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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
06/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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.

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.

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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

Study website
https://www.sheffield.ac.uk/scharr/sections/dts/ctru/dafneplus

Contact information

Type(s)

Public

Contact name
Mrs Elaine Scott

Contact details
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Sheffield
United Kingdom
S1 4DA
+44 (0)114 2225158
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
235621

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/03/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 662; UK Sample Size: 662

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
England

Scotland

United Kingdom

Study participating centre
Harrogate and District NHS Foundation Trust
United Kingdom
HG2 7SX

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
United Kingdom
CB2 0QQ

Study participating centre
University College London Hospitals NHS Foundation Trust
United Kingdom
NW1 2PG

Study participating centre
Worcestershire Acute Hospitals NHS Foundation Trust
United Kingdom
B97 4BD

Study participating centre
NHS Dumfries and Galloway
United Kingdom
DG1 4TG

Study participating centre
Derby Teaching Hospitals NHS Foundation Trust
United Kingdom
DE22 3NE

Study participating centre
Greater Glasgow and Clyde Health Board
United Kingdom
G42 9LF

Study participating centre
South Tees Hospitals NHS Foundation Trust
United Kingdom
TS4 3BW

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
United Kingdom
SE1 9RT

Study participating centre
Birmingham Community NHS Foundation Trust
United Kingdom
B21 0SY

Study participating centre
Hertfordshire Community NHS Trust
United Kingdom
SG1 4AB

Study participating centre
Nottingham University Hospitals NHS Trust
United Kingdom
NG7 2UH

Study participating centre
Hull University Teaching Hospitals NHS Trust
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Sheffield Teaching Hospital NHS Foundation Trust

Sponsor details
Herries Road
Sheffield
England
United Kingdom
S5 7AU

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Current publication and dissemination plan as of 12/05/2020:
The trial protocol will be published on an open access source. Submission is planned for June 2020. A number of academic outputs will be produced as the data are analysed throughout the trial. Journals will be selected based on the highest possible impact. Other stakeholder specific outputs in relevant formats will also be produced for commissioners, third sector, and user advocacy organisations. A website has been established to promote the work of the trial.

The outputs from the work will be provided to the 70+ DAFNE centres across the UK, in a form which will enable them to be readily communicated to clinical commissioning groups (in England) and the respective funders in the devolved nations. This will facilitate decisions on establishing and sustaining funding of this enhanced support for adults with T1D in the UK. Through Diabetes UK and the DAFNE collaborative the trialists will communicate their findings to the All Parliamentary Group on Diabetes, the National Clinical Director of Diabetes and NICE.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

Previous publication and dissemination plan:
The trial protocol will be published on an open access source. A number of academic outputs will be produced as the data are analysed throughout the trial. Journals will be selected based on the highest possible impact. Other stakeholder specific outputs in relevant formats will also be produced for commissioners, third sector, and user advocacy organisations. A website has been established to promote the work of the trial.

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IPD sharing statement
The data sharing plans for the current study are unknown and will be made available at a later date.

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?
Protocol article	protocol	18/01/2021	02/02/2021	Yes	No
HRA research summary			28/06/2023	No	No