

Community Pharmacist-Led Interventions in Patients with Type 2 Diabetes in Low-and Middle-Income Countries: A Scoping Review

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Abstract

Aims. To provide an overview of the types of interventions performed by community pharmacists and describe their effects on patients with type 2 diabetes mellitus (T2DM) in low- and middle-income countries (LMICs). **Methods.** This review was conducted according to the PRISMA-Scr guidelines. PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials were searched for (non-) randomized controlled, before-after, and interrupted time series design. There was no restriction in the publication language. Included interventions had to be delivered by community pharmacists in primary care and community settings. The study quality was assessed using the National Institute of Health tools. Results were analyzed descriptively. **Results.** Twenty-eight studies were included representing 4,434 patients (mean age from 47.4 to 59.5 years, 55.4% female). Four studies were single- and the remaining studies were multiple-component interventions. Face-to-face counseling of patients was the most common intervention, often combined with providing printed materials, remote consultations, or conducting medication reviews. Generally, studies showed improved outcomes in the intervention group, including clinical, patient-reported and medication safety outcomes. In most studies at least one domain was judged to be of poor quality, with heterogeneity among studies. **Conclusions.** Community pharmacist-led interventions among T2DM patients showed positive effects in LMICs, but the quality of the evidence was poor. Face-to-face counseling of varying intensity, often combined with other strategies, was the most common type of intervention. Although these findings support the expansion of the role of the community pharmacist in diabetes care in LMICs, better quality studies are needed to evaluate further impact.

Introduction

The burden of providing sufficient care for patients with type 2 diabetes mellitus (T2DM) has become a challenge for health care providers (HCPs) in low- and middle-income countries (LMICs)¹. Improving the quality of care for patients with T2DM in LMICs, based on evidence-based treatment guidelines, seems to be urgently needed². Community pharmacists appear under-used in their roles to support disease or health management³ and may lack public recognition, particularly in LMICs⁴. On the other hand, community pharmacists are considered to be very well accessible HCPs in LMICs⁴, and there are opportunities to expand their role in diabetes care⁵.

Together with the International Pharmaceutical Federation, the World Health Organization has developed guidance for community pharmacists' roles to provide optimal care for patients in need of medication and to educate and monitor patients and improve medication management⁶. In several high-income countries (HICs), community pharmacists have extended their role into health promotion, are part of primary care teams, and contribute to disease management programs^{7–10}. There is an evidence on the role of community pharmacists for T2DM patients in HICs¹¹. Several studies conducted in HICs reported that community phar-

macists can improve glycemic control or other clinical parameters related to cardiovascular control, such as blood pressure or lipid profile^{12,13}. Systematic reviews summarizing the community pharmacists' role in diabetes care have been undertaken. Those studies showed that pharmacist-led interventions improved clinical, humanistic as well as medication safety outcomes by delivering educational and clinical interventions^{14–19}. However, to what extent those findings apply to LMICs is unclear.

Better insight is needed on the types of community pharmacist-led interventions among T2DM patients in LMICs and their effect on relevant outcomes. This scoping review aims to provide an overview of the types of interventions performed by community pharmacists and their effects on patients with T2DM in LMICs.

Methods

This scoping review followed The Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA ScR) guideline²⁰. The scoping review was registered on the Open Science Framework (OSF) with the link <https://osf.io/vbrm6>.

Search strategy

The following three databases were systematically searched for eligible studies from inception until February 2021: PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials. No language restrictions were applied. The search strategy was adapted for each bibliographic database following its system and rules. It used a combination of medical subject subheading (MeSH) terms and other keywords, namely “diabetes”, “pharmacist”, and “low-and middle-income countries” (Supplementary 1). The most recent list of the world bank was used to define LMICs²¹.

Review questions and outcomes of interest

This review describes the types of community pharmacist-led interventions for patients with T2DM and their effects on relevant outcomes. The main outcomes were (1) the types of community pharmacists' interventions, (2) clinical outcomes, (3) patient-reported outcomes, (4) medication safety outcomes (see data extraction). Secondary outcomes were other effects of interventions.

Eligibility criteria

All titles and abstracts retrieved from the search were imported into a reference manager program to identify duplicate articles. The studies were screened using Rayyan QCRI article screening software to complete the blinded screening process after deleting duplications²². Two reviewers (IC and ML) independently reviewed each title and abstract of the articles and selected articles for full-text review. The full text of each potentially eligible article was screened in accordance with inclusion criteria in this review by two reviewers, IC and ML for the articles in English, FL and XL for Chinese articles, and ML and TO for articles in Spanish and Portuguese. Any disagreements between the two reviewers were solved by consensus with KT and/or PD.

The operational definition of inclusion criteria was developed to ensure the consistency and reliability of the review process. This review included studies using a (non-) randomized controlled, before-after or interrupted time series design, focusing on community pharmacist-led interventions for patients with T2DM in primary health care and community settings. Community pharmacist-led interventions were defined as interventions delivered by community pharmacists solely or in collaboration with other HCPs. Excluded study types were case reports, editorial letters, abstracts, posters, and reviews.

Data extraction and analysis

A data extraction form was developed to extract relevant information from the included studies consistently. The extracted data included general information (study title, author, year), study characteristics (country, study design, study setting, sample size, mean age, number of females, study population only T2DM or not, follow-up period, missing data, reasons for missing data), intervention characteristics (type of intervention, individual/group intervention, type of HCPs involved, intervention topics, frequency of intervention, duration of intervention, conditions of control group), training of pharmacists (trainer, duration of training, topic of

training), outcomes, conclusion, and remarks (if any). The types of intervention anticipated were face-to-face counseling, remote consultations, medication review, use of printed materials and combinations of such interventions.

The outcomes were categorized into the following categories. Firstly, clinical outcomes covered glucose control (HbA1c, blood glucose), blood pressure (systolic blood pressure (SBP), diastolic blood pressure (DBP)), body measures (body mass index, height, weight, waist circumference), lipid profile (Low-Density Lipoprotein (LDL), High-Density Lipoprotein (HDL), triglycerides, total cholesterol), renal function or others. Secondly, patient-reported outcomes included medication adherence, diabetes knowledge, quality of life (QoL), patients' satisfaction, or others. Additionally, medication safety outcomes comprised of the number of drug-related problems (DRPs), pharmaceutical interventions related to DRPs or adverse drug events. Finally, other outcomes were included as other category. Data were extracted and assessed by IC and ML for articles in English, FL and XL for articles in Chinese and ML and TO for articles in Portuguese and Spanish. The two reviewers for each language compared their extracted and assessed data. Any discrepancies between the reviewers were resolved through discussion with KT and/or PD. The data of the included articles were summarized in tables or figures and described narratively. Differences were considered statistically significant if $p < .05$.

Study Quality Assessment

The assessment of the studies' quality was conducted based on the National Heart, Lung and Blood Institute [National Institute of Health (NIH)] assessment tools for controlled intervention studies and before-and-after studies with no control group²³. The assessment components were categorized into the following domains: design, selection of participants, sample size, intervention, outcome assessment, drop-out/lost to follow up, and analysis. All assessments were summarized and rated into three categories, "good", "fair", and "poor" quality, based on the developed scoring system for the quality rating (Supplementary 2). The final decision of the studies' quality was determined based on the quality rating in the seven domains. Studies which had at least four good-quality domains out of seven domains were rated high quality-studies, whereas studies which had at least four poor-quality domains were rated low quality-studies and the remaining studies were rated as mixed-quality studies.

Results

In total the search yielded 3,336 publications, of which 621 were duplicates. Of the remaining 2,715 studies, 2,591 were excluded in the title and abstract screening process. Full texts of 124 were screened and 28 articles were included in the final review (Figure 1). Supplementary 3 shows the reasons to exclude studies. Mostly these were studies in which interventions were not delivered by community pharmacists, or studies which were only published as abstracts. Detailed information of the extracted data is provided in Supporting Information Supplementary 4.

Study characteristics

Among the included articles, 19 were controlled studies, of which six were non-randomized^{24–29} and 13 were randomized^{30–42}; nine studies were before-after studies with no control group^{43–51}. The study periods covered ranged from 2007 to 2020, 18 studies were published in English^{24,26,27,30–36,38,41–45,47,48}, seven studies in Spanish^{28,29,40,46,49–51}, two studies in Chinese^{37,39}, and one study in Portuguese²⁵. Studies conducted by Roblejo et al.^{49–51} and Correr et al.^{24–26} had the same study setting but reported different outcomes.

Seventeen studies were conducted in upper-middle-income countries, namely Argentina²⁹, Malaysia^{36,38}, Brazil^{24–26,44,48}, China^{37,39}, Paraguay⁴⁰, Mexico^{28,46}, Cuba^{49–51}, and Turkey⁴⁵; whilst 11 studies were conducted in lower-middle-income countries; Indonesia^{27,30,31}, Pakistan³⁵, India^{32–34,42}, Nigeria⁴⁷, Iran⁴¹ and Lebanon⁴³ (Table 1). In total, the included studies represented 4,434 patients with a mean age ranging from 47.4 to 59.5 years old and slightly more women (55.4%). More detailed study characteristics are shown in Table 1.

The follow-up period ranged from two to 12 months with varying frequency and intervals of outcome mea-

surement. Some studies conducted repeated outcome measurements within the study period (fortnightly⁴⁴, monthly³³, quarterly³⁵, and half yearly³⁹); while other studies assessed the outcome 1 month^{30,31}, 2 months³², 3 months^{31,37,47}, 4 months^{27,32,46,48,49}, 5 months⁴¹, 6 months^{29,30,34,36,38,40,46}, 8 months³², and 12 months^{24,26,42,43,48,50,51} after the intervention.

Study quality assessment

In general, not-reported information was the most common quality issue negatively affecting the assessment score. For controlled studies, the sample size, analysis and design were the domains in which most studies were rated as having poor quality. The authors did not report whether the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power and did not use an intention-to-treat analysis. Moreover, several studies did not fulfil the requirements for the randomization process. Additionally, the design was the domain in which all before-after studies without control group had poor quality, mainly because they did not use multiple assessments before and after the intervention (Table 3 and Supplementary 5). All studies except one³¹ had one or more of the domains rated as poor quality. The final scoring rating showed that there were three high-quality studies, 11 mixed-quality studies and 14 low-quality studies (Supplementary 5).

Types of intervention

Interventions were single- or multi-component interventions focusing on patients with T2DM. Two studies reported on a mixed group of patients with either T2DM, hyperlipidemia and/or hypertension^{38,46}. Face-to-face counseling as the single-component intervention was used in four studies^{30,33,38,47}. Multi-component interventions were applied in the remaining studies, including a combination of face-to-face counseling and printed materials (pamphlet, leaflet, brochure, booklet)^{31,32,34,43–45}, face-to-face counseling and medication review^{24–26,29,36,40,42,46,49–51}, face-to-face group session and medication review²⁸, face-to-face counseling, printed materials and remote consultations (SMS reminder, phone calls, text messages, WeChat)^{27,39,41}, face-to-face counseling, printed materials and medication review³⁵, face-to-face counseling, printed material, lecture and medication review⁴⁸, and one study combined face-to-face counseling, printed material, lecture and remote consultation³⁷.

Most of the interventions were delivered solely by community pharmacists^{24–28,30–34,36,37,39–42,44–47}; however, there were studies in which the interventions were delivered by a collaboration of HCPs, such as pharmacist and physician^{29,35,43,49–51}; pharmacist, physician, nutritionist, physiotherapist, and physical educator⁴⁸, or pharmacist, physician, nurses, and dietitians³⁸. The educational topics delivered to the patients related to disease information^{24,27,30,32–34,41,43–46,48}, lifestyle^{24,27,28,32–36,38,41,43–48}, self-management skills^{28,32,35,41,46}, self-monitoring blood glucose^{27,28,30,35,36,41,43,44}, individual care plan/goals setting^{24–26,31,48}, and motivating adherence^{24,27,31,35,38,41–43,46,47}. In all studies, medication was reported as one of the topics addressed by community pharmacists (Table 2).

The frequency of face-to-face counseling was once or repeated with varying interval; namely fortnightly, monthly, or bimonthly, while the duration for each intervention ranged from 15–40 minutes. On average, face-to-face counseling included around six sessions. Seven studies did not provide information on both frequency and duration of interventions^{25,29,37,46,49–51}, whereas ten studies did not report the duration of the intervention^{26,27,33,34,38–40,43,44,47}. The controlled studies delivered usual care to the control group, while in two studies, community pharmacists' interventions were provided to the control group at the end of the study^{33,34} (Table 1).

Ten studies reported that the community pharmacists who delivered the intervention received a training program to enhance the competencies before providing the intervention to the patients with a duration ranging from two to 60 hours^{24–26,30,31,36,41–43,48}. The topics of the training program mostly addressed communication skills, information on the study protocol, diabetes management, the concept of medication reviews, the concept of pharmacotherapeutic follow-ups, or pharmaceutical care.

Clinical outcomes

Figure 2 shows the changes in clinical outcomes from baseline to follow-up across the studies (see also Supplementary 6). Thirteen articles reported on HbA1c^{26–28,30,35,36,39–43,47,48}. Three controlled studies assessed the changes of HbA1c from baseline to the final follow-up between control and the intervention group statistically^{26,28,30} and showed a significant difference ($p < .05$) except for one study²⁸. Likewise, three before-after studies reported significant reductions in HbA1c in the intervention group^{43,47,48}. Controlled studies reported a greater improvement of HbA1c in the intervention group, ranging from -0.42% to -3.30% , compared with the control group (Supplementary 6, Figure 2).

Thirteen studies analyzed fasting blood glucose as outcome^{26,28,29,32,33,36,39,40,43,44,46–48}. Of those, four controlled studies assessed the changes from baseline to final follow-up between control and the intervention group statistically^{26,33,36,39}, and three studies showed a significant difference between the groups^{26,33,36}. Also, five before-after studies evaluated the changes in the intervention group statistically^{43,44,46–48}. For these, four studies reported a significant difference^{43,44,46,47}. The changes in the intervention group across those 13 studies ranged from -4.8 to -80 mg/dL. In addition, one study reported random capillary glucose (CBG)³⁴ and estimated average glucose (eABG)³⁵ which showed a significant improvement in the intervention group.

Twelve studies reported on blood pressure as one of the outcomes^{26,27,31,33,35,36,41,42,44,46–48}. Blood pressure had a greater improvement in the intervention group in most studies with differences ranging from -2 to -23 mmHg SBP and -1.2 to -10 mmHg DBP. Two controlled studies showed an increase on SBP⁴¹ and/or DBP^{33,41} in the intervention group after community pharmacists' intervention. Of the three controlled studies undertaking statistical analysis of the changes from baseline to final follow-up between control and the intervention group^{26,31,33}, one study showed a significantly improved SBP³³ of 9.1 mmHg ($p = .0001$). Furthermore, one study reported a significant improvement of 1.8 mmHg on DBP ($p = .003$)²⁶. Three studies showed a significant difference in SBP and DBP from baseline to the final follow-up in the intervention group^{35,46,48} out of seven studies assessing the results statistically^{27,35,36,44,46–48}. Of note, there were many factors that affected blood pressure measurements, including measurement technique or patient factors such as anxiety or activities before measurement.

Seven studies evaluated lipid parameters as an outcome variable^{27,28,35,36,42,46,48}, of which five studies assessed four parameters; namely, low-density lipoprotein cholesterol (LDL), triglycerides, total cholesterol (TC), and high-density lipoprotein cholesterol (HDL)^{27,28,35,36,48}. Additionally, one study reported LDL⁴² and one study provided triglycerides and TC data⁴⁶. Most studies showed a statistically significant reduction from baseline to final follow-up in the intervention groups on LDL, triglycerides and TC, whereas two studies reported non-significant changes in HDL level^{27,35} (Supplementary 6).

Eight studies described body mass index (BMI) as an outcome measure^{26,32,33,35,36,41,47,48}. In all these studies, mean BMI decreased in the intervention group from baseline to the final follow-up with a difference from -0.1 to -3.6 kg/m². Of those, two before-after studies had a significant difference with $p < .001$ ⁴⁷ and $.026$ ⁴⁸. Two controlled studies evaluated the changes from baseline to final follow-up between control and the intervention group^{26,33} and one study showed a significant difference³³. In addition, one study reported clinical outcomes on renal function; namely serum creatinine (SCr) and estimated glomerulus filtration rate (eGFR)³⁵ with both of those outcomes showing a significant improvement in the intervention group with a reduction in serum creatinine of 0.3 mg/dL ($p < .0001$) and an increase of 24 ml/min/1.73 m² in eGFR ($p < .001$).

The largest improvements on clinical outcomes for a single-component intervention of repeated counseling were Bello et al.⁴⁷ on HbA1c, blood glucose, BMI and Arun et al.³³ on SBP (Figure 2) in a mixed-quality⁴⁷ and a low-quality study³³ (Table 3). Whereas, for multi-component interventions were Javaid et al.³⁵ on HbA1c, Herrera-Huerta et al.⁴⁶ on blood glucose, blood pressure and lipid profile (TG and TC); Herrera et al.²⁸ on lipid profile (HDL and LDL) and Venkatesan et al.³² on BMI (Figure 2) in a mixed-quality study³² and three low-quality studies^{28,35,46} (Table 3).

Patient-reported outcomes

A summary providing the patient-reported outcomes across the included studies can be found in Supplemen-

tary 7. Six studies reported QoL as one of the outcomes measured^{24,30,33,34,38,40}. The assessment tools used across the studies were European Quality of Life 5 Dimensions 5 Levels (EQ-5D-5L)³⁰, European Quality of Life 5 Dimensions (EQ-5D)³⁸, Short Form-36 (SF-36)⁴⁰, Quality of life dictionary for diabetes (DQoL)²⁴, Ferrans and Powers Quality of Life Index-Diabetes version III³³, and Audit of Diabetes-Dependent Quality of life-18 (ADDQoL-18)³⁴. Three studies^{24,30,40} reported a statistical analysis of the changes from baseline to final follow-up between two groups and showed a significant difference ($p < .05$). Furthermore, four studies reporting a statistical analysis in QoL changes in the intervention group, also showed significant changes^{30,34,38,40}. One study did not report a statistical analysis³³.

In addition, ten studies assessed medication adherence of patients using various tools; namely Medication Adherence Questionnaire (MAQ) and Pill Count Adherence (PAQ)²⁷, Morisky Medication Adherence Scale (MMAS)^{39,41}, Morisky-Green-Levine (MGL)²⁸, Medication Adherence Report Scale (MARS)³¹, Morisky-Green adherence scale^{37,44}, the monthly retiring of medication from pharmacy²⁹ and self-developed questionnaire^{43,45}. The number of patients who adhered to the medication increased in most studies. One controlled study³¹ reported a statistical analysis in the difference of the changes between the control and the intervention group and showed a significant difference ($p < .05$).

Regarding patients' satisfaction, five studies explored the patient-reported information using a self-developed questionnaire^{39,41,43,51} or the pharmacy services questionnaire²⁴. Most patients felt satisfied with the community pharmacists' interventions. The domains assessed regarding the interventions were patients' satisfaction with the scheduled visits, pharmacists' respect, pharmacists' knowledge, pharmacists' roles as an educator, communicators during the counseling session, and the pharmacist-physician collaborative practice. Mouhtadi et al.⁴³ and Jahangard-Rafsanjani et al.⁴¹ showed that at least 80% of patients were satisfied in all domains in the self-developed questionnaire used as an assessment tool in the intervention group. Furthermore, Shen et al.³⁹ reported a significant difference ($p < .001$) between the intervention and the control group in the changes from baseline to final follow-up. Correr et al.²⁴ showed that on general satisfaction, the intervention group was not significantly different from the control group ($p = .120$); similarly, with the therapy management domain ($p = .254$); however, the friendly exposure domain had a significant difference ($p = .043$).

On diabetes knowledge, four studies showed a significant improvement in most of the questions in the questionnaire in the intervention group^{32,40,43,44} ($p < .05$). The assessment tools used to assess patients' knowledge were self-developed questionnaires^{40,43,44}, an unclearly validated knowledge, attitude, and practices questionnaire³⁴, and The Michigan Diabetes Research and Training Centre (MDRTC) brief diabetes knowledge test questionnaire³².

In addition, other outcomes related to medication beliefs³¹, self-care activity⁴¹, patients' lifestyles⁴⁵, diabetes care profile³², and safe treatment behavior³⁷ were reported. Jahangard et al.⁴¹ reported that community pharmacists' intervention could improve on self-monitoring blood glucose, general diet and foot care in the intervention group. Additionally, Ozkan et al.⁴⁵ reported the positive impacts of community pharmacists' role by increasing the number of patients undertaking physical exercises, performing weight control, stopping smoking and reducing alcohol consumption.

The largest improvements in patient-reported outcomes for single-component, repeated counseling interventions, was seen in a low-quality study³⁰ on QoL using EQ-5D-5L assessment tool but not for EQ-5D VAS score (supplementary 6). While, for multi-component, repeated counseling interventions could be found in Shen et al.³⁹ on medication adherence and Jahangard-Rafsanjani et al.⁴¹ on patients' satisfaction (Supplementary 6) in a mixed-³⁹ and a high-quality study⁴¹ (Table 3).

Medication safety outcomes

Eight studies assessing the DRPs as outcome showed that the interventions could detect and decrease the incidence of DRPs^{26,28,29,40,42,48,49,51}. Of those, four studies reported the number of pharmaceutical interventions and the number of negative outcomes which were prevented or resolved^{26,29,49,50}. One study assessing the changes of the number of DRPs statistically reported a significant decrease in the number of DRPs after the intervention⁴⁰. Assessment tools used to classify the incidence of DRPs were Pharmaceutical Care

Network Europe (PCNE)⁴², Pharmacist's Workup of Drug Therapy (PWDT)⁴⁸, a validated classification system⁴⁰, and The Third Consensus of Granada^{26,28,29,49,50}. Additionally, Shen et al.³⁹ showed that the number of adverse drug events, including hypoglycemia, weight gain, oedema, gastrointestinal reaction, and fatigue, occurring among T2DM patients could be reduced by the community pharmacist-led intervention. Studies evaluating the effects on medication safety showed that multi-component interventions and interventions collaboratively with other health care professional (physician) appeared the most successful^{29,49,50}.

Economic evaluation

One study reported the effectiveness and costs of the intervention using an indicator of effectiveness (changes in glycated hemoglobin), which was related to the costs of pharmaceutical care. The study's conclusion stated that the cost of reducing HbA1c with 1% was estimated at \$37.62 per patient per year²⁵.

Discussion

This review of 28 studies demonstrates that various types of community pharmacist-led interventions to improve the outcomes of patients with T2DM have been tested in LMICs. Commonly pharmacists performed face-to-face counseling of varying intensity, often combined with other strategies, such as providing printed materials, remote consultations or medication reviews. Six out of 14 of the interventions with medication reviews were conducted collaboratively with physicians. Positive effects on clinical, patient-reported and medication safety outcomes were reported in most studies, though not always significant and often in low-quality studies.

Previously, it was observed that educational, behavioral or combined interventions successfully improved diabetes outcomes in studies mainly performed in HICs^{14,16–19}. This review illustrates that community pharmacists in LMICs tested single or combined strategies to improve outcomes of patients with T2DM. It suggests that single-component interventions may be successful in LMICs, with all four studies using only face-to-face counseling showing significant improvements in HbA1c, fasting blood glucose or QoL^{30,33,38,47}. Of note, almost all studies that applied face-to-face counseling had several, often monthly, contact moments. Previously, it was suggested that the number of contacts was more influential than the duration of the contacts^{52,53}. Face-to-face counseling was often used to give information about various topics to the patients. But face-to-face counseling was not solely educational but included motivational interviewing and collecting information about the patient's needs and drug related problems in several of the included studies, particularly when counseling was combined with medication review.

Medication review was always combined with face-to-face counseling and a common intervention strategy in pharmacy-led interventions evaluated in LMICs. Fourteen studies implementing such combined strategies had positive effects on clinical and/or non-clinical diabetes outcomes. This is in line with studies conducted in other settings showing that clinical medication reviews, which commonly include patient counseling, undertaken by community pharmacists reduced the number of DRPs⁵⁴, improved patients' clinical outcomes⁵⁵, increased patient safety⁵⁶, and increased medication adherence⁵⁷.

Community pharmacists may collaborate actively with other HCPs. Several studies reported that pharmacist-led collaborative care management programs were effective in managing diabetes care^{58–61}. In this review, eight studies reported that community pharmacists in LMICs delivered the interventions by collaborating with other health care professionals, mostly physicians, but in one case also nurses, dietitians and physiotherapists^{29,35,38,43,48–51}. A previous review reported that non-physician health care workers, such as pharmacists and nurses were successful in task-sharing activities in diabetes management. Non-pharmacological interventions conducted by nurses and both non-pharmacological and pharmacological interventions by pharmacists showed clinically significant improvement in HbA1c in LMICs⁶². Even though, the challenges for community pharmacists commonly met in carrying out collaborative care interventions were lack of cooperation of physicians or lack of reimbursement⁵⁴. Furthermore, some studies in this review reported that community pharmacists involved the patients in developing individual plans or goal setting for their diabetes treatment^{24–26,31,48}. This is in line with a previous study suggesting that shared decision-making between patients and HCPs in which patients' needs and values were prioritized and treatment goals

individualized, could minimize the burden of treatment⁶³, improve adherence, and potentially improve health outcomes⁶⁴.

The room for improvement in diabetes care in LMICs seems to be higher than in HICs. A study in LMICs showed a high unmet need for diabetes care and low rates of diabetes control, especially in low-income countries². Similarly, a study reported that the mean HbA1c concentration among children in LMICs was higher than HICs⁶⁵. Moreover, less than one out of ten people with diabetes in LMICs received coverage of comprehensive diabetes treatment based on WHO recommendations⁶⁶ which was lower than HICs' coverage. Therefore, investments are needed to strengthen diabetes care in LMICs. Innovative care models, pharmacist involvement in delivering care and sustainable education programs by health care professionals were seen as important to improve T2DM management in LMICs⁶⁷.

In general, the quality of most of the included studies was rated as mixed or low. In particular, a lot of relevant information was not reported, which negatively affected the quality rating. Overall, there were often issues with the design or the selection of patients. Additionally, several studies had a limited sample size, in which selection bias may have occurred. Furthermore, various non-validated assessment tools were used specifically for non-clinical outcomes. Finally, most studies did not describe whether the pharmacists had received training to conduct the intervention nor whether the intervention was implemented as intended.

Strengths and limitations

This study has several strengths. Firstly, this review included studies published in English and other languages; namely Chinese, Spanish, and Portuguese. We were able to include a large number of e articles reported in original languages. Secondly, this study used a broad search strategy to retrieve relevant articles. By conducting a scoping review, we did not restrict our search on types of interventions or outcomes assessed. Finally, two reviewers conducted all review steps, and the quality of the studies was assessed. On the other hand, this scoping review also has some limitations. For the quality assessment, we used a self-developed scoring system to cover the range of different study designs. Therefore, based on this review no firm conclusions can be drawn regarding the optimal type of intervention in LMICs. In addition, this review describes the result of community pharmacist-led interventions in LMICs in general. However, there might be relevant cultural and organizational differences among the countries. Therefore, results from this review may not be extrapolated to all LMICs.

Clinical implications and future research

Our findings illustrate that both single- and combined- intervention strategies can be implemented by community pharmacists in LMICs for managing patients with diabetes. The potential impact observed is promising and can be used to expand the community pharmacists' roles in diabetes care or chronic diseases in general, particularly in primary care and community settings. Although only a few studies reported on training for the pharmacists, ranging from two to 60 hours of training, it is likely that such training can help to implement new strategies. Further researches are needed to assess which trainings and competency development programs for community pharmacists in LMICs to improve their skills and professionalism.

In addition, future studies are needed to evaluate and compare the effects of different types of interventions, particularly studies of higher quality by improving the study design, patient selection and reporting relevant study details. When before-after studies are used, the study design could be an interrupted time-series for the outcome assessment. Interrupted time-series can be useful to evaluate the effect of an intervention when a randomized controlled trial is not possible⁶⁸. Furthermore, improvements regarding randomization and included patients as well as sample size calculation are needed for controlled studies.

Conclusion

This review provides support that community pharmacist-led interventions in LMICs can have positive effects on clinical and patient-reported outcomes as well as medication safety in T2DM patients. Single-component face-to-face counseling may already be beneficial, although it cannot be concluded how many contacts are needed for success. Combined strategies including face-to-face counseling and medication review are also

found promising. Improving the quality of intervention studies in LMICs is needed to strengthen the evidence in this field. Given the need to improve diabetes care in LMICs, these findings are a good basis to expand the role of the community pharmacists in diabetes care in LMICs.

Competing interest

The authors declare that they have no conflicts of interest in this review.

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Contributors

IC, ML, KT, PD, were involved in study conception and design. IC, ML, TO, KT, PD, XL and FL analyzed and interpreted the data, IC drafted the article, and all authors critically revised the article and approved the manuscript for publication.

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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Table 1. Characteristics of the studies

Author, Year

Study Design

Setting/Country

No. of patients (n)

Missing data (n)

Age in years (Mean [SD])

Gender (%) female

Type of intervention

Number of contact moments (time)

Follow-up duration (months)

Control

Fajriansyah et al., 2020³⁰

A cluster-randomized controlled trial

4 primary healthcare centers (Puskesmas)/ Indonesia

No. of patients (IG/CG): 111/119 Missing data (IG/CG): 2/8 Age: 57.71 +- 5.6 Gender (IG/CG): 60.36/66.67

Face-to-face counseling

6 counseling sessions (15 min/session)

6

Usual care

Alfian et al., 2020³¹

A cluster-randomized controlled trial

10 community health centers (CHCs)/ Indonesia

No. of patients (IG/CG): 57/56 Missing data (IG/CG): 13/11 Age: non-elderly: 34.51%, elderly: 65.49% Gender (IG/CG): 75.4/89.3

Face-to-face counseling, personalized leaflet

2 counseling sessions (average 14.2 minutes/session)

3

Usual care

Besemah et al., 2020²⁷

A non-randomized controlled trial

2 primary healthcare centers (Puskesmas)/ Indonesia

No. of patients (IG/CG): 48/46 Missing data (IG/CG): 8/6 Age (IG/CG): 56.52+-6.00/ 57.17+-7.82 Gender (IG/CG): 52.5/57.5

Face-to-face counseling, SMS reminders, booklet

4 counseling sessions, 16 SMS reminders

4

Usual care

Javaid et al., 2019³⁵

A randomized controlled trial

1 primary care facility/ Pakistan

No. of patients (IG/CG): 123/121 Missing data (IG/CG): 40/69 Age (IG/CG): 50.3+-10.5/50.4 +-7.7
Gender (IG/CG): 68.67/67.3

Face-to-face counseling, printed leaflets, medication review

9 counseling sessions (15-30 minutes/session)

9

Usual care

Mouhtadi et al., 2018⁴³

A before-after study with no control group

9 community pharmacies/ Lebanon

No. of patients: 200 Missing data (IG/CG): NR Age: 59+-11.0 Gender: 40

Face-to-face counseling, pamphlet

12 counseling sessions

12

NA

Ayadurai et al., 2018³⁶

A randomized controlled trial

7 primary health practices/ Malaysia

No. of patients (IG/CG): 77/77 Missing data (IG/CG): 16/8 Age (IG/CG): 55+-9/58 +-10 Gender (IG/CG): 58.2/56.5

Face-to-face counseling, medication review

6 counseling sessions (20-30 minutes/session)

6

Usual care

Mao et al., 2018³⁷

A randomized controlled trial

In the community / China

No. of patients (IG/CG): 100/100 Missing data (IG/CG): NR Age: range from 50 to 70 Gender: 60.5

Face-to-face counseling, lecture, WeChat, medication brochures

NR

3

Usual care

Zatta et al., 2017⁴⁴

A before-after study with no control group

1 pharmacy/ Brazil

No. of patients: 20 Missing data: 2 Age: 51.6 +- 8.8 Gender: 50

Face-to-face counseling, pamphlet

4 counseling sessions

2

NA

Shen et al., 2016³⁹

A randomized controlled trial

In the community / China

No. of patients (IG/CG): 89/88 Missing data (IG/CG): 16/13 Age: NR Gender: NR

Face-to-face counseling, personalized cards, phone calls, text messages, or WeChat

12 counseling sessions

12

Usual care

Aryani et al., 2016³⁸

A randomized controlled trial

Primary health cares /Malaysia

No. of patients (IG/CG): 527/257 Missing data (IG/CG): 59/32 Age (IG/CG): 47.4+- 9.4/ 50.1+- 10.2

Gender (IG/CG): 38.9/44.4

Face-to-face counseling

6 counseling sessions

6

Usual care

Maidana et al., 2016⁴⁰

A randomized controlled trial

Community pharmacies/ Paraguay

No. of patients (IG/CG): 32/32 Missing data: 3 Age: 55.6+-10.6 Gender: 72

Face-to-face counseling, medication review

6 counseling sessions

6

Usual care

Jahangard-Rafsanjani et al., 2014⁴¹

A randomized controlled trial

1 community pharmacy/ Iran

No. of patients (IG/CG): 51/50 Missing data (IG/CG): 6/10 Age (IG/CG): 57.3+-8.6/ 55.9+-8.7 Gender (IG/CG): 49/52

Face-to-face counseling, phone calls, pamphlet

5 follow-up visits (30 minutes/session) and 5 phone calls

5

Usual care

Gangwar et al., 2014⁴²

A randomized controlled trial

2 community pharmacies/ India

No. of patients: 723 Missing data (IG/CG): NR Age n (%): non-elderly: 427 (59.10), elderly: 296 (40.90)
Gender: 49.20

Face-to-face counseling, medication review

5 sessions for psychological aspect treatment (25-30 minutes/ session) and 1 for medication review (10-15 min)

12

Usual care

Herrera et al., 2014²⁸

A non-randomized controlled trial

A rural community/ Mexico

No. of patients (IG/CG): 45/45 Missing data: 13 Age: 52 Gender: 94

Face-to-face group sessions, medication review

6 sessions (max 30 minutes/session)

12

Usual care

Badesso et al., 2013²⁹

A non-randomized controlled trial

1 community pharmacy/ Argentina

No. of patients (IG/CG): 74/27 Missing data (IG/CG): NR Age (IG/CG): 59.1/ 58.6 Gender (IG/CG): 67.6/66.7

Face-to-face counseling, medication review

NR

6

Usual care

Ozkan et al., 2012⁴⁵

A before-after study with no control group

1 pharmacy/ Turkey

No. of patients: 25 Missing data (IG/CG): NR Age: 59.48+-1.94 Gender: 32

Face-to face counseling, brochure

1 counseling session (30 minutes)

3

NA

Herrera-Huerta et al., 2012⁴⁶

A before-after study with no control group

A rural community/ Mexico

No. of patients: 436 Missing data: NR Age: 58 Gender: 79

Face to face counseling, medication review

NR

6

NA

Bello et al., 2012⁴⁷

A before-after study with no control group

1 primary health care facility/ Nigeria

No. of patients: 170 Missing data: NR Age: 56.7+-12 Gender: 48.82

Face-to-face counseling

3 counseling sessions

3

NA

Venkatesan et al., 2012³²

A randomized controlled trial

2 community pharmacies/ India

No. of patients (IG/CG): 19/20 Missing data (IG/CG): 0 Age (IG/CG): 51.47+-9.99/ 57.05+- 12.06 Gender (IG/CG): 57.9/50

Face-to-face counseling, printed material

4 counseling sessions (20-40 minutes/ session)

8

Usual care

Correr et al., 2011²⁶

A non-randomized controlled trial

6 community pharmacies/ Brazil

No. of patients: 161 Missing data: 65 Age (IG/CG): 58.1+-10.3/ 59.5+- 11 Gender (IG/CG): 56/50

Face-to-face counseling, medication review

12 counseling sessions

12

Usual care

da Silva, et al., 2011⁴⁸

A before-after study with no control group

1 pharmacy chain/ Brazil

No. of patients: 56 Missing data: 5 Age: 57.0 +- 10.7 Gender: 46.4

Face-to-face counseling, printed material, bimonthly lecture, medication review

12 counseling sessions (30-40 minutes/ session), 6 lectures

12

NA

Roblejo et al., 2011⁵¹

A before-after study with no control group

1 community pharmacy/ Cuba

No. of patients: 30 Missing data: NR Age: non-elderly: 33.33% elderly: 66.66% Gender: 80

Face-to-face counseling, medication review

NR

12

NA

Roblejo et al., 2011⁵⁰

A before-after study with no control group

1 community pharmacy/ Cuba

No. of patients: 30 Missing data: NR Age: non-elderly: 33.33% elderly: 66.66% Gender: 80

Face-to-face counseling, medication review

NR

12

NA

Roblejo et al., 2010⁴⁹

A before-after study with no control group

1 community pharmacy/ Cuba

No. of patients: 30 Missing data: NR Age: non-elderly: 33.33% elderly: 66.66% Gender: 80

Face-to-face counseling, medication review

NR

4

NA

Correr et al., 2009²⁵

A non-randomized controlled trial

6 community pharmacies/ Brazil

No. of patients: 161 Missing data: 65 Age (IG/CG): 58.1+-10.3/ 59.5+- 11.0 Gender (IG/CG): 56/50

Face-to-face counseling, medication review

NR

12

Usual care

Correr et al., 2009²⁴

A non-randomized controlled study

6 community pharmacies/Brazil

No. of patients: 161 Missing data: 65 Age (IG/CG): 58.1+-10.3/ 59.5+- 11.0 Gender (IG/CG): 56/50

Face-to-face counseling, medication review

12 counseling sessions (average 19.3 minutes/session)

12

Usual care

Arun et al., 2008³³

A randomized controlled trial

3 primary health centers/ India

No. of patients (IG/CG): 104/50 Missing data: NR Age (IG/CG): 57.5 +- 8.63/ 58.8 +- 9.95 Gender (IG/CG): 55.77/52

Face-to-face counseling

6 counseling sessions

6

Patient received counseling at the end of the study

Adepu et al., 2007³⁴

A randomized controlled trial

2 community pharmacies/ India

No. of patients (IG/CG): 35/35 Missing data (IG/CG): 3/7 Age (IG/CG): 51.45+-12.27/ 53.77+-10.35 Gender (IG/CG): 25.7/37.1

Face-to-face counseling, printed leaflets

3 counseling sessions

6

Patient received counseling and information leaflet at the end of the study

Notes: IG: intervention group, CG: control group, SD: standard deviation, NR: not reported, NA: not applicable

No	Author year	Intervention component	Frequency of Single/ multi-ter- ven- com- po-	Type of health care pro- fes- sion- (once sion-	Educational topic	Educational topic	Educational topic	Educational topic	Educational topic	Educational topic	Educational topic	Educational topic	Educational topic	Outcome	Outcome	Outcome	Outcome	Outcome	Outcome	Outcome
11	Alfian et al., 2020 ³¹	Multi-Repeated component	Pharmacist		[?]			[?]	[?]					[?]						
12	Besemi et al., 2020 ²⁷	Multi-Repeated component	Pharmacist		[?]	[?]		[?]		[?]				[?]*	[?]	[?]				
13	Javadi et al., 2019 ³⁵	Multi-Repeated component	Pharmacist Physician		[?]	[?]	[?]	[?]		[?]				[?]*	[?]*	[?]	[?]	[?]*	[?]*	
14	Ayad et al., 2018 ³⁶	Multi-Repeated component	Pharmacist		[?]	[?]		[?]						[?]*	[?]**	[?]	[?]	[?]		
15	Mao et al., 2018 ³⁷	Multi-NR component	Pharmacist		[?]															
16	Shen et al., 2016 ³⁹	Multi-Repeated component	Pharmacist		[?]									[?]*	[?]*					
17	Aryan et al., 2016 ³⁸	Single-Repeated component	Physician, phar- ma- cist, nurses, and dietitians		[?]	[?]				[?]	[?]									[?]*
18	Maidani et al., 2016 ⁴⁰	Multi-Repeated component	Pharmacists		[?]									[?]*	[?]					[?]**
19	Jahangir Rafsanjani et al., 2014 ⁴¹	Multi-Repeated component	Pharmacist		[?]	[?]	[?]	[?]		[?]				[?]*	[?] a		[?] a			

Table 3. The summary of the quality assessment of included articles

Study Design	Authors, Year				
Study Design	Authors, Year	Design	Selection of participants	Intervention	Outcome assessment