Johnson E, et al., J Addict Addictv Disord 2023, 10: 0135
DOI: 10.24966/AAD-7276/100135

HSOA Journal of Addiction & Addictive Disorders

Research Article

A Randomized Sexual Health Intervention for Women in Treatment for Opioid Use Disorder: Sex And Female Empowerment (SAFE) Increases Reproductive Knowledge and Contraceptive Self-Efficacy

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Abstract

Objectives: Women with Opioid Use Disorder (OUD) commonly report unintended pregnancies. Clinics providing Medication for OUD (MOUD) treatment serve as ideal sexual health education settings. Previous research reported that the Sex and Female Empowerment (SAFE) intervention had greater treatment completion, intervention satisfaction, attendance at the contraception consultation visit and receipt of Long-Acting Reversible Contraception (LARC) relative to usual care. This secondary analysis examined differences in important outcomes of sexual behavior, knowledge, and beliefs between SAFE study conditions.

Methods: N=90 non-pregnant, heterosexual, reproductive-age women receiving MOUD were randomized into one of three conditions (n=30 each): SAFE Face-to-face intervention, SAFE Computer-adapted intervention, or usual care (UC) and followed for six months. The three conditions were compared on five secondary outcomes: sexual behavior (frequency of unprotected sexual intercourse and use of barrier protection), knowledge (knowledge of reproduction and contraceptive methods), and beliefs (contraceptive self-efficacy).

Results: For past-30-day frequency of unprotected sexual intercourse and frequency of barrier protection, both the SAFE Face-to-face and UC conditions were found to significantly differ over time, decreasing their frequency of unprotected intercourse and increasing their barrier protection (p<.001). All three conditions increased both reproductive knowledge and contraceptive self-efficacy over the 6-month period, with effects more pronounced for both SAFE conditions relative to UC.

Conclusion: SAFE appears efficacious for helping women receiving MOUD to increase safe sex behaviors, gain reproductive knowledge, and improve contraceptive self-efficacy.

Keywords: Opioid use disorder; Sexual health; Women

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Citation: Johnson E, Ryan D, O'Grady KE, Slaughter G, Hairston E, et al. (2023) A Randomized Sexual Health Intervention for Women in Treatment for Opioid Use Disorder: Sex And Female Empowerment (SAFE) Increases Reproductive Knowledge and Contraceptive Self-Efficacy. J Addict Addictv Disord 10: 135.

Received: July 29, 2023; **Accepted:** August 14, 2023; **Published:** August 21, 2023

Introduction

Accurate knowledge of and self-efficacy as it relates to both reproduction and contraceptive methods may be important components of decision-making regarding reproductive life planning for women with OUD [1]. Empowering women to make informed decisions is imperative given that in the United States (US), it is estimated that almost 50% of pregnancies are considered unplanned [2] and among women with Opioid Use Disorder (OUD), this percentage can increase to over 80% [3-5]. The negative outcomes associated with unintended pregnancy are numerous and compounded for women with OUD as they face additional risks such as compromised OUD treatment retention [6,7]. The Substance Abuse and Mental Health Service Administration (SAMSHA) and the Opioid Treatment Program (OTP) both have guidelines recommending that reproductive health education needs to be provided for all patients, and that programs should make referrals for contraceptive services when appropriate [8]. While these guidelines are a critical part of empowering reproductive and contraceptive choice, increased empirical data to underpin these recommendations is needed.

Heil and colleagues [9] summarized several innovative clinical approaches focused on increasing access to contraceptive and reproductive life planning for women with OUD and other Substance Use Disorders (SUDs). One such approach is the co-location of SUD and obstetrical services. This has been shown to increase both access to knowledgeable providers and to improved postpartum Long-Acting Reversible Contraception (LARC; intrauterine device or implant) utilization in women with OUD [10]. A second approach is the integration of family planning services into SUD treatment settings. This has also shown some efficacy for pregnant women [11] and non-pregnant women with OUD [12]. A third approach among women treated for

OUD, is the distribution of contraceptive information with referrals to community family planning providers plus financial incentives for attending follow-up visits. This was found to yield higher proportions of women with continued prescription contraceptive use than without incentives [13,14].

Sex and Female Empowerment (SAFE) is a comprehensive approach that focuses on meeting the sexual health, family planning, and contraceptive needs of women with OUD. The randomized clinical trial comparing two versions of SAFE (Face-to-face or Computer-adapted version) and usual care among women receiving Medication for Opioid Use Disorder (MOUD) showed increased satisfaction for both SAFE conditions, with utilization of self-reported Long-Acting Reversible Contraception (LARC) reaching 75% for participants in the two SAFE conditions (77% face-to-face, 73% computer) versus only 23% of women assigned to usual care [15]. While LARC utilization increased as a result of the SAFE interventions, LARC methods do not provide adequate protection against Sexually Transmitted Infections (STIs). Of note, male condom use declined over the course of the trial in all conditions [15]. Given that the burden of STIs is higher for women with substance use disorders, a more complete examination of STI protective behaviors that assesses the use of barrier protection methods among study conditions is needed [16,17]. The present secondary analysis study examined the SAFE interventions compared to each other and a usual care condition for five key secondary outcomes: Frequency of both unprotected sexual intercourse and use of barrier protection, as well as knowledge of reproduction, knowledge of contraceptive methods and contraceptive self-efficacy.

Methods

The parent study was registered at ClinicalTrials.gov-(NCT02197715) and was approved by the University of North Carolina Institutional Review Board before commencing participant enrollment. It was designed and reported per CONSORT guidelines with methodology fully presented [15].

Participants

Two MOUD treatment program clinics in urban areas of central North Carolina were the sites of female enrollment from March 1, 2015, to March 30, 2017. All female identifying individuals receiving services during this time were provided with a study flyer and had the option of completing a 10-minute study eligibility interview screening either on-site or via phone. Participants completing screening were offered a set of items worth approximately $10 (e.g., tampons/pads, condoms, body lotion, soap). Inclusion criteria were: 18-40 years old; ability to provide informed consent; enrolled (and stabilized for more than 90 days) in one of the designated MOUD programs; not pregnant (confirmed with urine testing); reported heterosexual orientation; absence of tubal ligation or other sterilization; absence of plans to become pregnant in the next 6 months; and verifiable locator information provided. Female identifying individuals who screened eligible were offered study participation via an in-person informed consent meeting.

Treatment setting

Both of the MOUD treatment program clinic sites dispense methadone and buprenorphine for individuals seeking treatment for OUD. Services are offered to those who self-pay or receive Medicaid benefits. The programs provide a continuum of outpatient treatment services including individualized person-centered plans, access to treatment of comorbid mental health diagnoses, and individual and group therapy. As is typical of MOUD programs, services are offered to men, women, and non-binary individuals. The intervention took place in individual offices provided by the respective MOUD treatment program clinic.

Design and description of study conditions

Intervention allocation

Following the informed-consent process, participants were block randomized on a 1:1:1 basis into one of the three study conditions: (1) SAFE Face-to-face, (2) SAFE Computer-adapted, (3) Usual Care (UC), using a series of numbered envelopes that contained the random assignment of each participant to one of the three conditions. Both research staff and the participant learned the participant's intervention condition assignment at the time the envelope was opened.

Intervention conditions

The SAFE Face-to-face and the SAFE Computer-adapted interventions were both designed to be completed in three separate sessions of 45-60 minutes duration each. To support participants in completing the intervention, participants could reschedule a missed session for the next week on a day and time convenient to them. Thus, participants could successfully complete the 3-session intervention within 4 weeks.

SAFE face-to-face intervention

As described in the parent study, SAFE is grounded in social-cognitive theory and builds upon previous behavioral interventions to improve condom use [15]. BA-to-MA-level staff employed in the MOUD treatment facility provided the intervention. Four one-hour training sessions were provided to review the study and the content of the 3-session intervention. In addition, staff participated in role-play practices of all intervention components and received feedback. Study personnel provided supervision every other week to assist with problem solving any identified issues.

The intervention included Motivational Interviewing for each of the three sessions and study personnel used flipcharts to guide the discussions. The first session focused on basic body anatomy and reproductive biology and a review of available contraceptive methods. Examples of the different contraceptive methods were used to demonstrate how different methods look, feel and work. During session two, participants discussed thoughts about their optimal contraceptive option, ideas about how to talk to a healthcare provider about contraceptive practice options and received tips for how, where and when to talk to partners about contraceptive methods and condoms. Skills of active listening, positive language, "I feel" statements and physical and emotional safety techniques were provided to participants to encourage communication. Safer-sex negotiation skills focused on partner communication were provided and role-played. Session three focused on helping participants develop an action plan. A shared decision-making approach was used to aid participants in resolving their ambivalence and changing behavior through various intervention practices (e.g., personalized feedback on contraceptive use, discussing the pros and cons of such use, decisional balance, goal setting). At the end of each session, the participant was asked if she wanted to complete a plan to decide on a method of contraception. If ready, she was asked what method(s), and an appointment was made with a local contraceptive practice provider.

SAFE computer-adapted intervention

The SAFE Computer-adapted intervention provided the same information in the same order as the face-to-face intervention. Trained staff led the participant to a computer in a private space located in the MOUD clinic and oriented them to the computerized information. The participant could then navigate through information, use www.bedsider.org to find out more about each contraceptive option, listen to testimonials about contraceptive methods, listen to and read about how to talk to a healthcare professional about contraceptive practice options, and how, where and when to talk to her partner about condoms and other contraceptive methods. Participants observed the use of physical and emotional safety techniques, active listening skills, positive language, "I feel" statements, and safer-sex negotiation. At the end of each 45-60-minute computerized session, a set of questions was completed by the participant asking if she wanted to make a contraceptive decision and if so, what method(s) she wanted to discuss with her health care provider. A summary of the questions and answers was printed by the trained clinic staff and briefly discussed with the participant. The participant was asked if they wanted to complete a plan to make a decision regarding a method of contraception. If so, the participant was asked what method(s) she wanted to discuss with the health care provider, and an appointment was made with a local contraceptive practice provider.

Usual care

What normally occurs in the OUD treatment clinic was defined as Usual Care. The participant's counselor provided the individual with written information about sexual health and contraceptive methods and offered a referral to the local health department for more information and discussion. For study purposes, the trained clinic staff met with the participant immediately following the discussion and to ask if the participant wanted to discuss one or more methods of contraception with her health care provider. If the participant agreed, an appointment was made with a local contraceptive practice provider. If the participant responded no, the interventionist then contacted the participant weekly for two more weeks to ask if she wanted to discuss one or more contraceptive options with her health care provider. If the participant responded yes, then an appointment was made.

Assessment and retention

Participants were followed for 6 months. Assessments were made at study entry, post-intervention, 3- and 6-months follow-up. To maintain rapport, participants received bi-weekly phone calls. Snacks, drinks, and gift baskets of health, beauty and home items worth approximately $25 each were given at the completion of each study visit.

Outcomes

To provide a more comprehensive view of the primary outcome data, the secondary outcomes selected for analysis at the time of study design were self-reported behaviors including frequency of unprotected sexual intercourse and frequency of use of barrier protection. Knowledge outcomes included a knowledge of reproduction score, and knowledge of contraceptive methods score. These measures were meant to capture a belief central to the SAFE intervention: that increases in self-efficacy are needed as a central part of behavioral change.

Measures

The demographic and background characteristics and the measures of the four primary outcomes (intervention completion, intervention satisfaction, attendance at a contraception consultation visit, and Long-Acting Reversible Contraceptive (LARC) method receipt) have already been reported [15]. The additional measures reported in this paper were completed at baseline, post-treatment, 3-month follow-up and 6-month follow-up. The measures and the intervention were delivered by the same individual.

Past-30-day use of effective contraceptives

Participants completed a structured interview assessing contraceptive behavior in the past 30 days. The participant was told that many women might use only one method, while many other women might use multiple methods. She was then asked what methods she might have used in the past 30 days. If she reported only a single method, she was asked: "Is this the only method you have used?" If a participant reported multiple methods, she was asked; "Were there any other methods?" Finally, the participant was asked whether at any time during this 30-day period, did she have "Vaginal intercourse without the use of a birth control method?" Participants were classified as either: (1) using an effective method (abstinence or use of implant, IUD, injection, pill, patch, ring) or (0) using an ineffective method (no method or use of a non-effective method [withdrawal, spermicide, fertility awareness]) during the 30-day period.

Past-30-day unprotected sexual intercourse and use of barrier protection

A "Sexual Activities Questionnaire" was administered that asked about frequency of vaginal, oral, and anal sex in the past 30 days. If participants answered at least once to "How many times have you had vaginal/oral/anal intercourse in the past 30 days?" they then were asked "Of those times, how many times did you use a dental dam (oral) or a male or a female condom?" Two outcomes were derived from this measure: (1) frequency of unprotected sexual intercourse and (2) frequency of barrier protection use in the past 30 days.

Knowledge of reproduction

This SAFE-specific measure consisted of eight trinary multiple-choice questions about participants' understanding of the information presented to them in the 3 sessions about anatomy, menstruation, fertility and conception (e.g., "1. The opening to the uterus is called the: A. Vagina, B. Ovary, C. Cervix"). Possible scores ranged from 0 to 8.

Knowledge of contraceptive methods

This SAFE-specific measure consisted of 20 true-false questions about participants' understanding of the information presented to them in the sessions about contraceptive methods, including how hormonal contraceptives work and how to correctly use them; hormonal contraceptive side effects and ways to deal with them; which methods are effective against STIs/HIV; and correct condom use (e.g., "All methods of contraception require a prescription", "Breastfeeding is an effective birth control method"). Possible scores ranged from 0 to 20.

Contraceptive Self-Efficacy Scale (CSE)

The CSE [18] is designed to measure a female respondent's motivational barriers to effective contraceptive use, including obtaining contraceptives, using contraceptives with a partner, talking to a

partner about contraceptive use, using contraceptives despite partner approval, and preventing unprotected sexual intercourse. It is comprised of 15 5-point Likert-type items, with 1 item having 4 parts. Thus, possible CSE scores range from 18 to 90.

Statistical analysis

The Generalized Linear Mixed Model (GLiMM) was utilized for inferential statistical analyses. Outcome measures were assumed either to follow a normal distribution (Knowledge of Reproduction, Knowledge of Contraception and CSE scores) or a Poisson distribution (past-30-day frequency of unprotected sexual intercourse and past-30-day frequency of use of barrier protection). The statistical model included a fixed factor for Intervention Condition, a fixed factor for Time, with four levels, and the Intervention Condition X Time interaction. Degrees of freedom were determined by the Kenward-Roger approximation. For the past-30-day frequency of unprotected sex and past-30-day frequency of use of barrier protection, the past-30-day frequency of vaginal, oral, and anal sex served as covariates.

Testing of treatment impact focused on the Intervention X Time interaction. In the case of a significant interaction, all simple main effects were tested, and testing and interpretation of the main effects were not conducted (given a significant interaction indicates interpretation of unconditional effects will be misleading). Following detection of a significant simple main effect, all pairwise mean comparisons within that effect were then tested. A two-stage Bonferroni correction for this post hoc testing was applied. First-stage correction involved adjustment of α (Type I error rate) for the seven possible simple main effects tests. Second-stage correction involved correction of the first-stage α for the tests of the pairwise comparisons for each possible simple main effects test. α for testing all main effects and interaction effects was determined to be 0.13 at the time the study was designed and funded. This value was chosen in order to detect a medium effect with 90 participants. Thus, follow-up testing of simple main effect tests for a significant Intervention Condition X Time interaction effect were each conducted at 0.019 (0.13/7), and follow-up testing of simple pairwise comparisons for a significant simple main effect of Intervention condition within Time were each conducted at 0.0015 (0.019/12) and for a significant simple main effect of Time within Intervention Condition were conducted at 0.00077 (0.019/24).

Results

Participants

N=132 women were screened. A total of 20 were ineligible: older than 40 years of age (n=7); pregnant (n=3); non-heterosexual orientation (n=9); and tubal ligation or other sterilization (n=1). Of the eligible women (n=112), 22 declined participation because they were "not interested" (n=13), "do not trust/ had previous bad experience with medical providers" (n=5) or were "too busy" (n=4) (Figure 1). Consenting participants (n=90) were assessed at baseline, treatment completion, 3-month follow-up, and 6-month follow-up, as no participant was lost to follow-up. Less than 0.3% of data for the present analyses was missing, and given the choice of GLIMM, data from all participants could be included in all analyses (see detailed note in Table 1 regarding missing data). N=90 participants were majority White [54/90 (60%)], unemployed [57/90 (63%)], not married [65/90 (72%)], an average age of [M=27.4 years (SD=4.8)], and currently smoking cigarettes [77/90 (86%)] with M=11.2 (SD=1.0) years of education. Most participants (73/90; 81%) reported using prescribed contraception in the past. More than 40% reported no past-30-day contraception use at baseline. Among those reporting contraceptive method use, the most prevalent method was condomssee Jones et al., [15] for more information regarding participant baseline demographic and background characteristics, including gravity, parity and use of contraceptive method(s) throughout the study].

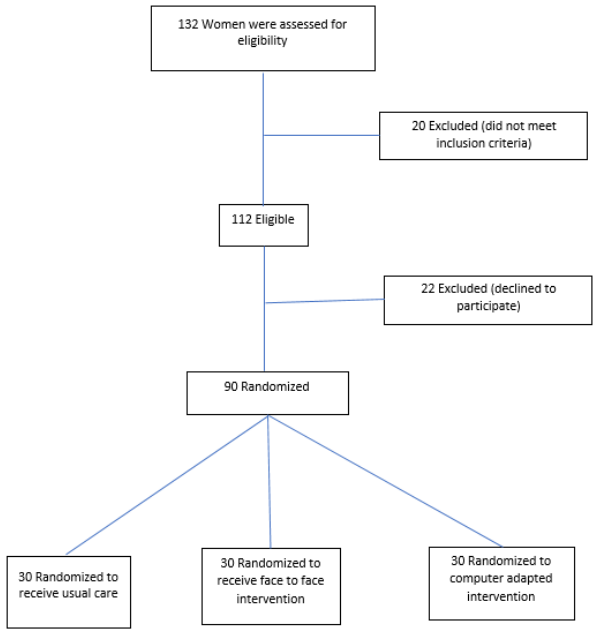

Figure 1: Participant flow diagram.

Outcomes

Table 1 provides F test statistics and their associated p values for the Intervention Condition main effect, Time main effect, and the Intervention Condition X Time interaction effect for the five secondary outcomes. The respective least squares means and standard errors for the Intervention Condition X Time interaction effect are shown in table 2. Table 3 contains abbreviated source tables for the simple main effects for the four secondary outcomes that had a significant Intervention Condition X Time interaction effect.

Past-30-day frequency of unprotected sexual intercourse

Simple main effect tests for the significant Intervention Condition X Time interaction effect found that only the SAFE Face-to-face and UC conditions changed over Time (both $p<.003$), and that the Intervention Conditions were significantly different only at 3-month follow-up ($p<.002$). The only significant simple mean comparisons for Time within the SAFE Face-to-face condition showed there was a significant decrease in the past-30-day frequency of unprotected sex from baseline to 1-month follow-up ($p<.0004$), while within the UC condition the respective decreases in the past-30-day frequency of unprotected sex from baseline to both 1- and 3-month follow-ups were significant ($p<.0001$). Simple mean comparisons among the Intervention Conditions at 3-month follow-up were all nonsignificant ($p>.0008$).

Outcome	Intervention Condition Main Effect		Time Main Effect		Intervention Condition X Time Interaction Effect	
	Test Statistic: F(df, df)	p	Test Statistic: F(df, df)	p	Test Statistic: F(df, df)	p
Past-30-day Frequency of Unprotected Sex	F(2, 92) = 1.2	0.30	F(3, 90) = 11.2	<0.001	F(6, 113) = 4.6	<0.001
Past-30-day Frequency of Use of Barrier Protection	F(2, 99) = 1.4	0.26	F(3, 95) = 12.2	<0.001	F(6, 116) = 3.7	<0.001
Knowledge of Reproduction	F(2, 87) = 0.3	0.71	F(3, 88) = 56.4	<0.001	F(6, 112) = 0.8	0.56
Knowledge of Contraceptive Methods	F(2, 87) = 9.1	<0.001	F(3, 88) = 88.8	<0.001	F(6, 112) = 3.3	0.005
Contraceptive Self-Efficacy	F(2, 87) = 10.0	<0.001	F(3, 88) = 282.4	<0.001	F(6, 112) = 11.5	<0.001

Table 1: Intervention condition main effect, time main effect, and intervention condition X time interaction effect test statistics and p values past-30-day frequency of unprotected sex, past-30-day frequency of use of barrier protection, knowledge of reproduction and contraceptive methods, and contraceptive self-efficacy outcomes (N=90).

Notes. α=0.13 for all tests. df = degrees of freedom. Degrees of freedom were determined by the Kenward-Roger approximation. Past 30-day Frequency of Unprotected Sex and Past-30-day Frequency of Use of Barrier Protection were both missing 5 observations due to 1 participant in the SAFE Face-to-face Condition failing to answer regarding past-30-day frequency of anal sex at 1-month follow-up, and 4 additional participants failing to provide answers regarding past-30-day vaginal, oral, and anal sex at 6-month follow-up: 1 in the SAFE face-to-face condition, 1 in the SAFE Computer-adapted condition, and 2 in the Usual Care condition. Frequency of vaginal, oral, and anal sex in the past 30 days during the same respective past-30-day period served as covariates for Frequency of Unprotected Sex and Frequency of Use of Barrier Protection in the past 30 days. All three covariates were significant (ps<0.046) for both outcomes.

Outcome	Baseline			Treatment Completion			3-month Follow-up			6-month Follow-up		
	SAFE Face-to-face	SAFE Computer-adapted	Usual Care	SAFE Face-to-face	SAFE Computer-adapted	Usual Care	SAFE Face-to-face	SAFE Computer-adapted	Usual Care	SAFE Face-to-face	SAFE Computer-adapted	Usual Care
Past-30-day Frequency of Unprotected Sex	6.99 (.22)	6.97 (.21)	7.23 (.22)	5.51 (.36)	6.20 (.39)	5.64 (.36)	6.68 (.39)	6.82 (.40)	5.06 (.32)	6.07 (.39)	6.10 (.40)	6.08 (.37)
Past-30-day Frequency of Use of Barrier Protection	1.46 (.18)	1.60 (.20)	1.22 (.18)	2.74 (.33)	2.21 (.32)	2.67 (.33)	1.55 (.27)	1.61 (.27)	3.24 (.38)	2.11 (.33)	2.21 (.34)	2.34 (.33)
Knowledge of Reproduction	5.4 (.26)	5.4 (.26)	5.7 (.26)	6.5 (.22)	6.4 (.22)	6.5 (.22)	7.2 (.18)	6.8 (.18)	6.9 (.18)	7.3 (.17)	7.1 (.17)	7.3 (.17)
Knowledge of Contraceptive Methods	13.5 (.56)	12.9 (.56)	12.4 (.56)	15.9 (.44)	15.4 (.44)	14.1 (.44)	17.7 (.33)	16.8 (.33)	15.1 (.33)	18.3 (.31)	18.2 (.31)	15.9 (.31)
Contraceptive Self-Efficacy	41.5 (1.97)	40.1 (1.97)	40.5 (1.97)	55.7 (1.76)	51.07 (1.76)	48.8 (1.76)	66.8 (1.73)	64.1 (1.73)	55.1 (1.73)	77.2 (1.42)	77.6 (1.42)	60.3 (1.42)

Table 2: Intervention condition X time interaction effect least squares means (standard errors) for frequency of unprotected sex, and frequency of use of barrier protection, knowledge of reproduction and contraceptive practices, and contraceptive self-efficacy outcomes (N=90).

Notes. Knowledge of Reproduction scores have a possible range from 0 to 20, Knowledge of Contraceptive Practices scores have a possible range from 0 to 8, and Contraceptive Self-Efficacy scores have a possible range from 18 to 90. See table 1 for an explanation of missing data. Frequency of vaginal, oral, and anal sex in the past 30 days during the same respective past-30-day period served as covariates for Frequency of Unprotected Sex and Frequency of Use of Barrier Protection in the past 30 days, so means are adjusted for the covariates.

Past-30-day frequency of use of barrier protection

Similar to what was found for past-30-day unprotected sex, simple main effect tests for the significant Intervention Condition X Time interaction effect found that only the SAFE Face-to-face and UC conditions changed over Time (p<0.001), and that the Intervention conditions were significantly different only at 3-month follow-up (p<0.0002). The only significant simple mean comparisons for Time within the SAFE Face-to-face condition was a significant increase in the use of barrier protection in the past 30 days from baseline to 1-month follow-up (p<0.0001), while within the UC condition the respective increases in the use of barrier protection in the past 30 days from baseline to both 1- and 3-month follow-ups were significant (p<0.0001). The only simple mean comparison that was significant among the Intervention conditions at 3-month follow-up was due to the fact that the mean use of barrier protection in the UC condition was higher than the corresponding mean in the SAFE Computer-adapted condition (p<0.0005).

Knowledge of reproduction

The Intervention Condition X Time interaction effect was not significant. Post hoc testing of the significant Time main effect indicated

Past-30-day Frequency of Unprotected Sex

Simple Main Effects of Treatment Condition within Time				
Assessment Time Point	df_n	df_d	F	p
Baseline	2	87	0.5	.63
Post-treatment	2	89	0.9	.39
3-month Follow-up	2	88	7.4	.001
6-month Follow-up	2	88	.00	.99

Simple Main Effects of Time within Treatment Condition				
Treatment Condition	df_n	df_d	F	p
SAFE Face-to-face	3	91	4.9	.003
SAFE Computer-adapted	3	86	1.9	.13
Usual Care	3	85	12.6	<.001

Past-30-day Frequency of Use of Barrier Protection

Simple Main Effects of Treatment Condition within Time				
Assessment Time Point	df_n	df_d	F	p
Baseline	2	89	1.1	.33
Post-treatment	2	90	0.7	.48
3-month Follow-up	2	91	9.5	<.001
6-month Follow-up	2	88	0.1	.88

Simple Main Effects of Time within Treatment Condition				
Treatment Condition	df_n	df_d	F	p
SAFE Face-to-face	3	94	6.0	<.001
SAFE Computer-adapted	3	89	2.0	.13
Usual Care	3	86	13.7	<.001

Knowledge of Contraceptive Methods

Simple Main Effects of Treatment Condition within Time				
Assessment Time Point	df_n	df_d	F	P
Baseline	2	87	1.0	.38
Post-treatment	2	87	4.3	.016
3-month Follow-up	2	87	16.3	<.001
6-month Follow-up	2	87	19.9	<.001

Simple Main Effects of Time within Treatment Condition				
Treatment Condition	df_n	df_d	F	p
SAFE Computer-adapted	3	85	43.6	<.001
SAFE Face-to-face	3	85	33.8	<.001
Usual Care	3	85	18.0	<.001

Contraceptive Self-Efficacy

Simple Main Effects of Treatment Condition within Time				
Assessment Time Point	df_n	df_d	F	P
Baseline	2	87	0.1	.88
Post-treatment	2	87	4.0	.02
3-month Follow-up	2	87	12.6	<.001
6-month Follow-up	2	87	48.8	<.001

Simple Main Effects of Time within Treatment Condition				
Treatment Condition	df_n	df_d	F	p
SAFE Face-to-face	3	85	125.7	<.001
SAFE Computer	3	85	141.2	<.001
Usual Care	3	85	38.7	<.001

Table 3: Tests of simple main effects for the 4 outcomes with a significant intervention condition X time interaction effect.

that all simple mean comparisons [M(SE) = 5.5 (0.15) at baseline vs. 6.5 (0.12) at post-treatment vs. 7.0 (0.11) at 3-month follow-up vs. 7.2 (0.10) at 6-month follow-up] were significant ($p<0.0009$).

Knowledge of contraceptive methods

Simple main effect tests for the significant Intervention Condition X Time effect found that all three Intervention Conditions changed over Time ($p<0.001$), and that the intervention Conditions were not significantly different at baseline ($p=0.38$) but were significantly different at post-treatment, 3-month follow-up, and 6-month follow-up ($p<0.017$). Simple mean comparisons for Time within Intervention Condition were all significant ($p<0.00074$), while simple mean comparisons for Intervention Condition within Time at post-treatment, 3-month-follow-up, and 6-month follow-up indicated only that the means for the two SAFE conditions were significantly higher than the Usual Care condition at 3-month and 6-month follow-up ($p<0.0004$). Consistent with these results, examination of the means in table 2 revealed that knowledge of contraceptive methods showed a general increase in all three conditions over the 6-month period, but that the increase was more pronounced for the two SAFE conditions relative to the UC condition.

Contraceptive self-efficacy

Simple main effect tests for the significant Intervention Condition X Time effect found that all three Intervention conditions changed over Time ($p<0.001$), and that the three Intervention conditions were not significantly different at baseline ($p=0.88$) and post-treatment ($p=0.02$), but were significantly different at 3- and 6-month follow-up ($p<0.001$). The simple mean comparisons for the Time within Intervention Condition were all significant ($p<0.0001$), while simple mean comparisons for the Intervention Condition within Time at 3- and 6-month follow-up indicated that only the means for two SAFE conditions were significantly higher than the Usual Care condition at 3-month and 6-month follow-up ($p<0.0004$). The means in table 2 revealed that contraceptive self-efficacy showed a general increase for all three conditions over the 6-month period, but that the increase was more pronounced for the two SAFE conditions relative to the UC condition.

Discussion

With current high rates of unintended pregnancy among women with opioid use disorder (e.g., over 80%; see [3-5]), there is a need to understand more about what influences the decision to use or not use contraceptive methods. Further, among women who decide to use contraceptive methods, we need to understand what factors influence the type of method used. While the primary outcomes from this randomized clinical trial showed an almost three-quarter utilization of self-reported Long-Acting Reversible Contraception (LARC) for those in the SAFE conditions (77% face-to-face, 73% computer) versus only 23% of women assigned to usual care [15], the factors underlying this behavior deserve focus. As such, the secondary outcomes of sexual behavior (frequency of unprotected sexual intercourse and use of barrier protection), knowledge (knowledge of reproduction and contraceptive methods), and beliefs (contraceptive self-efficacy) were examined.

The result that the SAFE intervention increased LARC use but did not reliably improve barrier method STI prevention behavior suggests future research questions need to focus on how to improve safe sex outcomes. The present results are in line with other research showing that women who intentionally switch to LARC do so in order to discontinue condom use [19]. Further, no published studies promoting concurrent condom use with LARC have demonstrated a sustained change beyond the first 12 months [20]. Decisions regarding condom use among women are influenced by multiple factors such as menstrual changes related to LARC in addition to mood and relationship dynamics. Of additional importance are desired outcomes such as pleasure, consent, and communication with partners [21]. While SAFE was social-cognitive, theory-driven intervention and designed to empower women, its primary focus was on its delivery of reproductive health education. The instability of the use of barrier methods among groups suggests that a booster session to review the key concepts covered during the SAFE intervention may be needed to prevent decay in the initial intervention effects [22]. Additionally, different approaches tailored for this population that go beyond contraceptive education to integrate other key concepts central to empowerment, such as condom negotiation, are in need of further investigation. Given the high prevalence of trauma in this population [23], it is imperative that the integration of these concepts be done in a trauma-responsive manner.

The fact that both SAFE conditions showed increases in reproductive and contraceptive knowledge over time compared to the Usual Care group highlights how more than a brochure and brief conversation is needed to effectively educate women receiving MOUD about sexual health issues. However, neither of the interventions demonstrated improvement in behavior-mediated safe sex outcomes compared to controls. Our findings are consistent with previous research on behavioral interventions aimed at increasing knowledge about contraception and high-risk sexual activity that also did not demonstrate long-standing change in behavior [24,25]. The current study suggests that simply improving reproductive health knowledge may not be the most important aspect in an intervention for this population as knowledge may not consistently translate into behavioral change. Future efforts should focus on adaptation of person-centered, trauma-informed interventions to women receiving MOUD that address not only knowledge but other components driving reproductive health behaviors including motivational barriers and partner-related factors.

Of note, the result that contraceptive self-efficacy showed a general increase for all three conditions over the 6-month period, but that the increase was more pronounced for the two SAFE conditions relative to the UC condition, is encouraging and suggests the intervention effect remained durable from post-intervention to the 6-month follow-up point. Such a pattern of findings is consistent with similar research focused on reducing HIV sex risks among individuals who use substances [26]. This encouraging finding may reflect the translational approach utilized to develop SAFE, as its content and delivery were informed by qualitative data gathered separately from women in treatment for OUD, men in OUD treatment who were not the women's partners and health care providers who care for women with OUD. This allowed SAFE's foundation to be rooted in the needs and desires of the target population, which when coupled with behavioral techniques such as motivational interviewing, may have led to higher likelihood of achieving its intended results. Although the results obtained in the experimental conditions in the present study are encouraging, the study has several limitations. First, the small sample size could adversely affect the precision of the estimate of the magnitude of the treatment effects. The absence of significant differences in participant characteristics between the treatment conditions argues weakly against this position, but only a replication using a larger-scale randomized design can adequately address that possibility. Second, the requirement of 90 or more days in MOUD treatment in each treatment condition is important to note and future studies may wish to include a more heterogeneous group of women with varying times in treatment. Additionally, the study occurred within two OUD treatment clinics in North Carolina with majority White participation limiting generalizability. These limitations notwithstanding, we consider these initial experimental results encouraging regarding the efficacy of this intervention for promoting effective contraceptive use among women receiving MOUD and at risk for unintended pregnancy.

While increased self-efficacy may be assumed to lead to increased utilization of effective contraception, some women may choose not to use such methods and such a choice should not be considered a failure. It is important to understand the need for bodily autonomy and that all women have the right to decide not to have a child as well as the right to have a child and parent in a safe and healthy environment [27]. To gain a fuller appreciation of the reasons that women with substance use disorders may use or not use effective contraception, future research needs to include a more racially/ethnically diverse participant population and the possible utilization of a mixed-methods approach to understand the unique barriers faced by women from marginalized backgrounds.

Declarations

Funding

This research was supported by the National Institute on Drug Abuse of the National Institutes of Health under grant R34 DA033442 and Dr. Martin's time was supported by K23DA053507.

Conflicts of interest

None.

Ethics approval

This study was approved by the University of North Carolina Institutional Review Board and registered at ClinicalTrials.gov (NCT02197715) before enrollment of any participants. This study was designed and is being reported using CONSORT guidelines.

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