RESEARCH: EDUCATIONAL AND PSYCHOLOGICAL ASPECTS

The DAFNEplus programme for sustained type 1 diabetes self management: Intervention development using the Behaviour Change Wheel

Stephanie H. Stanton-Fay1 | Kathryn Hamilton1 | Paul M. Chadwick1 | Fabiana Lorencatto1 | Carla Gianfrancesco2 | Nicole de Zoysa3 | Elizabeth Coates4 | Debbie Cooke5 | Hayley McBain6 | Simon R. Heller7 | Susan Michie1 | the DAFNEplus study group

1Clinical, Health and Educational Psychology/Centre for Behaviour Change, University College London, London, United Kingdom of Great Britain and Northern Ireland
2Sheffield Diabetes and Endocrine Centre, Sheffield Teaching Hospitals NHSF Trust, Sheffield, United Kingdom of Great Britain and Northern Ireland
3Diabetes Centre, King’s College Hospital, London, United Kingdom of Great Britain and Northern Ireland
4School of Health and Related Research, University of Sheffield, Sheffield, United Kingdom of Great Britain and Northern Ireland
5School of Health Sciences, University of Surrey, London, United Kingdom of Great Britain and Northern Ireland
6Health Services Research Centre, City, University of London, London, United Kingdom of Great Britain and Northern Ireland
7Department of Oncology and Metabolism, University of Sheffield, Sheffield, United Kingdom of Great Britain and Northern Ireland

Correspondence
Stephanie H. Stanton-Fay, Clinical, Health and Educational Psychology/ Centre for Behaviour Change, University College London, London, United Kingdom of Great Britain and Northern Ireland.
Email: s.stantonfay@gmail.com

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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).
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. 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. 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 levels and fewer than 20% meet recommended clinical treatment targets. While the relationship between self-management behaviours and euglycaemia is complex, 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. The Dose Adjustment For Normal Eating (DAFNE) programme is one such programme, recommended by the National Institute for Health and Care Excellence. It is a skills training course advocating flexible intensive insulin therapy, alongside freedom in dietary choices, and has been described in detail elsewhere. Participation in the DAFNE programme improves glycated haemoglobin (HbA1c) in the short term, although initial improvements are often not sustained beyond 6–12 months. 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. There are a wide range of influences on sustained self-management

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.

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

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.
behaviour, 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. Programme 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. However, while guidance exists on developing and evaluating novel complex interventions, 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. Co-producing intervention components and materials is recommended to increase the likelihood of adoption and effectiveness.

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) 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 elsewhere 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 v1); these are the smallest ‘active ingredients’ in an intervention. A published guide to using the BCW in intervention design provides theory-based linkages between COM-B influences on behaviour, intervention types and BCTs, which aids selection of intervention content (also see). A three-stage method is proposed for designing interventions: (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.

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.

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, 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.

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...
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. 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, 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) 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 BCTTv1 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. 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 DAFNEplus intervention were identified from the aforementioned published matrices pairing BCTs and intervention types with COM-B domains. 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 Equity) as a guide. BCTs judged by the group to broadly meet these criteria, with reasonable scope for relevant content, were selected for inclusion in DAFNEplus.

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

In parallel with Step 3, a modified Nominal Group Technique 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 DAFNEplus intervention

The DAFNEplus programme of research builds on previous work 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 DAFNEplus 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. DAFNEplus 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. Refinements between waves of piloting were agreed collaboratively by a multidisciplinary research group on the basis of data collected from DAFNEplus 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 behaviours produced three cycles of self-management behaviours
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.

### 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 DAFNEplus intervention

<table>
<thead>
<tr>
<th>Barrier/enabler</th>
<th>COM-B category</th>
<th>Intervention type</th>
<th>Example behaviour change technique(s)</th>
<th>Example of inclusion/operationalisation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barriers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impaired hypoglycaemia awareness/symptoms</td>
<td>Capability (physical)</td>
<td>Training</td>
<td>Instruction on how to perform the behaviour; Information about health consequences; Goal setting (outcome)</td>
<td></td>
</tr>
<tr>
<td>Difficulty incorporating DAFNE principles into everyday life and challenges</td>
<td>Capability (psychological)</td>
<td>Enablement</td>
<td>Information about antecedents; Problem solving; Self-talk</td>
<td></td>
</tr>
<tr>
<td>Feelings of failure and hopelessness</td>
<td>Motivation (automatic)</td>
<td>Persuasion Enablement</td>
<td>Goal setting (outcome); Information about health consequences; Credible source; Reattribution</td>
<td></td>
</tr>
<tr>
<td>Lack of confidence applying skills/DAFNE principles independently</td>
<td>Motivation (reflective)</td>
<td>Enablement</td>
<td>Goal setting (behaviour); Graded tasks</td>
<td></td>
</tr>
<tr>
<td>Bolus adviser eroding manual adjustment skill upkeep</td>
<td>Opportunity (physical)</td>
<td>Environmental restructuring</td>
<td>Adding objects to the environment</td>
<td></td>
</tr>
<tr>
<td>Inappropriate social support</td>
<td>Opportunity (social)</td>
<td>Enablement</td>
<td>Social support (unspecified); Information about emotional consequences</td>
<td></td>
</tr>
<tr>
<td><strong>Enablers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Establishing and maintaining routines</td>
<td>Capability (psychological)</td>
<td>Training</td>
<td>Habit formation</td>
<td></td>
</tr>
</tbody>
</table>

(Continues)
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 burnout 36 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 that all stakeholders’ views were considered, and anonymous submission of feedback generated numerous independent ideas.

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

### TABLE 3 (Continued)

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

The next stage for this research is to evaluate the clinical and cost-effectiveness of DAFNEplus 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.

ORCID
Stephanie H. Stanton-Fay https://orcid.org/0000-0001-5003-8072
Fabiana Lorencatto https://orcid.org/0000-0003-4418-7957
Debbie Cooke https://orcid.org/0000-0003-1944-7905
Simon R. Heller https://orcid.org/0000-0002-2425-9565

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**SUPPORTING INFORMATION**

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

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