Original Investigation

Reduction of Inappropriate Benzodiazepine Prescriptions Among Older Adults Through Direct Patient Education
The EMPOWER Cluster Randomized Trial

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IMPORTANCE The American Board of Internal Medicine Foundation Choosing Wisely Campaign recommends against the use of benzodiazepine drugs for adults 65 years and older. The effect of direct patient education to catalyze collaborative care for reducing inappropriate prescriptions remains unknown.

OBJECTIVE To compare the effect of a direct-to-consumer educational intervention against usual care on benzodiazepine therapy discontinuation in community-dwelling older adults.

DESIGN, SETTING, AND PARTICIPANTS Cluster randomized trial (EMPOWER [Eliminating Medications Through Patient Ownership of End Results] study [2010-2012, 6-month follow-up]). Community pharmacies were randomly allocated to the intervention or control arm in nonstratified, blocked groups of 4. Participants (303 long-term users of benzodiazepine medication aged 65-95 years, recruited from 30 community pharmacies) were screened and enrolled prior to randomization: 15 pharmacies randomized to the educational intervention included 148 participants and 15 pharmacies randomized to the "wait list" control included 155 participants. Participants, physicians, pharmacists, and evaluators were blinded to outcome assessment.

INTERVENTIONS The active arm received a deprescribing patient empowerment intervention describing the risks of benzodiazepine use and a stepwise tapering protocol. The control arm received usual care.

MAIN OUTCOMES AND MEASURES Benzodiazepine therapy discontinuation at 6 months after randomization, ascertained by pharmacy medication renewal profiles.

RESULTS A total of 261 participants (86%) completed the 6-month follow-up. Of the recipients in the intervention group, 62% initiated conversation about benzodiazepine therapy cessation with a physician and/or pharmacist. At 6 months, 27% of the intervention group had discontinued benzodiazepine use compared with 5% of the control group (risk difference, 23% [95% CI, 14%-32%]; intracluster correlation, 0.008; number needed to treat, 4). Dose reduction occurred in an additional 11% (95% CI, 6%-16%). In multivariate subanalyses, age greater than 80 years, sex, duration of use, indication for use, dose, previous attempt to taper, and concomitant polypharmacy (10 drugs or more per day) did not have a significant interaction effect with benzodiazepine therapy discontinuation.

CONCLUSIONS AND RELEVANCE Direct-to-consumer education effectively elicits shared decision making around the overuse of medications that increase the risk of harm in older adults.

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The US Patient Protection and Affordable Health Care Act encourages greater use of shared decision making in health care through provision of evidence-based information that apprises patients of the risks and benefits of different treatments.[1] Based on the concepts of patient-centered medicine and patient preferences, consumer education is a core tenet of promoting collaborative self-management for cost containment and health improvement.[2,3] However, the effect of involving patients in the decision to curtail medical treatments and resources is viewed by some as expecting too much.[4]

In 2012, the American Board of Internal Medicine (ABIM) Foundation launched its Choosing Wisely campaign to help physicians and patients select which interventions should be discontinued to reduce the overuse of medical resources that increase the risk of harm.[5] As part of this campaign, the American Geriatrics Society advised physicians and patients to refrain from using benzodiazepines as first-line treatment for insomnia in older adults.[6] The decision to target benzodiazepines derives from the potential for benzodiazepines to elicit cognitive deficits and increase the risk of falls and hip fractures.[7-10] Benzodiazepines comprise 20% to 25% of inappropriate prescriptions in the elderly,[11,12] with a reported prevalence of use ranging from 5% to 32% in community-dwelling older adults.[13-15] Although physicians recognize the risks associated with benzodiazepines, almost 50% continue to renew prescriptions, citing patient dependence and benefit as justification for their actions.[16-19]

The effect of direct-to-consumer patient education and empowerment to reduce benzodiazepine prescriptions has not yet been fully examined.[20] Direct-to-consumer advertising of prescription drugs by the pharmaceutical industry has clearly been shown to influence patient demand for medicines.[21] However, there is concern that inconsistent enforcement of the US Food and Drug Administration (FDA) requirement to provide consumers with a balanced presentation of risks and benefits in the drug information package, and the lack of subsequent revision to include data on drug harms from postmarketing pharmacoepidemiological research, has led to inappropriate overuse of some prescription drugs.[21,22] Educational interventions aimed at achieving patient empowerment around medication overtreatment has potential to catalyze shared decision making to deprescribe. Patient empowerment is a process that aims to "help people gain control, which includes people taking the initiative, solving problems, and making decisions, and can be applied to different settings in health and social care and self-management."[23]

The objective of the EMPOWER (Eliminating Medications Through Patient Ownership of End Results) cluster randomized trial was to test the effectiveness of direct patient education about drug harms on benzodiazepine therapy discontinuation among community-dwelling adults 65 years and older receiving long-term benzodiazepine therapy. Secondary objectives were to assess rates of dose reduction in addition to complete cessation and to conduct a process evaluation of subsequent events after receipt of the intervention. Cluster randomization served to prevent contamination between participants in the same pharmacy.

Methods

Design, Setting, and Participants

A 2-arm, parallel-group, pragmatic cluster randomized clinical trial was conducted in Quebec, Canada. The trial protocol has been published.[24] The Research Ethics Board of the Centre de Recherche de l'Institut Universitaire de Gériatrie de Montreal approved the study protocol on July 26, 2009. All patients signed an informed consent form prior to the screening interview. Recruitment occurred between July 2010 and November 2012.

The study included 30 community pharmacies (cluster units) in the greater Montreal area. Eligibility criteria for clusters included local community pharmacies with 20% or more of their clientele consisting of older adults and a minimum of 50 eligible participants. A full list of pharmacies within 200 km of the research center was obtained through collaboration with the pharmacy chain's headquarters. This list was randomized, and pharmacies were systematically contacted by the research team to assess interest in participating.

The sampling frame for individual participants was a list of all adults 65 years and older receiving long-term benzodiazepine therapy from each participating pharmacy, provided to pharmacists by the central database system of the pharmacy chain. Eligibility criteria for individual participants included a minimum of 5 active prescriptions, one being an active benzodiazepine prescription (short, medium, or long acting) dispensed for at least 3 consecutive months prior to screening. Participants with polypharmacy (>5 medications) were recruited to extend the generalizability of the findings from this trial to the typical elderly benzodiazepine user with multimorbidity and associated polypharmacy. Exclusion criteria included a diagnosis of severe mental illness or dementia, an active prescription for any antipsychotic medication and/or a cholinesterase inhibitor or memantine in the preceding 3 months, and residence in a long-term care facility. All clients meeting study criteria received a recruitment mailing followed by telephone call invitations from their pharmacists. Patients who expressed interest in participating in the study were directed to the study team and screened for eligibility via in-home interviews with a research assistant. Clients who were unreachable after 3 attempts were not recontacted. During the in-home interview, patients with evidence of cognitive impairment, defined by a screening score less than 21 on the Montreal Cognitive Assessment, were excluded.[25] Baseline demographic data and information on the indication for and duration of benzodiazepine use, as well as any previous attempts at discontinuation, were collected. Health status was determined (excellent, very good, good, fair, or poor). The presence of an anxiety disorder was ascertained by a score of 9 or higher on the Geriatric Anxiety Inventory.[26]

Intervention

The patient empowerment intervention consisted of an 8-page booklet based on social constructivist learning and self-efficacy theory, and its development and testing have been previously detailed.[24] The intervention comprises a self-

assessment component about the risks of benzodiazepine use, presentation of the evidence for benzodiazepine-induced harms, knowledge statements designed to create cognitive dissonance about the safety of benzodiazepine use, education about drug interactions, peer champion stories intended to augment self-efficacy, suggestions for equally or more effective therapeutic substitutes for insomnia and/or anxiety, and stepwise tapering recommendations.[24] Tapering recommendations consist of a visual 21-week tapering protocol showing a picture-based diminishing schedule of full-pill, half-pill, and quarter-pill consumption. The visual schematic for the deprescribing protocol was proposed by consumers during the development and usability testing of the intervention to enable application to any benzodiazepine, regardless of dose. The intervention asks participants to discuss the deprescribing recommendations with their physician and/or pharmacist. The information is included in a letter-size paper handbook, with the language set at a sixth-grade reading level and written in 14-point font to facilitate accessibility to the material. The intervention was personalized according to the participant's pharmacy profile to include the name of the specific benzodiazepine the participants was taking. The intervention was mailed to the intervention group within 1 week of group allocation while the usual care (wait list) group received the educational tool 6 months following group allocation. A full version of the intervention is available in the eAppendix in the Supplement.

Outcomes

The primary outcome was complete cessation of benzodiazepine use in the 6 months following randomization. Cessation was defined as an absence of any benzodiazepine prescription renewal at the time of the 6-month follow-up that was sustained for 3 consecutive months or more, in the absence of substitution to another benzodiazepine. This was ascertained via pharmacy renewal profiles, which contained information on drugs purchased, dates of purchase, dose, and quantity served. Dose reduction was defined as a 25% or greater dose reduction compared with baseline sustained for 3 consecutive months or more. A baseline average daily dose per month was established using pharmaceutical profiles for the 6 months before randomization. Dose reduction was then calculated by comparing patients' average daily dose per month at 6 months after randomization compared with baseline. All doses were converted to lorazepam equivalents. To ensure an accurate representation of the pharmaceutical profiles, a list of pharmacies visited by participants was collected at baseline. At follow-up, patients were queried whether they switched pharmacies. A complete follow-up with the pharmacy in use at the 6-month follow-up was completed for all study participants. One investigator (P.M.) and 1 research nurse, blinded to group allocation, independently assessed outcomes according to a prespecified protocol. Agreement was obtained in 94% of cases, with differences adjudicated by a third investigator (C.T.).

Process Evaluation

After the primary end point had been ascertained using the pharmacy renewal profiles and in order to understand the events that occurred after receipt of the intervention, a 6-month semistructured interview was conducted by telephone with participants in the intervention group. Interviews lasted approximately 30 minutes. Participants were queried whether they had discussed the possibility of tapering their benzodiazepine medication with a physician, pharmacist, or both (yes/no); what was decided during these discussions (open ended); whether tapering was attempted (yes/no); if any difficulties were encountered during the tapering process (open ended); reasons why any attempts failed (open ended); justification of why participants felt they did not want to discontinue their benzodiazepine medication (open ended); and satisfaction about learning about the risks of benzodiazepine use (yes/no).

Randomization and Allocation Concealment

A 1:1 allocation ratio was assigned by an independent statistician using nonstratified blocked randomization for groups of 4 pharmacies using computer-generated random digits. The study was described as a "medication safety study for older adults" without mention of benzodiazepines in particular; thus, participants remained blinded to the intervention at the time of enrollment. Group allocation was concealed from both the pharmacists and their clients by telling them that the intervention would be delivered to the clients at some point during the next year.

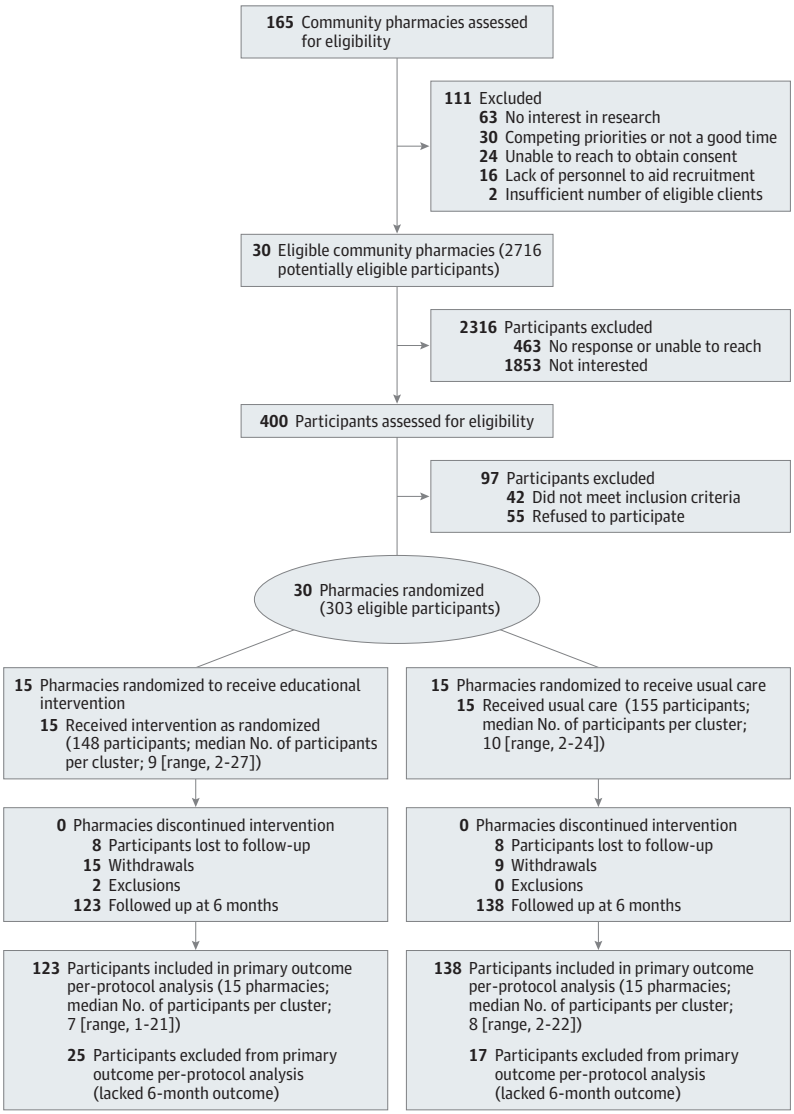
Sample Size

The study was powered at 80% (2-sided test α level of .05) to detect a minimal 20% difference in benzodiazepine therapy discontinuation due to the use of the intervention.[19,27-33] On the basis of the study results, we calculated a coefficient of variation (kappa) of 0.62, an intracluster correlation (ICC) of 0.008, and a median cluster size of 10.1, which resulted in a maximum design effect of 1.03. A minimal sample size per group of 60 individuals was therefore required.[34]

Statistical Methods

Differences in baseline characteristics between groups were compared. To assess the primary outcome, we estimated the unadjusted risk difference (prevalence of the outcome) and 95% confidence intervals via generalized estimating equations (GEEs) using the participant as the unit of analysis, the pharmacy as the cluster, an exchangeable correlation coefficient to account for clustering effects of participants within each pharmacy, and discontinuation as a dichotomous outcome, assessed for each participant at 6 months after randomization. Both intent-to-treat (ITT) and per-protocol analyses were performed. Participants who were lost to follow-up were designated as having neither discontinued nor reduced the dose of benzodiazepines in ITT analyses. Generalized estimating equations with an identity link and an exchangeable correlation structure were used to account for possible correlation between individuals in the same cluster.[35] The number needed to treat was calculated as the inverse of the difference in absolute event rates between the experimental and control groups.[36] In secondary analyses, to control for possible confounding effects between groups, multiple logistic regression

Figure 1. Trial Flow



models were used, with age (<80 years vs ≥80 years), sex, education (high school or less vs college or university), health status (fair and poor vs other), benzodiazepine use for insomnia (yes/no), anxiety disorder detected with the Geriatric Anxiety Inventory (yes/no), benzodiazepine dose (<0.8-mg/d lorazepam equivalent vs ≥0.8 mg/d),[37] previous attempt at tapering (yes/no), duration of benzodiazepine use (<5 years or ≥5 years), and number of medications (<10 per day vs ≥10 per day) included in the model. To determine whether any of the aforementioned-listed characteristics differentially impacted on cessation rates, analyses were performed to estimate risk differences for each of the subgroups using interaction terms in the GEE model under ITT and per-protocol conditions. Proportions of participants reporting having discussed discontinuation with a physician or pharmacist were calculated. Responses to the open-ended questions about failure to initiate discontinuation or abandonment of the tapering protocol were analyzed by content analysis according to emergent themes. All statistical analyses were run using RStudio 0.97.310.0, R-3.0.2, with statistics subpackage for GEE (RStudio Inc), an integrated development environment for R.

Results

Study Participants and Follow-up

A total of 165 community pharmacies were consecutively contacted over a 2-year period. Of these, 30 pharmacies (18%) consented. The most common reasons for nonparticipation in the project included lack of interest in participating in a research project (n = 63 [38%]), competing priorities (n = 30 [27%]), inability to reach the pharmacy owner to obtain consent (n = 24 [15%]), and inadequate personnel to aid recruitment (n = 16 [10%]) (**Figure 1**). The centralized electronic pharmacy records database identified 2716 potentially eligible clients in the participating pharmacies who were 65 years and older and who

Table 1. Participant Characteristics at Baseline

Variable	Intervention (n = 148)	Control (n = 155)
Age, mean (SD) [range], y	75.0 (6.5) [65-91]	74.6 (6.2) [65-95]
Female, %	70.3	68.4
College or university education, %	21.6	25.8
Lives alone, %	46.6	54.8
Self-reported fair or poor health, %	35.8	34.8
Montreal Cognitive Assessment, mean (SD) [range], score	25.4 (2.4) [21-30]	25.4 (2.5) [21-30]
Self-reported indication for benzodiazepine use, %		
Insomnia	60.8	60.0
Anxiety	45.9	49.0
Pain	2.7	3.2
Other	6.8	6.5
Anxiety disorder, %[a]	32.4	30.3
Benzodiazepine dose in mg of lorazepam equivalents per day, mean (SD) [range]	1.2 (0.8) [0-4.8]	1.3 (0.8) [0-4]
Benzodiazepine type, %[b]		
Short acting	29.1	24.5
Intermediate acting	66.2	72.9
Long acting	4.7	2.6
Duration of benzodiazepine use, mean (SD) [range], y	9.6 (8.7) [0.3-48.0]	11.2 (8.3) [0.5-40.0]
Previously attempted cessation, %	45.2	49.4
No. of medications per day	9.9 (3.9 6) [4-24]	9.9 (3.4) [4-21]

[a] Score of 9 or greater on the Geriatric Anxiety Index.

[b] Short-acting benzodiazepines: oxazepam and alprazolam; intermediate-acting benzodiazepines: lorazepam, bromazepam, clonazepam, and temazepam; and long-acting benzodiazepines: flurazepam and diazepam.

regularly renewed benzodiazepine prescriptions. Approximately 1 in 6 spoke with their pharmacist and agreed to meet with the research team. Four hundred clients were screened for eligibility, and 75% agreed to participate and were eligible to enroll in the trial. In total, 30 clusters and 303 eligible participants were randomized. Figure 1 depicts the study flow of the clusters and the participants for the trial. The median (range) number of participants per cluster was 10 (2-27).

Of the 303 participants randomized, 261 were available for 6-month follow-up (86%). There was no difference in the baseline characteristics of participants who withdrew or were lost to follow-up between or within trial arms. The mean (SD) age of the participants at baseline was 75 (6.3) years, 69% were women, and one-quarter (24%) had earned a college degree. The most common self-reported indications for taking a benzodiazepine were insomnia (60%) and/or anxiety (48%). Participants used benzodiazepines for mean duration of 10 years and had an average daily dose consumption of 1.3-mg equivalents of lorazepam (**Table 1**).

Outcomes

In ITT analyses, complete cessation was achieved in 40 of 148 participants (27%) compared with 7 of 155 controls (5%) (prevalence difference, 23%; 95% CI, 14%-32%) (**Table 2**). There was a crude 8-fold higher likelihood of achieving discontinuation among those who received the intervention compared with controls (odds ratio, 8.1; 95% CI, 3.5-18.5) and an adjusted odds ratio of 8.3 (95% CI, 3.3-20.9) when all baseline characteristics were accounted for. **Figure 2** illustrates the risk differences for discontinuation of benzodiazepines in subgroups of participants by treatment allocation using ITT analysis. No significant interactions were observed between the intervention assignment and participant characteristics, suggesting that the effect of the intervention was robust across variable predisposing characteristics. An additional 11% (95% CI, 6%-16%) of individuals who received the intervention achieved dose reductions. The number needed to treat for any discontinuation or dose reduction was 3.7 in ITT analyses (Table 2). Per-protocol analysis yielded similar results.

Patient Empowerment and Process Evaluation

Six-month telephone follow-up interviews with all participants in the intervention group who completed the trial (n = 123) revealed that 62% initiated discussions about benzodiazepine therapy discontinuation with their physician and/or pharmacist, and 58% attempted discontinuation (**Table 3**). The majority (72%) of participants desiring discontinuation opted to follow the tapering protocol provided. Others required a customized tapering protocol because more than 1 benzodiazepine was being used or because the type of benzodiazepine pills or capsules could not easily be halved or quartered and substitution was required to appropriately taper. Of the 71 participants who attempted cessation, 38 (54%) were successful; 16 (22%) achieved dose reduction, of which one-third was continuing the tapering process; and 17 (24%) failed. Withdrawal symptoms such as rebound insomnia or anxiety occurred in 42% of participants attempting to taper. No major adverse effects requiring hospitalization were reported. Of the 40 participants, 5 (13%) who discontinued benzodiazepine therapy received substitutions with trazodone (3 cases), paroxetine (1 case), or amitriptyline (1 case). In 7 individuals who attempted to taper, complete discontinuation was discouraged by their health professional. Among the 52 recipients who elected not to taper, discouragement by their physician or pharmacist was the most common reason provided (n = 17 [33%]), followed by fear of withdrawal symptoms (n = 13 [25%]), lack of concern about taking benzodiazepines (n = 12 [23%]), and difficult life circumstances (n = 6 [12%]). Several participants reported that their physician discouraged use of the tapering protocol because of a perceived absence of adverse effects from their benzodiazepine use. Of the 123 participants, 120 (98%) acknowledged satisfaction with receiving medication risk information.

Discussion

Delivery of an empowerment intervention to engage older adults in discussing the harms of benzodiazepine use with their physician and/or pharmacist yielded a benzodiazepine discontinuation rate of 27% compared with 5% in the control group

Table 2. Prevalence, Risk Difference, and Odds Ratios for Discontinuation and Discontinuation Plus Benzodiazepine Dose Reduction at the 6-Month Follow-up

Variable	Participants, No.	Outcome, No. (%)	Risk Difference (95% CI)[a]	No. Needed to Treat	Crude OR (95% CI)	Adjusted OR (95% CI)[b]
Discontinuation of benzodiazepine use						
Intention to treat analysis						
Intervention	148	40 (27.0)	0.23 (0.14-0.32)	4.35	8.05 (3.51-18.47)	8.33 (3.32-20.93)
Usual care	155	7 (4.5)				
Intracluster correlation			0.008		0.008	0.010
Per protocol analysis						
Intervention	123	38 (30.9)	0.26 (0.16-0.36)	3.85	8.53 (3.69-19.76)	8.10 (3.34-19.66)
Usual care	138	7 (5.1)				
Intracluster correlation			0.007		0.007	0.005
Discontinuation plus benzodiazepine dose reduction						
Intention to treat analysis						
Intervention	148	56 (37.8)	0.27 (0.18-0.37)	3.70	5.05 (2.66-9.59)	5.49 (2.78-10.84)
Usual care	155	17 (11.0)				
Intracluster correlation			0.006		0.006	0.010
Per protocol analysis						
Intervention	123	54 (43.9)	0.34 (0.22-0.45)	2.94	6.33 (3.10-12.92)	6.73 (3.12-14.55)
Usual care	138	16 (11.6)				
Intracluster correlation			0.030		0.030	0.020

[a] 95% Confidence intervals were calculated using robust standard errors.

[b] Adjusted for age, sex, education, health status, indication of benzodiazepine use for insomnia, anxiety disorder, benzodiazepine dose, previous attempt at tapering, duration of benzodiazepine use, and number of medications.

6 months after the intervention. An additional 11% of recipients achieved dose reductions. The effect of the intervention was robust across age, indication, dose, and duration of benzodiazepine use.

Strengths and Weaknesses of the Study

Strengths of this study include systematic recruitment of participants via community pharmacies; blinding of the study hypothesis from participants, physicians, pharmacists, and evaluators; and objective assessment of drug discontinuation rates from pharmacy prescription renewal profiles. Compared with previous studies, this trial exclusively targeted seniors older than 65 years, examined patient empowerment as a means of initiating shared decision making around potentially harmful medication, and addressed the issue from the patient's rather than the physician's perspective.[19,27-29,38,39] One limitation is the 6-month time frame for outcome reporting. Longer follow-up times could reveal relapse rates or higher discontinuation rates as several participants who achieved dose reductions were still following the tapering protocol at study end point. Recruitment rates for pharmacies (18%) and individual participants (11%) were low and excluded potential participants with cognitive impairment. Despite this, selection bias is unlikely because neither pharmacists nor participants were aware of the primary outcome of the study other than it being a medication safety study for older adults. Pharmacies were recruited systematically across socioeconomic and geographic living areas around Montreal, and although data on participant income could not be collected, no differences between groups were observed on other variables that correlate with poverty in the senior population such as female sex, educational status, and polypharmacy.[40,41] Subgroup analyses may have been underpowered to detect differences. Cursory content analysis of the events that followed receipt of the intervention may have been limited by patient recall and the nonintimate nature of the 6-month follow-up. The process of shared decision making around benzodiazepine therapy discontinuation and physicians' motivations for counseling against benzodiazepine therapy discontinuation could not be evaluated because there was no direct contact with physicians during the trial.

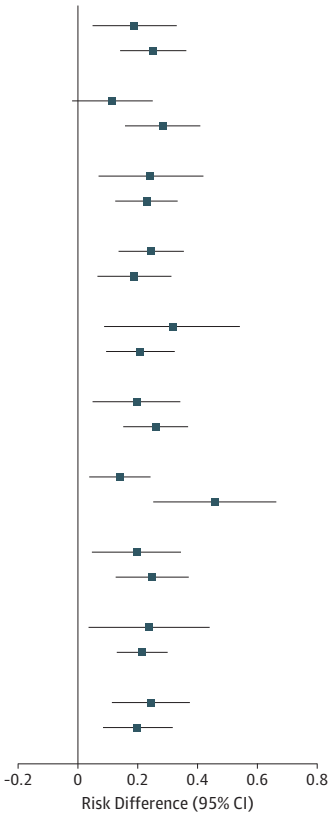
Relevance of the Findings and Implications for Clinicians

Our findings suggest that direct-to-consumer education successfully leads to discussions with physicians and/or pharmacists to stop unnecessary or harmful medication. Discontinuation or dose reduction of benzodiazepines occurred in more than one-third of the participants who received the empowerment intervention. The Beers criteria for inappropriate use of medications provide guidance for 53 drugs to be avoided in the elderly.[10] This trial only addressed deprescription of benzodiazepine medication, which arguably may be one of the most difficult classes of medication to withdraw because of psychological and physical dependence.[15,42]

Previous studies have examined the effect of other types of brief interventions by physicians on patient discontinuation of benzodiazepine use, as well as pharmacist-initiated communication with general practitioners to deprescribe potentially inappropriate medication.[31,43,44] Sending a letter of advice from family physicians to patients achieved a discon-

Figure 2. Risk Differences for Discontinuation of Benzodiazepines in Subgroups

Subgroup	Risk Difference, (95% CI)	ICC
Sex		
Men	0.19 (0.06 to 0.32)	0
Women	0.25 (0.15 to 0.35)	0.022
Age, y		
≥80	0.11 (-0.01 to 0.24)	0
<80	0.29 (0.17 to 0.40)	0.038
Education level		
University or college	0.25 (0.08 to 0.41)	0.126
<High school	0.23 (0.14 to 0.32)	0.012
General health status		
Good to excellent	0.24 (0.15 to 0.345)	0
Poor to fair	0.19 (0.08 to 0.30)	0
Anxiety disorder		
Yes	0.32 (0.10 to 0.53)	0.150
No	0.21 (0.10 to 0.31)	0.010
Indication for benzodiazepine use		
Insomnia	0.20 (0.06 to 0.33)	0.030
Other reasons	0.26 (0.16 to 0.36)	0
Dose		
High (>0.8-mg/d equivalent dose)	0.14 (0.05 to 0.23)	0.010
Low (≤0.8-mg/d equivalent dose)	0.46 (0.26 to 0.66)	0.110
Previously attempted to cease benzodiazepine use		
Yes	0.20 (0.06 to 0.33)	0.020
No	0.25 (0.14 to 0.36)	0
Duration of benzodiazepine use, y		
<5	0.24 (0.05 to 0.43)	0
≥5	0.22 (0.14 to 0.29)	0
No. of medications		
<10	0.24 (0.13 to 0.36)	0
≥10	0.20 (0.10 to 0.31)	0



Forest plot of risk differences (95% CIs) for benzodiazepine discontinuation due to the intervention within subgroups of interest. ICC indicates intracluster correlation.

Table 3. Effect of the Empowerment Intervention on Self-reported Participant Empowerment

Self-reported Participant Empowerment	Participants, No. (%)		
	All (n = 123)	Discontinuation of Benzodiazepine Use (n = 38)	Discontinuation or Benzodiazepine Dose Reduction (n = 54)
Discussion with a health professional after receipt of the intervention			
Physician only	44 (35.8)	14 (36.8)	20 (37.0)
Pharmacist only	5 (4.0)	2 (5.3)	2 (3.7)
Both	27 (21.9)	13 (34.2)	18 (33.3)
Neither	47 (38.2)	9 (23.6)	14 (25.9)
Attempt to discontinue			
Yes, using the tapering protocol in the brochure	51 (41.4)	26 (68.4)	32(59.3)
Yes, using a customized protocol from a physician or pharmacist	18 (14.6)	10 (26.3)	14 (25.9)
Yes, method not stated	2 (1.6)	2 (5.3)	2 (3.7)
No	52 (42.3)	0	6 (11.1)
Patient satisfaction with receipt of the intervention			
Appreciated receiving medication risk information	120 (97.5)	38 (100)	54 (100)

tinuation rate of 24% at 6 months, but the effect size was reported as much lower because 12% of participants in the control group also achieved discontinuation.[28] Our use of a cluster randomized design with prerandomization enrolment of participants may help explain the larger effect seen in the present study. Furthermore, the added value of directly educating the patient, in the absence of initial physician involvement, likely promotes patient buy-in for discontinuation at an early stage and allows the patient to act as a catalyst for initiating discussions about medication management, which is a more effective approach than the traditional paternalistic approach to patient care.[23] The booklet used for this trial, which

directly delivers information on drug harms to patients, could be distributed in the nonresearch environment in pharmacies or on the Internet in conjunction with other community education initiatives such as the American Geriatrics Society website (http://www.healthinaging.org), thus achieving widespread reach.

Three issues arise for future consideration. First, participants reported that their physician discouraged discontinuation of benzodiazepines in several cases. Many physicians continued to perceive the benefits of benzodiazepines as outweighing their risks.[19] Second, benzodiazepines were sometimes substituted with equally harmful sedative medication. A similar phenomenon was found to occur in US nursing home residents when coverage for benzodiazepine medications was interrupted during implementation of the Medicare Part D reimbursement policy in 2006.[45] Continuing medical education to physicians about the harms of all sedative hypnotic medication may eventually overcome this obstacle. Third, pharmacists were solicited less often than physicians to discuss benzodiazepine therapy discontinuation. With the expanding scope of pharmacists' practice and an increasing emphasis on interprofessional models of care, community pharmacists may be underutilized players to participate in efforts to reduce costly and unnecessary medical treatments.[46]

Conclusions

Supplying older adults with evidence-based information that allows them to question medication overtreatment appears safe and effective and is consistent with the priorities expressed by the ABIM Choosing Wisely campaign. Without a direct-to-patient educational component, promotional efforts for deprescription to physicians may fail or have a smaller impact. In an era of multimorbidity, polypharmacy, and costly therapeutic competition, direct-to-consumer education is emerging as a promising strategy to stem potential overtreatment and reduce the risk of drug harms. The value of the patient as a catalyst for driving decisions to optimize health care utilization should not be underestimated.

ARTICLE INFORMATION

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Additional Information: Patient-level data and the full dataset are available on request from the authors.

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Supplementary Online Content

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eAppendix. You May Be at Risk: You Are Currently Taking Ativan® (Lorazepam). (Reprinted with permission.)

This supplementary material has been provided by the authors to give readers additional information about their work

1
2

You May Be at Risk.

You are currently taking

Ativan® (Lorazepam)

TEST YOUR KNOWLEDGE

4

1. *Ativan®* is a mild tranquilizer that is safe when taken for long periods of time.

True ☐ False ☐

2. The dose of *Ativan®* that I am taking causes no side effects.

True ☐ False ☐

3. Without *Ativan®* I will be unable to sleep or will experience unwanted anxiety.

True ☐ False ☐

4. *Ativan®* is the best available option to treat my symptoms.

True ☐ False ☐

(Answers are found on the next page.)

-

2

ANSWERS

6

1. **FALSE.** It is not recommended to take *Ativan* for longer than 2 to 4 weeks. People who take it for longer periods of time are putting themselves at a :
   - ➢ 5 times more at risk of memory and concentration problems
   - ➢4 times increased risk of daytime fatigue
   - ➢2 times increased risk of falls and fractures (hip, wrist)
   - ➢ 2 times increased risk of having a motor vehicle accident while driving
   - ➢Problems with urine loss
2. **FALSE.** Even if you think that you have no side effects and even if you take only a small dose, your brain performance is worse and your reflexes are slower.
3. **TRUE.** Your body has probably developed a physical addiction to *Ativan®*. If you stop it abruptly, you would have trouble sleeping and feel greater anxiety. Millions of people have succeeded in slowly cutting this drug out of their lives and found alternatives that help their problem.
4. **FALSE.** Although it is effective over the short term, studies show that *Ativan®* is not the best long-term treatment for your anxiety or insomnia. It only covers up the symptoms without actually solving the problem. Please keep on reading to learn more about developing healthier sleep patterns and diminishing stress.

SO ASK YOURSELF...yes or no?

...HAVE YOU BEEN TAKING *ATIVAN®* FOR MORE THAN 4 WEEKS?

...ARE YOU STILL TIRED AND OFTEN GROGGY DURING THE DAY?

...DO YOU EVER FEEL HUNGOVER IN THE MORNING, EVEN THOUGH YOU HAVE NOT BEEN DRINKING?

...DO YOU EVER HAVE PROBLEMS WITH YOUR MEMORY OR YOUR BALANCE?

AS YOU AGE...

Age related changes take place in your body and change the way you process medications. Your chances of taking more than one pharmaceutical increase, as well as the possibility of a history of illness. Drugs stay in your body longer and lowered liver function and less blood flow to your kidneys may increase side effects.

Unfortunately this is important information that is often not passed on to patients who are taking this drug. Please consult your physician or pharmacist to discuss this further. New drugs are now on the market and could relieve your anxiety or improve your sleep with less side effects on your quality of life .

DID YOU KNOW?

Ativan® is in a family of drugs called **benzodiazepines** that is highly addictive and can cause many side effects. Except in special circumstances, it should not be taken for more than 4 weeks.

These drugs remain longer and longer in your body as you age. This means that they can stay for up to several days and could be making you tired, weak, impair your balance, and reduce your other senses.

Ativan® can also be associated with hip fractures, memory problems, and involuntary urine loss. Its sedative properties can cause you to be drowsy during the day which can result in car accidents and sleep walking. Even if you are not experiencing these symptoms, be sure to speak to your doctor or pharmacist so that you do not develop them in the future. New drugs are now on the market and could relieve your anxiety or improve your sleep with less side effects on your quality of life.

Please Consult your Doctor or Pharmacist Before Stopping Any Medication.

ALTERNATIVES

If you are taking *Ativan*® to help you sleep..

There are lifestyle changes that can help, in certain situations, instead of taking *Ativan*®.

✓ **Do not read in bed. Do so** in a chair or on your couch.

✓ **Try to get up in the morning and go to bed at night at the same time every day.**

✓**Before going to bed, practice deep breathing or relaxation exercises.**

✓ **Get exercise during the day, but not during the last three hours before you go to bed.**

✓ **Avoid consuming nicotine, caffeine and alcohol.**

If you do wake up for more than 30 minutes, try getting out of bed and doing a relaxing activity, like reading, listening to soft music, etc. Return to bed when you feel tired again.

If you are taking *Ativan*® to help your anxiety...

There are other solutions to deal with your stress and anxiety.

✓Talking to a therapist is a good way to help you work out stressful situations and talk about what makes you anxious.

✓Support groups help to relieve your stress and make you feel you are not alone in your situation.

✓Try new relaxation techniques like stretching, yoga or tai chi that can help relieve you of everyday stress and help you work through your anxiety.

✓Talk to your doctor about other anti-anxiety medications that have less serious side effects.

Mrs. Robinson's story

"I am 65 years old and took *Ativan®* for 10 years. A few months ago, I fell in the middle of the night on my way to the bathroom and had to go to the hospital. I was lucky and, except for some bruises, I did not hurt myself. I read that *Ativan®* puts me at risk for falls. I did not know if I could live without *Ativan®* as I always have trouble falling asleep and sometimes wake up in the middle of the night.

I spoke to my doctor who told me that my body needs less sleep at my age – 6 hours of sleep per night is enough. That's when I decided to try weaning off *Ativan®*. I spoke to my pharmacist who suggested I follow the step-by-step weaning program (on the next page).

I also applied some new sleeping habits I had discussed with my doctor. First I stopped exercising before bed; then I stopped reading in bed, and finally, I got out of bed every morning at the same time whether or not I had a good night's sleep.

I managed to get off *Ativan®*. I now realize that for the past 10 years I had not been living fully. Stopping *Ativan®* has lifted a veil, like I had been semi-sleeping my life. I have more energy and I don't have so many ups and downs anymore. I am more alert: I don't always sleep well at night, but I don't feel as groggy in the morning. It was my decision! I am so proud of what I have accomplished. If I can do it, so can you! "

STEP-BY-STEP WEANING PROGRAM

We recommend that you follow this program under the supervision of your doctor or pharmacist.

Weeks	Weaning Schedule							✓
	Mon	Tues	Wed	Thurs	Fri	Sat	Sun	
1 and 2	●	●	●	●	●	◖	●	
3 and 4	●	◖	●	◖	●	◖	●	
5 and 6	◖	◖	◖	◖	◖	◖	◖	
7 and 8	◖	◖	◖	◖	◖	◢	◖	
9 and 10	◖	◢	◖	◢	◖	◢	◖	
11 and 12	◢	◢	◢	◢	◢	◢	◢	
13 and 14	◢	◢	◢	◢	◢	○	◢	
15 and 16	◢	○	◢	○	◢	○	◢	
17 and 18	◢	○	○	◢	○	○	◢	
19	○	○	○	◢	○	○	○	
20	○	○	○	○	○	◢	○	
21	○	○	○	○	○	○	◢	
22	○	○	○	○	○	○	○	

Legend

●Full dose ◖Half dose ◢Quarter of a dose ○No dose