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Relationship Between Age and Weight Loss in Noom: Quasi-Experimental Study

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Abstract

Background: The prevalence of obesity and diabetes among middle-aged and older adults is on the rise, and with an increase in the world population of adults aged 60 years and older, the demand for health interventions across age groups is growing. Noom is an mHealth behavior change lifestyle intervention that provides users with tracking features for food and exercise logging and weighing-in as well as access to a virtual 1:1 behavior change coach, support group, and daily curriculum that includes diet-, exercise-, and psychology-based content. Limited research has observed the effect of age on a mobile health (mHealth) lifestyle intervention.

Objective: The goal of the research was to analyze engagement of middle-aged and older adults using a mobile lifestyle or diabetes prevention intervention.

Methods: A total of 14,767 adults (aged 35 to 85 years) received one of two curricula via an mHealth intervention in a quasi-experimental study: the Healthy Weight program (HW) by Noom (84%) or the Noom-developed Diabetes Prevention Program (DPP), recognized by the US Centers for Disease Control and Prevention (CDC). The main outcome measure was weight over time, observed at baseline and weeks 16 and 52.

Results: Linear mixed modeling found age to be a significant predictor of weight at week 16 ($F_{2,1398.4}$=9.20; P<.001; baseline vs week 16: β=–.12, 95% CI –0.18 to –0.07), suggesting that as age increases by 1 year, weight decreased by 0.12 kg. An interaction between engagement and age was also found at week 52 ($F_{1,14680.51}$=6.70; P=.01) such that engagement was more strongly associated with weight for younger versus older adults (age × engagement: β=.02, 95% CI 0.01 to 0.04). HW users lost 6.24 (SD 6.73) kg or 5.2% of their body weight and DPP users lost 5.66 (SD 7.16) kg or 8.1% of their body weight at week 52, meeting the CDC standards for weight loss effects on health.

Conclusions: Age and engagement are significant predictors of weight. Older adults lost more weight using an mHealth evidence-based lifestyle intervention compared with younger adults, despite their engagement. These preliminary findings suggest further clinical implications for adapting the program to older adults' needs.

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KEYWORDS

older adults; DPP; mHealth; weight loss; lifestyle intervention; engagement

Introduction

The prevalence of obesity among adults in the United States is on the rise, affecting nearly one half (40%) of adults aged 20 years and over, up 4% from 2014 [1,2]. Obesity is a known risk factor for insulin resistance associated with type 2 diabetes, placing individuals who are overweight or obese at risk for adverse health consequences [3]. Currently, 34.2 million

Americans of all ages have diabetes; however, risk of diagnosis increases with age, with 26.8% of adults aged 65 years or older affected [4]. Type 2 diabetes remains the seventh leading cause of death for all ages, with increasing death rates faced by older adults (aged 55 to 74 years) [5].

Obesity-related conditions such as heart disease, stroke, and diabetes are among the leading causes of preventable early death, according to the US Centers for Disease Control and Prevention (CDC) [6]. With 960 million people aged 60 and over in the global population, anticipated to increase to 1.4 billion older adults by 2030 and to 2.1 billion by 2050, the prevalence of these chronic diseases is expected to rise further [7]. Evidence-based preventive measures and treatments that are feasible and effective for the growing older adult population could be used to counter these trends.

It is well established that adopting healthier lifestyle behaviors is essential to treating diabetes, prediabetes, and obesity [8]. Lifestyle interventions are a known effective approach in targeting weight reduction through dietary and exercise interventions and have been shown to reduce diabetes incidence [9]. Moderate (5% to 10%) weight loss interventions, including diet and exercise, have been shown to reduce mortality of older adults with obesity [10]. However, promoting weight loss in older adults can be controversial [11].

Research shows a potential risk for sarcopenic obesity that occurs when the loss of skeletal muscle mass from a weight loss intervention exacerbates sarcopenia, a condition of muscle atrophy which can be debilitating for an older person [12]. Further, certain epidemiologic studies suggest a protective effect of obesity in certain circumstances in older adults, known as the obesity paradox [3]. Criticisms of the paradox findings note older adults included in mortality studies likely represent a small portion of the population who did not already face fatal obesity-related complications earlier in life [13]. In many studies demonstrating the obesity paradox, distinctions between intentional versus unintentional weight loss were not made, so outcomes that indicate health risks from weight loss may largely be explained by illness-related weight loss [14]. Healthful weight loss is less likely to carry the same risks and can improve health outcomes.

The Diabetes Prevention Program (DPP) is an intensive lifestyle intervention shown to be cost-effective and successful in decreasing diabetes risk [15]. Promoting healthy weight loss is a central aspect of the DPP. Traditional group-based and face-to-face DPP lifestyle interventions have demonstrated efficacy to prevent diabetes in older adults. Employing diet and exercise lifestyle behavior changes reduced the incidence of diabetes by 71% in older adults. Older adults were more likely to reach 7% weight loss than younger adults (age 45 to 59 years [59%] vs age 25 to 44 years [48%]). At its 10-year follow-up, the DPP lifestyle intervention continued to show the greatest effect on diabetes incidence for the oldest participants (aged 60 to 85 years) compared with any other age group [16]. Program adherence may have played a role: session attendance was positively associated with age; adults aged 60 to 85 years participated in nearly twice as many sessions as younger adults [16]. Therefore, in-person DPP interventions are effective in tackling obesity, particularly for older adults.

With the widespread use of mobile health (mHealth) apps and broad availability of mHealth apps geared toward weight loss [17], there are increasing opportunities to implement evidence-based lifestyle and diabetes prevention interventions using mobile devices. Older adults have regular access to digital communications: 59% of adults aged 65 to 69 years, 49% of adults aged 70 to 74 years, and 31% of adults aged 75 to 79 years currently own smartphones, making mHealth interventions a viable option [18].

While some studies exploring technology-based DPP adaptations have included older adults, none to our knowledge have explored potential age effects on weight outcomes. One study explored the effectiveness of mHealth interventions specifically for this population and found 92% of participants completed at least half of the core DPP lessons and lost 7.5% of their body weight at the 12 month follow-up [19].

Clearly, mHealth interventions hold great promise as a cost-effective and feasible approach to weight loss for older adults. More information is needed to understand the specific utility of mHealth lifestyle interventions with consideration of potential age effects, as found in the original DPP program. One mHealth lifestyle program that has shown to be effective is Noom (Noom, Inc), with positive results found for overweight and prediabetic adults (aged 37 to 61 years) [20,21]. However, little is known about the impact of age on weight outcomes within this population.

This study sought to evaluate the role of age in predicting weight of participants of Noom's Healthy Weight management (HW) and Noom's Diabetes Prevention Program (DPP) over a short-term (16 week) and long-term (52 week) maintenance period. We hypothesized that older age would be associated with greater weight loss. A secondary aim was to evaluate the role of program engagement associated with age in predicting weight. We hypothesized older adults would be more engaged than younger adults which would predict greater weight loss.

Methods

Recruitment

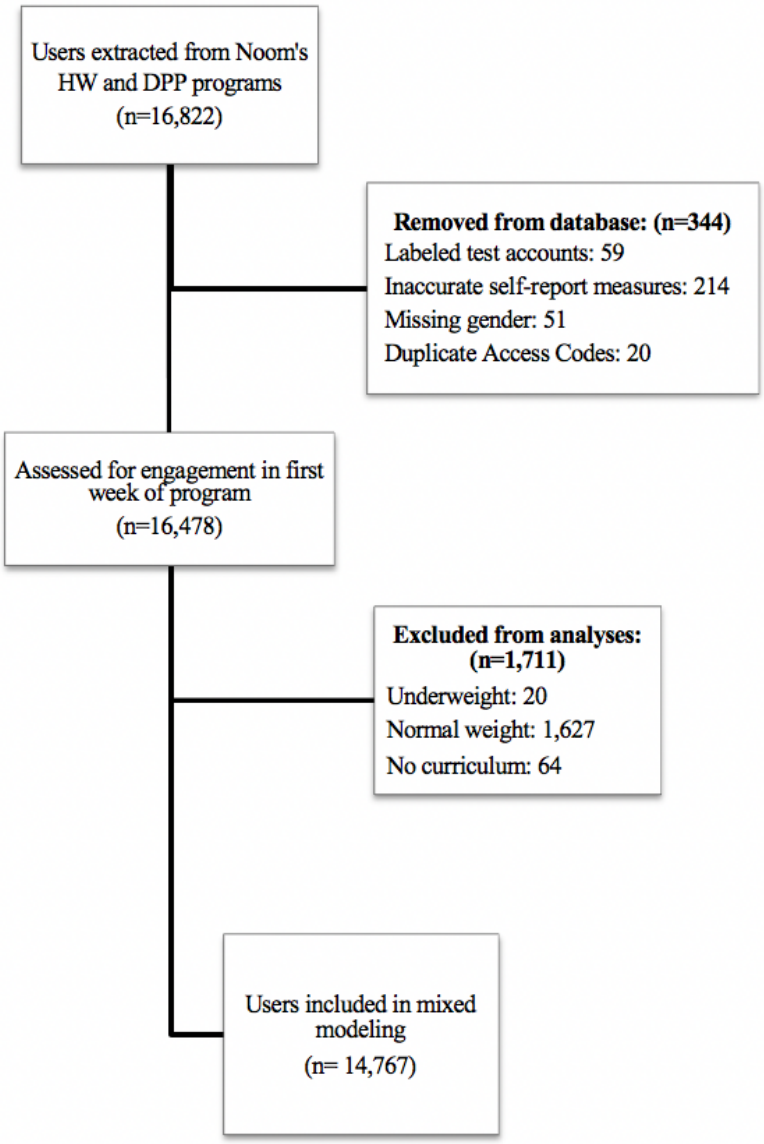
Retrospective cohort data were extracted directly from Noom's database in January 2019 and deidentified upon institutional review board approval from Albert Einstein College of Medicine. Noom is an mHealth behavior change lifestyle intervention that provides users with tracking features for food and exercise logging and weighing-in as well as access to a virtual 1:1 behavior change coach, support group, and daily curriculum that includes diet-, exercise-, and psychology-based content [20,21].

Participants were initially recruited by joining the Noom program in the app store (iTunes/Google Play). Informed consent to participate in research is provided by users during the initial sign-up for the program; users can choose to opt out of providing informed consent for research. Individuals in the HW program enrolled based on self-interest in weight loss and

purchased the program for $129 for 4 months, on average. Individuals in the CDC-recognized DPP program, however, were encouraged to join following a prediabetes diagnosis from their health care provider and were offered the program for free through a health insurance offer. All Noom users are assigned a virtual health coach who successfully completed a CDC-recognized training course and are placed in a virtual group led by their coach. Users in both programs have access to the same features; the only difference that exists is the program curriculum users receive. While both programs focus on weight, healthy eating, and physical activity, the DPP program includes specific diabetes prevention content stemming from the CDC's original DPP, which is not emphasized in the HW program.

Inclusion criteria were adults aged 35 years and older who began the HW or DPP program in June 2016 through January 2019 and had at least 1 program action within the first week of the program. The decision for selecting 35 years as the age minimum was made as a qualification of middle-aged adults whose degree of technology interaction was minimal during their youth. Users were considered ineligible and were excluded from the analyses if they self-reported a BMI categorized as underweight (<18 kg/m^2) or normal weight (18.5 to 24.9 kg/m^2; Figure 1) or were using the free version of Noom, as they do not have access to all program features (ie, no health coach, limited article content and tracking capabilities) and thus they did not receive the full intervention. Users were also excluded from analyses if they had inaccurate self-reported measures (as determined by large fluctuations in weight [ie, ±20 kg in 1 week]), test accounts (used by engineer developers at Noom to test the product), missing gender, and duplicate accounts (caused by errors with data extraction). Our study sample size is based on users who met the inclusion criteria.

Figure 1. Description of data exclusion and inclusion of those who met study criteria.



Measures

The primary outcome was self-reported weight, observed at baseline and weeks 16 and 52. To account for missing data at weeks of interest, 2-week ranges were observed around each time point and the mean of each range was used to calculate the final weight outcomes included in the analyses.

Engagement was observed in two ways. First, a definition was created to observe completion status. With the CDC's DPP session attendance definition as a frame, it was decided to further adapt this previously used definition, originally created for in-person DPP programs, to improve applicability to mHealth. Therefore, program starters were considered as those who attended at least 1 session, defined as reading 1 article per week over 3 consecutive weeks or more during week 2 to week 6 and weighing in at least once per week for 2 weeks or more during week 2 to week 6. Program completers were considered to be those who read at least 14 articles (60%), a minimum of 1 per week, during the first 24 weeks of the core curriculum.

Engagement was also measured by users' self-reported and behavioral-based program actions. Engagement variables included the number of self-reported meals logged, exercise logged, minutes of exercise logged, and frequency of weigh-ins, as well as behavioral-based steps recorded, articles completed (articles assigned divided by articles read), group interactions (group posts and comments), and messages to their individual coach, all tracked based on user program activity. The total value within each engagement variable was summed from baseline to week 52 and dichotomized (0 or 1); a score of 1 was given if a user logged at or above the 75th percentile cutoff for the individual variable. Composite scores for each user were calculated for all 9 engagement variables (score range of 0 = low engagement to 9 = high engagement).

Statistical Analysis

Descriptive statistics were calculated for users' baseline characteristics and expressed in means and standard deviations for continuous variables and frequencies and percentages for categorical variables (Table 1). Differences between demographics at baseline were observed using *t* tests for independent samples, chi-square analyses, and other nonparametric tests.

Linear mixed effects models evaluated changes in our primary outcome (weight). Linear mixed effects models estimate missing data within the analysis and are robust to data missing at random and not at random [22]. In our dataset, 2030 users of 14,676 recorded their weight at week 16 (±2 weeks) and 431 recorded their weight at week 52 (±2 weeks). Despite missing values and completion statuses, data from all users in the program were analyzed, and weight outcomes were predicted from the linear mixed models conducted.

Three analyses were completed. First, fixed effects were time and curriculum and their interaction to observe potential effects of curriculum. Second, age and time and their interactions were added, in addition to adjusting for curriculum, if found significant. Next, age, time, and total engagement and their interactions were included in the model. Time and the intercept for each participant were included as random effects in all models. Time was conceptualized as a 3-level categorical variable (week 0, 16, and 52). A first-order autoregressive covariance matrix yielded the best fit model for the repeated effect of time, using visual inspection and the Akaike information criteria. Significance tests were 2-sided with α set at .05. SPSS Statistics version 23 (IBM Corp) software was used to analyze the data.

Table 1. Descriptive statistics at baseline for participants of the Healthy Weight and Diabetes Prevention Program curricula.

Variable	HW[a] curriculum (n=12,378)	DPP[a] curriculum (n=2389)	*P* value
Gender, n (%)			.60
Male	1451 (11.7)	289 (12.1)	—
Female	10,927 (88.3)	2100 (87.9)	—
Age in years, median (IQR)	42.0 (38.0-47.0)	51.0 (44.0-58.0)	<.001
Completion status, n (%)			<.001
Never engaged	9662 (78.1)	1480 (62.0)	—
Engaged	372 (3.0)	60 (2.5)	—
Starters	1767 (14.3)	458 (19.2)	—
Completers	577 (4.7)	391 (16.4)	—
Initial weight (kg), mean (SD)	94.1 (20.4)	94.4 (20.5)	.53
Height (cm), mean (SD)	165.9 (7.1)	167.2 (9.5)	<.001
Baseline BMI (kg/m^2), median (IQR)	32.6 (29.0-37.6)	32.2 (29.0-37.0)	.01

[a]HW: Healthy Weight program.

[a]DPP: Diabetes Prevention Program.

Results

Baseline Characteristics

Baseline characteristics are included in Table 1. Of the individuals selected at baseline from Noom's database, 15.07% (2225/14,767) met criteria for starter in both the HW and DPP programs (Figure 1). Of the those who started both Noom programs, 43.51% (968/2225) of individuals completed the program (577/968 [59.6%] in HW and 391/968 [40.4%] in DPP). In the HW program, 88.27% (10,926/12,378) of participants were women, with a mean BMI of 32.6 (IQR 29.0 to 37.6) kg/m^2. In the DPP program, 87.90% (2100/2389) of participants were women, with a median BMI of 32.2 (IQR 29.0 to 37.6) kg/m^2.

DPP users were significantly older (median 51.0 [IQR 44.0 to 58.0] years) than HW users (median 42.0 [IQR 38.0 to 47.0] years; P<.001). Although the omnibus test suggested completion status differed between DPP and HW users (χ^2_3=520.93; n=14,767; P<.001), post hoc analyses yielded no significant differences with Bonferroni corrections (P<.006). DPP users were significantly taller (mean 167.2 [SD 9.5] cm) than HW users (mean 165.9 [SD 7.1] cm, t_{14765}=–7.61; P<.001). HW users had significantly higher baseline BMI (median 32.6 [IQR 29.0 to 37.6] kg/m^2) than DPP users (median 32.2 [IQR 29.0 to 37.0] kg/m^2, P=.01). No other demographic characteristics significantly differed between curriculum groups (Table 1). The total sum of mean engagement variables for HW and DPP users across the study are found in Table 2.

Prior to running the mixed models, we observed weight loss throughout the program from users who provided data at week 16 and week 52 to better identify the amount of weight lost compared with CDC standards. Results showed that users who completed (as defined by our completer definition) the HW program lost on average 4.74 (SD 4.66) kg or 3.5% of their body weight at week 16 and 6.24 (SD 6.73) kg or 5.2% of their body weight at week 52. Users who completed the DPP program lost on average 5.61 (SD 8.06) kg or 5.7% of their body weight at week 16 and 5.66 (SD 7.16) kg or 8.1% of their body weight at week 52.

Table 2. Descriptive statistics of engagement variables from baseline to weeks 16 and 52.

Engagement measures	HW[a,b] curriculum (n=2806), median, (IQR)	DPP[b,c] curriculum (n=665), median (IQR)
Meals logged		
Week 16	88.0 (3.0-57.0)	195.0 (6.0-184.8)
Week 52	91.0 (3.0-58.0)	218.0 (6.0-202.3)
Articles completed		
Week 16	4.0 (0.3-2.4)	7.2 (0.4-6.0)
Week 52	4.1 (0.3-2.4)	8.2 (0.4-6.7)
Coach messages		
Week 16	26.0 (2.0-16.0)	29.0 (3.0-28.0)
Week 52	26.5 (2.0-16.0)	35.0 (3.0-34.0)
Steps tracked		
Week 16	228,923.0 (13,284.0-182,434.0)	331,572.0 (25,837.0-329,239.0)
Week 52	267,270.5 (14,082.0-205,220.3)	629,241.0 (28,654.5-563,706.0)
Weigh ins		
Week 16	10.0 (1.0-11.0)	20.0 (4.0-27.0)
Week 52	10.0 (1.0-11.0)	31.0 (4.0-47.0)
Exercises logged		
Week 16	13.0 (2.0-22.0)	25.0 (3.0-46.0)
Week 52	13.0 (2.0-24.0)	33.0 (4.0-62.0)
Minutes of exercise logged		
Week 16	227.5 (30.0-471.9)	735.0 (60.0-1332.5)
Week 52	240.0 (30.0-490.0)	886.0 (60.0-1775.0)
Group comments		
Week 16	9.0 (2.0-16.0)	11.0 (2.0-22.0)
Week 52	9.0 (2.0-16.0)	13.0 (2.0-25.0)
Group posts		
Week 16	5.0 (1.0-4.0)	9.0 (1.0-9.0)
Week 52	5.0 (1.0-4.0)	9.0 (1.0-10.0)

[a]HW: Healthy Weight program.

[b]For participants who had engagement data available.

[c]DPP: Diabetes Prevention Program.

Curriculum Effects

Tables 3 to 5 provide estimates and confidence intervals for the linear mixed effects models, with weight as the outcome. Results from the linear mixed model revealed that there was a significant interaction effect between curriculum groups and time ($F_{2,1401.0}$=29.44; P<.001; Table 3). From baseline to week 16 and baseline to week 52, individuals in the DPP curriculum showed greater weight loss compared with HW users, losing 3.20 kg more at week 16 and 2.38 kg more at week 52 (baseline vs week 16: β=–3.20, 95% CI –4.02 to –2.37; baseline vs week 52: β=–2.38, 95% CI –4.17 to –0.59; Table 3). Therefore, the remainder of the models were adjusted for curriculum.

Age Effects

When we evaluated the effect of age, we found the interaction effect between age and time was significant ($F_{2,1398.4}$=9.20; P<.001; Table 4). From baseline to week 16, adults who were older lost more weight earlier on compared with younger adults, such that for each additional year in age, weight decreased by an additional 0.11 kg (baseline vs week 16: β=–.11, 95% CI –0.16 to –0.06). However, from baseline to week 52, age was not a significant predictor of weight (baseline vs week 52: β=.003, 95% CI –0.11 to 0.11; Figure 2).

Table 3. Mixed model evaluating changes in weight by time and curriculum.

Effect	Estimate[a]	Standard error	*P* value
Intercept	94.09	0.18	<.001
DPP[b]	0.29	0.46	0.53
HW[c]	N/A[d]	N/A	N/A
Baseline	N/A	N/A	N/A
Week 16	–3.42	0.26	<.001
Week 52	–4.55	0.76	<.001
DPP*baseline[e]	N/A	N/A	N/A
DPP*week 16	–3.20	0.42	<.001
DPP*week 52	–2.38	0.91	0.01

[a]Estimate represents predicted value of weight.
[b]DPP: Diabetes Prevention Program.
[c]HW: Healthy Weight Program.
[d]N/A: Reference group used.
[e]*=interaction.

Table 4. Mixed model evaluating changes in weight by age and time.

Effect	Estimate[a]	Standard error	*P* value
Intercept	91.95	0.97	<.001
Age	0.05	0.02	.02
Baseline	N/A[b]	N/A	N/A
Week 16	0.5	1.24	.69
Week 52	–5.99	2.76	.03
Age*baseline[c]	N/A	N/A	N/A
Age*week 16	–0.11	0.03	<.001
Age*week 52	0.003	0.06	.96

[a]Estimate represents predicted value of weight.
[b]N/A: Reference group used.
[c]*=interaction.

Table 5. Mixed model evaluating changes in weight by age, engagement, and time.

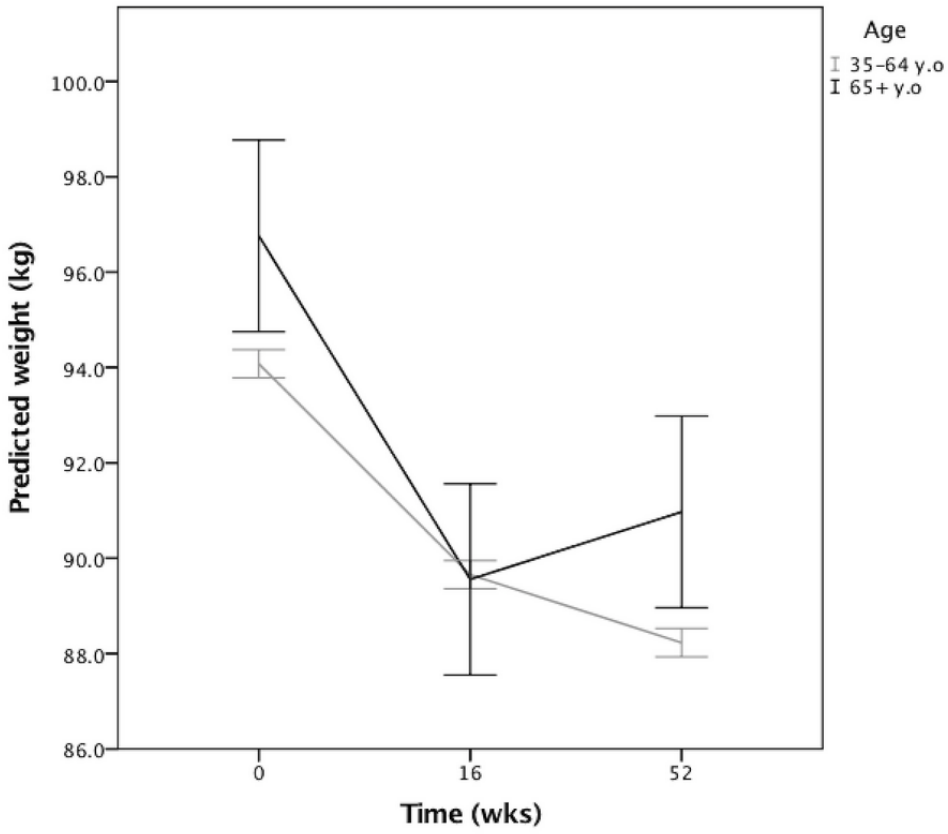
Effect	Estimate[a]	Standard error	*P* value
Intercept	93.68	1.12	<.001
Age	0.02	0.02	.40
Baseline	N/A[b]	N/A	N/A
Week 16	1.79	1.31	.17
Week 52	–1.85	3.03	.54
Engagement	–1.33	0.39	<.001
Baseline*age[c]	N/A	N/A	N/A
Week 16*age	–0.12	0.03	<.001
Week 52*age	–0.02	0.06	.67
Age*engagement	0.02	0.01	.01
Baseline*engagement	N/A	N/A	N/A
Week 16*engagement	–0.13	0.07	.06
Week 52*engagement	–0.44	0.15	.004

[a]Estimate represents predicted value of weight.

[b]N/A: Reference group used.

[c]*=interaction.

Figure 2. Interaction between age and time on predicted weight outcomes. Error bars: 95% CI. Data not distinguished by curriculum.



Engagement by Age and Time

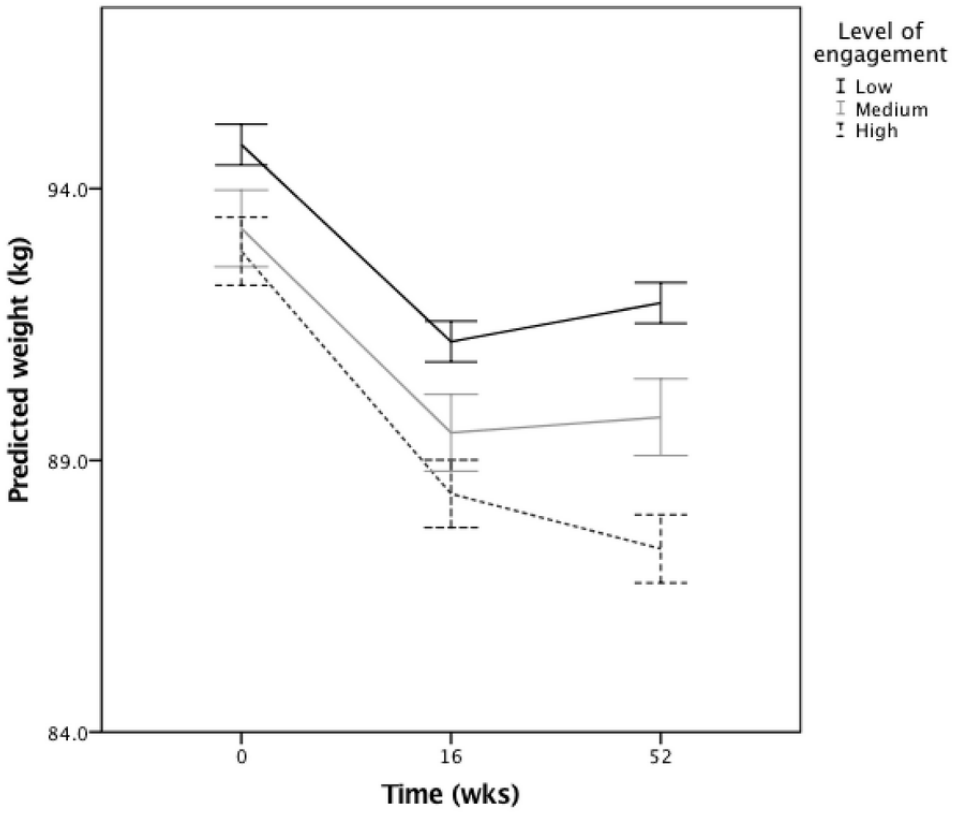
The last model evaluated interactions between age, time, and engagement, adjusting for curriculum. The 3-way interaction between age, engagement, and time was not significant and was removed from the model. Two-way interactions of engagement and time, age and time, and age and engagement were left in the model. A significant engagement effect ($F_{1,15238.5}$=14.6; P<.001) was modified by the interactions between engagement and time ($F_{2,1368.7}$=4.98; P=.01), age and engagement

($F_{1,14679.5}$=6.70; P=.01), and age and time ($F_{2,1351.7}$=10.37, P<.001; Table 5). In general, higher engagement was associated with lower weight over the entire study. At week 16, engagement was not yet significant as a predictor of weight (baseline vs week 16: β=–.13, 95% CI –0.27 to 0.00); at week 52, engagement was a significant predictor of weight such that as engagement increased by 1 composite score, weight decreased by 0.44 kg (baseline vs week 52: β=–.44, 95% CI –0.74 to –0.14; Figure 3).

The strength of the association between engagement and weight across the study differed by age; engagement was more strongly associated with weight for younger versus older adults (age and engagement interaction β=.02, 95% CI 0.01 to 0.04). Younger adults lost more weight when engaged; however, older adults lost weight over time despite their level of engagement.

As found in the prior model, age was associated with weight loss such that higher age was associated with greater weight loss at week 16 (β=–.12, 95% CI –0.18 to –0.07) but not at week 52 (β=–.02, 95% CI –0.14 to 0.09). Older adults lost more weight earlier on compared with younger adults such that for each additional year of age, weight decreased by an additional 0.12 kg.

Figure 3. Interaction between time and engagement on predicted weight outcomes. Error bars: 95% CI. Data not distinguished by curriculum.



Discussion

Principal Findings

This study explored the effect of age and engagement in predicting weight in a mobile intervention. To our knowledge, this is the first quasi-experimental study to consider age effects strictly in an mobile lifestyle intervention.

In support of our main hypothesis, higher age was associated with greater weight loss; older users lost more weight from baseline to week 16. Our second hypothesis that higher engagement would be associated with greater weight loss was supported, while our hypothesis that older users would engage more than younger adults was not found. Higher engagement was predictive of greater weight loss; however, the strength of the association differed by age. Although younger age was associated with engagement in predicting weight, older adults lost more weight from baseline to week 16 despite their level of engagement. These findings demonstrate that not only do older adults lose weight from mobile interventions, but they may benefit more compared with their younger counterparts.

Comparison With Prior Work

mHealth interventions are used by older adults and appear to be an effective approach to weight loss. A meta-analysis by Valenzuela et al [23] of electronic health exercise programs for older adults (aged 67 to 86 years) yielded promising findings of technology as a well-accepted method, with the mean adherence as 91.3%. This is consistent with Svetkey et al [24], who found adults aged 60 years and older had both greater initial and sustained weight loss over 3 years compared with younger adults (aged younger than 50 years and between ages 51 and 60 years) in both counseling and internet-based intervention groups.

In our study, older age was not associated with engagement in predicting weight, which is not consistent with the DPP findings

where adults aged 60 to 85 years attended nearly twice as much as adults aged 25 to 44 years [16]. Honas et al [25] found in a clinic-based weight loss program that younger adults were the only age group with an association with dropout (76% of individuals aged 51 to 60 years completed the program compared with 60% of participants aged 40 years and younger). A meta-analysis showed that in 13 studies, younger age was associated with higher attrition in weight loss interventions [26]. Additionally, adults aged 65 years and older were found to have higher self-monitoring rates and attend more sessions compared with younger adults (aged younger than 65 years) in an adapted DPP intervention [27]. One possible explanation for these findings is that older adults have a lack of work or family responsibilities (ie, fewer work demands). However, because we found program engagement mattered particularly for younger adults in our mobile intervention, these differences in findings compared with previous works may point to unique impacts of the use of technology, which younger adults likely have more experience with. Older adults experienced weight loss despite their total engagement, whereas younger adults benefited more from weight loss when they were engaged more with the program. It is likely that perception or presence of declining health may serve as a motivator for the aging population that extends beyond level of engagement to the mobile program. Further research should explore underlying motivators of engagement across age groups in mHealth interventions.

Our results showed that only 15% of users extracted from Noom met criteria for starters. One reason for this is that while we aimed to incorporate key engagement indicators, it is possible our definition may not capture true engagement within the program; thus, results may change with a different definition. Therefore, better mHealth definitions of engagement are needed. Dropout rates of 6% to 37% are common in mobile weight loss and diabetes interventions [28]; however, our high numbers particularly early in the program are likely related to a 2-week free trial period offered within the HW program at the time of extraction. More users may have joined who were not committed to long-term behavior change.

Throughout the 52 weeks, participants lost on average 6.24 (SD 6.73) kg or 5.2% of their body weight in the HW program and 5.66 (SD 7.16) kg or 8.1% of their body weight in the DPP program. These results meet the CDC standards that state that individuals who lose 5% of body weight or more can benefit from reduced risk for chronic diseases related to obesity [29]. Further research is needed to explore the feasibility of participants' experience with technology interventions to better understand potential barriers that may exist. Scheibe et al [30] showed that older adults reported difficulty in understanding the functionality of the apps' touch sensitive areas and that the visual representations were too small to be easily visible as reasons against using mobile diabetes interventions. As findings did not show a strong interaction of age and engagement for older adults, it is likely that barriers exist that affect the overall feasibility of the mobile intervention, requiring adaptations to enhance the users' experience.

Limitations

Participants were self-selecting and results may not generalize to populations with less intrinsic interest in weight loss. As our study is observational, the effect of the intervention against a control group is unknown. We decided to use initial weight versus first weigh-in as our baseline weight, given missing data concerns. It is likely the initial weight input at the time of sign-up may not reflect a true weight on a scale, as it is hypothesized many users estimate how much they believe they weigh during the sign-up phase. Third, completion status criteria for never engaged was determined based on overall engagement in week 1. Therefore, participants who were excluded may have engaged in later weeks. Additionally, as some forms of engagement included self-reports, it is hard to distinguish if a lack of exercise logged reflects a lack of exercise versus a lack of reporting. Therefore, behavioral-based engagement steps recorded are more likely to indicate a true level of engagement. Fourth, potential bias in motivational differences likely exists between users in HW and DPP, as users paid for the HW program versus users who received the DPP program for free.

Because of the retrospective design, it was not possible to assess whether users had a prediabetes or diabetes diagnosis in the HW program. The HW program is available to anyone who is able to afford it and owns a smartphone; thus, users may have additional underlying health conditions that were unknown. Finally, as mentioned previously, it is likely the CDC's definition of attendance does not directly apply to mHealth interventions and may not have optimally captured the true findings of dropout rate or completers of the program.

Conclusions

In conclusion, age and engagement appear to play a significant role in predicting weight while using a mHealth lifestyle intervention at weeks 16 and week 52 in this study. Not only did older adults lose more weight from baseline to week 16, but they may benefit more compared with younger adults. Further analyses are needed to explore potential age differences to better optimize older adults' experience within a mobile intervention.

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Authors' Contributions

LD contributed to the literature search, conception and design of study, data analysis, data interpretation, figure creation, and writing of the manuscript. TR contributed to the conception and design of study, data analysis, and writing of the manuscript. ES contributed to the study design, data interpretation, and revised the manuscript. AM revised the manuscript and provided scientific

input. CS contributed to the study design, data analysis, and revised the manuscript. All authors edited and approved the final draft.

Conflicts of Interest

This study was completed as part of a master's thesis and was not supported by grant funding. LD, TR, and AM are employees at Noom Inc and have received salary and stock options for their employment. In addition, AM reports a pending patent, "Scalable Population Health Management Tools For Clinicians." ES receives research support from the National Institute of Neurological Disorders and Stroke (K23 NS096107 PI: Seng) and has consulted for GlaxoSmithKline, Eli Lilly, and Click Therapeutics. ES has received travel funds from the American Psychological Association, American Academy of Neurology, American Association of Pain Medicine Foundation, and American Headache Society.

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Abbreviations

CDC: Centers for Disease Control and Prevention
DPP: Diabetes Prevention Program
HW: Healthy Weight
mHealth: mobile health

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Original Paper

Health App Use and Its Correlates Among Individuals With and Without Type 2 Diabetes: Nationwide Population-Based Survey

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Abstract

Background: Evidence suggests that mobile health app use is beneficial for the prevention and management of type 2 diabetes (T2D) and its associated complications; however, population-based research on specific determinants of health app use in people with and without T2D is scarce.

Objective: This cross-sectional study aimed to provide population-based evidence on rates and determinants of health app use among adults with and without T2D, thereby covering a prevention perspective and a diabetes management perspective, respectively.

Methods: The study population included 2327 adults without a known diabetes diagnosis and 1149 adults with known T2D from a nationwide telephone survey in Germany conducted in 2017. Rates of smartphone ownership and health app use were estimated based on weighted sample proportions. Among smartphone owners, determinants of health app use were identified for both groups separately in multivariable logistic regression models. Sociodemographic factors, diabetes-related factors or indicators, psychological and health-related factors, and physician-provided information were selected as potential determinants.

Results: Among participants without known diabetes, 74.72% (1690/2327) were smartphone owners. Of those, 49.27% (717/1690) used health apps, most often to improve regular physical activity. Among participants with T2D, 42.26% (481/1149) were smartphone owners. Of those, 41.1% (171/481) used health apps, most commonly to target a healthy diet. Among people without known diabetes, determinants significantly (all *P* values <.05) associated with an increased likelihood of health app use compared with their reference group were as follows: younger and middle age of 18 to 44 or 45 to 64 years (odds ratios [ORs] 3.89; *P*<.001 and 1.76; *P*=.004, respectively), overweight or obesity (ORs 1.58; *P*<.001 and 2.07; *P*<.001, respectively), hypertension diagnosis (OR 1.31; *P*=.045), former or current smoking (ORs 1.51; *P*=.002 and 1.58; *P*<.001, respectively), perceiving health as very good (OR 2.21; *P*<.001), other chronic diseases (OR 1.48; *P*=.002), and having received health advice from a physician (OR 1.48; *P*<.001). A slight or high perceived diabetes risk (ORs 0.78; *P*=.04 and 0.23; *P*<.001, respectively) was significantly associated with a decreased likelihood of health app use. Among people with T2D, younger and middle age (18-64 years; OR 1.84; *P*=.007), female gender (OR 1.61; *P*=.02), and using a glucose sensor in addition or instead of a glucose meter (OR 2.74; *P*=.04) were significantly positively associated with health app use.

Conclusions: In terms of T2D prevention, age, diabetes-related risk factors, psychological and health-related factors, and medical health advice may inform app development for specific target groups. In addition, health professionals may encourage health app use when giving advice on health behaviors. Concerning T2D management, only a few determinants seem relevant for explaining

health app use among people with T2D, indicating a need for more future research on which people with T2D use health apps and why.

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KEYWORDS

mobile app; smartphone; diabetes mellitus; type 2 diabetes; risk factors; health-related behavior; health promotion

Introduction

Background

Type 2 diabetes (T2D) is a common chronic metabolic disease that increases the risk for severe health complications and premature death [1,2] and is the cause of high economic costs both in Germany and worldwide [3,4]. Thus, current numbers of adults with diabetes and those who are at high risk for developing diabetes are alarming, both worldwide and for the German population [5,6]. However, mirroring the rising trend of diabetes-related risk factors such as obesity, the number of people with T2D is expected to rise, not only in the older generations but also in young people [7,8].

Mobile apps addressing health issues (health apps) provide an effective opportunity to support individuals in the prevention of diabetes, ie, health behavior change in general [9-11] or lowering diabetes risk in people without diabetes and with prediabetes [12], and in managing diabetes and preventing its complications [13,14]. Smartphones, which enable the use of health apps, are widespread as 81% of the German population older than 14 years used a smartphone in 2017 [15], and smartphone use is still increasing [16]. Therefore, apps have the potential to save health care costs [17] and to reach many people, those with and without illness conditions. Despite the effects and potential benefits of general and diabetes-related health apps, less is known about who uses health apps, especially when focusing on people without known diabetes and people with T2D. The investigation of health app use and its association with a range of physiological, personal, and environmental factors representing a persons' health and life background as conceptualized in the International Classification of Functioning, Disability, and Health model [18] among people with and without T2D may result in group-specific user characterizations. In turn, these may be valuable for needs-based and target group–specific health app development and health app promotion.

Although a few studies from a few countries exist that investigate the rates of health app use among the general population [19-22], research investigating the rates of smartphone and health app use among the general population having no diagnosed diabetes is scarce. This gap in the literature motivates the investigation of potential determinants relevant for prevention, ie, determinants that are only present in people without diabetes such as risk perception on developing diabetes. In the characterization of health app users among the general population, previous research consistently suggests that age is associated with health app use [19-23], whereas the investigation of sociodemographic factors such as gender or educational level revealed mixed results [19-23]. Besides electronic health (eHealth) literacy, health awareness, and health intentions [19,21,22], which seem to be correlated with health app use, previous studies focused on health-related behaviors [19-22] as they usually present the primary target of health apps. Evidence of the association with health app use was found for physical activity [19,21,22] but not for smoking [20,21], whereas it was unclear for BMI or obesity [20,21]. Thus, these factors, which are associated with the risk of developing T2D, shall be further explored alongside other factors that contribute to an actual diabetes risk, eg, as indicated by a diabetes risk test. However, an actual diabetes risk, can, but must not, reflect health beliefs. A previous study revealed that the perceived diabetes risk was low, even if the actual risk was high [24]. Thus, psychological and health factors should be explored in addition for the characterization of health app users. Furthermore, a healthy lifestyle or diabetes risk addressed by a health care professional has been found to be associated with adopting a healthy lifestyle [25,26]. This kind of taking care of ones' own health, which Cho et al [27] refer to as health consciousness, was found to be associated with health app use. Thus, physician-communicated health information shall be explored in the context of health app use.

Research focusing on user rates and the identification of potential determinants of health app use in people with T2D seems to exist even less. Although there have been estimations of user rates among people with known T2D among the Australian adult population [28], such estimates seem to be generally lacking for the German population. Previous studies examined the potential determinants of health app use among people with chronic conditions, including diabetes [29,30]. However, these studies did not investigate people with T2D separately. Zhang et al [29] found lower health app use in patients with T2D compared with patients with type 1 diabetes (T1D), indicating the need for differentiated examinations of health app use for each diabetes type. Trawley et al investigated associations between app use for diabetes management and sociodemographic, clinical, and psychosocial factors among people with T1D and T2D. However, subsequent analyses of individuals with T2D were not conducted because of an insufficient sample size [28]. Previous research indicated that clinical indicators and disease-related factors may be associated with the usage of mobile health (mHealth) or eHealth technology. Usage seemed to be more relevant for people with a shorter diabetes duration [28,31]. Kuerbis et al [32] discussed disabilities and functional capacities as potential barriers of usage. Another study found that patients with T2D most often chose an app that could receive blood sugar data from a blood glucometer [29]. Control beliefs seem to be relevant for patients' self-care behaviors [33] and thus might increase their likelihood to engage in health app use to improve diabetes management. To extend the literature on characteristics of health app users and nonusers among people with T2D, potential determinants

of health app use, similar to those in people without diabetes but also more disease related, should be explored.

Objectives

Identifying rates of smartphone ownership, health app use, and behavior types targeted by apps, as well as characterizing health app users and nonusers by using population-based data, might be helpful to promote health app use in specific health contexts such as diabetes prevention and management. To fill the gaps described earlier, this study aimed to provide user rates for adults without diabetes (ie, focusing on diabetes prevention) and for adults with T2D (ie, focusing on diabetes management) in Germany. For both samples, we particularly intended to explore associations between health app use and a range of potential determinants (partly group specific and partly overlapping between samples) that we summarized as sociodemographic factors, diabetes-related risk factors or indicators, psychological and health-related factors, and physician-provided information.

Methods

Study Design and Sample

The survey, *Disease knowledge and information needs—Diabetes mellitus (2017)*, was conducted in 2017 by the Robert Koch Institute (RKI), Berlin (Germany). This nationwide telephone survey focused on psychosocial and health care factors in adults without known diabetes and people with known diabetes. People were eligible to participate in the survey if they were German residents aged at least 18 years and had sufficient German language skills. For the survey, the aim was to include a sample of 2500 people without known diabetes and a sample of 1500 people with known diabetes to identify subgroups and to ensure stratified analyses with possibly low levels of error tolerance. The sampling procedure comprised a dual-frame approach. To ensure representativeness by considering all private households that were potentially reachable over the phone, a sample of landline and mobile telephone numbers was randomly generated. In a first step, a sample of the adult general population, including people with and without diabetes, was drawn using the Kish selection grid method. Assignment to one of the samples was based on the question "Have you ever been diagnosed with diabetes by a doctor?" (yes or no). Two respondents were excluded because of not answering the question with yes or no or because of missing information about the federal state of residence. To gain a larger sample of people with a physician-diagnosed diabetes, in a second step, a direct screening procedure was applied by asking for lifetime physician-diagnosed diabetes. More details are presented elsewhere [34]. Final samples comprised 2327 people without known diabetes and 1479 people with self-reported physician-diagnosed diabetes, respectively. Data were collected by an external market and social research institute between September and November 2017 applying computer-assisted telephone interviews. In this cross-sectional survey, all respondents were interviewed at a single point of measurement. Interviews were based on 2 different questionnaires, customized for people without and with diabetes. Questionnaires were developed by using preferably short and validated German-language instruments. English-language instruments used were translated into German language using the forward-backward translation [35]. Other questions were newly developed. Psychometric properties of multi-item measurements were investigated and will be the content of a separate publication that is currently under revision. Cognitive testing and a field pretest were conducted to assess the comprehensibility and length of the questionnaires. To ensure RKI quality standards of survey assessment, interviewers were trained, monitored, and supervised by the RKI [36]. Respondents' willingness of cooperation with the survey was strengthened by applying interview options and rules (eg, making appointments with target persons; limited number of contact attempts).

This study focused on individuals without known diabetes (n=2327) and on individuals with self-reported T2D (n=1149). People who reported types other than T2D were excluded from this study (n=330). This study was reported by following the Strengthening the Reporting of Observational studies in Epidemiology guidelines for cross-sectional studies [37].

The survey was approved by the ethics committee of the Berlin Chamber of Physicians in August 2017 (Ärztekammer Berlin; number Eth-23/17) and the Federal Commissioner for Data Protection and Freedom of Information. All participants were informed about the voluntary nature of their participation and the survey objectives and provided oral informed consent to participate in the survey before the interview started.

Survey Measures

Smartphone Ownership and Health App Use

Smartphone ownership (yes or no) was assessed identically in both samples by asking a single question. An overview of survey questions is given in Multimedia Appendix 1. Health app use, which was the dependent variable, was only assessed in people who stated they owned a smartphone. Participants of both samples were asked if they used a smartphone or app to improve a certain behavior in the last 12 months. Health behaviors listed were to (1) quit smoking, (2) be regularly physically active, (3) maintain a healthy diet, (4) reduce weight, (5) take medication regularly, (6) regulate blood pressure, and (7) regulate blood sugar (only in people with diabetes); this was adapted from the study by Ernsting et al [19]. People who stated that they use a smartphone or apps to improve at least one of the target behaviors were defined as health app users. Participants who answered *no* for all behaviors but used apps for behaviors not listed in the survey (derived from the question: "Is it correct that you do not use your smartphone or apps to improve behaviors?") were defined as health app users as well.

Determinant Variables in People Without Known Diabetes

The sociodemographic determinants assessed were age (subsequently categorized into 18-44, 45-64, and ≥65 years), sex, and educational level. The latter was determined following the Comparative Analysis of Social Mobility in Industrial Nations classification system [38] and was categorized as low, middle, or high [6]. Diabetes risk factors considered in this study comprised BMI (in kg/m²) and several components of the

German Diabetes Risk Score (GDRS [39,40]). BMI was calculated based on the participants' self-reported body height and weight (kg/m²) and categorized into normal (BMI<25 kg/m²), overweight (BMI≥25 kg/m²), and obese (BMI≥30 kg/m²) based on the World Health Organization's criteria [41]. The components of GDRS were hypertension diagnosis (yes or no), physical activity (more or less than 5 hours), smoking (current, former, or nonsmoker), and a family history of diabetes (ie, having at least one biological parent or sibling who was diagnosed with diabetes). Perceived health and presence of chronic diseases apart from diabetes were assessed with an item of the Minimum European Health Module [42] each. The perceived risk of getting diabetes over the next 5 years was assessed with an item adopted from a study by Kim at el [43]. Health advice obtained by a physician was assessed by asking those who had been at a medical practice in the last 12 months whether they had received advice on several health behaviors. Items were adapted from the German Health Interview and Examination Survey for Adults (DEGS1) [44]. Participants were defined as having obtained health advice if they stated that they had received advice on at least one health behavior. An increased diabetes risk communicated by a physician (yes or no) was assessed with a self-developed item.

Determinant Variables in People With Known Type 2 Diabetes

Age, sex, and educational level were assessed analogously for people without diabetes. Diabetes-related indicators included in this study were diabetes duration, BMI (kg/m^2), diabetes-related complications, comorbidities, current diabetes treatment, and the method of blood sugar measurement. Diabetes duration was calculated based on self-reported age and the time of diagnosis. Diabetes-related complications and comorbidities were assessed with several items adopted from DEGS1 [44]. Participants were asked for their current diabetes treatment with an item adopted from the German Health Update survey [45]. The method of blood sugar measurement was assessed with a self-developed item. People were asked if they use a blood glucose meter and a glucose sensor in the subcutaneous fatty tissue, ie, continuous glucose monitoring systems and flash glucose monitoring systems. Perceived health was assessed using the same item as for participants without diabetes. Personal control over diabetes was assessed by using the Personal Control subscale of a German version of the Revised Illness Perception Questionnaire (IPQ-R) [46,47]. The scale score was calculated following instructions that were presented in the German IPQ-R downloaded from the IPQ-R website [47]. The scale had a possible range from 4 to 20, with a higher score reflecting more personal control. Health advice obtained by a physician was assessed similarly to participants without diabetes, ie, participants with diabetes were directly asked if they received advice on health behaviors by a member of their medical treatment team in the last 12 months.

Statistical Analyses

All analyses were conducted separately for people without known diabetes and people with T2D. Logistic regression models, with health app use as the dependent variable, were performed only among those who stated that they owned a smartphone (sample without known diabetes n=1690; sample with T2D n=481). Participants who reported not owning a smartphone or not knowing were excluded from the analyses. For comparison, descriptive statistics and examinations comparing nonsmartphone users and smartphone users are presented in Multimedia Appendix 2. Separate models that included the single determinants only adjusted for age and sex were calculated for each sample (model 1). Then, a fully adjusted model, including all variables described above simultaneously, was calculated for each sample (model 2). Specific weighting factors were applied and calculated for people without and with diabetes, as previously described in more detail [34]. Logistic regression assumptions were tested, revealing no multicollinearity, no independence of residuals, and no linearity of continuous variables. The overall model fit was evaluated by the Hosmer-Lemeshow goodness-of-fit statistic [48] and the models' discrimination ability, ie, the area under the receiver operating characteristic (ROC) curve [48] with a value of 0.7 indicating acceptable discrimination.

Missing data were treated by applying multiple imputation separately to each initial sample, ie, people without known diabetes (n=2327) and people with T2D (n=1148). In the sample with T2D, one case was excluded before the imputation because of missing information on smartphone ownership. Chained equation imputation was performed based on the fully conditional specification (FCS) method assuming the pattern of missing data to be arbitrary and by choosing 20 imputations [49]. Two imputation models were built, one for each sample, ie, people without and with T2D. A model included all corresponding sample variables used for the logistic regression, or items, which were required to build those variables and the corresponding sample weight. In the sample of people without diabetes (n=2327), 149 (6.4%) participants had missing information in at least one variable. All variables included in the imputation model had less than 5% of missing values. Precise information on missing values for all variables is presented in Multimedia Appendix 3. In the sample of people with T2D (n=1149), 206 (17.9%) participants had missing information in at least one variable. Missing data made up less than 5% per variable for all variables (Multimedia Appendix 3). Logistic regression was run separately in the 20 imputation data sets, resulting in combined parameter estimates. The mean Cronbach alpha across 20 imputed datasets was alpha=.79 for the personal control scale.

All analyses were performed by using the statistic software SPSS (IBM SPSS version 25.0). *P* values <.05 were considered to indicate statistical significance.

Results

Smartphone Ownership and Health App Use

Within the initial sample of people without known diabetes (n=2327), the majority reported to own a smartphone (1690/2327, 74.72%; Figure 1). Among smartphone owners, ie, the analysis sample in this study, the mean age, after weighting, was 43.7 (SD 15.7) years, ranging from 18 to 91 years. The proportion of women and men, after weighting, was comparable (887/1690, 50.78% vs 860/1690, 49.22%,

respectively; Table 1). Among those who owned a smartphone (n=1690), about half of the participants (717/1690, 49.27%, which was 36.81% of the initial sample n=2327) reported using apps to improve health behaviors (Figure 1). Sample characteristics of the initial sample, smartphone owners, app users, and nonapp users without known diabetes are presented in Table 1.

Figure 1. A Flowchart of the hierarchical sample structure for people without known diabetes and people with known type 2 diabetes. Sample sizes (n) are given as unweighted data. Percentages are given as weighted.

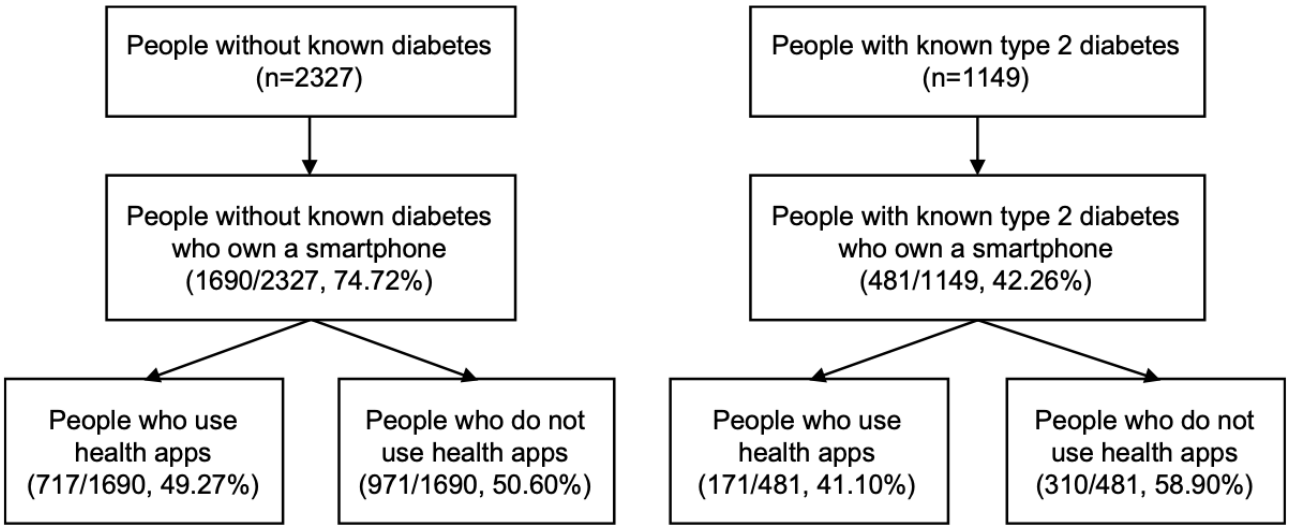


Table 1. Sample characteristics of the initial sample and of the sample of smartphone owners, app users, and nonapp users among individuals without known diabetes. (Data are given as weighted percentage or mean [SD]. Missing data were less than 5% for all variables).

Variables	Initial sample (n=2327)	Smartphone owners[a] (1690/2327; 74.72%[b])	App users[a] (717/1690; 49.27%)	Nonapp users[a] (971/1690; 50.60%)
Sociodemographic factors				
Age (years), mean (SD)	49.62 (18.55)	43.69 (15.73)	40.78 (15.06)	46.50 (15.88)
Age (years), %				
≥65	22.57	9.79	6.08	13.43
45-64	36.68	37.76	32.71	42.53
18-44	40.76	52.45	61.22	44.05
Gender, female (%)	51.68	50.78	50.49	50.94
Educational level (%)				
Low	30.70	23.61	22.58	24.68
Middle	42.16	45.48	49.49	41.69
High	26.93	30.63	27.51	33.49
Diabetes-related risk factors				
BMI (kg/m²), mean (SD)	25.61 (4.57)	25.38 (4.50)	25.59 (4.47)	25.19 (4.52)
BMI (kg/m²; %)				
BMI<25	50.55	53.31	49.71	56.70
25≤BMI<30	31.52	29.59	32.00	27.33
BMI≥30	15.85	15.07	16.24	13.97
Hypertension diagnosis (%)	32.60	25.82	25.75	25.96
Physical activity ≥5 hours/week (%)	72.49	73.46	74.28	72.59
Smoking (%)				
Not smoking	47.91	45.13	40.25	49.74
Former smoking	24.69	24.29	26.05	22.65
Currently smoking	27.40	30.58	33.70	27.62
Family history of diabetes (%)[c]	22.29	21.34	21.88	20.88
Psychological and health-related factors				
Perceived health (%)				
Very good	24.96	28.30	33.11	23.69
Good	48.77	50.25	47.22	53.07
Moderate/poor/very poor	26.23	21.44	19.66	23.23
Chronic diseases (%)[d]	43.86	40.65	41.30	39.86
Perceived risk of getting diabetes (%)				
Almost no risk	42.00	41.37	44.92	37.86
Slight risk	39.41	40.91	39.18	42.69
Moderate risk	11.52	11.88	12.72	11.00
High risk	2.27	2.52	1.26	3.76
Physician-provided information (%)				
Health advice obtained by physician	46.75	48.30	52.20	44.46
Diabetes risk communicated by physician	6.09	5.89	5.12	6.56

[a]Sample sizes (n) are given as unweighted.

[b]Percentages (%) are given as weighted.

[c]At least one parent or sibling was diagnosed with diabetes.

[d]Any chronic disease besides diabetes.

Within the initial sample of people with known T2D (n=1149), less than half of the participants reported owning a smartphone (481/1149, 42.26%; Figure 1). In smartphone owners, the mean age, after weighting, was 61.6 (SD 11.7) years, ranging from 18 to 95 years. In this sample, after weighting, 43.6% (200/481) were female (Table 2). Among those who owned a smartphone (n=481), 171 participants (41.1%, ie, 17.4% of the initial sample, n=1149) used apps to improve health behaviors (Figure 2). Sample characteristics of the initial sample, smartphone owners, app users and nonapp users with known T2D are presented in Table 2.

Health Behaviors Targeted by Apps

When considering single health behaviors targeted by apps among health app users without known diabetes (n=717), the most frequent target behaviors, after weighting, were improving physical activity (573/717, 66.6%), healthy diet (434/717, 50.4%), and weight loss (272/717, 31.6%; Figure 2). Apps were used least frequently for blood pressure adjustment (82/717, 9.5%), smoking cessation (92/717, 10.7%), and medication adherence (132/717, 15.4%). When focusing on combinations of multiple health behaviors targeted by apps (Figure 2), regular physical activity and healthy diet were most often reported to be simultaneously addressed by apps (273/717, 31.7%). Among health app users with T2D (n=171), single health behaviors targeted by apps most often were a healthy diet (104/171, 55.3 %), regular physical activity (95/171, 50.3%), and weight loss (81/171, 43.2%; Figure 2). App use was reported less often for medication adherence (57/171, 30.4%), blood sugar adjustment (54/171, 28.9%), blood pressure adjustment (40/171, 21.3%), and smoking cessation (10/171, 5.3%). The most frequent combination of multiple behaviors targeted by apps comprised a healthy diet and weight loss (61/171, 32.5%; Figure 2). Very few of the participants (20/171, 10.4%) reported using apps for a combination of regular physical activity, a healthy diet, medication adherence, and blood sugar adjustment.

Table 2. Sample characteristics of the initial sample and of the sample of smartphone owners, app users, and nonapp users among individuals with known type 2 diabetes. (Data are given as weighted percentage or mean [SD]. Missing data were less than 5% for all variables).

Variables	Initial sample (n=1149)	Smartphone owners[a] (481/1149; 42.26%[b])	App users[a] (171/481; 41.10%)	Nonapp users[a] (310/481; 58.90%)
Sociodemographic factors				
Age (years), mean (SD)	67.37 (12.06)	61.64 (11.73)	58.80 (13.95)	63.61 (9.43)
Age (years), %				
≥65	62.35	41.89	31.07	49.55
18-64	37.65	58.11	68.93	50.45
Gender, female (%)	50.95	43.58	51.01	38.40
Educational level (%)				
Low	49.15	37.19	33.94	39.45
Middle	38.35	46.28	52.22	42.13
High	12.43	16.54	13.84	18.42
Diabetes-related indicators				
Diabetes duration (years), mean (SD)	13.78 (9.75)	11.79 (8.61)	11.12 (8.41)	12.25 (8.74)
BMI (kg/m²), mean (SD)	30.53 (5.78)	30.81 (6.11)	30.59 (6.39)	30.97 (5.92)
BMI (kg/m²; %)				
BMI<25	15.25	15.51	19.12	12.99
25≤BMI<30	35.61	33.25	30.18	35.40
BMI≥30	46.78	50.15	49.70	50.47
Diabetes-related complications[c], at least one (%)	34.33	32.23	30.77	33.26
Comorbidities[d], at least one (%)	31.01	24.42	20.96	26.84
Treatment with insulin (%)	45.54	41.05	46.08	37.54
Treatment with tablets (%)	69.81	75.02	76.38	74.08
Treatment with healthy diet or physical activity (%)	73.18	78.94	83.29	75.91
Method of blood sugar measurement[e] (%)				
Glucose meter with blood sampling	62.12	61.35	61.78	61.05
Subcutaneous fatty tissue in addition to or instead of a glucose meter	4.96	5.10	8.34	2.84
No use of measurements or no blood sugar measuring in the last 7 days	31.75	32.99	28.94	35.82
Psychological and health-related factors				
Perceived health (%)				
Very good	6.51	8.82	8.92	8.74
Good	40.78	43.35	43.52	43.23
Moderate/poor/very poor	52.58	47.78	47.56	47.93
Personal control over diabetes, mean (SD)[f]	16.02 (2.79)	16.86 (2.67)	16.87 (2.95)	16.85 (2.47)
Physician-provided information				
Health advice obtained by physician (%)	81.91	83.60	86.53	81.56

[a]Sample sizes (n) are given as unweighted.

[b]Percentages (%) are given as weighted.

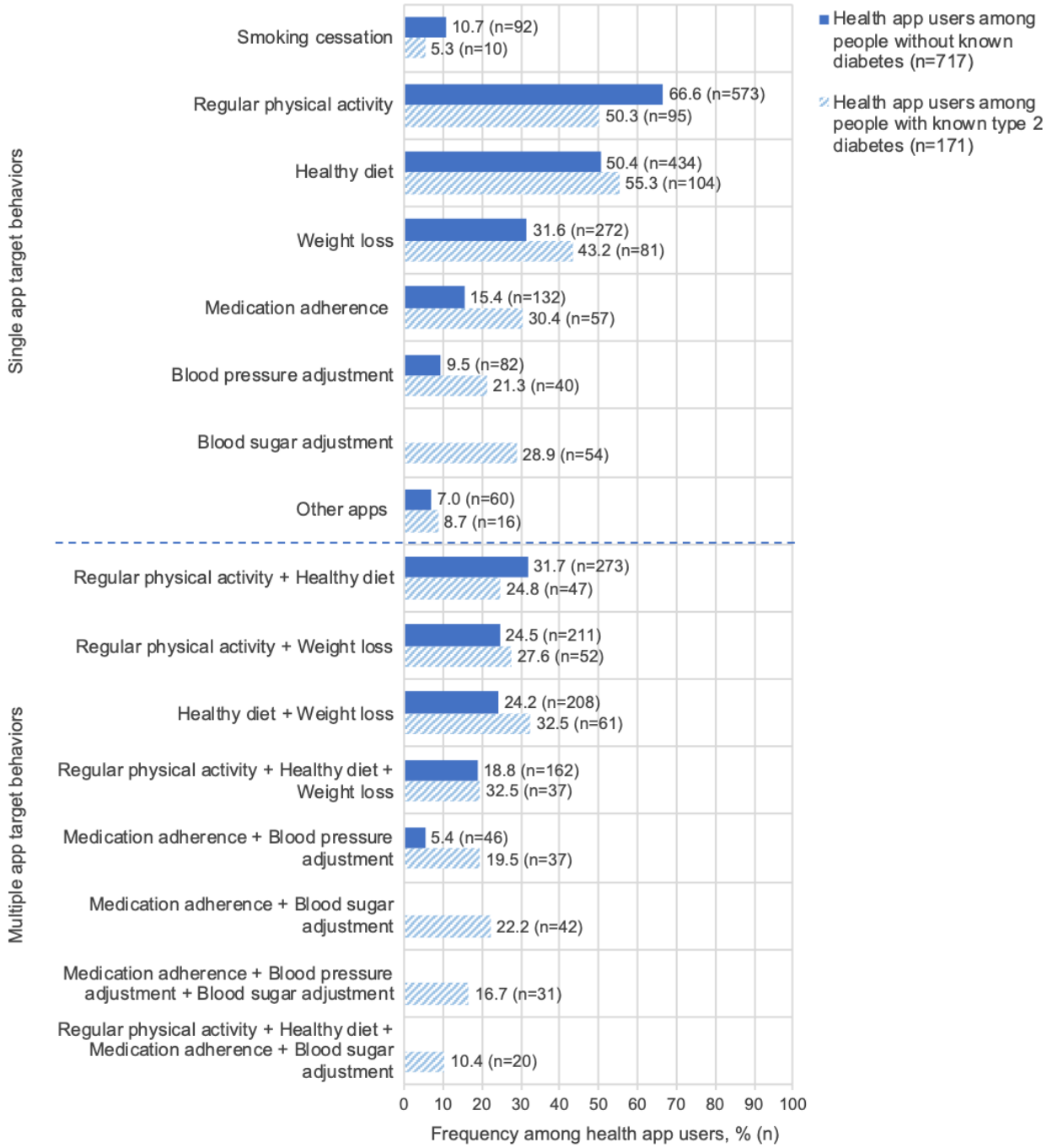
[c]Including kidney disease, eye disease, nervous disease, diabetic foot lesions, and amputations.

[d]Including heart attack, stroke, and coronary heart disease.

[e]Multiple answers were eligible.

[f]Possible score range: 4-20.

Figure 2. App use for single and multiple target behaviors among people without known diabetes and people with known type 2 diabetes. Frequencies are given as weighted percentage and n. App use targeting blood sugar adjustment was assessed only in people with type 2 diabetes and thus is not presented for people without known diabetes in the single and multiple condition.



Factors Associated With Health App Use

Logistic regression analyses among people without known diabetes who reported to own a smartphone (n=1690) revealed almost consistent patterns of results when comparing the age- and sex-adjusted models (model 1) with the fully adjusted model (model 2), except for educational level and perceived risk of getting diabetes (Table 3). For model 2, the Hosmer and Lemeshow test revealed a nonsignificant result (χ^2_8=13.8; P=.16), indicating that the model fits the data. The area under the ROC curve (0.68) indicated acceptable discrimination.

Table 3. Associations with app use among people without known diabetes owning a smartphone (n=1690). Analyses were based on imputed and weighted data. Model 1: adjusted for age and gender. Model 2: fully adjusted for all determinants. Model statistics for model 2 (values were averaged based on 20 imputed datasets): Hosmer and Lemeshow test: $\chi^2 8=13.8$; *P*=.16; area under the receiver operating characteristic curve=0.68.

Factors	Model 1		Model 2	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Sociodemographic factors				
Age (years)[a]				
≥65	__[b]	—	—	—
45-64	1.74 (1.21-2.50)	.003	1.76 (1.19-2.59)	.004
18-44	3.07 (2.16-4.36)	<.001	3.89 (2.62-5.78)	<.001
Gender (reference: male)[a]	0.96 (0.79-1.16)	.63	1.04 (0.85-1.29)	.69
Educational level				
Low	—	—	—	—
Middle	1.07 (0.83-1.38)	.61	1.23 (0.94-1.61)	.13
High	0.74 (0.56-0.97)	.03	0.86 (0.64-1.15)	.30
Diabetes-related risk factors				
BMI (kg/m^2)				
BMI<25	—	—	—	—
25≤BMI<30	1.56 (1.24-1.96)	<.001	1.58 (1.24-2.02)	<.001
BMI≥30	1.84 (1.35-2.51)	<.001	2.07 (1.45-2.96)	<.001
Hypertension diagnosis (reference: no)	1.45 (1.14-1.85)	.003	1.31 (1.01-1.70)	.045
Physical activity (≥5 hours per week; reference: <5 hours)	1.10 (0.87-0.137)	.43	1.00 (0.79-1.28)	.97
Smoking				
Not smoking	—	—	—	—
Formerly smoking	1.66 (1.30-2.12)	<.001	1.51 (1.17-1.96)	.002
Currently smoking	1.54 (1.22-1.94)	<.001	1.58 (1.24-2.01)	<.001
Family history of diabetes (reference: no)	1.17 (0.93-1.49)	.19	1.29 (1.00-1.66)	.06
Psychological and health-related factors				
Perceived health				
Moderate/poor/very poor	—	—	—	—
Good	0.91	0.70-1.18	.47	1.22 (0.90-1.64)	.20
Very good	1.28	0.96-1.71	.10	2.21 (1.55-3.16)	<.001
Chronic diseases (reference: no)	1.27	1.04-1.56	.02	1.48 (1.16-1.88)	.002
Perceived risk of getting diabetes				
Almost no risk	—	—	—	—	—
Slight risk	0.85	0.68-1.06	.14	0.78 (0.62-0.99)	.04
Moderate risk	1.07	0.78-1.50	.67	0.92 (0.64-1.33)	.67
High risk	0.29	0.14-0.60	.001	0.23 (0.10-0.51)	<.001
Physician-provided information				
Health advice obtained by physician (reference: no)	1.49	1.23-1.81	<.001	1.48 (1.20-1.83)	<.001
Diabetes risk communicated by physician (reference: no)	0.82	0.54-1.23	.34	0.69 (0.43-1.11)	.13

[a]The separate model was not adjusted for any other variable.

[b]Reference group.

Among people without known diabetes, results of model 2 (fully adjusted) revealed that younger and middle-aged participants (18-44 and 45-64 years) were more likely to use health apps compared with older participants (≥65 years; OR 3.89; *P*<.001; OR 1.76; *P*=.004). Sex and educational level were not significantly associated with health app use (Table 3).

Overweight or obese participants were more likely to be health app users compared with participants with a normal BMI (OR 1.58; *P*<.001; OR 2.07; *P*<.001). Participants who had been diagnosed with hypertension were more likely to use apps compared with participants who never had a hypertension diagnosis (OR 1.31; *P*=.045). Current and former smokers were more likely to use health apps compared with nonsmokers (OR 1.58; *P*<.001; 1.51; *P*=.002). Regular physical activity and having a family history of diabetes were the only risk factors that were not found to be significantly associated with health app use.

All psychological and health-related factors were found to be associated with health app use in model 2. Participants who perceived their health as very good were more likely to use health apps compared with participants with poorer self-perceived health (moderate to very poor; 2.21; *P*<.001). However, this difference could not be found for those who perceived their health as good. Participants with a chronic disease were more likely to use health apps than those without chronic disease (OR 1.48; *P*=.002). Participants who perceived themselves at a slight or high risk of getting diabetes in the next 5 years were less likely to use health apps compared with those who perceived themselves at almost no risk (OR 0.78; *P*=.04; OR 0.23; *P*<.001). However, this could not be observed for participants who perceived their risk as moderate.

Considering physician-provided information factors, participants who obtained health advice from a physician were more likely to use health apps compared with those who received no advice on any health behavior (OR 1.48; *P*<.001). A present diabetes risk communicated by a physician was not associated with health app use.

Subsequent logistic regression analyses exploring potential associations of smartphone ownership among people without diabetes revealed similar results as found for health app use (Multimedia Appendix 2). Remarkably, educational level and physical activity were found to be significantly associated with smartphone ownership, but BMI, chronic diseases, and perceived risk of getting diabetes were not.

Among people with T2D who reported owning a smartphone (n=481), the fully adjusted logistic regression analysis revealed similar results compared with results based on the age- and sex-adjusted models for each determinant (Table 4). Regarding model 2, the Hosmer and Lemeshow test revealed a nonsignificant result (χ^2_8=9.4; *P*=.33), indicating that the model fits the data. The area under the ROC curve (0.69) indicated acceptable discrimination.

In model 2 (fully adjusted), participants between 18 and 64 years of age were more likely to use apps compared with participants who were 65 years or older (OR 1.84; *P*=.007). Compared with men, women were more likely to use health apps (OR 1.61; *P*=.02). Of the remaining potential determinants, only the method of blood sugar measurement was associated with health app use. Participants who used both a glucose meter with blood sampling and a blood glucose sensor in the subcutaneous fatty tissue were more likely to use health apps compared with participants who only used a glucose meter with blood sampling (OR 2.74; *P*=.04).

Results of subsequent logistic regression analyses exploring potential associations of smartphone ownership among people with T2D were similar compared with those found for health app use (Multimedia Appendix 2). However, educational level, diabetes duration, perceived health, and personal control over diabetes were found to be significantly associated with smartphone ownership, whereas no association was found for the method of blood sugar measurement.

Table 4. Associations with app use among people with type 2 diabetes owning a smartphone (n=481). Analyses were based on imputed and weighted data. Model 1: adjusted for age and gender. Model 2: fully adjusted for all determinants. Model statistics for model 2 (values were averaged based on 20 imputed datasets). Hosmer and Lemeshow test: $\chi^2 8=9.4$; $P=.33$; area under the receiver operating characteristic curve=0.69.

Factors	Model 1		Model 2	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Sociodemographic factors				
Age (years)[a,b]				
≥a	__[c]	—	—	—
18-64	2.16 (1.47-3.19)	<.001	1.84 (1.19-2.86)	.007
Gender (reference: male)[b]	1.68 (1.15-2.44)	.007	1.61 (1.07-2.43)	.02
Educational level				
Low	—	—	—	—
Middle	1.36 (0.89-2.06)	.16	1.47 (0.95-2.21)	.09
High	0.97 (0.72-1.30)	.98	1.10 (0.63-2.01)	.75
Diabetes-related indicators				
Diabetes duration (years)	1.00 (0.97-1.02)	.72	0.99 (0.96-1.01)	.26
BMI (kg/m^2)				
BMI<25	—	—	—	—
25≤BMI<30	0.62 (0.34-1.11)	.11	0.63 (0.34-1.17)	.14
BMI≥30	0.60 (0.34-1.05)	.07	0.62 (0.34-1.12)	.11
Diabetes-related complications[d]				
At least one complication (reference: no complication)	0.98 (0.65-1.48)	.92	0.97 (0.61-1.54)	.89
Comorbidities[e]				
At least one comorbidity (reference: no comorbidity)	0.89 (0.56-1.42)	.63	0.87 (0.53-1.43)	.59
Treatment with insulin (reference: no)	1.45 (0.98-2.14)	.06	1.53 (0.92-2.55)	.11
Treatment with tablets (reference: no)	1.05 (0.68-1.63)	.82	1.10 (0.67-1.79)	.71
Treatment with healthy diet or physical activity	1.56 (1.24-1.96)	.07	1.58 (0.94-2.68)	.09
Method of blood sugar measurement				
Glucose meter with blood sampling	—	—	—	—
Blood glucose sensor in subcutaneous fatty tissue in addition to or instead of a glucose meter	2.50 (1.00-6.24)	.05	2.74 (1.06-7.09)	.04
No use of measurements or no blood sugar measuring in the last 7 days	0.76 (0.50-1.16)	.20	0.85 (0.52-1.38)	.50
Psychological and health-related factors				
Perceived health				
Moderate/poor/very poor	—	—	—	—
Good	1.06 (0.71-1.58)	.78	1.01 (0.65-1.58)	.97
Very good	0.90 (0.45-1.81)	.78	1.01 (0.49-2.10)	.98
Personal control over diabetes	0.97 (0.90-1.04)	.40	0.98 (0.91-1.06)	.60
Physician-provided information				

Factors	Model 1		Model 2	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Health advice obtained by physician (reference: no)	1.39 (0.81-2.39)	.23	1.28 (0.72-2.28)	.40

[a]The separate model was not adjusted for any other variable.

[b]Age categories *18-44* and *45-64* years were merged because of insufficient case numbers in the age category *18-44* years across other variables.

[c]Reference group.

[d]Complications asked in this survey were kidney disease, eye disease, nervous disease, diabetic foot lesions, and amputations.

[e]Comorbidities asked in this survey were heart attack, stroke, and coronary heart disease.

Discussion

Principal Findings

On the basis of data from a nationwide telephone survey targeting the German adult population, about 75% of people without known diabetes, ie, those who may be targets for diabetes prevention interventions, owned a smartphone. Among those, every second person used health apps. However, in people with known T2D, ie, who could be considered potential recipients of diabetes management interventions, about 40% of the diabetes sample owned a smartphone. Less than 3 out of 10 smartphone owners used health apps.

In people without known diabetes, results suggested a correlation of health app use with several determinants including age; diabetes risk factors; and psychological and health factors such as perceived health, chronic diseases, perceived risk, and medical health advice. However, in people with T2D, only a few correlates of health app use were identified including age, sex, and method of blood sugar measurement.

Strengths and Limitations

An essential strength of this study was the underlying nationwide survey of the German adult population covering both people without and with diabetes. Hence, the results of this study provided rates of smartphone ownership and updated rates of health app use as well as behaviors targeted by apps for the German population aged 18 years and above. However, only people with sufficient knowledge of the German language were eligible to participate in the survey. As a result, the survey data were not representative for people who do not speak German fluently, such as people with a recent history of migration. Moreover, as the survey mode comprised telephone interviews, a selected responsiveness to telephone calls and attendance in the survey cannot be ruled out, although sample weights were used to optimize representativeness. This study aimed to extend the literature on the characterization of health app users, which was previously addressed by only a few studies from a few countries. A wide range of determinants related to health app use were identified, contributing to a broader characterization of health app users and nonapp users among the general population without diabetes. However, the cross-sectional design did not allow for the investigation of causal relations, which should be investigated in subsequent research. Unfortunately, we were not able to find a similar range of determinants related to health app use among people with T2D. For instance, other factors that seem to influence the usage intention of telemedicine for diabetes management, eg, social influence or perceived ease of use [50], might play a more prominent role in predicting health app use. Nevertheless, we provided initial hints on population-based associations of actual health app use and gender, as well as the method of blood sugar measurement, in those with T2D. A limitation of the study is that findings may have been subject to biases because of self-reported data. Moreover, health app use as defined in this study, ie, using a smartphone or apps to improve health behaviors, may have differed from other definitions that, eg, referred to apps that were downloaded or categorized as health apps by common app stores. However, as this study focused on those who have engaged in health behavior improvements by using smartphone features or apps, our self-reported data still represent valuable insights.

Comparison With Prior Work

Smartphone Ownership, Health App Use, and Target Behaviors

The rate of smartphone owners among people without diabetes found in this study (1690/2327, 74.72%) was comparable with rates found for the German adult population (72%) in the Global Attitudes Survey conducted in 2017 by the Pew Research Center [51]. The proportion of health app users among people without diabetes owning smartphones in our study (717/1690, 49.27%) was found to be about twice as high compared with previous surveys conducted in Germany in 2015 (age >35 years) [19], in the United States in 2013, and in China in 2016 (age >18 years) [21,22], but lower than the one found in an US survey conducted in 2015 (58%; sample age range 18-81 years) [20]. In our study, the proportion of health app users among people with T2D owning a smartphone was 41.1% (171/481), whereas it was 8% in a 2015 Australian study examining people who reported to own suitable devices to access apps or who had internet access and who used apps to manage their diabetes (sample age range 30-75 years) [28].

Health Behaviors Targeted by Apps

In line with the results of this study in people without known diabetes, prior findings of US studies revealed physical activity, diet or food tracking, and weight to be the most frequent behaviors targeted by apps [20,52].

Among people with T2D, the 3 most frequently reported health behaviors targeted by health apps were the same as in people without known diabetes. App use for blood sugar adjustment was reported by only 28.9% (54/171) of people with T2D in this study. In contrast, for Australia, Trawley et al [28] showed that 69% (18/26) and 57% (21/37) of people with T2D using

insulin and not using insulin, respectively, used apps for recording their blood glucose levels. Although previous studies investigated whether diabetes management apps incorporated features according to the 7 self-care behaviors [53], this study revealed complementary results from a user perspective. Results showed that only 10.4% (20/171) of people with T2D used apps to simultaneously target regular physical activity, healthy diet, medication adherence, and blood sugar adjustment, all of which are part of the 7 self-care behaviors relevant for diabetes self-management [54].

Factors Associated With Health App Use

In people without known diabetes, the association of health app use and age found in this study was consistent with the results of various previous studies [19,20,22,55] contributing to the evidence of a higher health app relevance among younger people. Although previous studies from the United States [20,22,55] and China [21] have shown that health app use was associated with higher education, this study did not. This, however, is in accordance with other recent studies from Germany [19,23]. Concerning diabetes-related risk factors, results suggested health app use to be associated with BMI, smoking status, and hypertension diagnosis, but not with a family history of diabetes. Krebs et al also found app use to be more likely among people whose BMI are in the obese range [20]. However, previous studies did not find health app use or download to be associated with smoking status [19,21,55], a history of high blood pressure or cholesterol, or having a family member with diabetes [55]. Although physical activity was not found to be associated with health app use in this study, previous studies identified this association [19,21,22]. Among psychological and health factors in people without known diabetes, a better perceived health and having a chronic disease were associated with a more frequent health app use, similar to findings of prior research [19,21,22,30]. Regarding physician-provided information, results of this study revealed that people without diabetes who obtained health advice from a physician were more likely to use health apps compared with those who did not. Bender et al [55] found no association between health app download and discussing diabetes with a provider.

Among those with known T2D, we found health app use to be more likely in younger people compared with older people and in women compared with men. A recent survey from China found age differences in app use among people with any type of diabetes [29]. A larger proportion of female app users among those with T2D was found in a US survey from 2012 among the general population [52]. Other studies from Germany, Australia, and China did not find gender differences in app use in samples of older adults without diabetes [23], in people with T1D [28], and in people with any type of diabetes [29].

Interpretation of the Findings and Practical Implications

The comparatively high rates of smartphone ownership and health app use in people without diabetes based on a nationwide survey point toward the increasing relevance of health apps. However, these rates were low among people with T2D. The low rate of health app use can partly be explained by the high mean age of people with T2D in our study, which in turn is related to low mobile phone ownership that may drive this effect. Indeed, advanced age has been found to be associated with a lower likelihood for owning a smartphone [19,22]. Moreover, recent studies on diabetes patients found that most patients did not use diabetes apps but were in need of a good app or interested in trying an app [56,57]. However, not knowing that diabetes apps exist seemed to be the main reason for not using an app [56,57]. Other studies indicated that the usability of apps for patients with chronic diseases, including diabetes, was not satisfying and caused frustration in patients [58,59]. However, diabetes seems to be an attractive field for digital health developments with high market potential in the future [60]. To provide all possible benefits to people with T2D, efforts to increase patients' awareness of health apps are needed. In addition, developments of apps or smartphones should aim to increase adoption of patients by improving safety, effectiveness, interoperability with other tools, and compliance with clinical guidelines [58].

People without known diabetes, who may be considered as a potential target group for future diabetes prevention, and people with known T2D, who are the focus of complication prevention and diabetes management interventions, seem to have different health app use patterns. This may indicate specific preferences or needs for different health apps. Nevertheless, physical activity, a healthy diet, and weight loss were commonly sought app themes for both samples. In people without diabetes, health app use is likely not driven by the aim to prevent diabetes, but by motives related to general health improvement, illness avoidance, fitness, or appearance [61]. This may explain our findings of health app use being positively associated with behavioral diabetes-related risk factors (eg, smoking, a higher BMI, or hypertension) but being negatively associated with perceived risk of developing diabetes. Focusing on people with T2D who are already managing their diabetes, only 10.4% (20/171) of them used apps to simultaneously target 4 of the 7 self-care behaviors [62]. The explanation for this low rate may be twofold. On the one hand, the user either may just not perform multiple self-care behaviors or may have no need for app support to address multiple self-care behaviors. On the other hand, there might be a lack of convenient diabetes apps that target all self-care behaviors at once, as most diabetes management apps target only 2 to 3 self-care behaviors [53]. Developing apps that incorporate all self-care behavior domains may simplify and, thereby, encourage health app use for diabetes self-management.

Although health app use seemed not to be restricted to the higher educated in Germany, older age seemed to be an adverse factor when it comes to health app use, regardless of T2D diagnosis. Hence, future health interventions and health app developers should promote and support health app use among older people by considering age-related aspects such as age-specific design features, intuitive proceedings, easily understood training manuals, or presenting the clear purpose of the technology as health improvement [32]. In contrast to age and educational level, gender seemed to be a relevant correlate of health app use in people with T2D but not in people without diabetes. Guo et al [63] found that threat appraisal factors had a stronger effect

on the attitude toward adoption of mHealth among women. As a health threat may be more present in people with a disease like diabetes, this gender affect may have appeared in people with T2D. However, as gender differences for health app use were not found in other samples with chronic diseases, including diabetes [28,29,64], more research will be required to clarify this point.

Our findings that people with an increased risk for diabetes, assessed by several diabetes risk factors, were more likely to use health apps seems promising. The increased health app use in those with an elevated risk might reflect an increased health consciousness [27] and the motivation to improve health behaviors. Moreover, the results suggest that those who have the greatest need for health behavior change and who might benefit the most are using health apps already. A next step may involve user's guidance for choosing health apps, where health apps that have proven to be effective in achieving health improvements should be favored. Surprisingly, physical activity was not found to be associated with health app use. Different assessments of physical activity may explain the different results. We assessed physical activity according to the GDRS [39], ie, being physical active for less than 5 hours or 5 or more hours per week, whereas other studies used a cutoff of 2.5 hours or lower [19,22]. This indicates that the lower cutoff may be more applicable to explain health app use.

Our findings further indicate that it may be necessary to consider psychological factors when encouraging people to use health apps. Among people without known diabetes, those with an elevated perceived risk of getting diabetes were less likely to use health apps compared with those who perceived themselves at almost no risk. At first glance, this seems contradictive, as most social cognitive theories assume that a perceived health risk increases the likelihood of health-related preventive actions [65]. However, health app use presents only one possibility of support to improve health behaviors. Participants in this study were not asked for alternative strategies to improve health. Thus, those with high perceived risk might engage in health behavior change by using other strategies than apps. Moreover, the higher likelihood of health app use in participants with almost no perceived risk might be explained by the risk reappraisal hypothesis that suggests that the adoption of a preventive behavior reduces the perceived personal risk [66]. Thus, participants using health apps and maybe even acting preventive may, in turn, perceive themselves at low risk. Finally, high perceived risk but low perceived self-efficacy may lead to avoidance coping, which may also be linked with low app use rates, as shown in a study on health media use [67]. However, these hypothesizes cannot be tested in cross-sectional designs. Thus, future research including longitudinal designs might help to understand the association of health app use and risk perception.

The results of this study show that encouragement from health care providers to use health apps seems to be promising among people without known diabetes. Participants who received advice from a physician may have been more likely to use health apps because physicians may have recommended apps during health counseling. About 37% of physicians and about 40% of diabetologists were found to recommend health or diabetes apps [29,68]. Physicians who give advice on health behaviors may play an important role with the opportunity to encourage health app use among patients, but they should be supported by tools and guidelines to recommend appropriate apps [69]. However, as physician-communicated diabetes risk was not associated with health app use, the specific underlying mechanisms of the patient-provider context that promote health app use in patients need to be better understood.

Conclusions

The data of a German population–based survey reflect that among people without known diabetes about every third person used health apps, whereas health apps were used by almost every seventh person in people with known T2D. A better understanding of the reasons that may explain this discrepancy may be addressed by future studies. Efforts to increase health app use in both people without and with T2D should keep in mind potential barriers to smartphone and health app use among older generations. Among people with T2D, in addition to age, we found that only a few determinants seem to be associated with health app use. Moreover, in people without known diabetes, diabetes-related risk factors and psychological and health factors should be considered for future target group–specific health app development. Importantly, our findings point out that health app use seems to be less likely when the perceived diabetes risk is high, but physicians' health advice may play an important role in increasing health app use in patients.

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Authors' Contributions

LS, RP, CH, DZ, SH, PG, and CS conceptualized the survey. LS analyzed the data and drafted the manuscript. PG supported statistical analyzes. All authors critically reviewed and revised the manuscript for important intellectual content. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey questions for people without known and with diabetes.
[PDF File (Adobe PDF File), 111 KB - diabetes_v5i2e14396_app1.pdf]

Multimedia Appendix 2
Descriptive statistics and examinations comparing nonsmartphone users and smartphone users.
[PDF File (Adobe PDF File), 93 KB - diabetes_v5i2e14396_app2.pdf]

Multimedia Appendix 3
Precise information on missing values for all variables included in the study.
[PDF File (Adobe PDF File), 45 KB - diabetes_v5i2e14396_app3.pdf]

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Abbreviations

DEGS1: German Health Interview and Examination Survey for Adults
eHealth: electronic health
FCS: fully conditional specification
GDRS: German Diabetes Risk Score
IPQ-R: Revised Illness Perception Questionnaire
mHealth: mobile health
RKI: Robert Koch Institute
ROC: receiver operating characteristic
T1D: type 1 diabetes
T2D: type 2 diabetes

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Original Paper

Assessment of Training Outcomes of Nurse Readers for Diabetic Retinopathy Telescreening: Validation Study

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Abstract

Background: With the high prevalence of diabetic retinopathy and its significant visual consequences if untreated, timely identification and management of diabetic retinopathy is essential. Teleophthalmology programs have assisted in screening a large number of individuals at risk for vision loss from diabetic retinopathy. Training nonophthalmological readers to assess remote fundus images for diabetic retinopathy may further improve the efficiency of such programs.

Objective: This study aimed to evaluate the performance, safety implications, and progress of 2 ophthalmology nurses trained to read and assess diabetic retinopathy fundus images within a hospital diabetic retinopathy telescreening program.

Methods: In this retrospective interobserver study, 2 ophthalmology nurses followed a specific training program within a hospital diabetic retinopathy telescreening program and were trained to assess diabetic retinopathy images at 2 levels of intervention: detection of diabetic retinopathy (level 1) and identification of referable disease (level 2). The reliability of the assessment by level 1−trained readers in 266 patients and of the identification of patients at risk of vision loss from diabetic retinopathy by level 2−trained readers in 559 more patients were measured. The learning curve, sensitivity, and specificity of the readings were evaluated using a group consensus gold standard.

Results: An almost perfect agreement was measured in identifying the presence of diabetic retinopathy in both level 1 readers (κ=0.86 and 0.80) and in identifying referable diabetic retinopathy by level 2 readers (κ=0.80 and 0.83). At least substantial agreement was measured in the level 2 readers for macular edema (κ=0.79 and 0.88) for all eyes. Good screening threshold sensitivities and specificities were obtained for all level readers, with sensitivities of 90.6% and 96.9% and specificities of 95.1% and 85.1% for level 1 readers (readers A and B) and with sensitivities of 86.8% and 91.2% and specificities of 91.7% and 97.0% for level 2 readers (readers A and B). This performance was achieved immediately after training and remained stable throughout the study.

Conclusions: Notwithstanding the small number of trained readers, this study validates the screening performance of level 1 and level 2 diabetic retinopathy readers within this training program, emphasizing practical experience, and allows the establishment of an ongoing assessment clinic. This highlights the importance of supervised, hands-on experience and may help set parameters to further calibrate the training of diabetic retinopathy readers for safe screening programs.

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KEYWORDS

training; teleophthalmology; telemedicine; diabetic retinopathy; screening; referral; nurse

Introduction

Diabetic Retinopathy and Remote Screening

Diabetic retinopathy is the main cause of legal and functional blindness in the working-age population and in many developed countries [1,2]. Timely identification of individuals with diabetes who are at risk [3] and early management of diabetic retinopathy significantly reduces the progression to blindness [4].

The use of teleophthalmology programs to detect diabetic retinopathy and manage follow-up has been shown to be cost-effective [5] and valuable [6-9]. However, there are also concerns about accurate diagnosis and treatment decisions by retina specialists or ophthalmologists [7,10-20]. Family physicians trained to assess diabetic retinopathy have shown good levels of agreement with retina specialists [21-23]. In an attempt to improve resource management and relieve the reading interpretation burden on ophthalmologists, various diabetic retinopathy screening programs have introduced nonphysician trained graders to identify patients at risk of vision loss from diabetic retinopathy [23-29]. Previous studies have discussed the sensitivity of human graders for referable disease [30,31] and the workload required for graders to maintain expertise [32]. However, the literature is scant on specific reader training, involving only small numbers of trainees [33], and outcomes are evaluated without training specifications [34]. To our knowledge, other than the UK training program [35], there is no set minimum practical experience required for training diabetic retinopathy readers, and none that specifically addresses the performance curve with training experience.

Study Objectives

This study aimed to evaluate the performance, safety implications, and progress of 2 ophthalmology nurses in detecting diabetic retinopathy and identifying referable diseases following specific training in a diabetic retinopathy telescreening program. Their reading results were compared with those obtained from a retina specialist and the gold standard, consisting of a group-arbitrated consensus. A secondary objective was to determine the reason for reading discrepancies.

This study identifies training parameters to help tailor and standardize the training of nonophthalmologist readers for safe diabetic retinopathy interpretation in a screening program and validates the individual and group performance of trainee readers within this program. However, as with any screening program, the need for continuous monitoring and education of readers after the training process remains necessary.

Methods

Ethical Considerations

This study is approved by the Institutional Suitability Committee, the Scientific Evaluation Committee and the Research Ethics Committee of the Centre Intégré Universitaire de Santé et de Services Sociaux de l'Est-de-l'Île-de-Montréal, Montreal, Québec, Canada, where it was conducted (US Federal Wide Assurance numbers FWA00001935 and IRB00002087).

Study Population, Design, and Data Collection

This retrospective interobserver reliability study was conducted on 829 patients with type 2 diabetes who attended a screening visit within a hospital-based teleophthalmology program at the Maisonneuve-Rosemont University Ophthalmology Center between February 2016 and September 2018. A total of 4 patients with laser scars from diabetic retinopathy treatment were mistakenly included in the program, who were excluded from the analysis; therefore, the final analysis was conducted on 825 individuals (1650 eyes). Patients were imaged by an ophthalmic photographer with a nonmydriatic camera (iCam-Optovue) after pupil dilation with 1% tropicamide to reduce ungradable imaging. Two 45-degree image fields, 1 image centered on the disc and 2 centered on the macula, were obtained to ensure adequate macular imaging. Demographics were not collected.

The images were securely transmitted to a dedicated hospital server and accessed by all readers from a teleophthalmology diabetic retinopathy electronic platform (iVision from RetinaLabs), which allowed interpretation by various levels of readers. The images were reviewed nonstereoscopically at the capture resolution, with automated or manual image enhancement (magnification, brightness, and contrast) (Adobe Photoshop 7.0, Adobe Systems Inc). Images were assessed using a grading software that showed the grading scheme and the Early Treatment Diabetic Retinopathy Study (ETDRS) standard photographs as references at all times. The integrated grading scheme is based on the Scottish Diabetic Retinopathy Grading Scheme (2007) [36] described in Multimedia Appendix 1, which resembles that of the American Academy of Ophthalmology. It takes into account two 45-degree imaging fields and refers to the ETDRS standard photographs. In this program, the absence of any diabetic retinopathy leads to a 2-year imaging recommendation.

Through the teleophthalmology platform, level 1 readers determine for each eye, the image quality, if diabetic retinopathy is present (corresponding to ≥R1) or absent, and identify any other detected abnormalities. Level 2 readers determine image quality and grade diabetic retinopathy in 5 severity levels: no retinopathy (R0), mild (R1), moderate (R2), severe nonproliferative diabetic retinopathy (R3), and proliferative diabetic retinopathy (R4). They also specifically grade diabetic macular edema (DME) as none (M0), presence of any microaneurysm, hemorrhage, or exudate within 2 disc diameters (DD) of the fovea (M1), or within 1 DD of the fovea (M2). Any other abnormality was identified for ophthalmologic attention as well. Ungradable images are labeled as R6 for the general diabetic assessment and M6 for the macular assessment by all readers, which leads to an automatic referral for an in-person examination after validation by the level 3 reader (retina specialist). The level 3 reader (MB), who is blinded to the

trained readers, rereads all of the images on the same teleophthalmology platform, acting as a level 1 or level 2 reader.

For teaching and quality assurance purposes, a weekly group review was attended by all 3 readers, where any discrepancies of level 1 or 2 readings with that of the level 3 reader generated by the built-in quality assurance module of the electronic reading platform, were discussed. The final consensus of any reading disagreements was determined by group arbitration, which was established as the gold standard.

Training of the Readers

Two ophthalmology nurses (A and B), 1 technical and 1 clinical, voluntarily participated in this study and were trained successively to intervene as level 1 and level 2 readers. Outside of training for visual acuity measurement and instillation of dilating eye drops, they had no relevant experience or credentials in assessing diabetic retinopathy or prior involvement in any eye imaging.

The training of level 1 reading was provided by a validated interactive electronic platform [37] assuming no prior knowledge or background on diabetic retinopathy. The platform teaches the characteristic features of normal fundi, those of diabetic retinopathy, and the recognition of image quality. It allows the graders to grade in one or multiple sessions and lasts a total of about 3 hours. The training is concluded by a self-assessment quiz on 50 diabetic patients (100 eyes), of which 60% (30/50) had some diabetic retinopathy and were further subdivided as 80% (24/30) R1, 10% (3/30) R2, 3% (1/30) R3, and 6% (2/30) R4; 28% (14/50) had no diabetic retinopathy and 12% (6/50) showed insufficient image quality to allow reading. The self-assessment is performed in 1 session without any time limit, although it generally lasts about 2 hours. An arbitrary 80% success threshold allows access to level 1 reading with ongoing quality control by the retina specialist.

Training for level 2 reading involves weekly sessions of quality assurance and group reviews of all new level 1 individual readings. This enables progressive recognition of diabetic retinopathy severity, which leads to a referral to a level 3 reader (retina specialist if the severity is > R2 (exceeds a moderate level of retinopathy) or ≥ M2 (possible DME within 1 DD from the fovea. The precautionary referral of any uncertain or unusual findings, such as other pathology or atypical variation of normal characteristics, is emphasized.

The level 1 readers spontaneously reported feeling comfortable for level 2 reading after the group review and training on 266 imaged patients (532 eyes), of which reader A had individually assessed 114 patients and reader B, 152 patients. This was set as the starting point for the evaluation of their next readings for a total of 1118 level 2 eye readings in 559 patients (323 patients for reader A and 236 for reader B).

Statistical Analysis

The kappa (κ) statistic based on the Landis and Koch system [38] evaluates the reliability of the assessment beyond that of chance for the level 1 and level 2 readings in all readers against the consensus gold standard. It also evaluates the level 3 reader's reliability for each level 1 and 2 cohort and to the gold standard; 95% CIs were used, and *P* values of <.001 were considered significant.

The screening performance (sensitivity and specificity), diagnostic accuracy (95% CI), and the learning curve in 50-patient strata of the level 1 and level 2 readers were calculated with the consensus gold standard readings as those of the level 3 reader with respect to each level 1 and level 2 cohorts. Grading of the most affected eye was used to calculate the sensitivity and specificity of the patient readings.

Results

Demographics

There were 532 eyes (266 patients) evaluated at the level 1 reading level, of which level 1 reader A and reader B individually assessed 228 eyes (114 patients) and 304 eyes (152 patients), respectively. A total of 1118 eyes (559 patients) were assessed by the level 2 readers, which also included an evaluation for DME, and of which level 2 reader A and reader B assessed 646 eyes (323 patients) and 472 eyes (236 patients), respectively.

Excluding any ungradable images as per the consensus gold standard, the global prevalence of diabetic retinopathy (≥R1) was 46.2% (117/254) and 37.3% (196/526) in the level 1 and level 2 cohorts, respectively, and the total prevalence of diabetic macular involvement was 25.8% (135/523). The prevalence and distribution of disease severity and number of ungradable images were comparable between level 1 and level 2 cohorts and between reader A and B according to the consensus gold standard grading (Multimedia Appendix 2). They were also comparable for diabetic retinopathy severity, DME, and ungradable imaging in each individual level reader (Multimedia Appendices 3-5).

Referral Reasons

The most common reason for referral was DME (102/151, 67.5%), followed by severe diabetic retinopathy with DME (11/151, 7.3%), and severe diabetic retinopathy without DME (2/151, 1.3%; Table 1). DME represented 76% (70/92) and 57% (38/67) of the level 2 reader A and B referrals, respectively, and 72% (57/79) and 58% (36/62) of those of the retina specialist with respect to the level 2 reader images.

The kappa values in Table 2 show good agreement for referable disease in all eye readings and for all level readers. There is almost perfect agreement in identifying the presence of diabetic retinopathy by level 1 readers (κ=0.86 and 0.80) and in identifying referable disease (>R2) by level 2 readers (κ=0.80 and 0.83), compared with the gold standard. At least substantial agreement was measured in level 2 readers versus the gold standard for macular edema (M>1; κ=0.79 and 0.88) as well as for deciding if a referral to ophthalmology was warranted (κ=0.76 and 0.89). The level 3 reader, acting as a level 2 reader, achieved an almost perfect agreement with kappa values of 0.95, 0.95, and 0.95 for referable retinopathy, DME, and decision to refer to ophthalmology, respectively.

Table 1. Reasons for diabetic retinopathy referral in level 2 and level 3 readers and the consensus gold standard (N=559).

Diabetic retinopathy grading	Reader A, n (%)	Level 3 reader for reader A, n (%)	Consensus gold standard for reader A, n (%)	Reader B, n (%)	Level 3 reader for reader B, n (%)	Consensus gold standard for reader B, n (%)	Consensus gold standard for all readings, n (%)
M>1 only (including R6)	70 (76)	57 (72)	60 (72)	38 (57)	36 (58)	42 (62)	102 (67.6)
R6 and M6 only	16 (17)	17 (22)	17 (21)	18 (27)	19 (31)	19 (28)	36 (23.8)
R>2 and M>1	5 (5)	4 (5)	4 (5)	8 (12)	7 (11)	7 (10)	11 (7.3)
R>2 only (including M6)	1 (1)	1 (1)	2 (2)	4 (5)	0 (0)	0 (0)	2 (1.3)
Total referrals	92	79	83	67	62	68	151

Table 2. Agreements of level 1, 2, and 3 readings for referable (>R2) diabetic retinopathy and diabetic macular edema (>M1) and referral to ophthalmology for all eyes versus the consensus gold standard (level 1 reading [n=266] and level 2 reading [n=1118]).

Reader	Consensus gold standard referable diabetic retinopathy, κ[a] (95% CI)	Consensus gold standard referable diabetic macular edema grading, κ (95% CI)	Consensus gold standard referral to ophthalmology, κ (95% CI)
Level 1 reading (n=266)			
Reader A (n=114)	N/A[b]	N/A	0.859 (0.764-0.953)
Level 3 reader for reader A	N/A	N/A	1.00 (1.000-1.000)
Reader B (n=152)	N/A	N/A	0.803 (0.709-0.896)
Level 3 reader for reader B	N/A	N/A	1.00 (1.000-1.000)
Level 2 reading (n=1118)			
Reader A (n=646)	0.803 (0.757-0.850)	0.788 (0.733-0.842)	0.757 (0.677-0.838)
Level 3 reader for reader A	0.940 (0.912-0.968)	0.961 (0.935-0.986)	0.967 (0.935-0.999)
Reader B (n=472)	0.826 (0.777-0.874)	0.877 (0.830-0.925)	0.887 (0.822-0.952)
Level 3 reader for reader B	0.957 (0.930-0.983)	0.946 (0.914-0.979)	0.936 (0.886-0.987)

[a]κ: kappa coefficient. All kappas have *P* values <.001.

[b]Not applicable.

Reader Agreements and Referrals

With respect to the cohorts, good screening threshold sensitivities and specificities were obtained in all level readers (Table 3), with sensitivities of 91% and 97% and specificities of 95% and 85% for level 1 readers A and B, and sensitivities of 86.8% and 91.2% and specificities of 91.7% and 97.0% for level 2 readers. Reader B achieved slightly better sensitivities than reader A, and the level 3 reader achieved the highest sensitivity and specificity.

Table 3. Sensitivity and specificity for the identification of patient referrals by each reader versus the consensus gold standard.

Reader	Number of patients, n	Sensitivity, % (95% CI)	Specificity, % (95% CI)
Level 1 reading (n=266)			
Reader A	114	91 (82.70-98.44)	95 (89.66-100.51)
Level 3 reader for reader A	114	100 (100-100)	100 (100-100)
Reader B	152	97 (92.72, 101.12)	85 (77.57-92.55)
Level 3 reader for reader B	152	100 (100-100)	100 (100-100)
Level 2 reading (n=559)			
Reader A	323	86.8 (79.45-94.04)	91.7 (88.17-95.16)
Level 3 reader for reader A	323	95.2 (90.57-99.790)	100 (100-100)
Reader B	236	91.2 (84.43-97.92)	97.0 (94.45-99.59)
Level 3 reader for reader B	236	91.2 (84.43-97.92)	100 (100-100)

Level 2 and 3 reading discrepancies with the consensus gold standard and their impact on patient management are described in Table 4. Both level 2 readers show a higher overall patient disagreement rate with the consensus gold standard (66/323, 20.4% and 42/236, 17.8%) than the level 3 reader (18/323, 5.6% and 14/236, 5.9%), respectively, but a high proportion of the level 2 reader disagreements (57/66, 86% and 36/42, 86% respectively) had only minor or no impact on patient management.

A missed referral to ophthalmology is considered a significant misreading and occurred in 2.8% (9/323) and 2.5% (6/236) of patients in the level 2 readings, respectively, and respective to these cohorts, in 1.2% (4/323) and 2.5% (6/236) of patients in the level 3 readings. A comparable rate of significant misreading (excluding underappreciation of image quality) is shown in both level 2 readers (6/323, 1.9% and 5/236, 2.1%, respectively for reader A and reader B) and level 3 readers (4/323, 1.2% and 6/236, 2.5%). All image misreadings were related to unrecognized isolated microaneurysms located within 1 DD of the fovea in the absence of any exudate, except for 1 eye with neovascularization misinterpreted as an epiretinal membrane by the level 3 reader and confirmed on clinical examination.

Level 2 readers also show an overall underappreciation of ungradable imaging in 1.2% (4/323) and 0.8% (2/236) of the patients, respectively for reader A and reader B. Stratified analysis of 50 successive patients showed that as experience was gained, this rate was still maintained.

The consequences of misreading on patient management, such as the timing of new imaging or referral for in-person examination, were measured to be 73% (48/66) and 55% (23/42) in the level 2 reader cohorts, respectively, and in 67% (12/18) and 64% (9/14) of the level 3 reader, respectively, in the level 2 cohort.

Both level 2 readers tended to be more conservative in their actions, with 6.5% (21/323) and 2.1% (5/236) unnecessary referral recommendations, as compared with 0% for the level 3 reader, reimaging sooner than indicated in 4.3% (14/323) and 4.7% (11/236) of patients, respectively. Both level 2 readers acknowledged possible unnecessary referrals, but still referred patients as a precaution in 1.2% (4/323) and 0.4% (1/236) of all screenings, respectively, which represented 6% (4/66) and 2% (1/42) of their misreads.

Table 4. Level 2 and level 3 reader disagreements according to the consensus gold standard and impact on patient management (N=559).

Effect of disagreement	Reader A (n=323), n (%)	Level 3 reader for reader A (n=323), n (%)	Reader B (n=236), n (%)	Level 3 reader for reader B (n=236), n (%)
No impact on patient management	18 (5.6)	6 (1.9)	19 (8.1)	5 (2.1)
Impact on patient management	48 (14.9)	12 (3.7)	23 (9.8)	9 (3.8)
Total number of disagreements	66 (20.4)	18 (5.6)	42 (17.8)	14 (5.9)
No referral although indicated	9 (2.8)	4 (1.2)	6 (2.5)	6 (2.5)
Unnecessary referral	21 (6.5)	0 (0)	5 (2.1)	0 (0)
Imaging recommended sooner than necessary	14 (4.3)	0 (0)	11 (4.7)	1 (0.4)
Imaging recommended later than indicated	4 (1.2)	8 (2.5)	1 (0.4)	2 (0.9)
Significant misreads (no referral although indicated)				
Missed isolated microaneurysm within 1 DD[a] of the fovea.	6 (1.9)	3 (0.9)	5 (2.1)	6 (2.5)
Confusion of neovascularization with an epiretinal membrane	0 (0)	1 (0.3)	0 (0)	0 (0)
Under appreciation of ungradable imaging	3 (0.9)	0 (0)	1 (0.4)	0 (0)
Nonsignificant misreads				
Misreads with minimal impact on management	34 (10.5)	8 (2.5)	15 (6.4)	3 (1.3)
Referrals as a precaution	4 (1.2)	0 (0)	1 (0.4)	0 (0)
Under appreciation of ungradable imaging	1 (0.3)	0 (0)	1 (0.4)	0 (0)

[a]DD: disc diameter.

Learning Curve of Trained Readers

The per-strata sensitivities and specificities of level 1 and level 2 readers show high sensitivity and specificity for all readers, achieved immediately after training to detect any presence of diabetic retinopathy for level 1 readers and, for level 2 readers, to identify referable disease (>R2 and/or >M1), which were maintained throughout the study (Multimedia Appendices 6 and 7).

Figures 1 and 2 show the cumulative incidence of misreads with time and gained experience to be more related to specificity than sensitivity issues. The small number of disagreements in

each stratum impedes the analysis of tendencies for the reasons for disagreements as more experience is gained.

Figure 1. The cumulative incidence curve of misreadings for level 2 reader A image readings.

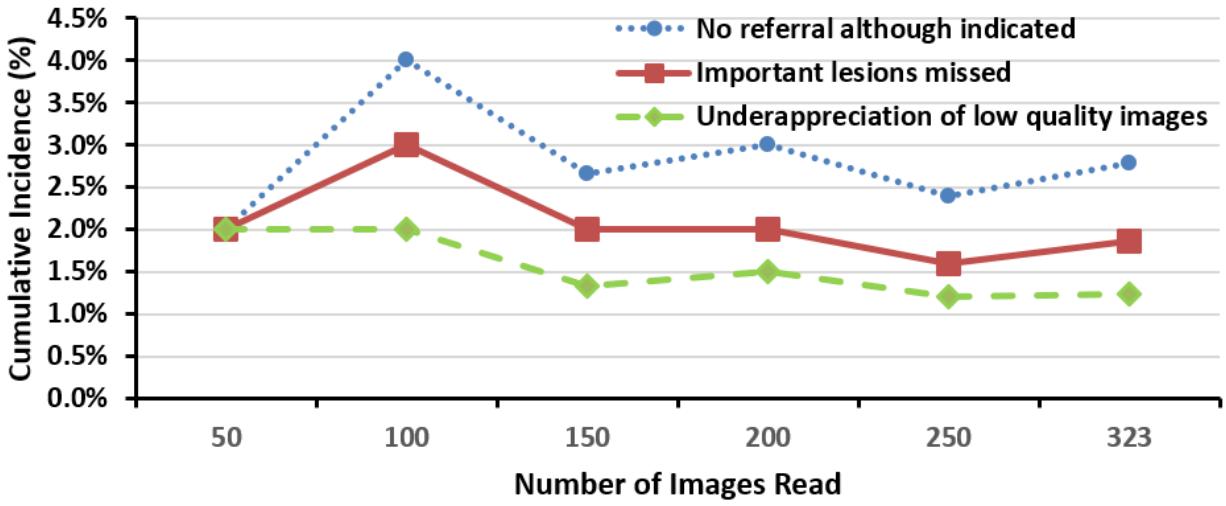
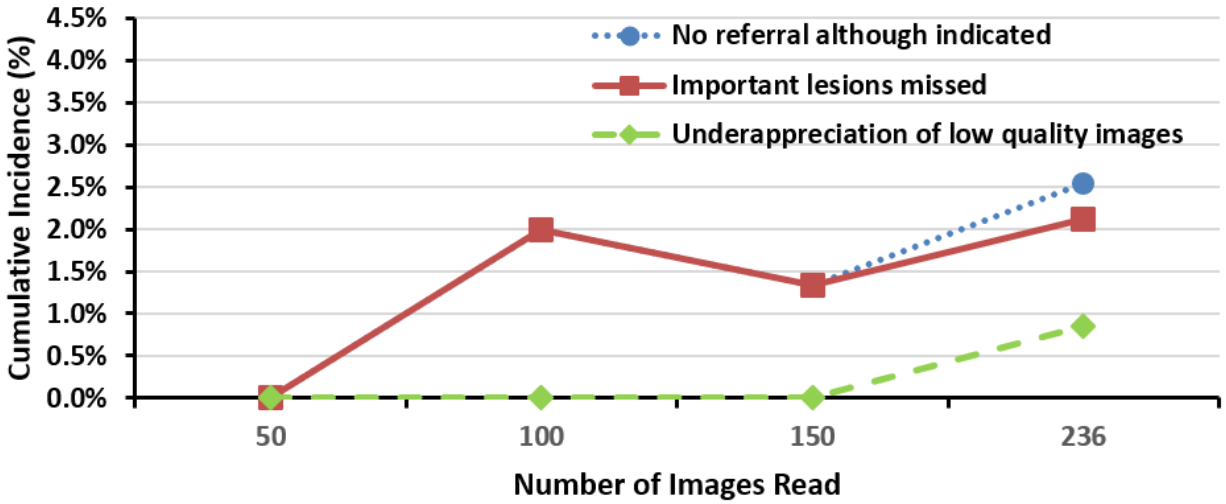


Figure 2. The cumulative incidence curve of misreadings for level 2 reader B image readings.



Discussion

Principal Findings

This study emphasizes the importance of practical experience and validates the screening performance and training of level 1 and level 2 diabetic retinopathy readers within this program. It may thus help set parameters to further calibrate the training of diabetic retinopathy readers for safe screening programs.

It shows 91% and 97% sensitivities, and 95% and 85% specificities in detecting any diabetic retinopathy, and 86.8% and 91.2% sensitivities, and 91.7% and 97.0% specificities in the identification of sight-threatening disease relative to the cohorts. These results are comparable to those reported in studies with similar conditions [33,39-42]. There is substantial overall intergrader agreement obtained by the 2 level 2 readers across all grading episodes for all referable retinopathy (κ=0.757, 95% CI 0.677-0.838 and κ=0.887, 95% CI 0.822-0.952, respectively). Although inferior to those of the retina specialist (κ=0.967, 95% CI 0.935-0.999 and κ=0.936, 95% CI 0.886-0.987), they compare favorably with the results by Goatman et al (κ median 0.78, interquartile range 0.70-0.84) [42] who also used a consensus reading gold standard and similar diabetic retinopathy severity grading and outcome schemes and who achieved 95.3% sensitivities for referable diabetic retinopathy. In a quality assurance audit of 6 trained graders, Patra et al [43] found a strong agreement between graders and the retina specialist reference standard with a kappa of 0.7. This study's kappa values were greater than those reported by Patra et al [43] and exceeded their 80% set audit standards for interobserver agreement.

Ruamviboonsuk et al [33] trained 3 reading photographers and 3 ophthalmology nurses in a 2-day course, which showed only fair agreement with the 3 retina specialists consensus group regarding retinopathy severity, macular edema, and referrals. They concluded that this course was insufficient to adequately train nonphysicians in the appropriate reading skills. In contrast, the practical training of this study is extensive, and the graders

of the Bhargava et al study underwent a 1-year rigorous training with regular auditing [41]. It is noteworthy that the graders of our study showed a high appreciation of the quality assurance and teaching procedures in their training.

Although not consistently met in many studies evaluating gold standards in diabetic retinopathy detection [30], targets of 80% and 90% to 95% sensitivity and specificity are recommended for diabetic retinopathy assessment by trained examiners [44,45]. The challenge of finding an appropriate gold standard in the grading of diabetic retinopathy, especially in ambiguous gradings, was met in our study by establishing a group-consensus arbitration gold standard. Although differences in diabetic retinopathy grading systems and reference gold standards complicate the comparisons, the previous authors also found a strong agreement between the graders and the retina specialist reference standard and concluded that trained nonphysician graders can provide high levels of accuracy in diabetic retinopathy and maculopathy detection and assessment.

Certification training programs, such as that of the United Kingdom National Health Service, suggest that good reading performance indicates good training but does not address minimal practical training experience for readers [32,46]. This study addresses the latter and found that practical training of level 1 readers on a teaching electronic platform and self-assessment on 50 patients resulted in a high intergrader agreement and high sensitivity and specificity rates for detecting diabetic retinopathy and identifying ungradable images, approaching those of the retina specialist and gold standard. Further training for referable diabetic retinopathy and macular edema through a group review of 532 eyes in 266 patients led to an immediate high agreement and sensitivity and specificity for this task, which was maintained in the next readings of 646 eyes in 323 patients and 472 eyes in 236 patients, respectively. This may be used as a threshold for similar practical training experience for nonophthalmologist diabetic retinopathy graders to meet quality standards in similar individuals and settings.

The failure of level 2 readers to recognize inadequate imaging under pupil dilation in 1.2% (4/323) and 0.8% (2/236) of all readings, respectively, represented 6% (4/66) and 5% (2/42) of all of their disagreements with the gold standard. In comparison, Farley et al [22] showed that 5.2% of eyes with inadequate imaging failed to be referred by trained primary care clinician readers in a study with a high rate of inadequate imaging due to nondilating pupils (29%). Although the readers of this study were provided objective gradable image guidelines, possible borderline-quality images could have led to subjective assessments. Failure to recognize inadequate imaging underlines the importance of pursuing reader education and regular monitoring. The underappreciation of ungradable images in our study is in contrast with that of Ruamviboonsuk et al, who interpreted their high proportion of ungradable images as a lack of confidence in reading rather than true image ambiguity [33].

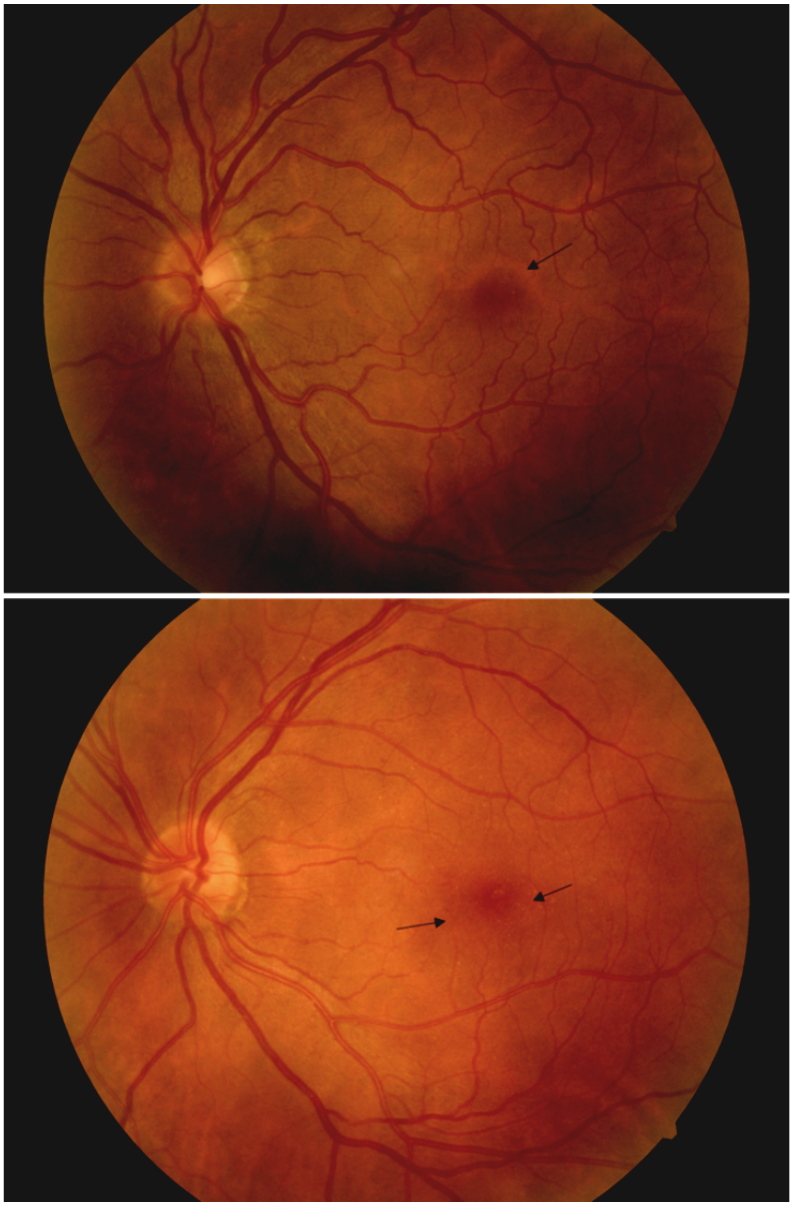
Level 2 readers made more conservative assessments, resulting in precautionary referrals in 1.2% (4/323) and 0.4% (1/236) of their readings versus none of the level 3 readings. Although these rates are small, further training to recognize unusual variants of normal and those having to be brought to the attention of the ophthalmologist as a precaution may help increase specificity and further reduce the workload on ophthalmologists.

Significant misreads causing missed referrals to ophthalmology were all related to missed isolated microaneurysms located within 1 DD of the fovea in the absence of any exudate, except for 1 level 3 reader misinterpretation of neovascularization as an epiretinal membrane. An isolated microaneurysm within 1 DD of the fovea does not signal DME unless associated with a positive optical coherence tomography establishing edema, but does signal a potential risk of DME with time. Missed detection of possible DME was found to be the worst scenario in 1.9% (6/323) and 2.1% (5/236) of level 2 reader significant misreads and in 0.9% (3/323) and 2.5% (6/236) of those of the level 3 reader. Level 2 readers appear to have greater sensitivity in detecting these isolated microaneurysms, as these misreadings represent 9% (6/66) and 12% (5/42) of all of their disagreements with the gold standard in comparison to 17% (3/18) and 36% (5/14) of those of level 3 respective to the cohorts. Moss et al [47] similarly showed that most disagreements with all level readers are related to the nondetection of isolated microaneurysms in very mild disease states.

DME was the major cause of referral in this study at 65% of all referrals, followed by 8.2% for severe diabetic retinopathy with DME and 1% for severe diabetic retinopathy without DME.

Although overall screening posed no visual safety threat in 98.0% (548/559) of patients assessed by the level 2 readers (317/323, 98.1% and 231/236, 97.9%, respectively) and 98.2% (549/559) of all level 3 readings, a small number could be put at risk with this process. The majority were related to difficult positive identification of isolated microaneurysms in the macular area at the limit of detection, which often resulted in arbitration for the final gold standard grading. These could potentially and eventually be resolved with the use of greater resolution cameras for screening. Recommendations for reimaging later than required could represent some level of risk in 1.2% (4/323) and 0.4% (1/236) of the patients assessed by the level 2 readers compared with those of the level 3 reader. Figure 3 shows images of 2 challenging cases of an isolated microaneurysm near the fovea.

Figure 3. Two challenging cases of an isolated microaneurysm near the fovea. Arrows are used to indicate the location of microaneurysms.



This study outperforms the screening results of Oke et al [48] showing that human readers miss 11% of sight-threatening diabetic retinopathy. They also conclude that low-grade-diabetic retinopathy misclassification is not uncommon but unlikely to lead to significant referral delays in sight-threatening diabetic retinopathy. The management of the small number of patients in whom a significant lesion is missed in 1 eye is also dependent upon the presence of other abnormalities in that eye or the other eye. As such, it cannot be shown if these patients would be referred had these lesions been present in an isolated state.

Limitations

Limitations of this study include its retrospective nature and the small number of trained readers, which only validates the individual and group performance of these readers within this specific training. These results may not apply to a larger reading group where possible individual performance variations could occur.

Conclusions

This study validates the screening performance and accuracy of the specific training of 2 nonphysician graders as level 1 (triage) and level 2 (referable diabetic retinopathy) graders who achieved a very high initial agreement that was maintained throughout the study and whose image interpretations compared favorably with that of a retina specialist and the consensus gold standard. It adds new information to scant literature on diabetic retinopathy reader training modalities, emphasizes the importance of training experience for reading, and suggests a starting threshold in a similar setting to train nonophthalmologist readers and meet quality standards. As with other studies [39,49], it supports the need for continual performance monitoring and education of diabetic retinopathy readers after their training to guarantee ongoing high standards expected in any diabetic retinopathy screening service. Although this study allows the establishment of an ongoing diabetic retinopathy assessment clinic with these readers, it only describes the results of 2 individual readers and possible significant individual performance variations could occur in larger trainee groups.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of the Scottish Diabetic Retinopathy Grading Scheme 2007 v1.1.
[PNG File , 49 KB - diabetes_v5i2e17309_app1.PNG]

Multimedia Appendix 2
Patient distribution of disease severity according to the worst eye and ungradable imaging between reader A and B, according to gold standard grading.
[PNG File , 30 KB - diabetes_v5i2e17309_app2.PNG]

Multimedia Appendix 3
Diabetic retinopathy findings and ungradable imaging in level 1 and level 3 readers and in the consensus gold standard.
[PNG File , 21 KB - diabetes_v5i2e17309_app3.PNG]

Multimedia Appendix 4
Findings and prevalence of diabetic retinopathy severity, diabetic macular edema, and ungradable imaging in patients by individual readers in level 2 and level 3 readings and the consensus gold standard.
[PNG File , 46 KB - diabetes_v5i2e17309_app4.PNG]

Multimedia Appendix 5
Findings and prevalence of diabetic retinopathy severity, diabetic macular edema, and ungradable imaging by individual readers for all eyes imaged in level 2 and level 3 readings and the consensus gold standard.
[PNG File , 45 KB - diabetes_v5i2e17309_app5.PNG]

Multimedia Appendix 6
Per-strata sensitivities and specificities of level 2 readers for every patient as determined by the eye with the worst grading severity.
[PNG File , 11 KB - diabetes_v5i2e17309_app6.PNG]

Multimedia Appendix 7
Per-strata sensitivities and specificities of level 2 readers for all eyes.
[PNG File , 12 KB - diabetes_v5i2e17309_app7.PNG]

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Abbreviations

DD: disc diameter
DME: diabetic macular edema
ETDRS: Early Treatment Diabetic Retinopathy Study

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Viewpoint

The Challenges of COVID-19 for People Living With Diabetes: Considerations for Digital Health

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Abstract

The coronavirus disease (COVID-19) is a global pandemic that significantly impacts people living with diabetes. Diabetes-related factors of glycemic control, medication pharmacodynamics, and insulin access can impact the severity of a COVID-19 infection. In this commentary, we explore how digital health can support the diabetes community through the pandemic. For those living with diabetes, digital health presents the opportunity to access care with greater convenience while not having to expose themselves to infection in an in-person clinic. Digital diabetes apps can increase agency in self-care and produce clinically significant improvement in glycemic control through facilitating the capture of diabetes device data. However, the ability to share these data back to the clinic to inform virtual care and enhance diabetes coaching and guidance remains a challenge. In the end, it requires an unnecessarily high level of technical sophistication on the clinic's part and on those living with diabetes to routinely use their diabetes device data in clinic visits, virtual or otherwise. As the world comes together to fight the COVID-19 pandemic, close collaboration among the global diabetes community is critical to understand and manage the sustained impact of the pandemic on people living with diabetes.

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KEYWORDS

diabetes; digital health; COVID-19; pandemic

The coronavirus disease (COVID-19) is a global pandemic and significantly impacts individuals living with diabetes. In China, Wu and McGoogan [1] reported that people living with diabetes who contracted the virus had a more than triple mortality rate of 7% in comparison to 2% in those without diabetes. These figures align with previous global pandemics, which were also associated with increased morbidity and mortality in people with diabetes [2]. During the 2009 H1N1 pandemic, Canadians living with diabetes had triple the risk of hospitalization and quadruple the risk of intensive care unit admissions [3]. The 2003 severe acute respiratory syndrome epidemic also resulted in increased hospitalization and disease severity for people with diabetes [4,5]. As global pandemics continue to occur and the prevalence of diabetes increases [6], the diabetes community will be increasingly confronted with ongoing public health challenges [7].

The World Health Organization has warned that older adults and those with pre-existing medical conditions like diabetes are at higher risk of COVID-19 exposure, complications, and death [8]. Since the majority of the diabetes population are older [9] and have multiple comorbidities of obesity, emphysema, hypertension, and heart failure [10,11], they are at greater risk of viral infection. Although data on COVID-19 presentation has yet to support an increased risk of viral contraction in people living with diabetes [12,13], evidence suggests that they may have worse outcomes should they contract the virus [13,14].

Poor glycemic control is a significant contributor to COVID-19 severity. Hyperglycemic events can lead to diabetes

ketoacidosis, which is a life-threatening condition that interferes with the immune response to mitigate sepsis and recovery [15]. Coronaviruses have also been shown to bind to their target cells through angiotensin converting enzyme-2 (ACE2). Fang et al [16] proposed that the expression of ACE2 is substantially increased in people managing their diabetes with ACE inhibitors and antihyperglycemic angiotensin II type-I receptor blockers [17]. As such, these individuals may be at an increased risk of developing severe and fatal COVID-19. To maintain adequate glycemic control, people living with diabetes are normally encouraged to eat well, exercise, and maintain good mental health [18-20]. However, efforts to minimize the risk of exposure to COVID-19 have required social distancing and quarantine practices that may exacerbate insulin sensitivity through lower levels of physical activity, abrupt changes in social routine, poor dietary diversity, and diabetes distress [21-24].

Guidelines authored by prominent diabetes societies encourage the use of insulin as the preferred treatment during the global pandemic [25,26]. However, the impact of COVID-19 on the global economy has compromised insulin production and access [27]. For people who are insulin-dependent, the risk of an insulin shortage or delayed delivery is deadly [28]. Health professionals are recommending people to have a 30-day supply of diabetes medication and supplies for their medical devices [29]. This advice may prove difficult to heed for the growing population of people in both urban (10.8%) and rural (7.2%) settings who experience socioeconomic disparities, specifically lower income, as they may not be able to afford adhering to such guidelines [13,30,31]. In addition, the shortage of commercial antibacterial products may impede sterilization techniques for insulin injections and blood glucose monitoring, and promote infection [32]. Significant decreases in traditional in-person clinic availability will require people to adopt and adjust to receiving digital diabetes care [33].

In response to social distancing guidance, outpatient diabetes clinics and family medicine practices have greatly curtailed their services to only the most urgent cases [34]. Even as restrictions are expected to ease over time, there will be continued caution in visiting clinics. In light of these circumstances, the use of previously restricted forms of communication between providers and their patients have been allowed. Most forms of audio, video, or texting technology have been allowed by jurisdictions through not only relaxing privacy and security requirements but also reimbursing providers for these services. Even telephone calls have become an accepted modality for conducting a clinical visit, allowing those without sophisticated consumer devices like smartphones to access services [35-37].

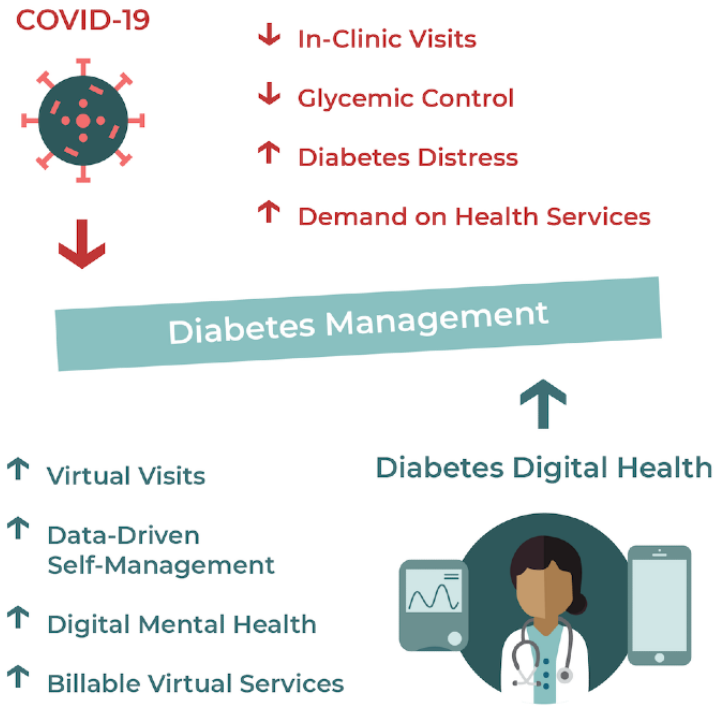
For those living with diabetes, this is an opportunity to be able to access care with greater convenience while not having to expose themselves to infection in an in-person clinic. If the use of virtual visits continues after the pandemic eases—as they are expected to [38]—it opens up a great opportunity to provide more timely access to not only physician care but services that are often scarce for those living with diabetes [39]. With physical distances no longer a factor, virtualizing the care provided by diabetes educators, dieticians, and specialized mental health professionals could improve access further than what was previously possible with in-person encounters [40]. These successes can only be realized if broader digital health inequities of access and literacy are addressed within the diabetes community [41].

Perhaps more compelling than improving access to health services through virtual care, digital health apps can also create greater agency in self-care. A series of studies in recent years have demonstrated that diabetes smartphone apps with the ability to capture diabetes data and other self-reported factors can produce clinically significant improvement in glycemic control for both those living with type 1 diabetes and type 2 diabetes [40,42,43]. These outcomes were achieved without the benefit of a provider facilitating care through the app. Additional studies have since shown that outcomes can be further enhanced with the addition of virtual care and the active use of diabetes data sharing to enhance diabetes coaching and guidance [44,45].

Despite the positive enablers for remote diabetes care, the ability to share diabetes device data back to the clinic remains a challenge [46]. As it stands, the current landscape of diabetes device data interoperability is a patchwork of proprietary technologies, open source tools, and restrictive electronic health record (EHR) policies. In the end, it requires an unnecessarily high level of technical sophistication on the clinic's part and on those living with diabetes to routinely use their diabetes device data in clinic visits, virtual or otherwise [47-49]. This technical burden will simply continue to hamper efforts to facilitate comprehensive virtual care. It continues to be a challenge to convince manufacturers of diabetes devices and EHR vendors to create truly interoperable systems to ease the burden on the diabetes communities [40]. It is hoped that the pandemic further reveals the flaws of the industry's business tactics to maintain exclusivity and their slow response in addressing the needs of the diabetes community.

As the world comes together to fight the COVID-19 pandemic, close collaboration among the global diabetes community is critical to understand and manage the sustained impact of the pandemic on people living with diabetes. Figure 1 presents a summary of the challenges of COVID-19 for people living with diabetes and the opportunities of diabetes digital health to support them in this time of need. Contribution and access to trusted diabetes resources that can communicate actionable insights on the status of COVID-19 are needed to support the community through these challenging times [12,13,50-55].

Figure 1. The challenges of COVID-19 for people living with diabetes and the opportunities of diabetes digital health.



Conflicts of Interest

None declared.

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Abbreviations

ACE2: angiotensin converting enzyme-2
COVID-19: coronavirus disease
EHR: electronic health record

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Original Paper

Diabetes Management Experience and the State of Hypoglycemia: National Online Survey Study

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Abstract

Background: Hypoglycemia, or low blood sugar levels, in people with diabetes can be a serious life-threatening condition, and serious outcomes can be avoided if low levels of blood sugar are proactively detected. Although technologies exist to detect the onset of hypoglycemia, they are invasive or costly or exhibit a high incidence of false alarms. Tremors are commonly reported symptoms of hypoglycemia and may be used to detect hypoglycemic events, yet their onset is not well researched or understood.

Objective: This study aimed to understand diabetic patients' perceptions of hypoglycemic tremors, as well as their user experiences with technology to manage diabetes, and expectations from a self-management tool to ultimately inform the design of a noninvasive and cost-effective technology that detects tremors associated with hypoglycemia.

Methods: A cross-sectional internet panel survey was administered to adult patients with type 1 diabetes using the Qualtrics platform in May 2019. The questions focused on 3 main constructs: (1) perceived experiences of hypoglycemia, (2) experiences and expectations about a diabetes management device and mobile app, and (3) beliefs and attitudes regarding intention to use a diabetes management device. The analysis in this paper focuses on the first two constructs. Nonparametric tests were used to analyze the Likert scale data, with a Mann-Whitney *U* test, Kruskal-Wallis test, and Games-Howell post hoc test as applicable, for subgroup comparisons to highlight differences in perceived frequency, severity, and noticeability of hypoglycemic tremors across age, gender, years living with diabetes, and physical activity.

Results: Data from 212 respondents (129 [60.8%] females) revealed statistically significant differences in perceived noticeability of tremors by gender, whereby males noticed their tremors more (P<.001), and age, with the older population reporting lower noticeability than the young and middle age groups (P<.001). Individuals living longer with diabetes noticed their tremors significantly less than those with diabetes for ≤1 year but not in terms of frequency or severity. Additionally, the majority of our participants (150/212, 70.7%) reported experience with diabetes-monitoring devices.

Conclusions: Our findings support the need for cost-efficient and noninvasive continuous monitoring technologies. Although hypoglycemic tremors were perceived to occur frequently, such tremors were not found to be severe compared with other symptoms such as sweating, which was the highest rated symptom in our study. Using a combination of tremor and galvanic skin response sensors may show promise in detecting the onset of hypoglycemic events.

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KEYWORDS

tremor; hypoglycemia; diabetes mellitus; remote sensing technology; survey methods; mobile phone

Introduction

Background

Diabetes is a chronic disease affecting more than 9.4% of the world's population [1], with an estimated US $327 billion in economic costs each year [2]. The majority (about 90%) of the population living with diabetes has type 2 diabetes mellitus (T2DM), while about 10% have type 1 diabetes mellitus (T1DM). Collectively, both types are responsible for around 12% of annual deaths in the United States alone [3]. The management of diabetes is burdensome and requires regular monitoring of blood sugar and careful attention to nutrition.

Fluctuating blood sugar levels outside the normal ranges tend to be common among people with T1DM [4]. Hypoglycemia or low blood glucose (BG) is a dangerous condition that affects people with diabetes when the blood glucose level falls below 70 mg/dL [5]. If the BG level continues to fall below 54 mg/dL, it may result in severe hypoglycemia [5]. Values below this level can cause severe cognitive impairment, seizure, loss of consciousness, and, in some cases, coma [6]. Severe hypoglycemia has also been associated with a higher mortality rate. In one study, 10% of the children surveyed had passed away by the time of follow-up [7]. Over time, recurrent hypoglycemia can inhibit the associated symptoms, leading the affected person to lose sensitivity to or become unaware of hypoglycemic symptoms [6]. When the body is unable to secrete epinephrine that generates hypoglycemic symptoms [8], the risk of death could increase by more than 3-fold [9]. This is particularly risky during sleep where nocturnal hypoglycemia leads to cases of "dead in bed" [10]. Despite evidence suggesting the existence of such self-unawareness and lost sensitivity to hypoglycemic symptoms, little research exists to document the extent of such a phenomenon among patients with diabetes.

The most prevalent technology to monitor BG, particularly for T2DM, is blood glucose meters, which require manual application of a test strip (typically by pricking a finger). The main limitation of traditional meters is that the measurement is periodic and manual. Continuous glucose monitors (CGMs) were commercialized at the beginning of this century [11] and have gained popularity especially among patients with T1DM as they are capable of monitoring BG levels continuously and autonomously. CGMs can provide information about BG trends and can warn against the onset of hyper- and hypoglycemia. However, these tools are invasive and costly and require regular maintenance and calibration [12]. In a large survey of patients with T1DM, around a third of the sample used CGMs [13], and in another survey of 877 CGM users, nearly half noted that they were not satisfied with the cost [14]. More recent studies also showed that CGMs in many cases are not cost-effective [15,16], which generally limits their utility, particularly in medically underserved areas where there is less access to health care [17], less health and technological literacy [18], and, in many cases, a low socioeconomic status. Therefore, there is a critical need to have affordable, noninvasive alternative methods and technologies for monitoring and self-management of diabetes and early detection of hypoglycemic onsets. However, the availability of alternatives, particularly for detection and monitoring of hypoglycemia, has been very limited. A few noninvasive devices such as HypoMon, GlucoWatch G2, and Diabetes Sentry made it to the market but exhibited a high incidence of false alarms and were sensitive to environmental conditions [19]. Those that could not be commercialized were prototypes with significant wearability issues [19]. One study even claimed that noninvasive options were incapable of competing with invasive methods in terms of accuracy [20]. Our overall research objective is to address this gap by designing a noninvasive and cost-effective technology that detects tremors associated with hypoglycemia.

Objectives

In a previous review, we reported that *tremors* and *trembling* have been found to be very common among patients with diabetes [19]. In another study surveying elderly subjects, trembling was reported in 71% of patients with diabetes [21]. Tremors have been shown to be a significant symptom of hypoglycemia in several other survey studies [22-25] as well as in laboratory studies [26,27]. In this paper, we documented findings from a large survey of patients with T1DM regarding their perception of hypoglycemic symptoms. In particular, we highlighted the differences in how patients perceive the frequency of occurrence, severity, and noticeability of hypoglycemic tremors across age, gender, years living with diabetes, and physical activity to inform the design of future interventions. Additionally, we highlighted patient experiences with technologies used to monitor their blood sugar levels and their preferences for a CGM-alternative wearable device.

Methods

Study Design

A cross-sectional internet panel survey of 212 US adults with T1DM was conducted using the Qualtrics platform in May 2019. The study was conducted in accordance with STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines [28]. After the institutional review board at the authors' institution reviewed and approved the study protocol, participants were recruited through a Qualtrics panel. Individuals who qualified for the survey based on self-reported demographic data (≥18 years, diagnosed with T1DM) were invited via email to join the panel. The email included information such as the title of the survey, its duration, and a link to follow if they were interested in participating, which would increase their points that can be redeemed later for a reward. To further evaluate this criterion and assess the quality of responses, a pilot data set consisting of the first 10% of responses (n=20) was shared with the research team. Additionally, an automated logic was added to the instrument to automatically remove data that were deemed unreasonable or responses that were not relevant to the question. No identifiable information was recorded, but latitude and longitude were stored by using Qualtrics for each respondent and used to confirm that all participants were located within the United States.

Survey Design

The survey was designed to target 3 main constructs: (1) perceived experiences of hypoglycemia, (2) experiences and expectations about a diabetes management device and mobile app, and (3) beliefs and attitudes regarding the intention to use a diabetes management device. Questions targeting the first set of constructs attempted to understand the frequency and severity of hypoglycemic tremors when compared with other symptoms of hypoglycemia [29,30]. Additional questions were related to the noticeability of hypoglycemic tremors. These questions were rated by the participants on a 10-point Likert scale (eg, 1=Not Frequent, 5=Neutral, 10=Very Frequent). Questions related to a second set of constructs attempted to document the variety and prevalence of type of technologies such as smartphone apps, CGMs, insulin pumps, and the regular BG meters used for diabetes self-management. Additionally, several questions were designed to elicit patients' preference for features and characteristics of an ideal diabetes management mobile app and issues related to wearability. Finally, participants were asked about their preference for the frequency of BG measurement and the time of the day in which they preferred such a measurement. Beliefs and attitudes relating to the intention to use a device will be reported elsewhere.

Analysis

After the pilot data collection and consultation with the research team, a Qualtrics team evaluated the responses for consistency, completeness, and speed of completion. All analyses were performed using JASP (JASP Team, version 0.10.2.). Nonparametric tests were used to analyze the Likert scale data [31]. To compare noticeability, frequency of occurrence, and severity of tremors across genders, a Mann-Whitney U test was performed. To compare them across age groups, years with diabetes, and physical activity, a Kruskal-Wallis test was performed. When a significant difference was found, the analysis was followed with a Games-Howell post hoc test to identify the different groups.

Results

Demographics

Participants' demographics and comparisons with national averages are summarized in Table 1. All participants were located in the United States and represented 40 out of 50 states. Of the 212 participants, 129 (60.9%) were female. A total of 117 participants were between the ages of 30 and 50 years, contributing to more than half the sample size (55.2%). As expected, our data overrepresents the middle age groups and underrepresents older adults who might not be inclined to take a web-based survey. Other demographic factors align with the national data available. A total of 182/212 (82%) individuals in our sample were white non-Hispanic, and 92 participants (43.4%) had a household income greater than US $60,000.

Table 1. Participant demographics.

Online data sample		National data		
Characteristics	Values, n (%)	Characteristics	Values, %	References
Gender				[32]
Female	129 (60.9)	—[a]	51.0	
Male	83 (39.1)	—	49.0	
Age (years)				[33]
18-29	34 (16.0)	20-29	18.4	
30-39	64 (30.2)	30-39	17.8	
40-49	53 (25.0)	40-49	16.6	
50-59	33 (15.6)	50-59	17.4	
≥60	28 (13.2)	≥60	29.8	
Race				[34]
White	182 (85.9)	—	76.5	
Native Hawaiian or Other Pacific Islander	2 (0.9)	—	0.2	
Black or African American	13 (6.1)	—	13.4	
Asian	6 (2.8)	—	5.9	
Two or more races	6 (2.8)	—	2.7	
Other	3 (1.4)	—	—	
White non-Hispanic	174 (82.1)	—	60.4	
Hispanic or Latino	17 (8.0)	—	18.3	
Smartphone				[35]
None	15 (7.1)	—	19.0	
Yes	197 (92.9)	—	81.0	
Android	103 (52.2)	—	51.1	
iOS	93 (47.2)	—	48.1	
Other	1 (0.5)	—	0.8	
Income level (US $)				[34]
<20,000	24 (11.3)	<25,000	19.1	
20,000 to 29,999	20 (9.4)	25,000 to 35,000	8.8	
30,000 to 39,999	23 (10.9)	35,000 to 50,000	12.0	
40,000 to 49,999	17 (8.0)	50,000 to 75,000	17.2	
50,000 to 59,999	29 (13.7)			
>60,000	92 (434)	>75,000	42.9	
Did not answer	7 (33)	Did not answer	—	
Educational level				[36]
Not available	—	None	1.4	
Less than high school	2 (0.9)	—	4.2	
High school	36 (17.0)	—	34.9	
Some college, no degree	43 (20.3)	—	21.0	
Bachelor's degree	61 (28.8)	—	18.8	
Associate degree or trade school	20 (9.4)	—	8.2	
Graduate or professional	50 (236)	—	11.5	
Years living with diabetes				

Online data sample		National data		
Characteristics	Values, n (%)	Characteristics	Values, %	References
≤1	69 (32.5)	—	—	
>1 and ≤10	46 (21.7)	—	—	
>10 and ≤25	39 (18.4)	—	—	
>25	58 (27.4)	—	—	
Daily blood sugar measurements				
0	12 (5.9)	—	—	
1-3	85 (41.7)	—	—	
4-10	107 (52.5)	—	—	

[a]Not available.

Android users constituted 52.3% (103/197) of smartphone users, and iOS users constituted 47.2% (93/197), while 15 (7.1%) participants indicated that they did not own a smartphone. Participants were also asked how many years they had lived with diabetes. More participants were recently affected (≤1 year; 69/212, 32.5%) or had lived with diabetes for more than 25 years (58/212, 27.4%), compared with >1 year but ≤10 years (46/212, 21.7%), and >10 years but ≤25 years (39/212, 18.4%). Participants were also asked to provide their overall level of physical activity as highly active, active, insufficiently active, or inactive per the guidelines specified by the Office of Disease Prevention and Health Promotion (ODPHP) [37]. The ODPHP definitions were provided as a reference. Of the 212 participants, 50/212 (23.58%) reported to be inactive, 74/212 (34.9%) reported being insufficiently active, 65 (30.6%) participants claimed to be active, and only 23/212 (10.8%) claimed to be highly active. When participants were asked how often they measured their BG level, they reported an average of 3.51 times per day (SD 2.18; range 0-10) with around 97/212 (47.5%) participants performing the measurements less than the required minimum of 4 times a day [38].

Perception of Hypoglycemic Symptoms

As shown in Table 2, none of the symptoms were rated as very severe or very frequent on average. However, 3 symptoms were reported to be severe (ie, had an average rating above 5). These were sweating, tingly feeling, and change in body temperature. Similarly, 4 symptoms were reported as frequent (sweating, tingly feeling, change in body temperature, and headaches). Severity and frequency were found to be positively correlated using the Spearman rank correlation ($\rho>0.8$; $P<.001$) for all symptoms listed.

Table 2. Average reported rating of severity and frequency of occurrence of different hypoglycemic symptoms.

Symptoms	Frequency[a]		Severity[b]		Spearman correlation, ρ
	Mean (SD)	Median	Mean (SD)	Median	
Nausea	4.15 (2.75)	4	4.08 (2.8)	4	0.88
Change in saliva	4.46 (2.88)	5	4.29 (2.88)	4	0.90
Tremor	4.83 (2.77)	5	4.59 (2.71)	4	0.84
Headache	5.36 (2.92)	6	4.95 (2.97)	5	0.85
Change in body temperature	5.59 (2.87)	6	5.24 (2.89)	5	0.86
Tingly feeling in limbs	5.76 (2.82)	6	5.26 (2.74)	5	0.82
Sweating	5.95 (2.78))	6	5.75 (2.81)	6	0.84

[a]1=extremely rare, 5=neither rare nor frequent, 10=extremely frequent.

[b]1=extremely mild, 5=neither mild nor severe, 10=extremely severe.

Although tremors were generally reported to have medium severity and frequency, when participants were asked how often they encounter hypoglycemic tremors, 110/212 (51.9%) participants reported having hypoglycemic tremors at least once a week (Table 3).

Table 3. Reported frequency of occurrence of tremors.

Tremor occurrence	Values, n (%)
Never	11 (5.2)
Rarely	48 (22.6)
Once a month	43 (20.3)
Once a week	36 (17)
Once every few days	39 (18.4)
Once a day	24 (11.3)
More than once a day	11 (5.2)

To compare the effect of hypoglycemia awareness on the perception of symptoms, the question on tremor noticeability was used to split participants into 2 groups. If tremors were rated as less noticeable (≤5), participants were categorized as hypoglycemia impaired; otherwise, they were categorized as hypoglycemia aware. A Mann-Whitney test showed that all symptoms were rated significantly higher in terms of frequency and severity for the hypoglycemia aware group (Table 4).

A separate analysis of variance for tremor noticeability, frequency, and severity was performed to compare differences across gender, age, years with diabetes, and physical activity. A Shapiro-Wilk test confirmed that the data did not adhere to the condition of normality (P<.001), possibly because the responses were performed on a 10-point Likert scale.

Table 4. Symptom frequency and severity across hypoglycemia impaired or aware groups.

Symptoms	Symptom frequency[a]			Symptom severity[b]		
	Impaired, mean (SD)	Aware, mean (SD)	P value[c]	Impaired, mean (SD)	Aware, mean (SD)	P value[c]
Nausea	3.08 (2.09)	5.29 (2.93)	<.001	2.87 (1.94)	5.38 (3.01)	<.001
Tremor	3.19 (1.97)	6.59 (2.40)	<.001	2.97 (1.84)	6.33 (2.4)	<.001
Headache	4.49 (2.72)	6.30 (2.84)	<.001	3.99 (2.67)	5.99 (2.93)	<.001
Change in saliva	3.12 (2.23)	5.9 (2.82)	<.001	2.92 (2.24)	5.76 (2.76)	<.001
Sweating	4.87 (2.67)	7.11 (2.41)	<.001	4.46 (2.51)	7.14 (2.44)	<.001
Change in body temperature	4.3 (2.52)	7.0 (2.55)	<.001	3.86 (2.43)	6.73 (2.59)	<.001
Tingly feeling in limbs	4.61 (2.78)	7.01 (2.28)	<.001	4.04 (2.46)	6.57 (2.41)	<.001

[a]1=extremely rare, 5=neither rare nor frequent, 10=extremely frequent.

[b]1=extremely mild, 5=neither mild nor severe, 10=extremely severe.

[c]Mann-Whitney test results.

Effects of Gender

First, the noticeability of tremors (dependent variable) was assessed across the 2 genders. A Mann-Whitney test revealed a significant difference (U=3887; P<.001), whereby males reported noticing their tremors significantly more than females. In terms of frequency of occurrence, tremors were reported to be higher in males than in females. Males tended to report more tremors once a day, while females reported more tremors *once a month* (Table 5). However, this difference was not statistically significant (U=4661; P=.11). The reported severity was significantly different (U=4428; P=.03) between females and males (Table 6).

Table 5. Frequency of hypoglycemic tremors across genders.

Charecteristics	Female, n (%)	Male, n (%)
Never	6 (5)	5 (6)
Rarely	30 (23)	18 (22)
Once a month	29 (22)	14 (17)
Once a week	23 (18)	13 (16)
Once every few days	25 (19)	14 (17)
Once a day	11 (9)	13 (16)
More than once a day	5 (4)	6 (7)
Total (N)	129	83

Table 6. Effect of gender on tremor noticeability, frequency, and severity.

Differences across gender	Participants, n	Median	Mean (SD)	*P* value
Noticeability[a]				
Gender				<.001
Female	129	5	4.94 (2.55)	
Male	83	7	6.23 (2.69)	
Frequency[b]				
Gender				.11
Female	129	4	4.57 (2.63)	
Male	83	5	5.24 (2.95)	
Severity[c]				
Gender				.03
Female	129	4	4.26 (2.61)	
Male	83	5	5.10 (2.80)	

[a]1=extremely unnoticeable, 5=neither unnoticeable nor noticeable, 10=extremely noticeable.

[b]1=extremely rare, 5=neither rare nor frequent, 10=extremely frequent.

[c]1=extremely mild, 5=neither mild nor severe, 10=extremely severe.

Effects of Age

The age groups listed in the demographics were divided into 3 groups. Participants were defined as young if their age was between 18 and 30 years, of middle age if they responded as being aged between 31 and 60 years, and of older age if they responded as being aged ≥60 years. The Kruskal-Wallis test showed a significant difference between the 3 groups (H_2=14.56; *P*<.001). The older group reported significantly lower noticeability rating compared to both the younger group (median=1.82; SE 0.617; *P*=.01) and middle age group (median=2.166; SE 0.57; *P*<.001). No difference was found between the younger and middle age groups (*P*=.66).

Differences in the perceived frequency of hypoglycemic tremors were assessed across the 3 age groups. The Kruskal-Wallis test showed no significant difference (H_2=4.2; *P*=.12) between the younger, middle age, and older groups. However, the older group reported a lower perceived frequency than the other 2 groups, as seen in Figure 1. In particular, the older group did not report any daily tremors; rather, they had a higher number of responses for *once a month* and *never* than the other age groups. A similar analysis was performed for the perceived severity of tremors for the 3 age groups. No significant difference was found (H_2=5.371; *P*=.07) between the younger group, the middle aged group, and the older group even though the older population tended to perceive the severity of their tremors to be low compared with medium for middle age and young respondents. Table 7 shows a summary of these differences.

Figure 1. Frequency of hypoglycemic tremors across age groups (top: youngest group [18-30 years]; middle: 30-60 years; bottom: oldest group [≥60 years]).

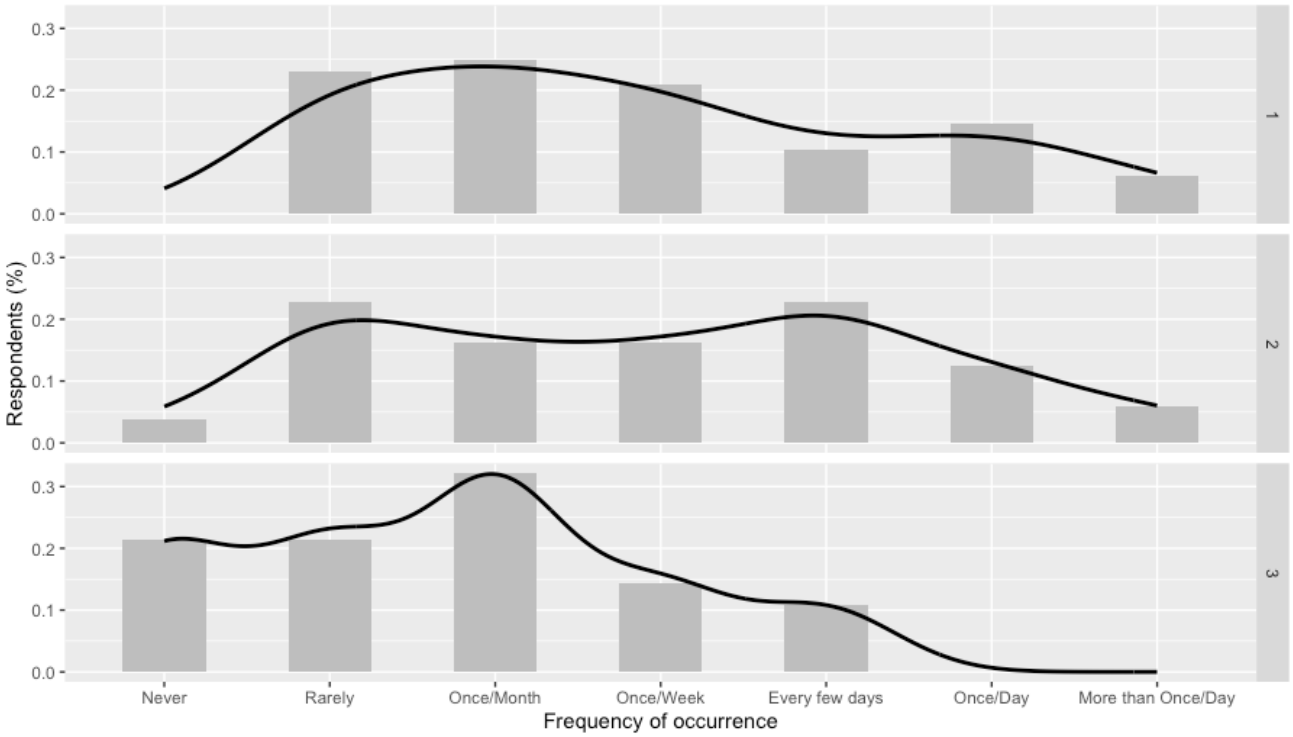


Table 7. Effect of age on tremor noticeability, frequency, and severity.

Differences across gender	Participants, n	Mean (SD)	Median	*P* value
Noticeability[a]				
Age group (years)				<.001
18-30	48	5.46 (2.32)	5	
31-60	136	5.81 (2.64)	6	
≥60	28	3.64 (2.74)	2.5	
Frequency[b]				
Age group (years)				.12
18-30	48	4.58 (2.583)	4.5	
31-60	136	5.09 (2.82)	5	
≥60	28	3.96 (2.76)	3	
Severity[c]				
Age group (years)				.07
18-30	48	4.56 (2.74)	4	
31-60	136	4.82 (2.71)	5	
≥60	28	3.54 (2.5)	3	

[a]1=extremely unnoticeable, 5=neither unnoticeable nor noticeable, 10=extremely noticeable.

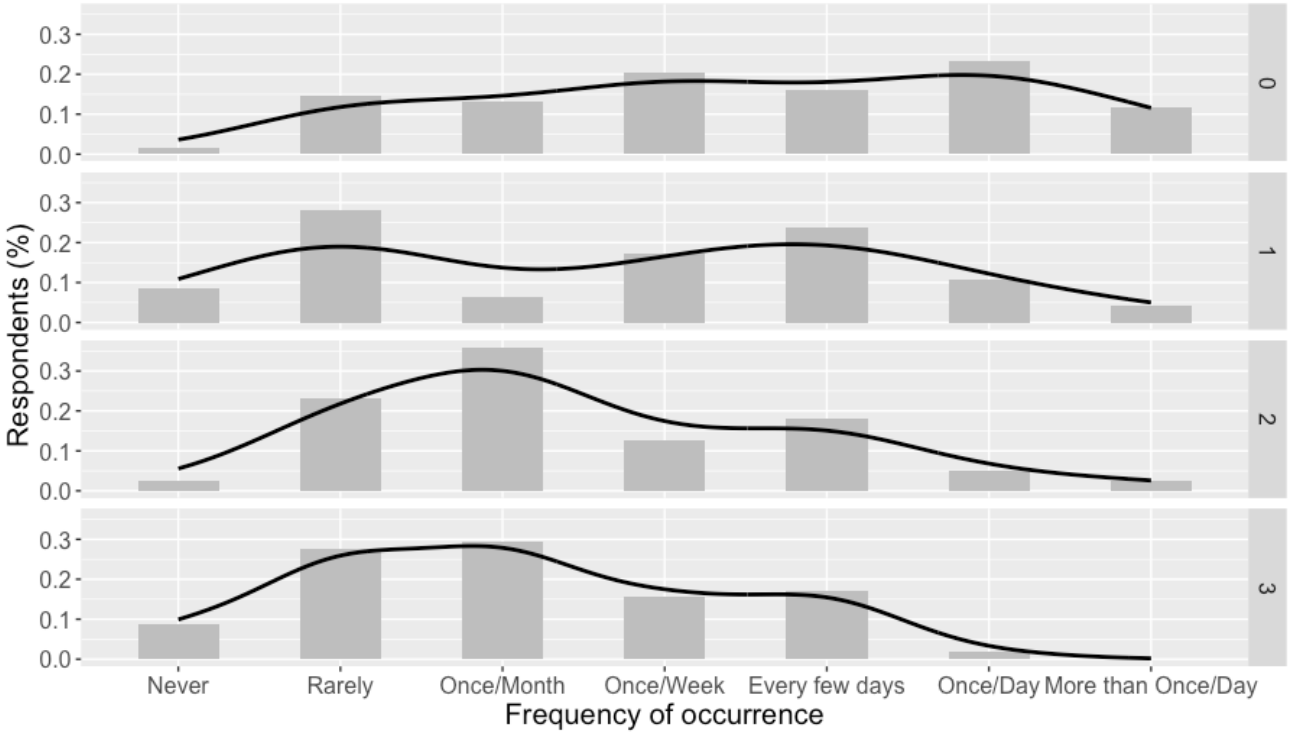
[b]1=extremely rare, 5=neither rare nor frequent, 10=extremely frequent.

[c]1=extremely mild, 5=neither mild nor severe, 10=extremely severe.

Effects of Years With Diabetes

A significant difference (H_3=6.322; *P*=.01) between groups was found with regard to the noticeability of hypoglycemic tremors. Those who were more recently diagnosed with diabetes (≤1 year) reported significantly more noticeable tremors (median=1.253; SE 0.479; *P*=.05) than those who had been living with diabetes for more than 25 years (Figure 2).

Figure 2. Frequency of hypoglycemic tremors across years with diabetes groups (top: most recently diagnosed; bottom: longest diagnosed).



The effect of years living with diabetes was also analyzed over the frequency of hypoglycemic events, but no significant difference was found (H_3=5.85; *P*=.12). Similarly, there was no significant difference with regard to the severity of these tremors (H_3=7.16; *P*=.07; Table 8).

Table 8. Effect of years living with diabetes on tremor noticeability, frequency, and severity.

Differences across years with diabetes	Participants, n	Mean (SD)	Median	*P* value
Noticeability[a]				
Years with diabetes				.01
≤1	69	6.03 (2.46)	6	
>1 and ≤10	46	5.44 (2.61)	6	
>10 and ≤25	39	5.41 (2.67)	5	
>25	58	4.78 (2.87)	5	
Frequency[b]				
Years with diabetes				.12
≤1	69	5.44 (2.89)	5	
>1 and ≤10	46	4.67 (2.65)	5	
>10 and ≤25	39	4.87 (2.76)	5	
>25	58	4.21 (2.65)	4	
Severity[c]				
Years with diabetes				.07
≤1	69	5.20 (2.79)	5	
>1 and ≤10	46	4.59 (2.74)	5	
>10 and ≤25	39	4.51 (2.50)	4	
>25	58	3.91 (2.62)	3	

[a]1=extremely unnoticeable, 5=neither unnoticeable nor noticeable, 10=extremely noticeable.

[b]1=extremely rare, 5=neither rare nor frequent, 10=extremely frequent.

[c]1=extremely mild, 5=neither mild nor severe, 10=extremely severe.

Effects of Physical Activity

The effect of physical activity levels was assessed with regard to the noticeability, frequency, and severity of hypoglycemic tremors, as summarized in Table 9. For noticeability of hypoglycemic tremors, no significant difference was found between the groups (H_3=3.98; *P*=.26). Similarly, there was no significant effect of activity level on the perceived frequency of hypoglycemic tremors (H_3=4.88; *P*=.18) or their perceived severity (H_3=6.39; *P*=.09).

Table 9. Effect of the level of physical activity on tremor noticeability, frequency, and severity.

Differences across levels of physical activity	Participants, n	Mean (SD)	Median	*P* value
Noticeability[a]				
Level of physical activity				.26
Highly active	23	6.48 (2.94)	7	
Active	65	5.17 (2.52)	5	
Insufficiently active	74	5.42 (2.40)	5.5	
Inactive	50	5.36 (3.06)	5	
Frequency[b]				
Level of physical activity				.18
Highly active	23	5.78 (3.06)	6	
Active	65	4.79 (2.70)	4	
Insufficiently active	74	4.34 (2.50)	5	
Inactive	50	5.18 (3.04)	5	
Severity[c]				
Level of physical activity				.09
Highly active	23	5.65 (3.01)	5	
Active	65	4.75 (2.78)	5	
Insufficiently active	74	4.00 (2.40)	4	
Inactive	50	4.76 (2.79)	4.5	

[a]1=extremely unnoticeable, 5=neither unnoticeable nor noticeable, 10=extremely noticeable.

[b]1=extremely rare, 5=neither rare nor frequent, 10=extremely frequent.

[c]1=extremely mild, 5=neither mild nor severe, 10=extremely severe.

Technology Preferences

When participants were asked if they had used any technology to manage their diabetes, the majority (150/212, 70.7%) reported that they currently used or had used at least one in the past. Among them, 107/150 (71.3%) used a BG meter, 57/150 (38%) had used a smartphone app, 41/150 (27.3%) had used a CGM, and 49/150 (32.6%) had used an insulin pump to help them with diabetes self-management. Additionally, around 79/150 (52.7%) technology users claimed that they used a combination of these technologies. When asked what device brands they used, the most frequent responses, as listed in Table 10, were *Medtronic*, *One Touch*, *Dexcom*, *Freestyle Libre*, *Accu-Check*, *Bayer Contour*, *Omnipod*, and *ReliOn*.

Table 10. Device brands reported.

Brand	Values, n (%)
Medtronic	25 (16.6)
One Touch	24 (15.9)
Dexcom	17 (11.3)
Freestyle Libre	10 (6.6)
Accu-Chek	7 (4.6)
Bayer Contour	7 (4.6)
OmniPod	7 (4.6)
ReliOn	4 (2.6)
True Metrix	3 (2.0)
Other brands	9 (6.0)
Don't know/unidentified	31 (20.5)

Participants were also asked to rate the important features in an ideal smartphone app that would help them manage hypoglycemia, as commonly found in diabetes management apps [39]. Although all features received favorable ratings, continuous glucose monitoring, insulin log, and graphical display of data received the highest ratings (Table 11).

Table 11. Rating of features for a smartphone app to manage diabetes.

Smartphone app features	Mean[a] (SD)	Median
Glucose monitor	7.11 (2.74)	8
Insulin log	6.59 (2.8)	7
Graphical display of diabetes data	6.55 (2.85)	7
Log for abnormal sugar levels	6.54 (2.9)	7
Food log	6.34 (2.98)	7
Medication log	6.16 (3.01)	7
Reminders	6.14 (3.06)	7
Educational content	5.59 (2.84)	6

[a]1=not important, 5=neutral, 10=very important.

When asked about the characteristics of a diabetes management tool reported in the literature [40,41], high accuracy of readings, low cost, low maintenance, and 24-hour monitoring received very high ratings (Table 12). Other characteristics such as no effects on daily habits, high privacy and security, customizability, and noninvasiveness also received favorable ratings. When asked for their preferred time of the day to measure BG, morning was most preferred (187/212, 88.2%), followed by evening (125/212, 58.9%), night (118/212, 55.6%), afternoon (114/212, 53.8%), and around noon (98/212, 46.2%).

Table 12. Rating of characteristics for a device to manage diabetes.

Device characteristics	Mean[a] (SD)	Median
High accuracy of reading	8.49 (1.88)	9
Low cost	8.21 (2.27)	9
Low maintenance	8.06 (2.18)	9
24-hour monitoring	8.02 (2.28)	9
Doesn’t affect daily habits	7.97 (2.16)	8
High privacy and security	7.85 (2.28)	8
Customizability	7.59 (2.36)	8
Not invasive	7.54 (2.57)	8
Sending health data to caregivers	6.92 (2.62)	7

[a]1=not important, 5=neutral, 10=very important.

A modified Comfort Rating Scale (CRS) [42] was used to evaluate the characteristics of a wearable wrist-worn sensor for hypoglycemia management. Although all constructs related to CRS were rated highly, size and minimized risk for harm received very high ratings followed by emotions felt by the user, social discreteness, and aesthetics (Table 13).

Table 13. Rating of items from the comfort rating scale.

Wearability characteristics	Mean[a] (SD)	Median
Aesthetics (I care about how the device looks)	6.59 (2.85)	7
Social discreteness (I don't want to feel that people look at my wrist and ask about my device)	6.65 (3.01)	7
Emotions (I don't want to feel anxious wearing it)	6.76 (2.95)	7.5
Harm (I don't want this device to cause harm to me)	7.71 (2.67)	9
Size (I want the device to not be bulky)	7.77 (2.34)	8

[a]1=not important, 5=neutral, 10=very important.

Discussion

A nationwide survey of 212 patients with type 1 diabetes was conducted to investigate noticeability of hypoglycemic tremors as well as perceived frequency and severity of such tremors among patients. Our findings suggest that while tremors are perceived to be less noticeable, frequent, or severe than other hypoglycemic symptoms such as sweating, changes in body temperature, and headache, in line with the literature [19,21], such hypoglycemic tremors occur at moderate frequency and are being noticed by most patients. Indeed, our study shows that more than 50% of the respondents encountered hypoglycemic events at least once a week. This is in line with the established evidence suggesting the rate of one to two mild episodes per week among patients with diabetes [43,44]. Given this prevalence, there is a timely need for the detection and mitigation of mild hypoglycemia before becoming severe [45,46]. However, according to these results, if tremors are tested and found to be a viable predictor of hypoglycemic onset in future work, tremors should be assessed in conjunction with other symptoms as seen in the study by Shechter et al [47]. In past research, relying solely on body temperature and skin conductance was shown to cause a high number of false alarms, which resulted in the devices being withdrawn from the market [48,49].

In addition to these aggregate trends, our findings show gender- and age-specific differences. Although evidence suggests similar occurrence rates of severe hypoglycemia among males and females [50], our findings suggest that males perceive their hypoglycemic tremors more than females. These results are in line with previous findings, which suggest that men were found to have a higher level of adrenaline [51], which is believed to trigger hypoglycemic tremors [52]. In addition, the younger population reported noticing their tremors significantly more than the older population. Similarly, those who had diabetes for a year or less reported noticing their tremors significantly more than those who had diabetes for a longer period. This is in line with previous findings that suggest a radical reduction in the incidence of hypoglycemic symptoms in elderly subjects compared with the younger population [53]. This evidence posits that recurrent hypoglycemia delays the onset of symptoms to lower levels of blood sugar [54] and corroborates previous evidence that patients with a longer history of diabetes may lose sensitivity to hypoglycemic symptoms or perceive such symptoms less [7,8]. These findings further highlight the importance of objective methods for continuous measurement and monitoring of hypoglycemic symptoms in older populations. Participants with higher levels of physical activity also noticed their tremor symptoms more, which may suggest being prone to declining blood sugar levels during and after exercise [55].

While diabetes self-management technologies are gaining popularity, findings from our nationwide survey show that nearly one-third of our sample has not used any technologies to monitor or manage their blood sugar, which suggests low adherence to the basic American Diabetes Association guidelines for the self-management of diabetes [56]. For those who reported using technology, technology adoption was limited to either a blood glucose monitor or a CGM, suggesting the low prevalence of nonintrusive methods for measurement of BG.

As a preliminary step to design a nonintrusive hypoglycemic tremor monitoring tool, we used a patient-centered approach to elicit and document intended users' preferences and expectations for various features, characteristics, and context of use. It is well understood that incorporating such feedback into the design of patient-facing tools facilitates adoption and increases the odds of sustainable usage [57]. For example, while CGM technologies have proven to be reliable [58], these technologies are not affordable, are invasive, and require frequent maintenance [12,59]. These limitations may explain our survey results, where more than 66% reported not using CGMs. In addition, as evident from our results, for a sensor to be deemed as *wearable* by patients, it should be comfortable, streamlined in appearance, accurate, affordable, and low maintenance. In addition, any smartphone app that connects to the device must provide a graphical display of the patient's BG data as well as an insulin log. Finally, when participants were asked when they preferred to measure their BG, the most common answers were in the morning and evening, which may suggest expectations for minimal interruptions to professional work. Participants also claimed that they measured their blood sugar approximately four times per day, which is the minimum requirement for T1DM as per several guidelines [38,60]. Although the reported number of measurements ranged from 0 to 10, approximately half of the respondents claimed that they did not check their blood sugar as advised. This bolsters the argument in support of continuous monitoring technologies [61,62], since reliance on users' memory to sustain usage has proven to be challenging not only for diabetes but also for other chronic diseases [63,64].

Although the study shed light on the nature of perceived hypoglycemic tremor among people with type 1 diabetes and provided information that may guide the design of future tremor-centric interventions, it had some limitations. First, the study only included patients with T1DM, and the results may not generalize to patients with T2DM, especially since hypoglycemia is less common among those patients [65]. In addition, participants were self-identified as T1DM with no objective evidence confirming their condition. Second, the data collected in this study were self-reported. Future work is needed to validate the findings in controlled laboratory environments. Third, since our data were based on Likert scale questions, the analysis was performed using nonparametric tests. However, we believe that our large sample size adds to the robustness of the inference [31]. Finally, a convenience sample was provided using Qualtrics panels. Ideally, a stratified nationwide sample should be used to improve the generalizability of findings.

Regardless of the differences observed in the population studied, this study established the potential efficacy of tremors for a subset of the population as a reliable yet nonintrusive metric for hypoglycemia monitoring technologies and confirms previously reported conclusions [27,47]. The evidence presented in this paper also supports the need for wearable continuous monitoring tools beyond CGMs that are affordable, nonintrusive, and easy to use. Work is in progress to design and evaluate a hypoglycemia monitoring technology that utilizes sensors to

detect hypoglycemic tremor and mobile health apps to enable self-management.

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Conflicts of Interest

None declared.

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Abbreviations

BG: blood glucose
CRS: Comfort Rating Scale
CGM: continuous glucose monitor

ODPHP: Office of Disease Prevention and Health Promotion
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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