

Handing control to the patient - structured education in diabetes

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This year we celebrate the centenary of the discovery of insulin, when researchers at the University of Toronto successfully treated the first individual with T1DM. It was undoubtedly a major breakthrough. Insulin transformed children and adults destined to die within 2-3 years into healthy individuals within a few weeks and many went on to live full and productive lives. Yet the optimism that the ready availability of insulin would result in a cure for a previously fatal disease was gradually replaced by a realisation that insulin was not a panacea. Over the years that followed, many of those on treatment developed serious microvascular complications resulting in blindness, amputation and renal failure. It gradually became clear that keeping glucose levels close to normal was key. But since blood glucose had to be measured in hospital labs and those with diabetes were only able to measure glucose in their urine the challenges of keeping levels at target were immense. Episodes of severe hypoglycaemia were common, and many authorities considered it too dangerous to attempt to keep glucose at near-normal levels.

With the advent of glucose monitoring in the late 1970s, pioneers such as Berger and Mühlhauser realised that this revolutionary technology could be used by patients at home to enable them to manage their diabetes themselves. Positive trial results were ignored by many healthcare professionals and it took another 30 years for the UK diabetes establishment to adopt this approach. In this chapter I describe how structured education in diabetes was developed, the evidence for its effectiveness and the remaining challenges which still need to be overcome.

Following the discovery of insulin, most healthcare professionals were slow to realise that it is the person with diabetes (or their family) who holds the key to implementing effective self-management. Yet there were some professionals around the world who grasped this. Perhaps the first was Elliot Joslin, who was working in Boston when insulin was discovered. He realised rapidly that for treatment to work properly the patients had to be trained to be their own doctors and had to learn to adjust insulin themselves. He wrote a

manual for patients in the early 1920s and, in a paper he wrote in 1946, he reflected that any insulin therapy was "a waste of time and money unless the patient was thoroughly instructed to manage his own case".¹

Karl Stolte, a paediatrician working in Rostock in Germany, argued in 1929 that children should be allowed to eat freely with insulin adjusted according to the amount of glucose in their urine.² It appears this was too much for the medical mainstream in Germany at that time and his insights went unheeded. Some British physicians did grasp the importance of self-management. RD Lawrence, whose own life was saved by the discovery of insulin, became head of the diabetes department at King's College Hospital and by 1929 had written two books, "The Diabetic Life" and "The Diabetic ABC" which provided instruction on managing diabetes for both professionals and patients.³

However, the general view in the UK was that doctors should remain in charge of treatment. Robert Tattersall, who together with Peter Sönksen and Clara Lowy were the first clinicians to introduce blood glucose monitoring into clinical practice in 1977, has written that an abstract, describing the Nottingham experience in using the technology in pregnancy, was rejected by the then BDA Medical and Scientific meeting. Furthermore, during the subsequent meeting, the proposition that patients could monitor their own blood glucose was met 'with incredulity' and a view that even if it was possible, 'it would be dangerous'.³

Yet at the same time, others in Europe realised the potential of self-monitoring of blood glucose (SMBG) to transform diabetes care by using the technology as part of a structured training package. Jean Philippe Assal had, with others, developed the concept of Therapeutic Education,⁴ an approach incorporating principles of modern adult education to promote self-management skills encouraging patient autonomy. Mühlhauser and Berger, working in the WHO centre in Dusseldorf, incorporated SMBG into a structured education course diabetes teaching and treatment programme (DTTP).⁵ They attempted to reproduce the physiology of insulin secretion therapeutically by separating insulin delivery into a longer-acting basal insulin (with NPH insulin injected twice daily) to control blood glucose in between meals and they covered meals with soluble insulin given before eating.

In the UK, carbohydrate exchanges had been used to impose a rigid eating pattern in response to fixed doses of insulin prescribed by the physician, which meant expecting adults and children to eat the same amount of carbohydrate (CHO) at the same time each day. In marked contrast, the DTTP promoted 'dietary freedom', with no forbidden foods and those with diabetes calculating their own insulin dose based on anticipated CHO intake and current

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blood glucose values. The course was delivered to groups of 8-10 adults over five days in an inpatient setting. Controlled trials demonstrated both improved glucose levels and reductions in severe hypoglycaemia. In an influential prospective observational study involving more than 9,500 adults in multiple German centres, HbA_{1c} had fallen by 7 mmol/mol (0.7%) to 60 mmol/mol (7.6%) and the incidence of severe hypoglycaemia had fallen significantly by ~50% to 0.21 episodes per individual per year.⁶

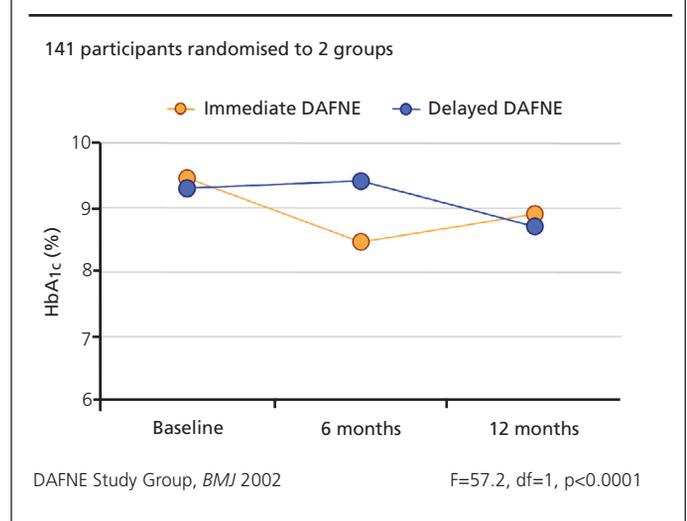
Yet despite this powerful evidence, published in high quality journals, centres in the UK either ignored or dismissed this work. In the early 1990s, carbohydrate exchanges had been discarded as futile, with the realisation that asking individuals to eat the same amount of carbohydrate at the same time every day was unrealistic for most. But in the absence of structured education, insulin was dosed haphazardly, and the prevailing approach was something called 'healthy eating'. Armed with their experience of the success of the DTTP, Berger and Mühlhauser were forthright in their criticisms of centres and countries where systematic training was not provided.⁷ They condemned the haphazard approach, selective use of the literature and claims of lack of resources to justify this stance. In particular, they emphasised the waste of time and money of using glucose monitoring without teaching patients how to use the results.

DAFNE results

Provoked by those comments during a lecture from Berger at the Helsinki IDF in 1997, delegations from three UK centres led by Sue Roberts attended the Düsseldorf centre and, having viewed the course, were impressed. They returned to the UK and, supported by one of the last Diabetes Project grants funded by Diabetes UK, they translated the curriculum into English (with the help of the Düsseldorf team) and conducted an RCT.⁸ In all, 169 participants either attended training immediately (immediate DAFNE) or acted as waiting list controls and participated in DAFNE training six months later. At 6 months, HbA_{1c} was significantly lower in immediate DAFNE patients (mean 8.4%) than in delayed DAFNE patients (9.4%). The impact of diabetes on dietary freedom measured by ADDQOL was significantly improved in immediate DAFNE patients compared with delayed DAFNE patients, as was the impact of diabetes on overall quality of life. General wellbeing and treatment satisfaction were also significantly improved. Improvements in quality of life were significant by one year. Thus, the trial confirmed that structured education could effectively improve biomedical outcomes and in addition led to marked benefits in quality of life and other psychological outcomes.

Subsequent studies have confirmed these results. In the REPOSE trial, DAFNE and multiple daily injections (MDI) were compared to DAFNE and pumps. The HbA_{1c} improved by 6mmol/L in both groups at two years, with improved psychological outcomes and major reductions in severe hypoglycaemia.⁹ A 12-month observational study conducted in 600 DAFNE graduates over 12 months reported falls in HbA_{1c} and severe hypoglycaemia, together with reductions in anxiety and depression.¹⁰ Forty percent of those with impaired awareness of hypoglycaemia experienced improved recognition. Another study, exploring the effect of DAFNE

Figure 1. Glycaemic control in the DAFNE trial



training on acute admissions, has shown substantial reductions in ketoacidosis and severe hypoglycaemia, emphasizing the cost saving attributable to falls in diabetic emergencies after DAFNE training.¹¹ Finally, the DAFNE collaborative, unlike most other UK structured education programmes, conducts annual audits demonstrating a mean reduction in HbA_{1c} of 0.7mmol/mol with 50% of DAFNE graduates achieving an HbA_{1c} below 59 mmol/mol.¹²

These results and uncontrolled reports from other programmes in the UK confirm that 4–5 days of structured education, delivered to groups and teaching flexible intensive insulin therapy, result in clinically relevant falls in HbA_{1c} and rates of severe hypoglycaemia and improved awareness of hypoglycaemia. They also lead to marked improvements in quality of life, anxiety and depression and are highly cost-effective.

Current NICE guidance, recently updated, continues to emphasise both the benefit of structured education programmes and the importance of attendance.¹³ The DAFNE trial and subsequent roll-out, together with provision of other similar courses, has changed practice in the UK. DAFNE is now delivered in around 75 centres throughout UK (roughly 50% of those responsible for care of adults with T1DM) and courses have been delivered to more than 50,000 individuals. Yet, despite these successes, DAFNE and perhaps other similar courses in the UK report levels of HbA_{1c} which fail to reach UK and international targets. In recent research we have focused on the limitations of current structured education and looked to others who have expertise in behavioural science, clinical psychology and technology to develop a more effective intervention.

Developing DAFNE further

With initial programme grant funding from NIHR, Lawton and Rankin conducted a series of qualitative research studies with DAFNE graduates. After a DAFNE course, participants reported markedly improved psychological outcomes, including quality of life, but they let glucose targets slip over time.¹⁴ Participants found it particularly challenging to maintain glucose diaries or reflect on progress. Relatively few maintained glucose levels

sufficient to prevent complications, reporting barriers such as reduced confidence and poor mathematical skills. They requested individualised follow-up and refreshers. We also found inconsistent course delivery by educators. We had previously assumed that merely becoming competent in flexible intensive insulin therapy would be sufficient, but it has become apparent that those attending courses require additional support which needs to be incorporated into the programme. Our findings highlighted the importance of regular reviews with DAFNE-trained staff, educational top-ups and better ways of habituating key self-management behaviours.

We concluded that for most adults with T1D, the currently offered five days of skills training plus unstructured, ad-hoc post-course support though valuable was insufficient. The course improved short-term glucose levels and quality of life but failed to establish sustained self-management behaviours effectively enough to improve long-term glucose control and so prevent complications.

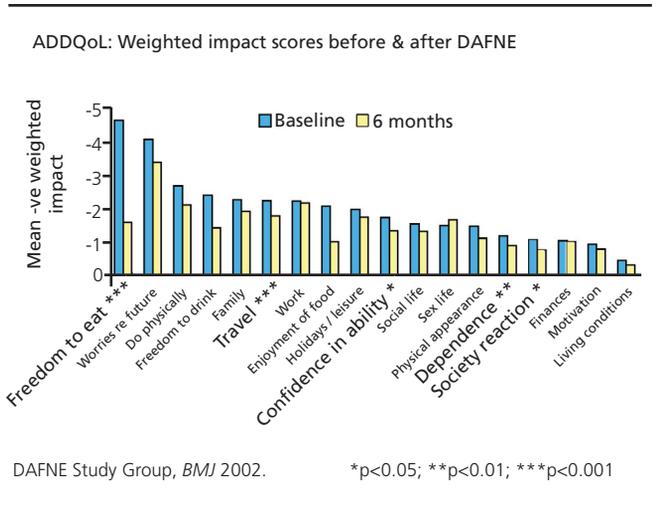
To enable individuals to self-manage diabetes successfully long-term we concluded that we needed to provide:

- 1) practical skills-based training, incorporating techniques that enable participants to acquire and sustain effective self-care behaviours
- 2) appropriate ongoing professional support as needed.

With additional NIHR programme grant funding we set out to develop a DAFNE course (which we termed DAFNEplus) that would result in both improved and sustained diabetes self-management behaviours together with better glucose control than is currently achieved without compromising quality of life.¹⁵

In phase 1 we worked with behavioural scientists who helped us to identify which behaviours we should target to ensure that the competencies which are taught during DAFNE would be sustained. Clinical psychologists in our group have adapted techniques from cognitive behavioural therapy to incorporate what is called cognitive restructuring. We also enlisted the help of bio-engineers who devised approaches which can automatically upload an electronic diary, including continuous glucose monitoring results, to facilitate communication between participants and educators. The professionals then use this information to provide individualized feedback and support, particularly for those who are struggling. We have also added online refreshers to enable DAFNE graduates to revisit educational topics.

Figure 2. Effect of structured skills training on quality of life



The expertise of our qualitative researchers and systematic reviewers was combined to help us identify how we should provide structured support following DAFNE in a meta-ethnographic review of qualitative research in this field. The Follow-Up Support for Effective type 1 Diabetes self-management (FUSED) study combined the results of these synthesised studies to identify elements of effective follow-up.¹⁶ These included working collaboratively to build confidence, building the skills of self-management gradually and incorporating behaviour change science.

Having completed phase 1 with the successful delivery in three pilot centres of the 'DAFNEplus' intervention, we then embarked on a randomised controlled cluster trial in 13 centres comparing standard DAFNE with DAFNEplus. The aim was to recruit 600 individuals in total, with HbA_{1c} as the primary outcome and completion of 1-year follow up in October 2022.^{17,18} We were recruiting to time and target until February 2020, when the COVID pandemic brought the trial to a complete halt since face-to-face education was not possible. We finally restarted the trial in August 2021. Our last course will be completed in November 2022, with final results available in late 2023. Unsurprisingly, it has not been possible to restart the trial in all of the original centres due to loss of staff and reduced capacity and the number of participants will fall below the

Table 1. Challenges in maintaining effective self-management following structured education

Challenges after attending course	Participants response to challenges	Recommendations for effective follow-up support
Complexity of life	Shift blood glucose targets	Modelling collaboration and empowerment
Disconnect between effort and reward	Stop or relax self-monitoring	Anticipating and addressing motivation
Lack of confidence in personal judgement	Over-rely on corrective doses	Facilitating social support
Insufficient professional support	Overtreat hypoglycaemia Simplify life by reverting to less flexible eating	<ul style="list-style-type: none"> ● Incorporating new technology ● Continuing to build knowledge and skills ● Reviewing and ongoing advice on monitoring, treatment, diet, management of hypoglycaemia and exercise

Adapted from Ref 16



Key messages

- Structured education improves A1c, quality of life and is highly cost-effective.
- Acquiring self-management competencies in type 1 diabetes is key to successful self-management and requires structured training and probably ongoing structured support.
- Ensuring all adults with type 1 diabetes have participated in a structured education course should be a major priority in all specialist centres

original target of 600. But we will still have recruited enough people (more than 300) to have sufficient statistical power to identify a significant difference in HbA_{1c} between the two groups.

As we wait for the completion of this study, it is worth reflecting on our current failure to ensure that structured education is accepted as a fundamental component of treatment. The national diabetes audit makes depressing reading in this respect.¹⁹ Although the proportion of adults with T1DM offered structured education has risen from 28% in 2012 to 50% in 2018, the proportion of those attending is unchanged at 13% and has actually fallen from 2015. These data may be an underestimate as this section of the audit is apparently often not completed. Nevertheless, it is surprising that despite the overwhelming evidence demonstrating benefit (particularly in quality of life and cost-effectiveness) and strong NICE guidance, many UK diabetes health professionals fail to convince their patients of its importance. It seems that the powerful criticisms of Berger and Mühlhauser still apply. There would appear to be a strong justification to insist on both better completion and a 'quality standard' of the proportion of adults completing as opposed to 'offered' structured education.

In conclusion, I would submit that 100 years after the first use of insulin, there is now an irrefutable case that structured education should underpin management in all individuals with T1DM. By integrating it with current and future technology, we can ensure that those with this most challenging of conditions are equipped with the tools to maintain glucose levels at levels which will minimise complications, as well as allowing them to lead better lives with diabetes until we eventually find a cure.

Conflict of interest None.

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