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# Online versus face-to-face metacognitive educational counseling program on anxiety and meta-worry in women with a history of miscarriage: A randomized clinical trial

Mina Ghiasi Shahamabadi, Tahmineh Farajkhoda<sup>1</sup>, Hassan Zareei Mahmoodabadi<sup>2</sup>

*Counseling in Midwifery (MSc), Student Research Committee, Midwifery Department, School of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd, Iran, <sup>1</sup>Reproductive Health (Ph.D.) and Clinical Psychologist, Research Center for Nursing and Midwifery Care, Shahid Sadoughi University of Medical Sciences, Yazd, Iran, <sup>2</sup>Counseling (Ph.D.), Department of Psychology and Educational Sciences, Yazd University, Yazd, Iran*

## Address for correspondence:

Dr. Tahmineh Farajkhoda, Reproductive Health and Psychologist, Research Center for Nursing and Midwifery Care, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.  
E-mail: farajkhoda\_t@yahoo.com

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## Abstract:

**BACKGROUND:** In the COVID-19 outbreak, women with a history of miscarriage need more mental health. Anxiety and meta-worry as consequences of miscarriage, besides concerns due to pregnancy during coronavirus, show the necessity of appropriate online and face-to-face educational counseling. This study aimed to evaluate the effectiveness of online metacognitive educational counseling versus face-to-face method on anxiety and meta-worry in these women.

**MATERIALS AND METHODS:** In this randomized clinical trial, 80 women with a history of miscarriage, anxiety, and meta-worry referred to Imam Jafar Sadeqh hospital (labor, women ward and women clinic), Meybod, Iran, were selected conveniently and randomly assigned into two groups ( $n = 20$ /each). The participants received 8-session metacognitive educational counseling package online or face-to-face. Data were collected by Beck Anxiety Inventory, Welz meta-worry questionnaire at baseline, week eight, and follow up as primary outcomes and analyzed via SPSS software (Anova and Repeated measure statistic tests).

**RESULTS:** Anxiety in the 12<sup>th</sup> week (online group  $13.75 \pm 3.59$  vs. face to face  $18.25 \pm 5.91$ ,  $P = 0.04$ ) was statistical significantly less than baseline (respectively  $22.15 \pm 5.67$  vs.  $22.35 \pm 4.93$ ,  $P = 0.56$ ); with fewer anxiety scores in the online group. Meta-worry in the 12<sup>th</sup> week (online group  $11.90 \pm 2.59$  vs. face to face  $15.70 \pm 4.06$ ,  $P = 0.03$ ) was statistically significant compared to baseline (respectively  $17.15 \pm 2.70$  vs.  $18.50 \pm 3.47$ ,  $P = 0.36$ ); with fewer meta-worry scores in the online group. Belief about worry in 12<sup>th</sup> week (online group  $66.50 \pm 14.60$  vs. face to face  $78.45 \pm 9.27$ ,  $P = 0.01$ ) was statistical significantly less than baseline (respectively  $85.50 \pm 8.87$  vs.  $86.05 \pm 8.85$ ,  $P = 0.96$ ); with less score of belief about worry in the online group.

**CONCLUSION:** Online and face-to-face metacognitive educational counseling methods decreased anxiety, meta-worry, and belief about worry in women with miscarriage. But online educational counseling was more effective. Distance online counseling in COVID-19 can help the mental health of women with miscarriage.

## Keywords:

Anxiety, concern, counseling, education, face to face, metacognition, miscarriage, online, pregnancy, women

## Introduction

Pregnant women may experience unwanted events during pregnancy.<sup>[1]</sup>

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Pregnancy loss or labor induction before the fetus can survive independently is defined as miscarriage that affects husbands and families.<sup>[1,2]</sup> The prevalence is 15% of clinically diagnosed pregnancies.<sup>[3]</sup> Anxiety,

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severe worry, depression, fear, and sleep disorders are the psychological consequences of miscarriage.<sup>[3-5]</sup> This situation indicates necessity of intervention program based on pregnant women's need.<sup>[6]</sup> Anxiety is an emotional state characterized by tension, anger, fear, and increased activity of the autonomic system, thus leading to a physical-psychological response. Anxiety stimulates several hormones like epinephrine, norepinephrine, serotonin, and oxytocin that influence the regulation of behaviors, fear, aggression, perception of pain, wellbeing, quality of life, and stress reactions by activating the Hypothalamic Pituitary Adrenal axis (HPA-axis) and the sympathetic and parasympathetic nervous system in pregnancy.<sup>[7-9]</sup> The increased stress-related hormones, also untreated and prolonged anxiety can emerge unpleasant pregnancy outcomes like miscarriage and may extend till labor and causes difficulties in cervical ripening and more cesarean section.<sup>[10,11]</sup> Meta-worry means worry about worry. Meta-worry triggers and aggravates anxiety signs and symptoms like increased heart rate, shortness of breath, hands tremor, feeling of nervousness or restlessness, sweating, and trouble concentrating. Whenever normal anxiety becomes a pathological concern, meta-worry arises.<sup>[12]</sup>

Educational interventions are considered as one of key elements of women health care.<sup>[13]</sup> There are several educational treatments methods for anxiety, including relaxation, logotherapy, medication, film therapy, and psychotherapy.<sup>[14]</sup> Psychological educational counseling is one way to treat anxiety<sup>[14]</sup> and reduces the patient's fears and anxieties due to lack of awareness.<sup>[15]</sup> One of the educational counseling methods is metacognitive therapy. It attempts to change metacognition, which unfavorably increases repetitive negative thoughts or common negative beliefs.<sup>[16]</sup> Metacognition denotes a multifaceted concept including knowledge (belief), processes, and strategies that evaluate, monitor, or control cognition.<sup>[17]</sup> Since the metacognitive techniques can reduce negative thoughts, they impinge on the expression of some polymorphisms in the serotonin gene, which ultimately raise serotonin release impact on.<sup>[18]</sup>

Today, online consulting methods in health services are emphasized. The benefits of these methods include flexibility, elimination of unnecessary traffic, reduction of costs, and adjustment of the level of learning according to the individual conditions of the client.<sup>[19]</sup> Online method disadvantages include the need for internet literacy, lack of eye contact in counseling, thus reducing the effectiveness of on-therapy relationships, the possibility of misunderstanding, and lack of internet access.<sup>[20,21]</sup> Internet-based interventions have been used more acceptable than face-to-face counseling.<sup>[22,23]</sup> However, in another study, face-to-face counseling has proved to be more accepted by participants than online counseling.<sup>[24]</sup>

A recent report has indicated that 92% of women with miscarriage seek postmiscarriage care. Only one-third of them receive this type of care, and many patients express their anger and dissatisfaction about receiving insufficient educational psychological support after miscarriage. To put it another way, more attention is paid to the physical complaints of women with miscarriage than to their psychological needs.<sup>[5]</sup> Another study has shown that lack of premiscarriage counseling can lead to postmiscarriage psychological problems.<sup>[25]</sup> Considering the COVID-19 outbreak, the importance of distance online counseling to help those who need these services has increased. The online method may help patients to receive these services without embarrassment with respect to privacy and regardless of time and place. Considering the limited number of online counseling studies, it was necessary to compare the effectiveness and sustainability of metacognitive counseling through online and face-to-face methods. The online and face-to-face intervention was conducted under the group counseling protocol once a week during eight 90-minute educational counseling sessions. It seems metacognition involves communicating with thoughts to prevent resistance or complex perceptual analysis and can eliminate maladaptive thinking strategies about anxiety and inflexible control over the threat in women with a history of miscarriage. The study question was which of two counseling metacognitive methods (online face-to-face) can better improve anxiety and meta-worry. This study aimed to compare the effectiveness of metacognitive educational counseling program via online versus face-to-face methods on the anxiety and meta-worry of women with a history of miscarriage.

## Materials and Methods

### Study design and setting

This parallel randomized clinical trial was conducted in Imam Jafar Sadeq hospital (labor, women ward and women clinic), Meybod, Iran.

### Study participants and sampling

Eighty women with a history of miscarriage referred to Imam Jafar Sadeq hospital, were assessed for study eligibility criteria by conveniently sampling. Inclusion criteria were Iranian ethnicity, being married, history of miscarriage with wanted pregnancy, having an Android or IOS mobile phone, willingness to participate in counseling sessions, being interested in performing the relevant tasks, having mild or moderate anxiety, and meta-worry. Exclusion criteria were: History of alcohol, smoking, use of Drugs, systemic, gynecological, or mental disorders based on self-report, as well as simultaneous participation in a similar study, presence of a problem that superimposed sadness, anxiety, and depression, such as the death of the loved ones, etc., in the previous 2 months, as well as pregnancy.

Each woman was given a code based on a simple random computerized table number generated by a statistics specialist. Each code was randomly assigned to one of the online counseling or face-to-face counseling (control) groups until the samples were completed in each group ( $n = 20$ /each). After that, each group was again randomly divided into two subgroups of 10 women using the coin toss method [Figure 1]. Women were aware of their intervention because of counseling intervention nature; therefore, blindness was not applicable.

**Sample size calculation**

The sample size was estimated to be 40 (20 in each group) based on a previous study<sup>[26]</sup> by considering  $\alpha = 0.05$ ,  $\beta = 0.2$ , and  $\sigma = 3.5$ ,  $\mu_1 - \mu_2 = 32.7$  with considering 10% attrition probability.

**Data collection tool and technique**

Data collection instruments were completed via the electronic link in the online group and paper-based in the face-to-face group.

1. Demographic Questionnaire: It included age, job, gravidity, and level of education
2. Beck Anxiety Inventory: A 21-item four-choice question is scored on a four-part spectrum from zero

to three points.<sup>[27]</sup> The test has a content validity and stability = 0.75; and internal consistency (Cronbach's alpha) = 0.92<sup>[27]</sup>

3. Meta-worry Wellz Questionnaire: A 7-item self-reported scale used to assess meta-worry, in four-point Likert scale (1-never to 4-always) with a minimum score of 7 and a maximum of 28. To measure belief in meta-worry, a 100-degree continuum (0-"I don't believe in this at all" to "I fully believe in this") was used at the end of this questionnaire. The content validity of meta-worry questionnaire is acceptable. The reliability (correlation coefficient) of the meta-worry questionnaire is between 0.72 and 0.87.<sup>[28]</sup> In Sharifi Saki's study, this scale's internal consistency coefficient was 0.81.<sup>[29]</sup>

**Interventions**

The online and face-to-face intervention was carried out under the group counseling protocol during eight 90-minute educational counseling sessions [Table 1] based on related other studies<sup>[30-32]</sup> by the first author who had studied Counseling in Midwifery and obtained a certificate of ability to perform a metacognitive course under the supervision of the second and third author. The content of the online educational counseling sessions was provided in the form of

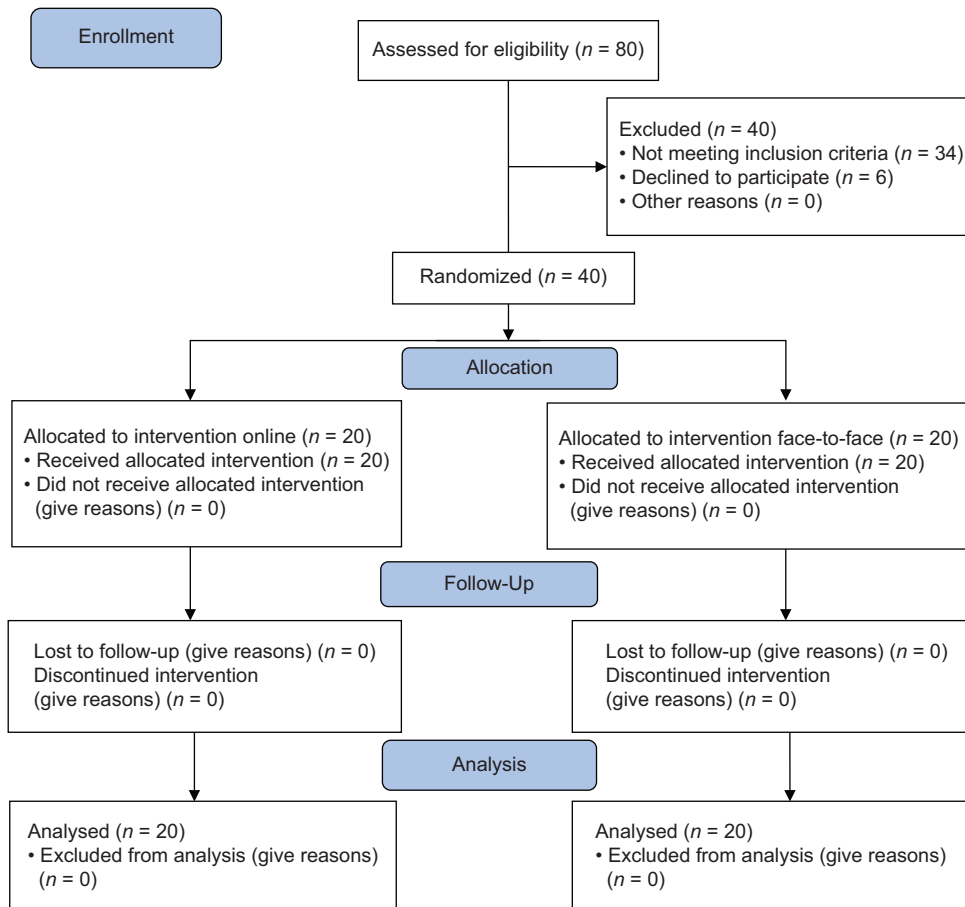


Figure 1: CONSORT flow diagram

**Table 1: Content of metacognitive educational counseling sessions**

Session	Content
1	Provision a summary of the miscarriage definition, its causes and treatment methods Evaluation of symptoms and introduction of emotional abnormality and attention bias, segregation of normal and problematic anxiety for individuals Identification of the need for treatment
2	Review of the logic of metacognitive therapy for psychological disorders and promotion of normal states Review of various treatment methods for emotional distress and attention disorders Medical information about miscarriage and its physical side effects to reduce anxiety and fear caused by lack of awareness, as well as information provision as to miscarriage being also a kind of loss or sorrow and therefore can lead to similar symptoms of grief
3	Assessment and identification the positive and negative metacognitive beliefs about miscarriage in individuals and analyzing the advantages and disadvantages of these beliefs Asking questions about patient's concerns and ambiguities around miscarriage and resolving them as far as possible Teaching and practicing metacognitive techniques
4	Identifying patient's metacognitive control strategies Analyzing anxiety and mental rumination about miscarriage Replacing more useful metacognitive control strategies instead of worrying about miscarriage
5	Overcoming overestimation of threat Dealing with metacognitive strategies and inefficient ideas (patients learn to deal with their thoughts about miscarriage as a "cloud" in their minds in case the thoughts do not need to be processed) Challenging with negative metacognitive beliefs about the dangers of miscarriage
6	Familiarizing patients with two strategies of anxiety and mental rumination as ineffective coping strategies for managing anxiety about miscarriage Analyzing the process of suppressing thoughts as an inefficient process (white tiger) and familiarizing them with the consequences of conflict with symptoms Teaching how to deal with worrying about the challenges of positive metacognitive beliefs about anxiety induced by miscarriage
7	Familiarizing patients with cognitive attention signals in the persistence of mental disorders Providing them with attention training technique and teaching them this as a supporting plan so as not to be worried about miscarriage
8	Assessment of changes in negative thoughts toward positive Situational attention refocusing as an effective metacognitive strategy and preparing members for closing sessions Identifying barriers to methods application, cause seeking and eliminating it and subsequently concluding Preventing relapse Discussing current mental state of the patients and their concerns about miscarriage

multimedia (video clip, power point, verbal chat) for two online groups ( $n = 20$ ) (randomly divided into two groups of ten) and presented once a week at a specific time according to the agreement of women through Whats App online software.

For the control group, however, face-to-face educational counseling was performed once a day in the week (in different days for each subgroup) with the agreement on exact time by the women participating in the study at Imam Jafar Sadegh hospital, Meybod, Yazd.

SMS reminders were sent before each session for all 40 women. At the beginning of each session, a summary of the contents of the previous session was reviewed, and they were asked to express their concerns and progress. Homework assignments accomplished by each woman were also reviewed by the counselor to report each woman's progress. Both 'online and face-to-face groups received the same counseling content in the same counseling length time by the same counselor.

### Outcomes

The primary outcomes of the study were the changes in the mean score of anxiety (measured by Beck Anxiety Inventory), meta-worry, and belief in meta-worry (measured by Meta-worry Wellz Questionnaire) that measured three times, including at the baseline, at the end of the intervention in the 8 week and follow up at 12<sup>th</sup> week after baseline in two groups.

### Statistical analysis

Descriptive statistical tests like frequency, percentage, mean, and standard deviation were used for data description. Fisher's exact test was used for the analysis of qualitative data in two groups. Because of the normal distribution of primary and secondary variables, including anxiety, meta worry, and belief about worry, parametric Independent Samples *t*-test and Repeated Measures test (ANOVA) were used.  $P < 0.05$  were considered significant.

### Ethical consideration

This study approved by the ethics committee of the Shahid Sadoughi University of Medical Science, Yazd, Iran (Code: IR.SSU.REC.1397.091) and registered in the Iranian Registry of Clinical Trials (IRCT Code: IRCT 20181120041707N1). All 40 women signed an informed consent form to participate in counseling sessions.

## Results

### Participant flow and numbers analyzed

The data of 40 women who fully completed the questionnaires in two online ( $n = 20$ ) and face-to-face groups ( $n = 20$ ) were analyzed.



**Participant characteristics**

Most participants in both groups were housewives, gravida II, and had a diploma’s degree or higher education level. The mean age of the online group was 27.55 ± 5.30 versus face-to-face group was 27.00 ± 6.86 years. The groups did not have statistically significant differences in terms of demographic characteristics [Table 2].

The mean score of anxiety in the 12<sup>th</sup> week (online group 13.75 ± 3.59 vs. face-to-face group 18.25 ± 5.91, *P* = 0.04) was statistical significantly less than baseline (respectively 22.15 ± 5.67 vs. 22.35 ± 4.93, *P* = 0.56); with fewer anxiety scores in the online group [Table 3].

**Table 2: Comparison of demographic characteristics between two groups**

Variables	Online group (n=20), n (%)	Face to face group (n=20), n (%)	<i>P</i>
Age	27.55±5.30	27.00±6.86	0.07**
Job			
Self-employer	7 (35)	3 (15)	0.33*
Employee	1 (5)	1 (5)	
Housewife	12 (60)	16 (80)	
Gravida			
First	1 (5)	0	0.20*
Second	16 (80)	12 (60)	
Third	3 (15)	6 (30)	
Fourth and more	0	2 (10)	
Level of education			
Cycle	3 (15)	1 (5)	0.08*
Diploma	8 (40)	15 (75)	
University	9 (45)	4 (20)	

\*Fisher’s exact test, \*\*Independent samples *t*-test

The mean score of meta-worry in the 12<sup>th</sup> week (online group 11.90 ± 2.59 vs. face-to-face group 15.70 ± 4.06, *P* = 0.03) had a statistically significant difference compared to baseline (respectively 17.15 ± 2.70 vs. 18.50 ± 3.47, *P* = 0.36); with fewer meta-worry scores in the online group [Table 3].

The mean score of belief about worry in the 12<sup>th</sup> week (online group 66.50 ± 14.60 vs. face-to-face group 78.45 ± 9.27, *P* = 0.01) was statistical significantly less than baseline (respectively 85.50 ± 8.87 vs. 86.05 ± 8.85, *P* = 0.96); with less score of belief about worry in the online group [Table 3].

**Discussion**

The mean score of anxiety, meta-worry, and belief about worry decreased in each group at 8<sup>th</sup> and 12<sup>th</sup> weeks following the intervention compared with baseline; however, this proved more significant in the online group. In a study to investigate the effect of preoperative multimedia training on preoperative anxiety in patients undergoing local anesthesia, results revealed that education through multimedia reduced the anxiety of these patients.<sup>[33]</sup> Another study showed that Mobile Apps psychoeducational interventions significantly reduced anxiety symptoms, and improved self-esteem,<sup>[34]</sup> consistent with our results. Golshani *et al.* showed face-to-face Cognitive Behavioral Therapy decreased the anxiety of Iranian women with infertility.<sup>[35]</sup> In a study by Akhteh *et al.*, the effectiveness of cognitive-behavioral training in stress management by face-to-face counseling method reduced anxiety and meta-worry in women

**Table 3. Comparison of means score of anxiety, meta-worry and belief about worry at baseline, week6, and follow up in two groups**

variables	mean±sd		<i>F</i>	<i>P</i> **
	Online group n=20	Face to face group n=20		
<b>Anxiety</b>				
Base line	22.15±5.67	22.35±4.93	0.33	0.56
End of the intervention at week 8	17.00±5.03	18.45±6.25	0.97	0.33
Follow up at 12 weeks after baseline	13.75±3.59	18.25±5.91	4.38	0.04
<i>P</i> *	<0.001	0.04		
<i>F</i>	15.260	3.255		
<b>Meta-worry</b>				
Base line	17.15±2.70	18.50±3.47	0.850	0.36
End of the intervention at week 8	14.40±3.16	15.80±4.07	0.961	0.33
Follow up 12 weeks after baseline	11.90±2.59	15.70±4.06	4.883	0.03
<i>P</i> *	<0.001	0.04		
<i>F</i>	17.196	3.351		
<b>Belief about worry</b>				
Baseline	85.50±8.87	86.05±8.85	0.002	0.96
End of the intervention at week 8	73.00±12.18	78.50±11.36	0.167	0.68
Follow up 12 weeks after baseline	66.50±14.60	78.45±9.27	6.284	0.01
<i>P</i> *	<0.001	0.02		
<i>F</i>	12.701	3.910		

\*Repeated measure, \*\*Independent Samples *T* Test, SD=Standard deviation

with recurrent miscarriages.<sup>[36]</sup> Delaram and Soltanpour demonstrated that counseling with these women, not having a history of hospitalization and a known mental illness in the third trimester of pregnancy, reduces their anxiety at the onset of their labor.<sup>[37]</sup> These studies are in line with results of present study.

Perhaps, a reason for the significant decrease in the mean score of anxiety, meta worry, and belief about worry in both groups at 8<sup>th</sup> and 12<sup>th</sup> weeks following the intervention in comparison with baseline is the content of educational counseling sessions, the counselor, length, and the number of sessions were the same in the present study. Counseling services parallel with medical facilities appears to be crucial for women with a history of miscarriage.<sup>[36]</sup> Another reason is related to the metacognition mechanism as an appropriate educational, psychological technique for women with miscarriage. An individual considers the need to worry as a coping strategy; she fails to break the chain of anxiety and thus regards worry as a factor in avoiding failure in the adaptation process.<sup>[36]</sup> Metacognitive techniques provide metacognitive capacity, the measurable cognitive processes which enable us to understand better ourselves and others in a flexible and evolving fashion and so support a sense of agency and cohesive sense of self; using better problem-solving skills, having better judgment and rational thinking.<sup>[30-32]</sup> Metacognitive counseling mechanism helps people identify situations that cause anxiety and stress, better understand them, identify their strengths and weaknesses, and then deal with coping strategies.<sup>[16]</sup>

The reason for more decrease in anxiety, meta-worry, and belief about worry in follow up in comparison with week eight is, the metacognitive technique needs enough skills training; therefore, women with miscarriage gradually learned how to use these taught skills in their daily life and how to manage their negative and positive thoughts and emotions to regulate their mood and experience a happier condition. In the study of Anthonysamy, the use of metacognitive strategies for uninterrupted online learning increased the capability of adding more effort in regulating their learning process.<sup>[38]</sup>

Due to another finding of the present study; it should be noted that anxiety and meta-worry decreased in this study. In women with miscarriages, the factor for inducing anxiety and subsequent meta-worry is highly evident.<sup>[29]</sup> Meta-worry is, in fact, the result of anxiety and stress so that by lowering the level of anxiety, it is possible to control meta worry as well.<sup>[39]</sup> People who acquire the coping skills needed to control anxiety bear the potential to control their anxiety and worrying thoughts; as a result, stress, anxiety, and meta-worry are continually reduced. The ineffective attitudes of women

with recurrent miscarriages in relation to infertility and miscarriage play an essential role in creating a negative view of oneself.<sup>[40]</sup>

Better improvement in anxiety, meta worry, and belief about worry scores in the online group compared with the face-to-face group indicated women in the online group more interested in counseling method. In line with current study results, SalehMoghaddam *et al.*, showed that the educational films significantly reduced preoperative anxiety compared to face-to-face and pamphlet training methods.<sup>[41]</sup> Ghalibaf *et al.* reported 93.3% of respondents being delighted with online counseling.<sup>[42]</sup> Online learning occurs with its, more significant impact on memory or a the more attractive way to present educational content. Online Metacognitive counseling provides the therapist a high possibility and flexibility in terms of location and time. It can extend the therapy relationship between therapist and counselor and protect clients from possible inflictions resulting from therapeutic relationship disconnections.<sup>[43,44]</sup> Online counseling is a new form of distance counseling with the ability to accessible transmit information, more visual and auditory attractiveness and excitement nature, more perceived enjoyment, more social effects, more perceived usefulness, and perceived ease of use which, to some extent, removes the limitations of the real world. Cost-effectiveness is considered one of the important advantages of remote counseling programs.<sup>[43,45,46]</sup> Perhaps, people who have more experience dealing with the world of the internet and virtual communications can better appreciate this treatment method.

In contrast, in a meta-analysis study conducted by Carlbring *et al.*, in 2018, results showed internet-based and face-to-face cognitive-behavioral therapy had a similar effect for treating psychiatric and somatic disorders.<sup>[47]</sup> Olthuis *et al.* concluded that internet cognitive-behavioral therapy for anxiety disorders had lower quality than face-to-face,<sup>[48]</sup> thus being inconsistent with the present study results. The reason for the difference in the results of two studies with the present study is the different method of studies and using a different type of psychologic intervention (cognitive-behavioral therapy in their studies in comparison with metacognitive intervention in the present study).

Providing intervention sessions specified for anxiety and meta worry about miscarriage, presenting a framework for online educational counseling, and trail design with active control group are considered as power of the study.

### Limitation and recommendation

The limitation of the present study was women's awareness of their intervention after participation in

the study because of the counseling intervention nature; thus, blindness was not applicable. This limitation had not any adverse effect on the study results because two groups received intervention separately. Women's awareness of psychological therapies may be changed by talking with other people in the community or through media. Further, the psychological state of women when completing questionnaire would affect their responses which those factors was managed by randomization. Since today, the lining (or the presence in the online space) in the daily lives of most Iranian women is of paramount importance, it recommends that online psycho education interventions are valuable approach for women's health in Iranian community.

## Conclusion

Both face-to-face and online metacognitive educational counseling have significantly reduced the anxiety, meta-worry, and belief about the worry of women with a history of miscarriage, but online counseling was more effective. This may be due to the significant impact of online software's attractiveness, cost-effectiveness, the possibility of dealing with concerns, thus providing the ease and effectiveness of counselor-client interaction. Considering the COVID-19 outbreak, distance online counseling is crucial to help those who need these services.

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## Ethics code

IR.SSU.REC.1397.091.

## Trial registration

ISRCTN, IRCT20181120041707N1, Prospectively registered, Registered 23 May 2019, <https://en.irct.ir/trial/35643/IRCT20181120041707N1>.

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## Conflicts of interest

There are no conflicts of interest.

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