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Uptake and impact of the English National Health Service digital diabetes prevention programme: observational study

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ABSTRACT

Introduction 'Healthier You', the National Health Service (NHS) diabetes prevention programme (DPP) offers adults in England at high risk of type 2 diabetes (T2DM) an evidence-based behavioral intervention to prevent or delay T2DM onset. This study assesses the impact of a pilot digital stream of the DPP (DDPP) on glycated hemoglobin (HbA1c) and weight.

Research design and methods A service evaluation employing prospectively collected data in a prospective cohort design in nine NHS local pilot areas across England. Participants were adults with non-diabetic hyperglycemia (NDH) (HbA1c 42–47 mmol/mol or fasting plasma glucose 5.5–6.9 mmol/L) in the 12 months prior to referral. The DDPP comprised five digital health interventions (DHI). Joint primary outcomes were changes in HbA1c and weight between baseline and 12 months. HbA1c and weight readings were recorded at referral (baseline) by general practices, and then at 12-month postregistration. Demographic data and service variables were collected from the DHI providers.

Results 3623 participants with NDH registered for the DDPP and of these, 2734 (75%) were eligible for inclusion in the analyses. Final (12-month) follow-up data for HbA1c were available for 1799 (50%) and for weight 1817 (50%) of registered participants. Mean change at 12 months was −3.1 (−3.4 to −2.8) kg, p<0.001 for weight and −1.6 (−1.8 to −1.4) mmol/mol, p<0.001 for HbA1c. Access to peer support and a website and telephone service was associated with significantly greater reductions in HbA1c and weight.

Conclusions Participation in the DDPP was associated with clinically significant reductions in weight and HbA1c. Digital diabetes prevention can be an effective and wide-reaching component of a population-based approach to addressing type 2 diabetes prevention.

Significance of this study

What is already known about this subject?

⇒ Published reviews provide evidence for diabetes prevention via lifestyle modifications including dietary changes and increasing physical activity.
⇒ Studies of face to face interventions to prevent diabetes demonstrate effectiveness in encouraging weight loss and increasing physical activity, however, less is known about the role of digital health interventions in diabetes prevention.
⇒ Recent reviews provide some evidence that digitally delivered diabetes prevention programs can be successful, however, little is known about the effectiveness of these in real world populations.

What are the new findings?

⇒ This is the first large-scale real-world evaluation of a digital service that aims to prevent or delay the onset of type 2 diabetes anywhere internationally.
⇒ Our results show that participation in the digital service was associated with clinically significant reductions in both HbA1c and weight at 6 and 12 months (−1.6 mmol/mol and −3.1 kg at 12 months for HbA1c and weight respectively).

How might these results change the focus of research or clinical practice?

⇒ Digital diabetes prevention could be viewed as an effective and wide-reaching component of a population-based approach to addressing type 2 diabetes prevention.
⇒ Digitally delivered diabetes prevention programs can be operationalised on a national scale.

BACKGROUND

Diabetes is a global health priority. The WHO estimates that diabetes was the seventh leading cause of death across the world in 2016.[1] Type 2 diabetes (T2DM) is associated with obesity and lack of physical activity and, for many people, may be preventable by changes to diet and activity.[2 3] There is high-quality international evidence that intensive group-based programs focusing on healthy eating, weight loss, and increase in exercise can reduce the risk of progression to T2DM in people at high risk.[4–7] In the UK, the 'Healthier You': National Health Service (NHS) diabetes prevention programme (DPP) offers adults in England at high risk of T2DM an evidence-based behavioral intervention to prevent

or delay T2DM onset. Early outcome data indicate that the DPP, which is delivered via face-to-face sessions, may lead to reductions in future T2DM incidence among participants.[6]

However, group-based programs do not suit everybody. People who work, have caring responsibilities, or who do not like groups may find it difficult to participate.[8] Digital health interventions (DHI) have been shown to be effective in increasing physical activity, changing diets and promoting weight loss in general populations.[9–11] There is emerging evidence to suggest that DPPs could be delivered effectively using digital technologies.[12–14] Digital programs may be more acceptable to some people than group-based programs, as they may be easier to fit into busy lifestyles, and may avoid the perceived stigma associated with attending a group.[8 15] Additional drivers for the use of DHIs include the potential for scalability across large populations, as well as some evidence of their cost-effectiveness.[16 17] However, there are considerable uncertainties around these potential advantages and little evidence of the effectiveness of digitally delivered DPPs in real world populations. There are also known challenges with widescale deployment of DHIs, including repeated failures of implementation,[18] concerns around the digital divide and impact on health inequalities,[19 20] and a lack of understanding of the most effective digital components or active ingredients of these interventions.

In light of these uncertainties, the NHS in England (led by the commissioning organization, NHS England), commissioned a pilot digital stream of the diabetes prevention programme (DDPP) with associated evaluation.[21] The digital stream offers similar support, assistance and guidance as the DPP but through the use of digital interventions such as wearable technologies that monitor levels of exercise, apps which allow users to access health coaches, online peer support groups, and the ability to set and monitor goals electronically.

The aim of this paper is to report on the observed uptake and impact of the DDPP pilot and explore the extent to which these are influenced by socioeconomic and other demographic factors, in people found to have non-diabetic hyperglycemia (NDH) through routine clinical practice.

RESEARCH DESIGN AND METHODS

Design

A service evaluation employing prospectively collected data in a prospective cohort design in nine NHS local pilot areas (LPA) across England.

The protocol for the study has been published (https://bmjopen.bmj.com/content/9/5/e025903).[21] A few variations from the protocol are worth noting here. The protocol cites eight demonstrator sites (referred to in this paper as LPA); however, nine LPA actually took part in the pilot. The pilot describes an overweight/obese cohort (participants who were not eligible for the NDH cohort and their body mass index (BMI) was 25 or over (or BMI>23 for those with Asian ethnic backgrounds)). This cohort was excluded from these analyses due to small numbers with adequate follow-up data.

Setting

Nine LPA, reflecting nine geographical regions across England, were selected to achieve geographic and demographic variation, including rural, semirural, urban, and metropolitan areas, with widely varying proportions of people from black and minority ethnic backgrounds, socioeconomic status and pre-existing levels of digital readiness and engagement with diabetes prevention. Fourteen per cent of the total number of General Practices in England in 2017 (1040 of 7346) were included in the LPA. The prevalence of NDH across the LPA reflected that of England as a whole (11%), as did the prevalence of type 2 diabetes (5%).

Participants

Adults, aged 18 or over, diagnosed with NDH, defined as having at least one glycated hemoglobin (HbA1c) reading of 42–47 mmol/mol or at least one fasting blood glucose reading of 5.5–6.9 mmol/L in the 12 months prior to referral. People already diagnosed with diabetes, pregnant women, and people with a BMI below 18 kg/m^2 were excluded. The referral pathway into the program differed across the various LPAs. In most areas, eligible participants were identified from general practice (GP) lists or at NHS Health Checks. NHS Health Checks are offered to people aged 40–74, living in England, who have not previously been diagnosed with conditions including heart disease, kidney disease, atrial fibrillation, stroke, hypertension, or diabetes.[22] Participants were informed they were at high risk of developing T2DM and offered referral to a DPP. The delivery model varied between areas, with some offering a choice of a face-to-face or digital program (choice model), some only offering a digital program (digital only), and some reserving the offer of a digital program for people who declined to attend a face-to-face program (decliners only). Recruitment started in December 2017 and continued for 12 months.

Interventions

Five different DHI providers were included in the pilot. DHIs offered behavior change support around diet, weight loss, and increased physical activity, including information, personalized goal setting, monitoring, and feedback. These DHIs were required to be delivered over 12 months, although the intensity of the delivery varied, with some providing intense support for the first 6 or 12 weeks, followed by less frequent monitoring. The providers of the DHIs were responsible for receiving referrals, contacting patients once they were referred, onboarding them onto the digital program, promoting engagement with the program and obtaining outcome data. The five DHIs varied in terms of their inclusion of wearables (eg, accelerometers, wireless weighing scales),

Table 1 Digital health intervention features

	Provider 1	Provider 2	Provider 3	Provider 4	Provider 5
Peer support			✓	✓	
Wearable	✓			✓	
Telephone service and website		✓			✓
Text service and smartphone app	✓		✓	✓	✓

the amount of human support provided (ranging from a brief onboarding phone call to weekly coaching phone calls), and the delivery platform (smart phone app, website)—see table 1 for a summary of DHI features and see the study protocol[21] for a full description of each of the DHIs.

Outcomes and data collection

The primary outcomes were change in HbA1c and weight between baseline and 12 months for all participants with complete case data, who provided 12-month HbA1c and weight data between 10 and 14 months postbaseline. Secondary outcomes included the proportion of those referred who registered with the program (conversion rate) and change in HbA1c and weight between baseline and 6 months for participants with complete case data, who provided 6-month HbA1c and weight data between 4 and 8 months postbaseline.

HbA1c and weight readings were recorded at referral (baseline) by GP practices, and then at the 6-month and 12-month postregistration points, usually by GP practices. The DHI providers were responsible for collecting outcome data, including data on the numbers referred, numbers registered on the digital program, baseline and follow-up weights and HbA1c values, and demographic data. The providers encouraged patients to return to primary care to have follow-up measures recorded.

HbA1c was assessed on venous blood samples at accredited NHS laboratories. One DHI provider, which spanned two LPAs, used home tests to assess HbA1c. Validation of these tests was conducted to ensure consistency with venous tests and that samples did not degrade. Where possible, weights were independently recorded on calibrated scales (eg, at the patient's general practice or a local chemist). Where this was not possible, weights that were submitted by participants via Wi-Fi enabled weighing scales were accepted. The majority of weight recordings for one provider (provider 4) were measured by patients on wireless scales.

Demographic data on age, sex, ethnicity, highest level of educational attainment, and postcode were collected as part of the referral and onboarding processes by the providers of the 5 DHIs using a standardized data collection form (the Participant Monitoring Data Form). Age was grouped into 18–44 years, 45–54 years, 55–64 years, 65–74 years, and 75+ years. Sex was grouped into male, female, or indeterminate. Ethnicity was grouped as Asian, black, mixed, other, or white. Social deprivation was defined by the Index of Multiple Deprivation 2019 associated with the lower layer super output area (LSOA) derived from the patient's postcode and grouped into quintile (from 1=most deprived to 5=least deprived). LSOA was used to derive the Local Authority District Code, which was then used to derive six Rural/Urban classification categories (1=Mainly rural (population ≥80% rural), 2=Largely rural (population 50%–79% rural), 3=Urban with significant rural (population 26%–49% rural), 4=Urban (population <26% rural) with city and town, 5=Urban (population <26% rural) with minor conurbation, and 6=Urban (population <26% rural) with major conurbation).[23] Baseline BMI readings were calculated at referral (baseline) by GP practices and participants were classified into categories of healthy-weight, overweight, or obese defined according to their reported ethnicity (or if their ethnicity was unknown, according to the white ethnicity group) in-line with UK National Institute for Health and Care Excellence guidelines.[24] Highest education level was grouped into no qualifications, school leaver, and higher education.

For ethical and information governance reasons, only those responsible for providing care (ie, the referring clinicians and the DHI providers) had access to identifiable data. Pseudonymized data, including LSOA codes, but not postcodes or other identifiable data, were transferred to the evaluation team for analysis.

Sample size and data analysis

The commissioner of the program, NHS England, set the target size for the cohort of people with NDH as 3500. It was calculated that this fixed sample size, assuming a 25% retention rate at 12 months, would provide 90% power at a 5% significance level to detect standardized effect sizes of d=0.11 (equivalent to mean changes in HbA1c and weight of 0.3 mmol/mol and 2.2 kg, respectively), assuming clustering by LPA was ignorable (ie, assuming a lack of correlation between outcomes for individuals sampled within the same LPA). A further power analysis allowing for clustering effects by LPA (with an intraclass correlation coefficient of 0.02) gave a minimum detectable effect size of 0.18. For the purpose of analysis, retention was defined as obtaining data on weight and HbA1c at 12 months.

A statistical analysis plan was approved by NHS England before data collection was completed. The primary analysis focused on determining the impact of the program on the two primary outcomes of HbA1c and weight at

12 months. The change from baseline to 12 months for each individual was calculated and the mean change for the whole cohort presented. Paired t-tests were used to test for the significance of observed changes. The impact of regression to the mean was accounted for by analysis of covariance (ANCOVA),[25] whereby each patient's follow-up measurement was adjusted according to their baseline measurement. Secondary analyses examined the change from baseline to 6 months. Multivariable linear regression models were used to assess whether changes in outcomes were associated with demographic factors (age, sex, ethnicity, deprivation, BMI, and highest education level) and digital features (peer support, wearables, telephone service provided and text service, website, and app) adjusting for baseline outcome scores. Two-level and three-level models, clustering by LPA and GP practice within LPA, respectively, were considered.

An assumption was made that participants who were engaged with the program would be more likely to provide follow-up data and more likely to show benefit than those who had dropped out of the program, and so it was considered unlikely that the follow-up data would be missing completely at random or missing at random (MAR). To investigate this, sensitivity analyses were conducted by weighting the observed data according to the probability of drop-out in order to reduce the potential for selection bias due to non-random attrition.[26] This involved fitting a logistic regression model to account for drop-out on the basis of baseline characteristics and then using inverse probability weighting (IPW) based on the inverse of the predicted scores from the logit model to fit the treatment effectiveness model. IPW is recommended in the literature for dealing with unit nonresponse in a longitudinal design that is missing not at random.[26] However, this approach may not remove drop-out bias in variables that are unobserved. Additional sensitivity analyses were conducted using multiple imputation, employing multivariate chained equations to impute missing covariate and outcome data, under the MAR assumption, and then comparing the results to the primary analyses.

RESULTS

Over the 12-month period, 5053 people with NDH were referred to the DDPP. Of these, 3623 (64%) registered with a digital provider. The conversion rate from referral to registration differed according to delivery model. In areas where the only DPP offered was a digital one (digital only), the conversion rate was 74% (2424 referrals, yielding 1783 registrations). In areas where people could choose between a digital or face-to-face provider (choice), the conversion rate to digital was 62% (2,267 referrals, 1412 registrations) and in areas where only those who had declined a face-to-face program were offered a digital program (decliners only), the conversion rate was 55% (779 referrals, 428 registrations).

The characteristics of participants who registered with one of the five DHI providers are presented in table 2; 49% of participants were male, the mean (SD) age was 58 (12.4) years and 16% were of Asian ethnicity, 5% of black ethnicity, and 68% of white ethnicity. There were higher proportions from the most deprived quintile compared with the least deprived quintile, 21% vs 15%, respectively, with the majority of participants from mainly urban areas. Nearly one-third (29%) of participants had a higher education qualification. The mean weight at start of the program was 87.7 kg and the mean BMI 31.1 kg/m^2. The mean HbA1c was 43.4 mmol/mol.

Of the 3623 participants who registered with the program, 2734 (75%) participants provided at least one weight or HbA1c measurement at 6 or 12 months; 2195 (61%) a 6-month weight measurement, 2104 (58%) a 6-month HbA1c measurement, 1817 (50%) a 12-month weight measurement, and 1799 (50%) a 12-month HbA1c measurement. Of those who provided at least one weight or HbA1c measurement, 2225 (81%) participants had no missing or unknown baseline data. Data were missing for age (<0.1%), sex (0.2%), ethnicity (6%), deprivation (0.1%), highest education level (17%), rural/urban (<1%), and BMI (<0.1%). There were no missing data from provider, location, or digital features.

Univariate analyses of primary outcomes are provided in table 3.

The mean baseline weight for participants with a 12-month weight measurement was 86.7 kg with a mean weight change at 12 months of −3.1 (−3.4 to −2.8) kg, p<0.001 (table 3). ANCOVA, involving adjustment for baseline weight, gave an identical estimate of mean weight change at 12 months to 1 decimal place, indicating that any effect of regression to the mean was negligible. Results of the multivariable regression analyses showed that for each 1 kg higher baseline weight, there was an additional 0.05 kg weight loss (online supplemental material S1). Having access to peer support, wearables and telephone service was associated with a significantly greater reduction in weight from baseline to 12 months compared with not having access to these features. Whether or not participants had access to a text service and smartphone app had no differential impact on the 12-month weight change. Older participants, those with a higher education qualification and from the second least deprived deprivation quintile lost more weight compared with those who were younger, with no qualifications and from the most deprived quintile, respectively. There were no significant differences for the other characteristics (online supplemental material S1).

The mean baseline HbA1c for participants with a 12-month HbA1c measurement was 43.2 mmol/mol with a HbA1c change at 12 months of −1.6 (−1.8 to −1.4) mmol/mol, p<0.001 (table 3). ANCOVA, involving adjustment for baseline HbA1c, gave an estimate of mean HbA1c change at 12 months of −1.6 (−1.7 to −1.5), indicating that any effect of regression to the mean was negligible. Results of the multivariable regression analyses

Table 2 Baseline demographic and clinical characteristics of the overall registered population

		N	Percentage
	Total	3623	100
Age	18–24	21	1
	25–34	128	4
	35–44	416	11
	45–54	784	22
	55–64	1105	30
	65–74	914	25
	75+	253	7
	Unknown	2	0.1
	Mean (SD) age	57.8 (12.4)	–
Sex	Male	1791	49
	Female	1826	50
	Indeterminate/unknown	6	0.2
Ethnicity	Asian	569	16
	Black	186	5
	Mixed	98	3
	Other	15	0.4
	White	2470	68
	unknown	285	8
Deprivation	IMD 1 (most deprived)	754	21
	IMD 2	768	21
	IMD 3	828	23
	IMD 4	710	20
	IMD 5 (least deprived)	559	15
	Unknown	4	0.1
Highest education level	No qualifications	326	9
	School leaver	1460	40
	Higher Education	1068	29
	Unknown	769	21
Rural/urban	Mainly rural	403	11
	Largely rural	651	18
	Urban with significant rural	261	7
	Urban with city and town	803	22
	Urban with major conurbation	1501	41
	unknown	4	0
BMI	Healthy	383	11
	Overweight	1250	35
	Obese	1975	55
	unknown	15	0.4
Provider	Provider 1	384	11
	Provider 2	930	26
	Provider 3	813	22
	Provider 4	494	14
	Provider 5	1002	28
Location	Location 1	282	8
	Location 2	200	6
	Location 3	304	8
	Location 4	307	8
	Location 5	309	9
	Location 6	594	16
	Location 7	882	24
	Location 8	621	17
	Location 9	124	3
Mean (SD) BMI (kg/m^2)	Male	30.7 (5.8)	–
	Female	31.5 (6.9)	–
	Overall	31.1 (6.3)	–
Mean (SD) weight (kg)	Male	89.6 (19.4)	–
	Female	85.9 (20.5)	–
	Overall	87.7 (20.0)	–
Mean (SD) HbA1c (mmol/mol)	Male	43.3 (2.4)	–
	Female	43.4 (2.3)	–
	Overall	43.4 (2.4)	–

BMI, body mass index; HbA1c, glycated hemoglobin; IMD, Index of Multiple Deprivation.

(online supplemental materials S1) showed that for each 1 mmol/mol higher baseline HbA1c, there was an additional 0.382 mmol/mol decrease in HbA1c. Having access to peer support and telephone service was associated with a significantly greater decrease in HbA1c from baseline to 12 months compared with not having access to these features, while having access to text service and smartphone app was associated with a significantly smaller decrease in HbA1c. Whether or not participants had access to wearables had no differential impact on the 12-month HbA1c change. Participants from largely rural areas and from urban areas had significantly smaller HbA1c reductions compared with those from mainly rural areas. There were no significant differences for other characteristics. Of the DHI features, peer support had the largest effect size for both HbA1c −1.51 (−2.40 to −0.62) mmol/mol, p<0.001 and weight change −4.47 (−6.30 to −2.64) kg, p<0.001, at 12 months.

Univariate analyses of secondary outcomes are provided in in the online supplemental material S2. The mean baseline weight was 87.2 kg with a mean weight change at 6 months of −3.5 (−3.7 to −3.3) kg, p<0.001. The mean baseline HbA1c was 43.2 mmol/mol with a mean HbA1c change at 6 months of −1.8 (−2.0 to −1.7) mmol/mol, p<0.001. ANCOVA gave identical estimates for both weight and HbA1c change at 6 months. Regression analyses showed that there were some differences in the characteristics of participants and digital features associated with secondary outcomes compared with primary outcomes (online supplemental material S3). For

Table 3 Primary outcomes (weight change and HbA1c change) at 12 months for participants with complete case data

		Weight change (N=1534)						HbA1c change (N=1502)					
		N	Mean baseline weight	Mean weight change at 12 months	95% CI lower	95% CI upper	P value*	N	Mean baseline HbA1c	Mean HbA1c change at 12 months	95% CI lower	95% CI upper	P value*
	Overall	1534	86.7	−3.1	−3.4	−2.8	n/a	1502	43.2	−1.6	−1.8	−1.4	n/a
Age	18–44	158	90.2	−2.1	−3.2	−1.0	0.0162	149	43.1	−1.8	−2.4	−1.2	0.6088
	45–54	290	91.0	−2.5	−3.2	−1.7		281	43.3	−1.6	−1.9	−1.2	
	55–64	500	87.3	−3.7	−4.2	−3.1		486	43.0	−1.5	−1.8	−1.3	
	65–74	449	84.5	−3.3	−3.8	−2.7		453	43.3	−1.7	−2.0	−1.4	
	75+	137	78.9	−3.2	−4.1	−2.4		133	43.4	−1.3	−1.8	−0.8	
Sex	Male	764	86.9	−3.1	−3.6	−2.7	0.9636	738	43.1	−1.5	−1.8	−1.3	0.5913
	Female	769	86.5	−3.1	−3.5	−2.7		763	43.3	−1.7	−1.9	−1.4	
	Indeterminate	1	73.0	−1.5				1	46.0	−4.0			
Ethnicity	White	1199	88.5	−3.6	−3.9	−3.2	<0.0001	1172	43.2	−1.6	−1.8	−1.4	0.4492
	Mixed	47	86.2	−2.1	−3.8	−0.5		45	43.3	−1.6	−2.5	−0.7	
	Asian	224	76.2	−1.2	−1.8	−0.7		227	43.1	−1.8	−2.2	−1.3	
	Black	57	91.4	−2.5	−4.3	−0.7		52	43.9	−1.6	−2.3	−0.8	
	Other	7	85.6	−0.9	−5.4	3.5		6	41.8	0.5	−5.2	6.2	
Deprivation	IMD 1 (most deprived)	226	88.0	−2.6	−3.5	−1.8	<0.0001	221	43.4	−1.9	−2.3	−1.6	0.3001
	IMD 2	298	87.8	−2.5	−3.2	−1.8		290	43.3	−1.4	−1.8	−1.0	
	IMD 3	379	87.2	−2.5	−3.2	−1.9		386	43.3	−1.6	−1.9	−1.2	
	IMD 4	343	86.1	−4.4	−5.0	−3.7		331	43.1	−1.5	−1.8	−1.1	
	IMD 5 (least deprived)	288	84.8	−3.4	−4.1	−2.7		274	42.8	−1.7	−2.1	−1.4	
Rural/urban	Mainly rural	204	87.6	−3.0	−3.8	−2.2	<0.0001	219	43.7	−2.4	−2.8	−1.9	<0.0001
	Largely rural	311	88.2	−3.2	−3.9	−2.5		310	43.3	−0.6	−0.9	−0.2	
	Urban with significant rural	170	88.3	−3.7	−4.7	−2.7		179	42.2	−0.9	−1.4	−0.4	
	Urban with city and town	379	85.9	−4.7	−5.3	−4.0		301	43.2	−2.2	−2.5	−1.9	
	Urban with major and conurbation	470	85.5	−1.7	−2.2	−1.2		493	43.3	−1.8	−2.1	−1.6	
BMI grouping	Healthy	182	65.9	−1.7	−2.2	−1.2	0.0007	180	43.1	−1.9	−2.2	−1.5	0.4325
	Obese	777	98.3	−3.6	−2.2	−1.2		752	43.4	−1.5	−1.8	−1.3	
	Overweight	575	77.7	−2.9	−2.2	−1.2		570	43.0	−1.6	−1.9	−1.4	
Highest education	No qualifications	177	85.1	−2.2	−3.2	−1.3	0.0773	176	43.4	−1.4	−1.9	−1.0	0.5798
	School leaver	755	87.3	−3.1	−3.5	−2.6		757	43.3	−1.7	−1.9	−1.5	
	Degree level	602	86.5	−3.4	−3.9	−3.0		569	43.0	−1.6	−1.8	−1.3	
Peer support	No	1071	86.3	−2.5	−2.9	−2.2	<0.0001	1104	43.1	−1.4	−1.6	−1.2	<0.0001
	Yes	463	87.8	−4.5	−5.1	−3.8		398	43.4	−2.2	−2.5	−1.9	

Continued

Table 3 Continued

		Weight change (N=1534)						HbA1c change (N=1502)					
		N	Mean baseline weight	Mean weight change at 12 months	95% CI lower	95% CI upper	P value*	N	Mean baseline HbA1c	Mean HbA1c change at 12 months	95% CI lower	95% CI upper	P value*
Wearables provided	No	1207	86.4	−2.5	−2.8	−2.2	<0.0001	1254	43.2	−1.6	−1.7	−1.4	0.4462
	Yes	327	87.9	−5.4	−6.2	−4.6		248	43.2	−1.7	−2.2	−1.3	
Telephone service	No	540	88.2	−4.2	−4.8	−3.6	<0.0001	477	43.6	−1.9	−2.2	−1.7	0.0039
	Yes	994	85.9	−2.5	−2.9	−2.2		1025	43.0	−1.4	−1.6	−1.3	
Text service	No	297	86.1	−2.6	−3.2	−1.9	0.0916	308	43.7	−2.3	−2.6	−2.0	<0.0001
	Yes	1237	86.9	−3.3	−3.6	−2.9		1194	43.1	−1.4	−1.6	−1.2	
Provider	Provider 1	77	90.8	−2.7	−4.1	−1.3	<0.0001	79	44.1	−0.8	−1.5	−0.1	<0.0001
	Provider 2	297	86.1	−2.6	−3.2	−1.9		308	43.7	−2.3	−2.6	−2.0	
	Provider 3	213	88.7	−2.4	−3.1	−1.6		229	44.0	−2.2	−2.5	−1.8	
	Provider 4	250	87.0	−6.2	−7.1	−5.4		169	42.8	−2.2	−2.7	−1.6	
	Provider 5	697	85.9	−2.5	−2.9	−2.1		717	42.8	−1.1	−1.3	−0.8	
Location	Location 1	160	84.3	−5.7	−6.8	−4.6	<0.0001	89	43.2	−2.4	−3.1	−1.6	<0.0001
	Location 2	157	90.0	−3.3	−4.3	−2.2		162	41.4	−0.6	−1.1	−0.1	
	Location 3	185	81.0	−0.9	−1.5	−0.2		183	42.0	−1.3	−1.8	−0.8	
	Location 4	109	89.5	−3.8	−4.9	−2.6		108	43.5	−2.7	−3.3	−2.2	
	Location 5	142	84.7	−3.0	−4.0	−2.0		141	43.5	−2.5	−2.8	−2.1	
	Location 6	138	89.1	−2.2	−3.2	−1.2		153	44.2	−2.0	−2.4	−1.5	
	Location 7	432	87.3	−3.0	−3.5	−2.4		451	43.8	−1.1	−1.4	−0.8	
	Location 8	155	87.3	−2.2	−3.0	−1.3		167	43.8	−2.2	−2.6	−1.8	
	Location 9	56	90.9	−7.8	−9.8	−5.8		48	41.2	−1.1	−2.2	−0.1	

*Analysis of variance.
BMI, body mass index; HbA1c, glycated hemoglobin; IMD, Index of Multiple Deprivation.

6-month weight change, there were no significant differences by age or deprivation, while for 12-month weight change, older participants and those from the second least deprived quintile, had greater weight change. Black participants and those from urban with city and town and urban with major and conurbation areas lost less weight at 6 months while there were no significant differences at 12 months. There were consistent findings for sex, highest education level, BMI grouping, and all digital features. For 6-month HbA1c change, there was no significant difference for participants from urban areas with major conurbation, while for 12-month HbA1c change, they had smaller HbA1c decreases. There were smaller HbA1c decreases for older participants and black participants at 6 months, while there were no significant differences at 12-month HbA1c change. There were consistent findings for sex, highest education level, deprivation, and BMI grouping. For digital features, there were inconsistent findings for text service and smartphone app, but consistent findings for all other digital features.

Multilevel regression analyses were considered but gave inconsistent results; clustering by LPA and clustering by GP practice within LPA, both had a significant effect for HbA1c change, but not for weight change. For this reason, only single-level models are presented. Sensitivity analyses using propensity score models and multiple imputation, showed no substantive changes in the direction and magnitude of the associations.

DISCUSSION

This is the first evaluation, to our knowledge, of a national digital program for the prevention of type 2 diabetes anywhere internationally. Findings suggest that the digital interventions were associated with clinically significant reductions in both HbA1c and weight at 6 and 12 months (−1.6 mmol/mol and −3.1 kg at 12 months for HbA1c and weight respectively). These reductions appear robust across all prespecified sensitivity analyses, and were not dependent on participant baseline HbA1c levels, sex, ethnicity, or BMI. However, other demographic characteristics were associated with greater weight loss (those who are older, with higher education, and from the second least deprived group) and greater reductions in HbA1c (those from mainly rural areas).

Despite emerging evidence to suggest that DPP could be delivered effectively using digital technologies,[12–14] there has been to date little evidence of effectiveness of these in real world populations. This study provides evidence to support widespread implementation of a DDPP, with findings suggesting that a digitally delivered DPP can be operationalized on a national scale and can achieve comparable changes in HbA1c and weight loss as face-to-face group-based sessions.[6] Significant reductions in HbA1c and weight across a population level could translate into considerable population benefit, particularly as these digitally delivered interventions can be delivered at scale.

Although a formal comparison of the effectiveness of different interventions was out of scope, this study suggests that specific features of the different interventions were associated with impact. Peer support, a designated website, and telephone service (as features of the digital programs) had the biggest effect on both HbA1c and weight reduction, and access to wearables also influenced weight loss. The role of peer support in disease prevention and management has long been recognized,[27–29] and group based face-to-face sessions comprise a core part of the NHS DPP. However, whether the benefits of peer support can be replicated digitally remains relatively unexplored in the literature. This study suggests that DHI which contain an element of peer support may be particularly effective in reducing the risk of diabetes, although this needs further exploration.

Those with higher education and from the second least deprived group achieved the greatest weight loss; however, no differences for education or deprivation level were observed for HbA1c outcomes. It is notable that there was no observed digital divide for the older population. In fact, older participants achieved greater weight loss at 12 months than younger participants. A smaller reduction in HbA1c was observed for those from largely rural and urban areas compared with those from mainly rural areas. There was also no effect of ethnicity on outcomes at 12 months, unlike comparable face to face programs that have observed those from ethnic minorities lose less weight and see smaller reductions in HbA1c.[6] Taken together, the findings of this study provide supporting evidence for a full-scale national roll out of a DDPP.

Strengths and limitations

This study has many strengths. This was the first large-scale real-world evaluation of a digital service that aims to prevent or delay the onset of type 2 diabetes implemented in different localities. It includes objective measures of weight, HbA1c, individual participant data, and assesses the impact on health inequalities. There was equitable access to the program across different groups, evidenced by the demographic diversity in the study population, which was broadly representative of local NDH populations. Intervention features were also assessed for their impact on outcome, contributing to the sparse literature on what the 'active ingredients' of DHI might be.

The uncontrolled nature of this analysis means that external confounders cannot be excluded, and there may have been other factors leading to weight loss and HbA1c reductions. The glycemic trigger for study eligibility was up to 12 months prior to DDPP referral; thus, it is possible some participants may have already reduced weight and HbA1c prior to study entry, and some participants may have embarked on behavior change following a NDH diagnosis, unrelated to intervention use. Also, diagnosis of NDH in routine clinical practice is based on a single test value within the NDH range, and a degree of discordance with a second test value has been reported

in clinical trial settings.[30] However, ANCOVA showed that regression to the mean resulting from random error in the distributions of HbA1c and weight was unlikely to be a cause of the observed improvements.

There were some missing data both in terms of baseline covariates and outcomes at 6-month and 12-month follow-up. A principled and pragmatic approach was taken to consider the effects on data interpretation. For the missing covariates, a multiple imputation analysis was conducted under the assumption that the data were MAR. However, this assumption may not hold for the missing follow-up data, as participants who were engaged with the program may be more likely to provide follow-up data than those who dropped out. We carried out a sensitivity analysis in which the observed data were weighted according to the probability of drop-out using an approach that that has been recommended for reducing the potential for selection bias due to non-random attrition. The sensitivity analyses do not vary in terms of the direction and broad magnitude of the findings in the primary analyses, providing some reassurance that the missing data have not appreciably biased the conclusions.

There is also the potential, as with any new digital technology, that a *novelty effect*[31] has been observed whereby adoption and use of the DHI is influenced by the newness of the technology, which may not reflect patterns of use once the technology ceases to be new. Longer term follow-up could add to the evidence of this phenomenon for DHIs.

CONCLUSION

This digitally delivered DPP achieved clinically significant HbA1c and weight reduction in a national population with NDH. Effects of the digital divide and health inequalities were not observed for age or ethnicity. Digital diabetes prevention could be viewed as an effective and wide-reaching component of a population-based approach to addressing type 2 diabetes prevention.

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Contributors JV, EM, BM, and KD conceived the research question. JV and BM secured funding for the study. EM, JV, KD, WEH and JI designed and planned the study. KD prepared the data. KD, WEH and EB statistically analyzed the data. WEH, KD, JI and EB had access to and verified the study data. All authors confirm that they had full access to all the data in the study, take responsibility for the integrity of the data and the accuracy of the analysis and accept responsibility to submit for publication. JADR drafted the initial and final versions of the manuscript. All authors critically revised early and final versions of the manuscript. JADR had final responsibility to submit for publication. EM and JV are the guarantors.

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Competing interests JV is National Clinical Director for Diabetes and Obesity at NHS England. EM and WEH received consultancy fees for their work on this evaluation. EM is managing director of a not-for-profit Community Interest Company, HeLP-Digital, which exists to disseminate a digital diabetes self-management program, HeLP-Diabetes, across the NHS.

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