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Synopsis

The effectiveness and cost-effectiveness of the NHS Diabetes Prevention Programme (NHS-DPP): the DIPLOMA long-term multimethod assessment

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Dedication
The DIPLOMA team would like to dedicate this report to Elizabeth Murray, a valued friend and colleague who passed away during the completion of this project.

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Abstract

Background: Type 2 diabetes is considered a critical challenge to modern healthcare systems. The National Health Service Diabetes Prevention Programme delivered an evidence-based behaviour change programme at a national scale to reduce the incidence of type 2 diabetes in England.

Objective(s): The Diabetes Prevention – Long-term Multimethod Assessment research programme provided a comprehensive assessment of the delivery of the National Health Service Diabetes Prevention Programme and its effectiveness and cost-effectiveness.

Design: Mixed-methods research including qualitative methods, observations, patient surveys and secondary analysis of administrative and survey data using statistical and econometric methods.

Setting: Community settings in England delivering the commissioned intervention, supported by general practices responsible for recruitment and referral.

Participants: Patients in community settings identified as being at high risk of type 2 diabetes offered and participating in the National Health Service Diabetes Prevention Programme, and staff involved in the organisation and delivery of the service.

Interventions: The National Health Service Diabetes Prevention Programme, including its evidence-based behaviour change intervention (using both face-to-face and digital platforms) and the associated services for patient recruitment.

Main outcome measures: Incidence of type 2 diabetes, cost-effectiveness, access to the programme and fidelity of intervention delivery.

Data sources: Interviews with patients and staff, document analysis and observations of the National Health Service Diabetes Prevention Programme delivery, patient surveys, secondary data (including National Health Service Diabetes Prevention Programme data, national surveys and audits).

Results: The National Health Service Diabetes Prevention Programme was associated with significant reductions in incidence of type 2 diabetes and was highly likely to be cost-effective.

Analyses of the delivery of the programme highlighted several aspects which impacted access to the programme and the fidelity with which the behaviour change intervention was delivered. For example, uptake and adherence were influenced by participants' psychosocial beliefs (e.g. chance of getting type 2 diabetes and whether taking part would reduce this). There were large differences between general practices in how many people they referred to the programme, with practices that offered higher-quality care for people with diabetes referring more. Variation in retention and outcomes was associated with differences in providers.

Limitations: Analysis of administrative data to explore effectiveness and cost-effectiveness may be influenced by confounding. Recruitment of diverse and representative samples for surveys, interviews and observations was likely impacted by selection.

Conclusions: The National Health Service Diabetes Prevention Programme is highly likely to be cost-effective. Data from Diabetes Prevention – Long-term Multimethod Assessment have been used to improve aspects of programme delivery and could suggest further enhancements to improve recruitment, retention and fidelity.

Future work: Future research should address the question of whether the National Health Service Diabetes Prevention Programme prevents or delays type 2 diabetes when longer-term follow-up data are available. We identified factors that could be targeted to impact on recruitment, retention and inequalities, and recommend a robust assessment of the link between fidelity and outcomes.

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Introduction

Healthier You: NHS Diabetes Prevention Programme (NHS-DPP) was the first initiative in England to implement a diabetes prevention programme (DPP) at national scale. It offered lifestyle education to individuals identified at risk of type 2 diabetes (T2D). The Diabetes Prevention – Long-term Multimethod Assessment (DIPLOMA) research programme (April 2017 to March 2023) was a comprehensive mixed-methods evaluation of this programme.

The DIPLOMA programme provided a rigorous independent evaluation while providing regular feedback to NHS-DPP stakeholders. All findings from individual DIPLOMA work packages (WPs) have been published separately in peer-reviewed journals (see list in *Additional information*), and this synopsis aims to provide an overview of the programme and a narrative synthesis of the findings. This synopsis is organised as follows:

- *The National Health Service Diabetes Prevention Programme* section provides a brief overview on the evidence underpinning the NHS-DPP, a brief

overview of the NHS-DPP, and a summary of changes throughout its implementation.
- *The Diabetes Prevention – Long-term Multimethod Assessment research programme* section provides an overview of DIPLOMA and its components, methods and governance.
- *Discussion* provides a narrative of the overall DIPLOMA findings and their impact, and reflections for future research.

The National Health Service Diabetes Prevention Programme

The Global Burden of Disease Study showed that global prevalence of diabetes increased by 130% between 1990 and 2017, from 211 million to 476 million. The study identified high body mass index (BMI) and behavioural factors (e.g. diet, smoking and physical activity) as the largest contributors to the deaths and disability-adjusted life-years due to diabetes.[1] In the UK, NHS England (NHSE) estimates the number of people with diagnosed diabetes will rise to 4.2 million people by 2030, approximately 9% of the population.[2] T2D is considered one of the major health challenges of the twenty-first century.[3]

To try to address this challenge, one approach to T2D prevention is to screen individuals to identify those with pre-diabetes, or at high risk of progressing to the disease,[4] and treat them by offering an intervention.[5] The definition of pre-diabetes can vary depending on the type of screening test, thresholds defined and variations over time.[4,6]

The NHS-DPP was first announced in 2014 in the *Five Year Forward View* as part of a wider prevention programme. It is led by a partnership between NHSE, Public Health England (PHE) and Diabetes UK, with long-term aims to support people at high risk of T2D to reduce their risk of T2D and its complications and reduce associated health inequalities. A short-term aim was to better identify people at risk of T2D, which could increase incidence as undiagnosed cases are uncovered.[7]

The NHS-DPP intervention is a 9- to 12-month behaviour change programme to support individuals adopting lifestyle changes to lose weight, increase physical activity and eat healthily. The first service specification, Framework 1,[8] was informed by National Institute for Health and Care Excellence (NICE) guidance PH38 for risk identification and interventions to prevent T2D in individuals at high risk,[9] and by a systematic review of lifestyle interventions for prevention of T2D.[10] More detailed descriptions of the NHS-DPP intervention in Framework 1 and subsequent changes to the programme are provided in *National Health Service Diabetes Prevention Programme implementation*.

Preliminary evidence base

Although a systematic review was not in scope for DIPLOMA, we briefly explore the evidence base for the design and commissioning of the NHS-DPP and examine evidence published since then on effectiveness, cost-effectiveness and effects on inequalities (*Table 1*).

Effectiveness

Three landmark trials exploring the effect of lifestyle interventions on diabetes risk were the Da Qing Diabetes Prevention Outcomes Study in China,[11] the Finnish Diabetes Prevention Study (DPS)[13,14] and the United States Diabetes Prevention Program (US DPP).[12]

The Da Qing study recruited 577 adults with impaired glucose tolerance (IGT), and randomised clinics to one of three intensive interventions (diet, exercise or diet plus exercise) or control. Interventions were delivered by professionals weekly for 1 month, monthly for 3 months, and then once every 3 months. Patients in the control clinics received general information about T2D. Risk of developing T2D at 6 years reduced by 31%, 46% and 42% ($p < 0.005$) for the diet, exercise and diet plus exercise interventions, respectively.[11]

The Finnish DPS randomised participants to an intensive lifestyle intervention or to usual care. The intervention consisted of seven 30- to 60-minute individualised counselling sessions during the first year and every 3 months afterwards for 3 years. Usual care involved general advice and annual examinations in primary care.[14] Results at 3 years indicated that the risk of diabetes reduced by 58% compared to usual care.[13]

The US DPP explored whether lifestyle intervention or pharmacological therapy (metformin) would prevent or delay T2D onset in individuals at high risk compared to placebo pill. The lifestyle intervention was intensive (16 one-to-one sessions) and delivered by either nutritionists, exercise physiologists or behavioural psychologists. Lifestyle intervention was more effective than metformin versus placebo (58% reduction in T2D compared to 31%).[12]

Subsequent studies have explored long-term effects. The Da Qing study reported that, after 30 years of follow-up, median delay in T2D onset was nearly 4 years compared to the control group.[21] For the Finnish DPP, 13 years after the initial study baseline, participants in the lifestyle intervention arm had nearly 39% lower risk of T2D than control.[22] In the US DPP, 22-year follow-up showed T2D incidence reduced by 25% and 18% in the lifestyle and metformin groups, respectively, compared with placebo.[23]

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In England, NICE published guidance PH38 in 2012 for risk identification and interventions to prevent T2D in individuals at high risk.[9] In 2014, the *Five Year Forward View* reported that the NHS 'was spending more on bariatric surgery for obesity than on a national roll-out of an intensive lifestyle intervention shown to cut obesity and prevent diabetes over a decade ago'.[3]

PHE commissioned a further review to assess the effectiveness of lifestyle interventions to prevent T2D in primary care and community settings.[10] The review included 36 experimental and observational studies which translated evidence from previous DPP trials into routine healthcare or community settings. Pooled results from 16 studies [11 randomised controlled trials (RCTs)] suggested the groups receiving a lifestyle intervention reduced their incidence of T2D by 26% (95% CI 7% to 42%) versus usual care.

Several other systematic reviews and meta-analyses have been published subsequently. In 2017 an updated Cochrane Review looked at the effectiveness of lifestyle interventions providing diet and/or physical activity interventions to people at increased risk of diabetes, but only where the intervention was at least 2 years long and intermediate hyperglycaemia was measured at baseline rather than using other factors (obesity, metabolic risk factors and family history). Pooled data from 11 RCTs estimated a reduction of 43% [risk ratio (RR) 0.57, 95% CI 0.50 to 0.64] in T2D incidence.[20] Another review in populations with pre-diabetes or diabetes risk factors (average follow-up 19.5 months) estimated a relative risk reduction of 29% in T2D risk (RR 0.71, 95% CI 0.58 to 0.88), based on data from seven controlled studies.[19] The latest systematic review included 50 RCTs up to June 2022 where participants were selected if they had impaired glucose/pre-diabetes or cardiometabolic risk factors and found a pooled incidence reduction from lifestyle interventions of 25% (RR 0.75, 95% CI 0.61 to 0.91).[18]

The studies included in these systematic reviews differ in their definition of pre-diabetes or 'at risk' of diabetes, with varying use of impaired fasting glucose (IFG), IGT or abnormal glycated haemoglobin (HbA_{1c}) criteria. In addition (*Figure 1*), thresholds to define the condition are different for the American Diabetes Association (ADA), World Health Organization, and the International Expert Committee,[4] with lower thresholds for IFG and HbA_{1c} at-risk diagnosis agreed by the ADA – which in turn have created a larger at-risk population.[16] Three of the four systematic reviews summarised here included participants without IGT based on glucose measures and had similar pooled results for diabetes risk reduction.[10,19,18] The systematic review restricting eligibility to studies where intermediate hyperglycaemia was defined at baseline had a higher risk reduction[20]. In the case of the NHS-DPP, the definition of 'at risk' follows the definition of non-diabetic hyperglycaemia (NDH) as blood glucose levels that are above normal but not in the diabetic range [HbA_{1c} 42–47 mmol/mol (6.0–6.4%) or fasting plasma glucose (FPG) 5.5–6.9 mmol/l].[24]

A separate question is the sensitivity and specificity of the different tests to diagnose risk. A meta-analysis of 49 studies looking at the diagnostic accuracy of screening tests estimated that HbA_{1c} had a mean sensitivity of 0.49 (95% CI 0.40 to 0.58) and specificity of 0.79 (95% CI 0.73 to 0.84) for identification of pre-diabetes, whereas FPG had a mean sensitivity of 0.25 (95% CI 0.19 to 0.32) and specificity of 0.94 (95% CI 0.92 to 0.96).[4] In addition, studies suggest progression to T2D is faster when both IFG and IGT have been diagnosed than when at-risk status has been defined based on HbA_{1c} or IFG alone. Most intervention trials have used a type of oral glucose tolerance test to identify the study population,[4,20] so evidence is needed as to whether results of previous trials can be translated to the at-risk population defined by an IFG or HbA_{1c} test alone.[16]

A recent RCT in Norfolk set out to test a 2-year group-based lifestyle intervention in people with pre-diabetes as per current UK guidelines and NHS-DPP eligibility criteria levels of HbA_{1c} (≥ 6.0% but < 6.5%) or FPG (5.6–6.9 mmol/l).[16] Although using the same HbA_{1c} and FPG levels as the NHS-DPP, one difference between the NHS-DPP specification and this RCT was that eligibility was restricted to FPG levels alone or HbA_{1c} and FPG levels in the at-risk range, whereas the NHS-DPP considers eligibility based on either test. The intervention was very similar to the Framework 1 version of the NHS-DPP, although provided over a longer period; it consisted of 6 core 2-hour group sessions for 12 weeks, followed by up to 15 maintenance sessions 8 weeks apart from month 4. The study had a second intervention arm where, in addition to the lifestyle intervention, participants were supported by a lay mentor. Controls received written information and a single 2-hour session about risk of diabetes and lifestyle modification. The study found no significant difference in progression to T2D between the two intervention arms, but when combined demonstrated an odds ratio (OR) of 0.57 (95% CI, 0.38 to 0.87; $p < 0.01$) compared to the control group. These results differ from a previous study carried out in primary care in England where a non-significant 26% reduced risk of developing T2D in the intervention arm compared to standard care [hazard ratio (HR) 0.74, 95% CI 0.48 to 1.14; $p = 0.18$]

Definition of terms

Oral glucose tolerance test

- Two-part blood test
- Part one: fasting plasma glucose (FPG). Blood test after overnight fast. If result is abnormal, diagnosis is impaired fasting glucose (IFG)
- Part two: 2-hour glucose tolerance test (2hrGTT). Blood test two hours after ingestion of sugary drink. If result is abnormal, diagnosis is impaired glucose tolerance (IGT)
- Both tests can be performed independently of each other

HbA_{1c}

- Measurement of glycated haemoglobin, which reflects glucose concentration over two to three months. Accuracy impaired by haemoglobinopathies

Pre-diabetes

- Arbitrary category to encompass either IFG or IGT or abnormal HbA1c

American Diabetes Association (ADA) diagnostic criteria

- Impaired fasting glucose 5.6–6.9 mmol/l
- Impaired glucose tolerance 7–11.1 mmol/l
- HbA_{1c} 'at-risk' range 39–47 mmol/mol (5.7–6.4%)

WHO diagnostic criteria

- Impaired fasting glucose 6.0–6.9 mmol/l
- Impaired glucose tolerance 7–11.1 mmol/l
- HbA_{1c} 'at-risk' range 42–47 mmol/mol (6.0–6.4%)

International Expert Committee (IEC) diagnostic criteria

- HbA_{1c} 'at-risk' range 42–47 mmol/mol (6.0–6.4%)

FIGURE 1 Definition of terms for screening and diagnosis at high risk of T2D. Reproduced from Barry *et al.*[4] with permission from BMJ Publishing Group Ltd.

was estimated using a less intensive intervention (6 hours group structured education programme) and in a more ethnically diverse population.[17]

Cost-effectiveness

Although effective, the interventions in these RCTs were resource-intensive to deliver. In the case of the US DPP, cost per participant during the first year of the intervention was US$1399[25] and US$2915 over its 3-year duration.[26] The high costs posed a major challenge for scaling up to a broader population in an economically sustainable way, so lower-intensity 'pragmatic' lifestyle programmes were trialled.

A systematic review of the cost-effectiveness of 27 DPPs between 2004 and 2016[26] found that lifestyle programmes appeared to be cost-effective in preventing T2D among high-risk individuals, albeit with variable estimates due to definition of pre-diabetes, participant eligibility criteria, and the intervention itself. As in previous systematic reviews looking at effectiveness, most of the studies in this review used IGT to identify eligible participants. The majority (21/27) were modelling studies, and more than half assumed reductions in T2D incidence equivalent to that achieved in the intensive RCTs (US DPP or the Finnish DPS). The review included studies of lifestyle interventions and metformin. Both intervention types appeared to be cost-effective from a health system perspective [median incremental cost-effectiveness ratios (ICERs) for lifestyle and metformin interventions were £7490 and £8428 per quality-adjusted life-year (QALY), respectively]. Metformin was more cost-effective than lifestyle interventions from a societal perspective due to lower costs to participants.

For the NHS-DPP, NHSE conducted an impact assessment study in 2016 with the purpose of identifying the costs

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TABLE 1 Randomised trials and systematic reviews of interventions for diabetes prevention

Study and design	Population and characteristics	Intervention(s)	Comparison	Outcome and follow-up	Effect estimates
Da Qing study, China[11] RCT	In 1986, 33 clinics in Da Qing, China, were assigned to control clinic or provide one of three interventions for 577 adults with IGT. 438 were assigned to an intervention group and 138 to the control group. Age: 45 (9.1) years BMI: 25.8 (3.8) kg/m^2 Women: 47% [but with higher % in the diet-only group (55%), and lower % in the exercise and diet plus exercise groups (43% and 44%)].	**Diet group:** Precise diet prescribed, plus in participants with BMI > 25 extra encouragement to lose 0.5–1.0 kg per month until they achieved a BMI of 23 kg/m^2. Patients received individual counselling by physicians concerning daily food intake, and counselling sessions (in small groups) weekly for 1 month, monthly for 3 months, and then once every 3 months for the remainder of the study. **Exercise group:** Precise guidance provided, tailored to each participant's health condition. Counselling sessions weekly for 1 month, monthly for 3 months, and then once every 3 months for the remainder of the study. **Diet plus exercise group:** similar to those for the diet-only and the exercise-only intervention groups.	General information about diabetes and IGT and informational brochures with instructions for diet and/or increased leisure physical activities.	Conversion to T2D. Follow-up conducted at 2-year intervals over a 6-year period.	Diet, exercise, and diet plus exercise interventions, were associated with 31% ($p < 0.03$), 46% ($p < 0.0005$), and 42% ($p < 0.005$) reductions in risk of developing diabetes compared with control, respectively.
US DPP[12] RCT	Individuals at high risk: 3234 non-diabetic participants with elevated fasting and post-load plasma glucose concentrations. Randomised from 1996 to 1999, 1082 to placebo, 1073 to metformin, and 1079 to the intensive lifestyle intervention Age: 51 years BMI: 34.0 kg/m^2 Women: 68% Ethnic minority: 45%	Pharmacological therapy (850 mg metformin twice daily), or lifestyle intervention involving 16 core individual sessions followed by twice- monthly maintenance sessions, plus aids such as meal replacements or access to exercise facilities; sessions delivered by specialist case managers who were either nutritionists, exercise physiologists or behavioural psychologists.	Placebo	Conversion to T2D during study period and whether participants lost 7% or more weight. Average follow-up: 2.8 years.	Reduction of T2D incidence from lifestyle intervention compared with placebo: 58% (95% CI 48% to 66%). Reduction of T2D incidence from metformin intervention compared with placebo: 31% (95% CI 17% to 43%). Participants in the lifestyle intervention lost 5–7% of body weight.

Study and design	Population and characteristics	Intervention(s)	Comparison	Outcome and follow-up	Effect estimates
Finnish DPS[13,14] RCT	Randomised 522 individuals with IGT Age: 55 years BMI: 31.0 kg/m^2 Women: 67%	Intensive lifestyle intervention aimed at reducing weight, total intake of fat and saturated fat, increasing intake of fibre and physical activity. Seven 30- to 60-minute individualised counselling sessions during the first year and every 3 months afterwards.	Usual care, consisting of general dietary and exercise advice at baseline and annual examinations.	Conversion to T2D; secondary outcome weight reduction. Mean follow-up: 3.2 years	Risk of T2D reduced by 58% in the intensive lifestyle intervention group compared with the control. Weight reduction after 1 and 3 years: 4.5 and 3.5 kg in the intervention group and 1.0 and 0.9 kg in the control, respectively.
SLIMMER Diabetes Prevention Trial, Netherlands[15] RCT	316 subjects aged 40–70 years with increased risk of T2D from 25 Dutch general practices. Age: 61 years Most had a low education level, family history of diabetes. 48% overweight (BMI ≥ 25 and < 30 kg/m^2), 42% obese (BMI ≥ 30 kg/m^2).	Combined dietary and physical activity lifestyle intervention based on the Finnish DPS, involving general practices, dietitians, physiotherapists and sports clubs. Intervention consisted of 10-month dietary and physical activity programme, tailored dietary advice given by a dietitian during 5–8 individual consultations, and one group session.	Usual care.	Primary outcome was fasting insulin at 12 and 18 months. Effectiveness on risk factors, diet, activity, and quality of life after 12 and 18 months.	Compared with control, after 12 months: body weight −2.7 kg (95% CI −3.7 to −1.7 kg) After 18 months: body weight − 2.5 kg (95% CI −3.6 to −1.4 kg). After 12 months: fasting insulin −12.1 pmol/l (95% CI −19.6 to −4.6 pmol/l) After 18 months: fasting insulin −8.0 pmol/l (95% CI −14.7 to −0.53 pmol/l).
Norfolk Diabetes Prevention Study, UK[16] RCT	1028 participants in high-risk intermediate glycaemic categories, from 135 practices in England. Randomised to intervention *n* = 424, intervention plus support *n* = 426, control *n* = 178 Age: 65.3 years BMI: 31.2 kg/m^2 Weight: 89.9–90.5 kg HbA_{1c}: 6.1% White ethnicity: 96–97.1% Men: 60.7– 65.5%	Group-delivered, theory-based lifestyle intervention with or without the support of trained lay volunteer mentors with T2D. Intervention was delivered by trained healthcare professionals alone or jointly with volunteer mentors. It consisted of 6 2-hour educational group sessions for 12 weeks, followed by up to 15 maintenance sessions 8 weeks apart from month 4. Maintenance sessions included a 50-minute supervised physical activity/muscle-strengthening exercise session.	Usual care (written information and 2-hour session on the risk of T2D).	Development of T2D. Measurement: at follow-up time point assessments (0, 6, 12, 24, 36, 40 months). Up to 46 months from August 2011 to January 2019, mean follow-up 24.7 months.	Lifestyle intervention: OR 0.54 (95% CI 0.34 to 0.85); *p* = 0.01. Lifestyle intervention and mentor support: OR 0.61 (95% CI 0.39 to 0.96); *p* = 0.033. Combined OR 0.57 (95% CI 0.38 to 0.87); *p* = 0.01. Absolute number needed to treat: 11. Combined intervention arms vs. control at 12 months Weight: −1.76 kg; (95% CI −2.55 to −0.97 kg), BMI: −0.59 kg/m^2 (95% CI −0.86 to −0.31 kg/m^2) At 24 months Weight: −1.47 kg; (95% CI −2.64 to −0.30 kg).

continued

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TABLE 1 Randomised trials and systematic reviews of interventions for diabetes prevention (*continued*)

Study and design	Population and characteristics	Intervention(s)	Comparison	Outcome and follow-up	Effect estimates
Let's Prevent Diabetes[17] RCT	Community-based 43 general practices randomised to standard care or the intervention. 880 participants (433 standard care, 447 intervention). Age: 63.9 years % males: control 64.2%, intervention 63.1%. White European: control 84.3%, intervention 84.5%. BMI: control 33.1 kg/m^2, intervention 32.0 kg/m^2 Weight: control 94.4 kg, intervention 89.9 kg. HbA_{1c} 6.0–6.4%: control 50.1, intervention 46.7.	Lifestyle intervention delivered to groups of 10, over 6 hours, either over a full day or two half-days, plus 3-hour refresher sessions at 12 and 24 months to reinforce key messages, review risk factors and update action plans. Participants also received a 15-minute telephone call every 3 months from healthcare professionals trained to offer support in behaviour change. Initial sessions were delivered by two trained educators, with the aim to increase knowledge and to promote healthy behaviour, aiming to reduce body weight by 5%, and saturated fat intake to 30% and 10% of total energy intake respectively, increasing fibre intake and promoting physical activity.	Usual care, written information on the risk of T2D and the effect of lifestyle modification on reducing this risk.	Primary outcome: progression to T2D during 3 years. Secondary outcomes included lipid levels, HbA_{1c}, blood pressure, weight, and BMI. Participants were followed up for 3 years.	Non-significant 26% reduced risk: HR 0.74, (95% CI 0.48 to 1.14); $p = 0.18$. Per-protocol analysis 35% reduction, still non-significant ($p = 0.07$).
PHE Systematic Review[10] systematic review and meta-analysis	Individuals pooled from 36 studies in high-risk populations. 19 studies reported data on gender at baseline. The percentage of males included ranged from 15% to 64%, median percentage 50%. The mean age of study participants ranged from 46 years up to 66 years (median 56 years).	Lifestyle interventions, diet or physical activity alone or in combination. Settings: routine healthcare; community, primary care, outpatient, workplace, home based, private.	Usual care.	Effectiveness of DPPs on delaying and reducing incidence of T2D, and on weight and glucose.	Relative: IRR: 0.74% (95% CI 0.58% to 0.93%). Based on 16 studies (11 RCTs), mean weight loss was: relative: 1.57 kg more than those receiving usual care: absolute: 2.46 kg. Based on 35 studies (20 RCTs), HbA_{1c}, pooled reduction was 0.07%, and when compared to usual care the intervention resulted in a reduction of 0.04% (95% CI −0.07% to −0.01%), based on 10 studies (9 RCTs). Not significant for FPG, 2-hour glucose.

Study and design	Population and characteristics	Intervention(s)	Comparison	Outcome and follow-up	Effect estimates
Sagastume[18] systematic review and meta-analysis	48 studies with 50 interventions were eligible, of which 56% were conducted in lower-middle-income countries, 44% in upper-middle, and none in low-income. Median number of participants of 246, 66.6% female, mean age of 46.3 years. At baseline, most overweight but presented normal glycaemic levels (BMI 27.3 kg/m^2, FPG 99.8 mg/dl). Most studies selected participants with impaired glucose or/pre-diabetes (52%).	Lifestyle interventions in the prevention of T2D and gestational diabetes in low- and middle-income countries in at-risk populations in middle and upper-income countries evaluating multitarget and multicomponent lifestyle interventions in at-risk populations conducted in low- and middle-income countries.	Usual care.	Main outcomes were incidence of T2D and gestational diabetes, and indicators of glycaemic control. A median of 246 (interquartile range 137–511) individuals participated in the interventions with a median duration of 6 (3–12) months. The interventions had a median duration of 6 months (interquartile range 3–12 months).	Lifestyle interventions decreased the incidence risk ratio of T2D by 25% (0.75, 95% CI 0.61 to 0.91). Reduced the levels of HbA_{1c} by 0.15% (95% CI 0.25% to 0.05%), FPG by 3.44 mg/dl (95% CI 4.72 to 2.17 mg/dl), and 2-hour glucose tolerance by 4.18 mg/dl (95% CI 7.35 to 1.02 mg/dl).
Galaviz[19] Systematic review and meta-analysis	63 studies were pooled in the meta-analysis between January 1990 and April 2015. *n* = 17,272 Age 49.7 years, 28.8% male, 60.8% White European. The prevalence of pre-diabetes at baseline ranged from 35% to 100% across studies (mean 62%).	Effectiveness/translation studies of any design testing strategies, targeting high-risk populations (with pre-diabetes or diabetes risk factors), and reporting diabetes incidence, weight, or glucose outcomes were included.	Usual care.	T2D incidence rates, weight, or glucose outcomes (fasting blood glucose, 2-hours postprandial glucose, or haemoglobin HbA_{1c}) measured before and after the intervention. Follow up ranged from 6 to 48 months [19.5 (12.7 SD)] with attrition rates from 0% to 40%.	Including controlled studies only (*n* = 7), diabetes cumulative incidence was 9% (intervention) and 12% (controls) (absolute risk reduction 3%; relative risk 0.71, 95% CI 0.58 to 0.88). Combining controlled and uncontrolled studies (*n* = 14), group education by healthcare professionals was effective (OR 0.67, 95% CI 0.49 to 0.92). Intervention was associated with 1.5 kg more weight loss than controls and 0.09 mmol/l greater fasting blood glucose decrease than controls.
Hemmingsen[20] Systematic review and meta-analysis	People at increased risk of developing T2D (*n* = 4511, 11 trials). Nine RCTs included participants with IGT, one included participants with IGT, IFG or both, and one included people with fasting glucose levels between 5.3 and 6.9 mmol/l.	Diet and physical activity RCTs with a duration of 2 years or more. Settings: outpatients.	Intervention vs. standard or no treatment.	Incidence of T2D. The definition of T2D incidence varied among the included trials. Up to 6 years, mean duration 3.8 years.	Relative RR 0.57 (95% CI 0.50 to 0.64).

This synopsis should be referenced as follows: Bower P, Soiland-Reyes C, Bennett C, Brunton L, Burch P, Cameron E, *et al.* The effectiveness and cost-effectiveness of the NHS Diabetes Prevention Programme (NHS-DPP): the DIPLOMA long-term multimethod assessment [published online ahead of print April 30 2025]. *Health Soc Care Deliv Res* 2025. https://doi.org/10.3310/MWKJ5102

associated with the new policy as well as the potential benefits from a healthcare perspective.[27] This study modelled the costs and outcomes generated over a 20-year period associated with providing the NHS-DPP to a cohort of 390,000 individuals across 2016–21. The model assumed PHE's systematic review base-case effectiveness of 26% in reducing T2D incidence. Compared to a 'do-nothing' scenario, the model estimated that, at an average cost of £270 per participant, the 5-year implementation of the NHS-DPP would start being cost-saving at year 14. Overall, it was predicted that the roll-out would generate 18,000 QALYs and a net cumulative impact of £35M over the 20-year period. Different scenarios were considered in sensitivity analyses using different effectiveness and cost assumptions. On one extreme, the lowest effectiveness and higher cost scenario could be cost-effective but would not become cost-saving. At the other end, the highest effectiveness and lower cost per participant scenario would be cost-effective from year 6 and cost-saving from year 9.

A more recent systematic review looked at cost-effectiveness of a wider range of T2D prevention interventions between 2008 and 2017.[28] The review identified 28 studies using a high-risk intervention approach (i.e. those identifying people at high risk of developing T2D), where interventions included lifestyle interventions that followed a DPP curriculum, lifestyle interventions that did not follow a DPP curriculum necessarily, or pharmacological interventions (metformin). Interventions were also grouped by delivery method (individual or group, in-person or remote), and by trainer type (healthcare professionals, lay trainers or educators). Using a healthcare perspective to assess costs and benefits, lifestyle and metformin interventions were cost-effective compared with no intervention (median ICERs of US$12,510 per QALY and US$17,089 per QALY, respectively). When comparing lifestyle interventions that followed a DPP curriculum versus those that did not, the former were more cost-effective (median ICER of US$6212 per QALY vs. $13,228 per QALY, respectively), whereas lifestyle interventions were more cost-effective than metformin interventions, regardless of analytical time horizon, delivery method, media, mode, and personnel type.

Another factor that drives whether an intervention is considered cost-effective is the evaluation perspective (i.e. whether healthcare, social care and societal costs and benefits are considered). A recent RCT in Dutch primary care delivered a lifestyle intervention based on the Finnish DPS. The intervention showed significant improvements in weight, glucose and quality-of-life measures at 12 and 18 months.[15] However, within-trial health economic analysis indicated a low to moderate probability of cost-effectiveness depending on whether a healthcare or societal perspective was used.

Overall, the available evidence suggests that interventions to prevent T2D among high-risk individuals can be cost-effective, but systematic reviews indicate there are some important determinants, including eligibility for the intervention; design and intensity of the intervention; whether screening is included as part of the intervention; uptake and enrolment rates; the extent to which the reduction in T2D incidence persists; the evaluation perspective; and the evaluation period.[26,28]

Health inequalities

Despite recent improvements in population health seen in high-income countries,[1] the gap in health outcomes between different population groups in the UK has increased.[29] Latest figures comparing life expectancy between the least and most deprived areas in England show that the gap is 9.7 years for men and 7.9 years for women, while the gap in healthy life expectancy is 18.6 years for males and 19.3 years for females.[30] As part of the legal duties on health inequalities set out by the Health and Social Care Act 2012, for any decision made or any policy developed, NHSE has a legal duty in relation to equality and to reducing health inequalities.[31]

Structural-level interventions target populations regardless of risk and aim to alter the wider context within which health is produced.[32] Preliminary evidence on individual-level interventions using a high-risk prevention approach[33] has indicated that, although high-risk approaches can improve population health overall, they require high agency levels from targeted individuals to mobilise their material and psychological resources in order to achieve the intervention benefits.[32] Individual-level interventions may create 'intervention-generated inequalities'.[34]

The systematic review of lifestyle interventions for the prevention of T2D commissioned by PHE explored groups for which the lifestyle interventions were more effective. Findings suggested that age and proportion of non-Caucasian participants were not associated with incidence of T2D, weight change or glucose outcomes, but that the percentage of males was positively associated with incidence of T2D.[10] However, caution is recommended in these subgroup analyses. A different systematic review reported that none of its 27 studies considered impact on equity of healthcare provision, with 24 of 27 studies undertaken in high-income, predominantly White nations.[26] However, the risk of developing T2D is strongly linked to sociodemographic factors. For example, diabetes

risk can be up to six times higher in certain ethnic minority groups, and diabetes is 45% more common in areas of high income deprivation.[3]

At the time of commissioning the NHS-DPP, NHSE carried out an equality impact assessment. It stated that, at that point in time, the lack of data meant a full assessment was not possible, but that going forward the programme committed to monitor differences in uptake and completion, adjusting the programme as necessary. To that purpose, provider contracts would include key performance indicators to monitor and promote recruitment to reflect NDH risk profiles in the local population.[27]

National Health Service Diabetes Prevention Programme implementation

Between 2015 and 2016 there were seven demonstrator sites that helped inform national roll-out of the NHS-DPP.[3] In 2016, the programme was rolled out in waves: wave 1 covered approximately 50% of primary care sites, with waves 2 and 3 covering approximately 25% each, achieving full coverage of England in 2018.

When the NHS-DPP was first commissioned, its mandate was to reach 100,000 referrals per year by 2020. This target was exceeded in 2018–9 with 105,000 referrals.[35] In 2019, the NHS Long Term Plan extended the programme for 5 more years and doubled its mandate to 200,000 places per year by 2023–4.[3] By March 2022, the NHS-DPP had received almost 1 million referrals.

To respond to the increase in capacity needed, as well as to apply learning from the initial waves, the NHS-DPP underwent rapid changes. The service specification is currently in its third version; Framework 2 was implemented in 2019[36] and Framework 3 in 2022.[37] The DIPLOMA research programme evaluated aspects of Framework 1 and Framework 2 only.

Figure 2 provides an overview of events and of the changes to the NHS-DPP since it was announced in 2014.

Framework 1 intervention

The NHS-DPP intervention provided lifestyle behaviour change education to encourage weight loss, increased physical activity and healthy eating. In its first version, eligibility was restricted to adults 18 years or over, not pregnant, and with NDH diagnosed or confirmed in the last 12 months based on HbA_{1c} blood results in the range 6.0–6.4% (42–47 mmol/mol), or 5.5 and 6.9 mmol/l for FPG.

For all frameworks, NHSE has commissioned the providers through commercial procurement calls, where a small number of providers are selected to deliver the programme nationally, with allocation at the local level carried out through mini-competitions.[7] The NHS-DPP National Service Specification Framework 1 was commissioned from four national providers. *Table 2* provides the names of the national provider organisations commissioned in the three frameworks to date.

In Framework 1, NHSE specified that the intervention should be delivered in groups, face to face, over a minimum of 13 sessions spread across a minimum of 9 months,[8] and required delivery of 19 behaviour change techniques (BCTs; the 'active' ingredients of interventions designed to change an individual's behaviour).[38,39] Identification, offer, consenting and referral were the responsibility of primary care, who identified participants via case-finding searches, the NHS Health Check Programme, or during ad hoc consultations.

Potentially eligible participants were invited via a letter or during a consultation. Individuals invited by letter approached the provider if interested, whereas individuals invited during consultation were asked for consent to be

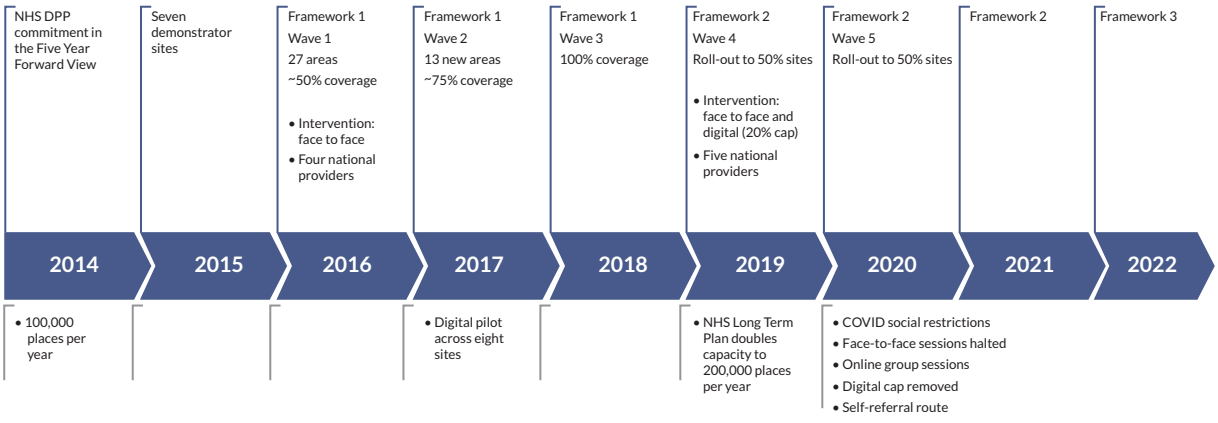

FIGURE 2 Timeline of the NHS-DPP.

TABLE 2 National Health Service Diabetes Prevention Programme providers commissioned in Frameworks 1–3

	NHS-DPP provider for face-to-face intervention (digital provider[a])	NHS-DPP provider for digital intervention[a]
Framework 1	Reed Momenta • National organisation delivering a range of programmes for health, well-being and employment ICS Health and Wellbeing • National organisation delivering a range of programmes for health and well-being Ingeus UK • National organisation delivering a range of programmes for health and well-being Living Well Taking Control • Non-profit organisation delivering the NHS-DPP	N/A
Framework 2	Reed Wellbeing, previously Reed Momenta (Second Nature) • National organisation delivering a range of programmes for health, well-being and employment ICS Health and Wellbeing (Oviva) • National organisation delivering a range of programmes for health and well-being Ingeus UK (Changing Health/Oviva) • National organisation delivering a range of programmes for health and well-being Living Well Taking Control (LIVA Healthcare) • Non-profit organisation delivering the NHS-DPP WW, previously Weight Watchers • Commercial organisation delivering weight loss programmes globally	Second Nature • Organisation delivering digital weight loss programmes globally Oviva • Organisation delivering a range of digital health programmes in locations across UK and Europe LIVA Healthcare • Organisation delivering a range of digital health programmes in locations across UK and Europe WW, previously Weight Watchers • Commercial organisation delivering weight loss programmes globally
Framework 3	Xyla Health and Wellbeing, previously ICS Health and Wellbeing (Oviva) • National organisation delivering a range of programmes for health and well-being Living Well Taking Control (LIVA Healthcare) • Non-profit organisation delivering the NHS-DPP Reed Wellbeing (Second Nature) • National organisation delivering a range of programmes for health, well-being and employment Thrive Tribe (Second Nature) • National organisation delivering a range of programmes for health and well-being	Oviva • Organisation delivering a range of digital health programmes in locations across UK and Europe LIVA Healthcare • Organisation delivering a range of digital health programmes in locations across UK and Europe Second Nature • Organisation delivering digital weight loss programmes globally

a For Framework 2 and Framework 3, face-to-face providers were allowed to partner with a second provider to deliver the digital intervention. Responsibility for the contract lay with the face-to-face provider.

contacted by the local provider.[36] In Framework 1, sites had a mandate to generate 10,000 referrals per year. This number acted as a target and a cap to balance provision across sites.[40] For future frameworks, targets were refined based on population size, ethnicity and deprivation. On receipt of a referral, providers offered an initial assessment, where their eligibility was confirmed. Individuals wishing to participate provided baseline data and were allocated to the next available local group. On completion of the programme, or earlier if a participant dropped out, providers discharged the participant and notified primary care. At this point NICE guidance for NDH recommends carrying out an annual review and blood test to check for progression to T2D.[9]

To track programme performance, NHS Digital introduced new clinical codes to log referral and completion of the NHS-DPP in primary care electronic health records.[41] A separate record of NHS-DPP referrals and participants'

progression was required from the providers, which captured participant characteristics and outcomes.

Framework 2 and Framework 3

Between 2017 and 2018, NHSE commissioned a pilot Digital Diabetes Prevention Programme (NHS-DDPP), to explore its feasibility in better meeting the needs of the working population, overcome perceived stigma of attending the NHS-DPP, and reduce costs. Despite evidence suggesting digital interventions were effective in promoting weight loss, there were concerns with engagement, adherence, and the 'digital divide'. An evaluation accompanied the pilot.[42]

NHS England commissioned five providers to deliver the DDPP in eight areas. Some of them offered digital interventions as a choice to patients alongside the NHS-DPP, while others offered the digital intervention only. Eligibility for the digital intervention required diagnosis with NDH and being overweight or obese. Interventions varied in the delivery platforms used, whether wearables were included, and the amount of human interaction. The evaluation analysed uptake, weight and HbA_{1c} outcomes and impact on health inequalities.[42] The evaluation concluded that a national DDPP was feasible, acceptable to patients and providers, and impacted on weight and HbA_{1c} in those who participated.[43]

Supported by the positive preliminary results from the NHS-DPP face-to-face intervention[44] and from the digital pilot, the 2018 NHS Long Term Plan announced a doubling in NHS-DPP capacity to 200,000 places, including a new digital option (see *Figure 2*).[3] A new specification, Framework 2, was implemented from August 2019.

One of the main changes was inclusion of digital delivery. At the time of the 2019 framework, results from the digital pilot were still emerging, and a cap of 20% was set on digital referrals. Also, the digital option was to be offered only after the face-to-face option had been declined.[35] Framework 2 was operational in nearly half of the local sites during its first year (wave 4).[36] Contracts were reprocured and face-to-face providers partnered with digital providers (see *Table 2*). As a result, some primary care sites had a change of provider between Framework 1 and Framework 2.

A second change included changes to payment schedules to incentivise retention of participants from more deprived backgrounds and from ethnic minorities. Early NHS-DPP analyses suggested the programme was achieving participation rates from deprived areas and ethnic minority groups above population percentages;[44] however, these groups were 25% less likely to complete the programme.[35]

Social distancing was imposed during the COVID-19 pandemic while Framework 2 was under way, and all face-to-face group sessions stopped. Participants were given the option to join remote group sessions via video conferencing and telephone consultations, to switch to a digital intervention, or to pause their programme.[37] For new participants, the 20% cap on DDPP was lifted, and these had a choice of remote group sessions or the online digital programme, even where Framework 2 had not started yet. Reduced availability of blood tests during the pandemic drove changes to the eligibility criteria for the programme, including NDH diagnosed based on a glycaemic test result within 24 months instead of 12 months, and roll-out of a 'self-referral' route whereby individuals were able to assess their risk of T2D via the online 'Know Your Risk' tool.

Once again, learning from its own NHS-DPP team, feedback from the DIPLOMA evaluation interim findings, and learning from the contingency implementation measures during the pandemic, NHSE commissioned Framework 3 of the programme in August 2022.[37] Framework 3 offers a choice of group face-to-face, digital and new remote tailored services for groups most likely to be impacted by health inequalities.

The Diabetes Prevention – Long-term Multimethod Assessment research programme

Aims and organisation

Previous sections have highlighted the evidence base underlying the NHS-DPP, but it remained uncertain whether these benefits could be achieved in practice across the whole of England, given the likely impact of issues such as access, uptake and fidelity on the translation of benefits demonstrated in trials into routine policy and practice.

The DIPLOMA programme was commissioned by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research (HS&DR), from 1 April 2017 to 31 March 2023, to evaluate the NHS-DPP. Prior to DIPLOMA, a formative evaluation of the demonstrator sites and wave 1 had been commissioned by NHSE.[40] DIPLOMA was evaluated by the HS&DR committee with input from the NHS-DPP management team.

The DIPLOMA study was a mixed-methods evaluation, structured into nine interconnected WPs. There were seven research WPs originally (WPs 1–7) and a 'study management' WP (WP8), and an additional research WP (WP9) was added later in the programme.

The three aims were to provide:

a. regular feedback to NHS-DPP stakeholders on the delivery and outcomes of the programme to support ongoing development and quality improvement
b. a rigorous longer-term assessment of the success of the NHS-DPP in meeting its aims of reducing T2D prevalence in a way that is cost-effective and sustainable for the NHS
c. an independent evaluation.

The latest (version 16.0) and previous versions of the protocol are available at https://fundingawards.nihr.ac.uk/award/16/48/07#/. Ethical approval for DIPLOMA was received from the North West – Greater Manchester East Research Ethics Committee (REC reference 17/NW/0426, sponsor University of Manchester). Progress was reviewed annually by a Study Steering Committee (SSC) appointed by NIHR, which comprised six academic researchers and two public contributors (see *Acknowledgements*).

Research pathway and methods

When DIPLOMA was commissioned in 2017, its scope was to evaluate the initial service specification (Framework 1). In 2018, DIPLOMA broadened to include Framework 2, focusing on areas where additional value could be provided and avoiding areas of overlap with NHSE (see *Reflections*).

Figure 3 illustrates the DIPLOMA WPs and their relationship to the NHS-DPP frameworks. A brief description of each WP is provided in *Table 3*. The next subsection provides additional information on some of the data sources used, especially those created to monitor NHS-DPP performance.

Data

For WPs 1, 2 and 3 an initial sampling strategy was devised aimed at reaching a diverse sample in terms of geography, deprivation, ethnicity, and urban or rural location. WP1 (qualitative aspects) undertook observations across Greater Manchester. WP6 recruited practices in Greater Manchester and the Thames Valley and South Midlands regions. Details of the samples recruited or considered in each WP are available in *Table 3*.

Information-sharing agreements with NHS-DPP providers were agreed, by which DIPLOMA committed to maintain confidentiality and anonymity, as data were commercially sensitive. Similarly, DIPLOMA made agreements for access to the national data sets.

Below we provide a brief overview of the data sources specifically set up by and for the NHS-DPP, drawing attention to their limitations, as these affected decisions on the study designs. Two important limitations were that the number of invitations made to the NHS-DPP was unknown, and that no single data set collated all the NHS-DPP information.

National Health Service Diabetes Prevention Programme minimum data set

The NHS-DPP minimum data set (MDS) was created, in part, to manage provider payment and performance, and NHS-DPP providers were contractually obliged to collect these data to receive reimbursement. It contains information on participant demographics, dates and sources of referrals, and information about subsequent programme attendances, as well as outcome measures. It evolved as the NHS-DPP moved through various frameworks. The MDS contains all the referrals received by NHS-DPP providers from primary care since the roll-out of wave 1 in Framework 1, up to ongoing referrals in Framework 3. The only exception was referrals to the digital pilot, managed on a separate data set (the Digital Pilot DPP data set).

Digital Pilot diabetes prevention programme data set

The Digital Pilot DPP MDS contained information on participant demographics, dates and sources of referrals, and outcome measures at baseline and at 6 and 12 months. The DDPP MDS sample includes everyone who enrolled on the DDPP during the 1-year period of the pilot.[45]

Clinical Practice Research Datalink

A data source used to analyse long-term outcomes was the Clinical Practice Research Datalink (CPRD). This is a primary care database of anonymised medical records, which contains information on diagnoses and comorbidities, appointments, prescriptions and referrals. New Read codes created specifically to track patient progress along the NHS-DPP, as well as a Read code for NDH diagnosis, enabled the use of CPRD to track conversion from NDH to T2D.

The CPRD anonymises practice identities, which limits potential for analyses by geography or practice characteristics. Additionally, Read codes on NHS-DPP

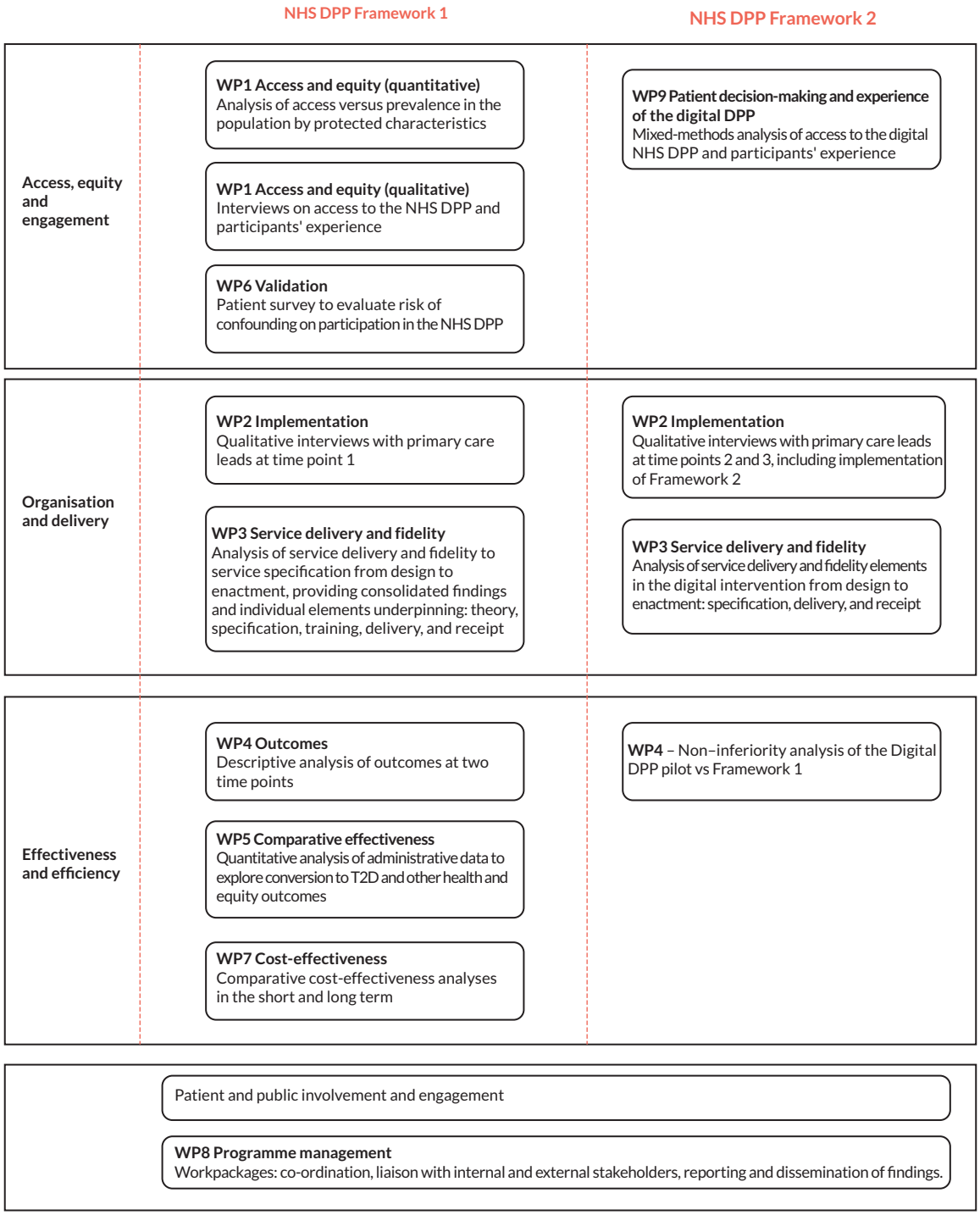

FIGURE 3 DIPLOMA research programme diagram.

participation milestones did not differentiate between attendance at face-to-face or to digital intervention, limiting its usefulness for comparing Frameworks 1 and 2.

National Diabetes Audit

The National Diabetes Audit (NDA) was first collected in 2003 to monitor the impact of the diabetes National Service Framework.[46] It contains information extracted from primary care records on care processes over the previous 12 or 15 months for individuals aged 15 years and over, diagnosed with any form of diabetes. Audit data cover nearly 98% of eligible practices in England.[47]

In 2017, the NDA received approval to include records from individuals diagnosed with NDH. In cases where a record had an NHS-DPP referral code but no NDH diagnosis code, these records could not be extracted. The

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TABLE 3 Work package aims and methods

WP and WP aims	Research questions	Methods	Data sources
WP1 Access and equity Aim: To assess whether sociodemographic factors influence access to the NHS-DPP, and to explore the experience of patients and professionals	1.1 Are there inequalities in the identification of patients eligible for the NHS-DPP? 1.2 Are there inequalities in the referral of patients to the NHS-DPP? 1.3 Are there inequalities in attendance and completion of the NHS-DPP?	Comparison of characteristics of patients identified with NDH in GP records to the characteristics of patients identified with NDH in representative survey data.	UKHLS[a] HSE[b] NDA NHS-DPP MDS
	1.4 What is the experience of patients and professionals in accessing the NHS-DPP?	Qualitative methods in a sample of 6–10 practices to reflect diversity in deprivation and ethnicity.	Interviews (n = 43) Observations (n = 16, across seven general practices within five different CCGs in North-West England)
WP2 Implementation (Framework 1 and Framework 2) Aim: To assess the process of implementation of the NHS-DPP, and explore the barriers and facilitators that affect the implementation of the NHS-DPP	2.1 What is the local context for implementation of the NHS-DPP? 2.2 What are the barriers and facilitators to the implementation of the NHS-DPP within areas? 2.3 What delivery arrangements were in place for the implementation of the new framework, how local organisation of the programme changed and with what consequences?	Longitudinal interviews to analyse the implementation process, its barriers and facilitators. A purposive sample of NHS-DPP sites was defined, with a mix of areas, rural/urban characteristics and population characteristics. Sample covered up to four case sites for each of the NHS-DPP national providers.	Telephone interviews (Framework 1, n = 24; Framework 2, n = 13) Incentives questionnaire (Framework 1, n = 57) Prospectus documents from NHS-DPP providers.
WP3 Service delivery and fidelity (Framework 1) Aim: To assess the theory, techniques and content of the NHS-DPP, examine variation in delivery, and report the extent to which the NHS-DPP is delivered with fidelity	3.1 (Study Design) What are the explicit theoretical principles, BCT content and mode of delivery of the NHS-DPP intervention as exemplified in provider documents?	Documented analysis of the NHS-DPP programme specification, including PH38 diabetes prevention guidance. These were compared with the intervention design from all four independent providers delivering the NHS-DPP. Documents were coded using the TIDieR framework and the BCTTv1.	Framework 1 NHS-DPP programme specification. NICE PH38 guidance Providers' Framework 1 response documents and programme manuals.
		A logic model was extracted from information in specification documents underpinning the NHS-DPP. To establish how each of the four providers expected their interventions to produce behavioural changes, information was extracted from their programme plans, staff training materials, and observations of staff training courses and coded using Michie and Prestwich's Theory Coding Scheme (TCS).	In addition to the above, notes from audio-recorded observations of mandatory staff training courses attended in 2018 (n = 10 trainers and n = 78 trainees).

TABLE 3 Work package aims and methods (*continued*)

WP and WP aims	Research questions	Methods	Data sources
	3.2 (Training) To what extent does the training of NHS-DPP staff address elements of theory and BCT content? What is the variation across providers, sites and settings?	Observation of training sessions from four sites per provider, purposively selected to cover variation in sociodemographic status and ethnicity. One set of mandatory training courses across the four NHS-DPP providers was audio-recorded, and all additional training materials used were collected. They were coded for BCT content using the BCTTv1 and checked against providers' intervention plans. Depth of training of BCT content was also documented.	Notes from audio-recorded observation of staff training courses in 2018 (n = 10 trainers and n = 78 trainees). Training materials from the four different providers.
	3.3 (Delivery) To what extent is the NHS-DPP intervention delivered with fidelity to intervention protocols and manuals?	Objective was to compare observed fidelity of delivery of BCTs that were delivered to (a) the NHS-DPP design specification and (b) the programme manuals of four provider organisations. Audio recordings were made of complete delivery of NHS-DPP courses at eight sites (two courses per provider). The BCTTv1 was used to code the contents of NHS-DPP design specification documents, programme manuals for each provider organisation, and observed group sessions.	Observation and audio recording of intervention sessions (n = 111 group session observations, including 390 patients, 19 accompanying persons and 35 facilitators). NHS-DPP design specification documents. Programme manuals for each provider organisation.
		Key features of NHS-DPP delivery were described using the TIDieR framework. Researchers wrote detailed field notes during each session, including observations of patient experience. Field notes were content analysed. Researchers compared observed patient experiences to variations in programme delivery.	Field notes taken during observation sessions, including observations of patient experience.
	3.4 (Receipt) To what extent is the content of the NHS-DPP intervention understood by recipients as intended by providers?	Qualitative interviews with people receiving the NHS-DPP. Topics included participants' understanding of self-monitoring of behaviour, goal-setting, feedback, problem-solving, and action planning. Participants were interviewed once, after their programmes had been completed. Transcripts were analysed thematically using the framework method. Sample taken from participants in sessions observed in 3.3.	Interviews with participants from the previous study involving observation of the programme at eight sites (two per provider).

continued

This synopsis should be referenced as follows: Bower P, Soiland-Reyes C, Bennett C, Brunton L, Burch P, Cameron E, *et al.* The effectiveness and cost-effectiveness of the NHS Diabetes Prevention Programme (NHS-DPP): the DIPLOMA long-term multimethod assessment [published online ahead of print April 30 2025]. *Health Soc Care Deliv Res* 2025. https://doi.org/10.3310/MWKJ5102

DOI: 10.3310/MWKJ5102

TABLE 3 Work package aims and methods (*continued*)

WP and WP aims	Research questions	Methods	Data sources
WP3 Service delivery and fidelity (Framework 2)	3.1.1 What are the explicit theoretical principles, BCT content and mode of delivery of the NHS-DDPP intervention as exemplified in provider's digital intervention designs? What is the observed variation in these across providers, sites and settings?	Analysis of documents and semistructured interviews using BCTTv1, TIDieR and TCS, assessing the specific BCTs designed into the intervention, key features of intervention delivery, and the extent to which the justification is explicitly based on theory. Providers' intervention design documents and interview transcripts coded for: BCTs using the BCTTv1; and underpinning theory, assessed using the TCS framework.	Framework 2 NHS-DPP programme specification. NICE PH38 guidance. Framework 2 intervention design documents. Interviews with professionals designing DDPP interventions (n = 6 across the four providers).
		Mixed-methods analysis to assess fidelity of service parameters to the NHS-DDPP specification. The analysis consisted of a document review of providers' design and delivery documentation, and use of the TIDieR framework to capture features of digital delivery. Documentation was supplemented by content analysis of interviews with programme developers and with health coaches.	Interviews with health coaches (n = 12).
	3.3.1 To what extent is the digital offering of the NHS-DPP intervention delivered with fidelity to the full programme specification?	Cross-sectional analysis to assess whether BCTs included in the NHS-DDPP specification were present in the delivery of the four digital providers' interventions. Delivery content was elicited from the following sources: (a) online platforms (e.g. apps), (b) educational materials and (c) health coaching (assessed via interviews with health coaches and audio-recorded telephone consultations). All materials were coded using the BCTT v1.	Document analysis of DDPP content. Interviews with health coaches (n = 12). Analysis of audio-recorded telephone calls (n = 2 service users at four and two time points, respectively; n = 6 calls).
	3.4.1 (Receipt) To what extent is the content of the digital offering of the NHS-DPP intervention understood and used by recipients as intended by providers? How do these vary across providers?	Semistructured interviews with participants. During recruitment, we targeted participants from deprived areas and minority ethnic groups. We conducted purposive sampling of respondents to the invitations, to secure a broad representation of participants across providers, age, gender and ethnic groups. Based on learning from our previous work (3.4 Receipt) on the possibility of recalling issues on BCT delivery, we interviewed participants twice: at 2–4 months into the programme, and at the end of the programme. Topics included participants' understanding and use of key self-regulatory BCTs (e.g. goal-setting) and the support they received via the programme. Transcripts were analysed thematically, informed by the framework method.	Telephone interviews with service users across all NHS-DDPP providers (n = 45), at two time points (February – December 2021).

TABLE 3 Work package aims and methods (*continued*)

WP and WP aims	Research questions	Methods	Data sources
	3.4.2 (Engagement) How do participants experience and engage with digital group support on the DDPP? 3.4.3 (Engagement) To what extent do service users on the NHS-DDPP engage with the digital programme for the 9-month duration?	We obtained usage data relating to intervention features of the NHS-DDPP, including self-monitoring and goal-setting (via an app), receiving information (via educational articles) and social support (via health coaches and group forums). Objectives were to: (1) describe duration of engagement on the app, (2) describe frequency of use of programme features, (3) describe patterns across time in engagement with programme features and (4) compare any differences in engagement with programme features between three DDPP providers over time. Median usage was calculated within nine 30-day engagement periods for longitudinal analysis of the dose of use for each feature.	Anonymous usage data from NHS-DDPP participants enrolled with three providers (*n* = 1826, December 2020 and June 2021).
WP4 Outcomes (Framework 1) Aim: To assess what outcomes participants achieve in the NHS-DPP, and whether outcomes vary by services delivered and patient characteristics	4.1 What services are delivered by the NHS-DPP Framework 1 and what is the extent of participation in the NHS-DPP intervention? 4.2 How does service delivery and participation in Framework 1 of the programme vary by provider, including variation within provider by area, and the associated variation in content and delivery between patient subgroups?	Analysis at two points. Early analysis described the extent of uptake and completion of the programme, based on the first 100,000 patients referred to the programme in 2016–7. The analysis modelled the association of various individual and service characteristics on uptake and completion. Methods used included logistic regression models to estimate associations between socioeconomic characteristics and programme characteristics with retention and completion. Multiple imputation was used to reduce bias for missing data.	NHS-DPP MDS
	4.3 What are the outcomes of patients in the NHS-DPP Framework 1 intervention, including well-being score, weight change, HbA_{1c} and mortality? 4.4 How do Framework 1 outcomes vary by provider (and any variation within provider by area) and the associated variation in content and delivery between patient subgroups based on data from WP3?	Analysis examines change, and factors associated with change, in measures of HbA_{1c} and weight in participants and completers of the programme between 2016 and 2019. Changes from baseline to both 6 months and completion in HbA_{1c} and weight were examined using mixed-effects linear regression, adjusting for patient characteristics, service provider and site/geographical area.	NHS-DPP MDS

continued

This synopsis should be referenced as follows: Bower P, Soiland-Reyes C, Bennett C, Brunton L, Burch P, Cameron E, *et al.* The effectiveness and cost-effectiveness of the NHS Diabetes Prevention Programme (NHS-DPP): the DIPLOMA long-term multimethod assessment [published online ahead of print April 30 2025]. *Health Soc Care Deliv Res* 2025. https://doi.org/10.3310/MWKJ5102

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TABLE 3 Work package aims and methods (*continued*)

WP and WP aims	Research questions	Methods	Data sources
WP4 Outcomes (Framework 2)	4.5 How do uptake, participation and clinical effectiveness outcomes for the Framework 1 face-to-face intervention compare to the NHS-DDPP pilot intervention, and how do these vary by population characteristics?	Non-inferiority analysis of outcomes (weight and HbA_{1c}), using individual-level data from the face-to-face participants and from participants on the digital pilot: those whose only choice was access to the digital pilot programme (digital only), and those able to choose between digital and face-to-face delivery and who chose digital (digital choice). Changes in outcomes from baseline to 6 months and to 12 months were analysed using regression, matching participants from the digital pilot to the face-to-face group. Interactions between baseline characteristics and delivery mode were evaluated.	NHS-DPP MDS Digital Pilot DPP data set.
WP5 Comparative effectiveness Aim: To assess whether the NHS-DPP is more effective than usual care in reducing conversion of NDH to diabetes, eventually reducing diabetes prevalence in England	5.1 What is the current epidemiology of NDH and diabetes?	Cohort study in UK primary care to estimate prevalence of NDH in each year between 2000 and 2015, and conversion to T2D using data from the CPRD. Baseline characteristics and conversion trends from NDH to T2D were explored. Cox proportional hazards models evaluated conversion over time and predictors.	CPRD Gold data set (approx. 7% of UK population). Patient-level deprivation data through the Office of National Statistics linkage.
	5.2 What is the effectiveness of the NHS-DPP at reducing the conversion of NDH to diabetes?	Matching of patients referred to the programme in referring practices to patients in non-referring practices. Random-effects parametric survival models evaluated the intervention, controlling for numerous covariates. Primary analysis was selected a priori: complete case analysis, one-to-one practice matching, up to five controls sampled with replacement. Various sensitivity analyses were conducted, including multiple imputation approaches.	CPRD Gold and Aurum (from 1 April 2016 to 31 March 2020). Controls were drawn from other UK countries; Wales, Northern Ireland, Scotland.
	5.3 What is the long-term impact of the NHS-DPP on diabetes prevalence?	Difference-in-differences to evaluate the impact at the population level of introducing the NHS-DPP on incidence rates of T2D. Incidence of T2D was analysed at least 19 months post programme, using pseudo-anonymised NDA records from individuals across England diagnosed with T2D by 31 December 2019. We compared patients enrolled in wave 1 (by 31 March 2017) and wave 2 (by 31 March 2018) to practices enrolled in wave 3 (after 1 April 2018).	NDA (T2D) NDA (NDH)

TABLE 3 Work package aims and methods (*continued*)

WP and WP aims	Research questions	Methods	Data sources
WP6: Validation sample Aims: To assess the risk of confounding in participation in NHS-DPP and allow adjustment in other WPs	6.1 To delineate the role psychological and social factors play in access ine-qualities, and identify factors potentially addressable by targeted interventions or programme modifications. 6.2 To determine the relative and overall influence of these factors on participation. 6.3 To assess the extent to which associations between referral, programme attendance, and development of diabetes are confounded with patient character-istics and to adjust the associations for those factors.	Survey questionnaire developed to collect data on a wide range of demographic, health and psychosocial factors that might influence participation in the NHS-DPP. The questionnaire was distributed to a random sample of 597 patients invited to the NHS-DPP via letter and referred to the programme across 20 practices. To be eligible, patients had to have been referred to the NHS-DPP between 3 and 15 months before recruitment to the study, and they could be at any point in their DPP course, from still waiting to start, to having completed. Univariate and multivariate regression analyses was used to identify and quantify predictors of programme participation.	WP1 qualitative interviews with patients and healthcare professionals. Survey questionnaire (n = 325 completed questionnaires and returned, 54% response rate).
WP7: Comparative long-term cost-effectiveness. Aims: To assess whether the NHS-DPP is cost-effective compared to usual care in terms of long-term costs and benefits	7.1 What are the additional costs of implementing and providing NHS-DPP to the range of commissioning agencies involved?	Additional costs of implementing and providing NHS-DPP estimated using information from the national commissioning agencies, work from WP2, contracted amounts paid to the providers and the costs to general practices of identifying, referring and following up on patients, excluding the costs that they would incur under care before the NHS-DPP.	Provider payment schedules from NHSE. Implementation costs from the 2016 Impact Assessment. WP2 Survey questionnaire NHS-DPP MDS.
	7.2 What are the short-term health benefits of NHS-DPP to participants in the scheme, and what are the cost consequences of the short-term changes in health service utilisation for partici-pants in the NHS-DPP?	Used data from programme providers to estimate the average increases in health-related quality of life reported by NHS-DPP participants. Focused initially on the short-term effects reported by participants.	NHS-DPP MDS.
	7.3 What are the expected long-term health benefit consequences of the introduction of NHS-DPP? What are the expected long-term cost consequences of the NHS-DPP?	Parameters needed for the long-term decision-analytic model for research question 7.4 were obtained from the literature.	Published literature.
	7.4 Is the overall NHS-DPP cost-effective compared to usual care?	Development of a decision-analytic model to evaluate the expected long-term cost-effectiveness of the NHS-DPP. Model inputs on cohort character-istics, costs and outcomes chosen to represent the actual delivery of the NHS-DPP in the first 4 years.	Results from WPs 4, 5 and 7.

continued

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DOI: 10.3310/MWKJ5102

TABLE 3 Work package aims and methods (*continued*)

WP and WP aims	Research questions	Methods	Data sources
WP9: Patient decision-making and experience of the NHS-DDPP **(Framework 2)** Aims: To describe and understand patterns of engagement with the DDPP, to produce recommendations on how to maximise engagement in the future	WP9.1 To describe mechanisms in place to promote patient uptake and initial use. Specifically, to describe (a) how engagement with the NHS-DPP is promoted via design features and strategies, and (b) describe participants' early engagement with the NHS-DDPP. WP9.2: To explore service user experience and patterns of engagement of the DDPP, using analysis of usage data.	Qualitative study: a secondary analysis of documents detailing the NHS-DDPP intervention design, and interviews with programme developers. Data were coded according to a framework of engagement with digital health interventions. Quantitative study: anonymous usage data, representing participants' first 30 days of use. Amount of use and engagement with intervention features were calculated for the whole cohort and differences between providers were explored.	Documentary analysis and semistructured interviews with professionals by WP3. Providers' data on engagement with the DDPP.
	WP9.3: Recommendations on patient experience of referral and how to maximise engagement with the DDPP.	To explore experiences of the process prior to referral to the DDPP, how and why patients choose to accept referral and engage, and perceptions of the advantages, disadvantages and expectations of the DDPP. Sampling for maximum variation by age, gender, ethnicity, socioeconomic status, area, provider and engagement.	Qualitative semistructured interviews with patients (n = 32).

BCTTv1, Behaviour Change Technique Taxonomy v1; CCG, Clinical Commissioning Group; GP, general practitioner; TCS, Theory Coding Scheme; TIDieR, Template for Intervention Description and Replication.
a UK Household Longitudinal Study.
b Health Survey for England.

NDH report for January 2020 to March 2021 reported that of the number of people referred to the NHS-DPP, about 62% had an NDH diagnosis code in their record, varying across CCGs, with some recording NDH in about 20% of referred cases.[24] NDH data extracted in the NDA are available from 1 January 2017; hence, NHS-DPP wave 1 referral data (1 April to 31 December 2016) are not included. The first publication of NDH data became available in July 2019. Since then NDH diagnosed prevalence increased from 2.8%[48] to 4.9% 3 years later.[24]

Like CPRD, the NDH module contains information on offers made to the NHS-DPP and whether a patient was recorded as having attended. DIPLOMA obtained a pseudonymised index to link referral data from the MDS with the NDA at person level. This allowed the linking of provider intervention data and outcomes with care processes data from primary care.

Details of the different data sets are shown in *Table 4*.

Patient and public involvement and engagement

Prior to the start of DIPLOMA, six patient and public involvement and engagement (PPIE) members – varying in age, gender, ethnicity, and with some experience of diabetes – provided feedback to the proposed programme of research. PPIE members suggested new research topics which we included in the research plans, such as confidentiality and links to GPs, choice of service, ability to cope with the risk of diabetes, the impact of wider social networks on uptake, and clarity of information provided at time of referral.

Throughout the duration of the programme, DIPLOMA recruited 10 contributors to its PPIE group, with 5 of them contributing regularly since 2020. Contributors included people at risk of T2D or with a family history of diabetes, from different backgrounds. A detailed account of the work carried out by the PPIE group, with reflections on the challenges and lessons learned, was prepared.[49] A brief summary of the reflections is provided later in this report.

During the evaluation, the group contributed to all WPs, initially by commenting on study materials, and subsequently providing feedback on the research findings and dissemination of results. In particular, the group played a very active role in the creation of dissemination materials for lay audiences by co-producing video scripts, inputting into storyboards, featuring in some of the videos, and providing feedback so that materials were appealing and understandable for the public. Materials included a video describing the research questions being explored by DIPLOMA.

TABLE 4 Data sets and their relationships

Data sets	Patient group included	Estimated number of patients [a]	Information included	Data period coverage	Issues
MDS only	Participated in the DPP, but do not have an NDH code in their primary care record	199,191 Approximately 19,033[b] DPP completers	Weight, HbA_{1c}, EQ-5D, number of sessions attended	Duration of individual's engagement with the programme, from referral to final engagement	Follow-up limited to the duration of engagement. We will not know if these individuals go on to develop T2D – unless they developed it during the programme.
MDS and NDA	Participated in the DPP, with an NDH code in their primary care record	326,565 Approximately 31,203(2) DPP completers	Weight, HbA_{1c}, EQ-5D, number of sessions attended, diagnosis of T2D	Duration of the programme NDH/T2D diagnoses up until 31 March 2020	For some of the later participants, there will not be any 'follow-up' data within the NDA (audit data only go to April 2020).
NDA only	Eligible but did not participate in the DPP (either not offered, or declined offer)	1,069,660	Diagnosis of T2D	NDH/T2D diabetes diagnoses up until 31 March 2020	
CPRD	Populations in a subset of English practices using Gold and Aurum software (approximately 7% and 13%, respectively)	–	Primary care resource use before and after DPP		Not linked to existing data sets. Relies on practice coding of NHS-DPP offer. No data on amount of engagement.

EQ-5D, EuroQol-5 Dimensions.
a Taken from the NDA/NDH Main Report 1819 (circulated to the NDA advisory group).
b Number of completers – assumed the same proportion across both groups (50,237 completers out of 525,726 referrals in the MDS – 9.6%), and took this percentage from the estimated number according to the NDA/NDH main report.

Three more videos described findings from the WPs on access, participant experience, and the importance of BCTs. These have been disseminated via social media channels. These resources are listed in the *Additional information* section of the report and are also available via the DIPLOMA NIHR Journals Library page.

Separate to the PPIE group, two lay members were recruited to our SSC alongside clinicians and researchers who provided programme oversight on behalf of the funder.

Discussion

Synthesis of combined findings

The DIPLOMA programme was designed to provide a comprehensive assessment of the delivery of the NHS-DPP and DDPP, with respect to access and equity (WP1, WP6 and WP9), organisation and delivery (WP2 and WP3), and effectiveness and cost-effectiveness (WP4, WP5 and WP7). The following sections give an overview of the main findings and the links to published papers, following the schema in *Figure 3*.

Access, equity and engagement (WPs 1, 6 and 9)

We used quantitative methods to understand the types of patients entering the various stages of the NHS-DPP from the wider population with NDH in the community.[50] We also analysed the NHS-DPP MDS to explore links between personal characteristics and participation in the programme.[51] We supplemented this analysis of national surveys and administrative data with our own survey of factors influencing participation.[52] In addition, we undertook detailed qualitative research to explore that journey.[53,54]

Although data from the NHS-DPP are very useful, they only allow exploration of the patient journey among those who actually engage with the programme. Our unique contribution was to use existing population cohorts (the UK Household Longitudinal Study and Health Survey for England) to map the cohorts within each stage of the NHS-DPP to the underlying population living with NDH in the wider community.[50] This enabled us to identify whether patients at different stages of the pathway are representative of the underlying population with NDH. We found that prevalence of NDH in the community was higher in older people, those reporting a disability and those living in areas of higher deprivation. We then found that younger (< 40 years) and older (80+ years) adults were less likely to participate in the NHS-DPP, as were those with disabilities and those living in more deprived areas, whereas ethnic minority patients were more likely to do so. Importantly, the high rates of involvement of ethnic minority patients fell away among those who completed the programme, although the rates were still higher than in the general population.

There was concern that the NHS-DPP may not have addressed the pre-existing inequalities in the burden of T2D across sociodemographic groups. Diagnosis of NDH has increased since the start of the DPP, but there was limited information on inequalities in whether an individual is detected as having NDH prior to developing T2D. Early diagnosis of NDH is important so that: patients are informed about their risk of developing T2D; there is an opportunity to prevent or delay T2D with interventions (including referral to the DPP); and patients can be monitored to minimise secondary health problems linked to uncontrolled T2D. Therefore, we used the unique opportunities created by the linked NDA datasets to examine sociodemographic inequalities in the diagnosis of NDH before the onset of diabetes.[55] We found that younger people and people living in more deprived areas who were newly diagnosed with T2D had lower odds of having had a prior diagnosis of NDH, higher HbA_{1c} at T2D diagnosis, and shorter duration of NDH among those who did receive a NDH diagnosis. More active NDH case-finding among younger age groups and people living in more deprived areas would increase opportunities for T2D prevention or delay and may help reduce inequalities in T2D incidence.

We undertook our own survey to provide a richer assessment of factors associated with decisions to participate in the NHS-DPP.[52] This showed that demographic and health factors were less significant in decision-making than psychological factors: beliefs about vulnerability to T2D and its consequences, belief in the ability to carry out and sustain behaviours necessary to reduce this risk, and confidence in the NHS-DPP to provide the understanding and skills required. The results also raised the possibility that psychosocial factors may account for the differences in uptake between demographic groups. These findings provide a useful set of targets for health messaging to enhance participation. Several of these factors were also found to be relevant in decisions about the DDPP, combined with perceptions of the advantages of the digital service in terms of access and convenience.[52]

We used qualitative research methods to provide the most detailed data on the process of accessing the NHS-DPP.

The scale and required reach of the NHS-DPP meant that high-volume, passive methods (e.g. mass mailing from practices) were a focus. Although such methods did provide a suitable flow of participants, there may have been an assumption that concepts such as 'NDH' are understood and accepted. In contrast, interviews and observations highlighted that the label and the assumptions about risk were potentially problematic,[53] findings replicated in the study of the DDPP participants.[56] That may have reduced the impact of passive recruitment methods. Although discussions with healthcare staff provided a platform for exploration of those issues, staff were not always well informed about the programme, and clearly such discussions have opportunity costs in a healthcare system under pressure. Furthermore, professionals evidenced ambivalence about the importance of NDH in groups such as older patients,[54] reflecting tensions between programme aims and concerns about risk/benefit in particular groups of patients.

Organisation and delivery (WP 2)

Our work on organisation and delivery initially focused on the experiences of local commissioning staff in NHS-DPP delivery.[57] Respondents highlighted the tension between the need to generate referrals to the programme and the need to avoid potential inequalities in the types of practices and patients who responded.

We also analysed data on variations in referral rates between general practices, especially whether they were linked to the well-established variations in access, resourcing and quality of clinical care. We found that referrals to the NHS-DPP were higher among general practices already reporting higher quality of care, suggesting that selection into the programme was driven in part by service rather than patient factors.[58] Relationships with access and resourcing were not so evident. We also explored the role of incentives provided to practices in increasing referral rates and found that offering payment for outcomes (patients participating in the programme) was more effective than offering payment based on process (e.g. sending out more invitations).[59]

We recommended that future implementation should: specify clear responsibilities for each actor in the system; encourage early engagement with new providers; provide forums for sharing learning; generate evidence and provide advice on incentive payments; and prioritise public and professional awareness of the programme. Our later interviews exploring the longer-term implementation of Framework 2 highlighted the importance of having a facilitation role to support implementation, as a mechanism to support practice engagement.[60]

Fidelity (WP 3)

The aim of the NHS-DPP is to support individuals to make lasting changes to their behaviour (e.g. improved diet and increased physical activity) to promote weight loss and thereby reduce T2D risk. The evidence base has suggested key intervention content which should be included in these programmes to help individuals reduce their risk of T2D,[10] and it is therefore important that the NHS-DPP retains fidelity to this evidence and theoretical base. A leading framework for assessing intervention fidelity is proposed by the National Institutes of Health Behavior Change Consortium (NIH-BCC).[61] Examinations of fidelity of national programmes such as NHS-DPP are rare but important – the NHS-DPP needs to deliver enduring behaviour change through multiple external providers using their own staff and systems.

We conducted a thorough assessment of intervention fidelity using the NIH-BCC framework[61] (*Figure 4*). We developed a detailed understanding of the proposed design of NHS-DPP and mapped that against what providers actually delivered. This included how providers intended to deliver the NHS-DPP (i.e. their own design blueprints), how they trained their staff, and what was actually provided across England as the programme was implemented. Our assessment has been summarised[62] and we outline the key findings below.

Fidelity of design Using standardised published frameworks, including Michie and Prestwich's Theory Coding Scheme,[63] the TIDieR framework[64] and BCTTv1,[38] we collected detailed information on programme content and how that mapped to the NHS-DPP specification.[65] We identified some important areas where there was potential loss of fidelity. Providers generally exhibited fidelity of design of service parameters (duration, frequency and group composition),[66] but the programme had no explicit logic model linking pathways between intervention content and outcomes,[65] resulting in issues in fidelity around important BCTs.[39] Clearly, gaps at such an early stage (see *Figure 4*) have potential for more significant 'downstream' influence on delivery.

Fidelity of staff training Observations of training courses for provider staff found gaps in coverage of a significant number of BCTs and a focus on instruction rather than more in-depth training of BCTs (e.g. modelling or practice).[67]

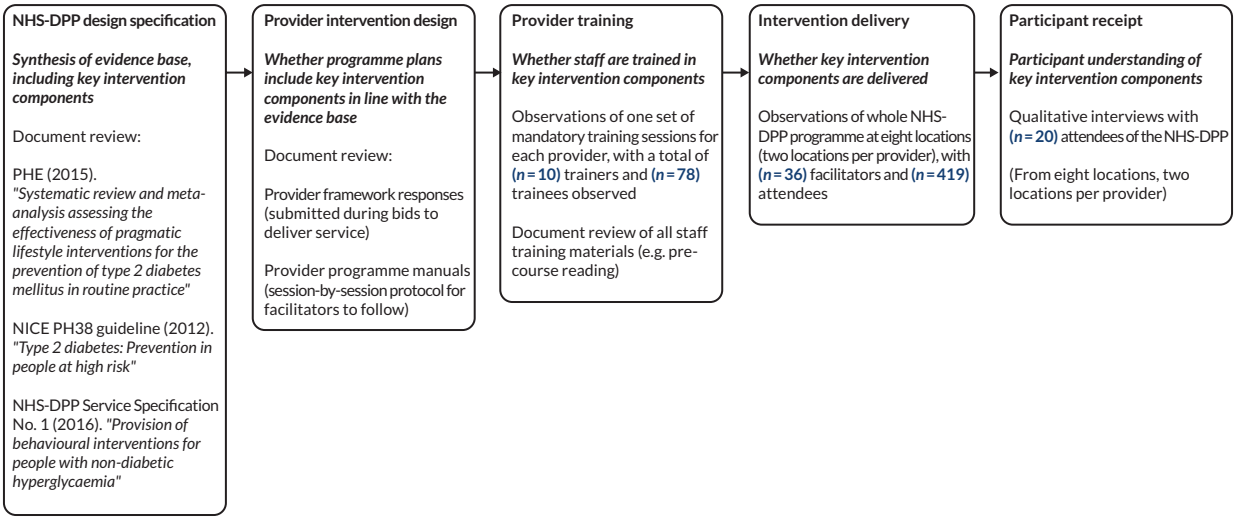

FIGURE 4 Schematic showing aspects of intervention fidelity assessed in the NHS-DPP.

Fidelity of delivery During observations of session delivery across all four providers, we found that delivery mapped better to their own plans than the NHS-DPP programme specification (as might be expected), and that there was again a selective focus on some BCTs that are easier to deliver (e.g. providing information) and less on self-regulatory BCTs (e.g. problem-solving).[68] When self-regulatory BCTs were delivered, there was room for improvement compared to current best practice.[69]

Fidelity of receipt and enactment Some of these issues were then reflected in the understanding of behaviour change in course participants. For example, there was a wide variation in understanding of BCTs across patients, particularly 'problem-solving' and 'goal-setting'.[70]

The findings on fidelity of the DDPP were largely similar,[71,72] although there was some evidence that fidelity was improved, likely reflecting both early findings from DIPLOMA and the amenability of digital delivery to greater standardisation. It was notable that digital partners reported adapting existing interventions for the DDPP rather than developing new interventions, which makes the lack of explicit logic models more problematic as they therefore lack a clear guide on what to include.[73] We did identify wide variation in structural features of delivery of the digital programme, particularly for the delivery of health coach support across providers (e.g. the use, dose and scheduling of support).[73,74] However, participants reported the health coach role to be crucial for providing emotional support, accountability and understanding of some key BCTs.[73] Support from health coaches delivering the digital programme was also associated with user engagement with key programme features such as self-monitoring, goal-setting and peer-to-peer group chats,[75,76] suggesting the importance of retaining a human element in digital behaviour change programmes.

Effectiveness and efficiency (WPs 4, 5 and 7)

We examined the effectiveness of the NHS-DPP in various ways (*Table 5*). We reported that uptake among adults referred to the programme was 56%, and that 34% achieved the required dose and 22% completed the full course.[51]

As well as showing that completing the NHS-DPP was associated with improved outcomes, the analyses also highlighted important variation across providers in their ability to ensure uptake and retention and factors (e.g. out-of-hours provision) which were associated with better performance in that regard.[51] We also identified differences in intermediate outcomes across providers, which remained after adjustment for differences in case mix.[77]

After initial analyses of changes over time in the rates of conversion from NDH to T2D before NHS-DPP was implemented (between 2010 and 2015),[6] we compared outcomes for 18,470 patients referred to NHS-DPP matched to 51,331 patients not referred to NHS-DPP in the CPRD data set and found that the probability of not converting to T2D 36 months after referral was 87.3% (95% CI 86.5% to 88.2%) for those referred and 84.6% (95% CI 83.9% to 85.4%) for those not referred. These reduced odds of converting to T2D remained significant after adjustment for covariates, with an adjusted HR of 0.80 (95% CI 0.73 to 0.87) for those referred to the NHS-DPP compared to those not referred.[78]

TABLE 5 Effectiveness estimates and analyses designs in DIPLOMA

Work package	Design	Estimate	Notes
WP4 Outcomes	Multivariable regression using MDS	What is the association between NHS-DPP uptake and short-term outcomes? What factors moderate the association between NHS-DPP uptake and outcomes?	Outcomes restricted to patients with complete data
WP5 Comparative effectiveness	Matched controlled before-and-after design using CPRD	What is the effect of the offer of the NHS-DPP on incidence of diabetes in patients in practices referring to the NHS-DPP, compared to a matched group of patients in practices not referring to the NHS-DPP?	Data restricted to those practices within CPRD
WP7 Cost-effectiveness	Difference-in-differences analysis using NDA	What is the effect of access to the NHS-DPP on incidence of diabetes in practices in areas with the NHS-DPP, compared to practices in areas without the DPP (controlling for a range of other factors)?	

We also estimated the population-level impact of the NHS-DPP by comparing diabetes incidence in practices in different waves of NHS-DPP implementation. Diabetes incidence rates in wave 1 practices were significantly lower (IRR = 0.938, 95% CI 0.905 to 0.972) than in wave 2 practices in 2018–9, and incidence rates were significantly lower in wave 2 practices than in wave 3 practices in 2019 (IRR = 0.927, 95% CI 0.885 to 0.972).[79] The results of the primary analyses from these two papers were robust across a wide range of sensitivity analyses.

In addition, using the linked MDS and NDA data, we examined the relationship between the level of attendance at the programme and the risk of progression to T2D.[80] We analysed data for 51,803 individuals that were referred to the programme between 1 June 2016 and 31 March 2018 and attended at least one programme session. We used survival analysis to examine whether there was a dose–response relationship between the number of programme sessions attended and risk of progression to T2D by 31 March 2020. The risk of developing T2D declined significantly for individuals attending 7 of the 13 programme sessions and continued to decline further up to 12 sessions. Attending the full 13 sessions was associated with a 45.5% lower risk (adjusted HR: 0.55, 95% CI 0.46 to 0.65). We therefore recommended that commissioners may wish to consider altering provider payment schedules to incentivise higher retention levels beyond the existing threshold set for programme 'completion' (60% of sessions).

Although a randomised comparison of face-to-face and DDPP would have been timely, a variety of factors mitigated against that. Instead, we used data from the DDPP pilot and the DPP MDS to explore the non-inferiority of the digital programme compared to face-to-face delivery.[81,82] This suggested that the effects were broadly comparable, and particularly good when patients were offered a choice of digital or face-to-face.

We then considered whether the NHS-DPP offered good value for money by analysing the cost-effectiveness of the NHS-DPP in both the short and the long term.

Our short-term cost-effectiveness analyses examined the costs and benefits of the NHS-DPP that occurred within the period when people were participating in the programme. We used estimates of the implementation and support funding for the programme and detailed information on the payments made to programme providers to cost the programme. We compared these to the estimated health-related quality-of-life gains that participants experienced based on how changes in EQ-5D scores during the programme were predicted by levels of session attendance and changes in weight. The estimates of cost per QALY generated by the programme were within the currently accepted willingness-to-pay threshold used by NICE (£20,000–£30,000 per QALY). The programme was also delivering more QALY benefit at lower cost than that predicted by the initial impact assessment for the NHS-DPP.[83]

It is important to note that this involves comparing all of the front-loaded costs of programme delivery to only the within-programme benefits of attending the NHS-DPP, and takes no account of reductions in the risk of incidence of T2D over the longer term that were found in the analyses of the individual and population-level impact of the NHS-DPP. Therefore, we then developed a decision-analytic model to investigate the cost-effectiveness of the NHS-DPP in the long term.

Several long-term cost-effectiveness models for DPPs have previously been published, so we focused on making

this analysis as programme-specific as possible. We tailored our model to the NHS-DPP in the following ways:

- Rather than assumed costs, we used information on the actual payments made to providers to represent the costs to commissioners of delivering the programme.
- We used the estimate of effectiveness in reducing diabetes incidence from WP5.
- In our main analysis, which we designed to be conservative, we assumed that the reduction in diabetes incidence only lasted for the 3 years we had analysed in CPRD. We then extended this assumption in sensitivity analysis.
- We included the estimates of short-term gains in health-related quality of life observed during programme participation.
- We modelled a synthetic cohort that had the same age profile as the referrals made to the NHS-DPP by April 2020.

Among a cohort of 1000 referrals, we estimated that over a 35-year period the NHS-DPP would reduce NHS costs by £45,134 and generate 34 QALYs, compared to usual care. Scaled to the 526,283 referrals received by 31 March 2020, we estimate that the first 4 years of the NHS-DPP will generate 17,920 additional QALYs and reduce NHS costs by £23.8M (at 2020 prices) over the next 35 years.[84]

All the elements included in the model are sampled from distributions to reflect that they are uncertain, so we ran the model 1000 times to measure how certain we could be that the NHS-DPP was cost-effective. In 99% of simulations, the NHS-DPP had an estimated cost per QALY below the accepted willingness-to-pay threshold and would therefore be deemed cost-effective. We also tested the sensitivity of these results to some key assumptions on duration of effect, costs in each health state, and probabilities of diabetes incidence, and the conclusion of long-term cost-effectiveness was shown to be robust.

DIPLOMA results in the context of the wider literature

Using the same data source, another group have recently examined the effectiveness of the programme in reducing recorded HbA_{1c}.[85] They focused on the subset of patients with HbA_{1c} values recorded in primary care in 2017 or 2018 and followed them up to March 2020. They compared patients just below and just above the HbA_{1c} thresholds recommended for referral to the programme and showed that patients just above the threshold had latest recorded HbA_{1c} values that were −0.10 mmol/mol (95% CI −0.16 to −0.03) lower than those just below the threshold. Unlike our study, however, they found that patients with recorded baseline HbA_{1c} values above the referral threshold value were more likely to develop T2D, suggesting more vigilant monitoring among this group.

The NHS-DPP was designed in part based on the results of the PHE systematic review. It could be argued that DIPLOMA sought to determine whether the positive impacts demonstrated in that review (and subsequent trials) could be delivered in routine NHS settings, and to explore how issues of access, fidelity and adherence may have attenuated those impacts when implemented at scale. Theoretically, such attenuation is not unexpected. Models in implementation science have suggested that two key impacts from large-scale translation into routine care are 'voltage drop' (reductions in effectiveness associated with moves from efficacy trials through to implementation, via mechanisms such as less control over patient selection and treatment delivery) and 'programme drift' (reductions in effectiveness via mechanisms such as changes in treatment delivery across different contexts and with a wider range of providers).[86] The NIH-BCC framework that guided the fidelity analysis in DIPLOMA only considers adaptation to a limited extent, although implementation science now recommends reporting adaptation alongside fidelity.[87] For example, when interventions are translated into routine care, adaptations to the intervention should be documented and considered as to whether they still adhere to the original intervention components, to avoid a 'drift' from the intended core elements of the intervention. Documenting such adaptations allows the impact of these to be evaluated.[88]

Our analyses of effectiveness suggest the NHS-DPP has reduced conversion to T2D, but that the effects are smaller than those found in RCTs (*Table 6*).

Below we describe the main reasons which might explain attenuation of effects.

Design

The published reviews and the Norfolk study are largely based on randomised trials. In our analysis we used real-world data and a variety of methods to match practices and patients to ensure comparison of like with like. Results from randomised trials have high internal validity (if they are well conducted) but potentially limited external validity, especially if the participants are selected and the effects of the intervention are expected to vary across populations. Results from observational studies based on real-world participants potentially have better external validity, but their internal

TABLE 6 Comparative effectiveness

WP5	Estimate (95% CI)	Wider literature	Estimate (95% CI)
Analyses of CPRD HR	0.80 (0.73 to 0.87)	Ashra *et al.*[10] review IRR	0.74 (0.58 to 0.93)
		Gillies *et al.*[89] review HR	0.51 (0.44 to 0.60)
		Hemmingsen *et al.*[20] review HR	0.57 (0.5 to 0.64)
		Sampson *et al.*[16] trial HR	0.53 (0.35 to 0.81)

validity is threatened by the possibility of unmeasured confounding. These fundamental differences in design should be taken into account when results are compared. The randomised trial effect sizes may be larger if they are estimated on participants selected to be most likely to benefit from the intervention and to complete the trial and its requirements. We would expect unmeasured confounding of our effectiveness analysis to bias the estimated effects of intervention upwards, because the probability of participating in the programme is higher in lower-risk populations.

Uptake and adherence

A second difference relates to the type of estimate. Both the trials and our matched analysis estimate the effects of the 'offer' of an intervention, as the trials generally use intention-to-treat analyses. Both designs are likely to demonstrate less than optimal uptake and adherence. Although in principle the different designs are estimating the same effect of an 'offer', in reality the rates of uptake and adherence in trials will be higher than studies in routine delivery. Extracting data from the trials in the published reviews is problematic as reporting was variable. Bhopal reported that visits were 'mostly completed as planned for participants' (mean number of visits 13.7/15),[90] Ma found a mean of 75% visits attended,[91] Ockene reported a median of 8/13 (62%) sessions[92] and Davies included 77% of attenders when they conducted per-protocol analyses.[17] By contrast, of the 419,055 offers recorded as not being declined, 44% had a corresponding referral in the MDS data set. Therefore, although both represent the effects of 'offers' of intervention rather than the effects of the intervention per se, the underlying ratio of offer to uptake was different. As we have identified in our analyses of dose response, the data show that attending more sessions is associated with reduced risk of diabetes onset.[80]

Population risk

We compared the characteristics of patients in the Norfolk diabetes study[16] with those in the CPRD sample. On some characteristics, there was broad comparability, including age (mean 65.3 years for Norfolk and 61.9 years for WP5) and BMI (31.2 kg/m^2 for Norfolk and 30.8 kg/m^2 for WP5). However, due to the differing selection criteria into the trial, the baseline levels of risk are very different. For example, in a 24-month follow-up within the Norfolk study, 22.8% in the control group progressed to T2D, compared with 15.4% in the 36-month follow-up in CPRD. To the degree that interventions are likely to show greater comparative benefits in populations at greater baseline risk, the population recruited to the Norfolk study had greater capacity to benefit.

Fidelity

Fidelity was assessed in detail in WP3, and showed some significant changes which might lead to 'voltage drop' and 'programme drift' (especially in the early stages of the roll-out before these issues were identified).[86] Although there was an assessment of fidelity in the Norfolk study, it has not been reported in a way that facilitates comparison. Nevertheless, the expectation would be that delivery in a trial setting using a single group of providers would have been less vulnerable to loss of fidelity than a national programme delivered through four external providers.

In summary, there is evidence that the effects of the NHS-DPP identified through DIPLOMA show less comparative effectiveness than that reported in the reviews on which it was based and subsequent trials. To the degree that those differences represent real loss of potency and not simply differences in analysis, there is evidence that the NHS-DPP was dealing with a lower-risk group and delivered a lower dose of intervention in terms of both uptake and adherence, and the quality of the content.

We are not able to estimate the relative importance of those effects, although a more important issue may be their amenability to change. Fidelity of delivery is the mechanism most amenable to change by the NHS-DPP, as delivering improved uptake and adherence would by necessity need to be mediated through participant behaviour during invitation in primary care. However, issues of uptake and adherence may show the greatest capacity for improvement. Raising thresholds for entry to NHS-DPP might select a group at higher risk where the benefits of intervention would be more profound but would prioritise comparative effectiveness over population impact.

Implications and recommendations for decision-makers and practice

We have conducted a comprehensive assessment of the NHS-DPP and outline the main implications.

Overall, the programme is effective and cost-effective, based on a variety of analyses using a range of designs and sources of data. This supports ongoing commissioning of the programme, as it has shown that behaviour change programmes for T2D prevention can be delivered at scale.

The question as to whether the programme should be expanded in terms of capacity is a wider one which cannot be answered by data from DIPLOMA alone, as it would need to consider both whether the benefits will be found in a larger group of patients who may differ in their characteristics, and whether there are alternative options (of a similar nature to NHS-DPP, or 'upstream' interventions) which might be a more effective use of funding.

In terms of the delivery of the current NHS-DPP, the papers summarised earlier have flagged issues of recruitment, delivery and retention that may be reducing its potential impact.

Although in principle recruitment through general practice is a strong platform for equitable access, we found evidence that it may also perpetuate some inequalities due to differential performance among practices.[58] In practices with lower quality of care, non-financial support mechanisms may be required, alongside alternative methods of referral such as self-referral. Our findings also highlight the importance of the referral process in encouraging uptake. To overcome reported problems (lost letters, referrals not being passed to providers and delays in responses), follow-ups and repeat offers of referral could be tested. This may provide opportunities for participants at times when they may feel more ready to engage.[56] Education for health professionals tasked with referring participants to the NHS-DPP needs to ensure familiarity with all delivery modes and to enhance communication about the programme goals and content, although that would depend on levels of knowledge of diabetes risk among generalist staff. A more complex issue is ensuring adequate discussion about pre-diabetes and T2D risk at diagnosis and when offering NHS-DPP. This would increase patient knowledge about disease severity, emphasise the preventable nature of T2D and challenge mistaken beliefs about diabetes risk and ability to reduce risk.[56]

Some changes are under more direct control of the NHS-DPP team. These would include improving aspects of fidelity (and reducing provider variation) by tighter specification of delivery and attention to BCTs and logic models. Large-scale programmes such as the NHS-DPP could benefit from commissioners providing a logic model from the outset to guide providers. The NHS-DPP now includes the DIPLOMA logic model in its commissioning documents, and providers are required to justify inclusion of specific BCTs in their bids submitted to NHSE. Feedback from DIPLOMA led to changes that may have increased effectiveness, such as increased involvement of behaviour change specialists in the procurement of Framework 2. Equally, the finding that flexible service provision, such as out-of-hours sessions, may improve retention rates could be reasonably easily actioned. In the DDPP, our findings suggested that accountability and monitoring affected participants' early experiences and encouraged uptake and engagement. Although we presented evidence that coaching is appreciated by patients, it remains unclear whether that is most cost-effectively done via coaching or through automated monitoring systems.[56]

Given the focus of the NHS-DPP, there are many potential roles for behaviour change specialists during all stages of programme implementation. This could include training provider staff to ensure an in-depth understanding of BCTs and supporting ongoing practice and delivery. There is also a need to ensure provider organisations deliver BCTs that promote self-regulation of behaviours, with the necessary support for participants to understand them. It is not appropriate to assume that passive receipt of a BCT means a person will be able to enact it in everyday life. Our analysis also confirms that understanding and enactment of key BCT content (e.g. problem-solving, goal-setting, reviewing goals, feedback on behaviour) is enhanced by support in both the face-to-face setting and DDPPs.

We identified concerns among participants about lack of feedback on T2D risk.[70] The requirement for providers to conduct blood tests to assess T2D risk in Framework 1 has evolved to directing participants towards a blood test from their GP in Framework 2. This could potentially impact upon their motivation for maintenance of behaviour change, and the data would suggest a need to consider options for providing a clearer route to access such feedback (including intermittent or continuous blood glucose monitoring).

Recommendations for future research

Many of our findings highlight the need for further research, and these are detailed in the published papers. Below we highlight some key priorities for future research.

Our findings highlight several mechanisms which could be targeted to impact on recruitment and retention, such as improved incorporation of psychosocial factors relating to T2D risk and its mitigation within NHS-DPP processes and materials. Many potential mechanisms could be subject to randomised or other comparative evaluation *within* the existing programme to explore effects on uptake across sociodemographic subgroups. Financial incentives were introduced for practices to encourage the recruitment of patients with certain characteristics after the DIPLOMA study period, and research is needed to assess their impact on recruitment and retention to the NHS-DPP. Further research is also needed to understand decisions to stop attending prevention services, particularly in relation to health inequalities.

Although we conducted a comprehensive assessment of fidelity, a robust assessment of the link between fidelity and outcomes was not possible. WP3 provided granular assessments of fidelity of the different providers, but these were either at provider level or based on a small sample of courses. Any linkage could not provide a robust assessment of the relationships. Future research could link usage of the DDPP to outcomes, to strengthen the evidence base on which programme features are linked to improved outcomes. As it stands, the MDS contains only limited indicators of fidelity (provider and trainer name and qualifications).

Detailed assessments of the actual delivery of BCTs were only undertaken in relation to goal-setting.[69] Future research could also utilise a similar framework to evaluate goal-setting delivery in other health behaviour change programmes delivered in routine practice, or indeed other key BCTs which evidence suggests are effective in changing behaviour (e.g. self-monitoring). Equally, research could explore whether specific demographic characteristics of participants or courses (e.g. individual or group) influence effective receipt of BCTs.[93]

Although our analyses provided evidence of the comparability of digital and face-to-face delivery, future research is warranted comparing the effectiveness of digital and face-to-face delivery of DPPs in the total referred population, rather than, as our data allowed, in participants. Research is also needed to compare dropout rates and achieved dose levels between digital and face-to-face delivery to further understanding of the potential for reducing health inequality.

Although our population-level analyses showed an impact on T2D incidence, it is not clear at this time whether NHS-DPP prevents or delays T2D, as the longest-duration data available are not sufficient to test this. Future research should address this question when longer-term follow-up data become available.

Finally, although the NHS-DPP has demonstrated the viability of prevention at scale using 'downstream' behaviour change, there will be interest in both comparing the relative impact of 'upstream' versus 'downstream' approaches and exploring potential synergies between them.

Now all practices have access to the DPP, the potential for rigorous comparative analyses at population level against non-participating practices is reduced. As a general point, there may be a shift to comparative evaluations (which may be randomised) to support decisions about specific aspects of the NHS-DPP beyond general effectiveness, including interventions to enhance retention among participants in the DPP and DDPP, optimal levels of coach support in the DDPP, and the effects of higher-level interventions such as incentives. The current NHS-DPP has demonstrated a commitment to evaluation and routine data collection which provides the important substrate for a 'learning health system', but moving towards adoption of such a system would require a step change in agility from both research and implementation.

Reflections

Engagement with partners and stakeholders

Throughout DIPLOMA we established mechanisms to provide feedback to the NHS-DPP management team on the delivery and outcomes of the programme that could support programme development and quality improvement (*Table 7*).

TABLE 7 Processes to maximise engagement and impact

Due to team sizes, we used a single point of contact (NHS-DPP director and DIPLOMA project manager).
Two to three meetings per year to report specific progress and resolve data issues, including an annual meeting where larger teams met to discuss progress, plans and challenges.
Sharing of preliminary findings ahead of peer-review publication for timely feedback. In the initial years of DIPLOMA, preliminary results were complemented with executive summaries of findings and recommendations, prior to peer-review publication. Findings were also presented to the NHS-DPP Expert Reference Group.
Collection of feedback on the impact of DIPLOMA on policy, practice, patients and the public, using an agreed template.
DIPLOMA researchers co-delivered workshops with providers, including webinars for Integrated Care System and CCG leads.
Agreement to share all dissemination work with the NHS-DPP ahead of publication.
DIPLOMA invited the NHS-DPP team to share their views on the impact from the evaluation at a DIPLOMA symposium at the Diabetes UK Conference, and at a dissemination event organised by DIPLOMA.

Engagement from the NHS-DPP team provided context on the issues driving changes in the programme, as well as access to stakeholders (commissioners, providers, NHS Digital), support with data access, and feedback on methods and findings. The NHS-DPP Expert Reference Group also provided valuable methodological input. The NHS-DPP team had their own experienced team of analysts, academic expertise of their own, and some advantages in terms of rapidity of data access. There was not always agreement over issues such as definitions of concepts such as 'uptake'.

Although DIPLOMA was an independent evaluation, close working was required in many cases to properly understand the operation of the NHS-DPP and changes that might impact on the evaluation. In the 6 years of DIPLOMA, we adopted a range of working models.

- Our analyses within WP3 began as independent, but their impact was such that rapid feedback led to eventual adoption of WP3 staff into the procurement process.
- For the analyses of effectiveness, where it could be argued that the need for independence was greatest, we developed our approach independently as far as possible, using the SSC as a key mechanism. However, even in this context, there was a need to use the NHS-DPP team for their expertise in terms of the programme and the meaning of data, and to ensure that the NHS-DPP team were aware of our approach and were in a position to comment (although not to demand change).
- There were aspects of the evaluation which were shared (e.g. the analyses of the within-programme outcomes in WP4). This could be problematic as the NHS-DPP had more rapid access to the data, which reduced the potential for impact from DIPLOMA. Although independent analyses in these cases were still useful as a robustness check and to protect against possible publication bias, such an approach is potentially inefficient.
- Due to this experience, our comparative evaluation of the DPP and DDPP was done using a closer model of collaboration (as agreed with the SSC and NIHR).

Real-world impact

Early feedback from the NHS-DPP team has indicated a number of real-world impacts:

- The WP2 recommendations supported the establishment of a National Diabetes Prevention Week, as well as changes to performance reports and key performance indicators for NHS-DPP, and also fed into discussions about incentives. To share knowledge across sites, the NHS-DPP used workshops to encourage collaborative working across sites.
- Work from WP3 informed the new Provider Framework specification. As reported by an NHS-DPP lead, 'having a subject matter expert who was familiar with the programme to support in assessing the bids was invaluable and certainly played a key role in ensuring that we assessed providers rigorously against the criteria'.
- In 2019 the NHS Long Term Plan extended the initial *Five Year Forward View* commitment to fund the NHS-DPP from 2019 for 5 more years.[3] In 2022, NHSE recommissioned a new round of the NHS-DPP under the Framework 3 specification, which will extend the service until 2025. The evaluation work from DIPLOMA has shown that the NHS-DPP is helping individuals completing the programme to reduce their risk in the short term, supporting recommissioning. On the recent publication showing 20% reduction

of the risk in developing T2D by taking part in the NHS-DPP,[78] the Secretary of State and NHS National Clinical Director for diabetes and obesity commented publicly on the results.
- In response to our finding that digital delivery was non-inferior to face-to-face delivery (alongside other evidence), patients starting the NHS-DPP have been offered a choice of face-to-face group-based delivery or digital delivery since 2022.

Collaborations/further funding/future work

The broad approach to the mixed-methods evaluation used in the DIPLOMA evaluation informed the funded evaluation of the Re-Mission Low Calorie Team (where PB chairs their SSC) and the methods used in the Social Prescribing national evaluation. Members of the DIPLOMA team subsequently won NIHR funding [HeLP Diabetes – Long-term Independent National Evaluation (HED-LINE) project] to evaluate the NHS Healthy Living programme. SC has presented to the team developing an Irish DPP, and SC and PB presented their experience of DIPLOMA to the Department of Health and Social Care evaluation group.

Researchers from WP3 (DF, EC) worked with NHSE in 2018 to evaluate the framework response bids for Framework 2. Building on this, researchers from WP3 (DF, RH, LM) subsequently worked with Solutions for Public Health and NHSE in June 2021 to revise the wording of the NHS programme specification and ensure key behaviour change content was included for the Framework 3 specification, based on results from the WP3 fidelity evaluation. This included the requirement for reporting of clear underpinning theory in providers' programmes. In December 2021, RH and LM sat on panels evaluating the framework response bids submitted by providers for the commissioning of Framework 3.

RH has independently worked alongside researchers on the NIHR-funded evaluation of the NHS Low-Calorie Diet Programme, where the Re-Mission team adapted the methods used to assess fidelity in DIPLOMA WP3. This resulted in the co-authorship of publications.[94,95]

DF and RH were invited to contribute to a review paper for the *Diabetic Medicine* journal, alongside five other authors leading in the field, to identify the current research gaps in behavioural science relating to T2D prevention, commissioned by Diabetes UK (DF lead author).

The DIPLOMA, HED-LINE and Re-Mission research teams have since consolidated findings from these three national policy evaluations and produced actionable insights via a dissemination event in May 2023 on structured education for T2D prevention and self-management, led by SC.

Challenges faced/limitations

Our published papers provide a fuller assessment of the limitations of individual studies within DIPLOMA, and our earlier description of future research priorities outlines research that was not possible within our funding. In terms of wider issues, our experience on a related project (HED-LINE) suggests that interviews with the NHS-DPP team could have been included, to explore strategic decision-making in the delivery of the programme (which was often shared informally in meetings but not actively captured for research).

DIPLOMA was a large and complex research programme designed to evaluate an existing (and evolving) intervention over a significant period of time (2016–23). This inevitably led to changes to the planned programme of work in response to developments in the NHS-DPP, changing access to data, and ongoing challenges of evaluation. Although we are confident that we delivered the bulk of the planned work, below we describe changes from our original plans.

For WP2 we had anticipated more active implementation in general practice and planned to explore this with relevant theory. However, practice-level strategies and processes were bypassed in favour of area-level implementation, partly to avoid additional burden on general practice. We responded by deploying a thematic analysis, and this enabled us to feed back timely insights to the national delivery team.

We planned to interview people eligible for the NHS-DPP but not referred, but this proved difficult as GPs did not have accurate information on those who had not been referred. In WP4 we had planned to match individual patient data from the MDS to service-level data from providers in different areas, but the data collected on providers were largely qualitative and from a restricted cohort, which reduced the utility of the analyses. We envisaged analysing additional outcomes of patients in the NHS-DPP, including well-being, weight change, HbA_{1c}, and mortality, but these were very poorly recorded in the MDS and analysis was not feasible.

We had proposed using an interrupted time-series design to quantify the overall effect of the introduction of the NHS-DPP on the prevalence and incidence of NDH (overall

and regionally), but instead we restricted the analysis of trends to the pre-NHS-DPP period[6] and concentrated our analytical resources on the stronger comparative cohort design[78] and a population-level analysis based on the phased roll-out of the programme.[79] We originally proposed reporting effects on service utilisation as secondary outcomes, but it was not possible to link the MDS and NDA to other data sets and we instead used published estimates on service utilisation in our model of long-term cost-effectiveness.

In the extension to the DIPLOMA work, our original plan was to extend the methods in the original DIPLOMA analyses, to provide longer-term follow-up on conversion rates for the participants in the original framework as well as providing new evidence on conversion rates and outcomes for participants in the face-to-face and digital versions of the new framework. This did not prove feasible, as we could not access sufficient data on long-term outcomes for the Framework 2 cohort by the time DIPLOMA finished in March 2023. Our assessment is that there have been no major changes in the programme or in the characteristics of the population being referred in the new framework that are likely to have a major impact on the estimates we have described above. Furthermore, one of the major changes between frameworks has been the introduction of the digital option, and our analyses have reported broad equivalence between face-to-face and digital delivery, such that the introduction of the digital option is unlikely to have had a substantial effect on overall cost-effectiveness. All digital options are facilitated, and therefore cost differences between group face-to-face and digital delivery many not be marked.

We also took advantage of new opportunities that arose through access to data, including analyses of how the effectiveness of the DPP varied by levels of participation and exploring the impact of different incentive schemes.

The DIPLOMA programme was able to benefit from access to significant data resources (e.g. MDS/NDA, which was not anticipated at the inception of the project) as well as support from the NHS-DPP and NIHR Clinical Research Network to recruit providers and patients for data collection. Nevertheless, we highlight some data access issues that were encountered. It took over 18 months to negotiate a data processing agreement with NHSE giving access to the MDS data (far longer than planned), which restricted time for analysis and meant that we were often producing results based on information that had already been superseded. Honorary contracts with NHS institutions have accelerated data access for researchers in other situations.

Our work on Framework 2 highlighted that it would be helpful for the research team to work with the commissioners during the planning stages of the research so appropriate data fields for the digital programme could be agreed to allow providers to send these data directly to NHSE. This would have meant an agreement could have been set up between University of Manchester and NHSE rather than with the four individual providers, enhancing efficiency and consistency of usage data fields from each of the providers. Alternatively, as seen in the HED-LINE evaluation, NHSE could have set a specification for the usage data to be collected by the service provider. There was a considerable amount of work required to obtain trust from external providers to share commercially sensitive data. Information sharing and data processing agreements helped to reassure providers, though this was time-consuming. Despite these agreements, one provider was still reluctant to share documentation.

We sought the views of the PPIE group on the lessons learned for facilitating PPIE in a commissioned research evaluation of a nationally implemented programme. One challenge was that their role as supporters of a research project evaluating the NHS-DPP, rather than designing the NHS-DPP, became clear later in the project. Although they embraced their role, there was some frustration in terms of providing feedback on the NHS-DPP. In relation to their role, the PPIE group reported finding some components, such as the effectiveness and cost-effectiveness analyses, more challenging. On reflection, we could have provided more learning and development opportunities, but PPIE members felt able to contribute and that their feedback was appreciated. Other challenges included ensuring the continuity of PPIE support in a long-term project like DIPLOMA, both in terms of group coordination and in commitment from PPIE members, and managing the transition to online meetings.

Equality, diversity and inclusion

Samples used in the effectiveness and cost-effectiveness analyses are based on national data sets (e.g. MDS, NDA, CPRD) and should be representative.

Our WP exploring access and equity specifically compared characteristics of the NDH population in national surveys against those with NDH within the NHS-DPP.[50] Comparisons with the NDA data suggest the NDA had a lower percentage of under-forties compared to national surveys, but a higher percentage aged 70–79 years; a considerably lower

percentage of the population with a disability; and higher representation of ethnic minorities than in surveys; but that the populations were comparable in terms of deprivation.

As to participation in qualitative interviews, focus groups, and observations, researchers aimed at reaching a diverse sample in terms of geography, deprivation, ethnicity, and urban or rural location, as practically as possible. Although the reach of our data collection varied from practices within local travel distance to national coverage, researchers periodically reviewed the mix of participants recruited and focused efforts on recruiting patients from minority groups, and when needed, translators were recruited (WP1). In our analyses of the digital sample, although efforts were made to secure a broad representation of participants across age, gender and ethnic groups, it is possible that those who proactively chose to take part in the study were not representative of all participants in the NHS-DDPP. Our sample was characterised by lower levels of deprivation and ethnic diversity.[70]

Conclusions

Our mixed-methods evaluation found that the NHS-DPP is highly likely to be cost-effective, and identified targets for improvement in recruitment, retention and fidelity.[96] The evaluation builds on the international literature in diabetes prevention and provides a comprehensive analysis of how behaviour change interventions can be delivered at national scale.

Additional information

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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data is used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

NDA, CPRD, NHS-DPP MDS and Digital Pilot MDS Data sets may be obtained from a third party and are not publicly available. Authors obtained access to these data sets via Data Processing Agreement with NHSE (NHS-DPP MDS) and Memorandum of Understanding (Digital Pilot MDS), Data Sharing Agreements with NHS Digital (NDA). The authors are not permitted to share these data. In particular, the NDA used in this study was obtained upon application to NHS Digital (reference: DARS-NIC-196221-K4K3Y). The use of this data is subject to various output rules, including rounding count values to the nearest 5. All data requests should be submitted to the corresponding author for consideration

Ethics statement

Ethics approval for the study was received from the North West – Greater Manchester East Research Ethics Committee (REC reference 17/NW/0426). The wider project protocol is available from: https://fundingawards.nihr.ac.uk/award/16/48/07

Information governance statement

We hold data from the National Diabetes Audit (NDA). NDA is a record of all people identified as having, or being at risk of developing, T2D based on primary care (general practice) records. We know the age, gender, ethnicity, area of residence deprivation and learning disability status of these patients, and their blood sugar level. We do not know who the patient is, their name or address, or any other information which could be used to accurately identify them. These data are not categorised as personal data as individuals cannot be identified.

The data controller is the University of Manchester. For more information see our Fair Processing statement at https://arc-gm.nihr.ac.uk/media/Resources/Diabetes/Fair%20Processing%20Statement%20NDA.pdf

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/MWKJ5102.

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Participation on a Data Safety Monitoring Board or Advisory Board

David Reeves, Evangelos Kontopantelis and Matt Sutton are members of the NHS Digital Advisory Board for the National Diabetes Audit: Non-Diabetic Hyperglycaemia, Diabetes Prevention Programme. Elizabeth Murray was a member.

Simon Heller chairs a DMSC for Eli Lilly and sits in the Advisory Boards for Zucara, Zealand and Vertex.

Consulting fees

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Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid

Simon Heller chairs the International Hypoglycaemia Study Group, sits in the subpanel for the NIHR PGfAR funding stream, and is the national specialty lead in Diabetes for the NIHR Clinical research network.

David French is President Elect for the European Health Psychology Society.

Memberships

Matt Sutton reports the following memberships: HS&DR POM Committee (current member), HS&DR Researcher-Led – Board Members (April 2012 to March 2016), HS&DR NHS 111 Online Sub Board (May 2012 to September 2020), HS&DR Funding Committee Members (May 2012 to September 2020), HS&DR Funding Committee (Bevan) (November 2020), HS&DR Funding Committee (Seacole).

Rachel Meacock reports the following memberships HS&DR Associate Board Members May 2012 to May 2017. HS&DR Researcher-Led – Associate Board Members (May 2012 to March 2016), HS&DR Funding Committee Members (January 2019 to January 2022), HS&DR Funding Committee (Seacole).

Simon Heller reports the following memberships: HTA Clinical Evaluation and Trials Committee.

David French reports the following memberships: PHR Research Funding Board June 2016 to June 2020.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

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Dissemination to participants and related patient and public communities

This has included three animation videos describing (a) the planned DIPLOMA evaluation at the start of the project, (b) the overall research findings at the end of the project, and (c) behaviour change in the NHS-DPP. We have also co-produced two 'Talking Heads' videos: the first video summarised a qualitative study on how service users understood their type 2 diabetes risk,[54] and the second video summarised research on service user uptake and experiences of the NHS Digital Diabetes Prevention Programme.[56]

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List of abbreviations

BCT	behaviour change technique
BCTT	Behaviour Change Technique Taxonomy
BMI	body mass index
CCG	Clinical Commissioning Group
CI	confidence interval
CPRD	Clinical Practice Research Datalink
DDPP	Digital Diabetes Prevention Programme
DIPLOMA	Diabetes Prevention – Long-term Multimethod Assessment
DPP	Diabetes Prevention Programme
DPS	Diabetes Prevention Study
EQ-5D	EuroQol-5 Dimensions
FPG	fasting plasma glucose
GP	general practitioner
HBA_{1C}	glycated haemoglobin
HED-LINE	HeLP Diabetes – Long-term Independent National Evaluation
HR	hazard ratio
HS&DR	Health and Social Care Delivery Research
ICER	incremental cost-effectiveness ratio
IFG	impaired fasting glucose
IGT	impaired glucose tolerance
IRR	incidence rate ratio
MDS	minimum data set
NDA	National Diabetes Audit
NDH	non-diabetic hyperglycaemia
NHS-DPP	NHS Diabetes Prevention Programme
NHSE	NHS England
NICE	National Institute for Health and Care Excellence
NIH-BCC	National Institutes of Health Behavior Change Consortium
NIHR	National Institute for Health and Care Research
OR	odds ratio
PHE	Public Health England
PPIE	patient and public involvement and engagement
QALY	quality-adjusted life-year
RCT	randomised controlled trial

RR	risk ratio
SSC	Study Steering Committee
T2D	type 2 diabetes
TIDIER	Template for Intervention Description and Replication
US DPP	United States Diabetes Prevention Program
WP	work package

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