



Evaluating the NHS Diabetes Prevention Programme (NHS DPP): the DIPLOMA research programme (Diabetes Prevention – Long term Multimethod Assessment)

Protocol

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Evaluating the NHS Diabetes Prevention Programme (NHS DPP): the DIPLOMA research programme (**D**iabetes **P**revention – **L**ong term **M**ultimethod **A**ssessment)

Summary of Research

The NHS Diabetes Prevention Programme (NHS DPP) is an ambitious programme to deliver an evidence-based behavioural change intervention ('the NHS DPP intervention') to patients at risk of developing diabetes, to encourage behaviour change and reduce risk of diabetes. The size of the programme and the complexity of its implementation present significant challenges for any evaluation.

The DIPLOMA research programme is a mixed methods evaluation delivered by an experienced multidisciplinary team, which is designed to provide:

- (a) feedback regularly 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 the aim of reducing diabetes prevalence in a way that is cost-effective and sustainable for the NHS.

We have the necessary skills and experience to deliver this evaluation. Our expertise includes quasi-experimental evaluations of population health initiatives,¹⁻⁴ use of routine datasets to support evaluation of policy,⁵⁻¹² mixed methods evaluation of regional and national policy,¹³⁻²⁷ design and evaluation of behaviour change interventions,²⁸⁻³⁶ implementation science^{37,38} and economic evaluation^{39,40} as well as experience of the evaluation of local diabetes prevention schemes.^{41,42}

The DIPLOMA research programme will have 8 work packages:

Work package 1 Access and equity will use quantitative analysis of national survey and administrative data to explore the characteristics of patients who enter the NHS DPP, and those who are eligible and do not enter. This analysis will be complemented by qualitative research on the process of accessing the NHS DPP, and the experience of patients and professionals.

Work package 2 Implementation will explore the process of implementation of the NHS DPP in selected sites, exploring the local organisation of the programme, workforce, funding, and pathways.

Work package 3 Service Delivery and Fidelity will analyse data on uptake and adherence to the NHS DPP intervention, combined with a detailed analysis of the degree to which providers adhere to the specification for the intervention.

Work package 4 Outcomes will use data collected by the NHS DPP to assess effects on patient outcomes within the programme. Data will also be linked to data from 'Implementation' and 'Service Delivery and Fidelity' work packages to explore factors influencing outcomes and 'active ingredients.'

Work package 5 Comparative Effectiveness will use quantitative analysis of administrative data to explore whether the NHS DPP leads to a reduction in the prevalence of diabetes and other outcomes, using quasi-experimental methods.

Work package 6 Validation sample will use a patient survey to evaluate the risk of confounding on participation in the NHS DPP, allowing adjustment for the effects of confounding.

Work package 7 Comparative Long Term Cost Effectiveness will use data from other work packages, the international literature and administrative data to create an economic model. This will compare NHS DPP costs with the benefits (reductions in diabetes prevalence, improvements in quality of life and mortality and reductions in health care utilisation) over the long-term.

Work package 8 Programme management will include management of the programme, co-ordination of the research work packages, liaison with stakeholders and dissemination of findings to internal (NHS DPP) and external academic, service and patient audiences.

Work package 9 Patient decision making and experience of the digital DPP will define patterns of engagement (defined as uptake and initial use) within the digital DPP by the target population with a view to producing recommendations on how to maximize engagement in the future

Background and Rationale

Non-diabetic hyperglycaemia is a term which is used to describe the decreased ability of the body to regulate glucose effectively, such as impaired glucose regulation (IGR), impaired glucose tolerance (IGT) and impaired fasting glucose (IFG). It accounts for conditions where blood glucose levels are above the normal range but are not high enough for a diagnosis of type 2 diabetes mellitus. People with non-diabetic hyperglycaemia often have no symptoms, but 5-10% of those with non-diabetic hyperglycaemia will go on to develop type 2 diabetes every year, if left untreated.

The health implications of type 2 diabetes are serious, with poor control (i.e. high blood pressure / low medication adherence) resulting in loss of vision, nerve pain, and in severe cases, limb amputation. Further, type 2 diabetes carries with it a high-risk of developing other cardiovascular health complications.⁴³ Type 2 diabetes is thought to cost the NHS £10 billion per year, around nine per cent of the total NHS budget.

These figures highlight the importance of diabetes prevention as a national public health concern. The main causes of non-diabetic hyperglycaemia are behavioural in nature, including poor diet and limited physical activity.⁴⁴ Indeed, evidence suggests that making changes to lifestyle behaviours which reduce weight, such as increasing physical activity, can decrease the risk of non-diabetic hyperglycaemia developing into type 2 diabetes by 50%.⁴⁵ However, the asymptomatic nature of non-diabetic hyperglycaemia means that people often go undiagnosed and untreated, therefore remaining at a higher risk of developing type 2 diabetes.⁴⁶

To tackle this problem, Diabetes Prevention Programmes have been developed and implemented worldwide, including the USA⁴⁷ and Finland.⁴⁸ Such programmes aim to reduce the incidence of diabetes by targeting dietary and physical activity behaviours of those considered at risk of developing type 2 diabetes. Large randomised controlled trials of these programmes have demonstrated that lifestyle interventions can reduce the risk of developing diabetes by up to 58%, through a relatively modest weight loss of 5-7%.⁴⁹ This illustrates the importance of weight loss, as the risk of diabetes was found to reduce by 16% for each kilogram of weight lost.⁴⁸ It also highlights the role of obesity in the rise of diabetes and supports the targeting of weight reduction for the prevention of diabetes.⁴⁴

The NHS DPP intervention will be delivered by 4 providers procured by NHS England based on a published specification. Although some variability is expected, the core intervention will involve a predominantly group-based model delivered in person across a minimum of 9 months, including at 16 hours contact time, with a focus on diet, physical activity and weight loss. People with non-diabetic hyperglycaemia will be identified through NHS Health Checks and registers in primary care. There will be a focus on systematic data collection to support the programme.

We have previous experience with the delivery and evaluation of services for patients with non-diabetic hyperglycaemia, including the Salford Care Call (telephone based) approach for people with non-diabetic hyperglycaemia.⁴² The results suggest that this approach may be effective at sustaining long-term behaviour change and improved outcomes, thus reducing risk of type 2 diabetes. However, these were small observational studies. Members of our team are also currently involved in the independent evaluation of the Salford Care Call as part of the NHS DPP demonstrator site work and we are keen to utilise the skills, tacit knowledge and understanding from the previous research in Salford to carry out an in depth, robust and valued evaluation of the national programme.

Evidence explaining why this research is needed now

NHS England, Public Health England and Diabetes UK have recently initiated a national diabetes prevention programme in England. This is a significant investment, based on the wider international evidence on the effectiveness of diabetes prevention programmes and the results of early demonstrator projects.

However, maintaining the effectiveness of interventions from the particular environment of clinical trials during roll-out to the context of routine NHS delivery remains a significant challenge. High quality evaluations are required, both to provide ongoing, independent feedback to the programme on the success of the roll-out,⁵⁰ to explore the impact of context and variability in delivery on effectiveness,⁵¹ and to provide a longer term, rigorous assessment of the degree to which the new programme is meeting its aims compared to usual care.

Digital NHS Diabetes Prevention Programme

The DPP developed a pilot digital workstream for the DPP in 2017. This included an embedded evaluation, which is being undertaken by RSM and University College London which will report around April 2020.

On August 2018, the NHS DPP released a new framework for 'Healthier You: NHS Diabetes Prevention Programme'. The aim of the new framework is to expand the programme and to improve take-up and adherence to the DPP, including better targeting of the working age population and addressing delays associated with courses in rural areas.

The new framework also includes implementation of digital support for diabetes prevention alongside existing face-to-face provision, which has the potential to be one of the largest implementations of a digital programme in the NHS. Recruitment onto the new framework will start in August 2019, covering 45% of the sites in England, with the remaining 55% covered in 2020.

For operational reasons the DPP team re-procured the DPP intervention before the digital pilot could report. Therefore, the initial re-procurement focused mainly on face to face prevention programmes. However, all five of the new framework providers have been required to offer a digital prevention programme to people who decline invitation to the face-to-face programme. Once the results from the Digital DPP pilot are released, the DPP management team might decide to open up choice between face-to-face or digital intervention.

Aims and objectives

The overall aim of the DIPLOMA research programme is to provide a comprehensive assessment of the implementation, delivery and outcomes of the NHS DPP to inform commissioning.

The individual work package aims are as follows:

Work package 1 Access and Inequality

To assess whether sociodemographic factors influence access to the NHS DPP, and to explore the experience of patients and professionals in accessing the NHS DPP

Work package 2 Implementation

To assess the process of implementation of the NHS DPP, and explore the barriers and facilitators that affect the implementation of the NHS DPP

Work package 3 Service Delivery and Fidelity

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

Work package 4 Outcomes

To assess what outcomes participants achieve in the NHS DPP, and whether outcomes vary by services delivered and patient characteristics

Work package 5 Comparative Effectiveness

To assess whether the NHS DPP is more effective than usual care in reducing conversion of non-diabetic hyperglycaemia to diabetes, eventually reducing diabetes prevalence in England

Work package 6 External Validation

To assess the risk of confounding in participation in NHS DPP and allow adjustment in other work packages

Work package 7 Comparative Cost effectiveness

To assess whether the NHS DPP is cost-effective compared to usual care in terms of long-term costs and benefits

Work package 8 Programme Management

To deliver the research to time, target and budget, and to ensure that the results are disseminated to key stakeholders and inform NHS decision-making

Work package 9 Patient Decision Making and Experience of Digital DPP

To describe and understand patterns of engagement (defined as uptake and initial use) within the digital DPP by the target population

We have structured our comprehensive research programme into separate work packages, although our management of the programme will take advantage of the synergies between them. We are aware that the resources required for this programme are significant, and in line with advice from HS&DR, we have costed each work package as accurately as possible to allow judgement of their individual contribution and value. To help meet our aims, we will draw on a range of theoretical frameworks. RE-AIM was developed to guide the development and determine the potential impact of public health interventions,^{52 53} and has been widely used to evaluate intervention implementation and

impact in a variety of settings including other diabetes prevention programmes.^{54 55} We will also draw on relevant social science frameworks relating to access and candidacy,⁵⁶ behaviour change theories from health psychology,⁵⁷ and normalisation process theory for implementation.⁵⁸

Research Plan / Methods

Work package 1 – Access and inequality (Whittaker, Chandola and Sanders)

Aims: To assess whether sociodemographic factors influence access to the NHS DPP, and to explore the experience of patients and professionals in accessing the NHS DPP

Rationale: Inequalities in health have been documented in England,⁵⁹ and are of global concern.⁶⁰ Inequalities may exist between several population groups, and providers of health care are subject to the Equality Act (2010) concerning equality of opportunity across protected characteristics: age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. This is in line with the NHS Constitution which seeks to deliver a service based on need.

Inequalities in health may manifest where inequalities in access exist.⁶¹ Understanding the effect that the NHS DPP may have on reducing inequalities in diabetes requires a thorough assessment of inequalities in access. We will draw on the 'reach' aspect of the Re-AIM theoretical framework, defined as 'the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative.'⁶² Reach depends on effective access among those at risk. Access to the NHS DPP intervention involves a process:

- (a) identification of patients 'at risk' in contexts such as NHS Health Checks
- (b) a blood test which show they have non-diabetic hyperglycaemia ('NHS DPP eligible' patients)
- (c) decision-making by professionals and patients about referral to the NHS DPP
- (d) invitation to the NHS DPP
- (e) initial attendance at the NHS DPP intervention ('NHS DPP attenders' and 'non-attenders')
- (f) completion of the NHS DPP intervention ('NHS DPP completers')

An overarching definition of access concerns empowerment of an individual to use services when needed.⁶³ Access may be related to multiple factors: availability of the NHS DPP in the area; awareness of NHS DPP among patients and professionals, acceptability of NHS DPP to professionals and patients; and the perceived 'costs' of NHS DPP (such as taking time off work). Each domain of access may be correlated with protected characteristics and social class.

To understand any issues in access to the NHS DPP and the impacts of the programme on diabetes incidence, we will assess whether inequalities in protected characteristics exist for:

1. the identification of patients eligible for the programme ('NHS DPP eligible' patients)
2. the referral of patients to the programme ('NHS DPP attenders' and 'non-attenders')
3. programme delivery and completion (working with work package 3)
4. the effectiveness of the programme (working with work package 4)

The experiences of those targeted to participate in the programme, as well as those delivering it, will also be crucial to its success. Previous research has demonstrated that factors such as age, gender, ethnicity, socio-economic status, employment status and relationship status, have an impact upon experience of living with or being at risk of type 2 diabetes, attendance at NHS Health Checks, as well as other aspects of help-seeking, health behaviour, and self-management.^{56 64 65}

Overview of methods: Work package 1 will use a combination of quantitative analysis of existing data sources, and qualitative research. The first research question will use data from the NHS DPP and existing administrative data sources to explore access. Research question 4 will explore if access is influenced by the understandings and experiences of participants.

When the initial research proposal was written, the National Diabetes Audit data was not considered useful, as at that point in time it did not contain data on non-diabetic hyperglycaemia. This information has since been added to the National Diabetes Audit. The National Diabetes Audit offers a more complete coverage of general practice than CPRD data, and so will now replace the CPRD analysis which was originally planned (conditional on checks of completeness and quality of the NDA).

Research question WP 1.1: Are there inequalities in the identification of patients eligible for the NHS DPP? Is there an under-representation of participants with protected characteristics in general practice compared to the general population of adults at risk of diabetes?

Methods: We will compare the characteristics of patients identified with non-diabetic hyperglycaemia in GP patient records (using the National Diabetes Audit dataset, NDA) to the characteristics of patients identified with non-diabetic hyperglycaemia in representative survey data for England.

The English Longitudinal Study of Ageing (ELSA); Understanding Society and the Health Survey for England (HSE) surveys record HbA1c test results (enabling an assessment of non-diabetic hyperglycaemia) and contain comparative measures of social class (sourced via Lower Super Output Area (LSOA) IMD score with LSOA and/or IMD score obtained via special access license), ethnicity, sex, and disability status. Multivariable probability analysis will be used to test if the probability of having non-diabetic hyperglycaemia differs across surveys for particular patient characteristics.^{66 67} This analysis will identify whether patients identified as non-diabetic hyperglycemic in primary care records differ from those in nationally representative surveys. We will use:

- a) Understanding Society waves 2 and 3 (2010-2012). All adult respondents are surveyed but blood samples were taken of 13,107/35,937 eligible (12,162 instances of HbA1c (mmol/mol) being recorded), all ages 16 and over, 964 participants with HbA1c between 42-47 mmol/mol
- b) ELSA - adults aged 50+ with 457 wave 2 participants, 1,297 wave 4 participants, 1,315 wave 6 and 806 wave 8 participants with HbA1c between 42-47 mmol/mol
- c) NDA (comparative observable factors e.g. age, gender, IMD, comorbidity; flags for non-diabetic hyperglycaemia)

Research question WP 1.2: Are there inequalities in the referral of patients to the NHS DPP?

Once a diagnosis of non-diabetic hyperglycaemia has been made, the GP may or may not refer the patient to NHS DPP. This decision to refer may be influenced by both the GP and patient, and may be related to patient or professional perceptions of the value of the service.

Method: We will compare the observable characteristics of patients referred to the NHS DPP in the Minimum DataSet (MDS) to patients identified with non-diabetic hyperglycaemia in the NDA dataset and those in surveys using analogous methods as those described in WP 1.1. The MDS contains information that providers of the DPP are contractually obliged to collect in order to receive financial reimbursement. It contains dates and sources of referrals and information about subsequent programme attendances, as well as participant outcome measures, as recorded by the providers of the programme.

Research question WP 1.3: Are there inequalities in attendance and completion of the NHS DPP?

Following a positive identification of non-diabetic hyperglycaemia, patient uptake and adherence to the NHS DPP intervention may vary. We can examine this in the MDS, using relevant codes for 'referral to the NHS DPP intervention', 'intervention started', 'declined' and 'completed'.

Method: Using MDS data (observable patient characteristics e.g. age, gender, IMD, co-morbidities). for those referred and on the programme we will compare the characteristics of patients and how this varies with course uptake and completion, the characteristics will be compared to patient characteristics in the NDA and survey datasets to understand at what point the characteristics of patients begins to change.

Research question WP1.4 What is the experience of patients and professionals in accessing the NHS DPP?

Access to care is a complex concept requiring a range of methods to understand the mechanisms that might underlie inequities in access.^{68 69} Focused qualitative work will be used to explore the experience of participants (and potential participants) and providers within the NHS DPP, to build a more comprehensive model of the 'reach' of the NHS DPP and to provide feedback to NHS DPP stakeholders on effective practice to support the ongoing programme.^{70 71}

Methods: We will sample 6-10 practices to reflect diverse populations at local level, including practices in areas with high and low deprivation, and high levels of BME patients.

We will conduct observations of relevant consultations between practice staff and patients with non-diabetic hyperglycaemia ('NHS DPP eligible' patients) to investigate how risk factors are discussed with attendees. Although opportunistic identification of such consultations in routine practice is likely to be logistically demanding, our experience during our pilot work in Salford is that many practices will set up specific clinics for such patients, enhancing the feasibility of such observational work.

Consultations will be recorded for detailed analysis (using audio- or video-tape according to feasibility and participant preference). We will aim to record 50 consultations with 10 professionals. We aim to achieve a maximum variation sample of patients according to protected characteristics such as age, gender, disability, and ethnicity and other factors like socio-economic status.

We will also recruit GPs/nurses in practices to participate in a one-to-one interview or focus group interview about their experiences of DPP and their views surrounding diabetes prevention

Some GP practices notify patients of their pre-diabetes diagnosis via letter only. If this is the case, patients are directed to phone the NHS DPP call centre if they are interested in going on the course. We therefore also intend to interview and observe the calls made to the DPP call centre. The patient side of the conversation will not be listened to as obtaining written consent will be difficult. The research team will only observe the call centre worker's responses and ask them questions about the sort of questions they are asked by patients.

Our recruitment strategy is based on two previous studies from the University of Manchester: WISE (REC 07/H1011/96) and Diabetes prevention in primary care (14/SC/0097)

To recruit patients, we will use two methods: (a) Researchers will attend the practices on agreed days for study recruitment (b) Practice staff recruit and consent patients.

We know that some practices may want to recruit and consent patients into the study without the presence of a researcher. This method of recruitment was suggested by GPs involved in another diabetes prevention study (14/SC/0097), as diabetes prevention advice is sometimes provided ad hoc.

In this method, primary care staff will answer any questions about the study, go through the Patient Information Sheet, and consent patients once they have understood the study.

Using the above strategies, patients will be provided with all necessary information about the study so they can make sure participation is right for them. Also, patients will be made aware of their right to withdraw their data and participation from the study at any time.

We are aware that some patients may enter the NHS DPP through routes other than primary care, such as response to adverts. If many sites are using referral options other than primary care, we will work with NHS DPP providers to recruit these patients to understand their experience of accessing the course. In these cases, we would ask the NHS DPP providers to send patients an invitation letter and a Patient Information Sheet, and ask those patients to return a 'consent to contact' form if they are willing to be interviewed

We will interview all professionals (n=10) after consultations and a proportion of patients (approximately 20) to gauge understanding of levels of risk and the meaning of relevant diagnostic information, as well as both perspectives on any decisions about referral and need for the NHS DPP intervention. We will follow the approach of our previous research^{72 73} to analyse observations alongside interviews to explore influences associated with access and use of the NHS DPP.

Additionally, we will interview people with a Read code for non-diabetic hyperglycaemia ('NHS DPP eligible' patients), but who have not been referred to the DPP. We will also include people for whom referral has been offered but declined ('NHS DPP attenders'). We will work with practices to identify such patients from their primary care records. Practices will send patients an invitation letter and patients who agree to participate will complete and return 'consent to contact form'.

Final sample sizes will be contingent on iterative analysis to inform sampling until saturation of data is achieved.

For observational data, we will ensure detailed transcription to allow a focus on language and interaction between patients and professionals within the consultation drawing on a conversation analysis approach. This will enable us to focus on how risk and test results are discussed with consequences for subsequent decisions and action. This is an approach we have previously adopted to investigate how practice within consultations supports or undermines self-management and diagnosis in primary care.^{72 73}

Interviews will be audio-recorded with consent, transcribed and thematically analysed, using a modified framework approach⁷⁴, and drawing on relevant theoretical frameworks such as candidacy,⁵⁶ cultural competence,⁷⁵ and the impact of practical and structural barriers.^{65 76 77}

We will ensure we include some patients who are non-English speakers, and translators will be used. We will also address variations in health literacy via this maximum variation sample.

Work package 2 – Implementation (Wilson)

Aims: To assess the process of implementation of the NHS DPP, and explore the barriers and facilitators that affect the implementation of the NHS DPP

Rationale: The NHS DPP has an ambitious plan to roll out nationally, using a staged approach across different 'areas' and building on work within initial pilots and demonstrators. Work in implementation science has highlighted the importance of context in the success or failure of health care innovations.^{51 78} This work package will explore the local context surrounding wider implementation of the NHS DPP.

Overview of methods: To meet our aims we propose a descriptive survey to develop a sampling frame, followed by qualitative case study research, to answer 3 questions.

Research question 2.1 What is the local context for implementation of the NHS DPP?

For the roll out of areas commencing April 2017, we will undertake an initial scoping phase to understand the organisational context for implementation.

Methods: we will contact the designated local lead and NHS DPP provider for each area. We will seek to obtain all available pilot contracts, and then undertake a rapid synthesis of these contracts to gather data on:

- (a) area specific aims and objectives
- (b) key performance indicators to measure 'success'
- (c) details of any incentive structures
- (d) targeted patient groups
- (e) workload and anticipated outcomes.

Where provider contracts are not accessible, we will supplement this data with short semi-structured telephone interviews with relevant commissioning leads. Data generated in this scoping phase will be used to develop a typology of areas to act as a sampling frame for detailed case study exploration.

It is anticipated that we will generate a purposive sample of up to 4 case sites for each of the 4 main providers of the NHS DPP intervention (n=16). We will recruit a mix of areas, varying on characteristics such as rural and urban locations, populations with different socio-economic characteristics, areas with particular GP recruitment and retention challenges, and those utilising a range of approaches to patient identification and referral.

Research question 2.2 What are the barriers and facilitators to the implementation of the NHS DPP within areas?

We will analyse the process of implementation in our selected sites, and explore barriers and facilitators to implementation.

Methods: In this second phase, we will conduct longitudinal interviews with the designated leads for each local area. Semi structured interviews will be conducted twice (at 3-6 months and 9-12) and will utilise a topic guide informed by data from the scoping phase.

Initial interviews will explore the process of local implementation of the NHS DPP, including the local organisation of the programme, expectations of and attitudes to the NHS DPP, funding, target populations and referral and clinical pathways.

Later interviews will explore reflections on implementation and sustainability as well any recruitment challenges and unintended consequences (such as who is actually referred, or whether pre-existing services for lifestyle change or diabetes prevention are displaced or foregone).

Research question 2.3 What are the barriers and facilitators to the implementation of the NHS DPP within practices?

To complement the area-level analysis, we plan to explore in-depth the development and implementation the NHS DPP at the level of the individual general practice. We will examine the organisational processes implemented to identify and refer patients to the NHS DPP intervention (such as case finding, NHS Health Checks, or opportunistic screening). This work will complement qualitative work within Work Package 1 looking at the experience of patients and professionals in accessing the NHS DPP.

Methods: Data generated from the area level exploration will be used to identify specific practice level examples of approaches to patient identification and referral. In up to 8 general practice sites, we will explore in-depth, the development and implementation of practice-level processes to identify and refer patients to the NHS DPP intervention. In each practice, we will conduct longitudinal telephone interviews with the practice manager and (where appropriate) the lead clinician.

Early interviews (around 3 months) will focus on the development and implementation of local practice-level strategies and processes to identify and refer patients to the DPP intervention. Later work (9-12 months) will focus on the extent to which 'case-finding' processes have become embedded into routine practice systems. In doing so, we will draw upon a theoretical approach known as Normalisation Process Theory^{58 79} which facilitates understanding of the extent to which new processes become part of normal practice. NPT proposes that for a complex intervention (in this instance case finding) to become part of routine care (where there will be competing priorities), we need to consider the following mechanisms: coherence ('what is the work'), cognitive participation ('who does the work'), collective action ('how does the work get done') and reflexive monitoring ('how is the work understood'). By focusing early and late practice interviews around these four constructs we believe we will be better able to understand any recruitment challenges and/or unintended consequences that arise from the practice-level processes as they develop over time.

At both time points, we will explore perceptions and attitudes towards the NHS DPP scheme, identify any recruitment challenges and any unintended consequences from practice-level processes or the NHS DPP intervention itself. Analysis of data from this work package will be undertaken in close collaboration with qualitative work within Work Package 1 to take advantage of synergies between the organisational perspectives adopted here, and those of patients and professionals in work package 1. Interviews will be audio-recorded with consent, transcribed and thematically analysed, using a modified framework approach.⁷⁴

Amendment to WP2:

Substantial Amendment: [see documents: WP2.1 NDPP Incentives Questionnaire V1.0 08.02.2018; Substantial Amendment 8_03.04.2018; Approval Letter_19.04.2018] Following completion of the majority of phase 1 interviews with the sampled area, we identified that there were considerable variations regarding the availability of incentives across and within areas. The information collated during interviews also revealed disparities between what was proposed in the initial prospectus and what has been implemented in practice. As incentives may impact upon the success of implementation, and potentially other programme outcomes, we have amended WP2 to include a short 'incentives' questionnaire to identify incentives available, explore any variations in support within areas and identify if any alternative resources are in place instead of incentives. Findings from the questionnaire will contribute to the aims of WP2/1 where it was indicated that we would speak to relevant leads where information in provider contracts was not acceptable.

Substantial Amendment: [see documents: Substantial Amendment 12 07.08.19; Approval Letter 25.09.19] The NHS DPP released a new framework for the Healthier You: NHS Diabetes Prevention Programme in August 2018. The aim of the new framework is to improve take-up and adherence, including better targeting of working age populations and addressing delays associated with running courses in rural areas. The most notable change from the previous framework is the inclusion of the offer of a remote/digital service as an adjunct to face-to-face delivery. The new framework will be operational from August 2019.

In light of the new framework outlined above, we have revised the plan of investigation for phase 2 of this work package.

We now plan to repeat the scoping exercise that we conducted in phase 1 (to scope all prospectuses of participating sites to develop our sampling frame for phase 2). In phase 2, we will build on this initial purposive sample of sites to ensure that we also include:

- At least 4 case sites for each of the main providers
- Case sites from waves 1 to 3
- Case sites incorporating remote options to support attendance and retention

Interviews

In phase 2, using this extended sample (we anticipate including around 24 sites), we will explore the implementation of the new framework and its associated delivery arrangements, exploring how local organisation of the programme has changed (if at all), and with what consequences (anticipated or unintended).

To do this we will seek to interview designated site leads as they implement the new framework in autumn 2019 and again in the spring 2020 to give them an opportunity to reflect on their implementation experience and where relevant on any differences between two framework processes. At both time points, we will explore perceptions and attitudes towards the NHS DPP, identify any delivery challenges and or unintended consequences. We anticipate conducting around 50 – 60 telephone interviews in total.

In phase 2, we previously proposed to undertake interviews with practice staff to explore in-depth, the development and implementation of the NHS DPP at the level of the individual general practice (*Research question 2.3*). However, data from our phase 1 interviews and from qualitative work in WP1 indicated more limited front line involvement in implementation than was initially anticipated. We indicated to NIHR that there would be little value in in depth exploration at this level and proposed to use the existing resource to explore the implementation of the new framework instead.

Incentives survey

In phase 2, we intend to repeat our 2018 email incentives questionnaire survey of all designated local leads for NHS DPP sites to obtain a comprehensive picture of specific financial incentives resourcing of approaches being deployed to support implementation. In autumn 2019 each local lead will be emailed and asked that as part of the DIPLOMA study we would like to understand more about the implementation of local incentives. We will attach a short questionnaire to be completed and returned by email or, if they prefer, offer to arrange a time to contact and complete the questions over the phone.

Work package 3 – Service Delivery and Fidelity (French)

Aims: 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

Rationale: The NHS DPP intervention is based on a systematic review and meta-regression identifying effective components of diabetes prevention programmes, which included the length of the intervention period, engagement of social support, targeting diet and physical activity, and use of well-established behaviour change techniques.⁴⁹ To achieve the potential benefits outlined in the review, the NHS DPP intervention will have to be delivered with fidelity to those components, across multiple sites and practitioners - a major challenge for any complex intervention.^{53 80 81}

Intervention fidelity as defined by the NIH Behaviour Change Consortium (NIH-BCC)⁵⁷ includes a number of elements:

- (a) Study design – is the intervention congruent with relevant theory and best practice?
- (b) Training - have practitioners been properly trained to deliver the intervention?
- (c) Delivery – has the intervention been delivered as designed?
- (d) Receipt – do patients understand the intervention and perform key skills during delivery?
- (e) Enactment – do patients perform relevant skills in real life setting?

Overview of methods: This work package use a combination of document review, observation and interviews to assessing whether the NHS DPP intervention is delivered with fidelity to the content and design principles specified. Work package 3 has 4 research questions.

Research question WP 3.1 Study design - what are the explicit theoretical principles, behaviour change technique (BCT) content and mode of delivery of the NHS DPP intervention as exemplified in (a) intervention protocol/manual, and (b) training materials? What is the observed variation in these across providers, sites and settings?

Methods: We will collect intervention protocols, manuals and training materials from at least the 4 main NHS DPP providers, and probably from 4 sites per provider, that are purposively selected to cover variation in socio-demographic status and ethnicity. We will code these materials in terms of BCT content, using the CALORE BCT taxonomy or BCTv1⁸² and the Theory Coding Scheme.⁸³ The CALO-RE BCT taxonomy provides a list of BCTs (e.g. setting behavioural goals, prompting self-monitoring) with definitions and guidance on how to assess whether a BCT is present. We will also use the TiDieR framework to describe the broader nature of the NHS DPP interventions.⁸⁴ The TiDieR framework provides a checklist of key intervention features, including mode of delivery, but also who delivered, where, and in what dose.

The primary analyses will report the specific BCTs designed into the intervention, key features of intervention delivery, and the extent to which the justification is explicitly based on theory. We will report these (broken down by provider and site) as well as for overall programme, where such documents exist.

Amendment to WP3.1

Substantial amendment: [see documents: Substantial Amendment 14 28.04.20].

In light of the new framework for the digital DPP, we propose to replicate methods used to assess fidelity of the face-to-face DPP in order to assess fidelity of the digital DPP.

WP 3.1.1 – Document analysis of the design of the digital DPP

Methods: We will conduct a document analysis of the 'new' NHS service specification (including new framework and procurement questions), and combine with existing analysis of NICE PH38 guidelines. This will provide us with (a) the intervention specification. We will also analyse the 2500 words each of five providers included in their framework responses on the digital approach. This will give us some indication of (b) intervention design, although it will be cursory and incomplete. There are no single documents for any providers that offer a full and complete summary of their planned online content (although we will try to elicit any relevant documents).

WP 3.1.2 – Interviews with professionals involved in design and development of digital DPP

Given the incomplete descriptions of intervention design for the five providers, we will also conduct interviews with professionals (employed by the providers and their digital partners) across England who were involved in the design and development of the digital interventions.

We will conduct up to three interviews with developers (i.e. up to 15 interviews). The aim will be to elicit as much detail as possible on the design of the intervention (planned intervention structure and content, and underpinning rationale, i.e. theory and evidence). Interviews will likely include representatives of primary providers and their digital partners. The interview schedule will be refined and may be revised throughout the process of interviews.

Interviews will be conducted by a researcher at the professionals' place of work or via telephone or Skype/Zoom. Interviews are anticipated to last between 30 and 60 minutes. The interview will be audio-recorded (and a separate audio recording for verbal consent) using an encrypted audio recorder. If professionals decide to take part in a Skype/Zoom interview, we will not use the recording function on those platforms, but instead we will use an encrypted audio recorder in line with GDPR requirements.

Written consent (or verbal consent for telephone or Skype/Zoom interviews, using an encrypted audio recorder) will be sought before commencing each interview. Interviews will be transcribed using a university approved transcription company who have signed an Information Sharing Agreement.

Non-substantial amendment: [see documents: Amendment Tool, 25.11.20].

In the event where participants are unable to answer one or more of our questions during the interview, and if they agree during the initial interview, we will send participants a follow-up email requesting any additional information they were not able to provide. For example, if the participant needs to refer to a colleague to provide more information, or further information can be supplied via a document. Any additional information we obtain over email will provide additional detail to answer the research question so that the research team can present the most accurate representation of each providers' DPP design.

Analyses: We will analyse documents using BCTTv1,⁸² TIDieR⁸⁴ and TCS.⁸³ The primary analyses will report the specific BCTs designed into the intervention, key features of intervention delivery, and the extent to which the justification is explicitly based on theory. Reporting of these will be broken down according to digital provider.

We will content analyse the interviews (and any corresponding email content, if applicable) using BCTTv1,⁸² TIDieR⁸⁴ and TCS.⁸³ The primary analyses will report the specific BCTs designed into the intervention, key features of intervention delivery, and the extent to which the justification is explicitly based on theory. Reporting of these will be broken down according to digital provider.

Given the limitations of getting a full intervention design specification from all five providers for evaluation of the digital DPP, we anticipate comparing other aspects of fidelity in subsequent work to the intervention specification (including the NHS Service Specification and NICE PH38 guideline) rather than intervention design (for the digital DPP only).

Research question WP 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?

Methods: We will observe training sessions from at least the 4 main NHS DPP providers, and probably from 4 sites per provider, purposively selected to cover variation in socio-demographic status and ethnicity. These sessions will be coded using schemes described in WP 3.1, but will involve observation of training sessions instead of documents.

Research question WP 3.3. Delivery - To what extent is the NHS DPP intervention delivered with fidelity to intervention protocols and manuals?

Methods: We will digitally record or otherwise capture a selection of NHS DPP intervention sessions, again from at least the 4 main NHS DPP providers, and probably from 4 sites per provider. We will aim to capture 5 sessions per site, to provide a total of 80 sessions for coding. We will not code the

use of theory, as it is not appropriate to provide detailed descriptions of theory when providing patients with intervention instructions.

For observation of group sessions, we will start with an overall sampling frame of DPP providers and sites that are in place during the evaluation period, and purposively sample on the basis of these, to get maximum variation in patient SES and ethnicity, as well as geographical location. Within sites, we will purposively sample sessions to provide to provide variation in terms of patient SES and ethnicity, as well as geographical location, and variation in duration that the site has been running and times of year.

Where possible, we will work with NHS DPP providers to send patients a Patient Information Sheet and consent form prior to their course starting. Our researchers will attend the course on the first date, and will be present to go through any outstanding consent forms, and answer any questions about the research prior to the course starting. We accept that failure to gain consent from any patients on the course means that we will be unable to observe or record any of the course. Eligible patients may attend a session with a partner or a carer who has not been invited to take part in the DPP programme. If this is the case, they will also be consented to participate in the study. If they refuse consent, this would also mean we would be unable to observe or record the course.

Together, these analyses (3.1, 3.2 and 3.3) will provide information on the extent to which the interventions as specified in intervention design contain specific BCTs, are theoretically based, as well as details of their mode of delivery. We can then examine variation across providers, sites and people delivering the intervention. Also, we can examine the extent to which there is a loss of fidelity to the key principles underlying the intervention in delivery, and where such loss occurs.

Amendments to WP3.3

Substantial amendment: [see documents: Amendment Tool, 16.12.2020].

In light of the new framework for the digital DPP, we are proposing additional sub-studies relating to WP3.3 to assess the delivery the digital offering of the NHS DPP:

- Document analysis of digital intervention content
- Interviews with health coaches delivering the digital DPP
- Analysis of a sample of one-to-one telephone calls between health coach and service user for one provider (see substantial amendment dated 29.07.2021, below).

WP 3.3.1 Document analysis of digital intervention content

Methods: We will capture online content of each of the providers' digital interventions and code for BCT content. As each of the digital providers offer a slightly different service provision, we will request any relevant material that captures what would be delivered to service users on the digital DPP. This will allow us to assess the intervention content that is *offered* to service users, whether or not they take it up. We will request at least the following documents from each of the digital providers, depending on their service provision:

- Guest log-in access to app (if available)
- Workbooks/ handbooks/ worksheets supplied to service users
- Any other hard copies of materials supplied to service users (e.g. recipe books)
- Email content (e.g. articles/ educational content/ encouragement sent via email to service users)
- All educational content that gets 'unlocked' throughout the intervention
- Pdf's, video content etc. sent to service users
- Scripts (or checklists/ instructions/ guidance) for IA/ discharge/ support calls with service users
- Instructions/ guidance for health coaches who moderate support groups
- Instructions/ guidance for health coaches who respond to queries via 1-1 messaging
- List of the content of any standard 'nudge'/ prompt/ reinforcement via automated SMS messages/ app notifications sent to service users

Analysis: We will code this intervention content for BCTs using the BCTTv1¹ and for intervention description using the TiDieR² framework. The BCT and TiDieR content will have previously been described for (a) the intervention specification (what should be delivered) and (b) the design

specification (what providers plan to deliver). We will assess the extent to which this material has retained fidelity to the original BCTs.

WP 3.3.2 Interviews with health coaches delivering the digital DPP

Methods: We will conduct qualitative interviews with health coaches employed by each of the digital DPP providers. We aim to recruit up to 25 health coaches per provider. The aim will be to elicit as much detail as possible on the roles of health coaches (e.g. one-to-one support, moderation of support groups, phone calls, etc.). The interview schedule will be piloted and refined and may be revised throughout the process of interviews.

Interviews will be conducted by a researcher via telephone or via online video conferencing (e.g. Skype/ Zoom/ MS Teams). Interviews are anticipated to last between 30 and 60 minutes. We intend to contact provider leads in the first instance and they will be sent the Participant Information Sheet to pass onto health coaches. The email and information sheet will ask any interested health coach to contact the research team directly, either by phone or email. If a health coach contacts the researcher for more information, the researcher will then reply to arrange a time to discuss further. Health coaches will be asked to provide a telephone number or email to arrange an interview, if they are still willing. This information will be stored electronically on a password protected Excel sheet, stored on a University of Manchester drive, and will only be accessible by the research team. Health coach contact details will only be used to discuss participation and arrange interviews.

Non-substantial amendment: [see Amendment Tool, 23.06.2021].

The research team will check with the management staff of each digital provider in the first instance whether their staff are allowed to accept an incentive for taking part in an interview. For those providers who do allow their health coach staff to accept an incentive, these health coaches will be offered £20 for taking part as a 'thank you' for their time. This amount is based on the standard amount offered in previous studies, including the previous WP3.4 interview studies, and is based on what DIPLOMA pay to PPI members for one hour of their time (£20), which follows INVOLVE's guidance on payment for public involvement. However, if the management staff of a digital provider confirms that their staff are not allowed to accept any incentives (e.g. due to company policies), health coach staff employed by that provider will not be offered an incentive and this will be specified in the PIS. Depending on which provider the health coach staff are employed by and whether their company can accept incentives, health coaches will receive an appropriate PIS detailing that they can or cannot opt to receive an incentive for taking part.

The interview will be audio-recorded (and a separate audio recording for verbal consent) using an encrypted audio recorder. If health coaches decide to take part in a Skype /Zoom/ MS Teams interview, we will not use the recording function on those platforms, but instead we will use an encrypted audio recorder in line with GDPR requirements.

In line with University of Manchester's 'Taking recordings of participants for research projects' Standard Operating Procedure, participants will be individually consented and verbal consent will be taken via a separate audio recording to the interview recording, using an encrypted audio-recorder. Researchers will complete and sign consent forms as they go through the consent process with the health coach over the telephone. When audio recording consent, researchers will ensure that the participant clearly states their name in the audio recording. The consent statements be read aloud individually, and the participant will confirm Yes or No to each statement. All optional consent statements will be made clear. Physical copies of consent forms will be kept separately in locked cabinets in locked rooms within the University of Manchester. Audio-recorded verbal consent will be stored on a secure University of Manchester server, only accessible to the research team.

Audio-recordings will be checked once transferred to the secure drive and then deleted from the recording device. Interviews will be transcribed using a university approved transcription company who have signed an Information Sharing Agreement, and the identity of participants will be anonymised (i.e. removal of names, places and provider organisation). Interview transcripts will be securely stored on a University of Manchester server, only accessible to the research team. Information will be kept in accordance with the University's Retention Schedule and Research Data Management Plan. Audio consent recordings and hard copy consent forms would be retained for 2 years after the end of the study, in line with the University's Retention Schedule.

Analyses: We will content analyse the interviews using BCTTv1¹ and TIDieR². The primary analyses will report the specific BCTs that coaches intend to deliver and a good indication of activities that health

coaches self-report to undertake on a daily basis. Reporting of these will be broken down according to digital provider. The research team may also be able to conduct a secondary analysis on health coaches' self-reported experiences of delivering a national digital behaviour change programme. We will use an inductive thematic analysis approach to develop themes representing health coach experiences.

Substantial amendment: [see documents: Amendment Tool, 29.07.2021].

WP 3.3.3 Analysis of sample of one-to-one telephone calls between health coach and service user

Following initial meetings with the digital providers it has become clear that, for one of the providers in particular, a proportion of the one-to-one support for service users is offered during telephone calls with health coaches. Further analysis of one-to-one support telephone calls would enable us to more comprehensively capture the behaviour change support for this provider that may not otherwise be apparent in that provider's app/web application or educational materials (e.g. goal setting, making a commitment to behaviour change, social support, etc.)

Methods: Following discussions with this provider, we have been told that they audio-record these calls for quality assurance purposes, but they do not routinely transcribe these recordings. We therefore seek to obtain a small sample of audio recordings of these one-to-one calls. Given that audio files contain personally identifiable information (e.g. service user's voice), the research team will first ensure that appropriate Data Processing Agreements (DPAs) are in place with the provider before we proceed with the collection of data.

Once the relevant DPA is in place with the provider, we will request a sample of up to 3 audio recordings of telephone calls between the health coach/dietician and service user for 5 participants (n = approx. 15 audio recordings in total). The digital provider will be supplied with a set of step-by-step instructions to ensure that all participants are fully consented and data is transferred securely (see additional file: instructions for DIPLOMA study).

Note that the provider's privacy policy states that telephone calls are recorded as needed for optimal customer service and quality management purposes (<https://oviva.com/uk/en/legal/#privacy>). The provider uses a system called 3CX to manage recorded telephone calls between the health coach and service user. Note that the calls are destroyed after use, but they can be downloaded from the 3CX system at any time. This means that the calls from those service user/health coach pairs who provided full consent (see consent procedures below) can be downloaded from the 3CX system and securely transferred to UoM.

The research team have sought advice from the provider's Information Governance Lead re: the transfer of data. Recordings will be transferred via UoM Dropbox for Business as this method of transfer is encrypted. The data will be immediately moved from the Dropbox to a secure UoM drive. If this method is unfeasible for the provider due to technical issues, we will request that the data files are encrypted as above and sent to UoM via email with a password shared by a separate communication. Data files will be held on the UoM secure server for the purposes of analyses and will only be accessed by the DIPLOMA research team. These recordings will be transcribed and anonymised with a University-approved transcription service who have already signed an Information Sharing Agreement. Transcription files will be stored on a secure University drive, only accessible by the research team. Information will be kept in accordance with the University's Retention Schedule and Research Data Management Plan. Audio consent recordings and hard copy consent forms would be retained for 2 years after the end of the study, in line with the University's Retention Schedule. The DIPLOMA Data Management Plan has been updated to reflect the above changes.

Consent of service users

During the first initial phone call with service users (onboarding call), the member of staff employed by the provider will provide information about the research and the national evaluation of the digital DPP. It was agreed with the provider that this is the most practical option for providing the service user with information about the study. Note that this first phone call will not be used for research purposes and will not be sent to the research team, rather, it is to explore whether or not the service user would be amenable to any future phone calls being recorded and used for research purposes. Information about the DIPLOMA research study will be read out by the provider staff during this onboarding call (see additional file: script to recruit service users).

If the service user sounds receptive during this onboarding call, they would then be sent the Participant Information Sheet (via email) to read before their next call with the health coach. Health coaches will keep a log of service users who have expressed an interest, and the health coach/dietician will follow-up with the service user at their next phone call to see if they still wish to take part. The service user will be given the opportunity to have any questions answered before they give full verbal consent. It is up to service users to decide whether or not they wish to take part. They will be informed that they are free to withdraw at any time without giving a reason, however it will not be possible to remove their data from the project once analysis has begun, so participants can withdraw up to a week after they have provided consent for the research team to have access to the audio recordings (see the Participant Information Sheet for service users). The names and contact details of the research team will be listed on the Participant Information Sheet if the service users wish to contact them to find out more information about the study before agreeing to take part. It is during this next call that the health coach would take the formal verbal consent with the service user. They will use a UoM-approved consent form, ask service users to clearly state their name and each statement on the consent form will be read out individually for the individual to consent yes or no to each statement.

Consent of health coaches

A second process will be completed to obtain full verbal consent from the health coaches conducting the one-to-one calls. The research team will discuss with the provider whether they want to identify the health coaches or the service users first, depending on what is most practical at their end (e.g. whether they provide the service users with information about the research study during the initial phone call to identify the 5 service users who are willing to take part and then consent the matching health coach/dietician they get referred to, or identify small number of health coaches/dieticians first to consent, then identify a subset of service users that are referred to them and subsequently consent the service user). The key point above is that identification of the health coach and service user pair will be done by the provider. The provider will be instructed to ensure any service user and/or health coach given a PIS to consider before the consent process takes place (with UoM for health coach, with health coach for service user).

The provider will identify the relevant health coaches to invite to take part and the health coach will be sent a PIS and the email addresses of the researchers involved in the study. The health coach will then be able to contact the researchers by their own volition if they express an interest in taking part in the study. A telephone call will be arranged between a researcher and a health coach to take verbal consent. A member of the research team will contact the health coach directly to take full verbal consent via telephone to allow collection of any data. Health coaches will clearly state their name in the audio recording, and each statement on the consent form will be read out individually for the health coach to consent yes or no to each statement. Verbal consent will be recorded by the researcher on an encrypted audio recorder and the consent file will be transferred and stored on a secure University drive. Audio-recorded consent will be kept separate from the research data, in line with good practice. Researchers will complete and sign consent forms as they go through the consent process with the participant over the telephone. Physical copies of consent forms will be kept separately in locked cabinets in locked rooms within the University of Manchester. These storage procedures will take place as soon as the researcher conducting the interview returns to their office at the University of Manchester. Health coaches will be offered £20 for taking part as a 'thank you' for their time and for taking full verbal consent of the service user. This amount is based on the standard amount offered in previous studies, including the previous WP3.3.2 health coach interview study and WP3.4 interview studies, and is based on what DIPLOMA have paid to PPI members for one hour of their time (£20).

Analyses: Anonymised transcripts will be coded for intervention content using the BCTTv1 and for intervention description using the TiDieR framework. The BCT and TiDieR analysis will complement the document analysis of the content and materials present via the app/web applications of each of the digital interventions. BCT and TiDieR content has previously been described for (a) the intervention specification (what should be delivered) and (b) the design specification (what providers plan to deliver). We will assess the extent to which this material, in addition to digital content/material delivered to service users via the app/web application, has retained fidelity to the original BCTs.

Research question WP 3.4. Receipt - To what extent is the content of the NHS DPP intervention understood by recipients as intended by providers?

Methods: We will undertake qualitative interviews with people receiving the NHS DPP intervention, to assess what they think the NHS DPP intervention is trying to do ('intervention receipt'). These interviews will also explore issues beyond the specific scope of the NIH-BCC, such as participant

experience of the NHS DPP intervention, their experience of the nature of interaction,⁷² the experience of different delivery modes, issues of cultural acceptability,^{75 77} and the impacts of the wider social network on access to and adherence to the intervention.^{85 86}

Again, we will sample from at least the 4 main NHS DPP providers, and from 4 sites per provider, interviewing 2 people per site, giving 32 interviews.

We will aim to sample patients in WP3.4 from those sessions that we are recording to assess intervention delivery in WP3.3. Given this, we will aim to recruit all patients to the interview study at the beginning of the group intervention, and then be able to sample from a larger group of patients than the two patients per site that we are aiming to interview. We will explicitly ask for permission to contact patients if they drop out of the intervention, and therefore be able to contact those patients who subsequently drop out as well as those who complete. Although people who drop out of interventions are usually less willing to take part in interview studies, we have previously recruited people who withdrew from a weight management service using similar procedures.

Analyses: Interviews will be audio-recorded with consent, transcribed and thematically analysed, using a modified framework approach for assessment of 'intervention receipt',⁷⁴ and grounded theory for the exploration of wider issues around participant experience.

Amendments to WP3.3 and WP3.4

Substantial amendment: [see documents: Amendment Tool, 27.10.2020].

In light of the new framework for the digital DPP, we are proposing two follow-on studies relating to WP3.3 and WP3.4, to assess the delivery and receipt of the digital offering of the NHS DPP:

- Telephone interviews with service users enrolled onto the digital DPP
- Analysis of usage data in the digital DPP

Telephone interviews with service users

We will conduct qualitative interviews with service users receiving the NHS DPP digital intervention (those who have completed initial screening calls and enrolled on the digital DPP), with aims to elicit what was delivered to service users in the digital programme ('intervention delivery') and elicit what service users think the digital DPP intervention is trying to do ('intervention receipt').

Therefore, these interviews have the following aims:

1. To assess what key intervention features are offered to service users at different time-points
2. To assess what key intervention features service users have used in the digital DPP
3. To assess service users' understanding of the key intervention features
4. To assess service users' engagement and satisfaction with the digital DPP

Methods: We will aim to recruit approximately 60 people, i.e. approximately 12 people from the five digital providers. Interviews will ask service users what they have been offered in the digital intervention (e.g. activities, support, coaching, etc.), what they have used (since the last interview), their understanding of different activities and their overall satisfaction with the digital DPP. The interview schedule will be refined and may be revised throughout the process of interviews. We aim to interview participants at two time-points; the first time-point at approximately months 2-4 of being enrolled onto the programme and the second time-point at approximately months 8-10 as they come to the end of the digital intervention. We also plan to interview any of the service users who drop out of the intervention before they are discharged, if they still wish to take part in a second interview.

Patients will be identified via each of the five digital providers of the NHS DPP, who are commissioned to provide this NHS service. We will ask providers to contact participants on our behalf. We will send providers an email template detailing the research study and inviting participants to take part along with a participant information sheet. We will ask providers to email all service users who are in their first month of being enrolled on the digital programme during the recruitment period.

The email and information sheet will ask any interested person to contact the research team directly, either by phone or email. If the participant contacts the researcher for more information, the researcher will then reply to arrange a time to discuss further. At this initial appointment, the researcher will explain the research and what will be involved, respond to any questions or other issues that the participant has about the research, and arrange a day and time for the telephone interview, if the participant is willing.

Initially we will ask providers to invite all service users who are in their first month of enrolment on the programme during a specified recruitment period in order to judge the uptake of the offer of participation in the research study. However, once recruitment has begun, we may ask providers to target the offer of participation in the research study. For example, we may ask providers to purposively sample people from certain ethnic backgrounds, gender, or areas of deprivation to ensure that we have a sample of participants that represent the wider UK population of people at risk of type 2 diabetes. After patients agree to be contacted, they will be asked to provide their email address and telephone number to arrange interview. This will only be used to discuss participation and arrange interviews with patients and will only be available to members of the research team (stored electronically on the secure University of Manchester server). Researchers will not have access to any other medical details or patient history, and we will not have access to their address, date of birth, or NHS number.

We will individually consent people. The Participant Information Sheet will be emailed to participants and they will be able to provide verbal consent via telephone. Verbal consent will be recorded on a separate audio recording to the interview, using an encrypted audio recorder. Researchers will complete and sign consent forms as they go through the consent process with the participant over the telephone. Physical copies of consent forms will be kept separately in locked cabinets in locked rooms within the University of Manchester. We will aim to interview each of these people on two occasions for up to 60 minutes. As a 'thank you' for taking part, participants will be offered £20 for the first interview and £30 for the final interview. This amount is based on the standard amount offered in previous studies, including the previous WP3.4 interview study, and is based on what DIPLOMA pay to PPI members for one hour of their time (£20), which follows INVOLVE's guidance on payment for public involvement. Reimbursements will be paid either by high street vouchers or bank transfers.

Interviews will be audio-recorded using an encrypted audio-recorder and transcribed using a University approved transcription company who have signed an Information Sharing Agreement. Participants will be given a unique identifier that only the research team will have access to, and all personal information (e.g. names and places) will be removed from transcripts to ensure participant confidentiality. The interview schedule will be refined and may be revised throughout the process of interviews.

Demographic information will be collected on the same occasion as the main interview. As part of the demographic data, with participant's permission, we will collect full postcodes of participants. We want to find out how many people being interviewed live in wealthy or deprived areas to comment on how representative our sample is of the population. We will give the patients the option of not providing us with this information and we will delete the postcode as soon as we have identified the deprivation indices. The postcode will be linked to the participant's unique identifier on the data collection sheet (and not their name). Demographic information will be collected via a separate digital recording, with responses being noted in a study spreadsheet shortly after recording. University of Manchester laptops will be used as these are encrypted. Storage of personal data will be on secure university servers (and not on the hard drives of laptops) and can only be accessed by the research team.

Analyses: To assess the delivery of the digital DPP, interviews will be content analysed using BCTTv1⁸² and TIDieR.⁸⁴ We will use Nvivo software to manage the data. Analyses will report specific BCTs and key intervention features that service users report are delivered/offered to them. To assess receipt/enactment of the digital DPP, analyses would use the framework approach to thematic analysis, and include deductive overall approach, with inductive analysis within each key topic (understanding, satisfaction, engagement).

Analysis of usage data in the digital DPP

According to the new framework for NHS DPP, providers must monitor service users' engagement with the service by collecting data on the amount, frequency, duration and depth of usage of the digital DPP e.g. viewing materials, completion of active elements, engaging with human coaches, inputting self-monitoring data and taking part in moderated sessions.

Methods: We will ask providers to share information about the data fields they routinely collect on usage of each interface of the digital NHS DPP (website/app) and in what format this may be available. We expect data fields to include the following to be used in WP3 to assess which behaviour change techniques are being delivered and received by participants (and in what dose and targeted at what behaviours):

- Page views (with reference to behaviour change technique content mapped out by prior work)
- Number, time and date stamps of pages above
- Links clicked (i.e. to ascertain whether data has been inputted, e.g. a food diary entry, or whether a user has clicked through to use another component of the intervention, e.g. a live chat with health coach). Please note it is whether these components have been used that is of interest to us, not the content in the food diary entry or live chat
- Users' bodyweight measurements

We will work with providers to ensure an opt-out consent process is in place for usage data by: 1) reviewing existing terms and conditions and consent statements that service users complete when registering to take part in the digital DPP, and 2) revising consent statements where necessary in conjunction with the provider.

Once an agreed opt-out consent process is in place, we will ask providers to identify a cohort of service users which will be followed up for the length of the intervention (9-12 months). We expect this cohort to be identified as all new registrants with the digital DPP for one month for each of the 5 providers. We will ensure that the data transferred to UoM from the providers is anonymised and does not contain any personally identifiable data. Providers will be specifically requested to do the following before sending any usage data to UoM:

- Remove any personally identifiable data (name, contact details, DOB, medical records, IP address)
- Remove any address details leaving only the first 3 letters of the postcode, which will allow us to assess the geographical spread of usage data we obtain
- Review any free-text entries from service-users that risk sharing personally identifiable data
- Quality assurance

We will request that providers encrypt the data files using an AES256 compliant encryption mechanism such as 7-zip. It will then be uploaded to a University of Manchester Dropbox for Business. The data will then be immediately moved from the Dropbox to a secure University of Manchester drive for storage. If this method is unfeasible for the provider due to technical issues, we will request that the data files are encrypted as above and sent to UoM by email with password shared by a separate communication.

We will request specific research data storage from UoM IT for the usage data files. Data files will be then held on The University of Manchester secure server (and backed-up as per usual UoM standards) for the purposes of analyses and will only be accessed by the DIPLOMA team. We will request providers transfer data to us on a monthly basis using this process.

Analyses: We plan to use the AMUsED (Analyzing and Measuring Usage and Engagement Data) framework¹ for evaluating digital interventions. This framework comprises three stages: 1) familiarisation with the intervention and its relationship with the captured data, 2) identification of meaningful measures of usage and specifying research questions to guide systematic analyses of usage data, and 3) preparation of datasheets and consideration of available analytical methods with which to examine the data.

We will identify core BCTs (e.g. goal setting, action planning, self-monitoring, feedback, reviewing goals, problem solving and others mentioned in the intervention specification) and identify a threshold by which each was delivered/received by service users. The raw usage data will be recoded according to this approach. For example, we will code whether the BCT is present in the intervention (yes/no) and we will code whether users engaged with that specific BCT (yes/no). Analyses will report specific BCTs and key intervention features which were (1) offered to users, and (2) which users effectively

¹ Miller S, Ainsworth B, Yardley L, Milton A, Weal M, Smith P, Morrison L. A framework for Analyzing and Measuring Usage and Engagement Data (AMUsED) in digital interventions. *Journal of medical Internet Research* 2019;21(2):e10966.

engaged in. This will allow assessment of delivery and receipt of the intervention. Reporting of these will be broken down according to digital provider.

Further, we expect providers to be collecting bodyweight data as part of the NHS DPP, as this is a requirement in the framework for the programme. If this data is collected as part of the usage data for the NHS DPP, we would like to conduct analyses to explore any relationship between BCT delivery/receipt within the intervention and bodyweight outcomes e.g. whether engagement with particular features of the digital DPP (e.g. BCTs) are linked to weight loss outcomes. DIPLOMA also has access to a Minimum Dataset (MDS) supplied by NHS England which includes a referral ID and bodyweight measurements at specific milestones recorded by the provider throughout the digital DPP. If the usage data supplied by the providers contains the same referral ID, we would like to explore conducting some analyses using the MDS linked with usage data to explore any relationship between BCT delivery/receipt within the intervention and bodyweight outcomes.

Work package 4 – Outcomes (Cotterill)

Aims: To assess what outcomes participants achieve in the NHS DPP, and whether outcomes vary by services delivered and patient characteristics

Rationale: High quality data collection and measurement of outcomes is increasingly seen as a critical aspect of effective health care.⁸⁷⁻⁸⁹ The NHS DPP will put in place a comprehensive protocol for data collection. Detailed analysis of this data will be critical to assessing the effectiveness of the programme in achieving improvements in well-being, behaviour change and lifestyle among those attending. Such data may provide useful feedback for providers on performance, and variation between providers, sites and professionals.

Overview of methods: This work package seeks to assess what outcomes participants achieve in the NHS DPP, and to identify which components of the NHS DPP intervention are effective, and for whom. It will identify the sources of any variation in outcomes among those who attend the NHS DPP intervention, and explore drivers of that variation.

Work package 4 will focus primarily on comparisons within the programme, and will link closely with analyses from work package 3 on Service Delivery and Fidelity. WP4 will analyse the individual level data set collected by NDPP providers to look at variation in participation, service delivery and outcomes. There will not be a comparator group, as the comparative analysis will be done more robustly in WP5. Analyses against external comparators will be considered by Work package 5.

Research question WP 4.1 - What services are delivered by NHS DPP and what is the extent of participation in the NHS DPP intervention?

Research question WP 4.2 - How does service delivery and participation in the programme vary by (a) the 4 NHS DPP providers (and any variation within provider by area) and the associated variation in content and delivery (b) between patient subgroups?

Research question WP 4.3 – What are the outcomes of patients in the NHS DPP intervention, including wellbeing score, weight change, HbA1c, and mortality?

Research question WP 4.4 – How do outcomes vary by (a) the 4 NHS DPP providers (and any variation within provider by area) and the associated variation in content and delivery (using data from work package 3) (b) between patient subgroups?

Methods: All research questions will be addressed using a minimum individual patient data set. NHS DPP have already stipulated that NHS DPP providers will be required to collect and supply this data, which will then be passed in anonymised form to the research team. The individual dataset will include 48 items, including referrer, delivery organisation, personal/demographic details, process data (including records of each session) and outcome data (Warwick-Edinburgh Mental Wellbeing Scale, weight change, and HbA1c).

Based on the NHS DPP announcement that it expects to provide 100,000 places per year by 2020 (<https://www.england.nhs.uk/ourwork/qual-clin-lead/diabetes-prevention>), we have made the assumption that there will be 50,000 individuals in 2017/18; 80,000 in 2018/19 and 100,000 in 2019/20, a total of 230,000 individuals.

We will match this individual patient data to service-level data on what is being provided by the providers in different areas, collected by the 'Implementation' and 'Service and Fidelity' work packages. This will be a rich individual level longitudinal dataset, that will allow patients be followed over time, through the steps of invitation, baseline assessment, enrolment, service delivery, completion, and end-of-service outcomes.

We anticipate that, like any administrative dataset, there will be error and missing data. As with other aspects of the evaluation, the DIPLOMA team will work closely with the NHS DPP to ensure that suitable processes are in place to ensure data collection is as accurate and complete as possible. We will provide feedback on missing data through our initial analyses, and follow up with providers if problems continue.

We will use descriptive statistics to assess overall outcomes, and multivariable regression methods to estimate the relationship between patient, provider and service characteristics and participation (question 4.2) or outcomes (question 4.4). For analysis, we will use multilevel modelling of individual characteristics (focusing on health inequalities – WP1) and service delivery (number of sessions attended; area/provider; and important elements of service delivery identified in WP3 (e.g. behaviour change techniques) on the outcomes collected by NDPP providers (weight, HbA1c, WEMWBs etc.). We will work closely with providers to minimise missing data, and we will report the extent of missing data. We will consider multiple imputation methods, if we assess that the data meets the assumption of NMAR.

WP4 will use the insights/models developed in the WP1-3 to influence the choice of variables in our statistical models: on health inequalities (WP1) and service delivery/fidelity (WP3). We will incorporate these to estimate their effect on participation, service delivery and outcomes for NDPP attenders.

We will produce regular reports to inform ongoing NHS DPP service delivery, drawing on exemplars such as the IAPT dataset.⁸⁷ To ensure the relevance of these reports, a detailed analysis plan will be written in advance, in negotiation with the NHS DPP, and this can be re-negotiated over the course of the project.

Timing of analysis: Analysis will be undertaken at three time points: Summer 2018 (using year 1 data, around 50,000 patients); summer 2019 (using Year 1 and 2 data, around 130,000 patients), summer 2020 (using complete dataset, around 230,000 patients). The earlier reports will focus on reporting who is invited to attend, baseline measures and enrolment, but as time progresses, we will be able to say more about the services delivered, completion rates and end-of-service outcomes.

Amendment to WP4

Non-substantial amendment

WP 4.5 Comparison of face to face and digital DPP – observational cohort study, secondary analysis

Rationale: The DIPLOMA project has been awarded additional funding to compare the face-to-face and digital delivery of the NHS Diabetes Prevention Programme (DPP), in terms of population characteristics, participation rates and health outcomes. Face-to-face and pilot digital DPP offered similar content with different delivery methods. The delivery of these two programmes at the same time offers a unique opportunity to compare face-to-face and digital delivery. This analysis will contribute to RQs 4.2 and 4.4.

Objectives:

1. Compare the population characteristics of those who take up the options of face-to-face and digital delivery.
2. Compare participation rates between face-to-face and digital delivery.
3. Compare the clinical effectiveness of face to face and digital delivery, among those who complete the programme

Populations

Face to face DPP was offered to adults with NDH. Digital DPP was offered to 1) adults with NDH; 2) adults who are overweight or obese. Overall, 4409 people registered for the programme during the 12 months pilot, 3612 with NDH and 797 who were obese. Of these, 2687 people provided outcome data

1. Choice (32.6% of registrations). Within the Digital DPP, four areas (BNSSG, Bucks, Lancs and Salford) offered patients a choice between digital and face to face. The NHSE Minimum Data Set (MDS) is available for the f2f providers in these areas, allowing a direct comparison.
2. Digital only (59.7% of registrations). This was delivered in areas where there was no F2F programme, but it did not last long, because F2F was gradually rolled out to all areas.
3. Decliners (7.7% of registrations). Only people who declined to take up the F2F programme were offered digital.

Data

Two datasets will be combined for analysis:

1. Face to face DPP dataset
2. Digital DPP dataset

These two anonymised datasets are supplied to us by NHS England, collected from patients participating in the NHS DPP (individual characteristics, referral source, extent of participation in the DPP, and health outcomes). No personal details will be available to the research team. We already have the first dataset (face-to-face MDS, as used in the previous WP4 analysis) and NHSE have agreed to provide us with the second dataset (digital DPP). The second dataset contains similar variables, but on a different population. We are signing a Memorandum of Understanding with NHSE to cover the data sharing and we will follow the same UoM information governance procedures as our current DIPLOMA analyses.

Power calculation

HbA1c at 6 months among those taking the F2F DPP is 39.9 mmol/mol (SD 4.08). A reduction in HbA1c of 5 mmol/mol (0.5%) or more is considered to be clinically important so if the difference in the means of the two groups is less than 5 they can be regarded as having a similar effect. Assuming a standard deviation in both F2F and digital DPP of 4.08, 90% power, alpha 5% and 5-to-1 allocation of controls to cases, to observe a difference of 2 mmol/mol we would need a total of 486 people (81 digital, 405 F2F). There are 2200 digital participants with 6 month outcomes, which should provide sufficient numbers, after matching.

Missing data

Multiple imputation by fully conditional specification will be used to reduce bias due to missingness (up to 30% among covariate values in the F2F MDS).^{24, 25} Multiple imputation has already been applied to the F2F dataset, and a similar approach will be implemented in the digital dataset.

The analysis of clinical effectiveness will focus on completers: in both datasets, outcome data was only collected on those who stayed in the programme until the outcomes were recorded, so there will be considerable, systematic bias in terms of differences between responders and non-responders.

Analysis

1. Descriptive statistics

We will describe patient participation (registrations, starts and completion) in digital and face to face, and explore differences between digital and face to face patients.

2. Differences in participation (start and completion)

We will estimate differences in participation (registration, start and completion) between digital and face to face. Differences will be explored using three approaches

a) Raw (uncorrected) differences in participation.

b) Adjusted differences in participation. During DIPLOMA1 our team has already developed logistic regression models to estimate the effect of demographic variables, baseline outcomes and service characteristics on participation in the F2F DPP. We will apply those models to the combined dataset, with the addition of a variable for F2F/digital. This will allow us to estimate the effect of DPP delivery method, controlling for known differences between the two cohorts in factors at baseline.

3. Matched cohort study (primary analysis) A propensity score approach attempts to mitigate the effects of selection bias by balancing the available covariates between the two treatment arms, increasing the validity of the between-group comparison in an observational study. Propensity scores for each individual will be developed from a logistic regression model, estimating the probability of receiving F2F or digital, conditional on available demographic, service and administrative baseline

covariates. We will use nearest neighbour 1:5 non-replacement matching. Once the matched dataset has been developed, it will be analysed using random effects logistic regression models adjusting for baseline scores, provider and CCG.

3. Differences in clinical outcomes (weight and HbA1c)

A similar approach will be followed to that utilised to analyse differences in participation outcomes.

All approaches will be analysed using random effects linear regression models adjusting for baseline scores, provider and CCG.

Work package 5 – Comparative Effectiveness (Kontopantelis and Reeves)

Aims: To assess whether the NHS DPP is more effective than usual care in reducing conversion of non-diabetic hyperglycaemia to diabetes, eventually reducing diabetes prevalence in England

Rationale: Although the NHS DPP is based on a strong international evidence base,⁴⁹ justifying the commissioning of such a large and complex programme requires rigorous scientific evidence that the programme is achieving benefits beyond those delivered by current prevention services. The roll-out of the programme makes formal randomised evaluation problematic. This work package will utilise administrative data and a range of complex statistical techniques to provide a rigorous estimate of the success of the programme in reducing conversion of non-diabetic hyperglycaemia to diabetes (incidence), and reducing the overall numbers of cases of diabetes (prevalence). Outputs from work packages 4 and 5 will complement each other and provide a complete evaluation of the outcomes of the scheme.

Overview of methods: For these analyses, we will use numerous sources of administrative data.

First, we plan to use the National Diabetes Audit (NDA), both in itself and also linked at the individual patient level to the DPP Minimum Dataset (MDS). The NDA plus MDS will provide a national-level source of data on patients with NDH, including their referral and participation in the DPP, and subsequent outcomes including diabetes diagnosis, HcA1c and BMI, across all GP practices. Initially data from the National Diabetes Audit was not considered for DIPLOMA as it lacked data on patients with non-diabetic hyperglycaemia, thus not allowing conversion to diabetes to be evaluated. That information has now been added (including retrospectively). Providing that the NDA dataset satisfies various completeness and quality checks, the NDA+MDS will be used as the primary data source.

The second major source of routine data will be the Clinical Practice Research Datalink (CPRD) GOLD, a large database of administrative primary care data. CPRD covers fewer GP practices than the NDA+MDS, though is still substantial in itself, and will become the primary data source should NDA+MDS be found not suitable. The database has been active since the 1980s with high quality data becoming available after 2000 with the introduction of the Quality and Outcomes Framework (QoF).⁹⁰ Complete data on all aspects of care (diagnoses, referrals, treatments, tests) have been collected from over 500 practices each financial year, covering approximately 7% of the UK population.⁹¹ The CPRD GOLD population is generally representative of the UK population, especially in terms of practice and patient deprivation, although it is largely tied to a single clinical computer system (Vision),⁹² and as a consequence the North-East of England is somewhat under-represented.⁹³ The CPRD data can be linked to Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data, allowing the construction of a more complete patient journey through primary and secondary care and the mapping of causes of mortality (e.g. diabetes, cardiovascular). From October 2017, CPRD has also access to GP practices with the IT software system EMIS Web, which is used in 56% of English practices. This larger data resource, which ensures better population coverage has similar characteristics to the GOLD database described above.

A third data source will be the general practice diabetes registers as collected for the QoF,⁹⁴ and related information about the general practices themselves. We will make use of free public health datasets from the ONS and the Health & Social Care Information Centre (HSCIC), including geographical data, 2011 census based population estimates, deprivation and rurality information,⁹⁵ to map diabetes at a low population level and also to scale up our findings to a national level. We will also obtain point of interest data from the Ordnance Survey (OS).⁹⁶ All these datasets will be linked at a low population level and will be used to map diabetes and non-diabetic hyperglycaemia prevalence rates and their associations with area and population characteristics nationally. Non-diabetic hyperglycaemia data in practice registers should become available after implementation of the NHS DPP nationally, and will be linked with existing datasets.

Research question WP 5.1 – What is the current epidemiology of non-diabetic hyperglycaemia and diabetes?

This work package will investigate rates and patterns of non-diabetic hyperglycaemia and its conversion into a diabetes diagnosis, to provide critical background information for the interpretation of findings related to the effects of the NHS DPP.

Methods: We will investigate the prevalence and incidence of non-diabetic hyperglycaemia using a specific list of Read codes which are routinely used in UK primary care.⁹⁷ A preliminary analysis using CPRD shows that the use of the codes has increased considerably over time. For the latest period (April 2015 to March 2016), at least one relevant code was found in the records of 71,521 patients (1.57%), implying around 900,000 people nationally with non-diabetic hyperglycaemia.

We will also estimate the association between diabetes and non-diabetic hyperglycaemia prevalence at the practice level. We expect a strong correlation which would indicate that diabetes data can be used as a reasonable proxy in the absence of data on non-diabetic hyperglycaemia data.

From 2016-17 onwards, we will use these historical codes and the new codes that will be introduced with the NHS DPP programme to calculate and report detailed information on non-diabetic hyperglycaemia. Excluding cases with an existing diabetes diagnoses, we will calculate both the prevalence and incidence of non-diabetic hyperglycaemia over time, nationally and regionally (such as CCGs or NHS England Local Area Teams). To better understand regional variation, we will calculate age-sex standardised prevalence and incidence rates. We will use longitudinal multivariable mixed-effects regression models to identify predictors of non-diabetic hyperglycaemia from a list of relevant covariates: age, sex, deprivation and QOF comorbidities (excluding diabetes mellitus).^{98 99} We will investigate changes in the characteristics of the non-diabetic hyperglycaemia populations over time, by including time interaction terms in the regression models.

We will use an interrupted time-series design² to quantify the overall effect of the introduction of the NHS DPP on the prevalence and incidence recording of non-diabetic hyperglycaemia (overall and regionally). This is a quasi-experimental design which we have applied in a number of previous studies, most notably to evaluate the impact of the QOF.^{93 100 101} Using a mixed-effects regression model we will control for any changes in the population demographics over time, to obtain a more reliable effect estimate.¹⁰² This design assumes a linear pre-intervention trend, which seems plausible according to our initial modelling. Nevertheless, we will statistically assess linearity and if rejected we will use alternative models with non-linear terms for prevalence of non-diabetic hyperglycaemia.

More inclusive criteria in the Health Survey for England have returned much higher prevalence estimates for non-diabetic hyperglycaemia, and we will explore implementing them to obtain more speculative estimates through which to conduct sensitivity analyses (i.e. based on HbA1c values and relevant Read codes).⁹⁷ However, for the purposes of all planned analyses in this and other work-packages, this is a relatively minor issue (except regarding the true non-diabetic hyperglycaemia prevalence rate). For example, the predictors of non-diabetic hyperglycaemia should be consistent across the two analyses (of conservative or more speculative cases) since we would not expect systematic bias in relation to the research questions (i.e. the predictors of non-diabetic hyperglycaemia should be the same whether a large percentage of patients is missed, or not). Even in there is some form of systematic bias (for example if Read code cases are more 'severe'), the findings from the conservative analysis would still be relevant and important. Finally, it might be the case that a conservative approach where we focus on definite non-diabetic hyperglycaemia cases which have been coded as such may be more desirable.

Research question WP 5.2 - What is the effectiveness of the NHS DPP at reducing the conversion of non-diabetic hyperglycaemia to diabetes?

The primary objective of the NHS DPP is to reduce, or at least slow, the rate at which patients with non-diabetic hyperglycaemia go on to develop a full diabetes diagnosis. In line with this, the main outcome in these analyses will be the conversion of non-diabetic hyperglycaemia to diabetes.

Methods: The primary analysis for assessing the effectiveness of the NHS DPP will use the NDA+MDS if assessed as fit for that purpose, otherwise the work will be done in the CPRD. For robustness, we will address the question using two different research designs.

WP 5.2 design 1: We will use all practices participating in the NHS DPP, and compare the conversion rate from non-diabetic hyperglycaemia to diabetes in patients prior to the start of the NHS DPP to the rate afterwards in equivalent patients. To accomplish this, we will match pre-intervention cases of non-diabetic hyperglycaemia⁹⁷ to post-intervention cases at the same practice and with the same practitioner if possible (excluding cases with a previous diabetes diagnoses). We will then compare the rates of conversion to diabetes within 2 years between these groups.

Earlier, we confirmed that risk-of-diabetes Read codes are already routinely being used. As the NHS DPP-specific Read codes are not available for patients prior to the scheme, we will conduct an initial exercise to identify the group of pre-existing codes that best identify patients classed as eligible using the NHS DPP-specific codes. We will then use the identified codes to classify patients as scheme-eligible both pre- and post-NHS DPP, to ensure comparability. We will use propensity score methods for the matching. In the logistic regression model to calculate the score we will include: age, sex, region, deprivation, QOF comorbidities and all available biological parameters (e.g. body mass index and HbA1c levels at baseline). Data will be complete for all covariates except the biological parameters, for which we expect a very high level of completeness for this group of patients. Nevertheless, we will use appropriate multiple imputation methods for longitudinal data if needed.¹⁰³

We will compare the conversion rates to diabetes between the two matched groups. Since practices are unlikely to refer all their cases of non-diabetic hyperglycaemia to the scheme (because of capacity limits), we will also compare those patients who were referred to their matched pre-intervention controls, while recognising that this comparison will be subject to confounding with any selection bias.

For the analyses we will use both logistic regression models to compare 2-year conversion rates (and over longer time-periods if the data are available) and more appropriate Cox proportional hazards and competing-risks survival regression models to account for censoring and competing risks (e.g. deaths). We will include a region covariate in the models to assess the heterogeneity of the effect, i.e. to investigate if the observed effect varies greatly across regions.

Sample size: We estimate 26,581 participants (people receiving at least one DPP treatment session) will be needed nationally to achieve 90% power to detect an intention to treat risk reduction of 25%. The NHS DPP aims to provide places for 100,000 patients each year by 2020. We assume a balanced design, alpha level of 5%, a conservative baseline 2-year conversion rate to diabetes of 7.5%,¹⁰⁴ and an intention to treat risk reduction of 25% in DPP participants (i.e. 2-year conversion rate of 5.625% or OR=0.735).⁴⁹ On this basis, we would need a total of 7331 patients to achieve 90% power to detect that level of risk reduction. As demonstrated earlier, we will have many times that number for the pre-intervention group (71,521 cases associated with non-diabetic hyperglycaemia in financial year 2015-16). For the post intervention group we would need 3,666 patients, a figure we would expect to be available in the NDA+MDS (and also CPRD if 52,371 invitations to the scheme are administered nationally; since the CPRD covers approximately 7% of the UK population). Assuming a 5 (pre- intervention) to 1 (NHS DPP) design and with all other assumptions unchanged, we would need a total of 11,164 to achieve 90% power, or 1,861 intervention patients. Only 26,581 participants nationally would be required to identify this number of participants in the CPRD.

We will explore a number of secondary outcomes. For hospitalisation, we will use all cases of hospitalisation and cases where the main reason for hospitalisation was diabetes, within 2 years of the index date (referral to the scheme). For primary care visits, we will use all visits to primary care within 2 years of the index date. For biological parameters (HbA1c and BMI) we will use the last available measurement within 1 year and 2 years of the index date (since HbA1c and BMI are expected to respond within a shorter period). We have developed relevant methodologies for BMI prediction and have used other methodological tools for multiple imputation of missing data, which we will consider using in this context.

All analyses will be repeated for the secondary outcomes with small changes in the analytic models: Poisson regressions for hospitalisations and primary care visits; linear regressions for HbA1c levels and weight/BMI; Cox proportional hazards regression for deaths. Sensitivity analyses will be used to assess the robustness of the results to different assumptions about patient eligibility, choice of covariates, and modelling options (e.g. multivariable regression instead of matching).

WP 5.2 design 2: For this analysis, we will only use data from the post-intervention period and compare non-diabetic hyperglycaemia-to-diabetes conversion rates. Our main analyses will involve within practice matching, of patients referred to the scheme versus matched patients not referred. However, we will also use across practice matching to control for potential unmeasured confounding in referrals, by matching referring practices to non-referring practices over a set time period, before matching referred patients (from the referring practice) to non-referred patients (from the matched non-referring practice). In the within practice matching we will match patients on age, sex, time of NDH diagnosis and practice. We will attempt to include more controls to increase power (5 to 1, if

possible). In the across practice matching we will match referring to non-referring practices within each English region, and patients will be matched on age, sex and time of NDH diagnosis.

Analyses will closely resemble those in the first design for both the primary (conversion to diabetes) and secondary outcomes (hospitalisation, primary care visits, HbA1c and BMI/weight levels, and death), and we will also investigate effect heterogeneity across regions in this design as well. The power considerations for an intention to treat analysis (comparing not invited and invited) are the same as in the first design. The analyses are potentially subject to confounding due to selection bias (at the patient and practice level, respectively), but no more than other types of comparisons based on CPRD or routinely collected health records. There are a variety of methods available for assessing/adjusting for unmeasured confounding,¹⁰⁵⁻¹⁰⁸ and we will apply selected methods to determine the likelihood that any results could be accounted for by this.

Research question WP 5.3 - What is the long-term impact of the NHS DPP on diabetes prevalence?

If successful, the scheme is designed to lead to a long-term reduction in the population-level prevalence of type 2 diabetes. Therefore we will also undertake a population-level investigation using national datasets of aggregate data. We calculate the power to detect a population-level effect for the NHS DPP. However, these analyses are secondary, since they rest on numerous assumptions.

As noted in WP 5.1, we will describe the national prevalence of diabetes over time, with routinely collected data from general practices used for calculating QOF payments. We have summarised currently available information, for both type 1 and type 2 diabetes. Although the data are aggregated across both types, 90% of diabetes cases are type 2¹⁰⁹ (around 95%).¹¹⁰⁻¹¹²

The investigation of non-diabetic hyperglycaemia at the population level will require that non-diabetic hyperglycaemia practice registers will become available after the full implementation of the NHS DPP (e.g. like QOF condition registers). Assuming this is the case, we will combine this dataset with ONS data on rurality, deprivation and other covariates we will identify as relevant and measured in the 2011 census. Using methodology which we have developed to link practice level data to low-level population statistics,¹¹³ we will explore the associations between the population characteristics at the Lower Super Output Area level (LSOA: low-level geographies containing an average of 1,500 people). We will also estimate the age-sex adjusted prevalence rates in each LSOA and using both adjusted and unadjusted rates, we will investigate for regional clusters of high prevalence of non-diabetic hyperglycaemia and rapid prevalence increase over time, compared to the national average. This analysis will identify hotspots of non-diabetic hyperglycaemia and will further inform on where best to target capacity for maximum impact. We will use the same approach to map diabetes prevalence, for which data are readily available. In the absence of non-diabetic hyperglycaemia register data we will use the strength of the association between non-diabetic hyperglycaemia and diabetes at the practice level (see WP2) to decide whether the diabetes register can act as a reasonable proxy in identifying hotspots of non-diabetic hyperglycaemia with this methodology.

To statistically assess the short- and long-term effects of the intervention on diabetes prevalence we will use an interrupted time series analysis.¹¹⁴ The method compares the level and trend in an outcome (e.g. diabetes prevalence) post-intervention, with a prediction made from the pre-intervention level and trend, to look for a significant change. Typically, the pre-intervention trend is assumed to be linear, but this can be tested and curvilinear pre-intervention trends also modelled. For each of the approximately 8,000 GP practices contributing QOF data, we will use interrupted time series to predict diabetes prevalence (i.e. the practice's QOF diabetes register) in each year subsequent to the start of the NHS DPP and compare these predictions to the actual prevalence rates in those years.

Numbers of patients receiving the intervention will be relatively small initially, but will increase over time and after a few years a cumulative population-level effect should begin to show, provided the scheme is successful. To assess the power that this design would have to detect a change in the national diabetes prevalence rate, we set up a simulation making the following assumptions:

A large pool of patients with hotspots of non-diabetic hyperglycaemia to receive the intervention.⁹⁷

30,000 NHS DPP interventions in 2016/17, 50,000 in 2017/18, 80,000 in 2018/19 and 100,000 in 2019/20, from a random sample of practices and 1% of patients in the NHS DPP intervention. Risk for developing diabetes in two years in those with hotspots of non-diabetic hyperglycaemia, varying 5-10% at the practice level.

A 25% risk reduction for those receiving the intervention (intention to treat).^{104 115}
A cumulative effect over time, i.e. those who do not develop diabetes because of the intervention in a specific year never do, and their numbers accumulate over time.⁴⁶

That the change in prevalence of diabetes over time (from 2007/08 to 2019/20) at the practice level would be linear, if the NHS DPP was not implemented.

Random noise at the practice level post-intervention in the form of variability in the diabetes register (between -5% to +5% of the register in the previous year).

After 1000 simulations (the code is available from the applicants), we estimate the power (at $\alpha=5\%$) to detect the cumulative effect on national diabetes prevalence in 2017/18 at 0.0%, in 2018/19 at 39.9%, in 2019/20 at 66.6% and in 2019/20 at 92.4%. The total number of patients at risk of diabetes who received the intervention and did not ever progress to diabetes was 4,853 under these simulation settings (averaged across the 1000 iterations).

A key assumption in the simulation is that the underlying trend in diabetes prevalence is linear and that any deviation from this would be due to the NHS DPP and not any other factors. However, even small changes in the prevalence due to external parameters (e.g. less severe cases being diagnosed, driven by the NHS DPP itself) could compromise the population-level investigation. In the actual analysis, we will test and adjust for any non-linearity in the pre-NHS DPP period.

It is also the case that not all practices will be referring to the NHS DPP in the first few years, and the introduction of the scheme will be gradual. Provided that information on participating practices becomes available, we will use it to compare trends between practices that are, and are not, accessing the NHS DPP, under the interrupted time series analysis. This will allow us to use the non-participating practices as a comparator group to better adjust the analyses for potential post-NHS DPP trend changes, not attributed to the NHS DPP, and conduct additional tests on our assumptions.

Post-NHS DPP, once we have completed our analyses, we will be able to revisit this section and scrutinize the assumptions made. We will combine our estimates of the incidence rate of non-diabetic hyperglycaemia and rate of conversion to diabetes, and the impact of the NHS DPP with population-level data, to make forward projections of:

- (i) future rates of diabetes incidence and prevalence, under differing assumptions about the numbers of NHS DPP places on offer
- (ii) what these trends would have been without the NHS DPP, and the reduction attributable to the NHS DPP.

This analysis will help to determine the intervention capacity required to produce a sustainable reversal in the current trend of increasing rates of both non-diabetic hyperglycaemia and diabetes.

The risks of not obtaining sufficient data for these analyses are closely linked to practice participation to the scheme, a parameter that is out of our control. With the CPRD we have 13% of UK primary care cover, which is representative in terms of deprivation and geography. If the uptake of the scheme is very poor, we may not be able to identify enough cases in the databases. Another potential risk would be if the practices contributing data to the databases were less likely to participate in the scheme. This is highly unlikely, however, since these are generally large and well organised practices and we would expect them to be keen to increase their income through participation to the scheme.

Data linkage

Within the dataset we will have access to information on personal characteristics, diagnoses of non-diabetic hyperglycaemia (NDH - and its predecessors impaired glucose regulation - IGR - and impaired glucose tolerance - IGT), exposure to the NHS-DPP and the primary outcome (progression to diabetes).

There will be no need for us to link patient-level variables from different data sources. CRPD data has already been successfully linked to Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data, allowing the construction of a more complete patient journey through primary and secondary care and the mapping of causes of mortality (e.g. diabetes, cardiovascular).

To complement the patient level analyses and deliver a more complete evaluation of the scheme, we will also use various national databases of aggregate data such as NDA at the practice or low geographical level. The aggregate datasets will be linked at the practice level using the NHS practice ID, and then all relevant data will be linked using the NHS attribution dataset (which links primary care patients to ONS lower super output areas using their residence postcode) to low-level geographical areas where they will be combined with deprivation and relevant census covariates. The patient-level data and the aggregate data databases will not be linked.

Work package 6 – Validation Study (Reeves and Cotterill)

Aims: To assess the risk of confounding in participation in NHS DPP and allow adjustment in other work packages

Rationale: The comparison in the effectiveness (WP 5) and cost effectiveness (WP 7) work packages are between those who do and do not participate in NHS DPP. However, in this observational comparison the influence of unmeasured confounders (that is, factors that have an effect on both DPP participation and progression to diabetes), cannot be excluded. To better evaluate the risk of confounding and adjust for it, we propose a validation study to collect data on the key potential barriers to access and confounders unavailable from the routine records, to inform the analysis and increase the robustness of our findings.

Methods:

Step 1: Initial scoping study

The purpose of the scoping study is to identify factors that may influence access to NHS DPP, to help us design a questionnaire for the validation study. Method: we will use data from the qualitative interviews with patients and health professionals in the Access work package to identify important potential influences on access. We will use this to draw up suitable questions, in discussion with patients and clinicians on the Research Advisory Group. We anticipate that this is likely to include factors such as health status, comorbidities, motivation to improve health, health literacy and competing demands (e.g. employment, caring responsibilities).

Step 2: Questionnaire survey

We will undertake a short questionnaire survey of 400 patients (using post, telephone and online methods), to collect data on key patient factors (identified from the scoping study) that are likely to influence the offer and take-up of referral to the NHS DPP (i.e. whether 'NHS DPP referred' patients are referred to and attend the programme), but that are unavailable in routine datasets.

The purpose of the survey is:

- (a) To delineate the role psychological and social factors play in access inequalities, and identify factors potentially addressable by targeted interventions or programme modifications;
- (b) To determine the relative influence of and overall influence of these factors on participation;
- (c) To combine the results with analyses of CPRD, the minimum dataset, and other data sources to assess the extent to which associations between referral, programme attendance, and development of diabetes are confounded with patient characteristics and to adjust the associations for those factors.

The sample will consist of up to 30 patients from each of 20 practices. A suitable approach to sample size estimation for building regression models is to include 20 cases per parameter to be estimated. Our questionnaire includes 20 predictors (some of the questions will be combined into composites), giving us a recruitment target sample size of 400. To achieve this we are approaching a total of 600 patients.

Practices will produce a list of people at risk of diabetes who have been referred to DPP at least 3 months ago. After checking the list, practices will use a randomisation list provided by researchers to randomly select patients in a 1:1 ratio according to whether they are:

- (a) 'NHS DPP non-attenders', referred to NHS DPP but who did not attend any sessions
- (b) NHS DPP attenders.

In practices where DPP attendance is not recorded we will send questionnaires to referred patients and ask about NDPP attendance as part of the questionnaire, to place each individual responder in the relevant attenders or non-attenders group. On average, 50% of people referred to DPP attend the programme, so this approach should result in roughly equal groups. Additionally, in practices which hold clinics to review patients at risk of diabetes, study information can be provided to eligible patients.

A high recruitment rate is essential to minimise bias in the validation sample. The questionnaire will be as short as practicable. We will use intensive recruitment and collection methods, working closely with professionals and the NIHR CRN locally, piloting the questionnaire prior to use with patients, and using financial incentives to patients and practitioners,^{116 117} aiming for a 70%-80% recruitment rate.

The high response rate required means that this work-package is 'high-risk'. If we manage to reach this target then our findings in this section will augment the quality of the analyses in work-package 5 and 7. However, the analyses in those work packages are not dependent on the success or otherwise of this survey. If a lower response rate is evident, the data will still be of considerable value, as it will allow us to examine the role of psychological and social factors in access inequalities, and study the relative influence of GPs and patient self-selection on NDPP participation.

Analysis: Descriptive statistics will be used to characterise the groups of people who attend, and do not attend, the DPP across a range of demographic, attitudinal and psychological factors; and comparisons will be made to available national data (e.g. from the DPP "minimum dataset"). We will use univariate and multivariate logistic regression methods to estimate and compare the role of the various factors in influencing attendance at the NHS DPP intervention. We will also compute a propensity score for each individual representing their probability of attending given their particular combination of factors, to provide a picture of the extent to which these factors as a whole are associated with attendance. The individual factor and propensity scores will further be used in combination with analyses of CPRD, the minimum dataset, and other data sources to assess the extent to which any observed associations between DPP referral and attendance and subsequent development of diabetes are confounded with demographic differences and to adjust the associations for those differences. These results will further feed into the health economics analysis of the cost-effectiveness of the programme, particularly in relationship to estimating effectiveness in patient sub-populations.

Work package 7 – Comparative Long-term Cost Effectiveness (Sutton and Meacock)

Aims: To assess whether the NHS DPP is cost-effective compared to usual care in terms of long-term costs and benefits

Rationale: As with work package 5, commissioning of the NHS DPP will also be dependent on a rigorous demonstration of cost-effectiveness. Diabetes is associated with compromised quality and length of life and significant long-term health care utilisation. Effective prevention has the potential to generate health benefits and significant cost-savings over the longer term. This work package will utilise economic modelling to explore the longer term costs and benefits of the NHS DPP.

Overview of methods: This work package will estimate the overall cost effectiveness of the NHS DPP taking account of the costs incurred by commissioners to deliver the programme and the long-term health benefits for participants and non-participants. It will draw together the findings of the other work packages and use an economic model to summarise the overall cost-effectiveness of the programme as implemented and identify major opportunities for enhancing its cost effectiveness.

Research questions WP 7.1 - What are the additional costs of implementing and providing NHS DPP to the range of commissioning agencies involved?

Methods: We will estimate the additional costs of implementing and providing NHS DPP using information from the national commissioning agencies and the Implementation work package (WP2). These costs will include the contracted amounts paid to the NHS DPP providers and the costs to general practices of identifying, referring and following-up on 'NHS DPP eligible' patients. We will need to identify the additional costs incurred by general practices due to the introduction of the NHS DPP, excluding the costs that they would incur anyway in identifying and managing this patient group. We will also examine whether general practices transfer the costs of providing services to the target group as a result of the introduction of a targeted scheme for these patients paid for by other means.

Research questions WP 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 participants in the NHS DPP?

Methods: We will use data from the Outcomes work package (WP4) to estimate the average increases in health-related quality of life reported by NHS DPP participants. We will model the expected effects on quality of life using mapping to the EQ5D 5L. We will use data from participants on health service utilisation and figures from NHS Reference Costs and the Unit Costs of Health and Social Care to estimate the changes in costs. We will focus initially on the short-term effects reported by participants.

Research questions WP 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?

Methods: NHS DPP is designed to increase individual awareness and help them to reduce their risks through lifestyle changes. We will use the ELSA (2004-2014) data to: a) estimate the benefits of lifestyle changes on the diagnosis of diabetes; and b) estimate the effect of diagnosis itself on lifestyle changes. We will use multivariable non-linear regression models to predict the benefit of lifestyle changes (measured by physical activity, BMI, consumption of fruit and vegetables) on the likelihood of developing diabetes for those who are at risk of diabetes in the first observation in ELSA (using glucose level measurements in ELSA). We will estimate these benefits by age and gender.

We will then determine the wider behavioural effects of the NHS DPP that arise from a non-diabetic hyperglycaemia diagnosis. International evidence suggests that individuals improve their lifestyles in response to diagnosis.^{119, 120} However, patients with non-diabetic hyperglycaemia could also decide to indulge in less healthy lifestyles anticipating increased and effective treatment in the future. We will estimate this behavioural response using dynamic models of lifestyle choices and comparing diabetics to a statistically defined group of people at 'risk' of developing diabetes using the propensity score model¹²¹ using a similar US survey, the Health and Retirement Survey.

Research questions WP 7.4 - Is the overall NHS DPP cost-effective compared to usual care? How does incorporation of equity consequences affect the overall cost effectiveness of NHS DPP? What changes to the NHS DPP would improve its short and long-term cost effectiveness?

Methods: It is expected that the NHS DPP will increase costs in the short term as participants make greater use of health services to better identify and manage their newly-identified needs. Health-related quality of life may also deteriorate in the short term as participants adjust to the discovery that they are at higher risk. As such, it is likely that the health benefits and cost reductions that are expected from the NHS DPP will be accrued in the longer-term.

Decision-analytic models are frequently used within economic evaluations, to extrapolate beyond observed data and to estimate the long-term effects of an intervention. Often, this involves modelling a hypothetical cohort over a lifetime horizon, using multiple sources of data. Inputs into decision-analytic models include parameters such as the probabilities of different events occurring (referred to as transition probabilities), the costs associated with events or resource use, and utility scores, which can be used to estimate quality-adjusted life years (QALYs).

Several decision-analytic models exist in the published literature*, which evaluate the cost-effectiveness of prevention strategies of developing Type 2 Diabetes. These models will be assessed to determine their strengths, weaknesses, validity and usability. In light of these assessments, one of the existing models will be selected and adapted, so that it can be used to evaluate the cost-effectiveness of the NHS DPP. As there is no model that currently evaluates the effectiveness of the NHS DPP, we will require effectiveness data to inform the model parameters.

The National Diabetes Audit (NDA) contains information on all of the patients identified as being at risk of developing Type 2 Diabetes, as well as the number of these that go on to develop the condition. This data will be used as an input in the decision-analytic model, comparing the number developing diabetes who have accessed the NHS DPP to those who receive usual care. Access to the data will be conditional on an application to NHS Digital, which will be reviewed by an Independent Group Advising on the Release of Data (IGARD), who determine whether the application is ethically acceptable, and that the appropriate data governance structures are in place.

Other data sources will include, the costs associated with implementing and running the NHS DPP, costs associated with the condition of Type 2 Diabetes, and published clinical data on the risk of various comorbidities and complications which arise as a result of Type 2 Diabetes.

In addition to estimating the overall value for money of the NHS DPP, the model will be used to estimate the uncertainty surrounding the result, using sensitivity analyses. Such analyses will include, varying the input parameters; to see how the end result is affected, as well as changing the structural assumptions of the model. We will use scenario analysis to generate proposals for ways in which the cost effectiveness of the programme can be improved. We will consider, for example, which groups generate the highest costs and are at most risk of harmful effects of diabetes.

Reflecting the importance of the distributional consequences of NHS DPP, we will use appropriate methods to consider how taking equity into account affects the overall judgement on the cost effectiveness of NHS DPP through the simulation model, linking with work package 1.¹²² This analysis will also identify where priority should be focused to improve contribution to social value.

* Roberts, S., Barry, E., Craig, D., Airolidi, M., Bevan, G. and Greenhalgh, T., 2017. Preventing type 2 diabetes: systematic review of studies of cost-effectiveness of lifestyle programmes and metformin, with and without screening, for pre-diabetes. *BMJ open*, 7(11), p.e017184.

Leal, J., Morrow, L.M., Khurshid, W., Pagano, E. and Feenstra, T., 2019. Decision models of prediabetes populations: a systematic review. *Diabetes, Obesity and Metabolism*.

Work Package 9 – Patient Decision Making and Experience of the Digital DPP (Murray)

Aims: To describe and understand patterns of engagement (defined as uptake and initial use) with the DDPP by the target population, with a view to producing recommendations on how to maximise engagement in the future.

Rationale: On August 2018, the NHS Diabetes Prevention Programme released a new framework for 'Healthier You: NHS Diabetes Prevention Programme'. The aim of the new framework is to expand the programme and to improve take-up and adherence to the DPP, including better targeting of the working age population and addressing delays associated with courses in rural areas. The new framework also includes implementation of digital support for diabetes prevention alongside existing face-to-face provision. Qualitative research from work package 1 has assessed the process of accessing the face-to-face DPP, and the experience of patients and professionals. We would like to further assess decision-making and engagement of the digital DPP.

This work package will focus on the question of engagement (defined as uptake and initial use) with the digital DPP (DDPP). Engagement can be extremely problematic with digital interventions. The providers in the pilot DDPP have invested heavily in maximising both uptake and ongoing use, with very substantial resources (time, staff) dedicated to the on-boarding (registration) process and subsequent phone calls to maintain engagement. It is not yet known what approach the providers of the new digital services will take.

Overview of methods: This work package use a combination of document review, interviews and assessment of usage data to describe and understand patterns of engagement with the NHS DPP digital intervention.

Research question WP 9.1: To describe mechanisms in place to promote patient uptake and initial use (e.g. invitation framing, 'on-boarding', and additional engagement strategies of the DDPP). Specifically, we aim to describe (a) how the DDPP is framed and delivered by providers, and (b) the onboarding process.

Methods: Qualitative study using documentary analysis and semi-structured interviews with health professionals. In order to gain a richer understanding of the intervention components and mechanisms in place to promote uptake of the interventions we will conduct an analysis of interview data from providers of the digital programmes which will be collected by WP3.

Up to three interviews with the five developers (i.e. up to 15 interviews) are being conducted by WP3 to elicit as much detail as possible on the design of the intervention (planned intervention structure and content, and underpinning rationale, i.e. theory and evidence). Within these interviews' providers will be asked two questions specifically to address the research aims of this work package. These questions will focus on the intervention components and mechanisms in place to promote uptake (e.g. invitation framing, 'onboarding', and additional engagement strategies). It is this data that we will focus our analysis on. See WP3 substantial amendment 3.1.2 for more details about the methods.

Analyses: We will conduct a descriptive analysis of the engagement strategies and onboarding process reported in the framework response documents. We will conduct an analysis of the interview data relevant to this research question collected by work package 3, with the developers and providers of the interventions. We will undertake a directed content analysis approach² in order to identify pathways to referral, and strategies of onboarding. This analysis will be used to add depth of understanding to the document analysis and provide us with a comprehensive description of the intervention mechanisms in place to promote patient uptake as well as to help to inform our recruitment of patients and development of our patient interview topic guides.

Research question WP 9.2: To explore service user experience and patterns of engagement of the DDPP, using analysis of usage data.

Methods: Two datasets will be accessed to describe participant engagement with the DDPP. Data on the number of referrals and registrations to the DDPP and the characteristics of the participants who are offered and take up the DDPP will be collected from the NHS Diabetes Prevention Programme

² Hsieh H-F, Shannon SE. Three Approaches to Qualitative Content Analysis. Qualitative Health Research. 2005;15(9):1277-88.

Minimum Dataset (MDS), provided by NHS England. This dataset includes a referral ID, personal and demographic information, recruitment (to the DDPP) data, and clinical outcome data.

We will use this dataset to describe:

- The total number of people referred to the DDPP
- The proportion of people referred who accept use of the DDPP
- The characteristics of people referred and accepting use of the DDPP
- The source of referrals
- The providers referred to
- The reasons (where applicable) that face to face education was declined
- The reasons (where applicable) for declining digital DPP
- Duration between referral and registration to the DDPP

Data on engagement with the DDPP will be collected from the providers of the DPP. According to the new framework for NHS DPP, providers must monitor service users' engagement with the service by collecting data on the amount, frequency, duration and depth of usage of the digital DPP e.g. viewing materials, completion of active elements, engaging with human coaches, inputting self-monitoring data and taking part in moderated sessions.

We will request data on:

- Individual logins (of app/website interface)
- Number, date and time of logins
- Pages visited

We will use this data to describe:

- The proportion of people who register who make use of the DDPP (use to be defined during interviews with providers and document review)
- How people make initial use of the DDPP

If the usage data supplied by the providers contains the same referral ID as the minimum dataset, we will link the two datasets to address the following questions:

- What are the characteristics of those who access and make initial use of the DDPP?
- Do patterns of use vary by demographic characteristics (with a particular focus on determining the likely impact of these digital programmes on health inequalities)?

We will work with providers to ensure an opt-out consent process is in place for usage data by: 1) reviewing existing terms and conditions and consent statements that service users complete when registering to take part in the digital DPP, and 2) revising consent statements where necessary in conjunction with the provider. Service users need to be able to opt-out of their anonymised individual level data generated as part of their participation in the digital NHS DPP being used for an independent evaluation.

Once an agreed opt-out consent process is in place, we will ask all five providers for the first four weeks of usage data for all new registrants to the DDPP. Preferably, we are seeking individual-level user data to allow longitudinal analyses across the initial period of use (defined as the first 4 weeks-further longitudinal analyses will be conducted by WP3). If this is deemed not feasible after discussion with a provider, we will seek median data.

We will ensure that the data transferred to UoM from the providers is anonymised and does not contain any personally identifiable data. Providers will be specifically requested to do the following before sending any usage data to UoM:

- Remove any personally identifiable data (name, contact details, DOB, medical records, IP address)
- Remove any address details leaving only the first 3 letters of the postcode, which will allow us to assess the geographical spread of usage data we obtain
- Review any free-text entries from service-users that risk sharing personally identifiable data
- Quality assurance

We will request that providers encrypt the data files using an AES256 compliant encryption mechanism such as 7-zip. It will then be uploaded to a University of Manchester Dropbox for Business. The data will then be immediately moved from the Dropbox to a secure University of Manchester drive for storage. If this method is unfeasible for the provider due to technical issues, we will request that the data files are encrypted as above and sent to UoM by email with password shared by a separate communication.

We will request specific research data storage from UoM IT for the usage data files. Data files will be then held on The University of Manchester secure server (and backed-up as per usual UoM standards) for the purposes of analyses and will only be accessed by the DIPLOMA team. We will request providers transfer data to us on a monthly basis using this process.

Analyses: Simple descriptive statistics will be used to analyse the MDS and describe the total number of people referred to the DDPP, the proportion of people referred who accept use of the DDPP, the characteristics of people referred and accepting use of the DDPP, the source of referrals, the providers referred to, the reasons (where applicable) that face to face education was declined, and the reasons (where applicable) for declining digital DPP and the duration between referral and registration to the DDPP.

Descriptive statistics will be used to calculate mean and standard deviation for the (or median and IQR if data are skewed) numbers of log-ins and other measures of use and describe the characteristics of those who access and make initial use of the DDPP. Tableau and other software programmes will be used to visualise the data on usage patterns, with a view to identifying patterns of use.

Logistic regressions will be conducted in order to determine whether patterns of use vary by demographic characteristics.

Amendment to WP9

Substantial amendment: [see documents: Amendment Tool, 16.12.20].

Rationale: In light of the new framework for the digital DPP, we are proposing an additional sub-study (WP9.3) relating to WP9, to explore patient experience of referral and engagement with the DDPP:

WP9.3: Qualitative interview study

Aim: Exploring patient experience of referral and engagement with the DDPP including:

1. Patient experiences of the process prior to referral to the DDPP including discussions in primary care about the DDPP, any alternative programmes discussed or offered, reasons for refusing face-to-face DPP (if applicable).
2. How and why patients choose to accept or decline referral to a digital programme, and how this differs from decision-making around the face-to-face programme;
3. How and why patients initially engage with the DDPP, including their experience of the referral and on-boarding process;
4. Patient perceptions of the advantages and disadvantages of embarking on the DDPP, perceptions of the advantages and disadvantages of embarking on the face-to-face programme, perceptions of the aim and scope of the DDPP, and expectations about potential impact of the DDPP on their personal health behaviours.

METHODS

Design: Qualitative study using semi-structured interviews with patients/service users.

Setting: The re-procured DPP is intended to cover the whole of England from August 2020. Five providers have been selected to deliver the DDPP and each local health service has chosen one or other of these providers. There are several pathways of referral into the DDPP:

Primary care referrals:

The original pathway for DDPP delivery was through primary care. Patients identified with pre-diabetes (determined by an eligible HbA1c reading in the last 12 months) by their general practice would be offered the face-to-face version of the DPP, either by letter or during consultations with health professionals. If a patient declined this offer of face-to-face DPP they would be offered it again on a further two occasions. If the patient declined face-to-face three times, then they were eligible to be offered DDPP by their health professional. There was also a cap of 20% of patients who could be referred to DDPP. Following the closure of many GP practices due to Covid-19 and subsequent pausing of the face-to-face version of the DPP, changes were made to the way that the DPP was offered to patients.

- i. A 'remote group' service has been developed, with group sessions delivered via online platform or via telephone for patients without access to a webcam.

- ii. In primary care patients are now offered a choice of 'remote group' or DDPP from the first offer (removing the need to have declined face-to-face before being offered DDPP).
- iii. The cap of 20% was removed so that all eligible patients could be offered the DDPP.
- iv. Eligibility criteria has been changed to allow patients with an eligible HbA1c reading within the last 24 months (instead of 12 months) to be contacted through primary care and offered 'remote group' or DDPP.

Once patients have been identified in primary care there are two main ways of them accessing the DDPP: a) Practices identify eligible patients and send letters explaining their risk of diabetes and offering the DDPP. Patients are asked to call the service provider of the DDPP to register. b) The DDPP is offered opportunistically by practices to patients during appointments, and a letter is sent to the provider by the practice.

Service providers of DDPP:

The changes to the referral route due to Covid-19 now allow service providers of the DDPP to directly contact patients who have previously declined offers of face-to-face from their own lists and offer them access to the DDPP.

Self-referral:

In August 2020, in response to the COVID-19 pandemic, the DDPP expanded access by moving from a referral only route (from general practice) to add a self-referral route via an online risk tool. Eligibility to self-refer into the programme is based on the Diabetes UK risk tool (a validated Type 2 diabetes risk assessment tool) which can be completed on the Diabetes UK website or on DPP providers' websites. People scoring at or above a risk threshold are signposted to self-refer with their local DPP provider (identified by postcode). Anyone scoring at or above the risk threshold is eligible to join provided they are aged 18-79, not pregnant and that they do not have a current Type 2 diabetes diagnosis. Once people have registered with the providers, they will be contacted to complete their registration. The providers will offer a choice of 'remote group' or DDPP. National and local advertising campaigns are currently advertising the risk tool.

Population: The target population for this study will be:

- Adults, aged 18 or over;
- Identified as having -nondiabetic hyperglycaemia, in accordance with the specification from NHSE; or identified as being at risk of developing type 2 diabetes in accordance with the 'Know your risk score'
- Offered, referred or self-referred to the DDPP
- Both those who accept and decline the DDPP

Recruitment: We will aim to recruit up to 30 patient/service user (terms used interchangeably) participants from across the five providers.

We aim recruit a maximum variation sample of patients with pre-diabetes, selected to vary by age, gender, ethnicity, SES, geographical area, digital programme used, and level of engagement with the digital diabetes prevention programme (never used, registered but didn't continue, some initial use). In order to ensure our sample reflects the population in the UK with diabetes, if needed we will purposively sample for patients from African-Caribbean, Black African, or South Asian ethnic groups and patients from regions of higher deprivation. Importantly we will aim to recruit patients who have been referred to the digital programme through different routes (self-referral and referral through providers/primary care). We will be taking the NIHR INCLUDE guidance into consideration with our sampling approach.

Patients will be offered the DDPP via different routes (referral through primary care, self-referral, direct contact from providers). Patients will also decide whether to take up the offer of the DDPP or not. As such we anticipate that our interview sample will represent patients who fall into the below categories. However, we acknowledge that some of these groups of people will be harder to access than others. As such we are not seeking equal numbers of participants from each group, rather we will strive to represent each of these groups with our interview sample.

1. Those offered the DDPP through primary care who take up the programme
2. Those offered the DDPP in primary care who decline/do not respond to the offer
3. Those who use the self-referral pathway, taking the 'diabetes know your risk' tool (with risk confirmed) and take up the DDPP

4. Those who use the self-referral pathway, taking the 'diabetes know your risk' tool (with risk confirmed) who do not take up the DDPP
5. (A subgroup of category 2 and 4) Those patients who are offered a choice of 'remote group' and DDPP and choose 'remote group' and not DDPP.

As we anticipate it being quite difficult to recruit people into the interview study we will use a range of recruitment strategies. We aim to use four different recruitment strategies:

Recruitment through primary care:

To recruit those offered the DDPP through primary care who take up the programme (category 1) and those offered the DDPP in primary care who decline/do not respond to the offer (category 2) we will work with the face-to-face partners and/or digital providers to identify practices from which patients are registering for the DDPP. This will give us an indication of where in primary care the DDPP is being offered to patients. We will then select practices that are offering the DDPP from across the English regions (North, Central, South East, South West).

We will ask for practices details from the DPP providers, and make contact with practices to discuss the research study. Participation for practices will involve screening practice registers and contacting eligible patients (eligibility criteria for referral to the DDPP is set by the providers/NHS). Practices will be asked to screen their patient lists for:

- Have been offered DPP by the practice (or if recorded in the patient record: Have been offered DDPP).
- Or (if this data isn't coded by practice systems)
- Individuals with a nondiabetic hyperglycaemia (defined as having an HbA1c of 42 – 47 mmol / 6.0 - 6.4% or fasting plasma glucose (FPG) of 5.5 – 6.9 mmol/l) reading within the last 24 months.
- 18-79 years of age
- Do not have a current Type 2 diabetes diagnosis
- Are not pregnant

Once patients have been identified, practices will be asked to contact patients to invite them to take part in this research study and will be provided with study information in email, letter and text format. We will work with practices to decide which method of patient contact is most appropriate. The information sent by post or email will contain details of the study in a flyer, a participant information sheet and details of how to contact the research team including the URL of the study website, phone number and email address. The information sent by text will briefly describe the research and provide a link to the study website and a contact number. Information will stress we are interested in interviewing people who have been offered the DDPP. Interested patients will contact the research team (by phone or email or via the website) who will then provide any further information on the study and answer questions. If the patient is happy to proceed, a time and date will be arranged with the researcher for the interview to take place. Copies of the consent form and patient demographic information form will be sent to participants in advance of the interview either by post or email or will be directed to versions hosted on the study website. The researchers will ask each participant their preferred method of receiving these documents and will collect the relevant contact details on a contact details spreadsheet in order to do so (i.e. name, email address or postal address).

Recruitment through providers:

To recruit both those offered the DDPP through primary care who take up the programme (category 1), and those who use the self-referral pathway, taking the 'diabetes know your risk' tool (with risk confirmed) and take up the DDPP (category 3) we will recruit through the DPP and DDPP providers. We will also ask the face-to-face providers to help recruit those who are offered a choice of 'remote group' and DDPP and choose 'remote group' and not DDPP (category 5). Currently, at the time of first contact with face-to-face providers, patients referred through primary care and those from the self-referral route are offered the option of either participating in 'remote group' or DDPP.

We will send providers (face-to-face and digital) an email template detailing the research study and inviting participants to participate along with a participant information sheet. We will ask providers to email all people who register for the DDPP or who decline the DDPP in favour of 'remote group' during the study recruitment period (currently January- August 2021) every four weeks.

The email and information sheet will ask any interested person to contact the research team directly, either by phone or email. The research team will provide any further information on the study, answer questions, and arrange to send the participant copies of the consent forms and participant demographic form via email or in the post. If a person is happy to proceed, a time and date will be arranged with the researcher for the interview to take place. Participant contact information will be stored electronically on a password protected Excel sheet, stored on a University of Manchester drive, and will only be accessible by the research team. Participant contact details will only be used to discuss participation and arrange interviews.

Initially, we will ask providers to invite all participants they are registering to the DDPP to the research study in order to judge the uptake of the offer of participation in the research study. However, once recruitment has begun, we may ask providers to target the offer of participation in the research study. For example, we may ask providers to purposively sample people from certain ethnic backgrounds, gender, areas of deprivation to ensure that we have a sample of participants that represent the wider UK population of people with type 2 diabetes.

It is possible that in some cases, for patients who have accepted the offer of the DDPP, the same patient may be identified through practice recruitment and provider recruitment and therefore will be sent information about the research study twice.

Digital recruitment:

In order to capture the views of people who use the self-referral pathway, taking the 'diabetes know your risk' tool (with risk confirmed) who do not take up the DPP (category 4) we will recruit using digital technology. There are several page clicks that make up the online self-referral pathway with each click launching a new page hosted by Diabetes UK and NHS. We will embed an exit pop-up within the self-referral pathway. We will aim to embed this popup at the point when people have completed the risk score tool, have been shown their results, have been identified as having moderate or high risk, have been informed that they may be eligible for the DDPP and are given some information about the programme. If the user closes the web page (hosted by Diabetes UK or NHS England) at this point, they have not completed the remaining steps needed to register for the DDPP. This strategy is designed to target those who have learnt they have a medium or high risk of developing type 2 diabetes but who have not, at this stage, taken up the chance to register for the DDPP. The exit pop-up will ask anyone closing down this webpage if they would be interested in participating in a UoM research study on diabetes risk. People will then have the option to click for more information or close the popup. If the person clicks for more information they will be taken to a UoM webpage.

This study webpage will be hosted by the NIHR Applied Research Collaboration Greater Manchester (www.arc-gm.nihr.ac.uk) as a separate page to the existing DIPLOMA research study page. The page will explain more about the research and how to participate. Potential participants will be asked to enter their name and email address, phone number or home address if they think they are eligible to participate and would like to discuss this with the researcher. The information entered into this form will be sent securely via the webpage form to the researchers UoM email address automatically. The research team will then follow the same procedure as above and email/post/telephone the participant study specific documentation. Alternatively, the website will contain the contact details of the researcher for the person to make contact with, if they prefer. Participant contact information will be stored electronically on a password protected Excel sheet, stored on a University of Manchester drive, and will only be accessible by the research team. Participant contact details will only be used to discuss participation and arrange interviews.

Recruitment via social media:

If necessary, we will supplement our recruitment strategies with recruitment via social media. For example, we will consider placing a banner advert on Facebook or other social media platform such as Twitter. We will target our population using social media algorithms, these are based on both demographic characteristics (such as location, age, gender) and "interests" which can be used by advertisers to filter and define target audiences. We will work with our PPI representatives to determine a potential list of interests with which to filter and target our audience.

The content of the advert will be tested with PPI representatives but will include text such as "Have you been told you're at risk of developing diabetes? Would you like to talk to us about it?". Clicking the

advert will take participants to the UoM webpage (see above). The research team will then follow the same procedure as above and email/post/telephone the participant study specific documentation.

The study website may also be advertised in other ways such as links to it on twitter posted by UoM and UCL research groups.

Inclusion and exclusion criteria:

The inclusion criteria for participation in the interview study is people eligible for the DDPP:

- Individuals at risk of diabetes (evidence by completion of a risk tool, or with a nondiabetic hyperglycaemia (defined as having an HbA1c of 42 – 47 mmol / 6.0 - 6.4% or fasting plasma glucose (FPG) of 5.5 – 6.9 mmol/l) reading within the last 24 months.
- 18-79 years of age

Exclusion criteria for the participation in the interview study is:

- Unable to provide informed consent. For example, due to:
 - Cognitive impairment
 - Severe mental illness

Data Collection: Semi-structured interviews will explore patient decision making around the DDPP. Specifically interviews will explore: patient perceptions and experience of pre-diabetes and type 2 diabetes, perceptions and experience of digital health technologies, how and why patients choose to accept or decline referral to the digital programme they are offered, how and why patients initially engage with a digital programme, including their experience of the referral and onboarding process (initial uptake); how and why patients continue or cease to engage with the digital programme; and perceptions of the pros and cons of the digital programme.

The interview topic guide will be informed by the document analysis and provider interviews and will focus on eliciting information on patient reasons for accepting or declining referral to the digital DPP, reasons for engaging with the DPP, perceptions of the pros and cons of embarking on the digital programme, and its perceived potential impact on health behaviour. The topic guides will be refined and revised iteratively throughout the process of interviews.

Demographic data and data on programme access will also be collected from the participants who take part in the patient interviews to allow description of the participants and to draw comparison with the total digital DPP population and guide interviews. Participants will be asked to complete a background questionnaire prior to interview including: age, gender, ethnicity, SES, education level, experience with digital programs, postcode, digital programme used (provider), level of engagement with the digital diabetes prevention programme (never used, registered but didn't continue, some initial use, ongoing use), referral routes (for example, through referral from a GP and self-referral), computer skills and digital access.

Procedure:

Interviews will be undertaken after explicit informed consent has been obtained. We will individually consent people. Participant information sheets will be sent to participants via email or post. Interviews will be conducted by a researcher via telephone or via online video conferencing (e.g. Skype/ Zoom/ MS Teams). Interviews are anticipated to last approximately 60 minutes.

The interviews will be audio-recorded (and a separate audio recording for verbal consent) using an encrypted audio recorder. If participants decide to take part in a Skype /Zoom/ MS Teams interview, we will not use the recording function on those platforms, but instead we will use an encrypted audio recorder in line with GDPR requirements.

As a 'thank you' for taking part, participants will be offered £25 for participating in the interview. This amount is inline with the standard amount offered in previous studies, including the previous WP3.4 interview study, and reflects the updated NIHR guidance (May 2021) on payments for research participants (which suggests £25 per hour of participant time). Reimbursements will be paid by high street vouchers.

In line with University of Manchester's 'Taking recordings of participants for research projects' Standard Operating Procedure, participants will be individually consented and verbal consent will be

taken via a separate audio recording to the interview recording, using an encrypted audio-recorder. Researchers will complete and sign consent forms as they go through the consent process with the participants over the telephone/online platform. When audio recording consent, researchers will ensure that the participant clearly states their name in the audio recording. The consent statements be read aloud individually, and the participant will confirm Yes or No to each statement. All optional consent statements will be made clear. Audio-recorded verbal consent will be stored on a secure University of Manchester server, only accessible to the research team.

Face to face: Given the current Covid 19 situation all interviews will be conducted by phone / zoom / skype initially. However, if the current situation changes to allow, then interviews may also take place face-to-face. Consent for these face-to face interviews will be taken in person by the researcher prior to the interview using a paper copy of the consent form. All interviews will be audio-recorded using an encrypted audio-recorder. Physical copies of consent forms will be kept separately in locked cabinets in locked rooms within the University College London.

Audio-recordings will be checked once transferred to the secure drive and then deleted from the recording device. Interviews will be transcribed using a university approved transcription company who have signed an Information Sharing Agreement, and the identity of participants will be anonymised (i.e. removal of names, places and provider organisation). Interview transcripts will be securely stored on a University of Manchester server, only accessible to the research team. Information will be kept in accordance with the University's Retention Schedule and Research Data Management Plan. Audio consent recordings and hard copy consent forms would be retained for 2 years after the end of the study, in line with the University's Retention Schedule.

Data Analysis: Transcripts from interviews with patients exploring patient experience of the digital DPP will be analysed inductively using thematic analysis by an experienced qualitative researcher. Analysis will be undertaken iteratively with data collection to allow for testing of emerging hypotheses or themes. Codes and emerging themes will be generated by the lead researcher and discussed with a multi-disciplinary group in data clinics to promote rigour and transparency in the analysis. We anticipate that the themes from this analysis will relate to the sociobehavioral and cognitive constructs of the existing behaviour change theories. If this is confirmed during the thematic analysis, we will conduct a comparative analysis of our themes and constructs of a theory of behaviour change, the Health Belief Model³, in which the inductively derived themes will be mapped to constructs of the HBM in order to further explain patient engagement with the DDPP. HBM is one of the most widely used conceptual frameworks for explaining and changing individual health behaviour. HBM evolved from a cognitive theory perspective and is a value-expectancy theory, which attempts to explain and predict individual's attitudes toward objects and actions. HBM posits that an individuals' perceived susceptibility to and severity of a disease influence the perceived threat of the disease which predicts the likelihood of self-management behaviours. Major components in HBM include perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy. The HBM suggests that for people to comply with participatory preventive interventions, they will need to perceive both risk and potential benefit. The HBM has been widely applied to studies of pre-diabetes, and the development and evaluation of digital health interventions.

Recruitment and data collection will cease once data saturation has been reached (i.e. when no new themes are emerging in subsequent interviews). Nvivo software will be used to facilitate the storing, coding and analysis of data.

National coverage within DIPLOMA

In terms of primary data collection (WP 1, 2, 3 and 6), we will seek to ensure that our data collection captures variation which will enable us to understand the national picture, in terms of key geographical factors such as deprivation and rurality. We expect that at least one site for these work packages will include London to ensure that we understand any specific issues.

CPRD Gold covers 6.9% of the UK population

(<http://ije.oxfordjournals.org/content/44/3/827.full.pdf+html>). Since submitting the bid we have now got approval to use CPRD Aurum data in addition to the CPRD Gold data which was approved initially. This dataset was launched in October 2017 and represents around 13% of the population of England [3]

As NDPP wave 1 covers some 26 million patients, we are confident there will be sufficient coverage across databases to enable our planned analyses to progress. All NHS-DPP participants will be coded as such in their GP electronic record, and we will be able to pick these up retrospectively in the CPRD (and identify participating and non-participating practices).

CPRD is a nationally representative group of practices in terms of deprivation, geography and ethnicity (although ethnicity is not coded reliably in the database prior to 2006). UK primary care has been computerised for some time now and we are confident on the completeness of electronic health records. In particular, completeness and reliability increased post 2004 when the QOF was introduced as this incentivised recording of processes and treatments for all major chronic conditions, which enables a comprehensive assessment of co-morbidity. Disability status will be inferred from relevant Read codes concerning BMI. Learning disabilities will be measured using recommended Read codes as specified in the 2015/16 GMS contract. Comorbidity will be measured using Read codes concerning major chronic conditions incentivized by the QOF (and hence well recorded)

Dissemination and projected outputs

We will make regular reports to NHS DPP stakeholders, especially NHS England and Public Health England, to ensure that our emerging findings can influence the delivery of the NHS DPP services. We will disseminate the projects outputs through a variety of media, including conference presentations and conventional academic publications, seminars and short accessible reports for stakeholders, and plain English summaries and podcasts for patients and the public. We will work closely with our Stakeholder Advisory Group and the Research Advisory Group to maximise the utility of our dissemination. We have costed in time for patient and public contribution to dissemination.

Plan of investigation and timetable

Pre-funding, we will prepare ethics and other approvals; initiate staff recruitment; negotiate external data access; and strengthen relationships with NHS DPP. **Year 1** we will conduct induction and training (WP 1,2,3,5&7), finalise access to external and NHS DPP data; select sites for case studies (WP2) and for qualitative research (WP1-3). We will set up Stakeholder Advisory, Research Advisory and Study Steering Groups and hold first meetings. We will begin work on WP1, 2 and 5, and discuss options for additional nested studies. **Year 2** we will begin work on all remaining WPs, with a focus on generating and disseminating findings from WP1, 2, 3 and 4. We will begin the WP6 validation study. **Year 3** we will complete the main analyses for WP1, 2, 3, 4 and 6, and start the main analysis for WP5 and 7. **Year 4** we will complete WP5, 6 and 7, complete final reports and publications.

We plan to start the programme on 1st April 2017. We will be in regular contact with key DPP stakeholders to ensure that we communicate early findings in summer 2017 during planned meetings.

Project management

DIPLOMA is a large and complex undertaking. We propose the following project management structure to meet our aims of delivering the research to time, target and budget, and to ensure that the results are disseminated to key stakeholders and inform NHS decision-making.

Given the size and complexity of the programme, we have identified programme management as a specific work package that will be jointly led by Sutton and Bower). This work package will have 5 functions:

Ensuring progress on the research work packages, and effective co-ordination between work packages on common data and issues.

Ensuring suitable patient and public involvement and engagement in the research project, via relevant training and support, ongoing dialogue, and use of opportunities for engagement of contributors at critical points (such as development of patient facing materials, and dissemination).

Reporting to the NIHR HS&DR Study Steering Committee, who will provide supervision on behalf of the Sponsor and Funder and ensure work is conducted to the standards in the Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The NIHR HS&DR Study Steering Committee will meet every six months.

Engagement with external stakeholders (Department of Health, NHS England, Public Health England, Diabetes UK, local NHS providers and commissioners and NHS DPP providers), feeding back on progress with the project, sharing of interim findings with stakeholders, and as a forum for sharing other information.

Engagement with NHS DPP. Certain work packages are dependent on data being collected effectively. For example, it is imperative that the referral to the NHS DPP code is used consistently and in an unbiased way by GPs. This work package will ensure that every effort is made to ensure accurate recording through regular audit and feedback.

Each of the work packages has a lead academic. Each work package will set up monthly meetings and will meet the Programme Management leads (Sutton and Bower) quarterly.

An advisory group will be created to provide important clinical and 'expert by experience' input in relation to key areas of the NHS DPP. The advisory group will meet every six months, and will be available for ad hoc advice and support throughout.

Patient and Public Involvement

We recruited 6 people (who were either diagnosed with diabetes, with family history, or 'at risk'), varying in age, gender and ethnicity. We sent our research plans to them and also asked what they would like to know about NHS DPP. Their responses confirmed our view of the core questions: the effect of NHS DPP on diabetes prevention and other outcomes; cost effectiveness; equal access; implementation and service delivery.

The PPI contributors also raised many other interesting issues. This has led to some changes in the content of the research. The contributors raised the issue of what patients might think of the use of commercial providers, and we will explore this issue in the WP1 qualitative interviews. Other areas they felt that it was important to explore included checking on the level of patient and public involvement in NHS DPP itself (WP2 interviews); issues such as confidentiality and links to GP (WP1 interviews); patient choice in NHS DPP, and how patients cope with identification of diabetes and associated issues of risk to health (WP1 and 3 interviews).

The group also felt that it was important to explore the impact of wider social networks on uptake. We have experience of work in social networks,^{127 128} and we will explore all these issues in the WP1 qualitative interviews and observations. Finally, our contributors highlighted the importance of patient experience of the consent process and accuracy of information provided during the referral process, and availability of services outside NHS DPP. Again, we will explore these issues through WP1 and 2.

Sanders will act as lead for PPI within the DIPLOMA programme. Co-ordination of PPI will be a key role of the programme manager funded through DIPLOMA. We have budgeted £10,000 for fees to contributors (66 days at INVOLVE rate of £150 per day) and £2,000 for public contributors to the programme to attend relevant conferences alongside the team.

An additional focus on public engagement would be highly relevant for this programme. Engagement is defined as 'the myriad of ways in which the activity and benefits of higher education and research can be shared with the public. Engagement is by definition a two-way process, involving interaction and listening, with the goal of generating mutual benefit'.¹ We will work alongside our PPI partners to create accessible web-based materials explaining the NDPP programme and the DIPLOMA evaluation, to ensure that patients and the public are informed about ongoing developments through the life of the programme.

The Patient and Public Involvement team at Salford Royal Foundation Trust will facilitate two-way public engagement through their existing links with the Research for the Future project and in particular their Help BEAT Diabetes programme. Research for the Future is an NIHR CRN Greater Manchester campaign which aims to encourage people to get more involved with NHS research. It consists of a series of 'Help BEAT' campaigns. There are currently 4200+ people on the Help BEAT Diabetes database, and they are expanding their remit to people at risk of diabetes. We will complement this resource by engagement work in other sites involved in DIPLOMA to ensure national coverage.

Expertise and justification of support required

The project has two co-principal investigators (Bower and Sutton). Bower will be the lead on the management of the research study (including ethics and governance).

The academic team is listed below. A team of research staff and project managers will be recruited once contracts are secured.

Matthew Sutton will be the Principal Investigator jointly with **Bower**, co-ordinating work packages (with a focus on the quasi-experimental WP5 and 7) and liaising with the NIHR Study Steering Committee, the Research Advisory Group and with stakeholders. He will also lead work package 7. Sutton is a Professor of Health Economics and NIHR Senior Investigator with a worldwide reputation in non-randomised studies of policy and health interventions. He co-authored MRC guidance on natural experiments.¹²⁹ His work includes high impact papers on financial incentives and pay for performance,⁹ resource allocation) and 7 day services, for which he was an expert witness to the House of Commons Health Select Committee. **Peter Bower** will act as co-PI, assisting with co-ordination (with a focus on the patient and organisation level health services research in WP1-4 and 6) and liaison with stakeholders. Bower is a Professor of Health Services Research with experience of design and delivery of policy-relevant evaluations, including the national evaluation of the Expert Patients Programme, the Whole Systems Demonstrators and complex interventions related to multimorbidity and integrated care. **William Whittaker** will co-lead the Access and Inequality work package with Chandola. Whittaker is a Research Fellow in Health Economics with experience with survey and administrative data. His work includes assessments of access to care, inequalities in health, resource allocation formulae,¹³⁰⁻¹³² evaluating dentistry services,¹³³ 7-day primary care,¹³⁴ and care inequalities by sexual orientation.¹³⁵ **Tarani Chandola** is a Professor of Medical Sociology. His research is primarily on the social determinants of health, focusing on health inequalities and psychosocial factors, and the analysis of longitudinal cohort studies. Much of his research is on stress at work and its effects on health. His current research projects include the MRC funded FRAILL study, the ESRC funded International Centre for Life course Studies in Society and Health and a work stress intervention study funded by the NIHR. **Paul Wilson** will lead the Implementation work package. He has considerable experience in evidence synthesis, knowledge transfer and implementation. He is part of the NIHR CLAHRC Greater Manchester and Deputy Editor in Chief of the journal Implementation Science. **David French** will lead the Fidelity work package. French is a Professor of Health Psychology and member of the Manchester Centre for Health Psychology. He has extensive experience of the design and evaluation of complex interventions to target health behaviours such as exercise, as well as experience of utilising theories of health behaviour change. **Sarah Cotterill** will lead the Effectiveness work package. Cotterill is a Senior Lecturer with research interests in public health, behaviour change and methodology. She has undertaken evaluation of diabetes prevention programmes, leading an evaluation of an NHS DPP pathfinder site in Salford. She is an NIHR Research Design Service adviser and part of NIHR CLAHRC Greater Manchester. **Caroline Sanders** will lead patient experience work in the Access and Inequality, Fidelity and Effectiveness work packages. Sanders is Senior Lecturer in Medical Sociology and highly experienced in conducting qualitative work using a variety of methods on clinical trials^{136 137} and large scale national evaluations, including the Whole Systems Demonstrators.²⁷ **Evan Kontopantelis** will lead the Effectiveness work package. Kontopantelis is a Professor in Statistics with world-leading expertise in the use of large scale databases to develop and evaluate health policy. His work includes analyses of the impact of the Quality and Outcomes scheme on mortality and inequality, as well as methodological work on optimal functioning of the scheme. **David Reeves** will work within the Effectiveness work package and lead the External Validation work package. Reeves is a Professor in Statistics and a health services researcher with extensive experience in the design of evaluations of relevance to health policy, as well as analyses of clinical databases to support health policy evaluation. **Rachel Meacock** will work with Sutton on the Comparative Long-Term Cost Effectiveness work package. Meacock is a Senior Lecturer in Health Economics. **Simon Heller** is Professor of Clinical Diabetes and National Diabetes Speciality Lead for the NIHR CRN and will provide clinical expertise. **Elizabeth Murray** will lead the Patient Decision Making and experience of the Digital DPP work package. Murray is a Professor of e-health in the Department of Primary Care and Population Health at UCL and a GP by background. She is an internationally recognized researcher in digital health with expertise in quantitative and qualitative research methods. She led the NIHR programme grant to develop, evaluate and implement a digital self-management programme for people with type 2 diabetes (HeLP-Diabetes), which has since been adopted by NHS England for national roll out. She was the independent expert on the RSM evaluation of the NHS England's Digital Diabetes Prevention Programme Pilot.