Self-reported effects of attending the Health Foundation's Co-Creating Health self-management programme for patients with type 2 diabetes mellitus in London, England

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Abstract

Introduction: The purpose of this study was to determine the impact of the Health Foundation's Co-Creating Health (CCH) group self-management programme (SMP) for adult patients with type 2 diabetes on patient activation and quality of life.

Material and methods: We conducted a multisite longitudinal study of 283 patients (mean age 62.3 years, SD 11.1; 43% ethnic minority; 51% female). Primary outcomes were patient activation, and diabetes and health related quality of life. Secondary outcomes included health status, psychological distress, and self-management ability. Data were collected immediately before the first SMP session (baseline) and 6 months after completing the programme. Quantitative analyses were based on mixed models using intent-to-treat and per-protocol procedures.

Results: Sixty percent of patients who signed up for SMP completed the programme. Patient activation significantly improved 6 months after the SMP ($p < 0.0001$), and 60.2% of course completers showed meaningful improvement. Diabetes-related quality of life also improved significantly 6 months post course ($p < 0.0001$). About a quarter of SMP completers showed substantial improvement in self-management skills.

Conclusions: Attending the UK SMP for adults with type 2 diabetes leads to improvements in patient activation, diabetes-related quality of life, and improved confidence and ability to self-manage their condition. Improvement in patient activation is an important finding because activated patients participate in collaborative decision-making with their clinicians, report improved health-related behaviours and clinical outcomes, and better adhere to treatment.

Key words: type 2 diabetes, self-management, patient activation.

Introduction

Nutritional intake and lifestyle modification are important self-management skills for people with type 2 diabetes mellitus (DM) [1]. Medically focused educational models of diabetes self-management can detract from the self-management of psychosocial and emotional aspects of diabetes [2]. These models can also reduce patient involvement in making decisions about their medical care and self-management. Patients who independently chose to make meaningful behaviour changes are more likely

to be motivated to initiate and sustain this change [3]. UK clinical guidelines for diabetes management highlight the importance of SM for people with diabetes [4, 5], including information provision as well as technical skills training, problem solving, and the impact of an individual's diabetes-specific beliefs and attitudes on behaviour [4–6].

A recent systematic review of 21 studies evaluating group self-management programmes for type 2 diabetes patients found improvements in clinical and lifestyle outcomes, diabetes knowledge self-management skills, empowerment, and self-efficacy [7]. A 2008 UK study by Davies *et al.* [8] was a cluster randomised controlled trial of the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND). DESMOND is a 6-hour group educational programme delivered by a trained healthcare professional. It is designed specifically for patients diagnosed with diabetes within the previous 12 weeks and focuses on lifestyle factors and promoting self-management [8]. Study results demonstrated that attending DESMOND leads to significant changes in weight loss and smoking cessation, and positive improvements in beliefs about illness at 12 months [8]. However, only improvements in some illness beliefs (e.g. beliefs about causes, severity of diabetes, need for medication, and prognosis) were sustained at 3 years [9]. In their 2006 UK study Deakin *et al.* evaluated the effectiveness of the X-PERT Programme [10]. The programme is based on theories of patient empowerment and patient-centred care and aims to improve participants' knowledge, skills, and confidence to effectively self-manage their diabetes [10]. Participation in the X-PERT Programme led to improvements in glycaemic control, total cholesterol level, body weight, requirement for diabetes medication, knowledge of diabetes, self-empowerment, self-management skills, and treatment satisfaction 14 months after completing the programme [10].

Participation in community-based, peer-led diabetes self-management resulted in decreased depression, improved communication with physicians, patient activation, and self-efficacy at 12 months, compared to a usual care control group [10]. Improvements in patient activation and self-efficacy were also demonstrated at 18 months [11]. Small, short-term improvements in participants' self-efficacy, self-rated health, and frequency of aerobic exercise have been demonstrated in other lay-led self-management education programmes for people with varying long-term conditions including type 2 DM [11], although there is currently no evidence to suggest improvements in quality of life, health status, or healthcare use.

As a part of the Co-Creating Health initiative (CCH) in the United Kingdom, a self-management programme (SMP) was delivered to patients with type 2 diabetes. CCH was a quality improvement programme commissioned by the Health Foundation and delivered between November 2007 and September 2010. The CCH programme aimed to demonstrate that increased self-management support (SMS) leads to improved health for patients with long-term conditions (LTCs).

The aim of this study was to see whether the SMP increased diabetes patients' activation, confidence to self-manage, health-related quality of life, and improved self-management skills 6 months after completing the programme.

Material and methods

Procedure

The study was conducted in two London healthcare organisations: Southwark Health and Social Care Trust with Guy's and St Thomas' NHS Foundation Trust, and Islington and Haringey Primary Care Trusts with Whittington NHS Hospital Trust. Patients with type 2 diabetes seen in primary or secondary care settings were informed by their providers about an opportunity to attend the SMP and received instructions how to enrol. Participants completed the baseline survey before the first SMP session and a follow up survey 6 months after the last session. The survey comprised a set of standardised measures including Patient Activation Measure (PAM) [12], measures of health status and health related-quality of life (EuroQol Index (EQ-5D Index) [13], EuroQolVisual Analogue Scale (EQ-5D VAS) [14], and the Diabetes Quality of Life Inventory (DQOL) [15]), a measure of psychological distress (Anxiety and Depression Scale (HADS) [16]) and self-management ability (hei-Q [17]. The study protocol was approved by the Brighton and Hove City Teaching PCT Multi Centre Research Ethics Committee 07/H1107/143.

Intervention

The self-management intervention was informed by social learning theory [18], and its content and delivery was modelled on the lay-led, generic, Expert Patient Programme (EPP) [19]. The EPP is a self-management course for people living with long-term conditions, designed to increase patients' confidence to effectively self-manage their condition and improve quality of life [19]. The primary goal of the SMP was to increase patient activation. Patient activation is similar to self-efficacy and refers to the extent that patients are motivated and use self-management support skills in their lives [12]. The SMP ran for 7 weekly sessions of 3 hours each. Each session was co-delivered by a health professional working with diabetes patients and a trained patient living with

type 2 diabetes. The consistency of delivery of the SMP content was promoted by using tutor manuals and contained 27 behavioural change techniques, including those that arely evidence based such as goal setting, action planning and problem solving, plus a weekly diabetes-specific content (Table I).

Measures

The primary outcome measure was the Patient Activation Measure (PAM) [12]. The PAM questionnaire comprises 13 items that assess patient knowledge, skill, and confidence for self-management. The PAM has a theoretical range from 0 to 100. Higher scores indicate greater activation. An improvement of four points on the PAM scale is considered meaningful because this is the level of increase that is associated with performing a range of self-management behaviours [20–22]. The EuroQolIndex (EQ-5D Index) [13] and the EuroQol Visual Analogue Scale (EQ-5D VAS) [14] are widely used measures of health status and health-related quality of life, respectively. The EQ-5D Index assesses patients' health state across five dimensions (self care, mobility, anxiety/depression, usual activities, and pain/discomfort) that are weighted to provide a utility value based on a population tariff; scores range from 0 (death) to a 100 (perfect health). The EQ-5D VAS is a vertical rating scale health score between 0 (worst imaginable health) and 100 (best imaginable health). The DQOL is a 15-item scale that includes three subscales (satisfaction with treatment, diabetes worry, and social worry), which are summed up to provide an overall total diabetes quality of life scale [15]. Psychological distress was assessed using the Hospital Anxiety and Depression Scale (HADS) [16]. The HADS is a brief and very well established self-report measure that provides separate scores for anxiety and depression and is appropriate for people with physical comorbidities. Scores ≥ 11 are considered to indicate probable clinical anxiety and depression ("caseness"). Self-management ability was measured using the heiQ, which has been specifically developed to assess the self-management skills and techniques taught on self-management programmes [17]. Patients are asked to rate items on a four-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (4). Higher scores represent higher levels of self-management abilities. The eight scales are: positive and active engagement in life; health directed behaviour; skill and acquisition technique; constructive attitudes and approaches; self-monitoring and insight; health services navigation; social integration and support; emotional well-being.

Table I. SMP for diabetes course content

Session number	Session activities
1	Tutors welcome, introduction and ground rules
	What is self-management?
	What is diabetes?
	Balancing life with diabetes
	Goal setting
	Planning for action
2	Welcome to session and follow-up
	What we believe about our diabetes
	Activity with diabetes
	Pursed-lip breathing
	Care of our feet
	Being thankful
	Planning for action
3	Welcome to session and follow-up
	Handling challenging or unhelpful emotions
	Eating well for diabetes health
	Becoming and staying active for everyone
	Planning for action
4	Welcome to session and follow-up
	Pacing
	Eating and drinking in social situations communicating with family and friends
	Introduction to mindfulness
	Problem solving and planning for action
5	Welcome to session and follow-up
	Recognising and managing setbacks
	Muscle relaxation
	Ways to manage when feeling unwell
	Managing our medication
	Being positive
	Planning for action
6	Welcome to session and follow-up
	Setting the agenda
	Complications of diabetes and monitoring diabetes
	Recognising and managing fatigue
	Using helpful distraction
	Planning for action
7	Welcome to session and follow-up
	Becoming a resourceful self-manager
	Making the most of our visits with the diabetes care team
	Making choices, deals and decisions
	Planning to stay well
	Guided imagery
	Sharing our successes and setting longer-term goals
	Closing comments: farewell and completion of final evaluation

Statistical analysis

All data analyses were conducted using IBM SPSS Statistics 20. The level of statistical significance was set at $p < 0.05$. Intention to treat (ITT) analysis was performed to ensure that the effectiveness of the programme was not overestimated [23]; this approach has been used in similar studies [24]. The ITT approach is often used to assess the effectiveness of the intervention because it mirrors actual practice by taking into account the fact that not everyone complies with treatment, and the treatment people receive may be changed according to how they respond to it [23]. All patients were included in the analysis regardless of the number of sessions they attended. Missing 6-month follow-up data were replaced with baseline data.

Changes in the mean values of the patient outcomes over time were compared using paired T Tests. The General Linear Model for repeated measures was used to determine the impact of other prognostic factors such as age, gender, co-morbidity, number of sessions attended, and socioeconomic factors (education, employment status). Effect sizes (Cohen's d) were calculated as follows: the mean score at 6 months minus the mean score at baseline divided by the standard deviation at baseline. The boundaries recommended by Cohen (1988) [25] were used to determine small (0.2), moderate (0.5), and large effect sizes (0.8). The hei-Q scale developers recommend a distribution-based cut-off of ES = 0.5 as a standardised cut-off [17]. Based on this cut-off, three categories of change were defined: 'substantial improvement' (ES ≥ 0.5), 'minimal/no change' (–0.50 < ES < 0.50), and 'substantial decline' (ES ≤ –0.5). We also examined the proportion of participants whose PAM scores improved by four points. Changes in caseness for anxiety and depression between baseline and 6-month follow up were tested using McNemar's test.

Results

Characteristics of participants

In total, 496 patients with diabetes contacted the recruitment helpline, and of these, 127 (26%) patients did not register to attend the SMP. In total, 369 patients started the course and 86 dropped out (attended 1–4 sessions). A total of 283 patients (77%) completed the SMP course (attended 5–7 sessions) and 285 patients completed baseline questionnaires. Where possible, direct pairing of data from patients who completed baseline and 6-month surveys and who attended ≥ 5 SMP sessions was established for the main analysis. There were 133 matched PAM scores (Figure 1).

There were no statistically significant differences in baseline outcome measure scores between SMP completers (those who attended ≥ 5 SMP sessions) and non completers (those who attended < 5 SMP sessions). There were no demographic

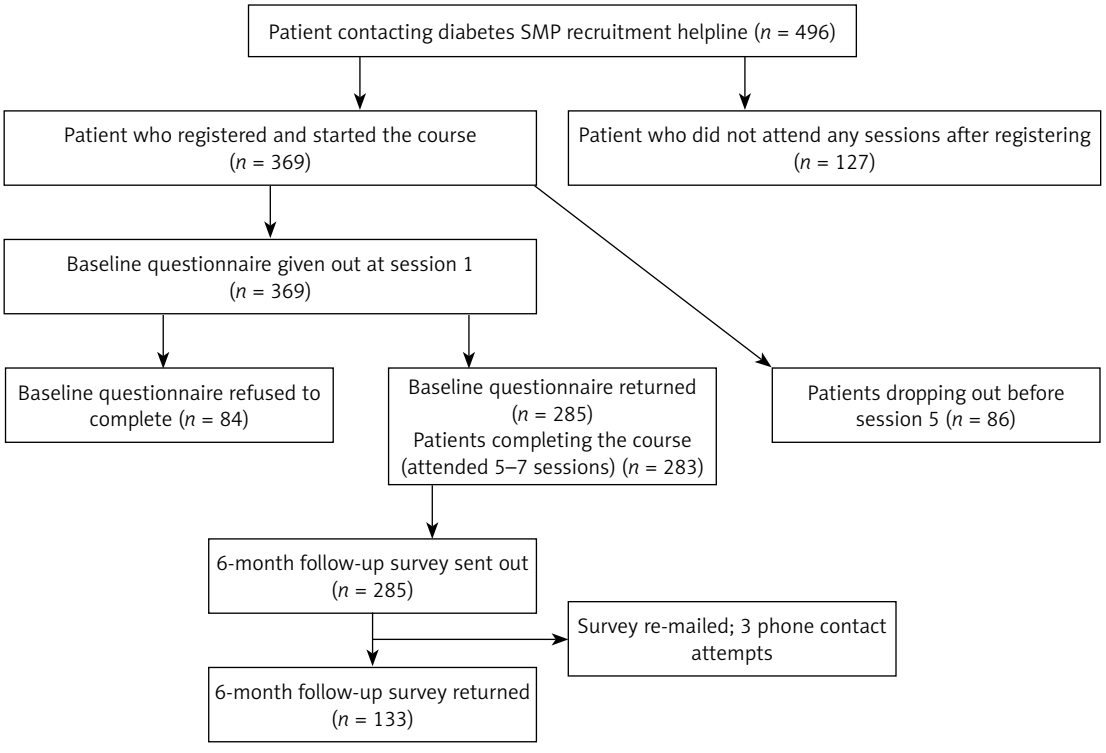

Figure 1. Diabetes SMP study flow chart

differences between patients who completed the SMP and those patients who did not complete the SMP, on variables of gender, ethnicity, house ownership, living arrangements, education, employment, and co-morbidity. There were also no differences between patients who completed only baseline questionnaires and those who completed both baseline and 6-month follow-up surveys.

The participants' mean age was 62.3 years (SD 11.1). There was almost an equal number of men and women (49% and 51%). While the main ethnicity was white, 43% of respondents represented ethnic minorities. More than half of the participants were of other ethnicities, less than a half lived with a partner, less than half were educated past the age of 19, and most had other co morbidities (Table II).

Table II. Characteristics of patient who enrolled on the SMP and who returned a baseline questionnaire (n = 285)

Characteristics	Results
Age, mean (SD)	62.3 (11.1)
Gender (%):	
Male	48.7
Female	51.3
Ethnic origin (%):	
White	44.5
Mixed ethnicity	15.1
Asian or Asian British	32.6
Black or black British	0.7
Chinese	10.2
Accommodation (%):	
Owner occupier	45.6
Shared/residential	54.4
Living arrangements (%):	
Live alone	36.6
Live with spouse/partner	43.5
Other (friend, children)	19.9
Age left education (%):	
Below 16 years	27.1
16–18 years	30.9
≥ 19	42.0
Employment (%):	
FT/PT	23.9
Other (retired, housewife/husband, student)	76.1
Comorbidity (%)	72.7

Primary outcomes

Per protocol analysis showed that participants' activation significantly improved 6 months after completing the SMP (t = –7.06 (117); p < 0.0001; ES = 0.81). Intention to treat (ITT) analysis produced similar results (F = 16.4 (2); p < 0.0001) (Table III). 60.2% of patients showed a meaningful improvement (i.e. ≥ 4 points) in patient activation scores. Among demographic variables, only employment status was a good predictor of the activation level after completing the SMP (F = 3.57 (2); p = 0.01). SMP attendees who were employed full or part time benefited from the course more than those who were not working (F = 4.18 (3); p < 0.001).

Per protocol analysis showed that patients' health-related quality of life did not change after completing the SMP (t = –1.47 (80); p = 0.14. ES = 0.17). However, diabetes-related quality of life (DQOL) significantly improved after completing the SMP (t = –4.73 (108); p < 0.0001, ES = 0.35). The ITT analysis produced similar results (Table III). None of the prognostic and demographic factors predicted changes in health or diabetes-related quality of life over time.

Secondary outcomes

Per protocol analysis showed that patients' health status as measured by EQ-VAS did not change after completing the SMP (t = –0.52 (93); p = 0.60, ES = 0.01). The ITT analysis produced similar results (Table III). Men generally reported better health status than women (F = 10.1 (2); p = 0.03).

Per protocol analysis showed that neither patients' anxiety nor depression changed significantly 6 months after completing the SMP (t = 1.18 (76); p = 0.07 and t = 0.90 (76); p = 0.36, ES = –0.17 and –0.08, respectively). The ITT analysis produced similar results (Table III). None of the prognostic or demographic factors predicted changes in anxiety and depression over time.

Of 77 patients who were in the anxiety caseness (≥ 11) category at baseline, only 8 remained in that category at 6-month follow up; the remaining 69 showed improvement. However, for the whole sample the decrease was not statistically significant (χ^2 = 70.99 (1); p = 0.18). At baseline 77 patients were in the depression caseness (≥ 11) category, and none of them showed significant improvement at 6-month follow up.

Per protocol analysis showed that patients' self-management skills in five out of eight hei-Q domains significantly improved 6 months after attending the SMP; Emotional Well-Being (t = –3.49 (77); p = 0.001), Self-Monitoring and Insight (t = –3.35 (77); p = 0.001), Skills and Technique

Table III. Baseline and 6-month follow-up scores (paired T test)

Outcome variable	*N* (per protocol)	Baseline, mean (SD)	6 months, mean (SD)	Effect size of change (per protocol)	Value of *p* main analysis	Value of *p* ITT (*n* = 285)
Patient activation measure (0–100 ↑ = better)	133	54.3 (11.5)	63.7 (16.0)	0.81	0.0001	0.0001
EQ-Index Health Status (0–1 ↑ = better)	94	0.7 (0.3)	0.7 (0.3)	0.00	0.602	0.137
EQ-VAS Quality of Life (0–100 ↑ = better)	81	68.3 (17.6)	71.3 (17.1)	0.17	0.143	0.865
DQOL (0–100 ↑ = better)	109	55.4 (10.0)	58.9 (8.9)	0.35	0.0001	0.0001
HADS Anxiety (0–21 ↓ = better)	77	6.3 (4.1)	5.6 (4.4)	–0.17	0.074	0.068
HADS Depression (0–21 ↓ = better)	77	4.8 (3.4)	4.5 (3.5)	–0.08	0.368	0.250
hei-Q (1–4 ↑ = better) Health-directed behaviour	78	3.0 (0.6)	3.1 (0.6)	0.16	0.357	0.858
Positive and active engagement	78	3.0 (0.6)	3.0 (0.6)	0.00	0.259	0.106
Emotional well-being	78	2.6 (0.5)	2.8 (0.6)	0.40	0.001	0.010
Self-monitoring and insight	78	3.0 (0.4)	3.2 (0.4)	0.50	0.001	0.003
Constructive attitude shift	78	3.1 (0.5)	3.2 (0.5)	0.20	0.063	0.032
Skills and technique acquisition	78	2.8 (0.6)	3.1 (0.5)	0.50	0.0001	0.0001
Social integration and support	78	2.8 (0.6)	3.0 (0.6)	0.33	0.033	0.0001
Health service navigation	78	3.0 (0.6)	3.1 (0.5)	0.16	0.002	0.002

Table IV. Distribution of the proportion of patients with "substantial improvement", "minimal/no improvement", or "substantial decline"

Outcome variable Hei-Q (n = 78)	Substantial improvement (ES ≥ 0.5) [%]	Minimal/no change (–0.50 < ES < 0.50) [%]	Substantial decline (ES ≤ –0.5) [%]
Health-directed behaviour	16.7	66.7	16.7
Positive and active engagement	17.9	71.8	10.3
Emotional well-being	23.1	73.1	3.8
Self-monitoring and insight	19.2	78.2	2.6
Constructive attitude shift	21.5	69.6	8.9
Skills and technique acquisition	32.1	61.5	6.4
Social integration and support	26.0	62.3	11.7
Health service navigation	20.5	75.6	3.8

Acquisition (t = –4.02 (77); p < 0.0001), Social Integration and Support (t = –2.17 (76); p = 0.03), and Health Service Navigation (t = –3.15 (77); p = 0.002). Effect sizes ranged from 0.50 for Skills and Technique Acquisition to 0.01 for Positive and Active Engagement (Table III). The ITT analysis produced similar results. None of the prognostic and demographic factors predicted changes in self-management skills over time.

As shown in Table IV, about one fifth of the patients showed substantial improvements in self-management skills, the exceptions being Skill and Technique Acquisition (32.1%), Health-Directed Behaviour (16.7%), and Positive and Active Engagement (17.9%).

Discussion

Of 496 diabetes patients registered to attend the course, 60% completed the programme (attended 5–7 sessions), which is comparable to other large UK self-management studies [26]. More men, ethnic minorities, people who lived alone, who did not own their homes, and who had no educational qualifications attended the SMP, compared to other UK self-management programmes [26]. This suggests that the SMP was relatively successful at recruiting patients who traditionally do not attend self-management programmes.

The primary outcome of patient activation improved significantly after completing the SMP. Additionally, 60.2% of participants achieved meaningful improvement (i.e. ≥ 4 points). It has been shown that patients who achieve meaningful improvement in PAM score are more likely to participate in collaborative decision-making with their clinicians, report improved health-related behaviours and clinical outcomes, and adhere to physical therapy [27]. Lorig *et al.* evaluated lay-led online and community-based diabetes self-management programmes similar to the SMP. Attending both programmes lead to significant improvement (> 4 points) in patient activation measured 12 months after completing the course [28, 29]. These findings suggest that diabetes self-management programmes generally have positive effects on patient activation regardless of whether they are lay- or lay and clinician-lead.

The current study is similar to others in providing no evidence to suggest that attending diabetes self-management programmes results in improvements in general health-related quality of life [2, 6–8]. However, in the current study patients reported improved diabetes-related quality of life 6 months after completing the programme, perhaps because the DQOL measure specifically asks questions about diabetes management and its impact on patients' everyday life.

The current study did not show any improvements in health status after completing the SMP, and other studies described in this paper did not examine this outcome. Diabetes patients reported better health status at baseline compared to the other long-term conditions, such as chronic pain, addressed by the Co-Creating Health programme in the UK, so there may have been less scope for improvement.

In the current study the frequency of clinically significant anxiety was reduced; however, depression did not change after completing the SMP. A review of self-management and educational programmes for diabetes patients conducted by Steed *et al.* showed that none of the self-management programmes resulted in changes in depression; however, a specific psychological stress management programme lead to reduced anxiety [6]. Davies *et al.* reported that attending the DESMOND programme reduced mean depression scores as measured by HADS, compared to a control group, although the improvement only emerged at 12-month follow up [8]. Lorig *et al.* reported a reduction in depression as measured by the PHQ-9 [28], which has been

shown to overestimate the severity of depression in diabetes patients compared to the HADS [30].

Five out of eight patients' self-management skills in hei-Q domains significantly improved 6 months after attending the SMP. Additionally, we observed that a quarter of the course completers achieved substantial improvement (ES $\geq$ 0.5) in all but two skills. This result is important given that the primary aim of the SMP is to enhance patients' ability and capacity to self-manage their condition.

When discussing the results of the study, its limitations need to be considered. We received 285 baseline surveys and 133 follow-up questionnaires, so we were only able to pair just under a half of the surveys. Response rates were lower for other outcome measures, as PAM data alone was collected at 6-month follow-up among those patients who were subject to repeat attempts to achieve a response to follow-up attempts.

We conducted ITT analysis to prevent overestimating of the programme effectiveness; however, the results need to be interpreted with caution. We have only collected self-report data, there was no control group, and follow up data was only collected once, 6 months after completing the programme. Unlike in many other studies assessing the effectiveness of diabetes self-management interventions [28, 29], we did not assess any medical outcomes (e.g. HbA_{1c}), so we cannot tell whether attending the SMP had any impact on participant's clinical outcomes. Moreover, patients who attended the SMP and completed the questionnaires were volunteers who might have been motivated to effectively self-manage and achieve positive changes. Possibly the positive impact of the programme was partially a result of patients' positive engagement and motivation to change, as well as the content and delivery of the course. Again, although ITT analysis should reduce the potential bias, it needs to be taken into consideration when interpreting the results.

This study showed that lay- and clinician-lead SMP for diabetes patients can produce meaningful improvements in important outcomes such as activation, diabetes-related quality of life, and self-management skills. Introducing a co-delivery model can be one of the factors contributing to the positive effects of the SMP. Studies of the impact of the co-delivery model on the effectiveness of self-management programmes are scarce. However, the results of a recent systematic review of self-management courses for patients with chronic pain conducted by Carnes *et al.* suggest that group-delivered self-management courses that had input from a healthcare professional show more beneficial effects [31]. Further research including a control group and longer follow-up period are required to determine what format, content, and delivery mode of diabetes self-management programme produces most benefits for its participants and savings for healthcare systems.

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