# The Impact of Health Literacy on Diabetes Self-Management Education

Jessica Vandenbosch[a,] Stephan Van den Broucke[a], Louise Schinckus[a], Peter Schwarz[b], Gerardine Doyle[c], Jürgen Pelikan[d], Ingrid Muller[e], Diane Levin-Zamir[f,g], Dean Schillinger[h], Peter Chang[i], Helle Terkildsen-Maindal[j] On behalf of the Diabetes Literacy Consortium

[a] Psychological Sciences Research Institute, Catholic University of Louvain, Louvain-la-Neuve, Belgium
[b] Faculty of Medicine Carl Gustav Carus, Technische Universität Dresden, Dresden, Germany
[c] UCD School of Business, University College Dublin, Dublin, Ireland
[d] Gesundheit Österreich, Vienna, Austria
[e] University of Southampton, Southampton, UK
[f] Clalit Health Services, Tel Aviv, Israel
[g] School of Public Health, University of Haifa, Israel
[h] UCSF Center for Vulnerable Populations, San Francisco, USA
[i] Taipei Medical University, Taipei, Taiwan
[j] Department of Public Health, Aarhus University, Denmark

## Abstract

**Background**. Diabetes self-management education (DSME) is generally considered to be a key determinant of the treatment outcomes and related costs of diabetes mellitus. While DSME programmes generally have positive outcomes, their effects may depend on certain factors such as the type of programmes provided and patients' level of health literacy (HL). Low HL has been associated with poorer self-management behaviours and poor medication adherence in diabetic patients, but its impact on the effects of DSME has not yet been systematically investigated. This study aimed to investigate the influence of HL on the self-reported effects of DSME programmes while taking the type of programme into consideration.

**Method**. 366 diabetic patients from nine countries completed a questionnaire measuring HL, self-management behaviours, problem perception, coping, perceived general health and well-being before and after participating in a DSME programme.

**Results.** DSME programmes were found to have positive effects on self-reported self-management behaviours and almost all psychological and health outcomes, regardless of HL level. Patients with high HL scored better on several diabetes outcomes than those with low HL, but all patients described benefiting from DSME. Individual and group-based programmes resulted in more positive effects on several diabetes outcomes than self-help groups, but no interaction with HL was found.

**Conclusion.** Our findings confirm those of previous studies showing that DSME programmes have positive effects and that low HL is associated with lower diabetes outcomes, but do not support the assumption that the effects of DSME programmes are influenced by the patient's HL. However, due to the limitations of this study, further investigation is necessary to support these findings and improve our understanding about the impact of HL on DSME programmes' effectiveness.

**Key words**: health literacy, type 2 diabetes, self-management education programmes, patient education

**Corresponding author:**

Jessica Vandenbosch, Université catholique de Louvain, Institut de Recherche en Sciences Psychologiques, Place Cardinal Mercier 10, 1348 Louvain-la-Neuve, Belgium
Email jessica.vandenbosch@uclouvain.be

Diabetes mellitus, which globally affects more than 415 million individuals, is one of the most common non-communicable diseases and one of the leading causes of death worldwide. In 2015, the International Federation for Diabetes estimated that 5 million deaths were directly attributable to diabetes and its related complications, such as kidney failure, heart attacks, stroke, and lower limb amputations (International Diabetes Federation, 2015). About 90% of all diagnosed cases are type 2 diabetes, which is typically associated with excess body weight and physical inactivity (Sabaté, 2003; World Health Organization, 2016). Lifestyle factors have a major role to play both in the prevention and treatment of type 2 diabetes, as a healthy diet, sufficient physical activity, and a normal body weight can help achieve adequate metabolic control, reduce the risk of complications, and even prevent or delay the onset of the disease (Lindström et al., 2010; Schwarz, Greaves, Lindström, Yates and Davies, 2012). As such, the success of diabetes prevention and treatment relies heavily on the individuals' abilities to manage their own illness and care process, and to adopt a healthy and active lifestyle. The practice guide of the American Association of Diabetes Educators specifies seven self-care behaviours that are essential for persons with diabetes: healthy eating, being active, blood glucose monitoring, taking medication, problem solving (e.g. when there is an obstacle to dietary compliance), healthy coping (e.g. speaking with friends or playing music to deal with stress), and changing behaviours that increase the risk of developing diabetes complications, such as smoking or alcohol consumption.

To improve these self-management capacities, diabetes self-management education (DSME) programmes for people living with diabetes are widely recommended (International Diabetes Federation, 2017). DSME programmes aim to provide patients with the knowledge and skills that are necessary to effectively manage and achieve control of their diabetes. They are available in different formats, including individual and group-based interventions conducted in hospitals, medical homes or other care organisations, as well as IT based (e.g., web-based or phone-based programmes) (Powers et al., 2015). DSME programmes have been shown to produce positive effects on clinical, psychological and behavioral outcomes in diabetic patients, including improved glycaemic control (Brunisholz et al., 2014; Ellis et al., 2004; Steinsbekk, Rygg, Lisulo, Rise and Fretheim, 2012; Weaver et al., 2014), improved quality of life (Cochran and Conn, 2008; Powers et al., 2015; Tang, Funnell and Oh, 2012; Thorpe et al., 2013), increased diabetes knowledge (Steinsbekk et al., 2012) healthier lifestyle behaviours (Tang et al., 2012; Toobert et al., 2011), more healthy coping (Thorpe et al., 2013) and enhanced self-efficacy (Steinsbekk et al., 2012; Tang et al., 2012).

However, although a significant number of studies reported positive effects of DSME on diabetes outcomes, their effectiveness may be influenced by certain factors such as the type of programmes. A recent systematic review (Chrvala, Sherr and Lipman, 2016) showed that although DSME was beneficial for all participants, improvement in glycaemic control was the largest in programmes that combined individual and group education, followed by individual education, group education, and IT-based interventions. The effectiveness of DSME may also vary depending on patients' individual characteristics. Apart from demographic factors such as age, gender, or ethnicity, a significant factor associated with diabetes self-management is the patients' level of health literacy. Health literacy (HL) refers to individuals' knowledge, motivation and skills to obtain, understand, appraise, and apply health information in order to take health-related decisions in everyday life (Sørensen et al., 2012). Although the definition and conceptualisation of HL vary across studies, three dimensions are often distinguished: (1) *functional HL*, which refers to basic skills in writing and reading that are required to effectively function in everyday situations; (2) *communicative/interactive HL*, which refers to more advanced skills that are needed to extract and understand information from various sources; and (3) *critical HL*, which refers to advanced cognitive skills that allow the individual to critically assess information and apply it to make health-related decisions (Ishikawa, Takeuchi and Yano, 2008; Nutbeam, 2000).

HL is increasingly recognized as a key factor in public health and in the development of public health interventions (Schwarz and Riemenschneider, 2016; Van den Broucke, 2014). Low HL has been associated with poor health outcomes for many diseases, especially chronic diseases such as diabetes (Berkman, Sheridan, Donahue, Halpern and Crotty, 2011; Martin, Williams, Haskard and DiMatteo, 2005; Sabaté, 2003; Van den Broucke, 2014). Several studies have shown that compared to patients with adequate HL, diabetic patients with low HL have poorer knowledge about their disease and its management (Bains and Egede, 2011; Fransen, von Wagner and Essink-Bot, 2012; Gazmararian, Williams, Peel and Baker, 2003; Powell, Hill and Clancy, 2007; van der Heide et al., 2014), adopt fewer self-management behaviours (Lai, Ishikawa, Kiuchi, Mooppil and Griva, 2013; van der Heide et al., 2014), and have poorer levels of glycaemic control and an increased risk of complications (Schillinger et al., 2002; van der Heide et al., 2014).

While the adverse effects of low HL on diabetes self-care behaviours and health outcomes seem well established, its impact on the effectiveness of DSME programmes has not yet been systematically assessed. So far as we know, only one published study (Kim, Love, Quistberg and Shea, 2004) has examined whether DSME improved self-care behaviours differently in patients with low or high HL. In this study, it was found that both high and low health literate patients benefited from diabetes education by showing an improvement in self-care behaviours. Surprisingly, patients with low HL reported higher scores for certain self-care behaviours at follow-up than those with adequate HL. However, this study had several methodological limitations, including a small sample size, the inclusion of patients who had previously received diabetes education, a measure of HL that was limited to basic reading comprehension skills (i.e., functional health literacy), and a limitation to one type of DSME programme (i.e., group classes). The present study aimed to investigate the influence of HL on the effectiveness of DSME programmes in a larger sample, drawing on a more comprehensive conceptual and operational definition of HL (Nutbeam, 2000; Sørensen et al., 2012), and taking the type of DSME programmes into consideration. The study was part of the EU-funded Diabetes Literacy project (2012-2015), which examined the factors influencing the self-reported effects of DSME programmes in a multinational sample of patients with diabetes type 2.

## Method

### *Study design*

A multicentre observational pre-post study design was used involving newly diagnosed diabetes patients enrolled in different DSM programmes in nine countries (Austria, Belgium, Denmark, Germany, Ireland, the UK, Israel, Taiwan and the USA). The programmes included in the study were existing programmes selected from a compendium of diabetes self-management education programmes developed as part of the Diabetes Literacy Project. Four different modes of delivery were represented: individual education in one-on-one sessions, group education, IT based education (e.g., web-based programmes), and self-help groups (also called peer-led groups). Individual and group-based education were structured programmes run by trained educators or health professionals in hospitals, medical homes or other care organisations, whereas self-help groups were less structured and consisted of regular meetings run by patients during which they could share their experiences and obtain support. Programmes were only selected if they were stand-alone programmes, aimed at the improvement of self-management skills, had a written curriculum, accepted new patients without previous DSM-experience during the time of the study, and were not tailored to specific target groups.

### *Sample*

Participants who were registered in a DSME programme meeting the previous criteria, who spoke the national language and gave their informed consent were recruited from October 2014 to June 2015 through the local personnel of the collaborating programmes. In group-based programmes, patients could individually agree to participate, therefore participants from one specific group intervention were not all included in the study and only those who gave their consent were selected.

A total of 628 patients met the inclusion criteria and participated in the study at baseline, of which 471 participated in the follow-up (75% of the initial sample). Another 105 participants (22%) were excluded on the basis of the following predefined exclusion criteria: (1) participated in another DSM intervention 3 months before or during the study; (2) attended less than one session of the programme; (3) answered less than ten questions in the follow-up-questionnaire; (4) had pre-diabetes and not type 2 diabetes; (5) had more than two missing values in the socio-demographic information. This resulted in an overall sample size of 366 (58%) patients.

### *Procedure*

Participants were asked to complete a series of questionnaires at the beginning of the programme, and again after three to six months. At baseline, they self-completed a written questionnaire (except for participants from Israel who were interviewed). For the follow-up measure, telephone interviews were conducted. If telephone interviews were not possible, participants could also fill in the follow-up questionnaire via an online survey. Participants, providers and on-site personnel did not receive any financial or material compensation for collaborating in this study. Ethical approval was obtained from each national institutions in which data were collected[1].

### *Measures*

*General health literacy* was assessed at baseline using the 6-item version of the Health Literacy Survey Questionnaire (HLS-EU-Q6) (Pelikan, Röthlin, Ganahl and Peer, 2014; Sørensen et al., 2013). Patients had to indicate on a 4-point scale how easy it was to perform a series of health-related tasks (e.g., use information the doctor gives them to make decisions about their illness, judge if the information on health risks in the media is reliable). The total mean score ranges from 1 to 4, with

---

[1] Ethical approval was obtained from the following national institutions: Ethics Committee of the city Vienna, Austria (EK 14-135-VK_N2); NHS National Research Ethics Service - Health Research Authority - NRES Committee London-Hampstead, UK (13/LO/0316); Ethikkommission an der TU Dresden, Germany (EK 375092013); University College Dublin Office of Research Ethics – Ethics and Medical Research Committee St. Vincent's Healthcare, Ireland (HS-E-13-95-DOYLE); Commission d'Ethique Hospitalo-Facultaire (CEBHF) de l'Université catholique de Louvain, Belgium (B403-2014-21-389); Human Research Protection Program – Committee on Human Research University of California San Francisco, USA (#076267); Ethics Committee Community Division – Clalit Health Services National Office, Israel; Institutional Review Board – Ethics Committee National Taipei Hospital, Taiwan (TH-IRB-00140010/2015); Danish data Agency (2014-41-3572).

higher scores reflecting higher levels of health literacy. The internal consistency of this scale in our sample was .78. The HLS-EU-Q distinguishes between three levels of HL: inadequate, problematic, and sufficient. However, when creating these categories highly unequal sample sizes were obtained for the three groups, with very few individuals in the inadequate HL category. Thus, to obtain more balanced groups of comparable size, categories of higher and lower health literacy were created using the median (2.83), with participants having a score equal or below the median categorized as lower health literate (N = 184) and those with a score above the median as higher health literate (N = 182).

Outcome measures of the DSME programmes were defined for the sub-categories of the Diabetes Self-Management Outcome Framework (DSMOF) (Röthlin, Pelikan and Ganahl, 2016), which represents the AADE7 self-care behaviours with the addition of criteria for individual DSM disposition and disease and health traits. The following outcome measures were used:

- *Diabetes specific health literacy* was measured at baseline and at follow-up using the scale developed by (Ishikawa et al., 2008). This scale consists of 14 items assessing functional HL (e.g., abilities to read and understand instructions or leaflets from hospitals/pharmacies), communicative HL (e.g., abilities to collect diabetes-related information from various sources, capacities to extract the information and apply it in daily life), and critical HL (e.g., abilities to assess the credibility and reliability of health information, to judge whether the information is applicable to one's own situation). Each item has four response options ranging from never (1) to often (4), so that patients scoring high have higher levels of diabetes specific HL. The internal consistencies (Cronbach α) of the three subscales in our sample were .82, .81, and .79 for the pre-test measures, and .82, .73, and .80 for the post-test.

- *Behavioural outcomes* related to self-management were measured at baseline and at follow-up with subscales of the Summary of Diabetes Self-care Activities Questionnaire (SDSCA) (D. J. Toobert, Hampson, & Glasgow, 2000). This questionnaire asks participants to indicate how many days in the preceding week they performed behaviours including dieting (5 items, α = .65), exercising (2 items, α = .73), blood glucose level checking (2 items, α = .87), appropriate medication use (2 items assessing each insulin injection and oral medications), and foot care (5 items, α = .68). Mean scores for each behaviour range from 0 to 7, with higher scores indicating higher frequency.

- *Psychological outcomes* included diabetes specific problem perception and healthy coping, assessed via the Problem Areas in Diabetes Questionnaire (PAID) (McGuire et al., 2010) and the Appraisal of Diabetes Scale (ADS) (Carey et al., 1991), respectively. The PAID-5 measures diabetes related distress with five items describing negative emotions commonly experienced by diabetic patients, such as worrying about the future and the possibility of serious complications, feeling depressed, or feeling that diabetes is taking up too much mental and physical energy every day. Each item has to be rated on a scale from 0 to 4, with 0 representing "no problem" and 4 "a serious problem". Scores on each item were reversed so that patients scoring low on this scale experience higher emotional distress and are more likely to perceive diabetes as a burden and a serious problem. The ADS assesses patients' appraisal of their diabetes (e.g., perceived control over their disease, perceived effectiveness in coping with diabetes, belief that achieving good diabetic control is due to their efforts as compared to factors beyond their control) with seven items that have to be rated on a 5-point scale. Patients scoring high on this scale have more positive appraisal of their disease and healthier coping strategies. The internal consistency of these two scales were α =.87 and α =.73, respectively.

- *Health outcomes* assessed at baseline and at follow-up included health-related quality of life measured via the general health perception subscale of the SF-36 (Hays, Sherbourne and Mazel, 1993), and well-being with the WHO-5 (Primack, 2003). The perceived general health measure includes five statements such as "*My health is excellent*" and "*I seem to get sick a little easier than other people*" with five possible answers ranging from "Definitely true" to "Definitely false". Scores on several item had to be reversed so that higher scores indicate better perceived general health. The WHO-5 includes five statements such as "*I have felt calm and relaxed*" and "*I have felt active and vigorous*" that have to be rated on a scale from 0 to 5, with 0 representing "at no time" and 5 "all of the time". Patients scoring high on this scale have higher well-being. The internal consistencies for these scales in our sample were .71 and .82, respectively.

Additional information collected at baseline included the participants' gender, age, years of education, and self-perceived social status. All outcomes were measured at baseline and at follow-up, except for socio-demographic variables and general HL, which were only collected at baseline.

### *Analyses*

The outcome measures were divided into three groups: (1) diabetes health literacy (DHL) and its three dimensions (i.e., functional, communicative, and critical); (2) diabetes self-management behaviours (diet, exercise, blood testing, and foot care); and (3) psychological and health outcomes including the perception of diabetes as a problem, healthy coping, perceived health, and well-being. Data were also obtained for medication adherence but it was not included in the following analyses due to the high homogeneity and ceiling effect in the sample (i.e., a majority of participants reported the maximum scores).

Repeated measures MANOVAs were performed for the three groups of outcomes, using Pillai's Trace V for multivariate testing (Mayers, 2013) and *F*-tests for univariate testing. Well-being was analysed separately due to missing values (N = 284). Repeated measures MANOVA were performed with general HL (high or low) as the between-group independent variable and the three groups of outcomes as within-group dependent variables. Additional analyses were performed including the type of DSME programme as a second between-group variable in order to assess the interaction between HL and type of programme, excluding the IT-based group due to its very low sample size (N = 13).

The assumptions underlying multivariate analyses (normal distribution, homogeneity of variances, and homogeneity of variance-covariance) were checked and overall met. Age, years of education and social status were considered for inclusion in the model as covariates but as the assumptions regarding these covariates (i.e., reasonable correlations between covariates and dependent variables, no between-group differences in covariates) were not met and these variables were not (or weakly) correlated with the dependent variables they were not included (Mayers, 2013).

All analyses were performed with IBM SPSS Statistics 24.

## **Results**

### *Participants' characteristics*

As shown in Table 1, participants were mainly elderly patients with a mean age of 62 years, with a relatively low educational attainment (11 years of education on average), and a low self-perceived social status (on average 5 on a 10-point scale). Most patients in the sample were taking oral medication (N = 212; 57.9%) or a combination of insulin injections and oral medication (N = 81; 22.1%). A minority had either no medication (N = 50; 13.7%), or insulin injections (N = 23; 6.3%). Most participants included in the sample followed a group-based intervention (N = 234; 63.9%), followed by self-help programmes (N = 67, 18.3%) and individual programmes (N = 52, 14.2%). A small proportion of patients received IT-based interventions (N = 13, 3.6%).

---

*Table 1 about here*

---

### *Correlates of health literacy*

Differences between patients with high and low HL with regard to age, gender, years of education, self-perceived social status, and type of medication were assessed with independent-samples t-tests for continuous variables and Chi-Square tests for categorical variables. As demonstrated in Table 1, higher and lower health literate participants did not differ significantly with regard to age, gender, and type of medication, but they did regarding education and social status, with lower health literate patients having lower educational attainment and lower self-perceived social status.

### *Effects on outcomes of DSME*

#### *Diabetes specific health literacy*

Repeated measures MANOVAs showed a significant multivariate between-groups effect for the combined diabetes health literacy variables across HL groups regardless of the time point, but no significant within-subjects multivariate effect of the intervention. A significant multivariate interaction effect of time x HL group was also found. Subsequent univariate analyses indicated that the between group multivariate effect would largely be attributed to the higher scores on functional and critical DHL for patients with higher HL compared to those with lower HL, while the scores on communicative DHL did not differ by HL level. Similar to the within-subjects multivariate effect, the univariate effects over time were not significant for any of the DHL dimensions, suggesting no improvement due to the intervention for these variables. A significant time x HL group interaction effect was however seen for functional DHL and communicative DHL. Although no overall effect of the intervention is found, these results indicate that after the intervention there was a small decrease of functional HL in the high HL group, while that of the low HL group remained constant. Communicative DHL was also found to increase after the intervention in participants with low HL, while it remained constant for those with high HL.

*Table 2 about here*

*Behavioural outcomes*

A highly significant multivariate within-subject main effect of the intervention over time was found for the combined model of diet, exercise, blood testing, and foot care. In contrast, no significant multivariate between-groups of time x HL group interaction effects were found. Univariate analyses confirmed that there were significant within-group differences over time for diet, exercise, blood testing, and foot care. These results suggest a positive effect of the intervention for all these behaviours regardless of patients' HL level, but that there were no significant differences between high and low health literate patients for any of the self-management behaviours, nor any significant interaction effects.

*Psychological and health outcomes*

Significant multivariate between- and within-subject effects over time were found for the model combining problem perception, healthy coping, and perceived general health. In contrast, no multivariate interaction effect was found. Univariate analyses showed significant between-group differences for the three variables, in the sense that problem perception scores were significantly lower in the lower HL group, while healthy coping was significantly higher in the high HL group. In other words, patients with high HL were less likely to experience negative emotions and distress related to diabetes (e.g., worry, depression, fear), and they were more likely to have healthy coping strategies and positive appraisal of their disease. A marginally significant difference was also found for perceived general health, which suggests that patients with high HL had higher scores than those with low HL. There were also significant main effects of time for problem perception, coping and perceived general health: scores for these outcomes were significantly higher at follow-up compared to the baseline, which suggests positive effects of the intervention regardless of patients' HL level. No significant univariate time x HL group interaction effects were found for the three psychological and health outcomes. Univariate analyses conducted on well-being showed a significant between-group effect of HL and a marginally significant within-subject effect of the intervention, but no significant interaction. So, these findings suggest that well-being improved after the intervention, and that patients with higher HL have higher well-being scores than those with lower HL regardless of the intervention.

**Effects on outcomes of DSME accounting for programme type**

The detailed table including the analyses with the type of programme as second between-subject variable is not provided as it is not the main focus of the present article, but it is available from the authors upon request. These additional analyses showed an interaction between time and type of programme for some behavioural and psychological outcomes, suggesting that individual and group-based interventions overall resulted in better outcomes than self-help programmes. For instance, interaction effects were found for foot care (F (2, 347) = 5.66, *p* = .020), problem perception (F (2, 347) = 3.72, *p* = .025), coping (F (2, 347) = 5.02, *p* = .007) and perceived general health (F (2,

347) = 4.11, *p* = .017), which suggests that these outcomes improved for participants in both individual and group-based programmes while they remained unchanged for the self-help group. However, no interaction effect was found between programme type and HL, suggesting that the effects of different types of DSME programmes did not differ between participants with low and high HL.

## Discussion

In this multicentre observational study, we investigated the influence of health literacy (HL) on the self-reported effects of diabetes self-management education (DSME) in a sample of newly diagnosed diabetes patients enrolled in different self-management programmes in nine countries. The question whether diabetes education has different outcomes for patients with lower or higher HL has thus far hardly been explored. We therefore evaluated programme outcomes in terms of diabetes specific HL, self-management behaviors, problem perceptions and problem solving capacities, and perceived health, and considered the impact of high and low HL on these outcomes, taking account of the type of DSME programme (i.e., individual education, group-based programme and self-help group).

The results showed that for all outcome variables except for diabetes-specific HL there was a significant improvement at follow-up compared to the baseline measures. This suggests that overall the DSME programmes had a positive effect on the patients' self-reported self-management behaviors, problem perception, coping, general health and well-being, thus confirming the findings from other studies reporting positive outcomes of DSME, while the effects on diabetes specific HL were limited.

A second finding from our study is that the self-reported outcomes differed significantly depending on the patients' level of HL regardless of the intervention. Patients in the higher HL group scored better on functional and critical dimensions of diabetes HL, problem perception (with higher scores indicating lower emotional distress and perception of diabetes as a serious problem), coping, perceived general health, and well-being than patients in the lower HL group (apart from behavioral outcomes). However, these effects of DSME programmes were not significantly different depending on patients' HL level, apart from some small interaction effects for diabetes specific HL. Specifically, communicative diabetes HL increased for participants in the low HL group, but remained constant for those in the high HL group. Thus, while overall differences in outcomes can be observed between patients with low and high HL, our results suggest that all participants benefited from DSME regardless of their HL level. This confirms the findings of Kim et al. (2004) that both high- and low health literate patients benefit from diabetes education in terms of an improvement in self-care behaviors.

A last finding is that while the effectiveness of diabetes education may depend on the type of programmes - in the sense that individual and group-based programmes had overall more positive effects on several behavioral and psychological outcomes than self-help groups – there was no significant interaction between time, type of programme and HL. This suggests that the differential self-reported effects of interventions depending on the type of programme is the same for patients with low and high HL.

### *Limitations*

Several limitations of the study must be acknowledged. A first limitation concerns the use of a self-report questionnaire. Patients might not have been willing to honestly report their unhealthy and poor self-management behaviours, especially by telephone. Moreover, as the questionnaire was also completed by patients with limited HL, it is not certain that they understood all the questions. Some interviewers reported that when interviewing patients for the follow-up, some of them showed difficulties in understanding and answering questions. It is then likely that some patients, particularly with low HL, also faced difficulty in understanding and answering the questionnaire at baseline. These problems in understanding might have negatively impacted the accuracy and validity of the answers.

Secondly, the 6-item version of the HLS-EU-Q may not provide the most accurate and valid measures of health literacy, as compared to longer versions of this questionnaire. Due to the skewed distribution of the scale score, the categories of health literacy defined in the original 47-item HLS-EU-Q (Sørensen et al., 2013) could not be established as this would have given very unequal sizes of the high and low health literacy groups. To avoid this, participants were divided in two HL categories on the basis of the median score, which means that in practice the HL group reflected the *relative* health literacy status of the patients. The use of the original 47-item version of the HLS-EU-Q (Sørensen et al., 2013) could have provided a more accurate measure of health literacy, and produced different results.

A third limitation is related to the use of different methods for data collection (i.e., paper-based self-report at baseline, and by telephone during the follow-up). The decision to collect data for follow-up by phone was a pragmatic choice, and helped to reduce subject attrition. However, it might have introduced a source of inconsistency, some interviewers also found it difficult to ask participants multiple-choices questions over the telephone, and patients also sometimes had difficulties in answering and providing precise answers.

Another limitation is that data from nine different countries were pooled, resulting in an important heterogeneity in the sample regarding patients' nationality with unequal numbers of patients per country and per type of DSME programmes. For instance, participants in group-based interventions were more heterogeneous and from more countries (Israel, UK, Taiwan, Austria, Ireland, USA, Germany, and Belgium), whereas individual and self-help programmes included participants from only certain countries (Taiwan, Belgium, USA, and Germany for individual interventions; Austria, Denmark and Germany for self-help programmes). This heterogeneity is explained by the fact that not all kinds of DSME programmes were available in all countries. Moreover, participants' characteristics slightly differed depending on the type of programmes. While there was no significant difference in educational attainment and self-perceived social status across all types of programmes, participants receiving group-based and self-help interventions tended to be older than those in the individual interventions.

Finally, as the study was conducted on existing education programmes in different countries and in various contexts, it was not feasible to include control groups and to randomly assign participants in different type of DSME programmes. Therefore, this research design limits the possibility of establishing causal relationships and the results should be interpreted with caution. Future studies could investigate more systematically the moderating effect of HL on the effectiveness of diabetes self-management education with strengthened research design including groups of patients receiving no intervention.

## Conclusion

Despite these limitations, the present study clearly adds to our understanding of factors influencing the self-reported outcomes of DSME programmes and of the role of health literacy. While in line with the findings from previous research that diabetes education leads to better self-management behaviours, better problem solving, better coping and better perceived health, the assumption that health literacy influences the effects of self-management education programmes for diabetic patients is however not supported by this study. Although patients with higher health literacy overall scored better on several diabetes outcomes than those with poorer health literacy, programmes were found to benefit all patients, regardless of their health literacy level. As previous studies, the findings of this study also highlight the importance of the type of self-management education programme on self-reported outcomes: individual and group-based programmes overall resulted in more positive effects on diabetes outcomes than self-help groups, regardless of the patient's level of health literacy. So, while it is important to develop and implement diabetes education programmes that are adapted to patients with low health literacy, this study suggests that factors such as the type of interventions are better predictors of programmes' self-reported outcomes than patients' health literacy. However, due to the limitations of this study, further investigation is necessary to support these findings and improve our understanding about the impact of health literacy on DSME programmes' effectiveness.

## Acknowledgements

This study was part of the Diabetes Literacy Project carried out between 2013-2015 by the Diabetes Literacy Consortium, composed of researchers from the Université catholique de Louvain, Belgium; Clalit Health Services, Israel; the Ludwig Boltzmann Institute Health Promotion Research, Austria; Maastricht University, the Netherlands; Taipei Medical University, Taiwan; Dresden University of Technology, Germany; University College Dublin, Ireland; the University of California San Francisco, USA; and the University of Southampton, United Kingdom, together with Aarhus University, Denmark and the University of Pretoria, South Africa as collaborating partners. The authors would like to thank all stakeholders and researchers who contributed to the study development and data collection, and who provided relevant comments and feedback on this manuscript.

## Funding

The Diabetes Literacy Project was funded by the European Union's 7th Framework Program for research, technological development and demonstration (grant agreement 306186) and the national organisations taking part in the project. Dean Schillinger was also supported by: NIH grant 2P30 NIDDK092924-06.

## References

Bains SS and Egede LE (2011) Associations Between Health Literacy, Diabetes Knowledge, Self-Care Behaviors, and Glycemic Control in a Low Income Population with Type 2 Diabetes. *Diabetes Technology & Therapeutics* 13(3): 335–341.

Berkman ND, Sheridan SL, Donahue KE, Halpern DJ and Crotty K (2011) Low health literacy and health outcomes: an updated systematic review. *Annals of Internal Medicine* 155(2): 97–107.

Brunisholz KD, Briot P, Hamilton S, Joy EA, Lomax M, Barton N, … Cannon W (2014) Diabetes self-management education improves quality of care and clinical outcomes determined by a diabetes bundle measure. *Journal of Multidisciplinary Healthcare* 7: 533–542.

Carey MP, Jorgensen RS, Weinstock RS, Sprafkin RP, Lantinga, LJ, Carnrike CL, … Meisler AW (1991). Reliability and validity of the appraisal of diabetes scale. *Journal of Behavioral Medicine* 14(1): 43–51.

Chrvala CA, Sherr D and Lipman RD (2016) Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. *Patient Education and Counseling* 99(6): 926–943.

Cochran J and Conn VS (2008). Meta-analysis of quality of life outcomes following diabetes self-management training. *The Diabetes Educator* 34(5): 815–823.

Ellis SE, Speroff T, Dittus RS, Brown A, Pichert JW and Elasy TA (2004). Diabetes patient education: a meta-analysis and meta-regression. *Patient Education and Counseling* 52(1): 97–105.

Fransen MP, von Wagner C and Essink-Bot ML (2012). Diabetes self-management in patients with low health literacy: ordering findings from literature in a health literacy framework. *Patient Education and Counseling* 88(1): 44–53.

Gazmararian JA, Williams MV, Peel J. and Baker DW (2003). Health literacy and knowledge of chronic disease. *Patient Education and Counseling* 51(3): 267–275.

Hays RD, Sherbourne CD and Mazel RM (1993). The RAND 36-Item Health Survey 1.0. *Health Economics* 2(3): 217–227.

International Diabetes Federation (2017) *Global Guideline for Type 2 Diabetes*. Available at: http://www.idf.org/sites/default/files/IDF-Guideline-for-Type-2-Diabetes.pdf (accessed 11 April 2017)

International Diabetes Federation (2015) *IDF Diabetes Atlas* 7th ed.. Brussels: Belgium.

Ishikawa H, Takeuchi T and Yano E (2008). Measuring functional, communicative, and critical health literacy among diabetic patients. *Diabetes Care* 31(5): 874–879.

Kim S, Love F, Quistberg DA and Shea JA (2004) Association of Health Literacy With Self-Management Behavior in Patients With Diabetes. *Diabetes Care* 27(12): 2980–2982.

Lai AY, Ishikawa H, Kiuchi T, Mooppil N and Griva K (2013) Communicative and critical health literacy, and self-management behaviors in end-stage renal disease patients with diabetes on hemodialysis. *Patient Education and Counseling*, 91(2): 221–227.

Martin LR, Williams SL, Haskard KB and DiMatteo MR (2005) The challenge of patient adherence. *Therapeutics and Clinical Risk Management*: 1(3): 189–199.

Mayers DA (2013) *Introduction to Statistics and SPSS in Psychology* (1st ed.). Harlow: Pearson.

McGuire BE, Morrison TG, Hermanns N, Skovlund S, Eldrup E, Gagliardino J, … Snoek FJ (2010) Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. *Diabetologia*, 53(1): 66–69.

Nutbeam, D. (2000). Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promotion International* 15(3): 259–267.

Pelikan JM, Röthlin F, Ganahl K and Peer S (2014) *Measuring comprehensive health literacy in general populations – le HLS-EU instruments*. Presented at the Second International Conference of Health Literacy and Health Promotion, Taipei, Taiwan.

Powell CK, Hill EG and Clancy DE (2007) The relationship between health literacy and diabetes knowledge and readiness to take health actions. *The Diabetes Educator* 33(1): 144–151.

Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, … Vivian E (2015). Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Diabetes Care* 38(7): 1372–1382.

Primack B (2003) The WHO-5 Wellbeing Index performed the best in screening for depression in primary care. *Evidence Based Medicine* 8(5): 155–155.

Röthlin F, Pelikan JM and Ganahl K (2016) Development of a Diabetes Self-Management Outcome Framework (DSMOF) for the Diabetes Literacy Project. Vienna: Ludwig Boltzmann Institute Health Promotion Research.

Sabaté E (2003) *Adherence to Long-term Therapies: Evidence for Action*. World Health Organization.

Schillinger D, Grumbach K, Piette J, Wang F, Osmond D, Daher C, … Bindman A (2002) Association of health literacy with diabetes outcomes. *JAMA* 288(4): 475–482.

Schwarz PEH and Riemenschneider H (2016). Slowing Down the Progression of Type 2 Diabetes: We Need Fair, Innovative, and Disruptive Action on Environmental and Policy Levels! *Diabetes Care* 39(2), 121-126.

Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z and Brand H (2012) Health literacy and public health: A systematic review and integration of definitions and models. *BMC Public Health*: *12*, 80.

Sørensen K, Van den Broucke S, Pelikan JM, Fullam J, Doyle G, Slonska Z, … Brand H (2013) Measuring health literacy in populations: illuminating the design and development process of the European Health Literacy Survey Questionnaire (HLS-EU-Q). *BMC Public Health* 13: 948.

Steinsbekk A, Rygg L, Lisulo M, Rise MB and Fretheim A (2012) Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. *BMC Health Services Research* 12: 213.

Tang T, Funnel MM and Oh M (2012) Lasting effects of a 2-year diabetes self-management support intervention: outcomes at 1-year follow-up. *Preventing Chronic Disease 9*: E109.

Thorpe CT, Fahey LE, Johnson H, Deshpande M, Thorpe JM and Fisher EB (2013) Facilitating Healthy Coping in Patients With Diabetes: A Systematic Review. *The Diabetes Educator* 39(1): 33–52.

Toobert DJ, Hampson SE and Glasgow RE (2000) The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care* 23(7): 943–950.

Toobert DJ, Strycker LA, King DK, Barrera M, Osuna D and Glasgow RE (2011) Long-term outcomes from a multiple-risk-factor diabetes trial for Latinas: ¡Viva Bien! *Translational Behavioral Medicine* 1(3): 416.

Van den Broucke S (2014) Health literacy: a critical concept for public health. *Archives of Public Health* 72: 10.

van der Heide I, Uiters E, Rademakers J, Struijs JN, Schuit AJ and Baan CA (2014) Associations among health literacy, diabetes knowledge, and self-management behavior in adults with diabetes: results of a dutch cross-sectional study. *Journal of Health Communication* 19*(2):* 115–131.

Weaver RG, Hemmelgarn BR, Rabi DM, Sargious PM., Edwards AL, Manns BJ, … James MT (2014) Association between participation in a brief diabetes education programme and glycaemic control in adults with newly diagnosed diabetes. *Diabetic Medicine: A Journal of the British Diabetic Association* 31(12): 1610–1614.

World Health Organization. (2016). Diabetes. Available at: http://www.who.int/mediacentre/factsheets/fs312/en/ (accessed 11 April 2017)

**Table 1 – Participants' characteristics by health literacy groups**

| | Total (N=366) | | Low HL (N=184) | | High HL (N=182) | | | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | t or $\chi^2$ | p |
| Age | 62.31 | 11.55 | 62.54 | 11.12 | 62.08 | 11.99 | .38 | .70 |
| Years of education | 10.94 | 4.48 | 10.26 | 4.49 | 11.63 | 4.39 | -2.93 | .00 |
| Self-perceived social status[1] | 5.40 | 2.07 | 5.02 | 2.15 | 5.78 | 1.90 | -3.57 | .00 |
| | N | % | N | % | N | % | | |
| Gender | | | | | | | | |
| Male | 185 | 50.5% | 93 | 50.5% | 92 | 50.5% | .00 | .99 |
| Female | 181 | 49.5% | 91 | 49.5% | 90 | 49.5% | | |
| Medication | | | | | | | | |
| Insulin injection | 23 | 6.3% | 13 | 7.1% | 10 | 5.5% | 6.29 | .09 |
| Oral medication | 212 | 57.9% | 112 | 60.9% | 100 | 54.9% | | |
| Insulin injection and oral medication | 81 | 22.1% | 42 | 22.8% | 39 | 21.5% | | |
| No medication | 50 | 13.7% | 17 | 9.2% | 33 | 18.1% | | |

---

[1] Perceived social status was measured on a 10-point scale, with 0 reflecting the most deprived individuals in society, and 10 reflecting individuals who are better off in terms of wage, education, and employment.

**Table 2 – Outcomes of DSME for High and Low health literate patients using repeated measures MANOVA**

| | **Total (N=366)** | | **Low HL (N=184)** | | **High HL (N=182)** | | $F_{\text{Time}}$ | $F_{\text{HL}}$ | $F_{\text{Interaction}}$ |
|---|---|---|---|---|---|---|---|---|---|
| | T1 | T2 | T1 | T2 | T1 | T2 | | | |
| | M (SD) | M (SD) | M (SD) | M (SD) | M (SD) | M (SD) | | | |
| *Diabetes Health Literacy* | | | | | | | | | |
| Functional | 2.80 (.76) | 2.75 (.79) | 2.57 (.76) | 2.60 (.82) | 3.03 (.69) | 2.90 (.74) | 2.03 | 28.16*** | 5.33* |
| Communicative | 3.11 (.74) | 3.16 (.63) | 3.05 (.74) | 3.16 (.64) | 3.19 (.73) | 3.16 (.63) | 1.66 | 1.22 | 3.87* |
| Critical | 2.96 (.81) | 2.99 (.79) | 2.86 (.82) | 2.91 (.76) | 3.06 (.78) | 3.07 (.80) | .38 | 6.66* | .09 |
| Combined[1] | | | | | | | 1.16 | 11.70*** | 3.25* |
| *Behavioral outcomes* | | | | | | | | | |
| Diet | 4.35 (1.51) | 4.54 (1.36) | 4.22 (1.52) | 4.49 (.1.33) | 4.47 (1.48) | 4.59 (1.39) | 7.04** | 1.72 | .93 |
| Exercise | 2.92 (2.29) | 3.41 (2.30) | 2.80 (2.21) | 3.35 (2.22) | 3.03 (2.36) | 3.47 (2.39) | 23.33*** | .65 | .25 |
| Blood Testing | 2.92 (2.84) | 3.27 (2.86) | 2.92 (2.85) | 3.21 (2.85) | 2.92 (2.83) | 3.32 (2.87) | 8.70** | .04 | .21 |
| Foot care | 3.63 (1.77) | 4.17 (1.66) | 3.46 (1.77) | 4.07 (1.66) | 3.80 (1.77) | 4.26 (1.65) | 37.21*** | 2.88 | .74 |
| Combined[1] | | | | | | | 15.42*** | .90 | .45 |
| *Psychological and health outcomes* | | | | | | | | | |
| Problem perception | 2.52 (1.09) | 2.75 (1.08) | 2.41 (1.10) | 2.59 (1.13) | 2.63 (1.08) | 2.91 (1.01) | 25.13*** | 6.74* | 1.09 |
| Coping | 3.53 (.65) | 3.68 (.67) | 3.44 (.65) | 3.57 (.67) | 3.63 (.63) | 3.80 (.64) | 26.43*** | 11.72** | .49 |
| General Health | 3.14 (.77) | 3.31 (.78) | 3.06 (.72) | 3.26 (.79) | 3.23 (.81) | 3.36 (.76) | 23.72*** | 3.50$^{\alpha}$ | 1.09 |
| Well-being[2] | 2.38 (.87) | 2.42 (.88) | 2.22 (.91) | 2.36 (.89) | 2.59 (.80) | 2.63 (.80) | 3.14$^{\alpha}$ | 13.39*** | .81 |
| Combined[1] | | | | | | | 14.47*** | 3.89** | 1.06 |

[1] Multivariate outcome indicating whether there are significant differences regarding the combined dependent variables

[2] The well-being variable was not included in the multivariate model due to missing values (N = 284) and was analysed separately using univariate test. The last multivariate outcome thus refers to the combination of problem perception, coping, and perceived general health.

** p < .05  ** p <.01  ***  p <.001* $^{\alpha}$*Significant at p <.10*