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Effectiveness of a Digital Lifestyle Change Program in Obese and Type 2 Diabetes Populations: Service Evaluation of Real-World Data

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Abstract

Background: The prevalence of type 2 diabetes mellitus (T2DM) and obesity is increasing, and the way people interact with health care is evolving. People traditionally access advice and support to improve their lifestyle and learn more about the self-management of T2DM in a face-to-face setting. Although these services have a strong evidence base, they have limitations for reaching specific groups of people. Digital programs could provide a new delivery model to help more people access health education and behavior change support, but long-term data supporting these programs are limited.

Objective: The purpose of this service evaluation was to analyze the weight change of people who participated in OurPath (also known as Second Nature), a UK-based digital lifestyle change program, for either weight management or diabetes-related weight management and structured education at 6 and 12 months.

Methods: Participants either paid to access the program privately (self-funded clients) or were referred by their general practitioner to participate in the program free of charge (funded by the National Health Service). Additional follow-up support was provided to help people to maintain lifestyle changes. To retrospectively assess potential weight loss, the analysis included data from participants who submitted weight readings at baseline and 6 and 12 months after starting the program. Changes in weight after 6 and 12 months were primary outcome measures.

Results: For the 896 participants who submitted baseline and 6- and 12-month data, a significant change in mean weight of −7.12 kg (−7.50%; SD 6.37; P < .001) was observed at 6 months. Data from the same participants at 12 months showed a change in mean weight when compared with a baseline of −6.14 kg (−6.48%; SD 6.97; P < .001).

Conclusions: The data presented here had several limitations, and there were too many uncertainties to make any reliable conclusions. However, these results suggest that digital lifestyle change programs could provide a new way to help people to access nutritional advice and support to achieve weight loss. Further research into digital education and coaching platforms is needed to establish their effectiveness.

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KEYWORDS

weight loss; mHealth; type 2 diabetes; OurPath; obesity; dietetics; cognitive behavioral therapy; empowerment; well-being; mobile app; behavior change; prevention; digital

http://diabetes.jmir.org/2020/1/e15189/
Introduction

Background

Estimates indicate that 1 in 11 adults worldwide and more than 3 million people in England are now living with type 2 diabetes mellitus (T2DM) [1-3]. Due to the clear links between obesity and T2DM, finding a solution to the obesity crisis is critical to reducing the prevalence of T2DM and improving health outcomes [4].

There is strong evidence that lifestyle interventions focused on giving balanced nutritional advice can help people to improve their blood sugar, lipid, and blood pressure levels [4-6]. As a result of this, the current guidelines in England encourage the referral of patients who are overweight to clinical weight management programs [7]. According to a recent randomized controlled trial, the effectiveness of these programs can range from 3.26 kg to 6.76 kg weight loss at 12 months, depending on the length and intensity of the intervention [8]. Published real-world evidence is limited, but recent research by Public Health England suggests that only 2 out of 7 services in the North of England helped more than a third of participants achieve over 5% weight loss [9]. Although traditional weight loss programs have taken place in a face-to-face setting, this variance in outcomes presents an opportunity for health systems to trial new solutions for delivering weight management.

There is some existing evidence that suggests that technology can help support weight management in people living with nondiabetic hyperglycemia [10] or T2DM [11]. The Diabetes Prevention Recognition Program in the United States recognizes more than 120 organizations delivering lifestyle change programs through digital or remote channels. This widespread real-world adoption suggests that digital services that offer remote monitoring, patient engagement, and remote support could be relevant components for facilitating lifestyle change. However, the variety of programs and the data supporting them is minimal [10]. To build on this emerging evidence base for digital programs, this single-arm study has been conducted to retrospectively analyze the outcomes for OurPath (also known as Second Nature), a digitally delivered behavior change program based in the United Kingdom.

In a previous study, the OurPath program demonstrated significant weight loss in a small cohort with data available after 3 and 6 months [12]. Of the participants who enrolled in the program, 61% (42/69) had submitted a weight reading and had achieved a mean weight loss of 6.7% ($P < .001$) after 3 months. Data available for 51.72% (15/29) participants who submitted a weight reading at 6 months demonstrated a mean weight loss of 8.2% ($P < .001$). In this study, data from a new group of participants were analyzed retrospectively to validate and build upon these previous findings.

Objectives

The objective was to investigate the weight change achieved for participants who continued to register weight readings 6 and 12 months after starting the program.

Methods

Program Description

OurPath is a 3-month digital behavioral change program combining one-to-one health coaching from a registered dietitian, group chat functionality with peers, structured education, and health tracking technology. All of these elements are combined within a smartphone app or Web browser–based app, accessed via compatible mobile and computer devices (see Figures 1 and 2).

Figure 1. Screenshots of the digital platform.
The program was designed to help participants make behavioral changes while also increasing their knowledge of nutrition, physical activity, adequate sleep, and general physical and mental well-being. Several behavioral change techniques, including those outlined in the Behaviour Change Wheel, were incorporated into the program [13]. The adoption of new behaviors was facilitated by reducing barriers to self-monitoring changes in health (eg, diet, weight, sleep, and physical activity); incentivization through social rewards (eg, group goals and achievement badges); and nonsessional, direct support and advice from credible sources (eg, health coaches and evidence-based content) [14-16].

Registered dietitians or nutritionists delivered one-to-one health coaching via a private, text-based instant messaging function within the app. Health coaches were available between 8 am and 6 pm and replied at the beginning of the next working window for any queries submitted outside of this time frame. Messaging took place in 2 separate formats: private and group. The private chat was only viewable by the health coach and the participant, but the group chat included up to 10 other participants. The private chat allowed participants to ask specific questions and receive prompt replies on a range of topics including, but not limited to, personalized dietary requirements, negative thought patterns, and other personal health–related information.

All members within the group chat were assigned the same health coach who supervised and moderated the conversations. To maintain privacy, only the health coach and the participant were able to view the messages. The health coach was responsible for facilitating behavior change [17]. Conversations between participants included, but were not limited to, cooking queries, nutritional debates, ingredient substitutes, and motivational support.

Participants could access educational articles with multimedia components, including plain text and video, viewed within the app. Table 1 outlines the educational themes covered during each week of the program. Each article was designed to take between 10 to 15 min to read with the ability to mark as complete when finished to track learning progress. Key educational themes covered, but were not limited to, nutrition, physical activity, stress, mental well-being, and sleep.

Every participant received a package containing a recipe book, nutritional handbook, wireless set of weighing scales, and a wearable activity tracker 3 to 4 days before starting the program. Participants and health coaches were able to view weight and daily step count within the app throughout the program. In general, participants were encouraged to register a weight reading once a week. However, the frequency of registering weight readings varied between participants, which was individualized and influenced by patient choice.

The program was divided into 2 periods: the initial phase of the program, named Core, and the maintenance phase, named Sustain. The core phase lasted for 12 weeks and was designed to be more intensive, encouraging daily engagement and primarily focusing on helping people to break pre-existing habits, form new healthier habits, and lose weight. This phase of the program was free to access for T2DM National Health Service (NHS) participants, but self-funded participants paid for the program privately. Sustain was designed to encourage weekly engagement and offer more sustainable advice, enabling people to maintain and monitor their reduced weight and healthier behaviors. During Sustain, the participants no longer had private support from the health coach, but they could still use the tracking technology and access the educational content and a forum consisting of other individuals who had completed the program, providing a supplementary level of peer support. T2DM NHS and self-funded participants both had ongoing access to the Sustain program.
Table 1. Educational themes explored during the digital program.

<table>
<thead>
<tr>
<th>Week</th>
<th>Theme</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Prepare for the program</td>
<td>Introduce nutritional basics around metabolism and the nutritional requirements of the body</td>
</tr>
<tr>
<td>1</td>
<td>Reset your lifestyle</td>
<td>Introduce self-monitoring of body weight and provide more detailed nutritional advice</td>
</tr>
<tr>
<td>2</td>
<td>Build healthy habits</td>
<td>Increase knowledge on sleep and physical activity</td>
</tr>
<tr>
<td>3</td>
<td>Tackling temptations</td>
<td>Introduce the role of insulin, exercise, and perceiving mistakes as learning opportunities</td>
</tr>
<tr>
<td>4</td>
<td>Try something new</td>
<td>Increase confidence in food and exercise</td>
</tr>
<tr>
<td>5</td>
<td>Keep your gut healthy and happy</td>
<td>More detailed advice on healthy nutrition, including the importance of fiber</td>
</tr>
<tr>
<td>6</td>
<td>Reflection on progress</td>
<td>Introduce self-reflection and recap on the program so far</td>
</tr>
<tr>
<td>7</td>
<td>How to overcome obstacles</td>
<td>Introduce acceptance and commitment therapy techniques and how to navigate time constraints</td>
</tr>
<tr>
<td>8</td>
<td>Boost your health</td>
<td>Further reinforcement of physical activity and nutritional advice</td>
</tr>
<tr>
<td>9</td>
<td>Remember—mind over matter</td>
<td>Advice on tackling challenging moments and fluctuating energy levels</td>
</tr>
<tr>
<td>10</td>
<td>Maximizing rest and relaxation time</td>
<td>Reinforce the importance of stress management and sleep</td>
</tr>
<tr>
<td>11</td>
<td>Top tips to take away</td>
<td>Recap on key points covered so far</td>
</tr>
<tr>
<td>12</td>
<td>Moving forward</td>
<td>Reflect on progress over the last 12 weeks and introduce sustain and develop strategies for long-term weight maintenance</td>
</tr>
</tbody>
</table>

To access the program, both groups of participants registered their details on the OurPath website. Each participant answered a series of questions about their current lifestyle and what changes they would like to make. After confirming that they were ready to make a change to their lifestyle, they created an account with a secure username and password and selected a date to start the program. After this registration process had been completed, participants were able to log into and access the full functionality of the app. This involved communicating with their health coach; speaking to other participants in their group; accessing educational articles; viewing recipes; and self-monitoring changes in their diet, steps, weight, and sleep.

National Institute of Health and Care Excellence guidelines, including Clinical Guideline 43 and Public Health Guideline 38, informed the advice and recommendations given by the health coaches [18,19]. This advice was focused around limiting highly processed goods while encouraging home-prepared, nutritionally balanced meals.

The program was designed and validated by a clinical advisory team consisting of diabetes specialist clinicians, general practitioners (GPs), psychologists, behavioral scientists, and registered dietitians.

This service evaluation did not require institutional review board approval as the project did not include any access to personally identifiable information. Data were routinely collected from participants, as part of the OurPath program, who had already consented for their data to be collected and anonymized for medical research purposes. For NHS T2DM participants, the program was part of usual care, and participants were not randomized to a treatment.

Participants

Participants either paid to access the program privately (self-funded clients) or were referred by their GP to participate in the program free of charge (funded by the NHS). Self-funded participants purchased the program for help to manage their weight. All participants referred through the NHS were already living with T2DM and were invited to participate in the program for weight management and behavioral change support. All participants included in this analysis were overweight, or living with obesity, with a BMI>25 kg/m².

Participants were adults, aged 18 years and older, and were living in the United Kingdom at the time of participation. Although time since diagnosis was not directly measured, it was also not set as an eligibility criterion for program participants. Medication usage was also not measured or used as an inclusion criterion.

All participants consented to their anonymized data being used for analysis and publication, taking part in the program between January 1, 2017, and August 1, 2018.

To assess the potential weight loss of people who continued to use the tracking technology, we only included participants who submitted weight readings at baseline and 6 and 12 months after starting the program.

Measures

Participants self-reported their gender, height, and age during the Web-based registration process, but all weight readings were collected using the wireless weighing scales provided. Participants were directed to place weighing scales on a hard and flat surface. Once they had been used, the wireless weighing scales automatically transmitted weight data directly to a central database, displaying readings as a graph on the smartphone app. For the collection of these data, the scales fed readings into a weight validation algorithm, which only accepted weight readings within an expected range. This calculation accounted for the value of previous weight reading and the time since that reading was registered, automatically notifying the participant of any invalid weight readings via email. This process was designed to exclude anomalous readings and ensure the capture of consistent and objective readings for analysis. The validated weight readings registered 4 weeks before or after the data...
collection milestones were retrieved from the database. For this analysis, the lowest retrieved weight reading within the 8-week window was used.

**Primary Outcomes**

A single-arm retrospective longitudinal study design was used to evaluate the effect on weight after having enrolled in the OurPath program. Primary outcome measures were changes in weight after 6 and 12 months. This change in weight was analyzed in kilograms and percentage reduction in initial body weight. The percentage of participants achieving more than 5% and 10% reduction in initial body weight was also included as a primary outcome measure.

**Statistical Analysis**

The R open-source statistical language was used through the R-Studio interface to calculate statistical tests with $P$ values and generate visual representations of the data. One-way Student $t$ tests were used, with the null hypothesis being an average weight loss of 0 kg (no weight loss) and the test hypothesis that the population mean was greater than 0. $P$ values reported in this publication also held significance at 95% level using a null hypothesis of 5.5 kg weight loss.

**Results**

**Baseline Characteristics**

The total number of participants who took part in the program between January 1, 2017, and August 1, 2018, was 3649 (see Figure 3). Of those, 2788 were in the self-funded group, and 861 were in the T2DM NHS group.

Of the 3649 participants of the OurPath program, 896 participants submitted both 6- and 12-month weight readings, meeting the criteria for the data analysis.

Due to the retrospective nature and real-world setting of this study, it was not possible to ensure an even distribution of comparable characteristics in each cohort (see Table 2). A higher proportion of females to males took part in the program, with 70% (627/895) female and 30% (269/895) male participants. Participants had a mean starting BMI of 33.7 kg/m$^2$ (SD 6.1) and starting weight of 94.7 kg (SD 18.9).

![Figure 3. Study participant flowchart. NHS T2DM: National Health Service type 2 diabetes mellitus.](image)
Table 2. Baseline characteristics of program participants.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall</th>
<th>Self-funded</th>
<th>National Health Service type 2 diabetes mellitus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>49.4 (12.6)</td>
<td>48.5 (11.8)</td>
<td>51.2 (12.6)</td>
</tr>
<tr>
<td>Weight (kg), mean (SD)</td>
<td>94.7 (18.6)</td>
<td>94.5 (20.5)</td>
<td>95.1 (18.6)</td>
</tr>
<tr>
<td>BMI (kg/m²), mean (SD)</td>
<td>33.7 (6.1)</td>
<td>33.9 (6.6)</td>
<td>33.4 (6.3)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>627 (70.0)</td>
<td>406 (82.9)</td>
<td>221 (55.4)</td>
</tr>
<tr>
<td>Male</td>
<td>269 (30.0)</td>
<td>84 (17.1)</td>
<td>185 (45.6)</td>
</tr>
</tbody>
</table>

Primary Outcomes

Data from the 896 participants who registered readings at both 6 and 12 months showed a statistically significant change in weight at 6 months (mean −7.1 kg, SD 6.4; −7.5%; \( P < .001 \)) and at 12 months (mean −6.1 kg, SD 7.0; −6.5%; \( P < .001 \)).

The proportion of people achieving more than 5% weight loss and more than 10% weight loss was also analyzed for all participants with data available at both milestones.

After 6 months, 60.1% (546/896) participants with data available achieved over 5% weight loss. This level of weight loss was achieved by 66.5% (270/406) of the T2DM NHS participants and 56.3% (276/490) of the self-funded participants.

In addition to this, 29.4% (264/896) of all the participants with data available achieved more than 10% weight loss. This level of weight loss was also seen in 31.5% (128/406) of the participants in the T2DM NHS group, and 27.8% (136/490) of the participants in the self-funded group also achieved over 10% weight loss at 6 months.

After 12-months, 53.3% (478/896) participants with data available achieved over 5% weight loss. This level of weight loss was achieved by 55.7% (226/406) of the participants in the T2DM NHS group and 51.4% (252/490) of the participants in the self-funded group. In addition to this, 23.5% (211/896) of all of the participants with data available achieved more than 10% weight loss. This level of weight loss was also seen in 24.6% (100/406) of the participants in the T2DM NHS group and 22.6% (111/490) of the participants in the self-funded group.

Table 3. The proportion of participants with data available achieving more than 5% and 10% weight loss.

<table>
<thead>
<tr>
<th>Level of weight loss achieved</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants with data available achieving &gt;5% weight loss (N=896), n (%)</td>
<td>546 (60.1)</td>
<td>478 (53.3)</td>
</tr>
<tr>
<td>NHS T2DM³ participants with data available achieving &gt;5% weight loss (N=406), n (%)</td>
<td>270 (66.5)</td>
<td>226 (55.7)</td>
</tr>
<tr>
<td>Self-funded participants with data available achieving &gt;5% weight loss (N=490), n (%)</td>
<td>276 (56.3)</td>
<td>252 (51.4)</td>
</tr>
<tr>
<td>Total participants with data available achieving &gt;10% weight loss (N=896), n (%)</td>
<td>264 (29.4)</td>
<td>211 (23.5)</td>
</tr>
<tr>
<td>NHS T2DM participants with data available achieving &gt;10% weight loss (N=406), n (%)</td>
<td>128 (31.5)</td>
<td>100 (24.6)</td>
</tr>
<tr>
<td>Self-funded participants with data available achieving &gt;10% weight loss (N=490), n (%)</td>
<td>136 (27.8)</td>
<td>111 (22.6)</td>
</tr>
</tbody>
</table>

³NHS T2DM: National Health Service type 2 diabetes mellitus.

In the self-funded group, 90% (449/490) of the participants lost weight at 6 months, and 85.1% (417/490) of the participants lost weight at 12 months (396/460). Moreover, 4.7% (23/490) of the participants gained weight at 6 months, and 10.2% (50/490) of the participants had gained weight at 12 months.

Discussion

Principal Findings

This study showed that participants who registered weight readings achieved statistically significant weight loss at 6- and 12-month milestones (see Table 4 and Figure 4). These results align with previous research and build on the emerging evidence base surrounding digital behavior change interventions [12,20]. The mean weight loss achieved at 12 months by those with data available exceeded a 5% reduction in initial body weight, which has been associated with a reduction in disease risk for T2DM [21].
Table 4. Weight change for participants at 6- and 12-month collection milestones.

<table>
<thead>
<tr>
<th>Cohort with data available</th>
<th>Data collection milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline weight (kg), mean (SD)</td>
</tr>
<tr>
<td></td>
<td>6-month weight (kg), mean (SD)</td>
</tr>
<tr>
<td></td>
<td>6-month weight change (kg), mean (SD)</td>
</tr>
<tr>
<td></td>
<td>12-month weight (kg), mean (SD)</td>
</tr>
<tr>
<td></td>
<td>12-month weight change (kg), mean (SD)</td>
</tr>
<tr>
<td>Consolidated participant weight change from baseline</td>
<td>94.3 (18.9)</td>
</tr>
<tr>
<td></td>
<td>87.2 (18.4)</td>
</tr>
<tr>
<td></td>
<td>−7.1 (6.4)</td>
</tr>
<tr>
<td></td>
<td>88.2 (19)</td>
</tr>
<tr>
<td></td>
<td>−6.1 (7)</td>
</tr>
<tr>
<td>Self-funded participant weight change from baseline</td>
<td>94.9 (19)</td>
</tr>
<tr>
<td></td>
<td>88.1 (18.7)</td>
</tr>
<tr>
<td></td>
<td>−6.7 (6.6)</td>
</tr>
<tr>
<td></td>
<td>88.9 (19.2)</td>
</tr>
<tr>
<td></td>
<td>−5.9 (6.8)</td>
</tr>
<tr>
<td>National Health Service type 2 diabetes mellitus participant weight change from baseline</td>
<td>93.7 (18.7)</td>
</tr>
<tr>
<td></td>
<td>86.1 (17.9)</td>
</tr>
<tr>
<td></td>
<td>−7.6 (6.2)</td>
</tr>
<tr>
<td></td>
<td>87.3 (18.7)</td>
</tr>
<tr>
<td></td>
<td>−6.4 (7.2)</td>
</tr>
<tr>
<td>Male participant weight change from baseline</td>
<td>102.2 (19.3)</td>
</tr>
<tr>
<td></td>
<td>93.3 (20.2)</td>
</tr>
<tr>
<td></td>
<td>−8.9 (7.8)</td>
</tr>
<tr>
<td></td>
<td>95.0 (20.8)</td>
</tr>
<tr>
<td></td>
<td>−7.1 (7.2)</td>
</tr>
<tr>
<td>Female participant weight change from baseline</td>
<td>91.8 (18)</td>
</tr>
<tr>
<td></td>
<td>85.3 (17.8)</td>
</tr>
<tr>
<td></td>
<td>−6.5 (5.7)</td>
</tr>
<tr>
<td></td>
<td>86.0 (18.3)</td>
</tr>
<tr>
<td></td>
<td>−5.8 (6.9)</td>
</tr>
</tbody>
</table>

Figure 4. Weight change of study participants over time.

When compared with the NHS T2DM group, a much higher proportion of the self-funded group were excluded from the analysis because of incomplete data. In total, 24.55% (896/3649) of the participants met the inclusion criteria for the data analysis. Of the T2D NHS participants who enrolled in the program, 47.5% (409/861) registered weight readings at 6 and 12 months compared with 17.57% (490/2788) in the self-funded group. There could be several reasons for the disparity in data available between the groups. For certain individuals, health-related motivation could promote more self-monitoring behavior. In addition, previous research has shown that significant weight loss can also positively influence motivation, and similarly, that any weight gain can be demotivating, leading to decreased engagement [22,23]. However, it could also be argued that fewer patients chose to self-monitor their weight as the program progressed as there were fewer prompts to do so, particularly after the program had ended. Without more complete weight data, further research is needed to establish the long-term outcomes of all participants.

Of those who registered weight readings, male participants lost more weight than female participants (see Figure 5). There could be several reasons for this, eg, the male cohort analyzed had a higher mean baseline weight of 102.2 kg (SD 19.3) compared with the female mean baseline weight of 91.8 kg (SD 18.0). Although there are several differences in the hormonal balance and metabolism of adipose tissue between males and females, the reason for these results was not clear within the remit of this study [24].
Similar results were achieved in the self-funded group and T2DM NHS group, suggesting that participants from both cohorts with data available were able to achieve weight loss. Weight change also varied between age brackets, with the analyzed participants who were older than 60 years achieving more weight loss. These results align with previous research indicating that older age can be associated with increased adherence to weight loss programs [22]. In addition to differences in gender, this trend could equally warrant further investigation to establish whether there is a correlation between age and adherence to digital programs.

As this was not a randomized controlled trial, and we used a single-arm study design, we were unable to compare the results with a control or a group receiving usual care. It was also difficult to control variability as an existing dataset was used for analysis. However, similar results were seen in the treatment arm of a randomized control trial conducted in the United Kingdom, which looked at weight loss in a 12- and 52-week weight management program, with a control group of participants receiving brief lifestyle advice [8].

Randomized controlled trials present several practical challenges, and because digital technology is constantly evolving, real-world evidence can provide an important and accessible way of evaluating new apps. Even in a controlled setting, the digital nature of the program would make it difficult to blind participants to the intervention. However, this study provides real-world evidence from free-living people outside of a controlled environment, supplementing findings from randomized controlled trials and furthering the understanding of a relatively new method of providing weight management services [25].

When compared with baseline, 8.4% (34/406) of T2DM NHS and 10.2% (50/490) of self-funded participants with data available at 12 months showed some level of weight gain. This proportion of participants is small but noteworthy and indicates that continued self-monitoring is not only demonstrated by people who successfully achieved weight loss. Future studies should include other indicators of health, such as hemoglobin A1c and blood pressure, which could demonstrate any broader benefits of lifestyle modification.

Implementing high-quality and cost-effective health education for people living with obesity or T2DM is a significant challenge for weight management services. In a digital setting, specialist health coaches can reach a large number of service users simultaneously, making the service efficient to maintain. Given the challenges surrounding NHS resourcing, particularly in dietetics, this method of digital delivery has the potential to cater to the vast number of people who potentially need support. Digital methods of delivery also have the potential to impact the accessibility of structured education. The educational content delivered through remote programs is continuously accessible and can be divided into more manageable quantities, making it easier for participants to assimilate [26]. The face-to-face setting of traditional programs can make this difficult for some people, as there is variability between existing knowledge and learning speeds [27,28]. Digital interventions could enable the service user to learn at their own speed through interactive content, enabling them to seek advice from a health coach whenever necessary.

The tracking technology provided enabled people to self-monitor their progress. For some people, this immediate feedback can provide further motivation, which has been shown to lead to further reinforcement of healthy behaviors, leading to more.
positive outcomes [29]. The monitoring of weight and physical activity also provides useful information for the health coach, allowing them to tailor their nutritional advice, activity recommendations, and goal setting according to a participant’s progress. This level of individualization could be an advantage of digitally delivered programs, and although the results from this study did not allow for any robust conclusions, it would be interesting to investigate this further in future studies. Furthermore, the extent of the data presented did not indicate which elements of the program were the most effective for facilitating behavior change and weight loss. More research is needed to determine whether it is the regular feedback from the health coach, the continual self-monitoring, the educational articles, or a combination of the components that work best for participants.

Limitations
As this study retrospectively analyzed real-world data, there was no control group. Without a control group, the results have limited validity and must be interpreted carefully. However, the results can be compared with a study that evaluated weight loss outcomes from another digitally delivered weight loss program. This study had a much larger sample size available for analysis but also found that users were successful in losing a significant amount of weight using a digital program. The results of this study suggest that frequent self-monitoring, weighing, and logging food and exercise resulted in more weight loss [30].

Conclusions
The majority of people who continued to register weight readings at 6 and 12 months did achieve significant weight loss. Although the data presented had several limitations, and there were too many uncertainties to make any reliable conclusions, this study adds to existing real-world data, which suggest that digital lifestyle change programs could be a useful tool to help people to access nutritional advice and support.

Conflicts of Interest
MW and FM are both employees of OurPath Ltd. JH is a minority shareholder of OurPath Ltd.

References
Abbreviations

GP: general practitioner
**NHS:** National Health Service  
**T2DM:** type 2 diabetes mellitus
Viewpoint

Novel Digital Architecture of a “Low Carb Program” for Initiating and Maintaining Long-Term Sustainable Health-Promoting Behavior Change in Patients with Type 2 Diabetes

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Abstract
Globally, the burden of noncommunicable diseases such as type 2 diabetes is crippling health care systems. Type 2 diabetes, a disease linked with obesity, affects 1 in every 30 people today and is expected to affect 1 in 10 people by 2030. Current provisions are struggling to manage the trajectory of type 2 diabetes prevalence. Offline, face-to-face education for patients with type 2 diabetes has shown to lack long-term impact or the capacity for widespread democratized adoption. Digitally delivered interventions have been developed for patients with type 2 diabetes, and the evidence shows that some interventions provide the capacity to support hyperpersonalization and real-time continuous support to patients, which can result in significant engagement and health outcomes. However, digital health app engagement is notoriously difficult to achieve. This paper reviews the digital behavior change architecture of the Low Carb Program and the application of health behavioral theory underpinning its development and use in scaling novel methods of engaging the population with type 2 diabetes and supporting long-term behavior change.

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KEYWORDS
type 2 diabetes; behaviour change; nutrition; digital intervention; low carb; type 2 diabetes remission; eHealth

Background
The prevalence of both prediabetes and type 2 diabetes is increasing globally. Currently, 4 million people are diagnosed with diabetes in the United Kingdom, 90% of whom have type 2 diabetes. By 2030, nearly 10% of the UK adult population may require diabetes treatment [1]. In terms of health inequality, diabetes more commonly affects people of low (rather than high) socioeconomic status, particularly women [2,3]. By 2035, the UK National Health Service (NHS) is predicted to spend approximately £17 billion a year on treatment for diabetes and avoidable diabetes-related complications, which is approximately 17% of its entire budget [4].

Patients diagnosed with type 2 diabetes are known to have difficulties adhering to their treatments (medications, diet, and lifestyle change) [5,6], and despite many recent technical breakthroughs in health care, human behavior remains the largest source of variance in health-related outcomes [7]. Nonadherence to treatment negatively affects NHS treatment efficacy and finances [8-11]. Nonadherent patients diagnosed with type 2 diabetes are more likely to have higher blood glucose levels (hyperglycemia), resulting in higher hemoglobin A1c (HbA1c) levels [12]. Previous prospective studies in patients with type 2 diabetes have shown an association between the degree of hyperglycemia and increased incidence and progression of microvascular complications (diabetic retinopathy, loss of vision, and nephropathy) [13,14], sensory neuropathy [13,15], myocardial infarction (heart attack) [13,16,17], stroke [18], macrovascular mortality [19-21], and all-cause mortality [20,22-25].

In the UK Prospective Diabetes Study, a 1% reduction in the average HbA1c level was associated with a 21% reduced risk
of any adverse outcome related to diabetes, 21% reduced risk for deaths related to diabetes, 14% reduced risk for myocardial infarction, and 37% reduced risk for microvascular complications [26].

Research has shown that having better glycemic control is associated with a better quality of life [27]. Psychosocial factors often determine self-management behaviors and the ability to adhere to treatment. Psychosocial variables (such as depression) are often strong predictors of medical outcomes such as hospitalization [28]. The American Diabetes Association released a position statement; the first recommendation stated that psychosocial care should be integrated with collaborative, patient-centered medical care and provided to all people with diabetes, with the goals of optimizing health outcomes and health-related quality of life [29].

Patients’ Behavior

Patients’ behavior directly contributes to their treatment success, with doctors relying on patients to take their prescribed medication alongside making and maintaining dietary and lifestyle changes. Many of the most significant challenges in health care, specifically in long-term or chronic conditions, such as type 2 diabetes, will only be resolved if we can influence behavior and support sustainable behavior change.

An analysis from a secondary care diabetes clinic in the United Kingdom found that 86% of those with type 2 diabetes are overweight or obese. Obesity is associated with significantly worse cardiovascular risk factors, suggesting that more active interventions to control weight gain would be appropriate to help address the increasing burden of obesity and type 2 diabetes on the NHS. The National Institute for Health and Care Excellence (NICE) guidelines established that adults with type 2 diabetes who are overweight, should be set an initial body weight loss target of 5%–10%. [30] Regardless of the interventions used to lose weight—pharmacological [31] or behavioral [32]—the weight is commonly regained [33]. Typically, half the weight lost is regained in the first year. Weight regain often continues up to 3-5 years after treatment and, on average, 80% of people return to or exceed their pretreatment weight [34]. Similarly, relapse rates are high for individuals who initiate attempts to stop smoking [35,36] and those who try to reduce alcohol consumption [37]. Therefore, effective interventions that consider known factors associated not only with initial weight loss but also critically with weight loss maintenance such as building on internal motivations to lose weight, establishing social support mechanisms, identifying coping strategies, or providing support for self-efficacy and autonomy can all enhance weight loss maintenance, which is crucial for the long-term success of any weight loss interventions [38].

There is considerable evidence that health behaviors can be effectively modified through behavior change interventions [39-42]. However, there is a disproportionate number of behavior change theories in the academic literature, including both those that assess the use of interventions for health behavior initiation and those that theorize interventions essential to behavior change maintenance [43]. In addition, behavior change theory is most frequently used to explain behavior itself rather than potential behavioral change interventions [44].

Novel Application of Behavior Change Theory

This paper introduces the Low Carb Program Health Behaviour Change platform—a digital architecture developed to initiate and maintain behavior change in patients with type 2 diabetes and other chronic metabolic health conditions.

The purpose of this paper is to explore the conceptual hypotheses and theories around which the digital architecture has been built, with the aim of contributing to current psychological literature, simulating research, and encouraging the development of new digital applications created with the intention of initiating and maintaining health-related behavior change.

The Low Carb Program is a digitally delivered, automated, structured health intervention for adults, personalized to people with type 2 diabetes, prediabetes, and obesity. User data are used to personalize the experience member’s receive. The use of user data has been suggested to improve patient engagement through individualization of the participant’s experience [45].

In the on boarding of the program, patients are instructed to select a health goal and input their current health status and demographics including age, gender, ethnicity, and dietary preferences—all of which are used to personalize the participant’s experience of the platform.

Participants are given access to therapeutic nutrition education modules. Education is personalized to the user’s health status, age, ethnicity, and dietary preferences. A new module is available each week over the course of 12 weeks. Lessons are taught through videos, written content, or podcasts of varying lengths (approximately 3-12 minutes long). The program encourages participants to make behavior changes based on “Action Points” or behavior-change goals at the end of each education module.

Participant’s health goals are supported with behavior change resources that are available to download including information sheets, meal plans, and suggested food substitution ideas.

Users are matched within the platform to a digital buddy and are given access to a peer-support forum available 24 hours a day. Behavior change is maintained through continual engagement, new modules, and nudges to track health outcomes and interact with the support community.

Automated feedback and nudges are provided to users based on their use of the program through emails and native in-app push notifications, and participants are notified when the next week’s module is available.

Outcomes of the Platform in the Real World

The 1-year outcomes of the Low Carb Program, which utilizes the behavior change architecture, were previously published...
The 1-year outcomes for people with type 2 diabetes were reported in a single-arm longitudinal study that assessed users engagement within the platform as well as their health outcomes including weight, HbA1c levels, and medication dependency. Participants who completed the program lost an average of 7% body weight and reduced their HbA1c levels by 1.2%; in addition, 40% eliminated a diabetes medication from their treatment. Further, 26% of participants completing the program were classified as being in remission from type 2 diabetes at 1 year. The platform also demonstrated a 71% retention at 1 year. The results were collected after a year of the individual joining the platform, indicating that the behavior change wheel is also of clinical importance for maintaining positive health behaviors acquired during the initiation period.

The Low Carb Program, launched in November 2015, is available as an iOS, Android, and Web app and has been downloaded over 425,000 times. It includes digital tools for submitting self-monitoring data on a number of different variables including blood glucose levels, blood pressure, mood, sleep, food intake, activity, medication consumption, and body weight. The program is integrated with wearable and Bluetooth-enabled devices. As such, data can also be brought into the platform without requiring user input (Multimedia Appendix 1 and 2).

The Capability, Opportunity, Motivation, and Behavior Model of Behavior Change and Low Carb Program

Overview

The COM-B (capability, opportunity, motivation, and behavior) model was developed as a response to the inability of the majority of prevailing theories to provide strategies to change behavior and as part of a “method for characterizing interventions and linking them to an analysis of the targeted behavior” [47]. It is essentially a behavioral system that posits the interaction of three components—capability, opportunity, and motivation—which result in the performance of behavior [48]. COM-B canvases a range of mechanisms involved in behavior change and is “intended to be comprehensive, parsimonious and applicable to all behaviours” [48].

Each component can be subdivided into two heuristics: capability can be either “psychological” (involving knowledge and psychological skills) or “physical” (involving physical skills); opportunity can be either “social” (involving social influences and cultural norms) or “physical” (involving environmental resources, triggers, time, locations, and physical barriers); motivation can be either “reflective” (involving conscious planning or evaluation) or “automatic” (involving emotional responses, impulses, and reflexive responses) [47].

The following section will map each feature within the Low Carb Program to the relevant COM-B domain.

Social Opportunity

Peer Support Feature

Social opportunity refers to the people’s environment that either hinders or facilitates their behavior [49]. Social influences can be defined as “interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours” and includes constructs such as social norms, social comparisons, modelling, social support, and social pressure [50].

Social relationships are adaptive and crucial for survival. Social connections have powerful influences on health and longevity. Lacking social connection qualifies as a risk factor for premature mortality [51].

Social support has received attention as a mediator or moderator of health outcomes [52]. Social support has been facilitated in behavior change interventions in distinctive approaches in diabetes education. Researchers have examined the impact of group-based training [53,54]; peer group support that included telephone calls [55,56]; organized internet peer group forums with and without the addition of personal coach support [57,58]; and support from peers, spouse, family, and friends [59].

An empirical study of knowledge creation and social support on a diabetes online community forum concluded that being a member of the community forum had a positive impact on its members’ wellbeing and can help members manage their relationship with health care professionals. The authors concluded that members felt less emotionally burdened while managing their diabetes as a result of being a member of the community [57].

In an overview of peer support models to improve diabetes self-management and clinical outcomes, interventions that facilitate peer support are found to be a low-cost approach to encouraging dietary changes both in weight and diabetes managements [60,61]. Social networking and publicly sharing your progress on social media has been shown to be a beneficial and effective strategy for weight loss [62,63]. The Low Carb Program accommodates a dedicated peer support community forum. Patients are able to access the forum 24/7, providing users a dynamic social network that allows real-time interactions with their peers on a continuous basis. This facilitates a constant source of information, knowledge, personal anecdotes, and behavioral reinforcement from their peers worldwide. Users are encouraged to ask questions and share their goals and progress via facilitated discussions such as “Weigh in Wednesday” threads. Users of the Low Carb Program have access to the social support forum even after they have completed all the education modules. It is hypothesized that a significant proportion of the success of the Low Carb Program could be attributed to the forum, even users who do not actively post are able to “lurk,” meaning that they regularly read threads but do not necessarily comment or actively engage with the content.

Buddy System Feature

The Low Carb Program seeks to facilitate the use of a social support network in a digital setting by partnering up new members with existing users who have successfully completed the intervention, providing each user with a digital “buddy.”
Members are matched on a number of attributes, including self-selected health goals, demographics including age and ethnicity, diabetes type, and starting medication regime. Buddies facilitate observational learning in a digital setting, “communicating” with the new members via emails and in-app push notifications. The “social opportunity” element of the behavior change wheel asserts that people can witness and observe a behavior conducted by others and then reproduce those actions. If individuals see successful demonstration of a behavior, they are also likely to complete the behavior successfully.

Research on the effectiveness of a buddy system in other digital settings is somewhat contradictory, particularly when analyzing different age groups. Sylvestsky et al [64] found that assigning young, healthy, and motivated volunteer partners or “buddies” to adolescents with type 2 diabetes did not result in an improvement of HbA1c levels; however, this was not the case for adults with type 2 diabetes, where “buddying up” resulted in an effective improvement of HbA1c levels. The latter findings were also observed by Greaney et al [65]: Individuals paired with a buddy who offered support showed greater reduction in multiple risk behaviors compared to nonpaired controls. This research suggests that engagement with individuals that share similar conditions and demographics could enhance goal attainment and result in more desirable health outcomes.

Reflective Motivation

Goal Setting Feature

Reflective motivation involves our conscious and reflective processes that motivate our behavior [47] and includes goal setting. Goals represent an individual’s goals to achieve personal self-change, enhanced meaning, and purpose in life [66]. Evidence suggests that goal setting can act as an effective behavioral treatment strategy to change health behaviors and improve adherence to lifestyle intervention programs, such as diabetes management [63] and obesity prevention [67]. To enhance engagement and adherence to behavior change interventions in adults with obesity, goal setting has been suggested to be essential in the improvement of health outcomes [67].

The Low Carb Program provides patients with the opportunity to self-select their goals for the platform. Beyond simply setting a goal, the “Crystal Ball Technique” [68] is used, whereby members are nudged to consider a future reality in which their goal has been achieved; they are asked to think about what achieving their goal would mean to them and draw on their social norms to share who they think will notice if they are to achieve their goal. If individuals see successful demonstration of a behavior, they are also likely to complete the behavior successfully.

Locke and Loatham [71] developed the theory of goal setting and theorized that in order for a goal to be motivating, it needs to be specific and challenging; it also requires commitment, feedback, and task complexity [71].

When setting a goal within the platform, users are nudged to reflect on how close they perceive themselves to be to achieve their goal using a sliding scale of 1 and 10 points. Periodically, as they are using the platform, they are prompted to “check-in” with their initial goal and report on the same scale.

When it comes to maintaining behavior change, a systematic review of the psychosocial and sociodemographic determinants of physical activity maintenance [72] revealed that maintainers had higher self-efficacy and intention compared with those who relapse. Therefore, beliefs about capabilities, motivations, and goals may be among the strongest variables associated with behavior change maintenance. Additionally, a motivation-focused weight loss maintenance program is an effective alternative to a skill-based approach [73]. The combined research on goal setting across many different contexts and fields of study demonstrates that goal setting encourages a person to try harder and for longer periods of time, with less distraction from the task at hand [74] and therefore is rightfully integral to the Low Carb Program.

Psychological Capability

Health Tracking Feature

Psychological capability refers to people’s physical psychological skills, for example, knowledge, strength, or stamina to engage in mental processes [49]. Included in this domain is “behavioural regulation” defined as “anything aimed at managing or changing objectively observed or measured actions” and includes constructs such as self-monitoring, action planning, and habit breaking [50].

Monitoring goal progress is an effective self-regulation strategy that promotes goal attainment, as it serves to identify discrepancies between the current state and the desired state and thus enables people to recognize when additional effort or self-control is needed. Interventions that increase the frequency of progress monitoring are likely to promote behavior change [75].

According to literature reviews, in addition to setting a goal to promote behavior change, tracking its progress is just as crucial and effective to promote sustained behavior change [63]. Recent findings suggest that program interventions that elevate the frequency of progress monitoring are likely to induce behavior change [75]. Among the several benefits of self-tracking and reviewing tracked data are the following: patients can identify trends and correlations from their data and become more independent in managing their conditions; tracking can also provide opportunities for patient education [76].

The Low Carb Program offers an integrated tracking mechanism whereby patients can self-track their weight, food, mood, blood glucose levels, medications, sleep, blood pressure changes, cholesterol levels, insulin levels, and ketone levels. The platform also has many wearable devices and Bluetooth-enabled devices such as blood glucose meters or weighing scales, with which...
users can bring in data from devices to monitor trends and view interactions with other variables they may be tracking. The platform also nudges patients to embrace novel methods of tracking progress, for example, taking selfies, from which there are machine learning algorithms that can predict waist-to-hip ratios. The Low Carb Program reinforces behavior change by providing intelligent insights based on the tracked data into trends. The platform then nudges users when their tracked data are congruent with the trends required for their self-selected goal attainment.

**Memory Aids and User-Engagement**

One reason that behavioral change interventions do not deliver sustained effects is that they do not consider unintentional reasons for patients failing to adhere to their treatment plan. “Simply forgetting” is an example of unintentional nonadherence and serves as the most commonly reported reason for people not taking their medication [77-79]. Recent trials have demonstrated the benefits of telephone interventions to remind patients to pick up new prescriptions and talk about adherence [80,81]. However, utilizing staff to telephone patients is often cost prohibitive. Short message service or text message reminders are a less expensive way forward [82]. Research suggests that reminders can significantly increase patient attendance to clinic appointments [83] and reduce no-shows across health care settings. A recent paper showed that sending multiple notifications could improve attendance and text notifications improved attendance [84]. A text messaging support system was also shown to improve self-efficacy and adherence, engaging a classically difficult-to-reach group of young people [85]. Texting messages has proven to be a productive communication method for promoting behaviors that support weight loss in overweight adults [86]. Unfortunately, text-message interventions are difficult to implement in organizations that do not have a large-scale text-message distributor. For these reasons, a richer and more comprehensive set of behavior change techniques and technology-based interventions should be explored. The Low Carb Program architecture (Figure 1) utilizes email and in-app push notifications to encourage user’s continual engagement with the program. Users receive notifications when a new module is added or opened with that week’s “actions.” When they have a new reply from a member of the community, they also receive nudges to continue tracking their progress and when feedback is provided, for example, a new insight is generated from their tracked data.

**Figure 1.** Low Carb Program Behaviour Change platform architecture.
The language used within these notifications and nudges is also considered, building on Locke’s Goal Setting Theory [87]: Telling someone to “Try hard” or “Do your best” is less effective than “Try to get more than 80% correct” or “Concentrate on beating your best time.” The Low Carb Program behavior change architecture encourages health promoting behavior such as “Try to log more hours of sleep” when they are getting less than the recommended amount or “Continue your great blood glucose streak today, track your readings and stay within your targets.” These notifications have been tested within the architecture and optimized for different users within the behavior change programs.

In addition to the emails and push notifications running alongside the initial implementation phases of the education programs, notifications and emails are used to re-engage users who have not maintained their engagement within the programs. Users are nudged back into the program with tailored messages based on demographics, time elapsed, and their self-selected goal.

Automatic Features

**Personalized Content Contextualized Within Cultural Norms**

Research has previously demonstrated that gender, attitudes, subjective norms, perceived pros, different self-efficacy expectations, and habit strength are significantly associated with healthy eating habits [88]. The NICE guidelines in the United Kingdom actually state that information should be provided in an accessible format (particularly for people with physical, sensory, or learning disabilities and those who do not speak or read English) and educational materials should be translated, if needed [89]. The general consensus from the behavior change literature is that tailored interventions, which address an individual’s specific circumstances and concerns, should be more likely to stimulate change than untailored interventions. Studies have found that compared to untailored messages, tailored messages are more likely to be read and remembered; saved; discussed with others and perceived by readers as interesting, personally relevant, and written especially for them [90-93]. In addition, culturally tailored education, health-promoting information, and guidance to ethnic/linguistic minority groups has found to significantly improve their risk factors for progression to diabetes such as excessive weight and obesity [94] as well as glycemic control and diabetes knowledge compared to nonculturally tailored content [95-97]. Across several economically developed countries, including the United Kingdom, a number of ethnic groups experience higher levels of morbidity and mortality compared to the majority of the white European-origin population. Thus, creating culturally tailored health-promoting approaches is essential to improve health outcomes in people affected by diseases such as diabetes [97].

However, some literature highlights that although tailoring information delivered as part of behavior change interventions is a proven approach to enhancing message applicability, it is not the only approach to do so, and under many circumstances, it may not be the preferred choice, with some researchers citing insufficient evidence on the clinical effectiveness or cost-effectiveness of these adapted approaches [96,98]. This is where the Low Carb Program behavior change architecture may be advantageous over other more traditional methods of education delivery. As a Web and mobile behavior change platform, the education can be tailored as an individual signs up to the program with intelligent coding used to determine the tailored information that users subsequently see; this includes personalized education video modules delivered in native language and tailored to cultural norms determined by users’ ethnicity and language preferences, modified meal plans, and recipes tailored to dietary preferences and tailored content within the “lifestyle” area of the app based on their self-selected goal, age, and gender. The onboarding process also assigns the users a virtual buddy based on a “best fit” criteria, matching previous program completers as far as possible to the user’s gender, age, and disease profile and starting a medication regime and self-selected goal, increasing the perceived personal relevance and applicability of the information received within the behavior change intervention.

**Incremental Stages of Change**

Key recommendations from leading experts in the field of behavior change advise to start with small behavioral changes and build upon these incrementally [49]. In addition, insights from goal setting theories that support sustainable behavior change show that deadlines at stages need to be set, and they need to apply an appropriate amount of pressure while still being achievable [71]. The Low Carb Program architecture has a number of elements to support incremental changes. These stages of change do not exclusively facilitate the five transtheoretical model stages of change, but support change, aggregating over time to establish sustainable health-promoting behavior. The education modules are unlocked on a weekly basis, encouraging incremental behavior changes over time. Each education module is supported with an “action points” video, outlining suggested changes to make over the subsequent 7 days before the next module opens; these are precise actions with a set deadline by which the behavior modifications are to be made. By delivering the education in this way, the user will not be overwhelmed with lifestyle changes and instead, build on them week by week. The user also gets the opportunity to pause and restart their program at any time, closing opened modules and restarting their journey to take account of circumstances that may be impeding their ability to succeed.

**Web-Based and Mobile-Based Delivery of Information**

In order to address the growing burden of type 2 diabetes, prediabetes, and obesity as well as other chronic conditions, the promotion of wellbeing and behavior change interventions requires the delivery of scalable, engaging, and effective interventions aimed at sustainable behavioral change. The internet and pervasiveness of mobile devices offers an opportunity to reach this goal.

Research demonstrates that smartphone or Web apps offer significant benefits for patients in terms of patient care, education, and promoting behavior change, although the impact on several aspects of Web and mobile health delivery have not been clear, such as the cost-effectiveness and the adequacy of the infrastructure [99]. Burner et al [100] suggest that mobile
health is a promising approach to support patients with diabetes and their health outcomes, and others [101] suggested that the integration of mobile apps with diabetes management can be beneficial for the lifestyle of the patients by providing useful health and nutritional information. However, research points to the need of further studies to be undertaken to establish the effectiveness of in-person delivery compared to Web-based delivery of behavioral change programs [102].

Internet-based interventions have been utilized with success in behavior change interventions promoting mental fitness [103] and to deliver cognitive behavioral therapy for people experiencing symptoms of depression and anxiety [104]. One of the major advantages of internet-based interventions is their scalability, as they are able to engage hard-to-reach individuals and can reduce the cost of care by reducing therapists’ time [105].

From a diabetes perspective, technology-enabled diabetes self-management solutions significantly improve blood sugar levels (usually, these effects are observed at 3-12 months). The evidence from this systematic review indicates that organizations, policy makers, and health care payers should consider integrating these solutions in the design of diabetes self-management education and support services. In conclusion, digital (mobile phone) health solutions that incorporate evidence-based, behaviorally designed interventions can improve access to diabetes self-management education and ongoing support [106].

A meta-analysis of 13 studies including 6 randomized controlled trials found that there were statistically significant reductions of HbA1c levels in the intervention groups at the end of the studies. The researchers concluded that beyond improving HbA1c levels in patients with diabetes, the use of apps reinforces the perception of self-care by contributing better information and health education to patients. Patients also become more self-confident in their ability to manage their diabetes, mainly by reducing their fear of not knowing how to deal with potential hypoglycemia episodes that may occur [107]. One interesting observation of the researchers was from an exploratory subgroup analysis, which showed that having a clinical decision-making function in app-based interventions was not associated with a greater HbA1c reduction. This implies that the value of the app-based delivery of behavior change may be in the self-efficacy generated by the patients themselves using the app rather than its use as a replacement of their clinical reviews with their own health care professional teams.

The use of the Low Carb Program digital platform was never designed or intended to replace the intricate relationship between patient and health care professionals. Instead, it serves to augment or assist usual care, for instance, support behavior and lifestyle changes, which doctors feel inadequately trained to counsel patients on [108,109], despite the fact that the NICE guidelines specify giving lifestyle advice as a first-line intervention for diabetes, obesity, and high cholesterol levels.

Conclusions

The prevalence of obesity and subsequent noncommunicable, metabolic conditions such as type 2 diabetes, polycystic ovarian syndrome, Alzheimer Disease, and some cancers is drastically increasing. Patients diagnosed with diabetes have problems adhering to their treatments including medications and lifestyle change. Current health care systems are struggling to provide adequate training and education provisions necessary to empower patients to adequately self-manage their conditions. Patients’ behavior contributes significantly to their treatment success, which implies the necessity for behavioral solutions to achieve long-term sustainable change. However, there still remains uncertainty over how long the behavior change effects last and the optimal methods of delivery, in particular, the intricate interactions of program characteristics required to support sustainable change.

The key elements that make up the Low Carb Program are grounded in the COM-B model and evidence-based behavior change techniques that are shown to be effective in digital platforms for behavior change interventions that support weight loss, increase physical activity, and improve self-efficacy of chronic disease management.

The Low Carb Program is an effective tool to help support the initiation and maintenance of health promoting behavior in people with type 2 diabetes, as demonstrated by industry-leading health and engagement outcomes of education delivered using the platform architecture. There is a clear requirement for programs to be utilized as an adjunct to the current care pathways for people with chronic conditions and obesity. This poses further research questions, such as how digital interventions can be used within a blended model of health care and other long-term health conditions.

Regarding the Low Carb Program, further research is required to systematically test the different elements of the ecosystem for their influence on both engagement and sustainable change. For instance, it may be the case that certain individuals require access to a peer support community to see long-term change and health outcomes, while others may require access to data to see real-time feedback to reinforce behaviors. Due to the size of the population within the platform, there is also an opportunity to understand how to improve the effectiveness of support for patients to achieve and maintain remission.

Research is required to explore the biological and psychological characteristics, online social engagement, interactions, and social context of patients with type 2 diabetes who use the digital platform and achieve type 2 diabetes remission and maintenance compared to patients who do not. This could be used to develop risk stratification models that can be applied to effectively triage patients and identify the targeted support they need to achieve and maintain type 2 diabetes remission as well as further hyperpersonalize the behavior change ecosystem.
Acknowledgments

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Conflicts of Interest

CS is employed by Diabetes Digital Media, which runs the Low Carb Program.

Multimedia Appendix 1

Low Carb Program apps on desktop, iOS, and Apple Watch.

Multimedia Appendix 2

App screenshot: home.

References


Abbreviations

**COM-B:** capability, opportunity, motivation, and behavior  
**NHS:** National Health Service  
**NICE:** National Institute for Health and Care Excellence
Feasibility, Acceptability, and Impact of a Web-Based Structured Education Program for Type 2 Diabetes: Real-World Study

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Abstract

Background: Structured education for people with type 2 diabetes improves outcomes, but uptake is low globally. In the United Kingdom in 2016, only 8.3% of people who were referred to education programs attended the program. We have developed a Web-based structured education program named Healthy Living for People with type 2 Diabetes (HeLP-Diabetes): Starting Out (HDSO), as an alternative to face-to-face courses. A Web-based program gives people more options for accessing structured education and may help improve overall uptake.

Objective: The aim was to explore the feasibility and acceptability of delivering a Web-based structured education program (named HeLP-Diabetes: Starting Out) in routine primary health care and its potential impact on self-efficacy and diabetes-related distress.

Methods: HDSO was delivered as part of routine diabetes services in primary health care in the United Kingdom, having been commissioned by local Clinical Commissioning Groups. Quantitative data were collected on uptake, use of the program, demographic characteristics, self-reported self-efficacy, and diabetes-related distress. A subsample of people with type 2 diabetes and health care professionals were interviewed about acceptability of the program.

Results: It was feasible to deliver the program, but completion rates were low: of 791 people with type 2 diabetes registered, only 74 (9.0%) completed it. Completers improved their self-efficacy (change in median score 2.5, \(P=.001\)) and diabetes-related distress (change in median score 6.0, \(P=.001\)). Interview data suggested that the course was acceptable, and that uptake and completion may be related to nonprioritization of structured education.

Conclusions: The study provides evidence of the feasibility and acceptability of a Web-based structured education. However, uptake and completion rates were low, limiting potential population impact. Further research is needed to improve completion rates, and to determine the relative effectiveness of Web-based versus face-to-face education.

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KEYWORDS
diabetes mellitus, type 2; self-management; patient education; internet; digital divide; social class; health literacy; computer literacy
Introduction

Background
Diabetes self-management education (DSME) aims to help people develop the knowledge and skills to manage their physical and emotional health [1]. There is evidence that DSME can improve glucose control [2,3] and prevent complications [4].

The National Diabetes Audit data in the United Kingdom indicates that only 8.3% of people who were referred to structured education attended in 2016 [5]. Established programs involve face-to-face group courses. Qualitative studies suggest that some people find the face-to-face courses difficult to attend because of timings of courses, lack of transport, work and family commitments, or they do not like taking part in groups [6].

Computer-based self-management interventions bypass some of the barriers to face-to-face education [7,8]. A 2013 Cochrane systematic review of computer-based diabetes self-management interventions found a small effect on glycemic control, which was larger in the mobile phone app subgroup [7]. A 2015 systematic review of internet-delivered DSME found significant improvements in glycemic control and clinic attendance compared with usual care [8]. Some studies in the review also found improvements in self-efficacy [9], diabetes knowledge [10-13], exercise behaviors [14,15], and self-care behaviors [14,16]. A 2017 systematic review of the reviews of technology-enabled diabetes self-management interventions found that 18 of 25 reviews reported a significant reduction in glycated hemoglobin; however, a meta-analysis was not conducted because of heterogeneity in interventions and study designs [17]. Reviews of Web-based diabetes self-management interventions are promising, but there are also challenges including low uptake and engagement, that can limit effectiveness and need further research [18].

In light of this, we developed a Web-based structured education program for people with type 2 diabetes mellitus (T2DM), called Healthy Living for People with type 2 Diabetes (HeLP-Diabetes): Starting Out (HDSO). The content and aims of the HDSO program were based on an earlier intervention named HeLP-Diabetes. The key difference between HeLP-Diabetes and HDSO was that HDSO was aimed at people who were newly diagnosed, and so it followed a structured written curriculum with specific aims and objectives, as recommended by the National Institute for Health and Care Excellence [19] and required for general practitioners (GPs) to receive quality and outcomes Framework remuneration for referral [20]. HeLP-Diabetes was developed for people at any stage of their illness, and contained information on 560 webpages, which people could dip in and out of without following a linear pathway. A randomized controlled trial (RCT) showed HeLP-Diabetes to be effective and cost-effective [21,22].

The HDSO program is discussed in this paper. HDSO was a Web-based intervention developed for use on desktop computers and tablets. The program development took an iterative user-driven approach informed by the human-computer interaction (HCI) design lifecycle [23,24] and the Medical Research Council (MRC) guidance on developing and evaluating complex interventions. The development process consisted of 3 phases: (1) initial design; (2) usability testing with volunteers; and (3) in the wild testing in the National Health Service (NHS) with people newly diagnosed with type 2 diabetes. The 3 stages of the development process are described in detail elsewhere [25].

In line with the MRC framework on the development and evaluation of complex interventions, and current advice on development and evaluation of digital health interventions [26,27], following the development process, we undertook a formative evaluation of the program to explore its feasibility, acceptability, and apparent impact on users. As this was a digital health intervention, it was appropriate to draw on methods more familiar to computer science and HCI researchers than biomedical ones, including an emphasis on real-world data, with participants using the intervention as they would in routine practice, rather than as part of an overt research project. Such real-world studies, also known as in the wild studies, provide a contextual backdrop for determining the strengths and weaknesses of the intervention accurately [28]. This allows digital health interventions to be tested by representative users attempting representative tasks in representative environments and makes any recommendations for further research user-led rather than researcher-led [29]. Studies in the wild can reveal complex and unexplained phenomena that can only emerge in the natural setting of the intervention [30]. They benefit from the strong external validity achieved by delivering the intervention as it will be used in routine practice, and not as part of an overt research project. In the wild studies are a necessary precursor to RCTs to determine effectiveness and cost-effectiveness as they allow for further refinement and optimization of the intervention, including the surrounding delivery package provided by health care professionals (HCPs), and a preliminary estimation of any associated changes in outcomes associated with the use of the intervention [27]. Such studies are not intended to, and cannot, determine any causal relationship between observed changes and the intervention tested.

In this study, we took advantage of the naturalistic, real-world setting and data provided by 5 Clinical Commissioning Groups (CCGs) commissioning HDSO in the NHS in the United Kingdom, as part of an overall menu of DSME offered to people with T2DM.

Objectives
The overall aim of the study was to determine the feasibility, acceptability, and potential impact of delivering a Web-based structured education program (HDSO) in routine primary health care. Specific objectives were as follows:

1. Describe people’s use of the program, including numbers (proportions) registering, starting, and completing the program.
2. Determine the demographic, clinical, and psychological factors associated with completion of the program.
3. Investigate the impact of the program on users’ levels of diabetes-related distress and diabetes self-management self-efficacy (DSMSE)
4. Explore the views of people with T2DM and health professionals about the program, including reasons for engagement or nonengagement.

**Methods**

This was a mixed method study with a strong emphasis on real-world data and external validity. Quantitative data included the proportion of people starting and completing the program, and diabetes-related distress and diabetes self-management self-efficacy scale (DSMSES) questionnaire scores. Interviews with program users and HCPs provided further insights.

**Setting**

The study was conducted during implementation of the program in the NHS. People with T2DM in GP practices in 5 London CCGs registered for the program as an NHS service, rather than as research participants. This meant that we were unable to randomize participants to an intervention or control group, or collect clinical outcome data as we did not have access to their clinical records. However, this meant that the participants more accurately reflected the population of interest (people with type 2 diabetes treated in NHS primary health care) [31]. The total population of the 5 CCGs was 1,384,000. The population was diverse, with over 30% of the population from black and minority ethnic (BAME) groups [32]. All 5 CCGs were in the top quartile for deprivation in England [33]. RCTs are more limited in their external validity because of the characteristics of people who volunteer, and the inclusion and exclusion criteria in trial protocols [34,35].

**Ethical Approval and Consent to Participate**

Ethical approval was granted by the Health Research Authority (HRA; reference number 159488). The program was offered to people as part of service delivery, so the use of the data on registrations, activities, and questionnaire scores generated through the Web-based program was permissible under the HRA clause that the secondary use of information collected in the course of normal care is generally excluded from the Research Ethics Committee review [36] and specific informed consent to participate in research is not required. However, everyone who volunteered to be interviewed provided full informed consent before being interviewed and was aware that the interviews were for research purposes.

**Participants for the Intervention**

The target population was adults with T2DM. Referral was not limited to people who were newly diagnosed, as many people only become ready for structured education after having come to terms with the diagnosis [37-39]. Referral therefore included people at any stage of diabetes to enhance uptake. As this was to terms with the diagnosis [37-39]. Referral therefore included people at any stage of diabetes to enhance uptake. As this was not appropriate for the study design.

**Participants for Interviews**

Everyone who registered for the program was invited to take part in interviews. We also invited HCPs working at practices who referred a high or low number of people with T2DM, and staff employed by the CCGs to support implementation of the program.

**Recruitment**

The program was offered to people with T2DM using referral packs sent by practices who identified eligible people from electronic medical records searches, text messages, flyers, or in consultations with doctors or nurses. In 1 CCG group, there was a dedicated Change Manager who visited practices to talk to staff and people with T2DM about the program. Data on the number of people who were offered the program and declined were not recorded by practices.

People with T2DM were asked to telephone or email the HDSO team, to be registered, and have baseline demographic and clinical data collected (see Outcome Measures). A username and password was emailed to users, along with contact information in case of problems. However, this process of telephone registration proved to be time consuming and caused delay in people being able to access the program. The registration process was therefore modified (see Multimedia Appendix 1) so that users had the option of Web-based self-registration. People with T2DM were given the registration webpage details at referral by HCPs and in referral packs, which they could access to enter their demographic details, and register a username and password to use to log into the program.

**Consent Procedures**

**Quantitative Data (Collected as Part of Service Evaluation)**

Users were informed that anonymized data on their use of the program and questionnaire scores were automatically collected by the website for service development. Users were asked to email the team if they did not wish their data to be used. Data were automatically pseudoanonymized and stored locally on a secure network drive. The data were password protected and were only made available to appropriate members of the research team, in keeping with University College London data protection regulations.

**Qualitative Data**

People with T2DM and HCPs who expressed interest in the interviews at registration were contacted by the lead researcher (SP) and given written information about the study and the opportunity to ask questions. After informed consent was received, audiorecorded interviews were undertaken via telephone or in person. Consent forms were stored securely and separately from questionnaire data and audio recordings.

**Intervention**

The intervention was a Web-based structured self-management program for people newly diagnosed with T2DM. It is described in detail in Multimedia Appendix 1, using the Template for Intervention Description and Replication (TIDier) checklist [40], and summarized here.
The content was based on HeLP-Diabetes [41], an online self-management intervention for everyone with T2DM. The theoretical basis was the Corbin and Strauss theory that self-management involves 3 tasks: managing the disease process, managing the emotional consequences, and managing the changes that occur in daily life [42]. HDSO was a 4-session program, comprising 4 or 5 modules per session, and questionnaires measuring diabetes-related distress and diabetes self-management self-efficacy score (DSMSES) in weeks 1 and 4. Each module took about 15 to 20 min to complete (see Table 1). Information was presented using text, images, and videos (see Multimedia Appendix 2). Email reminders were sent to users if they had not logged on for 7 days or more.

Table 1. Healthy Living for People with type 2 Diabetes: Starting Out program sessions and modules.

<table>
<thead>
<tr>
<th>Session title</th>
<th>Module title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1: Getting started</td>
<td>• Module 1: An introduction to type 2 diabetes</td>
</tr>
<tr>
<td></td>
<td>• Module 2: Self-assessment</td>
</tr>
<tr>
<td></td>
<td>• Module 3: Eating well for diabetes</td>
</tr>
<tr>
<td></td>
<td>• Module 4: Becoming more active</td>
</tr>
<tr>
<td>Week 2: Self-management</td>
<td>• Module 1: Taking control</td>
</tr>
<tr>
<td></td>
<td>• Module 2: Protecting my body and mind</td>
</tr>
<tr>
<td></td>
<td>• Module 3: Handling my feelings</td>
</tr>
<tr>
<td></td>
<td>• Module 4: Making changes (including My goals and plans)</td>
</tr>
<tr>
<td>Week 3: Improving my health and well-being</td>
<td>• Module 1: Making the most of the National Health Service</td>
</tr>
<tr>
<td></td>
<td>• Module 2: Medication</td>
</tr>
<tr>
<td></td>
<td>• Module 3: Reducing the risks of heart attacks and stroke</td>
</tr>
<tr>
<td></td>
<td>• Module 4: Updating my goals and plans</td>
</tr>
<tr>
<td></td>
<td>• Module 5: Understanding my moods</td>
</tr>
<tr>
<td>Week 4: Taking control of my diabetes</td>
<td>• Module 1: My diabetes review</td>
</tr>
<tr>
<td></td>
<td>• Module 2: Looking after my feet</td>
</tr>
<tr>
<td></td>
<td>• Module 3: Reviewing my goals and plans</td>
</tr>
<tr>
<td></td>
<td>• Module 4: Self-assessment</td>
</tr>
<tr>
<td></td>
<td>• Module 5: Moving on—the beginning of the end</td>
</tr>
</tbody>
</table>

Users were provided with their scores from the diabetes-related distress and DSMSES questionnaires, and individualized feedback developed by GPs and Diabetes Specialist Nurses (DSNs). The feedback in week 1 helped users identify gaps in knowledge or skills, and signposted to sessions of the program that could help them improve. The feedback in week 4 focused on improvements made and directed users to the HeLP-Diabetes website for ongoing support. Users were asked to set specific, measurable, achievable, realistic, time-bounded goals [43], and they were given opportunities to review their goals.

**Outcome Measures**

The data collected reflect the objectives of the study (see Table 2).

The server side of the website automatically collected anonymized data on user ID, date and time of login, and pages visited. These were used to determine how many people registered for and completed the program.

Data on personal characteristics included the following: (1) age; (2) gender; (3) ethnicity; (4) highest educational attainment; (5) internet access (home or public); (6) information technology skill level (basic, intermediate, or advanced; (7) duration of diabetes; (8) previously offered face-to-face education (yes or no); (9) previously attended face-to-face education (yes or no); and (10) diabetes management (lifestyle alone, or tablets and/or insulin). Education level was categorized using UK and US qualifications, and the International Standard Classification of Education [44].

Data on change in diabetes-related distress and self-efficacy in self-management were collected using the Problem Areas in Diabetes (PAID) [45] and DSMSES [46] questionnaires.
Table 2. Outcome measures.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measure</th>
<th>How and when collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>People’s use of the program, including numbers (proportions) registering, starting, and completing the program</td>
<td>Number of people with T2DM who registered with the program, started the program, and completed it</td>
<td>Data collected on the server side of the website throughout the study and analyzed at the end of the study</td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Age</td>
<td>Collected over the telephone by the HeLP program team, or using a Web-based questionnaire at registration</td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Highest educational attainment</td>
<td></td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Information technology skill level (basic, intermediate, or advanced)</td>
<td></td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Duration of diabetes (&lt;1 year/&gt;1 year)</td>
<td></td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Offered face-to-face education (yes or no)</td>
<td></td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Attended face-to-face education (yes or no)</td>
<td></td>
</tr>
<tr>
<td>Characteristics of people with T2DM registering for the program</td>
<td>Diabetes management (lifestyle alone or tablets and/or insulin)</td>
<td></td>
</tr>
<tr>
<td>Effect of the program on diabetes-related distress and DSMSES&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Change in Problem Areas in Diabetes and DSMSES questionnaire scores</td>
<td>Questionnaires completed online by users at baseline (week 1 of the program) and follow-up (week 4 of the program)</td>
</tr>
<tr>
<td>View of people with T2DM and health professionals about the program, including factors affecting acceptability of the program</td>
<td>Qualitative interview data from interviews with people with T2DM and HCPs&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Interviews conducted after quantitative data collected</td>
</tr>
</tbody>
</table>

<sup>a</sup>T2DM: type 2 diabetes mellitus.  
<sup>b</sup>DSMSES: diabetes self-management self-efficacy scale.  
<sup>c</sup>HCP: health care professional.

**Problem Areas in Diabetes**

Diabetes-related distress was chosen as an outcome measure as there is a strong correlation between diabetes-related distress and diabetes self-care behaviors, and strong predictive validity for glycemic control [47]. Furthermore, at least 4 in 10 people with diabetes experience diabetes-related emotional distress [48], and addressing emotional distress should be part of comprehensive care for everyone with T2DM [49]. PAID has 20 items on areas that can cause difficulty including social situations and social support [50]. Scores range from 0 to 100, with higher scores indicating more distress. A score of more than 40 is clinically significant [45]. The PAID questionnaire has been shown to have high reliability and validity [51].

**Diabetes Self-Management Self-Efficacy**

Perceived self-efficacy is an individual’s perception of their ability to undertake a task [52]. Diabetes requires a high level of self-efficacy because of the high number of self-management tasks required to prevent complications [46]. Perceived self-efficacy is a reliable predictor of initiation of healthy lifestyle behaviors [53,54]. The 20-item DSMSES questionnaire measures the individual’s expectations of being able to engage in self-management activities such as keeping to a healthy eating plan when away from home [46]. A self-efficacy score of 0 indicates no self-efficacy and a score of 150 indicates very high self-efficacy. The DSMSES questionnaire has strong face validity, and it is a reliable scale for measuring self-efficacy in diabetes research [46].

A total of 13 interviews were carried out by SP (a female academic GP) and 4 interviews were conducted by RB (a male HCI specialist). The interviews lasted between 30 and 60 min. Both interviewers used a topic guide containing questions addressing the aim of the study, including the experience of diagnosis and information seeking; registering for the program; factors that may have affected engagement with the program such as problems using the website; barriers to starting or working through the program; and features or content of the program they liked or disliked. The topic guide for HCPs was tailored for the different roles the staff had in promoting and referring to the program, for example, GPs and nurses were asked about their experiences of discussing HDSO during clinical encounters with people with T2DM, while professionals in nonclinical roles were asked about how they supported clinicians with referring people to the program. Despite using the same topic guide, the different professional roles and interviewing techniques of the 2 interviewers may have led to different responses from the people who were interviewed.

**Analysis**

**Quantitative**

Data on the number of people registered for the program and the pages they visited were used to calculate the proportions of people registered for the program who started and completed it. Web-based questionnaire scores were analyzed, and as they were not normally distributed, median and lower and upper quartiles of the scores were calculated. Nonparametric Wilcoxon signed-rank tests were used to determine whether there were any significant differences between the start (week 1) and end (week 4) of the program.
Characteristics of completers and noncompleters of the program were compared using Chi-square tests (or Fisher exact tests where appropriate) to see if there were any factors associated with completion. Mean baseline questionnaire scores of completers and noncompleters were compared using t tests. Statistical analyses were carried out using SPSS Statistics version 22 (IBM).

Qualitative

Interviews were recorded on a digital audiorecorder and transcribed verbatim by a professional transcription company. Transcripts were anonymized and checked for accuracy by the lead author (SP). Interview findings were analyzed thematically to explore the perspectives of people with T2DM and HCPs, with a particular focus on exploring similarities and differences between perspectives of professionals and people with T2DM [55,56].

Data were analyzed using the following steps: (1) The transcripts were read and re-read by the lead author to allow familiarization with the overall content; (2) the lead author then re-read the transcripts line by line looking for initial codes (text which was relevant to the research question). Codes were highlighted in MS Word; (3) once the lead author was confident that all the data relevant to the research question had been coded, these initial codes were copied and pasted into a separate document. Codes were compared with look for similarities and differences. Similar codes were grouped into potential themes; (4) to maximize rigor, transcripts, codes, and themes were also read by and discussed with FS, EM, and qualitative researchers attending 2 data clinics. The data clinics comprised exploration of the interpretations of the data, and consideration of refinements to existing themes and generation of new themes with 6 qualitative researchers from a range of disciplines (including health services research, sociology, and psychology). After these discussions with colleagues, the transcripts were re-read by the lead author (SP) who refined the themes and then discussed them with FS and EM until consensus was reached.

Applying Concepts of Normalization Process Theory to the Data

Once the themes were agreed upon, it became clear that some of the themes related closely to the constructs from Normalization Process Theory (NPT). NPT is concerned with making new interventions routine practices in health care (embedding) and sustaining embedded practices (integration) [57]. The theory operationalizes the work of implementation as 4 constructs: (1) coherence (sense making of the intervention); (2) cognitive participation (commitment of the participant); (3) collective action (the work participants do to make the intervention function); and (4) reflexive monitoring (how participants appraise the intervention). We used knowledge of the NPT constructs, the intervention, and the intervention setting to define intervention-specific meanings for each construct. We then mapped these constructs to the appropriate themes from the interviews. This 2-stage process of analysis has been used in other qualitative studies of complex interventions in primary health care [58] and provides a deeper analysis, by allowing researchers to embed the findings in existing theoretical concepts and in this way provide a theoretically informed interpretation in relation to implementation.

Results

Use of the Program

A total of 791 people registered for the program, 188 started it (completed at least the first module of the first session), and 74 completed all 4 sessions (see Multimedia Appendix 3).

Characteristics of Participants

Data on the characteristics of people with T2DM is given in Table 3. A total of 791 people with T2DM registered to use the program. Demographic data were self-reported at registration (by either telephone or Web-based questionnaire), and there is a large amount of missing data because of nondisclosure, particularly on previous offer and attendance at structured education and diabetes management. The average age of people with T2DM registering to use the program was 57.6 years, over half (316/586, 53.9%) were male, over half (310/605, 51.2%) were from BAME backgrounds, and nearly one-third (181/602, 30.1%) had no qualifications beyond high school leaving age (Table 3). Just over one-quarter (170/589, 28.9%) had had their diabetes <1 year, and while half (193/394, 49.0%) recalled being offered face-to-face education, only 9.4% (37/394) had attended it.

Characteristics of Completers

The only factors associated with completion were duration of diabetes ($P=.04$), and having been offered ($P=.001$) and having previously attended ($P=.002$) face-to-face education. Having advanced information technology skills was not associated with completing the program (see Table 3).
### Table 3. Characteristics of registered people with type 2 diabetes mellitus (T2DM), completers, and noncompleters.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Registered people with T2DM Mean (SD) or n (%)</th>
<th>Completers Mean (SD) or n (%)</th>
<th>Noncompleters Mean (SD) or n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>57.6 (12.9)</td>
<td>56.7 (13)</td>
<td>56.8 (20.9)</td>
<td>.63</td>
</tr>
<tr>
<td>Sex (male)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>287 (47.4)</td>
<td>37 (51)</td>
<td>250 (46.9)</td>
<td>.53</td>
</tr>
<tr>
<td>Black</td>
<td>206 (34.0)</td>
<td>24 (33)</td>
<td>182 (34.1)</td>
<td>N/A</td>
</tr>
<tr>
<td>Asian</td>
<td>67 (11.1)</td>
<td>8 (11)</td>
<td>59 (11.1)</td>
<td>N/A</td>
</tr>
<tr>
<td>Mixed</td>
<td>20 (3.3)</td>
<td>2 (3)</td>
<td>18 (3.4)</td>
<td>N/A</td>
</tr>
<tr>
<td>Other</td>
<td>17 (2.8)</td>
<td>0 (0)</td>
<td>17 (3.2)</td>
<td>N/A</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>8 (1.3)</td>
<td>1 (1.4)</td>
<td>7 (1.3)</td>
<td>N/A</td>
</tr>
<tr>
<td>GCSE/high school diploma</td>
<td>181 (30.1)</td>
<td>19 (28.4)</td>
<td>162 (32.9)</td>
<td>.45</td>
</tr>
<tr>
<td>Basic or intermediate information technology skills</td>
<td>406 (71.5)</td>
<td>46 (71)</td>
<td>360 (71.6)</td>
<td>.89</td>
</tr>
<tr>
<td>Diabetes duration &lt;1 year</td>
<td>170 (28.9)</td>
<td>32 (45.1)</td>
<td>138 (28.5)</td>
<td>.4</td>
</tr>
<tr>
<td>Offered face-to-face education</td>
<td>193 (49.0)</td>
<td>42 (69)</td>
<td>151 (45.3)</td>
<td>.001</td>
</tr>
<tr>
<td>Attended face-to-face diabetes education</td>
<td>37 (9.4)</td>
<td>11 (18)</td>
<td>26 (7.8)</td>
<td>.002</td>
</tr>
<tr>
<td>Lifestyle alone (ie, diet and physical activity)</td>
<td>111 (28.2)</td>
<td>19 (31)</td>
<td>92 (27.7)</td>
<td>.22</td>
</tr>
<tr>
<td>Tablets and/or insulin</td>
<td>283 (71.8)</td>
<td>43 (69)</td>
<td>240 (72.3)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*a*Refers to mean (SD).

bN/A: not applicable.
cGCSE: general certificate of secondary education.

### Impact of Completing the Program

Median DSMSES (self-efficacy) scores were significantly higher (better) in week 4 compared with week 1 (see Table 4).

### Table 4. Baseline and follow-up questionnaire scores.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Week 1 median (LQ, UQ)</th>
<th>Week 4 median (LQ, UQ)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAIDc</td>
<td>7.50 (4.00, 11.25)</td>
<td>5.00 (2.00, 9.00)</td>
<td>.001</td>
</tr>
<tr>
<td>DSMSESd</td>
<td>101.50 (78.00, 119.25)</td>
<td>107.50 (95.50, 130.50)</td>
<td>.001</td>
</tr>
</tbody>
</table>

aLQ: lower quartile.
bUQ: upper quartile.
cPAID: problem areas in diabetes.

### Views of People With T2DM and Health Professionals About the Program

Interviews were conducted with 17 participants (10 people with T2DM and 7 HCPs). Of the 10 people with T2DM, 7 had completed the program and 3 had registered for the program, but not completed it. Other characteristics are listed in Multimedia Appendix 4. Of the HCPs, 3 were DSNs, 2 were GPs, 1 was a HeLP-Diabetes Change Manager (employed by the local CCG to liaise with the GP Practices and promote the HDSO program) and 1 was a CCG Project Officer (providing support to senior CCG project managers). The data from people with T2DM and HCPs are combined in the results, as many of the subthemes are shared. Where a subtheme is unique to a particular group, this is stated in its description and illustrated with a quote.

Four major themes emerged from the analysis of the interview data, each with a number of subthemes (see Table 5). We mapped 2 of the major themes to NPT constructs. NPT explains whether and how complex interventions become embedded in health care practice. Hence, the themes that mapped to the
constructs were those that related to health care system factors (the value of discussion between HCPs and people with T2DM about DSME at the time of referral; and improving uptake of the HDSO program) rather than factors that related to people with T2DM or the program. The NPT constructs and the HDSO-specific meanings we defined for each construct are listed in Table 6. The themes and subthemes we mapped to the constructs are listed in Table 7.

Table 5. Major themes and subthemes from the qualitative data.

<table>
<thead>
<tr>
<th>Major theme</th>
<th>Subthemes</th>
</tr>
</thead>
</table>
| Lack of discussion between HCPs\(^a\) and people with T2DM\(^b\) about DSME\(^c\) at the time of referral | • Poor understanding of structured education by professionals  
• Lack of time to discuss structured education |
| Factors affecting people’s motivation toward DSME | • Competing priorities  
• Not being ready for information  
• Perceived lack of relevance  
• Perceived lack of need |
| User experience and advantages of a Web-based education program | • Convenience  
• Format  
• Emotional support |
| Improving uptake of the HDSO\(^d\) program | • Supporting HCPs with referrals  
• Changes to the program |

\(^a\)HCP: health care professional.  
\(^b\)T2DM: type 2 diabetes mellitus.  
\(^c\)DSME: diabetes self-management education.  
\(^d\)HDSO: Healthy Living for People with type 2 Diabetes: Starting Out.

Table 6. Normalization process theory constructs and Healthy Living for People with type 2 Diabetes: Starting Out–specific meanings of the constructs.

<table>
<thead>
<tr>
<th>Constructs</th>
<th>HDSO(^a)–specific meaning of the constructs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Coherence (sense-making of the intervention; anchoring in experience)</td>
<td>How well HCPs(^b) understood the HDSO program and how it was different to face-to-face courses. Whether HCPs valued the projected benefits of the HDSO program to people with T2DM(^c) and the primary care team, and whether they developed a shared sense of benefit of the program.</td>
</tr>
<tr>
<td>2. Cognitive participation (engagement and commitment of the participant)</td>
<td>The engagement of HCPs in the HDSO program, whether they thought it was a good idea, and whether they were willing to invest time, energy, and work into it.</td>
</tr>
<tr>
<td>3. Collective action (the work participants do to make the intervention function)</td>
<td>The additional work for practices of promoting the program (including sending recruitment packs or text messages, and printing and displaying flyers in waiting areas). The work for HCPs of fitting discussions about DSME and referrals to the HDSO program into time-limited consultations. Any additional training needed to be able to explain and demonstrate the program, and send referrals.</td>
</tr>
<tr>
<td>4. Reflexive monitoring (how participants reflect on or appraise the intervention)</td>
<td>Whether HCPs perceived the worth of the HDSO program, and its impact on their other tasks.</td>
</tr>
</tbody>
</table>

\(^a\)HDSO: Healthy Living for People with type 2 Diabetes: Starting Out.  
\(^b\)HCP: health care professional.  
\(^c\)T2DM: type 2 diabetes mellitus.
Table 7. Mapping of themes onto normalization process theory constructs.

<table>
<thead>
<tr>
<th>Major theme and subtheme</th>
<th>NPT(^a) construct</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major theme 1: Lack of discussion between HCPs(^b) and people with T2DM(^c) at the time of referral</strong></td>
<td></td>
</tr>
<tr>
<td>Poor understanding of structured education by professionals</td>
<td>Coherence</td>
</tr>
<tr>
<td>Lack of time to discuss structured education</td>
<td>Collective action</td>
</tr>
<tr>
<td><strong>Major theme 4: Improving uptake of the HDSO(^d) program</strong></td>
<td></td>
</tr>
<tr>
<td>Familiarizing professionals with the program</td>
<td>Collective action; reflexive monitoring</td>
</tr>
<tr>
<td>Health assistant or administrative assistant-led referral</td>
<td>Collective action</td>
</tr>
</tbody>
</table>

\(^a\)NPT: normalization process theory.  
\(^b\)HCP: health care professional.  
\(^c\)T2DM: type 2 diabetes mellitus.  
\(^d\)DSME: diabetes self-management education.  
\(^e\)HDSO: Healthy Living for People with type 2 Diabetes: Starting Out.

**Lack of Discussion Between Health Care Professionals and People with Type 2 Diabetes Mellitus About Diabetes Self-Management Education at the Time of Referral**

HCPs and people with T2DM both expressed a sense of dissatisfaction about the way structured education was discussed at the time of referral. When people with T2DM described how they were informed about structured educations they explained that they received written confirmation of referral to an education program, but no discussion with HCPs about what the education program involves or the benefits of attending.

*How much information did you get from your GP and your practice nurse about the diabetes when you first got it? [Interviewer]*  
*I don’t remember getting that much, just referrals. I got it in a letter. She didn’t call me and say, you have diabetes, so you have tipped over and we are now referring you.* [Participant 4, 63-year-old female noncompleter, duration of illness 1-5 years]

**Poor Understanding of Structured Education by Professionals**

People with T2DM did not express views on why discussions about DSME with HCPs were limited, but HCPs identified contributing factors as being lack of time in consultations (collective action) and poor HCP understanding of the nature and benefits of structured education (cognitive participation):

*The mode of referral played a part in how effectively people took up structured education programs. And a lot of this is due to, I think there are two main facts. One, lack of knowledge about what structured education is amongst health care professionals, and also the time and type of engagement that people have when engaging with patients who have been newly diagnosed with diabetes.* [Participant 14, GP, and Clinical Director]

**Lack of Time to Discuss Structured Education**

All the HCPs who were interviewed agreed that there is no opportunity for significant discussion of DSME, as there is not enough time in the consultation to explain or (in the case of the HDSO program) demonstrate the program, as well as manage the person’s other problems:

*I think you’re asking the impossible. GPs have a few minutes, the practice nurses probably have 20 minutes, at best... [Participant 17, Diabetes Specialist Nurse]*

**Factors Affecting People’s Motivation Toward Diabetes Self-Management Education**

We asked both HCPs and people with T2DM about factors which may have contributed to whether people who registered for the program used it or not. We were particularly interested in why people registered for the program but did not complete it. All 10 of the people with T2DM who were interviewed registered for the program. Then, 3 started the program but did not complete it, and 7 started the program and did complete it. Both completers and non-completers described how competing priorities got in the way of having time to work through the program. HCPs and people with T2DM questioned whether people at an earlier stage of their illness might not feel ready for the information in the program or perceive the information as lacking relevance to them.

**Competing Priorities**

People described having other priorities competing for their time when they were working through the program, which meant stopping and starting and having long periods of not using the program at all. Competing priorities included work, as most people with T2DM who were interviewed were working age, and family responsibilities.

*And yes, from time to time I got phone calls which were helpful and it just, again, just sort of urge you to get on to the program if you’d had a long gap from going on to doing it, yes. [Participant 5, 64-year-old female completer, duration of illness 1-5 years]*

*So was that something that you found difficult? Because what we try and get people to do, is to do a session a week or a session every two weeks so that*
Not Being Ready for Information

HCPs expressed their concern that people with T2DM at an earlier stage of the illness do not feel the need to take self-management seriously yet. They described how people with T2DM without complications may feel well and have no symptoms, and so are not ready or willing to take on information about changing their lifestyle through self-management.

If we’re talking about complications it’s too far away for them to think about, if we’re talking about behaviour change they think... It’s a disease with no symptoms, largely, and I think that that’s the massive issue. I think that people take it seriously when things start to go wrong. [Participant 17, Diabetes Specialist Nurse]

Perceived Lack of Relevance

Some people with T2DM saw themselves as newly diagnosed even if they had diabetes for more than a year, because they were not yet taking medication to manage the illness. These people talked about how they perceived much of the information in the program as being more relevant to people taking medication and less relevant to them:

A lot of the online (program) also I think targeted people who are on medication so much as a sort of a newly diagnosed I don’t know how helpful it was to be honest with you. Because some of it I just felt didn’t apply to me. [Participant 5, 64-year-old female completer, duration of illness 1-5 years]

Perceived Lack of Need

Some people expressed that they did not feel the need for more information about diabetes self-management, because they believed they already knew what they needed to know, particularly about diet changes:

They probably could give me further hints but at the same time, I just feel I really do know what to do—don’t eat any carbs or sugars or anything and you’ll keep it under control. [Participant 4, 63-year-old female noncompleter, duration of illness 1-5 years]

User Experience and Advantages of a Web-Based Education Program

Despite the low completion rate, people with T2DM reported enjoying being able to work through the program at their own pace, as opposed to being given a lot of information at one time on a 1-day face-to-face course. People also talked positively about the way information was presented in the program using text, graphics, and videos (particularly videos of others living with the illness). This is crucial in understanding the importance of giving people with T2DM a Web-based option for DSME.

Convenience

People with T2DM described a preference for taking their time to work through the large amount of information contained in a self-management education course, as opposed to processing information given in a 1-day face-to-face course:

I think that was the other thing which was really good about this site, is that with the DESMOND [Diabetes Education and Self-Management for Ongoing and Newly Diagnosed], it’s all there in one day, like packed into a day. And... I mean, yes, they... you go away with nice little booklets and that, but I don’t... I swear to God; I haven’t really even looked at it. Whereas this, it’s, sort of, like, telling you that you can make tiny little changes. [Participant 1, 61-year-old female completer, duration of illness 1-5 years]

Format

People with T2DM described enjoying the variety of formats in which the information was presented, including text, graphics, and videos. In particular, people with a preference for learning using visual information appreciated the videos accompanying the text:

The videos explain things... some things really, really well. I think everybody is different, aren’t they? Some people work well with visual stuff, and other people work well with written stuff. I’d always think if you read and look, you know, it gets into the brain. You know, I think those things were really, really good. [Participant 8, 60-year-old female completer, duration of illness less than 1 year]

Emotional Support

Some people with T2DM found the support provided by the program with managing the emotional side of the illness useful, particularly watching the videos of others talking about living with the illness. This emphasizes the need for structured education programs to acknowledge the emotional challenges of diabetes self-management and the need to include emotional support in courses:

I thought it concentrated a lot about your emotional side. And listening to some of the other people, and I thought, oh, it’s not just me who was annoyed. I know a lot of people got upset, and, I mean, I didn’t get upset, I was just annoyed. And so I felt that there were similar experiences, you know, other people probably, it’s not just me who was feeling that way. The other people reacted probably similar when they found out that they were diabetic. [Participant 1, 61-year-old female completer, duration of illness 1-2 years]
Improving the Uptake of Healthy Living for People With Type 2 Diabetes: Starting Out Program

The HCPs who were interviewed had a number of suggestions for improving the uptake of the HDSO program. These included supporting professionals to improve the discussion at the time of referral by encouraging them to familiarize themselves with the program before discussion with people with T2DM (collective action and reflexive monitoring); and delegating some of the workload by allowing health care assistants or administrative assistants to refer people to the program (collective action). Other suggestions were made by people with T2DM about changes to the program to provide more personalized information, and making the program available to access on smartphones.

Supporting Health Care Professionals With Referrals

As discussed above, all the HCPs expressed that there is not enough time in a clinical consultation to discuss and demonstrate the program to people with T2DM at the time of referral. Suggestions were therefore made about supporting HCPs with referral, including allowing health care assistants and administrative staff to refer people to the program before or after their clinical consultation with a doctor or nurse, when there is more time for discussion:

Ideally, if there were a health care assistant or an admin person who could catch the patient separately either before or after the appointment to show them the website and sign them up, I think that would work really well. [Participant 16, Diabetes Specialist Nurse]

Changes to the Program

Some people with T2DM expressed the need for more personalized information, particularly specific diet information on what they should and should not be eating. People mentioned that they would like to be able to use the program on their mobile phones, for convenience, and that they were unable to do so with the current format:

I, sort of, got on it and go through it, because I'm in that mood. Then go through two of the modules, let's say, from part four. I've done part four and part five today. But when I wanted to [unclear] on my mobile phone, when I was [unclear], I thought: right, no I'll sit down on the phone, you know. I jumped on my phone to do the modules. I found it, kind of, difficult. I find I had to re-start the modules on my mobile phone. It wasn't... it wasn't, sort of... it didn't jump out at me and I found it quite frustrating. [Participant 7, 47-year-old male completer, duration of illness <1 year]

Discussion

Principal Findings

This study found that it is feasible to deliver Web-based structured education in the NHS; a wide demographic can use it; and it may improve self-efficacy and diabetes-related distress. The quantitative data showed that there were problems with uptake and completion, with completion positively associated with duration of diabetes <1 year, and self-report of having been offered and/or attended structured education previously. The qualitative data helped us to explore the low uptake more fully. Findings from interviews with people with T2DM and health professionals suggested that professional factors, personal factors for people with T2DM, and program factors affected program acceptability and attrition. More research is needed on improving uptake and determining the relative effectiveness and cost-effectiveness of Web-based and group-based structured education.

Strengths and Limitations

The strengths of this study include the strong external validity, with our data drawn from real-world experience of implementation and delivery of the service within routine primary health care. Other strengths include the use of a mixed method, with quantitative data on uptake, usage, and outcomes, and qualitative data to explore the underlying reasons for these observed data, and the use of theory (NPT) in the data analysis. Using NPT allowed us to make a theoretically informed interpretation of the qualitative data in regard to implementation. The design was appropriate for the study objectives, namely, to determine acceptability, feasibility, and apparent impact of the program. Acceptability and feasibility related not only to patients but also to health professional factors, which NPT allowed to explore more deeply.

It is important to state clearly that this design cannot be used to determine effectiveness of the intervention, nor can any causal links be inferred. Determining effectiveness and ascribing a causal impact of an intervention requires an RCT design, with an appropriate comparator, and a sample size calculation. In light of the multiple tests undertaken, it is possible that the observed associations between likelihood of completion and duration of diabetes, and self-reported offer or attendance at structured education are because of chance. A specific weakness of our study was the lack of clinical outcome data and our reliance on proximal outcomes collected through self-reported outcome measures. This was a direct result of our emphasis on external validity and real-world data, so that people with T2DM used the program as part of their routine NHS care, and not as part of a research study. Hence, we could not obtain formal informed consent, except from those who participated in interviews, and as such, it would not have been ethical to have access to clinical data. A further limitation was our inability to invite people who were offered the program but did not register to use it to take part in interviews because of the ethical limitations. Interviewing these people would have helped us to understand why some people do not want to use Web-based structured education.

Comparison With Previous Work

The percentage of completers was low (9.4%) but compares favorably with attendance at face-to-face education (8.3%) [5] and adherence to other digital self-care interventions [8,59-63]. The interviews helped explore attrition from the program, and NPT improved interpretation and transferability of the themes. Reasons for low engagement were similar to findings from a 2016 systematic review of diabetes education programs [6] and suggest that personal factors for people with T2DM and HCP
factors, including nonprioritization, lack of enthusiasm from HCPs for education, and people feeling that they would benefit or that knew enough already, contributed to poor uptake and completion [6].

The study included people with any duration of diabetes, but one of the factors associated with completion was duration of diabetes of less than a year ($P=.04$). The rationale for including people with any duration of diabetes was that the literature suggests that many people only become ready for structured education after having come to terms with the diagnosis [37-39], and we did not want to limit uptake by only including people who were newly diagnosed. Our previous research had shown that uptake was lower when people with diabetes of duration greater than a year were excluded [25]. Overall, our findings therefore suggest that while offering structured education to people with diabetes of any duration does help improve uptake, overall uptake is still low, and it is the newly diagnosed group who are more likely to complete the course. This is consistent with a 2014 study by Roelofson et al, which found low overall participation in a Web-based patient platform for T2DM containing health data and educational information (110 people used the intervention out of 974 who were registered, 11.3%), but interest was higher in people with shorter duration of illness [64]. This suggests that DSME should be offered to everyone with T2DM, but people who are newly diagnosed are a group who should continue to be targeted and offered referral in the first year following diagnosis.

Having been offered face-to-face education ($P=.001$) and having attended face-to-face education ($P=.002$) also seemed to be associated with completion. The association between likelihood of completion and having been previously offered, or attended, structured education has not been reported previously in the literature. This association could reflect intrinsic characteristics, whereby people with more interest in and commitment to structured education are more likely to remember the offer and attend whatever education they are offered, or could reflect an effect of structured education, in that it makes people aware of how much there is to learn, and hence promotes engagement with subsequent offers. Further research is needed on whether people are more likely to take up structured education if they are offered it more than once, or whether more incentives are needed to increase intrinsic motivation and interest and commitment to complete a course.

Conclusions

If Web-based structured education can be found to be effective and cost-effective and have acceptable reach, this could give people with T2DM more options for learning about self-management and help improve structured education uptake.

Acknowledgments

Funding for a percentage of staff time, travel to practices, printing and postage of registration packs, posters about the program for practices, website development, and a percentage of hosting and maintenance of the website was provided by the National Institute for Health Research (NIHR) School for Primary health care Research (project reference 280). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. The authors thank the people with T2DM and staff who took part in the research, particularly those who gave their time to be interviewed and the staff who identified eligible participants and sent out registration packs. The authors also thank the HeLP-Diabetes: Starting Out team (Kingshuk Pal, Orla O’Donnell, Helen Gibson, and Rebecca Owen).

Authors' Contributions

SP, FH, and EM contributed to the research proposal. EM and SP are coprincipal investigators. SP collected and analyzed the data and drafted the manuscript. EM and FS examined and discussed the qualitative data. LM and FH examined and discussed the quantitative data. All authors read and approved the final manuscript.

Conflicts of Interest

EM is Managing Director of HeLP-Digital Community Interest Company, a not-for-profit social enterprise established to roll out HeLP-Diabetes. She is not remunerated for this role, and there is no financial gain from the publication of this paper.

Multimedia Appendix 1

Description of Healthy Living for People with type 2 Diabetes: Starting Out according to the Template for Intervention Description and Replication checklist.

[DOCX File, 22 KB - diabetes_v5i1e15744_app1.docx ]

Multimedia Appendix 2

Screenshot of Healthy Living for People with type 2 Diabetes: Starting Out.

[PPTX File, 491 KB - diabetes_v5i1e15744_app2.pptx ]

Multimedia Appendix 3

Flowchart showing numbers of people with type 2 diabetes mellitus registering, starting, and completing the program.
Multimedia Appendix 4
Characteristics of people who participated in interviews.

References


41. Poduval S. University College London. London: University College London; 2019. Online Structured Education for People Newly Diagnosed With Type 2 Diabetes URL: https://discovery.ucl.ac.uk/id/eprint/10066859/


Abbreviations

- BAME: black and minority ethnic
- CCG: Clinical Commissioning Group
- DSMSE: diabetes self-management education
- DSMSES: diabetes self-management self-efficacy scale
- DSN: diabetes specialist nurse
- GP: general practitioner
- HCI: human-computer interaction
- HCP: health care professional
- HDSO: HeLP-Diabetes: Starting Out
- HeLP-Diabetes: Healthy Living for people with type 2 Diabetes
- HRA: Health Research Authority
- MRC: Medical Research Council
Feasibility, Acceptability, and Impact of a Web-Based Structured Education Program for Type 2 Diabetes: Real-World Study

Shoba Poduval, Louise Marston, Fiona Hamilton, Fiona Stevenson, Elizabeth Murray. Originally published in JMIR Diabetes (http://diabetes.jmir.org), 06.01.2020. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Diabetes, is properly cited. The complete bibliographic information, a link to the original publication on http://diabetes.jmir.org/, as well as this copyright and license information must be included.
Using Social Media to Track Geographic Variability in Language About Diabetes: Infodemiology Analysis

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Abstract

Background: Social media posts about diabetes could reveal patients’ knowledge, attitudes, and beliefs as well as approaches for better targeting of public health messages and care management.

Objective: This study aimed to characterize the language of Twitter users’ posts regarding diabetes and describe the correlation of themes with the county-level prevalence of diabetes.

Methods: A retrospective study of diabetes-related tweets identified from a random sample of approximately 37 billion tweets from the United States from 2009 to 2015 was conducted. We extracted diabetes-specific tweets and used machine learning to identify statistically significant topics of related terms. Topics were combined into themes and compared with the prevalence of diabetes by US counties and further compared with geography (US Census Divisions). Pearson correlation coefficients are reported for each topic and relationship with prevalence.

Results: A total of 239,989 tweets from 121,494 unique users included the term diabetes. The themes emerging from the topics included unhealthy food and drink, treatment, symptoms/diagnoses, risk factors, research, recipes, news, health care, management, fundraising, diet, communication, and supplements/remedies. The theme of unhealthy foods most positively correlated with geographic areas with high prevalence of diabetes (r=0.088), whereas tweets related to research most negatively correlated (r=-0.162) with disease prevalence. Themes and topics about diabetes differed in overall frequency across the US geographical divisions, with the East South Central and South Atlantic states having a higher frequency of topics referencing unhealthy food (r range=0.073-0.146; P<.001).

Conclusions: Diabetes-related tweets originating from counties with high prevalence of diabetes have different themes than tweets originating from counties with low prevalence of diabetes. Interventions could be informed from this variation to promote healthy behaviors.

(JMIR Diabetes 2020;5(1):e14431) doi:10.2196/14431

KEYWORDS
social media; epidemiology; infodemiology; diabetes; prevalence; twitter

Introduction

Background
Diabetes affects 30 million people in the United States, and its prevalence varies by geographic region. A better understanding of the regional differences concerning diabetes could allow for better public health messaging. The colloquial person-to-person communication about diabetes might inform that understanding, but word-of-mouth communication has been hard to measure until social media created the possibility of listening in.
Social media platforms such as Twitter, Facebook, and Instagram have emerged as high-volume, real-time data sources to study and observe communications, including health-related communications, from broad population segments [1-5]. Web-based communities are often far reaching, offering various types of communication including person-to-person communication, information seeking and dissemination, social support, and broadcasting of ideas and opinions. In addition, these communities can have similar location-specific characteristics. The content and characteristics of social media posts are associated with the regional epidemiology of disease [6-8]. For example, Instagram users residing in areas with low access to grocery stores (food deserts) posted about and consumed foods higher in fat and cholesterol compared with users residing in areas with greater access to grocery stores [3]. Thus, a better understanding of how people talk about diabetes via social media could provide insights about how to provide better targeted disease management and treatment.

**Objective**

In this study, we sought to characterize language about diabetes on Twitter and examine the correlation between this language and the prevalence of diabetes.

**Methods**

**Data Source and Sample**

This was a retrospective study of data extracted from Twitter about diabetes. Using natural language processing methodology, we found diabetes-specific terms, grouped them into clusters, and then quantified associations with the prevalence of diabetes. This study was approved by the Institutional Review Board of the University of Pennsylvania.

Tweets are brief status updates (no more than 140 characters during the duration of this study) containing information about emotions, thoughts, behaviors, and other personally salient information. Twitter users are broadly represented across age, geography, and social distributions [9-11]. African Americans, Latinos, and those in urban areas are overrepresented on Twitter relative to the general population [12].

For this study, we examined a random 10.00% (3,700,000/37,000,000) sample of all tweets between July 2009 and February 2015 (37 billion total tweets). We then extracted all tweets in English language with the keyword *diabetes* that originated in the United States, with GPS coordinates or other identifying information sufficient for linking to a US county (such as direct reference to a named county within a state, such as Philadelphia County, Pennsylvania). Approximately 21% of Twitter users provide their location information [5].

**Twitter Topic Generation**

We first limited our analysis to diabetes-specific language by finding those words and phrases that had a significant association with posts mentioning diabetes. Specifically, we used a random sample of 25,000 tweets including the word *diabetes* and 25,000 tweets without the word *diabetes*, and out of the 5000 most frequently used words, we kept those that were used significantly more frequently in the diabetes-related messages according to a logistic regression (Benjamini-Hochberg corrected \( P < .05 \) [13]). This removed nondiabetes-related words such as *the* or *like*. We then grouped diabetes-specific vocabulary in topics (clusters of semantically related words) using Latent Dirichlet Allocation (LDA). LDA is an automated machine learning process by which frequently co-occurring words are organized into topics [14]. Topic usage is quantified on a scale, referred to as *topic probability*, from 0 to 1 (from not used at all to exclusively used), which corresponds to the percentage of words from the given topic.

Two research assistants then independently reviewed 100 topics and categorized them into common themes based on the language within the topics. Any deviations between the research assistants were discussed among the research team members to reach consensus.

**Relation of Diabetes Topics and Prevalence**

To determine how topics on diabetes relate to diabetes prevalence, topic probabilities were individually correlated with age-adjusted county diabetes rates from the Centers for Disease Control and Prevention at the county level for 2012 [15]. In addition, topics were regressed against the 9 US Census Divisions using logistic regression controlling for language of the division.

\( P \) values were corrected for multiple testing using the Benjamini-Hochberg procedure. Pearson correlation coefficients are reported for topics, with \( P < .01 \) indicating significance.

All statistical analyses were performed with the Differential Language Analysis Toolkit version 1.1 [16] and Python 2.7.10 (Python Software Foundation).

**Results**

From approximately 37 billion tweets, 1.8 billion included sufficient location information to map to US counties. Of those, 1.6 billion were in English, of which 239,989 tweets (0.15%) included the term *diabetes*, representing 121,494 unique users.

Topics categorized into themes are displayed in Table 1. Each row of words represents 1 topic within the theme. Examples of topics that correlated with diabetes-related tweets included unhealthy food and drink-themed topics ([cupcakes, whipped, Haribo, and sundae] and [chocolate, Cinnabons, meats, and soda]) as well as a risk factors theme ([body mass index, waist, drugs, alcoholic, and obese]) and a fundraising theme ([walk, charities, supporting, donation, and November]).

Twitter users from regions with high prevalence of diabetes were more likely to tweet about unhealthy foods ([candy bar, cookies, and Twinkies; \( r = .088 \); \( P = .002 \)], whereas twitter users from areas with low prevalence of diabetes were more likely to tweet about research ([clinical, published, and enrolling; \( r = .162 \); \( P < .001 \)].

http://diabetes.jmir.org/2020/1/e14431/
<table>
<thead>
<tr>
<th>Theme</th>
<th>Words within topics</th>
</tr>
</thead>
</table>
| Unhealthy food/drink   | • Cupcakes, whipped, Haribo, and sundae  
• Fattening, processed, and meats  
• Cinnabons, crispy, and sugar high  
• Kool-aid and lemonade  
• Candy, cookies, and bars  
• Sugar-sweetened, Kentucky Fried Chicken, soda, and Pepsi |
| Treatment              | • Exercise, diet, healthy, prevention, and managing  
• Medicine, treatment, symptoms, alternative, natural, and remedies  
• Pancreas, system, physical, and activity  
• Insulin, injections, and sensitivity |
| Symptoms/diagnoses     | • Overwhelmed, tiredness, and urination  
• Disease, excess, heart, and hereditary  
• Auto-immune, degenerative, Alzheimer, Crohns, and hyperlipidemia  
• Pregnancy, pre-eclampsia, gestation, and pre-existing  
• Charcot, gangrene, fungal, limbs, and ulcers  
• Unconscious, lightheaded, cramping, and sweating |
| Risk factors           | • Obesitiy, cardiovascular, and dysfunction  
• Obese, antipsychotics, adolescents, and teens  
• Alcoholic, drink, and rum  
• Drugs, statins, women, waist, and body mass index |
| Research               | • Mayo clinic.com, lifestyles, and interventions  
• Immunology, antigen, and enrolls  
• Variants, explanation, methylation, and blood |
| Recipes                | • Eggplant and recipe  
• Cookbook, ultrataasty, health, and recipes  
• Solution, health, and recipe book |
| News                   | • Health Day, Yahoo, health news, share, and boost  
• CDC\(^a\), Americans, worldwide, cases, and percent  
• Rates, CDC rising, and death  
• Syndrome, metabolic, and diagnosis |
| Health care            | • Bloodwork, source book, and Dr’s  
• Payer, insurance, professionals, and telemedicine |
| Management             | • Glucose, management, monitoring, complications  
• Nurse, pharmacy, education, clinic, patient system |
| Fundraising            | • Juvenile, sponsor, walk, annual, research, and donating  
• Walk, step, cure, register, supporting, and donation  
• Charities and revamping  
• Awareness, November, month, national, and advocate |
| Diet                   | • Mediterranean, diet, reverse, low-carb, high-fat, and paleo  
• Healthy, protein, carbs, meal, and stabilize  
• Plates, lose, eating, weight, and mindful |
| Communication          | • Blog, archive, post, and published  
• Community, topic, advocate, and educators  
• Support, group, education, self-management, and wellness |
| Supplements/remedies   | • Minerals, raspberries, anti-inflammatory, and chromium  
• Herbs, natural, and alternative care  
• Multivitamin, probiotics, and selenium |

\(^a\)CDC: Centers for Disease Control and Prevention.
Themes and topics about diabetes differed in relation to overall prevalence of diabetes across US geographic divisions. Areas with high prevalence of diabetes, such as the East South Central and South Atlantic divisions, also had topics referencing unhealthy food (standardized beta range=0.073-0.146). However, research and exercise were most highly correlated with diabetes prevalence in the Northeast (standardized beta for research and exercise was .107 and .142, respectively).

Discussion

Principal Findings
This study reveals that (1) there is variation in what people post on Twitter about diabetes and (2) topics vary by county-level prevalence of diabetes. Unhealthy food–related topics were positively associated with high prevalence of diabetes; conversely, topics about research were negatively correlated with the prevalence of diabetes. The causal directions of these associations, if any, are unclear, but the results suggest opportunities to target online health messages relative to the prevalence of the disease.

This growing body of research utilizing social media platforms to explore public health topics may be helpful for targeting specific patient populations for public health messaging via appropriate language and message content. The ability to relate to different patient populations based on language can better align public health professionals and patients [17,18]. Subpopulations of patients, based on geography, disease severity, or other factors, may use different synonyms or metaphors for symptoms not known to the general public or health professionals. Local health care organizations and professionals could, for example, utilize language common to a particular geographic area with high prevalence of diabetes to target healthy messaging on social media and print media. These organizations may also utilize healthy messaging from other areas with low prevalence of diabetes to influence health behaviors. Large national organizations may also utilize regional differences in content and language to better personalize and position tweets within particular geographic contexts [19].

Content may also be enhanced by tweet modifiers (eg, hashtags and emotion) shown to impact dissemination of cardiovascular health–related Twitter posts [7]. Mining social media to find these nuances within a population posting about diabetes would be useful for outreach and message targeting. Furthermore, learning how different message types (ie, shocking or humorous) are related to gaining knowledge of serious health effects for particular health behaviors is crucial to influence behavior change [2].

Strengths and Limitations
This study has several limitations. Twitter users are not nationally representative, and tweets are not a direct proxy for all person-to-person communication. Tweets are short, and content is presumably what users are eager to share broadly (vs what they may be focused on privately). Nevertheless, tweets offer a window into public discourse about diabetes. This study also has strengths: it starts from an enormous sample of tweets, systematically addresses their content via machine learning techniques, and associates that content with disease prevalence. In doing so, it advances our understanding of public perceptions of diabetes.

Conclusions
This study demonstrates that the language used to discuss diseases is variable and complex. Systematic assessment of social media about posts on diabetes could suggest targets for promoting healthy lifestyles and behaviors.

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Conflicts of Interest
HG, HAS, LU, AMB, FKB, NM, and RMM declare no conflicts of interest. DAA owns stock in Berkshire Hathaway. He is a partner in and part owner of VAL Health; and has received compensation and/or travel support for speaking, writing, or consulting from the following organizations: AFYA, MTS Health Partnership, Children’s Hospital of Philadelphia, University of Virginia, Salzburg Global Seminars, GlaxoSmithKline (GSK), John F Kennedy Health System, Cosmetic Boot Camp, Meeting Designs, Capital Consulting, Healthcare Financial Management Association, Joslin Diabetes Center, National Academy of Medicine, the Commonwealth Fund, Massachusetts Medical Society, Endocrine Society, Osteoarthritis research society international, Baystate Medical Center, Weill-Cornell Medical College, Association of American Medical Colleges, Technology, Entertainment, Design(TED) Medical (MED), National Alliance of Health Care Purchaser Coalitions, Deloitte, Harvard University, American Association for Physician Leadership, Brandeis University, University of Rochester, Partner’s Health Care System, John Dolan Lectureship, Johns Hopkins University, and MITRE.

References


**Abbreviations**

LDA: Latent Dirichlet Allocation