

A randomized controlled trial of a community-based consultation service to prevent falls

David B. Hogan,^{*†} Frank A. MacDonald,^{*} Jennifer Betts,^{*} Sheila Bricker,^{*} Erika M. Ebly,[†] Barb Delarue,^{*} Tak S. Fung,[§] Cathy Harbidge,^{*} Maggie Hunter,^{*} Colleen J. Maxwell,[‡] Barb Metcalf^{*}

Abstract

Background: Multifaceted programs that combine assessment with interventions have been shown to reduce subsequent falls in some clinical trials. We tested this approach to see whether it would be effective if offered as a consultation service using existing health care resources.

Methods: The subjects of this randomized controlled trial had to be aged 65 years or more and had to have fallen within the previous 3 months. They were randomly assigned to receive either usual care or the intervention, which consisted of in-home assessment in conjunction with the development of an individualized treatment plan, including an exercise program for those deemed likely to benefit. The primary outcomes were the proportion of participants who fell and the rate of falling during the following year. Visits to the emergency department and admissions to hospital were secondary outcomes.

Results: One hundred and sixty-three subjects were randomly assigned to either the control or the intervention group, and 152 provided data about their falls. There were no significant differences between the control and intervention groups in the cumulative number of falls (311 v. 241, $p = 0.34$), having one or more falls (79.2% v. 72.0%, $p = 0.30$) or in the mean number of falls (4.0 v. 3.2, $p = 0.43$). Analysis of secondary outcomes (health care use) also showed no significant differences between the intervention group and the control group. In the Cox regression analysis, there was no significant difference between the groups in the proportion of subjects having one or more falls ($p = 0.55$), but there was a significantly ($p < 0.001$) longer time between falls in the intervention group. In a post hoc subgroup analysis, subjects with more than 2 falls in the 3 months preceding study entry who had been assigned to the intervention group were less likely to fall ($p = 0.046$) and had a significantly longer time between falls ($p < 0.001$), when compared with the group who received usual care.

Interpretation: The intervention did not decrease significantly the cumulative number of falls, the likelihood of participants having at least one fall over the next year or the mean number of falls. It did increase significantly the time between falls in a survival analysis when age, sex and history of falling were used as covariates.

An estimated 25%–35% of elderly people fall each year.¹ Falls are a leading cause of accidental death, morbidity and admissions to hospital among those aged 65 years and over.^{1,2} Elderly people who have had an injurious fall are significantly more likely to use health care services in the following year.³

The Canadian Task Force on the Periodic Health Examination (CTFPHE) in 1993 stated that there was good evidence to refer elderly people for a multidisciplinary

Research

Recherche

From ^{*}Specialized Geriatric Services, Calgary Regional Health Authority, Calgary; the Departments of [†]Medicine and [‡]Community Health Sciences, University of Calgary, Calgary; and the [§]University Computing Services, University of Calgary, Calgary, Alta.

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nary assessment after they had fallen.⁴ This recommendation was arguably premature, because it was based on a case series and a randomized controlled trial (RCT) of elderly subjects living in a residential facility.^{5,6} This RCT did not show significantly fewer falls with treatment but did report significantly fewer admissions to hospital at the end of the 2-year follow-up period in the intervention group.⁶ The CTFPHE recommendation has been supported by a number of subsequent studies. Recently published guidelines for the prevention of falls recommended multifaceted programs that combined assessment with interventions.⁷

The primary objective of this RCT was to determine whether a standardized, multidimensional, in-home assessment of elderly people who had fallen, coupled with a subject-specific care plan, would reduce the likelihood of further falls compared with usual care. Health care use was examined as a secondary outcome measure.

Methods

A randomized, controlled experimental design was used. We estimated that the 1-year occurrence of falls would be 75%⁶ and that our intervention would reduce this by 30% to 52.5%.⁸⁻¹³ We calculated that a sample size of 156, which included an anticipated 10% attrition rate, would be required for satisfactory statistical power ($\beta = 0.2$) to show a significant reduction ($\alpha = 0.05$) in the proportion of subjects who fell at least once during the study period. Subjects were recruited between June 1997 and June 1999 inclusive.

The study population consisted of community-dwelling (e.g., in a private dwelling, apartment, residential facility), ambulatory (with or without an aid) and competent (to give consent) residents of Calgary, Alta., who were aged 65 years and over and had fallen within 3 months of entry into the study. For inclusion of a subject in the study, the qualifying fall could not have occurred during vigorous or high-risk activities (e.g., cycling, climbing ladders), while in an active treatment hospital, or because of syncope or an acute stroke. A fall was defined as unintentionally coming to rest on the ground, floor or other lower level.¹⁴ The qualifying fall could not have resulted in a lower-extremity fracture. Although we did allow self-referral, we anticipated that most of our study population would be identified by health care professionals.

Eligible subjects had a home visit conducted by a research assistant (RA). The RA obtained informed consent, collected data (sociodemographic data, information about the qualifying fall and other falls, information about current medications) and performed a number of standardized assessments.¹⁵⁻¹⁸

Subjects were then stratified and assigned randomly to either the control or the intervention group. Stratification was based on whether the subject had had one fall or more than one fall in the previous year, because a history of falling is a strong predictor of subsequent falls.^{19,20} The allocation sequence was computer generated and concealed (in a locked cabinet) prior to randomization. The RA remained blinded throughout the study as to each subject's group assignment.

Control subjects

After being randomly assigned, subjects in the control group received a home visit from a recreational therapist who per-

formed a leisure assessment. After a brief explanation of the study and what was expected of participants, subjects were asked about their past leisure involvement (e.g., memberships in clubs, hobbies, cultural interests, family pets), personal interests, what motivated them to take part in leisure activities, present activity level and support systems. This visit was similar in duration to the assessment performed on the intervention group. A letter was sent to each control subject's attending physician informing him or her of the study and summarizing the baseline information obtained by the RA.

Intervention subjects

The individuals who were randomly assigned to the intervention group were visited at home by an assessor. These assessors were a specialist in geriatric medicine, 2 nurses, 2 occupational therapists and a physiotherapist who had volunteered their time to develop and implement the fall assessment program. This program was based on the premise that the number of risk factors for falling is related to the likelihood of falling and that modifying identified risk factors would be effective in preventing falls. They trained to be able to perform a comprehensive evaluation looking for both host (i.e., subject) and environmental risk factors. A data collection form incorporating standardized measures was used.²¹⁻²⁴

One assessor visited each subject; assessors were assigned to subjects in a nonrandom manner. Initial visits took 1-2 hours. Upon completion of this initial assessment, all assessors met to discuss the results and agree on an individualized plan designed to decrease the subject's risk of falling. This took about 20 minutes per subject. Recommendations were then communicated in writing to the subject, the attending physician and the source of the referral source (if different). Although advice would be given by the assessors about how to act on the recommendations, the suggestions were not implemented by the assessors other than referring certain subjects to the exercise class.

Appendix 1 shows examples of the targeted risk factors and the corresponding interventions recommended for them. Subjects were referred to an exercise class designed for elderly people who had fallen, if they had performed poorly on the balance and gait measures, were not attending an exercise program and agreed to the referral. This was provided in a geriatric day hospital. Subjects participated on average 3 times in the exercise class. Subjects were also given instruction in an exercise program that they were advised to follow at home.

Outcome measures

The occurrence of falling and the number of falls were measured. Data about falls were obtained in 2 ways. Subjects were asked to record the date of any fall(s) on a calendar, which was to be returned monthly in a stamped, addressed envelope. Approximately half (47.8%) of the monthly calendars were returned. The RA visited all subjects (both control and intervention) at 3 and 6 months after randomization and called them 12 months after randomization. At these times, the RA asked about any falls since the last contact.

Subjects in the intervention group had a home visit performed 6 months after randomization by their assessor to document adherence to recommendations. Adherence was categorized as none, partial or complete. For example, if it was recommended that 3 rugs be removed from the subject's dwelling,

full adherence would require the removal of all 3, partial would be defined as the removal of 1–2 and nonadherence would be the removal of none.

Data concerning hospital and emergency department use were obtained from the Calgary Regional Health Authority for all subjects for the 6 months before and the 12 months after study entry. ICD-9 codes for classifying external causes of injury (i.e. E codes) for selected accidental falls (E880, E884.2, E885, E886.9, E887, E888) were used to identify fall-related use of hospital services.²⁵

Statistical analysis

Descriptive statistics, the Mann-Whitney *U* test, Student's *t*-test and χ^2 analyses were performed as indicated. Statistical significance was set at 0.05 (two-tailed). Subjects had to provide at least one month of data about their falls after study entry to be included in our evaluation of falls ($n = 152$). Falls were examined up to the end of the 12-month follow-up or to the point of withdrawal for those who did not complete the study. Cox regression analyses, using age, sex and number of falls during the previous year as covariates, were carried out to test for significant differences in the likelihood of subjects falling during the study. This analysis of time-to-event data offers several advantages for longitudinal studies. Data concerning subjects lost to the study at various times were incorporated into the analyses, and it was possible to examine the independent effects (and relative importance) of specific subject characteristics on their risk of falling. The Andersen-Gill extension of the Cox model for falls was also carried out,²⁶ permitting examination of multiple events per subject.^{27,28} Subjects were censored at the time of withdrawal from the study for any reason. Total and fall-related visits to the emergency department and hospital admissions were compared for the 2 groups. All subjects who were randomly assigned to a group (control 84, intervention 79) were included in the examination of health care use.

Subgroup analysis

An exploratory subgroup analysis based on history of falling was performed, because this factor has been found to be an important predictor of further falls.^{19,20,27} We considered subjects who had had one fall ($n = 83$) and those who had had 2 or more falls ($n = 69$) in the 3 months prior to study entry. Although the randomization was stratified by falls during the previous year, most ($n = 120$) of the recruited subjects who subsequently provided data about their falls had more than one fall during the previous year, leaving few individuals ($n = 32$) in this one-fall group.

This study received ethical approval from the Conjoint Research Ethics Board of the Faculty of Medicine, University of Calgary.

Results

A total of 163 subjects were randomly assigned either to the control or the intervention group. There were 11 withdrawals (13.1%) from the control group ($n = 84$) and 13 (16.5%) from the intervention group ($n = 79$) (Fig. 1). There was no significant difference in the proportions of subjects who withdrew (or in their reasons). There were no significant differences in age, sex or history of falling be-

tween those who withdrew and those who completed the study. The control and intervention subjects are compared in Table 1.

Intervention subjects were assessed by a nurse (35 subjects), an occupational therapist (14), a physiotherapist (16) or a specialist in geriatric medicine (14). Forty-five (56.9%) were referred to the exercise class. The mean number of risk factors per subject was 5.71 (standard deviation [SD] 2.4). The mean number of recommendations per subject was 4.71 (SD 2.4). Recommendations commonly dealt with environmental hazards (58 subjects), balance and mobility abnormalities (56), neurologic and sensory impairments (50), behaviour (38), lower-extremity disability (32), drug and alcohol use (30), and postural hypotension (18). Overall adherence with recommendations was 81.1% (full and partial adherence).

The bivariate analysis of the main results is presented in Table 2. No statistically significant differences were seen in any of the comparisons shown or in the total use of hospital services (emergency department visits or admissions to hospital). The median number of falls was 2.0 for the control group and 1.6 for the intervention group. There were 5 fractures (3 femoral) in the control group and 3 (2 femoral) among the intervention subjects.

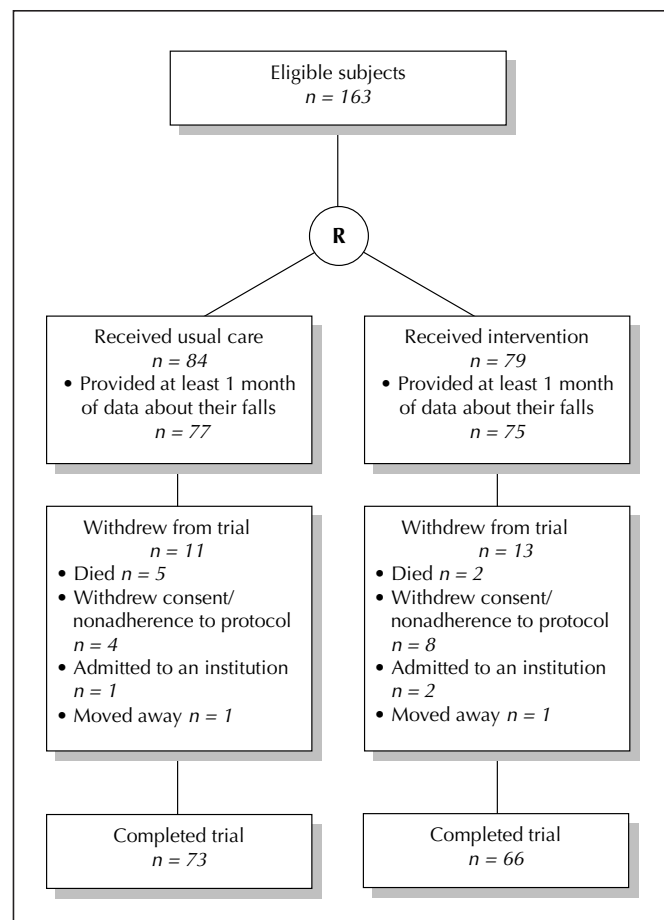


Fig. 1: Flow of subjects through the study. R = randomization.

Fig. 2 shows the survival curves for the occurrence of a fall. There was no significant difference ($p = 0.55$) in the proportions of the 2 groups who had had one fall or more. The Andersen-Gill extension of the Cox model showed that those who received the intervention had a significantly longer time between falls ($p < 0.001$). When all the covariates (age, sex, number of previous falls) were considered simultaneously, the relative risk of falling per unit of time (day) was 0.74 (95% confidence interval 0.62–0.88) that of a control subject. Subjects who had an adherence (full or partial, or both) rate to the recommendations of 80% or more had fewer falls than those with an adherence rate of less than 80%, but this difference was not significant (mean number of falls 2.3, SD 3.2, v. 4.07, SD 7.8; $p = 0.29$).

Cox regression analysis, using age and sex as covariates, showed that a significantly lower likelihood of falling ($p = 0.046$) was associated with the intervention for the subgroup who had had 2 or more falls in the previous 3 months. The Andersen-Gill extension of the Cox model showed that in the group with 2 or more falls, those who received the intervention had a significantly longer time between falls ($p < 0.001$). In the one-fall subgroup, the Cox regression analysis

showed no significant effect ($p = 0.36$) of the intervention on falling during the following year. The 2 subgroups did not differ significantly in the mean number of risk factors, mean number of recommendations, the proportion referred to the exercise group or rates of adherence to the recommendations. At baseline, the group with 2 or more falls had a significantly higher mean number of prescribed medications, "Up and Go" times,¹⁵ and Falls Efficacy Scores (Table 1).¹⁸

Interpretation

Nine-fall prevention trials concerning community-dwelling elderly people have been published since 1994.^{8–13,29–31} With 2 exceptions,^{29,31} they have shown a significantly decreased risk of falling with treatment. The most effective or efficient approach remains uncertain. The programs described used a variety of targeting strategies and interventions. The only cost-effectiveness study published found that the program that was examined was cost-effective, particularly for individuals at a high risk of falling.³² The trials carried out to date have systematically screened for subjects from well-defined populations. Although this eases the identification of subjects and proba-

Table 1: Baseline characteristics of study subjects

Characteristic	Groups; no. (and %) of study subjects*		
	Control <i>n</i> = 84	Intervention <i>n</i> = 79	<i>p</i> value
Mean age (and SD), yr	77.9 (6.2)	77.4 (7.3)	0.66
Female	62 (73.8)	55 (69.6)	0.55
Referral source†			
Self	41 (51.3)	36 (47.4)	0.63
Home care or public health nurse	20 (25.0)	26 (34.2)	0.21
Physician	14 (17.5)	9 (11.8)	0.32
Emergency department	5 (6.2)	1 (1.3)	0.11
Type of residence			
Private home	48 (57.1)	50 (63.3)	0.42
Apartment	25 (29.8)	21 (26.6)	0.65
Residential facility or other	11 (13.1)	8 (10.1)	0.55
Current or former drinker of alcohol	50 (59.5)	50 (63.3)	0.62
Mean no. of falls in previous year (and SD)	4.3 (4.8)	4.9 (7.8)	0.54
Qualifying fall outside home‡	40 (47.6)	39 (50.0)	0.76
> 2 falls in previous 3 mo	45 (53.6)	32 (40.5)	0.10
Mean no. of prescribed medications (and SD)	4.1 (2.9)	4.1 (2.8)	0.92
Mean SMAF score (and SD)‡‡	-7.02 (6.2)	-6.79 (6.4)	0.82
Mean MMSE score (and SD)‡‡	27.8 (1.7)	27.6 (2.2)	0.53
Mean time (sec) for "Up and Go" test (and SD)‡‡	21.9 (180.0)	19.4 (12.9)	0.31
Mean Falls Efficacy Score (and SD)‡‡	104.0 (29.1)	107.8 (27.3)	0.40

Note: SD = standard deviation, SMAF = Functional Autonomy Measurement System,¹⁷ MMSE = Mini-Mental State Examination.¹⁶

*Unless stated otherwise.

†Data not available for all subjects. Referral source was missing for 4 control and 3 intervention subjects; 1 value was missing (intervention group) for the location of the qualifying fall; 4 values were missing (3 control, 1 intervention) for SMAF; 10 (4 control, 6 intervention) for MMSE; 1 (control) for the "Up and Go"; and, 4 (3 control, 1 intervention) for the Falls Efficacy Score.

‡The SMAF disability scale is scored from 0 to -87, with lower scores indicating greater disability; a score of -5 indicates that the subject has a significant loss of independence. The MMSE is a brief cognitive assessment measure scored from 0 to 30, with higher scores signifying better cognitive performance. In the "Up and Go" test,¹⁵ healthy elderly volunteers can perform the task (stand, walk 3 m, turn, return and sit down) within 10 sec. The Modified Falls Efficacy Scale is scored out of 140; lower scores signify less confidence when doing specific activities.¹⁸

bly improves adherence, this recruitment strategy raises concerns about generalizability. Our approach was to provide a consultation service. Compared with other studies,^{8,9,11-13,30,31} our intervention was limited in duration and intensity. We believe that it is a model that could be replicated elsewhere.

With the intervention, we did not see a significant impact on any of our fall-related outcomes (Table 2, Fig. 1) other than finding a longer time between falls. The clinical significance of this latter finding is unknown. It has been argued that as an outcome the rate of falls is of greater importance than the proportion of subjects who have fallen.²⁷ Each fall carries with it a small risk of serious morbidity. For intervention studies, the most important outcome may also vary with the health status of the study population: for fitter elderly people the focus would be on how many people fall, whereas for the less robust, the target outcome should be the rate of falls.³³

No significant differences were seen in health care use. This latter finding could be because the power of the study to detect a 50% difference in rates of use was less than 0.25 for any of the comparisons made. The subgroup with more falls in the 3 months preceding study entry may have been particularly helped by the intervention. The degree of reduction in falls in intervention studies appears to correlate with the functional status of the population examined.³³ Greater reductions are seen in more disabled groups. Our group with more than 2 falls may have had more pre-existing problems with ambulation, as indicated by the baseline differences.

It is unclear which components of the complex interventions used for fall prevention are the most effective. Research does show that risk of falling is directly related to the number of risk factors present.^{19,20,33} Measures that de-

crease the magnitude of risk should be effective in preventing falls. It may not be possible to select which specific component(s) are universally effective, because those that are most important will vary depending on the individual.

As falls are likely to recur, we would recommend the evaluation of interventions designed to decrease the likelihood of fall-related injuries. These interventions would include energy-absorbing flooring, hip protectors,³⁴ and the prevention and treatment of osteoporosis.^{1,8,35} For individuals at lower risk of falling, an exercise program⁹ or a community-based fall prevention program,³⁵ or both, might be more effective than our individualized risk reduction approach.

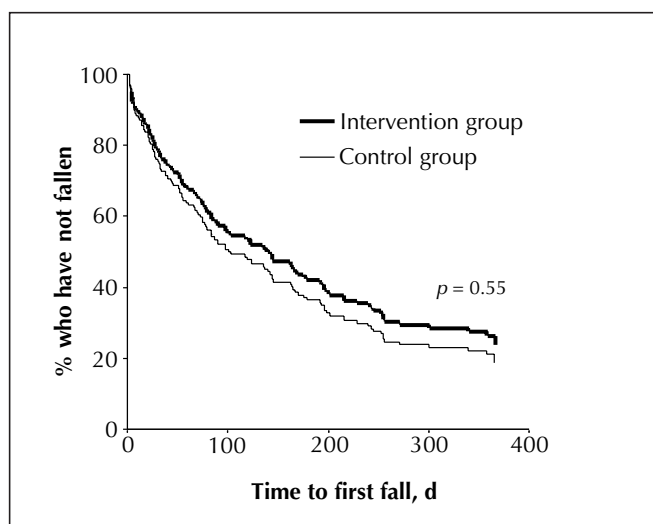


Fig. 2: Estimated survival curves (Cox regression analysis) for the control and intervention groups, adjusted for age, sex and number of falls before study entry. Curves show data for up to 1 year after randomization.

Table 2: Main outcomes of study subjects

Outcome	Control <i>n</i> = 84	Intervention <i>n</i> = 79	<i>p</i> value
Cumulative no. of falls*	311	241	0.34†
No. (and %) of subjects reporting ≥ 1 fall*	61 (79.2)	54 (72.0)	0.30
Mean time to first fall (and SD), d*	147.8 (128.7)	144.9 (128.8)	0.89
Mean no. of falls per subject (and SD)*	4.0 (7.4)	3.2 (5.4)	0.43
No. (and %) of subjects reporting ≥ 3 falls*	35 (45.5)	26 (34.7)	0.18
No. (and %) of subjects with fall-related ED visit‡	8 (9.5)	9 (11.4)	0.69
No. (and %) of subjects with fall-related admission to hospital‡	6 (7.1)	5 (6.3)	0.84

Note: ED = emergency department.

*Fall comparisons are based on the 152 subjects (77 control, 75 intervention) who provided more than 1 month of data about falls.

†Mann-Whitney test.

‡Use of emergency department and hospital services is based on all subjects in each group.

Competing interests: None declared.

Contributors: Dr. Hogan and Mr. MacDonald were co-principal investigators. They led the effort to design the study and were involved as assessors of subjects in the execution of the study. Dr. Hogan designed the plan for analysis and took the lead in writing up the results. Mr. MacDonald provided input into the analysis and the writing-up of the results. Ms. Betts was involved in the design and execution of the study. She was one of the assessors and contributed to revisions of the manuscript. Ms. Bricker made substantial contributions to the design and execution of the study. She was one of the assessors and contributed to revisions of the manuscript. Dr. Elby made substantial contributions to the analyses and the writing up of results. Ms. Delarue made substantial contributions to the design and execution of the study. She had a lead role in the design of the exercise program that was offered to selected participants and contributed to revisions of the manuscript. Dr. Fung made substantial contributions to the analysis and writing up of the results. He advised us on our statistical methods and in particular on the Andersen-Gill extensions of the Cox regression analysis. Ms. Harbridge made substantial contributions to the design and execution of the study. She was one of the assessors in the study and provided input into the design of the exercise program for selected participants. She also contributed to revisions of the manuscript. Ms. Hunter made substantial contributions to the design and execution of the study. She was particularly involved in the design and delivery of the exercise program for selected participants and contributed to revisions of the manuscript. Dr. Maxwell made substantial contributions to the analysis and the interpretation and writing up of the results. Ms. Metcalf made substantial contributions to the design and execution of the study. She was one of the assessors and contributed to revisions of the manuscript.

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Correspondence to: Dr. David B. Hogan, Health Sciences Centre, 3330 Hospital Dr. NW, Calgary AB T2N 4N1; fax 403 283-6151; dhogan@ucalgary.ca

Appendix 1: Examples of risk factors for falls and corresponding interventions

Category	Risk factor	Intervention
Environmental hazard	No rails to aid getting in or out of bathtub or shower	Give advice on how to obtain grab bars; refer to supplier
Balance and mobility abnormality	Gait abnormality	Suggest referral for detailed assessment (e.g., by PT); refer to exercise program; give advice on assistive devices or referral to supplier
Neurologic and sensory impairment	Impaired vision (best corrected vision < 6/12*)	Suggest referral to optometrist or ophthalmologist
Behaviour	Climbing on chairs or using unsafe stepstool to reach items in cupboards	Advise against this behaviour; suggest moving items to more accessible cupboards
Lower-extremity disability	Weakness of leg(s)	Suggest resistive exercises; refer to exercise program
Drug and alcohol use	Use of sedative-hypnotic, antidepressant, neuroleptic or narcotic medications	Suggest review of necessity; advise attempt to taper off and discontinue; suggest nonpharmacologic options for insomnia
Postural hypotension	Symptomatic drop of 20 mm Hg or more in systolic BP when standing	Suggest review of medication; elevate head of bed; correct hypovolemia (e.g., increasing salt intake)

Note: PT = physiotherapist.

*Equivalent to visual acuity of 20/40.

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We're looking for spoofs of medical research, reflective essays on life and tales of medical adventure (or misadventure) for our 2001 Holiday Review. For inspiration, click on Back Issues at www.cma.ca/cmaj and go to the December issues for 1998, 1999 and 2000. Last year, for example, we published a report on the psychiatric problems facing Winnie T. Pooh and colleagues.

This year, we plan to sprinkle a variety of tidbits throughout the issue, and we need your help. Send us:

- a letter to the editor that could find a home nowhere but the Holiday Review
- a postcard from the place where you live, with an anecdote about your practice
- an original cartoon inspired by your medical career
- a photograph of a day in the life of your office, hospital or clinic (you'll need to get signed consent from any people in the photo)
- an obscure quotation on a holiday theme
- the title of the book you would bring with you if you were admitted to hospital, and the reason why you made this selection
- instructions on how someone in your medical specialty should approach the task of preparing, cooking and carving the holiday bird. The prize: the glory of publishing a winning entry in the first (and probably only) *CMAJ* Talk Turkey contest.



To discuss an idea for the Holiday Review issue, contact the Editor, Dr. John Hoey (tel 800 663-7336 x2118; john.hoey@cma.ca) or the News Editor, Pat Sullivan (800 663-7336 x2126; pat.sullivan@cma.ca). Articles should be no more than 1200 words, and illustrations are encouraged. Submissions received by Oct. 1, 2001, are more likely to be published.