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Original Paper

Effectiveness of an Immersive Telemedicine Platform for Delivering Diabetes Medical Group Visits for African American, Black and Hispanic, or Latina Women With Uncontrolled Diabetes: The Women in Control 2.0 Noninferiority Randomized Clinical Trial

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Abstract

Background: Medically underserved people with type 2 diabetes mellitus face limited access to group-based diabetes care, placing them at risk for poor disease control and complications. Immersive technology and telemedicine solutions could bridge this gap.

Objective: The purpose of this study was to compare the effectiveness of diabetes medical group visits (DMGVs) delivered in an immersive telemedicine platform versus an in-person (IP) setting and establish the noninferiority of the technology-enabled approach for changes in hemoglobin A_{1c} (HbA_{1c}) and physical activity (measured in metabolic equivalent of task [MET]) at 6 months.

Methods: This study is a noninferiority randomized controlled trial conducted from February 2017 to December 2019 at an urban safety net health system and community health center. We enrolled adult women (aged ≥18 years) who self-reported African American or Black race or Hispanic or Latina ethnicity and had type 2 diabetes mellitus and HbA_{1c} ≥8%. Participants attended 8 weekly DMGVs, which included diabetes self-management education, peer support, and clinician counseling using a culturally adapted curriculum in English or Spanish. In-person participants convened in clinical settings, while virtual world (VW) participants met remotely via an avatar-driven, 3D VW linked to video teleconferencing. Follow-up occurred 6 months post enrollment. Primary outcomes were mean changes in HbA_{1c} and physical activity at 6 months, with noninferiority margins of 0.7% and 12 MET-hours, respectively. Secondary outcomes included changes in diabetes distress and depressive symptoms.

Results: Of 309 female participants (mean age 55, SD 10.6 years; n=195, 63% African American or Black; n=105, 34% Hispanic or Latina; n=151 IP; and n=158 in VW), 207 (67%) met per-protocol criteria. In the intention-to-treat analysis, we confirmed noninferiority for primary outcomes. We found similar improvements in mean HbA_{1c} by group at 6 months (IP: -0.8%, SD 1.9%; VW: -0.5%, SD 1.8%; mean difference 0.3, 97.5% CI -∞ to 0.3; P<.001). However, there were no detectable improvements in physical activity (IP: -6.5, SD 43.6; VW: -9.6, SD 44.8 MET-hours; mean difference -3.1, 97.5% CI -6.9 to ∞; P=.02). The proportion of participants with significant diabetes distress and depressive symptoms at 6 months decreased in both groups.

Conclusions: In this noninferiority randomized controlled trial, immersive telemedicine was a noninferior platform for delivering diabetes care, eliciting comparable glycemic control improvement, and enhancing patient engagement, compared to IP DMGVs.

Trial Registration: ClinicalTrials.gov NCT02726425; <https://clinicaltrials.gov/ct2/show/NCT02726425>

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KEYWORDS

type 2 diabetes mellitus; virtual world; women; digital health; diabetes self-management education; self-management; health equity; Hispanic or Latina; Black or African American; group visit; shared medical appointment

Introduction

Minority and low-income women with type 2 diabetes mellitus (T2DM) face widening disparities in diabetes care and clinical outcomes, highlighting the pressing need to improve diabetes care for underserved communities [1-5]. Diabetes medical group visits (DMGVs) are shared appointments where groups of patients receive diabetes self-management education (DSME), peer support, and a clinical visit within a 2-hour appointment. Compared to usual care for adults living with diabetes, the in-person (IP) DMGV model has been associated with improved diabetes outcomes and lower costs [6-9]. Moreover, receiving care as a group can reduce disparities by fostering more equitable patient-provider relationships, creating relationships of care between patients, and improving health literacy and self-management skills [10]. Yet, many disadvantaged communities report poor access to DMGVs as health systems find them difficult to implement [11,12]. Patient engagement in group-based diabetes care is also often low due to social stigma, lack of transportation, and time constraints [11,13].

Telehealth solutions have gained unprecedented traction with the onset of the COVID-19 pandemic. Early evidence has shown that virtual worlds (VWs) and virtual reality platforms are feasible and potentially more effective alternatives to IP programming [14,15]. A VW is a 3D, computer-based simulated environment where users engage in immersive, experiential learning with animated educational content [16]. Users create avatars, digital manifestations of self, to engage in peer group programming virtually [17]. This environment is intrinsically designed for users to enact behavioral change among peers and restructure old habits [18,19].

To our knowledge, the possibilities of avatar-based VW DSME have not been rigorously tested. We developed an immersive telemedicine platform, linking an interactive VW learning environment with videoconferencing software, to overcome the common barriers to diabetes group-based care while maintaining clinical effectiveness at scale. We implemented Women in Control 2.0 (WIC2) in 2015 to study the comparative effectiveness of delivering DMGVs in a VW versus the traditional IP classroom for women from Black, African American, Hispanic, or Latina backgrounds with uncontrolled T2DM (trial protocol in [Multimedia Appendix 1](#)) [20].

Methods

Trial Design

From February 2017 to October 2019, we recruited 17 cohorts of African American or Black or Hispanic or Latina women with uncontrolled T2DM. A total of 309 participants were enrolled and randomly assigned to the VW or IP DMGV conditions. Participants attended 8 weekly DMGVs and were followed for 6 months.

Participants

Eligible participants were adult women (≥ 18 years) who self-identified as African American, Black, Hispanic, or Latina with uncontrolled T2DM, defined by a hemoglobin A_{1c} (HbA_{1c}) value $\geq 8\%$. Participants were English-speaking or Spanish-speaking, had telephone access, permanent or stable housing, a clinician-supervised diabetes treatment plan, and could provide informed consent. Exclusion criteria included scheduling conflicts with DMGV programming, enrollment in another program, a history of diabetic ketoacidosis, oxygen-dependent chronic obstructive pulmonary disease, stroke within the last 6 months, and an acute coronary event or chronic heart condition within the last year. Pregnancy, recent glucocorticoid therapy, dialysis, active substance abuse, active cancer treatment, and any medical contraindications to study dietary recommendations were also exclusionary.

Recruitment

Overview

We identified participants from Boston Medical Center and a local community health center using a weekly electronic medical record query. We contacted eligible participants with an introductory letter and follow-up call [21]. Additional recruitment strategies included participant or provider referrals and posted flyers. We screened participants by phone and reconfirmed eligibility at an IP enrollment appointment. Participants provided written informed consent and were eligible for up to US \$300 in compensation or a new laptop.

Randomization and Masking

After stratification by language, we used one-to-one block randomization (alternating blocks of 6 and 8) to assign participants to the VW or IP DMGV conditions. A biostatistician generated the randomization sequence, and randomization occurred after informed consent. We randomized participants prior to obtaining baseline data. Investigators were blinded to the randomization process, but assignments were revealed to participants and investigators post consent.

Intervention

Assigned to cohorts of 6-12 participants based on study arm, participants convened in clinical or virtual settings for 8 weekly DMGVs. Each session lasted approximately 120 minutes and started with the completion of an intake form to document acute or chronic symptoms, health system usage, and self-management activities, followed by the measurement of vital signs and the delivery of DSME. Sessions included a one-on-one clinical consult. Study clinicians were 4 board-certified physicians and 2 nurse practitioners. Nonclinical group facilitators received training on core DSME topics and facilitation skills from lead faculty (SEM, PG). All participants received a paper curriculum booklet.

Prior to the first virtual DMGV, staff provided laptops and wireless internet to VW participants and conducted IP computer training. All participants then met weekly for 8 weeks, according to a session schedule. During DMGVs, all participants received the same WIC2 curriculum, which was adapted from *Power to Prevent* [22] and consisted of 8 modules highlighting topics such as diabetes self-monitoring, preventative care, healthy eating, exercise, and stress management. Three bilingual staff, who were native Spanish speakers and included a certified interpreter, used the forward-backward method of translation, in tandem, to produce a culturally equivalent, Spanish-language

curriculum [23,24]. The curriculum content was reviewed by 2 patient advisory groups. To develop avatar-driven learning experiences and incorporate chat and telehealth capabilities, instructional design was adapted for a VW environment using game design theory [25]. VW participants customized avatars to represent themselves and engage in DMGVs, including practicing positive health behaviors such as dance and social support (Figure 1).

During each session, a clinician met individually with participants (in a separate physical space or via secure telehealth platform or telephone depending on study group) to review blood glucose readings and hyper or hypo glycemic data, conduct diabetes medication reconciliation, and address concerns. Recommendations for medication adjustments were based on an algorithm [26] and shared with primary care providers via progress notes in the electronic health record.

To ensure fidelity of DMGV protocols and standard operating procedures, we used checklists, audits of session recordings, and participant observation field notes.

Following the 8-week DMGV sessions, participants entered a 16-week maintenance period. They were encouraged to self-monitor (tracking blood glucose, blood pressure, diet, and exercise) using a paper booklet or mobile app. No formal DMGVs occurred.

Figure 1. Illustration of avatars in the virtual world.



Outcomes

The primary outcomes were mean changes in (1) HbA_{1c} and (2) physical activity (metabolic equivalent of task [MET]-hours) by study arm from baseline to 6 months. Secondary outcomes included mean changes in HbA_{1c}, physical activity, and medication changes at 9 weeks after enrollment and changes in the 17-item Diabetes Distress (DD) scale, depressive symptoms (Patient Health Questionnaire-8 [PHQ-8]), physical function (Patient-Reported Outcomes Measurement Information System [PROMIS-29] measure), 13-item Patient Activation Measure (PAM), weight, and step count at 6 months [27-31].

Data Collection and Management

Baseline data collection included sociodemographic characteristics, HbA_{1c} values (blood draw), physical activity (per accelerometers), and survey measures. Baseline HbA_{1c} was obtained within 30 days of the first DMGV. Physical activity was measured within a 14-day window, with participants wearing an accelerometer on the wrist for 7 consecutive days. Follow-up data collection occurred 9 weeks and 6 months post enrollment (within a 28-day window). Study data were stored using secure Research Electronic Data Capture (REDCap) software hosted by Boston University [32,33]. Unique study identification numbers were used to label all participant forms.

Sample Size Calculations

We used the average overtime change in HbA_{1c} and physical activity by study arm as coprimary outcomes, measured from baseline to 6-month follow-up. Data obtained from the WIC 1.0 pilot study was used to estimate the sample size necessary to establish the noninferiority margin of VW DMGVs compared to IP DMGVs at reducing HbA_{1c} and increasing total physical activity levels [34]. For HbA_{1c}, we assumed a noninferiority margin of 0.7 based on a clinically meaningful decrease [35,36], a pooled SD of 2, an α of .05, and a power of 80% based on the pilot study results [34]. For physical activity, we assumed a noninferiority margin of 12, a pooled SD of 35, an α of .05, and a power of 80%. We required 106 participants per arm. We did not expect the dropout rate for WIC2 to exceed 7%; thus, we aimed to enroll and randomize 228 and retain 212 participants.

Statistical Analysis

Sociodemographic characteristics were compared by arm using chi-square and Fisher exact tests as appropriate for categorical variables and 2 sample *t* tests or Wilcoxon rank sum tests for continuous variables. Within-group changes from baseline to follow-up on mean HbA_{1c} and mean physical activity between the VW and IP study arms were assessed with paired *t* tests; between-group changes were assessed with multiple linear regression models, both at an α level of .025 after applying a Bonferroni correction for multiple testing. Between-group differences in the likelihood of achieving a 0.4% reduction or more in HbA_{1c} at follow-up were examined by logistic regression. One-sided *P* values and 97.5% CIs were calculated to assess the noninferiority hypothesis, using margins of 0.7% for HbA_{1c} and 12 MET-hours for physical activity. Other statistical tests and confidence intervals were 2-sided. Per-protocol (PP) analyses were limited to participants who

completed the protocol as intended, by attending ≥ 6 out of 8 DMGVs. PP and intention-to-treat (ITT) analyses were conducted on a full data set that used multiple imputation via predictive mean matching to impute missing baseline, 9-week, and 6-month primary and secondary outcomes. Analyses were replicated on unimputed data to check the sensitivity of results to imputation.

Accelerometry data was used to calculate participants' mean change in physical activity behavior from baseline to 6 months. For each participant, we randomly selected the 2 weekdays with the longest wear-time. We considered missing wear time data in a 24-hour day as sedentary activity. For each weekday, we estimated total MET-hours by a weighted sum of the number of hours in light (1.5 MET), moderate (4 MET), vigorous (6 MET), and very vigorous (8 MET) activity as measured by the accelerometer using the Freedson et al cut points [37,38]. We then averaged the estimated MET-hours for the 2 weekdays with the longest wear-time to obtain weekday average MET-hours per participant.

Sensitivity analyses were performed to evaluate the influence of language preference on our primary outcome results. Participant characteristics with, versus without, baseline HbA_{1c} were assessed to detect potential bias from missing data. Characteristics of participants who adhered to the session protocol (attended ≥ 6 vs < 6 sessions) were also assessed, and primary outcome PP analyses were replicated controlling for characteristics found to be correlated with protocol adherence. All analyses were performed using SAS/STAT software (SAS version 9.4; SAS Institute) or the R programming language (version 3.4.3; R Core Team).

Ethics Approval

This study was conducted according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines [39] and approved by the Boston University/Boston Medical Center Institutional Review Board (H-34220).

Results

Study Population

Of 1960 potentially eligible patients, 1349 were screened, and 309 participants were randomized; 29 patients had a change in eligibility status before the first DMGV (Figure 2). The PP sample included 207 (108 VW and 99 IP; 67%) participants who met *a priori* criteria by attending ≥ 6 DMGVs. At baseline, participants' mean age was 55 (SD 10.6) years, their mean weight was 195 (SD 41.8) lb, and their mean physical activity was 104.1 (SD 34.3) MET-hours. All participants were female, with 63% (195/309) of African American or Black race and 34% (105/309) Hispanic or Latina ethnicity (Table 1). A majority (219/309, 71%) were insured by Medicaid, Medicare, or both, and 59.6% (184/309) had home internet. The mean DD score was 2.3 (SD 1.0), which is moderately high, and the PHQ-8 score for depressive symptoms was 5.5 (SD 5.0), which is mild. More IP participants owned a smartphone. Mean HbA_{1c} values differed by VW and IP groups (mean 9.7%, SD 1.7% vs mean 10.2%, SD 1.8%), respectively. Participant characteristics with complete versus missing baseline HbA_{1c} data and changes

in eligibility status were compared (Tables S1 and S2 in Multimedia Appendix 2 [27-31]). Because no participant characteristic was identified as accountable for the imbalance

in mean baseline HbA_{1c}, we attributed the difference in baseline HbA_{1c} to random imbalance and controlled for baseline HbA_{1c} in our outcome analyses.

Figure 2. Flowchart of Women in Control 2.0 (WIC2) participants. DMGV: diabetes medical group visit; ITT: intention-to-treat.

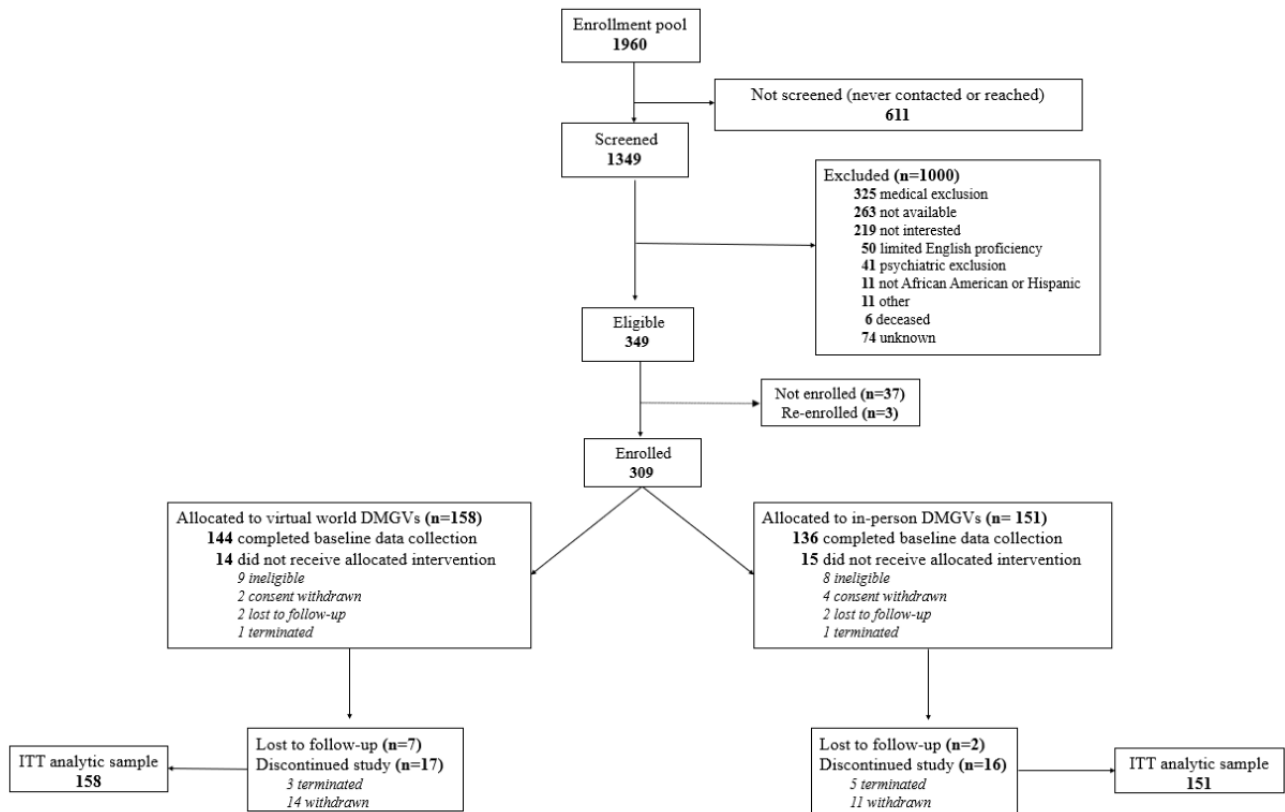


Table 1. Baseline characteristics of Women in Control 2.0 (WIC2) study participants.

Characteristic	Overall (n=309) ^a	In-person (n=151)	Virtual world (n=158)
Age (years)			
Mean (SD)	55.4 (10.6)	55.20 (9.6)	55.54 (11.5)
Participants, n	300	146	154
Race, n (%)			
African American or Black	195 (63.1)	96 (63.6)	99 (62.7)
White	26 (8.4)	13 (8.6)	13 (8.2)
Missing	10 (3.2)	5 (3.3)	5 (3.2)
Other ^b	78 (25.2)	37 (24.5)	41 (25.9)
Hispanic, Latina, or Spanish ethnicity, n (%)	105 (34.0)	49 (32.5)	56 (35.4)
Spanish-speaking, n (%)	73 (23.6)	35 (23.2)	38 (24.1)
Insurance, n (%)			
Commercial	69 (22.3)	31 (20.5)	38 (24.1)
Medicare or Medicaid	219 (70.9)	109 (72.2)	110 (69.6)
No insurance	4 (1.3)	2 (1.3)	2 (1.3)
Education, n (%)			
High school graduate or less	152 (49.2)	74 (49.0)	78 (49.4)
Any college, vocational, or trade school	132 (42.7)	65 (43.1)	67 (42.4)
Any postgraduate	14 (4.5)	6 (4.0)	8 (5.1)
Missing	11 (3.6)	6 (4.0)	5 (3.2)
Employment status, n (%)			
Full-time	75 (24.3)	36 (23.8)	39 (24.7)
Part-time	44 (14.2)	24 (15.9)	20 (12.7)
Not employed	156 (50.5)	75 (49.7)	81 (51.3)
Other	12 (3.9)	6 (4.0)	6 (3.8)
Missing	22 (7.1)	10 (6.6)	12 (7.6)
Financial insecurity, n (%)			
Does not have enough money to make ends meet	161 (52.1)	77 (51.0)	84 (53.2)
Annual income, n (%)			
≤US \$29,999	166 (53.7)	87 (57.6)	79 (50.0)
≥US \$30,000	59 (19.1)	24 (15.9)	35 (22.2)
Refused to answer or don't know	75 (24.3)	35 (23.2)	40 (25.3)
Missing	9 (2.9)	5 (3.3)	4 (2.5)
Marital status, n (%)			
Married	74 (24.0)	34 (22.5)	40 (25.3)
Single with partner	34 (11.0)	17 (11.3)	17 (11.8)
Single for any reason	192 (62.1)	95 (62.9)	97 (61.4)
Missing	9 (2.9)	5 (3.3)	4 (2.5)
Health care head of household, n (%)	118 (38.2)	57 (37.8)	61 (38.6)
Has internet access, n (%)	184 (59.6)	90 (59.6)	94 (59.5)
Has smartphone, n (%)	237 (76.7)	125 (82.8)	112 (70.9)
Low health literacy, n (%)	87 (28.2)	44 (29.1)	43 (27.2)

Characteristic	Overall (n=309) ^a	In-person (n=151)	Virtual world (n=158)
BMI (kg/m²)			
Mean (SD)	34.12 (6.9)	33.95 (6.7)	34.29 (7.2)
Participants, n	285	138	147
HbA_{1c}^c, %			
Mean (SD)	9.93 (1.7)	10.16 (1.7)	9.70 (1.7)
≥9.0, n (%)	181 (58.6)	95 (62.9)	86 (54.4)
Participants, n	284	138	146
PHQ-8 score^d			
Mean (SD)	5.49 (5.0)	5.10 (4.8)	5.86 (5.2)
Participants, n	299	145	154
Diabetes distress score^e			
Mean (SD)	2.69 (1.4)	2.65 (1.5)	2.72 (1.4)
Participants, n	298	145	153

^aPercentages are based on the n value of each column (column %).

^bOther category: 66 participants reported “some other race”; 8 reported “multiple races”; 1 reported Native Hawaiian, Pacific Islander; and 3 reported American Indian or Alaska Native.

^cHbA_{1c}: hemoglobin A_{1c}.

^dAssessed using the Patient Health Questionnaire-8 (PHQ-8), which ranges from 1 to 8 [29].

^eAssessed using the Diabetes Distress Scale- 17 [27,28].

Fidelity

The 17 study cohorts were conducted with 98% fidelity to the 8-week curriculum. The median number of sessions attended by participants was 6 in the IP arm and 7 in the VW arm. Among participants who attended WIC2 DMGVs, 98.2% (1618/1648 total events) completed the clinician consult and intake forms. In the VW condition, participants completed the clinical consult via telehealth (540/823, 65.6%), telephone (54/823, 6.6%), or either modality (230/823, 27.9%).

Coprimary Outcomes—ITT

Changes in HbA_{1c} and physical activity are reported in [Tables 2 and 3](#). In the ITT sample, we found within-group HbA_{1c} improvements of 0.8% among IP participants, from 10.2% at baseline to 9.4% at 6 months, and 0.5% among VW participants, from 9.7% at baseline to 9.2% at 6 months. Improvements in HbA_{1c} values were not statistically significant between groups and were noninferior (the mean difference across study arms was 0.3 (97.5% CI $-\infty$ to 0.3); $P < .001$). The upper limit did not cross the predetermined noninferiority margin of 0.7%. It would require a noninferiority margin of less than 0.3% to fail to reject the null hypothesis of inferiority.

Table 2. Changes in HbA_{1c} among Women in Control 2.0 (WIC2) participants.

Analysis type and study arm	HbA _{1c} ^a , % Baseline to 6 months			HbA _{1c} noninferiority (margin of 0.7)	
	Baseline	6 months	Change	Mean difference (1-sided 97.5% CI)	<i>P</i> value
PP^b (n=207)				0.2 (−∞ to 0.3)	<.001
IP ^c , mean (SD)	10.1 (1.8)	9.4 (2.1)	−0.7 (1.8)		
IP, mmol/mol	87	79	N/A ^d		
VW ^e , mean (SD)	9.6 (1.7)	9.1 (1.8)	−0.5 (1.6)		
VW, mmol/mol	81	76	N/A		
ITT^f (n=309)				0.3 (−∞ to 0.3)	<.001
IP, mean (SD)	10.2 (1.8)	9.4 (2.2)	−0.8 (1.9)		
IP, mmol/mol	88	79	N/A		
VW, mean (SD)	9.7 (1.7)	9.2 (2.1)	−0.5 (1.8)		
VW, mmol/mol	83	77	N/A		

^aHbA_{1c}: hemoglobin A_{1c}.^bPP: per-protocol.^cIP: in-person.^dN/A: not applicable.^eVW: virtual world.^fITT: intention-to-treat.**Table 3.** Changes in physical activity among Women in Control 2.0 (WIC2) participants.

Analysis type and study arm	Work week MET ^a -hours Baseline to 6 months			Work week MET-hours noninferiority (margin of 12)	
	Baseline	6 months	Change	Mean difference (one-sided 97.5% CI)	<i>P</i> value
PP^b (n=207)				−3.0 (−8.9 to ∞)	.008
IP ^c , mean (SD)	105.3 (35.3)	101.4 (34.9)	−5.2 (37.7)		
VW ^d , mean (SD)	106.6 (35.4)	100.6 (38.4)	−8.1 (37.7)		
ITT^e (n=309)				−3.1 (−6.9 to ∞)	.02
IP, mean (SD)	105.5 (40.1)	106.3 (45.4)	−6.5 (43.6)		
VW, mean (SD)	106.4 (37.1)	105.1 (46.9)	−9.6 (44.8)		

^aMET: metabolic equivalent of task.^bPP: per-protocol.^cIP: in-person.^dVW: virtual world.^eITT: intention-to-treat.

For physical activity, IP and VW participants had mean within-group decreases of 6.5 MET-hours and 9.6 MET-hours, respectively. Between-group differences were not detected from baseline to post intervention. Still, the noninferiority of the VW approach was confirmed (the mean difference across arms was −3.1 MET-hours, 97.5% CI −6.9 to ∞; *P*=.02). It would require a noninferiority margin of less than 9 MET-hours to fail to reject the null hypothesis of inferiority.

PP Results

Among the 207 participants who attended at least 6 DMGVs, within-group mean HbA_{1c} values improved by 0.7% among IP

participants, from 10.1% at baseline to 9.4% at 6 months, and by 0.5% among VW participants, from 9.6% at baseline to 9.1% at 6 months. Noninferiority was confirmed with a mean difference of 0.2 (97.5% CI −∞ to 0.3; *P*<.001) in HbA_{1c} across study arms. Improvements of ≥0.4% were achieved by 56% (56/99) of IP and 52% (56/108) of VW participants from baseline to 6 months, while nearly one-third (75/207, 36.02%) achieved a 1% improvement. IP and VW participants' physical activity decreased, on average, by 5.2 MET-hours and 8.1 MET-hours, respectively. Noninferiority was confirmed in the PP sample (the mean difference across arms was −3.0, 97.5% CI −8.9 to ∞; *P*=.008). Similar to the ITT analyses,

between-group changes in HbA_{1c} and accelerometer-measured physical activity were not statistically significant.

Secondary Outcomes

We analyzed mean changes in HbA_{1c} and physical activity data at 9 weeks from baseline, which were similar to the 6-month results (Table S3 in [Multimedia Appendix 2](#)). We compared the mean change in DD, depression symptom burden, physical functioning, patient activation, weight, and step count by study arm, and adjusted for the baseline values. We observed substantial within-group improvements in both study arms for total DD and some DD subscales (emotional burden, regimen,

and interpersonal). We observed substantive but nonsignificant improvements in both study arms for depression symptom burden, physical functioning, and patient activation, and mixed results for weight (Table 4). Notably, the total participants reporting moderate DD (scores of ≥ 2) decreased from 53% (156/294) to 33% (77/237), and the proportion with clinically meaningful depressive symptoms (scores of ≥ 5) decreased from 48% (142/295) to 40% (95/237) from baseline to 6 months (Table S4 in [Multimedia Appendix 2](#)). Physical activity assessment using step count revealed high baseline step counts, small decreases at 6 months, and overall null findings (Table 4). Results of sensitivity and unimputed analyses are in Table S5-S10 in [Multimedia Appendix 2](#).

Table 4. Group changes in secondary outcomes among Women in Control 2.0 (WIC2) study participants.

	Baseline, mean (SD)	Changes from baseline to 9 weeks		Changes from baseline to 6 months	
		LS ^a , mean (SE)	Between-group <i>P</i> value	LS, mean (SE)	Between-group <i>P</i> value
Total DD^b					
PP^c			.14		.33
IP ^d	2.3 (1.0)	-0.5 (0.1)		-0.3 (0.1)	
VW ^e	2.3 (1.0)	-0.3 (0.1)		-0.2 (0.1)	
ITT^f			.35		.69
IP	2.2 (1.0)	-0.4 (0.1)		-0.2 (0.1)	
VW	2.3 (1.1)	-0.2 (0.1)		-0.2 (0.1)	
DD: emotional burden					
PP			.01		.28
IP	2.7 (1.5)	-0.7 (0.2)		-0.3 (0.1)	
VW	2.7 (1.5)	-0.4 (0.2)		-0.2 (0.1)	
ITT			.26		.68
IP	2.6 (1.5)	-0.6 (0.2)		-0.2 (0.1)	
VW	2.7 (1.4)	-0.3 (0.2)		-0.2 (0.1)	
DD: physician					
PP			.27		.31
IP	1.5 (0.9)	-0.2 (0.1)		-0.1 (0.1)	
VW	1.5 (1.0)	0.0 (0.1)		-0.1 (0.1)	
ITT			.53		.98
IP	1.5 (0.9)	-0.1 (0.1)		0.0 (0.1)	
VW	1.6 (1.1)	0.0 (0.1)		-0.1 (0.1)	
DD: regimen					
PP			.08		.76
IP	2.7 (1.3)	-0.7 (0.2)		-0.3 (0.1)	
VW	2.7 (1.4)	-0.4 (0.2)		-0.3 (0.1)	
ITT			.34		.56
IP	2.6 (1.3)	-0.5 (0.2)		-0.2 (0.1)	
VW	2.7 (1.3)	-0.3 (0.2)		-0.2 (0.1)	
DD: interpersonal					
PP			.77		.62
IP	2.0 (1.3)	-0.3 (0.2)		-0.2 (0.1)	
VW	2.0 (1.3)	-0.3 (0.2)		-0.2 (0.1)	
ITT			.98		.98
IP	1.9 (1.3)	-0.2 (0.1)		-0.1 (0.1)	
VW	2.0 (1.3)	-0.2 (0.2)		-0.1 (0.1)	
PHQ-8^g					
PP			.66		.12
IP	4.9 (4.8)	-0.7 (0.7)		-0.5 (0.3)	
VW	5.5 (5.1)	-1.1 (0.7)		-0.3 (0.4)	

	Baseline, mean (SD)	Changes from baseline to 9 weeks		Changes from baseline to 6 months	
		LS ^a , mean (SE)	Between-group <i>P</i> value	LS, mean (SE)	Between-group <i>P</i> value
ITT			.86		.99
IP	5.1 (4.8)	-0.4 (0.6)		-0.2 (0.3)	
VW	5.9 (5.3)	-0.7 (0.6)		-0.3 (0.3)	
Physical functioning^h					
PP			.42		.30
IP	45.8 (9.8)	2.3 (1.3)		1.0 (0.7)	
VW	46.5 (9.0)	1.0 (1.2)		0.3 (0.6)	
ITT			.53		.36
IP	45.8 (9.2)	2.6 (1.2)		0.9 (0.6)	
VW	46.1 (8.9)	1.1 (1.2)		0.7 (0.5)	
Patient activationⁱ					
PP			.02		.63
IP	67.5 (20.4)	7.7 (2.8)		1.6 (1.4)	
VW	68.8 (17.4)	0.1 (2.5)		0.7 (1.2)	
ITT			.12		.36
IP	66.5 (21.1)	5.1 (2.5)		1.1 (1.2)	
VW	66.0 (20.3)	0.4 (2.3)		1.1 (1.2)	
Weight (lb)					
PP			.02		.91
IP	193.2 (38.7)	-0.6 (5.6)		-0.6 (2.8)	
VW	199.7 (45.6)	0.8 (6.1)		-0.6 (3.1)	
ITT			.30		.83
IP	194.0 (40.5)	-0.2 (5.0)		-0.6 (2.4)	
VW	196.2 (44.7)	3.1 (5.1)		1.13 (2.9)	
Step count					
PP			.01		.24
IP	9779.4 (3187.1)	397.0 (483.2)		-219.8 (217.6)	
VW	10,008.1 (2977.4)	-476.7 (417.1)		-338.2 (202.4)	
ITT			.03		.35
IP	9631.4 (3304.2)	297.2 (424.4)		-150.9 (198.6)	
VW	9798.9 (3060.2)	-317.9 (378.7)		-168.3 (175.0)	

^aLS: least squares.

^bAssessed using the Diabetes Distress [DD] Scale-17, which ranges from 1 to 6 [27,28].

^cPP: per-protocol.

^dIP: in-person.

^eVW: virtual world.

^fITT: intention-to-treat.

^gAssessed using the Patient Health Questionnaire-8 (PHQ-8), which ranges from 1 to 8 [29].

^hAssessed using the physical function subscale on the Patient-Reported Outcomes Measurement Information System (PROMIS-29) measure [30].

ⁱAssessed using the Patient Activation Measure (PAM)-13 [31].

Lifestyle Behaviors

Self-management behaviors were assessed through a weekly self-report to detect changes in diet, exercise, and diabetes-related medication. Nearly a third of all participants (89/309, 28.8%) reported ≥ 1 dietary change, with a greater proportion in the VW group compared to the IP group (55/158, 34.8% vs 34/151, 22.5%).

Of all participants, 65.7% (203/309) engaged in at least 20 minutes of exercise weekly during the intervention (VW: 106/158, 67.1% vs IP: 97/151, 64.2%). Only 17.2% (53/309) reported any type of change (increase, decrease, or switch) in their diabetes medication regimen (VW: 29/158, 18.4% vs IP: 24/151, 15.9%).

Adverse Events

One study-related severe adverse event in the VW group occurred due to emotional distress.

Discussion

Principal Findings

To our knowledge, this is the first fully powered clinical trial to demonstrate the effectiveness of delivering DMGVs using an immersive 3D telemedicine platform versus IP care. Both approaches were similarly effective in reducing mean HbA_{1c} over 6 months. Our PP sample is indicative of a high patient retention rate. No significant changes in physical activity were detected. Altogether, this research demonstrates that 3D immersive telemedicine DMGVs are an effective alternative to IP group diabetes care for high-risk patients in a safety net health system.

Our preliminary study compared IP versus immersive DSME delivery among 89 low-income African American women with uncontrolled T2DM [34]. Results showed substantial improvements in mean HbA_{1c}. Other pilot studies demonstrated positive impacts on patient outcomes but faced methodological limitations, including lack of a comparison group, small sample size, and inadequate power, and none used a DMGV format [40,41]. In contrast, the WIC2 study was randomized with an active DMGV control condition and fully powered to rigorously test the primary outcomes.

Nearly half of our participants at baseline had measurable depressive symptoms and diabetes distress. Prior research has

revealed a strong correlation between depression, diabetes distress, and uncontrolled diabetes [42,43]. Interestingly, we found that the proportion of WIC2 participants with depressive symptoms (PHQ-8 ≥ 5) and diabetes distress (DD ≥ 2) decreased from baseline to 6-month follow-up, indicating the WIC2 intervention improves glucose control and mental health. This finding is important as interventions that address both physical and mental health can reduce patients' treatment burden.

Given our pilot study showed increased physical activity among study participants, the null finding in physical activity in WIC2 was unexpected [34]. We experienced challenges with accelerometry wear due to participants' discomfort with the devices. A literature review revealed that accelerometry-measured activity for middle-aged women with chronic disease has limitations [44], such that physical activity can be underestimated or inconsistent across the life span [37,45,46]. More research is needed to establish activity assessment guidelines for older adults.

Limitations

We acknowledge several study limitations. We had a small imbalance in HbA_{1c} at baseline. After careful assessment of participant characteristics, it was determined that this imbalance occurred at random and was unrelated to the fidelity of the study protocol. It is not possible to rule out unobserved confounding of protocol adherence, such as participants' access to transportation, digital literacy, work or childcare conflicts, or financial constraints impacting access to medication. Finally, this study was conducted with women in an urban safety net health system, which may limit its generalizability. The ongoing challenges with access to digital resources and digital literacy for underserved communities may also limit the immediate generalizability of our study findings to similar populations.

Conclusions

Immersive technologies can reduce disparities by improving effectiveness and access to evidence-based diabetes care. We showed that when given the tools, adults from digitally underserved communities robustly adopt health technology tools with improved health outcomes. More effort is warranted to design technology tailored to the needs, capabilities, and life perspectives of diverse communities to avoid leaving behind those most in need of better health care.

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manuscript; and decision to submit the manuscript for publication. SEM had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Data Availability

The WIC2 team agrees to share deidentified individual participant data that underlie the results reported in this study, the study protocol, and the statistical analysis plan. Data will be available for 6 months following publication for 5 years. Data will only be shared with academic researchers who provide a methodologically sound proposal to achieve aims related to primary or secondary outcomes and upon completion of a data use agreement. Requests should be directed to Suzanne.Mitchell2@umassmed.edu.

Authors' Contributions

SEM and PG conceived and designed the study. SEM, PG, AB, IAM, KNP, and JM-H carried out the study intervention and collected participant data. MRW, MJR, AB, IAM, and BAD performed data validation and analyses. SEM, MRW, MJR, AB, and BAD interpreted results. All authors contributed to the preparation of the manuscript, critically reviewed the results, and approved the manuscript for submission. SEM obtained funding. JM-H, KNP, AB, and BAD provided administrative, technical, and material support.

Conflicts of Interest

SEM is a consultant on health communication and relationship-centered care and has provided workshops and lectures on this topic funded by pharmaceutical and other industry sponsors. No product endorsement is permitted during these programs. SEM also holds equity in See Yourself Health LLC, a digital health service provider.

Multimedia Appendix 1

Women in Control 2.0 (WIC2) trial protocol.

[\[PDF File \(Adobe PDF File\), 286 KB-Multimedia Appendix 1\]](#)

Multimedia Appendix 2

Additional statistical analyses.

[\[DOCX File , 92 KB-Multimedia Appendix 2\]](#)

Multimedia Appendix 3

CONSORT eHEALTH checklist (V 1.6.1).

[\[PDF File \(Adobe PDF File\), 14076 KB-Multimedia Appendix 3\]](#)

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials

DD: diabetes distress

DMGV: diabetes medical group visit

DSME: diabetes self-management education

HbA_{1c}: hemoglobin A_{1c}

IP: in-person

ITT: intention-to-treat

MET: metabolic equivalent of task

PHQ-8: Patient Health Questionnaire-8

PP: per-protocol

T2DM: type 2 diabetes mellitus

VW: virtual world

WIC2: Women in Control 2.0

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