaching intervention on diet, psychosocial, and decision outcomes among people with type 2 diabetes, *Patient Educ. Counsel.* 100 (7) (2017) 1367-1373.