# Basic Results Reporting

**Figure 1. Participant Flow:**

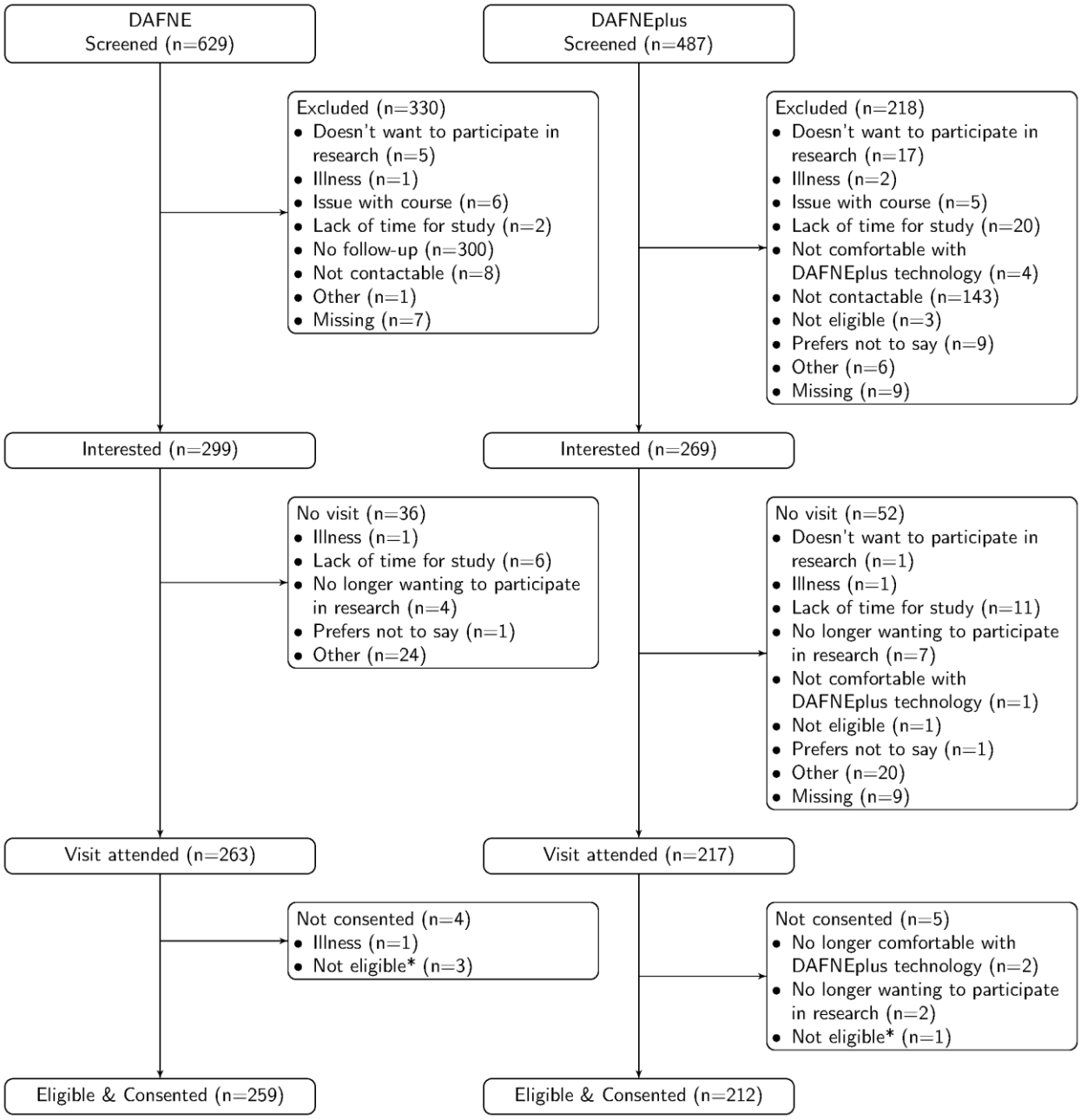


**Table 1: Baseline Characteristics:**

| | | **DAFNE** | ***DAFNEplus*** |
|---|---|---|---|
| | | N = 176 | N = 133 |
| Age at consent | n | 176 | 132 |
| | Mean (SD) | 43.4 (15.1) | 42.5 (14.0) |
| | Median (IQR) | 43.0 (31.0, 54.0) | 41.5 (30.0, 54.0) |
| | Min, Max | 18, 83 | 18, 74 |
| Index of Multiple Deprivation Decile | n | 175 | 76 |
| | Mean (SD) | 6.5 (2.8) | 5.0 (3.4) |
| | Median (IQR) | 7 (4.0, 9.0) | 5.0 (1.0, 8.0) |
| | Min, Max | 1, 10 | 1, 10 |
| Sex | n | 176 | 132 |
| | Male | 84 (47.7%) | 77 (58.3%) |
| | Female | 92 (52.3%) | 55 (41.7%) |
| Ethnicity | n | 176 | 132 |
| | White | 153 (86.9%) | 124 (93.9%) |
| | Non-white | 21 (11.9%) | 7 (5.3%) |
| | Prefer not to say | 2 (1.1%) | 1 (0.8%) |
| Highest qualification gained | n | 175 | 132 |
| | No formal qualifications | 7 (4.0%) | 9 (6.8%) |
| | GCSE (or equivalent) | 44 (25.1%) | 44 (33.3%) |
| | A level (or equivalent) | 46 (26.3%) | 35 (26.5%) |
| | Undergraduate degree (or equivalent) | 54 (30.9%) | 30 (22.7%) |
| | Postgraduate degree (or equivalent) | 24 (13.7%) | 14 (10.6%) |
| HbA1c (%) at baseline | N | 176 | 133 |
| | Mean (SD) | 9.1 (1.4) | 9.1 (1.3) |
| | Median (IQR) | 8.8 (8.1, 9.7) | 8.6 (8.0, 9.7) |
| | Min, Max | 7.5, 15.5 | 7.5, 12.9 |
| HbA1c (mmol/mol) at baseline | n | 176 | 133 |
| | Mean (SD) | 75.9 (15.0) | 75.6 (14.1) |
| | Median (IQR) | 72.5 (64.8, 82.0) | 71.0 (64.0, 82.0) |
| | Min, Max | 59, 146 | 59, 118 |
| HbA1c source at baseline | n | 176 | 133 |
| | Central lab | 163 (93%) | 130 (98%) |
| | Local lab | 13 (7%) | 3 (2%) |
| | Self-test | 0 (0%) | 0 (0%) |

**Outcome Measures:**

**Table 2: Biomedical Outcome Measures**

| | DAFNE | DAFNE*plus* | Adjusted Effect Size (95% CI)[1] | P-value |
|---|---|---|---|---|
| HbA1c (%) at baseline[2] | 176; 9.1 (1.4) | 133; 9.1 (1.3) | - | - |
| HbA1c (%) at 6 months[2] | 117; 8.4 (1.3) | 69; 8.2 (1.0) | -0.112 (-0.373, 0.150) | 0.400 |
| HbA1c (%) at 12 months[2] | 122; 8.2 (1.2) | 91; 8.1 (1.1) | -0.014 (-0.284, 0.255) | 0.915 |
| Improved glycaemic control at 6 months[3] | 73/117 (62.4%) | 39/69 (56.5%) | 0.85 (0.45, 1.59) | |
| Improved glycaemic control at 12 months[3] | 74/122 (60.7%) | 57/91 (62.6%) | 1.23 (0.68, 2.23) | |
| At least one episode of severe hypoglycaemia up to 12 months[3] | 8/125 (6.4%) | 3/93 (3.2%) | 0.46 (0.11, 1.93) | |
| At least one episode of severe hypoglycaemia resulting in hospitalisation up to 12 months[3] | 2/125 (1.6%) | 0/93 (0%) | - | |
| At least one episode of DKA up to 12 months[3] | 5/126 (4%) | 4/95 (4.2%) | 1.16 (0.27, 4.90) | |
| At least one episode of DKA resulting in hospitalisation up to 12 months[3] | 2/126 (1.6%) | 2/95 (2.1%) | 1.92 (0.22, 16.93) | |
| BMI (kg/m2) at 12 months[2] | 82; 27.6 (5.8) | 73; 28.1 (5.3) | 0.34 (-0.27, 0.95) | |
| BMI (kg/m2) at 6 months[2] | 104; 26.8 (4.9) | 58; 27.6 (5.7) | 0.36 (-0.25, 0.98) | |
| Diastolic blood pressure at 12 months[2] | 34; 78.4 (11.0) | 55; 79.0 (10.4) | - | |
| Systolic blood pressure at 12 months[2] | 34; 134.2 (23.2) | 55; 132.1 (18.0) | - | |
| Cholesterol (mmol/L) at 12 months[2] | 85; 4.4 (0.8) | 69; 4.6 (1.0) | - | |
| HDL cholesterol (mmol/L) at 12 months[2] | 75; 1.6 (0.4) | 65; 1.6 (0.6) | - | |
| LDL cholesterol (mmol/L) at 12 months[2] | 68; 2.3 (0.7) | 31; 2.6 (0.8) | - | |
| Weight (kg) at 12 months[2] | 82; 81.5 (19.6) | 73; 82.0 (16.6) | 0.40 (-1.35, 2.16) | |
| Weight (kg) at 6 months[2] | 104; 79.7 (17.8) | 58; 80.8 (15.1) | 0.99 (-0.77, 2.75) | |

**Table 3: Psychological outcome measures**

| | DAFNE[1] | DAFNE*plus*[1] | Adjusted Effect Size (95% CI)[2] | P-value |
|---|---|---|---|---|
| **Diabetes-specific Quality of life** (ADDQoL-15 AWI score at 12 months): | 148; -2.3 (1.8) | 97; -1.9 (1.7) | 0.2 (-0.1, 0.5) | 0.21 |
| **Diabetes-specific Quality of life** (Dawn Impact of Diabetes Profile score at 12 months): | 149; 4.5 (0.8) | 97; 4.4 (0.9) | -0.1 (-0.3, 0.1) | 0.32 |
| **Diabetes-specific Distress** (Problem areas in diabetes score at 12 months): | 149; 14.4 (10.2) | 96; 10.9 (8.6) | -3.3 (-5.2, -1.4) | **0.001** |
| **Diabetes-specific Positive Well-being** (4-item subscale Well-Being Questionnaire score at 12 months) | 149; 7.5 (2.4) | 96; 8.5 (2.7) | 0.9 (0.3, 1.4) | **0.004** |
| **Hypoglycaemia avoidance** (Hypoglycaemia Fear Survey- Behaviour subscale at 12 months): | 148; 4.5 (3.5) | 96; 3.4 (3.2) | -1.1 (-1.9, -0.4) | **0.002** |
| **Hypoglycaemia worries (**Hypoglycaemia Fear Survey- Worry subscale at 12 months): | 148; 6.4 (4.4) | 96; 5.5 (3.6) | -0.9 (-1.7, -0.001) | 0.05 |

[1]n; Mean (SD). [2]Adjusted mean difference. Full intention-to-treat analyses.

**Table 4: DAFNE and DAFNE*plus* course costs**

| | **DAFNE** | **DAFNE*plus*** |
|---|---|---|
| **Education Course Costs** | | |
| Courses with data (n/N) | 10/14 | 2/7 |
| Facilitator time + Admin overhead (Mean, 95% CI) | £5948, 95% CI (5342, 6553) | |
| Other Course costs (Mean, 95% CI) | £231, 95% CI (143, 318) | |
| Mean number of participants per course | 6.2 | |
| Mean cost per participant | £999 | |
| **Structured Follow Up Costs** | | |
| Number of people (n/N) | NA | 155/178 |
| Number of contacts (Mean, 95% CI) | NA | 3.5 (3.2,3.8) |
| Costs<br>(Mean, 95% CI) | NA | £508.44<br>(£468.22,<br>£548.66) |
| **Technology Costs** | | |
| *Website Costs* | | |
| Website cost per person | NA | £1 |
| Website costs annual | NA | £30,000 |
| Number of people receiving DAFNE per annum | NA | 3,611 |
| Website cost per person per year | NA | £9.31 |
| *Withcare+ Box Costs* | | |
| Annual data collection technology for people who do not use CGM | NA | £18.98 |
| Proportion of population using CGM | NA | 90% |
| Cost of data collection per person using DAFNE*plus* | NA | £1.90 |
| **Total Costs per participant** | | |
| Total Cost | £999 | £1,519 |
| DAFNE, dose adjustment for normal eating; CI, confidence interval; CGM, continuous glucose monitoring | | |

**Table 5: Health economic key outcome measures**

| Scenario | Description | Incremental Cost (£, DAFNE*plus* v DAFNE) | Incremental QALY / Incremental Benefit (DAFNE*plus* v DAFNE) | ICER (£ per QALY gained) | Net Benefit* |
|---|---|---|---|---|---|
| **Base case** | Base Case | +£611.32 | +0.008 | £78,147 | -£455 |
| **1** | Complete Case Analysis | +£707.19 | +0.025 | £28,750 | -£215 |
| **2** | HASMID-10 derived utilities | +£611.11 | +0.013 | £46,652 | -£349 |
| **3** | EQ5D & Van Hout utilities | +£611.31 | +0.010 | £61,450 | -£412 |
| **4** | EQ5D & Devlin utilities | +£610.78 | +0.005 | £131,564 | -£518 |
| **5** | HASMID-10 is valued in monetary terms, using general population values | +£611.11 | +£16.81† | NA | -£594 |
| **6** | HASMID-10 is valued in monetary terms, using people with diabetes values | +£611.16 | +£31.78† | NA | -£579 |
| **7** | Separate education costs by arm | +£748.76 | +0.008 | £95,716 | -£592 |
| **8** | 7 & include outlier education course time data | +£911.35 | +0.008 | £116,500 | -£755 |
| **9** | Costed the DAFNE*plus* structured follow ups using unit costs | +£363.02 | +0.008 | £46,403 | -£207 |
| **10** | Per Protocol Population | +£945.65 | +0.010 | £98,577 | -£754 |
| **11** | Baseline HbA1c ≥ 7.5% | +£583.61 | +0.010 | £55,741 | -£374 |

DAFNE, dose adjustment for normal eating; QALY, quality adjusted life year; ICER, incremental cost-effectiveness ratio; NA, not applicable
*, QALYs are valued at £20,000 per QALY; †, these values are in monetary terms, not QALYs

**Table 6: Serious Adverse Events:**

| | | DAFNE | | DAFNE*plus* | |
|---|---|---|---|---|---|
| | | N = 245 | | N = 178 | |
| | | Events | Individuals | Events | Individuals |
| All SAEs | | 26 | 18 (7.3%) | 12 | 8 (4.5%) |
| Category | DKA | 3 | 3 (1.2%) | 6 | 3 (1.7%) |
| | Severe hypo | 4 | 4 (1.6%) | 1 | 1 (0.6%) |
| | Other | 19 | 12 (4.9%) | 5 | 4 (2.2%) |
| Seriousness | Death | 2 | 2 (0.8%) | 1 | 1 (0.6%) |
| | Life threatening | 1 | 1 (0.4%) | 1 | 1 (0.6%) |
| | Inpatient hospitalisation | 22 | 14 (5.7%) | 9 | 7 (3.9%) |
| | Considered medically significant by the investigator | 1 | 1 (0.4%) | 1 | 1 (0.6%) |
| Frequency | Isolated | 17 | 14 (5.7%) | 8 | 7 (3.9%) |
| | Intermittent | 6 | 2 (0.8%) | 1 | 1 (0.6%) |
| | Continuous | 0 | 0 (0.0%) | 1 | 1 (0.6%) |
| | Unknown | 2 | 2 (0.8%) | 2 | 2 (1.1%) |
| Intensity | Mild | 2 | 2 (0.8%) | 4 | 4 (2.2%) |
| | Moderate | 13 | 8 (3.3%) | 3 | 2 (1.1%) |
| | Severe | 9 | 7 (2.9%) | 5 | 4 (2.2%) |
| Action taken | None | 18 | 10 (4.1%) | 7 | 6 (3.4%) |
| | other | 7 | 7 (2.9%) | 5 | 4 (2.2%) |
| Outcome | Death | 2 | 2 (0.8%) | 1 | 1 (0.6%) |
| | Recovered | 16 | 14 (5.7%) | 6 | 4 (2.2%) |
| | Improved | 3 | 2 (0.8%) | 2 | 2 (1.1%) |
| | Unchanged | 2 | 1 (0.4%) | 2 | 2 (1.1%) |
| | Persisted | 3 | 1 (0.4%) | 1 | 1 (0.6%) |
| Expected? | Yes | 3 | 3 (1.2%) | 0 | 0 (0.0%) |
| | No | 23 | 15 (6.1%) | 12 | 8 (4.5%) |
| Relationship to DAFNE*plus* course | No reasonable possibility of being related | 25 | 17 (6.9%) | 12 | 8 (4.5%) |
| | Not assessable | 1 | 1 (0.4%) | 0 | 0 (0.0%) |
| Stayed in CCU | | 1 | 1 (0.4%) | 0 | 0 (0.0%) |
| Stayed in ITU | | 2 | 1 (0.4%) | 0 | 0 (0.0%) |