# One-to-one structured education using the Diabetes Manual: Evidence of effectiveness


## Jackie Sturt on behalf of members of the Diabetes Manual Development and Evaluation Team


**Article points**

1. The Diabetes Manual is a one-to-one structured education programme for people with type 2 diabetes.
2. It meets the national criteria for structured education.
3. In a randomised controlled trial, it improved patient self-confidence in managing their diabetes and reduced diabetes anxiety levels.
4. Feedback has shown that the programme is feasible for one-to-one delivery of structured education.


**Key words**

- Diabetes Manual
- One-to-one structured education
- Research evidence



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**The Diabetes Manual is a one-to-one structured education programme for people with type 2 diabetes. It aims to help them develop skills and confidence in the management of their condition quickly and progressively. It includes a 2-day facilitator training course to develop health professionals' confidence in supporting people through the programme. The Diabetes Manual meets the national criteria for structured education. This article describes the development of the Manual and a randomised controlled trial that provides evidence of its effectiveness and acceptability. Data from patient records offer some information about how people with type 2 diabetes use the Diabetes Manual. Practice-nurse focus groups found the programme acceptable and feasible for use in clinical settings.**


The provision of structured education for people with type 1 or type 2 diabetes is becoming mainstream for PCTs as a result of the publication of the NICE (2003) guidance and the joint Department of Health [DH]/Diabetes UK Patient Education Working Group report (DH, 2005). The national criteria for assessing structured education programmes (DH et al, 2006) are that they should:

- Have a structured, written curriculum.
- Have trained educators.
- Be quality assured.
- Be audited.

These criteria are fundamental to the work of the Diabetes Education Network (2008) in promoting good clinical practice.

Despite national vigour in implementing structured education in primary care, the Healthcare Commission (2007) reported that only 11% of people with diabetes have accessed diabetes education. There have also been anecdotal reports from PCTs and clinicians that, despite sending invitations to individuals with a new diagnosis to attend group-based programmes as preferred by NICE, around 50% of those invited are not taking up the invitation. Furthermore, an updated systematic review (Loveman et al, 2008) indicates that there is a lot

of work still to do in identifying the components of the most effective programmes, particularly in relation to training and quality assurance of diabetes education facilitators.

This paper contributes to this body of evidence by describing the development and evaluation of a one-to-one structured education programme that offers an alternative tool for use by diabetes specialist nurses, diabetes lead practice nurses and other diabetes healthcare professionals in delivering education to a diverse population in primary care.

## The Diabetes Manual

The Diabetes Manual is a one-to-one structured education programme for people with type 2 diabetes, which aims to help them develop skills and confidence in the management of their condition quickly and progressively. The Diabetes Manual has five components, which can be summarised as follows:

- A 2-day facilitator training course for health professionals.
- A 12-week patient manual.
- A relaxation CD.
- A CD with frequently asked questions (FAQs) for people with diabetes and carers.
- Telephone support from facilitators in weeks 1, 5 and 11.

Details of these components are presented in *Table 1*.

The Diabetes Manual is a 12-week structured education programme, with participants being guided towards using the programme for 1 hour each day. One hour is a realistic assessment of the time it takes to undertake some of the new behaviours and skills, for example learning to do blood glucose monitoring or building up the confidence to do it at work, or climbing the stairs in public buildings rather than taking the lift. People might also choose to spend some of this time reading the Manual or practising their

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1. The Diabetes Manual components took more than 18 months to develop, in consultation with two expert panel.
2. The effects of the Diabetes Manual were evaluated in a randomised controlled trial (RCT) undertaken between 2004 and 2007 in 48 GP practices in the West Midlands.

relaxation skills using the CD.

The Diabetes Manual meets the national criteria for structured education outlined earlier. *Table 2* shows how the Manual meets these criteria.

### Development of the Manual

The Diabetes Manual components took more than 18 months to develop, in consultation with two expert panels. The first panel was formed of people with diabetes, and the second comprised health professionals who routinely provide diabetes care, psychologists, educators, exercise-on-prescription trainers and researchers. Both panels met four times with the writer of the workbook over the course of 12 months to develop and refine the text, making sure it was accurate, was evidence based, used the appropriate language and had content that was important to both panels. The scripts for the CDs and the training curriculum were also scrutinised by the expert panels.

Following the complete drafting, the programme was given to 12 people with diabetes who used it for 2 weeks and then joined a focus group to assess its face validity (including design and language), the validity of content, and its feasibility (Sturt et al, 2006a).

## Effects of the Manual

The effects of the Diabetes Manual were evaluated in a randomised controlled trial (RCT) undertaken between 2004 and 2007 in 48 GP practices in the West Midlands (Sturt et al, 2006b; 2008).

### Aim of the trial

The aim of the trial was to assess the effectiveness of the Diabetes Manual against a deferred intervention control group, for improving glycaemic control, cardiovascular risk factors, self-efficacy and diabetes distress levels at 6 months and maintenance of effect at 12 months in the intervention group. A nested qualitative study aimed to assess its feasibility for delivery in primary care and to understand the ways in which people with diabetes engaged with it.

### Methods

General practices, drawn from 24 PCTs across the West Midlands, in which the practice nurse had undertaken post-registration diabetes care training were invited to participate. Adults with type 2 diabetes, not taking insulin, able to read and write English and a most recent $HbA_{1c}$ >7% were eligible to participate. Practices were computer randomised by a remote statistician to either

**Table 1. The five components of the Diabetes Manual.**

| Diabetes Manual programme component | Knowledge and coaching syllabus |
|---|---|
| 2-day facilitator training for practice nurses, diabetes specialist nurses and other healthcare professionals experienced in diabetes | Diabetes Manual work book, CDs and theory<br>Self-efficacy theory and adult learning<br>Develop skills in using empowering communication strategies<br>Develop skills in providing telephone support |
| Patient workbook approached over 12 weeks | ● Diabetes facts<br>● Goal setting and evaluation<br>● Nutrition<br>● Weight loss<br>● Tests<br>● Medication<br>● Stress, anxiety and depression<br>● Metabolism<br>● Exercise<br>● Blood glucose monitoring<br>● Smoking cessation<br>● Complications<br>● Patient stories<br>● Cholesterol |
| Relaxation CD | Teach relaxation techniques and help patient to identify times and places where stress might be a problem and where relaxation might be a solution |
| Question and answer CD | Provides quick diabetes self-management recall for patient and also for use by family and friends to promote understanding of the condition and its management |
| Telephone support from facilitator | Use new theoretical learning to help patient to assess goal progress and achievement, problem solving, find opportunities to practise and master new skills, find peers to help initiate and sustain changes |

the Diabetes Manual intervention group or a deferred intervention control group, whereby the latter would receive the intervention once the 6-month data collection was complete: baseline data are shown in *Table 3*. The primary outcome was between-group difference in $HbA_{1c}$, and secondary outcomes were blood pressure, cholesterol level, BMI, diabetes distress (measured by the Problem Areas in Diabetes Scale [PAID]; Welch et al, 2003) and self-efficacy measured by the Diabetes Management Self-Efficacy Scale (DMSES; Sturt and Hearnshaw, 2003). The intervention participants were followed-up at 12 months to assess maintenance of effects. Further detailed description of the methods, outcomes measured, analysis methods and results can be found in the full RCT paper (Sturt et al, 2008).

## Results

Forty-eight GP practices participated and recruited 249 individuals, and 202 of these provided $HbA_{1c}$ data at the 6-month follow-up. Intervention group participants (n=88) were followed beyond 6 months, and 67 provided 12-month data.

The between-group difference in $HbA_{1c}$ at 6 months was a reduction 0.08% in the intervention group, which was not significant ($P$=0.39). No statistically significant effects were detected between the groups in changes in blood pressure, cholesterol or BMI. On the psychological outcomes, the mean PAID score for all participants completing the study was lower by 4.5 points, indicating lowered diabetes-related distress in the intervention group compared with the delayed intervention group ($P$=0.012). The mean DMSES score was 11.2 points higher, indicating increased confidence to self-care in the intervention group compared with the delayed intervention group ($P$=0.0014). When intention-to-treat analysis was performed, the statistically significant difference remained between the groups (Sturt et al, 2008).

Results of the intervention group who were followed up to 12 months (*Table 4*), show a reduction of median $HbA_{1c}$ in this group at 6 months compared with baseline, and this remained lower at 12 months, however, the sample is too small to generalise from.

### *Telephone support*

The telephone support offered to participants in weeks 1, 5 and 11 of the programme was

**Table 2. National criteria for structured education programmes (DH et al, 2006) and how the Diabetes Manual meets them.**

| **Criteria 1: "A structured curriculum" needs to …** | **How the Diabetes Manual meets the criteria** |
|---|---|
| 1. Be person centred, incorporating individual needs assessment | ● Initiated according to individual assessment<br>● Person with diabetes prioritises areas of interest in workbook |
| 2. Be reliable, valid and comprehensive | ● Evidence- and policy-based<br>● Stakeholder input to development |
| 3. Be theory driven | ● Self-efficacy, cognitive behaviour theory and adult-learning theories |
| 4. Be flexible and available to diverse groups | ● Self-managed by the individual, 1 hour per day including exercise regimen, limited contact time with nurse negotiated<br>● Reading age of 12 years<br>● Culturally sensitive use of patient stories, cartoons, nutritional and dietary information |
| 5. Use different teaching media | ● Text, pictures, personal reflection and evaluation, CD, one-to-one contact with nurse |
| 6. Be resource effective | ● Total 45 minutes additional nurse contact time per patient<br>● Currently costs £35 per person treated to purchase, including training and CDs |
| 7. Be written down | ● 230 page workbook |
| **Criteria 2: "Trained educators" need to …** | **How the Diabetes Manual facilitator training meets the criteria** |
| 1. Understand education theory as relevant to particular learners | ● Taught principles of self-efficacy theory and adult learning relevant to individual patient learning needs<br>● Small group, facilitator role play, using education theories to guide the one-to-one Diabetes Manual consultations |
| 2. Be trained and competent in the delivery of the education theory | ● Role play and rehearsal of face-to-face and telephone consultation using empowering and efficacy-enhancing communications |
| 3. Be trained and competent in the delivery of the principles and content of the specific programme they are offering | ● Diabetes Manual workbook is evidence-based<br>● Material used as a reference source for nurse if required<br>● Skill development in working with the Diabetes Manual components, for example orienting the person with diabetes to the workbook; orientation and encouragement regarding relaxation therapy; telephone consultation skills; patient focused agenda setting and goal evaluation. |
| **Criteria 3: "A structured curriculum" need to be quality assured** | ● Facilitator self-assessment of quality assurance (QA) is required in the first 12 months post-training, and on every fifth delivery of the Diabetes Manual using the QA protocol.<br>● External QA by another facilitator or trained diabetes educator should take place every 30th delivery or 6-monthly (whichever is the sooner) using the QA protocol.<br>● Internal and external QA records will be requested by the Diabetes Manual team triggered by the re-ordering of patient materials, or 9 months following course completion. |
| **Criteria 4: "A structured curriculum" needs to be audited** | **The Diabetes Manual is auditable by NHS providers against a number of of standards and criteria, for example:**<br>● The numbers of people with diabetes undertaking the programme in 6 months<br>● The numbers completing it<br>● Its effect (for example, on knowledge, attitude, self-care confidence and quality of life and on their biomedical outcomes such as $HbA_{1c}$, lipids, blood pressure or weight)<br>● The Diabetes Manual team will work with providers to develop the audit standards and criteria of interest to the NHS trust |

**Table 3. Baseline characteristics of study participants in each group.**

| Characteristic | Intervention group | Deferred intervention control group |
|---|---|---|
| Number of individuals | 114 | 131 |
| Mean age (years) | 62 | 62 |
| Men | 70 (61%) | 78 (60%) |
| White British, White Irish or White other | 92 (81%) | 102 (78%) |
| Diabetes duration | | |
| <1 year | 9 (8%) | 15 (11%) |
| 1–15 years | 87 (76%) | 105 (80%) |
| >15 years | 8 (7%) | 8 (6%) |
| Missing | 10 (9%) | 3 (2%) |
| Mean $HbA_{1c}$ (%) | 8.9 (±1.5) | 8.8 (±1.5) |

provided by their Diabetes Manual facilitator; throughout the trial, this was the participant's practice nurse.

The facilitators were asked to complete a telephone proforma after each of the three telephone support calls. On the proforma they recorded what self-care activity the individual was concentrating on, issues requiring support, intended goals for the following 4–6 week period and call length.

### *Use of the Diabetes Manual*

Twenty practice nurses completed 249 proformas following calls with 87 people with diabetes. The mean call duration was 9 minutes. Four researchers worked with 10 sets of proformas (that is, 10 individuals) to identify different types of Diabetes Manual user. Once the research team had reached agreement on the different types of user, the remaining sets of proformas were analysed independently by two researchers. A good level of agreement (80%) was reached between the two researchers in assessing the type of Diabetes Manual user that each set of proformas represented.

### *Types of Diabetes Manual user*

Three types of Diabetes Manual user were identified:

- Embracers (n=24, 30%).
- Dippers (n=34, 42%).
- Non-embracers (n=23, 28%).

*Table 5* shows examples of each type of user.

***Embracers*** were defined as reporting good adherence to the programme, and describing behavioural and attitudinal changes.

***Dippers*** reported dipping into components of the programme such as the relaxation tape or the physical activity aspects. Alternatively, Dippers adhered to the programme until distracting life events occurred, such as a spouse became ill, they went on holiday or they became busy at work. They used the programme as an information resource and attempted some behavioural change, which was not always sustained during the trial period.

***Non-embracers*** were defined as reporting little or no change in attitude or behaviour, although they may report gaining new information. Since they often reported finding nothing they did not already know, they cannot be regarded as not embracing self-management, only as not embracing the Diabetes Manual.

The Diabetes Manual website features a podcast of an individual who "embraced" the Diabetes Manual in the trial, and especially found the emotional support provided in the programme very positive (available at: www2.warwick.ac.uk/fac/med/study/cpd/subject_index/diabetes/manual/). She reported the following benefits:

> ***"Since I've had the Manual, you can look through that, you can think should I be feeling like this, is it wrong to feel like this, has someone else felt like this***

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2. Three types of Diabetes Manual user were identified: embracers, dippers and non-embracers.

**Table 4. $HbA_{1c}$ data for participants in the Diabetes Manual group who continued in the study to 12 months (n=67).**

| | Baseline | 6 months | 12 months |
|---|---|---|---|
| Median $HbA_{1c}$ (%) (25–75th centile) | 8.80 (7.9, 9.6) | 8.00 (7.5, 9.5) | 8.2 (7.5, 9.0) |

**Table 5. Types of Diabetes Manual user as determined by the telephone proforma data.**

| Type of user | Call no. | Data example from telephone proforma |
|---|---|---|
| Embracer | 2 | Feels much better – has lost weight, over 1 stone. Book very useful – keeping records. Working at own pace. Not feeling pressured at all. Meets targets set from last time. Mood now lifting – feels much better! |
| Embracer | 2 | Patient has already started exercise on prescription and is going twice weekly, the manual has encouraged her to do more exercise. |
| Embracer | 3 | Plans to continue using Manual. Having smoking cessation support from practice and wants to stop smoking. May join a group with her daughter. |
| Dipper | 3 | Tapes [contain] too much talking, not enough music for the relaxation. Not benefited from the [FAQ CD] tapes. Checking blood sugars more regularly, more focused on diabetes in general, will relate to the Diabetes Manual. |
| Dipper | 3 | Mixed response due to stress. Found it difficult to focus. Found it difficult with going back and forth through the Manual. Tapes have been very beneficial. Altered diet, comfort eats with chocolate – has managed to cut down. Feeling less tired, is walking a lot more. |
| Non-embracer | 3 | Finds the information tape patronising, hates the relaxation tape. Has cramp every time she stretches. Will use the manual to "dip in and out of". Too set in her ways now. |
| Non-embracer | 3 | Patient has been bogged down with Diabetes Manual [DM] due to busy lifestyle. He thinks the Manual would be especially useful for newly diagnosed [people with diabetes]. Finds it time consuming. As a result of DM is much more aware of the importance of exercise although feels the exercises in DM are too easy for him, he prefers to walk and intends to increase exercise level in the new year. He doesn't believe he has learned anything new with regard to the correct food but is more aware of labelling. |

*and how did they cope with it? … You're not on the end of the phone bugging the nurse or down at the doctor … It gives them [people with diabetes] a sense of independence."*

### *Is the Diabetes Manual programme a feasible programme for one-to-one structured education in primary care?*

Once the trial was completed, all the intervention nurses were invited to take part in a focus group with the aim of understanding their experience of facilitating the Diabetes Manual in primary care. A discussion schedule was developed to enquire about the feasibility and appropriateness of practice nurses delivering the Diabetes Manual, and the extent to which the facilitator training had prepared them for their role. Following a single letter of invitation, 11 of the 23 facilitators (48%) who had been using the manual with people with diabetes agreed to participate. The focus group was facilitated by a senior teaching fellow in diabetes experienced in this method and a medical student undertaking an undergraduate research scholarship. Once informed consent was obtained from participants, the focus group was audio-recorded, transcribed and thematic analysis undertaken by the focus group facilitator and the author, with three strong themes emerging from this single focus group around (i) job satisfaction, (ii) an indication that the nurses had an instinct about who would benefit from it and (iii) preparedness for the role.

### *Job satisfaction*

Using the Diabetes Manual had a positive impact on the nurses' job satisfaction. They felt more confident and skilled, it extended their own learning and practice experience, and confirmed for them that they were already delivering the correct information.

*"[I feel] good, simply good because … what we are doing is having an impact on their life and they can see the impact it's having on their life."* (nurse 6)

*"That's the benefit of it … That frustration has gone – that sort of pressure that you're*

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1. During the trial, the facilitators had been restricted by the inclusion and exclusion criteria, which meant that they were not able to offer it to the people they particularly had felt would find it useful.
2. Group-based programmes are effective and efficient learning environments, but it is increasingly recognised that they do not suit everyone.

> ***not achieving anything and actually now they can do it for themselves."*** (nurse 4)

This indicates that the nurses felt they were now able to structure the education components of their consultations, but also warns that there is a danger of passing the whole responsibility to the person with diabetes along with the Diabetes Manual resources, and there may be some need to assess a person's readiness for this.

***Who should it be offered to?***

During the trial, the facilitators had been restricted by the inclusion and exclusion criteria, which meant that they were not able to offer it to the people they particularly had felt would find it useful. They felt that $HbA_{1c}$ was not always the most appropriate indicator of whether someone would benefit from a structured education programme, and that there were other criteria, such as time since diagnosis, that may be more useful.

> ***"[The manual might be useful] 6 or 12 months in, when they get stuck, but when they've sort of tried living with diabetes …"*** (nurse 5)

The practice nurse facilitators were clear about which individuals they would have liked to have offered the Diabetes Manual to, and who would have engaged with it:

> ***"You think: 'If only I could just give you this manual'..."*** (nurse 3)

> ***"Yes, because they're looking for something but you haven't got the time to give them [it] in surgery."*** (nurse 6)

> ***"Well, actually, I did, I actually gave one [non-trial] person the manual."*** (nurse 7)

This dialogue between three of the facilitators draws out many of the challenges facing practice nurses in the delivery of diabetes care: identifying patient need, and being constrained in meeting that need because of both internal (time and workload) and external (PCT policy) factors.

Group-based programmes are effective and efficient learning environments, but it is increasingly recognised that they do not suit everyone. In their study of self-management education in coronary heart disease, Dalal

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1. Many people have caring and work-related responsibilities that demand a flexible approach to learning.
2. The Diabetes Manual is a feasible programme for one-to-one delivery of structured education.
3. The trial facilitators reported that the facilitator training met their needs, and they felt confident on completion.
4. Since the trial, two Diabetes Manual facilitator courses have been undertaken by a broader range of health professionals, several of whom have also been trained to deliver group-based structured education.

and Evans (2004) found that older people, the self-employed and the rurally located preferred a home-based one-to-one programme to a centrally based (for example, hospital or PCT) group programme. Many people have caring and work-related responsibilities that demand a flexible approach to learning. There are also people for whom a group programme is impossible, such as those with severe mental health problems or in custody. Feedback from the RCT and, subsequently, from the trained facilitators, has shown that the Diabetes Manual is a feasible programme for one-to-one delivery of structured education.

***How prepared were the nurses to become Diabetes Manual facilitators?***

The trial facilitators reported that the facilitator training met their needs, and they felt confident on completion. They acknowledged that they had difficulty in recalling theory surrounding unfamiliar elements of care delivery, such as telephone support calls or consultation techniques, once they were back in the practice situation:

> *"And then I ended up asking yes and no questions as opposed to open questions … and then you sort of go back and try and think why do they keep saying yes or no when that's not what I'm asking them"* (nurse 7)

Several nurses reported using the techniques outside diabetes care with people with other long-term conditions:

> *"I found it was sort of beneficial with all chronic disease … it's meeting the [nGMS] contract quite well."* (nurse 3)

Since the trial, two Diabetes Manual facilitator courses have been undertaken by a broader range of health professionals, several of whom have also been trained to deliver group-based structured education. As a consequence of course evaluations from these facilitators regarding overlapping aspects of the one-to-one and group-based curriculums, such as philosophy, theory and empowering communication skill development, a 1-day Diabetes Manual facilitator training course has been developed for health professionals who are already delivering group-based structured education. This training will run alongside the 2-day courses designed for those unfamiliar with diabetes structured education.

## Conclusion

The Diabetes Manual is a feasible and appropriate form of structured education for one-to-one use with people with type 2 diabetes. Trial participants demonstrated improved confidence in self-managing their diabetes and a reduction in their diabetes anxiety levels.

The research has shown that the Diabetes Manual benefits the majority of individuals on the course and results in considerable improvements in diabetes management for some. Further research is being undertaken to establish who might benefit most from the Manual, and how to make it more effective in improving both psychosocial and clinical outcomes for a broader range of individuals. ■

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