

Educational programme for patients with type 2 diabetes at community health centres: What is the evidence?

Saviour Cilia

Abstract

With increasing prevalence of diabetes mellitus type 2, more patients will require intensive management with diet, exercise, oral hypoglycaemic medication, and insulin replacement therapy in the primary care setting. The true challenge of diabetes care is to help patients balance short- and long-term quality of life against the burden of daily intensive self-management. Many guidelines refer to patient diabetes education (PDE) as the way people are enabled to maintain glycaemic control and experience the best possible quality of life. PDE programmes are often offered on an ad hoc basis and are not ongoing, nor are they based on any proven educational or behavioural principles which limit their effectiveness. PDE interventions are very complex and it is difficult to identify the active ingredients with any precision.

Key words

Diabetes mellitus type 2; patient diabetes education; health outcomes; evidence-based knowledge

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Dr Cilia was born in Qormi. He attended Qormi primary school and subsequently received his secondary education at Vassalli Lyceum, Tal-Handaq. After completing his post secondary studies, in 1988 he entered University and graduated as doctor of medicine and surgery in 1993. He worked in various departments in St. Luke's hospital for the period 1993-1997, after which he got appointed as a general practitioner in the Department of Primary Health Care. Thereafter, he furthered his professional development, and obtained two post-graduate diplomas from the Irish College of General Practitioners. The first one (2002) was in Therapeutics, while the second one (2004) was in Preventive Medicine. In 2004 he started reading for a Masters in General Practice and graduated with distinction posthumously in 2007.

Dr Cilia was actively involved in promoting the specialty of general practice. He was the representative on the Medical Association of Malta (MAM) for health centre doctors, and was part of the council of the Malta College of Family Doctors.

This review article is being published posthumously following the tragic death of Dr. Saviour Cilia. The editorial board is publishing the paper as submitted by the author in the weeks prior to the tragedy.

Although most primary studies and systemic reviews have shown that PDE programmes produce statistically significant improvement in health outcomes, the exact mechanism of action is still not identified. Despite the limitation of available evidence-based knowledge, PDE programmes are still highly recommended by experts and guidelines due to their perceived indispensability for effective diabetes care

Introduction

The objective of this article is to explore the effectiveness of the presently available patient diabetes education (PDE) (also referred to as diabetes self-management education) interventions at community setting and to critically review scientific literature and international standards in order to form an evidence-based opinion. The clinical effectiveness and applicability of diabetes educational interventions for the local community setting is evaluated.

Type 2 diabetes mellitus is a progressive and life threatening disease with potentially devastating consequences for health, quality of life, and economic burden. It accounts for about 95% of all diabetic patients and is the most common chronic endocrine disorder, affecting an estimated 7-8% of the adult population in Malta.¹ The accompanying shift in life-style to more sedentary activity with higher fat, lower fibre diets and resultant obesity, may underlie the increasing prevalence of type 2 diabetes.² Despite increasingly stringent clinical guidelines for glycaemic control, over 60% of diabetic patients are not reaching recommended glycaemic goals and about 50% remains undiagnosed.³ With increasing prevalence of type 2 diabetes, more patients will require intensive management with diet, exercise, oral hypoglycaemic medication, and insulin replacement in primary care setting. The true challenge of diabetes care is to help patients balance short- and long-term quality of life against the burden of daily intensive self-management.⁴

The value of PDE in achieving this is evident from many research studies.⁵ Many guidelines refer to PDE as the way people are enabled to maintain glycaemic control and experience the best possible quality of life.^{6,7,8} This may be achieved through educational programmes focusing on general knowledge of diabetes, adherence to medication, lifestyle changes and, self-monitoring of blood glucose,⁹ in addition to empower and motivate people to use knowledge and practical skills in problem-solving and self-management.^{7,10,11} Although, PDE is

frequently hailed as the cornerstone of care for all individuals with diabetes,¹² PDE programmes are often offered on an *ad hoc* basis and are not ongoing, nor are they based on any proven educational or behavioural principles which limit their effectiveness.^{13,14}

Computerised databases were searched from January 1980 up to March 2006, including PubMed, Embase, PsycINFO, CINAHL, and ASSIA, ERIC, and Science Citation Index databases. The medical subject headings (MeSH) searched were *diabetes mellitus* and *diabetes education* combined with the following headings: *community, primary care, patient education, health education, self-care, self-management*. Text word searches were also performed. The initial literature search yielded 369 citations of articles related to PDE. Studies that satisfied the criteria described in Table 1 were selected for full evaluation (Figure 1).

Critical appraisal of primary clinical trials

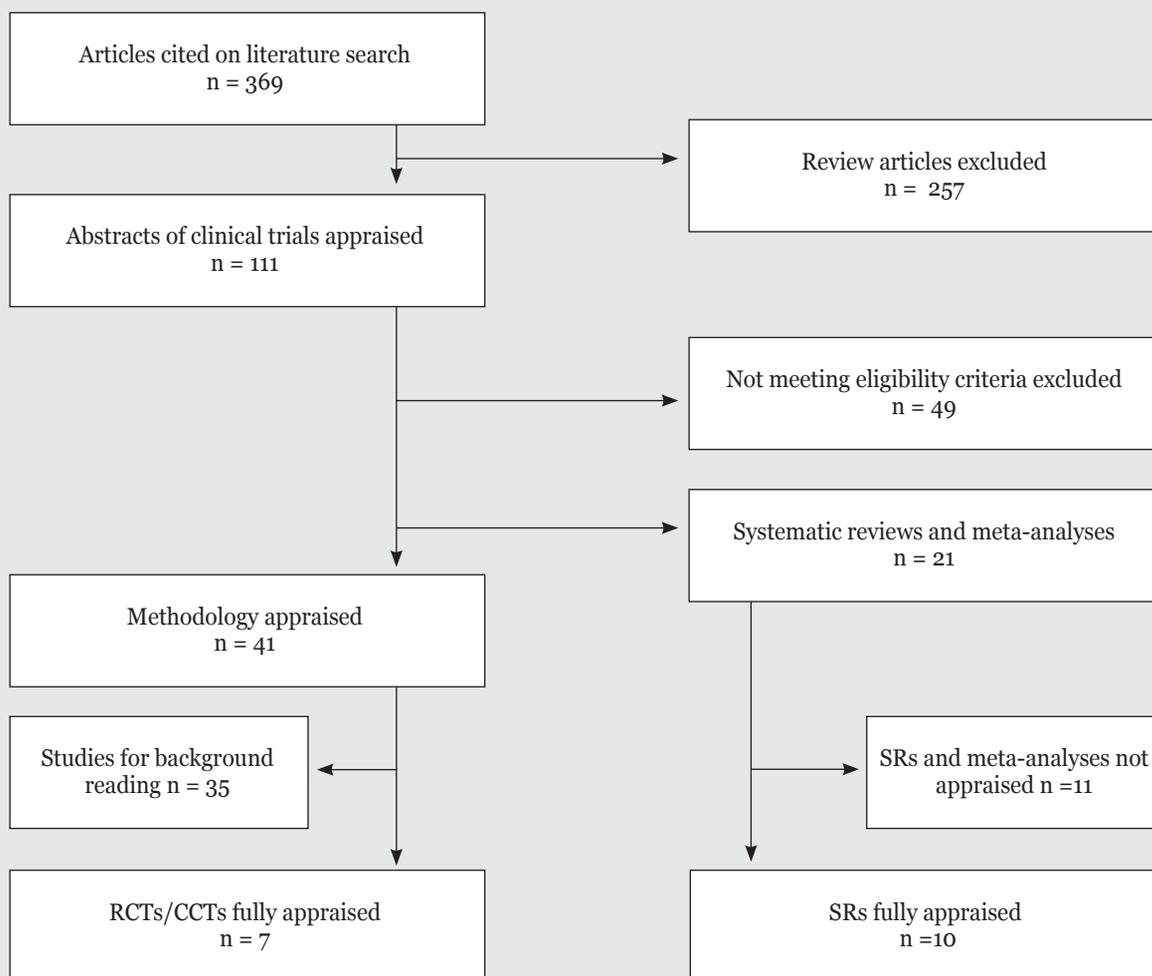
Seven trials were critically appraised, four randomised controlled trials (RCTs)¹⁵⁻¹⁸ and three clinical controlled trials (CCTs).¹⁹⁻²² The quality of reporting, methodology and statistical

analyses used by these studies were generally poor. The inclusion and exclusion criteria were well described by all seven trials. They were different in different trials, making comparison somewhat difficult. The method of randomisation and concealment of allocation was only reported in detail in two studies,^{15,17} in the rest it was not clearly described. The similarity of the baseline characteristics of the intervention group and control group was better achieved in some studies,^{15-17,19} than in others^{18,20,21}. Four studies provided adequate description of drop-outs¹⁵⁻¹⁹ while others gave only an incompletely description.^{16,20,21} In general, not all patients who entered the trials were properly accounted for and in studies with high attrition, this may cause interpretation bias.

Interventions

Five studies compared an intervention group with a usual care group.^{15-17,19,20} The other two studies compared education in more than two groups of patients.^{18,21} The topics covered in the interventions were similar and included: nutrition/diet, exercise/physical activity, weight reduction, and self-monitoring of blood/urine glucose. Unfortunately, the descriptions of

Figure 1: Flowchart of identified of primary and secondary studies



Randomised controlled trials = RCTs, Clinical controlled trials = CCTs, Systemic reviews = SRs

the interventions were often fairly limited and vague. Most of the studies did not mention that they were based on any particular theory of health or behaviour change. Campbell et al used cognitive-behavioural strategies,¹⁸ while Brown et al and Gilliland et al developed a culturally specific intervention.^{16,21}

Providers of the interventions varied but generally involved health care professionals such as dietitians, nutritionists, diabetes nurses, general practitioners, and community workers.

Table 1: Eligibility criteria

1. Type 2 diabetic patients (not including gestational diabetes),
2. Adults or over 18 years of age,
3. High quality studies (RCTs and CCTs),
4. Describe educational intervention,
5. Conducted in community setting,
6. Methodology described in detail and reproducible,
7. The duration of the study was for 12 months or more,
8. Outcome measures included HbA1c and/or quality of life assessment.
9. Full text article available

In the study by Brown et al, the intervention was given by a team of professionals¹⁶ in the rest the intervention was given by a single provider. There was considerable variation in the number of hours of contact and whether sessions were provided over a short interval or spaced out over time. The length of follow-up from inception varied from 12 to 18 months and was completed in all trials.

Findings and results of the studies

In general, the interventions had limited impact on outcomes. Statistical effect of education on diabetic control, as measured by HbA1c, was demonstrated in three major trials.^{15,16,17} There was little effect on weight loss, with only three studies reporting statistical difference,^{17,19,20} and no effect at all on lipids. Four studies reported reduced usage of oral hypoglycaemic agents in the intervention groups.^{15,19-21} Very few studies reported outcomes relating to diabetic complications.

Few studies included measures of quality of life or knowledge utilising validated instruments. Deakin et al and Kronsbein et al reported higher knowledge in intervention group.^{17,20} Only Deakin et al measured level of empowerment, quality of life

Table 2: Different measured outcomes in diabetes care

Intermediate outcomes	Short-term outcomes	Long-term outcomes
Knowledge	Glycemic control <ul style="list-style-type: none"> • Glycosylated haemoglobin • Blood glucose 	Macrovascular complications <ul style="list-style-type: none"> • Peripheral vascular disease • Coronary heart disease • Cerebrovascular disease
Skills <ul style="list-style-type: none"> • Problem-solving skills • Self-monitoring of blood glucose • Medication administration 	Physiologic outcomes <ul style="list-style-type: none"> • Weight • Lipid levels • Foot lesions • Blood pressure • Microalbuminuria • Retinopathy 	Microvascular complications <ul style="list-style-type: none"> • Decreased vision • Peripheral neuropathy • Renal disease • Periodontal disease • Foot lesions, amputations
Psychosocial outcomes <ul style="list-style-type: none"> • Self-efficacy • Health beliefs • Mood • Attitude • Coping skills • Self-assessed health status • Locus of control • Perceived barriers to adherence 	Lifestyle <ul style="list-style-type: none"> • Physical activity • Diet • Smoking 	Morbidity and mortality <i>Quality of life</i> <ul style="list-style-type: none"> • Disability/function
Healthcare system outcomes <ul style="list-style-type: none"> • Regular source of care • Regular visits • Availability of patient education • Medication adherence • Screening foot & eye exams • Monitoring of glycaemic control • Monitoring of CVD risk factors 	Mental health outcomes <ul style="list-style-type: none"> • Depression • Anxiety Work-related outcomes <ul style="list-style-type: none"> • Work days lost • Restricted duty days 	Economic outcomes <ul style="list-style-type: none"> • Outpatient utilization • Hospitalization rates • Cost-effectiveness • Cost-benefit Pregnancy outcomes <ul style="list-style-type: none"> • Neonatal morbidity • Neonatal mortality • Maternal morbidity

and psychosocial self-efficacy experienced utilising validated questionnaire and found significant difference.

Relevance, validity and generalisability

These findings have to be interpreted with great caution when one considers the poor methodological and analytical designs. The study sample size varied from 58 to 256. Sample size calculation and power calculation were only stated in three studies,^{15,17,20} making it impossible to decide on the precision and strength of the results of the studies. In all trials blinding of patients, educators and researchers was not achieved. Consequently, educator or researcher induced bias could not be excluded. Only three studies reported an analysis by intention to treat (ITT),¹⁵⁻¹⁷ while only one study mentioned the costs involved.¹⁶ Consequently the likely benefits, potential harms and costs cannot be estimated from these trials.

In many studies, the intervention had positive effects on each outcome considered, but few were statistically significant. It is impossible on the basis of the limited effects to determine which specific characteristics of PDE will reliably produce significant impacts on any of the reported outcomes. Because of the variations in interventions and their impacts and also the methodological and analytical limitations of these studies, no firm conclusions are possible about effective educational interventions that would have significant, long-lasting benefit on diabetes outcomes.

Critical appraisal of systematic reviews

Through the computerised literature search ten recent systematic reviews (SRs) dealing with PDE interventions in community setting were selected.²²⁻³¹ In general, the SRs were well conducted and followed rigorous methodology and data analyses as required by today's standards. These SRs searched a broad range of databases and, included mostly RCTs and CCTs that met minimum quality standards, although they focused

Table 3: Summary of current evidence on PDE from systematic reviews

1. PDE programmes within intensification of treatment in type 2 diabetes produced significant improvements in HbA1c.^{15, 21-24,27-30,34}
2. PDE programmes produced significant improvements in SPB;^{30,34} hence contributing to a reduction in microvascular and macro vascular complications.³⁵
3. PDE programmes are effective by reducing body weight.^{15,19,20,30}
4. PDE programmes are effective by reducing requirement for diabetes medication.^{19,20,30}
5. PDE programmes are effective by improving diabetes knowledge, lifestyle and psychosocial outcomes.^{18,20,30,41,42}
6. PDE programmes are effective by reducing health costs.^{26, 43}
7. Structured PDE programmes interventions cause no harm.¹⁵⁻³¹

mainly on studies reported in English language. Apart from type 2 diabetes in adults and HbA1c as primary outcome, they used different eligibility criteria. In particular, most did not impose any requirement for a long-term follow-up, and have focused on various outcomes (Table 2).

Results of systematic reviews

Different SRs have reported varying effectiveness of different outcomes. Seven SRs have found beneficial effects on HbA1c and some other outcomes.^{22-24,27-30} Norris et al have concluded that PDE is effective in the short term.²²⁻²⁴ Three SRs have concluded that there was no clear benefit from PDE.^{25,26,31} Corabian *et al.* stated that reliable conclusions could not be made as to types of programmes or components that are most effective in improving diabetes care outcomes.²⁵ All SRs reported that PDE interventions did not cause measurable harm.

Limitations of the systematic reviews

The SRs were limited by the quality and quantity of the primary studies cited. Most SRs consisted of a small number of trials, varying from 8 to 72, and small number of cumulative

Table 4: Recommendations from national and international guidelines⁴⁵⁻⁴⁸

Standard care

- Make education an integral part of the management of all people with Type 2 diabetes: from around the time of diagnosis, on an ongoing basis, based on annual assessment of need, and on request.
- Use trained multidisciplinary team to provide education to groups of people with diabetes, or individually if group work is considered unsuitable. Where desired, include a family member or friend.
- Include in education teams a health-care professional with specialist training in diabetes and delivery of education for people with diabetes.
- Ensure that education is accessible to all people with diabetes, taking account of culture, ethnicity, psychosocial, and disability issues, perhaps delivering education in the community or at a local diabetes centre, and in different languages.
- Use techniques of active learning adapted to personal choices and learning styles.
- Use modern communications technologies to advance the methods of delivery of diabetes education.

Comprehensive care

- This would be as for standard care but would also include the availability on demand of individual advice, through a named key contact.

Minimal care

- This would be as for standard care but education would be provided by an appropriately skilled individual rather than a team.
- Consider how available technologies can best be used to deliver education.

participants. Although only RCTs/CCTs have been included these were often described as either moderate or poor quality with limitations in methodology and data analyses due to heterogeneous population characteristics, settings, interventions, outcomes, and lengths of follow-up. Internal validity and reliability was frequently compromised by lack of blinding of the assessor, unfeasibility of blinding study subjects, high attrition, contamination of the control group, unintended co-interventions, lack of detail on allocation concealment, response-set bias, and deficits in the reliability and validity of the instruments used to measure outcomes.

The measurement of some educational components was imprecise and some factors contributing to glycaemic control may not have been properly assessed.³² In addition, most studies compare a more intensive intervention to usual care, as it is generally considered unethical to randomise a group to receive no education, thus minimizing measured effects of the intervention. Frequently, there was an inadequate description of study interventions and participants, including the representativeness of study populations. The behavioral theories and tools on which interventions were based were documented in only few studies. Data provided were insufficient to determine which behavioral theories and tools were most advantageous.³³ All these limitations have negative impact when interpreting the findings.

Some SRs did not carry out meta-analysis^{23,26,27,31} and in those who did significant heterogeneity between studies precluded meta-analysis on several of the main outcomes such as self-management skills, empowerment and quality of life.^{22,24,29,30} Hence p values, confidence intervals and ITT analysis were frequently not reported, thus further compromising the validity and relevance of the findings.

Only rarely, non-experimental study designs were considered. Nonetheless, non-experimental designs may reveal important information about the effectiveness of PDE interventions. RCTs/CCTs are not always feasible or desirable owing to the complexity and multifaceted nature of PDE interventions.

The study populations in the reviews were heterogeneous and may not truly represent the Maltese adult population with type 2 diabetes. The studies were carried out in different countries with lingual, cultural, and healthcare systems diversity. Participants tend to be a more committed and motivated subgroup and generally receive more attention when participating in a clinical trial. This may affect the generalisability of the results and if PDE programmes were provided as routine treatment to the general adult population may result in a bigger attrition and smaller effect sizes.³³

Conclusions

PDE interventions are very complex and it is difficult to identify the active ingredients with any precision. Therefore, although most reviews have shown that PDE programmes at community level produce statistically significant health

outcomes (Table 3), the exact mechanism of action is still not identified and their relevance and validity are still debatable. However, more recent systemic reviews have demonstrated that integrating theories of behaviour change into educational interventions (including psychosocial concepts such as patient-centered care, self-efficacy and empowerment) may help to strengthen the link between PDE and self-management in type 2 diabetic patients.^{29,30,31} Despite the limitation of available evidence-based knowledge, PDE programmes at primary care and community setting are still highly recommended by experts and are included in most guidelines (Table 4) due to their perceived indispensability for effective diabetes care.

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