DAFNEplus Frequently Asked Questions for Sites

If you can't find the answer to your question here please email the DAFNEplus team: dafneplus@sheffield.ac.uk

Q. Do admin staff who are assisting with data entry need to have GCP training?
A. No - GCP training is not required for staff who are not working in a patient facing role in this trial.

Q. Can sites run mixed courses i.e. including research participants as well as patients who have not consented to the research?
A. We are currently working on the basis that research and non research participants must attend separate courses. However, we recognise that this could have an impact on workload at certain sites and we are keeping this under review. Control sites who are not audio recording can run mixed courses if required.

Q. What is the minimum and maximum number of patients needed to run a course?
A. Minimum of 4 and maximum of 8 people.

Q. What happens if a participant is recruited, and then is unable to attend all 5 sessions, e.g. through illness, or for some other reason?
A. To be counted as having completed a DAFNE course for the purposes of statistical analyses, participants must have attended 4 days (including the first 2 days) as well as 3 of the 5 follow up sessions. This could include attending half days. Participants who don't complete these sessions will still be followed up as research participants if they agree to this. Participants who don't meet these criteria can be offered another DAFNE course if they want to attend

Q. Should research participants who drop out of the DAFNE course (control or intervention) be followed up and be asked to provide further information as part of the study?
A. A participant who has attended and received part of the intervention (DAFNE or DAFNEplus) should be followed up and research data should be collected. The extent to which they agree to follow up is of course up to them and we have a form (participant preferences) within the Ongoing Data Collection booklet that captures to what extent they agree to follow up: face-to face, questionnaires, interviews. Participants who have received part of the intervention would not be eligible to restart a DAFNE or DAFNEplus course as part of the DAFNEplus trial, but they would be able to start a non-research DAFNE course at their convenience and when a course is available. We would collect data about their attendance at any subsequent DAFNE course within the trial follow up period.

For participants who consent but for whatever reason do not attend any of the intervention, it is acceptable to delay their start on the course until they are able to. Please discuss this with the DAFNEplus study team

Q. Can the course be shared between more than 2 educators/facilitators?
It is definitely better for consistency to have just 2 facilitators, however if 3 are to deliver, at least 1 should be there for all 5 weeks and there needs to be good communication / feedback about the participants during and in between course days.

Q. Can the course be delivered on different days of the week in different weeks e.g. Monday to Friday but across 5 weeks?
It would clearly be much better for participants to be attending the course on the same day each week; there would be the potential for confusion and drop-out if the day changes each week. If this is unavoidable (e.g. bank holidays), then there should be a minimum of 5 days and a maximum of 9 days in between course dates (similar to the 5x1 RCT).

Q. What training/ experience do prospective educators/ facilitators need to have to be eligible to deliver the DAFNEplus (intervention arm) course as part of the study?
The requirements are that facilitators will need to have previously completed the standard DAFNE training and ideally also have completed the conversion course so that they can deliver DAFNE over 5 weeks.

There are no requirements to have delivered any specific number of courses before they can attend the training to deliver DAFNEplus, but it would be preferable if they had some experience of delivery.

Q. Relatives sometimes attend the course and ours is being audio-recorded. Do we have to consent relatives?
A. No - you do not have to formally consent relatives who may attend a course with a participant. Only verbal consent is required from relatives when they have been informed that the session is being recorded.

Q. Who should we contact if we or our patients are having a problem with any part of the Intervention WITHCARE technology?
A.Contact the Helpdesk:
Phone: 0114 222 8765
Email: med-it@sheffield.ac.uk
Please quote reference « DAFNE »

Participants receive these contact details in the WITHCARE box and can contact the helpdesk directly themselves.

Q. Do participants have to use the Aviva Expert Meter?
A. All participants in both arms should be offered the option to use the Aviva Expert Meter. One of the main findings from previous DAFNE research is that graduates struggle to keep diaries. For the RCT we decided to use the Expert meter to enable collection of BG, carb and insulin data as easily as possible. There is good evidence from the REPOSE trial that bolus advisors help maintain glycaemic control, as they automatically calculate active insulin on board. The Libre can give bolus advice but this is only available from capillary checking, not scans, and the advisor is not as flexible as the Expert in terms of individualising times, exercise settings, hypo reminders etc.

People using Libre meters still need to perform capillary checking according to DVLA guidelines and need to check the accuracy of the scanned readings in the hypo or hyper range, as well as when it is changing rapidly. Therefore the trial protocol is that participants should be encouraged to use the Expert meter for bolus advice, checking pre-meal and before bed

to enable safe insulin dosing, collation of carb and insulin data as well, to aid reflection and pattern recognition. If the Libre is being used alongside too, this will help with trends, encouraging bolusing pre-meal, and can be particularly useful to help assess background insulin during carb free periods.

If the participant declines to use the Expert meter then they should be encouraged to use the bolus advisor on the Libre, and failing that, manually enter carbs and insulin via the notes section when they scan prior to consuming carb, or performing a correction.

In addition to this, participants should be encouraged to use Glucollector in preference to Libreview *(this only applies to participants in the intervention arm)*. Therefore the protocol is participants are encouraged to upload data from all meters in use via the Withcare+ box at least weekly, to capture a full record of the data available, in order to enable Glucollector to support pattern management.

If you are experiencing problems with the prescription of test strips and lancets for use with the Expert Meter please report these to Elaine Scott, Study Manager.

Q. Do patients using the Freestyle Libre have to test and use the bolus calculator function on the Aviva Expert meter during the trial?

A. Participants can use Freestyle Libre in both arms of the trial. In the intervention arm of the trial information can be downloaded onto the Glucollector site so that it is available to view with the rest of their data. In the intervention arm of the trial participants should use the Aviva expert meter, irrespective of Libre use, to do their pre-meal BGs and before bed BG, to get the bolus advice and enable them to record their carbs, QA and BI doses. We are also advising use of the Aviva expert meter in control sites, for the same reasons.

Q. I have heard that the Aviva Expert meter is due to be phased out, should we still be using them?

A. The Expert meter is being withdrawn over the next 12-18 months. However, this is for new users only, so please continue to use it for trial participants. Roche have confirmed that they will ring-fence enough meters to support the DAFNEplus trial. Please discuss this with your local Roche rep and let them know that the meters are required for the DAFNEplus trial. You will be able to request 'strips' from your usual prescriber. These are widely used and not due to be phased out.

Q. Do we have to give participants a DAFNE number as well as a study ID number?

A. Yes, please do this at the completion of the course participants attend. Please include this number on the 'Post Course Data' form for the trial, and enter it on Prospect Database. When the trial is completed the data from Prospect will be automatically migrated to the DAFNE central database

Q. Do sites have to enter participant data onto both the Prospect database as well as the DAFNE database?

A. No - sites only need to enter data onto Prospect; it has been agreed with the National Director of the DAFNE Programme that the team in Sheffield will send data to the DAFNE database team at study completion

Q. How close to the 6-month and 12-month date do research follow-up appointments need to be?

A. The follow-up research appointments should be held as close as possible to the date 6 or 12-months from the **end of the course.** This should be within 4 weeks before or after the appropriate date.

Q. Do you have guidance on scheduling follow up appointments in the DAFNEplus (intervention) arm of the trial?

A. The follow up dates can be flexible because in reality they need to be. These are not like the research appointments where they need to be within a certain window.

The essential points are - the aim is to offer 5 follow up appointments over one year with increasingly longer time periods in between. The recommended format based on the pilots are post course at 2 weeks, 6 weeks, 12 weeks, 6 months and one year. However, the timing can be flexible to suit the service and the participants. Cancellations and re-arrangements will be inevitable, making flexibility with timing also important. Therefore, for example someone may be seen at 3 weeks , 7 weeks and 11 weeks, then 6 months and 12 months. Record these dates on the Structured DAFNEplus follow-ups form.

The minimum number of follow up appointments for participants to be classed as having 'completed' the intervention is three. This may occur due to cancellations, non-attendance or because the DF and participant have agreed that not all follow up appointments are required. Follow up can be via skype or telephone as well as face to face.

Q. If a participant becomes pregnant during the follow-up period, would this be classed as a "clinician decision to withdraw"?

A. No - Pregnant participants don't need to be withdrawn, unless, like any other participants, they become too unwell to continue. Pregnancies need to be reported using the Pregnancy Information sheet which is held within the 'Ongoing Data Collection' booklet. A pregnancy in itself is not considered a Serious Adverse Event (SAE), but any untoward outcome of the pregnancy is and an SAE form should be completed.

Q. What is the end recruitment date?

A. Each site has a 15-month recruitment period from the date of the first participant consented.

Q. What are the time frames for recruitment and delivery of trial?

As you are aware there have been substantial delays to the trial and the timeline is currently under review. A funded extension application has been made to the NIHR. We will provide updates about this as soon as possible.

Q. Can people with secondary diabetes (diabetes related to another medical condition) be included in the trial?

No - participants in the trial should have a diagnosis of type 1 diabetes

Q. What are the training requirements for site staff involved in the delivery of the DAFNEplus trial?

This depends upon a number of factors, for instance whether the site that you are based at is delivering the control or intervention, please see the tables below for details.

Control (DAFNE as usual care)

	Delegated activities entered on delegation log	GCP training	Research Training (2 hour teleconference)
Administrative staff, with no patient contact	✓	Not needed	Not needed
Principal Investigator	✓	✓	✓
Research Nurse (collecting data/ informed consent but not delivering DAFNE course)	✓	✓	✓
Facilitators/ educators (control arm)	✓	✓	✓

Intervention (DAFNEplus)

	Delegated activities entered on delegation log	GCP training	Research Training (2 hour teleconference)	Self directed learning (4 hours)	Self directed learning (16 hours)	Face to face training (3 days)
Administrative staff, with no patient contact	✓	Not needed	Not needed	Not needed	Not needed	Not needed
Medical staff delivering DAFNEplus QA sessions	✓	Not needed unless collecting data/ gaining informed consent	Not needed unless collecting research data/ gaining informed consent	✓	Not needed	Not needed
Principal Investigator	✓	✓	✓	Not needed unless PI is a medic delivering QA sessions	Not needed unless PI is a facilitator delivering DAFNEplus sessions	Not needed unless PI is a facilitator delivering DAFNEplus sessions

Research Nurse (collecting data/ informed consent but not delivering DAFNEplus)	✓	✓	✓	Not needed	Not needed	Not needed
Facilitators/ educators (intervention arm)	✓	✓	✓	Not needed	✓	✓