Comparing the Effectiveness of Telemedicine and Traditional Surveillance in Providing Diabetic Retinopathy Screening Examinations: A Randomized Controlled Trial

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Abstract

Objective: *To determine the effectiveness of telemedicine for providing diabetic retinopathy screening examinations compared with the effectiveness of traditional surveillance in community health clinics with a high proportion of minorities, including American Indian/Alaska Natives.* ***Subjects and Methods:*** *We conducted a multicenter, randomized controlled trial and assigned diabetic participants to one of two groups: (1) telemedicine with a nonmydriatic camera or (2) traditional surveillance with an eye care provider. For those receiving telemedicine, the criteria for requiring follow-up with an eye care provider were (1) moderate nonproliferative diabetic retinopathy or higher, (2) presence of clinically significant macular edema, or (3) "unable to grade" result for diabetic retinopathy or macular edema.* ***Results:*** *The telemedicine group (*$n = 296$*) was more likely to receive a diabetic retinopathy screening examination within the first year of enrollment compared with the traditional surveillance group (*$n = 271$*) (94% versus 56%,* $p < 0.001$*). The overall prevalence of diabetic retinopathy at baseline was 21.4%, and macular edema was present in 1.4% of participants. In the telemedicine group, 20.5% would require further evaluation with an eye care provider, and 86% of these referrals were because of poor-quality digital images.* ***Conclusions:*** *Telemedicine using nonmydriatic cameras increased the proportion of participants who obtained diabetic retinopathy screening examinations, and most did not require follow-up with an eye care provider. Telemedicine may be a more effective way to screen patients for diabetic retinopathy and to triage further evaluation with an eye care provider. Methods to decrease poor quality imaging would improve the effectiveness of telemedicine for diabetic retinopathy screening examinations.*

Key words: *ophthalmology, telemedicine, telehealth, diabetic retinopathy, retinopathy screening*

Introduction

Research suggests that the number of people with diabetes in the United States will increase from 23.7 million in 2009 to 44.1 million by 2034.[1] Diabetes disproportionally affects American Indian/Alaska Natives and other minorities with a prevalence approximately two times higher than non-Hispanic whites.[2–6] The prevalence of diabetic retinopathy is 78% for those with diabetes 15 or more years, and diabetic retinopathy is the leading cause of blindness in working-age adults.[7] Early diagnosis and treatment of diabetic retinopathy are key public health interventions because treatment is 90% effective in preventing blindness.[8] However, fewer than 50% of those with diabetes receive annual diabetic retinopathy screening examinations.[3,9] Obtaining eye examinations from eye care providers has been problematic for minorities (compared with non-Hispanic whites) because of greater difficulty with transportation, ability to access eye care providers, co-pays and other costs of the eye examination, and/or lack of health insurance.[10–12]

Telemedicine may increase the number of patients with diabetes who receive diabetic retinopathy screening examinations in rural and limited-access populations because it allows for rapid retinal imaging without dilation in primary care clinics. This imaging has shown excellent diagnostic precision for diabetic retinopathy compared with examinations in eye care providers' offices with dilated pupils.[13–15] However, most studies comparing the ability of telemedicine to improve the proportion of patients with diabetes that receive screening examinations were not designed as randomized controlled trials and have not been examined outside government health systems.[16]

The Tribal Vision Project was designed to determine the comparative effectiveness of telemedicine versus current surveillance techniques (examinations with eye care providers) using a randomized

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controlled trial design. It addresses two recommendations from the Institute of Medicine's priority topics for comparative effectiveness research.[17] This includes a first quartile priority topic of "Compare the effectiveness of interventions to reduce health disparities in *diabetes*…" and a second quartile priority topic of "Compare the effectiveness of new remote monitoring and management technologies (e.g., telemedicine, internet, remote sensing) and usual care in managing chronic diseases, especially in rural settings." Overall, this information will help determine the most effective method of providing diabetic retinopathy screening examinations to address an escalating public health issue.

Materials and Methods

STUDY POPULATION

The Institutional Review Boards of Legacy Health (Portland, OR), Oregon Health and Science University (Portland), and the Northwest Portland Area Indian Health Board (Portland) reviewed and approved the study protocol. All participants gave informed consent, and the study was conducted in accordance with the tenets of the Declaration of Helsinki.

We included patients from two clinics (Yellowhawk Tribal Health Center [Pendleton, OR] and Hunter Health Clinic [Wichita, KS]) that serve a large number of patients with diabetes who have difficulty acquiring annual diabetic retinopathy screening examinations. We used community-based participatory research methods to increase staff input, provide hands-on training, hire local staff, develop the protocol, recruit participants, and collect and report data. Our inclusion criteria were diabetic patients 18 years or older who were scheduled to visit their clinic primary care provider. We included all eligible participants, including those who reported a recent eye exam. Our exclusion criteria were cognitive impairment preventing informed consent and inability to transfer to a chair to perform nonmydriatic imaging. Research assistants contacted eligible patients prior to their primary care visit to inform them about the study and enrolled them during their clinic appointment.

We randomly assigned participants to either the telemedicine or traditional surveillance group. Telemedicine with nonmydriatic cameras cannot detect all eye disease and, at this time, is not considered a replacement for a comprehensive eye examination.[18] Therefore, the clinics encouraged all participants to see an eye care provider once a year regardless of their group assignment for the study.

TELEMEDICINE GROUP

Clinic technicians performed nonmydriatic testing at the most convenient time for the patient: before their primary care visit if they arrived early, in the middle of the visit if they were waiting for prescriptions, or after their visit at a mutually convenient time. A vacant room inside the clinic held the nonmydriatic camera.

The technicians performing nonmydriatic imaging did not have experience in retinal photography prior to the study. An experienced photographer trained them over a 3-day period and provided ongoing feedback as needed. The technicians used a digital nonmydriatic fundus camera (model NM-1000; NIDEK, Fremont, CA) and a modified Diabetic Retinopathy Study protocol to capture six undilated, 1.5-megapixel, 45° fundus photographs of each eye: a stereo pair centered on the optic disc, a stereo pair centered on the macula, a single image centered on the superior temporal retina, and a single image centered on the inferior temporal retina.[19,20] This protocol shows excellent agreement (kappa > 0.9) compared with dilated fundus examinations.[20,21] In addition, the technicians would take extra images if needed to move shadows to different locations if they occurred in a particular image.

The technician performed sequential, stereoscopic optic disc and macula photographs according to the manufacturer's instructions by moving the internal fixation target on the "left-most parentheses mark" on the camera screen for the first optic disc image and over the "right-most parentheses mark" for the second optic disc shot. Live infrared video allowed the technician to verify the different orientation of the second image. The technician performed a similar procedure for the macula. Glaucoma and macular degeneration were not a primary focus of this study, but we reported abnormal results to the clinics.

Devers Eye Institute created its own telemedicine system using a software-as-a-service framework.[22] The software encrypts, compresses, and transfers the retinal images and participant data to a secure Health Insurance Portability and Accountability Act (HIPAA)-compliant, password-protected relational database and then e-mails two experienced Devers Eye Institute investigators (S.D. and S.L.M.) when images are ready to be reviewed. A video demonstration of the software is available through Youtube (http://www.youtube.com/watch?v=dpN1Sp-P074&feature=email).

The study investigators graded images using criteria (*Table 1*) based on an international classification scale and the Proliferative Diabetic Retinopathy study.[23,24] They used a Screen-Vu stereoscope (PS Manufacturing, Portland, OR) to provide stereoscopic views of the optic discs and macula. They also graded the quality of the whole set of images (acceptable, poor but gradable, or too poor to grade). They determined "poor but gradable" if one or more images was blurry or contained shadows but other images allowed this area to be evaluated. If diabetic retinopathy or macular edema could not be fully assessed, the investigators would grade the images as "too poor to grade."[25] The investigators entered all information into electronic forms within the telemedicine system. The telemedicine system automatically created and e-mailed the evaluation report to the staff at the clinic.

TRADITIONAL SURVEILLANCE GROUP

The traditional surveillance group represented the usual process at each clinic for arranging diabetic retinopathy screening exams. At each visit, the primary care providers performed their usual preventive diabetic exams such as hemoglobin A1c (HbA1c) testing and asked participants to see an eye care providers for an eye exam once a year. The patient was responsible for arranging his or her appointment and transportation. The primary care clinics referred to a small number of community eye care providers. The study investigator (S.L.M.) contacted these eye care providers to explain the project and sent data entry forms. The data entry form used the same criteria as

Table 1. Description of Stages of Retinopathy and Macular Edema in the Tribal Vision Project 2011

STAGE	DESCRIPTION
Stage 0	No abnormalities
Stage 1 (mild NPDR)	Microaneurysms only
Stage 2 (moderate NPDR)	More than just microaneurysms (such as venous beading) but less than severe NPDR
Stage 3 (severe NPDR)	Contains one of the three characteristics termed the 4:2:1 rule: (1) approximately 20 dot blot hemorrhages in all four midperipheral quadrants, (2) venous beading in two quadrants, or (3) severe intraretinal microvascular abnormalities in one quadrant without PDR
Stage 4 (PDR)	Neovascularization of the optic disc or elsewhere, vitreous hemorrhage associated with neovascularization of any part of the eye, or evidence of previous panretinal photocoagulation
Macular edema	Retinal thickening within 500 μm of the fovea, exudates associated with retina thickening within 500 μm of the fovea, or retinal thickening of one disc diameter in size within one disc diameter of the fovea

This terminology is adapted from proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales.[23,24]

NPDR, nonproliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.

the telemedicine group (*Table 1*). The eye care providers could fax or mail the data entry form back to the research staff or primary care medical clinics for entry into the participant's medical record. Research technicians would periodically survey the participant's medical record to determine if he or she had received an eye exam. If yes, the results of this exam were entered in the research database. If the patient history indicated that the eye exam had been completed but no data entry form had been received, the research technician would verify the visit with the eye care provider and ask him or her to return a completed form.

DATA ANALYSIS

We used the R statistical program (available at www.R-project.org [last accessed August 8, 2010]) to perform all analyses. We compared baseline characteristics (age, gender, primary ethnicity, blood pressure, HbA1c, and duration of diabetes [in years]) between the telemedicine and traditional surveillance groups using an unpaired *t* test or Fisher's exact test, as applicable.

Proportion of diabetic retinopathy screening examinations. A "diabetic retinopathy screening examination" in the telemedicine group was nonmydriatic testing. A "diabetic retinopathy screening examination" in the traditional surveillance group was a retinal evaluation in an eye care provider's office. We compared the comparative effectiveness of telemedicine versus traditional surveillance to obtain a diabetic retinopathy screening examination. We determined that a sample size of 194 participants (97 participants per group) was required to detect a 10% increase in the proportion of diabetic retinopathy screenings in the telemedicine group using an alpha level of 0.05 and power of 0.80. We enrolled more participants than required because we also were interested in long-term results, which we will report in a future article.

Demographic characteristics, prevalence and stage of diabetic retinopathy, and referral proportion. We used person-based analyses and calculated the highest stage of diabetic retinopathy between eyes to define the prevalence and stage of diabetic retinopathy. We used a grade of "unable to determine" if either eye was assigned this grade because telemedicine would refer a participant to an eye care provider if one eye could not be examined. To determine the factors associated with obtaining a diabetic retinopathy screening examination, we compared the demographic characteristics of those that received an examination to those that did not.

Similar to previous studies, we used the criteria of diabetic retinopathy stage 2 (moderate nonproliferative diabetic retinopathy) or higher, presence of clinically significant macular edema, or "unable to grade" for either diabetic retinopathy or macular edema to estimate the burden of referral to an eye care provider when using telemedicine to triage patients with diabetes.[26,27] We used a Fisher's exact test to compare the stage of diabetic retinopathy between the groups. To determine the burden of referral from inadequate examinations in the telemedicine group, we compared the demographic characteristics of those with a grade of "unable to determine" for diabetic retinopathy or macular edema with the same parameters of those who had gradable images to determine whether there were demographic factors associated with not being able to obtain a diabetic retinopathy screening examination with telemedicine.

Risk factors for diabetic retinopathy. In contrast to the analyses above that included a person-based analysis (one eye per participant), we used both eyes of a participant to determine the risk factors for diabetic retinopathy. We were interested in whether the risk factors may have changed with recent advances in medications and treatment regimens to improve blood sugar control.[28] This information is also important to allow comparisons with other studies and to determine the burden of referral. To account for inter-eye correlations between eyes of a subject, we used the R library geepack and the geeglm function to create a mixed-effects model with subject number as a random effect.[29,30] We excluded eyes with an "unable to determine" grade, dichotomized diabetic retinopathy as not present (stage 0) versus present (stage 1 or higher), and determined in a multivariate analysis whether diabetic retinopathy was associated with age, gender, primary ethnicity, blood pressure, HbA1c, or duration of diabetes.

Results

DEMOGRAPHICS AND MEDICAL HISTORY

Study personnel evaluated 646 diabetic patients, with 567 (87.8%) enrolled and 79 (12.2%) not included. Of those not included, 78 refused participation, and 1 person was not eligible (not a health clinic

patient). There were no differences in age ($p=0.57$), duration of diabetes ($p=0.52$), or HbA1c level ($p=0.80$) between those not included and those enrolled. However, females were more likely to enroll (52% enrolled versus 38% not included, $p=0.03$).

Table 2 shows no significant differences between the telemedicine ($n=296$) and traditional surveillance ($n=271$) groups in demographic and medical characteristics. When primary, secondary, and tertiary race/ethnicity data were combined, 50.3% of the subjects reported American Indian/Alaska Native heritage, and 72.3% reported a non-white primary, secondary, and/or tertiary race/ethnicity. Overall, the subjects had high HbA1c levels, with a mean of 8.3% (reference range, 4–5.9%; <7.0% recommended in treated diabetic patients).[31,32]

Table 2. Demographics and Medical History in the Tribal Vision Project 2011

	OVERALL ($N=567$)	TELEMEDICINE ($N=296$)	TRADITIONAL SURVEILLANCE ($N=271$)	P[a]
Age (years)	51.1 (11.8)	50.5 (12.3)	51.7 (11.3)	0.23
Gender (% female)	51.7	52.0	51.3	0.86
Primary ethnicity (white versus other) (%)				0.45
White	52.9	51.7	54.2	
AI/AN	16.8	18.6	14.8	
African American	18.0	16.9	19.2	
Hispanic/Latino	10.9	11.8	10.0	
Asian/other	1.2	0.7	1.8	
No response	0.2	0.3	0.0	
Secondary ethnicity (white versus other) (%)				0.79
White	6.2	6.8	5.5	
American Indian/ Alaska Native	32.6	33.1	32.1	
African American	0.5	0.3	0.7	
Hispanic/Latino	1.8	2.0	1.5	
Asian/other	0.2	0.3	0.0	
No secondary ethnicity	58.6	57.1	60.1	
No response	0.2	0.3	0.0	
Blood pressure (mm Hg)				
Diastolic	76.9 (12.2)	76.8 (12.4)	77.0 (12.0)	0.85
Systolic	127.7 (19.8)	127.5 (19.8)	127.9 (19.7)	0.81
Hemoglobin A1c (%)	8.3 (2.4)	8.5 (2.4)	8.2 (2.4)	0.18
Duration of diabetes (years)	9.5 (8.1)	9.5 (8.0)	9.6 (8.3)	0.83

Data are mean (standard deviation) values unless otherwise specified.

[a]p value comparing telemedicine group with traditional surveillance group (by unpaired t test or Fisher's exact test as applicable).

AGREEMENT FOR PHOTOGRAPHY REVIEW

Two investigators (S.D. and S.L.M.) independently reviewed 30 sets of photographs randomly chosen from the study to calculate interobserver agreement[33] for optic disc assessment, macular edema, and stage of diabetic retinopathy. Their agreement for optic disc assessment (normal, glaucomatous, or unable to determine), macular edema (detected, not detected, or unable to determine), and diabetic retinopathy (stage 0 to stage 4 or unable to determine) was 87%, 97%, and 97%, respectively.

COMPARATIVE EFFECTIVENESS OF TELEMEDICINE VERSUS TRADITIONAL SURVEILLANCE TO PROVIDE DIABETIC RETINOPATHY SCREENING EXAMINATIONS

When comparing those with ($n=429/576$, 75.6%) and without ($n=138/567$, 24.3%) a diabetic retinopathy screening examination, we found no statistical differences in age, gender, primary ethnicity, systolic blood pressure, HbA1c level, or duration of diabetes. However, diastolic blood pressure at baseline was slightly higher in those without an examination (79.0 versus 76.2 mm Hg, $p=0.02$).

Table 3 shows the prevalence and severity of diabetic retinopathy in the eye with more advanced retinal disease of 429 participants with a telemedicine or eye care provider examination. The telemedicine group obtained a diabetic retinopathy screening examination within 12 months of enrollment more frequently than the traditional surveillance group (94% [278/296] versus 56% [151/271], $p<0.001$).

Twenty percent (20.5%, 57/278) of the telemedicine group would be referred to an eye care provider when using the criteria of "stage 2—moderate nonproliferative diabetic retinopathy or worse," "macular edema present," and "unable to determine" for either diabetic retinopathy or macular edema. Using this definition for referral in the telemedicine group, 86.0% (49/57) of referrals were because of "unable to determine" for diabetic retinopathy or macular edema.

"Unable to determine" was more common in the telemedicine group than in the traditional surveillance group for both diabetic retinopathy (9.4% versus 2.6%, $p=0.01$) and macular edema (17.6%

Table 3. Prevalence and Severity of Diabetic Retinopathy in the Eye with More Advanced Retinal Disease in the Tribal Vision Project 2011

	OVERALL ($N=429$)[a]	TELEMEDICINE ($N=278$)	TRADITIONAL SURVEILLANCE ($N=151$)	P[b]
Stage of DR (%)				
None	71.6	72.3	70.2	0.66
Mild NPDR	13.8	13.7	13.9	0.98
Moderate NPDR	4.7	2.9	7.9	0.03
Severe NPDR	0.7	0.0	2.0	0.04
PDR	2.3	1.8	3.3	0.33
Unable to determine	7.0	9.4	2.6	0.01
Macular edema (%)				
Not present	83.4	82.0	86.1	0.34
Present	1.4	0.4	3.3	0.02
Unable to determine	15.2	17.6	10.6	0.07
Requiring referral (%)[c]	21.9	20.5	24.5	0.40

[a]Eighteen and 120 persons did not obtain a diabetic retinopathy (DR) screening examination in telemedicine and traditional surveillance groups, respectively. A "diabetic retinopathy screening examination" was defined as a nonmydriatic telemedicine examination for the telemedicine group and as a retinal evaluation in an eye care provider's office for the traditional surveillance group.

[b]p value comparing telemedicine and traditional surveillance groups for each category (by Fisher's exact test).

[c]Requiring referral: DR stage 2 (moderate nonproliferative DR [NPDR]) or higher, presence of clinically significant macular edema, or "unable to grade" for either DR or macular edema.

PDR, proliferative DR.

versus 10.6%, $p=0.07$). When comparing the "unable to determine" group ($n=67$) with those with an adequate diabetic retinopathy screening examination ($n=362$), older age (55.1 versus 50.9 years, $p=0.007$) was the only demographic or clinical variable associated with an "unable to determine" result.

RISK FACTORS FOR DIABETIC RETINOPATHY

Table 4 shows that diabetic retinopathy was significantly associated with non-white primary ethnicity, higher diastolic blood pressure, higher systolic blood pressure, higher HbA1c levels, and longer duration of diabetes in univariate analyses.

Discussion

This project addressed two recommendations from the Institute of Medicine for the escalating public health issue of diabetes and diabetic retinopathy.[17] We showed that telemedicine using nonmydriatic cameras increased the proportion of participants who obtained diabetic retinopathy screening examinations and that a minority of participants had levels of diabetic retinopathy requiring further evaluation with an eye care provider. This suggests that telemedicine could be used to triage patients with diabetes for further evaluation with an eye care provider, especially in minority and low-access settings.

Our findings demonstrate that telemedicine increases in the proportion of diabetic retinopathy screening examinations within 1 year of enrollment, from 56% in the traditional surveillance group to 94% in the telemedicine group. The increase in diabetic retinopathy examinations was also found in three other randomized controlled trials in different populations.[34–36] Conlin et al.[34] reported an increase in diabetic retinopathy screening examinations from 77% to 87% in a mostly white, male Veterans Affairs Hospital population in Boston, MA, whereas Davis and colleagues[35] reported an increase from 14% to 77% with telemedicine in a rural, largely African American community in South Carolina. Other nonrandomized observational studies have demonstrated a 50–250% increase in diabetic retinopathy screening examinations with telemedicine.[36,37]

Similar to previous studies we used "moderate diabetic retinopathy" or worse, "macular edema," and "unable to determine" as the criteria for further evaluation, which resulted in approximately 21% of participants requiring referral in the telemedicine group.[26,27] If we ignore "unable to determine" and use only "severe diabetic retinopathy or worse," our proportion of referral (2%) would be similar to a previous study with 4.4%.[38] However, we used "unable to determine" as the criteria for referral because most telemedicine protocols would recommend referral if the eye was unable to be examined with photographs.[26,27]

Poor-quality images were the most common reason (86% of referrals) for referral in our study. Poor-quality nonmydriatic imaging may occur because of small pupil size or ocular media abnormalities (e.g., cataract) because these conditions decrease illumination of the retina. Our study demonstrated that "unable to determine" was more common in older participants. Such a finding is not unexpected because age is associated with smaller pupils and cataract. When imaging is difficult, a telemedicine protocol may recommend dilation of the pupil to increase illumination.[39] Laser-based imaging techniques (such as scanning laser ophthalmoscopy or optical coherence tomography) may be promising as these methods are able to scan through smaller pupils and ocular media abnormalities.[39,40]

Our study has several limitations. Because diabetic retinopathy requires life-long surveillance, long-term follow-up is critical to evaluating the effectiveness and sustainability of telemedicine. Our study will have up to 5 years of follow-up data, and we will report this longitudinal data in a future article. The overall prevalence of any diabetic retinopathy in our study participants was 21.5%, which is

Table 4. Risk Factors for Diabetic Retinopathy in the Tribal Vision Project 2011

	NO DR (N=650 EYES)[a]	DR (N=159 EYES)	P	
			UNIVARIATE[b]	MULTIVARIATE[c]
Age (years)	51.3 (11.7)	51.4 (11.7)	0.99	0.35
Gender (% female)	53.8	49.7	0.49	0.65
Primary ethnicity (white versus other) (%)			0.006	0.04
White	56.5	40.3		
American Indian/ Alaskan Native	18.2	20.8		
African American	14.0	25.8		
Hispanic/Latino	10.2	10.7		
Asian/other	1.2	2.5		
Blood pressure (mm Hg)				
Diastolic	75.3 (11.3)	79.3 (14.6)	0.007	0.41
Systolic	125.2 (18.1)	135.0 (22.8)	<0.001	0.03
Hemoglobin A1c (%)	8.1 (2.3)	9.0 (2.3)	0.001	0.003
Duration of diabetes (years)	8.8 (7.6)	13.6 (7.2)	<0.001	<0.001

Data are mean (standard deviation) values unless otherwise specified.

[a]Not all participants with diabetic retinopathy (DR) had blood pressure and hemoglobin A1c measurements (n=648 eyes for diastolic and systolic pressure and n=646 eyes for hemoglobin A1c).

[b]p value for univariate analysis of risk factors for DR (binomial mixed-effects model with both eyes of a participant).

[c]p value for multivariate analysis including all risk factors for DR (binomial mixed-effects model with both eyes of a participant).

less than the 28.5% found in the 2005–2008 National Health and Nutrition Examination Survey (NHANES).[38] If NHANES accurately represents the national proportion of diabetic retinopathy in patients with diabetes, a higher proportion of referral may be seen with more widespread use.

More than 10% of the traditional surveillance group had an "unable to determine" result for macular edema—which is higher than we expected. When we queried the eye care providers, the reasons included media opacities, small pupils, or difficulty obtaining a good stereo image for other reasons such as patient movement. However, even with this high proportion in the traditional surveillance group, our study showed that telemedicine was more likely to have an "unable to determine" result.

Although telemedicine with nonmydriatic cameras may detect many eye diseases, it may miss ocular hypertension, or refractive error. Therefore, our protocol encouraged all participants to see an eye care provider once a year regardless of their telemedicine or traditional surveillance results. Future studies should examine the frequency of requiring a comprehensive eye examination with an eye care provider if a diabetic retinopathy screening examination result does not meet referral criteria and participants have no symptoms of eye disease.

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Author Contributions

S.L.M., T.M.B., and K.W. participated in the design of the study. S.L.M., K.W., and C.S. participated in the conduct of the study. K.W., S.L.M., C.S., and S.D. participated in data collection. S.L.M. and C.S. performed data management. S.L.M., K.G., S.G., and C.S. performed data analysis. S.L.M., K.G., S.G., C.S., S.D., K.W., and T.B. participated in data interpretation. S.L.M., K.G., and C.S. participated in manuscript preparation. S.L.M., K.G., S.G., C.S., S.D., K.W., and T.B. participated in manuscript review and approval. As Principal Investigator, S.L.M. had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Disclosure Statement

No competing financial interests exist.

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