Original Article

# Overcoming Reproductive and Psychological Concerns of Breast Cancer Survivors: A Randomized Controlled Trial

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## Abstract

**Objective:** After developing breast cancer, women experience changes in their sexuality, femininity, and fertility. These changes lead to poor mental health and increased psychological stress. Therefore, this study aimed to investigate the effects of Good Enough Sex (GES)-based, couple-centered group counseling on reproductive and sexual concerns of breast cancer survivors.

**Materials and methods:** This was a quantitative randomized controlled clinical trial (RCT) conducted at Omid Hospital, West Azerbaijan, Urmia, Iran from March 2018 to October 2020. After completing the informed consent forms, 100 women were assigned to the intervention and control groups (50 individuals per group) using a randomized block design. The intervention included four 90-120-minute sexual counseling sessions with 2 and 3 month follow-ups. The data were collected using the socio-demographic and clinical characteristics, the Persian version of Depression, Anxiety and Stress Scale (DASS-21), Reproductive Concerns after Cancer (RCAC) scale, and Female Sexual Function Index adaptation for Breast Cancer patients (FSFI-BC). Data were collected, from control and intervention groups, at three intervals; before, besides two months and three months post intervention, then were analyzed in SPSS 20 using descriptive and repeated measures analysis of variance (ANOVA) test.

**Results:** Significant reduction in the mean score of DASS-21, RCAC and improvement of FSFI-BC is reported between the intervention and control groups in favor of intervention group ($P<0.001$). However, no significant differences are observed within intervention group over two- and three-months post intervention ($P > 0.05$).

**Conclusion:** The designed Good Enough Sex (GES)-based, couple-centered group counseling effectively reduced reproductive and sexual concerns of females' breast cancer survivors. Therefore, these training and counseling programs can be organized by relevant service centers to promote the reproductive health of women with breast cancer.

**Keywords:** Breast Cancer; Anxiety; Depression; Reproductive Health, Psychology; Sexual Function

## Introduction

Breast cancer is the most common cancer type and the second leading cause of death due to cancer worldwide (1, 2). According to the Iranian Cancer Research Center, breast cancer is the most common with the highest number of newly diagnosed cases reported in 2018 (3). Moreover, it is the second

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leading cause of death in West Azerbaijan, Urmia. Meanwhile, Urmia is on the cancer-prone geographical line of the world (4). The average age of breast cancer development in Iran has been reported to be at least 10 years lower than in developed countries (5). However, the number of women survivors who will live for a long time is growing (3, 6, 7). In countries like Iran, female survivors may have different concerns and needs than those in other countries (8, 9) due to the young age of cancer survivors and women's reluctance to talk about sexual issues or to seek professional help.

Following the initial treatment, women with breast cancer experience are not only cancer-related taboos, but also changes in their sexuality, femininity, and fertility (10). Sexual dysfunction is predictable in the long run affecting the quality of sexual life. It can occur during diagnosis or treatment period and can persist for years after treatment. Sexual dysfunction can cause as much anxiety as cancer itself (11). Breast cancer is a tremendous disease for females because it is associated with common psychological problems such as stress and anxiety (12, 13).

Studies have shown that breast cancer females have different concerns about their reproductive health. These women can discuss their concerns with a reproductive health specialist before and during treatment (14). They should talk with a specialist about the effects of treatment on menstruation, pregnancy, and premature menopause. The specialist has to assess the possibility of infertility and sexual problems, including sexual relationships and examine alternative methods such as womb renting or follicle cryopreservation (15).

There are growing concerns about the impact of invasive breast cancer treatments (*e.g.* mastectomy) on patients' lives. Moreover, mastectomy is highly prevalent surgical treatment for breast cancer in Iran (16), and its psychosocial consequences and postoperative rehabilitation care have been generally overlooked; therefore, several psychosocial and sexual interventions must be designed and evaluated to assess the reproductive health of these patients in Iran.

The Good Enough Sex (GES) model is a new concept in the sexuality and sex therapy field. It aims to promote healthy partners (male and female) and improve couple sexuality through building a realistic and positive meaning of the intimate lives, ensuring pleasure as well as sexual function, and promoting mutual emotional acceptance (17).

There is a lack of studies investigating the sexual and reproductive concerns of surviving females from breast cancer. Therefore, this is the first study conducted in Iran and is aimed to investigate the effects of GES-based, couple-centered group counseling on reproductive and sexual concerns of breast cancer survivors in West Azerbaijan, Urmia, Iran.

## Materials and methods

***Study design:*** We conducted a single center, randomized, parallel-group clinical trial in Urmia, Iran, and due to the nature of the intervention, blinding was not possible.

***Setting:*** The sampling site in the present study was Omid Hospital, West Azerbaijan, Urmia, Iran. An average of 1,500 cancer patients is admitted to the center each year.

***Randomization Scheme:*** Participants were divided into two groups (intervention and control) through blocked randomization. All possible modes were considered for the placement of letters 'A' and 'B' in four blocks producing six total possible modes. These six cases were numbered from 1 to 6, whereas the number of the required 4-unit blocks was determined based on the number of the studied samples. The 100 participants were then divided into 25 blocks consisting of 4 participants each. According to the required number of blocks (25 blocks), random numbers had been then arranged in a row based on a table of random numbers, and numbers greater than six had not been considered. Based on the order of numbers extracted from the table, the blocks corresponding to each number were listed in order. Finally, when the samples entered the study, each participant took a specific letter in the resultant order. For instance, according to the order (AABB/ABAB), the fifth participant was placed in Group A (intervention). Finally, participants were divided into two groups of intervention and control based on the quadratic blocking method. The group assignments were concealed in a sealed, opaque envelope until clinic admission.

***Sample size and sampling:*** Participants were enrolled through convenience sampling. Sampling was performed on the population of married women with breast cancer admitted to Omid Hospital (Urmia, Iran) from April 2019 to July 2019. The sample size was determined as 100 (50 individuals per group) based on the study of Khamseh *et al.* (18), using the "difference between two independent means" formula in G*Power, and by rounding the obtained number and considering a loss to follow-up of 20%. Participants were assigned to intervention and control

groups using a randomized block design.

***Intervention:*** Women in the intervention group (group A) received four 90-120-minute GES-based counseling sessions at weekly intervals. At the end of the study, the researcher sent the content of the training sessions in the form of 4 one-hour audio files to those in the control group via Telegram (the most popular messaging application in Iran). All participants were also monitored for possible interventions performed at hospitals (*e.g.* visiting a counselor, attending training classes, *etc.*) during the study.

Finally, the status of participants in both groups was assessed 2 and 3 months after the last session via telephone interviews with the Persian version of DASS-21, RCAC, and FSFI-BC questionnaires. During the study, one individual in the intervention group and two persons in the control group were excluded from the study due to either unwillingness to continue participation or recurrence of the disease.

***Inclusion and exclusion criteria:*** All non-pregnant and non-lactating married women of reproductive age (18-49 years old) at stage I, II, or IIIa breast cancer, with no chronic diseases, and whose husbands were at home for at least two weeks per month, and had experienced mastectomy procedure were enrolled. Another inclusion criterion was completing the radiotherapy and chemotherapy treatments at least six months and at most 5 years before the intervention. The main exclusion criteria included suffering from any physical, mental illness or mental trauma (confirmed by a physician) that affected the sexual function of the woman and /or her husband, and getting pregnant during the study, *etc.*

***Ethical considerations:*** Consent was obtained from participants after explaining the purpose of the study. Anonymity and confidentiality were ensured and protected. In addition, voluntary participation was also ensured in which patients had the right to withdraw anytime they felt a need to discontinue the study. The study has been registered at the Iranian Registry of Clinical Trials (IRCT20120609009975N8) and ethics code from the university (IR.TUMS.FNM.REC.1396.4865). Patients' information and the study data were reserved with the corresponding author closet for at least one year.

***Measurements and data collection:*** A semi-structured interviewed based questionnaire was used to collect the necessary information. The first part was about the socio-demographic (ten items) and clinical characteristics (six items) of participating women. The second part was the *Depression, Anxiety and Stress Scale (DASS-21).* This 21-item scale was developed by Lovibond *et al.* (19) to measure negative emotional states of depression, anxiety, and stress. It included three 7-item self-report subscales of stress, depression, and anxiety. For each subscale, the items were scored on a 4-point Likert scale [not at all (score 0), slightly (score 1), highly (score 2), and extremely (score 3)]. The overall score of each subscale was calculated separately (Min: 0; Max: 21).

Lovibond and his colleagues confirmed the validity and reliability of the instrument and the test-retest reliability of the three subscales of depression, anxiety, and stress was 0.89, 0.84, and 0.82, respectively. The internal consistency of the scale was also confirmed by calculating a Cronbach's alpha of 0.83 (19). Hosseini *et al.* (20) assessed the psychometric properties of the Persian version of this questionnaire. The reliability coefficient of the tool was confirmed with a Cronbach's alpha of 0.96 indicating acceptable reliability (20).

The third part was the *Reproductive Concerns After Cancer (RCAC) scale.* This multidimensional scale was designed by Gorman *et al.* (21) to assess a wide range of reproductive concerns of women at reproductive age as survived breast cancer. This scale contained 18 items that were scored on a 5-point Likert scale [strongly disagree (score 1) to strongly agree (score 5)]. This tool had six dimensions including concerns about "fertility potential", "partner disclosure", "child's health", "personal health", "acceptance, and "becoming pregnant". Gorman and his colleagues obtained adequate reliability ($\alpha = 0.82$) (21). The Persian version showed good validity as confirmed by 10 reproductive health specialists in which the items and scales content validity index were calculated accordingly. In addition, the internal consistency reliability was confirmed with a Cronbach's alpha of 0.87.

The fourth part was the *Female Sexual Function Index adaptation for Breast Cancer patients (FSFI-BC).* This self-report tool was developed by Bartula1 and Sherman (22), and the subscales included changes after cancer (5 items), desire/arousal (6 items), lubrication (4 items), orgasm (3 items), pain (3 items), and distress (6 items). All items were scored on a 5-point Likert scale. Only those related to the subscale of "lubrication" were scored on a 6-point Likert scale. Higher scores in each subscale indicate better sexual functioning. Scores lower than 18, 9, 9, 24, 12, and 15 were interpreted as sexual dysfunction (requiring treatment) in the subscales of "changes after cancer", "desire/arousal", "lubrication", orgasm, pain, and

distress, respectively. Masjoodi *et al.* (23) assessed the validity and reliability of the Persian version of this scale. The scale had high internal stability and acceptable test-retest reliability, as Cronbach's alpha of 0.81 and 0.74 were calculated for the sexually active and non-active groups, respectively. Item correlation between 0.81 and 0.97 was also obtained for sexually active and non-active groups, respectively. The content validity index (CVI) and content validity ratio (CVR) were 0.80 and 0.60, respectively (23).

Participants in the intervention and control groups did fill the questionnaire three times; before the intervention, and twice after the intervention at two- and three-month post intervention.

***Analysis:*** Descriptive statistics were used to summarize the quantitative findings of the study in the form of frequency distribution tables. Chi-square tests were used to assess the groups in terms of demographic variables and clinical characteristics of the participants. Repeated measures ANOVA test was used to assess participants' sexual function and satisfaction during the study. All statistical calculations were performed in SPSS 20 based on the intention-to-treat principle ($P < 0.05$).

***Patient and public involvement:*** Patients and/or the public were not involved in the design, nor conducted, reported, or disseminated the plans of this research

## Results

***Baseline and clinical characteristics of participating women:*** Participating females' age is divided into three categories; 18-28, 29-38, and 39-49. Distributions of females are almost similar between the intervention and control groups. The majority of women in both groups are literate and have at least a diploma. Common contraceptives used in the two groups are condoms, intra uterine device (IUD) and discontinuation (Table 1).

**Table 1:** Comparison the demographic characteristics of the patients in the intervention and control groups

| Variable | | Control group | | Intervention group | | Statistics |
|---|---|---|---|---|---|---|
| | | % | n | % | n | |
| Age (year) | 18-28 | 18 | 9 | 12 | 6 | $X^2$=1.89 |
| | 29-38 | 36 | 13 | 38 | 19 | P=0.38 |
| | 39-49 | 56 | 28 | 50 | 25 | |
| Marriage duration (year) | 0.5-2 | 4 | 2 | 6 | 3 | P=0.6 |
| | 2-5 | 12 | 6 | 8 | 4 | |
| | 5-10 | 20 | 10 | 30 | 15 | |
| | >10 | 64 | 32 | 56 | 28 | |
| Number of children | 0 | 46 | 23 | 34 | 17 | X2=0.07 |
| | 1 | 30 | 15 | 50 | 25 | P=0.12 |
| | ≥2 | 24 | 12 | 16 | 8 | |
| Level of patient's education | Illiterate | 10 | 5 | 14 | 7 | X2=0.82 |
| | Under diploma | 54 | 27 | 40 | 20 | P=0.41 |
| | Diploma | 20 | 10 | 32 | 16 | |
| | Collegiate | 16 | 8 | 14 | 7 | |
| Level of spouse's education | Illiterate | 28 | 14 | 24 | 12 | P=0.71 |
| | Under diploma | 28 | 14 | 22 | 11 | |
| | Diploma | 40 | 20 | 46 | 23 | |
| | Collegiate | 4 | 2 | 8 | 4 | |
| Economic status | Income more than expenses | 16 | 8 | 24 | 12 | X2=0.66 |
| | Income less than expenses | 18 | 9 | 22 | 11 | P=0.44 |
| | Income equals expenses | 66 | 33 | 54 | 27 | |
| Method of contraception | Condom | 30 | 15 | 40 | 20 | P=0.49 |
| | Contraceptives | 4 | 2 | 6 | 3 | |
| | Discontinuous | 30 | 15 | 24 | 12 | |
| | Progesterone ampoules | 4 | 2 | 2 | 1 | |
| | Intra uterine device (IUD) | 30 | 5 | 20 | 10 | |
| | Without prevention | 2 | 1 | 8 | 4 | |
| Occupation of patient | Employed | 26 | 13 | 34 | 17 | X2=0.76 |
| | Housewife | 74 | 37 | 66 | 33 | P=0.38 |
| Occupation of spouse | Unemployed | 14 | 7 | 6 | 3 | X2=3.18 |
| | Labor | 18 | 9 | 12 | 6 | P=0.52 |
| | Employed | 22 | 11 | 28 | 14 | |
| | Self-employed | 34 | 17 | 36 | 8 | |
| | Retired | 12 | 6 | 18 | 9 | |

**Table 2:** Comparison the clinical characteristics of the patients in the intervention and control groups

| Variable | | Control group | | Intervention group | | Statistics |
|---|---|---|---|---|---|---|
| | | % | n | % | n | |
| Duration of disease (year) | 1-5 | 13 | 26 | 19 | 38 | $X^2$=2.80 |
| | 5-7 | 25 | 50 | 17 | 34 | P=0.24 |
| | 7-10 | 12 | 24 | 14 | 28 | |
| Age at the time of diagnosis (year) | 18-28 | 26 | 13 | 22 | 11 | P=0.78 |
| | 29-38 | 34 | 17 | 36 | 18 | |
| | 39-49 | 40 | 20 | 42 | 21 | |
| Type of surgery | Mastectomy | 82 | 41 | 72 | 36 | $X^2$=1.41 |
| | Lumpectomy | 18 | 9 | 28 | 14 | P=0.23 |
| Stage of breast cancer | I | 22 | 11 | 20 | 10 | $X^2$=2.96 |
| | II | 40 | 20 | 56 | 28 | P=0.22 |
| | III | 38 | 19 | 24 | 12 | |
| Drug treatment regimen | Hormone therapy | 76 | 38 | 78 | 39 | $X^2$=3.96 |
| | Herceptin | 4 | 2 | 4 | 2 | P=0.41 |
| | Herceptin plus hormone therapy | 14 | 7 | 10 | 5 | |
| | Without medicine | 6 | 3 | 8 | 4 | |
| Breast cancer subtype (receptor variation) | HR+/HER2- | 70 | 35 | 64 | 32 | $X^2$=1.92 |
| | HR-/HER2- | 16 | 8 | 20 | 10 | P=0.17 |
| | HR+/HER2+ | 10 | 5 | 14 | 7 | |
| | HR-/HER2+ | 4 | 2 | 2 | 1 | |

Moreover, distribution of females based on age at the time of diagnosis is also quite similar between intervention and control group. Most women underwent mastectomy in the intervention (82%) and control groups (72%). In addition, they are also under hormonal therapy (76% and 78%, respectively) (Table 2).

***Mean score comparison of DASS-21, RCAC, and FSFI-BC between intervention and control group:*** According to Table 3, a significant reduction in the mean score is observed between the control and intervention groups concerning DASS-21 and RCAC ($P < 0.001$) two and three months after the intervention. In return, a significant increase is noticed in the mean score of FSFI-BC ($P < 0.001$) two- and three months post intervention. Within intervention group, significant differences are observed in the mean score of DASS-21, RCAC and FSFI-BC in at least two stages of study (before, two- and three-months post intervention) ($P < 0.001$) (Table 3).

**Table 3:** Comparison the Depression Anxiety Stress, Reproductive Concerns and Sexual Function before intervention, two and three months after the intervention in the intervention and control group

| Variable | Group<br>Time | Intervention<br>Mean± SD | Control<br>Mean± SD | Statistics |
|---|---|---|---|---|
| Depression Anxiety Stress Scales (DASS-21) | Before intervention | 49.22±4.76 | 48.61±5.06 | F=5248.61 |
| | Two months post intervention | 48.96±5.16 | 32.14±4.99 | P<0.001 |
| | Three months post intervention | 48.46±5.38 | 32.10±4.98 | |
| | Tests | F=1.48 | F=143.21 | |
| | | P=0.23 | P<0.001 | |
| Reproductive Concerns After Cancer scale (RCAC) | Before intervention | 74.08±6.74 | 74.34±1.01 | F=5662.56 |
| | Two months post intervention | 73.64±7.55 | 46.31±0.76 | P<0.001 |
| | Three months post intervention | 73.28±8.15 | 47.51±1.02 | |
| | Tests | F=0.27 | F=26.58 | |
| | | P=0.76 | P<0.001 | |
| Female Sexual Function Index adaptation for Breast Cancer patients (FSFI-BC) | Before intervention | 80.64±8.89 | 80.62±9.40 | F=16541.95 |
| | Two months post intervention | 80.58±9.65 | 95.66±6.43 | P<0.001 |
| | Three months post intervention | 80.38±9.85 | 95.83±6.29 | |
| | Tests | F=0.129 | F=74.83 | |
| | | P=0.87 | P<0.001 | |

**Table 4:** Comparison the Depression Anxiety Stress, Reproductive Concerns and Sexual Function before and after intervention in the intervention group

| Variable | Group / Time | | Intervention | |
|---|---|---|---|---|
| | | | Difference of means | P-value |
| Depression Anxiety Stress Scales (DASS-21) | Before intervention | 2 months after intervention | 16.46 | <0.001 |
| | | 3 months after intervention | 16.51 | <0.001 |
| | Two months post intervention | 3 months after intervention | 0.04 | 0.72 |
| Reproductive Concerns After Cancer scale (RCAC) | Before intervention | 2 months after intervention | 28.02 | <0.001 |
| | | 3 months after intervention | 26.83 | <0.001 |
| | Two months post intervention | 3 months after intervention | -1.19 | 0.91 |
| Female Sexual Function Index adaptation for Breast Cancer patients (FSFI-BC) | Before intervention | 2 months after intervention | -15.04 | <0.001 |
| | | 3 months after intervention | -15.20 | <0.001 |
| | Two months post intervention | 3 months after intervention | -0.16 | 0.69 |

Considering the significance of the Repeated Measures ANOVA test, Bonferroni's Post Hoc test was used to provide a pairwise comparison of the means.

As shown in Table 4, in the intervention group, Bonferroni's test results showed that the mean score of DASS-21, FSFI-BC, and RCAC is significantly noticed between pre and two- or three months post intervention ($P < 0.001$). However, no significant findings between post intervention periods, two- and three months post intervention, ($P > 0.05$).

## Discussion

This study presented a novel and significant finding. The study showed that implementing the psychosexual GES-based Counseling on Reproductive and Sexual Concerns of Female Breast Cancer Survivors has resulted in a significant reduction, in the short run, in means score of stress, anxiety and depression using the DASS-21, reproductive concern using the RCAC, and improvement of female sexual function using the FSFI-BC.

The GES model emphasizes that physiological, psychological, and interpersonal relaxation is a base for proper sexual functioning and high marital satisfaction. Physiological and psychological relaxation is lost when one tries too much to be perfect. This, in turn, causes functional stress and anxiety and results in a vicious cycle. Therefore, the development of cognitive, emotional, and behavioral skills is a prerequisite to sexual therapy (24). The result of a systematic meta-analysis showed that continuous supportive-cognitive therapy is the most effective psychological intervention in improving anxiety, depression, quality of life, and sexual function of female breast cancer survivors who have undergone mastectomy (25). This is consistent with the results of the present study, as well as with the findings of Shandiz *et al.* (26). In the present study, we may attribute the participants' good psychological outcomes to improvements in their sexual indicators.

Khatibian et al. (27) found that psychosocial interventions are helpful to cancer patients because these interventions help patients cope with their negative automatic thoughts and replace them with positive thoughts; thus, they can reduce negative psychological outcomes in cancer survivors.

Nabipour *et al.* (28) concluded that mindfulness-based cognitive therapy reduces depression, stress, and anxiety levels in female breast cancer survivors. Considering the effect of the psychosocial approach of GES-based group therapy on the psychological status of breast cancer survivors, as well as the interaction between mental health of these people and the quality of their sexual lives, sex therapy programs must focus on the psychological status of these individuals.

In a multifaceted prospective cohort study entitled "Cancer and Fertility", Vu *et al.* (29), investigated the effect of training and counseling intervention on breast cancer survivors in the United States, and found that counseling and training programs provided along with routine cancer treatments encourage women with breast cancer to talk about their fertility concerns. The intervention resulted in an increasing number of requests for assisted reproductive treatment, and thus reduced women's fertility concerns (30). In another hand, Kufel-Grabowska *et al.* (31) revealed that the most appropriate time to provide fertility counseling is after diagnosis and before starting the treatment process. This is also in line with the findings of Macklon *et al.* (32).

Information provided during the counseling sessions is seen to have a positive effect on psychological concerns. A review performed by Deshpande *et al.* (33), improved the desirable effect

of fertility preservation counseling on the improvements of the quality of life and psychological outcomes of female breast cancer survivors. However, the information given should be accurate, attainable, and standardized to meet women's reproductive and sexual health needs (32). These findings are also in line with the results of the aforementioned studies (34, 35).

The GES-based group counseling significantly improved the sexual function of female breast cancer survivors. The GES-based group counseling was designed creatively as a set of principles and rules in the form of sexual cognitive-behavioral therapy to reflect the meaning and value of sex, accentuate sexual intimacy and psychological relaxation, and promote sexual function of the participants at the end and after the intervention. Our finding is consistent with Fatehi *et al.* study (36). Additionally, Hummel *et al.* (37) emphasized the importance of cognitive-behavioral therapy during sexual counseling, as a dynamic problem-solving process, to improve the quality of sexual life.

In another study conducted by Lampic et al. (38), the Fex-Can intervention (a web-based self-help training program) significantly improved participants' sexual satisfaction and function of women with breast cancer. Accordingly, the psychological interventions resulted in reducing feelings of sexual and reproductive inability, fear of the unknown and psychological distress. This is indeed consistent with the present results, as well as with the findings of Farah et al. (39), León-Pizarro (40), Reese et al. (41), and Fatehi et al. (36) who investigated the effectiveness of “group training on sexual skills”, “group counseling on sexual function and sexual quality of life in breast cancer survivors”, “in-person training and telephone interviews on the management of sexual concerns”, and “psycho-sexual counseling on quality of life and sexual function”, respectively .

Similar to the present study, many studies have highlighted the role of distance counseling and training (e.g. telephone interviews (42), and Internet-based interventions (37)) on sexual function and sexual quality of the life of female breast cancer survivors who have undergone mastectomy.

This is the first study conducted in Iran to determine the effectiveness of psychosexual GES based counseling on reproductive and sexual concerns. Due to cultural contexts, Iranians feel embarrassed to talk about sexual issues; therefore, the researcher provided a private environment and established an intimate relationship with the participants to encourage them to participate in the study.

## Conclusion

The GES-based, couple-centered group counseling significantly reduced stress, anxiety, depression, and reproductive concerns of female breast cancer survivors, while improving their sexual function. In the future, several psychosocial and multidisciplinary interventions can be performed with larger sample sizes to improve the sexual condition of breast cancer patients in the long run.

## Conflict of Interests

Authors have no conflict of interests.

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