


Process evaluation of a pharmacist-led intervention aimed at deprescribing and appropriate use of cardiometabolic medication among adult people with type 2 diabetes

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Abstract

Background: A quasi-experimental study investigated a pharmacist-led intervention aimed at deprescribing and medication management among adult patients with type 2 diabetes at risk of hypoglycaemia.

Objective: This study aimed to evaluate the process of implementing the intervention consisting of a tailored clinical medication review (CMR) supported by a training and a toolbox.

Methods: Mixed-methods study based on the Grant framework, including the domains “recruitment,” “delivery of intervention” and “response” of pharmacists and patients. Data collected were administrative logs, semi-structured observations of patient consultations ($n = 8$), interviews with pharmacists ($n = 16$) and patient-reported experience measure (PREM) questionnaires ($n = 66$).

Results: Tailored CMRs were conducted largely as intended for 90 patients from 14 pharmacies. Although patient selection based on a medication-derived hypoglycaemia risk score was considered useful, pharmacists experienced barriers to proposing deprescribing in patients with recent medication changes, without current hypoglycaemic events, or treated by medical specialists. The training and toolbox were evaluated positively by the pharmacists. Overall, patients were satisfied with the CMR.

Conclusion: Pharmacists and patients valued the CMR focusing on deprescribing and medication management. To optimize implementation and effectiveness of the intervention, improvements can be made to the patient selection, pharmacist training and the collaboration between healthcare professionals.

KEYWORDS

deprescribing, hypoglycaemia, pharmaceutical care, pharmacists, process evaluation, type 2 diabetes

Gert Baas and Stijn Crutzen are first co-authors.

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1 | INTRODUCTION

Overtreatment with cardiometabolic medication and difficulties in managing medication are common in patients with type 2 diabetes. These situations may lead to adverse events like hypoglycaemia and preventable medication-related hospitalizations.^{1–3} Some patients with type 2 diabetes experience challenges in managing their blood glucose due to misjudging how much nutrition and physical activity affect their blood glucose level, which may lead to hypoglycaemic events.^{4–6} Furthermore, too strict glycaemic control, particularly among older patients, puts them at risk of hypoglycaemic events. In approximately 20% of older Dutch patients using blood glucose-lowering agents, glycaemic control is stricter than recommended by clinical guidelines.^{7,8}

While overtreatment with cardiometabolic medication in older patients is common, deprescribing is rarely initiated in patients with type 2 diabetes.^{9–13} Multiple barriers to—and facilitators of—deprescribing in primary care, for both patients and health care professionals, have been identified, including in the fields of knowledge, organization, and communication.^{14,15} We took these factors into consideration in the development of a community pharmacist led-intervention. This intervention consisted of a tailored clinical medication review (CMR) aimed at deprescribing and appropriate use of glucose-, blood pressure-, and/or lipid-lowering agents and targeting adult patients with type 2 diabetes at risk of hypoglycaemia and was supported by a training and a toolbox.¹⁶ Although the intervention focused on patients for whom it might be useful to deprescribe in order to decrease the risk of hypoglycaemia, during the CMR, other reasons for deprescribing cardiometabolic medication, such as absence of expected benefits, were also taken into account. In addition, difficulties of patients to manage their medication were addressed, particularly in relation to the risk of hypoglycaemia.

According to the widely used guidance of the UK Medical Research Council for developing and evaluating complex interventions,¹⁷ a process evaluation can be performed. This evaluation aims to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes and to provide insight to aid implementation. Process evaluations are especially valuable in cases of “complex interventions”: namely, interventions such as CMRs that contain multiple interacting components¹⁸ and involve multiple groups (e.g., pharmacists, patients, general practitioners [GPs] and nurse practitioners [NPs]). Both the intervention design and implementation can be optimized based

on a process evaluation. This study aimed to evaluate the process of a pharmacist-led tailored CMR targeting adult patients with type 2 diabetes in primary care in order to understand variations in implementation and outcomes.

2 | METHODS

2.1 | Study design

The study was conducted in accordance with the *Basic & Clinical Pharmacology & Toxicology* policy for experimental and clinical studies.¹⁹ The study was a mixed-method process evaluation, combining interviews, observations, questionnaires and administrative logs. Various frameworks have been developed to guide systematic process evaluations. The framework of Grant et al. captures the recruitment, delivery and responses at both the practice level (i.e., the pharmacists) and the individual patient level, which are considered relevant elements for a process evaluation of a complex intervention.²⁰ In addition, it includes aspects such as the maintenance, unintended consequences and context of the intervention. The framework was used to structure the data collection and report the findings of this study. Table 1 summarizes the framework domains, the linked research questions, the related topics and the data sources used.

2.2 | Setting

This study was performed in the Dutch community pharmacy setting. In the Netherlands, community pharmacists are actively involved in patient care and deliver patient-specific services.²¹ Most patients are registered in one community pharmacy, from which they collect all their medications. Training in performing CMRs is part of both graduate and postgraduate community pharmacists' education. Dutch community pharmacists and GPs regularly collaborate in performing CMRs for older patients with polypharmacy in a five-step process in accordance with the Dutch multidisciplinary guideline²² (for details on the division of tasks, see the description of the intervention). Per pharmacy, pharmacists collaborate with an average of four GPs. The regular patient check-ups in GP practices for patients with chronic conditions such as type 2 diabetes are conducted by NPs. This study was conducted in pharmacies of Service Apotheek, a large franchise organization covering approximately 475 pharmacies in the Netherlands.

TABLE 1 Summary of methods and research questions for each framework domain.

Domain (Grant ²⁰)	Question	Topics	Data source(s)
Processes involving pharmacists	How are the pharmacists recruited? Why did the pharmacists withdraw? What were the pharmacists' characteristics? Why did the pharmacists participate?	Recruitment procedure Reasons for withdrawal Pharmacists characteristics Reasons for participation	Administrative logs Semi-structured pharmacist interview
	Delivery to pharmacists	Training delivery	Administrative logs
	Response of pharmacists	Number of conducted CMR Use of toolbox materials Process of deprescribing	Administrative logs Semi-structured pharmacist interview
Processes involving patients	Which patients received the intervention and was there selection bias?	Patient selection process Potential for deprescribing in selected patients Patients' response to invitation	Administrative logs Semi-structured pharmacist interview
	How was the intervention conducted and was this as intended?	Content of patient consultation Patient willingness to stop	Semi-structured observation and semi-structured pharmacist interview
	What is the patients' satisfaction level with the service?	Patient satisfaction with service	Questionnaires
General	How was the intervention sustained during the study period and thereafter?	Intention to continue the intervention	Semi-structured pharmacist interview
	Were there any unintended changes in process or outcomes?	Unintended consequences	All collected data
	What are the effects on the primary and secondary outcomes?	Previously published ¹⁶	n/a
	What was the wider context in which the intervention was conducted (e.g., organization of healthcare, financial incentives, pandemic, experience in performing a clinical medication review)?		Semi-structured pharmacist interview

2.3 | Description of the intervention

In the intervention study, pharmacists conducted tailored CMRs together with a GP and/or NP, aimed at deprescribing and appropriate use of cardiometabolic medication, supported by a training and a toolbox (see below) and targeting adult type 2 diabetes patients at risk of hypoglycaemia. The pharmacists conducted the tailored CMRs with the intervention patients following the steps in the Dutch multidisciplinary guideline, “Polypharmacy in older patients.”²² This process starts with a consultation from the pharmacist with the patient, either at the pharmacy or at the patient’s home, about their medication use, health problems and treatment preferences (step 1). Pharmacists were asked to focus on deprescribing, appropriate use of cardiometabolic medication and diabetes-related problems, including hypoglycaemia; however, they were allowed to propose changes to other medication as they saw fit. During this consultation, pharmacists could use a provided conversation aid and advise patients on how to use their diabetes medication in order to prevent hypoglycaemia.¹⁶ Afterwards, the pharmacist identified drug-related problems (step 2); pharmacists paid extra attention to potential for deprescribing of cardiometabolic medication, based on the provided summary of the deprescribing guidelines. The recommendations were discussed with the GP or NP (step 3) as in a regular CMR. This led to a pharmaceutical care plan for the patient, including the actions to be carried out, when they were to be carried out, and by whom (e.g., the pharmacist, GP, NP). In the following telephone or face-to-face consultation between the patient and the pharmacist, GP or NP, these actions were discussed and implemented (step 4) and then monitored after several weeks (step 5). Three months after the tailored CMR, the pharmacists determined and documented which changes—if any—had been implemented.

Before performing the intervention, a training was provided, see Box 1. The training was based on previous research and was provided by experienced instructors. All pharmacists were trained except in one case, where a pharmacy technician (BSc, pharmaceutical consultant) took part instead of the pharmacist. Due to the nature of the intervention and the leading role of the pharmacist, this 6-h accredited group training was mandatory for participating pharmacists and voluntary for the GPs and NPs. One month after the start of the study, an accredited conference call was organized to discuss the intervention progress and the barriers to and enablers of the CMRs, as perceived by the pharmacists.

After the training, the pharmacists received a list of patients with high hypoglycaemia risk scores as estimated with a previously developed algorithm, including

BOX 1 Overview of training components.

Training components

Before performing the intervention, a training was provided addressing the following three topics:

1. Knowledge about managing medication to prevent hypoglycaemia in patients with type 2 diabetes.
2. Knowledge of guideline recommendations on deprescribing of cardiometabolic medication.
3. Skills for conducting patient consultations about deprescribing.

During the training, three tools were introduced and training exercises using these tools were performed:

1. Conversation aid: a scheme with topics and sample questions to support consultations on deprescribing and hypoglycaemia.
2. Summary of deprescribing guidelines: a concise overview of the deprescribing recommendations for glucose-lowering medications, antihypertensive medications, and statins.
3. Agreement card: a patient card for documenting changes in medication, provided advice, and personal target values agreed with a patient.

information about age, sex, number and types of medication used,²³ generated from the pharmacy information system (NControl) used by Service Apotheek pharmacies. This screening tool was applied to all registered patients in the pharmacy who were ≥ 45 years old and filled a prescription for insulin and/or a sulfonylurea in the past 4 months. The pharmacists then selected eligible patients together with the GP and/or NP. The aim was to enrol 10 intervention and 10 control patients (usual care) per pharmacy.

2.4 | Data collection and analysis

The following methods were used to collect the data: administrative logs, semi-structured observations of patient consultations, semi-structured pharmacists’ interviews and patient questionnaires. The data were collected between November 2019 and April 2020 and focused on

the perspectives of pharmacists and patients. No data from the perspective of GPs or NPs were collected. Figure 1 presents an overview of the intervention, with the corresponding data collection of this process evaluation study.

2.4.1 | Administrative logs

The research team maintained logs of the recruitment and training process. These data were used to identify possible barriers to and facilitators of study participation and training participation. Also, the number of patients on the lists per pharmacy and number of conducted CMRs was documented. Furthermore, researchers registered frequency and content of the monitoring phone calls with the participating pharmacists and the conference call. These data were summarized and used to determine study progress.

2.4.2 | Semi-structured observations

In eight pharmacies, a semi-structured observation of the first or second patient consultation was performed by one observer (SS). These pharmacies were pragmatically chosen for the ability to conduct the observations in a limited period of time. The observations were semi-structured due to the use of a checklist (Appendix S1, originally developed in Dutch and translated to English), which was developed with the use of the Dutch guidelines for pharmacists²¹ and the study-specific communication tool. It contained all items that were supposed to be addressed in the consultation, under the headings of four topics: managing medication to prevent hypoglycaemia, hypoglycaemia, deprescribing, current medication use and related health problems and the structure and communication process. Directly after the consultation, a short semi-structured interview took place in which the pharmacist was asked to elaborate on choices made during the patient consultation—for example, regarding certain

topics that had not been addressed or explored further. A descriptive analysis of the consultation item results was performed. The notes on the structure and depth of the consultation and the connection with the patient were narratively summarized to obtain a general assessment of the conduct of the consultations.

2.4.3 | Patient questionnaire

A patient satisfaction questionnaire was designed based on the validated patient-reported experience measurement (PREM) version for chronic health (Appendix S2, originally in Dutch and translated to English).²⁴ The questionnaire consisted of a rating of overall satisfaction with the service of the pharmacist, nine items on satisfaction with and usefulness of received treatment and/or advice, trust in the pharmacist, communication by the pharmacist (5-point Likert scale), five items on the preferred content of the patient consultation (5-point Likert scale) and two open-ended questions on positive points and points for improvement. The questionnaire was sent by post or mail, according to the patient's preference, around 4 weeks after the patient consultation. Quantitative data were analysed in SPSS version 21, using descriptive statistics. Free text information was thematically classified by two researchers (GB and MH).

2.4.4 | Semi-structured pharmacist interviews

A topic list for the semi-structured interviews with the participating pharmacists was developed based on the framework of Grant et al.²⁰ (Appendix S3, translated from Dutch to English). The topic list contained items related to six Grant domains, as stated in Table 1: recruitment of pharmacists (1) and patients (2), delivery to patients (3), response of pharmacists (4), maintenance (5) and context (6). Questions concerned the actual

Key intervention elements	Recruitment pharmacies	Training pharmacists, GPs and NPs	Selection & invitation patients	Clinical medication review	Follow-up	Follow-up
Intervention	Pharmacists were invited to the intervention	Training day: Pharmacists, GPs and NPs received information about intervention	Pharmacists together with NP/GP selected and invited ten patients	Pharmacist conducted specific review	After 2-3 weeks the pharmacist conducted a follow-up with the patients	After 3 months the pharmacist conducted a second patient follow-up
Data collection process evaluation (executed by the researchers)	Recruitment logs	Training day logs	Monitoring phone calls and conference call	Semi-structured observation	Patients' experience questionnaire	Semi-structured interview

FIGURE 1 Overview of the intervention and corresponding data sources of the process evaluation.

conduct of the CMR intervention, barriers to and facilitators of all steps of this intervention and the pharmacist's perception of and experience with the intervention in general. All participating pharmacists were interviewed by GB or SC by telephone 1–3 months after completing the intervention. The interviews were audio recorded, transcribed verbatim, and coded independently by GB and SC using Atlas.ti (version 8.4). The text was coded using Grant domains as indicated. In addition, the text was coded as “barrier” or “facilitator,” and attribute codes for descriptive information about the intervention steps and consultation content were added. The barriers and facilitators were analysed per Grant domain, thematically clustered and discussed by GB, MH and SC, leading to domain-specific key issues relevant for the implementation of the intervention. Quotes to illustrate key issues were selected and translated by GB.

2.5 | Ethics and confidentiality

The Medical Ethics Review Board of the University Medical Center Groningen concluded that the study did not

require a WMO approval because it was not a clinical study with human participants, as defined by the Dutch Medical Research Involving Human Subjects Act. The participating pharmacists and patients each signed to indicate their informed consent.

3 | RESULTS

3.1 | Recruitment of pharmacists

A general call was published in the newsletter of Service Apotheek to recruit pharmacists. Following this, pharmacists thought to be interested in implementing advanced pharmaceutical care services were approached by telephone. The aim was to recruit a minimum of 24 pharmacists, and this was successfully achieved by calling 10 pharmacists in addition to those who self-nominated in response to the newsletter. Of the 24 pharmacists who initially agreed to participate, eight withdrew before or during the intervention study (Figure 2); this was mainly because of time constraints due to unexpected staff shortages, but pharmacists also stated that their GP was not

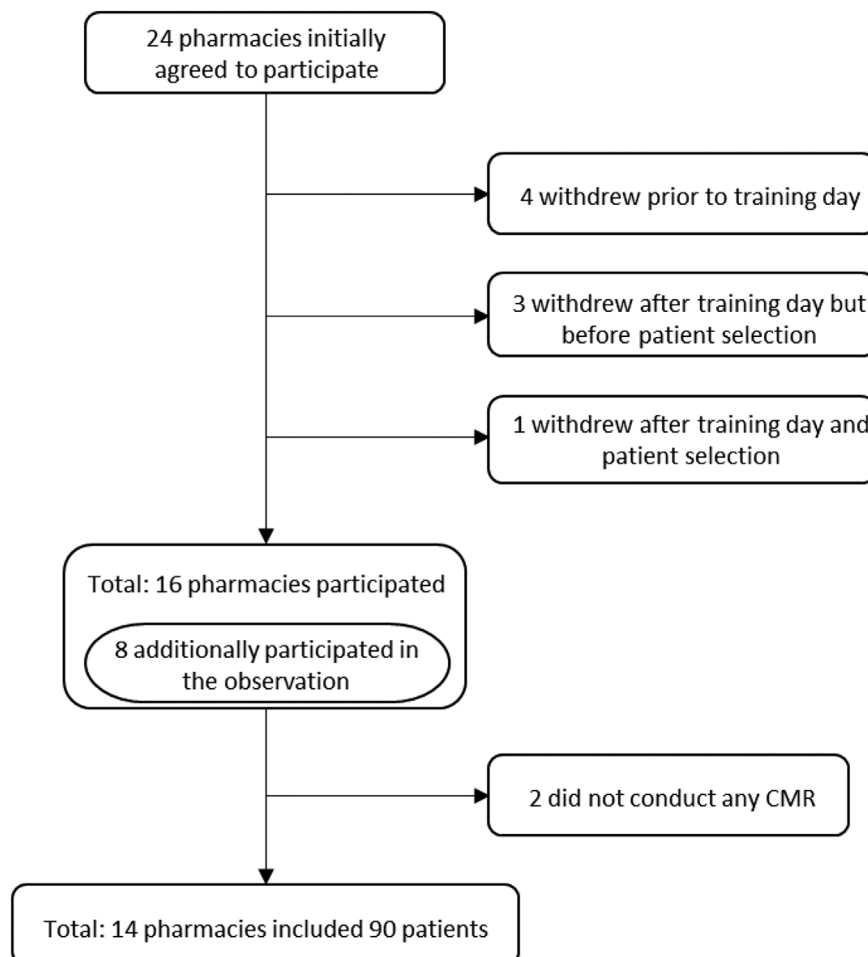


FIGURE 2 Flowchart of the recruitment process of the pharmacies.

willing to participate in this study. The participating pharmacies were spread over the Netherlands, in both rural and urban areas, and 13 of the 16 pharmacies were located in primary healthcare centres. Thirteen of the participating pharmacies had more registered patients than the Dutch average of 8000, and the data for one pharmacy were missing.

The interviews showed that the main *reasons for participation* were to provide better patient care, to develop and improve competencies as a pharmacist, and to contribute to scientific research to develop the pharmacist profession, as deprescribing was considered an interesting topic with importance for the future although it might need a different kind of reimbursement (Table 2, Q1).

3.2 | Delivery to pharmacists

One pharmacist per pharmacy participated in the study. Fourteen pharmacists, two GPs, and five NPs attended the training day. Two were unable to attend because of the long travel distances and thus received the training via videoconferencing. All pharmacists attended the conference calls.

3.3 | Response of pharmacists

Administrative logs were kept to assess the conduct of CMRs and semi-structured interviews with all pharmacists were performed in order to assess how the intervention and provided tools were integrated and adapted by the pharmacists. Of the 16 participating pharmacists, 14 (87.5%) conducted at least one tailored CMR. A total of 90 CMRs were performed, ranging from 2 to 10 per pharmacy, not reaching the intended 10 CMRs per pharmacy. Two pharmacists did not conduct any tailored CMR, due to challenges in patient recruitment. Moreover, the conduct of the intervention was affected to some degree by the COVID-19-pandemic, which reached the Netherlands in February 2020. Although most tailored CMRs had already been conducted before the start of the pandemic, some needed to be cancelled (Table 2, Q2). Some pharmacists conducted the patient consultations mainly at home, and others conducted most consultations at the pharmacy, according to their regular CMR procedures. The average duration of the patient consultations was 35 min. Although pharmacists were trained and instructed to conduct the review themselves, in one pharmacy, the pharmacy technician conducted the patient consultations.

In the interviews, the pharmacists reported that the usability of the *conversation aid* was good (Table 2, Q3). Several pharmacists experienced improvements in their

consultation skills when using the conversation aid (Table 2, Q4). Others still found it difficult to discuss certain topics mentioned in the conversation aid, in particular regarding the use of insulin due to lack of skills and knowledge (Table 2, Q5 and Q6). Some used the conversation aid only to prepare for the conversation, as they experienced that consultations otherwise felt unnatural (Table 2, Q7). The *deprescribing guidelines* helped pharmacists to inform patients and GPs/NPs to consider or accept deprescribing of cardiometabolic medication (Table 2, Q8 and Q9). Moreover, the guideline was useful for the pharmacists themselves, giving direction on when and how to deprescribe (Table 2, Q10). The agreement card was seldom used by the pharmacists, because they felt that their proposals for intervention needed to be discussed with the GP/NP first before such information could be handed to the patient.

Regarding the actual *deprescribing process*, most pharmacists were positive about their ability to conduct deprescribing (Table 2, Q11). Previously, the effort and time to get agreement of GPs on deprescribing recommendations as part of a regular CMR was perceived demotivating by some (Table 2, Q12).

3.4 | Recruitment and reach in patients

Pharmacists selected eligible participants from a list of patients with high hypoglycaemia risk scores, together with the GP and/or NP. The lists comprised an average of 140 patients (range: 61–223) per pharmacy, registered with several GPs. In the interviews, most pharmacists reported that this list based on the screening tool for high risk of hypoglycaemia was very useful for the identification of eligible patients. However, it was not always feasible to recruit 10 patients per pharmacy because each pharmacist collaborated for this study with only one or two GPs. Furthermore, the list also contained patients treated for their cardiometabolic conditions primarily by a medical specialist. Some pharmacists did not include these patients because of perceived difficulties in consulting specialists (Table 2, Q13). The two pharmacists who did not conduct any tailored CMR reported issues primarily related to patient recruitment, which was indicated as being quite difficult because of (a) research-specific reasons related to informed consent and data collection and (b) time constraints due to unexpected staff shortages.

With regard to the *potential for deprescribing in selected patients*, some pharmacists reported that they had invited patients for whom medication was recently intensified or for whom deprescribing had already been conducted by the NP (Table 2, Q14). In addition,

TABLE 2 Quotes illustrating various topics per domain.

Processes involving pharmacists	Domain (Grant ²⁰)	Pharmacist	Quote number	Quote				
Recruitment of pharmacists	Recruitment of pharmacists	Topic: reasons for participation	6	Q1	“I think deprescribing is the future and I hope that this kind of research will help to demonstrate the added value of addressing deprescribing in medication reviews in order to change the business model of pharmacies, which still is based on the number of medicines dispensed.”			
			Response of pharmacists	Topic: use of toolbox materials; conversation aid	4	Q2	“I have conducted only seven tailored CMRs, due to coronavirus. I had to cancel three CMRs, because at that time we had no time left at all.”	
					14	Q3	“In general, I used the conversation aid to structure the consultation. I asked all the suggested questions, so it was very different from a regular CMR.”	
			Response of pharmacists	Topic: use of toolbox materials; conversation aid	14	Q4	“Using the conversation aid, I have noticed that my conversation technique has improved. For example, I noticed that I did not always ask in-depth questions. And I have begun to formulate questions differently: what can be done better? What is important to you?”	
					10	Q5	“As a pharmacist, I think we lack the practical skills that a nurse practitioner has. [...] We are not used to asking these questions.”	
					3	Q6	“If I had to give advice on how to adjust use of insulin when, for example, a patient experiences a hypo in the evening, I found that difficult.”	
			Response of pharmacists	Topic: use of toolbox materials; conversation aid	Topic: use of toolbox materials; deprescribing guideline	6	Q7	“I just prepared some questions for myself. [...] The conversation tool feels like a checklist that you have to complete.”
						11	Q8	“It helps to explain that there are new guidelines. For example, you explain that the new target for blood pressure in older patients is higher. Most patients understand that.”
			Response of pharmacists	Topic: use of toolbox materials; conversation aid	Topic: use of toolbox materials; deprescribing guideline	1	Q9	“Nurse practitioners in particular are willing to reduce or stop medication if there is evidence for it.”
						13	Q10	“I think it is good that there is some evidence and a guideline. [...] What if the kidney function suddenly

TABLE 2 (Continued)

Domain (Grant ²⁰)	Pharmacist	Quote number	Quote
Processes involving patients	Topic: process of deprescribing 16	Q11	deteriorates? A guidance on what and how to stop medication is useful.”
		Q12	“Reducing medication? Yes, pharmacists can do that very well or at least in collaboration with the GP. And as pharmacists, we are well able to support the patient in reducing and stopping medication.”
		Q13	“Two months ago, I proposed that we could stop the insulin. Due to all kind of circumstances it happened only a few weeks ago, and I am getting tired of it.”
Recruitment and reach in patients	Topic: patient selection process 7	Q14	“This project promotes collaboration between the GP and pharmacist. [...] Because collaboration with the internist is more difficult, we excluded patients treated by internists.”
		Q15	“The GP did not agree with my proposal for stopping short-acting insulin, because the patient recently started insulin and the GP was planning a dose increase.”
		Q16	“The patients we selected from the list were actually patients who had no actual hypo experience at all. [...] You will only learn about that during the consultation. So, that’s difficult. I put effort into it, but it was not very useful.”
Delivery to patients	Topic: patient willingness to stop 14	Q17	“I made the selection from that list that I received and called the patients. They were all enthusiastic about participating.”
		Q18	“But suppose you could wish for something. [...] Then he said, ‘Well, you know, deep down in my heart, I wish not to use insulin’.”

Abbreviations: CMR, clinical medication review; GP, general practitioner; Q, quote.

although patients were selected on the basis of hypoglycaemia risk scores, pharmacists reported that there were patients without recently experienced hypoglycaemia, which in the opinion of some pharmacists made it less needed or more difficult to propose deprescribing (Table 2, Q15).

Patients' response to the invitation of the pharmacist was in general perceived as positive (Table 2, Q16). When patient recruitment was reported as being difficult, this was primarily for research-specific reasons related to informed consent and data collection.

3.5 | Delivery to patients

In order to assess whether the intervention was conducted as intended, a semi-structured observation of one consultation followed by a semi-structured interview about the consultation was conducted for eight pharmacists. The consultations generally met standards for effective communication and structure. Regarding the *content of the consultations*, in most observed consultations, the pharmacists provided sufficient information related to structure and communication, including the purpose, expectations and follow-up. Pharmacists provided comprehensive information on medication use, adverse effects, health problems and deprescribing. However, some important topics related to the focus of the intervention, for example, errors in insulin use or details about experienced hypoglycaemia, were seldom addressed. Furthermore, some pharmacists did not adequately address or follow up on issues raised by patients during the consultations, including difficulties with hypoglycaemia unawareness ($n = 2$), issues with hypotension ($n = 2$) or increased comorbidity ($n = 2$). In the interviews after these consultations, pharmacists mentioned they just had forgotten to address the issue or they felt it was not needed or not their responsibility to address that particular issue.

3.6 | Response of patients

Sixty-six of 90 intervention patients completed the PREM questionnaire (response rate 73%) in order to assess *patient satisfaction*. Their mean age was 71.5 years, including 8% <60 years and 43% >75 years, and 56% were males. Overall, the care and service provided by the pharmacists were well appreciated by the patients. When asked to indicate on a scale of 0–10 how likely they were to recommend the tailored medication review, the median score was 8 (range 3–10, 3 patients giving a score of ≤ 5). Most patients trusted their pharmacist ($n = 62$; 94%) and were satisfied with the information provided on

the (dis)advantages of stopping cardiometabolic medication during the consultations ($n = 45$; 68%). Fifty-three percent of the patients ($n = 35$) agreed that the pharmacist was helping them to better manage their chronic disease. The most important topics of discussion for patients were their satisfaction with their medication (70% agreed or strongly agreed) and asking questions about their medication (71% [strongly] agreed; Appendix S2, Table B). Additionally, 102 positive and eight negative comments were noted in the free text fields by 56 patients. Patients reported many positive comments about the pharmacists' attitudes (30 patients) and consultation content (25 patients), while negative comments were related to issues with the follow-up on agreements.

3.7 | General

The domain of *maintenance* was assessed using the responses from the semi-structured interviews with the pharmacists. Nine pharmacists intended to continue with the intervention because of the positive results seen for patients and the positive impact on the local collaboration. Three pharmacists did not want to continue the intervention, primarily due to time and financial constraints, as well as a preference for conducting general CMRs rather than tailored CMRs for patients with diabetes. Two pharmacists had doubts about continuing the intervention and mentioned that they would need an improved patient recruitment list for this.

No *unintended consequences* were reported. With regard to the *context*, it is noted that the COVID-19 pandemic reached the Netherlands in February 2020, during the study period. In addition to its influence on the conduct of tailored CMR, as mentioned earlier, the pandemic had major consequences for the follow-up, including limited monitoring of clinical values in the second quarter of 2020. Unintended consequences (e.g., large increases in HbA1c values) may have been missed because of less intensive follow-up.

4 | DISCUSSION

4.1 | Summary

Particularly pharmacists working in primary healthcare centres who were interested in deprescribing were reached, and all except one received the training and toolbox as intended. The automated screening of patients with a high hypoglycaemia risk score was useful, although there were several suggestions for improving the patient selection process. From this selection, patients

were recruited who were managed by the participating GPs for their cardiometabolic medication. Most pharmacists included less than the intended 10 patients and two did not conduct any tailored CMRs. The CMRs were largely conducted as intended but some topics were not fully addressed. Most pharmacists were positive about the deprescribing consultations after following the training and using the toolbox. Nevertheless, there were still issues which some pharmacists found difficult to discuss with patients. Deprescribing was experienced to be easiest in patients with recent hypoglycaemic events or other health problems. Pharmacists experienced barriers to deprescribing of cardiometabolic medication for patients in stable health conditions or with recent intensified therapy. The deprescribing guideline was helpful for pharmacists in guiding their clinical reasoning, as well as in their consultations with patients and GPs to discuss available evidence.

4.2 | Comparison with previous research

Looking at *Recruitment of pharmacists*, those having close relationships with GPs may be more open to conducting CMRs focusing on deprescribing and thus were reached with our intervention. Good relationships and a multidisciplinary approach have previously been mentioned as facilitators to deprescribing.¹⁴ *Recruitment of patients* appeared difficult for some pharmacists, but this was largely for research-related reasons. Using the algorithm resulted in including patients that were prescribed on average >5 medications, which is considered a relevant criterion for conducting a CMR.²² Algorithms to select patients for CMR can help to make the conduct of CMRs more efficient.²⁵ Our algorithm selecting adult patients with a high hypoglycaemia risk score based on medication use was intended to include adult patients in general, for whom adequate medication management is important, and frail older patients where deprescribing can be considered. Not all of these patients would require a full CMR, but pharmacists may lack relevant information to distinguish the need beforehand.²⁵ Of note, around 40% of patients included in the intervention study reported they had never experienced hypoglycaemic events in the past.¹⁶ However, based on *Response of patients*, their satisfaction with the intervention was high. In the literature, data on patient satisfaction with CMR are very limited.^{26,27} In general, patient satisfaction with specific pharmaceutical services tends to be high and is often related to the high degree of personal attention.^{28–30}

Barriers to deprescribe, as perceived by healthcare professionals, include (1) a lack of guidelines, knowledge and skills; (2) negative beliefs, fears and unwilling

patients; and (3) a lack of support, collaboration, time and resources.^{14,31} Based on the results in the domains *Response of pharmacists* and *Delivery to patients*, it appears that our training and support tools largely addressed the first group of barriers. In particular, the guidelines in our toolbox were highly appreciated. Lack of confidence and competency in discussing deprescribing with patients was partly overcome by the training and the conversation aid. However, several pharmacists still experienced difficulties in talking about deprescribing with patients who had not experienced any problems. This originated in the pharmacists' own feelings of urgency, as well as both patients and GPs in the latter case being less open to deprescribing. However, the purpose of deprescribing is not only to solve current problems (reactive deprescribing) but also to limit future risk and decrease unnecessary medication burden (proactive deprescribing).^{32,33} Thus, deprescribing should also be considered in patients without current health or medication problems. While reactive deprescribing is a routine activity, proactive deprescribing is a new concept for many pharmacists,³⁴ and it may require more training and support than was offered in our study.

Finally, in our training, some attention was paid to organizational aspects of the deprescribing process. Nevertheless, lack of time and resources remained a substantial barrier. This was the most important reason for withdrawal from the study and also for not wanting to continue with the tailored CMRs for diabetes patients. Better financial compensation may be needed to overcome this barrier. In addition, a different pharmacy reimbursement scheme could potentially contribute to a sustainable implementation.

4.3 | Implications

The pharmacy-led intervention, which previously showed the potential to increase deprescribing and improve appropriate use of cardiometabolic medication in type 2 diabetes patients at risk of hypoglycaemia, was sufficiently implemented as planned and appreciated by both patients and pharmacists.¹⁶ However, several recommendations can be made to optimize the intervention. First, the patient selection process may be improved. For a deprescribing intervention, patients whose medication has recently been intensified or deintensified are less suitable candidates. However, for improving medication management it is important to be aware that patient needs and problems can often only be identified during a patient conversation. It might be helpful to provide a more clear distinction between both groups for the pharmacists preparing the CMR.

Second, further training to increase the pharmacists' knowledge and improve their consultation skills may be indicated. Bringing up and discussing deprescribing in patient consultations is often perceived by pharmacists as a barrier. It has been recommended that, particularly for deprescribing, the patient's perspective and patient-oriented goal-setting should guide the decision-making process.^{35–37} Our observations showed that the depth and content of the conversations could be improved, for example, addressing insulin use in relation to food intake and exercise and details about experiencing hypoglycaemia. These could be topics that are more familiar to GPs and NPs than pharmacists. To support pharmacists in addressing topics not directly related to medication, further training to improve their knowledge and confidence might be helpful.³⁸

Third, local collaboration and agreements on patient advice and deprescribing are needed. The observations also showed that pharmacists sometimes did not pay attention to issues raised by patients during the consultations, particularly related to symptoms or comorbidity. They considered some of these issues the responsibility of other healthcare professionals. Some pharmacists did not feel comfortable discussing the details of their insulin therapy. Moreover, pharmacists reported that GPs sometimes had different opinions on the need for deprescribing. In addition, the process of implementing actions and scheduling follow-ups could benefit from clear agreements and planning. Special attention is needed for patients who are primarily managed by medical specialists: pharmacists, GPs, and NPs were hesitant to conduct interventions with these patients, although deprescribing may also be appropriate for some. Regional agreements or protocols could increase clarity about the roles and responsibilities for these patients.

Further studies are needed to assess the effects of counselling and involving patients in medication management and deprescribing by different healthcare professionals. A pragmatic study in Australia with a GP-led approach showed that interactive deprescribing training and an extended deprescribing consultation with patients also resulted in more frequent deprescribing, including deprescribing of glucose-lowering medication, diuretics and statins.³⁹ Our study conducted in the Netherlands used a pharmacy-led intervention, based on Dutch guidelines and fitting current practice of conducting CMRs. This enhanced implementation and consistency of care in the study setting. It is important to recognize that the processes of deprescribing are highly dependent on the care trajectories of the health system, which can vary significantly between countries. As such, while the findings of this study on the integration of the intervention and usefulness of the supplied tools and can be

informative and valuable in other countries, it is essential to consider the unique realities of care in those settings when interpreting and applying these results. Adapting the intervention to suit the local context, such as incorporating the perspectives and practices of other healthcare professionals, may be necessary for successful implementation in other countries.

4.4 | Strengths and limitations

A strength of this process evaluation is its mixed-methods design, gathering both qualitative and quantitative data. We combined data derived from all pharmacists ($n = 16$) and 73% ($n = 66$) of the patients. The use of the Grant framework ensured a structured and broad approach, incorporating all potentially relevant aspects. The Grant framework explicitly includes both the pharmacist level and the patient level. A limitation of the study is that no data from the perspective of the GPs or NPs were collected. In addition, semi-structured observations were only gathered for half the pharmacists and one of their patient consultations. The timeframe of this study did not permit a more extensive observational assessment of the patient consultations. Finally, mostly pharmacists working in primary healthcare centres participated and not all invited patients were willing to participate in the intervention study. Therefore, it is important to conduct further research to test the feasibility and cost-effectiveness of the intervention in other settings and populations.

5 | CONCLUSION

Both the pharmacists and patients were generally positive about the pharmacist-led intervention for patients with type 2 diabetes at risk of hypoglycaemia. They both valued the consultation about deprescribing, supported by tools. The intervention was largely implemented as intended but adapted procedures for patient selection, additional training of pharmacists, and making local agreements on deprescribing are suggested to optimize the effects of the intervention. Further attention should be paid to training of healthcare professionals to conduct proactive deprescribing.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests.

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REFERENCES

- Sturkenboom MC, van den Bemt PMLA, Smet PAGMD, Hek K. Eindrapport: Vervolgonderzoek medicatieveiligheid - Rapport - Rijksoverheid.nl [Internet] 2017. Available from: <https://www.rijksoverheid.nl/documenten/rapporten/2017/01/31/eindrapport-vervolgonderzoek-medicatieveiligheid>
- Ministerie van Volksgezondheid Welzijn en Sport. HARM-WRESTLING: Een voorstel van de Expertgroep Medicatieveiligheid m.b.t. concrete interventies die de extramurale medicatieveiligheid op korte termijn kunnen verbeteren. 2008:23.
- Gerstein HC, Miller ME, Genuth S, et al. Long-term effects of intensive glucose lowering on cardiovascular outcomes. *N Engl J Med*. 2011;364(9):818-828. doi:10.1056/NEJMoa1006524
- Crutzen S, van den Born-Bondt T, Denig P, Taxis K. Type 2 diabetes patients' views on prevention of hypoglycaemia—a mixed methods study investigating self-management issues and self-identified causes of hypoglycaemia. *BMC Fam Pract*. 2021;22(1):114. doi:10.1186/s12875-021-01466-0
- Yanai H. Causative anti-diabetic drugs and the underlying clinical factors for hypoglycemia in patients with diabetes. *World J Diabetes*. 2015;6(1):30-36. doi:10.4239/wjd.v6.i1.30
- Bonds DE, Miller ME, Dudl J, et al. Severe hypoglycemia symptoms, antecedent behaviors, immediate consequences and association with glycemia medication usage: secondary analysis of the ACCORD clinical trial data. *BMC Endocr Disord*. 2012;12(1):5. doi:10.1186/1472-6823-12-5
- Hart HE, Rutten GE, Bontje KN, Vos RC. Overtreatment of older patients with type 2 diabetes mellitus in primary care. *Diabetes Obes Metab*. 2018;20(4):1066-1069. doi:10.1111/dom.13174
- Boels AM, Hart HE, Rutten GE, Vos RC. Personalised treatment targets in type 2 diabetes patients: the Dutch approach. *Prim Care Diabetes*. 2017;11(1):71-77. doi:10.1016/j.pcd.2016.08.001
- Oktora MP, Kerr KP, Hak E, Denig P. Rates, determinants and success of implementing deprescribing in people with type 2 diabetes: a scoping review. *Diabet Med*. 2020;38(2):e14408. doi:10.1111/dme.14408
- Sussman JB, Kerr EA, Saini SD, et al. Rates of deintensification of blood pressure and glycemic medication treatment based on levels of control and life expectancy in older patients with diabetes mellitus. *JAMA Intern Med*. 2015;175(12):1942-1949. doi:10.1001/jamainternmed.2015.5110
- McAlister FA, Youngson E, Eurich DT. Treatment deintensification is uncommon in adults with type 2 diabetes mellitus: a retrospective cohort study. *Circ Cardiovasc Qual Outcomes*. 2017;10(4):1-7. doi:10.1161/CIRCOUTCOMES.116.003514
- Page AT, Etherton-Beer CD, Clifford RM, Burrows S, Eames M, Potter K. Deprescribing in frail older people—do doctors and pharmacists agree? *Res Social Adm Pharm*. 2016; 12(3):438-449. doi:10.1016/j.sapharm.2015.08.011
- Hart HE, Ditzel K, Rutten GE, et al. De-intensification of blood glucose lowering medication in people identified as being over-treated: a mixed methods study. *Patient Prefer Adherence*. 2019;13:1775-1783. doi:10.2147/PPA.S208947
- Abou J, Crutzen S, Tromp V, et al. Barriers and enablers of health care professionals to deprescribing cardiometabolic medication in older patients: a focus group study. *Drugs Aging*. 2022;39(3):209-221. doi:10.1007/s40266-021-00918-7
- Crutzen S, Baas G, Abou J, et al. Barriers and enablers of older patients to deprescribing of cardiometabolic medication: a focus group study. *Front Pharmacol*. 2020;11(August):1268. doi:10.3389/fphar.2020.01268
- Crutzen S, Baas G, Denig P, Heringa M, Taxis K. Pharmacist-led intervention aimed at deprescribing and appropriate use of cardiometabolic medication among people with type 2 diabetes. *Res Social Adm Pharm*. 2022;19(5):783-792. doi:10.1016/j.sapharm.2022.11.009
- Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008; 337(7676):979-983. doi:10.1136/bmj.a1655
- Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350(mar19 6):h1258. doi:10.1136/bmj.h1258
- Tveden-Nyborg P, Bergmann TK, Jessen N, Simonsen U, Lykkesfeldt J. BCPT policy for experimental and clinical studies. *Basic Clin Pharmacol Toxicol*. 2021;128(1):4-8. doi:10.1111/bcpt.13492
- Grant A, Treweek S, Dreischulte T, Foy R, Guthrie B. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials*. 2013;14(1):15. doi:10.1186/1745-6215-14-15
- Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie [Royal Dutch Pharmacists Association]. KNMP-richtlijn Medicatiebeoordeling [KNMP guideline Medication Review]. Published 2013. Available from: <https://www.knmp.nl/patientenzorg/medicatiebewaking/medicatiebeoordeling/knmp-richtlijn-medicatiebeoordeling>
- Nederlands Huisartsen Genootschap ism andere beroepsorganisaties/instanties/verenigingen [Dutch College of General Practitioners in collaboration with other professional organisations]. Module Medicatiebeoordeling, Onderdeel van de Multidisciplinaire Richtlijn Polyfarmacie bij ouderen [Multidisciplinary Guideline Polypharmacy in Elderly]. 2019; (September). Available from: https://richtlijnen.nhg.org/files/202005/final_module_medicatiebeoordeling_2019.pdf
- Crutzen S, Nagaraj SB, Taxis K, Denig P. Identifying patients at increased risk of hypoglycaemia in primary care: development of a machine learning-based screening tool. *Diabetes Metab Res Rev*. 2020;37(7):e3426. doi:10.1002/dmrr.3426
- Hendriks M, Krol M, Zuizewind C. PREM Eerstelijnszorg en PREM Chronische zorg Cognitieve validatie van twee vragenlijsten over patiëntervaringen met de zorg in de eerste lijn. Published 2016. <http://www.nivel.nl/>
- Crutzen S, Schuling J, Hugtenburg JG, et al. Development and piloting of an algorithm to select older patients for different types of medication review. *Front Pharmacol*. 2021;12:217. doi:10.3389/fphar.2019.00217

26. Petty DR, Knapp P, Raynor DK, House AO. Patients' views of a pharmacist-run medication review clinic in general practice. *Br J Gen Pract J R Coll Gen Pract.* 2003;53(493):607-613.
27. Snell R, Langran T, Donyai P. Patient views about polypharmacy medication review clinics run by clinical pharmacists in GP practices. *Int J Clin Pharmacol.* 2017;39(6):1162-1165. doi:[10.1007/s11096-017-0538-z](https://doi.org/10.1007/s11096-017-0538-z)
28. Naik-Panvelkar P, Saini B, LeMay KS, et al. A pharmacy asthma service achieves a change in patient responses from increased awareness to taking responsibility for their asthma. *Int J Pharm Pract.* 2015;23(3):182-191. doi:[10.1111/ijpp.12134](https://doi.org/10.1111/ijpp.12134)
29. McCann LM, Haughey SL, Parsons C, et al. A patient perspective of pharmacist prescribing: "crossing the specialisms-crossing the illnesses". *Health Expect.* 2015;18(1):58-68. doi:[10.1111/hex.12008](https://doi.org/10.1111/hex.12008)
30. Bajorek BV, LeMay KS, Magin PJ, Roberts C, Krass I, Armour CL. Management of hypertension in an Australian community pharmacy setting—patients' beliefs and perspectives. *Int J Pharm Pract.* 2017;25(4):263-273. doi:[10.1111/ijpp.12301](https://doi.org/10.1111/ijpp.12301)
31. Reeve E, Low LF, Hilmer SN. Beliefs and attitudes of older adults and carers about deprescribing of medications: a qualitative focus group study. *Br J Gen Pract.* 2016;66(649):e552-e560. doi:[10.3399/bjgp16X685669](https://doi.org/10.3399/bjgp16X685669)
32. Anderson TS, Goyal P, Marcum ZA. Implementing a proactive deprescribing approach to prevent adverse drug events. *J Gen Intern Med.* 2020;35(12):3694-3696. doi:[10.1007/s11606-020-05886-z](https://doi.org/10.1007/s11606-020-05886-z)
33. Hui RL, Chang CC, Niu F, et al. Evaluation of a pharmacist-managed antidiabetic deprescribing program in an integrated health care system. *J Manag Care Spec Pharm.* 2019 Aug; 25(8):927-934. doi:[10.18553/jmcp.2019.25.8.927](https://doi.org/10.18553/jmcp.2019.25.8.927)
34. Wright DJ, Scott S, Bhattacharya D. Deprescribing: routine pharmacy practice or an exciting research opportunity? *Int J Pharm Pract.* 2019;27(5):406-407. doi:[10.1111/ijpp.12513](https://doi.org/10.1111/ijpp.12513)
35. Reeve E, Low LF, Hilmer SN. Attitudes of older adults and caregivers in Australia toward deprescribing. *J Am Geriatr Soc.* 2019;67(6):1204-1210. doi:[10.1111/jgs.15804](https://doi.org/10.1111/jgs.15804)
36. Reeve E, Thompson W, Farrell B. Deprescribing: a narrative review of the evidence and practical recommendations for recognizing opportunities and taking action. *Eur J Intern Med.* 2017;38:3-11. doi:[10.1016/j.ejim.2016.12.021](https://doi.org/10.1016/j.ejim.2016.12.021)
37. Reeve E, Shakib S, Hendrix I, Roberts MS, Wiese MD. Review of deprescribing processes and development of an evidence-based, patient-centred deprescribing process. *Br J Clin Pharmacol.* 2014;78(4):738-747. doi:[10.1111/bcp.12386](https://doi.org/10.1111/bcp.12386)
38. Ayadurai S, Sunderland B, Tee LB, Hattingh HL. A training program incorporating a diabetes tool to facilitate delivery of quality diabetes care by community pharmacists in Malaysia and Australia. *Pharm Pract.* 2019;17(2):1457. doi:[10.18549/PharmPract.2019.2.1457](https://doi.org/10.18549/PharmPract.2019.2.1457)
39. Anderson K, Freeman C, Foster M, Scott I. GP-led deprescribing in community-living older Australians: an exploratory controlled trial. *J Am Geriatr Soc.* 2020;68(2):403-410. doi:[10.1111/jgs.16273](https://doi.org/10.1111/jgs.16273)

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