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Original Research

Preventing Diabetes in Primary Care: A Feasibility Cluster Randomized Trial

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ABSTRACT

Objective: To determine the feasibility of implementing a large-scale primary care-based diabetes prevention trial.
Methods: A feasibility cluster randomized controlled trial was conducted in British Columbia, Canada, amongst adults with prediabetes using the Facilitated Lifestyle Intervention Prescription (FLIP) vs. usual care. FLIP included lifestyle advice, a pedometer, and telephone support from a lifestyle facilitator for 6 months. Indicators of feasibility included recruitment rates of family practices, participants and facilitators, as well as feasibility and retention rates in the FLIP program and study protocols.
Results: Six family practices participated; 59 patients were enrolled between October 2012 and March 2013. The trial protocol was acceptable to practices and participants and had a 95% participant retention rate over the 6 months (56/59). Adherence to the intervention was high (97%), with 34 of 35 patients continuing to receive telephone calls from the facilitator for 6 months. The mean cost of the intervention was C$144 per person. Compared with control, intervention participants significantly reduced weight by 3.2 kg (95% CI, 1.7 to 4.6); body mass index by 1.2 (95% CI, 0.7 to 1.7) and waist circumference by 3 cm (95% CI, 0.3 to 5.7).
Conclusions: It is feasible to implement FLIP and to conduct a trial to assess effectiveness. A larger trial with longer follow up to assess progression to diabetes is warranted.

Mots clés :
changement de comportement
prévention du diabète
intervention sur le mode de vie
soins de santé primaires

RÉSUMÉ

Objectif : Déterminer la faisabilité de mettre en place un essai à grande échelle sur la prévention du diabète fondée sur les soins de santé primaires.
Méthodes : Un essai clinique aléatoire par grappes sur la faisabilité a été mené en Colombie-Britannique, au Canada, auprès d'adultes souffrant d'un prédiabète en utilisant la FLIP (Facilitated Lifestyle Intervention Prescription) *vs* les soins habituels. La FLIP comprenait des conseils sur le mode de vie, un pédomètre et le soutien téléphonique d'un éducateur en mode de vie durant 6 mois. Les indicateurs de la faisabilité comprenaient les taux de recrutement des cliniques de médecine familiale, des participants et des éducateurs aussi bien que la faisabilité et les taux de rétention du programme FLIP et des protocoles d'étude.
Résultats : Six (6) cliniques de médecine familiale ont participé; 59 patients ont été inscrits entre octobre 2012 et mars 2013. Le protocole d'essai a été acceptable pour les cliniques et les participants et a eu un taux de rétention des participants de 95 % au cours des 6 mois (56/59). L'observance de l'intervention a été élevée (97 %), soit 34 des 35 patients qui ont continué à recevoir les appels téléphoniques de l'éducateur durant 6 mois. Le coût moyen de l'intervention s'est élevé à 144 $ CA par personne.

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Comparativement aux témoins, les participants ont significativement réduit leur poids de 3,2 kg (IC à 95 %, 1,7 à 4,6), leur indice de masse corporelle de 1,2 (IC à 95 %, 0,7 à 1,7) et leur tour de taille de 3 cm (IC à 95 %, 0,3 à 5,7).

Conclusions : Il est possible de mettre en place la FLIP et de réaliser un essai pour évaluer l'efficacité. Un essai plus vaste associé à un suivi plus long pour évaluer la progression du diabète est justifié.

Introduction

Type 2 diabetes is an increasingly common chronic condition with a worldwide prevalence estimated to reach 439 million by 2030 (1). In Canada, the prevalence of diabetes will reach 3.7 million by 2018-2019. (2), with the greatest increase forecast to be amongst adults aged 30 to 49 years in Ontario, British Columbia, Saskatchewan and the Northwest Territories (2). The direct cost of diabetes care accounts for about 3.5% of public healthcare spending in Canada, and this is likely to rise (3). Diabetes predisposes people to cardiovascular, renal, neurologic and eye complications, reduces quality of life and accounts for more than 10% of deaths in Canadian adults (2). Those with impaired fasting glucose and/or impaired glucose tolerance, "prediabetes," are at higher risk for developing both diabetes and cardiovascular disease. Diabetes incidence in those with prediabetes is 66.1 /1000 person-years, with a hazard ratio of 2.35 (95% CI, 1.84 to 3.01) compared with individuals with normal glucose tolerance during a median 7.8-year follow up (4). Progression from prediabetes to diabetes can be reduced and sustained by comprehensive lifestyle interventions, showing a relative risk reduction of 65% (95% CI, 15% to 86%) up to 10 years postintervention (5). The evidence from efficacy trials of lifestyle interventions supports their translation into implementation trials and scaling up for widespread adaption within specific contexts (6). However, the high costs and context-specific nature of the programs present barriers to widespread dissemination and implementation (6,7).

The Facilitated Lifestyle Intervention Prescription (FLIP) is a low-cost program in primary care designed for those with prediabetes. We conducted a pilot study to obtain data concerning the feasibility of implementing FLIP to prevent progression from prediabetes to diabetes in Canadian primary care settings. We aimed to collect data to aid in study design, considering processes, resources, management and scientific reasons that would lead to a more definitive trial (8). This is translational research, implementing existing efficacy evidence into everyday primary care where evidence, to date, is sparse.

Methods

Design and setting

This was a community-based feasibility cluster, randomized controlled trial with the family practice as the unit of randomization. The cluster design was selected to prevent potential contamination of intervention between participants, because members of the same family or friends may be recruited into the study. Family practices, recruited from rural, urban and ethnically diverse communities across British Columbia, were randomly assigned (central number generator) to FLIP intervention or usual care. Family physicians were asked to recommend people suitable to be trained as lifestyle-change facilitators for their patients.

Study participants

Potential study participants were identified by family physicians using an algorithm in the electronic health record or opportunistically. The algorithm generated a list of adults (aged ≥18 years) who had glycated hemoglobin (A1C) in the range of 5.7% to 6.4%, and/or fasting blood glucose levels of 6.1 to 6.9 mmol/L, and/or 2-hour 75 g oral glucose tolerance test levels of 7.8 to 11.0 mmol/L within the past year, according to the American Diabetes Association definition for prediabetes at the time of study design. The study excluded subjects with type 1 or 2 diabetes, unstable angina, uncontrolled congestive heart failure, unstable arrhythmia, heart valve disease, severe hypertension (systolic ≥200 mm Hg or diastolic ≥120 mm Hg), pregnant women, those with life expectancy <1 year, those waiting for major surgery, and those at high risk for fracture. Recruitment letters were sent from the patients' family physicians to eligible patients, and follow-up telephone calls were made by study personnel.

Intervention and control treatments

The FLIP program was designed following a review of current evidence (5,9–23) and was informed by focus groups that included local family physicians. FLIP consisted of 3 elements: 1) lifestyle prescription; 2) a pedometer; and 3) support by a community-based facilitator for 6 months.

The lifestyle prescription comprised brief advice and a statement of intent to modify health behaviour, including long-term goals for healthy eating, weight and physical activity. The prescription was based on Canadian recommendations for healthy eating and activity (24,25). It was agreed upon, completed and signed by both the physicians and the participants, with copies for the patients, physicians and lifestyle change facilitators. The patients were also offered pedometers to use as an aid to increasing physical activity.

The lifestyle change facilitators contacted the participants by telephone within 10 days of their receiving the lifestyle prescription. Telephone calls, based on motivational interviewing techniques (26) were made twice per month for 6 months to aid the participants in forming, attaining and sustaining sequential short-term goals and were conducted according to the intervention manual developed by the research team.[1] Facilitators were trained for 1 week by the lead author prior to the study. Every call was tailored to the individual participants using the readiness for behaviour change model (27) to engage and evoke their motivations for change, clarify their strengths and aspirations and weekly successes, and promote autonomy of decision making. The subjects, supported by the facilitators, developed their plans, introducing changes in eating habits and engagement in both aerobic and resistance activity. Through attaining these short-term goals, it was anticipated that they would achieve the long-term healthy eating, weight and physical activity goals agreed upon in the prescription—the goals that conform to the Canadian recommendations (24,25).

Control participants received usual care from their family practice physician, consistent with Canadian Diabetes Association guidelines (28).

Outcomes

Indicators of feasibility included recruitment rates of family practices, participants and facilitators, as well as feasibility and retention rates in the FLIP program and study protocols. Costs of the program delivery were collected.

[1] Information about the manual is available from the lead author on request.