

Impact of Pharmacist-Provided Education Using New Information Sheets on Activation in Patients Treated with Oral Antineoplastic Drugs (IMPACT-OAD Project)

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ABSTRACT

Background: Oral antineoplastic drugs (OADs) play an increasing role in the treatment of cancer. Patients must have a high degree of understanding and autonomy to manage the numerous adverse effects at home. In Quebec, recommendations have been made for oncology pharmacists to systematically counsel all patients who are starting an OAD.

Objective: To measure the impact of education provided by oncology pharmacists on patient activation.

Methods: In this prospective, single-centre, observational cohort study, patients starting an OAD received education from oncology pharmacists, who used the 2020 updated version of information sheets from the Groupe d'étude en oncologie du Québec (GEOQ, www.geoq.info). The Patient Activation Measure (PAM-13) questionnaire was used to measure patients' activation before and after the intervention.

Results: Of the 43 patients recruited in the intention-to-treat analysis, 41 were included in the modified intention-to-treat analysis. The mean difference between PAM-13 scores before and after the intervention was 2.30 (standard deviation [SD] 11.85) ($p = 0.22$) in the intention-to-treat analysis and 3.63 (SD 10.33) ($p = 0.032$) in the modified intention-to-treat analysis; these differences were less than the 5 points required for a result to be considered clinically meaningful. None of the effect-modifying variables for which data were collected had a significant impact on the degree of activation; however, a weak negative correlation was observed between the level of health literacy and the change in PAM-13 score.

Conclusions: The study did not show a clinically meaningful change in patient activation following pharmacist-provided education, according to the updated GEOQ information sheets. Further studies are needed to evaluate these data in a larger population and to determine whether the impact of education persists beyond the first treatment cycle.

Keywords: oral antineoplastic drugs, oncology pharmacist education, patient activation measure

RÉSUMÉ

Contexte : Les médicaments antinéoplasiques par voie orale (MAVO) occupent une place grandissante dans le traitement du cancer. Les patients doivent avoir un degré élevé de compréhension et d'autonomie pour gérer les nombreux effets indésirables à domicile. Au Québec, des recommandations ont été émises pour que les pharmaciens en oncologie conseillent systématiquement tous les patients qui débutent des MAVO.

Objectif : Mesurer l'impact des enseignements effectués par les pharmaciens en oncologie sur l'activation du patient.

Méthodes : Dans cette étude de cohorte prospective, monocentrique et observationnelle, les patients qui commençaient à prendre des MAVO ont reçu un enseignement effectué par un pharmacien en oncologie. Ceux-ci utilisaient les feuillets d'information pour les patients du Groupe d'étude en oncologie du Québec (GEOQ, www.geoq.info) mis à jour en 2020. Le questionnaire de Mesure d'activation du patient (MAP-13) a été utilisé pour mesurer l'activation des participants avant et après l'intervention.

Résultats : Sur les 43 participants recrutés dans l'analyse en intention de traiter, 41 ont été inclus dans l'analyse en intention de traiter modifiée (mITT). La différence moyenne entre les scores MAP-13 avant et après était de 2,30 (écart type [SD] 11,85) ($p = 0,22$) dans l'analyse en intention de traiter et de 3,63 (SD 10,33) ($p = 0,032$) dans l'analyse mITT; ces différences étaient inférieures aux 5 points requis pour qu'un résultat soit considéré comme cliniquement significatif. Aucune des variables modificatrices d'effet pour lesquelles des données ont été recueillies n'a eu d'effet significatif sur le degré d'activation; cependant, une faible corrélation négative a été observée entre le niveau de littératie en santé et la variation du score MAP-13.

Conclusions : L'étude n'a pas démontré de changement cliniquement significatif dans l'activation des patients à la suite de l'enseignement effectué par le pharmacien en oncologie sur la base des feuillets d'information actualisés du GEOQ. D'autres études sont nécessaires pour évaluer ces données chez une plus grande population et pour déterminer si l'impact de l'enseignement perdure au-delà du premier cycle de traitement.

Mots-clés : médicaments antinéoplasiques par voie orale, enseignement par le pharmacien en oncologie, mesure d'activation du patient

INTRODUCTION

Oral antineoplastic drugs (OADs) play an increasing role in therapy for many cancers.¹ Indeed, in 2015, approximately 25% of antineoplastics were in oral form.² In Quebec, given the growing use of OADs and the considerable risks associated with their utilization, pharmacist organizations recommend that oncology pharmacists provide patient education about these drugs using information sheets developed by, among others, the Groupe d'étude en oncologie du Québec (GEOQ).³ This practice differs considerably from one facility to another, in part because of the significant resources involved.³ The information sheets developed by the GEOQ are short and are intended for patients taking an OAD. Each information sheet includes, among other details, precautions regarding the particular drug and the management of main adverse effects. The sheets were modified in winter 2020 to standardize their content and to focus on the relevant information, with the addition of a treatment diary, pictograms, and colour-coded recommendations to help the patient be more independent in managing their treatment.

Patient activation is defined as having the knowledge, skills, and confidence required to successfully manage one's health or a chronic disease.⁴ Patients with higher levels of activation tend to have better adherence, to adopt self-management behaviours, to manage their adverse effects, and to have better health outcomes.^{1,5-9} There is a lack of data in the literature supporting the effect of pharmacist-provided education on patient activation, although a few studies have shown positive effects.¹⁰⁻¹² Health literacy is another factor that can potentially affect activation, but mixed results have been reported in the literature.¹³⁻¹⁶

The purpose of this study was to measure the effect of education led by an oncology pharmacist, using the GEOQ's new information sheets (available in both French and English), on patients receiving an OAD, by assessing patient activation with validated questionnaires. This study was conducted by pharmacy residents and their preceptors in the context of a Master in Advanced Pharmacotherapy curriculum at the Université de Montréal.

METHODS

Study Population

This prospective, single-centre, observational cohort study involved patients starting an OAD. Patients were eligible for enrolment if they were 18 years of age or older, were starting a new OAD, and were patients of the Centre intégré de cancérologie de Laval (CICL) oncology clinic during the data collection period (May to November 2020). The exclusion criteria were a prescription for an OAD that had no dedicated GEOQ information sheet; hormone therapy alone for breast or prostate cancer (because the regimens are less complex and have a more tolerable side-effect profile);

concomitant treatment with a parenteral antineoplastic or curative radiotherapy (because such patients already have more intensive follow-up by the radio-oncology team); a prescription for lenalidomide, pomalidomide, or venetoclax (because patients taking these drugs already receive education provided by an external specialty pharmacist); participation in another research project; inability to self-manage the antineoplastic therapy (based on their answer, when asked during screening, to the question of whether they manage their own medications); and inability to speak French or English (because GEOQ information sheets are available only in those languages).

Questionnaires

To measure patient activation, the 13-item Patient Activation Measure (PAM-13) questionnaire of Insignia Health was used (<https://www.insigniahealth.com/pam/>).^{4,17} This questionnaire has been validated for face-to-face or telephone administration in several languages, including French and English.^{18,19} Participants' answers were entered into an Excel spreadsheet provided by Insignia Health, which then generated a PAM-13 score between 0 and 100, with higher scores being associated with better activation.^{4,17}

To measure the effect of health literacy, the validated Set of Brief Screening Questions (SBSQ) presented by Chew and others²⁰ was chosen, because of its simplicity. The potential responses to the 3 SBSQ questions (referred to as "confident with form", "help read", and "problems learning") correspond to choices on a Likert scale from 0 to 4, depending on the response.²⁰ A score of less than 3 indicates an inadequate level of health literacy, whereas a score of 3 or higher indicates adequate health literacy.^{20,21}

Study Protocol

Potentially eligible patients were referred by hematologist-oncologists and by oncology pivot nurses. The recruitment interviews were conducted by telephone because of the COVID-19 pandemic. After giving informed verbal consent, each patient completed the baseline PAM-13 and SBSQ questionnaires. Subsequently, education was provided by an oncology pharmacist by telephone using the pertinent GEOQ sheet, previously sent to the patient by email or regular mail. The PAM-13 questionnaire was completed a second time 7 days after initiation of the OAD or, if the OAD had already been started, 7 days after the provision of education. At the end of the first treatment cycle, the patient returned the completed treatment diary, and the final data collection was carried out. Patients could withdraw their consent at any time, and pharmacist-led education was offered even if they declined to participate in the study or were not eligible.

Outcomes

The primary outcome was the degree of activation among patients starting an OAD following oncology

pharmacist-led education using the new GEOQ sheets. The secondary outcomes were the relationship between health literacy level and degree of patient activation, patients' use of health professionals (as indicated by number of calls to a CICL team member and number of visits to the emergency department), associated interventions performed during the first treatment cycle, use of the treatment diary section of the GEOQ sheet, and treatment adherence.

Statistical Analysis

Assuming a standard deviation (SD) of 15, based on the literature, a minimum sample size of 73 participants was required to detect a clinically meaningful difference of 5 points in the PAM score, with 80% power and 2-sided α of 0.05.^{6,22,23}

The data were normally distributed, and parametric tests were therefore used for all analyses. In the intention-to-treat (ITT) analysis, a paired-observations *t* test was used to compare the mean pre- and post-intervention scores on the PAM-13 questionnaire. Univariate and multivariate linear regressions were performed to adjust for effect-modifying variables and to examine the relationship between the level of health literacy (based on SBSQ scores) and the change in PAM-13 scores. The Pearson correlation coefficient (*r*) was chosen to simplify the presentation of regression results, the relationship between the effect-modifying variables, and changes in the PAM-13 scores. Absolute correlations less than 0.20 were considered negligible.¹⁰ An independent-observations *t* test, not included in the original protocol, was used to compare the mean PAM-13 scores between 2 subgroups (those with adequate and inadequate levels of health literacy).

A sensitivity analysis for the primary outcome, not included in the original protocol, was performed to exclude participants in special situations. In this modified ITT (mITT) analysis, 2 participants were excluded because of a significant protocol violation.

For the descriptive analysis, continuous variables are represented by the mean and SD and categorical variables by numbers and percentages. A *p* value less than 0.05 was considered statistically significant.

Ethics Approval

The original protocol and an amendment were submitted to and approved by the ethics board of the Centre intégré de santé et de services sociaux de Laval. Recruitment for the study was suspended for 10 weeks because of the COVID-19 pandemic. Before the study was allowed to resume, the protocol was amended to specify that all communication with participants would be by telephone.

RESULTS

Of the 81 patients who were referred, a total of 43 were recruited. Among those not recruited, 24 were excluded

because they met various exclusion criteria; the other 14 declined to participate (Figure 1). In addition, 1 patient who was initially recruited did not complete the study because the OAD was discontinued. Data for the primary outcome were therefore available for 42 participants (98%). Of these, 2 participants were excluded from the mITT analysis because the interval between their PAM-13 questionnaires was much longer than initially planned.

Demographic and clinical data for the 43 patients initially recruited are shown in Table 1. These patients were predominantly female (60%), their mean age was 65.7 (SD 11.3) years, they were predominantly receiving palliative therapy (86%), and most were not antineoplastic-naïve (84%). None of the patients had received their diagnosis of cancer within the 2 weeks preceding the first PAM-13, which could have influenced the results (Insignia Health: Best practices when administering PAM; internal document consulted on October 19, 2019). The results for the primary outcome, patient activation, are shown in Table 2. The mean score on the first PAM-13 was 67.11 (SD 14.30), whereas the mean score on the second PAM-13 was 69.09 (SD 11.90).

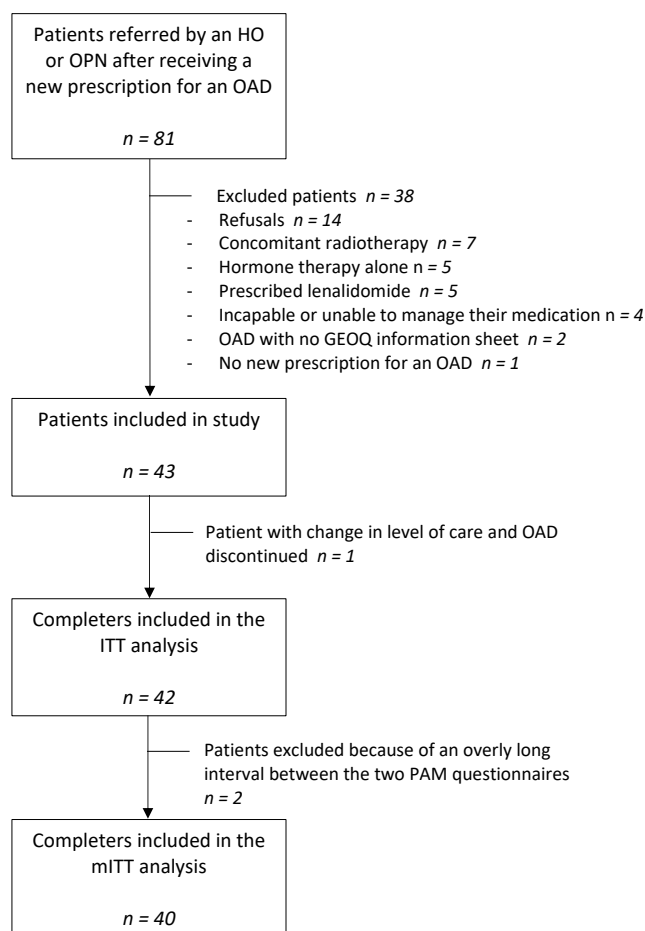


FIGURE 1. Patient selection. GEOQ = Groupe d'étude en oncologie du Québec, HO = hematologist-oncologist, ITT = intention to treat, mITT = modified ITT, OAD = oral antineoplastic drug, OPN = oncology pivot nurse, PAM = Patient Activation Measure.

TABLE 1. Baseline Characteristics

Characteristic	No. (%) of Patients ^a (n = 43)	
Age (years) (mean ± SD)	65.7 ± 11.3	
Sex		
Men	17	(40)
Women	26	(60)
Goal of care		
Adjuvant	6	(14)
Palliative	37	(86)
Tumour site or type		
Breast	16	(37)
Colorectal	8	(19)
Kidney	5	(12)
Lung	4	(9)
Chronic myeloid lymphoma	3	(7)
Other ^b	7	(16)
Oral antineoplastic drug started		
Capecitabine	10	(23)
Trifluridine–tipiracil	5	(12)
Palbociclib–fulvestrant	3	(7)
Palbociclib–letrozole	3	(7)
Alectinib	2	(5)
Cabozantinib	2	(5)
Everolimus–exemestane	2	(5)
Imatinib	2	(5)
Osimertinib	2	(5)
Pazopanib	2	(5)
Ribociclib–letrozole	2	(5)
Other ^c	8	(19)
Antineoplastic-naïve	7	(16)
ECOG performance status		
0	8	(19)
1	11	(26)
2	4	(9)
Unknown	20	(47)
Charlson comorbidity index (mean ± SD)	7.7 ± 2.7	
No. of concomitant drugs (mean ± SD)	6.0 ± 3.6	
Education		
No diploma	8	(19)
High school diploma	12	(28)
Vocational diploma	4	(9)
Diploma from private college or general and vocational college	6	(14)
Certificate, diploma, or other university degree	13	(30)
Caregiver present	10	(23)

ECOG = Eastern Cooperative Oncology Group, SD = standard deviation.

^aExcept where indicated otherwise.

^bOther tumours and sites were non-Hodgkin lymphoma, gastrointestinal stromal tumour, myxofibrosarcoma, myeloproliferative neoplasm–myelofibrosis, esophagus, thyroid, and site of origin unknown.

^cOther oral antineoplastic drugs were axitinib, dasatinib, ibrutinib, nilotinib, regorafenib, ruxolitinib, sorafenib, and sunitinib.

The mean interval between the 2 questionnaires was 14.8 (SD 10.0) days, ranging from 7 to 58 days (median 12 days). The reasons for intervals longer than 7 days were not systematically noted, but included patient preference, patient leaving on vacation, delay for insurance acceptance or for the pharmacy to receive the medication, and hospitalization.

In the ITT analysis, the mean difference between the 2 PAM-13 questionnaires was 2.30 (SD 11.85) ($p = 0.22$). There was no statistically significant difference between participants with adequate and inadequate levels of health literacy (1.25 [SD 12.86] versus 5.26 [SD 8.15], $p = 0.34$). In the mITT analysis, the mean difference was 3.63 (SD 10.33) ($p = 0.032$). Various effect-modifying variables such as age, sex, goal of care, antineoplastic naivety, health literacy level as determined by the SBSQ, education level, presence of a caregiver during counselling, and the Charlson comorbidity index did not have a significant effect on the degree of activation.

Results for the secondary outcomes are shown in Table 3. The mean responses to the SBSQ questions were 3.4 (SD 0.9) for each of the first 2 questions and 3.5 (SD 0.8) for the third question; these results indicate an adequate level of health literacy. The Pearson correlation coefficients (r values) between health literacy level as determined by the 3 SBSQ questions and the degree of activation were -0.183 ($p = 0.25$) for the first question, -0.079 ($p = 0.62$) for the second question, and -0.164 ($p = 0.30$) for the third question. The correlation between health literacy level and degree of activation was therefore weak, given that the Pearson correlation coefficients were below the 0.20 threshold established in the literature.

Results describing patients' use of health professionals were available for all 43 participants, but only 38 returned their treatment diaries for evaluation of the secondary outcomes pertaining to this tool. The total number of treatment-related calls to the treatment team during the first cycle was 33, or 0.77 calls per patient, and a total of 25 interventions, or a mean of 0.58 interventions per patient, were performed as a result of these calls. The mean number of visits to the emergency department was 0.09 per patient, based on 4 of the 43 patients making such a visit during their first treatment cycle. The rate of utilization of the treatment diary was 82% for the diaries returned. Adherence was determined from the number of days "ticked" in the diary; about two-thirds of participants (25/38) had good adherence (75%–100%), and about one-third (12/38) had poor adherence (0%–25%).

DISCUSSION

This study was designed to measure activation among patients starting a new OAD before and after provision of education by an oncology pharmacist using GEOQ information sheets. The ITT analysis showed no significant difference in the degree of activation following the intervention, although the required sample size was not reached. In contrast, a statistically significant difference between

TABLE 2. Results for Primary Outcome

Result	Patient Activation Measure (PAM); Score			p Value ^a
	First PAM	Second PAM	Difference	
Intention to treat				
No.	43	42	42	
Mean ± SD	67.11 ± 14.30	69.09 ± 11.90	2.30 ± 11.85	0.22
Modified intention to treat				
No.	41	40	40	
Mean ± SD	66.25 ± 14.08	69.51 ± 11.92	3.63 ± 10.33	0.032

SD = standard deviation.

^aA *t* test for paired observations was performed.

TABLE 3. Results for Secondary Outcomes

Secondary Outcome	Result
Health literacy (no. and %, <i>n</i> = 43)	
Adequate (SBSQ ≥ 3)	32 (74)
Inadequate (SBSQ < 3)	11 (26)
Total no. of calls to team (<i>n</i> = 43)	33 (0.77 per patient)
Total no. of interventions performed (<i>n</i> = 43)	25 (0.58 per patient)
Total no. of visits to ED (<i>n</i> = 43)	4 (0.09 per patient)
Treatment adherence rate (no. and %, <i>n</i> = 38)	
0%–25%	12 (32)
26%–50%	1 (3)
51%–75%	0 (0)
76%–100%	25 (66)
Use of treatment diary (no. and %, <i>n</i> = 38)	31 (82)

ED = emergency department, SBSQ = Set of Brief Screening Questions.

scores on the 2 PAM-13 questionnaires was found in the post hoc mITT analysis. However, the difference was not clinically meaningful, given that a 5-point difference was required with the calculated sample size. The mean and median intervals between the PAM surveys (14.8 and 12 days, respectively) were within expectations, as a 7-day interval is the shortest interval permitted, and patients often started their OAD a few days after the pharmacist-led education. In the mITT analysis, 1 participant was excluded because of an 8-week interval between their PAM-13 questionnaires (because of a hospital admission); another went on vacation for 5 weeks before starting their treatment. These long intervals increased the risk of events that could have affected the calculated difference in activation, such as patients not remembering enough of the advice received; therefore, these patients were excluded from the analysis.

In a similar study, Bates and others¹⁰ used the PAM-10, a 10-item questionnaire, before and after oncology pharmacist-led education to investigate activation in patients receiving new chemotherapy. However, patients with a solid malignancy were not included, and the before

and after PAM-10 questionnaires were administered 2 business days apart.¹⁰ A statistically significant difference in the PAM-10 score was observed, specifically, an increase from 68.5 (SD 14.7) to 75.0 (SD 14.3) (*p* = 0.001), and a weak negative correlation with health literacy level also appeared to affect the degree of activation.¹⁰ The shorter interval between the 2 questionnaires in the study by Bates and others¹⁰ potentially had an effect on the results, but the goal of a minimum interval of 7 days in the current study was intended to enable patients to experience taking their medication and applying the knowledge acquired during the education.

According to the authors of the PAM-13, a 1-point difference in the PAM-13 score could be clinically meaningful if the desired sample size is reached (Insignia Health: Patient activation measure (PAM) basics: understanding health activation; administering the PAM survey: internal document consulted on October 19, 2019), which was not the case here. In addition to the 2 participants excluded from the mITT analysis, others who experienced suboptimal conditions for completing the PAM-13 questionnaire may

have negatively influenced the results (e.g., 1 participant was in severe pain during questionnaire administration).

The level of health literacy as determined by the SBSQ showed a weak negative correlation with the change in the PAM-13 score, which suggests that the lower the health literacy level, the greater the post-intervention difference. Most participants' activation tended to increase nonsignificantly following the pharmacist-led education with the GEOQ information sheets, and this effect appeared to be greater among those with lower health literacy level.

Certain hypotheses can be derived from the descriptive data gathered for the secondary outcomes. Some emergency department visits did not require a call to the treatment team beforehand because the patient was able to manage their adverse event well, possibly thanks to the information sheet and education. However, 8 (24%) of the 33 patient calls would not have been necessary had the patients referred to their information sheet (e.g., for management of mild nausea)—the patients could have handled these calls themselves. Some patients seemed to need confirmation from the treatment team of the measures they took, despite having the necessary information available.

This study had several strengths. In evaluating a knowledge transfer method, the study addressed a fundamental issue, namely, the information provided to patients for the purpose of optimizing management of their disease and their treatments. This is especially important in oncology, considering the complexity that management can entail. Also, compared with patients who are receiving parenteral antineoplastics, whose treatment is provided at a health care facility, patients taking OADs receive less close follow-up at home. Therefore, optimal-quality initial education is important, and it is essential to evaluate the methods used to ensure their continuous improvement. Using a prospective cohort study design, we evaluated the actual impact of information provided to patients on their management skills to ensure good external validity. In terms of the results, there were few treatment discontinuations and losses to follow-up. Furthermore, additional analyses were performed to identify any confounding variables, but no effects were found, apart from a weak negative correlation with the level of health literacy.

The study also had some limitations. First, the absence of a control group prevented a comparison with patients not exposed to the intervention. It was assumed that pharmacist-provided education using the new information sheets was superior to no education or to using the previous version of the information sheets. We could therefore not control certain variables that can modify the effect of pharmacist-led education on activation, which might have led to confounding bias. Second, the small number of participants can be explained by the COVID-19 pandemic, which led to the suspension of recruitment for several weeks, although recruitment was later extended for 2 months to

compensate. The decrease in cancer screening and diagnosis during the COVID-19 pandemic probably reduced the number of patients eligible for this research project.²⁴ The recruitment difficulties can also be explained by the relatively strict exclusion criteria for patients who had more frequently scheduled medical follow-up or who might have been better equipped by their follow-up with other oncology professionals during their treatment. In the absence of a control group, these criteria were essential to limit confounding and better isolate the effect of the intervention. Furthermore, the fact that all of the interventions were conducted by telephone resulted in additional difficulty communicating with certain participants because of the absence of nonverbal components. However, being able to read the information sheet before the education sessions aided comprehension for a number of participants, as it gave them the opportunity to prepare for the interview and write down their questions. It would have been interesting to assess whether participants reviewed the materials in advance and how doing so might have affected their activation. Participants may also have obtained additional instruction from other health professionals, which could have increased their activation.

In other respects, the intervention was measured in the short term. It is therefore not possible to evaluate the effect of the intervention over longer periods. In addition, the responses probably reflected social desirability bias because the data were self-reported or came from a treatment diary completed by the participant. For example, 12 participants added a checkmark for no more than 25% of their OAD doses. It is possible that these participants took their medication but forgot to put a checkmark in the diary. Lastly, a few participants seemed to realize the complexity of their treatment only after treatment had started. Consequently, their confidence in managing the treatment in its entirety may have been influenced upward on the first PAM questionnaire but downward on the second, which would have led to a reduction in the measured difference.

CONCLUSION

This study did not show a clinically meaningful change in patient activation following pharmacist-provided education with the updated GEOQ information sheets, possibly because of failure to reach the target sample size and the presence of confounding factors. However, the results showed a statistically nonsignificant trend in favour of pharmacist-led education using the information sheets for activation in participants with lower health literacy levels. The various effect-modifying variables measured had no effect on participants' activation. Further studies are needed to evaluate these data in a larger population and to determine whether the effect of education persists after the first treatment cycle.

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