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Canadian Journal of Diabetes

journal homepage:
www.canadianjournalofdiabetes.com

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Original Research

Diabetes Nurse Case Management in a Canadian Tertiary Care Setting: Results of a Randomized Controlled Trial

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ARTICLE INFO

Article history:

Received 2 May 2016

Received in revised form

17 October 2016

Accepted 21 October 2016

Keywords:

diabetes nurse case manager
randomized controlled trial
tertiary care setting
diabetes distress
psychosocial outcomes

Mots clés :

infirmière gestionnaire de cas de diabète
essai clinique à répartition aléatoire
cadre des soins tertiaires
détresse liée au diabète
critères de jugement psychosociaux

ABSTRACT

Objectives: To examine the effects of a 6-month nurse case manager (NCM) intervention compared to standard care (SC) on glycemic control and diabetes distress in a Canadian tertiary-care setting.

Methods: We recruited 140 adults with type 2 diabetes and glycated hemoglobin (A1C) levels >8% (64 mmol/mol) from 2 tertiary care facilities and randomized them to: 1) a 6-month NCM intervention in addition to SC or 2) SC by the primary endocrinologists. Assessments were conducted at baseline and at 6 months. Primary outcomes included A1C levels and diabetes distress scores (DDS). Secondary outcomes included body mass index, blood pressure, diabetes-related behaviour measures, depressive symptoms, self-motivation and perception of support.

Results: At the 6-month follow up, the NCM group experienced larger reductions in A1C levels of -0.73% compared to the SC group ($p=0.027$; $n=134$). The NCM group also showed an additional reduction of -0.40 (26% reduction) in DDS compared to those in the SC group ($p=0.001$; $n=134$). The NCM group had lower blood pressure, ate more fruit and vegetables, exercised more, checked their feet more frequently, were more motivated, were less depressed and perceived more support. There were no changes and no group differences in terms of body mass index, medication compliance or frequency of testing.

Conclusions: Compared to SC, NCM intervention was more effective in improving glycemic control and reducing diabetes distress. It is, therefore, a viable adjunct to standard diabetes care in the tertiary care setting, particularly for patients at high risk and with poor control.

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R É S U M É

Objectifs : Examiner les effets de l'intervention de 6 mois d'une infirmière gestionnaire de cas (IGC) par rapport aux effets des soins courants (SC) sur la régulation de la glycémie et la détresse liée au diabète dans le cadre canadien des soins tertiaires.

Méthodes : Nous avons recruté 140 adultes atteints du diabète de type 2 qui avaient des concentrations d'hémoglobine glyquée (A1c)>8% (64 mmol/mol) de 2 établissements de soins tertiaires et les avons répartis de manière aléatoire comme suit : 1) intervention de 6 mois d'une IGC en plus des SC ou 2) SC par les endocrinologues traitants. Les évaluations ont été réalisées au début et après 6 mois. Les critères de jugement principaux étaient les concentrations de l'A1c et les scores de la détresse liée au diabète (SDD). Les critères secondaires étaient les suivants : l'indice de masse corporelle, la pression artérielle, les mesures du comportement lié au diabète, les symptômes de dépression, la motivation personnelle et la perception du soutien.

Résultats : Au suivi après 6 mois, le groupe IGC montrait des réductions plus grandes des concentrations de l'A1c de -0,73% que celles du groupe SC ($p=0,027$; $n=134$). En plus, le groupe IGC montrait une réduction des SDD de -0,40 (réduction de 26%) par rapport au groupe SC ($p=0,001$; $n=134$). Les adultes du groupe IGC avaient une pression artérielle plus basse, mangeaient plus de fruits et de légumes, faisaient plus d'exercice, vérifiaient leurs pieds plus fréquemment, étaient plus motivés, étaient moins dépressifs et s'apercevaient d'un plus grand soutien. Il n'y avait aucun changement et aucune différence entre les groupes en ce qui concerne l'indice de masse corporelle, l'observance thérapeutique ou la fréquence des analyses.

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Conclusions : Comparativement aux SC, l'intervention d'une IGC était plus efficace pour améliorer la régulation de la glycémie et réduire la détresse liée au diabète. Par conséquent, il s'agit d'un complément viable aux soins courants offerts aux diabétiques dans le cadre des soins tertiaires, particulièrement chez les patients exposés à un risque élevé qui ont une régulation médiocre.

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Introduction

The prevalence of diabetes is rising worldwide, primarily because of an aging and increasingly obese population. In 2010, 2.7 million (7.6%) people in Canada were diagnosed with diabetes, and this number is projected to reach 4.2 million (10.8%) by 2020 (1). Diabetes and its associated complications are a significant burden on the Canadian economy, costing \$11.7 billion in 2010 and expected to rise to \$16 billion by 2020 (1).

Despite compelling evidence that tight glucose control can prevent or delay complications (2), outcomes are poor, and improvements are needed. For instance, among 3002 Canadian patients in a primary care setting, Braga et al (3) found that 30%, 39% and 53% achieved treatment targets for blood pressure (BP), glycated hemoglobin (A1C) and cholesterol, respectively. Moreover, only 7% achieved all 3 goals. Clearly, greater efforts are needed to help patients improve diabetes-related health outcomes in Canada.

Among the various models investigated to improve diabetes care delivery, case management has produced the most favourable evidence (4,5). In fact, a meta-analysis of 11 different quality-improvement strategies for diabetes care found that interventions involving case-management strategies led to the greatest reductions in A1C levels (5). Case management encompasses the assessment, implementation, coordination and monitoring of options and services required to meet individual health needs (6). It can include patients' education, coaching, treatment adjustment, monitoring and care coordination (7).

Several systematic and integrative reviews have shown diabetes case management interventions to be effective in improving glycemic control (6–10) by up to 0.89% (6). In addition, a study of 556 patients receiving care in a Veteran Affairs healthcare system found that, compared to controls, a greater proportion of patients randomized to a nurse case manager (NCM) intervention achieved the collective treatment target for A1C levels, BP and low-density lipoprotein levels (11).

Although there is overwhelming evidence supporting NCM models in the treatment of diabetes, these studies have been conducted predominantly in primary care and community-based settings in the United States and Europe (6). In fact, of the 29 case management studies in the meta-analysis of Welch et al (6), only 1 study was conducted with patients attending a tertiary care clinic in Canada. That randomized controlled trial of 46 patients with diabetes found a significant reduction in A1C levels associated with a telephone-based nursing intervention compared to standard care conditions (12). However, the study recruited patients with both type 1 and type 2 diabetes requiring insulin, and it focused on insulin titration to the exclusion of other core self-management issues, such as healthful eating, physical activity and psychosocial well-being. To our knowledge, no studies of NCM-assisted patients with diabetes have been conducted in a Canadian tertiary care setting that focus on comprehensive care of patients with type 2 diabetes only who are being treated with oral agents and/or insulin.

The current study is the first randomized controlled trial (RCT) to evaluate the impact of NCM intervention for patients with poorly controlled type 2 diabetes who were recently discharged from 2 tertiary care hospitals in Canada or referred by tertiary hospital-affiliated endocrinologists. In addition, this Canadian-based study is the first to include both a primary clinical outcome (A1C levels) and a psychosocial outcome (diabetes distress).

Methods

Study design, setting and population

This study was approved by the University of British Columbia and Providence Health Clinical Research Ethics Boards. It is an RCT of a 6-month NCM intervention compared to standard care (SC). The study was initiated in September 2012, enrollment was completed in July 2014, and follow up was completed in January 2015. The protocol is viewable at <https://clinicaltrials.gov/ct2/show/NCT01659294>.

The study was conducted at BCDiabetes.ca, based in the Gordon and Leslie Diamond Health Care Centre. The centre is the main tertiary care centre in Vancouver, British Columbia, and brings together outpatient services at Vancouver General Hospital, including specialty clinics, along with medication education, physician teaching clinics and research, at a single site.

Inclusion/exclusion criteria

To be eligible for the study, patients had to 1) have physician-diagnosed type 2 diabetes; 2) be ≥ 18 years of age; (3) have A1C levels $\geq 8\%$ and 4) to be able to read and write English. Patients were excluded if they had previously worked with an NCM or had any serious health conditions (e.g. terminal cancer), serious psychiatric illness or self-reported excessive alcohol or illicit drug use that would impede meaningful participation in the study.

Recruitment

Study participants were recruited using 2 streams: 1) patients who had been recently discharged from 2 tertiary care hospitals in Vancouver (Vancouver General Hospital or St. Paul's Hospital) and 2) patients referred by endocrinologists affiliated with the 2 tertiary care hospitals. If recruited from the hospital, the invitation to participate in the study was made by a member of the treating endocrine team (endocrinology fellow or resident). The primary endocrinologist or the member of the team briefly described the study and its eligibility criteria. The NCM contacted interested patients and scheduled initial visits during which she described the study in greater detail, obtained informed consent and conducted baseline assessments. In the case of outpatient referrals, the invitations came from the treating endocrinologist. These patients had been referred to the treating endocrinologist by their community-based family (primary) physician. All potential subjects who met the study entry criteria were approached by treating endocrinologists to participate in the study. As such, participants were representative of new diabetes referrals (with A1C levels >8.0) seen by the referring endocrinologists.

Randomization process

Each participant was randomly assigned to the intervention or control group by using a stratified permuted block randomization scheme, with the endocrinologist being the sole stratification factor. The permuted block aspect of the randomization scheme ensured that treatment assignment remained balanced throughout the enrolment period. Randomized assignments were completed in advance and kept in individual, sealed, sequentially labelled envelopes that were opened at the time of the randomization of each participant.

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