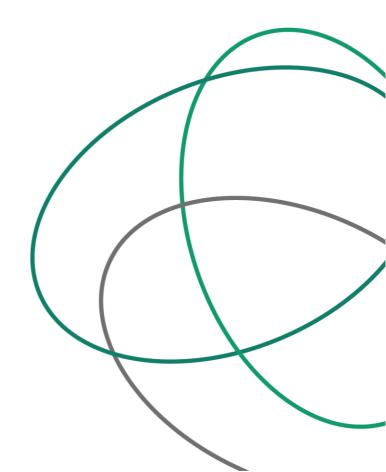


Diabetes Digital Behaviour Change Programmes: North West London Pilot

Evaluation Report Dr Wayne Smith, Imperial College Health Partners 26th March 2018



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1 Executive summary

Key points

- This study compared three smartphone-based digital behaviour change programmes lasting 8 to 12 weeks for patients with Type 2 Diabetes (T2DM): Changing Health, OurPath and Oviva Diabetes Support.
- All three programmes resulted in mean improvements in clinical measures relevant to T2DM (weight, BMI, HbA1c and blood pressure).
- Differences between the three programmes for clinical outcomes were marginal. Patients on Oviva Diabetes Support had the largest improvements in HbA1c and blood pressure. Patients on OurPath had the largest improvements in BMI.
- Patient feedback on all three digital behaviour programmes was generally positive, although access to a compatible smartphone was a barrier for some.
- Completion rates appeared to be much higher for the digital behaviour change programmes than for face-to-face diabetes structured education.
- Within the limitations of this pilot, results support the wider use of smartphone apps for delivering structured diabetes education.

The North West London (NWL) Self-Care Project Delivery Group and Digital Health London are working to develop agreed protocols for the provision of smartphone apps to support the population of NWL in managing their long-term health conditions (LTCs). As part of this initiative, a pilot project was conducted in patients with Type 2 Diabetes Mellitus (T2DM) to provide a proof of concept and gain a better understanding of the usability and uptake of smartphone apps for delivery of digital behaviour change programmes and structured diabetes education.

The three digital behaviour change programmes selected for evaluation in this pilot were Changing Health, OurPath and Oviva Diabetes Support. Each of the selected programmes offers structured diabetes education and lifestyle tracking (e.g. diet and fitness) through a smartphone app, with support from a trained behaviour change coach or diabetes educator. OurPath also offers peer support and connected monitoring devices (weighing scales, activity tracker). Programmes last between 8 weeks (Oviva) and 12 weeks (Changing Health and OurPath), but patients have ongoing access to the smartphone apps and educational resources after completion. Five self-nominated Clinical Commissioning Groups (CCGs) took part in the pilot (West London, Central London [Westminster], Hammersmith & Fulham [H&F], Harrow, and Hillingdon). Each CCG nominated between 3 and 6 GP pilot sites. Four hundred and thirty (430) adults with T2DM were recruited at 18 GP pilot sites between March and August 2017. Recruitment tactics included face-to-face conversations with healthcare professionals (HCPs), text messages, emails or letters. Recruitment materials were sent either from the GP practice (facilitated referrals), or directly from the programme provider (patient self-referrals). The greatest uptake was generated from self-referrals.

Qualitative and quantitative data were collected for programme evaluation. Nonidentifiable demographic and clinical data (weight, body mass index [BMI], glycated haemoglobin [HbA1c], blood pressure, and medication use) were extracted from patients' medical records before and after participation. The Patient Activation Measure (PAM) was collected at baseline and completion, either by the referring HCP, or by the programme provider. Uptake, engagement, completion, usability and patient experience metrics were collected by the programme providers. Further qualitative feedback was collected by online survey and patient focus groups.

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Data from 295 patients were available for analysis (69% of those recruited to the pilot). Uptake on referrals was >70% for OurPath and Oviva and 50% for Changing Health. Completion data were available for >80% of patients on Oviva and 53% on OurPath. These completion rates were much higher than for face-to-face diabetes structured education (<6.3% completion for DESMOND, DAFNE and X-PERT) at participating practices.

Most patients (51%) were PAM level 3 before enrolment. Patients at this PAM level typically know key facts about their health and strive for best practice behaviours based on specific goals. There was a similar distribution of PAM levels at baseline across the three programmes. Mean PAM score for enrolled patients was 58, which is similar to the mean PAM score (59.2) among adults with diabetes nationally.ⁱ Change in PAM score during the programme was available for 9 participants; seven had a positive change.

Participation in a digital behaviour change programme resulted in a significant improvement in median T2DM-associated clinical indicators (BMI, HbA1c, SBP) across the pilot study population. Change in clinical indicators during the programme was not significantly correlated (p>0.05) with PAM score, PAM level or Index of Multiple Deprivation (IMD).

Mean weight decreased by 2.5kg, and mean BMI decreased by 0.99 kg/m² during participation. Most patients across the study population had a reduction in weight and BMI during participation. Average weight loss was highest for patients taking part in OurPath. Modest weight losses of 5 to 10% have been associated with significant improvements in cardiovascular risk factors among overweight patients with T2DM.ⁱⁱ Mean HbA1c decreased by 6.9 mmol/mol during the programme, with most patients across the study population experiencing a reduction in HbA1c. Average change in HbA1c was largest for patients taking part in Oviva. Reduction of HbA1c by 11 mmol/mol in a T2DM population has been associated with a 25% decrease in risk

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of microvascular complications as well as decreased risk of ischaemic heart disease and peripheral vascular disease.^{iii,iv}

Reductions were observed in mean systolic blood pressure (SBP, -3 mmHg) and diastolic blood pressure (DBP, -2 mmHg) during the programme. Participation in Oviva was associated with the greatest reductions in both SBP and DBP. Any reduction in SBP in patients with T2DM has been associated with a decreased risk of cardiovascular complications.^v

According to prescription data extracted from medical records, 23 patients discontinued metformin while taking part in the programme. Reductions in HbA1c, weight and blood pressure for these patients indicates they may have been able to discontinue metformin because clinical indicators improved during the programme. Patient feedback on all three digital behaviour programmes was generally positive. The Net Promoter Score (NPS), which measures the likelihood of recommending a service to family, friends or colleagues, was positive for Changing Health and OurPath. Oviva participants did not complete NPS, but most patients said they would recommend the programme to family and friends. Most patients said they had experienced a benefit from taking part in the programme (in some cases describing it as "life changing"). Some patients reported improvements in their general wellbeing and motivation, and others said that they had avoided needing to start medication by taking part. The main negative comments from patients related to technical problems with the smartphone app or a connected device, or incompatibility with (or not owning) a smartphone. A few patients, particularly those who were already wellinformed about diabetes, did not feel their digital behaviour change programme or smartphone app were useful for them.

Most GP practices did not give feedback on their experience with this pilot programme. Among those who did respond, five (5) out of 8 practices agreed that participation had helped them to provide better support options for their patients with

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diabetes, and that their patients had responded positively to the experience. Benefits mentioned by HCPs included improved engagement and empowerment for patients. Several HCPs mentioned the administrative burden associated with the pilot, as well as the technological barrier to participation for many of the target population. Overall, high completion rates coupled with positive change in clinical indicators for digital behaviour change programmes in this pilot suggest they may be an effective alternative to face-to-face structured diabetes education programmes. Patients may prefer digital diabetes programmes because of their easy access, flexibility and integration of educational resources and support through a single medium (i.e. a smartphone app). Within the limitations of this pilot, results support the wider use of smartphone apps for delivering structured diabetes education within the NHS. Cost effectiveness analyses (CEA) are needed to compare face-to-face programmes with digital programmes offered online or via an app.

2 Introduction

2.1 Background

The health needs of the population in NWL are changing. People are generally living longer and, as a result, a growing number are suffering from complex LTCs. The way that our population is interacting with healthcare is also evolving as internet use grows across all age groups. Two thirds of the national population own smartphones, and off-the-shelf health apps are increasing in popularity.

There is consensus across NWL for an increasing role of technology to empower our patients by helping them to develop knowledge, skills and confidence to manage their health. This is underpinned by the Sustainability and Transformation Programme (STP) Delivery Area 2e: Patient Activation and Self-Management, and the Local Digital Roadmap. Since October 2016, the NWL Self-Care Project Delivery Group has been working in partnership with Digital Health London to develop agreed protocols for the provision of digital apps to support the population of NWL to develop their self-management skills.

2.2 Diabetes structured education currently offered in NWL

Patients diagnosed with T2DM in NWL are routinely offered face-to-face structured education. This is typically either DESMOND^{vi} or X-PERT Health^{vii}. DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) involves 6 hours of structured group education for up to 10 people in one day or two half-day formats. Modules are available for people within the first 12 months of a T2DM diagnosis, and for those with established diabetes. X-PERT Health delivers three programmes: X-PERT Prevention of Diabetes (X-POD), X-PERT Diabetes and X-PERT Insulin. All programmes offer 15 hours of group education, which is delivered by trained educators in weekly 2½ hour sessions over 6 weeks. According to Whole Systems Integrated Care (WSIC) data from GP practices participating in this NWL pilot, 2–6.3% of patients referred to a face-to-face structured diabetes education programme completed the course (Table 1). This is in line with the NHS Digital National Diabetes Audit results for March 2016.^{viii}

Table 1 Referral and attendance at face-to-face diabetes structured education in NWL pilot practices.

Patients with T2DM	Referred to structured education	Completed structured education*	Declined structured education*	Did not attend*
7254	1553	28–98	382–407	12–42

Source: Whole Systems Integrated Care (WSIC), February 2018. Note, patients can opt out of being included in the WSIC database, so actual counts may be more than shown here. Read codes used to determine completion status are available in Appendix 1. *Data were suppressed from practices with <5 patients in a category. Face to face structured education programmes may be offered as a per patient cost (£65 per participant for X-PERT and £76 per participant for DESMOND) or a block contract cost.^{ix,x} This may differ by CCG and level of service provided. A freedom of information request can provide more detailed information on the service provided by a CCG. This could include the length of the contract commissioned and cost, number of courses, number of sessions per course and the number of patients per course. DESMOND has been shown to be cost effective at a threshold of £20,000 per quality adjusted life year (QALY) compared to usual care (no education or *ad hoc* and unevaluated education).^{x,xi} Poor completion rates are likely to affect value for money of the block contract by effectively increasing the mean cost per participant.

3 Aims and scope

The aim of this pilot project was to evaluate digital behaviour change programmes (delivered using smartphone apps) that support people with T2DM to manage their condition and/or improve their current level of wellbeing. Three programmes were piloted between March and August 2017 within self-nominated CCGs in NWL to develop an evidence base on their impact. Evaluation was led by Imperial College Health Partners (ICHP) in partnership with North West London Collaboration of CCGs, Strategy and Transformation Team, Delivery Area 2. The outputs from this pilot will provide a platform on which to expand the concept across NWL and other agreed LTC pathways.

4 Methods

4.1 Programme selection process

Digital behaviour change programmes for the NWL pilot were selected based on a competitive application process. Submissions were invited from providers whose programmes met the following specification:

- Supports patients with T2DM, through one or more of:
 - Wellbeing approaches to increase confidence and motivation
 - o Developing patients' knowledge and skills in managing their LTC
 - Supporting healthy approaches to living, including increasing activity and healthy eating
- Available in a variety of languages to support the diverse population of NWL
- Culturally sensitive to the demographic variety of the NWL population
- Facilitates collection of non-patient identifying data to support evaluation
- Provides an initial time-limited licence, not exceeding 3 months, for use of the smartphone app.

Applicants were also required to provide:

- Technical support for use of the smartphone app
- Maintenance support of any physical equipment (e.g. fitness tracking devices) provided as part of the licence
- Guidance for HCPs to inform them of the target audience and deliverables
- Evidence on the impact of the programme on patients' experience and clinical indicators (e.g. BMI, activity rates, knowledge of managing their LTC)
- A smartphone app that is ready to use at the start of the pilot (March 2017)
- Assurance that the digital behaviour change programme has been evaluated by relevant specialist clinicians and subject matter specialists for business credibility and potential to meet NHS needs. They must, at a minimum, have received an informal review by NICE.

Applications were reviewed by a panel, comprising Dr Tony Willis (Diabetes Clinical Lead for North West London), Kalwant Sahota (West London Self Care Commissioning Manager) and Aran Porter (North West London Self Care Lead). Potential providers were scored based on: their approach to delivering the work according to the specification outlined above; evidence of positive impact on patient experience; ability to support evaluation as part of the NWL pilot; and their ability to address the diverse needs of NWL populations.

Programme name	Panel's feedback	Suitable for this pilot
Dynamic Health Systems		
MumoHealth	Insufficient evidence of effectiveness.	No
LiveSmart	Insufficient evidence of effectiveness. Not available in other languages.	No
Changing Health	Evidence-based programme that offers a digital version of structured education plus coaching. Ready to start in March 2017.	Yes
OurPath	Evidence-based programme suitable for pre-diabetics and newly-diagnosed patients. Includes equipment. Ready to start in March 2017.	Yes
Oviva	Structured education plus dietician/coach and peer support. Ready to start in March 2017.	Yes

Table 2 Digital health solutions shortlisted for use in this pilot study.

4.2 Specification of selected programmes

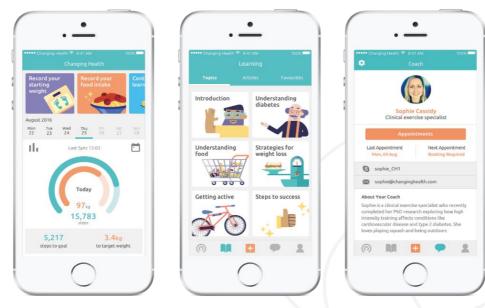
4.2.1 Changing Health

Changing Health is an evidence-based service to support healthy diet and exercise habits for people with T2DM. It has undergone a cluster-based controlled trial reviewed by NHS England and NICE and has been submitted for approval as a mobile digital service.

The 12-week programme includes:

- Online access to X-PERT, a T2DM education programme that has been shown to have a clinically meaningful impact on weight and glycaemic control, together with ongoing learning using a referenced knowledge base.
- Evidence-based behaviour change tools on a smartphone app, including the ability to create goals, make specific plans and self-monitor by tracking step count directly from the phone's pedometer. The smartphone app also enables participants to track their weight and record food intake by taking pictures with their phone's camera.
- Communication with a personally-assigned coach, trained in evidence-based behaviour change techniques. For the NWL pilot, patients received a total of 40 minutes of coaching by phone. After completion of the 12-week programme, patients have continued access to the app.

Figure 1 Screenshots of the Changing Health smartphone app showing the dashboard, learning modules and coach appointments



4.2.2 OurPath

OurPath is an evidence-based digital behaviour change programme for people with pre-diabetes or newly-diagnosed T2DM. OurPath technology was informally

reviewed by a technical advisor from NICE prior to being accepted onto the Digital Health London programme.

The 12-week programme provides smart technology to deliver:

- Structured education on nutrition, exercise, sleep, stress management, and positive psychology, based on cognitive behavioural therapy.
- Peer group support (participants are assigned to a health coach-led group of 10 participants). During the programme, participants are given a daily or weekly task or a competition such as walking a certain number of steps per day, tracking their sleep, or taking a photo of their meal and posting to their support group.
- Personalised health mentorship delivered by a health coach with appropriate training and accreditation as mandated by the National Diabetes Prevention Programme (NDPP). Interaction with the health coach is primarily via text chat through the app.

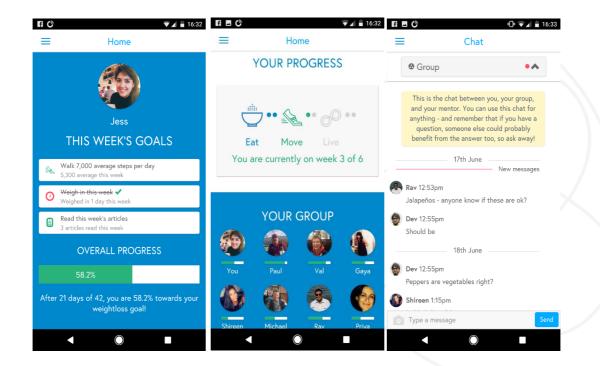


Figure 2 Demonstration screenshots of the OurPath smartphone app showing the home screen, peer support group, and chat forum.

OurPath provides participants with:

- 3G-enabled weighing scales
- Wearable activity tracker
- Access to Android/iOS app, and web app
- Nutrition book

At the end of the programme, participants can continue to use the app and the smart technology provided for the programme.

4.2.3 Oviva Diabetes Support

Oviva Diabetes Support (referred to in this document as Oviva) is a NICE-aligned technology-enabled diabetes structured education programme that combines personal support from a dietitian with remote high-frequency coaching (via a smartphone app and/or telephone) calls and access to supporting educational content.

The 8-week programme consists of 4 main elements:

1. An initial engagement call with an Oviva health coach to explain programme benefits and activate them for behavioural change through motivational interviewing.

2. Two 30- to 45-minute video (or telephone) calls via the Oviva app with a trained diabetes specialist dietitian educator delivering a core NICE-aligned curriculum, including goal setting

3. An 8-week behavioural change programme providing text message-based dietitian coaching on food intake, activity, weight and questions via the app.

Optional self-directed learning within the Oviva app (e.g. behaviour change
 Oviva audio 'podcast' series called 'Food for Thought'), and a written educational
 Support Pack.

Patients can ask their dietitian for help or support using the app at any time during the programme, and they also have the option to contact Oviva's "digital clinic" if necessary for technical support with the app.

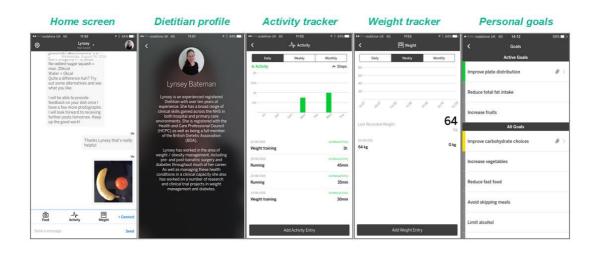


Figure 3 Oviva smartphone app screenshots.

Upon completion of the programme, patients can continue to use the Oviva app for life as a self-monitoring tool (e.g. photo food diary, weight and activity tracking), as well as retaining access to all learning materials, such as podcasts and written resources. Furthermore, patients retain email access to their personal dietitian for questions or *ad hoc* support for up to one year from the time of referral.

4.3 Pilot site selection

All CCGs in NWL were given the opportunity to participate in the pilot. Five CCGs – West London, Central London (Westminster), Hammersmith and Fulham (H&F), Harrow, and Hillingdon – confirmed their interest to participate. Hillingdon nominated six GP pilot sites and the other participating CCGs each nominated three pilot sites. It was decided to offer only one of OurPath, Oviva, or Changing Health to patients at each GP pilot site. This was to enable the staff at the site to learn about the features of one app and focus on promoting its use.

Table 3 GP pilot sites allocated t	o each digital behaviour	change programme

Digital	Site name (CCG)	List size*	Patients
behaviour		(number of GPs)	diagnosed
change			with T2DM*
programme			
p 3			
Changing	Brook Green Medical	12,722 (14)	404 (3.18%)
Health	Centre (H&F)		
	Srikrishnamurthy Harrow	2,130 (1)	229 (10.75%)
	Road Surgery (West)		
	The Pinn Medical Centre	19,523 (23)	1,047 (5.36%)
	(Harrow)		
	Marylebone Health Centre	8,222 (8)	176 (2.14%)
	(Central)		
	Mountwood Surgery	10,085 (7)	628 (6.22%)
	(Hillingdon)		
	Shakespeare Health	4,190 (5)	382 (9.12%)
	Centre (Hillingdon)		
OurPath	The Golborne Medical	5,043 (3)	405 (8.03%)
	Centre (West)		
	Richford Gate Medical	10,219 (9)	390 (3.82%)
	Centre (H&F)		
	Cavendish Health Centre	5,610 (3)	125 (2.23%)
	(Central)		
	GP Direct (Harrow)	2751 (14)	390 (14.18%)
	Central Uxbridge Surgery	16,553 (7)	864 (5.22%)
	(Hillingdon)		
	Willow Tree Surgery	3,658 (2)	Not available
	(Hillingdon)		
Oviva	Sands End Health Clinic	8,649 (10)	242 (2.78%)
	(H&F)		
	Crawford Street Surgery	4,746 (3)	138 (2.91%)
	(Central)		
	Portland Road Practice	8,363 (7)	227 (2.71%)
	(West)		

The Stanmore Medical	12,987 (5)	827 (6.37%)
Centre (Harrow)		
Eastbury (Hillingdon)	7,613 (4)	405 (5.32%)
Kincora Doctors Surgery	3,000 (2)	199 (6.6%)
(Hillingdon)		

*Source: Whole Systems Integrated Care (WSIC), February 2018. Note, patients can opt out of being included in the WSIC database, so actual counts may be more than shown here.

4.4 Engagement with HCPs at pilot sites

- Changing Health employees had face-to-face meetings with practice teams to provide information on the intended benefits of the programme for their patients, as well as training on the registration process for patients.
 Communication with GPs regarding data collection for auditing and other administrative tasks was delivered via the CCG.
- OurPath delivered face-to-face training to the GP practices and provided handouts for HCPs to explain the programme.
- Oviva followed a structured process to engage with GP practices and present their programme, which included:
 - o Email sent to GP practice to introduce the service
 - Face-to-face visit from Oviva dietitian to meet clinicians and the practice manager and demonstrate the technology
 - A simple and efficient referral process to reduce administrative requirements (e.g. the referral form was integrated onto clinical systems, and practices were supported with outcome collection)
 - Printed and electronic promotional leaflets to be given to potential participants
 - Frequent ongoing communication between Oviva and clinicians, including bi-weekly emails, updates on referral numbers versus the target and the option of additional meetings

 Participant discharge letter sent via email (including read codes for the GP record system).

4.5 Patient eligibility

Each GP pilot site was encouraged to recommend their allocated digital behaviour change programme to 38 patients (19 per site in Hillingdon), up to a potential total of 576 patients. Patient selection criteria varied slightly by programme.

Table 4 Eligibility criteria for participants in the pilot scheme, as defined by Changing Health, OurPath and Oviva

	Changing Health	OurPath	Oviva
Inclusion criteria	 Diagnosed with T2DM Aged ≥ 18 years BMI ≥ 25 kg/m² Not previously offered, OR have been offered and did not attend T2DM structured education 	 Diagnosed with T2DM Aged ≥ 18 years Able to speak English No special communication needs 	 Diagnosed with T2DM Aged ≥ 18 years Access to a smartphone that runs either iOS or Android as well as the internet
Exclusion criteria	 Pregnant, planning pregnancy or lactating Insulin treated Contradiction to exercise or weight loss Mental or physical incapacity which makes self- management inappropriate 	 Pregnant or planning pregnancy Past or planned bariatric surgery 	 Pregnancy Significant learning difficulties Mental health condition that prevents a person from engaging in care

4.6 Patient recruitment

Patient recruitment tactics varied depending on the pilot site's preferences and available resources. Options included face-to-face conversations with the HCP, text messages, emails, or letters sent either from the programme provider or directly from the practice.

4.6.1 Changing Health patient recruitment

Changing Health initially planned for facilitated referral of patients from GP practices. However, during the pilot a patient self-referral system was created and adopted by 5 of the 6 pilot sites, which reduced their administrative workload.

- For facilitated referrals through a GP practice, HCPs were responsible for outlining the programme to potential participants and patients were given a one-page leaflet describing the service. Practices received letter templates and a talking points document for recruitment calls.
- Clinical records systems were used to identify potentially eligible patients for self-referral. Patients were sent a text message containing a link to a selfregistration page that included information about the service (www.changinghealth.com/nwl). Patient cohorts were segmented to ensure minimal impact on clinical practice (e.g. only people with blood test results within the last 3 months were targeted).

4.6.2 OurPath patient recruitment

Recruitment tactics varied according to the preferences and available resources at the pilot site. At some practices, HCPs initially contacted patients to discuss the programme face-to-face; other practices (e.g. Richford Gate) sent letters; others (e.g. Cavendish) sent text messages directly to their patients. Following a referral from the GP pilot site, OurPath phoned patients prior to sign-up. Personalised email followups were sent after the phone call(s) and/or after making several attempts to reach the patient.

4.6.3 Oviva patient recruitment

Recruitment tactics used for Oviva included text messages and templated letters from the GP site inviting patients to take part. Letters included an overview of the what the programme involved, a description of key benefits, emphasis on ease of access, and explanation of what they needed to do to sign-up. The letter template also included motivational techniques and phrases to encourage engagement. Referrals to Oviva were received from GP practices using an integrated referral form sent through NHS mail. Upon receipt of a patient referral, Oviva undertook the following actions:

- Initial attempt to contact the patient within 2 working days of receiving a referral
- At least 3 phone call attempts on different days and times
- If no response was received from the patient, a letter was sent asking the patient to contact Oviva within 4 weeks if they wish to participate in programme.

4.7 Data collection

4.7.1 Quantitative analyses

Definitions of patient process metrics and clinical indicators used in the pilot are shown in Table 5.

	Changing Health	OurPath	OVIVA
Uptake	Number of	% of enrolments	% of accepted
metrics	individuals who	from e-referral	referrals enrolled to
	downloaded the app	received	the programme

Table 5 Quantitative metrics collected for the NWL pilot study

Engagement	Number of	Number of event	
metrics	individuals who	counts (weight	 Did not attend rate for all sessions
	accessed the	readings,	
	learning modules	messages sent,	 Average number of sessions per
		and articles	patient
		read)	 Average number of
			app messages per
			day, per participant
Completion	People completing	Interaction with	% of participants who:
metrics	all digital content	mentor during	Complete the core
	and accessing	final week of the	curriculum
	coaching	programme	Complete the 8-
			week behaviour
			change programme
			(engage with the
			programme for >4
			out of 8 weeks,
			including any of:
			use of app;
			attending weekly
			phone calls;
			accessing self-
			directed learning
			materials).
Clinical	Weight and step	Weight is	Weight, height, BMI,
indicators and	count collected via	continuously	HbA1c, waist
demographics	the app.	tracked using	circumference, SBP,
		smart scales.	DBP can be entered in
			the app by the patient.
	For GP practices usir	ng SystmOne, clinica	al indicators and
	demographic details	were extracted remo	otely using a MyQuest
	query. For practices u	using EMIS, cliniciar	ns were given an Excel
	spreadsheet to enter	data manually. Data	a extracted were age,
	ethnicity, index of mu	Itiple deprivation (IN	1D) 2015, HbA1c, and

	blood pressure, pre-enrolment and post-participation. Data were	
	removed if the reading did not make practical sense (e.g.	
	implausible changes in blood pressure).	
Medication	Medication use information was extracted remotely using a	
use	SystmOne MyQuest query.	

4.7.1.1 Patient activation measure

PAM is a patient-reported measure of skills and confidence in managing health, which is known to be associated with clinical outcomes and healthcare costs. ^{xii} It has been robustly demonstrated to predict health behaviours. It is closely linked to clinical outcomes, costs of health care and patients' ratings of their experience.^{xiii} PAM stratifies patients into one of four levels of activation:

Level 1: Passive and lacking in confidence with poor adherence. Prefers to leave doctor in charge of their health

Level 2: Some knowledge is present but with significant gaps, with the feeling that their health is largely out of their own control.

Level 3: Know key facts and strive for best practice behaviours based on specific goals

Level 4: New behaviours have been adopted to preserve a healthy lifestyle.

Patients act as their own advocate

PAM assessment is a key deliverable of Delivery Area 2e with the target of all patients with an LTC in NWL receiving a PAM assessment by 2020/21. The use of PAM to tailor support according to a patient's level of knowledge, confidence and skill in managing their LTCs underpins the delivery of digital apps and supports the evaluation of their impact. For the evaluation of the NWL pilot, PAM scores were collected at baseline, and on completion. This was done in a different way for each of the programme providers:

- Changing Health carried out PAM scoring calls for all patients referred into the programme, regardless of referral route.
- OurPath GP practices collected baseline PAM scores at the start of the pilot.
- Oviva completed the baseline PAM assessment as part of enrolment, and again as part of the final telephone contact.

4.7.2 Analytic approach

The following analyses were conducted based on quantitative data extracted as part of this pilot programme.

Descriptive analyses:

- Demographic variables (age, gender and ethnicity)
- PAM score and PAM level before and after participation
- Clinical indicators (HbA1c, blood pressure, weight and BMI) before and after participation

Inferential analyses:

- Dependent sample t-test to determine whether there was a significant change in pre-enrolment and post-participation clinical indicators (or Wilcoxon signedrank test if assumptions for t-test are not met).
- Correlation between PAM score, IMD2015 and clinical indicators.
- Anova tests analyse differences in means (for age, PAM score, and length of pilot) between programmes. Significant results will imply these variables should be included in a forward regression
- Forward regression analysis based on the covariates age, PAM score, length of pilot (if Anova tests show significant results), will identify any significant differences between programmes for:
 - 1. HBa1C
 - 2. BMI

- 3. Weight
- 4. Diastolic and systolic blood pressure

4.7.3 Qualitative analyses

4.7.3.1 Patient experience

Patient experience was collected using the UMUX-LITE and Net Promotor Score (NPS) measures for the Changing Health and OurPath programmes. Oviva used the NHS Friends & Family Test.^{xiv} Oviva also asked participants about their confidence with managing diabetes pre-enrolment and post-participation, on a 10-point scale (minimum 1, maximum 10).^{xv}

UMUX-LITE^{xvi}

UMUX-LITE is the short-form variant of the Usability Metric for User Experience. It aims to measure perceived usefulness and usability of software or technology.^{xvii} The UMUX-LITE questions are:

- For each of the following statements, mark one box that best describes your EXPERIENCE with this APP (strongly disagree =1, strongly agree =7):
 - a. This APP capabilities meet my requirements
 - b. This APP is easy to use
- Describe any issues you experienced in use, or problems related to this APP that you would like to report.

Net Promotor Score xviii

NPS measures the loyalty that exists between a provider (e.g. a brand or service), and the user of a service. It is based on response to a single question (graded extremely likely = 10, not at all likely = 0): *To what extent would you recommend this APP to your family, friends or colleagues who have diabetes?* People who score 9 or 10 are promoters of the product or service, those scoring 8 or 7 are passive (or neutral), and those scoring 6 or below are detractors. NPS is calculated by subtracting the percentage of responders who are detractors from the percentage who are promoters. The NPS therefore ranges from - 100 to +100. This score is followed up with a free text response about why this score has been given.

Focus groups

Patients who had participated in the NWL pilot were invited to provide extended feedback in one of three focus groups (one for each digital behaviour change programme). Patients who were not available to participate in a focus group also had the opportunity to complete an online survey. Responses were collected using free text as well as feedback on ease of use based on a 5-point scale.

4.7.3.2 HCP experience

Experience of HCPs at participating GP practices was collected using an emailed survey.

4.7.3.3 Project management experience

The three digital behaviour change programme providers were invited to contribute feedback on their experiences with the pilot and any changes they would make in preparation for a wider roll-out.

5 Results

5.1 Patient population

Overall, 430 patients were recruited to a digital behaviour change programme, at 18 GP pilot sites. Data are available for 295 patients (69% of recruited patients) because of limitations with the methodology of data collection (see Section 6.3 for details).

Programme	Site name	Patients	Patients with
		recruited	data available
			for analysis
Changing	Brook Green Medical	18	18
Health	Centre		
	Harrow Road Surgery	19	16
	The Pinn Medical Centre	56	59
	Marylebone Health Centre	26	Not submitted
	Mountwood Surgery	36	39
	Shakespeare Health	12	12
	Centre		
	Total (Changing Health)	167	144
OurPath	The Golborne Medical	37	17
	Centre		
	Richford Gate Medical	51	29
	Centre		
	Cavendish Health Centre	14	5
	GP Direct	9	6
	Central Uxbridge Surgery	7	5
	Willow Tree Surgery	15	8
	Total (OurPath)	133	70
Oviva	Sands End Health Clinic	60	34
	Crawford Street Surgery	14	12
	Portland Road Practice	30	19
	The Stanmore Medical	1	1
	Centre		
	Eastbury Surgery	19	14
	Kincora Doctors Surgery	6	1
	Total (Oviva)	130	81

Table 6 Recruitment and data availability for the NWL pilot

5.1.1 Referral and recruitment process

For more detail on recruitment methodology, see section 4.6.

5.1.1.1 Changing Health patient recruitment

For the 167 patients recruited to Changing Health, 66 were referred directly from their GP practice (HCP-facilitated referrals), and 101 patients were self-referred. Self-referral was useful for case finding specific patient cohorts with minimal administrative burden for the practice. HCP referral was better suited to newly-diagnosed patients seen in clinic. Self-referred patients (compared with HCP-registered patients) were significantly more likely to become active programme participants (65% vs 57% of referrals) and were less likely to withdraw during the programme. HCP-registered patients were more likely to decline the service (19% vs 5%). Reasons for declining the service included:

- Age (1 person)
- Type 1 diabetes (1 person)
- Not interested/not informed about the benefits of the programme (6 people)
- Not having the time or suitable technology to participate (8 people)

5.1.1.2 OurPath patient recruitment

Direct-to-patient phone calls were the most successful recruitment tactic for OurPath in this pilot study. Practices that explained the programme to their patients in-person during appointments had higher uptake than practices who referred patients via text message only. Reasons for ineligibility of patients referred to OurPath included:

- starting BMI <25kg/m²
- did not have a computer, smartphone, internet access or an email address
- not able to read English or write/speak English
- referred on the understanding that they would be supported to complete the programme using a friend/family member's device

5.1.1.3 Oviva patient recruitment

For the Oviva programme, the most effective recruitment methods were (i) recruiting patients directly from face-to-face appointments, and (ii) sending targeted communications to eligible patients. Six referrals were "rejected" as inappropriate (3 did not have a diagnosis of T2DM, and 3 did not have access to a smartphone).

5.1.2 Demographics

For the subset of participants with available demographic data, mean age was 57 (range, 32 to 89). Most participants (79%) were non-white.

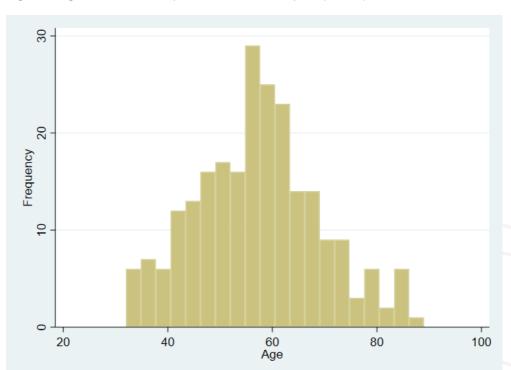




Table 7 Ethni	icity (where availa	ble) of patients	participating in	n NWL pilot.
	iony (minoro avanc		paraoipaang n	

Ethnicity	Frequency	Percent
Asian	27	22.69
Black	32	26.89
Mixed	19	15.97
Other	16	13.45
White	25	21.01
Total	119	

* Data for ethnicity were only available for patients in practices that used SystmOne

Table 8 Distribution of gender for sub-sample

Gender*	Freq.
Female	89
Male	89

*Data on gender were not available for the entire sample

5.2 Quantitative results

5.2.1 Engagement metrics

Patient process metrics (uptake, engagement, and completion) were defined in

different ways by the different programmes, so are not directly comparable. Uptake

was >70% for OurPath and Oviva.

Programme	Uptake (% of referred patients enrolled)	Engagement	Completion
Changing Health	83/167 (50%)	41/83 (49%)	No data
	individuals	engaged with	available
	downloaded the	coaching	
	арр		
OurPath	133/186	70/133 (53%)	70/133 (53%)
	72%	had an event	had completion
		count >10	data available
Oviva	88/120	204/252 (81%)	82% completed
	73%	scheduled	the programme
		dietitian	
		appointments	
		completed	
		Average	
		appointments	
		per patient: 5	

Table 9 Process metrics for Changing Health, OurPath and Oviva in the NWL pilot

5.2.2 Patient activation measure

Pre-enrolment and post-participation PAM scores were collected as part of each digital behaviour change programme. The route of collection varied between programme providers (see section 4.7.1.1). There was a low completion rate for this assessment. Baseline PAM scores are available for 159 participants (Figure 6). Most patients (51%) had PAM level 3 before enrolling on the programme. There was a similar distribution in PAM level at baseline across the three programmes (Figure 7). Mean PAM score for enrolled patients was typical of adults with T2DM nationally.¹

Table 10 Mean pre-enrolment PAM scores by programme and overall

Programme	Number of observations	Mean PAM	Std. Dev.	Min	Max
Changing					
Health	97	58.1	11.4	33.0	100
OurPath	18	57.3	8.2	42.2	70.2
Oviva	45	58.0	12.3	38.1	100
All	159	58.0	11.3	33.0	100

Figure 5 Distribution of pre-enrolment PAM scores across the programme

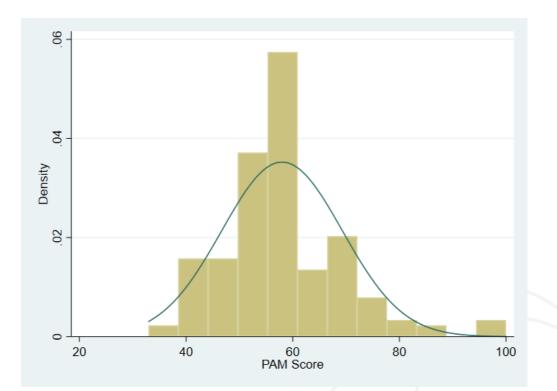


Figure 6 Pre-enrolment PAM level for participants in the NWL pilot

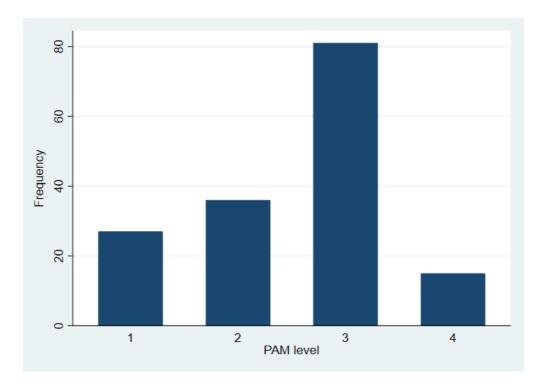
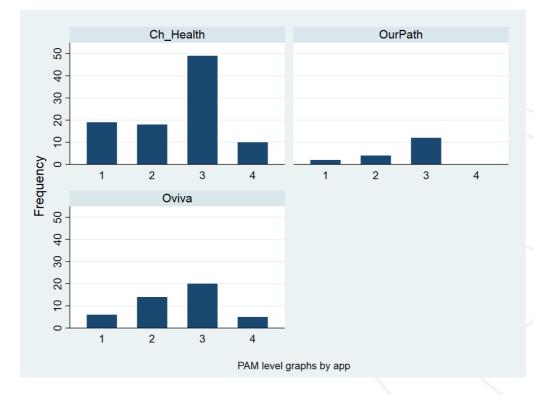


Figure 7 Pre-enrolment PAM level by digital behaviour change programme



PAM scores pre-enrolment and post-participation were only available for 9 patients (Figure 8). Seven of these patients had an increase in PAM score following

participation. Two patients had a decrease in PAM scores (see discussion Section 6.1).

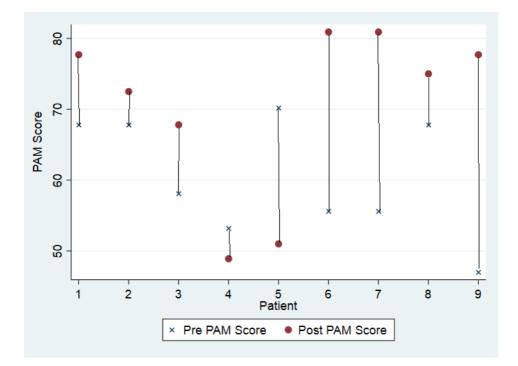


Figure 8 Pre-enrolment and post-participation PAM scores for 9 patients

5.2.3 Clinical outcomes

Several T2DM-associated clinical indicators were collected before and after participation in the pilot programme (Table 11). A reduction was observed in weight, BMI, HbA1c, systolic and diastolic blood pressure (SBP and DBP). Owing to missing data, this should be interpreted as change across the overall study population, rather than change for individuals.

Table 11 Summary of changes in	T2DM clinical	indicators duri	na the NIV/L nilot
Table II Guilling of changes in		indicators duri	Ig the INVE phot

Variable	Obs	Mean change	Std. Dev.	Min	Max
Weight change (kg)	140	-2.5	4.7	-17.6	10.0
BMI change (kg/m²)	112	99	1.8	-8.4	5.2
HbA1c change (mmol/mol)	160	-6.9	14.6	-70.0	36.0
SBP change (mmHg)	151	-3	15	-50	56
DBP change (mmHg)	151	-2	10	-31	40

HbA1c

Most patients in the study population had a reduction in HbA1c (below the red vertical reference line, Figure 9). Mean reduction in HbA1c during the programme was 6.9 mmol/mol. Mean change in HbA1c was negative (i.e. a reduction) for all three digital behaviour change programmes, with the largest reduction seen for Oviva (Figure 10).



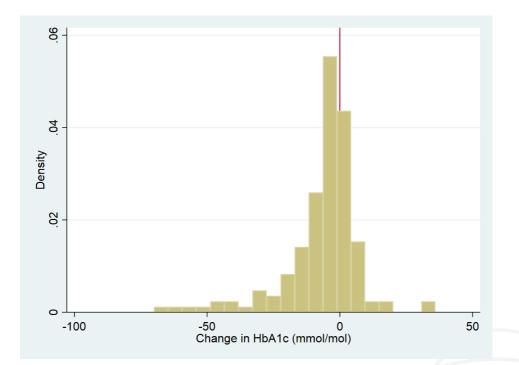
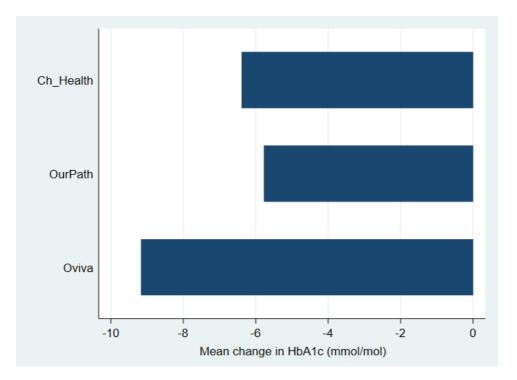


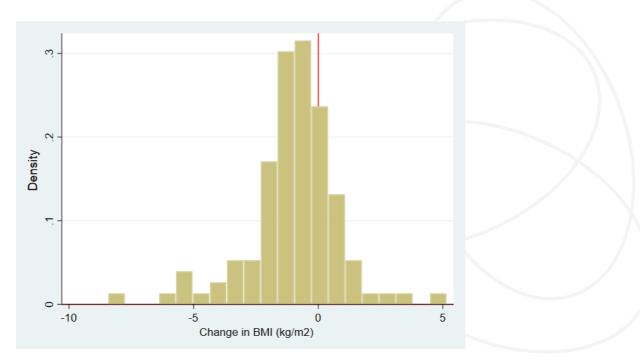
Figure 10 Mean change in HbA1c for Changing Health, OurPath and Oviva



Body mass index (BMI)

Most people in the study population had a reduction in BMI (below the red reference line on Figure 11). The greatest mean change in BMI (Figure 12) and weight (Figure 13) was seen for participants in OurPath.







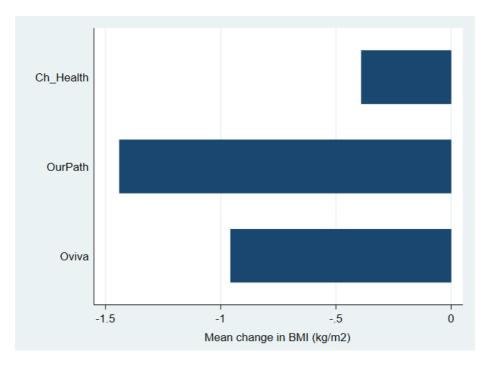
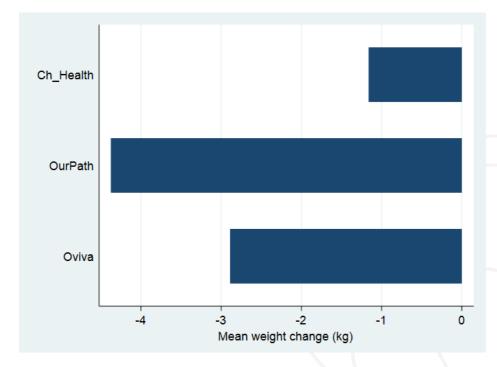


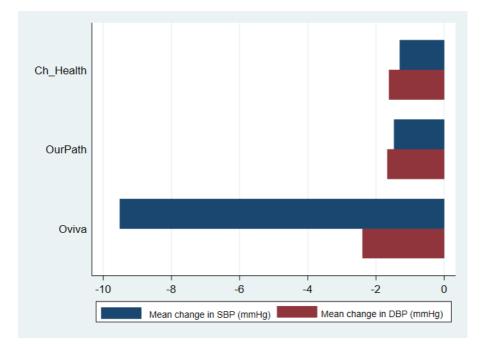
Figure 13 Mean change in weight for Changing Health, OurPath and Oviva



Blood pressure

Mean reductions in SBP and DBP were observed among participants in all three digital behaviour change programmes. Participation in Oviva was associated with the greatest reductions in both SBP and DBP (Figure 14).





5.2.4 Statistical significance of change in clinical indicators

Median HbA1c, BMI and SBP was significantly lower after participation in a digital behaviour change programme compared with pre-enrolment values, based on a Wilcoxon signed-rank test. *Note:* The Wilcoxon signed-rank test was used because clinical indicators (other than DBP) did not meet the assumptions of normality required for a dependent sample t-test.

5.2.5 Correlation between PAM, IMD 2015 and clinical indicators

There was a poor relationship between PAM score or IMD 2015^{xix} and change in clinical indicators (HbA1c, BMI, blood pressure) during this pilot programme. The correlation was not significant (Pearson's correlations, p>0.05, see

Table 12).

	PAM Score	IMD2015
PAM Score	1	
IMD2015	-0.018	1
Change HbA1c	0.1317	0.2172
Change BMI	-0.075	0.1544
Change in SBP	-0.066	-0.131
Change in DBP	-0.145	-0.189

Table 12 Pearson's correlation between PAM score or IMD 2015 and change in clinical indicators during the NWL pilot programme. Correlations were not significant.

There was also poor relationship between PAM level and clinical indicators (HbA1c, BMI, blood pressure), as assessed by Spearman's Rank correlation. Correlations were not significant.

5.2.6 Inferential statistics

Anova tests showed no significant differences in ages and PAM scores of participants between the three programmes (p>0.05). This suggested that including age and PAM scores as covariates in a regression would not affect the outcome. Effect sizes following regression analyses (including length of pilot as a covariate) showed minimal differences between programmes, although OurPath identified a significant change in BMI and weight compared to the other programmes.

5.2.7 Medication use

Information regarding medication use was available for 118 patients pre-enrolment and post-participation. Most patients were taking metformin before the programme and did not have a change in medication. Twenty-three patients had no medication use documented after participation. Where available, medical records for these patients show mean decreases in HbA1c, BMI, weight and DBP (Table 13), which might suggest metformin may have been discontinued due to improvement in clinical indicators.

Table 13 Change in clinical indicators for 23 patients who had a change in metformin use
documented after participation in the NWL pilot programme

Variable	Observations	Change
HbA1c (mmol/mol)	14	-1.71
BMI (kg/m²)	19	-1.41
Weight (kg)	19	-5.7
DBP (mmHg)	12	-2.92
SBP (mmHg)	12	1.92

5.3 Qualitative results

5.3.1 Patient experience

5.3.1.1 Changing Health and OurPath assessment of patient experience

All patients who participated in the OurPath or Changing Health programmes assessed their experience using UMUX-LITE and NPS (see section 4.7.3.1). This assessment was done in a different way for Oviva users.

Table 14 UMUX-LITE results for OurPath and Changing Health

	OurPath	Changing	
	(n=55)	Health (n=16)	
The app capabilities met my requirements	Mode 3	Mode 5	
(1=strongly disagree; 7= strongly agree)			
The app is easy to use	Mode 3	Mode 7	
(1=strongly disagree; 7= strongly agree)			
Issues in use, or problems related to this APP			
Technical problems with the app or a	10 mentions	8 mentions	
connected device			
Access problems (i.e. Not having a	4 mentions	1 mention	
compatible smartphone)			
Targets being unachievable/inappropriate	1 mention	2 mentions	
Not motivated by the content	0 mentions	1 mention	

Table 15 NPS results for OurPath and Changing Health

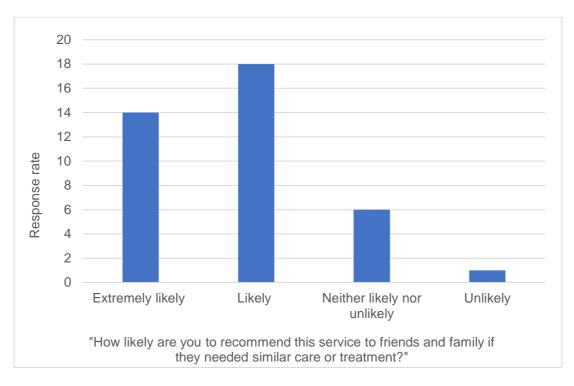
	OurPath	Changing
	(n=55)	Health (n=16)
To what extent would you recommend the	41 promoters	7 promoters
OurPath programme to your family, friends	(75%)	(44%)
or colleagues who have diabetes? (out of	3 detractors	3 detractors
10)	(5%)	(19%)
	NPS score: +70	
		NPS score +
		25
Why did you give this answer?		1
Progress with clinical target (e.g. "weight	13 mentions	0 mentions
loss", "lower blood sugar", "didn't need		
medication")		
General wellbeing (e.g. "has helped me", "I	12 mentions	4 mentions
feel better", "suited my needs")		
Increased motivation	4 mentions	2 mentions
Education/learning about diabetes	4 mentions	2 mentions
Better understanding of own behaviours	1 mention	0 mentions
Convenience	0 mentions	1 mention
Ineffective or not engaging	2 mentions	3 mentions
Technical issues	1 mention	1 mention

All patients who participated in the OurPath or Changing Health programmes assessed their experience using UMUX-LITE and NPS (see section 4.7.3.1). This assessment was done in a different way for Oviva users.

5.3.1.2 Oviva assessment of patient experience

Oviva used the NHS Friends and Family (F&F) test to gain feedback from participants about their experience. Most respondents said they were likely/extremely likely to recommend the programme to friends and family (Figure 15).

Figure 15 F&F Test results for Oviva participants (n= 39)



Oviva participants also reported a mean "confidence in managing diabetes" score of 6.475 at baseline and 8.2 after programme completion (1=minimum; 10 =maximum).

5.3.1.3 Focus group and online survey follow-up

Three focus groups were conducted between 3 and 8 November 2017. All patients participating in one of the digital behaviour change programmes were invited. Thirteen (13) people attended a focus group in person, and a further 6 people completed an email survey.

Changing Health focus group (n=6)

Two women and three men attended the Changing Health focus group, and one further person completed feedback online. English was not the first language for four of the attendees, but they all spoke and understood English well. The group mirrored the age and ethnicity of people with T2DM in NWL. Four attendees had used health apps (e.g. a Fitbit[®] type device) in the past and were familiar with technology. One person had previously taken part in a face-to-face diabetes structured education programme.

Participant feedback

- All focus group participants said they found the smartphone app useful. The email respondent rated the app "a bit useful" (2 on a 5-point scale) for meeting their current health needs and did not agree that it suited their lifestyle.
- The telephone-based support service was well received, although it focused on the psychology of behaviour change rather than diabetes specifically.
- Participants mostly liked the food photography feature of the smartphone app but did not think it was suitable for home-made recipes.
- The educational material was useful, but the content was freely available on the internet.
- Some participants knew that their T2DM clinical indicators had improved since completing the programme. Participation was a reminder to attend regular blood tests.
- Most participants would like to continue using the app and thought that the Changing Health programme should be rolled out across NWL.

Potential to improve the patient experience

- More peer-to-peer support, and 'nudges' when they began to go off track with their lifestyle changes.
- Too focussed on weight and eating, and not enough on T2DM management or exercise.

OurPath focus group (n=8)

Two men and three women attended the OurPath focus group and three further people completed feedback online. All spoke English as their first language. All focus group participants had used health apps in the past. Most had previously experienced a DESMOND diabetes structured education programme and found it very useful. All participants had completed the core 6-week OurPath programme; some were unaware that the full programme was 12-weeks.

Participant feedback

- Referrals from a diabetes clinic or GP were good. Text message referrals were too impersonal.
- The programme was straightforward, and the equipment was easy to set up. Technical problems were quickly resolved by the telephone helpline.
- The programme was useful and either enhanced what they were already doing to improve their health or provided incentive to start making healthy lifestyle choices.
- Participants who had previously used a fitness tracker alone preferred the OurPath programme.
- OurPath app would complement face-to-face education, but it should be offered at the pre-diabetic stage.
- The chat forum received mixed feedback. Those with little experience of managing their health and fitness found the discussion and support useful, and it helped them persist with the programme. Those who were already trying to make healthy lifestyle changes found the information too basic and felt some questions were posed that were not responded to.
- Most participants liked the element of competition with other patients in their group (e.g. for daily step count).
- No participant was aware of any clinical benefits from taking part in the programme, as follow-up tests had not been completed. One had a resting heartrate was lower than before they started the programme.
- Three participants said they feel much better following the programme, including feeling slimmer, healthier and happier. One said that the behaviour change programme had "changed her life".

Potential to improve the patient experience

- Some participants were frustrated by inappropriate or impersonal recruitment (via letter or text message).
- One participant had an old android smartphone that was not compatible with the programme. She needed support from her son who uploaded the information onto her laptop.
- Participants felt there was little peer support and the forum discussion centred on technical issues rather than personal stories or support for each other.
- One participant found the advice given within this programme very basic. He did not believe the dietary suggestions were based on the latest evidence or tailored to T2DM.
- Recipes were not widely used.
- A food diary should be included.

Oviva focus group (n=5)

Two men and one woman attended the Oviva focus group, and an additional two participants provided email feedback. English was not their first language. They did not represent the diversity of patients in NWL but did mirror the typical demographics of the T2DM population. One participant was not confident with reading and two participants struggled with using technology.

Participant feedback

- The programme was very easy or quite easy to set up and use.
- Telephone support from the coach/dietician was good.
- No participants had any test results since completing the programme but did mention that it reminded them to have regular blood tests.

- The programme had renewed their focus on healthy diet, particularly as it relates to cooking ethnic cuisine, and made them more proactive with exercise.
- The only participant who had previously attended face-to-face diabetes structured education said that they preferred the app because they could use it in their own time.

Potential to improve the patient experience

- Two focus group participants felt the programme was overwhelming, as they were not familiar with technology. One sought help from family members.
- A portion size guide would have been helpful.

5.3.2 HCP experience

An online survey was sent to all participating GP practices. Eight out of 18 practices completed the survey. Four responses were received from practices using Changing Health; two responses from practices using OurPath; two responses were received from practices using Oviva.

Table 16 Responses to HCP survey for Changing Health, Our Path and Oviva

	Changing Health	OurPath	Oviva
- <u>-</u>			
The app has helped	Somewhat agree	Strongly agree	Strongly agree
you to provide better	(n=1)	(n=2)	(n=1)
support options for	Neutral (n=3)		Somewhat agree
patients with diabetes			(n=1)
(1 – strongly agree to 5			
 strongly disagree) 			
Overall the tool has	Neutral (n=3)	Strongly agree	Somewhat agree
supported patients to	Somewhat	(n=2)	(n=2)
self-care in relation to	disagree (n=1)		
their diabetes			
(1 – strongly agree to 5			
 strongly disagree) 			

How would you rate the	4 (n=2)	1 (n=2)	1 (n=1)
quality of the support	1 (n=2)		2 (n=1)
you have received from			
the Diabetes app			
company?			
(1 – best to 5 – worst)			
Issues that came up	Strongly agree	Strongly agree	Strongly agree
during the pilot were	(n=1)	(n=2)	(n=2)
dealt with appropriately	Neutral (n=1)		
by the app company	Slightly disagree		
(1 – strongly agree to 5	(n=2)		
 strongly disagree) 			
How have patients	Very positive	Positive (n=2)	Positive (n=2)
responded to the option	(n=1)		
of using a digital health	Neutral (n=3)		
tool?			
(1 – very positive to 5 –			
very negative)			

Changing Health HCP experience (n=4)

Feedback from the practices was mixed. One practice commented that the programme had been a good solution for patients who were not able to access diabetes structured education sessions for whatever reason. Another commented that use of the app saved them time in their consultations that may otherwise have been spent discussing diet and exercise. Practices needed additional support to recruit patients and to understand the app and how to use it themselves.

OurPath HCP experience (n=2)

Both practices had generally positive experiences with the programme. They recommended the app particularly for supporting significant lifestyle changes, improving engagement with the healthcare team and increasing motivation and empowerment among patients who completed the course. The OurPath programme

was particularly suitable for patients who want to avoid starting medication. Drawbacks of the programme included the fact that a portion of the "target" population has difficulty accessing or using this sort of technology.

Oviva HCP experience (n=2)

Both practices reported generally positive experiences with the programme. One said that it had enabled access to structured education that did not involve group sessions, and that patients can use during working hours. They commented that some patients did not have access to apps on their phones so were not able to benefit from the programme.

5.3.3 Project management experience

The three digital behaviour change programme providers were asked to provide their feedback on the NWL pilot, including any factors that affected success.

5.3.3.1 Changing Health project management feedback

- PAM assessment was a barrier to entry, particularly as some of the surgeries weren't confident in using this tool.
- The relatively short recruitment phase of the pilot meant that registrations needed to be as proactive as possible rather than just via normal clinics (as would happen in real-world deployment, where more organic recruitment could be expected).

The following changes were made during the pilot:

- The introduction of text message to increase the number of self-referrals.
- Dedicated website landing page for patients registering on the NWL pilot, and for NWL pilot sites.

5.3.3.2 OurPath

The following changes were made during the pilot:

- Increased frequency of communication during the recruitment phase to explain the programme before patients signed up (changed from 1 email and text message, to 3-4 over the course of a week).
- Revised recruitment tactics: emails and texts sent before following up by phone.
- Eligibility criteria were re-assessed (e.g. people who required additional support from family members were not included).

4.1.3.3 Oviva

No changes were made to the programme or app during the pilot. However, some small changes were made to the referral pathway to increase referrals and uptake:

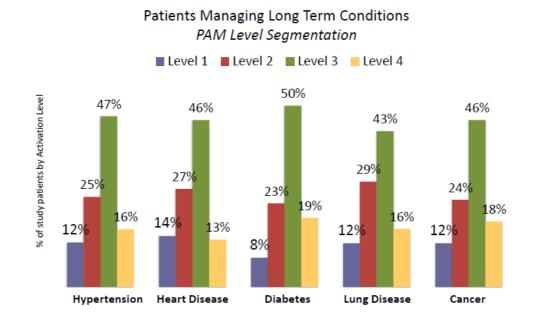
- Oviva took over responsibility from GP practices for collecting / recording baseline outcome data and completing PAM assessment
- The service was opened to self-referrals for the final month of the pilot

6 Evaluation

6.1 Summary of results

Four hundred and thirty patients were recruited at 18 GP pilot sites in NWL between March and August 2017. Data were available for 295 patients (69% of those recruited for the pilot). Uptake on referrals was >70% for OurPath and Oviva and 50% for Changing Health. Completion data were available for Oviva (>80% of patients completed the 8-week programme) and OurPath (53% of patients had completion data available).

Most patients (51%) were PAM level 3 before enrolling. People at this PAM level would tend to know key facts about their health and strive for best practice behaviours based on specific goals. There was a similar distribution in PAM level at baseline across the three programmes. Mean PAM score for enrolled patients was 58, which is slightly lower than the mean score of 59.23 among patients with diabetes reported in a national telephone survey of 3000 adults aged \ge 45 (2005, Figure 16).^{xx} Change in PAM score during the programme was only available for 9 participants, but most of these had a positive change. Two patients had a decrease in PAM scores. Decreases in PAM scores are known to occur when a patient receives a new diagnosis or a new complication, as they need to develop the knowledge, skills and confidence required to cope with their changed disease state.^{xxi} *Figure 16 PAM distribution for patients with LTCs from a Picker Institute UK Study (2005)*



Source: Picker Institute UK Study 2005. N=2,890. Patients managing LTCs

Participation in a digital behaviour change programme resulted in a significant reduction in T2DM-associated clinical indicators (weight, BMI, HbA1c, SBP, DBP). Owing to data gaps, changes represent those in the overall study population, rather than data collected from the same patient(s) before and after the intervention. Change in clinical indicators during the programme was not significantly correlated (p>0.05) with PAM score or PAM level. Mean weight decreased by 2.5kg, and mean BMI decreased by 0.99 kg/m² during the pilot programme. Most patients across the study population had a reduction in weight and BMI during the programme. Average

weight loss was highest for patients taking part in OurPath. Modest weight losses of 5 to 10% have been associated with significant improvements in cardiovascular risk factors among overweight patients with T2DM.xxii Mean HbA1c decreased by 6.9 mmol/mol, with most patients across the study population experiencing a reduction in HbA1c during the programme. Average change in HbA1c was largest for patients taking part in Oviva. Reduction of HbA1c by 11 mmol/mol in a T2DM population has been associated with a 25% decrease in risk of microvascular complications as well as decreased risk of ischaemic heart disease and peripheral vascular disease.xxii,xxiv Reductions were observed in mean systolic blood pressure (SBP, -3 mmHg) and diastolic blood pressure (DBP, -2 mmHg) during the programme. Participation in Oviva was associated with the greatest reductions in both SBP and DBP. Any reduction in SBP in patients with T2DM has been associated with a decreased risk of cardiovascular complications.^{xxv} Twenty-three (23) patients appeared to have discontinued metformin while taking part in the programme, potentially because of an observed improvement in their clinical indicators (HbA1c, weight and blood pressure).

Patient feedback on all three digital behaviour programmes was generally positive, except for those patients who were already highly confident with managing their health and fitness. HCP feedback highlighted the technological barrier to participation for many of the target population, and the importance of selecting the right patients to take part. Within the limitations of this pilot, results support the wider use of digital behaviour change programmes delivered using smartphone apps for structured diabetes education programmes.

6.2 Comparison of digital programmes with face-to-face structured education

Higher completion rates coupled with positive changes in clinical indicators suggest digital health programmes may be an effective alternative to face-to-face structured education. Digital programmes may be particularly suited to groups of patients who may have a general preference for using smartphone technology. Furthermore, patients may prefer digital programmes because of their easy access, flexibility and integration of educational resources and support through a single medium (i.e. smartphone app).

Table 17 Features of digital behaviour change programmes and face-to-face diabetes structured education.

	Digital behaviour change	Face-to-face diabetes
	programmes	structured education
Data collection	Clearer picture of engagement	Data on engagement and
	through data collection. For	uptake may be less readily
	example, monitoring number	available
	of times patients access	
	various elements of each	
	programme	
Completion rates	Although completion was	Completion rates
	defined differently between	according to the literature
	programmes the overall rates	and data collected through
	appeared to be higher (>50%)	the WSIC Database
	for the digital programmes	(Table 1) are lower in
	compared with face-to-face	comparison to the digital
	diabetes structured education.	programmes in this pilot.
	Consistent definition of	
	completion is needed for a	
	clearer assessment of these	
	digital programmes	
Patient self-	Patients can simultaneously	Not applicable
monitoring	and regularly monitor	
	outcomes such as weight,	
	activity (number of steps), and	
	diet along with accessing	
	educational content	
Accessibility	Particularly useful for patients	Useful for patients who
	who have problems with	prefer groups sessions or

	mobility, transport, do not work	who are less comfortable
	well in group sessions,	with technology
	problems attending due to	
	work and other commitments.	
Feasibility	Capacity and scale-up would	Currently used
	need to be assessed in more	
	detail	
Cost	Provider payment to be	Block contract already in
	negotiated e.g. price per	place. Lump sum
	patient who has completed the	independent of the
	course or incentivised through	number of patients
	staged payments for achieving	
	milestones defined by levels of	
	engagement	

See section 2.2 for background on DESMOND and X-PERT diabetes structured education currently offered in NWL as a block contract. Poor completion rates in a block contract service leads to an inefficient procurement of services. No cost effectiveness analysis (CEA) studies have been identified which compare face-toface programmes (e.g. DESMOND) with digital health programmes offered on-line or via an app. CEAs are needed to provide additional evidence for the use of digital health structured education programmes in the NHS.

6.3 Limitations of the NWL pilot study

The following restrictions in the methodology of this pilot programme should be considered when reviewing the results in the context of a large-scale roll-out:

- No adequate system in place to share and link patient process (engagement and activity) data and clinical indicators between programme providers and the GP practices.
- 2. The level of sensitive information shared between the programme providers and the GP practices differed.

 Overall communication, engagement and partnership working between the programme providers and GP practices were constrained by time and poor coordination.

Notably, the success of data extraction was dependent on whether the practice was using EMIS versus SystmOne:

- EMIS practices provided non-identifiable clinical data by manually populating Excel spreadsheets. No follow-up data extractions could be done to capture missing data.
- SystmOne practices generated a strategic ID numbers for patients on the NWL pilot. Strategic ID numbers could not be linked to NHS numbers, but they could be used for repeat extractions for that group of patients. Although this approach was more powerful for data capture, it did require several administrative steps for the GP, programme providers and ICHP.

As a result, there were large amounts of missing data, particularly for EMIS practices. Oviva provided additional support to extract data for EMIS practices, so their dataset was more complete than Changing Health and OurPath. Data gaps were found across demographic and clinical indicators, including age, gender, ethnicity, pre-enrolment and post-participation PAM scores, weight, and BMI. Therefore, the power of regression approaches was affected by the sample size of the datasets.

Patient experience and usability (UMUX-LITE) data were provided as aggregated scores, rather than individual (linked) patient-level responses, and therefore these could not be compared with clinical indicators using regression techniques. There were also insufficient pre-enrolment and post-participation PAM observations to enable evaluation of whether completion and clinical data were linked to baseline PAM scores or change in PAM scores. Other outcomes such as completion and

engagement rates were defined differently across programmes and therefore direct comparisons were less informative.

For any similar pilot projects conducted in future, ICHP recommends the following steps to ensure programme evaluation can be completed as planned:

- Identify key people at the programme provider and GP practice who are willing to take responsibility for data collection and data transfer during the pilot
- Review information sharing agreements with programme providers and respective practices to ensure that are all the relevant systems in place for data protection and sharing before starting.
- Agree the method for extracting data across all practices and across both platforms:
 - Use MyQuest queries for EMIS and SystmOne
 - Practice manager to give permission for data to be extracted remotely
 - Refine the pathway for extraction and merging data with the data analytics team
 - Use the strategic ID generated from MyQuest query to follow patient outcomes for 6-month to 12-month periods.
- Harmonise outcome measures across all programmes (e.g. define engagement, completion etc.), and make usability assessment part of the programme (e.g. add UMUX-LITE and NPS to the apps).
- 5. Use a single process for collecting PAM scores, with an agreed timepoint for assessment collection to tie in with the evaluation process.
- Select an appropriate evaluation period to allow for recruitment (based on previous uptake) and completion (based on the expected length of the programmes).

6.4 Recommendations for future study/analysis

Given more time/complete data, ICHP recommends further study/analyses on:

- Clinical outcomes for a cohort of patients in WSIC who have taken part in a digital behaviour change programme, compared with those taking part in faceto-face structured diabetes education. The ICHP business intelligence and information governance teams have recent experience of including data from WSIC and could oversee this.
- Cost effectiveness for patients who have taken part in a digital behaviour change programme, compared with those taking part in face-to-face structured diabetes education.

6.5 Requirements for wider roll-out of digital programmes in NWL

For roll-out across NWL, digital behaviour change programmes should be available in languages that reflect the diversity of the population. The status of language support for the three digital behaviour change programmes is:

- Changing Health is currently developing their service in the following languages: Urdu, Punjabi, Bengali (Standard and Sylheti), Gujarati, Polish, Dutch. Other languages will be developed as demand requires.
- By mid-2018, OurPath plans to begin translating their programme content into different languages, starting with South Asian languages (e.g. Urdu, Punjabi, and Gujarat).
- Oviva is exploring the option of creating language-specific versions of the smartphone app and learning materials. An Arabic version of the smartphone app has been created for use in the Middle East.

The following steps were recommended by the programme providers to improve patient recruitment if the programmes are rolled out across NWL:

- Website containing a how-to-guide and all documents required for GP practices to recruit people to the programme
- Patient self-registration websites that can also be used by HCPs in clinic.
- Clear performance indicators and reporting for GP practices on number of referrals expected
- Additional resources to promote the programmes (e.g. video testimonials, education sessions, local service user champions, presentations)
- Additional project management support for GP practices.



Appendix 1

WSIC read codes used to determine completion rates for face-to-face structured

education programmes (SEP) at participating practices.

ReadCode	Description	Status
9OLB.	Attended diabetes SEP	Attended
90LE.	Attended DESMOND SEP	Attended
90LH.	Attended DAFNE diabetes SEP	Attended
90LF.	Diabetes SEP completed	Complete
90LJ.	DAFNE diabetes SEP completed	Complete
90LK.	DESMOND diabetes SEP completed	Complete
90LL.	XPERT diabetes SEP completed	Complete
8IEa.	Referral to DAFNE diabetes SEP declined	Declined
90LM.	Diabetes SEP declined	Declined
9NiA.	Did not attend diabetes SEP	DNA
9NiC.	Did not attend DAFNE diabetes SEP	DNA
9NiD.	Did not attend DESMOND diabetes SEP	DNA
9NiE.	Did not attend XPERT diabetes SEP	DNA
8181.	Did not complete diabetes SEP	Not Complete
8182.	Did not complete DAFNE diabetes SEP	Not Complete
8183.	Did not complete DESMOND diabetes SEP	Not Complete
8184.	Did not complete XPERT diabetes SEP	Not Complete
8Hj0.	Referral to diabetes SEP	Referral
8Hj3.	Referral to DAFNE diabetes SEP	Referral
8Hj4.	Referral to DESMOND diabetes SEP	Referral
8Hj5.	Referral to XPERT diabetes SEP	Referral

SEP – structured education programmes

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