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13

Development of a Diabetes Self-Management Outcome Framework (DSMOF) for the Diabetes Literacy Project

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Development of a Diabetes Self-Management Outcome Framework (DSMOF) for the Diabetes Literacy Project.

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Content

1. Introduction

Diabetes is one of the most common non-communicable diseases (NCDs). According to the newest data of the IDF´s DIABETES ATLAS (Whiting, Guariguata et al. 2013) there are almost 32 million diabetes cases (in the adult population between 20 and 79 years of age) in the European Union of which almost 50% are undiagnosed. Another 37 million EU citizens have impaired glucose tolerance (IGT) a form of pre-diabetes. Diabetes and diabetes related conditions can impose severe health risks. In 2012 almost 272 000 people died EU wide from diabetes related causes. Diabetes is also of economic importance, since throughout the EU the diabetes related expenditures amounted in 2012 to more than 82 Billion Euros (Calculated from IDF estimates on expenditures per person with diabetes and number of diabetes cases for every EU country which amounted to 118.2 Billion Dollars).

The American Diabetes Association (2013) regards diabetes mellitus (type II)as a chronic illness that requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications. Diabetes education programs and diabetes self-management programs (DSM) are global standards for optimal diabetes care (see for example the IDF clinical guideline on Type 2 diabetes: http://www.idf.org/sites/default/files/IDF-Guideline-for-Type-2-Diabetes.pdf, accessed: 02.08.2013) and other chronic conditions (Pruitt, Annandale et al. 2002), and are therefore the focus of this research.

Although there is evidence that DSM interventions have beneficial effects on patients glycemic control (net HBA1C reduction of 0.32) (Ellis, Speroff et al. 2004) the field has not been extensively researched. There is only sparse knowledge about the specific elements and conditions that make DSM programs especially effective, or whether they are equally effective across sub-populations.

Some of these unknowns could be filled through evaluation research of the comparative effectiveness of different DSM programs. This is a primary goal of the Diabetes Literacy Project, an EU and nationally funded FP7 (Seventh Framework programme) project that aims for a better understanding of diabetes self-management for diabetes type II patients.

The Diabetes Literacy Project has a number of ambitious targets. One target is to evaluate diabetes self-management programs in various countries with regard to their (cost-) effectiveness. This will be accomplished by a pre-post evaluation study of four different kinds of DSM programs for diabetes type II patients, which differ by their channels of communication (mode of deliverance). Of particular interest are programs with (1)

individual education in one-on-one sessions, (2) group based education, (3) self-help groups and (4) IT/web-based educations.

The development of a comparative effectiveness study is a task of the Diabetes Literacy Project´s work package (WP) 5 (led by Ludwig Boltzmann Institute Health Promotion Research LBIHPR). The primary research question is: Are some channels for diabetes Type II patient self-management interventions more effective than others?

This working paper documents the first step in answering the primary research question: The development of an outcome framework for the Diabetes Literacy project.

After an initial systematic metaliterature search in PUBMED and an assessment of the retrieved literature, WP5 research team concluded that existing studies and reviews could not provide the necessary information to consistently answer the question if some interventions are more effective than others. Different studies in the field use a plethora of psychological-, social-, behavioral-, clinical- and wellbeing-outcomes. This in fact reveals not only the field´s complexity but the many different perspectives on what may or may not be regarded as desirable outcomes of DSM interventions.

In order to deal with the different kinds of DSM outcomes, WP5 research team (Ludwig Boltzmann Institute Health Promotion Research) initiated an in-depth investigation of outcomes used in the DSM literature, with the aim to develop a DSM outcome framework (DSMOF) for the Diabetes Literacy Project. This framework or map was a necessary condition for the Diabetes Literacy Project to develop rationales on how to deal, not only with questions about program comparability, but also for developing an empirical research instrument and study design.

2. Background: Disease Self-Management (DSM) Outcomes: the American Association of Diabetes Educators (AADE) Framework

Disease Self-Management (DSM) outcomes themselves are not a new research area. The most prominent endeavor to further develop the field was started as early as in 1997 by the AADE (American Association of Diabetes Educators). An AADE working group began to systematize DSM outcomes and, in this way, started to develop a DSM outcome framework (Tomky, Weaver et al. 2000). After a year-long process the "comprehensive framework for DSM outcomes" (Mulcahy, Maryniuk et al. 2003) was developed with seven (AADE7) self-care behaviors at its core (American Association of Diabetes Educators, 2008).

The AADE outcome framework is essentially an attempt to order possible DSM outcomes according to when they are measurable. The rationale is that outcomes that can be evaluated immediately (at the time of intervention), for example, acquired knowledge, constitute the first outcome category (reasonably labelled as immediate outcomes). The other outcome categories (intermediate and post-intermediate) result over time and comprise behavioral (in the intermediate category) and clinical (in the post-intermediate category) measures. Finally, the last category (long-term outcomes) comprises outcomes such as quality of life and health status improvement. Implicitly, the AADE outcome framework incorporates some causal assumptions where the first category leads to the second, the second to the third and so forth. The assumptions also include feedback mechanisms. Therefore, the AADE outcome framework connects DSM outcomes using a circular model.

The core of the AADE outcome framework is the AADE7. Seven behavioral categories (intermediate outcomes in the AADE framework) are considered as the primary outcomes of DSM education (American Association of Diabetes Educators, 2008). The categories are healthy eating (Povey, Clark-Carter, 2007), being active (Kavookjian, Elswick et al. 2007), monitoring (of blood glucose) (McAndrew, Schneider et al. 2007), taking medication (Odegard, Capoccia, 2007), problem solving (Hill-Briggs, Gemmell, 2007) (e.g. addressing barriers for DSM), reducing risks (of complications)(Boren, Gunlock et al. 2007) and healthy coping (Fisher, Thorpe et al. 2007) (e.g. reduction of general and diabetes related distress).

3. Adapting the American Association of Diabetes Educators (AADE) Framework for the Diabetes Literacy Project.

The AADE framework (see: Figure 1) focuses with the AADE7 behaviors on the axiom that behavior change is the core outcome of DSM programs or interventions. (American Association of Diabetes Educators, 2008) Consequently, the framework is most useful when systematizing DSM behaviors, in the intermediate category, using the seven subcategories of the AADE7 behaviors. This well elaborated part of the framework was adapted to the Diabetes Self-Management Outcome System (DSMOF) of the Diabetes Literacy Project without changes.

The other categories in the framework however are not as distinctive and less useful in ordering the many non-behavioral outcomes that are as well reported in evaluations of diabetes specific or general disease self-management programs or interventions.

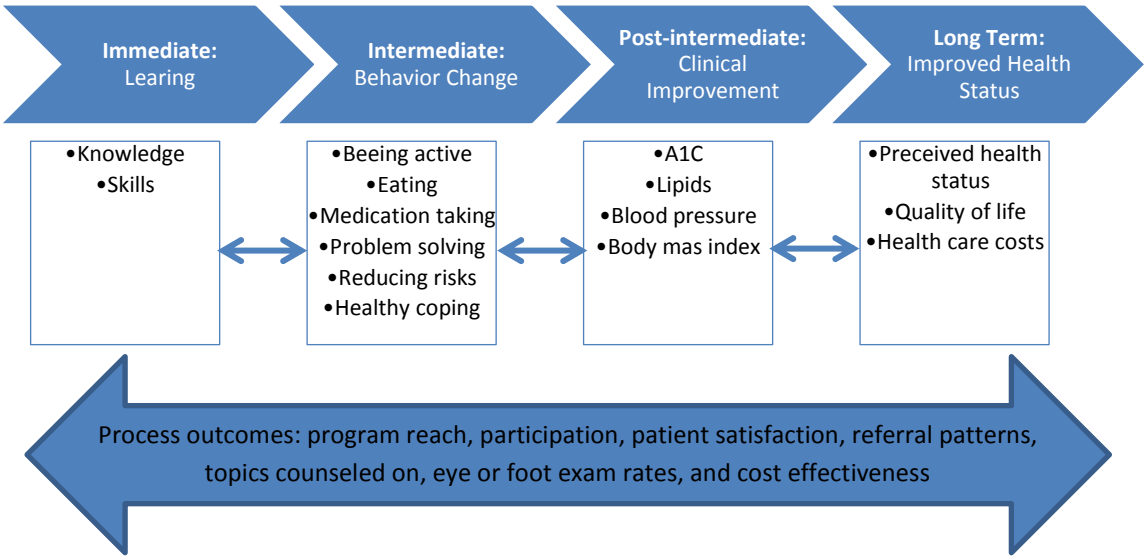


Figure 1: Diabetes self-management education (DSME) outcome continuum. Source: Adapted from AADE Position Statement: AADE7™ Self-Care Behaviors, 2008,

4. The Logic of the Diabetes Self-Management Outcome Framework (DSMOF) for the Diabetes Literacy Project

The primary target of the development of DSMO –framework (based on the AADE framework; see chapter 3) is to enable further research in the Diabetes Literacy Project, mainly a comparative pre-post evaluation study on DSM programs. DSM interventions are complex, in the sense that they are composed of multiple components. (Hawe, Shiell et al. 2004). The main issue in effectiveness trials of complex intervention is the question of comparability. A possible way to compare interventions is to standardize the form (the components) of interventions (Hawe, Shiell et al., 2004) (e.g. sites distribute the same written patient information kit). Since this is not always possible in complex interventions Hawe et al. proposed the standardization of 'functions', as an alternative way to make interventions comparable. (Hawe, Shiell et al., 2004) (e.g. all sites devise ways to distribute information tailored to local literacy, language, culture, and learning styles). The 'function' of DSM programs are the strategies and mechanisms which directly influence individual dispositions and are reflected in the DSMO framework as Outcome I.

In the DSM context, comparing programs according to their impact on behavioral and disease/health outcomes, respectively, is an additional strategy that is frequently realized, for example in systematic literature reviews (see reviews below). Together there are therefore 4 elements of program standardization that can be applied in a comparative trial of DSM programs are:

1) Program form (e.g. program context, program characteristics, etc.),
2) Outcome I (e.g. increased diabetes knowledge, improved DSM skills, etc.),
3) Outcome II (e.g. behaviors like healthy eating, taking medication, etc.)
4) Outcome III (e.g. health related quality of life, etc.) (see Figure 2, below).

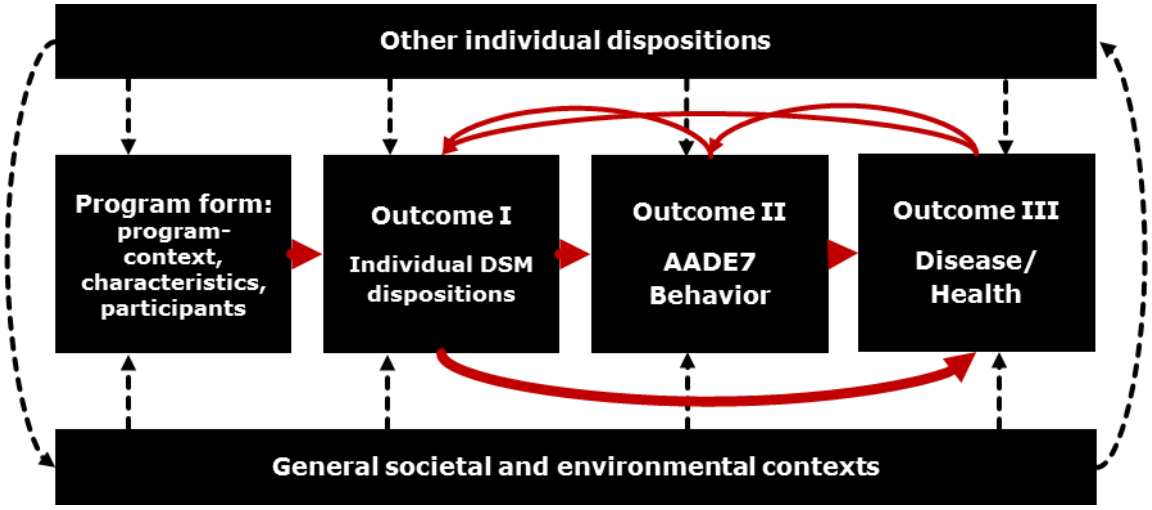
Outcome II and Outcome III comprise outcomes of health behavior and disease/health outcomes. _Since these are the outcomes of interest in the Diabetes Literacy Project, they will be evaluated in the planned study. The program form and Outcome I elements on the other hand are used first to identify comparable DSM interventions.

Program form is elaborated with program context, program characteristics and characteristics of program participants. Outcome I comprises outcomes that are closely related to the programs' 'function', meaning, the mechanisms through which diabetes patients are to be empowered for managing their condition. The other outcome elements elaborate on specific DSM behaviors, or disease specific and general health outcomes of the program.

Together, the four main elements are a map of DSM programs and outcomes. The four elements connected sequentially represent a basic cause and effect model. Diabetes patients attend DSM programs of a distinct form and function to change individual DSM

dispositions. This then leads to behavior changes that in turn produce health outcomes. By adding further connections between the main elements it is possible to depict, more complex cause-effect conditions, since DSM programs, may also produce behavior or health outcomes through processes that are not captured by a simple linear cause-effect model. This is especially true when programs are set up over long time spans and feedback loops can be an issue (see red arrows in Figure 2). Furthermore, health behavior is not only dependent on DSM interventions, but also on more general behavior affecting conditions. The general societal and environmental contexts, as well as other individual dispositions, may play a role in influencing all four main elements of the DSMOF and are therefore as well reflected in the framework.

Figure 2: The logic of the diabetes self-management outcome framework (DSMOF)



5. Diabetes Self-Management Outcome Framework (DSMOF) Element Program Form:

The sub-categories and dimensions of the program form main element were identified in DSM literature or reflect the specific demands of the Diabetes Literacy Project. These sub-categories and dimensions represent a list of important properties that are not exhaustive for all applications and can be further adapted and extended.

1. Sub-category program contexts: Deakin et al. (Deakin, McShane et al. 2005) propose to identify the (1) program care context and use in their review the primary-, secondary-care notion to identify comparable and incomparable program contexts.. Secondary-care contexts however can be further specified for (2) in- and outpatients. Since cross-contamination of parallel interventions is an issue in comparative studies, situations where (3) parallel DSM programs might influence outcome measures, should be identified.
2. Sub-category program properties: Specifically for the Diabetes Literacy Project, the most important program property that needs to be considered is the communication channel (one-on-one sessions, group sessions, IT, self-help). Other properties are: (1) Disease specificity of a program. (e.g., is it exclusively set up for diabetes participants or are different chronic conditions addressed? (Deakin, McShane et al., 2005). (2) Program intensity (number of sessions, length of sessions) (Norris, Engelgau et al. 2001a). (3) Timing of the program with regard to the initial diabetes diagnosis in order to control for time related cross-contamination, (e.g. an earlier program exerts effects) and 4) Skills and readiness of the clinician(s). This will be substituted by asking individuals if they have already attended another DSM program.

3. Sub-category characteristics of program participants: (1) specific target groups (Deakin, McShane et al., 2005): Are patients themselves addressed, or patients and their peers, or peers only? (2) Specific age groups: Is the program tailored for a specific age group? (3) Specific gender group: Is the program exclusively for men or women? (4) Specific needs group: Is the program specifically tailored for special needs like geriatric patients or for participants with depression, or from a particular ethnic background?

6. Diabetes Self-Management Outcome Framework (DSMOF) Element Outcome I : Individual DSM Dispositions

This element comprises strategies that are related to the change processes of individuals that frequently are preliminary to behavior change outcomes. It is informed by behavioral change models and theories that concern themselves with the factors (and the relation between those factors) that precede behavioral changes in individuals.

Whitehead states in his review the most important behavioral change theories and models in the health sector (Whitehead, 2001) are terms like knowledge, attitudes, beliefs and values and refers to the concepts of self-efficacy, self-attribution, self-evaluation, locus of control, social norms, cost-benefit analysis, perception of effectiveness/value of interventions and perception of risk and severity of disease. Together with the Integrated Change Model (Vries, Mesters et al. 2005) from Vries et al., these concepts and theories provide a multitude of possibilities for diabetes educators to empower their clients to change their health and disease management behavior. For the DSMOF seven individual dispositions have been formulated as sub-categories that cover most of the concepts used in behavioral change theories and models:

1. Increase diabetes specific self-efficacy and locus of control;
2. Increase diabetes knowledge;
3. Change attitudes and beliefs towards diabetes;
4. Raise diabetes awareness;
5. Increase perceived social support/desirability of DSM behaviors;
6. Enhance self-reflection on DSM behaviors and
7. Improve DSM skills.

While these empowerment strategies seem exhaustive, there is no guarantee of their completeness. Hence the DSMOF needs to be understood as a flexible tool that can, in the light of new literature or empirical research, be further adapted, extended and changed. The seven patient empowerment strategies of the DSMOF have been successfully used to classify patient empowerment strategies. These strategies have been reported in the 14 systematic literature reviews on DSM that have been completed in the past 20 years (see below), as well as for 22 taxonomic statements of behavior change techniques from Abraham and Michie (Abraham & Michie, 2008). Regarding the field of DSM, these 7 strategies seem therefore to be sufficient.

However, the (causal) relationships between these concepts, as well as the importance ascribed to them, are varying, depending on the school of thought or the behavioral change model. This complexity is not further elaborated in the DSMOF.

7. Diabetes Self-Management Outcome Framework (DSMOF) Element Outcome II: AADE7 Behavior

The AADE7 behaviors are further described in section 0 on page 9.

8. Diabetes Self-Management Outcome Framework (DSMOF) Element Outcome III: Disease/Health

An analysis of the reviews in the DSM field showed that clinical as well as psychosocial health outcomes are an important outcome class that is frequently reported in clinical trials and evaluation studies. Three different sub-categories of clinical outcomes are distinguished in the third DSMOF element.

18. Sub-category disease (diabetes) related outcomes: Examples for these are (1) glycosylated haemoglobin (HbA1c); (2) fasting blood glucose and (3) need for medication. One study used a (4) clinical composite score as reported outcome.

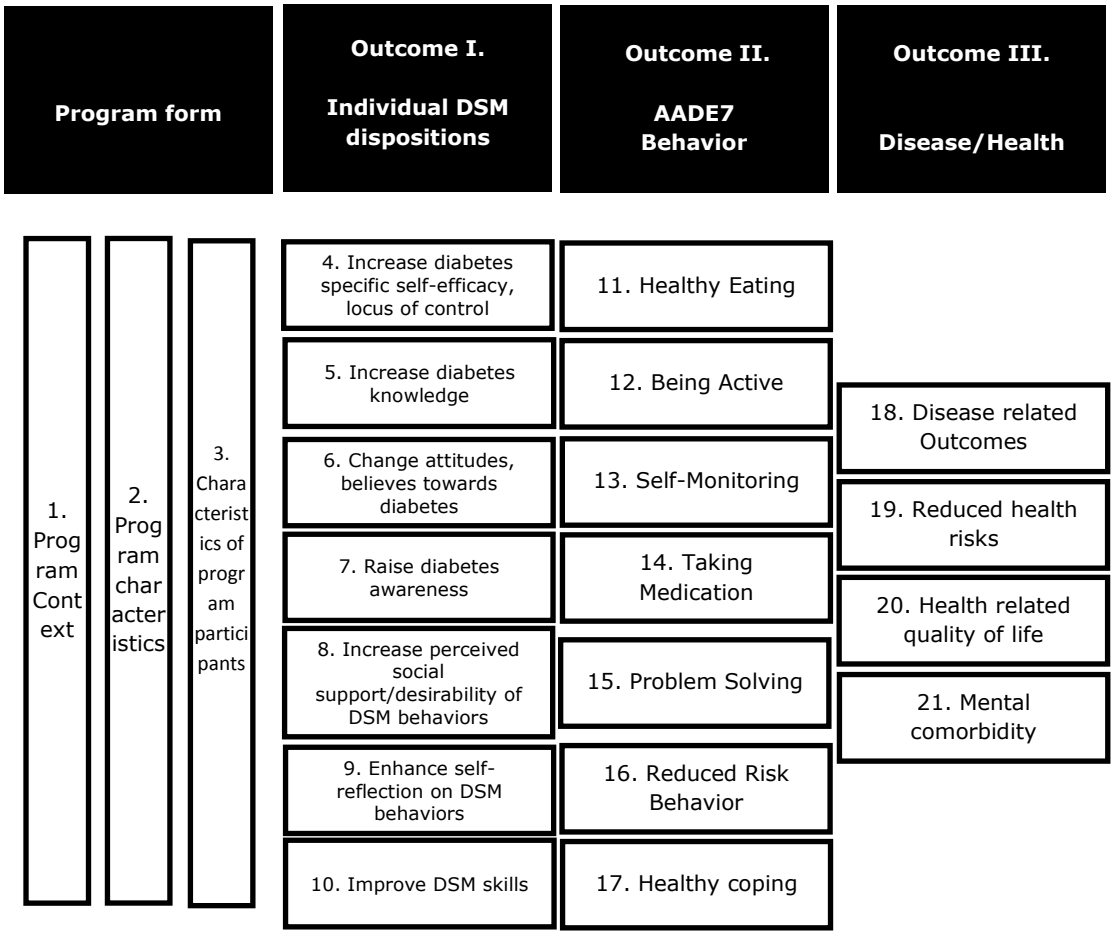
19. Sub-category reduced health risks: In light of the design of the Diabetes Literacy Project's effectiveness evaluation study that uses self-administered questionnaires, some health risk outcomes can be measured, while others would need a more specialized design. A health risk outcome measurable with a questionnaire design is: (1) body weight (reduced BMI) which can be self-reported. Other measures like (2) waist circumference are more problematic in self-report designs since they require measurement skills that cannot be expected in general populations. Other measures are even more specific and would require highly trained study-personnel in order to be recorded in a reliable, valid and ethical way. Examples of such would be: (3) diastolic/systolic blood pressure, (4) cholesterol, (5) triglycerides, (6) high density lipoprotein (HDL), (7) low density lipoprotein (LDL), etc.

20. Sub-category health related quality of life (HRQL): Since there is a growing research body relating to this measure (Vadstrup, Frolich et al. 2011b) (Cochran, Conn, 2008) HRQOL measures are its own sub category of the DESMOF.

21. Sub-category mental comorbidity: Examples are (1) depressive symptoms, (2) anxiety or (3) hyper- and hypoglycaemic distress.

Similar to the outcome I element, the DSMOF disease/health outcome element should be perceived as adaptable, extendable, and changeable, in the light of additional research.

Figure 3: DSMOF outcome elements and sub-categories



9. Classifying Diabetes Self-Management Outcome Framework (DSM) Outcomes in the literature using the DSMOF:

A major part in developing the DSMOF and in testing its comprehensiveness was grounded in an assessment of 13 systematic reviews in the DSM field that were retrieved from the PUBMED database. Only systematic reviews were included to reduce the complexity and to find categories in which the comparable DSM-programs can be selected and their outcomes compared. Subsequently the use of the DSMOF in ordering outcomes will be exemplified on these 13 retrieved DSM effectiveness reviews. Since some studies classified measures of the DSMOF function as outcomes, these have been listed as well.

10. General Effectiveness:

The general effectiveness of self-management in diabetes care was assessed by (Norris, Engelgau et al. 2001b) for diabetes and by (Newman, Steed et al. 2004) for general chronic disease.

11. Group based self-management support:

5 systematic reviews were retrieved that are concerned with the effectiveness of group based self-management support. ((Payne, 1995), (Deakin, McShane et al., 2005), (Molsted, Tribler et al. 2007), (Zabaleta, Forbes, 2007), , (Steinsbekk, Rygg et al. 2012) all specifically for diabetes type II, only (Payne, 1995) reviewed general chronic disease.

The PUBMED search terms were (review[Title/Abstract] AND group[Title] AND diabetes) AND (intervention OR training OR education).)

12. Individual based self-management support:

3 systematic reviews (Duke, Colagiuri et al. 2009), (Fan, Sidani, 2009), (Ellis, Speroff et al., 2004) researched the effectiveness of individual interventions, while the review from Fan et al. compared (Fan, Sidani, 2009), among other things, individual-based DSM programs to group-based DSM. Ellis, Speroff et al., (2004) identified the intervention components of face-to-face delivery, cognitive reframing teaching method, and exercise content as most effective in improving glycemic control.

The PUBMED search terms were (review[Title/Abstract] AND individual[Title] AND diabetes) AND (intervention OR training OR education)

13. IT/web based interventions:

5 systematic reviews were concerned with the effectiveness of web based interventions ((Dalton, 2008),(Ramadas, Quek et al. 2011),(Azar, Gabbay, 2009)). One researched this topic especially for older adults (50+)(Stellefson, Chaney et al. 2013). One review researched the effectiveness of cell phone based interventions (Krishna, Boren, 2008). One review conducted an evaluation of web accessible tools for diabetes self-management and related cardiovascular risk factors (Yu, Bahniwal et al. 2012). Finally, one review researched effectiveness of web based self-management education for cancer related chronic diseases (Kuijpers, Groen et al. 2013)

The PUBMED search terms were (review[Title/Abstract] AND (IT[Title] OR web[Title] OR internet[Title])AND diabetes) AND (intervention OR training OR education)

14. Self-help groups/peer groups:

No systematic review was found regarding the effectiveness of self-help peer group-based DSM programs.

The PUBMED search terms were (review[Title/Abstract] AND (self-help[Title] OR peer[Title]) AND diabetes) AND (intervention OR training OR education)

15. Reported effectiveness in existing reviews

Channel	Review	Self-man. strategy	Behavior							Health			
			Healthy Eating	Being Active	Self-Monitoring	Taking Medication	Problem Solving	Reduced Risk Behavior	Healthy coping	Disease related Outcomes	Reduced health risks	HQRL	Mental comorbid.
Group	(Payne, 1995)	-	-	-	-	-	-	-	-	-	-	-	-
Group	(Deakin, McShane et al., 2005)	+A	-	-	-	-	-	-	-	+A[1,2,3];B[2] +C	+A,D[1]	-	-
Group	(Molsted, Tribler et al., 2007)	+G,C	-	-	-	-	-	-	-	+A[1,2,3]	-	-	-
Group	(Zabaleta, Forbes, 2007)	-	-	-	-	-	-	-	-	no:A	-	-	-
Group	(Steinsbekk, Rygg et al., 2012)	+A[1,2]; D[1]; G[1];	-	-	+	-	-	-	-	+A[1,2,3];B[2] no:B[1]	+A[2]; no:A[1];B,C,D,E,F,G,H	No	-
Indiv.	(Duke, Colagiuri et al., 2009)	-	-	-	+	-	-	-	-	No:A[1,2];	no:B,C,D,	-	-
Indiv. vs. Group	(Fan, Sidani, 2009)	No: A	+: Pooled self-management behaviors							+ pooled	no: pooled	-	-
Indiv. vs. else	(Ellis, Speroff et al., 2004)	-	-	-	-	-	-	-	-	+A[controlled]	-	-	-
Web.	(Dalton, 2008)	-	-	-	-	-	-	-	-	-	-	-	-
Web.	(Ramadas, Quek et al., 2011)	+D,E	+	+	+	-	-	-		+A,B,D	+A,B,E,J	+	+B
Web	(Azar, Gabbay, 2009)	+G	-	-	+	-	-	-	-	+A	-	-	-
Web	(Jackson, Bolen et al. 2006)	-	-	-	-	-	-	-	-	~:A	-	-	
TELE	(Farmer, Gibson et al. 2005)	-	-	-	-	-	-	-	-	~A	-	-	

[1] Month 4-6; [2]Month 12-14; [3]Month 24 or more; -=not stated, no=not effective, ~=mixed; +=effective

Patient self-management approach:

A=Knowledge; B=Attitudes, believes; C=Awareness; D=Self-efficacy, locus of control; E=Perceived social support/desirability; F=Self-reflection; G=Self-care skills

Behavioral outcomes:

Healthy Eating; Being Active; Self-Monitoring; Taking Medication; Problem Solving; Reduced Risk Behavior; Healthy coping

Health outcomes:

Disease related outcomes: A= reduced glycated hemoglobin (HbA1c); B= reduced fasting blood glucose; C= reduced need for medication; D= clinical composite score;

Reduced health risks: A= reduced body weight; B= reduced BMI; C= diastolic blood pressure; D= systolic blood pressure; E= total cholesterol; F= triglycerides; G= high density lipoprotein (HDL); H= low density lipoprotein (LDL); J= waist circumference

Health related quality of life: A= increased quality of life

Psychosocial outcomes: B= measures of depression; C= hyper- and hypoglycaemic distress

16. Additional information

Most studies of web-based interventions suffer from severe selection biases, since individuals with no access to the web or no web literacy are excluded. The web interventions included in the reviews are not websites with diabetes information, but mainly web-based interactive health communication applications (IHCAs) combining health information with decision support, social support and/or behavior change support. (Weymann, Harter et al. 2013) (monitoring apps that additionally allow for professional-patient communication). Cost reduction can be observed mainly on the patient side. The results for providers are mixed.

Some newer studies (after 2009) that compare individual and group based interventions were also retrieved. Schillinger et al. (2009) compared group visits to automated telephone self-management support and found that automated telephone seem to be a more effective in improving behavior and quality of life than group visits. Rankin and others (Rankin, Cooke et al. 2012) found that for patients with Type I diabetes, patients profited more from one-to-one sessions with professionals in order to maintain self-care practices over time. In their evaluation of a Type II diabetes prevention program, Rautio et al. (Rautio, Jokelainen et al. 2012) found no differences between group and individual-based interventions. In their randomized trial of the Copenhagen Type II Diabetes project, Vadstrup et al. found that both approaches (Vadstrup, Frolich et al. 2011a) decreased HbA1c levels in participants, but that the individual counselling program was significantly more effective in this regard than the group-based rehabilitation program. This however was not true for health-related quality of

life (Vadstrup, Frolich et al., 2011b), although the individually intervened experienced a significant relief in hyper- and hypoglycaemic distress as compared to the group intervention.

By comparing two fitness interventions (being active), one being individualized fitness, and the other, group based brisk walking, Preat et al. (Praet, van Rooij et al. 2008) found that individual and group based interventions were equally effective in modulating glycaemic control and cardiovascular risk profiles in patients with type II diabetes.

The results of these newer studies indicate that individual training might be more effective in order to reach some outcomes (HbA1c levels) but not for other outcomes, like quality of life. However, individual education seems to be more effective regarding the psychological outcome of reduced disease related stress.

17. Further development of DSMOF

The DSMOF is comprehensive enough to systemize outcomes in the DSM field. It not only allows researchers to detect knowledge or evidence gaps, but presents sub-categories that reflect various DSM processes (patient empowerment) and contents (patient behaviors) as well as possible health gains of DSM programs. The elements and sub-categories can be used to develop outcome measures that can be tailored for each program and yet still provide a rationale for the comparability of those programs.

The DSMOF was initially developed in order to work for the specific research questions in the Diabetes Literacy Project and to guide instrument development in a pre-post program evaluation study. The authors nevertheless attempted to build the DSMOF as a collection of different modules, so that it can be put to use in more general ways.

The DSMOF elements and sub-categories are a useful tool for mapping DSM programs and identifying gaps in regional service provision.

By adding outcome elements and sub-categories, the DSMOF can be used for patient education and self-management research in additional fields, aside from diabetes.

Researchers and practitioners can add outcome modules to the DSMOF, for example, program related outcomes like reach, size, attrition, meeting the needs of the population, quality of planning, implementation fidelity, cost for the provider, job security for staff and many more, in order to further develop DSMOF to meet their specific research and planning needs. This might even be realized in the Diabetes Literacy Project itself, when at a later stage of the project research efforts of various work packages are integrated.

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