The influence of group education on self-efficacy in patients with diabetes mellitus type 2

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1. Abstract

Context: Diabetes mellitus type 2 is a chronic metabolic disorder that is spreading rapidly worldwide. Patients have to deal with various self-care tasks on a daily basis in order to prevent complications. Positive self-care behaviour in patients can be stimulated through enhancing their self-efficacy. Self-efficacy is described as the extent of one's belief in one's ability to complete tasks and reach goals. Self-efficacy is an interesting concept for education, because it can be influenced by verbal persuasion.

Research question: In our literature research we want to investigate whether education can positively influence self-efficacy in patients. In our research project we want to investigate whether group education organised by the Local Multidisciplinary Network (LMN) Zuid-Oost Limburg can positively influence self-efficacy in patients with non-insulin-dependent diabetes mellitus.

Methods: A systematic literature research in the database MEDLINE with the search engine PubMed was conducted on 08/12/2014. An update was conducted on 09/02/2016. As MeSH terms 'self-efficacy' and 'education' were used. For our research project self-efficacy was measured before and after group education organised by the LMN Zuid-Oost Limburg using an adapted version of the Dutch Diabetes Mellitus Self-Efficacy Scale (DMSES). All participants were patients with non-insulin-dependent diabetes who registered for group education between 01/01/2015 and 31/12/2015.

Results: In our literature research we found 13 articles dealing with the effect of education on self-efficacy. According to these articles, various types of education can lead to an increase in self-efficacy. A total of 33 patients participated in our research project. After statistical analysis, we found that the mean total DMSES score after group education was significantly higher ($P<0.001$) than the mean total DMSES score before group education.

Conclusion: Self-efficacy can be increased by education. On the basis of the results of our research project, it can be concluded that group education organised by the LMN Zuid-Oost Limburg has a positive influence on self-efficacy in patients with non-insulin-dependent diabetes.

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ICPC-code: T90.02 (diabetes mellitus type 2)

2. Literature

a. Introduction

Diabetes mellitus type 2 is a global health problem that is spreading rapidly. The epidemic has grown in parallel with the rise in sedentary lifestyles and obesity. According to the International Diabetes Federation (IDF), diabetes affects 1 in 12 adults worldwide. The IDF predicts that the number of people with diabetes will increase from 387 million in 2014 to 592 million in 2035 (1). According to the Intego Database, the incidence of non-insulin-dependent diabetes in Flanders was 8,350 per 1000 patients per year in 2013 (2). Type 2 diabetes comprises over 90% of people with diabetes (1).

If left untreated, diabetes can cause various complications. Acute complications include hyperglycaemia and hypoglycaemia, both which can lead to coma and death. Chronic complications are related to both macrovascular and microvascular blood vessel diseases such as coronary heart disease, diabetic retinopathy, nephropathy and neuropathy. As a consequence, diabetes imposes an increasing economic burden on health care systems worldwide. Health care expenditures for people with diabetes have been found to be two- to three-fold higher than people without diabetes. It was estimated that diabetes accounted for 12% of worldwide health expenditures in 2015 (3).

Treatment of diabetes mainly involves lowering blood glucose levels, but also eliminating or treating other risk factors that damage blood vessels such as arterial hypertension, hypercholesterolemia and smoking. Behavioural change is an important factor in this process, because people with diabetes have to deal with a complex package of self-care tasks. Blood sugar control, correct use of medication and lifestyle adaptations with regard to nutrition and physical exercise are examples of self-care activities which the patient needs to carry out on a daily basis.

We can stimulate positive self-care behaviour in patients with diabetes by enhancing their self-efficacy (4,5). The concept of self-efficacy was first used by the American psychologist Albert Bandura in 1977 (6). It is a central concept in his social cognitive theory, which supposes that people have self-motivating, self-steering and self-reflecting capabilities that allow them to have control over their actions. Bandura described self-efficacy as “people’s judgments of their capabilities to organize and execute courses of action required to attain designated types of performances” (7). In other words, it is the extent of one’s belief in one’s ability to complete tasks and reach goals (8). Self-efficacy can play a major role in how people react to challenges because people that believe they can perform well are more likely to execute tasks successfully. The higher the self-efficacy, the greater the chance of initiating health behaviour change, the more effort will be mobilised in a given task and the higher the level of perseverance in the face of difficulties and setbacks and the better the outcomes.

Self-efficacy is influenced by several sources of information. The four most important sources are performance accomplishments, vicarious experience, physiological information and verbal persuasion (6)(7). These sources may come in various forms. Performance accomplishments include positive experiences in performing a behaviour (for example measuring blood glucose levels during several years). Vicarious experience is the observation of others engaging in similar behaviour; for patients with type 2 diabetes this might involve observing another patient with type 2 diabetes measuring blood glucose levels successfully. Physiological information is influenced by the degree of emotional arousal. Patients are more likely to expect success when they are relaxed than if they are tense and viscerally agitated. Verbal persuasion may come from other patients, family members, friends, doctors or educators. That makes self-efficacy an interesting concept for education.

In this literature study, we will investigate whether education can positively influence self-efficacy in patients.

b. Research question

The literature study was executed to find an answer to the following question: Can education positively influence self-efficacy?

c. Methodology

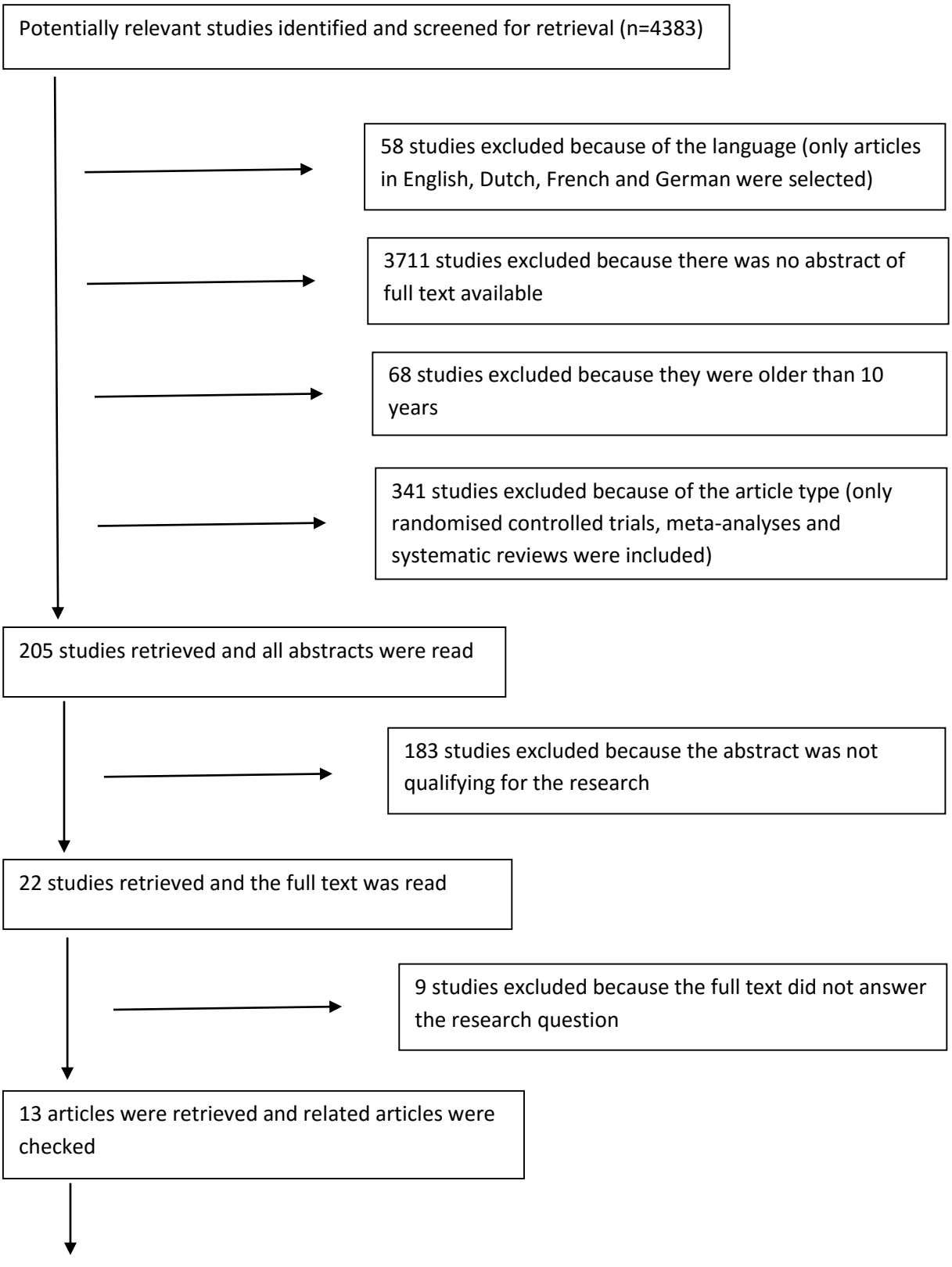
In our literature search we used the following PICO (Patient, Intervention, Comparison, Outcome):

- P: Man/woman, all ages
- I: Education
- C: The degree of self-efficacy before and after education
- O: Is there an increase in the degree of self-efficacy after education?

A search was conducted in the database MEDLINE with the search engine PubMed on 08/12/2014. An update was conducted on 09/02/2016. As MeSH terms, 'self-efficacy' and 'education' were used.

The search was rewarded with a total of 4383 articles (Figure A). 58 articles were excluded because of their language. Only articles in English, Dutch, French and German were selected. 3711 articles were excluded because there was no abstract or full text available. 68 articles were excluded because they were older than ten years. 341 articles were excluded because of the article type, only randomised controlled trials, meta-analyses and systematic reviews were included. In 205 articles the

abstract was read. 183 studies were excluded because the abstract was irrelevant for the search. 22 studies were retrieved and the full text was read. 9 studies were excluded based on the content of the full text. From 13 articles the references were checked. Finally 13 of the articles were retrieved.



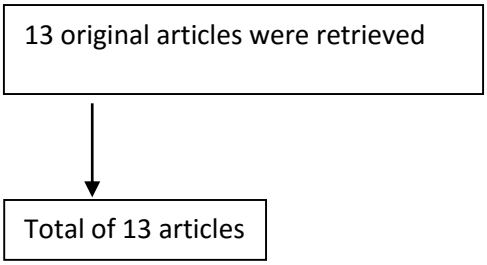


Figure A: Flow Diagram

d. Results

Figure A shows a flow diagram of the selection of studies as described above. Ultimately 13 articles of our literature search were retrieved.

Through the years, we see that several researchers were exploring the effect of different types of education on self-efficacy.

According to several reviews, self-efficacy can be increased by self-management education. Self-management education is the process of facilitating the knowledge, skill and ability necessary for self-care. The overall objectives are to support informed decision-making, problem-solving and active collaboration with the healthcare team and to improve clinical outcomes, health status and quality of life. One systematic review concludes that group-based diabetes self-management education in people with type 2 diabetes results in improvements in psychological outcomes, such as self-efficacy (9). Another review states that lay-led self-management programmes lead to improvements in self-efficacy in patients with chronic conditions in general, although those improvements are small and relatively short-term (10). One article shows that arthritis self-management educational programmes, with or without exercise interventions, improved self-efficacy in patients with knee osteoarthritis (11). Another review finds evidence to support the use of self-management programmes to improve self-efficacy in elderly people with age-related macular degeneration (12). One article suggests that school-based asthma education improves knowledge of asthma, self-efficacy and self-management behaviour (13).

There is also evidence that other types of education can enhance self-efficacy. One review shows that especially interventions that include collaborative goal-setting are associated with improved metabolic outcomes and self-efficacy in patients with type 2 diabetes living in rural areas (14). Another article concludes that also family-based interventions for adults with diabetes improve patients' self-efficacy, perceived social support, diabetes knowledge and diabetes self-care (15).

Educational group visits may improve self-efficacy in patients with chronic health conditions (also glycaemic control) (16). Telephone coaching for people with chronic conditions such as diabetes can also improve health behaviour, self-efficacy and health status (17). A systematic review concluded that life coaching of patients increases self-efficacy (18).

There is also evidence that exercise interventions based on the self-efficacy theory increase self-efficacy in patients with heart failure. Findings of this study suggest a positive relationship between self-efficacy and initiating and maintaining exercise in heart failure (19). Another review shows that especially exercise interventions which included the following techniques increase self-efficacy in older adults: “set graded tasks”, “prompt self-monitoring of the behavioural outcome”, “provide information on where and when to perform the behaviour” and “motivational interviewing” (20).

Both short-term and long-term educational interventions can improve self-efficacy in patients with heart failure, demonstrating that the duration of the intervention can vary and still be successful (21).

e. Conclusion

Self-efficacy can be increased by different types of education, such as self-management group education, family-based interventions, life coaching and exercise interventions.

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3. Research Project

a. Introduction

Since September 2013, the Local Multidisciplinary Network (LMN) Zuid-Oost Limburg is organising group education for patients with diabetes mellitus who aren't involved in a diabetes care programme. These educational sessions are taking place in the city of Bilzen (Flanders, Belgium) and are organised 4 to 5 times a year depending on the amount of participants, with 5 to 10 participants per group. The sessions include exercise education as well as self-management education.

In this research project, we will investigate whether this group education can increase self-efficacy in patients with non-insulin-dependent diabetes.

b. Research question

Can group education organised by the Local Multidisciplinary Network (LMN) Zuid-Oost Limburg in the city of Bilzen (Flanders, Belgium) positively influence self-efficacy in patients with non-insulin-dependent diabetes?

c. Methodology

Design

The design of this research project can be characterised as a prospective observational study. The Ethical Committee of the University of Brussels approved the study protocol of this research project (B.U.N. 143201524353).

Population and recruitment

The patients were recruited through the educational project organised by the LMN Zuid-Oost Limburg in the city of Bilzen (Flanders, Belgium). Every patient with diabetes mellitus who wasn't involved in a diabetes care programme could participate, but the target group were patients who were recently diagnosed with type 2 diabetes and who didn't receive education yet. There was also a possibility for their partners to register. The majority of patients who participated were referred by their general practitioner, but there were also patients who registered themselves.

The patients who participated in this study were recruited from January 2015 to December 2015, during this period a total of 5 educational programmes were organised by the LMN Zuid-Oost Limburg.

Inclusion criteria for this research project:

- Patients with non-insulin-dependent diabetes mellitus

Exclusion criteria for this research project:

- Patients with type 1 diabetes mellitus
- Patients with insulin-dependent type 2 diabetes mellitus
- (Healthy) partners of patients with type 2 diabetes

Finally, a total of 33 patients were recruited to participate in this study.

Content of the educational programme

The project consisted of an educational programme that included four sessions of 2,5 hours of group education, each session a week apart. One session included 2 hours of diabetes-specific self-management education and 30 minutes of exercise education. Each of the four sessions had its own theme. The participation cost of the educational programme amounted to 10 euro per patient, this price also included a glucometer, a pedometer, an exercise stretcher and various folders and brochures.

During the first session an exercise coach supplied information about the benefits and the utmost importance of exercise for diabetics. The current exercise recommendations were discussed, with the emphasis on the advice to take 10000 steps a day. The patients were asked to measure their amount of steps taken a day during the next week, without increasing their steps on purpose. For this reason, they were handed a pedometer. Next, a diabetes educator provided information about the pathophysiology of diabetes, using a conversation map to stimulate interactivity. A glucometer was administered to each patient and they were taught how to use it correctly.

In the following session the exercise coach evaluated the measurements of the amount of steps taken by each patient during the past week and helped to set individual new goals for the next week. Subsequently the exercise coach demonstrated various exercises using a stretcher. The patients were asked to follow the example and try to do these exercises at home on a regular basis. They were each provided a stretcher and a folder containing information and drawings about the correct execution of

the exercises. The diabetes educator discussed a number of relevant topics with the patients using conversation maps, such as coping with the diagnose of diabetes, dealing with hyper- or hypoglycaemia, the importance of smoking cessation, other tips to live a healthier lifestyle and the importance of medical care and follow-up. Brochures about the Flemish Diabetes Association (Vlaamse Diabetes Vereniging) and the Diabetic Federation (Diabetes Liga) were handed out.

During the third session the exercise coach reassessed the individual goals and adjusted them in consultation with the patients if necessary. He demonstrated a few other exercises that were easy to implement at home. Next, a nutritionist gave diabetes-specific information about meal planning, frequency, healthy foods and the use of sugar and fat in a diabetic diet.

In the last session the exercise coach summarised the information given in the previous sessions and demonstrated a number of other exercises. Diabetes foot care education was provided by a podiatrist, with special attention for diabetes foot self-care behaviour, how to choose good footwear and the importance of a yearly physical examination by their general practitioner.

During all sessions, there was room for questions, comments and suggestions.

Self-efficacy and the Diabetes Mellitus Self-Efficacy Scale

Self-efficacy is described as the extent of one's belief in one's ability to complete tasks and reach goals (1). Self-efficacy beliefs determine how patients behave when confronted with a certain task or challenge, such as achieving a healthy weight. In other words, people's behaviour in specific situations is influenced by their image of their personal competence. People with a strong sense of self-efficacy are more willing to take on challenging goals and to persevere in their actions. They view their tasks as challenges to be mastered. In contrast, people with a low self-efficacy have lower aspirations and are more likely to give up in case of setbacks or failure. They tend to avoid new tasks when they feel that they exceed their capabilities. Also, they have higher stress levels and higher risks of depression than those with a higher self-efficacy (2). Thus, self-efficacy can be considered a crucial factor in diabetes self-care behaviours.

Measurement of self-efficacy is related to three dimensions: magnitude, strength and generality (3). Magnitude refers to how challenging a person finds it to adopt a new behaviour, strength refers to how certain a person is of accomplishing a task and generality refers to how difficult a person finds it to accomplish a certain task in other situations.

During the past years, several tools have been developed for evaluating self-efficacy in patients with diabetes, the most widely used being the Diabetes Mellitus Self-Efficacy Scale (DMSES), developed in 1999 by the members of the International Partnership in Self-Management and Empowerment. The psychometric properties of the scale were found to be acceptable for patients with type 2 diabetes in several countries: Australia (4), the Netherlands (5), the United Kingdom (6), Turkey (7) and Taiwan (8).

The DMSES is developed to evaluate self-efficacy in patients with non-insulin-dependent diabetes mellitus through measuring the strength of self-efficacy with regard to several clusters of diabetes self-care activities which patients have to carry out on a regular basis in order to manage their disease. These self-care activities can be divided in three groups (9): performing activities (use of medication, keeping to a diet, physical exercise), self-observation (blood sugar control, foot care, body weight control, general health condition) and self-regulating activities (correction of hyperglycaemia or hypoglycaemia, variation in nutrition, self-regulation in case of vacation, stress,..).

The DMSES is a self-reporting instrument and it measures the self-efficacy at the moment of completing the scale. The Dutch version includes 20 questions concerning self-efficacy and 10 optional general questions (sex, age, occupation,…). It uses a 5-point Likert scale. The five answering options are phrased as follows: yes, surely; most likely yes; probably yes; maybe yes/maybe no; probably not. The total score is the sum of the scores of the 20 individual items, so the range is 20-100. A higher score indicates a higher self-efficacy. The level of measurement of the DMSES is ratio/interval.

For this research project, the Dutch DMSES was used. The content of question 18 was adapted from 'I think I am able to consult my doctor once a year for diabetes follow-up' to 'I think I am able to consult my doctor four times a year for diabetes follow-up', according to the most recent guidelines for type 2 diabetes management (10). One question was added to the scale ('I think I am able to consult an ophthalmologist once a year'), but these scores were not included in the total scores.

Statistical analysis

The scale was transformed into a digital dataset. Data were analysed statistically using Excel 2016. Normality was assessed by the Shapiro-Wilk test. A dependent t-test for paired samples was used. A significance level of $P<0.001$ was considered statistically significant. There were no scales that contained missing fields in the 20 mandatory questions. The open answers from the 10 optional questions were incorporated as citations to give background information.

d. Results

The DMSES was individually presented to a total of 33 patients before the start of the first educational session and after the ending of the last educational session. All 33 patients were willing to participate. Completion of the DMSES was always guided by myself for clarification where needed. Preceding the DMSES, patients would sign an informed consent. A total of 33 patients completed the scale (response rate 100%). There were 51.52% male responders, 48.48% female. The mean age was 61.7 years old, with a range 44-81.

One patient achieved a lower total DMSES score after education. In one patient there was no difference between the before and after total DMSES score. The remaining 31 patients all achieved higher total DMSES scores after education (Table 1). The mean total DMSES score before education was 63.97/100, the mean total DMSES score after education was 78.61/100.

For further analysis, the dependent t-test for paired samples was used. Both parameters were normally distributed (P>0.05) according to the Shapiro-Wilk test.

To see if there was a significant difference between the total DMSES scores before and after education, the following null hypothesis was used: the mean total DMSES score of the population before group education (μ_1) did not differ from the mean total DMSES score of the population after group education (μ_2) so that H_0: $\mu_1 = \mu_2$ or H_0: $\mu_2 - \mu_1 = 0$. When $\mu_Z = \mu_2 - \mu_1$ we could state that H_0: $\mu_Z = 0$ and H_1: $\mu_Z > 0$, where μ_Z is the mean of the differences between all pairs.

To calculate T the formula $T = \frac{Z* - 0}{S}\sqrt{n}$ was used, where Z* is the mean and S is the standard deviation of the differences of all pairs and n is the population sample. Using Excel 2016, we found that the mean Z* equals to 14.636 and the standard deviation S equals to 11.168 so that $T = \frac{14.636 - 0}{11.168}\sqrt{33} = 7.527$.

The formula $P(T \geq t; H_0) = P(T(32) \geq t) = \alpha = 0.001$ was used to see if we could reject the null hypothesis. We found that t equals to 3.365 so that T > t. Thus, the null hypothesis could be rejected at a significance level of 0.001. This means that the mean total DMSES score after group education is significantly higher than the mean total DMSES score before group education.

Total DMSES score per patient before education (X)	Total DMSES score per patient after education (Y)	Difference Z (Z = Y – X)
92	100	8
76	81	5
61	78	17
58	70	12
49	59	10
83	68	-15
68	87	19
53	59	6
65	72	7
59	76	17
59	81	22
49	64	15
71	86	15
59	87	28
84	87	3
56	78	22
65	87	22
62	94	32
61	81	20
46	79	33
60	72	12
70	73	3
91	91	0
69	89	20
42	77	35
47	74	27
42	69	27
62	75	13
78	80	2
81	90	9
79	83	4
57	84	27
57	63	6

Table 1: Total DMSES scores per patient before and after education and the calculated difference Z

e. Discussion

This prospective observational study investigated whether group education organised by the LMN Zuid-Oost Limburg could positively influence self-efficacy in patients with non-insulin-dependent diabetes mellitus. The educational sessions consisted of a combination of self-management and exercise education.

Self-efficacy was measured before and after the educational sessions using the Diabetes Mellitus Self-Efficacy Scale. According to van der Bijl et al (5), the psychometric properties of the DMSES are satisfactory. The content validity was evaluated to be sufficiently secured and the stability of the DMSES, measured with a time interval of 5 weeks, was evaluated as good. The test-retest reliability was calculated by means of the Pearson correlation-coefficient and resulted in a coefficient of 0.79 ($P<0.001$). With regard to internal consistency the homogeneity of the instrument was considered to be insecure and with regard to construct validity it might be argued that the DMSES is not a unidimensional scale, because it measures strength with regard to several clusters of self-care activities. Nevertheless, the DMSES was considered to be a reliable scale.

The present study confirms previously found associations between education and self-efficacy. A significantly higher DMSES score was achieved after the educational sessions ($P<0.001$).

As far as we know, this study is the first that investigated whether group education in Flemish patients with type 2 diabetes could positively influence their self-efficacy. The high response rate of 100% on the DMSES could make it a valuable instrument in the discussion about the organisation and quality of future diabetes educational sessions.

However, this study has some limitations. The respondents may have given socially acceptable answers to the questionnaire, although they knew the data would be analysed anonymously. Further, the patients who participated in this study all signed up for the diabetes educational sessions organised by the LMN Zuid-Oost Limburg and are likely to be highly motivated patients who are interested to learn more about the self-care activities that they should perform to prevent short- and long-term complications. Taking this into account, the results could overestimate the positive influence of group education on self-efficacy. Also, it is beyond the scope of this study to make conclusions about the long-term influence of diabetes education on self-efficacy, because there was no follow-up of the patients after the ending of the group education. In addition, only non-insulin-dependent patients were included in this study, therefore generalised conclusions about the entire type 2 diabetes population could not be made. Moreover, this was a relatively small study with 33 participants. Finally, we adapted one question from ‘I think I am able to consult my doctor once a

year for diabetes follow-up' to 'I think I am able to consult my doctor four times a year for diabetes follow-up', according to the most recent guidelines for type 2 diabetes management (10). This could have led to a lower score because it could be considered more difficult to consult the doctor four times a year in comparison to one time a year.

Future research is recommended to focus on the long-term effect of diabetes education on self-efficacy and to determine which type of education is best for increasing self-efficacy.

f. Conclusion

This prospective observational study investigated whether group education organised by the LMN Zuid-Oost Limburg has a positive influence on self-efficacy in patients with non-insulin-dependent diabetes. Previously found associations between education and an increase in self-efficacy were confirmed in this study.

g. References

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4. Votes of Thanks

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5. Appendix

Appendix a: Approved study protocol

PROTOCOL

Problem statement.

Self-efficacy is defined by Bandura as "people's judgments of their capabilities to organize and execute courses of action required to attain designated types of performances". People's behaviour in specific situations is influenced by their image of their personal competence. The higher the self-efficacy, the greater the chance of initiating health behaviour change, the more effort will be mobilized in a given task and the longer the perseverance in the face of difficulties and setbacks and the better the outcomes. Self-efficacy is influenced by several sources of information. The four most important sources are performance accomplishments, vicarious experience, physiological information and verbal persuasion (1, 2).

Especially the latter makes self-efficacy an interesting concept for diabetes education, because people with diabetes mellitus have to deal with a complex package of self-care tasks on a daily basis. This in order to regulate their disease and prevent complications such as damage to the nervous system and the cardiovascular system. Blood sugar control, correct use of medication and lifestyle adaptations with regard to nutrition and physical exercise are examples of self-care activities which the patient needs do on a daily basis. The learning of this self-care behaviour is often liable to setbacks. Patients indicate that they consider this daily regimen of self-care activities more difficult than the diagnosis of diabetes mellitus itself (3, 4).

International studies investigating self-efficacy in patients with diabetes mellitus, show that self-efficacy positively influences the health behaviour and the outcomes of these behaviour of patients with diabetes mellitus (5-10).

Research question.

In this research project, we will investigate whether group education can positively influence the self-efficacy in patients recently diagnosed with non-insulin-dependent type 2 diabetes.

Methods.

Population. Patients recently diagnosed with non-insulin-dependent diabetes mellitus type 2 who voluntarily enroll in sessions of group education on diabetes, organised by 'Lokaal Multidisciplinair Netwerk Zuid-Oost Limburg' in Belgium.

Intervention. Measurement of self-efficacy in patients participating in four sessions of group education on diabetes. An adapted version of the Dutch Diabetes Management Self-Efficacy Scale (DMSES) will be administered to an estimated 30 patients before the beginning and after the ending of the group sessions.

Measuring the degree of self-efficacy in patients will be operationalized as measuring the degree of self-efficacy in diabetes self-care activities. These self-care activities can be divided into three groups: performing activities (use of medication, keeping to a diet, physical exercise, consultation of health practitioners), self-observation (observation and reporting on glucose in blood, body weight, skin condition of the feet) and self-regulating activities (correction of hypo- and hyperglycaemia, preparation for a vacation, variation in nutrition and self-regulation in case of extra body weight, illness and stress).

During the sessions of group education, an important emphasis will be placed on implementation strategies including design, setting, communication, didactic skills, knowledge and availability of the educators, quality of educational materials (visual and content aspects), interactivity and follow-up in general practice after the ending of the group sessions.

Comparison. The results of the measurements of self-efficacy before the beginning and after the end of the group sessions will be compared.

Outcome. Measuring the degree of self-efficacy in patients will be operationalized as measuring the degree of self-efficacy in diabetes self-care activities. These self-care activities can be divided into three groups: performing activities (use of medication, keeping to a diet, physical exercise, consultation of health practitioners), self-observation (observation and reporting on glucose in blood, body weight, skin condition of the feet) and self-regulating activities (correction of hypo- and hyperglycaemia, preparation for a vacation, variation in nutrition and self-regulation in case of extra body weight, illness and stress).

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Appendix b: Favourable opinion Ethical Committee

Universitair Ziekenhuis Brussel

Vrije Universiteit Brussel

COMMISSIE MEDISCHE ETHIEK (O.G. 016)
Reflectiegroep Biomedische Ethiek
Laarbeeklaan 101
1090 BRUSSEL

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Brussel, 13-05-2015

Ons Kenmerk: **2015/130**

ADVIES VAN DE COMMISSIE MEDISCHE ETHIEK

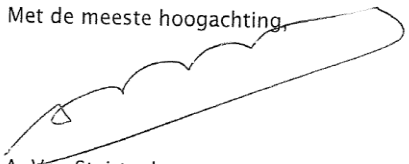
Betreft :
The influence of group education on self-efficacy in patients with type 2 diabetes
B.U.N. 143201524353

Na kennis genomen te hebben van de documenten betreffende het bovenvermelde project, besluit de Commissie Medische Ethiek tijdens haar vergadering van **13 mei 2015**

dat deze studie mag ondernomen worden.

Deze goedkeuring blijft geldig voor de duur van het project. De Commissie wenst een jaarlijks overzicht van de stand van zaken van het project te ontvangen. De studieresultaten dienen overgemaakt te worden aan de Commissie bij het beëindigen van de studie. Zij herinneren de verantwoordelijke van het experiment eraan dat dit experiment onder zijn persoonlijke verantwoordelijkheid zal worden uitgevoerd. Het gunstig advies van de Commissie betekent geenszins dat de Commissie de verantwoordelijkheid van het experiment op zich neemt. De Commissie Medische Ethiek werkt en is georganiseerd volgens de richtlijnen van ICH-GCP.

Met de meeste hoogachting,



A. Van Steirteghem, voorzitter

Cc: FAGG, Departement R&D, Eurostation blok 2, Victor Hortaplein 40 / 40, 1060 BRUSSEL

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Meeting date: 13-05-2015

Ons Kenmerk : 2015/130

MEMBERS OF THE MEDICAL ETHICS COMMITTEE UZ BRUSSEL - VUB
(since 08-10-2014)

Name	Function	Gender
Prof. Dr. Em. A. Van Steirteghem, PhD	CHAIRMAN UZ BRUSSEL	M
Dr. J. Marchand, MD	VICE- CHAIRMAN Pediatrics UZ BRUSSEL	M
Dr. Y. Adriaenssens, MD	General Practitioner Van Hoeystraat 7, Mechelen	M
Dr. K. Beeckman, PhD	Nursing and Midwifery research group UZ BRUSSEL	F
Dr. Apr. V. Caveliers, PhD	Pharmacist UZ BRUSSEL	F
Prof. Dr. H. De Boeck, MD	Pediatric Orthopedics UZ BRUSSEL	M
Prof. Dr. J. De Grève, MD	Medical Oncology UZ BRUSSEL	M
Prof. Dr. J. De Mey, MD	Radiology UZ BRUSSEL	M
Mrs. M. De Win	External Member	F
Mr. D. Danschutter	Head Nurse UZ BRUSSEL	M
Prof. Dr. P. Lacor, MD	Internal Medicine UZ BRUSSEL	M
Prof. Dr. J. Poelaert, MD	Anesthesiology UZ Brussel	M
Prof. Dr. C. Schotte, PhD	Clinical Psychology UZ BRUSSEL	M
Prof. Dr. J. van der Werff ten Bosch, MD	Pediatrics UZ BRUSSEL	F
Prof. Dr. T. Vanhaecke, PhD	Toxicology - Faculty of Medicine and Pharmacy VUB	F
Dr. L. Wostyn, MD, Master of Laws	Master of Laws VUB External member	M

If member of the Ethics Committee, the investigator does not participate to the vote

Appendix c: Adapted Dutch Diabetes Mellitus Self-Efficacy Scale

AANGEPASTE DIABETES MANAGEMENT SELF-EFFICACY SCHAAL (DMSES) VOOR MENSEN MET TYPE II DIABETES

Ontwikkeld door:

Dr. Jaap van der Bijl

Drs. Ada van Poelgeest-Eeltink

Prof. dr. Lillie Shortridge-Baggett

Originele versie aangepast door: Dr. Stefanie Geens en Prof. dr. Liesbeth Borgermans

Referenties:

Bijl, J. van der, Poelgeest-Eeltinck, A. van, & Shortridge-Baggett, L.M. (1999). The psychometric properties of the diabetes management self-efficacy scale for patients with Type 2 diabetes mellitus. *Journal of Advanced Nursing, 30(2)*, 352-359

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AANWIJZINGEN VOOR HET INVULLEN VAN DE VRAGENLIJST

Voor wie bedoeld:
Deze vragenlijst is bedoeld voor patiënten met diabetes, ook wel suikerziekte genoemd. Het gaat hierbij om het type diabetes dat alleen met een dieet en/of tabletten (diabetes type II) wordt behandeld. Dus niet het type diabetes dat met insuline (spuiten) wordt behandeld.

Waarover gaat het:
Wij willen graag van u weten of u denkt (= uw eigen inschatting) dat u in staat bent de verschillende handelingen uit te voeren die nodig zijn om met uw diabetes om te gaan. Allereerst krijgt u 21 vragen te beantwoorden over het omgaan met uw diabetes. Aan het einde van de vragenlijst volgen nog enkele algemene vragen over onder andere leeftijd, geslacht enzovoort.

Hoe in te vullen:
Bij de eerste 21 vragen kunt u kiezen uit 5 antwoorden. Er is maar één antwoord mogelijk. Kies het antwoord dat het beste uw mening weergeeft.

- o Waarschijnlijk niet
- o Misschien wel, misschien niet
- o Waarschijnlijk wel
- o Hoogstwaarschijnlijk wel
- o Zeker wel

Voorbeeld:
Ik denk dat ik in staat ben om zelf mijn belastingformulier in te vullen:

- o Waarschijnlijk niet
- o Misschien wel, misschien niet
- X Waarschijnlijk wel
- o Hoogstwaarschijnlijk wel
- o Zeker wel

Is uw antwoord “waarschijnlijk wel” (het derde antwoord), dan zet u met een pen een kruisje tussen de haakjes bij het derde antwoord, zoals hierboven is voorgedaan.

Het is de bedoeling dat u alle vragen beantwoord. Alleen de vragen 20 en 21 (over het gebruik van tabletten) zijn niet voor iedereen van toepassing. Als u geen tabletten gebruikt kunt u deze twee vragen overslaan.

De vragenlijst begint op de volgende bladzijde.

VRAGENLIJST: Inschatting van de eigen effectiviteit in het omgaan met suikerziekte (diabetes type 2 : niet-insuline afhankelijk)

1. Ik denk dat ik in staat ben om mijn bloedsuiker zelf te controleren als dat nodig is:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

2. Ik denk dat ik in staat ben om een te hoge bloedsuiker te verhelpen:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

3. Ik denk dat ik in staat ben om een te lage bloedsuiker te verhelpen:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

4. Ik denk dat ik in staat ben om zelf de juiste voeding voor mijn diabetes te kiezen:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

5. Ik denk dat ik in staat ben om zelf in mijn voeding variatie aan te brengen:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

6. Ik denk dat ik in staat ben om zelf mijn gewicht onder controle te houden:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

7. Ik denk dat ik in staat ben om zelf mijn voeten op wondjes te controleren:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

8. Ik denk dat ik in staat ben om zelf te zorgen voor voldoende lichaamsbeweging, door bijvoorbeeld te wandelen of te fietsen:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

9. Ik denk dat ik in staat ben om mijn voeding aan te passen, wanneer ik ziek ben:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

10. Ik denk dat ik in staat ben om mij meestal aan mijn voedingsvoorschriften te houden:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

11. Ik denk dat ik in staat ben om aan extra lichaamsbeweging te doen, wanneer dit door de arts wordt geadviseerd:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

12. Ik denk dat ik in staat ben om mijn voeding, als dit nodig is, aan te passen, wanneer ik extra lichaamsbeweging neem:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

13. Ik denk dat ik in staat ben om mij aan mijn voedingsvoorschriften te houden, wanneer ik van huis ben:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

14. Ik denk dat ik in staat ben om mijn voeding aan te passen, wanneer ik van huis ben:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

15. Ik denk dat ik in staat ben om mij aan mijn voedingsvoorschriften te houden, wanneer ik op vakantie ben:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

16. Ik denk dat ik in staat ben om mij aan mijn voedingsvoorschriften te houden, wanneer ik op een receptie of feestje ben:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

17. Ik denk dat ik in staat ben om bij spanning of stress mijn voeding aan te passen:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

18. Ik denk dat ik in staat ben om vier keer per jaar de huisarts te raadplegen voor controle van mijn diabetes:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

19. Ik denk dat ik in staat ben om één keer per jaar de oogarts te raadplegen voor controle:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

Wilt u de volgende twee vragen nog invullen wanneer u tabletten voor uw diabetes gebruikt. Wanneer u geen tabletten voor uw diabetes gebruikt kunt u de vragen 20 en 21 overslaan en doorgaan met de algemene vragen op de volgende bladzijde.

20. Ik denk dat ik in staat ben om mij aan mijn geneesmiddelenvoorschriften te houden, wanneer ik van huis ben:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

21. Ik denk dat ik in staat ben om de dosering van mijn tabletten aan te passen, wanneer ik ziek ben:
    - Waarschijnlijk niet
    - Misschien wel, misschien niet
    - Waarschijnlijk wel
    - Hoogstwaarschijnlijk wel
    - Zeker wel

Algemene vragen

Tot slot willen wij u nog een paar algemene vragen stellen. Het antwoord dat op u van toepassing is, kunt u aankruisen of invullen.

1. Wat is uw geslacht? (aankruisen)
   - o Man
   - o Vrouw

2. In welk jaar bent u geboren? ……
   (jaartal invullen)

3. Welke schoolopleiding heeft u gehad? ……
   (hoogste opleiding invullen)

4. Heeft u genoeg financiële middelen om de kosten die het hebben van diabetes met zich meebrengt te dekken?
   - o Ja, meer dan genoeg
   - o Ja, genoeg
   - o Nee, soms niet genoeg
   - o Nee, te weinig

5. Wanneer is er bij u diabetes geconstateerd? ……
   (jaartal invullen)

6. Heeft u naast uw diabetes nog last van een andere aandoening, waar u al langer dan drie maanden last van heeft?
   - o Ja
     Zo ja, welke aandoening? ……
   - o Nee

7. Woont u alleen?
   - o Ja
   - o Nee

8. Bent u lid van de Vlaamse Diabetes Vereniging?
   - o Ja
   - o Nee

9. Bent u van:
   - o Belgische afkomst
   - o Nederlandse afkomst
   - o Turkse afkomst
   - o Marokkaanse afkomst
   - o Anders, namelijk …….

Appendix d: Informed consent

TOESTEMMINGSFORMULIER VOOR DE PATIENT

"Onderzoeksproject : De invloed van groepseducatie op de self-efficacy van patiënten met diabetes type 2."

Dit onderzoek wordt uitgevoerd door Dr. Stefanie Geens, HAIO aan de KU Leuven, in het kader van de masterproef behorende tot de opleiding 'Master in de huisartsgeneeskunde'. De promotor van deze masterproef is Prof. Dr. Liesbeth Borgermans.

Ik heb de informatie voor deelname aan de studie gelezen en begrepen.

Ik kon aanvullende vragen stellen. Mijn vragen zijn genoeg beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.

Ik weet dat meedoen helemaal vrijwillig is. Ik weet dat ik op ieder moment kan beslissen om toch niet mee te doen. Daarvoor hoef ik geen reden te geven.

Ik weet dat sommige mensen mijn gegevens kunnen zien. Die mensen staan vermeld bovenaan het formulier.

Ik geef toestemming om mijn gegevens te gebruiken, voor de doelen die in de informatiebrief staan.

Ik geef toestemming om gegevens nog maximaal 5 jaar na afloop van dit onderzoek te bewaren voor nadere analyse (indien van toepassing).

Ik vind het goed om aan dit onderzoek mee te doen.

Naam proefpersoon:

Handtekening:

Datum : __ / __ / __

Ik verklaar hierbij dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening:

Datum: __ / __ / __

Aanvullende informatie is gegeven door (indien van toepassing):

Naam:

Functie:

Handtekening:

Datum: __ / __ / __

Appendix e: Information for the patient

INFORMATIE VOOR DE PATIËNT

"Onderzoeksproject : De invloed van groepseducatie op de self-efficacy van patiënten met diabetes type 2."

Dit onderzoek wordt uitgevoerd door Dr. Stefanie Geens, HAIO aan de KU Leuven, in het kader van de masterproef behorende tot de opleiding 'Master in de huisartsgeneeskunde'. De promotor van deze masterproef is Prof. Dr. Liesbeth Borgermans.

Het betreft patiënten met diabetes mellitus type 2 die zich vrijwillig hebben ingeschreven voor de groepseducatie over diabetes mellitus, georganiseerd door het LMN Zuid-Oost Limburg. Voor de start en na het einde van de groepseducatie wordt er een vragenlijst ingevuld die de self-efficacy bij zelfzorgactiviteiten meet van patiënten met diabetes mellitus type 2, die niet behandeld worden met insuline.

Self-efficacy of 'zelfeffectiviteit' wordt gedefinieerd als het vertrouwen dat iemand heeft in zijn eigen bekwaamheid om te slagen in specifieke zaken, zoals het uitvoeren van bepaalde activiteiten. In dit onderzoek gaan we de self-efficacy van patiënten met diabetes type 2 meten bij bepaalde zelfzorgactiviteiten (zoals bijvoorbeeld het controleren van de voeten, het correct gebruik van medicatie, het eten van een gevarieerde en gezonde voeding, het uitoefenen van lichamelijke activiteit…).

De resultaten hiervan zijn alleen bestemd voor dit onderzoek en zijn anoniem. De resultaten en conclusies zullen geformuleerd worden in de masterproef.