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Review

Assessment of implementation fidelity in diabetes self-management education programs: A systematic review

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ABSTRACT

Objective: As diabetes requires extensive self-care, self-management education is widely recommended to enhance the effectiveness and reduce the costs of treatment. While a variety of diabetes self-management (DSM) programs are available, the conditions for their effective implementation are not well documented. This paper reviews the literature on implementation fidelity (IF), the degree to which programs are delivered as intended, as a factor influencing the effectiveness of diabetes education.
Methods: Medical, psychological and educational research databases were searched to identify published studies on diabetes education describing the implementation process. Studies detailing the intervention adherence/fidelity/integrity were included to assess the way key elements of IF were addressed.
Results: From an initial 418 abstracts, 20 published papers were retained for an in-depth analysis focusing on the components of IF. Intervention content was mainly assessed through observation, whereas intervention dose was more often assessed through self-report measures. Only one study addressed the relationship between IF and intervention effectiveness.
Conclusion: Despite the importance of IF to achieve program outcomes, IF of DSM programs remains largely under-investigated.
Practice implications: The results of this review suggest that reports on DSM education should systematically describe how the program was implemented. The impact of IF on program outcomes needs further investigation.

Contents

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1. Introduction

Diabetes mellitus (DM) is one of the most challenging health problems of our time. As one of the most common non-communicable diseases globally, it is the fourth or fifth leading cause of death in high-income countries, and is rapidly becoming epidemic in many developing and newly industrialized countries. In 2011, the number of persons suffering from diabetes was estimated at 366 million worldwide, almost 50% of whom are unaware of their condition [1]. By 2030 this number is expected to rise to 552 million. As treatment and complications are costly, diabetes care takes up between 5 and 15% of total health expenditure, depending on the country [2].

Of the three main types of DM (type 1 diabetes caused by the body's failure to produce insulin, afflicting mainly children and teens; type 2 diabetes resulting from insulin resistance related to aging, sedentary lifestyle, poor, diet, genetic influence, and obesity; and gestational diabetes occurring in pregnant women without a previous diagnosis of diabetes), type 2 diabetes is by far the most common, making up approximately 95% of all DM cases. Its prevalence is rising rapidly and is expected to increase in the coming years as a result of aging populations, increasing urbanization, obesity, dietary changes, reduced physical activity, and other unhealthy behaviors [3]. As early diagnosis and appropriate management of type 2 diabetes significantly increases the chances of preventing harmful and costly complications, the care for patients with this type of diabetes focuses strongly on the disease management, and especially on self-management by patients.

1.1. Diabetes self-management programs

Because diabetes requires extensive self-care, the capacities of patients to manage their own illness and care process are considered as a key determinant of treatment outcomes [4]. To enhance these capacities, education of diabetes patients is widely recommended and carried out [5]. Diabetes self-management (DSM) education is defined as the process of teaching persons with diabetes to manage their illness and treatment by providing them with the knowledge and skills that are needed to perform self-care behaviors, manage crises, and make lifestyle changes [6,7].

The above definition allows for a variety of educational approaches to DSM. Educational interventions range from brief instructions by physicians, nurses, or dieticians to more formal and comprehensive programs [6]. A meta-analysis by Brown [9] showed a significant shift in the types of education programs over time. In the 1960s and 1970s, DSM interventions were brief, individually oriented, and mostly delivered in the hospital setting by a nurse or a dietician. From 1980 onwards, more specific programs have been set up for diabetes patients and their relatives, whereby health care professionals with different disciplinary backgrounds educate patients in their own domain of expertise. In addition to individual education of patients, more cost-effective alternatives such as group-based education [10], information technology (IT)-based education [11] and self-help programs or support groups have been developed [12].

2. Implementation fidelity

The success of a diabetes education program not only depends on the strategy and methodology that is used, but also on the quality with which it is implemented. Given the demonstrated efficacy of existing strategies to improve glycemic control, increase physical activity and improve diet, the main public health challenge is not to find new efficacious treatments, but to implement the proven programs with consistency and efficiency [14].

A key element of the quality of implementation is its *fidelity*, or the degree to which the intervention is delivered as intended [15]. There are several reasons why implementation fidelity (IF) merits attention [16]. (a) Without information about the program delivery, the absence of significant effects may lead to a false attribution of the lack of an intervention's effectiveness to the shortcomings of the intervention itself, when it could have resulted from poor implementation. This phenomenon has been dubbed the "type III error" [17]. (b) Information about IF can help one understand *why* an intervention succeeded or failed. (c) Assessing IF can help to identify which components have been adapted to meet the specific needs of the health system and its patients, and how these adaptations influenced the outcomes. (d) Information on IF can help to assess the future feasibility of implementing the intervention, thus serving formative in addition to summative evaluation purposes.

There are different approaches to assess the IF [18]: (a) According to the *critical components approach*, a program is composed of several critical components, and the outcomes of the program depend on their presence or absence. To assess IF, researchers need to verify whether all the critical components have correctly been implemented. In this perspective, tools to assess IF look like a "fidelity index" that are very specific to a particular program [e.g. 19]. (b) The *structure and process approach* follows the logic of critical components and tries to characterize each component as "structure" or "process". Structural components can be related to resources and framework for service delivery, whereas procedural components can be related to roles and behaviors, or to the way in which services are delivered. According to this approach, IF depends on both the composition (structure) and the human interaction that occurs during the delivery (process) [e.g. 20]. (c) The *dimensional approach* considers IF as a multidimensional concept whereby each dimension can be assessed separately. Although certain dimensions such as adherence, exposure and quality are commonly mentioned [e.g. 21,22], other dimensions vary between authors. These three different approaches may lead to very different IF measurements. As such, the critical components approach makes it possible to assess very specific aspects of the intervention, whereas the dimensional approach may allow researchers to compare the IF of different kinds of interventions.

Of the various theoretical models proposed to consider IF, the model developed by Carroll et al. [15] is the most comprehensive [23]. This model has a dimensional approach but integrates the notion of critical components in one of its dimensions, notably the content of the intervention. The principal concept in this model is

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