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# Diabetes education and self-management for ongoing and newly diagnosed (DESMOND): Process modelling of pilot study

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#### Abstract

*Objective:* To determine the effects of a structured education program on illness beliefs, quality of life and physical activity in people newly diagnosed with Type 2 diabetes.

*Methods:* Individuals attending a diabetes education and self-management for ongoing and newly diagnosed (DESMOND) program in 12 Primary Care Trusts completed questionnaire booklets assessing illness beliefs and quality of life at baseline and 3-month follow-up, metabolic control being assessed through assay of HbA1c.

*Results:* Two hundred and thirty-six individuals attended the structured self-management education sessions, with 97% and 64% completing baseline and 3-month follow-up questionnaires. At 3 months, individuals were more likely to: understand their diabetes; agree it is a chronic illness; agree it is a serious condition, and that they can affect its course. Individuals achieving a greater reduction in HbA1c over the first 3 months were more likely to agree they could control their diabetes at 3 months (r = 0.24; p = 0.05), and less likely to agree that diabetes would have a major impact on their day to day life (r = 0.35; p = 0.006).

*Conclusion:* Pilot data indicate the DESMOND program for individuals newly diagnosed with Type 2 diabetes changes key illness beliefs and that these changes predict quality of life and metabolic control at 3-month follow-up.

*Practice implications:* Newly diagnosed individuals are open to attending self-management programs and, if the program is theoretically driven, can successfully engage with the true, serious nature of diabetes.

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Keywords: Type 2 diabetes mellitus; Newly diagnosed; Structured education; Patient self-management; Illness beliefs; Quality of life

#### 1. Introduction

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Type 2 diabetes is a condition predominantly managed by the person with diabetes, with the support and guidance of health care professionals [1,2]. To be able to make informed choices about diabetes self-management (medication taking, dietary choices, physical activity and monitoring), individuals with diabetes need to receive structured self-management

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education. However, there is substantial variability in the effectiveness of diabetes self-management education programs, with some intervention studies reporting a negative effect on glycaemic control [3].

Most people in the UK are offered some form of 'education' at the time of their diagnosis [4,5]. However, there are wide variations between services in the length, content and style of educational options provided. Furthermore, most educational programs are unstructured, very few have been formally evaluated and few individuals who deliver education have been formally trained for this purpose [4,5]. There is insufficient evidence currently available to recommend a specific type of education or provide guidance on the setting for, or frequency of, sessions [6]. In particular, reviews have highlighted a shortage of high-quality information regarding the efficacy of structured selfmanagement education in diabetes [7-9], although one meta-analysis would suggest that self-management education programs that use a theoretical rationale [10] and use cognitive reframing [11] (a marker for being more psychologically informed), have better outcomes.

Despite this lack of evidence to provide clear guidance on the form of diabetes self-management education, the American Diabetes Association (ADA) in conjunction with the American Association of Diabetes Educators (AADE) have provided a set of standards around the delivery of structured self-management education [12], which is similar to the principles of best practice provided by the National Institute for Health and Clinical Excellence (NICE) in the UK [6]. Key issues in these standards are the use of appropriately trained health professionals, a clear theoretical and empirical rationale for the content and process of selfmanagement education, a non-didactic approach and clear quality assurance processes.

Despite being well-publicised, there are few published studies of rigorously evaluated self-management interventions for people with Type 2 diabetes that meet these standards. Furthermore, systematic reviews have not identified any such programs for individuals newly diagnosed with Type 2 diabetes. Given the importance and impact of care at, and shortly after, diagnosis [13], and the recently issued guidance in the UK [6], to provide structured self-management for newly diagnosed individuals, there is an urgent need to develop and evaluate such programs.

Given the complex nature of such interventions, a systematic framework to guide their development is essential. In the UK, the Medical Research Council (MRC) has provided such a framework [14] (Fig. 1), comprised of five key steps. The first is the theoretical work underpinning the design of the intervention. In the case of the diabetes education and self-management for ongoing and newly diagnosed (DESMOND) initiative, this was undertaken by a multidisciplinary, multicentre collaborative that combined the experience of several centres already



Fig. 1. MRC Framework for the evaluation of complex interventions. Campbell, M., et al., 2000. BMJ 321, 694–696. Reproduced with permission from the BMJ Publishing Group.

running programs for individuals newly diagnosed with Type 2 diabetes, in order to form a new program.

In line with ADA/AADE's first standard for self-management education 'The DSME entity will have documentation of its organizational structure, mission statement and goals ...', the DESMOND Collaborative agreed upon a core set of philosophical principles. The philosophy can be summarised as that of 'informed choice', which the Collaborative believe to be the key to empowerment [15,16], and based on a

humanistic view of the individual. However, there are challenges to implementing an empowerment philosophy, e.g. what does this mean for the health care professional? What are the roles and responsibilities for health professionals when facilitating self-management programs? To clarify this, the Collaborative used the four statements underpinning empowerment philosophy to articulate the key roles and responsibilities for health care professionals that derive from these existential truths (Table 1).

Table 1

Table I						
Summary of	f the principles of	f empowerment a	and the der	ived responsibili	ties of health	care professionals

Underlying principle	What health care professionals are responsible for
It is acknowledged that nearly all the day-to-day, minute-by-minute decisions (e.g. food choices, physical activity, medication taking, monitoring, etc.) which affect patient outcomes are made by the individual with diabetes. As such, the individual is responsible for managing their condition (except where the individual	• Ensuring individuals with diabetes and their carers are provided with honest, up to date, evidence-based information regarding the causes, effects and options for the management of Type 2 diabetes
has a formal mental disability which prevents them from making informed decisions)	• Ensuring people living with Type 2 diabetes are aware of their specific ongoing health risks for developing complications
	<ul> <li>Providing an expert forum for individuals to discuss methods of reducing their identified risk factors</li> <li>Ensuring individuals are supported in developing their own diabetes management plan</li> </ul>
	• Providing systems of care which are accessible to everyone
It is acknowledged that all individuals should be supported to make what they perceive to be the best possible decisions for themselves in order to progress towards achieving the best possible quality of life, as they understand that to be	<ul> <li>Ensuring individuals with diabetes are supported in processing and understanding the information provided to them</li> <li>Ensuring everyone is treated non-judgementally and with respect, regardless of how they decide to manage their diabetes</li> </ul>
	<ul> <li>Ensuring everyone is offered equitable access to pharmaceutical and technological resources, regardless of how they decide to manage their diabetes</li> <li>Ensuring everyone is offered the same equitable access and quality of care, regardless of how they decide to manage their diabetes</li> </ul>
	• Ensuring no-one will ever be excluded from any education or care activity should they choose not to self-manage at any time, and will be invited to participate in the future, as an individual
It is acknowledged that nearly all the barriers to effective self-management lie within the individual's personal and social world	<ul> <li>Ensuring empathy and warmth is demonstrated in all clinica and educational interactions</li> <li>Ensuring people with Type 2 diabetes are given the</li> </ul>
	opportunity to reflect on the possible barriers to their
	• Ensuring individuals are supported in developing general self-management skills such as goal setting, action planning and problem solving
	• Ensuring individuals are supported in developing diabetes-specific self-management skills such as self-monitoring, management of hypoglycaemia and hyperglycaemia, foot care and cardiovascular risk
It is acknowledged that nearly all the consequences of diabetes self-management decisions accrue to the individuals with diabetes, their families and carers	<ul> <li>Ensuring individuals are provided with a forum or space in which to discuss and explore their experiences of being newly diagnosed</li> <li>Ensuring individuals are supported in managing their emotional responses to diabetes, its impact on their life and the impact of its complications</li> <li>Ensuring individuals experiencing significant emotional distress are offered appropriate help</li> </ul>

Building on this philosophical grounding, the content and process of the program was developed around three theoretical approaches. The Common Sense Model of Illness [17,18] focuses on an individual's illness representation or personal model of diabetes as a key determinant of an individual's behavioural and emotional response to illness. Research in this field has identified five core elements across cultures that form our illness representations, and these beliefs are consistent predictors of self-care behaviour and effects across a wide variety of illness populations [19–21].

Social Learning Theory [22] focuses on the individual's perception of their ability to enact behaviours and follow through on their action plans. Self-efficacy (or confidence) is the primary concept in this model, which has been shown to be one of the most consistent predictors of an individual's self-care behaviour [23–25], and has been incorporated into most health psychology models in one form or another [26].

The third theoretical approach relates to the process of education/learning for the participants, and was guided by several theoretical concepts, the main ideas being that as Vygotsky identified, learning needs to take place in the learner's 'zone of proximal development', with the educator's role being to provide an environment that could be described as providing scaffolding for the learning process [27]. In reality, this means using a discovery learning process, with the participants contributing most of the content and which looks very similar to the concepts found in the literature on systematic processing [28].

The second phase of the MRC process is to undertake modelling, to test that the intervention works as anticipated. Therefore, the DESMOND Collaborative recruited 12 Primary Care Trusts (PCT) in England to deliver two to three programs using the DESMOND module for individuals newly diagnosed with Type 2 diabetes, and to collect baseline pre-group and 3-month post-group data to undertake the modelling analysis required. This paper reports this analysis of the DESMOND pilot study for individuals newly diagnosed with Type 2 diabetes, to determine whether process measures change as hypothesised and that these process measures are related to outcome measures at 3month post-group.

# 2. Methods

#### 2.1. Participants

In each of the 12 Primary Care Trusts, a small number of GP practices were recruited to refer patients newly diagnosed with Type 2 diabetes into the pilot. All individuals over the age of 18 years newly diagnosed with Type 2 diabetes within the participating GP practices were invited to attend the DESMOND program within 4–6 weeks of diagnosis. All patients over the age of 18 years newly diagnosed with Type 2 diabetes were potentially eligible to participate if they could attend a program within the required

time frame. Individuals were excluded if they had severe and enduring mental health problems (as determined by referring GP), were not primarily responsible for their own care, were unable to participate in a group program (e.g. housebound) or had insufficient understanding of English to participate in the group education.

## 2.2. Measures

Two primary outcome measures were used for this pilot study: quality of life and metabolic control. Quality of life was assessed using the WHOQOL-BREF [29]. This is a short version of a measure of general quality of life developed by the WHO simultaneously in 17 different countries to ensure cultural comparability and generalisability (WHOQOL) [30]. This short version generates a total score and four subscales: physical, psychological, social and environmental quality of life, and has been previously validated in individuals with Type 2 diabetes [31]. Metabolic control was assessed using HbA1c, drawn from a venous sampling and assayed locally in each Primary Care Trusts. As all trusts use laboratories which are effectively DCCT aligned, there was no need for centralised assaying. Furthermore, as the analysis undertaken here is a within subject analysis, and results are not affected if we control for centre, we feel this issue is not a problem with our current data.

Five key process measures, focusing on key illness and self-beliefs targeted by the intervention, were assessed. The individual's perception that they understand their diabetes (illness coherence); the individual's perception of the duration of their illness (timeline); the individual's perception of their ability to affect the course of their diabetes (personal control), were all assessed by using the relevant items from the Illness Perceptions Questionnaire-Revised (IPQ-R) [32], which has been validated in a number of chronic illness populations including individuals with Type 2 diabetes. The perceived seriousness and the perceived impact of diabetes was assessed using the appropriate items from the Diabetes Illness Representations Questionnaire (DIRQ) [33], which was developed from the original Illness Perceptions Questionnaire [34] and the Personal Models of Diabetes Interview [35] and has been shown to have good internal consistency, predictive and construct validity in Type 2 diabetes [36].

## 2.3. Procedure

Each participating GP practice was visited by an educator or the local project co-ordinator for each Trust, and a referral system established. When an individual was newly diagnosed with Type 2 diabetes, according to the WHO criteria, they were also told about the project study and invited to attend a DESMOND program. Individuals who wished to attend a DESMOND program within 6 weeks of their diagnosis, were then asked to complete a baseline

Table 2 Outline of the DESMOND module for individuals newly diagnosed with Type 2 diabetes

	Theory	Sample activity	Duration (min)
Session 1			
Introduction			10
Patient story	Common Sense Model	Participants asked to tell their story of how they discovered they had diabetes and their current knowledge of diabetes	40
Professional story	Common Sense Model dual process theory	Use participants' stories to support them learning how the body regulates blood glucose	55
Taking control 1	Social Learning Theory dual process theory	Knowledge and skills for food choices to control blood glucose	40
Monitoring	Social Learning Theory dual process theory	Support participants exploring benefits of monitoring and how to use it for feedback	30
How am I doing	Social Learning Theory	Participants reflect on what issues have come up from the program so far	5
Session 2			
Reflections	Social Learning Theory	Participants reflect on what issues have come up from the program so far	15
Professional story	ofessional story     Common Sense Model dual process theory     Use participants' stories to support them discovering how other risk factors (BP, lipids, depression, etc.) affect diabetes and development of complications		45
Physical activity	Physical activity Social Learning Theory Exploration of benefits and barriers to physic dual process theory		20
Taking control 2	Social Learning Theory dual process theory	Knowledge and skills for food choices to reduce risk factors	55
Self-management plan	Social Learning Theory	Participants supported in developing their self-management plan	30
Burning questions	Common Sense Model	Check that all questions raised by participants throughout have been answered and understood	10
What happens next		Follow-up care outlines	5

questionnaire, which they subsequently brought with them to the DESMOND program and handed to the educators on arrival. Subsequently, a second questionnaire was sent at 3month follow-up, returned by post to the local PCT coordinator and forwarded by them to the central research office. Blood results and other biomedical measures were obtained from practices by the local co-ordinator prior to attendance at a DESMOND course, so that patients could use these for considering their personal risk factors and creating personal action plans as part of the session. Subsequently, these were anonymised and returned to the project's central office.

#### 2.4. Self-management education program

The DESMOND program for individuals newly diagnosed with Type 2 diabetes, was developed by a multidisciplinary team, integrating the experience and research undertaken by centres already engaged in structured education for this population [37,38]. In total, 280 individuals received 6 h of group education, delivered in one of three formats: 1 day, 2 half-days or three 2-h sessions. The content and process used in the three formats were the same (see Table 2, for a broad outline of the sessions). To prepare them for delivering the program, educators, who were a mixture of registered dieticians, practice nurses or nurse specialists, completed 2 days of training led by a consultant dietician, two diabetes nurse consultants, a consultant clinical psychologist and a chartered health psychologist, which included modelling of the program and interactive sessions. Throughout, the training modelled the style and methods used to deliver the patient program. As the format (one, two or three sessions) is confounded with site and only two to three programs were run per site, this study would not have the power to explore the differential effect of format. Therefore, this analysis has not been undertaken at any point and analysis is focused purely on the modelling of the proposed theoretical mechanisms of the intervention.

# 3. Results

#### 3.1. Recruitment and attrition

Of the 280 individuals referred to the study, 236 (84%) attended a program, with 33% of these bringing an additional person with them (these were partners or close family members, some with and some without diabetes but the details of accompanying persons were not recorded). Of those who attended, 226 (97%) completed and returned baseline measures, of which 152 (64%) also returned completed questionnaires at 3 months. Respondents at baseline had a mean age of 62.6 years (S.D. = 11.5), 51% were male, 97% were from a Caucasian background and

15% were a current smoker. Individuals who returned a follow-up questionnaire were older (return mean = 64 years, S.D. = 10; non-return mean = 59 years, S.D. = 13; t = -3.2; d.f. = 224; p < 0.005), but there were no significant differences for any other biomedical (HbA1c, fasting glucose, blood pressure, total cholesterol, HDL, LDL, triglycerides, weight, waist or height), quality of life or illness beliefs measures.

#### 3.2. Changes in process measures

There were no significant effects of gender on any of these measures and no significant differences between participants from different Primary Care Trusts on any illness beliefs measures. However, prior to attending the program, older individuals were less likely to agree that diabetes was a chronic illness (r = 0.17; p = 0.01), that they could affect the course of their diabetes (r = 0.13; p < 0.05) and that it was serious condition (r = 0.17; p < 0.01).

Paired *t*-tests were undertaken comparing the coherence, timeline, impact, seriousness and personal responsibility scales at baseline with responses at 3 months. All comparisons showed a significant difference at follow-up with participants more likely to report they understood their diabetes (t = -10.3; d.f. = 131; p < 0.001; pre-mean = 14.5, S.D. = 4.1; post-mean = 18.0, S.D. = 3.8), to agree that it is a chronic illness (t = 3.1; d.f. = 133; p < 0.005; premean = 10.5, S.D. = 4.1; post-mean = 9.4, S.D. = 4.1), to agree it is a serious condition (t = 3.1; d.f. = 133; p < 0.005; pre-mean = 16.4, S.D. = 3.4; post-mean = 15.5, S.D. = 3.5), that they can affect its course (t = 3.2; d.f. = 132; p < 0.005; pre-mean = 11.6, S.D. = 3.5; post-mean = 10.8, S.D. = 3.1) and that it will have less impact (t = 3.4; d.f. = 133;p = 0.001; pre-mean = 25.4, S.D. = 4.4; post-mean = 26.2, S.D. = 3.8) at 3-month follow-up than at baseline (see Table 3, for sample response to scale items).

The fact that individuals do have greater understanding of their diabetes at three months is confirmed by the observation that individuals who report having greater understanding are also more likely to agree they will have it for the rest of their life (r = 0.29; p < 0.001), rate diabetes as more serious (r = 0.14; p < 0.01), agree they can affect the course of their diabetes (r = 0.28; p < 0.001) and agree that it will have less impact (r = 0.25; p < 0.001).

# 3.3. Relationship between process and outcome measures

If the education sessions are facilitating self-management as theorised, then beliefs should be related to outcomes at 3 months. The physical quality of life subscale of the WHOQOL-BREF showed significant improvement from baseline to 3 months, with individuals who agree more strongly that they understand their diabetes (r = 0.15): p < 0.05), that diabetes is a chronic illness (r = 0.21; p < 0.01), that they can affect the course of their diabetes (r = 0.16; p < 0.05) and that diabetes will not have a major impact on their life (r = 0.31; p < 0.0001) reporting better quality of life at 3 months. For metabolic control, neither gender, age, smoking status or ethnicity were associated with metabolic control at baseline or 3 months. Individuals who had a greater reduction in HbA1c over the first 3 months were more likely to agree that they can control their diabetes at 3 months (r = 0.24; p = 0.05), and less likely to agree that diabetes would have a major impact on their day to day life (r = 0.35; p = 0.006).

Finally, illness beliefs do not act in isolation, but it is the interaction between various beliefs that will be predictive of subsequent active self-management. Therefore, an interaction term was generated for personal responsibility with seriousness (by centering each variable and multiplying the centered scores). Correlating this interaction effect indicates

Table 3

Response to sample items from process measure scales at 3-month follow-up and change from baseline

	Strongly agree/agree	Uncertain	Disagree/strongly disagree
Coherence item: I do not understand	my diabetes		
Baseline (%)	41	28	31
3-month follow-up (%)	11	20	69
Duration item: I will have diabetes for	or the rest of my life		
Baseline (%)	66	28	6
3-month follow-up (%)	78	14	8
Seriousness item: my diabetes is a se	rious threat to my health		
Baseline (%)	47	39	14
3-month follow-up (%)	60	28	12
Personal responsibility item: the cour	se of my diabetes depends upon me		
Baseline (%)	85	13	2
3-month follow-up (%)	90	10	0
Impact item: my diabetes changes my	v daily activities		
Baseline (%)	8	22	70
3-month follow-up (%)	7	17	76

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that individuals who more strongly agree that diabetes is a serious threat to their health and that they can affect the course of their diabetes, reported a greater reduction in HbA1c over the 3-month follow-up (r = 0.33; p < 0.05) and lower HbA1c values at 3 months (r = 0.28; p < 0.05). All three variables (impact, personal responsibility and serious personal responsibility) correlating with change in HbA1c, were then entered into a multiple regression using stepwise entry, with the seriousness by responsibility interaction variable being the only significant predictor ( $\beta = 0.35$ ; t = 2.47; p = 0.018; r = 0.12).

# 4. Discussion and conclusion

#### 4.1. Discussion

The results presented here indicate that the DESMOND program for individuals newly diagnosed with Type 2 diabetes, is working as theorised. Participants' beliefs about diabetes change in the predicted direction following their attendance at the program, and these beliefs are related to an improvement in the physical domain of HR-QoL and HbA1c at 3 months. Without a control group it is not possible to establish that the change in beliefs was completely as a result of attending the DESMOND program, as the normal process of care for these participants may well have contributed to these changes. This issue can only be addressed through a robust, randomised controlled study, which is currently ongoing for the DESMOND program.

A second important point is that although participants report diabetes to be more serious or a greater risk to their health, and agree more strongly that they will have diabetes for life, they also report that it will have less of an impact on their daily activities. This is clearly in line with one of the key messages in the program, that small sustainable changes can have lasting long-term benefits. As perceived impact has been shown to be a strong predictor of psychological distress and depression in people with diabetes, this would suggest there is no negative emotional response to the provision of information concerning the seriousness of diabetes. Furthermore, the quality of life data, presented elsewhere [39] indicates no negative effects of attendance on generic or emotional facets of quality of life.

The most important feature of the results presented here is the association between the process measures and outcomes of care. Many studies demonstrate the efficacy of structured self-management education on biomedical outcomes in diabetes, and other chronic illness, and others report changes in intermediate process variables, such as knowledge, attitudes, beliefs and self-efficacy [7–9]. However, few report process analysis to show that the changes in process variables or intermediate outcomes are related to changes in outcome measures. This is a major failing in the self-management education literature, for unless researchers can demonstrate that an intervention works as hypothesised, they cannot claim that in fact the intervention is responsible for outcomes given. Since most self-management education studies do not control for contact time, the effects seen, unless supported by theoretical modelling, could be due to a study effect alone. Alternatively, changes in outcomes may occur purely due to optimisation of treatment, again a factor that cannot be ruled out unless process modelling is undertaken.

Since only 64% of individuals attending the program completed and returned 3-month follow-up questionnaires, it is possible that these positive results are because those who perceived benefits were more likely to cooperate with study procedures. However, there were no differences between those who dropped out and those who returned questionnaires, suggesting that the relatively low ascertainment did not influence the results. Furthermore, as in this study we are attempting to model the process of the intervention, and not demonstrate its efficacy, the problem of attrition does not pose a substantial problem for the reliability of these results. In addition, to modelling the intervention, this study has enabled us to pilot our methodology so that for the following randomised controlled trial we address this problem, and implement strategies to prevent this affecting the integrity and validity of the trial results. Another limitation is that it is not possible to establish causal relationships between the process measures and outcome measures, as changes in symptoms (as a result of improved control) may influence an individual's beliefs as well as changing beliefs, and driving changes in self-care which result in improved outcomes. In addition, it would be anticipated that the changes in illness and self-beliefs would result in more active self-management, which would influence quality of life and glycaemic control. Therefore, future analysis should be undertaken to demonstrate this additional step in the causal path, although there is data from studies with adolescents with Type 1 diabetes that demonstrates changes in beliefs drive changes in glycaemic control [40].

It should also be noted, that despite the significant changes in participants' beliefs about diabetes and their role in its management, a significant proportion of participants retained beliefs that did not fit the current medical view of diabetes (see Table 3). This could be because the DESMOND program failed to engage these individuals in the learning process or persuade them of the permanent nature of diabetes. Alternatively, this may reflect the intransigence of illness beliefs and their resistance to change, especially if this is not consistent with the beliefs of other health professionals or systems of care. It is still not uncommon for health care professionals in primary care to refer to 'mild diabetes', 'borderline diabetes' and 'the type that does not need insulin', which results in the message that Type 2 diabetes is not something to be concerned about [41]. Furthermore, Lawton et al. [13] have shown that the way the system of care is structured can also convey very different messages about the nature of diabetes and its seriousness. Without monitoring the input of other health professionals,

family, friends and the media, it is difficult to ascertain why so many individuals maintain beliefs that are not congruent with the messages articulated within the DESMOND program. However, the pilot study and feedback from both participants and educators has led to some revisions of the program which will hopefully further enhance its efficacy.

#### 4.2. Conclusions

The data reported here clearly indicate that delivering structured education at diagnosis of Type 2 diabetes is feasible, efficacious and has no negative effects on patients' emotional well-being.

# 4.3. Practice implications

With 84% of individuals invited attending the program, it is clear that individuals with newly diagnosed Type 2 diabetes are open to and willing to attend structured selfmanagement programs. The data also indicate that a theoretical driven program, can engage people in the true serious nature of diabetes, without having a negative impact on participants' emotional well-being. One of the benefits of such a program is that health care professionals in primary care who have little contact time, can focus this time more on the active management of diabetes, once individuals have attended a program like DESMOND, rather than supporting individuals through the difficult explanation of diabetes and its potential complications.

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