



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

The DAFNEplus randomised controlled trial (RCT) is the final phase of the NIHR funded DAFNEplus programme which sets out to evaluate whether 1) modifying the existing DAFNE curriculum and incorporating techniques for initiating and sustaining behaviour change, 2) develop structured follow-up support and 3) develop, test and assess how digital information communication technology can be included to benefit both patients and healthcare professionals. Professor Simon Heller is the Chief Investigator for the programme, which is sponsored by Sheffield Teaching Hospitals and managed by the Clinical Trial Research Unit at the University of Sheffield.

The overall aim of the research is to investigate whether the DAFNEplus programme will produce improved and sustainable diabetes self-management behaviour and better glucose control than currently achieved, without compromising quality of life in the longer term, when compared to the existing DAFNE programme.

Our pragmatic, cluster RCT opened in autumn 2018 with the primary objective of comparing the new DAFNEplus intervention to the existing DAFNE 5x1 programme. DAFNEplus is a complex intervention so as well as the primary objective of assessing the effects of the intervention on glycaemic control, as measured by HbA1c at 12 months, we are also:

- Assessing the effects of the intervention on the diabetes-specific quality of life.
- Assessing the effects of the intervention on diabetes distress and other biomedical outcomes.
- Undertaking a process evaluation to aid understanding of the RCT findings, and to inform decision making about the implementation of DAFNEplus in clinical care post-trial.
- Assessing the fidelity of delivery of the DAFNEplus intervention.
- Undertaking a health economic analysis to determine the cost-effectiveness of DAFNEplus versus standard DAFNE.

The national lockdown due to Covid-19 in March 2020 stopped all recruitment to the trial by our clinical sites. At this stage recruitment to the trial was over 50% complete. We have continued to collect data for participants in the trial who had completed their courses. Throughout the pandemic participants have continued to be engaged – completing research and support appointments remotely, undertaking self-sampling for HbA1c testing where they were unable to access clinical services and completing the Patient Reported Outcome Measure questionnaires. We applied to and received further funding from the NIHR to extend the period to complete the trial. We have now re-opened to recruitment with the intention of completing the trial and publishing our findings. Our timescales have been extended, with

recruitment to be completed at the end of August 2022, final data collection due in November 2023. The final report for the programme is due to be completed in November 2024.

We would like to thank all the wonderful clinical sites and participants who have been involved with the study to date, in some very difficult times for all involved. We know how challenging sustaining this research has been for sites across the country while they have been so pressured clinically.

Further information about the trial can be accessed via our website:

<https://www.sheffield.ac.uk/scharr/research/centres/ctru/dafneplus>

Elaine Scott

DAFNEplus Trial Manager

Clinical Trials Research Unit

SCHARR

University of Sheffield

Elaine.Scott@sheffield.ac.uk