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DAFNEplus cluster randomised controlled trial

Submission date
08/05/2018

Recruitment status
No longer recruiting

Registration date
17/05/2018

Overall study status
Completed

Last Edited
30/09/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 31/12/2019:

Background and study aims
DAFNE stands for Dose Adjustment For Normal Eating. It is a 5-day training course for adults with type 1 diabetes (T1D), delivered in small groups. DAFNE has been delivered to over 30,000 adults in the UK. Recent research confirmed that after attending a DAFNE course, people have better quality of life, better glucose levels (in the short term), and are admitted to hospital less often for diabetes emergencies. Although participants find DAFNE training useful, some find it tough to keep up the skills needed to maintain glucose levels to prevent diabetic complications. After the course, people also find it hard to get support from health professionals. They have asked to improve the course to help others develop and keep their skills over the long term. The aim of this study is to develop and convert DAFNE into a lifelong package to help people better manage their blood glucose levels in the longer term,as high levels can cause dangerous complications. This is done by revising the course, putting together structured follow-up with health professionals after the course, and using technology to help people maintain the skills they need to manage their type 1 diabetes effectively.

Who can participate?
Patients aged 18 and over with T1D referred to DAFNE courses at participating centres

What does the study involve?
Participating centres are randomly allocated to provide either the current DAFNE course or the newly developed DAFNEplus, with seven centres providing each course. Participants who are in sites allocated to DAFNEplus attend the DAFNEplus course one day per week over five consecutive weeks, which includes the use of technology to transmit and display blood glucose data to support pattern recognition and interpretation (and provision of a bolus calculator to support insulin dose calculations) and up to five structured follow-up appointments in the 12 months after the course. Participants at the other sites receive treatment as usual and attend the current DAFNE course one day per week over five consecutive weeks. A bolus calculator is provided to support calculation of insulin dose. There is no structured follow-up appointments beyond those provided in usual care.

What are the possible benefits and risks of participating?
All those who complete a DAFNE course should feel more confident about managing their

diabetes and be able to adjust their insulin dose correctly to suit their choice of food. This should mean greater freedom, improved quality of life and improved blood glucose control. It is also hoped that the information collected from people in this study will help to show whether there is any advantage to doing the new DAFNEplus programme when compared with standard DAFNE. This is a low risk study - no risks to participation have been identified.

Where is the study run from?
1. Harrogate and District NHS Foundation Trust (UK)
2. Cambridge University Hospital NHS Foundation Trust (UK)
3. University College London Hospitals NHS Foundation Trust (UK)
4. Worcestershire Acute Hospital NHS Foundation Trust (UK)
5. NHS Dumfries and Galloway (UK)
6. Derby Teaching Hospitals NHS Foundation Trust (UK)
7. Greater Glasgow and Clyde Health Board (UK)
8. Guy's and St Thomas' NHS Foundation Trust (UK)
9. South Tees Hospitals NHS Foundation Trust (UK)
10. Hertfordshire Community NHS Trust (UK)
11. Nottingham University Hospitals NHS Trust (UK)
12. Hull University Teaching Hospitals NHS Trust (UK)
13. Birmingham Community NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2016 to January 2024 (updated from July 2022)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Elaine Scott (Trial manager)
dafneplus@sheffield.ac.uk

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Previous plain English summary:

Background and study aims
DAFNE stands for Dose Adjustment For Normal Eating. It is a 5-day training course for adults with type 1 diabetes (T1D), delivered in small groups. DAFNE has been delivered to over 30,000 adults in the UK. Recent research confirmed that after attending a DAFNE course, people have better quality of life, better glucose levels (in the short term), and are admitted to hospital less often for diabetes emergencies. Although participants find DAFNE training useful, some find it tough to keep up the skills needed to maintain glucose levels to prevent diabetic complications. After the course, people also find it hard to get support from health professionals. They have asked to improve the course to help others develop and keep their skills over the long term. The aim of this study is to develop and convert DAFNE into a lifelong package to help people better manage their blood glucose levels in the longer term,as high levels can cause dangerous complications. This is done by revising the course, putting together structured follow-up with health professionals after the course, and using technology to help people maintain the skills they need to manage their type 1 diabetes effectively.

Who can participate?
Patients aged 18 and over with T1D referred to DAFNE courses at participating centres

What does the study involve?
Participating centres are randomly allocated to provide either the current DAFNE course or the newly developed DAFNEplus, with seven centres providing each course. Participants who are in sites allocated to DAFNEplus attend the DAFNEplus course one day per week over five consecutive weeks, which includes the use of technology to transmit and display blood glucose data to support pattern recognition and interpretation (and provision of a bolus calculator to support insulin dose calculations) and up to five structured follow-up appointments in the 12 months after the course. Participants at the other sites receive treatment as usual and attend the current DAFNE course one day per week over five consecutive weeks. A bolus calculator is provided to support calculation of insulin dose. There is no structured follow-up appointments beyond those provided in usual care.

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6. Derby Teaching Hospitals NHS Foundation Trust (UK)
7. Greater Glasgow and Clyde Health Board (UK)
8. South Tees Hospitals NHS Foundation Trust (UK)
9. Northumbria Healthcare NHS Foundation Trust (UK)
10. Essex Partnership University NHS Foundation Trust (UK)
11. Hertfordshire Community NHS Trust (UK)
12. Nottingham University Hospitals NHS Trust (UK)
13. Hull and East Yorkshire Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2016 to July 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Patrick Phillips
p.phillips@sheffield.ac.uk

Contact information

Type(s)
Public

Contact name

Mrs Elaine Scott

Contact details
Clinical Trials Research Unit
School of Health & Related Research
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United Kingdom
S1 4DA
+44 (0)114 2225158
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Additional identifiers

Integrated Research Application System (IRAS)
235621

Protocol serial number
38046

Study information

Scientific Title
A cluster randomised controlled trial of the DAFNEplus (Dose Adjustment for Normal Eating) intervention: a lifelong approach to promote effective self-management in adults with type 1 diabetes

Acronym
DAFNEplus

Study objectives
DAFNE stands for Dose Adjustment For Normal Eating. It is a 5-day training course for adults with type 1 diabetes, delivered in small groups. DAFNE has been delivered to over 40,000 adults in the UK. Our recent research confirmed that after attending a DAFNE course, people have better quality of life, better glucose levels (in the short term) and are admitted to hospital less often for diabetes emergencies. Although participants find DAFNE training useful, some find it tough to keep up the skills needed to maintain glucose levels to prevent diabetic complications. After the course, people also find it hard to get support from health professionals. They have asked us to improve the course to help others develop and keep their skills over the long term.

The aim of DAFNEplus is to develop and convert DAFNE into a lifelong package to help people better manage their blood glucose levels in the longer term, as high levels can cause dangerous complications. We are doing this by revising the course, putting together structured follow-up with health professionals after the course, and using technology to help people maintain the skills they need to manage their type 1 diabetes effectively.

Following a successful pilot study which piloted and refined the prototype DAFNEplus programme in three NHS diabetes centres, we will now conduct a pragmatic cluster randomised controlled trial (RCT) to compare DAFNEplus with standard DAFNE.

A cluster RCT design is required since DAFNE educators, trained in the new programme would be 'contaminated' if they delivered current DAFNE, so we are randomising centres rather than individuals. The trial will take place in 14 centres across the UK, and will recruit a total of 662 participants (331 will receive DAFNEplus and 331 will receive standard DAFNE).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter Research Ethics Committee, 14/05/2018, ref: 18/SW/0100

Primary study design
Interventional

Study design
Randomized; Both; Design type: Treatment, Prevention, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
Participating centres will be randomised on a 1:1 basis to control (standard DAFNE courses) or the intervention arm (DAFNEplus course) of the trial. As there are numerous stratification variables that have been identified as clinically important and the small number of randomising centres, a covariate constrained methodology will be employed. The centres will be matched on the number of patients within the centre, number of educators within the centre and number of previous DAFNE courses delivered (as a marker of centre experience) to balance centres between the two arms of the trial.

Intervention
Following informed consent, participants who are in sites allocated to the intervention arm will attend the DAFNEplus course one day per week, over five consecutive weeks. The intervention includes the use of technology to transmit and display blood glucose data to support pattern recognition and interpretation. A bolus calculator to support insulin dose calculations will also be provided. Five structured follow-up appointments are also scheduled in the 12 months following the course.

Control
Participants who are recruited at the control sites will receive treatment as usual and will attend the DAFNE course one day per week, over five consecutive weeks. A bolus calculator will be provided to participants in the control arm to support calculation of insulin dose. There will be no structured follow-up appointments beyond those provided in usual care.

Intervention Type
Other

Primary outcome(s)
The primary biomedical outcome is glycaemic control, defined as the change in HbA1c (using a centralised assay to ensure standardisation), in those entering the trial with HbA1c >7.5% (estimated at 75% of those currently undertaking DAFNE courses based on our research database); Timepoint(s): End of the study

The primary psychological outcome is diabetes-specific quality of life, measured using the DAWN Impact of Diabetes Profile at baseline and 12 months

Key secondary outcome(s)
Current secondary outcome measures as of 31/12/2019:
Secondary biomedical outcome:
Number of participants achieving either an HbA1c <7.5% (58 mmol/mol) or a decrease in HbA1c of ≥0.5% (≥5.5 mmol/mol) (using a centralised assay to ensure standardisation). These endpoints will be calculated using data collected at baseline and 12 months after the course.

Other secondary biomedical outcomes will include:
1. Severe hypoglycaemia, as defined by the American Diabetes Association, denotes severe cognitive impairment requiring external assistance for recovery, both rates and proportion of those affected, measured at baseline at 12 months after the course
2. Diabetic ketoacidosis, both rates and proportion of those affected, collected at baseline and 12 months after the course
3. Weight, measured at baseline and 12 months after the course
4. Body Mass Index, measured at baseline and 12 months after the course
5. Blood pressure, measured at baseline and 12 months after the course
6. Lipids, measured at baseline and 12 months after the course
7. Albumin/ creatinine, measured at baseline and 12 months after the course

Psychological outcomes, measured at baseline, course completion, 3, 6 and 12 months:
1. Dawn Impact of Diabetes Profile (DIDP)
2. Problem Areas in Diabetes Scale (PAID-11)
3. Diabetes-specific positive well-being (W-BQ-28)
4. Hypoglycaemia Fear Survey (HFS-11)

Process measures:
5. Diabetes Management Experiences Questionnaire (DMEQ)
6. Self-Regulation/Behavioural Regulation Questionnaire (SRQ-T1D)
7. Diabetes Strengths & Resilience Questionnaire (DSRQ)
8. Confidence in Diabetes Scale (CIDS) assesses beliefs about capabilities (self-efficacy).
9. Diabetes Self-Care Behaviours – SCB-T1D
10. Hypoglycaemia Confidence Scale (HCS)
11. Beliefs about consequences of engaging in DAFNE behaviours and weaving diabetes management into everyday routines.
12. The System Usability Score
13. Use and dose received of the DANFEplus programme assessed via logs of attendance at group and individual sessions, and use of the DANFEplus website

Hypoglycaemia Awareness
14. Hypoglycaemia awareness assessed via Gold score

Health economic measures assessed at baseline, course completion, 6 and 12 months using:
1. Health status – EQ-5D-5L
2. Health and Self-Management in Diabetes HASMID
3. Healthcare utilisation using a bespoke questionnaire
4. Contact between professionals and course participants will also be recorded at each site using questionnaires and data from the DANFEplus website (in the intervention arm)

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Previous secondary outcome measures:
Secondary biomedical outcome:
Number of participants achieving either an HbA1c <7.5% (58 mmol/mol) or a decrease in HbA1c of ≥0.5% (≥5.5 mmol/mol) (using a centralised assay to ensure standardisation). These endpoints will be calculated using data collected at baseline and 12 months after the course.

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3. Weight, measured at baseline and 12 months after the course
4. Body Mass Index, measured at baseline and 12 months after the course
5. Blood pressure, measured at baseline and 12 months after the course
6. Lipids, measured at baseline and 12 months after the course

Psychological outcomes, measured at baseline, course completion, 3, 6 and 12 months:
1. Diabetes self-care behaviours, measured using SCB-T1D
2. Belief about capabilities (self-efficacy): bespoke study questionnaire with 9 items mirroring the wording in the self-care behaviour scale
3. Personal Models of Diabetes Scale
4. Hyperglycaemia Avoidance Scale
5. Diabetes-specific positive well-being
6. Hypoglycaemia Fear Survey
7. Hypoglycaemia awareness assessed via Gold score
8. The System Usability Score
9. Use and dose received of the DAFNEplus programme assessed via logs of attendance at group and individual sessions, and use of the DAFNEplus website

Health economic measures assessed at baseline, course completion, 6 and 12 months using:
1. EQ5D - L
2. A bespoke healthcare use questionnaire
3. HASMID

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. Adults (≥18 years)
2. Diagnosis of type 1 diabetes for at least 6 months, or post-honeymoon
3. Prepared to undertake multiple daily injection (MDI) therapy and frequent self-monitoring of blood glucose
4. Confirms availability to attend all sessions as part of the intervention
5. Investigator has confidence that the patient is capable of adhering to all the trial protocol requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
471

Key exclusion criteria
Current exclusion criteria as of 31/12/2019:
1. Current use of continuous subcutaneous insulin infusion (CSII) pump therapy
2. HbA1c > 12%/108 mmol/mol (Investigators can use their judgement, informed by standard DAFNE guidelines and in agreement with the trial team, to include participants with HbA1c >12% /108 mmol/mol)
3. Serious diabetic complications (e.g. blindness, renal dialysis). (Investigators can use their clinical judgement, informed by standard DAFNE guidelines and in agreement with the trial team).
4. Other serious co-morbidities e.g. psychosis, diagnosed eating disorder (Investigators can use their clinical judgement, informed by standard DAFNE guidelines and in agreement with the trial team).
5. Previous participation in standard DAFNE course less than 5 years before proposed study enrolment date
6. Unable to hear/speak/understand/read/write in English
7. Unable to give written informed consent

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Previous exclusion criteria:
1. Current use of continuous subcutaneous insulin infusion (CSII) pump therapy
2. HbA1c > 12%

3. Serious diabetes-related complications (e.g. blindness, renal dialysis), or other serious co-morbidities (e.g. psychosis, diagnosed eating disorder)
4. Previous participation in standard DAFNE course less than 5 years before proposed study enrolment date
5. Unable to hear/speak/understand/read/write in English
6. Unable to give written informed consent

Date of first enrolment
01/09/2018

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Harrogate and District NHS Foundation Trust
Harrogate District Hospital
Lancaster Park Road
Harrogate
England
HG2 7SX

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
Worcestershire Acute Hospitals NHS Foundation Trust
-
-
England
B97 4BD

Study participating centre
NHS Dumfries and Galloway
Grierson House
The Crichton
Bankend Road
Dumfries
Scotland
DG1 4ZG

Study participating centre
Derby Teaching Hospitals NHS Foundation Trust
-
-
England
DE22 3NE

Study participating centre
Greater Glasgow and Clyde Health Board
-
-
Scotland
G42 9LF

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre

Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

Study participating centre
Birmingham Community NHS Foundation Trust
-
-
England
B21 0SY

Study participating centre
Hertfordshire Community NHS Trust
-
-
England
SG1 4AB

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Sponsor information

Organisation
Sheffield Teaching Hospital NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0514-20013

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2026	30/09/2026	Yes	No
Protocol article		18/01/2021	02/02/2021	Yes	No
Basic results			17/09/2026	No	No
HRA research summary			28/06/2023	No	No
Other publications	Secondary analysis	08/01/2026	30/09/2026	Yes	No
Plain English results		11/08/2026	17/09/2026	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes