





RESEARCH: EDUCATIONAL AND
PSYCHOLOGICAL ASPECTS

The DAFNE^{plus} programme for sustained type 1 diabetes self management: Intervention development using the Behaviour Change Wheel

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Abstract

Aims: Self-management programmes for type 1 diabetes, such as the UK's Dose Adjustment for Normal Eating (DAFNE), improve short-term clinical outcomes but difficulties maintaining behavioural changes attenuate long-term impact. This study used the Behaviour Change Wheel (BCW) framework to revise the DAFNE intervention to support sustained behaviour change.

Methods: A four-step method was based on the BCW intervention development approach: (1) Identifying self-management behaviours and barriers/enablers to maintain them via stakeholder consultation and evidence synthesis, and mapping barriers/enablers to the Capability, Opportunity, Motivation-Behaviour (COM-B) model. (2) Specifying behaviour change techniques (BCTs) in the existing DAFNE intervention using the Behaviour Change Techniques Taxonomy (BCTTv1). (3) Identifying additional BCTs to target the barriers/enablers using the BCW and BCTTv1. (4) Parallel stakeholder consultation to generate recommendations for intervention revision. Revised materials were co-designed by stakeholders (diabetologists, psychologists, specialist nurses and dieticians).

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Results: In all, 34 barriers and 5 enablers to sustaining self-management post-DAFNE were identified. The existing DAFNE intervention contained 24 BCTs, which partially addressed the enablers. In all, 27 BCTs were added, including ‘Habit formation’, ‘Credible source’ and ‘Conserving mental resources’. In total, 15 stakeholder-agreed recommendations for content and delivery were incorporated into the final DAFNEplus intervention, comprising three co-designed components: (1) face-to-face group learning course, (2) individual structured follow-up sessions and (3) technological support, including blood glucose data management.

Conclusions: This method provided a systematic approach to specifying and revising a behaviour change intervention incorporating stakeholder input. The revised DAFNEplus intervention aims to support the maintenance of behavioural changes by targeting barriers and enablers to sustaining self-management behaviours.

KEY WORDS

Type 1 diabetes, behaviour change, diabetes self-management education, Behaviour Change Wheel, intervention revision

1 | INTRODUCTION

Type 1 diabetes management necessitates daily intensive insulin administration and other self-care tasks aimed at maintaining euglycaemia. This reduces the risk of long-term complications arising from prolonged hyperglycaemia such as retinopathy and neuropathy, as well as the more immediate risk of hypoglycaemia.^{1,2} Self management is a broad concept referring to everything a person does to manage the symptoms, treatment and psychosocial consequences of living with a long-term condition.³ Type 1 diabetes is one of the most behaviourally complex and demanding long-term conditions, involving calculation and administration of insulin multiple times a day using injections or a pump based on blood glucose monitoring and other activities, including estimating carbohydrate intake and physical activity levels. Fewer than 50% of people achieve optimal glucose levels⁴ and fewer than 20% meet recommended clinical treatment targets.⁵ While the relationship between self-management behaviours and euglycaemia is complex,⁶ identifying strategies to support people to sustain self-management behaviours and weave these into their daily lives is needed to improve both long-term clinical outcomes and quality of life.

Self-management programmes aiming to support people in self-management behaviours are recognised as a critical component of diabetes care.^{7,8} The Dose Adjustment For Normal Eating (DAFNE) programme is one such programme, recommended by the National Institute for Health and Care Excellence.⁹ It is a skills training course advocating flexible intensive insulin therapy, alongside freedom in dietary choices, and has been described in detail elsewhere.¹⁰ Participation in the DAFNE programme improves glycated haemoglobin (HbA1c) in the short term,^{11,12} although initial improvements are often not sustained

Novelty statement

- Sustained engagement in self-management behaviours is important in prolonging improvements in type 1 diabetes clinical outcomes and quality of life.
- Behavioural science frameworks may be useful in developing existing self-management programmes to support complex behaviour maintenance.
- The Behaviour Change Wheel framework guided the analysis and development of the DAFNE programme. Additional behaviour change techniques were identified to address known barriers to, and enablers of, sustained self management following DAFNE, incorporated with stakeholder recommendations for revision and delivery.
- The revised DAFNEplus intervention consists of three co-designed components (group course, individual structured support and technological support) and contains 51 embedded behaviour change techniques.

beyond 6–12 months (13, 14, although see, 15). The behaviours involved in type 1 diabetes self-management are complex and cyclical, and maintaining them requires self-regulatory skills (i.e. the ability to review the extent to which behaviour is in line with goals and modifying it when necessary), including monitoring, planning, reviewing and problem solving (Hamilton et al., submitted). Traditional structured education programmes, particularly those focused on didactic knowledge and skills transfer, have not typically been designed for developing these skills.¹⁶ There are a wide range of influences on sustained self-management

behaviour,¹⁷ but the extent to which existing programmes target these influences is unclear. Very often, little rationale is provided for the selection and application of intervention development methods and components, with limited description of the development process and decisions.¹⁸ Programmes would therefore benefit from review and revision with a focus on supporting participants to develop knowledge and skills to adapt their behaviour to the varying demands of the condition.

Developing an intervention through revising an existing one is often preferable to designing *de novo*, as successful elements and experience can be retained, maximising the efficient use of resources and increasing likelihood of intervention adoption.¹⁹ However, while guidance exists on developing and evaluating novel complex interventions,²⁰ less has been written about how to adapt existing interventions in light of new theories and evidence. Attention is needed as the healthcare and technological context may have undergone significant change since the existing intervention was developed. Guidance on the intervention development process advocates incorporating a variety of evidence-based components that may include clinical outcomes data, behaviour change theory, and research on participant and practitioner experience, within an appropriate framework to provide a structure for integrating and balancing these evidence sources.²⁰ Co-producing intervention components and materials is recommended to increase the likelihood of adoption and effectiveness.²¹

Behavioural science frameworks provide a structure for integrating different evidence sources in developing self-management programmes, together with providing theory to identify the potential influences supporting or disrupting initiation and maintenance of behaviour change. The Behaviour Change Wheel (BCW)²² has been used to design behaviour change interventions and refine existing interventions that have been implemented but achieved modest success, or which were not maintained (e.g. 23). The BCW has been described in detail elsewhere²² and consists of three components. At its hub is the COM-B model of behaviour, which represents the influences on a behaviour and requirements for it to occur: Capability, Opportunity and Motivation. The second component of the BCW represents nine general types of intervention, such as Education, Persuasion and Incentivisation. The third component is policy categories—high-level strategies to support implementation of intervention types. An intervention achieves its function(s) through the use of behaviour change techniques (BCTs, as specified in the Behaviour Change Techniques Taxonomy v1²⁴); these are the smallest ‘active ingredients’ in an intervention. A published guide to using the BCW in intervention design²⁵ provides theory-based linkages between COM-B influences on behaviour, intervention types and BCTs, which aids selection of intervention content (also see²⁶). A three-stage method is proposed for designing interventions²⁵: (1) specify target behaviours and identify influences on these behaviour(s);

(2) identify potentially effective intervention types and behaviour change techniques and (3) identify implementation strategies. Guidance for adapting this method to revise existing interventions is presented on an individual case basis.²⁵

The aim of this study was to revise the existing DAFNE intervention for type 1 diabetes self-management to support sustained engagement in self-management behaviours, guided by the BCW framework. This work was completed within a wider programme of research named ‘DAFNEplus’ which aims to optimise the original DAFNE intervention.²⁷

Specific objectives were as follows:

1. To identify type 1 diabetes self-management behaviours, and barriers and enablers to sustaining these behaviours post-DAFNE;
2. To specify the BCTs comprising the existing DAFNE intervention, and the extent to which they address the identified barriers and enablers;
3. To identify additional BCTs to address the identified barriers to and enablers of sustaining self-management behaviours;
4. To formulate recommendations for intervention revision from stakeholder consultation, based on critical review of the existing DAFNE intervention;
5. To integrate these steps in co-production of a revised intervention and materials: DAFNEplus.

2 | PARTICIPANTS AND METHODS

2.1 | Study design

A modified four-step version of the BCW approach to intervention development was used,²⁵ with an additional step added to analyse the existing DAFNE intervention and identify additional BCTs (steps summarised in Table 1). The intervention was piloted for feasibility with small modifications incorporated according to a Collaborative Working Group approach.²⁸

Ethical approval for intervention development was granted by the University College London Research Ethics Committee (CEHP/2016/556) and for feasibility piloting by the National Health Service Research Ethics Committee (16/WS/0230). Written informed consent was obtained from participants involved in the feasibility pilots.

2.2 | Step 1: Analysis of target behaviours and barriers and enablers using the COM-B model

A behavioural analysis identified first the behaviours involved in type 1 diabetes self-management, and second, the barriers

TABLE 1 Summary of steps to revise the DAFNE intervention, adapted from the Behaviour Change Wheel (BCW) framework for intervention design

Methodological step	Data source(s)
BCW Stage 1: Understand the behaviour in context	
Intervention revision step 1: Specify target behaviours involved in sustained type 1 diabetes self-management and analyse barriers/enablers using the COM-B model	Cycles of self-management behaviours and barriers/enablers to self-management behaviours, mapped to COM-B (Hamilton et al., submitted)
Intervention revision step 2: Specify behaviour change techniques in existing intervention	Content analysis of existing DAFNE programme
BCW Stage 2: Identify intervention options	
Intervention revision step 3: Identify extent to which existing content targets enablers and identify additional intervention types and behaviour change techniques to address barriers/enablers	Published BCW matrices (Michie et al., 2014)
BCW Stage 3: Identify content and implementation options	
Revision step 4: Identify mode of delivery options and additional considerations for revision	Stakeholder recommendations for intervention revision

and enablers to sustaining these behaviours following participation in DAFNE. The methodology and findings of this analysis comprising Step 1 are reported in detail elsewhere.²⁹ To summarise, the behaviours involved in type 1 diabetes self-management were first identified and refined via a multidisciplinary stakeholder consultation involving diabetologists with experience of delivering or developing DAFNE ($n = 5$), specialist nurse- and dietician-DAFNE educators ($n = 3$), health and clinical psychologists and behavioural scientists with expertise in type 1 diabetes ($n = 6$, two of whom also had type 1 diabetes), and independent representatives of a patient advisory group who had attended a DAFNE course ($n = 2$). A larger patient advisory group also participated in this process.

Stakeholders were asked to identify actions involved in self-managing type 1 diabetes, which were collaboratively refined by behavioural scientists into flow diagrams representing cycles of self-management behaviours. Second, influences on the self-management behaviours were extracted from three sources (a published systematic review and meta-ethnography,¹⁷ educator-generated 'red flags' indicating need for additional support and user-generated frequently asked questions following DAFNE participation). Influences were then synthesised and categorised according to their direction of influence (barrier/enabler) and domain in the COM-B model: Capability (e.g. knowledge or skill), Opportunity (e.g. aspects of the physical or social environment) or Motivation (e.g. belief about ability).

2.3 | Step 2: Specifying behaviour change techniques within the existing intervention

The DAFNE intervention (described in detail elsewhere^{11,12}) promotes flexible insulin therapy, whereby insulin is matched to food intake, and aims to encourage dietary freedom. The programme comprises a 40-hour group learning-based

course delivered over 5 days by two 'educators' (one diabetes specialist nurse and one dietician), and attended by up to eight participants. Participants also receive an individual pre-course appointment to discuss their clinical insulin requirements, and following the course, they are invited to a group refresher session and have access to a support website in addition to their routine clinical care.

A content analysis of intervention materials was conducted to specify BCTs within the DAFNE intervention. Course documents (published in 2014), including curriculum manual, participant workbook, blood glucose monitoring and food diaries and carbohydrate portion list, were coded into component BCTs using the BCTTv1²⁴ as a coding framework. All coding was performed in NVivo (version 11) by two researchers independently who were familiar with the BCCTv1. To ensure consistency, the two coders met after coding the first half of the manual. Any disagreements were discussed until consensus was reached and the remaining materials were then coded.

2.4 | Step 3: Identifying additional behaviour change techniques to target barriers and enablers

Barriers and enablers coded to COM-B categories (from Step 1) were mapped to corresponding intervention types and BCTs using published matrices which pair COM-B with intervention types in the BCW and BCTs in the taxonomy.²⁵ For example, to target a barrier influenced by Motivation, the intervention type Persuasion can be achieved with techniques including 'Information about health consequences' (e.g. providing information about the impact of checking blood glucose on HbA1c) and 'Social comparison' (e.g. eliciting the blood glucose checking behaviours of group members to emphasise four daily checks as normal).

First, the extent to which the existing DAFNE intervention addressed the identified enablers to self management was determined by comparing these mapped BCTs with the BCTs coded within DAFNE materials (from Step 2). Second, additional BCTs to potentially include in the revised DAFNE^{plus} intervention were identified from the aforementioned published matrices pairing BCTs and intervention types with COM-B domains.²⁵ These matrices provide a long list of BCTs likely to be relevant and effective in addressing different types of barriers and enablers within Capability, Opportunity and Motivation. These potential BCTs, and examples of their application, were discussed with clinical psychologists ($n = 2$) and clinicians with expertise delivering the DAFNE programme ($n = 8$), who shortlisted the candidate BCTs using the APEASE criteria (Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects and Equity²⁵) as a guide. BCTs judged by the group to broadly meet these criteria, with reasonable scope for relevant content, were selected for inclusion in DAFNE^{plus}.

2.5 | Step 4: Stakeholder consultation based on critical review of the existing intervention

In parallel with Step 3, a modified Nominal Group Technique³⁰ was used to structure a multidisciplinary stakeholder consultation involving review of DAFNE intervention content and generation of recommendations for revision. In all, 30 stakeholders familiar with the DAFNE programme were invited to review materials and suggest revisions to content or aspects of delivery. Stakeholders represented four groups: specialist nurse- and dietician-DAFNE educators ($n = 6$), clinical diabetologists ($n = 6$), behavioural scientists and health or clinical psychologists with expertise in type 1 diabetes ($n = 10$) and type 1 diabetes patient advisory group members who had previously attended a DAFNE course ($n = 8$).

Stakeholders read the DAFNE curriculum manual and submitted feedback on elements of the intervention judged essential to retain, to be changed or added, together with any relevant evidence or theory. Feedback content was inductively synthesised by two behavioural scientists into overarching categories. Stakeholders were invited to comment on the feedback or propose further recommendations for revision via an online communication and decision-making platform (Loomio). Stakeholders were able to make comments over a 3-week period, and review each other's comments prior to adding their own. Comments were synthesised by two behavioural scientists and refined for clarity and specificity, with 'conflicting viewpoints' highlighted. These synthesised comments fed into a face-to-face consensus meeting attended by representatives from each group of stakeholders ($n = 16$; six behavioural scientists/psychologists [two of whom had type 1 diabetes], three DAFNE educators, five clinicians and two patient advisory group representatives/DAFNE graduates).

At this consensus meeting, guided discussion of each set of comments and recommendations took place until agreement was reached on a recommendation for the revised programme. Agreed recommendations were later circulated to meeting attendees to give the opportunity for wording amendments.

2.6 | Co-production of the DAFNE^{plus} intervention

The DAFNE^{plus} programme of research²⁷ builds on previous work³¹⁻³³ suggesting three components to be included when revising the DAFNE programme: (1) a group learning course, (2) structured individual follow-up support and (3) technological innovation to facilitate electronic collection and interpretation of data on blood glucose, insulin dose and other factors. To generate content for these components, the selected BCTs (from Step 3) were integrated with the broader stakeholder recommendations (Step 4) in producing content and guidelines for delivery. Participant and provider materials were generated by stakeholders and research collaborators, with clinical and health psychologists generating psychological and behavioural content and clinical diabetes experts developing clinical content. Engineers developed digital technological support, including a device for blood glucose data transmission and a multi-function DAFNE^{plus} website incorporating data management and interactive learning components.

Intervention materials and technologies were piloted in three hospitals across the UK to assess feasibility. Group courses were observed by two behavioural scientists to assess how the materials and guidelines for delivery worked in practice, and what improvements might be made. DAFNE^{plus} participants and 'facilitators' (educators, in previous terminology) were interviewed following course delivery to assess perceived value of components, ease of delivery and any further suggested changes. Materials were iteratively refined in line with the UK Medical Research Council complex intervention development guidelines.²⁰ Refinements between waves of piloting were agreed collaboratively by a multidisciplinary research group on the basis of data collected from DAFNE^{plus} participants, facilitators delivering the programme and research observations (see 28 for further detail of methodology).

3 | RESULTS

3.1 | Step 1: Analysis of key self-management behaviours necessary for type 1 diabetes self-management and barriers and enablers to sustaining them following participation in DAFNE

Analysis of type 1 diabetes self-management behaviours²⁹ produced three cycles of self-management behaviours

TABLE 2 Most frequent behaviour change techniques (from the Behaviour Change Techniques Taxonomy, version 1) included in the existing DAFNE intervention alongside frequency in the DAFNE_{plus} intervention (see Supplementary Table 1 for all behaviour change techniques included in each intervention)

BCT	BCT definition	Frequency in DAFNE intervention	Frequency in DAFNE _{plus} intervention
Information about health consequences	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	17	32
Action planning	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive)	13	14
Goal setting (outcome)	Set or agree on a goal defined in terms of a positive outcome of wanted behaviour	11	17
Instruction on how to perform the behaviour	Advise or agree on how to perform the behaviour	10	28
Self monitoring of outcome(s) of behaviour	Establish a method for the person to monitor and record the outcome(s) of their behaviour	7	8
Self monitoring of behaviour	Establish a method for the person to monitor and record their behaviour	6	19
Behavioural practice/rehearsal	Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, to increase habit and skill	5	24
Demonstration of the behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly, for example, via film, pictures, for the person to aspire to or imitate	5	20
Problem solving	Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators	5	15
Behavioural experiments	Advise on how to identify and test hypotheses about the behaviour, its causes and consequences, by collecting and interpreting data	5	6

NB. Multiple instances of a BCT within a session or other component (e.g. website) are not counted in frequency calculation.

reflecting different temporal and situational aspects of type 1 diabetes self-management: Routine, Reactive and Reflective cycles (see Figure S1). Each cycle contained stages of planning, implementation (e.g. dose adjustment), monitoring/reviewing (e.g. blood glucose levels) and problem solving (e.g. identifying reasons for blood glucose out of range), reflecting the self-regulatory element of type 1 diabetes management.

In all, 34 barriers and 5 enablers to sustaining self-management behaviours were identified (see Table S3 for further detail), which were coded within the COM-B model. Barriers relating to Capability ($n = 9$) included *Difficulty adapting self management in the face of changing life events and challenges*, and physical symptoms such as *Impaired awareness of hypoglycaemia*; those relating to Opportunity ($n = 7$) included *Lack of access to appropriate support*, and *Inadequate access to monitoring equipment*; and those relating to Motivation ($n = 18$) included *Lack of confidence applying skills independently*, and *Anxieties/fears*. The single enabler relating to Capability was *Establishing and maintaining routines*; enablers relating to Motivation ($n = 2$) included

Feeling empowered by new knowledge and skills; and those relating to Opportunity ($n = 2$) included *Technology assisting the application of DAFNE principles*.

3.2 | Step 2: Behaviour change techniques within the DAFNE intervention

In all, 24 unique BCTs were identified in DAFNE intervention materials (see Table 2 for the most frequently included BCTs in DAFNE, and Table S1 for all BCTs included in both interventions). Each group session of the face-to-face course as specified in the manual contained between one and 10 BCTs. The most common techniques used were ‘Information about health consequences’ (e.g. information on insulin timing leading to reduced risk of severe hypoglycaemia), ‘Action planning’ (e.g. forming a plan for dose adjustment) and ‘Goal setting (outcome)’ (e.g. providing blood glucose targets to aim for). In all, 18 unique BCTs were identified in participant resources including the workbook and carbohydrate-counting

resource (see Table S2 for BCTs within each intervention component).

3.3 | Step 3: Additional behaviour change techniques identified to address barriers and enablers to sustained self management

Two of the five identified enablers (*Group experiences adding credibility* and *Having clear targets and guidelines*) were judged to be adequately addressed by BCTs included in the existing DAFNE intervention. The remaining three enablers were judged to be not or only partially addressed by existing BCTs (see Table S3).

Six intervention types were identified to further target the barriers and enablers to sustaining self-management behaviours after DAFNE. Table 3 details the examples of intervention types and BCTs included in the DAFNEplus programme to address identified barriers and enablers (see Table S4 for all barriers and enablers with BCTs and examples of their inclusion). Following discussion informed by APEASE with colleagues co-producing DAFNEplus intervention materials, 51 unique BCTs were included in the final DAFNEplus programme: 22 in the pre-course appointment, 49 in the group course sessions (and participant workbook, the content of which mirrored the sessions), 27 in the individual support sessions and 15 in the digital technological support/website. In all, 27 of these BCTs were additional to the existing DAFNE programme, while one BCT in the original DAFNE materials ('Vicarious consequences', appearing once) did not appear in the DAFNEplus programme due to content updates. See Table S2 for a comparison of BCTs in DAFNE and DAFNEplus programme components.

3.4 | Step 4: Stakeholder recommendations for the revised DAFNEplus intervention

Stakeholders submitted a total of 474 comments after reviewing the DAFNE curriculum manual. Comments were synthesised thematically into nine threads for online discussion representing three overarching categories: content (e.g. target blood glucose levels, impact of distress, skills to develop), principles of programme delivery (e.g. focusing on positives, language, terminology) and delivery format (e.g. layering content). Each thread received between 9 and 14 comments from at least one participant within each of the four stakeholder groups. Online commenters tended to indicate a high degree of agreement with the points synthesised in the threads and with each other, often suggesting further detail. Example comments were as follows: *'Agree with points made on goal setting and action planning; we need to define in detail how these are carried over and reviewed from the 5 week course*

to the structured follow up programme'; *'Agree with underlying proposals here; I would echo the point about the importance of training of HCPs to support these'*. These online comments were synthesised thematically into draft recommendations and circulated to meeting participants ahead of the face-to-face consensus meeting. In all, 15 final recommendations for the revised intervention were agreed (see Table S5), relating to intervention content and design, delivery of the face-to-face components, and content and structure of the technological and follow-up support components pre-specified by the DAFNEplus research programme.³⁰

3.5 | The revised DAFNEplus intervention

During feasibility piloting, small changes were made to programme structure and materials, such as re-ordering certain sessions and providing structured templates to aid task completion, but no substantive changes were made to content or BCTs. The DAFNEplus intervention consists of three broad components: (1) Face-to-face group learning course comprising 39 sessions delivered by two DAFNE-trained facilitators (nurse and dietician) one day a week across 5 weeks, plus an individual pre-course appointment; (2) structured individual follow-up support, comprising up to five individual sessions, incrementally spaced over 1 year and (3) digital technologies comprising the DAFNEplus website, blood glucose meter with integrated bolus calculator and a home device for linking these together. The DAFNEplus website has multiple functions. These include an automated diary for recording blood glucose, carbohydrate intake, physical activity and other factors; data analysis and graphical feedback, such as percentage blood glucose in range; support with recognising and interpreting patterns in blood glucose; a communication system between participants and healthcare professionals; e-learning area to refresh knowledge of programme principles; challenges and rewards; and reminder systems. See Table S6 for a summary of DAFNEplus intervention components.

To support programme delivery, the DAFNEplus statement of philosophy was revised, and facilitator training was developed to enhance the 'learning environment' and support a focus on sustained behaviour change. This was achieved via training on the behaviour change process, delivery style and conversation tools to maximise participant engagement and promote resilience.

4 | DISCUSSION

The revised DAFNEplus programme consists of three components (group learning course, structured individual follow-up support and technological support) that together aim to facilitate sustained self-management behaviours with concurrent

TABLE 3 Examples of barriers to and enablers of self management of type 1 diabetes following participation in DAFNE according to the COM-B model, with example of intervention types and behaviour change techniques (from the Behaviour Change Techniques Taxonomy, version 1) included in the revised DAFNE_{plus} intervention

Barrier/enabler	COM-B category	Intervention type	Example behaviour change technique(s)	Example of inclusion/ operationalisation
Barriers				
Impaired hypoglycaemia awareness/symptoms	Capability (physical)	Training	Instruction on how to perform the behaviour; Information about health consequences; Goal setting (outcome)	Facilitators explain that hypoglycaemia symptoms can be restored by aiming to avoid hypos (e.g. increased attention to staying within range for three months).
Difficulty incorporating DAFNE principles into everyday life and challenges	Capability (psychological)	Enablement	Information about antecedents; Problem solving; Self-talk	New session on behavioural lapses vs. relapses added, where influences on participants' own behaviour are discussed, participants consider setbacks or challenges they might encounter and strategies to manage these, and write 'cheerleading statements' to add to 'Rainy Day Plan'.
Feelings of failure and hopelessness	Motivation (automatic)	Persuasion Enablement	Goal setting (outcome); Information about health consequences; Credible source; Reattribution	Facilitators advise countering perfectionism by aiming for 'good enough' HbA1c and BG (explain evidence shows 30% of BG checks can be out of range while still achieving an optimal HbA1c/avoiding complications) and acknowledging uncontrollable influences on HbA1c.
Lack of confidence applying skills/ DAFNE principles independently	Motivation (reflective)	Enablement	Goal setting (behaviour); Graded tasks	Facilitators guide participants in identifying one activity and action step each week to try before the next session, and recommend that they practise and master one new skill at a time before moving onto another.
Bolus adviser eroding manual adjustment skill upkeep	Opportunity (physical)	Environmental restructuring	Adding objects to the environment	An online resource is provided showing how to manually calculate insulin doses and change bolus adviser settings.
Inappropriate social support	Opportunity (social)	Enablement	Social support (unspecified); Information about emotional consequences	In the social support session, examples are discussed of mismatches between support needed and offered, consequences and tips on how to ensure support is appropriate.
Enablers				
Establishing and maintaining routines	Capability (psychological)	Training	Habit formation	In action planning sessions, participants are prompted to think how they could make their chosen action step routine/ automatic.

(Continues)

TABLE 3 (Continued)

Barrier/enabler	COM-B category	Intervention type	Example behaviour change technique(s)	Example of inclusion/operationalisation
Feeling empowered by new knowledge and skills	Motivation (reflective)	Incentivisation	Social reward	Facilitators praise appropriate behaviours and successes for each person, writing them on a flipchart in individual review sessions.
Technology/bolus adviser assisting application of DAFNE principles	Opportunity (physical)	Environmental restructuring	Adding objects to the environment	A BG meter with bolus adviser is provided to be used alongside the data management website.
Group experiences adding credibility	Opportunity (social)	Persuasion	Social comparison	Facilitators facilitate discussion on whether and how participants have changed their hypo treatment practices since the start of the DAFNEplus course.

sustained improvements in outcomes. DAFNEplus draws on behavioural science to specifically target the barriers and enablers experienced by DAFNE graduates to maintaining behaviours. It focuses on facilitating the self-regulatory aspects of type 1 diabetes self-management, together with specific content addressing psychological influences and tools to facilitate self-management routines. The three programme components aim to enable DAFNEplus participants to more effectively integrate self-management behaviours into their daily lives and adapt them during future challenges, increasing the likelihood that effective self management and improvements in outcomes including quality of life are maintained over the longer term.

A large body of literature recognises the many challenges that people with type 1 diabetes face in sustaining self-management behaviours (e.g.³⁴), including those that are psychological, such as non-acceptance,³⁵ burnout³⁶ and a higher incidence of depression and anxiety, all of which require responsive healthcare support.³⁷ Some intensive education-based self-management programmes may not be best designed to address these challenges, being relatively short-term in nature and largely focused on type 1 diabetes skill acquisition without parallel consideration of behavioural change processes or due consideration of psychological challenges that may arise within the context of 'normal' diabetes experiences. We hope that greater attention to the behaviours that people with type 1 diabetes must sustain over a lifetime, together with the influences on sustaining these behaviours in light of fluctuations in life challenges, physiological changes and adjustment capability, leads to setting a standard of self-management programmes that recognise and fulfil a need for ongoing and multifaceted support.^{17,30,38}

By revising an existing intervention that has proved beneficial, we aimed to retain successful elements of the original while addressing limitations associated with maintenance of outcomes or with implementation. The method used provides

a structure for managing potential tensions between retaining existing vs. revising components, integrating 'top-down' behavioural framework-driven and 'bottom-up' stakeholder expertise-driven elements. The systematic and transparent methodology allows the revision process to be replicated. A further strength of this method is that the resulting intervention is theory-based, rather than simply theory-inspired, using an explicit causal pathway grounded in evidence.³⁹ This allows the intervention's proposed mechanisms of action to be studied in a process evaluation. Furthermore, combining frameworks within the Behaviour Change Wheel methodology provided additional structure to the intervention revision. Use of the modified Nominal Group Technique³⁰ ensured that all stakeholders' views were considered, and anonymous submission of feedback generated numerous independent ideas.

Limitations of this method include challenges of co-production design, including the potential for theory-based recommendations to be lost in translation during integration of the steps and co-production of the materials (e.g. 40). This was not formally documented as part of the intervention development process, although a detailed fidelity assessment (the extent to which the intervention was delivered as originally intended⁴¹) will be undertaken as part of the DAFNEplus evaluation.²⁷ While the modified Nominal Group Technique consensus method ensured the final agreed recommendations were supported by all stakeholders, which was important to ensure stakeholder commitment to implementing the revisions, completely anonymised commenting on proposed intervention components would facilitate unreserved feedback. This development approach was resource-intensive due to the complex nature of this intervention and the range of stakeholders involved in creating the DAFNEplus programme. Additional work is needed to evaluate how it could be adapted to suit less complex contexts

or with fewer resources, and delivered more rapidly. Finally, training on the behavioural changes required by providers of a revised intervention as well as those receiving it may be needed; this was incorporated in DAFNE_{plus} intervention provider training.

The next stage for this research is to evaluate the clinical and cost-effectiveness of DAFNE_{plus} vs. DAFNE in a cluster randomised controlled trial across 13 NHS Trusts (registered trial ISRCTN42908016; Coates et al., submitted). Outcomes include clinical (e.g. HbA1c, hospitalisations due to severe hypoglycaemia or diabetic ketoacidosis), behavioural (e.g. number of blood glucose checks performed within a set time period) and psychosocial measures (e.g. quality of life). A parallel process evaluation will explore how the intervention is working using mixed methods, including fidelity assessment to evaluate the extent to which the programme is delivered as intended.


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CONFLICT OF INTEREST

SRH has undertaken consultancy for Eli Lilly, Novo Nordisk, Sanofi Aventis, Zealand Pharma, manufacturers of analogue insulin and treatment for hypoglycaemia for which his institution has received remuneration. He has also served on speaker panels for Novo Nordisk for which he has received remuneration. The remaining authors have no conflict of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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