**Supplementary material 1** **– WHO Trial Registration Dataset**

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| **Data Category** | **Information** |
| Primary registry and trial identifying number | <http://www.isrctn.com/ISR> ISRCTN42908016  |
| Date of registration in primary registry | 08/05/2018 |
| Secondary identifying numbers | Sheffield CTRU: J13-003Sponsor ID: STH20111IRAS: 235621Funding ref: RP-PG-0514-20013REC: 18/SW/0100 |
| Source(s) of monetary or material support | National Institute for Health Research (NIHR) (UK) |
| Primary sponsor | Sheffield Teaching Hospitals NHS Foundation Trust |
| Secondary sponsor(s) | N/A |
| Contact for public queries | Trial manager (Elaine Scott) 0114 222 5158 or dafneplus@sheffield.ac.uk |
| Contact for scientific queries | Trial manager (Elaine Scott) 0114 222 5158 ordafneplus@sheffield.ac.uk |
| Public title | DAFNE*plus* Cluster RCT |
| Scientific title | A cluster randomised controlled trial (RCT) of the DAFNE*plus* (Dose Adjustment for Normal Eating) intervention: A lifelong approach to promote effective self-management in adults with type 1 diabetes |
| Countries of recruitment | England and Scotland |
| Health condition(s) or problem(s) studied | Type 1 diabetes |
| Intervention(s) | DAFNE*plus* (Dose Adjustment for Normal Eating) intervention |
| Key inclusion and exclusion criteria | *Inclusion criteria:* * Adults (≥18 years);
* Diagnosis of type 1 diabetes for at least 6 months, or post-honeymoon;
* Prepared to undertake multiple daily injection (MDI) therapy;
* Prepared to undertake frequent self-monitoring of blood glucose;
* Confirms availability to attend all sessions as part of the intervention;
* Investigator has confidence that the patient is capable of adhering to all the trial protocol requirements.

*Exclusion criteria:* * Current use of continuous subcutaneous insulin infusion (CSII) pump therapy
* 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).
* 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).
* 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).
* Previous participation in standard DAFNE course less than 5 years before proposed study enrolment date
* Unable to speak/hear/understand/read write in English
* Unable to give written informed consent
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| Study type | Multi-centre cluster randomised controlled trial with process evaluation and economic evaluation, comparing DAFNE*plus* to standard DAFNE for adults with type 1 diabetes. |
| Date of first enrolment | 01/09/2018 |
| Target sample size | 662 participants – 47 per centre.Fourteen secondary care diabetes centres in the National Health Service in England and ScotlandIn addition, we aim to recruit 20 DAFNE*plus* facilitators to take part in qualitative interviews for the process evaluation. |
| Recruitment status | Recruiting |
| Primary outcome(s) | The primary biomedical outcome is glycaemic control, defined as the change in HbA1c at 12 months (using acentralised 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). |
| Key secondary outcomes | Secondary biomedical outcome:Number of participants achieving either an HbA1c <7.5% (58 mmol/mol) or a decrease in HbA1cof ≥0.5% (≥5.5 mmol/mol) (using a centralised assay to ensure standardisation). These endpointswill 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 severecognitive impairment requiring external assistance for recovery, both rates and proportion ofthose affected, measured at baseline at 12 months after the course2. Diabetic ketoacidosis, both rates and proportion of those affected, collected at baseline and12 months after the course3. Weight, measured at baseline and 12 months after the course4. Body Mass Index, measured at baseline and 12 months after the course5. Blood pressure, measured at baseline and 12 months after the course6. Lipids, measured at baseline and 12 months after the course7. Albumin/ creatinine, measured at baseline and 12 months after the courseThe primary psychological outcome is the measurement at 12 months of the Audit-Dependent Diabetes Quality of Life Questionnaire (ADDQoL-15), a thirty-item measure of diabetes-specific quality of life.Psychological outcomes, measured at baseline, course completion, 3, 6 and 12 months:1. Dawn Impact of Diabetes Profile 2. Problem Areas in Diabetes Scale 3. Diabetes-specific positive well-being 4. Hypoglycaemia Fear Survey Process measures: 5. Diabetes Management Experiences Questionnaire 6. Self-Regulation/Behavioural Regulation Questionnaire 7. Diabetes Strengths & Resilience Questionnaire 8. Confidence in Diabetes Scale assesses beliefs about capabilities (self-efficacy). 9. Diabetes Self-Care Behaviours 10. Hypoglycaemia Confidence Scale 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 DANFE*plus* programme assessed via logs of attendance at group and individual sessions, and use of the DANFE*plus* websiteHypoglycaemia Awareness14. Hypoglycaemia awareness assessed via Gold scoreHealth economic measures assessed at baseline, course completion, 6 and 12 months using:1. Health status – EQ-5D-5L2. Health and Self-Management in Diabetes HASMID3. Healthcare utilisation using a bespoke questionnaire4. Contact between professionals and course participants will also be recorded at each site using questionnaires and data from the DANFE*plus* website (in the intervention arm) |