EFFECTIVENESS OF DEMENTIA CARE MANAGEMENT IN PRIMARY CARE

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ABSTRACT

Introduction: Dementia is a public health priority. Evidence-based interventions alleviate the burden of the disease. Objective: To determine the effectiveness of dementia care management in primary care. Methods: A pragmatic, cluster-randomized intervention study was conducted with two arms, an intervention group and a usual care group. Finally, 634 patients were included. Results: A significant decrease in patients' behavioral and psychological symptoms of dementia was observed (b = -7.45; 95 % CI, -11.08 to -3.81; P < 0.001). Conclusions: Dementia care management is an effective and safe collaborative care model.

Keywords: Dementia, primary care, intervention.

RESUMEN

Introducción: La demencia es una prioridad de salud pública. Las intervenciones basadas en la evidencia alivian la carga de la enfermedad. Objetivo: Determinar la efectividad de la gestión de la atención de la demencia en atención primaria. Método: Se realizó un estudio de intervención pragmático, aleatorizado por grupos con 2 brazos, un grupo de intervención y un grupo de atención habitual. Se incluyó finalmente a 634 pacientes. Resultados: Se observó una disminución significativa en los síntomas conductuales y psicológicos de demencia de los pacientes (b = −7,45; IC del 95 %, −11,08 a −3,81; P < 0,001). Conclusiones: La gestión de la atención de la demencia es un modelo de atención colaborativa eficaz y seguro.

Palabras claves: Demencia, atención primaria, intervención.

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INTRODUCTION

Dementia is a public health priority affecting 47.5 million people worldwide. The rapid growth in the number of people with dementia challenges healthcare systems. People with dementia need comprehensive medical, nursing, psychological and social support to slow disease progression and maintain autonomy and social inclusion. Primary care has been identified as the first point of contact for people with dementia and is, therefore, a promising setting for identification, comprehensive assessment of needs, and initiation of dementia-specific treatment and care. However, primary care systems worldwide are unprepared for these tasks[1].

Evidence-based interventions alleviate the burden of the disease, as there is currently no curative treatment available. It is important to involve caregivers in intervention because they provide the greatest proportion of care for people

with dementia. General challenges in dementia management include providing anti-dementia medication treatment, addressing neuropsychiatric symptoms and behavioral problems, reducing inappropriate use of psychoactive medications, and managing caregiver burden[2].

Collaborative care programs address these challenges. There is some evidence that general practitioner-based dementia care programs can be successfully implemented in health systems. However, the scientific evidence does not currently match the enthusiasm for these programs. The effectiveness of care management must be tested before primary care implementation[3].

A 2015 Cochrane review[4], analyzed from 13 randomized clinical trials, revealed beneficial effects of care management, specifically in reducing patient behavioral disorders and caregiver burden and depression, as well as in improving caregiver well-being and social support. However, there is heterogeneity in interventions, study designs, sample size, and outcomes measured. Therefore, the review concluded that there is a need for rigorous studies in intervention design and delivery. In addition, intervention modules and standard outcome measures should be clearly defined to improve comparability[4].

The present study describes the effectiveness of dementia care management on relevant patient- and caregiver-oriented outcomes, including quality of life, caregiver burden, behavioral and psychological symptoms of dementia, anti-dementia drug therapy, and potentially inappropriate medication use.

METHOD

A pragmatic intervention study was conducted, based on general practitioners, randomized by groups with two arms, an intervention group and a usual care group (GAH). This study was approved by the Universidad Regional Autónoma de Los Andes (UNIANDES). General practices were the unit of randomization and determined the status of the patient group. A total of 854 physicians from 5 parishes in Ambato were invited to participate by mail. In addition, the investigators visited general practitioners who expressed interest in the study to convey more detailed information. Finally, 136 general practitioners (15.9%) gave written informed consent to participate and agreed to join the study. There were no restrictions regarding the treatment of patients by general practitioners.

General practitioners assessed patient eligibility (≥70 years, living at home) and systematically selected patients. The study was conducted from January 2018 to December 2020. Patients who tested positive for dementia were informed about the study by their primary care physician, invited to participate, and asked to provide written informed consent. If patients mentioned a caregiver, he or she was also asked to participate. When patients could not provide written informed consent, their legal representative was asked to sign the consent form. In total, 634 patients were recruited.

Dementia care management aims to provide optimal care by integrating multi-professional and multimodal strategies to improve patient- and caregiver-related outcomes within the regular health care and social services system. It was developed following current guidelines, targeted at the individual participant level, and delivered in patients' homes by six nurses with dementia-specific qualifications. A computer-based intervention management system supported it to enhance the systematic identification of unmet patient and caregiver needs. In addition, the nurses conducted an in-depth assessment.

During the first six months of the intervention, the nurse made six home visits with an average duration of 1 hour, performing her usual intervention tasks in close collaboration with the caregiver, primary care physician, and health and social services professionals. During the following six months, the study nurse supervised the completion of all intervention tasks.

The database and statistical processing of the data were performed and analyzed in the SPSS 26 statistical program (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used for the results collection, presentation and interpretation. The significance level was set at 0.05 to consider a result significant. Summary measures were used for quantitative data, such as arithmetic mean and standard deviation. Baseline and follow-up values were compared using paired *t-tests* or McNemar's tests, as appropriate.

Simple 1:1 randomization is used without stratification or matching. This procedure was sufficient because of the large number of groups expected in the study, and general practitioners were not informed of their randomization status. However, because of the type of intervention, general practitioners became aware of their status throughout the study. The participating physicians recruited and enrolled the patients, but the study center assigned them to the study group because blinding was impossible because baseline assessment, primary outcome assessment, and intervention administration were to be performed by the same nurses.

RESULTS

Primary outcomes were assessed in identical, standardized, computer-assisted face-to-face interviews in patients' homes by expressly qualified nurses during an average of 3 separate visits at baseline and 12 months after baseline where (1) quality of life, measured by the Quality of Life in Alzheimer Disease instrument[5], which assesses physical health, mental health, and social and financial domains, was assessed; (2) caregiver overload, measured by the Berlin Inventory of the Burden of Caregivers with Dementia Patients[6], an inventory with 88 items in 20 different dimensions, which assesses subjective and objective burden; (3) behavioral and psychological symptoms, measured by the Neuropsychiatric Inventory[7], a proxy interview on 12 dimensions of neuropsychiatric behaviors; (4) pharmacotherapy use with antidementia medications, which included the following substances recommended by relevant guidelines: donepezil, galantamine, rivastigmine, and memantine; and (5) use of potentially inappropriate medication (PIM), which is defined as a drug in which the risk of an adverse drug effect outweighs the clinical benefit.

Overall, 634 patients gave written informed consent, and a total of 407 (64.2 %) received the intended treatment (dementia care management (DMM), 291 [71.5 %]; GAH, 116 [28.5 %]). While all 407 participants were included in the per-protocol analyses, all patients with valid baseline variables were included in the attention-to-treat (AIPT) analyses (Table 2). In total, 227 patients were lost to follow-up. Most patients dropped out before starting the initial home evaluation (118 of 634 [18.6 %]), which took place on average 138 days after initial screening by the primary care physician due to the study procedure.

The dropout rate between completion of baseline and follow-up was lower (94 of 516 [18.2 %]) and more frequent in the control group (GAD, 46 of 348 [13.2 %] vs. GAH, 48 of 168 [28.6 %]). There was no statistical difference between patients evaluated at follow-up (n = 407) and those who dropped out before follow-up (n = 227) in age, sex, and score. The intervention was safe, as there were no reported dropouts due to physician advice or problems with the intervention reported by dementia patients or caregivers. There was no significant effect of the study group on mortality.

Table 1. Baseline characteristics of patients with dementia.

Feature	Usual Care (n =116)	Dementia care management n = 291)
Age, mean (SD), years	79,8 (5,0)	80,6 (5,7)
Female gender	70 (60,3)	178 (61,2)
Caregiver included	75 (64,7)	227 (78,0)
Do not live alone	58 (50,0)	148 (50,9)
Living alone	53 (45,7)	151 (51,9)
Cognitive status (Mini-Mental Status Examination score), mean (SD	22,7 (5,2)	22,8 (4,6)
Formal diagnosis of dementia	43 (37,1)	113 (38,8)
Functional impairment (B-ADL Activities of daily living score), mean (SD)	3.2 (2.4)	3.8 (2.6)

Comorbidities, mean (SD)	14,0 (6,9)	13,5 (8,0)
Visit to a neurologist/psychiatrist	21 (18,8)	86 (30,1)
Quality of life (Qol-AD Quality of Life in Alzheimer's Disease score), mean (SD)	2,8 (0,4)	2,7 (0,4)
Neuropsychiatric symptoms (Neuropsychiatric Inventory score), mean (SD)	7.2 (9.8)	7,6 (14,6)
Antidementia drug treatment	27 (23,5)	84 (28,9)
Potentially inappropriate medication	25 (21,7)	72 (24,7)
Caregiver burden (BIZA-D Berlin Inventory of the Burden of Caregiving for Dementia Patients score), mean (SD)	-0,07 (2,57)	-0,14 (2,62)

Source: statistical analysis, data are reported as number (%) unless otherwise indicated, p≤ 0.05.

Table 2. Regression analysis for the treatment effect of dementia care management.

Primary result	Remarks	Treatment effect (95% CI)	p-value	Effect size
Quality of Life	379	0,02 (-0,09 a 0,05)	0,26	0,07
Neuropsychiatric symptoms	261	-7,45 (-11,08 a -3,81)	0	-0,50
Caregiver overload	241	-0,50 (-1,09 a 0,08)	0,45	-0,18
Antidementia drug treatment	401	1,97 (0,99 a 3,94)	0,03	N/A
Potentially inappropriate medication	401	1,86 (0,62 a 3,62)	0,97	N/A

Source: statistical analysis, Mixed effects regression analysis with random effects for general practitioner adjusted for age, sex, living situation and baseline value; study group was the predictor of interest; P values are given one-sided, data are reported as Number (%) unless otherwise stated, p≤ 0.05

Primary analyses (AIPT) included generalized regression models, with model specifications corresponding to the scale level of the outcome variable. The AIPT was modified for all cases with valid baseline data, and the per-protocol analysis included only complete cases. Multiple imputations imputed missing data in the follow-up variables through chained equations. The outcome variable at follow-up was the dependent variable, and the study group was the predictor of interest. To account for the stochastic dependence of patients treated by the same primary care physician, primary care physicians were included as random effects. The baseline value of the outcome variable was included as a covariate to reduce residual variance and to account for interindividual variance at baseline. In addition, age, sex, and living situation (alone or not alone) were included as covariates. A positive intervention effect was defined as a significant regression coefficient of the study group variable *P values* and 95 % CI by bootstrapping (2000 replicates). All *P* values for primary analyses are one-sided.

In AIPTs, a significant decrease in patients' behavioral and psychological symptoms of dementia (b = -7.45; 95 % CI, -11.08 to -3.81; *P* < 0.001) and caregiver burden (b = -0.50; 95 % CI, -1.09 to 0.08; *P* = 0.05) was observed in the intervention group compared with GAH. Dementia patients receiving GAD were more likely to receive antidementia drug treatment (GAD, 114 of 291 [39.2 %] vs. GAH, 31 of 116 [26.7 %]) after 12 months (odds ratio, 1.97; 95 % CI, 0.99 to 3.94; *P* = 0.03). There was no effect on the quality of life (b = 0.02; 95 % CI, -0.09 to 0.05; *P* =

.26) or MPI (GAD, 77 [26.5 %] vs. GAH, 19 [16.4 %]; odds ratio, 1.86; 95 % CI, 0.62 to 3.62; *P* = .97) after 12 months. Secondary analyses indicated a significant effect on the quality of life in the intervention group (b = 0.08; 95 % CI, 0 to 0.17; *P* = .03) for patients who did not live alone.

According to secondary outcomes, we found no significant effect on patient cognitive status, activities of daily living, or institutionalization. Overall, 24 of 407 patients (5.9 %) were institutionalized one year after baseline (GAD, 16 [5.5 %] vs. GAH, 8 [6.9 %]).

Sensitivity analyses confirmed the results of the AIPTs. As expected, clinical characteristics showed significant clustering and sociodemographic variables, such as sex, age and standard of living, were not dependent on the primary care physician.

DISCUSSION

In this study, GAD was beneficial in optimizing treatment and care in patients with dementia. Medium to large effects of GAD is found for community-dwelling dementia patients in primary care on behavioral and psychological symptoms, caregiver burden, and pharmacological treatment with antidementia medications. Concerning neuropsychiatric symptoms measured by the Neuropsychiatric Inventory, a decrease of 4 points would be considered clinically significant.[21]

In the analysis, GAD reduced neuropsychiatric symptoms by 8 points, with a larger effect size compared with previous studies included in the Cochrane review by Reilly et al. [4] (standardized mean difference, -0.20; 95 % CI of difference, -0.41 to 0.01; n = 368; I^2 = 83 %; *P* = 0.06). Regarding caregiver burden, the effect size of GAD was medium but larger compared with other studies (-0.18 vs. -0.07). Therefore, our results indicate significant clinical relevance. Furthermore, the study methods were in line with the demand to use standardized sets of outcome measures and well-defined interventions to improve comparability across studies, and the results add empirical evidence to the currently inconclusive research on ADM approaches in primary care[8–10].

The results suggest that GAD increased the quality of dementia care. Improvements included increased use of antidementia medications. Although this is a simple indicator of good dementia care, the data do not indicate whether drug treatment aligns with guidelines. Till now, there is no benchmark for the percentage of people who should be treated with anti-dementia medications in primary care that could be used for comparison. The data suggested using a cautious approach to anti-dementia drug treatment, with a prevalence of 39% in the intervention group. This proportion is comparable with other studies[11–14]. Many international guidelines recommend the use of anti-dementia drugs. However, in this study, one could not assess compliance with the guidelines in all their complexity due to the limited sample size. [22]

Neuropsychiatric symptoms and caregiver burden are among the most critical risk factors for the institutionalization of people with dementia. The study is the first to show positive effects on both factors. Another risk factor is functional disabilities. Because anti-dementia medications can positively impact functional abilities, the three effects of GAD are likely synergistic in delaying institutionalization. This could save costs in the long term[15,16].

A small effect on the quality of life was limited to patients who did not live alone. This result should not be overestimated because the validity and reliability of quality-of-life measures in people with dementia are limited[17,18]. However, this finding implies that further analyses could identify target groups with greater benefit. For example, the efficacy of GAD might be associated with socioeconomic status, functional ability, or severity of dementia.

There was no effect of GAD on the frequency of MPI. This is unexpected because comprehensive medication management was part of the intervention. This trial's intensity was probably too low because recommendations to the primary care physician regarding medication management were provided only once. Effective reduction of PPMs may require a higher intensity of care management and follow-up reviews[19,20].

Limitations

Screening and recruitment were part of routine care, so selection bias cannot be ruled out. Furthermore, any systematic screening

mechanism would have interfered with routine GPs, causing adverse effects, including GP dropout. However, all participating physicians agreed to recruit systematically while complying with the study design requirements.

It is possible that differences in access and availability of healthcare resources in other healthcare systems may affect effectiveness. However, the challenges of dementia care are primarily caused by the disease itself and require similar resources available in different regions and health care systems.

CONCLUSIONS

Computer-based dementia care management is an effective and safe collaborative care model with clinically relevant patient- and caregiver-related effects on treatment and care. Therefore, routine care implementation could benefit people with dementia and their family caregivers. Further analyses should identify specific subgroups of people with dementia with increased effectiveness of ADM and should assess the cost-effectiveness of adapting it to other settings and health care systems.

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