

1     **The Diabetes Self-management educational programs and their integration in the usual care: a**  
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3     **systematic literature review**  
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7     **Abstract**  
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10    The increasing prevalence of type 2 diabetes has highlighted the importance of evidence-based  
11    guidelines for effective prevention, management and treatment. Diabetes self-management education  
12    (SME) produces positive effects on patient behaviours and health status. We analyzed the literature to  
13    identify (i) the level of integration between usual care and SME programs and (ii) any possible  
14    differences across them in terms of outcomes.  
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21    Searches were made on three databases - PubMed, Scopus and Web of Science - to identify relevant  
22    publications on diabetes SME to 2015, which also describe the provider of usual care. In total, 49  
23    studies met the inclusion criteria. We identified three levels of integration (high, medium and low)  
24    between usual care and SME programs based on the level of involvement of usual care professionals  
25    within the SME programs. In most cases, the primary care physician was responsible for the diabetes  
26    patients. Patient health behaviors and/or outcomes improve in most of the studies, independently from  
27    the level of integration. However, findings suggest that when patients/participants could perceive that  
28    usual care provider is highly involved in SME delivery, educational programs produced results that  
29    appear to be more positive.  
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43    **Keywords:** Self-management, education, diabetes, usual care, integration, systematic review  
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## Introduction

One of the public health challenges worldwide is diabetes mellitus (DM). It is the fifth leading cause of death in high-income countries, and rapidly becoming an epidemic in low and middle-income countries. The global number of adult people suffering from diabetes in 2014 was estimated at 422 million, and this number is expected to rise to 592 million by 2035, while 175 million people remain undiagnosed [1]. Diabetes care is expensive and the condition can lead to serious complications such as kidney failure, myocardial infarction, stroke, blindness and limb amputation [2]. It imposes a huge economic burden on national health care systems globally. [3]

Approximately 95% of people diagnosed with diabetes have type 2 DM [3], a condition characterized by beta cell dysfunction and insulin resistance. The epidemiological trend indicates that the prevalence of type 2 DM is expected to continue rising in the forthcoming years due to increasing urbanization, reduced physical activity, unhealthy behaviors, dietary changes, increasing obesity and aging populations [4]. However, available evidence indicates that early diagnosis and effective management could increase the chances of reversing this trend [5,6]. Among the management strategies, patient education programs are considered a significant component of treatments for type 2 diabetes to help prevent complications and reduce associated costs [7-11, 12] as well as an effective strategy in supporting patients [13-15].

SME is defined as a systematic intervention involving active patient participation in self-monitoring and/or decision making [16] and providing diabetic patients with the necessary knowledge and skills to perform self-care behaviors, manage crises, and make effective lifestyle changes [17].

Existing programs involve a variety of educational, psychological and behavioral interventions; and a combination of didactic, interactive and collaborative teaching methods tailored to patient's specific needs [18]. Education sessions range from brief instructions by lay leaders, physicians, dieticians or nurses to more formal and comprehensive programs [18]. Self-efficacy [19], which refers to an individual's confidence in his or her capacity to perform a particular behavior, has been considered an essential part of the strategic concept of SME.

1 Several empirical studies have demonstrated that diabetes SME programs have a beneficial effect on  
2 patients' health status, health behavior, and healthcare utilization, which subsequently produces cost  
3 reduction for treating diabetic patients [20-25]. Systematic reviews have also shown improvements in  
4 terms of outcomes such as better glycemic control, increased weight loss, increased knowledge,  
5 decreased blood pressure, improved dietary and exercise habits, and decreased need for diabetes  
6 medication [26,27]. A significant role on the effectiveness of SME is played by delivery mode [28-  
7 32], patient profile [20, 33, 34-40] and the quality of the SME implementation process [41].

8 Worldwide, SME programs for chronic patients are undertaken or supported by several voluntary  
9 health care agency, centers for disease control and prevention, clinic or primary care providers, health  
10 organizations, social (e.g. religious) and patients' organizations, etc. Over the years, policymakers,  
11 managers and professionals are putting attention to the SME topic, with a greater attempt to integrate  
12 self-management programs into health systems, as observed in some European Countries such as  
13 Germany, Denmark, [42]. However, in the past, several barriers to the integration of SME in the  
14 health systems were identified: 1) the clinicians' lack of engagement with the program and difficulties  
15 in recruitment, due to the feeling that patient education is not part of their work, 2) lack of available of  
16 trained professionals, 3) accountability for the quality of education provided, and 4) financial  
17 constraints [43].

### 43 **The aim of the study**

44 With this paper, we offer a systematic review of studies investigating the characteristics of the  
45 existing self-management education (SME) programs. The final aim of this work is to identify (a)  
46 who are the professionals providing the usual care of diabetes patients attending SME programs and  
47 the setting of usual care; (b) whether usual care and SME programs are integrated, (c) whether the  
48 patients' behaviors and outcomes vary according to the setting of care and the level of integration  
49 between usual care and SME programs. This work does not intend either to evaluate the effectiveness  
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1 of SME or to be a meta-analysis; it rather aims to describe the SME characteristics in relationship  
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3 with the level of integration of usual care provider within the SME programs.  
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## 10 **Methods**

11 We focused our analysis on studies evaluating the effectiveness of SME programs and dealing with  
12 type 2 diabetics, as SME programs are known to produce more positive effects on long-term  
13 complication risk features of this group of patients [16]. Four independent reviewers read abstracts  
14 and full papers, sharing common criteria for their selection; one of the fourth member checked the  
15 extraction and the inclusion to ensure consistency and accuracy of the work; any differences in  
16 opinion, regarding the papers' eligibility, were discussed and resolved by the reviewers during the  
17 reading process.  
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### 30 ***Study selection***

31 A four-step procedure of study identification and selection was followed in this review (Figure 1).  
32 Firstly, we conducted a primary search on three databases (Web of Science, PubMed and Scopus) to  
33 identify relevant peer-reviewed and quantitative English language publications to 2015 using the  
34 following search string: *(diabet\*) AND (patient\* OR person\* OR individual\*) AND (education\**  
35 *program\* OR education\* activ\* OR "self-management" program\* OR self-management program\*)*  
36 *AND (outcome\* OR benefit\* OR consequence\* OR effect\*) AND English*. The search identified a  
37 total of 3,620, however the total number of articles was reduced to 2,628 after deleting duplicated  
38 results.  
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50 Secondly, in order to identify eligible papers, we carefully read the titles and abstracts of these 2,628  
51 papers focusing on three main criteria: (a) paper population was composed by diabetic patients, (b)  
52 paper focuses on SME program, (c) paper reports SME outcomes. A paper had to meet all criteria in  
53 order to be included in the next stage of our review. Following this procedure, we excluded 2,038  
54 articles.  
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1 Thirdly, the remaining 590 articles were fully read and further inclusion criteria were considered:

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3 they must not be review/report/protocol articles; they had to

- 4 • exclusively refer to diabetes type 2;
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- 6 • not focus only on a topic of self-management;
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- 8 • report at least one outcomes of diabetes SME program among the more common and relevant
- 9 for diabetes SME ones (HbA1C, BMI; diet, physical activity, mental health, self-efficacy,
- 10 healthcare services' utilization);
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- 12 • specify the type of health professional providing usual care to diabetic patients.;
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- 14 • be peer-reviewed published papers;
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- 16 • not be review, report, protocol, validation studies, etc..
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24 After this third step, 541 articles were excluded. The reasons for exclusions were: lack of outcome  
25 assessment; not reporting any reference to the diabetes care provider or focusing on either type 1 or  
26 both type 1 and type 2; focusing on more than one chronic disease; no considering the intervention's  
27 impact on patients, focus on a single aspect of the self-management topics, etc.

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29 Finally, the remaining 49 articles were considered eligible for the review and analyzed. All of them  
30 focused on the effectiveness of SME programs for type 2 diabetes patients and reported information  
31 on the professionals involved in the usual care.  
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### 33 *Paper analysis*

34 For each eligible paper, the research team retrieved information on: sample size, study site (country),  
35 study design, intervention type (individual, group etc.), length of program, main outcomes, program  
36 leader (dietician, nurse, peer educator, physician etc.), setting of diabetes care (clinic, general medical  
37 practice, hospital etc.), diabetes care provider (general practitioner, specialist etc.) and their role in the  
38 SME program.  
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41 In our analysis, we only considered the following SME outcomes: glycated hemoglobin (HbA1c),  
42 body mass index (BMI), diet, physical activity, self-efficacy, mental health, health service utilization,  
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1 and reading of nutritional labels. The positive (+), neutral (=) or negative (-) effect of SME on each  
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3 outcome was reported.  
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5 We defined three levels of integration between usual care and SME programs by considering the  
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7 involvement of the provider of care in the delivery of SME programs. On the basis of the information  
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9 available into the papers, we grouped homogenous roles by considering lower the integration when  
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11 the usual care provider has a passive role and higher the integration when an active role of the usual  
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13 care provider is observed.  
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## 18 **Figure 1**

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## 25 **Results**

### 26 *Description of Studies*

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28 The sample size considered by the studies varied; the minimum was 20, whilst the maximum was  
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30 1,920 participants. Seventeen studies were conducted in the US; fifteen in Europe; fifteen in Asia  
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32 (Japan, Taiwan and Korea); two in South America (Argentina, Brazil). Seventeen articles were  
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34 randomized controlled trials. The remaining studies were: non-randomized controlled trials, single  
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36 group pre-and post-test designs, quasi experimental studies, single cohort time-series design,  
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38 retrospective case control, and clinically controlled trial. Details on study characteristics can be found  
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40 in Table 1, while a description of the study designs is reported in the note at the end of the manuscript.  
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## 47 **Table 1**

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### 54 *Self-Management Education Program*

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56 Most of the studies did not specify the name of the SME program evaluated. The well-known diabetes  
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58 SME interventions mentioned were the X-PERT and the DESMOND programs. Twenty of the SMEs  
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1 were group led, seven were both individually and group led, six were individually led, four were  
 2 delivered using other methods (telephone, mail and online); the remaining ones were a combination of  
 3 individual, group, and other methods. The programme leaders (educators) were all healthcare  
 4 professionals, with exception of nine of the studies where the educators were peer leaders. Nurses  
 5 were the most frequently mentioned program leaders, followed by a combination of nurses and  
 6 dietitians. Some studies had a comprehensive team (nurses, a physician, a physiotherapist, a lay  
 7 person and a nutritionist) approach to patient education. Duration of the interventions varied with the  
 8 shortest being 6 hours long, delivered between one and two days and the longest lasting over 2.5  
 9 years. Details for each study are reported in table 2.

## 21 **Table 2**

### 26 *Outcomes*

27 Table 3 displays results of the main outcomes of the 49 studies.

28 *Health status* – Forty-six studies reported on HbA1c levels. The majority of these studies showed that  
 29 diabetes SME programmes significantly reduced the latter. For instance, a study by Rickheim et al.  
 30 [62] revealed that the study participants' HbA1c levels decreased from  $8.5 \pm 1.8\%$  at baseline to  $6.5 \pm$   
 31  $0.8\%$  at 6 months ( $p < .001$ ). Twenty-one studies report on BMI outcomes. For example, Merakou et  
 32 al. [46] reported in their study that the study participants had a significant reduction in BMI,  $-0.7$   
 33  $(95\% \text{ CI: } -0.9, -0.1)$ , ( $P = .007$ ), while some studies showed no significant improvements in patients'  
 34 BMI. Mental health was measured in four studies, all indicating positive effects. As mental health,  
 35 Rickheim et al. [62] revealed that patients' mental health scores improved significantly (from  $51.1 \pm$   
 36  $8.8$  to  $54.3 \pm 8.3$ ,  $p < .01$ ) at six-month follow-up.

37 *Lifestyles* - Fourteen studies reported changes in physical activity. One [46] of these studies indicated  
 38 that patients' physical activity levels measured by pedometer increased by 1,266 steps per day ( $p =$   
 39  $0.043$ ), from baseline. Dietary outcomes were reported by twelve studies.

40 *Other outcomes* - Seven studies reported on self-efficacy. For instance, Pena- Purcecell et al. [53]  
 41 reported that the study intervention group had significantly higher self-efficacy scores (median  
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1 increase in scores of 27.5%) compared with the control group. Only three studies reported on health  
 2 service utilization; no significant reduction in healthcare use was indicated. One of the studies  
 3 assessed diabetes SME's effect on patients' habit of reading and using nutritional labels.  
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### 11 **Table 3**

#### 12 *Care Provider and care setting*

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 19 Most of the studies (15 out of the 49 studies) included participants who were receiving care from  
 20 primary care providers. Eighteen studies mentioned "physician"/"doctor" as patients' care providers  
 21 without specifying the types of physicians, the others reported general practitioners (GPs), specialists,  
 22 both diabetes nurses and GPs, clinic physicians, and both GPs and specialists as care providers. The  
 23 clinical care settings were mainly primary care, then hospitals, and community health centres or  
 24 community clinics, and combined settings (hospital and clinic, hospital and community health centre,  
 25 etc). Twelve studies did not indicate where participants were receiving care.  
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#### 37 *Integration of SME into usual care*

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 39 Table 4 describes the levels of integration between usual care and SME programs based on the role of  
 40 the providers of usual care into the educational programs. In details, providers defined or confirmed  
 41 patients' targets [45, 48, 81, 82], changed drugs prescriptions or diet [54, 60, 61, 80, 85, 86], gave  
 42 advice or preliminary contents [65, 83] (medium integration); followed the upgrades of patients  
 43 through periodical reports produced by programs' leaders [49, 51, 67, 70, 76, 78], were available on  
 44 the web for a consultation [55], was involved in preparing the program's materials [58] (medium  
 45 integration). In other studies, health professionals provided those delivering the educational programs  
 46 with patients' data [52, 64, 74, 75, 90] or referred patients to be enrolled in the program [46, 50, 56,  
 47 57, 59, 66, 68, 69, 71, 73-75, 78, 79, 84, 87-89] (low level of integration). Finally, nine studies do not  
 48 give this information [44, 47, 52, 62, 63].  
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### *Provider of Care, Integration “usual care-SME programs” and SME Outcomes*

As mentioned before, only a few papers clearly specify the profile (specialist, GPs, etc.) of the physician responsible for the patient’s usual care, while the setting of care is always clear, with exception of few studies that do not report this information.]. For this reason, hereinafter we concentrate our attention on the level of integration between usual care and SME provision.

Focusing on the evidence in terms of outcomes across the three levels of integration between usual care and SME programs, that we defined like the involvement of the usual care provider within the SME delivery process, we observed that HbA1c always significantly improves at all levels of integration, with the exception of four studies where the integration is low [50,52,74] and high [45]. When a high level of integration exists, more evidence of improvement in BMI [61,60, 65, 82, 83, 86] and physical activity [48, 61,60, 80, 83] were observed; more evidence of improvement in diet were reported by the studies describing low levels of integration [59, 64, 75, 79]. No variation in BMI was described in all of the level of integration [45,48,49,50]; no variation was also observed for physical activity outcomes at medium and low levels of integration [52, 58, 64].

#### **Table 4**

#### **Discussion**

Diabetes is a complex, chronic condition that requires both high quality clinical care and effective self-management. Different healthcare professionals within different settings of care are responsible for providing clinical care to patients with type 2 diabetes, and several SME programs are delivered to improve patients’ skills in self-managing diabetes symptoms and/or risk factors. However, usual care and SME programs should be integrated as parts of the same patient’s journey. This is overlooked in the studies that investigate the effectiveness of educational programs, nor is it properly considered in

1 the programs' design. Within our systematic review, we analyzed the literature in order to identify the  
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3 level of integration between care and SME programs by evaluating the involvement of usual care  
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5 providers within SME programs. Our findings aim to gain an understanding of whether the level of  
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7 integration determines any difference in terms of the effects of SME programs.  
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10 Generally, the outcomes of SME programs showed positive effects. 19 out of the 21 studies reported  
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12 positive effects on at least one of the outcome measures selected for this review. No study reported  
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14 that patients' conditions deteriorated after participating in the SME programs. 10 studies reported that  
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16 the effects of the SME programs on at least one outcome measure were not statistically significant.  
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18 Our findings therefore support the literature in that diabetes SME programs produce beneficial effects  
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20 on patients' behaviors and outcomes [20- 27].  
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23 Our review identifies several settings of usual care (primary care practices, hospitals, community  
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25 centers) with a high prevalence of participants assisted by a primary care professional. These findings  
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27 confirm the literature in that most diabetic patients are followed by primary care physicians [94] and  
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29 that most of the educational interventions are delivered in a primary care setting [95]. Additionally,  
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31 primary care is the setting with the largest evidence as regards the positive impact of SME on HbA<sub>1c</sub>,  
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33 BMI and physical activity, whereas quality of diet seems to improve when usual care is delivered by a  
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35 professional of a community health center.  
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38 We also observed three levels of integration between usual care and SME programs, depending on to  
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40 what extent usual care professionals were involved within the SME programs. There are providers of  
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42 usual care (i) who are actively involved in the definition of the SME goals or change prescriptions  
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44 accordingly to the SME results (high level); (ii) who have a passive role in promoting new  
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46 behaviors/lifestyle (medium level); and (iii) who are simply informed on the participation of their  
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48 patients in the educational programs (low level).  
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51 Analyzing the effectiveness of the reviewed studies through this classification, we observed that the  
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53 health and behaviors of SME participants improve in most of the studies, independently from the level  
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55 of integration – i.e. there is no evidence of variation in participants' health and behaviors across the  
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57 three levels.  
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1 However, we also observed that at the high and medium level of integration studies reported  
2 improvements for all measured outcomes when patients/participants can perceive the involvement of  
3 the care providers in SME delivery. It surely is the case of providers who change prescriptions  
4 accordingly to the SME results [54,60,61] or who followed patients' improvements during the SME  
5 delivery [51]. The involvement of the usual care provider in the delivery of SME programs can  
6 produce continuity as regards assistance (team based continuity) and the information provided  
7 (informational continuity). This makes patients more confident and willing to modify their behaviors.  
8 Indeed, it was observed that a good relationship between care providers and diabetic patients  
9 promotes healthy behaviors [95]. Additionally, in some cases the SME programs aim specifically at  
10 improving that relationship, with a focus on the communication process (e.g. CDSMP). In a study of  
11 752 diabetic patients, effective patient-provider communication was associated with healthier self-  
12 reported behaviors such as physical activity, foot care, and dietary adherence [96]. Another factor that  
13 could account for these differences might be the degree of collaboration that exists between the care  
14 providers and the self-management educators. Pearson et al., 2007 [97] observed that those SME  
15 programs that foster effective collaboration between patients' care providers and self-management  
16 educators report better outcomes. Unfortunately, the lack of detailed information about care providers  
17 and their role in the studies prevented us from establishing which education programs fostered  
18 effective collaboration between diabetes care providers and patients, and between care providers and  
19 program instructors. In fact, in our review only a few articles reported whether educators were  
20 members of the usual care team [44, 63].

21 There are some limitations in this systematic review. First, the quality of each study was not  
22 systematically assessed and rated for all the studies, due to the wide heterogeneity of the research  
23 designs applied by the authors. Indeed, there is not a unique protocol to homogeneously evaluate  
24 them. However, we observed differences into the use sample dimension, the recruitment procedure  
25 and patients inclusion criteria. Furthermore, also the programs are different each other: we selected  
26 only papers that approach the typical topic of the SME program (health, diet, physical activity,  
27 diabetes, etc.), excluding the programs focusing on a single topic (e.g. foot, cardiovascular disease  
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1 risk, etc.). Differences refer also to the mode of administration and to the length of the education  
2 intervention. The readers have to consider all these elements when focus their attention on the SME  
3 outcomes. Second, information on the provider's involvement within SME delivery is often missing,  
4 therefore the phenomena of integration between usual care and SME programs might have been  
5 underestimated. Finally, this work is not a meta-analysis: we did not evaluate the summative effect by  
6 each level of integration, nor we can conclude that the improvement in health and behaviors varies  
7 across the three levels and to what extent.  
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## 21 **Conclusion**

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25 The findings of our review show that scholars give little attention to the integration between usual  
26 care and SME programs' delivery in their studies, even if education is considered part of the diabetic  
27 patient's journey as much as usual care [15]. Among the few articles that report who is the  
28 professional in charge of the patient's usual care and his/her role in the SME delivery, we observed  
29 slight differences in terms of evidence on the effectiveness of SME programs by the settings of care  
30 and by the level of integration between SME programs and usual care. Nevertheless, there appear that  
31 when patients/participants can perceive the usual care provider's involvement into the SME delivery,  
32 the SME programs produce improvements for all the behaviors and health indicators monitored.  
33 Hence, even if SME is rightly considered a component of patient journey, this review does not  
34 provide enough evidence to argue that the setting of care and the involvement of the provider of usual  
35 care play an effective role on behaviors and outcomes.  
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50 However, the findings can support the policymakers into an early evaluation process of the level of  
51 implementation of self-management education interventions within the chronic management  
52 programs. Indeed, most of the structured chronic management models, e.g. the Chronic Care model,  
53 promote the adoption of educational actions to activate chronic patients and their families.  
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1 Furthermore, the lack of evidence on these topics should stimulate professionals and scholars to carry  
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3 out more studies and produce data for evidence-based debates in their communities about to what  
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5 extent the professionals who are responsible for the patients' care should be involved the SME  
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23 Note: Definitions from Cochrane Glossary (<http://community.cochrane.org/glossary#letter-2>)  
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26 Randomized controlled trials: “An experiment in which two or more interventions, possibly including  
27 a control intervention or no intervention, are compared by being randomly allocated to participants. In  
28 most trials one intervention is assigned to each individual but sometimes assignment is to defined  
29 groups of individuals (for example, in a household) or interventions are assigned within individuals  
30 (for example, in different orders or to different parts of the body).”  
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34 non- randomized studies: “Any quantitative study estimating the effectiveness of an intervention  
35 (harm or benefit) that does not use randomisation to allocate units to comparison groups (including  
36 studies where ‘allocation’ occurs in the course of usual treatment decisions or peoples’ choices, i.e.  
37 studies usually called ‘observational’). To avoid ambiguity, the term should be substantiated using a  
38 description of the type of question being addressed. For example, a 'non-randomised intervention  
39 study' is typically a comparative study of an experimental intervention against some control  
40 intervention (or no intervention) that is not a randomised controlled trial. There are many possible  
41 types of non-randomised intervention study, including cohort studies, case-control studies, controlled  
42 before-and-after studies, interrupted-time-series studies and controlled trials that do not use  
43 appropriate randomisation strategies (sometimes called quasi-randomised studies).”  
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48 cohort studies: An observational study in which a defined group of people (the cohort) is followed  
49 over time. The outcomes of people in subsets of this cohort are compared, to examine people who  
50 were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor  
51 of interest. A prospective cohort study assembles participants and follows them into the future. A  
52 retrospective (or historical) cohort study identifies subjects from past records and follows them from  
53 the time of those records to the present. Because subjects are not allocated by the investigator to  
54 different interventions or other exposures, adjusted analysis is usually required to minimise the  
55 influence of other factors (confounders).  
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59 retrospective studies: “A study in which the outcomes have occurred to the participants before the  
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1 study commenced. Case-control studies are usually retrospective, cohort studies sometimes are,  
2 randomised controlled trials never are.”  
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4 clinical trials: “An experiment to compare the effects of two or more healthcare interventions. Clinical  
5 trial is an umbrella term for a variety of designs of healthcare trials, including uncontrolled trials,  
6 controlled trials, and randomized controlled trials.”  
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