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Clinical Monograph

The *Prevent* Online Diabetes  
Prevention Program (DPP)

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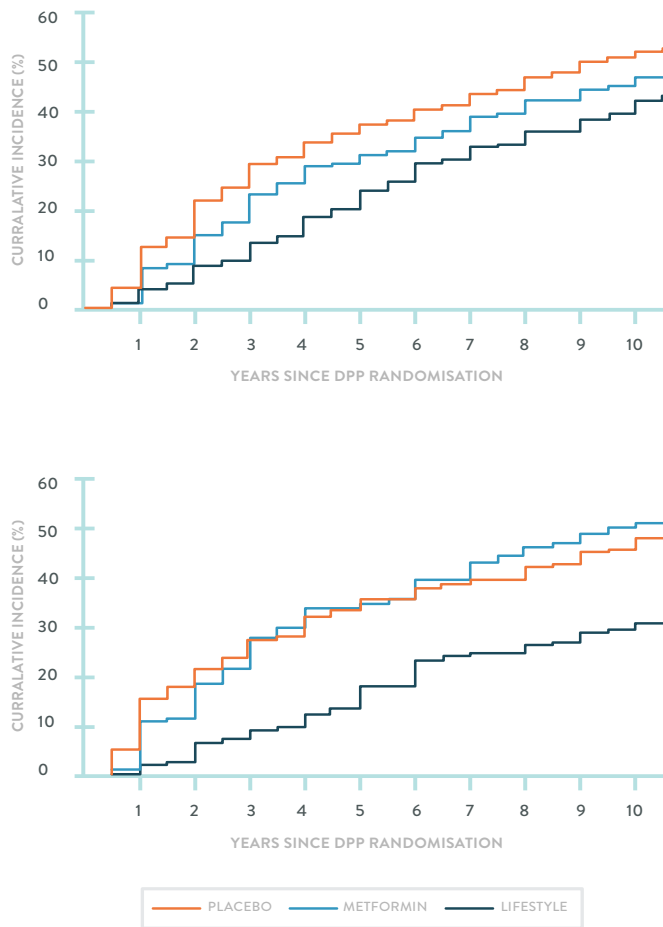
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## The Diabetes Prevention Program (DPP) Clinical Trial

The Diabetes Prevention Program (DPP) is an evidence-based lifestyle change program for preventing type 2 diabetes. It is based on the lifestyle change program tested in the NIH's original DPP clinical trial that concluded in 2002. The original DPP included 16 core sessions focused on making moderate changes in both diet and physical activity, as well as a 'post core phase' focused on sustaining those changes over the rest of the year.<sup>1</sup> The goal of the DPP is to achieve modest weight loss over the first 4-6 months in the range of 5-10% of baseline body weight and maintain these lifestyle changes over the remainder of the year.<sup>2</sup>

The DPP clinical trial showed that compared to placebo, the DPP lifestyle change group reduced their risk of developing diabetes by 58% after 3 years and 34% after 10 years, outperforming the medication group, which reduced risk by 31% after 3 years and 18% after 10 years (Figure 1). Lifestyle change worked particularly well for participations aged 60 and older, reducing their diabetes risk by 71% over 2.8 years and 49% after 10 years (Figure 2).<sup>1,7</sup>

Further analyses of DPP data showed that lifestyle change participants who met the specified diet, exercise, and weight loss goals of DPP had the greatest diabetes risk reduction.<sup>9</sup> In particular, weight loss was the strongest predictor of reduced diabetes risk in the lifestyle change group: those who lost 5% or more of their body weight reducing their risk by 54%, and those who lost 10% or more of their body weight reducing their risk by 85%.<sup>10</sup> The authors concluded that diabetes risk reduction efforts should emphasize weight loss, which is aided by increased exercise. Additional analyses have also shown that the DPP lifestyle change program also helped prevent metabolic syndrome and led to reductions in blood pressure, triglycerides, HDL cholesterol, C-Reactive Protein (CRP), and fibrinogen (risk factors for heart disease).<sup>6</sup>



(Top) Figure 1. Cumulative Incidence of Diabetes By Study Group (All Ages) (Bottom) Figure 2. Cumulative Incidence of Diabetes By Study Group (Ages 60+)

## DPP Lifestyle Interventions – How They Perform in the Real World

Since the DPP was considered a landmark clinical trial, its initial results were published in 2002 in the *New England Journal of Medicine*, and influenced organizations such as the American Academy of Clinical Endocrinologists to include it as the cornerstone intervention in their treatment guidelines for prediabetes: “Given its safety and the strength of evidence for its effectiveness in improving glycemia and reducing CVD risk factors, the preferred treatment approach for prediabetes is intensive lifestyle management.”<sup>11</sup>

As a result of the DPP lifestyle change program’s significant success in reducing diabetes risk, there have been dozens of efforts to translate the intervention to real-world settings, in both the US and internationally. A systematic review and meta-analysis of real-world DPP translation studies found that 22 studies (with 24 study groups) had outcome data for weight loss at 12 months (Figure 3).<sup>12</sup> Real-world translations showed a mean weight loss of -2.4% at 12 months, considerably lower than the original DPP clinical trial, in which the lifestyle arm achieved -6.9% weight loss at 12 months. It is important to note that the original DPP clinical trial used methods to maximize efficacy—including a 3-week practice period to screen out participants who were not motivated to adhere to treatment, as well as small financial incentives—which were not included in the real-world studies analyzed.<sup>13</sup>

Despite the lower average weight loss in real-world translations, the meta-analysis showed that real-world DPP translations still likely produced a clinically meaningful effect on diabetes incidence, and those that adhered more to guidelines for behavioral strategies used in diabetes prevention programs produced the greatest weight loss outcomes. Another systematic review of DPP programs investigated the behavioral strategies used in randomized control trials and found that “a robust behavioral change strategy is an essential part of an effective lifestyle modification program.”<sup>14</sup>

## The *Prevent* Online Diabetes Prevention Program

The CDC’s National Diabetes Prevention Program has tried to disseminate DPP programs nationwide, but these efforts have been hindered by several factors: 1) the brick-and-mortar DPP programs cannot scale to reach all the people it must; 2) most Americans cannot consistently fit fixed weekly meetings into otherwise busy lives; 3) health coaches (who are not typically employed by the providers) are difficult to track and manage across disparate physical sites; and 4) it is a challenge to consistently track progress and harness insights across larger groups. As a result, Omada Health, Inc. designed the *Prevent* program to translate the DPP into a digital format that makes evidence-based treatment of prediabetes accessible and engaging to millions of Americans. *Prevent* includes 4 major intervention components: small-group support, personalized health coaching, DPP curriculum, and digital tracking tools.

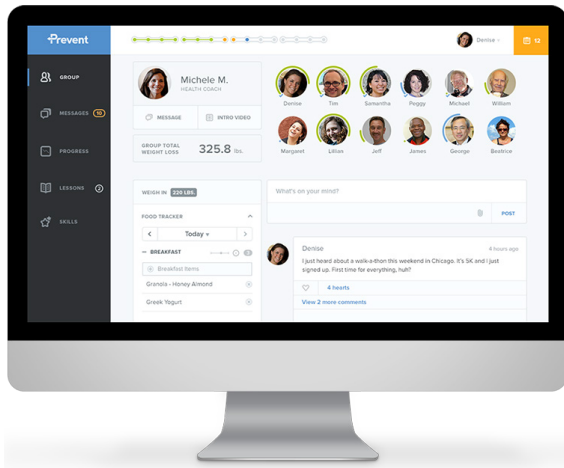


Figure 3. Screenshot of *Prevent* program's online social network.

To re-create the experience and group dynamic of an in-person program, participants are demographically matched into online groups of around 15 participants to maximize social relatedness (based on similar location, age, and Body Mass Index (BMI)). Participants communicate with each other via a private online social network, which resembles popular social networks such as Facebook (Figure 3). An online group discussion board allows participants to post and reply to comments about how they were doing and progressing. Participants can “like” and “understand” comments to express social support and empathy, which mimic key group

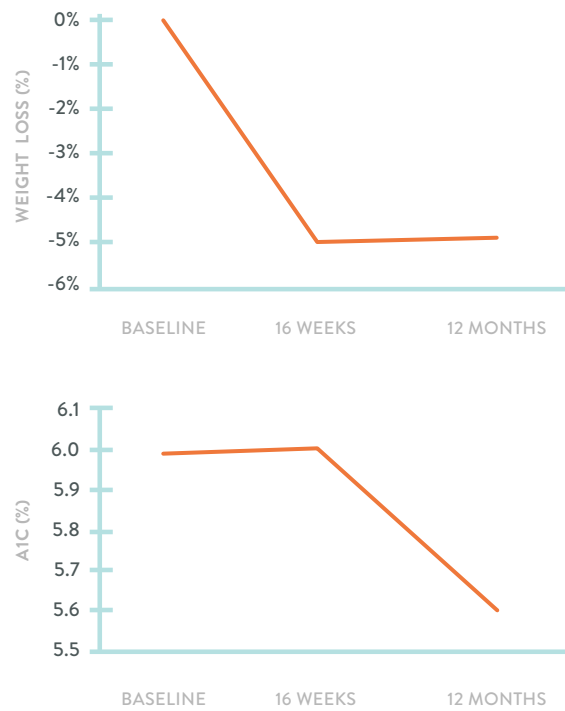
therapeutic processes. Group discussion is asynchronous, rather than live, to make the intervention more flexible and convenient. Visual progress bars allow group members to see each other's relative progress towards the shared 5-10% weight loss goal, and provide social support and accountability to one another.

Each group is led by a professional health coach, trained in a manner consistent with CDC DPRP standards for lifestyle coaches. Health coaches serve an important moderating and personalizing function by communicating with participants via online private messages or telephone calls and text messages. Health coaches keep participant discussions on track, provided feedback on food logs and physical activity progress, and provide individualized counseling using techniques such as motivational interviewing, personalized recommendations on diet and exercise, etc.

The DPP curriculum is presented in an online format that resembles popular online learning platforms such as Coursera. *Prevent* begins with a 16-week core program phase, consisting of 16 online weekly lessons adapted from the CDC NDPP core curriculum. Lessons are posted every Sunday morning, and participants are encouraged to complete them at their own convenience within the week. Lessons resemble an online workbook, in which individuals read curriculum content and answer relevant free response questions, which are shared with their health coach and groups. A lesson is considered complete if a participant clicks through all of the pages and answers the free response questions to indicate engagement and understanding.

## Prevent 1-Year Study – Published Outcomes

A pilot usability study was published in April 2014 on the clinical outcomes of the *Prevent* online DPP program. 220 participants who reported a clinical diagnosis of prediabetes within the past year were recruited and enrolled via online advertisements during 2012.<sup>15</sup> Participants underwent the *Prevent* ‘core’ 16-week intensive lifestyle change intervention, and were then offered to continue with a ‘post-core’ lifestyle maintenance intervention, with the entire intervention (core plus post-core) totaling 12 months. 187 participants met analysis criteria for the core program and achieved an average of 5.0% and 4.8% weight loss at 16 weeks and 12 months, respectively (Figure 4). They also had a 0.37% reduction in their A1C level at final measurement, decreasing from an average A1C in the prediabetes range to an average A1C in the normal range. 144 of these same participants also met inclusion criteria for the post-core program and achieved an average of 5.4% and 5.2% weight loss at 16 weeks and 12 months, respectively, and a 0.40% reduction in A1C at final measurement (Figure 5).



(Top) Figure 4. *Prevent* study Adjusted mean weight loss among core and post-core participants. (Bottom) Figure 5. *Prevent* study Adjusted mean A1C among core and post-core participants.

Results indicate that *Prevent* meets CDC DPRP outcome standards for diabetes prevention programs, and that its ~5% average weight loss outcome in the initial pilot study compares favorably to the 2.4% average weight loss seen in other real-world DPP translations.<sup>10</sup> The results suggest that online delivery platforms like *Prevent* offer an effective and scalable solution to address the obesity and diabetes epidemics.

## Commercial Results of *Prevent* to Date

Since the pilot study, over 1000 real-world participants have engaged in *Prevent*'s 16-week core program. Participants were a mix of those who were self-referred, physician-referred, or employer-referred. No participants were received financial incentives for participation in the program. These participants have achieved an average weight loss of 5.1% at 16 weeks. Of the over 100 participants who have 1-year data, they show an average weight loss of 5.9% at 1-year (Figure 6).

Continued experience with *Prevent* to date suggests that the program continues to improve despite roll-out into real-world settings. This effect, rarely seen for medical interventions, is likely due to key features of the digital DPP intervention itself:

- Full-time DPP health coaches that are dedicated to the program and thus learn quickly about effective techniques for participant management.
- Continued refinement and enhancement of digital user interfaces and intervention processes, overseen in an analytical and central fashion by Omada Health, Inc.

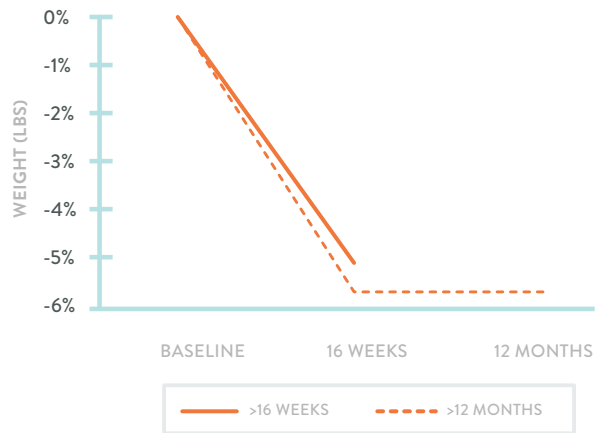


Figure 6. Mean weight of Commercial participants who enrolled at least 16 weeks and 52 weeks ago.

Furthermore, real-world weight-loss results of *Prevent* compare even more favorably to real-world in-person DPP translations, suggesting that a 'digital therapeutics' approach to the DPP may be the preferred choice for the majority of persons living with prediabetes.

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