

The DAFNEplus Programme Theory

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The DAFNEplus Intervention

DAFNEplus is a complex intervention to support individuals with Type 1 Diabetes (T1D) to use the principles of Flexible Intensive Insulin Therapy (FIIT) to manage their diabetes to achieve the best possible glycaemic management available to them throughout the life course, without compromising quality of life or psychological wellbeing. It comprises an adapted DAFNE course (delivered one day a week over five weeks), five Individual Support (IS) sessions spaced at increasing intervals over one year following the course and bespoke (Glucollector) technology developed for the programme.^[1]

The development of DAFNEplus

Drawing upon research undertaken during an earlier programme of work and other relevant literatures, developers and stakeholders sought to identify the barriers to sustaining FIIT.^[2-11] Barriers included a range of biopsychosocial factors, which prevented or impaired the three cycles of behavioural management key to diabetes.^[12] A COM-B analysis^[13] identified the Behaviour Change Techniques (supported by clinical and health psychology theories) that could increase the capability, opportunity, and motivation to sustain FIIT behaviours.^[14] Enhanced technology (Glucollector) enabled these behaviours to be guided by meaningful and timely data analysis^[15-17] and an updated training package was developed to support staff to deliver the revised elements of the programme.^[18]

The DAFNEplus Programme Theory

The DAFNEplus Programme Theory describes the different components of the DAFNEplus intervention, the practical and intellectual resources used in its development, the outcomes it hopes to achieve, and the mechanisms of action by which it is hypothesised to deliver those outcomes. The DAFNEplus programme theory was adapted from guidance reported in Kellogg et al^[19] and describes:

- the *problem(s)* that the intervention is trying to address (i.e. influences on the sustained use of FIIT principles to manage T1D)
- the *resources* utilised in creating an intervention to overcome that problem
- the intellectual *theories* and social and technical *inputs* that contributed to its development
- the *activities* that formed the features of the intervention
- the *outputs* showing the changes enabled within the participants and
- the *outcomes* - measurable behavioural, glycaemic and psychosocial changes that would indicate that the intervention has addressed the problem.

More detailed description of the content of the DAFNEplus Programme Theory is presented within the tables below.

Table 1: Problems contributing to lack of sustained enactment of FIIT principles (Problems)

Number	Problems
I1_HealthLit	Low health literacy
I2_SkillFIIT	Lack of knowledge and skills to enact Flexible Insulin Intensive Therapy (FIIT)
I3_ForgetTarget	Forgetting blood glucose targets
I4_AdjTarget	Intentional upward adjustment of blood glucose targets
I5_AdaptFIIT	Inability to adapt FIIT principles in response to life events or transitions
I6_OverTxHypo	Over-treatment of hypoglycaemia using carbohydrate
I7_ShortInsHyper	Over-reliance on short acting insulin doses to manage hyperglycaemia
I8_AccHcpFIIT	Lack of access to Health Professionals trained in FIIT principles
I9_NonAutonHCP	Health Professional interactions that do not support autonomous motivation
I10_LackInfoFIIT	Lack of access to reliable information about type 1 diabetes and its management using FIIT principles
I11_LackSupport	Lack of support from friends and family on diabetes-related issues
I12_LowConFIIT	Low confidence in decision making about use of FIIT principles
I13_ProcAvoid	Thinking patterns associated with procrastination or avoidance in relation to self-management
I14_EffortReward	Low effort/reward trade-off for engaging in FIIT
I15_Hopelessness	Hopelessness about long-term consequences of type 1 diabetes
I16_LackSelfCompass	Lack of self-compassion in situations where self-management feels difficult or does not result in expected outcomes
I17_HighBurden	Perceived burden associated with enacting FIIT principles and other diabetes self-management behaviours
I18_NegEmoState	Negative emotional states associated with enacting FIIT principles

Table 2: Summary of DAFNEplus intervention components (Activities)

Summary of component	Objectives of the component
<i>Group Course</i> A standardised psychoeducational curriculum delivered by two trained facilitators in one day-long session per week over 5 consecutive weeks. The objective of the group course was to help participants acquire the foundational knowledge and skills required to manage blood glucose levels using the principles of FIIT, and to enact the three behavioural cycles identified as being critical for sustained long-term glycaemic control.	The group course includes content and activities to enable participants to: 1. Gain sufficient understanding of the physiology of type 1 diabetes and its management. 2. Understand the principles of, and develop the skills to manage T1D using Flexible Intensive Insulin Therapy (FIIT). 3. Apply behavioural self-management* to implement FIIT within the context of their own lives over the long term. 4. Prevent diabetes-related ketoacidosis (DKA) and severe hypoglycaemia and/or improve management of such episodes. * using the principles of Cognitive-Behavioural Long-Term Condition Self-Management (CBLTC-SM)
<i>Glucollector</i> A web-based portal and associated technology to enable collection and processing of blood glucose, insulin, and carbohydrate data.	Glucollector was designed to: 1. Create a convenient way of enabling monitoring, recording and reviewing of blood glucose, carbohydrate and insulin data. 2. Incentivise the collection of blood glucose, carbohydrate and insulin data to increase the quality of data available to participants and facilitators. 3. Provide visualisations of blood glucose, carbohydrate and insulin data in ways that support participants and facilitators to identify patterns and trends in data. 4. Support timely and effective communication between health professionals and participants about blood glucose data, carbohydrate and insulin data. 5. Provide a source of reliable and valid information about aspects of type 1 diabetes and its management using FIIT.
<i>Individual Support (IS)</i> A series of five appointments with one of the Facilitators who delivered the group course, arranged over a year, and which reduce in frequency during that period. The objectives of IS were to reinforce and support personalisation and application of the knowledge and skills learned in the group course, with particular emphasis on supporting the transition towards sustained independent management of insulin regimens.	The IS component was designed to: 1. Reinforce the knowledge and skills around FIIT, and self-management introduced in the group course. 2. Support personalisation and application of the knowledge and skills learned during the group course. 3. Foster automisation of routine diabetes management. 4. Increase participant activation to support engagement with FIIT, monitoring and appropriate help-seeking between appointments. 5. Support transition towards sustained independent management of FIIT.

Table 3: Summary of theories, models and frameworks used in DAFNEplus (Theories)

Theory / Construct	General principles of intervention derived from construct	Example of theory-based intervention in DAFNEplus	Component of DAFNEplus
THEORIES AND MODELS FROM HEALTH AND CLINICAL PSYCHOLOGY			
<i>Self Determination Theory (Ryan and Deci, 2000)</i>^[20]			
Autonomy (need to be in control of one's own decisions and actions);	Create opportunities to elicit and understand the persons wishes, preferences and perspectives and providing them with information related to the desired change that is consistent with these, as well as promoting choice and avoiding attempts to control or pressure them	Facilitators support participants to identify their own goals during action planning process before offering direct suggestions	Group course, Individual support
Competence (need to be able to control outcome of behaviour and experience mastery)	Provide opportunities to engage in the behaviour that are sufficiently challenging to promote learning and growth, encouraging a sense of initiation and experimentation, and providing structure to enable people to succeed or learn from attempts at changing behaviour	Participants offered opportunity to practice key skills such as carbohydrate counting in session, under supervision	Group course
Relatedness (need to be connected to and experience caring for others)	Create conditions where others are involved and show interest in a person's attempts to change behaviour and respond with empathy and care	Participants work together in pairs to reflect on previous weeks goals and progress in individual review sessions,	Group course
<i>Health Belief Model (Marshall and Becker, 1984)</i>^[21]			
Perceived Severity (how severe the health consequences is)	Provide information to increase accuracy of perceptions of the health consequences of behaviour	Provision of information about long-term consequences of type 1 diabetes	Group course
Perceived susceptibility (the degree to which they believe they may experience the health consequence)	Provide information about potential health consequences that are personalised to the individual	Provision of estimate of A1C to help make connection between behaviour and metrics indicating likelihood of developing complications	Glucollector
Perceived benefits (the degree to which they will experience health benefits from performing the behaviour)	Provide information and/or experiential learning experiences to help people understand the benefits of performing self-management behaviours	Provision of information of reductions in long-term complications if FIIT principles are consistently enacted over long term	Group course

Theory / Construct	General principles of intervention derived from construct	Example of theory-based intervention in DAFNEplus	Component of DAFNEplus
Perceived barriers (the perceived barriers to performing the behaviour)	Provide information and/or experiential learning experiences to help people understand and overcome potential barriers to enacting self-management behaviours	Provision of technology that removes cognitive and practical burdens associated with blood glucose self-monitoring	Glucollector
Cues (the presence of triggers for the behaviour)	Provide information and/or support to help people put in place cues to help them remember to perform self-management behaviours	Provision of flashcards to remind people of blood glucose targets and emergency strategies	Group course
Self-efficacy (the degree to which they believe they can enact the behaviour)	Provide information and/or experiential learning experiences to increase people's belief and confidence in being able to enact self-management behaviours	Repeated opportunity to implement self-management strategies, receive feedback and refine behaviour	Group course
Cognitive Behavioural Theory (White, 2001)^[22]			
Four areas model (human experience comprises physical, cognitive, emotional and behavioural components which exert reciprocal influences on each other)	Educate participants about the four areas of human experience and how they reciprocally influence each other to set up positive or negative behavioural cycles that influence self-management	Provide participants with information on the 4 areas model and how it can be used to identify and deal with cognitive and emotional barriers to engaging with self-management behaviours	Group course
Thinking errors (how typical cognitive heuristics might influence decision making about self-management)	Educate and train participants in how to identify how perfectionism, all-or-nothing and catastrophic thinking patterns might influence the way they perform self-management behaviours, using the four areas model as an overarching framework	Case studies illustrating how thinking patterns affect emotions and behaviour using the four areas model	Group course
Relapse prevention (three stage approach to identifying and managing lapses)	Educate participants about the principles of relapse prevention (lapse, relapse, collapse) and how they might apply to the process of changing self-management behaviour	Case studies illustrating how to apply response prevention methods to lapses in self-management	Group course
Habit development (a process by which a stimulus generates an impulse to act as a result of a learned stimulus-response association; (Gardner, 2015) ^[23]	Educate participants about the principles of habit development and how this may be used to support implementation of FIIT principles	Use of 'Habit' as one of the six core principles in the Behaviour Change Toolkit	Group course, Individual Support

Theory / Construct	General principles of intervention derived from construct	Example of theory-based intervention in DAFNEplus	Component of DAFNEplus
CONDITIONS FOR CHANGE			
<i>Person-centred communication (an approach to healthcare communication which invites and encourages patients to actively participate in decision-making about their needs).</i>	Facilitators were trained in how to use person-centred skills in both the group and individual support sessions, including active listening, non-verbal communication, asking before advising, use of open-ended questions, reflection, affirmation, empathy and normalisation. This included the use of people-first approach to communicating about when talking about diabetes was also part of person-centred communication.	Use of person-first language in all written materials	Glucollector, Group course, Individual support
<i>Solution-focussed communication / Motivational Interviewing (involves responding to individuals in ways that model non-judgemental curiosity about their experience, and focusses attention on what an individual did well in a challenging situation, avoiding responses that lead participants to focus on the negatives or what they might have done wrong, and encourages individuals to reflect on their experience to inform creation of new goals for behaviour.</i>	Solution-focussed communication was used throughout the intervention, but particularly in the individual support sessions. The IS curriculum was structured to set the agenda collaboratively (see above) and to deliberately ask about what had gone well first before asking about challenges. The curriculum also used specific 'checking back' questions to make an explicit link between <i>reward and effort</i> e.g., 'If you keep going with this change, what do you think you might notice in the future? and to highlight previous successes/useful strategies e.g. What thoughts could you recognise from XXX when they faced setbacks? Towards the end of the programme, intervals between the IS sessions were spaced further apart to encourage practice in <i>independent decision-making</i> .	Use of Meet and Move technique to respond to participants presenting barriers to change	Group course, Individual Support

Theory / Construct	General principles of intervention derived from construct	Example of theory-based intervention in DAFNEplus	Component of DAFNEplus
Group Therapeutic Factors (12 factors that influence the degree to which individuals working in groups together will have a positive experience (Yalom, 2021))			
Altruism	Communicating expectation that participants should be willing to support others in the group	Use of group rules to create expectation of mutual support	Group course
Cohesion	Communication that participants are meeting for a common purpose to improve diabetes management	Use of group rules to create expectation of mutual support	Group course
Universality	Identification and exploration of common issues in participants experience of diabetes	Facilitators draw attention to common themes in participants experience across the group	Group course
Interpersonal learning	Communication, setting expectations and encouragement that participants can learn from each other by sharing experiences and responding to each other	Course philosophy emphasises the importance of peer-to-peer and peer-to-facilitator learning	Group course
Imparting information	Provision of information about diabetes and its management	Provision of information in group course	
Catharsis	Communication of the acknowledgement and acceptance of expressions of strong emotions in response to the experience of diabetes and its self-management	Course philosophy makes reference to acceptability of experiencing and sharing strong emotions	Group course
Self-understanding	Creating activities to support understanding of participants emotional response to diabetes and the tasks of self-management	Opportunities for engaging in exercises that promote personal reflection	Group course
Instillation of hope	Communication of belief that it is possible to live healthily with diabetes in the long-term	Session on the prevalence and preventability of long-term negative health consequences of diabetes	Group course
Existential factors	Communication of the reality and acceptance of the seriousness and impact of diabetes	Explicit acknowledgement of the seriousness and potentially life-threatening nature of diabetes	Group course

Table 4: Expected Outputs of DAFNEplus (Outputs)

Output Identifier	Output (Changes in Elements of Capability, Opportunity or Motivation to Enact Behaviours Associated with FIIT)
C1_KnowT1D	Increased knowledge of type 1 diabetes
C2_KnowFIIT	Increased knowledge of Flexible Intensive Insulin Therapy (FIIT)
C3_SkillFIIT	Increased skills in applying FIIT
C4_SkillCBSM	Increased knowledge and skills in applying principles of cognitive and behavioural self-management skills for type 1 diabetes
C5_SkillCong	Increased ability to achieve congruence between FIIT principles and life demands
C6_AttHyper	Reduction in over-reliance on corrective insulin dosing to manage hyperglycaemia
C7_AttHypo	Reduction in over-treatment of hypoglycaemia using carbohydrate
O1_TimeHCP	Increased access to timely and appropriate health professional support over a year
O2_PracEmSupp	Increased access to practical and emotional non-professional social support for self-management
O3_HCPAuton	Exposure to health professional interactions that support autonomy in self-management and avoid stigma
O4_T1DModel	Exposure to other models of people with type 1 diabetes learning how to implement FIIT and self-management strategies
O5_TechAccess	Access to technology that supports capability and motivation to enact FIIT and other diabetes self-management strategies
M1_ConfAdjust	Increases in confidence to independently adjust insulin and ratios to accommodate changes in the condition, life events and transitions
M2_ValueFIIT	Increased perception of the value of enacting FIIT principles
M3_Burden	Reduction in perception of burdens associated with enacting FIIT principles and other diabetes self-management behaviours
M4_EmpwrFIIT	Increases in feelings of success and empowerment in relation to enacting FIIT principles
M5_RedNegEmo	Reduction in emotional states associated with enacting FIIT principles
M6_Hope	Reduced feelings of hopelessness and increased optimism about positive long-term health consequences of type 1 diabetes
M7_SelfCompass	Increases in self-compassion in situations where self-management feels difficult or does not result in expected outcomes
M8_Think	Decrease in thinking patterns associated with procrastination or avoidance in relation to self-management behaviours (e.g. perfectionism, all-or-nothing, catastrophising)

Att=Attitudes, Know=Knowledge, Intent=Intention, Norm=Normative Behaviours, Skill=Behavioural Skills

Illustration of the DAFNEplus approach and how it can guide Delivery Principles for Facilitators

To support facilitators to deliver the DAFNEplus intervention as intended and promote fidelity, a revised training approach was designed. This included nine guiding principles developed from the *Resources* (p1) identified in the Programme Theory. The following illustrates how each principle helps facilitators address specific *Problems* related to FIIT (Table 1) to produce the desired *Outputs* (Table 4) that support behaviours associated with optimal management. It also describes the main *theory, model, or framework* from which each principle is derived (Table 3). The facilitator principles are not a formal part of the Programme Theory but, instead, provide an illustrative example of how different elements can interact for a specific purpose e.g., developing guiding principles for intervention delivery.

1. Shift the focus to behaviours and independent behaviour change

The problem of over reliance on Healthcare Professionals (9 NonAutonHCP; 12 LowConFIIT – Table 1) can diminish participants' confidence in independent decision-making. Self-determination Theory (Table 3) emphasises the importance of supporting 'autonomy' to enable behaviour change. A new action planning workbook* gives participants behavioural prompts to enable them to set their own goals, with individualised action plans to review regularly. A key motivational output is to increase confidence to independently adjust basal insulin and insulin-to-carbohydrate ratios (ICRs) over the longer-term (M1 ConfAdjust – Table 4).

* See the **Group Course Logic Model and IS Logic Model** for more detail
(<https://www.sheffield.ac.uk/ctru/current-trials/dafneplus>) Downloads section

2. Build on successes and minimise the number of changes

The problem of over reliance on correction doses (7 ShortInsHyper – Table 1) can contribute to the perceived burden of maintaining optimal blood glucose levels (17 HighBurden – Table 1). The Health Belief Model (Table 3) suggests perceived self-efficacy (the belief that your actions will influence your diabetes outcomes) will influence behaviour change. A new online data visualisation system – Glucollector* (with coaching from Facilitators) was designed to highlight patterns in behaviour and the impact of making fewer, but more clinically meaningful changes. A key motivational output is to increase the perceived value of FIIT and sustain its implementation over the long-term (M2 ValueFIIT – Table 4).

* See the **Glucollector Logic Model** for more detail
(<https://www.sheffield.ac.uk/ctru/current-trials/dafneplus>) Downloads section

3. Help participants develop realistic expectations of themselves and their ability to make change

The problem of needing to adapt FIIT to accommodate changing life circumstances (5 AdaptFIIT – Table 1) and the low 'effort to reward' ratio associated with this (14 EffortReward - Table 1) can make diabetes feel unmanageable. The Health Belief Model (Table 3) suggests people are influenced by the barriers they perceive to optimising diabetes management. A revised 'Monitoring Long-Term Health' group session presents evidence to challenge catastrophic thinking around complications, highlight the impact of 'good enough' diabetes management on mitigating risk of complications and the role of early screening in prevention, delay and reversal.

A key motivational output is to reduce feelings of hopelessness and increase feelings of optimism about long-term health (M6 Hope – Table 4).

4. Focus on the positives.

Repeated exposure to negative emotional states relating to self-management (18 NegEmoState – Table 1) can contribute to feelings of defeat (15 Hopelessness – Table 1). The Solution Focussed Communication Model (Table 3) suggests that optimism can be nurtured by highlighting strengths, successes and choices. This model informs the new 'Individual Review' session which asks about what went well first, focusses upon actions rather than outcomes, and encourages an attitude of 'feedback rather than failure' when reviewing data. A key motivational output is to reduce the intensity and frequency of negative emotions in relation to practising FIIT (M5 RedNegEmo – Table 4).

5. Create a supportive environment that avoids criticism and judgement.

A lack of supportive relationships (11 LackSupport – Table 1) can mean unhelpful behaviours such as over treating hypos (6 OverTxHypo – Table 1) or forgetting targets (3 ForgetTarget – Table 1) can re-occur over time. Self-determination Theory (Table 3) highlights the importance of 'relatedness' (i.e., feeling connected to and cared for by others) in supporting behaviour change. Group Therapeutic Factors (Table 3) can start to model this 'relatedness' within a group setting. A new group session called 'Social Support – who's there for you?' highlights better ways to access appropriate support and care from family, friends/colleagues and healthcare professionals. A key motivational output is to reduce the perception of burden (via isolation) in self-management of diabetes (M3 Burden – Table 4).

6. Harness a variety of different learning styles

The problem of reduced health literacy (1 HealthLit – Table 1) can lead of a lack of access to reliable information (10 LackInfoFIIT – Table 1). The Health Belief Model (Table 3) highlights the role of 'cues' in triggering appropriate health behaviours. The group course curriculum introduces various metaphors (e.g. putting your own oxygen mask on first in an airplane), visual analogies (e.g. the 'messy cupboard'), simplified numbers and ranges (e.g. for treating hypos) and cue cards. A key motivational output is to increase the sense of empowerment and success (M4 EmpwrFIIT – Table 4) by enabling relevant clinical information to be accessed more easily.

7. Enhance motivation by addressing its influences

The problem of harsh self-judgement (16 LackSelfCompass – Table 1) can drive procrastination and avoidance when managing diabetes (13 ProcAvoid – Table 1). Cognitive Behavioural Theory (CBT – Table 3) highlights how negative automatic thoughts can influence behaviours, feelings and physical sensations. The DAFNE*plus* philosophy expands the concept of self-management to include identifying unhelpful thinking patterns and attending to emotional wellbeing, as well as practical FIIT strategies. A key motivational output is to increase self-compassion and promote a resilient mindset around lapses and struggles (M7 SelfCompass – Table 4).

8. Allow time to process new information

The problem of having insufficient knowledge of and skills to use FIIT (2 SkillFIIT – Table 1) can reduce confidence in independent decision making (12 LowConFIIT). Self-determination Theory

(Table 3) suggests ‘competence’ is a key factor in health behaviour change. The DAFNE*plus* group timetable enables layered learning by splitting topics across weeks, and across the behavioural cycles of diabetes management*. A key motivational output is to increase a sense of empowerment and success (M4 EmpwrFIIT – Table 4) by providing space for information to be assimilated, practiced, and reviewed over a longer time-frame.

* Reactive; Routine; Reflective Cycles – see: Hamilton et al^[12]

9. Personalise the programme

The problem of not having access to DAFNE trained HCPs (8 AccHCPFIIT – Table 1) and struggling to adapt to changes in life circumstances (5 AdaptFIIT – Table 1) may contribute to blood glucose targets drifting upwards over time (4 AdjTarget – Table 1). The Person-Centred Communication Model (Table 3) emphasises the importance of considering the whole person living with diabetes and not just the condition itself. This model informs the Individual Support* component of DAFNE*plus*: x5 structured, one-to-one, appointments provided after the group course to reinforce and adapt FIIT principles over the following year. A key motivational output is to increase confidence in adapting FIIT to accommodate changing life circumstances (M1 ConfADjust – Table 4)

* See the **Individual Support Logic Model** for more detail

(<https://www.sheffield.ac.uk/ctru/current-trials/dafneplus>) Downloads section

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