BMJ Open

Evaluation of the Digital Diabetes Prevention Programme Pilot: Uncontrolled Mixed Methods Study Protocol.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025903
Article Type:	Protocol
Date Submitted by the Author:	07-Aug-2018
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Keywords:	DIABETES & ENDOCRINOLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, digital health, PREVENTIVE MEDICINE

Title Page

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Word count: 3,759

Abstract

Introduction

The prevalence of type 2 diabetes is rising steeply. National Health Service England (NHSE) are exploring the potential of a digital diabetes prevention programme (DDPP) and have commissioned a pilot with embedded evaluation.

Methods.

Aim: to determine: "Whether, and if so, how, should NHSE implement a national digital diabetes prevention programme?"

Design: Mixed methods pretest – posttest design, underpinned by theory.

Theoretical frameworks: the CALO-RE taxonomy of behaviour change techniques for the digital interventions and the Consolidated Framework of Implementation Research for implementation processes.

Setting: Eight pilot areas across England.

Populations: people with non-diabetic hyperglycaemia (NDH) (HbA1c 42 – 47 mmol/mol) and people without NDH who are overweight (BMI >25) or obese (BMI >30).

Intervention: 5 digitally delivered diabetes prevention interventions.

Comparator: This is an uncontrolled study, with no comparator population.

Outcomes: The two primary outcomes are reduction in HbA1c (for people with NDH) and reduction in weight (for people who are overweight or obese) at 12 months. Secondary outcomes include use of the intervention, satisfaction, physical activity, patient activation and resources needed for successful implementation.

Data collection: Quantitative data will be collected at baseline, 6 months and 12 months by the digital intervention providers. Qualitative data will be collected through semi-structured interviews and focus groups with commissioners, providers, health care professionals and patients.

Analysis: Quantitative data will be analysed descriptively and using generalised linear models to determine whether changes in outcomes are associated with demographic and intervention factors. Qualitative data will be analysed using framework analysis, with data pertaining to implementation mapped onto the CFIR.

Ethics and Dissemination

The study has received ethical approval from the Public Health England Ethics and Research Governance Group (reference R&D 324). Dissemination will include a report to NHSE to inform future policy, and publication in peer reviewed journals.

Key words: Diabetes Mellitus, type 2; Health promotion; Primary Prevention; eHealth; internet; Digital Divide; Health Policy.

Strengths and limitations of this study

- This will be the first large-scale evaluation of digital diabetes prevention programmes internationally, and will provide data on effectiveness, uptake rates, and on resources required for effective implementation, allowing a realistic determination of potential population impact.
- It benefits from real-world experience and data, providing strong external validity.
- The lack of a comparator or any randomisation means that any changes in outcomes observed during the study cannot be said to be due to the interventions offered. Changes observed may be due to the impact of identification and measurement, the interventions offered, regression to the mean, or some other unmeasured confounder.

Introduction

Diabetes is a national and international priority for health services, with a steeply rising prevalence. Globally, it affects over 400 million people, or around 9% of the adult population (1), and of these, over 90% have type 2 diabetes (T2DM). There were an estimated 3.7 million people with diabetes in England in 2016 – 17 (2). People with diabetes are at risk of complications including cardiovascular disease, nephropathy, retinopathy and neuropathy. The costs of treating diabetes and its complications are estimated at 10% of the total NHS budget, or some £10 billion per annum (3, 4).

Risk factors for developing T2DM include diet, lack of physical activity, obesity, genetic factors and deprivation. For many people, T2DM is a preventable illness, with prevention focused on the modifiable factors of diet, physical activity and weight. There is high quality international evidence that face-to-face programmes focusing on these three factors can reduce the rate of progression to T2DM in high risk individuals (5-16). To be successful, these programmes appear to require intensive sustained input over a prolonged period of time (7). In light of this evidence National Health Service England (NHSE) launched *Healthier You: The NHS Diabetes Prevention Programme* (NHS DPP) in 2015, initially in seven demonstrator sites, and subsequently rolled out across England. All programmes within the NHS DPP must offer at least 16 hours of face-to-face contact, spread over 13 sessions, with the total programme lasting at least 9 months (17).

NHSE is also considering a national digital diabetes prevention programme (DDPP), and in order to generate the evidence to inform future policy in this area, launched a pilot DDPP in 2017, called "*Healthier You: NHS Diabetes Prevention Programme digital stream*" (18). The rationale for exploring whether a digital DPP can be effective includes:

- Systematic review evidence that digital health interventions can be effective in increasing physical activity, changing diets and promoting weight loss (19-28);
- Face to face programmes, although effective, are costly. In theory, a digital DPP could be rolled out at scale, and if effective, could be more cost-effective;
- Effective face to face programmes require patients to attend a considerable number of sessions, which can be difficult for those people who work or have other commitments in their lives. It is possible that digital interventions could be more easily integrated into busy lifestyles;
- Digital programmes could avoid the perceived stigma of face to face programmes.

However, there is little evidence to support these potential advantages (29), and there are some well documented challenges in the delivery of digital health interventions. These include:

- Problems with engagement and adherence, with many digital health interventions showing low rates of initial uptake as well as high rates of subsequent attrition from the intervention, thus limiting their potential for population impact (30);
- Uncertainty as to how best to improve engagement and adherence – although there are data which suggest that a certain amount of human input, for example in the form of supportive or coaching telephone calls, can improve engagement, the requirement for human input can impact on the scaleability and costs of digital health interventions (31-33);
- Concerns around the "digital divide", or the divide between those who do and do not make regular use of digital technology. As those with greatest health need (older people, people with long term health problems, and those with low incomes) are also people who make less use of digital technology (34, 35), there is a real concern that the use of digital health interventions will widen health inequalities (36-38);

- Challenges of implementation, with few examples of successful integration of digital health interventions into routine health care and considerable uncertainty as to how best to achieve such integration.

In the light of this potential, coupled with these major areas of uncertainty, NHS England has decided to run a pilot DDPP, involving 8 demonstrator sites and 5 digital diabetes prevention interventions, with a view to generating the evidence to inform future policy. The main national DPP is being evaluated through an NIHR-funded research programme (DIPLOMA; (39)). The DIPLOMA programme will determine the population impact of the overall programme; this evaluation of the digital pilot focuses only on the population of people referred to the digital programme. This protocol paper reports the proposed evaluation of the DDPP.

Aims and objectives

The overarching aim of this evaluation is to determine:

"Whether, and if so, how, should NHS England roll out a national digital diabetes prevention programme at the end of the pilot?"

Subsidiary objectives are to:

1. Determine uptake and use of the digital diabetes prevention interventions by people referred to them through the DDPP;
2. Determine the effects of digital diabetes prevention interventions on people referred to them through the DDPP;
3. Explore the extent to which uptake, use and effects vary across populations, with a view to exploring the potential impact of a DDPP on health inequalities;
4. Explore the extent to which these benefits vary according to differences in key features of the selected digital diabetes prevention interventions;
5. Explore user views about the acceptability of digital diabetes prevention interventions, including perceptions relating to use / non-use and impact on relevant behaviours;
6. Describe the various implementation strategies applied in the 8 demonstrator sites;
7. Determine the costs associated with implementing and delivering a DDPP, from an NHS perspective;
8. Explore commissioner, health care professional and provider views about key factors influencing implementation, uptake, and impact of the digital diabetes prevention interventions.
9. Synthesise these findings into a report to inform future NHS E policy and decision making in this area.

Methods.

Design: Mixed methods pretest – posttest design, underpinned by theory.

Theoretical frameworks:
This evaluation will be underpinned by two theoretical frameworks: one pertaining to the effectiveness of the digital diabetes prevention intervention (DDPI), and one pertaining to the implementation processes.

Understanding the likely and observed effectiveness of the selected DDPI will be promoted by applying the CALO-RE taxonomy of behaviour change techniques (40) and describing interventions using the TiDIER framework (41) (Appendix 1).

To help with describing and understanding the implementation processes we will use the Consolidated Framework for Implementation Research (CFIR) (42). This specifies that the key constructs which determine whether an intervention is successfully implemented or not are: Intervention characteristics; Outer setting; Inner setting; Individual characteristics; and the Implementation Process (for details see Appendix 2).

Setting: the 8 demonstrator sites selected by NHS E. These cover a wide range of geographies and demographies, including rural, semi-rural, urban and metropolitan areas, with widely varying proportions of people from Black and Minority Ethnic (BME) backgrounds, socio-economic status, and pre-existing levels of digital readiness and engagement with diabetes prevention.

Populations and participants:
There were three populations specified by NHS E: (i) people with non-diabetic hyperglycaemia (NDH), defined as having had a glycated haemoglobin (HbA1c) measurement of 42 – 47 mmol/mol, or a fasting glucose measurement of 5.5-6.9 mmol/l, in the 12 months prior to referral; (ii) people who are overweight (Body Mass Index of 25 to < 30) without NDH; and (iii) people who are obese (BMI of 30 or over) without NDH. The implementation model was such that it was the responsibility of the Local Health Economies in the demonstrator sites to identify people who fell into these populations, communicate their risk status to the individuals identified, and refer appropriately to a digital diabetes prevention intervention.

Interventions:
A total of five digital diabetes prevention interventions (DDPI) were selected following a rigorous, multi-stage selection process undertaken by an independent assessor (Our Mobile Health) under contract to NHS England. The selection process was as follows:

- An invitation for applications from digital product manufacturers whose products aim to prevent Type 2 diabetes in those at high risk was published by Our Mobile Health. Awareness of the invitation was raised via information through social media, direct emails, newsletters, and key networks such as the Academic Health Science Networks in England and the European Union mHealth working group.
- From 84 applications, 30 products were assessed by the independent assessor as addressing Type 2 diabetes prevention and as suitable for further review.
  The review stage involved completion by product manufacturers of a self-assessment questionnaire developed over the preceding 2 years under the National Information Board (NIB) Health Apps and Wearables Work-stream, a collaborative piece of work involving NHS England, Public Health England, the National Institute of Health and Care Excellence and the Medicines and Healthcare products Regulatory Agency. This questionnaire covered the domains of: overview of the service provided by the digital product; regulation; safety; usability and accessibility; interoperability; privacy, consent and security; change management; technical stability; indicators of effectiveness; and pricing (43).
- This self-assessment step resulted in 14 products assessed as suitable to be taken to the next stage review where the self-assessments and the products themselves were reviewed by subject matter experts including behaviour change theory experts, clinical safety officers, GPs, diabetologists, diabetes specialist nurses and diabetes specialist dieticians.

- NHS England procured a second partner, RSM, to collaborate in selecting the final 5 products from the 14 assessed by Our Mobile Health, to contract for services with the digital product manufacturers thus selected, and to undertake the programme evaluation. This final selection aimed to achieve a maximum variety sample which varied according to factors known to be important in influencing uptake, use and effectiveness of digital health interventions, namely: the delivery platform (smart phone vs. not); the amount of human interaction to promote uptake; and inclusion (or not) of wearables. Within this, interventions with better pre-existing evidence for uptake, use and effectiveness as well as capabilities and infrastructure to implement at scale, were prioritised.

The interventions will be described according to the TiDIER Framework for describing complex interventions (41) and the CALO-RE Behaviour Change Technique taxonomy (40).

Patients will be referred to the interventions by their health care professionals. This will usually be their GPs (or staff employed by their General Practice), but may be alternative providers contracted to undertake assessment of cardiovascular risk as part of the NHS Health Check Programme, which includes a two stage assessment that aims to identify NDH and undiagnosed Type 2 diabetes (44). Referral forms will include basic demographic and clinical data, including HbA1c and weight recorded in the previous three months to confirm eligibility. Referring health care professionals are responsible for discussing the referral with patients, to ensure patients understand their diagnosis, the type of intervention they are being referred to and the expected benefits.

Outcomes:

The primary outcomes were pre-specified by NHS England, and were change between baseline and 12 months in HbA1c for the population with NDH and weight for all three populations. Changes over 6 months are considered secondary outcomes.

Secondary and explanatory outcomes have been selected according to our pathway of action model, which posits that the digital diabetes prevention intervention achieves its goal of reducing a user's risk of diabetes by promoting behaviour change, specifically, promoting dietary change and an increase in physical activity. Taken together these behaviour changes result in reduced HbA1c and reduced weight. To achieve these changes requires the user to: register with the intervention; use the intervention; initiative behaviour change; and sustain behaviour change. Effects at each stage will be moderated by intervention factors and by patient factors (see Figure 1). The context and implementation process will also affect the overall population uptake and impact.

Secondary outcomes are listed in Table 1 and include intervention uptake, use and satisfaction; behavioural and clinical outcomes; and costs related to implementation, although it should be noted that a formal health economic analysis was excluded from the brief. Data will be collected at baseline, 6 months and 12 months.

Measures used are the Friends and Family Test (FFT) (45) to measure satisfaction with care, the International Physical Activity Questionnaire (46) to measure physical activity, and the 13 item Patient Activation Measure (PAM-13)(47).

Demographic characteristics are collected at baseline only and will be used as explanatory factors. Demographic data to be collected includes age (date of birth), gender, ethnicity, postcode (to be used for determining socio-economic status by mapping against the Index of Multiple Deprivation (IMD)) and highest level of education attained.

Qualitative and explanatory outcomes
Reasons for observed differences in quantitative outcomes will be explored through qualitative interviews and focus groups. These will be undertaken with a range of stakeholders, including commissioners / leads for the DDPP in selected Local Health Economies (LHE); health care professionals (GPs, practice nurses, diabetes nurses, health care assistants, practice managers); Digital Diabetes Intervention providers; the implementation teams charged with implementing the DDPP in the selected LHE; and patients.

Interviewees will be selected through purposive sampling, aiming for variation across geographical area, digital diabetes intervention provider, disciplinary backgrounds, and areas of high and low uptake.

Interviews will be conducted using semi-structured topic guides, by trained interviewers. The topic guides will vary according to the background of the stakeholder, with the main areas covered summarised in Table 2. Interviews will be undertaken in waves, with Wave 1 taking place during initial implementation and set up, Wave 2 once the programme is well established and Wave 3 toward the end of the pilot.

Data collection

Quantitative data
The digital diabetes prevention intervention providers are responsible for collecting all quantitative data. Baseline data will be obtained from referral forms and supplemented with data obtained during on boarding interviews with patients. Follow up self-report data (FFT, IPAQ and PAM-13) will be collected online. HbA1c and weights will be measured by the DDPI providers or by patients' General Practices, with the method and site of measurement recorded.

HbA1c measurements may be done on either venous or capillary blood samples, using either registered NHS labs or validated point-of-care testing kits. Whichever measurement process is used at baseline should be used at follow-up. Weights will be recorded using calibrated scales, with patients wearing light indoor clothing.

Data Analysis

Quantitative data
The baseline characteristics of the three cohorts (NDH, overweight and obese) will be summarised with respect to sociodemographic characteristics, intervention uptake, behavioural and clinical outcomes and economic outcomes. Continuous data will be summarised in terms of the mean, standard deviation, and number of observations or, where skewed, median and interquartile range. Binary/categorical data will be summarised in terms of frequency counts and percentages. Descriptive statistics will also be used to explore differences in baseline characteristics across the 8 demonstrator sites and five DDPIs.

For continuous outcomes, the overall effectiveness of the programme will be assessed in pre-post analyses by comparing the mean outcomes in each cohort from baseline to 6m, and from baseline to 12m (presented with 95% confidence intervals for the estimated change in outcomes). The statistical significance of any changes will be assessed using a paired t-test. For categorical outcomes, pre-post analyses will be conducted using McNemar's test.

Multivariable generalised linear models will be used to determine whether changes in outcomes are associated with demographic factors, adjusting for baseline outcome scores. Where necessary, continuous outcomes will be transformed to ensure good regression model fit. Exploratory analysis of the influence of potential mediators will be conducted by adding variables relating to usage and features of the digital diabetes prevention interventions to the regression models. Reasons for missing data will be documented and the baseline characteristics of those with and without missing data compared. The primary analysis will be based on participants with complete data but we will undertake sensitivity analyses using various imputation models. No formal adjustment for multiple significance testing will be applied.

Sample size

Target referral and registration numbers were pre-set by NHSE as part of the tender at 3,500 registrations for the NDH population and 1,500 for the overweight / obese population. We estimated minimum detectable effect sizes at 90% power and a 5% significance level for the key research questions, given these fixed sample sizes. Assuming a 25% completion rate (at 12 months), it will be possible to detect standardised effect sizes of d=0.11 and d=0.17 when assessing overall effectiveness in the NDH and overweight/obese groups respectively. This compares favourably with a weighted mean effect size of d=0.22 (95% CI: 0.20 to 0.23) estimated in a meta-analysis by Johnson et al (48) for behaviour change interventions targeting eating and physical activity.

Qualitative data

Interviews will be recorded, transcribed verbatim, and anonymised prior to analysis. Transcripts will be analysed using framework analysis (49) which is well suited to policy-relevant research, with specific questions and a priori issues. The five steps of framework analysis are (i) familiarisation; (ii) identifying a thematic framework; (iii) indexing; (iv) charting and (v) mapping and interpretation. Familiarisation will be achieved by reading and re-reading transcripts, with an a priori framework based on the Consolidated Framework for Implementation Research used to index and chart the data. Data that cannot be coded using CFIR will be noted. Mapping and interpretation will take place in multi-disciplinary data clinics where interpretations can be proposed, discussed and refined.

Ethics, research governance and data security

Ethics and Research governance:

Public Health England is the sponsor for this research. Ethical approval has been granted by the Public Health England Research Ethics and Governance Group, reference R&D 324.

Data security and information governance:

Data will be handled according to the principles of the General Data Protection Regulation (GDPR), the EU framework for data protection which became law in the UK in May 2018.

Quantitative data: the digital diabetes prevention intervention providers will be responsible for obtaining the quantitative data. No personally identifiable data will handled by RSM. All participant data must be pseudonymised by the digital diabetes prevention intervention provider by assigning each data subject a unique participant identification number (PIN) upon referral / registration. This PIN will be used to label all individual level participant data processed by the providers and LHEs over the life of the programme. The PIN will be used to link baseline, follow-up and usage data for each participant. Digital diabetes prevention intervention providers will keep a separate database linking PINs with identifiable data. Postcode mapping for IMD will be undertaken by the LHE (with support from RSM).

Qualitative data:

(i) Patients. Patients will be invited to participate in the interviews via the digital diabetes prevention providers and / or the local health economies. Patients who express an interest in being interviewed will be asked to return an expression of interest form to the RSM team, thus providing implicit consent for sharing personal contact data. Patients who return an EOI form will be sent full participant information, including a participant information sheet and a consent form. Interviews will only be undertaken after completion of a consent form.

(ii) Health Care Professionals, Commissioners and Providers. RSM have the contact details for these individuals as RSM are also responsible for the implementation of the DDPI. These informants will be recruited by RSM through written (letter or email) invitations to participate. Those who agree will be sent a participant information sheet and a consent form, and interviews will only take place after completion of a consent form.

Interview tapes will be stored securely on RSM servers. Only anonymised transcripts will be shared with the evaluation team outside RSM.

Dissemination

Contracted outputs include a 12 month report to the funder, based on 6 month follow up data, and a final report, based on 12 month follow-up data. The findings will inform the scale of future provision of digital approaches within the NHS Diabetes Prevention Programme.

Academic dissemination will also be undertaken in the form of conference presentations and publications in peer-reviewed journals. These presentations and publications will require advance approval from NHS England. Approval will not be unreasonably withheld, but academic dissemination may have to be delayed till after major policy decisions have been taken and made public.

Authors' contributions:
EM and JI developed the initial outline evaluation plan in response to the NHSE tender; this was developed, refined and operationalised by EM, KD, WH and AL. WH led on the statistical analysis plan. EM wrote the first draft of the protocol paper; all authors have read and commented on drafts and have approved the final version.

Funding statement: This work was supported by NHS England, as part of the overall contract for implementation and evaluation of the Digital Diabetes Prevention Programme. EM is part-funded by the NIHR School for Primary Care Research and the NIHR Collaboration for Leadership in Applied Health Research and Care, North Thames. AL is funded by the HEE Deanery (North Thames).

Competing interests statement
JI is a partner and KD a management consultant at RSM. RSM hold the contract from NHSE to implement and evaluate the Digital Diabetes Prevention Programme. EM and WH receive consultancy fees for their work on the evaluation. EM is Managing Director of a not-for-profit Community Interest Company, HeLP-Digital, which exists to disseminate a digital diabetes self-management programme, HeLP-Diabetes, across the NHS.

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Table 1: Quantitative Outcomes

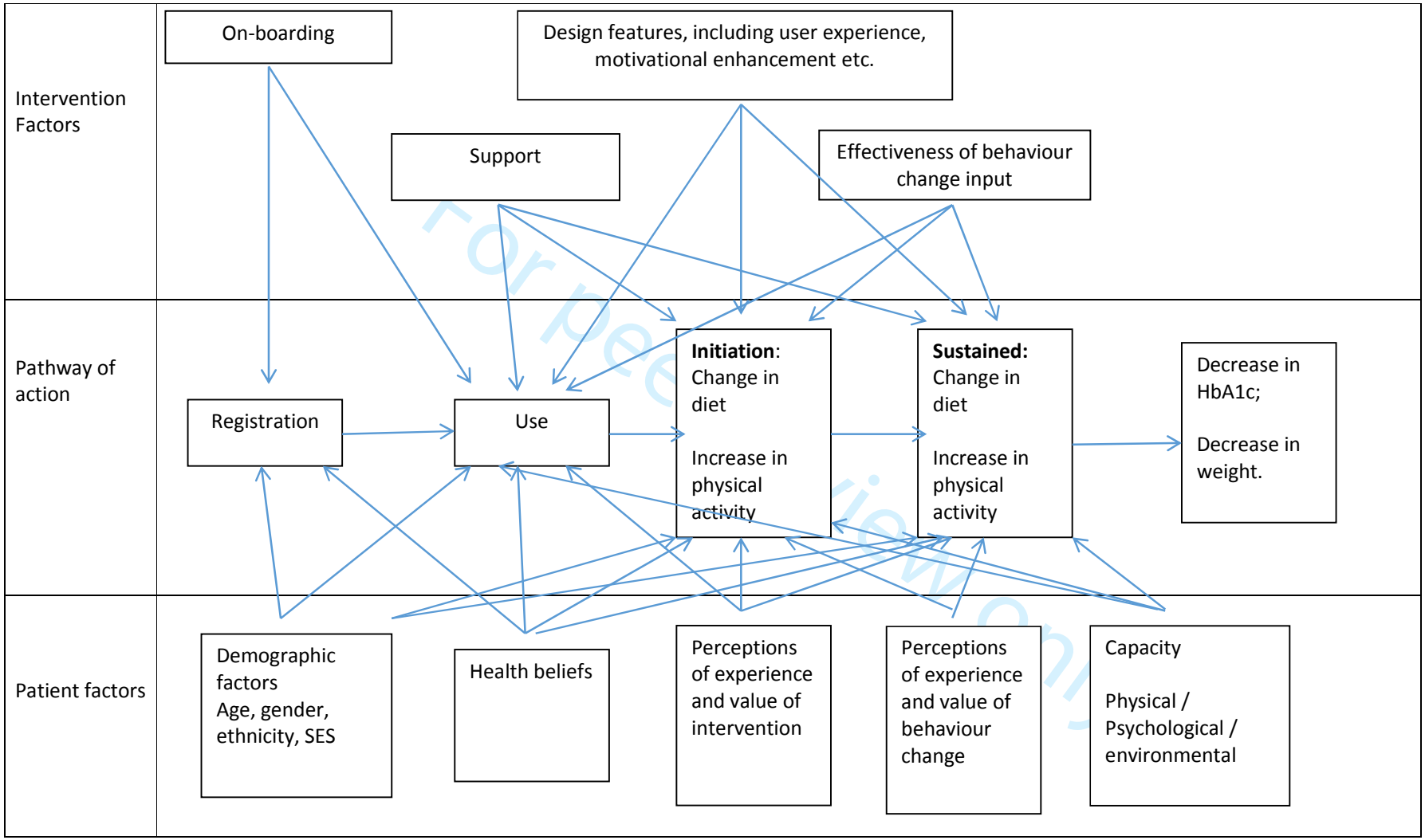
	Population		Time point for collection		
	NDH	Overweight / Obese	Baseline	6m	12m
Primary Outcome	HbA1c Weight	Weight	X	X	X
Secondary outcomes					
Intervention Factors					
Amount of human support planned and delivered (coaching, phone calls, emails).	X	X		X	X
Numbers referred	X	X	X	X	X
Numbers registered	X	X	X	X	X
Numbers who start to use the intervention	X	X	X	X	X
Numbers who complete the intervention	X	X	X	X	X
Usage data for each user	X	X	X	X	X
Friends and Families Test	X	X		X	X
Behavioural and Clinical Outcomes					
Height for calculation of BMI	X	X	X		
Physical activity (IPAQ)	X	X	X	X	X
Patient activation (PAM-13).	X	X	X	X	X
Economic outcomes					
Cost of the digital diabetes prevention intervention	X	X	X		
Types of staff involved in implementation in each LHE	X	X	X	X	X
Time spent by each member of staff on implementation of the DDPP (estimated)	X	X	X	X	X
Additional costs	X	X	X	X	X

Table 2: Qualitative and explanatory outcomes

Stakeholder group	Main areas of topic guide	Time point for collection		
		Wave 1	Wave 2	Wave 3
Local Health Economies (Commissioners, diabetes leads, health service managers)	About the LHE: • Geography, demography and priorities • Culture and organisational style • Rationale for engaging with DDPP (hopes, expectations, fears)	X		
	About the DDPI selected • How and why this DDPI was selected • Views of the selected intervention	X	X	X
	About the implementation plan • Describe the implementation plan • Reflections on progress, strengths, weaknesses, amendments proposed or made	X	X	X
	Resources required • Types and numbers of staff involved • Time per staff member (estimated) • Other costs / resources	X	X	X
	Overall lessons learnt			X
Health care professionals	• Local geography, demography and clinical priorities	X		
	• Understanding and prioritisation of DDPP	X	X	X
	• Views about DDPI in use in local area	X	X	X
	• Views about potential benefits / harms of DDPP, including impact on health inequalities	X	X	X
	• Views about implementation process locally	X	X	X
	• Overall lessons for future national delivery		X	X
Digital Diabetes Programme Intervention Providers	• Describe the intervention	X		
	• Describe the evidence base for the intervention • Onboarding process	X		
	• Views on how the implementation is going in participating LHE	X	X	X
	• Explanations and reflections on reasons for successes / challenges in implementation	X	X	X

	• Views on whether and how this programme could be scaled up nationally • Observed usage and impact of intervention on patients, and reasons for these • Overall lessons learnt	X	X X X	X X X
Patients	• Knowledge about diabetes and its prevention • Relative prioritisation of diabetes prevention • Experience of DDPP including identification, referral, onboarding to DDPI, use of DDPI • Reasons for use / non use of DDPI • Impact of DDPI on lifestyle and health behaviours • Preferences for digital vs. face-face • Suggestions for improvement • Overall views about the programme		X X X X X X X X	

Figure 1: Theory of change / pathway of action for effects of intervention.



NB; all taking place within different contexts (local health economies) and with different implementation processes.

Appendix 1: TIDIER check list.

Items included in the Template for Intervention Description and Replication (TIDieR) checklist: information to include when describing an intervention. Full version of checklist provides space for authors and reviewers to give location of the information

Item No	Item
Brief name	
1	Provide the name or a phrase that describes the intervention
Why	
2	Describe any rationale, theory, or goal of the elements essential to the intervention
What	
3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)
4	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities
Who provided	
5	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given
How	
6	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group
Where	
7	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When and How Much	
8	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose
Tailoring	
9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
Modifications	
10*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	
11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them
12*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

*If checklist is completed for a protocol, these items are not relevant to protocol and cannot be described until study is complete.

Appendix 2: Key constructs of CFIR

I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
B	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental

		or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
A	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.
D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
4	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.

E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
3	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
V. PROCESS		
A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.

2	Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.
4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

BMJ Open

Evaluation of the Digital Diabetes Prevention Programme Pilot: Uncontrolled Mixed Methods Study Protocol.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025903.R1
Article Type:	Protocol
Date Submitted by the Author:	14-Dec-2018
Complete List of Authors:	Murray, Elizabeth; University College London, Research Department of Primary Care and Population Health Daff, Kerry; RSM UK Consulting LLP Lavida, Anthi; University College London, Primary Care and Population Health Henley, W; Institute of Health Research, University of Exeter Medical School, College House, St Luke's Campus, Exeter, Devon, UK, EX1 2LU Irwin, Jenny; RSM UK Consulting LLP Valabhji, Jonathan; NHS England, Medical Directorate; Imperial College Healthcare NHS Trust, Diabetes and Endocrinology
Primary Subject Heading:	Public health
Secondary Subject Heading:	Diabetes and endocrinology, General practice / Family practice, Health policy, Health services research
Keywords:	DIABETES & ENDOCRINOLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, digital health, PREVENTIVE MEDICINE

Title Page

Title: Evaluation of the Digital Diabetes Prevention Programme Pilot: Uncontrolled Mixed Methods Study Protocol.

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Word count: 4,286

Abstract

Introduction

The prevalence of type 2 diabetes is rising steeply. National Health Service England (NHSE) are exploring the potential of a digital diabetes prevention programme (DDPP) and have commissioned a pilot with embedded evaluation.

Methods.

Aim: to determine: "Whether, and if so, how, should NHSE implement a national digital diabetes prevention programme?"

Design: Mixed methods pretest – posttest design, underpinned by theory.

Theoretical frameworks: the CALO-RE taxonomy of behaviour change techniques for the digital interventions and the Consolidated Framework of Implementation Research for implementation processes.

Setting: Eight pilot areas across England.

Populations: adults with non-diabetic hyperglycaemia (NDH) (HbA1c 42 – 47 mmol/mol, or fasting plasma glucose 5.5-6.9 mmol/l) and adults without NDH who are overweight (BMI >25) or obese (BMI >30).

Intervention: 5 digitally delivered diabetes prevention interventions.

Comparator: This is an uncontrolled study, with no comparator population.

Outcomes: The primary outcomes are reduction in HbA1c and weight (for people with NDH) and reduction in weight (for people who are overweight or obese) at 12 months. Secondary outcomes include use of the intervention, satisfaction, physical activity, patient activation and resources needed for successful implementation.

Data collection: Quantitative data will be collected at baseline, 6 months and 12 months by the digital intervention providers. Qualitative data will be collected through semi-structured interviews with commissioners, providers, health care professionals and patients.

Analysis: Quantitative data will be analysed descriptively and using generalised linear models to determine whether changes in outcomes are associated with demographic and intervention factors. Qualitative data will be analysed using framework analysis, with data pertaining to implementation mapped onto the CFIR.

Ethics and Dissemination

The study has received ethical approval from the Public Health England Ethics and Research Governance Group (reference R&D 324). Dissemination will include a report to NHSE to inform future policy, and publication in peer reviewed journals.

Key words: Diabetes Mellitus, type 2; Health promotion; Primary Prevention; eHealth; internet; Digital Divide; Health Policy.

Strengths and limitations of this study

- This will be the first large-scale evaluation of digital diabetes prevention programmes internationally, and will provide data on effectiveness, uptake rates, and on resources required for effective implementation, allowing a realistic determination of potential population impact.
- It benefits from real-world experience and data, providing strong external validity.
- The lack of a comparator or any randomisation means that any changes in outcomes observed during the study cannot be said to be due to the interventions offered. Changes observed may be due to the impact of identification and measurement, the interventions offered, regression to the mean, or some other unmeasured confounder.

Introduction

Diabetes is a national and international priority for health services, with a steeply rising prevalence. Globally, it affects over 400 million people, or around 9% of the adult population (1), and of these, over 90% have type 2 diabetes (T2DM). There were an estimated 3.7 million people with diabetes in England in 2016 – 17 (2). People with diabetes are at risk of complications including cardiovascular disease, nephropathy, retinopathy and neuropathy. The costs of treating diabetes and its complications are estimated at 10% of the total NHS budget, or some £10 billion per annum (3, 4).

Risk factors for developing T2DM include diet, lack of physical activity, obesity, genetic factors and deprivation. For many people, T2DM is a preventable illness, with prevention focused on the modifiable factors of diet, physical activity and weight. There is high quality international evidence that face-to-face programmes focusing on these three factors can reduce the rate of progression to T2DM in high risk individuals (5-16). To be successful, these programmes appear to require intensive sustained input over a prolonged period of time (7). In light of this evidence National Health Service England (NHSE) launched *Healthier You: The NHS Diabetes Prevention Programme* (NHS DPP) in 2015, initially in seven demonstrator sites, and subsequently rolled out across England. All programmes within the NHS DPP must offer at least 16 hours of face-to-face contact, spread over 13 sessions, with the total programme lasting at least 9 months (17).

NHSE is also considering a national digital diabetes prevention programme (DDPP), and in order to generate the evidence to inform future policy in this area, launched a pilot DDPP in 2017, called "*Healthier You: NHS Diabetes Prevention Programme digital stream*" (18). The reasons cited by NHSE for exploring the potential of a digital DPP are two-fold: firstly, digital delivery may overcome some of the challenges affecting face-to-face programmes; and secondly, systematic review evidence that digital health interventions can be effective in increasing physical activity, changing diets and promoting weight loss (19-28), all behaviours which are effective in preventing type 2 diabetes. Challenges affecting the population impact of face-to-face programmes include problems of acceptability, as their intensive nature may make it difficult for people who work or have other commitments in their lives to attend; and there may be perceived stigma in attending a programme aimed at prevention of type 2 diabetes. Finally, the face to face programmes are costly, particularly when implemented at scale and a digital programme could potentially be easier to deliver at scale and more cost-effective.

However, there is little evidence to support these potential advantages (29), and there are some well documented challenges in the delivery of digital health interventions. Three of the most important of these challenges are problems with engagement and adherence; concerns around the "digital divide"; and well documented problems with implementation. Many digital health interventions show low rates of initial uptake as well as high rates of subsequent attrition from the intervention, which limits their potential for population impact (30). Moreover, there is uncertainty as to how best to improve engagement and adherence – although there are data which suggest that a certain amount of human input, for example in the form of supportive or coaching telephone calls, can improve engagement, the requirement for human input can impact on the scaleability and costs of digital health interventions (31-33). There is real concern that the "digital divide" (the divide between those who do and do not make regular use of digital technology) will exacerbate health inequalities, as many of those with greatest health needs (older people, people with long term health problems, and those with low incomes) are also people who make less use of digital technology (34-38). Thirdly, the challenges of successful implementation of digital health interventions are well known (39, 40), with few examples of successful integration of digital health interventions into routine health care and considerable uncertainty as to how best to achieve such integration.

In the light of this potential, coupled with these major areas of uncertainty, NHSE commissioned a pilot DDPP with associated evaluation to run alongside the national DPP. In the initial tender document, NHSE specified that the goal of the pilot and associated evaluation was to inform future policy in this area, and as such, the overarching aim of the evaluation was to determine: ***"Whether, and if so, how, should NHSE roll out a national digital diabetes prevention programme at the end of the pilot?"*** Specific areas of interest were around uptake, use, and impact on weight and glycated haemoglobin; the likely impact of a digital programme on health inequalities; and how the interventions should be integrated into NHS workflows, including determining the resource requirements for successful implementation. Although a formal comparison of the effectiveness of different interventions was out of scope, NHSE were interested in whether specific features of different interventions appeared to be associated with variation in observed uptake, use or impact. The tender specified that a formal health economic analysis was out of scope.

The specific objectives of the evaluation can be grouped into three areas: uptake, use and impact of the interventions; the extent to which uptake, use and impact vary by socio-economic status as an indicator of likely impact on health inequalities; and factors relating to implementation.

Objectives pertaining to uptake, use and impact:

1. Determine uptake and use of the digital diabetes prevention interventions by people referred to them through the DDPP;
2. Determine the effects of digital diabetes prevention interventions on people referred to them through the DDPP;
3. Explore the extent to which these benefits vary according to differences in key features of the selected digital diabetes prevention interventions;
4. Explore user views about the acceptability of digital diabetes prevention interventions, including perceptions relating to use / non-use and impact on relevant behaviours;

Objectives pertaining to health inequalities:

5. Explore the extent to which uptake, use and effects vary by SES;

Objectives pertaining to implementation:

6. Describe the various implementation strategies applied in the 8 demonstrator sites;
7. Determine the costs associated with implementing and delivering a DDPP, from an NHS perspective;
8. Explore commissioner, health care professional and provider views about key factors influencing implementation, uptake, and impact of the digital diabetes prevention interventions.
9. Summarise and synthesise these data in a report which can be used to inform the policy decisions about whether, and if so, how, to roll out a digital diabetes prevention programme across England.

Methods.

Design: Mixed methods pretest – posttest design, underpinned by theory.

Theoretical frameworks:

This evaluation will be underpinned by two theoretical frameworks: one pertaining to the effectiveness of the digital diabetes prevention intervention (DDPI), and one pertaining to the implementation processes.

Understanding the likely and observed effectiveness of the selected DDPI will be promoted by applying the CALO-RE taxonomy of behaviour change techniques (41) and describing interventions using the TiDIER framework (42) (Appendix 1).

To help with describing and understanding the implementation processes we will use the Consolidated Framework for Implementation Research (CFIR) (43). This specifies that the key constructs which determine whether an intervention is successfully implemented or not are: Intervention characteristics; Outer setting; Inner setting; Individual characteristics; and the Implementation Process (for details see Appendix 2).

Patient and Public Involvement:

The Board overseeing the NSHE programme in diabetes and diabetes prevention is made up of a triumvirate of NHSE, Public Health England (PHE), and Diabetes UK (DUK). DUK is the largest charity representing the voice of people with diabetes in the UK. PPI involvement in this study was therefore provided by DUK, through their membership of the Board. This Board determined the how the digital diabetes prevention programme should be piloted and evaluated, what the requirements for the evaluation were, including overall design (numbers of demonstrator sites, digital diabetes prevention interventions, pre- post- test design, primary outcomes and duration of study). The Board also provides oversight of the conduct and progress of the study and will receive the reports of the study. Hence there was PPI input into determining the research questions, outcome measures, study design and dissemination.

Setting:

Eight demonstrator sites were selected by NHSE in parallel with the selection of the evaluator team, who had no input into site selection. Sites volunteered to participate in the digital pilot, and were selected to achieve a range of geographies and demographies, including rural, semi-rural, urban and metropolitan areas, with widely varying proportions of people from Black and Minority Ethnic (BME) backgrounds, socio-economic status, and pre-existing levels of digital readiness and engagement with diabetes prevention.

Populations and participants:

There were three populations specified by NHSE: (i) adults with non-diabetic hyperglycaemia (NDH), defined as having had a glycated haemoglobin (HbA1c) measurement of 42 – 47 mmol/mol, or a fasting glucose measurement of 5.5-6.9 mmol/l, in the 12 months prior to referral; (ii) adults who are overweight (Body Mass Index of 25 to < 30) without NDH; and (iii) adults who are obese (BMI of 30 or over) without NDH. It is the responsibility of the 8 demonstrator sites to determine how they will identify people who fell into these three populations, how GPs and patients will be informed about the programme, and how patients will be referred to a digital diabetes prevention intervention. In most sites, patients will be referred to the interventions by their health care professionals, usually their GPs. In some areas identification and referral may be undertaken by alternative providers contracted to undertake assessment of cardiovascular risk as part of the NHS Health Check Programme, which includes a two stage assessment that aims to identify NDH and undiagnosed Type 2 diabetes (44). Referring health care professionals are responsible for discussing the referral with patients, to ensure patients understand their diagnosis, the type of intervention they are being referred to and the expected benefits. Referring health care professionals are responsible for sending the patient's name and contact details to the relevant digital diabetes prevention intervention provider; that provider is then responsible for contacting the patient and onboarding them to the intervention. These processes are identical to those used in the national face-to-face diabetes prevention programme (45), with the only difference being that the provider is offering a digital, rather than a face-to-face, intervention.

Interventions:
A total of five digital diabetes prevention interventions (DDPI) were selected following a multi-stage selection process undertaken by an independent assessor (Our Mobile Health) under contract to NHSE. Following widespread advertising of the opportunity, 84 companies registered an interest and underwent initial screening against six criteria. These were: (i) that the intervention supported behaviour change; (ii) was available by June 2017; (iii) was localised for the English market; (iv) was underpinned by an evidence-based approach; (v) did not require any further integration with existing health IT systems before launching; (vi) had a pricing system in place (although cost itself was not a criterion). 30 providers met these criteria and progressed to a self-assessment exercise which explored 8 criteria: safety; privacy and security; pricing; evidence-base or indicators of effectiveness; usability and accessibility; technical stability; change management; and interoperability. The self-assessment questionnaire can be found at https://developer.nhs.uk/daq (46). This led to a shortlist of 14 interventions, which were reviewed by subject matter experts including behaviour change theory experts, clinical safety officers, GPs, diabetologists, diabetes specialist nurses and dieticians. The final sample were selected to vary on factors known to be important in influencing uptake, use and effectiveness of digital health interventions, namely: the delivery platform (smart phone vs. not); the amount of human interaction to promote uptake; and inclusion (or not) of wearables. Within this, interventions with better pre-existing evidence for uptake, use and effectiveness as well as capabilities and infrastructure to implement at scale, were prioritised.

All five interventions focused on dietary intake, weight loss and physical activity, and all interventions set personalised goals and provided feedback on progress toward these goals.

Intervention A (Buddi Nujjer) is a smartphone app, which links to a wristband for monitoring physical activity. The participants log their eating habits and activities via the programme, receive three motivational messages from the app per day, and complete a total of 22 learning modules over the course of the 12-month programme. Onboarding is done by an initial phone call and email for registration. A customer services team is available for those who have technical difficulties, but apart from that, the service is entirely digital.

Intervention B (Hitachi) is smartphone (Android and Apple), tablet and desktop compatible. The solution provides a hybrid of digital and non-digital interactions with a website and a series of phone calls with an experienced health advisor, whose advice follows NHS guidelines. Participants and health advisors set an action plan at the start of the programme. Participants then self-report their outcomes and log their lifestyle on the website to understand their progress against key milestones and objectives. This information goes back to the health advisor team who prompt on guidance and can interact with participants. Health advisors contact participants monthly for the first six months and have one more step-down call at the 8-month mark. Pedometers and scales can be provided on request. Onboarding is done through an initial brief phone call, at which point a longer, goal setting telephone call is arranged.

Intervention C (Liva) is smartphone (Android and Apple), tablet and desktop compatible. There is an initial face to face appointment with a health coach for onboarding and goal setting, followed by 26 coaching sessions with the same coach, delivered weekly for the first 12 weeks and then tapering off in frequency. There is an online peer support group.

Intervention D (Ourpath) is smartphone (Android and Apple), tablet and desktop compatible and includes wireless weighing scales and a wearable activity tracker. Participants are entered into a peer group of up to 10 other people with similar goals who live locally. Groups interact by group messaging, and group targets are set as well as individual ones. The programme has three stages: the 'Core' programme with daily education content received through the app for the first 6 weeks, the 'Sustain' programme with weekly education content

until the 6-month mark, and the final 6 months where the user will have completed all the education modules but still have access to the dietician and group support. Onboarding is done through two phone calls – an initial introductory one, and a second one to set the participant up with the programme and group.

Intervention E (Oviva) is an app (Android and Apple compatible) with supporting material (learning materials, podcasts, recipes) delivered through an online portal. For patients without a smartphone, the content can be delivered via phone calls. The app allows users to track their activity, weight, and food and drink intake (using a photo food diary). The programme is a mix of digital and non-digital interactions with a series of phone calls accompanying the app. The programme is more intense at the start with a weekly phone call in the first 8 weeks to cover the 16-topic curriculum, tapering to a monthly phone call thereafter. The phone calls are all conducted by the same dietician who is a specialist diabetes dietician with at least two years experience. Onboarding is done by the dietician in the first phone call.

The interventions will be described according to the TiDIER Framework for describing complex interventions (42) and the CALO-RE Behaviour Change Technique taxonomy (41)

Outcomes:

The primary outcomes were pre-specified by NHS England, and were change between baseline and 12 months in HbA1c for the population with NDH and weight for all three populations. Changes over 6 months are considered secondary outcomes.

Secondary and explanatory outcomes have been selected according to our pathway of action model, which posits that the digital diabetes prevention intervention achieves its goal of reducing a user's risk of diabetes by promoting behaviour change, specifically, promoting dietary change and an increase in physical activity. Taken together these behaviour changes result in reduced HbA1c and reduced weight. To achieve these changes requires the user to: register with the intervention; use the intervention; initiative behaviour change; and sustain behaviour change. Effects at each stage will be moderated by intervention factors and by patient factors (see Figure 1). The context and implementation process will also affect the overall population uptake and impact.

Secondary outcomes are listed in Table 1 and include intervention uptake, use and satisfaction; behavioural and clinical outcomes; and costs related to implementation, although it should be noted that a formal health economic analysis was excluded from the brief. Data will be collected at baseline, 6 months and 12 months.

Measures used are the Friends and Family Test (FFT) (47) to measure satisfaction with care, the International Physical Activity Questionnaire (48) to measure physical activity, and the 13 item Patient Activation Measure (PAM-13)(49).

Demographic characteristics are collected at baseline only and will be used as explanatory factors. Demographic data to be collected includes age (date of birth), gender, ethnicity, postcode (to be used for determining socio-economic status by mapping against the Index of Multiple Deprivation (IMD)) and highest level of education attained.

Table 1: Quantitative Outcomes

	Population		Time point for collection		
	NDH	Overweight / Obese	Baseline	6m	12m
Primary Outcome	HbA1c Weight	Weight	X	X	X
Secondary outcomes					
Intervention Factors					
Amount of human support planned and delivered (coaching, phone calls, emails).	X	X		X	X
Numbers referred	X	X	X	X	X
Numbers registered	X	X	X	X	X
Numbers who start to use the intervention	X	X	X	X	X
Numbers who complete the intervention	X	X	X	X	X
Usage data for each user	X	X	X	X	X
Friends and Families Test	X	X		X	X
Behavioural and Clinical Outcomes					
Height for calculation of BMI	X	X	X		
Physical activity (IPAQ)	X	X	X	X	X
Patient activation (PAM-13).	X	X	X	X	X
Economic outcomes					
Cost of the digital diabetes prevention intervention	X	X	X		
Types of staff involved in implementation in each LHE	X	X	X	X	X
Time spent by each member of staff on implementation of the DDPP (estimated)	X	X	X	X	X
Additional costs	X	X	X	X	X

Qualitative and explanatory outcomes

Reasons for observed differences in quantitative outcomes will be explored through qualitative interviews. These will be undertaken with a range of stakeholders, including commissioners / leads for the DDPP in selected Local Health Economies (LHE); health care professionals (GPs, practice nurses, diabetes nurses, health care assistants, practice

managers); Digital Diabetes Intervention providers; the implementation teams charged with implementing the DDPP in the selected LHE; and patients.

Interviewees will be selected through purposive sampling, aiming for variation across geographical area, digital diabetes intervention provider, disciplinary backgrounds, and areas of high and low uptake. Recruitment of interviewees will continue until a) all digital diabetes intervention providers and representatives from each demonstrator site have been interviewed, and b) data saturation is achieved.

Interviews will be conducted using semi-structured topic guides, by trained interviewers, working for RSM. The topic guides will vary according to the background of the stakeholder, with the main areas covered summarised in Table 2. Interviews will be undertaken in waves, with Wave 1 taking place during initial implementation and set up, Wave 2 once the programme is well established and Wave 3 toward the end of the pilot.

Table 2: Qualitative and explanatory outcomes

Stakeholder group	Main areas of topic guide	Time point for collection		
		Wave 1	Wave 2	Wave 3
Local Health Economies (Commissioners, diabetes leads, health service managers)	About the LHE: • Geography, demography and priorities • Culture and organisational style • Rationale for engaging with DDPP (hopes, expectations, fears)	X		
	About the DDPI selected • How and why this DDPI was selected • Views of the selected intervention	X	X	X
	About the implementation plan • Describe the implementation plan • Reflections on progress, strengths, weaknesses, amendments proposed or made	X	X	X
	Resources required • Types and numbers of staff involved • Time per staff member (estimated) • Other costs / resources	X	X	X
	Overall lessons learnt			X
Health care professionals	• Local geography, demography and clinical priorities	X		
	• Understanding and prioritisation of DDPP	X	X	X
	• Views about DDPI in use in local area	X	X	X

	• Views about potential benefits / harms of DDPP, including impact on health inequalities • Views about implementation process locally • Overall lessons for future national delivery	X X	X X X	X X X
Digital Diabetes Programme Intervention Providers	• Describe the intervention • Describe the evidence base for the intervention • Onboarding process • Views on how the implementation is going in participating LHE • Explanations and reflections on reasons for successes / challenges in implementation • Views on whether and how this programme could be scaled up nationally • Observed usage and impact of intervention on patients, and reasons for these • Overall lessons learnt	X X X X X	X X X X X	X X X X
Patients	• Knowledge about diabetes and its prevention • Relative prioritisation of diabetes prevention • Experience of DDPP including identification, referral, onboarding to DDPI, use of DDPI • Reasons for use / non use of DDPI • Impact of DDPI on lifestyle and health behaviours • Preferences for digital vs. face-face • Suggestions for improvement • Overall views about the programme		X X X X X X X X	

Data collection

Referral forms will include basic demographic and clinical data, including HbA1c and weight recorded in the previous three months to confirm eligibility.

Quantitative data
The digital diabetes prevention intervention providers are responsible for collecting all quantitative data. Baseline data will be obtained from referral forms and supplemented with

data obtained during on boarding interviews with patients. Follow up self-report data (FFT, IPAQ and PAM-13) will be collected online. HbA1c and weights will be measured by the DDPI providers or by patients' General Practices, with the method and site of measurement recorded.

HbA1c measurements may be done on either venous or capillary blood samples, using either registered NHS labs or validated point-of-care testing kits. Whichever measurement process is used at baseline should be used at follow-up. Weights will be recorded using calibrated scales, with patients wearing light indoor clothing.

Data Analysis

Quantitative data

The baseline characteristics of the three cohorts (NDH, overweight and obese) will be summarised with respect to sociodemographic characteristics, intervention uptake, behavioural and clinical outcomes and economic outcomes. Continuous data will be summarised in terms of the mean, standard deviation, and number of observations or, where skewed, median and interquartile range. Binary/categorical data will be summarised in terms of frequency counts and percentages. Descriptive statistics will also be used to explore differences in baseline characteristics across the 8 demonstrator sites and five DDPIs.

For continuous outcomes, the overall effectiveness of the programme will be assessed in pre-post analyses by comparing the mean outcomes in each cohort from baseline to 6m, and from baseline to 12m (presented with 95% confidence intervals for the estimated change in outcomes). The statistical significance of any changes will be assessed using a paired t-test. For categorical outcomes, pre-post analyses will be conducted using McNemar's test.

Multivariable generalised linear models will be used to determine whether changes in outcomes are associated with demographic factors, adjusting for baseline outcome scores. Where necessary, continuous outcomes will be transformed to ensure good regression model fit. Exploratory analysis of the influence of potential mediators will be conducted by adding variables relating to usage and features of the digital diabetes prevention interventions to the regression models. The potential for clustering effects by demonstrator site will be considered by inclusion of random effects for the demonstrator site in the generalised linear models. Three level models accounting for clustering by GP practice within demonstrator sites will also be explored.

Reasons for missing data will be documented and the baseline characteristics of those with and without missing data compared. The primary analysis will be based on participants with complete data but we will undertake sensitivity analyses using various imputation models. The potential for bias due to non-random attrition will be addressed by fitting a propensity score model to account for drop-out on the basis of baseline characteristics and then using inverse probability weighting (IPW) based on the propensity score to fit the treatment effectiveness model (50). No formal adjustment for multiple significance testing will be applied.

Sample size

Target referral and registration numbers were pre-set by NHSE as part of the tender at 3,500 registrations for the NDH population and 1,500 for the overweight / obese population. We estimated minimum detectable effect sizes at 90% power and a 5% significance level for the key research questions, given these fixed sample sizes. Assuming a 25% completion rate (at 12 months), it will be possible to detect standardised effect sizes of d=0.11 and d=0.17 when assessing overall effectiveness in the NDH and overweight/obese groups respectively,

assuming clustering is ignorable. This compares favourably with a weighted mean effect size of d=0.22 (95% CI: 0.20 to 0.23) estimated in a meta-analysis by Johnson et al (51) for behaviour change interventions targeting eating and physical activity. Further power analysis allowing for clustering effects by demonstrator site (with an intraclass correlation coefficient (ICC) of 0.02 based on a median estimate of 0.0185 in a study of ICCs in adults with diabetes in primary care practices(52)) gave minimum detectable effect sizes of d=0.18 and 0.22 in the NDH and overweight/obese groups respectively, assuming a 25% completion rate at 12 months.

Qualitative data
Interviews will be recorded, transcribed verbatim, and anonymised prior to analysis. Transcripts will be analysed using framework analysis (53) which is well suited to policy-relevant research, with specific questions and a priori issues. The five steps of framework analysis are (i) familiarisation; (ii) identifying a thematic framework; (iii) indexing; (iv) charting and (v) mapping and interpretation. Familiarisation will be achieved by reading and re-reading transcripts, with an a priori framework based on the Consolidated Framework for Implementation Research used to index and chart the data. Data that cannot be coded using CFIR will be noted. Mapping and interpretation will take place in multi-disciplinary data clinics where interpretations can be proposed, discussed and refined.

Ethics, research governance and data security

Ethics and Research governance:
Public Health England is the sponsor for this research. Ethical approval has been granted by the Public Health England Research Ethics and Governance Group, reference R&D 324.

Data security and information governance:
Data will be handled according to the principles of the General Data Protection Regulation (GDPR), the EU framework for data protection which became law in the UK in May 2018.

Quantitative data: the digital diabetes prevention intervention providers will be responsible for obtaining the quantitative data. No personally identifiable data will handled by RSM. All participant data must be pseudonymised by the digital diabetes prevention intervention provider by assigning each data subject a unique participant identification number (PIN) upon referral / registration. This PIN will be used to label all individual level participant data processed by the providers and LHEs over the life of the programme. The PIN will be used to link baseline, follow-up and usage data for each participant. Digital diabetes prevention intervention providers will keep a separate database linking PINs with identifiable data. Postcode mapping for IMD will be undertaken by the LHE (with support from RSM).

Qualitative data:

(i) Patients. Patients will be invited to participate in the interviews via the digital diabetes prevention providers and / or the local health economies. Patients who express an interest in being interviewed will be asked to return an expression of interest form to the RSM team, thus providing implicit consent for sharing personal contact data. Patients who return an EOI form will be sent full participant information, including a participant information sheet and a consent form. Interviews will only be undertaken after completion of a consent form.

(ii) Health Care Professionals, Commissioners and Providers. RSM have the contact details for these individuals as RSM are also responsible for the implementation of the DDPI. These informants will be recruited by RSM through written (letter or email) invitations to participate. Those who agree will be sent a participant information

sheet and a consent form, and interviews will only take place after completion of a consent form.

Interview tapes will be stored securely on RSM servers. Only anonymised transcripts will be shared with the evaluation team outside RSM.

Dissemination

Contracted outputs include a 12 month report to the funder, based on 6 month follow up data, and a final report, based on 12 month follow-up data. The findings will inform the scale of future provision of digital approaches within the NHS Diabetes Prevention Programme.

Academic dissemination will also be undertaken in the form of conference presentations and publications in peer-reviewed journals. These presentations and publications will require advance approval from NHS England. Approval will not be unreasonably withheld, but academic dissemination may have to be delayed till after major policy decisions have been taken and made public.

Authors' contributions:

EM and JI developed the initial outline evaluation plan in response to the NHSE tender; this was developed, refined and operationalised by EM, KD, WH and AL. WH led on the statistical analysis plan. JV chairs the NHSE Programme Board which developed and oversaw the tender. EM wrote the first draft of the protocol paper; all authors have read and commented on drafts and have approved the final version. PPI involvement was provided by Diabetes UK membership of the Board overseeing this work.

Funding statement: This work was supported by NHS England, as part of the overall contract for implementation and evaluation of the Digital Diabetes Prevention Programme. EM is part-funded by the NIHR School for Primary Care Research and the NIHR Collaboration for Leadership in Applied Health Research and Care, North Thames. AL is funded by the HEE Deanery (North Thames).

Competing interests statement

JI is a partner and KD a management consultant at RSM. RSM hold the contract from NHSE to implement and evaluate the Digital Diabetes Prevention Programme. EM and WH receive consultancy fees for their work on the evaluation. EM is Managing Director of a not-for-profit Community Interest Company, HeLP-Digital, which exists to disseminate a digital diabetes self-management programme, HeLP-Diabetes, across the NHS. JV is the National Clinical Director for Diabetes and Obesity at NHS England.

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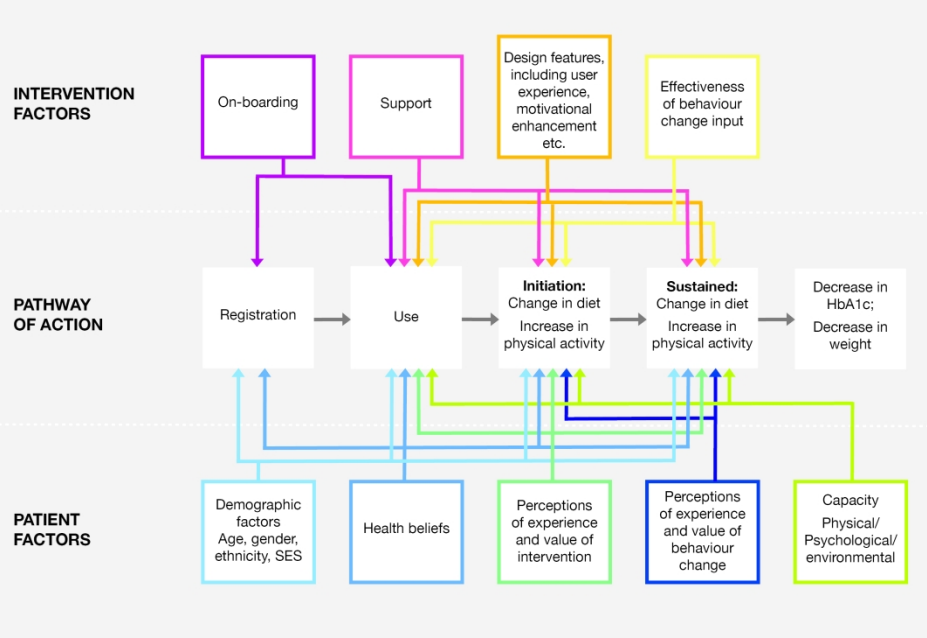

Figure 1: Theory of change / pathway of action for effects of intervention

297x209mm (300 x 300 DPI)

Appendix 1: TIDIER check list.

Items included in the Template for Intervention Description and Replication (TIDieR) checklist: information to include when describing an intervention. Full version of checklist provides space for authors and reviewers to give location of the information

Item No	Item
Brief name	
1	Provide the name or a phrase that describes the intervention
Why	
2	Describe any rationale, theory, or goal of the elements essential to the intervention
What	
3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)
4	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities
Who provided	
5	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given
How	
6	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group
Where	
7	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When and How Much	
8	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose
Tailoring	
9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
Modifications	
10*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	
11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them
12*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

*If checklist is completed for a protocol, these items are not relevant to protocol and cannot be described until study is complete.

Appendix 2: Key constructs of CFIR

I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
B	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental

		or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
A	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.
D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
4	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.

E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
3	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
V. PROCESS		
A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.

2	Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.
4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

BMJ Open

Evaluation of the Digital Diabetes Prevention Programme Pilot: Uncontrolled Mixed Methods Study Protocol.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025903.R2
Article Type:	Protocol
Date Submitted by the Author:	02-Apr-2019
Complete List of Authors:	Murray, Elizabeth; University College London, Research Department of Primary Care and Population Health Daff, Kerry; RSM UK Consulting LLP Lavida, Anthi; University College London, Primary Care and Population Health Henley, W; Institute of Health Research, University of Exeter Medical School, College House, St Luke's Campus, Exeter, Devon, UK, EX1 2LU Irwin, Jenny; RSM UK Consulting LLP Valabhji, Jonathan; NHS England, Medical Directorate; Imperial College Healthcare NHS Trust, Diabetes and Endocrinology
Primary Subject Heading:	Public health
Secondary Subject Heading:	Diabetes and endocrinology, General practice / Family practice, Health policy, Health services research
Keywords:	DIABETES & ENDOCRINOLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, digital health, PREVENTIVE MEDICINE

Title Page

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Word count: 4,286

Abstract

Introduction

The prevalence of type 2 diabetes is rising steeply. National Health Service England (NHSE) are exploring the potential of a digital diabetes prevention programme (DDPP) and have commissioned a pilot with embedded evaluation.

Methods and analysis

This study aims to determine whether, and if so, how, should NHSE implement a national digital diabetes prevention programme, using a mixed methods pretest – posttest design, underpinned by two theoretical frameworks: the CALO-RE taxonomy of behaviour change techniques for the digital interventions and the Consolidated Framework of Implementation Research for implementation processes. In eight pilot areas across England, adults with non-diabetic hyperglycaemia (NDH) (HbA1c 42 – 47 mmol/mol, or fasting plasma glucose 5.5-6.9 mmol/l) and adults without NDH who are overweight (BMI >25) or obese (BMI >30) will be referred to one of 5 digitally delivered diabetes prevention interventions. The primary outcomes are reduction in HbA1c and weight (for people with NDH) and reduction in weight (for people who are overweight or obese) at 12 months. Secondary outcomes include use of the intervention, satisfaction, physical activity, patient activation and resources needed for successful implementation. Quantitative data will be collected at baseline, 6 months and 12 months by the digital intervention providers. Qualitative data will be collected through semi-structured interviews with commissioners, providers, health care professionals and patients. Quantitative data will be analysed descriptively and using generalised linear models to determine whether changes in outcomes are associated with demographic and intervention factors. Qualitative data will be analysed using framework analysis, with data pertaining to implementation mapped onto the CFIR.

Ethics and Dissemination

The study has received ethical approval from the Public Health England Ethics and Research Governance Group (reference R&D 324). Dissemination will include a report to NHSE to inform future policy, and publication in peer reviewed journals.

Key words: Diabetes Mellitus, type 2; Health promotion; Primary Prevention; eHealth; internet; Digital Divide; Health Policy.

Strengths and limitations of this study

- This will be the first large-scale evaluation of digital diabetes prevention programmes internationally, and will provide data on effectiveness, uptake rates, and on resources required for effective implementation, allowing a realistic determination of potential population impact.
- It benefits from real-world experience and data, providing strong external validity.
- The lack of a comparator or any randomisation means that any changes in outcomes observed during the study cannot be said to be due to the interventions offered. Changes observed may be due to the impact of identification and measurement, the interventions offered, regression to the mean, or some other unmeasured confounder.

Introduction

Diabetes is a national and international priority for health services, with a steeply rising prevalence. Globally, it affects over 400 million people, or around 9% of the adult population (1), and of these, over 90% have type 2 diabetes (T2DM). There were an estimated 3.7 million people with diabetes in England in 2016 – 17 (2). People with diabetes are at risk of complications including cardiovascular disease, nephropathy, retinopathy and neuropathy. The costs of treating diabetes and its complications are estimated at 10% of the total NHS budget, or some £10 billion per annum (3, 4).

Risk factors for developing T2DM include diet, lack of physical activity, obesity, genetic factors and deprivation. For many people, T2DM is a preventable illness, with prevention focused on the modifiable factors of diet, physical activity and weight. There is high quality international evidence that face-to-face programmes focusing on these three factors can reduce the rate of progression to T2DM in high risk individuals (5-16). To be successful, these programmes appear to require intensive sustained input over a prolonged period of time (7). In light of this evidence National Health Service England (NHSE) launched *Healthier You: The NHS Diabetes Prevention Programme* (NHS DPP) in 2015, initially in seven demonstrator sites, and subsequently rolled out across England. All programmes within the NHS DPP must offer at least 16 hours of face-to-face contact, spread over 13 sessions, with the total programme lasting at least 9 months (17).

NHSE is also considering a national digital diabetes prevention programme (DDPP), and in order to generate the evidence to inform future policy in this area, launched a pilot DDPP in 2017, called "*Healthier You: NHS Diabetes Prevention Programme digital stream*" (18). The reasons cited by NHSE for exploring the potential of a digital DPP are two-fold: firstly, digital delivery may overcome some of the challenges affecting face-to-face programmes; and secondly, systematic review evidence that digital health interventions can be effective in increasing physical activity, changing diets and promoting weight loss (19-28), all behaviours which are effective in preventing type 2 diabetes. Challenges affecting the population impact of face-to-face programmes include problems of acceptability, as their intensive nature may make it difficult for people who work or have other commitments in their lives to attend; and there may be perceived stigma in attending a programme aimed at prevention of type 2 diabetes. Finally, the face to face programmes are costly, particularly when implemented at scale and a digital programme could potentially be easier to deliver at scale and more cost-effective.

However, there is little evidence to support these potential advantages (29), and there are some well documented challenges in the delivery of digital health interventions. Three of the most important of these challenges are problems with engagement and adherence; concerns around the "digital divide"; and well documented problems with implementation. Many digital health interventions show low rates of initial uptake as well as high rates of subsequent attrition from the intervention, which limits their potential for population impact (30). Moreover, there is uncertainty as to how best to improve engagement and adherence – although there are data which suggest that a certain amount of human input, for example in the form of supportive or coaching telephone calls, can improve engagement, the requirement for human input can impact on the scaleability and costs of digital health interventions (31-33). There is real concern that the "digital divide" (the divide between those who do and do not make regular use of digital technology) will exacerbate health inequalities, as many of those with greatest health needs (older people, people with long term health problems, and those with low incomes) are also people who make less use of digital technology (34-38). Thirdly, the challenges of successful implementation of digital health interventions are well known (39, 40), with few examples of successful integration of digital health interventions into routine health care and considerable uncertainty as to how best to achieve such integration.

In the light of this potential, coupled with these major areas of uncertainty, NHSE commissioned a pilot DDPP with associated evaluation to run alongside the national DPP. In the initial tender document, NHSE specified that the goal of the pilot and associated evaluation was to inform future policy in this area, and as such, the overarching aim of the evaluation was to determine: ***"Whether, and if so, how, should NHSE roll out a national digital diabetes prevention programme at the end of the pilot?"*** Specific areas of interest were around uptake, use, and impact on weight and glycated haemoglobin; the likely impact of a digital programme on health inequalities; and how the interventions should be integrated into NHS workflows, including determining the resource requirements for successful implementation. Although a formal comparison of the effectiveness of different interventions was out of scope, NHSE were interested in whether specific features of different interventions appeared to be associated with variation in observed uptake, use or impact. The tender specified that a formal health economic analysis was out of scope. The evaluation is due to report in 2020.

The specific objectives of the evaluation can be grouped into three areas: uptake, use and impact of the interventions; the extent to which uptake, use and impact vary by socio-economic status as an indicator of likely impact on health inequalities; and factors relating to implementation.

Objectives pertaining to uptake, use and impact:

1. Determine uptake and use of the digital diabetes prevention interventions by people referred to them through the DDPP;
2. Determine the effects of digital diabetes prevention interventions on people referred to them through the DDPP;
3. Explore the extent to which these benefits vary according to differences in key features of the selected digital diabetes prevention interventions;
4. Explore user views about the acceptability of digital diabetes prevention interventions, including perceptions relating to use / non-use and impact on relevant behaviours;

Objectives pertaining to health inequalities:

5. Explore the extent to which uptake, use and effects vary by SES;

Objectives pertaining to implementation:

6. Describe the various implementation strategies applied in the 8 demonstrator sites;
7. Determine the costs associated with implementing and delivering a DDPP, from an NHS perspective;
8. Explore commissioner, health care professional and provider views about key factors influencing implementation, uptake, and impact of the digital diabetes prevention interventions.
9. Summarise and synthesise these data in a report which can be used to inform the policy decisions about whether, and if so, how, to roll out a digital diabetes prevention programme across England.

Methods.

Design: Mixed methods pretest – posttest design, underpinned by theory.

Theoretical frameworks:

This evaluation will be underpinned by two theoretical frameworks: one pertaining to the effectiveness of the digital diabetes prevention intervention (DDPI), and one pertaining to the implementation processes.

Understanding the likely and observed effectiveness of the selected DDPI will be promoted by applying the CALO-RE taxonomy of behaviour change techniques (41) and describing interventions using the TiDIER framework (42) (Appendix 1).

To help with describing and understanding the implementation processes we will use the Consolidated Framework for Implementation Research (CFIR) (43). This specifies that the key constructs which determine whether an intervention is successfully implemented or not are: Intervention characteristics; Outer setting; Inner setting; Individual characteristics; and the Implementation Process (for details see Appendix 2).

Patient and Public Involvement (PPI):
The Board overseeing the NSHE programme in diabetes and diabetes prevention is made up of a triumvirate of NHSE, Public Health England (PHE), and Diabetes UK (DUK). DUK is the largest charity representing the voice of people with diabetes in the UK. PPI involvement in this study was therefore provided by DUK, through their membership of the Board. This Board determined the how the digital diabetes prevention programme should be piloted and evaluated, what the requirements for the evaluation were, including overall design (numbers of demonstrator sites, digital diabetes prevention interventions, pre- post- test design, primary outcomes and duration of study). The Board also provides oversight of the conduct and progress of the study and will receive the reports of the study. Hence there was PPI input into determining the research questions, outcome measures, study design and dissemination.

Setting:
Eight demonstrator sites were selected by NHSE in parallel with the selection of the evaluator team, who had no input into site selection. Sites volunteered to participate in the digital pilot, and were selected to achieve a range of geographies and demographies, including rural, semi-rural, urban and metropolitan areas, with widely varying proportions of people from Black and Minority Ethnic (BME) backgrounds, socio-economic status, and pre-existing levels of digital readiness and engagement with diabetes prevention.

Populations and participants:
There were three populations specified by NHSE: (i) adults with non-diabetic hyperglycaemia (NDH), defined as having had a glycated haemoglobin (HbA1c) measurement of 42 – 47 mmol/mol, or a fasting glucose measurement of 5.5-6.9 mmol/l, in the 12 months prior to referral; (ii) adults who are overweight (Body Mass Index of 25 to < 30) without NDH; and (iii) adults who are obese (BMI of 30 or over) without NDH. It is the responsibility of the 8 demonstrator sites to determine how they will identify people who fell into these three populations, how GPs and patients will be informed about the programme, and how patients will be referred to a digital diabetes prevention intervention. In most sites, patients will be referred to the interventions by their health care professionals, usually their GPs. In some areas identification and referral may be undertaken by alternative providers contracted to undertake assessment of cardiovascular risk as part of the NHS Health Check Programme, which includes a two stage assessment that aims to identify NDH and undiagnosed Type 2 diabetes (44). Referring health care professionals are responsible for discussing the referral with patients, to ensure patients understand their diagnosis, the type of intervention they are being referred to and the expected benefits. Referring health care professionals are responsible for sending the patient's name and contact details to the relevant digital diabetes prevention intervention provider; that provider is then responsible for contacting the patient and onboarding them to the intervention. These processes are identical to those used in the national face-to-face diabetes prevention programme (45), with

the only difference being that the provider is offering a digital, rather than a face-to-face, intervention.

Interventions:
A total of five digital diabetes prevention interventions (DDPI) were selected following a multi-stage selection process undertaken by an independent assessor (Our Mobile Health) under contract to NHSE. Following widespread advertising of the opportunity, 84 companies registered an interest and underwent initial screening against six criteria. These were: (i) that the intervention supported behaviour change; (ii) was available by June 2017; (iii) was localised for the English market; (iv) was underpinned by an evidence-based approach; (v) did not require any further integration with existing health IT systems before launching; (vi) had a pricing system in place (although cost itself was not a criterion). 30 providers met these criteria and progressed to a self-assessment exercise which explored 8 criteria: safety; privacy and security; pricing; evidence-base or indicators of effectiveness; usability and accessibility; technical stability; change management; and interoperability. The self-assessment questionnaire can be found at https://developer.nhs.uk/daq (46). This led to a shortlist of 14 interventions, which were reviewed by subject matter experts including behaviour change theory experts, clinical safety officers, GPs, diabetologists, diabetes specialist nurses and dieticians. The final sample were selected to vary on factors known to be important in influencing uptake, use and effectiveness of digital health interventions, namely: the delivery platform (smart phone vs. not); the amount of human interaction to promote uptake; and inclusion (or not) of wearables. Within this, interventions with better pre-existing evidence for uptake, use and effectiveness as well as capabilities and infrastructure to implement at scale, were prioritised.

All five interventions focused on dietary intake, weight loss and physical activity, and all interventions set personalised goals and provided feedback on progress toward these goals.

Intervention A (Buddi Nujjer) is a smartphone app, which links to a wristband for monitoring physical activity. The participants log their eating habits and activities via the programme, receive three motivational messages from the app per day, and complete a total of 22 learning modules over the course of the 12-month programme. Onboarding is done by an initial phone call and email for registration. A customer services team is available for those who have technical difficulties, but apart from that, the service is entirely digital.

Intervention B (Hitachi) is smartphone (Android and Apple), tablet and desktop compatible. The solution provides a hybrid of digital and non-digital interactions with a website and a series of phone calls with an experienced health advisor, whose advice follows NHS guidelines. Participants and health advisors set an action plan at the start of the programme. Participants then self-report their outcomes and log their lifestyle on the website to understand their progress against key milestones and objectives. This information goes back to the health advisor team who prompt on guidance and can interact with participants. Health advisors contact participants monthly for the first six months and have one more step-down call at the 8-month mark. Pedometers and scales can be provided on request. Onboarding is done through an initial brief phone call, at which point a longer, goal setting telephone call is arranged.

Intervention C (Liva) is smartphone (Android and Apple), tablet and desktop compatible. There is an initial face to face appointment with a health coach for onboarding and goal setting, followed by 26 coaching sessions with the same coach, delivered weekly for the first 12 weeks and then tapering off in frequency. There is an online peer support group.

Intervention D (Ourpath) is smartphone (Android and Apple), tablet and desktop compatible and includes wireless weighing scales and a wearable activity tracker. Participants are entered into a peer group of up to 10 other people with similar goals who live locally. Groups

interact by group messaging, and group targets are set as well as individual ones. The programme has three stages: the 'Core' programme with daily education content received through the app for the first 6 weeks, the 'Sustain' programme with weekly education content until the 6-month mark, and the final 6 months where the user will have completed all the education modules but still have access to the dietician and group support. Onboarding is done through two phone calls – an initial introductory one, and a second one to set the participant up with the programme and group.

Intervention E (Oviva) is an app (Android and Apple compatible) with supporting material (learning materials, podcasts, recipes) delivered through an online portal. For patients without a smartphone, the content can be delivered via phone calls. The app allows users to track their activity, weight, and food and drink intake (using a photo food diary). The programme is a mix of digital and non-digital interactions with a series of phone calls accompanying the app. The programme is more intense at the start with a weekly phone call in the first 8 weeks to cover the 16-topic curriculum, tapering to a monthly phone call thereafter. The phone calls are all conducted by the same dietician who is a specialist diabetes dietician with at least two years experience. Onboarding is done by the dietician in the first phone call.

The interventions will be described according to the TiDIER Framework for describing complex interventions (42) and the CALO-RE Behaviour Change Technique taxonomy (41).

Outcomes:

The primary outcomes were pre-specified by NHS England, and were change between baseline and 12 months in HbA1c for the population with NDH and weight for all three populations. Changes over 6 months are considered secondary outcomes.

Secondary and explanatory outcomes have been selected according to our pathway of action model, which posits that the digital diabetes prevention intervention achieves its goal of reducing a user's risk of diabetes by promoting behaviour change, specifically, promoting dietary change and an increase in physical activity. Taken together these behaviour changes result in reduced HbA1c and reduced weight. To achieve these changes requires the user to: register with the intervention; use the intervention; initiate behaviour change; and sustain behaviour change. Effects at each stage will be moderated by intervention factors and by patient factors (see Figure 1). The context and implementation process will also affect the overall population uptake and impact.

Secondary outcomes are listed in Table 1 and include intervention uptake, use and satisfaction; behavioural and clinical outcomes; and costs related to implementation, although it should be noted that a formal health economic analysis was excluded from the brief. Data will be collected at baseline, 6 months and 12 months.

Measures used are the Friends and Family Test (FFT) (47) to measure satisfaction with care, the International Physical Activity Questionnaire (48) to measure physical activity, and the 13 item Patient Activation Measure (PAM-13)(49).

Demographic characteristics are collected at baseline only and will be used as explanatory factors. Demographic data to be collected includes age (date of birth), gender, ethnicity, postcode (to be used for determining socio-economic status by mapping against the Index of Multiple Deprivation (IMD)) and highest level of education attained.

Table 1: Quantitative Outcomes

	Population		Time point for collection		
	NDH	Overweight / Obese	Baseline	6m	12m
Primary Outcome	HbA1c Weight	Weight	X	X	X
Secondary outcomes					
Intervention Factors					
Amount of human support planned and delivered (coaching, phone calls, emails).	X	X		X	X
Numbers referred	X	X	X	X	X
Numbers registered	X	X	X	X	X
Numbers who start to use the intervention	X	X	X	X	X
Numbers who complete the intervention	X	X	X	X	X
Usage data for each user	X	X	X	X	X
Friends and Families Test	X	X		X	X
Behavioural and Clinical Outcomes					
Height for calculation of BMI	X	X	X		
Physical activity (IPAQ)	X	X	X	X	X
Patient activation (PAM-13).	X	X	X	X	X
Economic outcomes					
Cost of the digital diabetes prevention intervention	X	X	X		
Types of staff involved in implementation in each LHE	X	X	X	X	X
Time spent by each member of staff on implementation of the DDPP (estimated)	X	X	X	X	X
Additional costs	X	X	X	X	X

Qualitative and explanatory outcomes

Reasons for observed differences in quantitative outcomes will be explored through qualitative interviews. These will be undertaken with a range of stakeholders, including commissioners / leads for the DDPP in selected Local Health Economies (LHE); health care professionals (GPs, practice nurses, diabetes nurses, health care assistants, practice

managers); Digital Diabetes Intervention providers; the implementation teams charged with implementing the DDPP in the selected LHE; and patients.

Interviewees will be selected through purposive sampling, aiming for variation across geographical area, digital diabetes intervention provider, disciplinary backgrounds, and areas of high and low uptake. Recruitment of interviewees will continue until a) all digital diabetes intervention providers and representatives from each demonstrator site have been interviewed, and b) data saturation is achieved.

Interviews will be conducted using semi-structured topic guides, by trained interviewers, working for RSM. The topic guides will vary according to the background of the stakeholder, with the main areas covered summarised in Table 2. Interviews will be undertaken in waves, with Wave 1 taking place during initial implementation and set up, Wave 2 once the programme is well established and Wave 3 toward the end of the pilot.

Table 2: Qualitative and explanatory outcomes

Stakeholder group	Main areas of topic guide	Time point for collection		
		Wave 1	Wave 2	Wave 3
Local Health Economies (Commissioners, diabetes leads, health service managers)	About the LHE: • Geography, demography and priorities • Culture and organisational style • Rationale for engaging with DDPP (hopes, expectations, fears)	X		
	About the DDPI selected • How and why this DDPI was selected • Views of the selected intervention	X	X	X
	About the implementation plan • Describe the implementation plan • Reflections on progress, strengths, weaknesses, amendments proposed or made	X	X	X
	Resources required • Types and numbers of staff involved • Time per staff member (estimated) • Other costs / resources	X	X	X
	Overall lessons learnt			X
Health care professionals	• Local geography, demography and clinical priorities	X		
	• Understanding and prioritisation of DDPP	X	X	X
	• Views about DDPI in use in local area	X	X	X

	• Views about potential benefits / harms of DDPP, including impact on health inequalities • Views about implementation process locally • Overall lessons for future national delivery	X X	X X X	X X X
Digital Diabetes Programme Intervention Providers	• Describe the intervention • Describe the evidence base for the intervention • Onboarding process • Views on how the implementation is going in participating LHE • Explanations and reflections on reasons for successes / challenges in implementation • Views on whether and how this programme could be scaled up nationally • Observed usage and impact of intervention on patients, and reasons for these • Overall lessons learnt	X X X X X	X X X X X	X X X X
Patients	• Knowledge about diabetes and its prevention • Relative prioritisation of diabetes prevention • Experience of DDPP including identification, referral, onboarding to DDPI, use of DDPI • Reasons for use / non use of DDPI • Impact of DDPI on lifestyle and health behaviours • Preferences for digital vs. face-face • Suggestions for improvement • Overall views about the programme		X X X X X X X X	

Data collection

Referral forms will include basic demographic and clinical data, including HbA1c and weight recorded in the previous three months to confirm eligibility.

Quantitative data

The digital diabetes prevention intervention providers are responsible for collecting all quantitative data. Baseline data will be obtained from referral forms and supplemented with

data obtained during on boarding interviews with patients. Follow up self-report data (FFT, IPAQ and PAM-13) will be collected online. HbA1c and weights will be measured by the DDPI providers or by patients' General Practices, with the method and site of measurement recorded.

HbA1c measurements may be done on either venous or capillary blood samples, using either registered NHS labs or validated point-of-care testing kits. Whichever measurement process is used at baseline should be used at follow-up. Weights will be recorded using calibrated scales, with patients wearing light indoor clothing.

Data Analysis

Quantitative data

The baseline characteristics of the three cohorts (NDH, overweight and obese) will be summarised with respect to sociodemographic characteristics, intervention uptake, behavioural and clinical outcomes and economic outcomes. Continuous data will be summarised in terms of the mean, standard deviation, and number of observations or, where skewed, median and interquartile range. Binary/categorical data will be summarised in terms of frequency counts and percentages. Descriptive statistics will also be used to explore differences in baseline characteristics across the 8 demonstrator sites and five DDPIs.

The primary analysis will be based on participants with complete data. For continuous outcomes, the overall effectiveness of the programme will be assessed in pre-post analyses by comparing the mean outcomes in each cohort from baseline to 6m, and from baseline to 12m (presented with 95% confidence intervals for the estimated change in outcomes). The statistical significance of any changes will be assessed using a paired t-test. For categorical outcomes, pre-post analyses will be conducted using McNemar's test.

Multivariable generalised linear models will be used to determine whether changes in outcomes are associated with demographic factors, adjusting for baseline outcome scores. Where necessary, continuous outcomes will be transformed to ensure good regression model fit. Exploratory analysis of the influence of potential mediators will be conducted by adding variables relating to usage and features of the digital diabetes prevention interventions to the regression models. The potential for clustering effects by demonstrator site will be considered by inclusion of random effects for the demonstrator site in the generalised linear models. Three level models accounting for clustering by GP practice within demonstrator sites will also be explored.

Reasons for missing data will be documented and the baseline characteristics of those with and without missing data compared. Although the primary analysis will be based on participants with complete data, we will undertake sensitivity analyses using various imputation models. The potential for bias due to non-random attrition will be addressed by fitting a propensity score model to account for drop-out on the basis of baseline characteristics and then using inverse probability weighting (IPW) based on the propensity score to fit the treatment effectiveness model (50). No formal adjustment for multiple significance testing will be applied.

Sample size

Target referral and registration numbers were pre-set by NHSE as part of the tender at 3,500 registrations for the NDH population and 1,500 for the overweight / obese population. We estimated minimum detectable effect sizes at 90% power and a 5% significance level for the key research questions, given these fixed sample sizes. Assuming a 25% completion rate (at 12 months), it will be possible to detect standardised effect sizes of d=0.11 and d=0.17 when assessing overall effectiveness in the NDH and overweight/obese groups respectively, assuming clustering is ignorable. This compares favourably with a weighted mean effect size

of d=0.22 (95% CI: 0.20 to 0.23) estimated in a meta-analysis by Johnson et al (51) for behaviour change interventions targeting eating and physical activity. Further power analysis allowing for clustering effects by demonstrator site (with an intraclass correlation coefficient (ICC) of 0.02 based on a median estimate of 0.0185 in a study of ICCs in adults with diabetes in primary care practices(52)) gave minimum detectable effect sizes of d=0.18 and 0.22 in the NDH and overweight/obese groups respectively, assuming a 25% completion rate at 12 months. For the purpose of analysis, completion is defined as obtaining data on weight and HbA1c at 12 months.

Qualitative data
Interviews will be recorded, transcribed verbatim, and anonymised prior to analysis. Transcripts will be analysed using framework analysis (53) which is well suited to policy-relevant research, with specific questions and a priori issues. The five steps of framework analysis are (i) familiarisation; (ii) identifying a thematic framework; (iii) indexing; (iv) charting and (v) mapping and interpretation. Familiarisation will be achieved by reading and re-reading transcripts, with an a priori framework based on the Consolidated Framework for Implementation Research used to index and chart the data. Data that cannot be coded using CFIR will be noted. Mapping and interpretation will take place in multi-disciplinary data clinics where interpretations can be proposed, discussed and refined.

Ethics, research governance and data security

Ethics and Research governance:
Public Health England is the sponsor for this research. Ethical approval has been granted by the Public Health England Research Ethics and Governance Group, reference R&D 324.

Data security and information governance:
Data will be handled according to the principles of the General Data Protection Regulation (GDPR), the EU framework for data protection which became law in the UK in May 2018.

Quantitative data: the digital diabetes prevention intervention providers will be responsible for obtaining and pseudonymising the quantitative data. No personally identifiable data will handled by RSM. Postcode mapping for IMD will be undertaken by the LHE (with support from RSM).

Qualitative data:
(i) Patients. Patients will be invited to participate in the interviews via the digital diabetes prevention providers and / or the local health economies and will opt in to providing fully informed consent for interviews.
(ii) Health Care Professionals, Commissioners and Providers. RSM have the contact details for these individuals as RSM are also responsible for the implementation of the DDPI. Written informed consent will be obtained prior to undertaking interviews.

Interview tapes will be stored securely on RSM servers. Only anonymised transcripts will be shared with the evaluation team outside RSM.

Dissemination
Contracted outputs include a 12 month report to the funder, based on 6 month follow up data, and a final report, based on 12 month follow-up data. The findings will inform the scale of future provision of digital approaches within the NHS Diabetes Prevention Programme.

Academic dissemination will also be undertaken in the form of conference presentations and publications in peer-reviewed journals. These presentations and publications will require

advance approval from NHS England. Approval will not be unreasonably withheld, but academic dissemination may have to be delayed till after major policy decisions have been taken and made public.

Authors' contributions:
EM and JI developed the initial outline evaluation plan in response to the NHSE tender; this was developed, refined and operationalised by EM, KD, WH and AL. WH led on the statistical analysis plan. JV chairs the NHSE Programme Board which developed and oversaw the tender. EM wrote the first draft of the protocol paper; all authors have read and commented on drafts and have approved the final version. PPI involvement was provided by Diabetes UK membership of the Board overseeing this work.

Funding statement: This work was supported by NHS England, as part of the overall contract for implementation and evaluation of the Digital Diabetes Prevention Programme. EM is part-funded by the NIHR School for Primary Care Research and the NIHR Collaboration for Leadership in Applied Health Research and Care, North Thames. AL is funded by the HEE Deanery (North Thames).

Competing interests statement
JI is a partner and KD a management consultant at RSM. RSM hold the contract from NHSE to implement and evaluate the Digital Diabetes Prevention Programme. EM and WH receive consultancy fees for their work on the evaluation. EM is Managing Director of a not-for-profit Community Interest Company, HeLP-Digital, which exists to disseminate a digital diabetes self-management programme, HeLP-Diabetes, across the NHS. JV is the National Clinical Director for Diabetes and Obesity at NHS England.

Figure 1 caption: **Figure 1: Theory of change / pathway of action for effects of intervention.**

Figure 1 foot-note:
NB: all taking place within different contexts (local health economies) and with different implementation processes.

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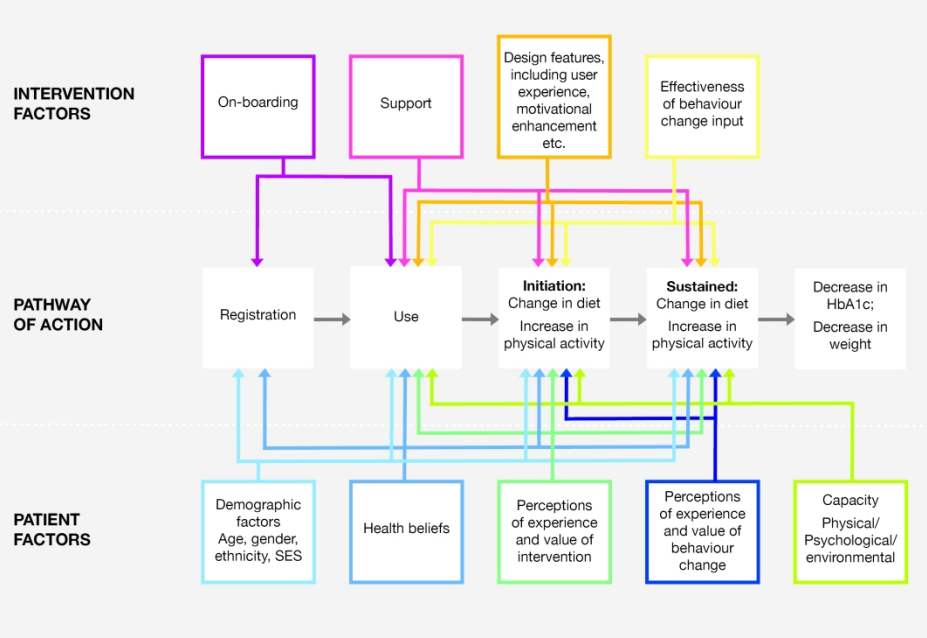

Figure 1: Theory of change / pathway of action for effects of intervention

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Appendix 1: TIDIER check list.

Items included in the Template for Intervention Description and Replication (TIDieR) checklist: information to include when describing an intervention. Full version of checklist provides space for authors and reviewers to give location of the information

Item No	Item
Brief name	
1	Provide the name or a phrase that describes the intervention
Why	
2	Describe any rationale, theory, or goal of the elements essential to the intervention
What	
3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)
4	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities
Who provided	
5	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given
How	
6	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group
Where	
7	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When and How Much	
8	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose
Tailoring	
9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
Modifications	
10*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	
11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them
12*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

*If checklist is completed for a protocol, these items are not relevant to protocol and cannot be described until study is complete.

Appendix 2: Key constructs of CFIR

I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
B	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental

		or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
A	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.
D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
4	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.

E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
3	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
V. PROCESS		
A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.

2	Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.
4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.