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Efficacy of a nurse-led multidimensional preventive programme for older people at risk of functional decline. A randomized controlled trial

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Abstract

Objective: to verify the efficacy of a multidimensional preventive programme on functional decline of older people.
Design: randomized controlled trial.
Setting: community of Sherbrooke City, Quebec, Canada.
Subjects: a representative sample of individuals aged over 75 living at home and identified to be at risk of functional decline by postal questionnaire ($n = 503$).
Intervention: subjects randomized to the study group ($n = 250$) were assessed at home by a nurse on 12 dimensions (including medication, depressive mood, risk of falls, hearing). A report of the assessment was sent to the general practitioner with recommendations for interventions. A monthly telephone contact was carried out by the nurse for surveillance and to verify if the recommendations had been applied.
Methods: the primary outcome—functional decline—was defined as either death, admission to an institution or increase of $\geqslant 5$ points on the disability score of the Functional Autonomy Measurement System (SMAF) scale during the reference year. Secondary outcomes were functional autonomy (on the SMAF), well-being (General Well-being Schedule), perceived social support (Social Provisions Scale) and use of health care services.
Results: of the 494 subjects who completed the study, 48 (19.6%) of 245 in the study group and 49 (19.7%) of 249 in the control group had functional decline (relative risk 1.00; 95% confidence interval 0.82–1.23). There were no differences between the groups in all secondary outcomes.
Conclusions: this study confirms the inefficacy of multidimensional programmes for preventing functional decline in the older population. More effort should be devoted to improving the efficacy of specific interventions for conditions causing functional decline.

Keywords: *assessment and surveillance programme, autonomy, evaluation, functional decline, postal questionnaire, randomized controlled trial, screening*

Introduction

Functional decline is a major health problem, particularly in ageing countries [1]. The prevalence of disabilities increases dramatically with age from 30% in those aged 65–74, to 50% in the 75–84 age group and 80% in those over 85 [2]. The annual incidence of functional decline in people over 75 years living at home is nearly 12% [3]. Geriatric services often intervene only after the process of functional decline has started or even ended. The effectiveness of these tertiary prevention programmes is limited by the irreversibility of the damage already

done. Early detection of older people at risk of losing their autonomy (secondary prevention) and the application of an assessment and surveillance programme might prevent or delay the onset of functional decline.

Over the last 20 years, some assessment and screening programmes for older people have been proposed and evaluated [4–12]. A meta-analysis by Stuck *et al.* [13] of these preventive home assessment programmes concluded that they seem to have a significant effect only on mortality and institutionalization. In general, the impact of these programmes on functional autonomy has been rather limited. There are three reasons for this: identification of the target population, measurement of the outcome, and structure of the intervention programme. Most of the programmes targeted all older people in a given area, thus diluting the potential beneficial effect on those subjects at higher risk. Pathy and his collaborators [14] showed that a selective, two-stage approach (screening individuals at risk and intervention) may be more effective and efficient. The screening method that has received most attention is the postal questionnaire proposed by Barber [15].

In the first stage of our work, we tested the predictive validity of a similar postal questionnaire (the Sherbrooke Postal Questionnaire) with a representative sample of 842 subjects over 75 living at home who were followed-up for 1 year after the questionnaire was mailed [16]. Not returning the questionnaire or a positive response to more than one question (out of six) identified 56% of the subjects as being 'at risk' with a sensitivity of 75% and a specificity of 52%. The group identified as positive presented an annual incidence of functional decline of 38%, while the incidence among the negative group was only 16% for a relative risk of 2.4 and an attributable risk of 22%. If this risk could be modified, it would have a major impact on the functional decline and health status of older people.

The outcome measure for testing the efficacy of such interventions should be functional autonomy. For most of the published programmes, efficacy was tested on questionable indicators (e.g. mortality, health services use), on a crude proxy for functional decline (e.g. admission to a nursing home) or using a global unresponsive measure of functional autonomy. Given the high probability of functional transitions within 1 year in this population [3], the outcome should be measured within a short interval. Using a longer interval increases the risk of measuring confounding factors.

Most programmes already tested are based on a virtually unstructured assessment by a nurse. A structured programme targeting specific physical, psychological and social aspects using validated clinical assessment instruments (such as the one suggested by Rubenstein *et al.* [17]) would have more chance of being successful.

In the second phase of our study, such an assessment and surveillance programme was designed for the population identified as being at risk by postal questionnaire. We selected the specific interventions proposed in this programme from a literature review on the four following criteria: (i) major prevalence of the condition, (ii) proven impact of the condition on autonomy, (iii) evidence that the condition might be modified by a diagnostic or therapeutic intervention, and (iv) the existence of a simple, effective measuring instrument for that condition that could be administered by a nurse. The selected dimensions and evaluation methods are listed in Table 1 [18–24].

Each condition is evaluated by a nurse using a standardized instrument. The results are sent to the family physician (with the patient's authorization) on a form similar to a laboratory report, together with suggestions for the diagnosis or treatment of the condition. The nurse then monitors the proposed interventions and periodically monitors the subject's progress. This programme was pre-tested in a quasi-experimental pilot study that confirmed its feasibility and suggested a significant effect on the autonomy and well-being of the participants [25].

Table 1. Components of the evaluation programme for elderly people at risk of functional decline

Dimension	Evaluation method	Interventions recommended to the general practitioner
Medication	>3/day; compliance problems; interactions	General suggestions; multidisciplinary assessment of the medication profile and specific recommendations
Cognitive functions	3MS < 80/100 [18, 19]	Assessment at the memory clinic
Depression	Geriatric Depression Scale > 14 [20]	Geriatric psychiatric assessment and treatment
Balance or risk of falling	Tinetti's Gait and Balance Test < 27/40 [21]	Balance and gait rehabilitation programme
Orthostatic hypotension	Difference in systolic BP > 20 mmHg	Assessment and treatment by the general practitioner
Environmental risks	Inventory of risks	Occupational therapy assessment of the home and corrections
Social support	SMAF (handicap score > 0) [22]	Social assessment and intervention
Nutrition	Payette's Malnutrition Risk Questionnaire > 2/16 [23]	General recommendations and dietary assessment and intervention if > 5
Arterial hypertension	BP > 160/120 (two measures taken lying down)	Assessment and treatment by the general practitioner
Vision	Visual acuity and fields	Ophthalmological assessment and treatment
Hearing	Hearing Handicap Inventory for the Elderly [24]	Audiological assessment and treatment
Incontinence	SMAF [22]	Urodynamic assessment and intervention

BP, blood pressure; 3MS, Modified Mini-Mental State; SMAF, Functional Autonomy Measurement System.

The objective of this study was to verify the efficacy of the programme in preventing functional decline and in improving well-being and perception of social support, and to document its impact on health care use.

Methods

Subjects

The study was a randomized controlled trial on a population-based sample of older people living at home. From the list of the Quebec Health Insurance Plan, a universal public plan, we selected all people over 75 years old living at home in Metropolitan Sherbrooke and born between 1 December and 30 April ($n = 1752$). A few days before their birthday, they received a birthday card together with the Sherbrooke Postal Questionnaire. We sent two reminders (after 1 week and 1 month), according to the method described by Hébert *et al.* [16]. Subjects with more than one risk factor who had not returned the questionnaire were contacted again and invited to participate.

Subjects who spoke either French or English and who agreed to participate (by signing the consent form) were assessed at baseline by the interviewer. They were then randomized either to the study group (that received the programme) or the control group (that continued to benefit from the usual health care). Randomization was stratified according to sex, age (75–84 and over-84) and level of disability [three groups according to the Functional Autonomy Measurement System (SMAF) score: 0–7, 8–15, 16 and over]. The randomization lists were generated with random permuted blocks of 4–6.

Programme

Subjects assigned to the study group were then visited by a trained nurse who administered the evaluation detailed in Table 1. Authorization was obtained to request medical information about the diagnoses from the general practitioner (GP). Results of the assessment were sent to the GP. For some problems, the nurse made a direct referral to the relevant specialized resources (e.g. balance and gait rehabilitation programme, occupational therapist assessment of the home, dietary assessment, audiological assessment); in other cases, the nurse telephoned the GP to discuss the case and request help for planning referrals to other health services.

The nurse also contacted the subjects every month to check whether recommendations had been implemented, particularly for medication and references to a specialist. She also left a phone number where she could be reached in case of problems or if more information was needed.

Outcome measures

At the baseline interview and 1 year later, the following instruments were administered: the SMAF disability scale, the General Well-being Schedule and the Social Provisions Scale. At both assessments, the interviewers were blinded to the assignment of the subjects. A questionnaire on health services use was also administered every month by telephone.

The SMAF [22] is a 29-item scale based on the World Health Organisation classification of disabilities [26]. It measures functional ability in five areas: activities of daily living (seven items), mobility (six items), communication (three items), mental functions (five items) and instrumental activities of daily living (eight items). Each item is scored on a 5-point scale from 0 (independent) through 0.5 (with difficulties) to 3 (dependent) for a maximum score of 87. An increase in the score represents a decrease in functional ability.

The SMAF must be administered by a trained health professional who scores the individual's functional ability after obtaining the best information available by questioning the subject and proxies, and by observing and sometimes testing the subject.

A reliability study showed that the intraclass correlation coefficients for total SMAF scores was 0.95 for test–retest, and 0.96 for inter-rater reliability [27]. The responsiveness of the scale has been studied and the Guyatt index was 14.53 [28]. Using both an internal method and an external criterion, the minimal metrically detectable and clinically important change of the SMAF score has been established to be 5 points [29].

Dupuy's General Well-being Schedule [30, 31] is a 18-item questionnaire that covers six dimensions: anxiety, depression, positive well-being, self-control, vitality and general health. The total score is out of 110, where the higher the score, the greater the well-being.

The Social Provisions Scale is a 24-item scale developed by Cutrona and Russell [32] that explores six dimensions of perceived social support: attachment, social integration, reassurance of worth, reliable alliance, guidance and opportunity for nurturing. Each dimension is assessed by four 4-point questions for a total score out of 96, where the higher the score, the greater the perception of social support.

The primary outcome, functional decline, was a dichotomous variable defined as one of the following: (i) an increase of $\geqslant 5$ points on the SMAF score between baseline and post-test assessment; (ii) admission to a nursing home or long-term care hospital; (iii) death during the reference year. This definition was used in a previous study to validate the postal questionnaire [16].

Analysis

We compared subjects who refused to participate with participants on their answers to the postal questionnaire

by using χ^2 statistics. We compared study and control groups at baseline using independent *t*-test and χ^2.

The primary hypothesis was tested on an intention-to-treat basis by using the relative risk of functional decline and its 95% confidence interval. We compared secondary outcomes (SMAF, General Well-being Schedule and Social Provisions Scale) at post-test by using analysis of covariance, baseline results being incorporated as co-variates. Health services use was compared between the two groups using χ^2 (or the Fisher exact test) and the Mann–Witney *U* test. All analyses were carried out on SAS software.

The target sample size was estimated at 500 subjects (250 per group) in order to detect a 30% reduction of functional decline from the expected 38% in this high-risk population [16] to 26% with 80% power and a two-tailed α error of 5% [33].

Results

Of the 1752 subjects on the list from the Quebec Health Insurance Plan, 454 were not eligible for the study (284 admitted to an institution or in hospital, 71 dead, 34 moved outside the region, four did not speak French or English, 61 could not be found). Of the 1298 subjects who received a postal questionnaire, 778 were at risk of functional decline (60%), and 503 of these agreed to participate in the study, giving a participation rate of 64.7%. At post-test, nine subjects refused to be interviewed, so 245 subjects in the study group and 249 in the control group were included in the analysis for the primary outcome. Figure 1 summarizes the flow of the participants.

Table 2 compares the 250 subjects randomized to the study group with the 253 in the control group on the socio-demographic variables and on the three outcome variables at baseline. There was no significant difference between the groups at this point.

In the study group, 24 subjects refused to continue to participate in the programme after the baseline interview. Of the remaining 226 subjects, only 23 (10.2%) did not receive any recommendation following the assessment (because no problem was identified). Forty-eight subjects (21.2%) had one problem identified, while 64 subjects had two problems, 45 (19.9%) three, 21 (9.3%) four and 25 (11.1%) five and over. The most prevalent problem was nutritional deficiency (54%) followed by medication problems (48%) and cognitive impairment (18%). Table 3 summarizes the recommended interventions and the compliance with these recommendations.

Of the subjects randomized to the study group, 12 died, five were admitted to an institution and 31 showed an increase in the total SMAF score of $\geqslant 5$ points during the year; therefore, 48 subjects (19.6% of the group) presented a functional decline. In the control group, the figures were: 18 deaths, five admissions to an institution and 26 increases in the SMAF score, giving a total of 49 (19.7% of the group). The relative risk of functional decline for subjects randomized to the study group was thus 1.00 (95% confidence interval 0.82–1.23).

Table 4 presents the results on the secondary outcome variables. We found that the programme had no effect on functional autonomy, well-being or perceived social support. Similarly, there was no difference between the groups on any of the variables related to health service utilization.

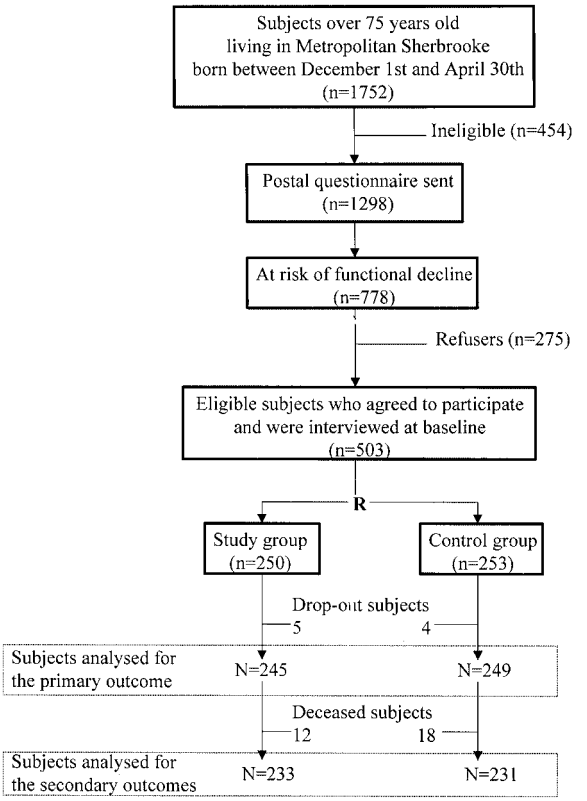

Figure 1. Flow of participants.

Table 2. Comparison of the study and control groups at baseline

Variable	Study ($n = 250$)	Control ($n = 253$)	*P* value
No. of women (%)	160 (64.0%)	163 (64.4%)	0.92
Mean age, years (SD)	80.2 (4.2)	80.3 (4.5)	0.79
No. married (%)	111 (44.4%)	118 (46.6%)	0.28
Mean schooling, years (SD)	7.6 (4.2)	7.6 (4.1)	0.92
Mean score (SD)			
SMAF	9.6 (8.4)	10.1 (9.2)	0.50
GWBS	75.1 (15.7)	75.3 (17.4)	0.86
SPS	71.8 (9.4)	72.8 (8.1)	0.20

GWBS, Dupuy's General Well-being Schedule; SMAF, Functional Autonomy Measurement System; SPS Social Provisions Scale.

Table 3. Number of recommendations made for each problem and compliance with the recommendations

	No. of interventions					
			Not carried out			
				GP refusal		
Problem	Recommended[a]	Done[b]	Subject refusal	Justified	Unjustified	Death or insufficient information[c]
Medication	119/226 (53%)[d]	67/91 (74%)	4	9	11	28
Depression	18/226 (8%)	4/16 (25%)	8	4	0	2
Cognitive impairment	44/226 (20%)	15/38 (40%)	17	6	0	6
Nutritional deficiency	136/250 (54%)[e]	131/132 (99%)	1	0	0	4
Visual impairment	44/226 (20%)	14/42 (33%)	3	25	0	2
Hearing disability	35/226 (16%)	12/34 (35%)	17	4	1	1
Orthostatic hypotension	42/226 (19%)	35/37 (95%)	1	0	1	5
Gait and balance	30/250 (12%)	12/28 (43%)	15	1	0	2
Environmental risk of falls	6/226 (3%)	1/4 (25%)	3	0	0	2
Hypertension	27/226 (12%)	11/18 (61%)	1	5	1	9
Urinary incontinence	24/250 (10%)	5/17 (29%)	10	2	0	7
Lack of social support	4/250 (2%)	2/3 (67%)	1	0	0	1
Total	529	304/455 (67%)	81	56	14	74

GP, general practitioner.
[a]Proportion of subjects for whom a problem was identified and an intervention recommended.
[b]Proportion of subjects for whom the information was available.
[c]The nurse was unable to judge at the monthly telephone contact whether or not the intervention had been carried out.
[d]A multidisciplinary assessment of the medication profile was performed and specific recommendations made for 80 subjects.
[e]A detailed dietary assessment and a specific dietary intervention were performed for 30 subjects.

Table 4. Comparison of study and control groups at post-test on the secondary outcome variables

	Mean score (SD), by group		
Outcome variable	Study ($n = 224$–233)[a]	Control ($n = 226$–231)[a]	*P* value (ANCOVA)
Total SMAF (out of 87)	10.7 (10.0)	10.4 (10.9)	0.34
GWBS (out of 110)	74.8 (17.5)	75.4 (17.9)	0.87
SPS (out of 96)	72.5 (7.6)	73.5 (8.4)	0.31

GWBS, Dupuy's General Well-being Schedule; SD, standard deviation; SMAF, Functional Autonomy Measurement System; SPS, Social Provisions Scale.
[a]Sample sizes vary since some of the surviving subjects at post-test did not complete all the questionnaires.

Discussion

This study had many strengths. First, the internal validity was high since it was a randomized controlled design, interviewers were blinded to the assignment for the main outcome and three of the four secondary outcomes, and subjects were unaware of the group to which they were randomized. Secondly, the external validity was also strong: it was a population-based sample and the programme was 'ecological', i.e. integrated in the existing health care system without duplicating services. If such a programme had been efficacious, it would have been feasible to implement it in the health care system despite current financial constraints. Incidentally, a cost–benefit analysis of the programme was planned as part of the study but was not performed given the results. Thirdly, the sample size was large enough to detect a 10% decrease in the annual incidence of functional decline in this at-risk population (with 80% power).

However, before concluding that such programmes are ineffective, some questions must be examined. First, the observed incidence of functional decline in the control group (19.7%) is lower than expected from a similar population identified as at risk by means of the same postal questionnaire (38%; 95% confidence interval 33–43%) [16]. This could be due to the general improvement in care for older people in the study area acting as a competing programme. Since there is a university institute of geriatrics, Sherbrooke is one of the Canadian areas where geriatric services are the most developed—including an assessment unit (40 beds), a rehabilitation unit (35 beds), a day-hospital, a geriatric outpatient clinic (with specialized clinics for memory, incontinence, etc) and two day-centres for an older population of 25 000. Moreover, the existence of a research centre and an expertise centre devoted to gerontology and geriatrics could have contributed to the improvement of the health services' and professionals' competence in the area.

Secondly, the hypothesis of contamination between the groups should be considered. Contamination could have been introduced by the monthly telephone contacts, which can by themselves be an effective intervention via the improvement of well-being and social support. However, in neither group, was there any significant increase in the scores on the two instruments measuring

these variables. Contamination could also have taken place via the GPs, who may have applied the recommendations suggested for their patients in the study group to patients who had been randomized to the control group. In fact, 50% of the GPs of subjects in the study group also had subjects in the control group as patients. To verify if there was contamination by learning and transferring, we examined the prescription pattern of the subjects at post-test, medication being the problem where this contamination would have been most obvious. The number of potentially inappropriate prescriptions [34] in the control group subjects was not related to the fact that their GP was also the physician of subjects in the study group.

Thirdly, we should examine the implementation of the programme. Since the nurses were associated with the research centre, the planned activities were carried out in their entirety. In only 10% of the subjects was no intervention recommended. This low false-positive rate confirms the validity of the screening postal questionnaire. The compliance of subjects and physicians with recommendations was high when modifications of medications were involved (medication problems, hypertension, orthostatic hypotension). However, it was relatively low when a reference to specialized resources was suggested. It was the subjects themselves who refused to comply with the recommendations, except for visual impairments (where it was mainly the GP who refused to comply, generally because they stated that the subjects had already been evaluated and/or were followed by a specialist). Overall, the compliance was acceptable and similar to that which could have been expected in real life.

Despite the fact that we tried to overcome the problems encountered in previous studies that attempted to verify the efficacy of such preventive programmes on functional decline, our study reached the same conclusions as most of them [4–10]. However, two studies carried out more recently in the USA reported significant results. Fabacher *et al.* [11] demonstrated that subjects in the study group presented a lower rate of functional decline, particularly in instrumental activities of daily living, than the control group. In that study, the number of subjects without physicians also decreased significantly from 13 to 1%. Stuck *et al.* [12] reported significant effects of their programme on functional autonomy and admission to an institution after 3 years. However, these two studies were carried out with volunteers, and demented subjects were excluded. Also, medical surveillance of the population seems to have been less than optimal in Fabacher and co-workers' study [11] if one considers the proportion of subjects without a GP (11%). Generalization of these results to countries with a public universal health care system is questionable.

In conclusion, this study confirms that the efficacy of structured screening programmes for preventing functional decline in the older population remains to be demonstrated [35]. Despite the fact that at-risk individuals can be easily identified, either with an universal approach (such as the postal questionnaire [16]) or by an opportunistic approach (targeting those who visit emergency room or use home-care services [36, 37]), there is no indication that this risk can be decreased. More efforts are necessary to improve the efficacy of specific interventions such as prevention of falls, medication misuse and cognitive decline, rehabilitation of hearing and nutritional intervention before multidimensional screening programmes can be shown to be efficacious in modifying the risk of functional decline. Negative results such as those reported here should stimulate the search for preventive solutions in order to compress the morbidity associated with ageing and improve the quality of life of older people.

Key points

- A postal questionnaire can screen people over 75 who are at risk of functional decline.
- In a randomized controlled trial, a multidimensional diagnostic and intervention programme had no effect on functional decline, functional autonomy, well-being, perceived social support or use of health-care services.
- More research is needed on improving the efficacy of treatment of the major causes of functional decline. Only then might multidimensional programmes be efficacious.

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