The effectiveness of online metacognitive versus face-to-face counseling on anxiety and metaworry in women with a history of spontaneous miscarriage: A Randomized clinical trial

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Research article

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Abstract

Background

Online and face-to-face counseling interventions can be performed on women with a history of miscarriage, which causes their anxiety and metaworry. The aim of this study was to compare effectiveness of metacognitive counseling methods, online and face-to-face, on anxiety and metaworry of women with miscarriage.

Methods

In this parallel randomized clinical trial, 40 women with a history of miscarriage, anxiety and metaworry were randomly assigned to two groups (n = 20/each): group I receiving metacognitive counseling via online network and software, and group II (control) receiving face-to-face metacognitive counseling with same content and time, 90-minute sessions. Data were collected demographic form, Beck Anxiety Inventory, Wellz metaworry questionnaire and satisfaction scale. Primary outcomes included changes in the scores of anxiety, metaworry were measured in both groups in three times including at the base line, and at the end of week eight and twelve of the intervention initiation. Satisfaction with counseling method was assessed as secondary outcome at the end of week eight and twelve of the intervention beginning in both groups.

Results

In both groups, mean score of anxiety in 12th week was significantly different from before the intervention; difference was more significant in online group (p = 0.04). In both groups, the mean score of metaworry in 12th week had a statistically significant difference compared to the beginning of the study, and the decrease was again more significant in the online group (p = 0.03). Satisfaction with the counseling method had statistically significant difference between the two groups in week eight and twelve (respectively p ≈ 0.00).

Conclusions

Metacognitive counseling both online and face-to-face improves anxiety and metaworry in women with miscarriage. Online counseling was more effective, satisfying, and longer compared with face-to-face counseling method, especially in corona virus19 outbreak.

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

Background

Miscarriage or spontaneous abortion is defined as the pregnancy loss or labor induction before the fetus is able to survive, independently[1, 2], the prevalence of which in Iran is 9.8 cases per 1000 pregnancies
per year[3]. Stress, anxiety, and severe concern are the psychological consequences of miscarriage[4]. Psychological symptoms of women with miscarriage are similar to those of mothers who have lost their babies [5]. Anxiety is an emotional state characterized by feeling of tension, anger, anxiety, fear, and increased activity of the autonomic system, thus leading to a physical-psychological response [6]. Metaworry means worry about worry. Whenever normal anxiety becomes a pathological concern, metaworry arises[7].

There are several treatments' methods for anxiety, including relaxation, logo therapy, medication, film therapy, the use of electric shock, and psychotherapy[8, 9]. Psychological counseling is one way to treat anxiety [8] and reduces the patient's fears and anxieties due to lack of awareness[10]. One of the counseling methods is metacognitive therapy, attempting to change metacognition, which unfavorably increases repetitive negative thoughts or common negative beliefs[11]. Metacognition denotes a multifaceted concept including knowledge (belief), processes, and strategies that evaluate, monitor, or control cognition [12]. The metacognitive therapies can impinge on the expression of some polymorphisms in the serotonin gene, which ultimately raise serotonin release [13].

Today, online methods of consulting in health services are emphasized compared to the traditional methods, the benefits of which include flexibility, elimination of unnecessary and costly traffic use to participate in the counseling courses, reduction of costs, and adjustment of the level of learning according to the individual conditions of the client[14]. Online method disadvantages include the need for internet literacy, lack of eye contact in counseling, thus reducing the effectiveness of on-therapy relationship, the possibility of misunderstanding and lack of internet access [15, 16]. Internet-based interventions have been used which have shown to be more acceptable than face-to-face counseling[17, 18]. However, in another study, face-to-face counseling has proved to be more accepted by participants than the online type[19].

Recent report has indicated that 92% of women with abortion seek post-miscarriage care, out of which only one-third receive this type of care; additionally, many patients express their anger and dissatisfaction as for receiving insufficient 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 [5]. In one study has shown that lack of pre-miscarriage counseling can lead to post-miscarriage psychological problems[20]. Considering corona virus outbreak, the importance of distance online counseling to help who needed these services is crucial, although the online method enjoys lack of embarrassment on the part of the patient, regards privacy, and is independent of time and place, due to the limited number of online counseling studies in Iran, it was necessary to compare the effectiveness, sustainability, and satisfaction of metacognitive counseling through online and face-to-face methods. The study questions were which of two counseling metacognitive methods online and face-to-face had more effectiveness on improvement of anxiety and metaworry, and associated with more satisfaction. The aim of this study was to compare the effectiveness of metacognitive counseling via online and face-to-face methods on the anxiety and metaworry of women with a history of spontaneous miscarriage.
Methods

Study design

In this parallel Randomized clinical trial (random allocation and concealment, presence of face to face metacognitive group as control group, IRCT registration Code: IRCT20181120041707N1).

Participants and randomization

80 women with a history of spontaneous abortion referred to Imam Jafar Sadegh hospital, Meybod, Iran were assessed for study eligibility criteria. All participants were eligible according to the inclusion criteria consisted of Iranian ethnicity, being married, history of spontaneous abortion, wanted pregnancy, having an Android or IOS mobile phone, willingness to participate in counseling sessions, having interest to perform the relevant tasks (attending all or at least 6 sessions, and performing more than 75% of assignments at the discretion of the counselor), having mild or moderate anxiety and a metaworry score < 10. Exclusion criteria were the history of alcohol, tobacco, or medications use such as antidepressants according to the individual herself report, presence of systemic disorders, gynecologic or mental diseases based on women self administration, 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 two months, as well as pregnancy.

Due to lack of eligibility criteria in some women and high probability of women withdrawal in each group during the study stages, 80 women with a history of spontaneous abortion referred to Imam Jafar Sadegh hospital, Meybod, Iran were assessed for eligibility criteria in 26.5.2019. Each of the women was then given a code based on a simple random computerized table number that generated by a statistics specialist. First author enrolled participants, and assigned participants to interventions under supervision of second author. 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). The final samples were called; the purpose and method of the study were explained to them. Women that did not wish to attend the study (six women), did not meet inclusion criteria (34 women) or for other reasons (none of women) were excluded from the study and replaced with another one (Figure 1). After random allocation of 40 eligible women into two online consulting group (n=20) and face-to-face counseling group (as control group n=20), women in each group were randomly divided into two groups (two sub groups) of ten women (B and A) using the coin toss method again. Forty eligible women signed an informed consent form to participate in counseling sessions. Women were aware from their intervention because of counseling intervention nature, therefore blindness was not applicable.

Sample size estimation

The sample size was estimated to be 40 (20 in each group) based on previous studies [21, 22] by considering $\alpha = 0.05$, $\beta = 90\%$, and $\sigma = 3.5$, and to achieve a significant difference of at least 5 points in the mean scores of the anxiety questionnaire as well as considering 10% attrition probability. We used the
statistical formula \( n = \frac{2(\frac{z_{1-a/2} + z_{1-b}}{2})^2 s^2}{(\mu_1 - \mu_2)^2} \) for sample size determination. In this study 20 women (in two groups of 10) were receiving metacognitive counseling through online consulting and 20 others (in two groups of 10) receiving face-to-face counseling.

**Data collection instruments (4 tolls)**

*Demographic Questionnaire:* It included age, gravidity, level of education, occupation, number of miscarriages, gestational age at the time of miscarriage, the time interval since the last abortion, history of anxiety, and previous efforts to reduce anxiety.

*Beck Anxiety Inventory:* A 21-item four-choice question is scored on a four-part spectrum from zero to three points [23]. The test has a content validity, stability = 0.838; and internal consistency (Cronbach's alpha) is 0.92 [24].

*Metaworry Wellz Questionnaire:* This is a 7-item self-reported scale designed to assess the risk aspect of metaworry and the frequency and extent of belief in anxiety. To assess the frequency of metaworry beliefs, the responses on this scale are based on a four-point Likert scale (1-never to 4-always) with a minimum score of 7 and a maximum of 28, and to measure a belief in metaworry. It is calculated based on a 100-degree continuum (0-"I don't believe in this at all" to "I fully believe in this"). The correlation coefficient of the metaworry questionnaire is between 0.72 and 0.87 [25]. In Sharifi Saki's study, the internal consistency coefficient of this scale turned out to be 0.81 [26].

*Satisfaction with the counseling method scale:* This variable investigated at the end of the researcher-made scale using relevant references in the form of score scales between 1 and 10 in seven questions at weeks eight and twelve after the intervention that were responded by women in both groups [27, 28].

**Interventions**

The online and face-to-face intervention was carried out under the group counseling protocol during eight 90-minute counseling sessions (Table 1) based on related other studies [29, 30] by first author who had studied counseling and obtained a certificate of ability to perform a metacognitive course under supervision of first and second author. The content of the online counseling sessions was provided in the form of multimedia for two online groups (n=20) (randomly divided into two 10 women) at a specific time and day in week according to the agreement reached with the participants through on line software and Whats App software. At the beginning of each session, a summary of the contents of the previous session was reviewed, and while providing counseling materials online, they were asked to participate in online counseling discussions and express their concerns as well as their progress and report to the counselor with online chat. In order to encourage them more in the counseling topics, appropriate questions were prepared based on the principles of metacognitive counseling, that were all discussed in the group. At the end of each session, the important points were repeated and summarized. Online
assignments accomplished by each individual were also reviewed by the counselor so that each person's progress was reported. It was also possible to ask the counselor questions online and in person. In case the person was absent from the online session, she would be asked via SMS to join the group. In case of internet disconnection, the meeting would be held online again with the agreement of the members.

For the control group (n=20) (face-to-face counseling group randomly was divided into two 10 women groups), however, face-to-face counseling was performed for both two face to face groups once day in week with the agreement on exact time by the women participating in the study at Imam Jafar Sadegh hospital, Meybod, Yazd for providing appropriate space and facilities for counseling sessions. This group, as in the online group, was involved in a beginning session, an invitation outline to actively participate in the group counseling session, and the possibility of asking private questions after the group meeting in person. Both of two groups’ online and face to face groups, received same counseling content in same counseling length time by the same counselor.

Table 1. Content of metacognitive therapy sessions based on related other studies [29, 30]
<table>
<thead>
<tr>
<th>Homework assessment</th>
<th>Aims</th>
<th>Contents</th>
<th>Sessions</th>
</tr>
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<tbody>
<tr>
<td>In each session, a number of participants were asked to do the assignment at the presence of the researcher. In online method, participants were also asked to describe the assignments. Each evaluation was regarded as acceptable or unacceptable, and required feedback was presented.</td>
<td>· Provision of 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 social anxiety for individuals, · Identification of the need for treatment</td>
<td>· Welcome · explain the venue, the number of sessions, the length of the course and the duration of each session, and the group’s rules and regulations, · Introducing the group members to each other, · Providing a summary of the treatment method and the purpose of the sessions</td>
<td>1</td>
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<td></td>
<td>· Presentation of the logic of metacognitive therapy for psychological disorders and promotion of normal states, · Study of the symptoms of emotional abnormality and attention disorders in individuals, · Study of the possible effective causes in the etiology of emotional abnormality and attention disorders, · Review of various treatment methods for emotional distress and attention disorders, · Explanations about the logic of metacognitive therapy for emotional abnormality 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</td>
<td>· Expressing the summary the content of the previous session with the help of the members, Providing homework and emphasis on homework, · Receiving feedback</td>
<td>2</td>
</tr>
</tbody>
</table>
can lead to similar symptoms of grief

- Assessing and identifying the positive and negative metacognitive beliefs about miscarriage in individuals and analyzing the advantages and disadvantages of these beliefs,
- Asking questions about patients’ concerns and ambiguities around miscarriage and resolving them as far as possible
- Receiving feedback from the previous session,
- Reviewing the exercises and homework of the previous session,
- Teaching and practicing metacognitive techniques,
- Presenting homework

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</table>

- Identifying patients’ metacognitive control strategies,
- Analyzing the advantages and disadvantages of metacognitive control strategies used,
- Replacing more useful metacognitive control strategies instead of worrying about miscarriage
- Receiving feedback from the previous session,
- Discussing homework,
- Teaching and exercising, presenting homework,
- Receiving feedback

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</table>

- 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
- Receiving feedback from the previous session,
- Discussing homework,
- Teaching and exercising,
- Presenting homework,
- Receiving feedback

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</table>

- Familiarizing patients with two strategies of anxiety and mental rumination as ineffective coping strategies for
- Receiving feedback from the previous session,
managing anxiety about miscarriage,
· Analyzing advantages and disadvantages of anxiety and mental rumination 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 delay worrying about the challenges of positive metacognitive beliefs about anxiety induced by abortion

· 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

· 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

· discussing homework,
· Teaching and exercising, presenting homework,
· Receiving feedback

· Receiving feedback from the previous session,
· Discussing homework,
· Teaching and exercising, presenting homework,
· Receiving feedback

· Receiving feedback from treatment sessions and its impact on group members,
· Reviewing assignments and answering questions and problems,
· Practicing the techniques learned in previous sessions with the participation of members,
· Expressing the need to use the
Ethic

The study protocol was approved by of the ethics committee Shahid Sadoughi University of Medical Science, Yazd, Iran (Code: IR.SSU.REC.1397.091) and registered in Iranian Registry of Clinical Trials (IRCT Code: IRCT 20181120041707N1). Written informed consent was obtained from each women participating in the study.

Outcomes

Primary outcomes

The primary outcomes of the study were the changes in the mean score of anxiety, metaworry that measured three times including at the base line and at the end of the eighth and twelfth weeks of the intervention in the two groups. These outcomes were measured in face to face metacognitive counseling group via face to face interview by Beck Anxiety Inventory, Metaworry Wellz Questionnaire at the baseline and at the end of eighth and twelfth weeks (fallow up) of intervention. In online metacognitive counseling group the same online questionnaires were sent to each women of the online metacognitive counseling group at the same times as face to face metacognitive counseling group.

Secondary outcomes

The secondary outcome of the study was measurement of satisfaction with the counseling method that was assessed at the end of the eighth and twelfth weeks of the intervention in the two groups. It was assessed at weeks eight and twelve after the intervention via face to face (for face to face metacognitive counseling group) and online (for online metacognitive counseling group) in both groups.

Statistical analysis

Statistical analysis was done using Statistical Package for the Social Sciences, frequency, percentage, mean, and standard deviation as well as, and Smirnov's normality, Chi-square, Student's t test, and Repeated measure. For both primary and secondary outcomes Student's t test, and Repeated measure were used. P-value < 0.05 were considered significant.

Results
Participant flow and numbers analyzed

The data of 40 women in two online group (n=20) and face to face group participating in the study were analyzed after ending the trial in 12th week after initiation of intervention when the study completed based on figure 1.

Participant characteristics

Kolmogorov Smirnov's normality test was done. Most participants in both groups being housewives, gravida II, had a diploma's degree or higher of education level. The mean age of the participants was 27.27 ± 6.06 years with a minimum age of 18 and a maximum of 39 years. The groups did not have statistically significant differences in terms of demographic characteristics (Table 2).

Table 2. Comparison of demographic characteristics between two study groups (n=20/each)
<table>
<thead>
<tr>
<th>Group</th>
<th>Face to face consultation (control)</th>
<th>Online counseling</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percent</td>
<td>Frequency</td>
</tr>
<tr>
<td>Job</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free</td>
<td>3</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>Governmental</td>
<td>1</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Housewife</td>
<td>16</td>
<td>80</td>
<td>12</td>
</tr>
<tr>
<td>The number of pregnancy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Second</td>
<td>12</td>
<td>60</td>
<td>16</td>
</tr>
<tr>
<td>Third</td>
<td>6</td>
<td>30</td>
<td>3</td>
</tr>
<tr>
<td>Fourth and more</td>
<td>2</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Level of Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cycle</td>
<td>1</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>75</td>
<td>8</td>
</tr>
<tr>
<td>Diploma</td>
<td>4</td>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td>University</td>
<td>4</td>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td>Number of abortions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One</td>
<td>12</td>
<td>60</td>
<td>16</td>
</tr>
<tr>
<td>Two</td>
<td>7</td>
<td>35</td>
<td>4</td>
</tr>
<tr>
<td>Three and more</td>
<td>1</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>History of anxiety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
<td>35</td>
<td>8</td>
</tr>
<tr>
<td>No</td>
<td>13</td>
<td>65</td>
<td>12</td>
</tr>
</tbody>
</table>

* Chi-square test

** Independent Samples t Test

**Primary outcomes**

**Table 3.** Comparison mean anxiety score and its changes in before and after intervention in two groups (n=20/each)
<table>
<thead>
<tr>
<th>Groups</th>
<th>Face to face consultation (control n=20)</th>
<th>online consultation (n=20)</th>
<th>F</th>
<th>Independent Samples T Test**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td></td>
<td></td>
<td>p-value</td>
<td></td>
</tr>
<tr>
<td>Base line (mean standard deviation) ±</td>
<td>4/93 ±22/35</td>
<td>5/67±22/15</td>
<td>0/33</td>
<td>0/56</td>
</tr>
<tr>
<td>8 weeks after the intervention (mean standard deviation) ±</td>
<td>6/25±18/45</td>
<td>5/03±17/00</td>
<td>0/97</td>
<td>0/33</td>
</tr>
<tr>
<td>Fallow up 12 weeks after the beginning of intervention (mean ± standard deviation)</td>
<td>5/91±18/25</td>
<td>3/59±13/75</td>
<td>4/38</td>
<td>0/04</td>
</tr>
<tr>
<td><strong>F</strong></td>
<td>3/255</td>
<td>15/260</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p-value</td>
<td>0/04</td>
<td>≈0/00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeated measure *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Repeated measure

**Independent Samples T Test

The mean score of anxiety before the intervention (p = 0.56) and 8 weeks after the intervention (p = 0.33) did not differ significantly between the study groups. However, 12 weeks after the intervention, the mean changes of anxiety score were significantly different between the two groups (p = 0.04), so that the effectiveness of online counseling were higher than that of face-to-face method. Intergroup comparisons showed the mean anxiety score decreasing significantly in 8 and 12 weeks after the intervention in the online counseling group (p ≈ 0.00) compared with that of before. Further, in the face-to-face counseling group, the anxiety level decreased in 8 and 12 weeks after the intervention which was significantly lower than that of before the intervention (p = 0.04), but the mean anxiety score in the online counseling group proved to be lower (Table 3).

**Table 4:** Comparison mean of metaworry score in before and after intervention in two groups
<table>
<thead>
<tr>
<th>Groups</th>
<th>Face to face consultation (control n=20)</th>
<th>online consultation (n=20)</th>
<th>F</th>
<th>Independent Samples Test**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td></td>
<td></td>
<td>p-value</td>
<td></td>
</tr>
<tr>
<td>Base line (mean± standard deviation)</td>
<td>3/47±18/50</td>
<td>2/70±17/15</td>
<td>0/850</td>
<td>0/36</td>
</tr>
<tr>
<td>8 weeks after the intervention (mean standard deviation) ±</td>
<td>4/07±15/80</td>
<td>3/16±14/40</td>
<td>0/961</td>
<td>0/33</td>
</tr>
<tr>
<td>Fallow up12 weeks after the begining of intervention (mean ± standard deviation)</td>
<td>4/06±15/70</td>
<td>2/59±11/90</td>
<td>4/883</td>
<td>0/03</td>
</tr>
<tr>
<td>F</td>
<td>3/351</td>
<td>17/196</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p-value</td>
<td>0/04</td>
<td>≈0/00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Repeated measure*

**Independent Samples T Test**

The mean score of metaworry before intervention (p = 0.36) and 8 weeks after intervention (p = 0.33) did not differ significantly between the studied groups, but the mean change in 12 weeks after the intervention turned out to be significantly different between the two groups (p = 0.03); so that the effectiveness of online counseling showed higher than that of face-to-face counseling. Intergroup comparisons also revealed that in the online counseling group, the mean score of metaworry diminished significantly in the 8 and 12 weeks after the intervention (p≈ 0.00). In the face-to-face counseling group, the metaworry rate also decreased in 8 and 12 weeks after the intervention which stood significantly lower than that of before the intervention (p = 0.04); this rate, however, was lower compared to the online counseling group (Table 4).

**Table 5.** Comparison mean scores of belief about worry in before and after intervention in two groups
<table>
<thead>
<tr>
<th>Groups</th>
<th>Face to face consultation (control n=20)</th>
<th>online consultation (n=20)</th>
<th>F</th>
<th>p-value</th>
<th>Independent Samples Test**</th>
</tr>
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<tbody>
<tr>
<td>Variable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Base line (mean standard deviation) ±</td>
<td>8/85±86/05</td>
<td>8/87±85/50</td>
<td>0.002</td>
<td>0.96</td>
<td></td>
</tr>
<tr>
<td>8 weeks after the intervention (mean standard deviation) ±</td>
<td>11/36±78/50</td>
<td>12/18±73/00</td>
<td>0.167</td>
<td>0.68</td>
<td></td>
</tr>
<tr>
<td>Fallow up 12 weeks after the beginning of intervention (mean ± standard deviation)</td>
<td>9/27±78/45</td>
<td>14/60±66/50</td>
<td>6.284</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>3/910</td>
<td>12/701</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p-value</td>
<td>0.02</td>
<td>≈0.00</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Repeated measure*</td>
<td></td>
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</tbody>
</table>

*Repeated measure

**Independent Samples T Test

The mean score of belief in concerns before intervention (p = 0.96) and 8 weeks after intervention (p = 0.68) had no significant difference between the studied groups, but 12 weeks after the intervention, the mean changes appeared to be significantly different between the two groups (p = 0.01); the effectiveness of online counseling was, however, higher than that of face-to-face method. Intergroup comparisons demonstrated the mean score of belief in concerns significantly decreased in the 8 and 12 weeks after the intervention in the online counseling group (p ≈0.00). The mean of belief in concerns as for face-to-face group also significantly reduced in 8 and 12 weeks after the intervention (p = 0.02), but this was lower than the online counseling group (Table 5).

**Secondary outcomes**

Table 6. Comparison of total satisfaction score in 8th and 12th weeks after intervention in two groups
## Discussion

In this study, the effectiveness of online and face-to-face metacognitive counseling on anxiety and metaworry in women with a history of miscarriage was compared. Our results demonstrated the significant decrease in the mean score of anxiety and metaworry in both groups at 8th and 12th weeks following the intervention; this, however, proved more significant in the online group. Jilala and co-workers conducted a study to investigate the effect of preoperative multimedia training on preoperative anxiety in patients undergoing local anesthesia. Their results revealed that education through multimedia reduced the anxiety of these patients [31]. Kresting and colleagues, in 2013, showed that short internet-based interventions for 5 weeks significantly reducing post-traumatic stress symptoms, prolonged grief, depression, and anxiety[32], which is consistent with the results of the present study. One of the main reasons for the positive effect of online counseling method is the new and exciting visual and auditory nature and simulations that by knowing that the setting is online, the patient attempts to adapt to it, establish a constructive interaction, and eliminate the limitations of the real world.
Olthuis and others concluded that cognitive-behavioral therapy through internet would fail to affect the patients with post-traumatic stress disorders, anxiety, and phobias[33], thus being inconsistent with the results of ours. Perhaps the justification for this discrepancy can be attributed to different geographical settings of the two studies and the way the intervention was conducted, as the two studies were conducted in two countries with two varying educational systems, or maybe the difference in the perspective of the participants, the training technique used, and duration of using these techniques, is the reason. Our results showed that in the face-to-face counseling group, the level of anxiety and metaworry decreases significantly after the intervention in the eighth and twelfth weeks. In line with these results, Delaram and Soltanpour conducted a study in 2012 to identify the effect of counseling in the third trimester of pregnancy on the anxiety of women on gravida 1 at the onset of labor. The results 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[34]. In a study by Akhteh and co-workers, the effectiveness of cognitive-behavioral training in stress management by face-to-face counseling method reduced anxiety and metaworry in women with recurrent miscarriages[35]. Considering the psychological aspects can follow their better and more rapid treatment. Compared with fertile and healthy women, determining the emotional problems prevalent among infertile women who have experienced recurrent abortion and providing them with counseling services parallel with medical facilities appears to be regarded as crucial. In addition, providing required training to these women using related training workshops, training packages, as well as presenting media-based information to every person in the society can remarkably help reducing these patients' problems, thus being consonant with the results of ours[35].

It can be said that in face-to-face counseling, the counselor can benefit from communication skills and its possible positive effects and improve the awareness of the person being trained. On the other hand, the training provided to these people can be effective in this promotion.

Comparison of the mean anxiety and metaworry scores in the two online and face-to-face counseling groups before the intervention and the end of eighth and twelfth weeks exhibited no significant difference between the mean score of these variables before the intervention and 8 weeks after the intervention. However, 12 weeks after the intervention, anxiety and metaworry mean scores were significantly different between the two groups. So that, the effectiveness of online counseling turned out to be more significant than face-to-face procedure. In line with the results of the present study, Saleh Moghadam and colleagues showed that, the educational films were able to significantly reduce preoperative anxiety in patients who were candidates for open-heart surgery compared to face-to-face and pamphlet training methods[36]. It is because information is easily passed on to patients through instructional and multimedia videos; therefore, for the educational film it is not far-fetched to act more effective in reducing pre-operative anxiety compared with the intervention group. In addition, Carlbring and others in 2018 conducted a meta-analysis study with the aim of comparing two methods of internet-based and face-to-face cognitive-behavioral therapy for the treatment of mental and physical disorders. They studied 2078 articles and finally concluded that there was no significant difference between the two methods [37]. Our results proved to be consistent with the results of this study.
Furthermore, the results of the present study illustrated the mean score of anxiety and metaworry not differing significantly between the studied groups before the intervention and 8 weeks afterwards; however, it shows that metacognitive counseling method is a good way to reduce the variables in both groups. Moreover, although there was no significant difference between anxiety and metaworry scores by week 8 compared to that of before the intervention, this could differentiate between the three time periods for the variables mentioned and trigger them to diminish significantly. Additionally, intragroup comparison of the results demonstrated a gradual reduction in the mean score of anxiety before the intervention and weeks 8 and 12 after the intervention in both groups; although statistically the difference was significant in both groups, the online counseling group had a greater reduction than the face-to-face one. Therefore, because the counseling method has exerted its desired effects on reducing anxiety and metaworry, and this positive effect has occurred in both groups, no statistically significant difference has been observed between the two groups at the end of week 8. Comparing the mean score of anxiety and metaworry between two groups at the end of 12th week indicated the changes in the mean scores being significantly different between the two groups thus revealing the effectiveness of online procedure being more evident compared to face-to-face counseling. The reason for this is likely persisting on online learning that occurs with its greater impact on memory or as a more attractive way for presenting educational content.

Comparison of mean satisfaction scores of counseling method at the end of the eighth and twelfth weeks showed that in both groups, satisfaction with the counseling method was significant, so that the level of online counseling satisfaction was higher than face-to-face counseling. Our results also showed that the intervention performed significantly increased the overall satisfaction score in 12th week compared to 8th week in the online and face-to-face counseling groups. Moreover, a study by Rufinigo and co-workers (2009) revealed that film-based training could reduce anxiety and increase patient satisfaction[38]. In addition, Ghalibaf and colleagues (2015) reported that 93.3% of respondents being very satisfied with online counseling[39]; this is also consistent with the results of ours. In justifying these findings, it can be maintained that metacognitive counseling through the internet and online space provides the therapist a high possibility and flexibility in terms of location and time, so could be replaced the need to meet and solve the problem in face to face method. The ease of treatment from any place and time can potentially be addressed in several ways including financial phase, time, and energy. Online counseling, contrary to face-to-face method, can extend the therapy relationship between therapist and counselor and protect clients from possible inflections resulting from therapeutic relationship disconnections. All of these factors increase the client’s satisfaction compared with face-to-face counseling[40, 41].

As a result, it can be concluded that metacognitive counseling has been effective on anxiety and metaworry for the reason that an individual considers the need to worry as a kind of coping strategy; in other words, she fails to come up with breaking the chain of anxiety and thus regards worry as a factor in avoiding failure in the adaptation process[35]. The reason why both anxiety and metaworry decreased in this study is that in infertile women with frequent miscarriages, the factor for inducing anxiety and subsequent metaworry is highly evident [26] Metaworry is, in fact, the result of anxiety and stress so that
by lowering the level of anxiety, it is possible to control metaworry as well [42]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 metaworry are continually reduced. The ineffective attitudes of women with recurrent miscarriages in relation to infertility and miscarriage play an important role in creating a negative view of oneself [43] Given the fact that metacognitive counseling mechanism helps people identify situations that cause anxiety and stress, gain a better understanding of them, identify their strengths and weaknesses, and then deal with coping strategies, it seems that metacognition is a good psychological technique for women with miscarriages [11].

The reason for the effectiveness, continuity, and satisfaction of the metacognitive online counseling method in the present study can likely be that online counseling is a new form of distance counseling emerged with the development of information and communication technology. Distinctive features of the online counseling method include the ease of transmitting information and its attractive and exciting visual and auditory nature, which, to some extent, removes the limitations of the real world. On the other hand, cost effectiveness is considered as one of the important advantages of remote counseling programs[44, 45]. As the concluding remarks, the researcher believes people who have higher experience in dealing with the world of internet and virtual communications can better appreciate this treatment method. Today, onlining (or the presence in the online space) in the daily lives of most Iranian women is of paramount importance; for this reason, online counseling can prove to be more effective and satisfying than face-to-face techniques due to its special benefits and attractiveness.

Limitation of the present study was women awareness of their intervention because of counseling intervention nature, thus blindness was not applicable.

Conclusions

Based on the results of the present study, it can be concluded that although both face-to-face and online methods have been able to significantly reduce the anxiety and metaworry of women with a history of miscarriage, online counseling was more effective, more sustainable, and more satisfying. Considering corona virus 19 outbreak, the importance of distance online counseling to help who needed these services is crucial. This may be due to the significant impact of online space as well as attractiveness, cost-effectiveness, the possibility of readily designing questions and dealing with concerns compared with other techniques, thus providing the ease and effectiveness of counselor-client interaction.

Abbreviations

Abbreviation was not used in this manuscript.

Declarations

Ethics approval and consent to participate
The study protocol was approved by the ethics committee of 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). Written informed consent was obtained from all women participating in the study.

Consent for publication

Not applicable.

Availability of data and material

The authors are not permitted to share sources of data publicity without authorization of the Vice Chancellor for Technology Research of Shahid Sadoughi University of Medical Sciences except being necessary.

Competing interests

All three authors MG, TF and HZ including MG is a midwifery counselor, TF (as director of research) is a faculty member of Shahid Sadoughi University of Medical Sciences, and HZ is a faculty member of Psychology Department in Yazd University declare they have no competing interests.

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Authors’ contributions

MG contributed in study design, sampling, intervention and findings interpretation of findings. TF (as director of research) selected study topic and cooperated in study design, supervised on data collection, sampling, intervention and performed data analysis and interpretation. HZ contributed in providing content of consulting sections and data analysis and interpretation. MG, TF and HZ participated in manuscript writing.

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**Figures**

![Diagram Consort](image)

**Figure 1**

Diagram Consort
Supplementary Files

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