Quarterly individual outpatients lifestyle counseling after initial inpatients education on type 2 diabetes: The REDIA Prev-2 randomized controlled trial in Reunion Island

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Abstract

Aims. – This study aimed to describe the 1-year evolution of type 2 diabetes (T2D) patients who attended inpatients education, and to assess whether quarterly outpatients counseling visits by nurses and dietitians can improve metabolic control and health-related behaviours.

Methods. – Following in-hospital educational sessions, 398 adult T2D patients were randomized to either attend quarterly individual lifestyle counseling visits by a nurse and a dietitian (intervention group), or receive the usual care (control group). Primary (HbA1c) and secondary endpoints (fasting blood glucose, lipids, body mass index, waist circumference, fat mass, blood pressure, diet, physical activity) were assessed at baseline and at 12 months.

Results. – HbA1c changes from baseline to 12 months were −1.74 ± 2.64% (P < 0.0001) for the intervention group and −2.02 ± 2.57% (P < 0.0001) for the control group. There was no statistically significant difference between the intervention group (n = 153) and the controls (n = 166) for any of the clinical and biological outcomes. In both groups, total energy and fat intakes decreased significantly from baseline levels. Also, no difference was found between the groups for any dietary outcome. A slight enhancement in sports activity was observed in the intervention group, but the difference between the two groups did not reach statistical significance, and no difference was found concerning any other physical activity scores.

Conclusion. – In this study of adults with T2D, patients significantly improved their metabolic control, and dietary and exercise habits, 1 year after receiving intensive inpatients education, whereas subsequent quarterly outpatients counseling visits with nurses and dietitians have not demonstrated any superiority compared with the usual care.

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1. Introduction

The prevalence of type 2 diabetes is increasing worldwide [1]. Given the high burdens related to its complications, type 2 diabetes is a major public-health concern. Clinical trials have clearly demonstrated that better control of blood glucose levels and other risk factors is effective for preventing or retarding the complications of the disease. Patients have to deal with the four key elements contributing to effective management of the disease: dietary and eating habits; physical activity; therapeutic goals; and compliance with medical monitoring. Patients’ education should complement disease management by providing the knowledge and tools aimed at coping with the disease on a daily basis [2].

Reunion Island, a French overseas territory located in the Indian Ocean, is characterized by a high prevalence of type 2 diabetes (17.7% in those aged 30–69 years) [3], with huge human, social and economic costs. The overall prevalence is three- to fourfold higher than that in mainland France [4], and similar to that observed in the neighbouring island of Mauritius [5]. The REDIA (Reunion Diabetes) study showed that control of the disease was far from optimal, with a mean HbA1c of 8.4% with oral antidiabetic drug (OAD) treatment and 9% in insulin-treated patients [3], in spite of standard care comparable to that available in Europe. Reunion Island is composed of a multicultural population with a mix and crossbreeding of vastly different ethnic groups (African, Malagasy, Indian, Chinese and European). Also, almost 24% of the population lacks financial security. The social divisions are significantly wide, but this by no means prevents the expression of a “Creole identity” that is shared by the majority of the inhabitants of Reunion Island, particularly in terms of language, religion and cuisine. The result is a modern society characterized by both excess and deprivation [6]. In addition, data collected during the REDIA study revealed discrepancies between medical knowledge and patients’ perceptions of their illness [7].

Self-management education is known to be effective for improving clinical outcomes and quality of life at diabetes onset, as well as later over the course of the disease. For the majority of low-income patients, hospitalizations are more frequent and often represent their sole source of effective treatment and education. Well-trained teams in specialized units are able to deliver meaningful education to inpatients. However, individual sustained progress is critical for the long-term outcome, whereas little is known of the nature, type, amount and timing of patients’ support after the initial self-management programme [8,9]. The role and favourable impact of case management by specialized nurses and/or other health professionals have been underlined in some studies [9,10]. For this reason, we here describe the effect of quarterly individual type 2 diabetes outpatients lifestyle counseling visits by nurses and dietitians on HbA1c, metabolic control and health-related behaviours at 1 year after initial in-hospital education.

2. Research design and methods

2.1. Participants

Participants in the REDIA Prev-2 study were recruited from the two endocrinology departments of the Regional Hospital of Reunion Island (from August 2002 to December 2004). Men and non-pregnant women (≥ 18 years of age) with type 2 diabetes (defined as either non-insulin-requiring or insulin-treated, but with no insulin treatment within the first year of diagnosis), but with no contraindications to moderate physical activity (cardiopathy, uncontrolled high blood pressure, ischaemic or proliferative retinopathy, proteinuria, vegetative neuropathy and diabetic foot), were considered eligible for the study. Patients were invited to enter the study after having completed a course of inpatients education by an education nurse, a dietitian and an exercise physiologist (1 to 2 hours sessions, with two to six patients per session) dedicated to the following topics: understanding diabetes, blood glucose goals and issues; the five food groups; reduction of dietary fats; physical activity; and prevention of foot complications. The sessions combined interactive lectures and focus group discussions. Physical activity workshops were also organized (10 min of stretching and warm-up exercises, then a 30 to 40 minutes walk, followed by assessments of blood pressure, blood glucose and heart rate), as well as cooking workshops. Following their informed consent, the patients had their baseline measurements taken and completed questionnaires. Participants were randomized to either the intervention or control arm of the study before leaving hospital (stratification by centre, technical envelopes, balancing after every six patients). The Inserm Ethics Committee approved the whole of the research protocol.

2.2. Intervention

Quarterly outpatients counseling visits with a nurse, followed by an encounter with a dietitian, were scheduled at months 3, 6 and 9 in hospital for those in the intervention arm. A brief introductory educational recall of the dietary and physical
activity recommendations was followed by free discussion of the difficulties encountered in daily life in applying these recommendations, based on individual assessments, with culturally tailored goals set for personalized strategies to overcome barriers, and follow-ups including evaluation and problem-solving. The nurse assessed levels of physical activity, compliance with medication, and level of self-care for diabetic complications and management of daily stress. The dietitian assessed the patients’ eating patterns. Creole-speaking educators trained in counseling techniques gave individual assessments of the patient’s educational and other needs, and addressed the implementation of strategies for change. Postal and telephone reminders were used to maximize participation in the scheduled visits in the intervention group. In contrast, the controls were required to attend just one visit, 1 year after their initial hospitalization, for patients’ education. Both patient groups were asked to continue their standard medical follow-ups until the evaluation at 12 months. The response to the 12-month follow-up was optimized by the use of postal contact and up to three telephone reminders.

2.3. Outcomes

The primary endpoint was the change in HbA1c at 12 months (using high-performance liquid chromatography [HPLC]). Other outcomes of clinical and biological relevance were body mass index (BMI), waist circumference, fat mass, blood pressure, current treatment, diet and physical activity, fasting blood glucose and lipid profile (plasma total cholesterol, high-density lipoprotein [HDL] cholesterol and triglycerides). Each patient’s prescribed antidiabetic treatment was recorded at study inclusion and at 12 months, with categories of intensification defined as: no treatment or diet only; OADs without insulin; and insulin treatment. Waist circumference was measured in the standing position to the nearest cm at the level of the umbilicus. Fat mass was obtained with a bipedal impedancemetry device (TBF 310; Tanita, Neuilly-sur-Seine, France). Dietary changes were measured using a frequency questionnaire [11] adapted for the population of Reunion Island, and nutritional intakes were analyzed with GENI (v 6.5) software (Microsys Nancy). Regular physical activity was assessed using a questionnaire derived from Baecke et al. [12]. Professional and home physical activity scores were based on the arithmetical mean of five items dealing with the frequency of sitting, standing, walking, lifting heavy loads and sweating during activity (five-point scale score). In addition, for each sports activity reported, another score combining intensity (MJ/h), time spent each week (h/week) and perseverance (months/year) was calculated. The final sports score comprised the arithmetical mean of the sports scores and frequency of sweating during the sports activity (five-point scale score). A leisure physical activity score, using the same principles, was generated for walking, cycling and gardening.

2.4. Sample size

For the present study, the sample size was based on a 95% power to detect a minimum absolute difference of 0.85% in HbA1c with a 2% standard deviation (SD) and a two-sided
Data are means ± SD or number (%); HbA1c: glycated haemoglobin percentage; BMI: body mass index; BP: blood pressure; HDL: high-density lipoprotein.

3.2. Characteristics of participants at baseline

At baseline, the participants allocated to the intervention group did not differ from those allocated to the control group in terms of age, gender, literacy and employment. Similarly, diabetes duration did not differ in the intervention vs. control groups (9.0 vs. 9.6 years; \(P=0.29\)). However, at baseline, patients of the intervention group were twice as likely to be untreated for diabetes than those in the control group (12.6% vs. 6.2%; \(P=0.037\)).

As the rate of dropouts could be another outcome of interest, the baseline results for our study participants at 12 months are presented in Table 1; there were no significant differences in clinical and biological characteristics, except for triglycerides, which were higher in the controls. More patients of the intervention group were untreated or insulin-treated compared with patients in the control group, who were more likely to be using OADs (Table 1; \(P=0.022\)). Low literacy and employment rates were similar in the two groups.

3.3. Biomedical outcomes

Mean HbA1c decreased, from baseline to 12 months, from 10.0 ± 2.2% to 8.2 ± 1.6% (\(P<0.0001\)) in the intervention group, and from 10.3 ± 2.2% to 8.3 ± 1.5% (\(P<0.0001\)) in the control group. However, the mean changes in HbA1c value were not statistically different between the two groups (\(P=0.22\); Table 2). Also, mean changes in fasting blood glucose, and total and HDL cholesterol, were not statistically different between the two groups. Triglycerides increased by \(49 ± 347\) mg/dL in the intervention group and decreased by \(-43 ± 256\) mg/dL in the control group (\(P<0.03\), intervention vs. control), whereas BMI, waist circumference, fat mass and blood pressure mean changes did not differ between the two groups. At 12 months, 59.7% of the participants in the intervention group and 52.9%
Biomedical outcome differences (means ± SD) and comparisons between participants allocated to quarterly visits (intervention group) and to usual care (control group) in the REDIA Prev-2 study in Reunion Island (2002–2005).

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Differences (12 months minus baseline)</th>
<th>Interventions/control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Intervention group</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>146</td>
<td>–1.74 ± 2.64</td>
</tr>
<tr>
<td>Fasting blood glucose (mg/dL)</td>
<td>141</td>
<td>0.04 ± 0.85</td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>146</td>
<td>0.02 ± 0.44</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>146</td>
<td>0.49 ± 3.47</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dL)</td>
<td>135</td>
<td>0.07 ± 0.14</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>153</td>
<td>0.73 ± 1.77</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>144</td>
<td>1.73 ± 5.46</td>
</tr>
<tr>
<td>Fat mass (%)</td>
<td>147</td>
<td>0.85 ± 4.13</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>151</td>
<td>13.95 ± 20.62</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>150</td>
<td>7.04 ± 12.34</td>
</tr>
</tbody>
</table>

HDL: high-density lipoprotein.

in the control group were insulin-treated (not significant [NS]; P = 0.24). In addition, the proportion of patients with intensification of treatment was not significantly different between the intervention and control groups (OADs or insulin at 12 months in initially untreated patients: 94.5% vs. 83.3%, respectively; P = 0.27; insulin in initially OAD-treated patients: 45.0% vs. 37.9%, respectively; P = 0.39). Of the 92 (60.1%) participants in the intervention group and the 108 (65.1%) in the controls who kept to a non-intensified treatment, reductions of HbA1c were −1.39 ± 2.5% (P < 0.0001, 12 months vs. baseline) and −1.63 ± 2.47% (P < 0.0001, 12 months vs. baseline), respectively, and did not differ significantly between the two groups (P = 0.39).

On multivariate analysis, a between-group comparison of the mean HbA1c at 1 year was still not significant after controlling for the main prognostic factors (centre, age, gender, initial diabetes treatment, initial HbA1c level and triglycerides (data not shown).

3.4. Lifestyle outcomes

Over the 12-month study period, there were significant reductions in total energy intakes, energy percent values of protein and fat, and ratio of saturated-to-unsaturated fatty acids in both groups, although a comparison between the intervention and control groups did not show a significant difference (Table S1; see supplementary material associated with this article online). Likewise, although the declared amounts of oil and sugar bought by the participants’ families decreased in both groups, there was no significant difference between groups. Although sports activity increased significantly (P = 0.048) in the intervention group, the difference vs. the control group was not significant. For the other outcome measures, physical activity at 12 months did not differ from either baseline in both groups or between groups (Table 3).

4. Discussion

The present interventional study does not confirm the findings of previous studies highlighting the benefits of outpatients visits with trained staff (a nurse and/or a dietitian) as part of routine care in improving metabolic control and health-related behaviours after 1 year [13,14]. The statistical power of our study was adequate for comparisons of primary outcomes between groups. Patients in both groups similarly improved their glycaemic control, as evidenced by the mean HbA1c values achieved. There were also significant reductions in total energy intakes, in energy percent values of protein and fat, and in the ratio of saturated-to-unsaturated fatty acids. However, these changes were not statistically significantly different between the groups.

Previous studies have documented the effectiveness of self-management education for glycaemic control and lifestyle behaviours in type 2 diabetes [15–17]. Indeed, improvements in glycaemic control and other outcome variables were modest in diabetics undergoing comprehensive care, but better in poorly controlled diabetic patients at baseline. However, most of these studies looked at self-management education with interventions lasting from a few days to a year, with wide discrepancies in the amount of time spent with health professionals. Although hospitalization in diabetes units is a frequent mode of initial access to patients’ education [18], no previous studies have assessed the effects of monitoring patients’ support after the initial intensive inpatients education. In chronic illness, disease management has been highlighted as a cornerstone of the long-term maintenance of beneficial effects of care, especially in underserved populations [8,19]. For this reason, a quarterly lifestyle support system from nurses and dietitians was tested after an intensive in-hospital self-management course of education. As the organization and realization of such an individually based systematic intervention can be potentially time-consuming and costly, a demonstration of its value is required.

The present study has some limitations. In the intervention group, attendance rates were high: 91% of the patients who completed the study at 12 months attended two to three visits, while 71% attended all three visits. Overall, the dropout rate was 20%, which was less than the 30% oversampling of the study, thereby accommodating the potential attrition. However, the dropout rate was higher in the intervention group compared with the control group. When taking the dropouts into account, the actual
The attendance rate for the three visits was 54%, and 73% for at least two visits, in the intervention group. Thus, the low overall level of participation could have minimized the impact of the intervention and led the hospital staffs to question the feasibility of such counseling interventions. Nearly half of the participants dropped out before attending the first visit and half after one to two visits, but very few dropped out after three visits.

As for the participants who completed the 12-month follow-up, both groups remained comparable for baseline characteristics and covariates, except for categories of treatment and higher triglyceride levels. More participants at 12 months in the intervention group were insulin-treated patients at 1 year.

The effectiveness of self-management education is well recognized, but the long-term sustainability of the benefits, and the location, amount and timing of contact, and modalities and methods of interventions are still a subject of discussion. The likelihood of better maintenance of glycaemic control after sustained patients’ education has been well documented [2,23]. More important, the total contact time, timing of the contact and amount (‘dose’) of intervention have been found to be predictors of improved glycaemic control [16,22]. In our present study, the first counseling visit after the initial educational session took place at 3 months, which was probably too long, and the quarterly counseling visits in the intervention group lasted approximately 30 min each, with a maximum of 1–2 hours for the entire monitoring session, over a total time period of 9 months, which was most likely insufficient.

Although the focus on diet and physical exercise has been highlighted [23,24], other nurse- or dietitian-led interventions have yielded weak results across different settings [14,17]. In the study reported by Shibayama et al. [25], no beneficial effects on HbA1c, lipids and BMI were found after monthly one-on-one self-management visits with a nurse at 1 year.

Data are means ± SD.

Table 3

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Differences (12 months minus baseline)</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention group</td>
<td>Control group</td>
</tr>
<tr>
<td></td>
<td>n = 152</td>
<td>P</td>
</tr>
<tr>
<td>Physical activity scores*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work activities</td>
<td>−0.10 ± 1.43</td>
<td>0.57</td>
</tr>
<tr>
<td>Housework</td>
<td>0.05 ± 1.01</td>
<td>0.44</td>
</tr>
<tr>
<td>Leisure</td>
<td>0.12 ± 1.39</td>
<td>0.49</td>
</tr>
<tr>
<td>Sports</td>
<td>0.25 ± 1.37</td>
<td>0.048</td>
</tr>
<tr>
<td>Nutrient intakes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy (kcal/day)</td>
<td>−200 ± 591</td>
<td>0.014</td>
</tr>
<tr>
<td>% energy from carbohydrates</td>
<td>1.47 ± 9.15</td>
<td>0.14</td>
</tr>
<tr>
<td>Simple/complex carbohydrates ratio</td>
<td>0.01 ± 0.32</td>
<td>0.33</td>
</tr>
<tr>
<td>% energy from proteins</td>
<td>1.37 ± 5.34</td>
<td>0.002</td>
</tr>
<tr>
<td>% energy from fat</td>
<td>−2.83 ± 9.18</td>
<td>0.004</td>
</tr>
<tr>
<td>Saturated/unsaturated fats ratio</td>
<td>0.03 ± 0.19</td>
<td>0.042</td>
</tr>
<tr>
<td>Fibre content (g/day)</td>
<td>−0.15 ± 10.51</td>
<td>0.90</td>
</tr>
<tr>
<td>Sugar bought (kg/month per person)</td>
<td>−0.13 ± 0.55</td>
<td>0.0166</td>
</tr>
<tr>
<td>Oil bought (L/month per person)</td>
<td>−0.24 ± 0.91</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Data are means ± SD.
* 0=no change in physical activity; increased score (difference >0)=increased physical activity; decreased score (difference <0)=decreased physical activity.
interventions lasting more than 2 years have proved more effective in type 2 diabetes [26,27].

The lack of any differential effect of monitoring support on glycaemic control in the present study might be explained in part by the location of the intervention, as outpatients visits took place in hospitals after an initial intensive course. Monitoring education at a community level or closer to where patients live might have been more effective.

5. Conclusion

To more precisely explore the impact of hospitalization and inpatients education, the present REDIA Prev-2 study included a qualitative study combining semi-structured home interviews and ethnographic observations 6 to 12 weeks after discharge. The results have been reported elsewhere [28]. In brief, the findings demonstrated the complexities associated with changes in, and the acquisition of, sustained behaviours. Analysis of the networks of interdependence has revealed how knowledge imparted in hospital may or may not be capable of transforming, regulating or modifying the participants’ relationship with their disease. When patients leave the hospital unit, the extent to which the acquired knowledge and practices can be maintained depends mainly on the individual’s circumstances, social relationships and support systems. The multidimensional differences between the centralized hospital support team and the contextual features of each individual’s everyday social life are elements of paramount importance [29]. Recent studies have suggested the beneficial translation of educational intervention to primary care and community settings [14,22,30]. Theory-based group interventions that are socially and culturally appropriate should also be considered. In the present study, counseling visits took place in hospital, and were not sufficiently culturally tailored nor embedded in the individual and social contexts of the patients [28]. Education and training given on healthcare premises could perhaps be planned so as to take account of the characteristics of the recipients’ usual environments and the multiple aspects of the disease [22,31]. More integrated managed care needs to be considered for case-management strategies, including intensive individualized care combined with continuity of care, and in coordination with primary and specialized care [8,10,32].

A substantial body of evidence supports the contention that the long-term sustainability of the effects of patients’ education on individual practices and outcomes requires the specific adaptation of programmes that are yet to be defined. On its own, the planning of individual quarterly outpatients counseling and support visits by staff fail to add sufficient beneficial effects at 1 year to an initial course of education combined with in-hospital care. The timing and “dose” of educational activities, as well as the thorough integration of culturally and contextual disease management and self-management, need to be considered to achieve long-term success. Healthcare organizations are now working in Reunion, as in mainland France, to integrate multidisciplinary disease management with secondary specialized units associated with primary care and local facilities as part of a network of diabetes healthcare management [30].

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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Protocol Record RBM 01–23, type 2 Diabetes Secondary Prevention, has been reviewed and published on the ClinicalTrials.gov public site, identifier: NCT01207349.

Appendix A. Supplementary data


References


