Improving management of type 1 diabetes in the UK: the Dose Adjustment For Normal Eating (DAFNE) programme as a research test-bed. A mixed-method analysis of the barriers to and facilitators of successful diabetes self-management, a health economic analysis, a cluster randomised controlled trial of different models of delivery of an educational intervention and the potential of insulin pumps and additional educator input to improve outcomes

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Scientific summary

The Dose Adjustment For Normal Eating (DAFNE) programme

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Scientific summary

Background

Many people with type 1 diabetes develop severe microvascular complications and experience premature death from cardiovascular disease. The human cost in terms of loss of quantity and quality of life (QoL) is matched by the economic consequences. Around 2–3% of those with diabetes in the UK currently account for 10% of the NHS budget. The annual UK cost for managing kidney disease is around £150M in type 1 diabetes.

Keeping blood glucose close to non-diabetic levels reduces microvascular complications. In the Diabetes Control and Complications Trial, a reduction in glycated haemoglobin (HbA_{1c}; a measure of glucose control) of 2% halved the risk of diabetic complications. However, this evidence did not initially lead to improved clinical practice in the UK.

The main reason that tight metabolic control is difficult to achieve is that current methods of insulin delivery cannot reproduce physiological insulin release by the pancreas. Furthermore, the relentless behavioural and technical demands of calculating appropriate doses of insulin and adjusting for different situations (e.g. stress, exercise, carbohydrate consumption), attempting to reproduce normal physiology (in which correct amounts are released automatically), are very challenging. Using injected insulin to control glucose levels aggressively is also hazardous, with increased risks of hypoglycaemia, although the rewards are a reduced chance of microvascular complications and a prolonged life expectancy.

Despite these limitations, insulin therapy can control blood glucose effectively if patients can integrate different principles, including (1) understanding the effects of insulin, (2) appreciating which foods raise blood glucose and by how much, (3) recognising and treating hypoglycaemia and (4) anticipating exercise. Diabetes health-care professionals understand these principles and the crucial test is whether they can teach them to patients. In the 1980s the Düsseldorf Diabetes Centre developed a 5-day structured training programme in intensive self-management using these principles, which demonstrated markedly improved glucose control yet reduced hypoglycaemia.

In 2002, a multidisciplinary team, based in three centres and part of the group undertaking the work of this report, completed the Dose Adjustment For Normal Eating (DAFNE) trial, a randomised controlled trial (RCT) of the German intervention adapted for the UK. There were major improvements in QoL, sustained for up to 12 months (despite increased injections and blood tests), and falls in HbA_{1c} of 1.0% at 6 months and 0.5% at 12 months.

These results had a profound impact on the management of type 1 diabetes in the UK. They prompted the National Institute for Health and Care Excellence to evaluate structured education models in diabetes, acknowledging that the DAFNE approach, together with the German programmes, appeared to be effective. The approach was identified as one of the few interventions in type 1 diabetes that met criteria agreed by a Department of Health working group into structured diabetes education. This led to the formation of the DAFNE collaborative, with courses delivered to > 27,000 adults in > 70 centres across the UK and Ireland. There is an active user group, two members of whom sit on the executive; other patients have constructed an online website offering support, including an area where patients can obtain professional advice.

A review of the original DAFNE cohort showed that, after 4 years, the HbA_{1c} level was only 0.2% below the baseline level although psychosocial benefit was maintained. These data and others showing that around half of DAFNE graduates remain poorly controlled emphasised that DAFNE courses were just a start. More research was needed to improve the effectiveness of the intervention so that patients could manage their diabetes more effectively.

Objectives

The aim of the study was to use the DAFNE collaborative as a research test-bed to improve complex educational interventions for the management of type 1 diabetes and other long-term conditions.

Our objectives were to:

1. Develop an electronic database to record outcomes and progress in adults with type 1 diabetes undertaking structured education.
2. Undertake psychosocial studies to determine factors explaining why individuals do well or badly after structured education using linked qualitative and quantitative approaches. We aimed to:

    i. identify which aspects of the complex intervention do and do not promote improved biomedical and psychosocial outcomes
    ii. establish why some patients benefit more from DAFNE training than others
    iii. identify factors that explain why improved glycaemic control following DAFNE training tends to decline over time.

3. Undertake two RCTs (one pilot) to improve self-management and develop an additional intervention to address glycaemic outcomes.
4. Utilise user involvement to develop more effective interventions.
5. Measure the cost-effectiveness of interventions over the short and long term.

Objective 1: to develop an electronic database to record outcomes and progress, and explore whether or not it was possible to collect research data routinely in busy units

We constructed a database to record clinical outcomes and support other workstreams. Data were collected at baseline and annually on demographic, biomedical, health-related and psychosocial outcomes. From December 2008 we enrolled 2002 patients, 82% of whom were eligible. Follow-up data collection rates at 12, 24 and 36 months were 79%, 71% and 62%, respectively, at December 2013.

We established that creating a high-quality research database was feasible within clinical practice to evaluate educational interventions but to do this effectively requires additional administrator support and/or routine electronic data capture and input.

Objective 2: to undertake psychosocial studies to determine factors and experiences that explain why individuals do well or badly after DAFNE training

A combination of qualitative (interview and observation) and quantitative (questionnaire) assessment methods were employed with 262 adults with type 1 diabetes before commencing DAFNE training and at 1 year. The quantitative model developed in this study, based on social learning theory, explained between 14% and 20% of the variance in HbA_{1c} and between 28 and 62% of the variance in diabetes-specific QoL, over 1 year. Thus, demographic and psychosocial characteristics showed minimal explanatory power for glycaemic control but good explanatory power for diabetes-specific QoL. Qualitative data suggest that assessing numeracy, critical for insulin dose adjustment and carbohydrate counting, would help to determine whether or not additional training and support are required both before and during structured education. Analyses showed that, although DAFNE courses imparted knowledge and skills, they were less effective at helping participants establish key self-management practices such as regular diary keeping. Revising course curricula may facilitate the complex, ongoing behaviour change required to achieve effective self-management. Technological innovations to reduce the complexity and provide support while facilitating behaviour change domains are important areas to develop.

Objective 3: to undertake two randomised controlled trials (one pilot) to improve self-management of type 1 diabetes and develop an intervention for patients with hypoglycaemia problems

Developing and evaluating a course delivered for 1 day per week over 5 weeks

This was designed as a non-inferiority RCT. Adults with type 1 diabetes were randomised to receive either a standard 1-week DAFNE course or a 5-week DAFNE course. An embedded qualitative study helped understand and interpret outcomes. In total, 213 patients were randomised in seven centres across England and 160 completed the study procedures. For patients with a baseline HbA_{1c} of > 7.5%, the mean change was –0.20% at 6 months ($p = 0.016$) and –0.18% at 12 months ($p = 0.055$). Severe hypoglycaemic episodes fell by 82% in the 12 months after DAFNE training compared with the 12 months before (estimated relative risk 0.18; $p = 0.04$). Psychosocial outcomes improved significantly by 6 months and were maintained at 12 months. For all outcomes the difference between treatment arms was not significant. Qualitative interviews revealed that patients overwhelmingly preferred the format that they received. In conclusion, there were no major differences in outcomes between the 5-week course and the 1-week-course; glycaemic control improved less than in the original trial but severe hypoglycaemia was reduced. As participants valued both formats highly, and some found it easier to attend one type than the other, we will provide both in the future.

Feasibility/pilot study of a 5-day course providing both DAFNE and insulin pump training

We conducted a pilot feasibility study exploring the potential of a trial in which participants were randomised to DAFNE training involving either multiple insulin injections [multidose injection (MDI)] or insulin pumps. DAFNE educators developed a 5-day curriculum incorporating both DAFNE principles and the skills necessary to use a pump. Of 160 eligible individuals, 55 were randomised to either the pump course or the MDI course, of whom 47 both completed the course and attended the 6-month follow-up. HbA_{1c} levels improved in those attending the pump course, comparable to improvements in the original trial; severe hypoglycaemia was reduced and psychosocial outcomes improved. Participants generally remained on their allocated therapy over 6 months.

This pilot demonstrated the feasibility of the proposed full multicentre RCT, including a robust power calculation for the primary end point, and helped in obtaining Health Technology Assessment (HTA) programme funding for the full trial.

Developing an additional intervention for patients who experience hypoglycaemic problems after DAFNE training: DAFNE-HART (Hypoglycaemia Awareness Restoration Training)

Following recognition of the importance of hypoglycaemia to patients on the DAFNE programme in the psychosocial studies (see *Objective 2: to undertake psychosocial studies to determine factors and experiences that explain why individuals do well or badly after DAFNE training*), we collaborated with the diabetes research programme at King's College Hospital, London, in the design and piloting of a 6-week intervention that emphasised hypoglycaemia avoidance and addressed unhelpful beliefs concerning unawareness, incorporating motivational enhancement and cognitive–behavioural approaches. In total, 24 people with type 1 diabetes, impaired hypoglycaemia awareness and problematic hypoglycaemia attended pilot courses and were reviewed 3 months later. One was lost to follow-up. In the remaining 23, the Gold score (a measure of unawareness) improved (from 5.5 to 4.4; $p < 0.001$). The annualised rate of severe hypoglycaemia fell from a median (range) of 3.5 (0–70) to 0 (0–40) ($p = 0.14$), with a fall in moderate episodes from 14 (0–100) to 1 (0–11) per 6 weeks. Depression scores (Hospital Anxiety and Depression Scale) improved (from 5.4 to 4.6; $p = 0.04$) and HbA_{1c} remained stable. We conclude that this intervention helps individuals with impaired hypoglycaemia awareness to reduce hypoglycaemia that persists following DAFNE training.

Objective 4: to utilise user involvement to develop more effective interventions

Dose Adjustment For Normal Eating graduates were represented on different workstreams through the Dose Adjustment For Normal Eating Users Action Group (DUAG). DUAG consists of DAFNE graduates from across the country who have volunteered to contribute to further aspects of DAFNE work. This includes the creation of a website (DAFNE-online), liaison and representation on the DAFNE executive (which administers and supports the DAFNE collaborative) and participating in different research activities. The latter includes the DAFNE programme grant work and the trial of insulin pumps funded by the HTA programme [the Relative Effectiveness of Pumps Over MDI and Structured Education (REPOSE) trial].

A longitudinal evaluation of their impact on the research programme was undertaken, including an evaluation of the initial training provided. We used a mixed-methods approach including (1) semistructured interviews and (2) non-participant observation at DAFNE meetings where users were present.

User involvement in the DAFNE research programme was not maximised because participants were not involved at the grant-writing stage and some DUAG members found it difficult to represent the spectrum of DAFNE participants.

Findings suggest that, if users are assigned to different workstreams, it is preferable to assemble the group first and deliver training on research methods later. This allows users to bond while the research team and users establish training needs.

The DUAG members gave important support to the work of the DAFNE-HART and 5 × 1-day trials. This included developing participant information and discussing inclusion and exclusion criteria while emphasising the contributions that service users can make.

At DUAG's request, users were not paid for their time but received expenses. The resulting difficulty in obtaining time off work might explain why users could not attend all meetings. In future programme grants, investigators should cost users' time to maximise attendance.

Objective 5: to use economic evaluation to assess the cost-effectiveness of interventions over the short and long term

The health economics workstream included development of a health economic model of type 1 diabetes, the re-estimation of the cost-effectiveness of DAFNE training compared with no DAFNE training using the new model, estimation of the cost-effectiveness of 5-week compared with 1-week DAFNE training and integration of psychological and behavioural characteristics into the model.

The key conclusions were that DAFNE training is cost-effective compared with no education, even with limited HbA_{1c} benefit, and that the 1-week and 5-week versions of the course have similar cost-effectiveness. Other results include a set of health-related QoL values for people with type 1 diabetes with varying degrees of diabetes-related complications and that predicting HbA_{1c} response to DAFNE training from individuals' psychosocial characteristics and restricting access to training based on these predictions would not be cost-effective. The Sheffield Type 1 Diabetes Policy Model can be used to answer future policy questions relating to the treatment and self-management of type 1 diabetes.

Key conclusions

1. DAFNE training confers major benefits in improving different aspects of QoL and is highly valued by participants but is less effective in improving and sustaining blood glucose control in the UK than in other European health-care systems.
2. Courses do not always help participants to instil and habituate key self-management practices such as regular diary/record keeping into their lives.

3. DAFNE graduates need structured professional support following training, which is currently unavailable or is provided ad hoc.
4. Demographic and psychosocial characteristics have minimal explanatory power in terms of predicting glycaemic control but good explanatory power regarding prediction of diabetes-specific QoL over 1 year of follow-up after DAFNE training attendance.
5. There were no major differences in outcomes between the 5-week and the 1-week DAFNE courses; glycaemic control improved by less than in the original DAFNE trial but severe hypoglycaemia was reduced.
6. The insulin pump pilot study demonstrated the feasibility of the proposed full multicentre RCT, including a robust power calculation for the primary end point. It also contributed to the success in obtaining HTA funding for the full trial.
7. The DAFNE-HART intervention may help individuals with impaired hypoglycaemia awareness to reduce the risk of hypoglycaemia.
8. DAFNE is a cost-effective intervention compared with no structured education (indeed, cost-saving in the majority of our analyses), even with limited HbA_{1c} benefit, and this supports its provision by the NHS to people with type 1 diabetes in the UK. The 1-week and 5-week versions of the course have similar cost-effectiveness.
9. User involvement was particularly useful in contributing to the trials but could have been maximised by involving users at the grant-writing stage. Training for users should be delayed until their participation is established. In future programme grants, investigators may need to ensure resource for users' time to maximise attendance.
10. It is feasible to run a research database of quality within clinical practice to evaluate self-management interventions such as DAFNE training but to do this effectively requires additional administrator support and/or routine electronic data capture and input.

Proposals for future work

1. Perhaps the most important finding of this programme was that teaching the rationale and skills of flexible intensive insulin therapy in a stand-alone intervention was insufficient to ensure that most individuals initiate and sustain effective self management. We now strongly believe that long-term conditions need integrated skills training and structured lifelong professional support. Thus, structured education in self-management needs to include a package that instils the principles of self-management and then supports individuals and their families to achieve success. This should be applied to other long-term conditions.
2. We should modify the current DAFNE curriculum to incorporate the emerging understanding of behaviour change to instil and habituate key self-management behaviour in addition to key competencies.
3. An assessment of numeracy, critical for insulin dose adjustment and carbohydrate counting, may help to identify the need for additional training/support.
4. Technological innovations to reduce the complexity of insulin dose calculations, record keeping and blood glucose pattern recognition combined with addressing behaviour change domains (knowledge, motivation and goal-setting) are important areas to incorporate into improved educational interventions seeking to improve diabetes self-management.
5. Models of structured follow-up involving professionals warrant development and evaluation. Technological interventions may contribute to overcoming the barriers identified above and enable participants to incorporate effective self-management strategies and behaviours into their everyday lives.
6. We should seek funding to conduct a multicentre RCT of the DAFNE-HART intervention for individuals with hypoglycaemia unawareness.
7. In future work we should ensure that users contribute to all elements of the research. This includes the different workstreams and how they should operate and the technological support needed.
8. We should ensure that future work includes a detailed assessment of the fidelity of educational interventions, including the extent to which educators maintain the principles on which DAFNE training is based.

Trial registration

This trial is registered as ClinicalTrials.gov NCT01069393.

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