

# The impact of an interactive multimedia educational platform on patient comprehension and anxiety during fertility treatment: a randomized controlled trial

Abigail L. Bernard, M.D.,<sup>a</sup> Ashley K. Barbour, B.A.,<sup>b</sup> Clare Meernik, M.P.H., Ph.D.,<sup>c</sup>  
Jody L. Madeira, M.S., J.D., Ph.D.,<sup>d</sup> Steven R. Lindheim, M.D., M.M.M.,<sup>e</sup> and Linnea R. Goodman, M.D.<sup>a,f</sup>

<sup>a</sup> Department of Obstetrics and Gynecology, University of North Carolina, Chapel Hill, North Carolina; <sup>b</sup> The Brody School of Medicine, East Carolina University, Greenville, North Carolina; <sup>c</sup> Department of Epidemiology, University of North Carolina Gillings School of Global Public Health, Chapel Hill, North Carolina; <sup>d</sup> Maurer School of Law, Indiana University, Bloomington, Indiana; <sup>e</sup> Department of Obstetrics and Gynecology, Boonshoft School of Medicine, Wright State University, Dayton, Ohio; and <sup>f</sup> University of Virginia, Virginia Fertility and IVF, Charlottesville, Virginia

**Objective:** To assess the impact of an interactive multimedia educational platform and consent process on patient comprehension and anxiety state compared with standard fertility counseling and paper consents in patients undergoing ovulation induction–intrauterine insemination (OI-IUI) or in vitro fertilization (IVF) throughout their first infertility treatment cycle.

**Design:** Prospective randomized controlled trial.

**Setting:** A university-affiliated reproductive endocrinology and infertility clinic.

**Patient(s):** Patients aged 18–45 years undergoing their first OI-IUI or IVF cycle.

**Intervention(s):** An interactive multimedia educational and consent platform (EngagedMD-[EMD]) before and during the first infertility treatment, in addition to standard fertility counseling by the physician and nurse team.

**Main Outcome Measure(s):** Three survey time points: before the start of treatment (T1), at the start of treatment (T2), and at the completion of the treatment cycle (IUI or oocyte retrieval; T3). The main outcome measure was the comprehension score on a 15-question assessment administered at 2 time points (T2 and T3). The anxiety state at all 3 time points was assessed using a modified Spielberger State-Trait Anxiety Inventory score.

**Result(s):** Eighty-six patients were included: 21 in the OI-IUI conventional (i.e., standard fertility counseling group) group, 22 in the IVF conventional group, 21 in the OI-IUI EMD group, and 22 in the IVF EMD group. Overall, the average number correct on the 15-question comprehension assessment was significantly higher in the EMD groups than in the conventional groups at T2 (EMD:  $13.2 \pm 1.8$  vs. conventional:  $11.7 \pm 1.8$ ) but not at T3. For those undergoing IVF, the average number correct was significantly higher at both T2 and T3 in the EMD vs. the conventional group (T2:  $14.1 \pm 1.3$  vs.  $12.4 \pm 1.8$ ; T3:  $14.1 \pm 1.7$  vs.  $12.5 \pm 1.5$ ). The average State-Trait Anxiety Inventory scores at each time point were similar between the EMD and conventional groups for both OI-IUI and IVF groups. Age  $\leq 35$  years and IVF treatment were significant predictors of increased State-Trait Anxiety Inventory scores.

**Conclusion(s):** The addition of an interactive multimedia educational platform significantly improved patient comprehension at the initiation of OI-IUI and IVF cycles for patients undergoing fertility treatment for the first time. Those undergoing IVF with access to EMD had sustained, improved comprehension at the end of their treatment. The supplementation of a multimedia platform did not alter anxiety throughout the treatment. Younger patients undergoing IVF may benefit from increased psychological resources.

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**Key Words:** Multimedia platform, assisted reproductive technology, informed consent, patient comprehension

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Reprint requests: Abigail L. Bernard, M.D., Department of Obstetrics and Gynecology, University of North Carolina, Chapel Hill, 3020 Old Clinic, CB # 7570, Chapel Hill, North Carolina 27599 (E-mail: [Abigail.bernard@unhealth.unc.edu](mailto:Abigail.bernard@unhealth.unc.edu)).

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Informed consent is a necessary procedure before surgical interventions and requires that the patient comprehends the proposed procedure, risks, benefits, and alternatives. Traditionally, obtaining informed consent involves a clinician-patient conversation and a document that the patients sign when they believe that they have an adequate understanding of the intervention. However, medical literature reports that patient recall after traditional informed consent is often limited, highly variable, and frequently leaves the patient unsatisfied with the amount of information received (1–6).

As advances in the medical field become more complex, so does obtaining valid informed consent with appropriate patient comprehension. This is particularly evident in those undergoing assisted reproductive technology (ART). The procedures involved in ART not only involve scientific concepts unfamiliar to many people but also are emotionally charged because patients usually have experienced significant stress attempting to conceive. Furthermore, there are additional ethical and legal considerations that must be considered, such as the disposition of unused embryos. Unlike emergency surgical procedures such as appendectomy, fertility treatment is usually not an emergency; thus, there is time to process and comprehend these multifaceted procedures and their potential consequences.

Researchers within other disciplines have studied whether the addition of multimedia educational interventions can improve patient comprehension in the informed consent process and mitigate anxiety levels. Two recent systematic reviews and a Cochrane meta-analysis reported that most audiovisual and interactive tools studied improved patient comprehension (7–9). Additionally, the recent meta-analysis concluded that patient anxiety, both in general and in relation to the consent process, was no different in those who received the informed consent intervention than in those who did not (9). To our knowledge, there is only one such multimedia intervention, EngagedMD (EMD), that has been studied within the context of ART. This platform includes brief educational modules followed by comprehension assessments (and explanations for incorrect answers) that cover topics within ART, including in vitro fertilization (IVF), ovulation induction (OI), and intrauterine insemination (IUI). In a prospective survey study, Madeira et al. (10) recently reported responses from >3,000 patients and providers at 13 fertility centers in the United States. The survey concluded that the multimedia platform better prepared most patients to sign consent documents, was a helpful supplement to their physician and nurse consultations and reinforced key ART concepts.

To further evaluate this multimedia platform, we performed a randomized controlled trial to evaluate if access to this intervention improves patient comprehension, the consent process, and patients' emotional well-being during treatment compared with standard physician/nurse counseling. We hypothesized that EMD would be superior to traditional counseling and would improve patient comprehension.

## MATERIALS AND METHODS

We conducted a single-site prospective randomized controlled trial in an academic reproductive endocrinology

and infertility practice with 5 physicians. The institutional review board and the Office of Human Research Ethics at the University of North Carolina at Chapel Hill (#18-3258) approved the study, and information regarding the study was provided on [clinicaltrials.gov](https://clinicaltrials.gov) (reference number: NCT03962257). All participants provided written informed consent.

The inclusion criteria were English-speaking patients aged 18–45 years who were undergoing either their first OI/superovulation with IUI or autologous IVF retrieval cycle and had access to a computer or a smartphone. The exclusion criteria were donor egg cycles, egg freezing cycles, or frozen embryo transfers. All eligible patients were recruited by their primary physicians and clinical care nurses and consented to by one of the study investigators (LG) at the University of North Carolina Fertility Clinic. The patients were told that they might have access to the virtual multimedia platform or may not. They were counseled that regardless of participation, they would receive the standard education and counseling. Both groups were aware that the other existed.

After presenting the informed consent, patients were randomized to either receive standard fertility counseling with their primary physician and nurse team (conventional group) or to receive unrestricted access to an interactive online multimedia platform (EMD) in addition to standard fertility counseling (EMD group) with 4 groups: OI-IUI conventional, OI-IUI EMD, IVF conventional, and IVF EMD. Randomization was achieved using an online randomization tool. Block randomization in groups of 4–6 was used. A clinical nurse unaffiliated with the study prepared opaque randomization envelopes, which were sequentially numbered with study participants' identifications in advance of the study start and kept in a secure location.

The physician and nursing staff led standard teaching for all patients. The primary physician covered the general principles of either OI-IUI or IVF with individualized counseling and reviewing the patient's plan of care. The nursing staff provided education on the logistics of treatment implementation, including cycle instructions and medication teaching. Patients randomized to the conventional group received paper copies of the consents and submitted signed copies at the nurse teaching visit. Patients assigned to the experimental group were given access to the EMD platform and signed online consents. Nurses were aware of which group the patients were randomized to because they were responsible for obtaining the consent documents. The physicians were not aware of patients' randomization until the consent documents (after counseling had occurred) were signed.

EngagedMD is an online multimedia video library that uses voice, text, and 3-dimensional computer animation. Patients undergoing OI-IUI were granted access to the OI-IUI video library, which included 9 videos covering 46 minutes of content, including topics such as genetic prescreening and the process of controlled ovarian stimulation. Patients undergoing IVF were granted access to the IVF video library, which included 13 videos covering 73 minutes of content that reviewed ART procedures, genetic prescreening, the process of controlled ovarian stimulation, fertilization and embryo development, and pregnancy complications of IVF.

Embedded within each video were comprehension assessments that served as “knowledge checks” where patients could solidify their own understanding of these treatments. If a question was answered incorrectly, the platform provided the correct answer with an explanation. The videos were accessible from any online device and could be viewed an unlimited number of times. Patients in the experimental group completed consent forms online through the EMD platform. All patients in the EMD group completed all videos because the consents were not available to the patients until the modules were completed. The consents were signed at any time point after T1 and before T2.

Three time points were defined within the study. The first time point, T1, occurred when the patient signed the study consent, which was before treatment, before the beginning of the standard teaching session, and before access to EMD was granted for the EMD group. The second time point, T2, occurred after patients’ standard counseling sessions and at the start of their OI-IUI or IVF cycle (typically within a month of T1, but occasionally later because of treatment initiation timing). The third time point, T3, occurred at the completion of the patients’ treatment cycle (i.e., IUI or oocyte retrieval). This interval was usually approximately 2 weeks. The patients in the EMD group received access to the EMD multimedia platform between T1 and T2. The patients received the link to complete their T3 survey immediately after oocyte retrieval or IUI before the cycle outcome was known.

At T2 and again at T3, a 15-question comprehension assessment was administered to those undergoing OI-IUI and IVF to assess patients’ understanding of the respective treatment process (Appendix 1, available online). The comprehension assessment (specific to OI-IUI and IVF) included questions that assessed the physiology of the menstrual cycle, reproductive pharmacology, and risks of treatment. The patients were asked identical questions at T2 and T3. The comprehension assessment was developed from the core consent and evaluated through several revisions made by JM, SL, and LG. The questions were attempted to be written at a high school reading level. A maximum score of 15 at these time points was collected for each patient. The patient’s primary physician and nurse team were not informed of the patient’s comprehension score.

Additionally, a modified Spielberger State-Trait Anxiety Inventory (STAI) questionnaire was used at T1, T2, and T3 to assess the emotional well-being throughout treatment (11). This validated test measures state anxiety (how one feels at the moment: “feel questions”) and trait anxiety (how one generally feels: “am questions”). The complete STAI questionnaire includes 40 questions assessing both trait and state anxiety. Each question is rated on a 4-point scale from 1–4, from “Not at all” to “Very much so,” and scores are additive, with high-frequency negative emotions scoring higher and high-frequency positive states scoring lower. Low scores indicate a calm state, and higher scores indicate higher anxiety (11). In our study, we used a modified version of the STAI questionnaire only using anxiety state questions because we were not assessing anxiety traits, only states during treatment. Nineteen of the 20 STAI statements were assessed, with the statement “I feel strained” omitted because it was deemed

confusing by focus groups (Appendix 2). The range in our study was 19–76.

This study’s primary outcome was to assess if the EMD platform enhances patients’ understanding of fertility treatment compared with the standard fertility counseling with their physician and nurse team, as evidenced by their score on a 15-question comprehension assessment. Secondary outcomes were to qualitatively assess the impact of the EMD platform on patients’ overall experience, perceptions of the informed consent process, and its impact on the levels of anxiety during treatment.

Assuming a 20% difference with a 60% (9/15) correct answer rate in the conventional group vs. 80% (13/15) correct answer rate in the EMD group, using a 2-sided test with an  $\alpha$  value of 0.05 and a  $\beta$  value of 0.2, a sample size of 76 women (38 per arm [19 for OI-IUI and 19 for IVF]) were required for this study. To account for the loss of follow-up, a total goal of 50 patients in each arm was recruited. The study was powered to evaluate comprehension in the EngagedMD compared with the conventional group but not to evaluate subgroups comparing IUI vs. IVF groups.

Categorical data were compared using chi-square tests or Fisher’s exact tests when cell counts were  $<5$ . Continuous data were compared using  $t$  tests. Univariate linear regression models examined associations between comprehension scores at T2 and T3 and STAI score at each time point with treatment (IUI or IVF), exposure (EMD platform or conventional teaching), subjective knowledge at T1, T2, or T3, and patient characteristics including age, race, ethnicity, education, household income, length of trying to conceive, and diagnosis. Variables significant at a 2-sided  $\alpha$  level of 0.05 were then entered into multivariable linear regression models. Analysis was performed using SAS 9.4 (SAS Institute, Cary, NC).

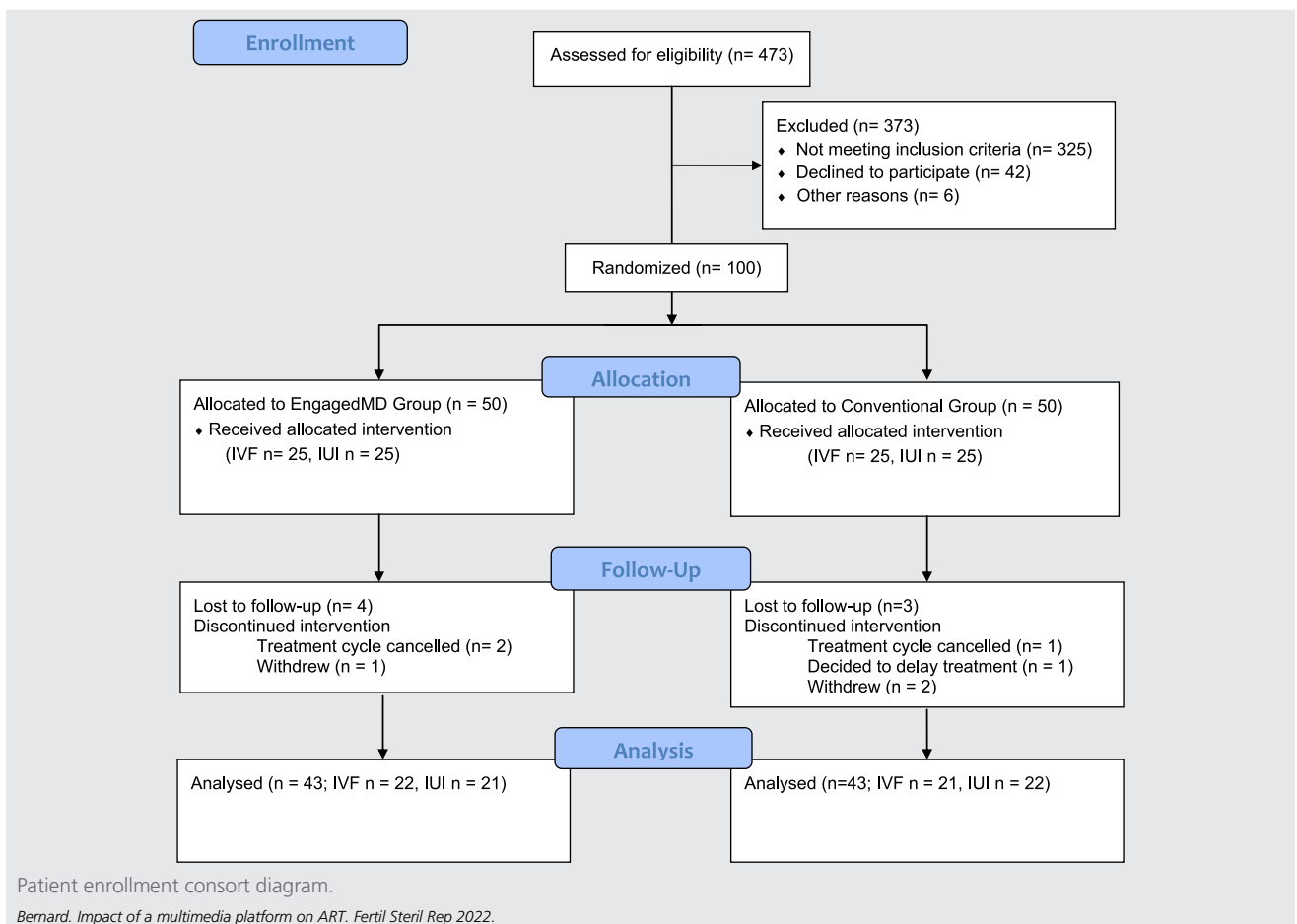
## RESULTS

From June 2019 to February 2021, 100 women were enrolled in the study, with 86 participating in all 3 surveys (Fig. 1). Participant characteristics, including age, race, and ethnicity, were similar between the groups, although there was a significant difference in the distribution of unexplained infertility in both EMD vs. conventional groups and between the 4 subgroups (OI-IUI EMD, IVF EMD, OI-IUI conventional, IVF conventional). There was a significant difference in the distribution of participants with “other infertility diagnoses” in the 4 subgroups (Table 1).

With respect to comprehension scores, overall, the average number “correct” on the 15-question comprehension quiz was significantly higher in the EMD group than in the conventional group at T2 (13.2 vs. 11.7,  $P=.001$ ) but not at T3 (Fig. 2). Subjectively, the EMD group was more likely to report higher knowledge (“quite a bit” or “a lot” vs. “only a little” or “average”) regarding treatment at T2 than the conventional group (82% vs. 48%,  $P=.001$ ), although no differences were noted at T1 or T3.

For those undergoing OI-IUI treatment, the average number correct was significantly higher at T2 in the EMD group than in the conventional (12.2 vs. 11.1,  $P=.04$ ) but similar at T3. For those undergoing IVF, the average number correct

FIGURE 1



was significantly higher at both T2 (14.1 vs. 12.4,  $P=.002$ ) and T3 (14.1 vs. 12.5,  $P=.009$ ) for the EMD group (Fig. 2).

With respect to emotional well-being, the overall average STAI scores at T1, T2, and T3 were 33.5, 38.6, and 37.0, respectively. At each time point, the overall average STAI scores between the EMD and conventional groups were similar (Fig. 3); the same trend was observed between the EMD and conventional groups for both OI-IUI and IVF groups. When comparing differences on the basis of treatment (OI-IUI vs. IVF), significantly higher anxiety scores in the IVF group were only observed at T2 (41.0 vs. 36.0,  $P=.01$ , Fig. 3).

With respect to the informed consent process, no differences were observed between the EMD and conventional groups reported at T1 or T2 (including feeling it was “helpful,” “bureaucratic,” “easy to understand,” or “a legal formality”), except that the participants in the EMD group were more likely than those in the conventional group to report at T2 that the duration of the consent conversations was “just right” (85% vs. 58%,  $P=.01$ ) as opposed to “too short” (15% vs. 42%,  $P=.01$ ).

In those using the EMD platform, a high proportion of participants felt that it provided adequate information (71%), was interesting (42%), and flexible (50%).

Eighty-two percent of the participants reported that the EMD platform was easy or very easy to understand; 68% agreed or strongly agreed that the online, multimedia platform did more with the consent process than could have been done with the paper documents; 84% agreed or strongly agreed that it was user-friendly, saved them time (59%), and that videos were easy to follow (84%); and most agreed or strongly agreed that they would recommend EMD to a friend (76%). Fifteen percent referred back to the e-learning application after completing it. On a scale of 1–100, with 100 being absolutely satisfied with the overall treatment, there was no difference in treatment satisfaction at T2 or T3, regardless of whether participants had access to the EMD platform or not ( $85.2 \pm 21.1$  vs.  $83.8 \pm 18.5$ ;  $P=.82$ ).

Factors identifying positive or negative predictors of the comprehension scores are presented in Supplemental Table 1 (available online). Results suggested that a significant predictor of increased comprehension scores at T2 was a patient report of higher subjective knowledge ( $\beta = 1.19$ ,  $P=.009$ ). Factors including education level, household income, and anxiety level were not positive or negative predictors of comprehension score throughout treatment.

TABLE 1

Patient demographics.								
Demographic	EMD total n = 43 (%)	Conventional total n = 43 (%)	P value <sup>a</sup>	EMD IVF, n = 22 (%)	EMD OI-IUI n = 21 (%)	Conventional IVF n = 22 (%)	Conventional OI-IUI n = 21 (%)	P value <sup>a</sup>
Age (y)								
26–30	11 (25.6)	8 (18.6)	.13	6 (27.3)	5 (23.8)	6 (27.3)	2 (9.5)	.16
31–35	14 (32.6)	24 (55.8)		6 (27.3)	8 (38.1)	9 (40.9)	15 (71.4)	
36–40	13 (30.2)	6 (14.0)		6 (27.3)	7 (33.3)	3 (13.6)	3 (14.3)	
41–45	5 (11.6)	5 (11.6)		4 (18.2)	1 (4.8)	4 (18.2)	1 (4.8)	
Race								
Black or African American	3 (7.0)	2 (4.7)	.30	1 (4.5)	2 (9.5)	1 (4.5)	1 (4.8)	.81
Asian (includes Native Hawaiian or Pacific Islander)	2 (4.7)	5 (11.6)		1 (4.5)	1 (4.8)	3 (13.6)	2 (9.5)	
American Indian or Alaskan Native	0	0		0	0	0	0	
White	34 (79.1)	35 (81.4)		18 (81.8)	16 (76.2)	18 (81.8)	17 (80.9)	
Other (includes prefer not to answer)	4 (9.3)	1 (2.3)		2 (9.1)	2 (9.5)	0	1 (4.8)	
Ethnicity								
Hispanic or Latino	2 (4.7)	1 (2.3)	.62	0	2 (9.5)	1 (4.5)	0	.44
Not Hispanic or Latino	40 (93.0)	42 (97.7)		21 (95.5)	19 (90.5)	21 (95.5)	21 (100)	
Prefer not to answer	1 (2.3)	0		1 (4.5)	0	0	0	
Highest level of education completed								
HS/GED	1 (2.3)	0	.43	0	1 (4.8)	0	0	.12
Some college	1 (2.3)	5 (11.6)		1 (4.5)	0	4 (18.2)	1 (4.8)	
2-year degree (Associates)	5 (11.6)	5 (11.6)		4 (18.2)	1 (4.8)	3 (13.6)	2 (9.5)	
4-year-degree (B.A., B.S.)	19 (44.2)	16 (37.2)		10 (45.5)	9 (42.9)	10 (45.5)	6 (28.6)	
Master's Degree (M.A., M.S.)	11 (25.6)	8 (18.6)		3 (16.4)	8 (38.1)	4 (18.2)	4 (19.0)	
Doctoral degree (Ph.D.)	1 (2.3)	4 (9.3)		0	1 (4.8)	0	4 (19.0)	
Professional Degree (J.D., M.D., D.O., Pharm.D.)	5 (11.6)	5 (11.6)		4 (18.2)	1 (4.8)	1 (4.5)	4 (19.0)	
Household income								
\$10,001–\$50,000	4 (9.3)	0	.51	0	4 (19.0)	0	0	.19
\$50,001–\$100,000	14 (32.6)	16 (37.2)		8 (36.4)	6 (28.6)	8 (36.4)	8 (38.1)	
\$100,001–\$150,000	8 (18.6)	9 (20.9)		2 (9.1)	6 (28.6)	3 (13.6)	6 (28.6)	
\$150,001–\$200,000	5 (11.6)	4 (9.3)		2 (9.1)	3 (14.3)	3 (13.6)	1 (4.8)	
>\$200,000	8 (18.6)	10 (23.3)		6 (27.3)	2 (9.5)	6 (27.3)	4 (19.0)	
Prefer not to answer	4 (9.3)	4 (9.3)		4 (18.2)	0	2 (9.1)	2 (9.5)	
Length of trying to conceive								
<1 y	7 (16.3)	4 (9.3)	.51	6 (27.3)	1 (4.8)	2 (9.1)	2 (9.5)	.26
1–3 y	25 (58.1)	29 (67.4)		9 (40.9)	16 (76.2)	14 (63.6)	15 (71.4)	
>3 y	11 (25.6)	9 (20.9)		7 (31.8)	4 (19.0)	5 (22.7)	4 (19.0)	
Unknown	0	1 (2.3)		0	0	1 (4.5)	0	
Diagnosis								
Unexplained	17 (39.5)	28 (65.1)	.02	4 (18.2)	13 (61.9)	9 (40.9)	19 (90.5)	<.0001
Male Factor	17 (39.5)	10 (23.3)	.10	9 (40.9)	8 (38.1)	5 (22.7)	5 (23.8)	.44
Tubal Factor	7 (16.3)	2 (4.7)	.16	5 (22.7)	2 (9.5)	2 (9.1)	0	.12
Endometriosis	3 (7.0)	0	.24	3 (13.6)	0	0	0	.06
Ovulatory Disorder	12 (27.9)	15 (34.9)	.49	8 (36.4)	4 (19.0)	8 (36.4)	7 (33.3)	.57
Other	7 (16.3)	2 (4.7)	.16	7 (31.8)	0	1 (4.5)	1 (4.8)	.003

Note: EMD = educational and consent platform (EngagedMD); GED = graduate education degree; HS = high school; IVF = in vitro fertilization; OI-IUI = ovulation induction–intrauterine insemination.

<sup>a</sup> P value from chi-square or Fisher's exact tests when cell counts were <5.

Bernard. Impact of a multimedia platform on ART. Fertil Steril Rep 2022.

Positive or negative predictors of STAI state scores are presented in [Supplemental Table 2](#). Age  $\leq 35$  was a predictor of elevated STAI state score at each time point evaluated (T1  $\beta = 4.07$ ,  $P = .005$ ; T2  $\beta = 6.46$ ,  $P = .01$ ; and T3  $\beta = 9.88$ ,  $P < .01$ ). Undergoing OI-IUI for treatment predicted a decreased STAI-S score at T2 ( $\beta = -5.03$ ,  $P = .04$ ). Exposure (EMD vs. conventional) was not associated with statistically significant differences in STAI state score at any point during treatment.

## DISCUSSION

Infertility treatments are complex and stressful procedures. Obtaining adequate informed consent, including appropriate patient comprehension, has grown more challenging given the increasing complexities within the field, including preimplantation genetic testing and completing gamete or embryo directives before the cycles. As medical technology advances, so can interventions that can assist in obtaining valid and appropriate informed consent. Recently, the use of multimedia platforms to improve the informed consent process has been an active research area. To our knowledge, this is the first randomized study assessing the use of a multimedia platform in ART, although other areas within obstetrics and gynecology have addressed the impact of such interventions with varying results (12, 13).

In our study, those in the EMD group who were given access to a multimedia platform in addition to standard counseling had significantly higher comprehension scores at the start of the treatment. Higher comprehension scores were persistent at the end of the treatment for those in the IVF EMD group, but this was not seen in the OI-IUI EMD group. These results are in contrast to the results in a 2004 systematic review by Flory and Emanuel (14) evaluating multimedia resources in research participants, but they are consistent with 2 recent systematic reviews and a Cochrane meta-analysis evaluating the effect of multimedia interventions on patients before medical or surgical procedures (7–9). Specifically, Schenker (7) reported in a 2010 systematic review that most included studies (11 of 15) showed improved patient comprehension of medical and surgical procedures when audiovisual or multimedia tools were used either in conjunction with or in place of standard written consents. However, Schenker (7) noted significant variability among the audiovisual tools evaluated and in the way patient comprehension was measured. Similar to the comprehension retention in our IVF EMD group, Rossi et al. (15) reported that comprehension in their audiovisual intervention group was retained at a follow-up visit averaging approximately 10 weeks after the exposure. Unlike that study, in which patients received one exposure, our patients with access to the EMD multimedia platform were able to reference back to the resource as often as desired or needed. Of note, our comprehension assessment questions were written at an attempted high school reading level. All participants reported completing at least a high school education (Table 1).

In a 2020 systematic review, Glaser et al. (8) reported outcomes from interactive interventions requiring active patient

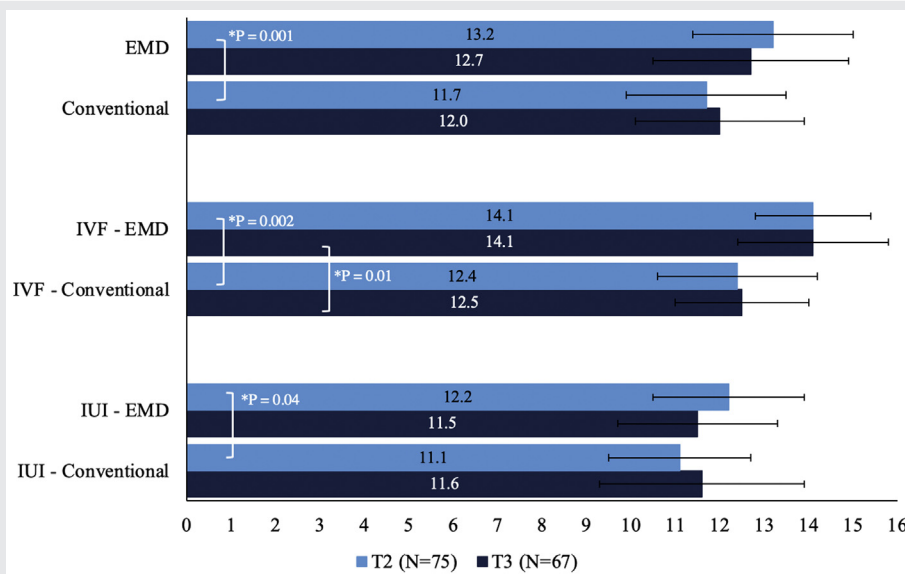
participation. Eighty-five percent (11/13) of the studies reported improved patient comprehension. Regardless of the intervention medium (written, audiovisual, interactive), all interventions that included test/feedback or teach-back components improved patient comprehension. The EMD multimedia platform in our study incorporated interactive components: knowledge checks at the end of video modules that elaborated on incorrect answers. It is likely that this interactive feature assisted with patient comprehension, although we did not study the platform with and without the interactive component.

Participants with access to the EMD multimedia platform were more likely to report confidence in their knowledge base at the start of treatment than patients without such access, consistent with a prior study (16). Our results show that the patients who reported high subjective knowledge were usually correct, as subjective reporting of a high knowledge base at T2 was associated with an increased comprehension score at T2. Notably, high comprehension scores were not predicted for higher education level or age. Additionally, STAI scores, whether high or low, also did not predict high or low comprehension scores in our population.

Prior research has assessed the impact of multimedia interventions on anxiety, with conflicting reports (9,17). In our study, access to the EMD multimedia platform did not significantly alter anxiety scores. At the initiation of the study, our patient population had an STAI state score average of 33.5. This average is similar to that reported in a 1983 study conducted in New Zealand that reported mean STAI state scores for females in various age groups (age 16–19 years, mean STAI state score 36.09; age 20–29 years, mean STAI state score 34.11; age 30–39 years, mean STAI state score 34.47; age 40–49 years, mean STAI state score 32.47) (18). The pooled average of all women within the age group included in our study population was 34.09, although it is important to note this average includes females aged 16–17 years and 46–49 years (who were not included in our study) and includes the question that we omitted. For additional reference, a recent study evaluated the state anxiety of university undergraduates (ages 18–24 years) who were caregivers for dependent relatives. The study found the average STAI state score for current caregivers was 45.85, and the average state anxiety of noncaregivers was 39.92 (this study included all 20 STAI state questions, whereas our study included 19) (19). For further reference, a separate study (also asking all 20 STAI state questions) found that the average state anxiety score for caregivers of people with advanced cancer was  $45.21 \pm 2.31$  (20).

Throughout the treatment, our patients' anxiety scores increased, especially in those undergoing IVF. Although it is well known that infertility treatment is anxiety-provoking, our findings suggest that providing a multimedia educational resource does not enhance or obviate anxiety (21). Consistent with our results, a recent Cochrane review reported no difference in general anxiety or anxiety with the consent process using audiovisual interventions (9). In another systematic review, Nehme et al. (17) reported on 12 trials (10 of which were randomized controlled trials) that assessed anxiety levels at various time points (all studies reported anxiety levels after

FIGURE 2



Comprehension assessment score by exposure. Average comprehension assessment scores at T2 and T3, by exposure alone or by treatment and exposure. Significance is noted by an asterisk (\*). If not noted, the comparison was not significant. EMD = educational and consent platform (EngagedMD); IUI = intrauterine insemination; IVF = in vitro fertilization; T2 = survey time point at the start of treatment; T3 = survey time point at the completion of the treatment cycle.

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tool, with only some studies evaluating before tool). Only 3 studies reported a significant difference in anxiety between the 2 groups, with those exposed to the multimedia intervention having decreased anxiety (22–24).

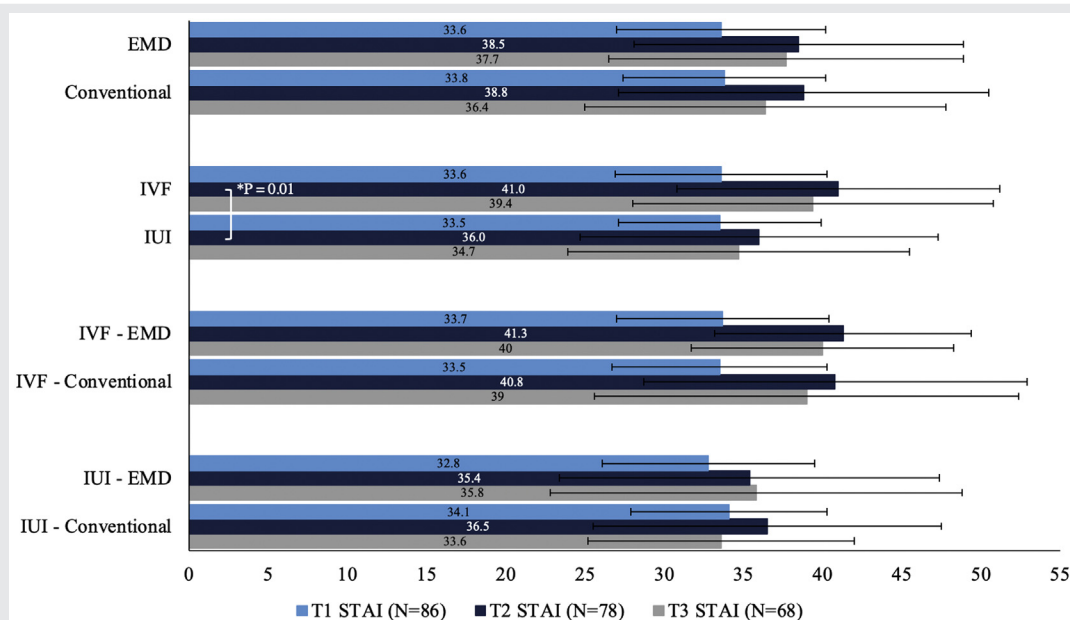
Factors associated with increased STAI state scores included age and IVF treatment, where patients aged  $\leq 35$  years were significantly more anxious throughout the treatment process. This is consistent with the findings of a study of infertile Korean women, where anxiety scores were highest in those aged  $< 30$  years (25). It is surprising that the anxiety levels were higher in younger patients because their predicted chance of success during treatment based on age alone is higher than that of older patients. It makes more clinical sense, however, that those undergoing IVF were more likely to be anxious at the start of their treatment than those undergoing OI-IUI, given that IVF is more invasive, carries more risks, and has higher out-of-pocket costs than OI-IUI intervention. It would be useful to identify patients before treatment, such as younger patients undergoing IVF, who may benefit from additional psychological resources. Examples of additional resources could include access to a reproductive counselor, extra visits throughout treatment with their provider team, fertility mindfulness exercises, or access to online support groups.

In our present study, the EMD multimedia platform was well accepted by those receiving the intervention and did not significantly impact patients' level of satisfaction with their overall fertility treatment. Furthermore, patients' overall perception of the informed consent process was not significantly different with access to the platform, with the

exception that most patients in the EMD multimedia platform group felt their consent conversation was an appropriate length. In the future, the incorporation of EMD may save time in the office setting. The EMD platform can provide basic introductory information for all patients, allowing the consent conversation with providers to be more personalized and directed at patient-specific questions and concerns. Potentially, the nurse's injection teaching visit could be forgone as EMD addresses this as well. An area of future study includes identifying if the mandatory injection teaching is necessary for all patients or potentially could be individualized on the basis of patient-specific needs (i.e., all patients may not need this teaching).

The limitations of the study include that, although the measures of anxiety were assessed with validated instruments, the study used a knowledge questionnaire that had not been previously validated as an assessment tool. On reviewing the literature, to our knowledge, there are no published validated questionnaires pertaining to these specific issues. Although this study used a randomized controlled design, differences in infertility diagnosis between groups before randomization and variability in counseling by the physician and nurse team among different providers could have impacted outcome differences. The study also did not evaluate reproductive treatment outcomes; therefore, anxiety and satisfaction at the time points during and after procedure may have been impacted by the outcome of the treatment, with patients who did better than expected having more positive experiences and those that did worse the opposite. Most patients filled out the T3 survey before knowing the outcome

FIGURE 3



The STAI state scores by group, by exposure, and by exposure and group. The average STAI scores at T1, T2, and T3, by exposure, by group, and by exposure and group. Significance is noted by an asterisk (\*). If not noted, the comparison was not significant. EMD = educational and consent platform (EngagedMD); IUI = intrauterine insemination; IVF = in vitro fertilization; STAI = State-Trait Anxiety Inventory; T1 = survey time point before the start of treatment; T2 = survey time point at the start of treatment; T3 = survey time point at the completion of the treatment cycle.

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of their fertility treatment, with 91% of patients undergoing IVF completing T3 before their frozen embryo transfer and 93% of patients undergoing IUI completing T3 within a week after IUI; hence it is unlikely that the final reproductive outcomes biased the results. It would be an interesting area of future study to examine if treatment success or failure contributes to the overall perception of anxiety and experience. Lastly, although our study was powered to detect differences between the EMD and conventional groups, it was not powered to detect differences between the subgroups, and the number of patients within each subgroup was low.

## CONCLUSION

The rationale for informed consent is to improve patient autonomy to enable patients to make their own informed decisions. Our results suggest that the use of a multimedia intervention before infertility treatment leads to improved patient comprehension without contributing to a heightened anxiety state. The EMD intervention is easy to use, allows the patient independence in reviewing information, is well tolerated, and improves patients' confidence in their knowledge base, although it should always supplement consultation with the physician and nurse team. Identifying patients who may benefit from additional psychologic intervention before and during treatment is critical regardless of whether any multimedia platforms are used, particularly in younger women and those undergoing IVF. Furthermore, future

studies are needed to address the cost-effectiveness and time efficiency of this multimedia platform.

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