



Early Outcomes From the English National Health Service Diabetes Prevention Programme

Diabetes Care 2020;43:152–160 | <https://doi.org/10.2337/dc19-1425>

Jonathan Valabhji,^{1,2,3} Emma Barron,⁴
Dominique Bradley,¹ Chirag Bakhai,^{1,5}
Jamie Fagg,⁴ Simon O'Neill,⁶ Bob Young,⁶
Nick Wareham,⁷ Kamlesh Khunti,⁸
Susan Jebb,⁹ and Jenifer Smith⁴

OBJECTIVE

To assess weight and HbA_{1c} changes in the Healthier You: National Health Service Diabetes Prevention Programme (NHS DPP), the largest DPP globally to achieve universal population coverage.

RESEARCH DESIGN AND METHODS

A service evaluation assessed intervention effectiveness for adults with nondiabetic hyperglycemia (HbA_{1c} 42–47 mmol/mol [6.0–6.4%] or fasting plasma glucose 5.5–6.9 mmol/L) between program launch in June 2016 and December 2018, using prospectively collected, national service-level data in England.

RESULTS

By December 2018, 324,699 people had been referred, 152,294 had attended the initial assessment, and 96,442 had attended at least 1 of 13 group-based intervention sessions. Allowing sufficient time to elapse, 53% attended an initial assessment, 36% attended at least one group-based session, and 19% completed the intervention (attended >60% of sessions). Of the 32,665 who attended at least one intervention session and had sufficient time to finish, 17,252 (53%) completed: intention-to-treat analyses demonstrated a mean weight loss of 2.3 kg (95% CI 2.2, 2.3) and an HbA_{1c} reduction of 1.26 mmol/mol (1.20, 1.31) (0.12% [0.11, 0.12]); completer analysis demonstrated a mean weight loss of 3.3 kg (3.2, 3.4) and an HbA_{1c} reduction of 2.04 mmol/mol (1.96, 2.12) (0.19% [0.18, 0.19]). Younger age, female sex, Asian and black ethnicity, lower socioeconomic status, and normal baseline BMI were associated with less weight loss. Older age, female sex, black ethnicity, lower socioeconomic status, and baseline overweight and obesity were associated with a smaller HbA_{1c} reduction.

CONCLUSIONS

Reductions in weight and HbA_{1c} compare favorably with those reported in recent meta-analyses of pragmatic studies and suggest likely future reductions in participant type 2 diabetes incidence.

The increase in prevalence of type 2 diabetes is a threat to the sustainability of health systems internationally. There is good evidence from randomized controlled trials that behavioral interventions to support people with impaired glucose tolerance to lose weight, adopt a healthy diet, and increase physical activity can significantly decrease the incidence of type 2 diabetes (1–3). Recent systematic reviews and meta-analyses of trials assessing the effectiveness of pragmatic lifestyle interventions for the

¹NHS England, London, U.K.

²Imperial College Healthcare NHS Trust, London, U.K.

³Imperial College London, London, U.K.

⁴Public Health England, London, U.K.

⁵Luton Clinical Commission Group, Luton, U.K.

⁶Diabetes UK, London, U.K.

⁷MRC Epidemiology Unit, University of Cambridge, Cambridge, U.K.

⁸Diabetes Research Centre, Leicester Diabetes Centre, University of Leicester, Leicester, U.K.

⁹Nuffield Department of Primary Care Health Science, University of Oxford, Oxford, U.K.

Corresponding author: Jonathan Valabhji, jonathan.valabhji@nhs.net

Received 19 July 2019 and accepted 22 October 2019

This article contains Supplementary Data online at <http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc19-1425/-/DC1>.

© 2019 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. More information is available at <http://www.diabetesjournals.org/content/license>.

prevention of type 2 diabetes in routine practice have demonstrated relative risk reductions in incidence of 26% and 29% (4–6).

There is limited experience in the implementation of diabetes prevention programs (DPPs) at scale. The U.S. DPP reported on 14,747 participants (7), the Australian lifestyle intervention program Life! reported on 8,412 participants (8), and the National Type 2 Diabetes Prevention Program in Finland (FIN-D2D) reported on 2,798 participants (9).

In 2016, the National Health Service (NHS) in England established the Healthier You: NHS Diabetes Prevention Programme (NHS DPP) and just over 2 years later has seen England achieve universal population coverage. The NHS DPP was developed to prevent or delay the onset of type 2 diabetes in adults already identified to be at high risk, which is defined as having nondiabetic hyperglycemia (NDH) (HbA_{1c} 42–47 mmol/mol [6.0–6.4%] or fasting plasma glucose [FPG] 5.5–6.9 mmol/L). The rationale, justification, development, and early implementation of the program have been described previously (10), and an impact analysis has demonstrated the potential for realizing return on investment within 12 years (11). The approach is based on National Institute for Health and Care Excellence Public Health Guidance on Type 2 Diabetes: Prevention in People at High Risk (NICE PH38) (12) and is complemented by primary preventive interventions to tackle obesity (the major modifiable risk factor for type 2 diabetes), such as a levy on sugar-sweetened beverages, outlined in the U.K. government's Childhood Obesity Plan (13,14).

Using data from the first 2.5 years of activity, we aimed to assess weight and HbA_{1c} changes in the NHS DPP and to assess whether these changes are comparable to uncontrolled pre/post summary effect sizes reported in the most recent meta-analyses of pragmatic studies on which some of the assumptions in the impact analysis were based. We also aimed to quantify access through uptake and program completion and to assess the impacts of age, sex, ethnicity, baseline BMI, and socioeconomic status.

RESEARCH DESIGN AND METHODS

Study Design

A service evaluation in England was used to assess the effectiveness of the NHS

DPP through prospectively collected national service-level data related to all people referred from program launch in June 2016 to the end of December 2018.

Intervention

The NHS DPP delivers behavioral interventions that encourage weight loss or the maintenance of a healthy weight; achievement of U.K. dietary recommendations related to fiber, fruits and vegetables, oily fish, saturated fat, salt, and free sugars (15); and achievement of the U.K. chief medical officers' physical activity recommendations (16). The intervention is delivered according to a national service specification by one of four service providers selected through a national competitive process: Reed Momenta (London, U.K.), ICS Health & Wellbeing (Leeds, U.K.), Ingeus UK (London, U.K.), and Living Well Taking Control (Birmingham, U.K.). The specification was developed by an expert group on the basis of the evidence for clinical and cost effectiveness and on the suggested mechanisms for achieving behavior change described in NICE PH38 (12). These include information provision to raise awareness of the benefits and types of lifestyle changes needed to achieve and maintain a healthy weight, exploration and reinforcement of participants' reasons for wanting to change and their confidence about making changes, goal setting, action planning, coping plans, and relapse prevention.

Each provider's service follows the same broad structure of an initial assessment, core sessions, and maintenance sessions, with a minimum total of 13 face-to-face group-based sessions, over at least 9 months, constituting a least 16 h contact time. Each provider must use a known framework for behavior change.

Participants

Individuals are eligible if they have a blood test indicating NDH conducted within the previous 12 months and are ≥ 18 years of age, not pregnant, and not previously diagnosed with type 2 diabetes. Individuals are identified after an NHS Health Check (17), through retrospective searches of general practice records, or through routine clinical practice. Individuals referred are invited to attend an initial assessment at which

further program details are provided, and participants are assigned to a group for intervention delivery.

Data Collection

All program providers are contractually required to collect a minimum data set, including demographic and clinical information. Age, sex, postcode, and referral HbA_{1c} or FPG measurement are recorded at referral receipt. Ethnicity, weight, and height are recorded at initial assessment. Coaches employed by the provider measure the participant's body weight in light indoor clothing at each intervention session using class 3 scales. Providers assess HbA_{1c} values for each participant at the initial assessment if the referral HbA_{1c} or FPG is >3 months old, at 6 months after the first intervention session, and at the end of the program for those still attending. This service evaluation involves assessment of anonymized data collected during routine service delivery; NHS England has published an information governance framework setting out the legal basis for data collection and data flows, ensuring that the service and its evaluation are delivered in compliance with data protection legislation (18).

Program Moderators

Individual factors (age, sex, ethnicity, socioeconomic status, baseline BMI, and number of sessions attended) and program factors (provider) were identified as potential outcome moderators. Sex was recorded as male, female, or indeterminate. Participants were grouped into 5-year age bands and self-reported ethnicity as white, Asian, black, mixed, or other. Socioeconomic status was measured using quintiles of the Index of Multiple Deprivation associated with the lower super output area derived from participant postcodes (19). All variables also include an unknown category where either the participant declined to give the relevant information or a value was not recorded. BMI was calculated, and participants were classified as healthy weight/underweight, overweight, or obese as defined according to their reported ethnicity; if their ethnicity was not known or not recorded, participant BMIs were classified according to the white ethnicity group in line with World Health Organization thresholds (20).

Outcomes

The primary outcomes for the evaluation were change in weight and change in HbA_{1c} analyzed on an intention-to-treat basis. In secondary analyses, data from participants who completed the program were assessed separately.

Weight change, percentage weight change, and the proportion of participants who achieved a weight loss of $\geq 5\%$ were calculated for all participants associated with cohorts that had had time to finish the program. The baseline measurement was defined as the weight measured at the first intervention session attended to avoid including weight change during the period between initial assessment and intervention commencement. Weight change greater than 5 SDs from the mean was deemed erroneous and recorded as missing.

All providers elected to assess point-of-care tested (POCT) HbA_{1c} values. POCT devices used by providers were the DCA Vantage (Siemens Healthcare, Guildford, U.K.), Afinion (Abbott Diagnostics, Maidenhead, U.K.), and A1CNow+ (BHR Pharmaceuticals, Nuneaton, U.K.). The same device was used for repeated measures within individuals. Consistent with a recent systematic review and meta-analysis (21), there was a significant negative bias for POCT HbA_{1c} values compared with referral, laboratory-measured HbA_{1c} values, greater than could be attributed to regression to the mean and greater than concurrent weight change would suggest was attributable to behavior change between referral and initial assessment. Therefore, mean HbA_{1c} change was calculated only for the subgroup of participants who had had their HbA_{1c} measured at initial assessment so that all values for the same individual had been derived using the same device.

Program retention was assessed by following cohorts of participants who attended at least one intervention session; those associated with cohorts where sufficient time had elapsed to have reached the final session were defined as having finished the program. Completion of the program was defined as attendance of at least 60% of sessions (at least 8 sessions for three providers who offered 13 sessions, at least 11 sessions for one provider who offered 18 sessions). This aligns with the a priori criterion used for provider payment, where

providers were paid for participants who attended $\geq 60\%$ at each of five milestones. Completion rates were calculated with the number of participants who had attended at least one intervention session as the denominator.

Statistical Analyses

Intention-to-treat weight change analysis included participants for whom all data fields, except HbA_{1c}, were complete, with weight change calculated as the weight difference between the first and last sessions attended. HbA_{1c} change analysis included the subset of these participants who also had an HbA_{1c} measurement at initial assessment, with HbA_{1c} change calculated as the HbA_{1c} difference between initial assessment and the last value recorded. Data for program completers was assessed in secondary analyses.

Sensitivity analyses were conducted using multiple imputation that used multivariate chained equations to impute missing data and then comparing the results to the primary analyses. Both univariate and multivariate analyses were repeated using multiple imputation data sets, and results were compared to ensure that missing data did not introduce bias.

Because of time delays between referral and attendance at initial assessments and first intervention sessions, the proportion of participants who attended either the initial assessment or at least one intervention session was calculated using the number of referrals received up to December 2017 as the denominator, with numbers of corresponding attendees either at initial assessment or at an intervention session, respectively, by December 2018 as the numerator.

A mixed-effects logistic regression model was used to identify characteristics associated with program completion. Age, sex, ethnicity, baseline BMI, deprivation, and provider were considered as fixed effects and local referral area as a random effect, with the contribution of the random effect quantified using the intraclass correlation coefficient (ICC). Local referral areas are only associated with a single provider and, therefore, incorporate the same facilities and facilitators used by that provider. Variation among the four providers was directly accounted for by a

fixed effect in the model. Mixed-effects linear regression models were used to identify factors associated with change in weight and change in HbA_{1c}. The number of sessions attended and provider and participant characteristics were considered as fixed effects and local referral area as a random effect.

Statistical significance was defined as $P < 0.05$, and CIs were set at 95%. All data were analyzed using Stata 15 software.

RESULTS

Between June 2016 and the end of December 2018, 324,699 people were referred to the program. Of these, 152,294 had attended an initial assessment, and 96,442 had attended at least one of the group-based intervention sessions. Including only those referred up until the end of December 2017, to allow sufficient time to have joined a group, 53% attended an initial assessment, and 36% attended an intervention session. There were 32,665 participants who had attended an intervention session and had had sufficient time to finish the program. Among these participants, 17,252 (53%) attended at least 60% of sessions for an overall completion rate of 19% of those referred. Figure 1 outlines the number of participants at each stage of the program.

Characteristics of participants at each program stage are shown in Table 1: 46% were male, the mean (SD) age was 62 (13) years, and there was broadly equal representation from all deprivation quintiles at referral. Mean HbA_{1c} at referral was 43.7 (1.5) mmol/mol (6.1% [0.1%]). Ethnicity and weight were not recorded until the initial assessment, at which point 20% of participants were of black, Asian, mixed, or other ethnicity; 69% were white; and 11% were unknown. The mean weight was 83.9 (19.1) kg at initial assessment, and the mean BMI was 30.3 (6.1) kg/m². The largest decrease in the proportions of people retained was between referral and initial assessment, where there were significant decreases in the proportions of males, people aged < 60 years, and people from the most deprived quintile (all $P < 0.001$). Except for the proportion of males ($P = 0.52$), these decreases continued between initial assessment and program completion (all $P < 0.001$).

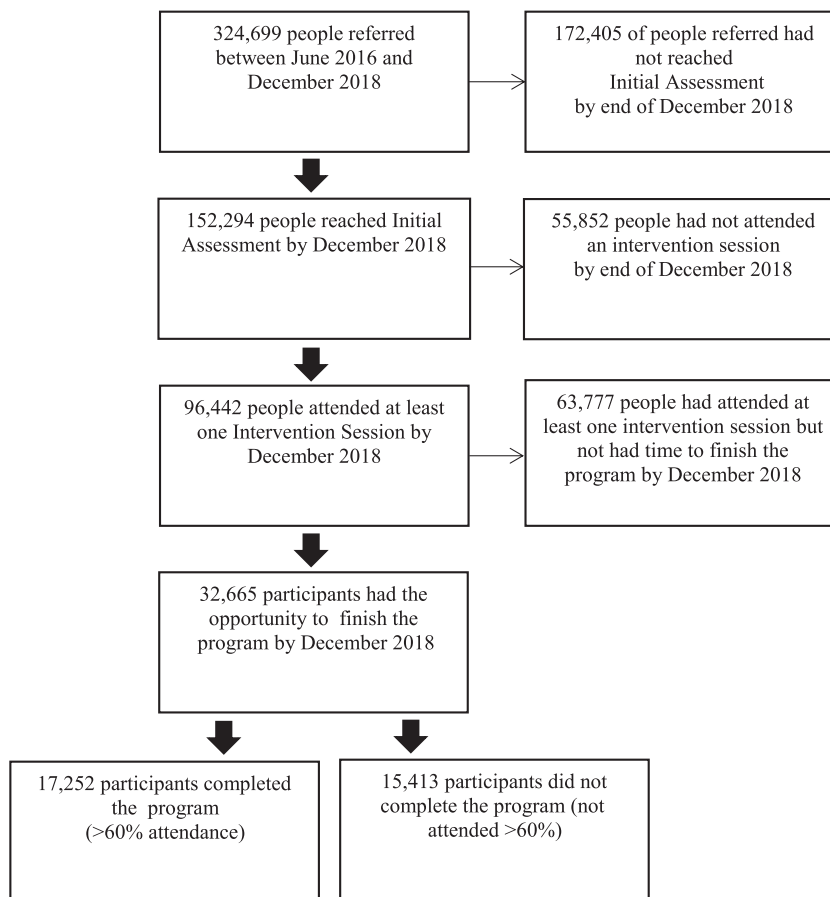


Figure 1—Flowchart of participants at each stage in the program.

Completion, weight change, and HbA_{1c} change were assessed for participants associated with cohorts that had finished the program. Of those, 26,753 (82%) had no missing or unknown data (excluding HbA_{1c}). There were no missing data for age, provider, local referral area, and number of sessions attended. Data were missing for participant postcode (and therefore deprivation quintile) (0.3%), sex (0.5%), BMI (7%), and ethnicity (10%). Data on weight was missing at either baseline or end of program for 7% of participants. There were 19,891 (61%) participants who had their HbA_{1c} measured using a POCT device at initial assessment, of whom 16,083 had no missing data (49% of all participants).

Univariate analyses of primary outcomes are provided in Table 2 (with secondary outcomes in Supplementary Table 1). The mean (SD) number of days in the program was 179.8 (136) and the mean number of intervention sessions attended was 8.2 (4.6). For the providers

offering a total of 13 sessions, the mean number of sessions attended was 7.6 (3.8), and for the provider offering 18 sessions, the mean number of sessions attended was 9.6 (5.8). The regression analysis indicated that participants who were older (up to 70 years of age), from less deprived backgrounds, and with a lower BMI were more likely to complete the program, but there was no effect of sex. Relative to white groups, Asian and mixed ethnic groups had lower completion rates, with no significant differences for other ethnic groups. There were significant differences in completion by provider (Supplementary Tables 2 and 3). Clustering by local referral area made a proportionately small contribution to the outcomes (ICC 3.9% [95% CI 2.1, 7.2]).

Using an intention-to-treat analysis, mean baseline weight was 83.4 kg with a mean weight change of -2.3 kg (95% CI $-2.3, -2.2$). Mean percentage weight change was -2.7% ($-2.7, -2.6$), and 24% of participants lost $\geq 5\%$ of

baseline weight. Weight loss increased with the number of sessions attended (Fig. 2). The regression analysis indicated that for each additional session attended, there was a 0.32-kg greater weight loss, and for each 1-kg higher baseline weight, there was an additional 0.03-kg weight loss. Older participants (up to 75 years of age), men, those from areas in the least deprived quintile, and those with a higher BMI lost more weight. Asian and black ethnic groups lost less weight, with no significant differences for other groups. There were significant differences by provider independent of the number of sessions in their program (Supplementary Table 4). The ICC was 0.4% (95% CI 0.2, 0.8).

The mean baseline POCT HbA_{1c} was 41.8 mmol/mol (6.0%), with a mean change of -1.26 mmol/mol (95% CI $-1.31, -1.20$) (-0.12% [$-0.12, -0.11$]). HbA_{1c} change increased with the number of sessions attended (Fig. 2). The regression analysis indicated that for each additional session attended, there was an additional 0.18 mmol/mol (0.02%) decrease in HbA_{1c}, and for each 1 kg in weight reduction, there was a 0.15 mmol/mol (0.01%) reduction in HbA_{1c}. For each 1 mmol/mol (0.09%) increase in baseline HbA_{1c}, there was a further corresponding decrease of 0.32 mmol/mol (0.03%). There were significantly smaller HbA_{1c} reductions for older participants, women, those from the most deprived quintile, and those with a higher BMI. There was a significantly smaller HbA_{1c} reduction for black participants, with no significant differences for other ethnic groups (Supplementary Table 4). The ICC was 1.3% (95% CI 0.7, 2.3).

For completers, the mean baseline weight was 82.4 kg with a mean weight change of -3.3 kg (95% CI $-3.4, -3.2$). The mean percentage weight change was -4.0% ($-4.0, -3.9$), and 37% of participants lost $\geq 5\%$ of weight. The mean baseline POCT HbA_{1c} was 41.8 mmol/mol (6.0%) with a mean change of -2.04 mmol/mol ($-2.12, -1.96$) (-0.19% [$-0.19, -0.18$]). Analysis of characteristics associated with outcomes gave similar results to the intention-to-treat analysis, although weight loss did not differ by sex (Supplementary Table 5).

Sensitivity analysis using imputed data showed that there were no substantive changes in direction and magnitude of

Table 1—Participant characteristics at each stage in the program between June 2016 and December 2018

	Referred		Referred and attended an IA		Attended at least one group-based IV		Associated with cohorts that finished the program		Completed the program*		χ^2 P value		
	n	%	n	%	n	%	n	%	n	%	Reached IA vs. referred	Attended at least one IV vs. reached IA	Completed vs. finished
Overall	324,699	100	152,294	100	96,442	100	32,665	100	17,252	100	NA	NA	NA
Sex													
Male	147,890	46	68,780	45	43,517	45	14,487	44	7,700	45	<0.001	<0.001	0.52
Female	172,252	53	82,637	54	52,511	54	18,017	55	9,465	55			
Indeterminate/ unknown†	4,557	1	877	1	414	0	161	0	87	0			
Age band (years)													
<40	17,797	5	5,818	4	2,781	3	832	3	228	1	<0.001	<0.001	<0.001
40–44	15,811	5	5,593	4	2,841	3	903	3	301	2			
45–49	22,604	7	8,449	6	4,602	5	1,469	4	525	3			
50–54	32,021	10	12,735	8	7,256	8	2,388	7	967	6			
55–59	37,938	12	16,647	11	10,016	10	3,383	10	1,655	10			
60–64	40,880	13	19,656	13	12,743	13	4,247	13	2,305	13			
65–69	46,787	14	25,481	17	17,517	18	6,205	19	3,710	22			
70–74	48,106	15	26,616	17	18,229	19	6,244	19	3,684	21			
≥75	62,641	19	31,281	21	20,457	21	6,994	21	3,877	22			
Unknown	114	0	18	0	0	0	0	0	0	0			
Mean age	62	—	64	—	65	—	65	—	67	—			
SD	13.4	—	12.4	—	11.7	—	11.5	—	10.2	—			
Ethnicity													
Asian	NA	NA	17,364	11	10,249	11	3,381	10	1,382	8	NA	<0.001	<0.001
Black	NA	NA	9,567	6	5,402	6	2,099	6	959	6			
Mixed	NA	NA	2,539	2	1,673	2	559	2	249	1			
Other	NA	NA	1,432	1	765	1	220	1	82	0			
White	NA	NA	105,315	69	69,477	72	23,113	71	13,006	75			
Unknown	NA	NA	16,077	11	8,876	9	3,293	10	1,574	9			
Deprivation quintile													
IMD 1 (most deprived)	68,616	21	29,388	19	16,357	17	5,634	17	2,500	14	<0.001	<0.001	<0.001
IMD 2	65,469	20	29,604	19	17,472	18	6,368	19	3,222	19			
IMD 3	62,733	19	30,141	20	19,378	20	7,038	22	3,865	22			
IMD 4	61,798	19	30,446	20	20,300	21	6,747	21	3,725	22			
IMD 5 (least deprived)	65,108	20	32,247	21	22,721	24	6,779	21	3,888	23			
Unknown	975	0	468	0	214	0	99	0	52	0			
BMI grouping at IA													
Underweight/ healthy	NA	NA	22,953	15	14,033	14	4,373	13	2,558	14	NA	<0.001	<0.001
Overweight	NA	NA	50,850	33	32,640	34	10,393	32	5,938	34			
Obese	NA	NA	67,390	44	43,370	45	13,516	41	6,809	39			
Unknown	NA	NA	11,101	7	6,399	7	4,383	13	1,947	11			
Mean (kg/m ²)	NA	NA	30.3	—	30.3	—	30.3	—	29.9	—			
SD	NA	NA	6.1	—	6.0	—	5.9	—	5.7	—			
Weight at IA (kg)													
Mean	NA	NA	83.9	—	84.0	—	83.6	—	82.6	—			
SD	NA	NA	19.1	—	18.9	—	18.7	—	18.1	—			

IA, initial assessment; IMD, Index of Multiple Deprivation; IV, intervention session; NA, not available. *Finished and attended >60% of sessions. †Indeterminate and unknown grouped together because of suppression of small numbers.

the associations (Supplementary Tables 6–9). Statistically significant covariates in the complete-case analysis remained significant in the imputed analysis, with the exception of a single age band (60–64 years) for weight change and mixed ethnicity for completion, the latter placing some uncertainty on the

significance of mixed ethnicity. A number of subcategories were significant in the imputed analysis but not in the complete-case analysis. In these cases, there were no substantial differences in the magnitude and sign of the associated coefficient, and no suggested change to the interpretation.

CONCLUSIONS

A national program to provide behavioral support to people with NDH in England was associated with a significant reduction in weight and HbA_{1c} among the 36% of people referred who attended at least one of the group-based intervention sessions. There was a clear

Table 2—Primary outcomes (weight change and HbA_{1c} change) for participants who have finished the program, including respectively those for whom all data fields, except HbA_{1c}, were complete (N = 26,753) and for those with all data fields complete (N = 16,083): univariate analysis

	Mean weight change (kg), intention-to-treat					Mean HbA _{1c} change (mmol/mol), intention-to-treat				
	n	Baseline	Change	95% CI	P value	n	Baseline	Change	95% CI	P value
Total	26,753	83.4	−2.3	−2.3, −2.2	NA	16,083	41.8	−1.3	−1.3, −1.2	NA
Sex										
Male	11,942	90	−2.5	−2.6, −2.5	<0.001	7,065	41.7	−1.4	−1.4, −1.3	<0.001
Female	14,800	78.1	−2.0	−2.1, −2.0		9,010	41.8	−1.2	−1.2, −1.1	
Indeterminate	11	84.7	−2.8	−5.1, −0.5		8	42.1	−0.1	−2.9, 2.7	
Age band (years)										
<40	604	90.3	−1.0	−1.3, −0.8	<0.001	342	41.1	−0.7	−1.0, −0.3	<0.001
40–44	693	90.6	−1.0	−1.3, −0.8		388	41.5	−0.7	−1.0, −0.5	
45–49	1,116	90.4	−1.6	−1.8, −1.4		629	41.5	−0.6	−0.8, −0.4	
50–54	1,873	88.8	−1.7	−1.9, −1.5		1,082	41.9	−1.0	−1.2, −0.9	
55–59	2,723	87.8	−2.1	−2.2, −1.9		1,599	41.7	−1.1	−1.2, −0.9	
60–64	3,489	85.2	−2.4	−2.5, −2.3		2,161	41.7	−1.2	−1.4, −1.1	
65–69	5,201	83.8	−2.6	−2.7, −2.4		3,216	41.7	−1.4	−1.6, −1.3	
70–74	5,161	81.6	−2.6	−2.7, −2.5		3,167	41.8	−1.5	−1.6, −1.4	
≥75	5,893	77.2	−2.2	−2.3, −2.1		3,499	42	−1.3	−1.4, −1.1	
Ethnicity										
Asian	3,087	74.8	−1.0	−1.1, −0.9	<0.001	1,844	42.1	−0.9	−1.0, −0.8	<0.001
Black	1,821	86.3	−1.7	−1.9, −1.6		1,167	42.2	−0.8	−1.0, −0.6	
Mixed	513	84.1	−1.7	−2.0, −1.4		285	42.2	−1.0	−1.3, −0.7	
Other	181	80.9	−1.5	−2.0, −1.1		95	41.3	−0.6	−1.1, −0.0	
White	21,151	84.5	−2.5	−2.5, −2.4		12,692	41.7	−1.4	−1.4, −1.3	
Deprivation										
IMD 1 (most deprived)	4,430	84.8	−1.8	−1.9, −1.6	<0.001	2,631	41.9	−0.9	−1.0, −0.7	<0.001
IMD 2	5,161	84	−2.1	−2.2, −2.0		3,287	41.7	−1.2	−1.3, −1.1	
IMD 3	5,922	83.1	−2.2	−2.3, −2.1		3,741	41.9	−1.3	−1.4, −1.2	
IMD 4	5,635	83.2	−2.5	−2.6, −2.4		3,268	41.7	−1.3	−1.4, −1.2	
IMD 5 (least deprived)	5,605	82.4	−2.6	−2.7, −2.5		3,156	41.8	−1.5	−1.7, −1.4	
BMI group										
Underweight/healthy	4,205	62.7	−1.4	−1.5, −1.3	<0.001	2,630	41.3	−1.4	−1.5, −1.3	0.001
Overweight	9,865	76.5	−2.2	−2.3, −2.1		6,033	41.6	−1.3	−1.4, −1.2	
Obese	12,683	95.7	−2.6	−2.6, −2.5		7,420	42.1	−1.2	−1.2, −1.1	
Provider										
Ingeus UK	5,868	84.9	−2.1	−2.2, −2.0	<0.001	35	39.7	−1.0	−2.4, 0.4	<0.001
Living Well Taking Control	3,067	84.2	−1.9	−2.1, −1.8		2,066	40.9	−0.5	−0.6, −0.4	
ICS Health & Wellbeing	11,752	82.4	−2.3	−2.3, −2.2		8,890	42.3	−1.3	−1.4, −1.2	
Reed Momenta	6,066	83.7	−2.6	−2.7, −2.4		5,092	41.2	−1.5	−1.6, −1.4	

IMD, Index of Multiple Deprivation; NA, not available.

dose-response relationship, and people who attended more sessions experienced greater reductions in both weight and HbA_{1c}.

Strengths and Limitations

This report describes the largest cohort of people to our knowledge to be offered an intervention within a DPP, achieving universal population coverage. It includes objective measures of weight, HbA_{1c}, individual participant data, and flow through the program and assesses the impact on health inequalities. There are some missing data, and we have taken a principled and pragmatic approach to consider the effects on data interpretation. Our 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 our conclusions. 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 HbA_{1c} reductions, including secular trends.

Data on HbA_{1c} change are only available for half the participants in whom a baseline measure of POCT HbA_{1c} was performed so that it was directly comparable to subsequent measurements. However, given the cause of these missing data, it is unlikely that this has introduced a specific bias. Moreover, the

characteristics of the subset are similar to the complete data set. At an individual level, the clinical significance of a 1.26 mmol/mol (0.12%) reduction in HbA_{1c} is difficult to gauge because very few data are available internationally with regard to HbA_{1c} reductions in response to interventions in the nondiabetic range. However, a left shift in HbA_{1c} distribution of 1.26 mmol/mol is likely to be significant at the population level.

A current limitation is that the last recorded weight available is that measured at the last session attended, and at present, we do not have data on longer-term outcomes. However, mechanisms for the acquisition of longer-term data have been established, and meanwhile,

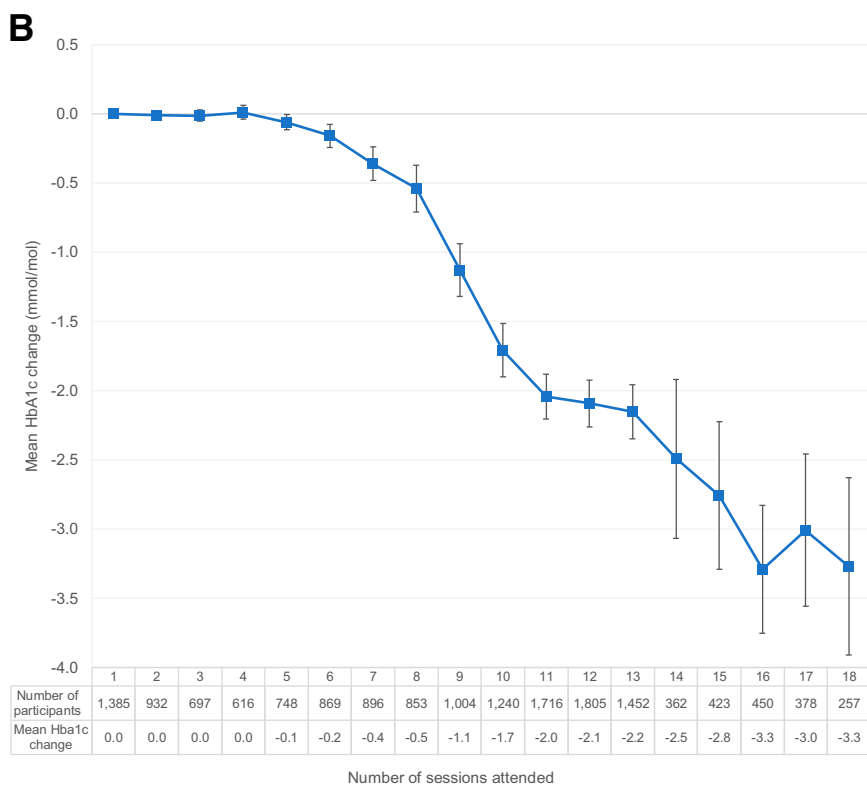
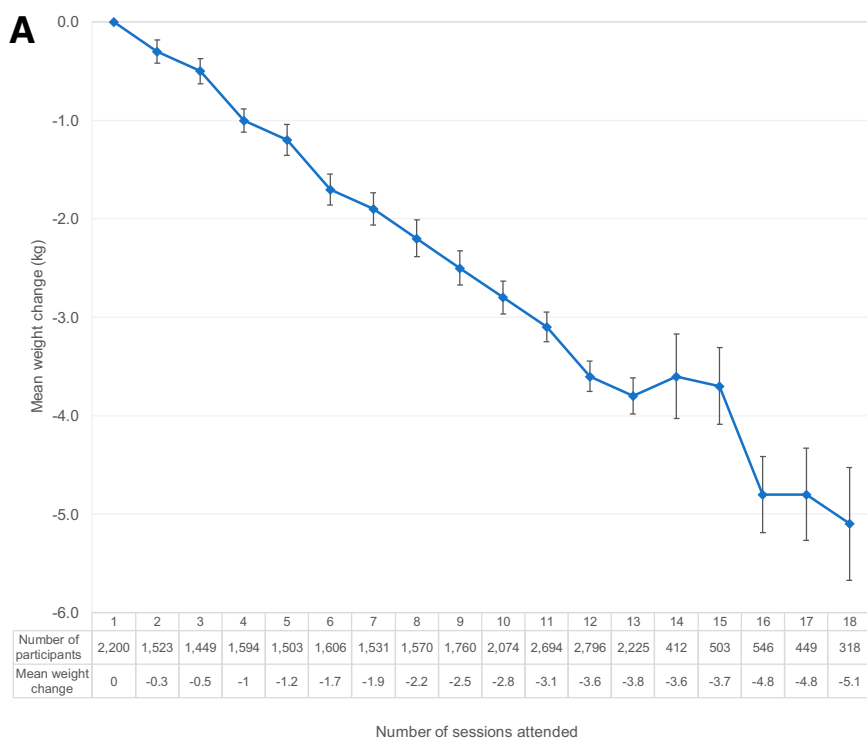


Figure 2—A: Mean weight change (kg) by number of sessions attended, including those for whom all data fields, except HbA_{1c}, were complete (*n* = 26,753). **B:** Mean HbA_{1c} change (mmol/mol) by number of sessions attended, including those for whom all data fields were complete (*n* = 16,083). Number of participants refers to the number who attended exactly the given number of sessions; for example, in panel A, 2,200 participants attended only one intervention session before finishing the program, 1,523 participants attended exactly two intervention sessions before finishing the program, and so forth.

initial weight loss is a strong predictor of weight loss outcomes in subsequent years (22). From 2017/2018, the National Diabetes Audit in England, which involves extracts from health care data sets held in primary care settings and hospitals, was expanded to include people at high risk of type 2 diabetes, including those with NDH and, hence, eligible for the NHS DPP (23). Data will be systematically extracted for those coded with NDH and linked with the NHS DPP data set, permitting longitudinal tracking of HbA_{1c} and, therefore, type 2 diabetes incidence, weight, and other recorded cardiovascular risk factors, including blood pressure and lipids, microvascular and cardiovascular disease incidence, and mortality. Recent 30-year follow-up data from the Da Qing Diabetes Prevention Outcome Study demonstrated that lifestyle intervention in people with impaired glucose tolerance, in addition to delaying the onset of type 2 diabetes, also reduced the incidence of cardiovascular events, microvascular complications, and cardiovascular and all-cause mortality and increased life expectancy (3).

Implications of This Evaluation

The NHS DPP design was based on a Public Health England–commissioned systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes in routine practice over 12–18 months. This found such programs to be associated with weight loss of 2.5 kg (95% CI 1.99, 2.99) and HbA_{1c} reduction of 0.07% (95% CI 0.01, 0.14) (4,5). The pooled incidence rate ratio of type 2 diabetes among patients attending a DPP compared with those receiving usual care was 0.74 (95% CI 0.58, 0.93), a reduction of 26%. A more recent global systematic review and network meta-analysis of pragmatic DPP studies reporting effects on incidence, weight, and glycemic parameters demonstrated a similar relative risk reduction of 29% associated with 2.5 kg (95% CI 1.90, 3.00) weight loss but no evidence of a reduction in HbA_{1c} (6). NHS DPP data demonstrate similar weight loss and greater reductions in HbA_{1c}, providing optimism that this program may lead to reductions in future type 2 diabetes incidence among participants.

The U.S. DPP reported a mean percentage weight reduction of 4.2% (7), greater than the 2.7% weight loss seen in the NHS DPP intention-to-treat analysis, although the U.S. analysis only included participants who had attended at least four intervention sessions. When compared with the 4.0% weight loss seen among completers in the NHS DPP, the results are similar. The Finnish DPP reported weight losses of 1.3 kg in men and 1.1 kg in women (9), and the Australian DPP reported losses of 1.4 kg for participants completing sessions 1–5 and 2.5 kg for participants completing session 1–6 (8). Differences in weight loss across the four programs may reflect differences in intensity, ranging from a median of 14 sessions in the U.S. DPP, a mean of 6 in the Australia DPP, and a mean of 2.9 in the Finnish DPP compared with 8 in the NHS DPP (7–9). Differences in starting weight may also have been contributory: U.S. DPP participants had a mean baseline measurement of 96.8 kg; Australian DPP participants, 87.3 kg; and Finnish DPP, 95.8 kg in men and 83.8 kg in women compared with 83.4 kg for NHS DPP participants. None of the programs in other countries have reported the effects on glycemic parameters, although the Finnish DPP reported beneficial effects on type 2 diabetes incidence and cardiovascular risk factors (9).

Beyond the national DPPs, it is unusual for behavioral programs to take a whole-population approach. We are only aware of one randomized controlled trial of a behavioral intervention for weight loss that was offered opportunistically in primary care. The Brief interventions for Weight Loss (BWEL) trial found that 40% of people offered support attended, and 24% completed, a 12-week program (24), similar to the proportions seen in the NHS DPP, which is a longer program.

People from more deprived areas were less likely to complete the program, lost less weight, and had smaller reductions in HbA_{1c}. Similarly, the Brief Interventions for Weight Loss trial found that participants from lower socioeconomic backgrounds attended fewer sessions, leading to less weight loss (25).

Black, Asian, mixed, and other ethnic groups are overrepresented in those attending an initial assessment (26), but the adjusted odds ratio of completion among Asian groups is 25% lower than in white groups. Asian and black groups lost

less weight, and black groups had smaller reductions in HbA_{1c}. Uniquely, the effect of ethnicity is independent of socioeconomic status.

Program engagement, retention, and adherence are crucial to attain the desired effects. The findings highlight the need to actively target engagement, retention, and adherence in specific groups to avoid widening inequalities. There has already been a new round of provider procurement for the NHS DPP, with newly appointed providers starting in August 2019. The payment schedule has been adjusted to provide greater incentives to providers to retain participants of black, Asian, mixed, and other ethnicity and those from more deprived backgrounds. Recognizing that a large proportion declined or failed to attend the face-to-face group-based interventions, digital modes of program delivery will be offered for those who decline or fail to attend the face-to-face interventions. Such programs have been shown to be associated with weight loss, although the effects on glycemic control are less clear (27). A large uncontrolled pilot of digital prevention interventions conducted in live service environments in England is currently under way (28).

In summary, reductions in weight and HbA_{1c} demonstrated in the NHS DPP are encouraging and compare favorably with those reported in recent meta-analyses of pragmatic studies. Furthermore, they are potentially indicative of future reductions in participant type 2 diabetes incidence.

Funding. NHS England funded program development, implementation, and evaluation. K.K. acknowledges support from National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care East Midlands and the NIHR Leicester Biomedical Research Centre. S.J. is funded by the NIHR Oxford Biomedical Research Centre and NIHR Collaboration for Leadership in Applied Health Research and Care Oxford.

Duality of Interest. All authors have completed the International Committee of Medical Journal Editors uniform disclosure form and declare the following: J.V. is the national clinical director for diabetes and obesity at NHS England and is the clinical lead for the Healthier You: NHS DPP. E.B. is the head of health intelligence (diabetes) for Public Health England and leads analysis of the DPP. D.B. is an analyst for NHS England and is actively involved in analysis of the program. C.B. is the primary care advisor to the NHS DPP. J.F. was the diabetes evidence and evaluation lead

at Public Health England until September 2018. S.O. is the clinical director at Diabetes UK. B.Y. is clinical lead of the National Diabetes Audit for England and Wales and a trustee of Diabetes UK. N.W. was chair of the program development group for NICE Public Health Guidance on Type 2 Diabetes Prevention: Population and Community-Level Interventions (NICE PH35). K.K. was chair of the program development group for NICE PH38. K.K. is also co-director of the Leicester Diabetes Centre, and one of the program providers, Ingeus UK, provided interventions on the basis of the type 2 DPP developed by Leicester Diabetes Centre. J.S. represents Public Health England on the NHS England Diabetes Programme Board. No other potential conflicts of interest relevant to this article were reported.

Author Contributions. All authors are members or attendees of the Healthier You: NHS Diabetes Prevention Programme Expert Reference Group, chaired by J.V. Members from inception (J.V., S.O., B.Y., N.W., K.K., S.J.) were responsible for developing the service specification for the behavioral intervention and for developing the data fields for the minimum data set. All authors advised on the operational delivery of the program and on the interpretation of data derived via the minimum data set on a quarterly basis since inception in 2015. J.V., E.B., and D.B. were responsible for evaluation design and initial manuscript drafting. E.B. and D.B. performed the data analyses, and J.F. advised on the overall analytic design and multiple imputation. C.B., J.F., and S.J. contributed to early draft development. All authors reviewed drafts of the manuscript and provided constructive feedback and criticism. J.V. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility of the integrity of the data and the accuracy of the data analysis.

Prior Presentation. Parts of this study were presented in abstract form at the Diabetes UK Annual Professional Conference, Liverpool, U.K., 6–8 March 2019, and the European Association for the Study of Diabetes Annual Conference, Barcelona, Spain, 16–20 September 2019.

References

1. Tuomilehto J, Lindström J, Eriksson JG, et al.; Finnish Diabetes Prevention Study Group. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001;344:1343–1350
2. Knowler WC, Barrett-Connor E, Fowler SE, et al.; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346:393–403
3. Gong Q, Zhang P, Wang J, et al.; Da Qing Diabetes Prevention Study Group. Morbidity and mortality after lifestyle intervention for people with impaired glucose tolerance: 30-year results of the Da Qing Diabetes Prevention Outcome Study. *Lancet Diabetes Endocrinol* 2019;7:452–461
4. Public Health England. A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of Type 2 diabetes mellitus in routine practice [Internet]. Available from

- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733053/PHE_Evidence_Review_of_diabetes_prevention_programmes_FINAL.pdf. Accessed 18 May 2019
5. Dunkley AJ, Bodicoat DH, Greaves CJ, et al. Diabetes prevention in the real world: effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations: a systematic review and meta-analysis. *Diabetes Care* 2014;37:922–933
 6. Galaviz KI, Weber MB, Straus A, Haw JS, Narayan KMV, Ali MK. Global diabetes prevention interventions: a systematic review and network meta-analysis of the real-world impact on incidence, weight, and glucose. *Diabetes Care* 2018;41:1526–1534
 7. Ely EK, Gruss SM, Luman ET, et al. A national effort to prevent type 2 diabetes: participant-level evaluation of CDC's national diabetes prevention program. *Diabetes Care* 2017;40:1331–1341
 8. Dunbar JA, Jayawardena A, Johnson G, et al. Scaling up diabetes prevention in Victoria, Australia: policy development, implementation, and evaluation. *Diabetes Care* 2014;37:934–942
 9. Saaristo T, Moilanen L, Korpi-Hyövälti E, et al. Lifestyle intervention for prevention of type 2 diabetes in primary health care: one-year follow-up of the Finnish National Diabetes Prevention Program (FIN-D2D). *Diabetes Care* 2010;33:2146–2151
 10. Barron E, Clark R, Hewings R, Smith J, Valabhji J. Progress of the Healthier You: NHS Diabetes Prevention Programme: referrals, uptake and participant characteristics. *Diabet Med* 2018;35:513–518
 11. Thomas C, Sadler S, Breeze P, Squires H, Gillett M, Brennan A. Assessing the potential return on investment of the proposed UK NHS diabetes prevention programme in different population subgroups: an economic evaluation. *BMJ Open* 2017;7:e014953
 12. National Institute for Health and Care Excellence. Type 2 diabetes: prevention in people at high risk [Internet], 2012. Available from <https://www.nice.org.uk/guidance/ph38/>. Accessed 18 May 2019
 13. UK Government. Childhood Obesity: a plan for action [Internet], 2016. Available from www.gov.uk/government/publications/childhood-obesity-a-plan-for-action. Accessed 18 May 2019
 14. UK Government. Childhood Obesity: a plan for action, chapter 2 [Internet], 2018. Available from <https://www.gov.uk/government/publications/childhood-obesity-a-plan-for-action-chapter-2>. Accessed 18 May 2019
 15. Public Health England. The Eatwell guide [Internet], 2018. Available from <https://www.gov.uk/government/publications/the-eatwell-guide>. Accessed 23 September 2019
 16. Department of Health and Social Care. Physical activity guidelines [Internet], 2019. Available from <https://www.gov.uk/government/collections/physical-activity-guidelines>. Accessed 23 September 2019
 17. Public Health England. NHS Health Check best practice guidance [Internet], 2017. Available from <https://www.healthcheck.nhs.uk/commissioners-and-providers/national-guidance/>. Accessed 18 May 2019
 18. NHS England and NHS Improvement. Diabetes Prevention Programme Information Governance and Data Flows Framework [Internet], 2016. Available from <https://www.england.nhs.uk/wp-content/uploads/2019/09/diabetes-prevention-programme-information-governance-and-data-flows-framework.pdf>. Accessed 23 September 2019
 19. Department for Communities and Local Government. The English indices of deprivation [Internet], 2015. Available from <https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015>. Accessed 23 September 2019
 20. WHO Expert Consultation. Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies [published correction appears in *Lancet* 2004;363:902]. *Lancet* 2004;363:157–163
 21. Hirst JA, McLellan JH, Price CP, et al. Performance of point-of-care HbA1c test devices: implications for use in clinical practice - a systematic review and meta-analysis. *Clin Chem Lab Med* 2017;55:167–180
 22. Greenberg I, Stampfer MJ, Schwarzfuchs D, Shai I; DIRECT Group. Adherence and success in long-term weight loss diets: the dietary intervention randomized controlled trial (DIRECT). *J Am Coll Nutr* 2009;28:159–168
 23. National Diabetes Audit and Diabetes Prevention Programme (NDA-DPP) pilot study [Internet], 2017. Available from <https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/national-diabetes-audit-and-diabetes-prevention-programme-nda-dpp-pilot-study>. Accessed 18 May 2019
 24. Aveyard P, Lewis A, Tearne S, et al. Screening and brief intervention for obesity in primary care: a parallel, two-arm, randomised trial. *Lancet* 2016;388:2492–2500
 25. Graham J, Tudor K, Jebb SA, et al. The equity impact of brief opportunistic interventions to promote weight loss in primary care: secondary analysis of the BWeL randomised trial. *BMC Med* 2019;17:51
 26. NOMIS Official Labour Market Statistics. Ethnic group by sex and age [Internet]. Available from www.nomisweb.co.uk/census/2011/lc2101ew. Accessed 18 May 2019
 27. Joiner KL, Nam S, Whittemore R. Lifestyle interventions based on the diabetes prevention program delivered via eHealth: a systematic review and meta-analysis. *Prev Med* 2017;100:194–207
 28. Murray E, Daff K, Lavida A, Henley W, Irwin J, Valabhji J. Evaluation of the digital diabetes prevention programme pilot: uncontrolled mixed-methods study protocol. *BMJ Open* 2019;9:e025903