Translating research evidence into practice: A community-based lifestyle programme for the prevention of type 2 diabetes

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There is clear evidence from large clinical trials that type 2 diabetes can be prevented in high-risk individuals using intensive lifestyle change. The challenge for healthcare systems such as the NHS, however, is to translate these findings into routine clinical care and be as successful. We implemented a care pathway based on existing NICE guidelines for the management of people at high risk of type 2 diabetes at seven GP practices in Dorset. This 12-month intervention consisted of 16 group sessions, one individual appointment and participation in an already established community-based exercise programme. Twenty overweight or obese adults were enrolled in this pilot phase. In this article, we summarise our findings and provide evidence that diabetes prevention programmes can be translated and implemented in the routine primary care setting.

In the UK, the number of people with type 2 diabetes is expected to rise to 5 million by 2025 (Diabetes UK, 2014), mostly driven by excess weight gain. It has been estimated that type 2 diabetes currently costs the NHS around £10 billion annually, and these costs are expected to rise to £16.9 billion in the next 20 years (Hex et al, 2012). Data from large randomised clinical trials in the US (Knowler et al, 2002), Finland (Tuomilehto et al, 2001; Lindström et al, 2006), China (Pan et al, 1997) and India (Ramachandran et al, 2006) have shown that, for many individuals at risk of type 2 diabetes, onset of the condition can be delayed or prevented with intensive lifestyle interventions focusing on diet and exercise. Overall, it appears that modest weight loss and physical activity is associated with a 58% reduction in the risk of developing type 2 diabetes, with persistent incidence reductions of over 30% after 10-year follow-up (Knowler et al, 2002, Lindström et al, 2006, Pan et al, 1997).

Public Health England (PHE), in conjunction with NHS England, have set the development of evidence-based diabetes prevention services as one of their new key initiatives (PHE, 2014). In the UK, NICE (2012) recommends two action points for primary care teams: firstly, identifying individuals at risk of developing type 2 diabetes using a validated risk assessment score and either a fasting blood glucose or HbA_{1c} test and, subsequently, enrolment of high-risk individuals in a quality-assured, evidence-based, intensive lifestyle change programme. However, in routine clinical practice, replication of the results from clinical trials is challenging, especially in terms of finding the right balance between efficacy (intensity, follow-up) and feasibility (Craig et al, 2008) due to lack of resources or reimbursement, lack of practitioners' time or skill, and practical difficulties with recruitment and patient retention.

The aim of this study was to examine the feasibility of implementing a type 2 diabetes prevention intervention, based on modification of existing NICE guidance, into routine clinical practice in a primary care setting.

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Article points

1. In this study, the feasibility of a primary care-based programme to prevent development of type 2 diabetes in at-risk overweight/obese people was evaluated.
2. The 12-month programme comprised 16 group sessions and one individual session, led by a registered dietitian with specialist training in behavioural change techniques.
3. Of 20 participants, 16 completed the programme and had a mean body weight reduction of 10.6% at 12 months, along with significant improvements in diabetes and cardiovascular risk markers.
4. The group setting meant that the dietitian's direct time spent per patient was only 3.68 hours.

Key words

- Diabetes prevention programme
- Primary care
- Weight management

Authors

Author details can be found at the end of the article.

Methods

Recruitment

This pilot study was carried out in Christchurch, Dorset, between 2013 and 2014. Christchurch has seven primary care practices, each of which was asked to search its electronic database to identify a random sample of up to 30 people (age, 18–75 years) fitting the NICE criteria for high risk of developing type 2 diabetes (HbA_{1c}, 42–47 mmol/mol [6.0–6.4%]; fasting blood glucose, 5.5–6.9 mmol/L; and/or an oral glucose test confirming impaired glucose tolerance). As the programme was group-based, with the key goal being modest weight loss, an additional inclusion criterion was a BMI of 28–40 kg/m^2. A non-randomised, single-arm intervention design with repeated measurements at baseline and after 6 and 12 months was used.

Care pathway

The care pathway is laid out in *Figure 1*.

Measurements

Data were collected on clinical outcomes, quality of life (RAND 36-Item Health Survey; Hays et al, 1993), physical activity and group session attendance rates. Clinical measurements included weight, height, waist circumference, HbA_{1c}, fasting blood glucose level and lipid profiles. Data were also collected on family history of diabetes and heart disease, as well as comorbidities.

Height was assessed using a standard stadiometer.

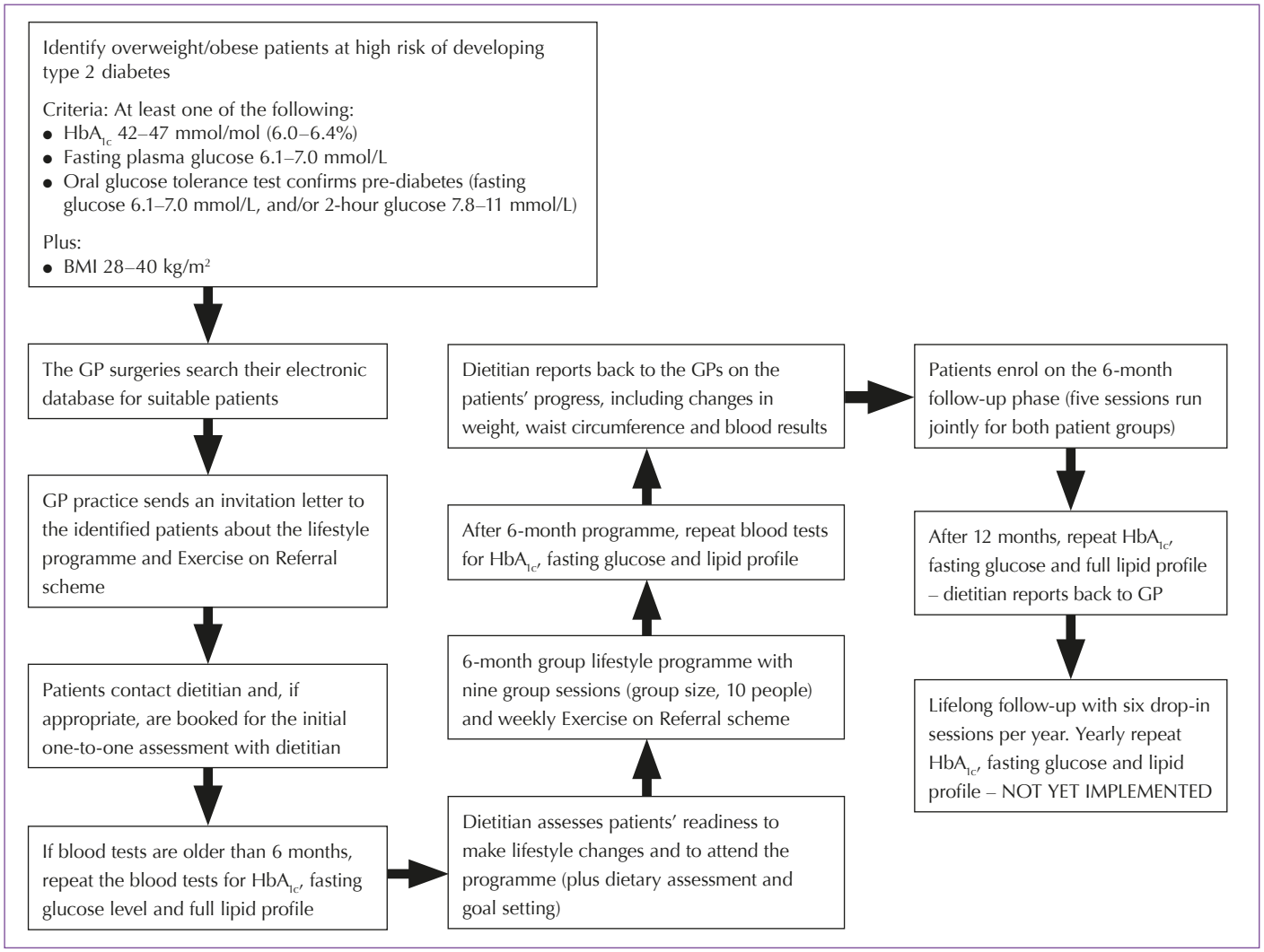

Figure 1. Diabetes prevention care pathway for the primary care teams.

Weight was measured in light clothing using the Tanita BF-350 body composition analyser (Tanita Europe, Amsterdam, the Netherlands). Waist circumference was measured at the level of the iliac crest to the nearest 0.1 cm using a standard tape measure with the participants in the standing position. Seated blood pressure (BP) was measured after a 5-minute rest using an automated device. Three measurements were obtained, with the average used to represent the BP.

Participants were also provided with an "Exercise on Referral" form for a scheme that allowed once-weekly access to the leisure centre for the discounted cost of £1 per session.

Intervention

Content for the group-based programme was adopted from publicly available materials from the US DPP (Diabetes Prevention Program; DPP Research Group, 2002; 2011), with modifications to adapt to the local community setting. The key difference from the DPP was the use of a group approach, rather than one-to-one sessions, with less frequent contact times. Each participant also received an individualised diet plan. The programme was run by a registered dietitian with specialist training in behavioural change techniques. Details of the content of each session and the frequency are set out in *Table 1*.

The 12-month programme consisted of two phases comprising 16 group sessions and one individual session in total. Participants could choose between morning and evening sessions to fit in with their timetable. The venue for the sessions was close to the participants' homes and next door to the leisure centre that took part in the Exercise on Referral scheme.

The intensive, 6-month phase 1 consisted of an initial 1-hour consultation followed by 11 structured, 75-minute group sessions, with two groups of 10 people, and a weekly exercise programme. Phase 2 was a 6-month follow-up with five sessions, in which members from both groups attended the same session. For this phase, participants could choose the topics for the sessions provided by the dietitian or could suggest their own, and most talks were given by outside speakers or participants themselves. Outside speakers delivered two of the five follow-up sessions on topics of yoga and mindfulness, and small monetary donations were made from the study funds to cover their time. Two sessions were delivered by the participants on topics they were experts on (i.e. by a retired doctor/biochemist and by a participant with over 20 years' expertise in Tai Chi techniques and theory). Participants were reminded by e-mail, text message or phone call to attend each session.

Intensive lifestyle intervention

Each group session started with a confidential weigh-in, followed by an education session. Each session covered a topic related to healthy eating, physical activity and behavioural change, with emphasis on reducing the potential risks of type 2 diabetes and heart disease. The change in lifestyle was facilitated using established goal-based behaviour change techniques (NICE, 2007). Key strategies included self-monitoring, stimulus control, goal setting, slowing rate of eating, ensuring social support, problem solving, relapse prevention, stress management and cognitive restructuring (modifying thoughts aimed at positive thinking). Participants were taught the importance of self-management using food and activity diaries and of weighing themselves weekly.

Dietary intervention

Information gathered at the initial appointment was used to design participants' individualised diet plans and to help set their individual short- and long-term lifestyle and weight loss goals. The plan was adopted from British Heart Foundation (2011) material and was a food portion plan with a daily caloric target, with a description of portion sizes for each food group and examples of snacks of different caloric values. Each participant's daily recommended energy requirements were estimated based on 7-day food records and Schofield's (1985) equation, with a 400–1000 kcal/day deficit depending on current body weight and typical dietary intake. The dietary advice was based on The Balance of Good Health guidelines (Food Standards Agency, 2001).

The intervention was aimed at inducing 7% weight loss at 6 months and encouragement to continue with the weight loss up to 12 months, but ensuring that the final BMI did not drop below 24 kg/m^2. The weight management targets were in line with the DPP (Knowler et al, 2002).

Page points

1. This intervention comprised a 6-month intensive phase with an intital one-to-one consultation followed by 11 group sessions, and then a 6-month follow-up phase with five group sessions.
2. The phase 1 sessions featured education on healthy eating, and exercise, with the use of goal-based behaviour change techniques to facilitate lifestyle changes.
3. Each participant was also given an individualised diet plan aimed at losing 7% of body weight at 6 months.
4. In phase 2, the content of the sessions was decided by the participants and also featured talks from outside speakers.

Table 1. The group lifestyle change programme – Phase 1.

Session	Content of the session
Week 1	1. Introduction to the programme and to other group members 2. Why are we at risk of type 2 diabetes and what can we to do to prevent it? 3. Importance of exercise 4. Finalising short- and long-term goal setting (weight loss, exercise, blood test, blood pressure) 5. Exercises – setting your future lifestyle goals – visualisation exercise
Week 3	1. Description of the diet and how you will achieve sustained weight loss 2. Your individual diet plan 3. Exercises – changing your eating style
Week 5	1. Sugar in your diet 2. Blood glucose – what do your individual results mean? 3. Intensive sweeteners (aspartame and others) 4. Exercises – your aims and goals revisited
Week 7	1. Dietary fat and heart health 2. Do you eat enough omega fats and why do you need them? Supplements? 3. Your blood cholesterol and blood pressure results – what do your individual results mean? 4. Exercises – change your environment to change your eating
Week 10	1. Glycaemic index and glycaemic load, dietary fibre, wholegrains 2. Exercises – work with feelings of hunger and fullness
Week 12	1. Relapse management 2. How do people make permanent lifestyle changes and what holds them back?
Week 14 (pre-Christmas session)	1. How to maintain your weight and enjoy Christmas 2. Alcohol
Week 18	1. Stress and fat around the middle 2. Exercises – stress release
Week 20	1. Discover your internal dialogue and change it to work in your best interests 2. [Give out blood test forms and ask to bring the results to week 26]
Week 22	1. Vitamins and minerals 2. Nutritional deficiencies
Week 26	[6-month assessment: weight, waist circumference, blood pressure, quality of life questionnaire, collect blood test results] 1. What's next? Review the weight loss goals and start planning individual long-term goals 2. Group will choose the topics for the next five sessions: • Mindful eating • Salt and blood pressure • Food labels, E numbers, organic foods • Red meat • Osteoporosis • Anti-obesity medications and bariatric surgery • Fruit, vegetables • Spices • Essential vitamins and minerals • Nutritional supplements • Anti-ageing diet and lifestyle • Exercise and health

Participants were encouraged to increase their activity levels to a minimum of 150 minutes per week, as advised by the Department of Health (2011). In addition, participants were advised to monitor their daily number of steps and to aim for 10 000 per day, and to keep step diaries. They were not provided with pedometers but were encouraged to buy their own, or they could borrow pedometers for a period of several weeks to learn if this form of self-assessment suited them.

Results

Patient recruitment

A total of 127 invitation letters were sent out by seven primary care practices in the Christchurch area. More than a third of contacts (n=46) were interested; however, 13 were excluded because their body weight was within the healthy range. Ultimately, 20 participants (mean age, 60.3±6.4 years; 13 men) were recruited.

Attrition and attendance rates

Over 12 months, four participants dropped out (two in the first 6 months). Among completers (n=16; defined as those who attended at least 60% of the group sessions and were present at the 6-month and 12-month assessments), the rate of attendance for the education sessions was 90% for the first 6 months and 75% for the post-6-month follow-up sessions.

Body weight

Mean body weight decreased by 9.1% (8.3±5.0 kg; P<0.001) at 6 months, and by 10.6% (9.8±6.9 kg; P<0.001) at 12 months (*Table 2*). Changes in weight in the individual participants are presented in *Figure 2*. At 12 months, 75% of completers had achieved more than 7% weight loss. All except one participant lost weight by 12 months. The average BMI for the group moved from the obese category of 32.6±3.9 kg/m^2 to the overweight category of 29.2±2.6 kg/m^2 (P<0.001) over the 12 months.

Diabetes and cardiovascular risk markers

Fasting blood glucose and HbA_{1c} levels had significant reductions (P<0.05) at 6 months, changes which were sustained at 12 months (*Table 2*). Ten participants finished the programme with HbA_{1c} levels below 42 mmol/mol (6.0%) and seven finished with fasting blood glucose levels below 5.5 mmol/L. Mean systolic and diastolic BP had reduced significantly at 12 months, by 11.7 and 8.3 mmHg, respectively (P<0.05).

Mean waist circumference (P<0.001) and triglyceride levels (P<0.05) had significant reductions

Table 2. Anthropometric and biochemical data at baseline and change from baseline after 6 months and 12 months of lifestyle intervention (n=16).

	Baseline (mean; SD)	Change from baseline at 6 months (mean; SD)	Change from baseline at 12 months (mean; SD)
Weight (kg)	91.4 (8.9)	–8.3 (5.0)**	–9.8 (6.9)**
BMI (kg/m^2)	32.6 (3.9)	–3.6 (2.8)**	–3.4 (2.4)**
Waist circumference (cm)	105 (9.0)	–10.6 (5.3)**	–10.5 (6.7)**
Systolic BP (mmHg)	155 (14)	–15.7 (10.9)*	–11.7 (12.6)*
Diastolic BP (mmHg)	89 (10)	–8.0 (8.6)*	–8.3 (11.3)*
Fasting blood glucose (mmol/L)	5.9 (0.5)	–0.4 (0.5)*	–0.5 (0.7)*
HbA_{1c} (mmol/mol)	43.1 (3.6)	–2.9 (3.8)*	–3.3 (4.3)*
Total cholesterol (mmol/L)	5.1 (1.5)	–0.1 (0.8)	–0.1 (1.1)
LDL-cholesterol (mmol/L)	2.9 (1.4)	+0.1 (0.7)	–0.1 (1.0)
HDL-cholesterol (mmol/L)	1.37 (0.36)	+0.08 (0.14)	+0.14 (0.19)*
Triglycerides (mmol/L)	1.7 (0.7)	–0.4 (0.4)*	–0.4 (0.2)*
HDL:total cholesterol ratio	3.8 (1.2)	–0.2 (0.5)	–0.4 (0.7)

*P<0.05 based on 2-tail paired t-test; **P<0.001.
BP=blood pressure; SD=standard deviation.

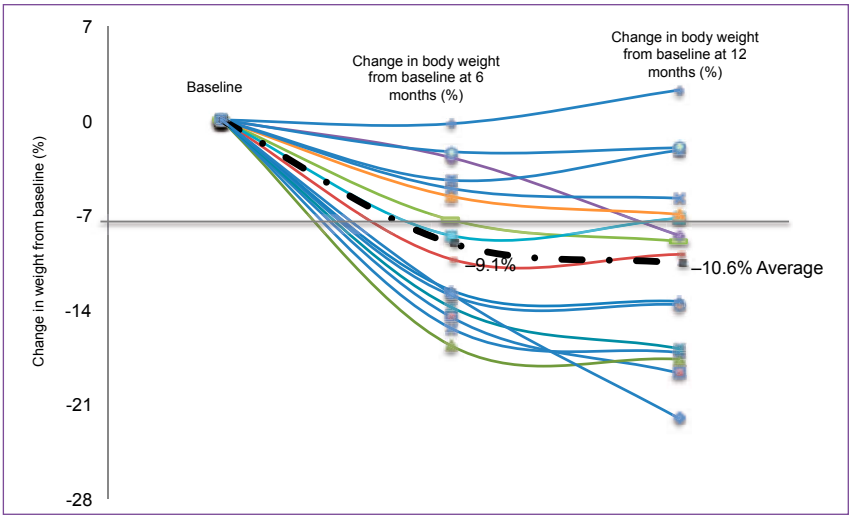

Figure 2. Percentage change in weight from baseline at 6 and 12 months for each participant.

Summary of results (*n*=16)

1. Mean body weight decreased by 9.1% at 6 months and 10.6% at 12 months, with 75% of participants who completed the programme losing more than 7% of body weight.
2. There were significant reductions at both time points in HbA_{1c}, waist circumference and triglyceride levels, as well as a significant reduction in systolic and diastolic blood pressure at 12 months.
3. At 6 months, there were significant improvements in three quality of life domains: pain, physical functioning and role limitations due to emotional problems. At 12 months there were significant improvements in the physical functioning and energy and fatigue domains.
4. Over the 12 months, each participant received a total of 22.25 hours of intervention time, equating to 3.68 hours of the dietitian's time per person.

at 6 months, and this improvement was maintained at 12 months (*Table 2*). No change was observed in total cholesterol or LDL-cholesterol levels at any time point. The mean HDL-cholesterol level was unchanged at 6 months but had significantly improved by 0.14±0.19 mmol/L (11.1%; $P<0.05$) at 12 months.

Quality of life

After 6 months, the RAND 36-Item Health Survey showed significant improvements in three domains: physical functioning (score, 82 vs. 72 at baseline), role limitations due to emotional problems (91 vs. 68) and pain (86 vs. 72; $P<0.05$ for all comparisons based on a 2-tail paired *t*-test). At the 12-month follow-up, significant improvement was reported in two domains: physical functioning (score, 80 vs. 72) and energy and fatigue (72 vs. 56; $P<0.05$ for both comparisons).

Physical activity

Of the 16 completers, 11 used the Exercise on Referral offer regularly, with an average attendance of 16 gym sessions over 6 months. Five people did not take up the Exercise on Referral offer: three were already members of a gym and two were in recovery (one from breast cancer and one from hip surgery) and were unable to exercise at the time. All participants were encouraged to monitor their daily number of steps and keep step diaries; however, this was for their own assessment only and data are not available.

Educators' time demands to conduct the programme

Table 3 compares the direct time requirements for the educators per patient over 1 year in the US DPP (Hernan et al, 2003) and in the current project. Over 12 months, each participant received a total of 22.25 hours of intervention time (i.e. 1 hour for the initial appointment plus 17 × 1.25 hours for the sessions), but as the sessions were group-based, dietitian direct time spent per participant was only 3.68 hours.

Discussion

This study provides evidence that it is feasible to introduce an evidence-based lifestyle change programme into a UK primary care setting that reduces the risk of developing type 2 diabetes in those at high risk of the condition. The reductions in weight and waist circumference and significant improvement in biochemical and psychological measures fit well with the benchmark set by randomised controlled trials (Knowler et al, 2002; Lindström et al, 2006). This pilot study implemented existing NICE guidelines based upon a care pathway which could be easily and successfully applied in GP practices across the NHS (NICE, 2012).

The overall conclusion reached from the DPP and other large randomised trials, as well as observational studies (Chan et al, 1994; Wannamethee and Shaper, 1999), is that any successful intervention to reduce the risk of developing type 2 diabetes should have weight loss as the primary aim. In the current study, participants lost a mean of 8.3 kg (9.1%) of body weight at 6 months and 9.8 kg (10.6%) at 12 months, with 75% of completers achieving more than 7% weight loss. In the DPP, it was estimated that every kg of weight loss reduced the risk of diabetes by 16%, but that those subjects who lost 5–7% of body weight and who met physical activity and dietary fat goals reduced their risk by over 90% (Hamman et al, 2006). Similar conclusions were also reached in the Finnish Diabetes Prevention Study (Tuomilehto et al, 2001) and the Nurses' Health Study (Hu et al, 2001).

In our study, the mean BP had reduced by 11.7/8.3 mmHg at 12 months, a clinically significant reduction as demonstrated by large BP-lowering trials, which show that reducing BP by 10/5 mmHg lowers the 5-year risk of coronary heart disease events by 22% and of stroke by 41% (Law et al, 2009). Our study also shows that obese sedentary adults can lose weight and show improvement in quality of life.

A common problem in most "real-world" programmes is difficulty in recruiting male participants (Johnson et al, 2013). In our study, 65% of the participants were men. Similarly, our attrition rate was 20% at 12 months, which is lower than reported in previous behavioural and psychological interventions in primary care (Zayas et al, 2004; Graffagnino et al, 2006).

Taking example from similar real-world diabetes prevention programmes (Johnson et al, 2013), we adopted a group approach in order to reduce the educators' time demands per participant, along

Table 3. Direct time spent by educators per patient in year 1 of the education programme in the US DPP (Hernan et al, 2003) and the Christchurch Diabetes Prevention Project. Costs of the exercise programme, room rent, educational material and indirect costs are not included.

	DPP					Christchurch Diabetes Prevention Project				
Item	**Provider**	**Description**	**Units**	**Time per unit (h)**	**Total direct time per patient (h)**	**Provider**	**Description**	**Units**	**Time per unit (h)**	**Total direct time per patient (h)**
Baseline history and physical exam	Physician		1	Not declared	Not declared	Dietitian	1 × 1-hour one-to-one session per patient	1	1	1
Core curriculum – initial 6 months	Lifestyle case manager	16 × 1-hour one-to-one sessions per patient	16	1	16	Dietitian	11 × 1.25-hour group sessions per 10 patients	1.1	1.25	1.38
Lifestyle group sessions – 6-month follow-up	Lifestyle case manager	1.89 × 1.25-hour group sessions per 5.23 patients (average)	0.36	1.25	0.45	Dietitian	6 × 1.25-hour sessions per 16 patients	0.375	1.25	0.47
In-person visits	Lifestyle case manager	7.65 × 0.25-hour in-person contacts per patient (average)	7.65	0.58	4.44	n/a	n/a	0	0	0.00
Phone calls	Lifestyle case manager	2.32 × 0.25-hour calls per patient (average)	2.32	0.25	0.58	Dietitian	1 × 0.33-hour call per patient	1	0.33	0.33
Reminder phone calls	Secretary		29.41	0.08	2.35	Dietitian	1 patient required a phone call, the rest received e-mail reminders	0.1	5	0.50
TOTAL direct time per patient					**23.82**					**3.68**

DPP=Diabetes Prevention Program.

with an initial one-to-one session and one phone call. Over 12 months, each participant received a total of 22.25 hours of intervention time, but as the sessions were group-based, the dietitian's direct time spent per patient was only 3.68 hours (*Table 3*). In comparison, the DPP used an individual one-to-one approach with 16 core curriculum sessions in the first 6 months, followed by group lifestyle sessions, in-person individual appointments and phone calls during the 6-month follow-up, which equated to 23.8 hours of educator time in the first year (DPP Research Group, 2003).

It does seem that achieving the desirable 5–7% weight loss in a majority of participants requires a relatively intensive programme. For instance, in the DiAlert study (Heideman et al, 2015), which implemented a very low-intensity group programme consisting of 130 minutes of intervention time in total, there was no weight change in the intervention group over the 12-month period. In comparison, in the HELP PD (Healthy-Living Partnerships to Prevent Diabetes) project (Katula et al, 2011), a community-based diabetes prevention trial based on the DPP protocol, with weekly group sessions

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over the first 6 months (i.e. 24 sessions) and three individual sessions, followed by two individual sessions, a phone call and one group session during the 6-month follow-up, weight loss averaged 7.1 kg at 12 months. Therefore, it seems that intervention intensity should lie somewhere in between these two examples. The current study seemed to be closer to the optimum intensity, in line with the NICE (2012) guidelines.

Strengths and limitations of the study and implications for future research

This study demonstrates that it is feasible to translate the DPP protocol into the UK primary care setting, achieving similar outcomes in our small sample of 20 participants. The NICE (2012) guidelines regarding patient recruitment and the setup and design of such a programme were also successfully applied in the primary care setting.

One of the limitations of this study was that it was single-arm intervention rather than a randomised controlled trial. We can justify this with the fact that the efficacy of lifestyle modification on diabetes prevention has already been established by earlier prevention studies; as the evidence regarding intervention is so strong, the focus of this study was its implementation in primary care and its preliminary efficacy (Campbell et al, 2000; Absetz et al, 2007). However, as it was a pilot study with a small sample size, the lack of adequate power precludes strong conclusions regarding the statistical significance of the results.

This study was conducted in a single affluent geographic area, where participants might be assumed to be more receptive to the programme. It remains to be seen whether similar outcomes could be achieved in areas with a different socioeconomic make-up. Furthermore, this programme was able to join with an established community exercise scheme, Exercise on Referral, which most participants were not aware of before joining the intervention, and we benefited from being able to make use of existing resources.

This intervention was designed for those people at high risk of diabetes whose body weight was above the healthy range, as weight loss was a key aim of the programme. For people at high risk but with a healthy body weight, and for those unable to attend the group sessions due to home or work priorities or discomfort with the group setting, this particular programme would not be suitable. Therefore, development of an online and semi-online prevention programme would be a valuable area for future research.

The programme lasted 12 months, but the challenge remains regarding life-long follow-up support, and further research would be required to assess the best approaches for implementation. A mixed approach of phone messages, online reminders, prompts and drop-in sessions, as well as reminders about yearly blood tests, might be an option worth considering for future research. To learn about the longer-term effect of the programme, follow-up 1 year after completion would inform about the sustainability of the achieved results. No plans have been made regarding the follow-up session as yet, but if they were to be put in place it would only require approximately half a day of the dietitian's time to spend organising and running the follow-up session for the 16 completers, as well as money to rent the meeting room for a 2-hour session.

Conclusion

This study provides evidence that a diabetes prevention programme can be translated and implemented in the routine primary care setting by registered dietitians, with data suggesting reductions in diabetes risk factors similar to those observed in clinical trials. Further work is needed to see whether similar outcomes could be achieved in geographic areas with a different socioeconomic make-up. ■

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