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Reducing the Anxiety and Concern of Pregnant Women during Antenatal Anomaly Screening Tests: A Systematic Review

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Abstract

Objectives: Although antenatal anomaly screening tests (AAST) provide valuable information about fetal health, performed to prevent the birth of children with chromosomal abnormalities, uncontrolled stress while performing such tests may negatively affect the mother's mental health. This study aimed to systematically review clinical trial studies in which reducing pregnant women's anxiety and concern in the process of performing AAST was among their objectives.

Materials and Methods: In this systematic review, six electronic databases (Scopus, Cochrane Library, Science Direct, PubMed, Google Scholar, and CINAHL) were searched. Data extraction was performed through randomized controlled trials (RCTs) in English, which the core fell onto designing an intervention to reduce pregnant women's anxiety and concern associated with performing AAST.

Results: Out of the 1946 studies, six were included in this systematic review. In most studies, a positive impact on knowledge and satisfaction with the information received was observed. However, no effect was reported regarding decreasing or increasing the anxiety and concern of pregnant women in the process of performing AAST. Studies were heterogeneous in terms of intervention type and gestational age of participants.

Conclusions: Interventions aimed at providing pregnant women with specific information about prenatal screening for chromosomal abnormalities have no impact on reducing their anxiety and concern. Therefore, designing educational-psychological interventions to prevent and reduce anxiety and concern of pregnant women in this period is recommended.

Keywords: Pregnant women, Antenatal screening, Anxiety, Systematic review

Introduction

Today, antenatal anomaly screening tests (AAST) are among routine pregnancy cares in most countries. According to the American College of Obstetrics and Gynecology guidelines, taking these tests is emphatically recommended to all pregnant mothers. In addition, the need to provide the conditions for informed choice is accentuated (1). An informed choice refers to an option for each person, which causes them more satisfaction and less anxiety about their decision. To make informed decisions, individuals may seek information about the experience of a particular health condition and how individuals cope with a negative experience (2).

Approximately 5 out of every 100 pregnant women who undergo the first-trimester screening tests receive high-risk results. Almost 3 out of every 100 women, who acquire high-risk results and take diagnostic tests, expect children with Down syndrome (3). Hence, most women experience unreasonable anxiety in the process of performing such tests (4). Parents go through challenging times while anticipating test results since they are concerned about the unfavorable results (5). Individuals who receive high-risk results experience increased anxiety and stress as they must undergo diagnostic tests, which increases the risk of miscarriage (6). Health care providers do not appear to devote enough time to train pregnant women before screening tests and ultrasounds, leading to concern and reduced informed choice among parents (5,7-9).

Although screening tests are ultimately advantageous in improving community health and reducing the costs of caring for children with chromosomal abnormalities, uncontrolled stress during this period might adversely affect the mother's mental health. Studies indicate that women's anxiety levels significantly increase after receiving a positive result in a screening test (10). In some mothers, the anxiety persists even after receiving a normal result to screening and/or diagnostic tests (11). Pregnancy anxiety can increase the incidence of postpartum depression (12), preterm labor, and low birth weight (13,14). Postpartum depression has a high prevalence (56.9%) in Iranian society (15), so interventions are needed to alleviate these concerns. Reducing anxiety at this critical stage of a woman's life can influence the life quality and prenatal health.

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Key Messages

- Providing pregnant women with information about AAST can increase their knowledge and satisfaction and make informed choices.
- Interventions to provide specific information about AAST to pregnant women do not decrease their anxiety and concern.

Studies show that providing information to pregnant women about prenatal screening for Down syndrome can improve their knowledge, bring satisfaction, reduce anxiety and impact their ability to make informed choices (16,7). To date, no systematic review has been conducted to investigate the effect of interventions on reducing maternal anxiety and concern in the AAST process. This study aimed to review articles that compared the impact of different interventions to provide required information to pregnant women using the randomized controlled trial to reduce their concern and anxiety during AAST.

Materials and Methods

Search Strategy

The interventions and programs were reviewed in this field to determine the appropriate intervention to reduce the anxiety and concern of pregnant women in the AAST process. Accordingly, Scopus, Cochrane Library, Science Direct, PubMed, Google Scholar, and CINAHL databases were searched between 2000 and 2020. This search process used appropriate keywords based on MeSH (Medical Subject Headings index) guidelines, and various keywords were employed (Table 1). This review was based on a prospective protocol and the PRISMA statement (Figure 1) (18).

Study Selection

The following search strategy based was identified on PICOS (Patient, Intervention, Comparison and Outcome):

- *Population*: Pregnant women who were requested for AAST in the first or second trimester;
- *Intervention*: Interventions to reduce the anxiety and concern of pregnant women in the process of performing AAST;
- *Comparison*: The intervention group was compared with the control group who received routine care;
- Outcome: Concern and anxiety of pregnant women;
- *Study Design*: RCTs.

First, all articles extracted from the databases were transferred to EndNote software, and duplicate articles were removed. Afterward, two authors independently evaluated the remaining articles based on inclusion and exclusion criteria. Through reading the title and summary of articles, suitable decisions were made regarding inclusion and exclusion criteria. In the absence of satisfying explanations in the article's abstract, the inclusion criteria were reviewed and discussed by three authors through reading the full text of the paper until a consensus was reached. If required, pertinent authors and/or study sponsors were contacted for additional information.

Inclusion Criteria

1. Articles that recruited pregnant women in the first and second trimester;
2. Articles in which designing an intervention to reduce pregnant women's anxiety and concern associated with performing AAST was one of their objectives;
3. Articles in which anxiety and concern as one of the outcomes of the trial;
4. Articles conducted used the RCT method and the control group;
5. English articles.

Exclusion Criteria

1. Studies had a non-experimental (cross-sectional, case-control, case reports, case series, cohort, and other retrospective studies) design;
2. Studies had a quasi-experimental (non-randomized or uncontrolled) design;
3. Unable to obtain adequate details of study methodology or results;
4. Qualitative and mixed methods studies;
5. Studies were represented only as abstracts with no complete description of findings;
6. On-going clinical studies;
7. Review papers, letters to editor and editorials, protocol studies, guidelines, reports, booklets, books, and panels.

We also went through the references and the citation lists of relevant publications. According to this approach, six articles were reviewed, one of which was identified by searching the list of references.

Quality Assessment

All included studies were assessed for quality and risk

Table 1. Mesh Terms Were Used in PubMed Search

Patients				Interventions		Outcome
Pregnant woman OR Pregnancy	AND	Chromosomal screening test OR Antenatal anomaly screening test OR Fetal anomaly screening OR Down syndrome	AND	Psychological intervention OR Educational intervention OR Educational model OR Information dissemination OR Informed consent OR Information management OR Patient education OR Decision aid OR Counseling intervention OR Management	AND	Worry OR Anxiety

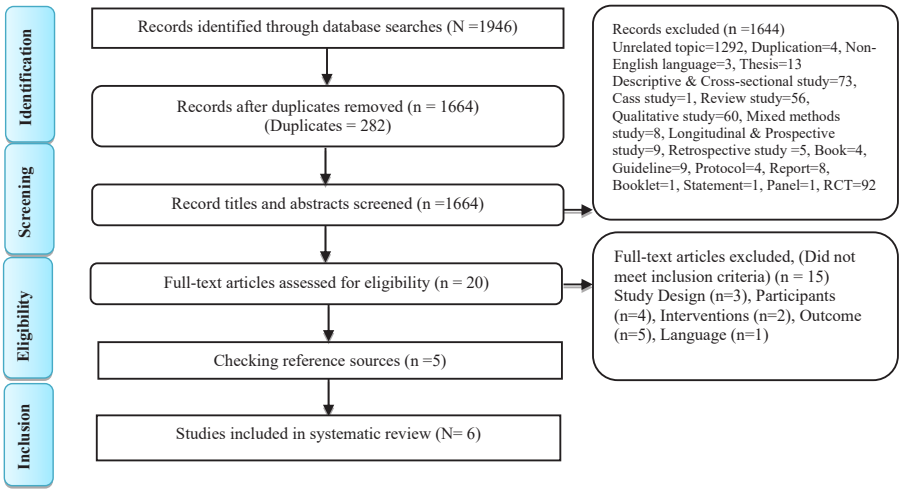

Figure 1. Study Flow Diagram.

of bias using the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies. The EPHPP came into effect in 1998 based on the Ontario Ministry of Health and Long-Term Care fund. For six components, including study design, selection bias, methods of collecting data, confounders, withdrawals, dropouts, and blinding, the risk of bias was examined at the study level (Table 2). Each component was rated on a three-point scale: strong, moderate, or weak, which led to an overall methodological rating as follows, strong (without WEAK ratings), moderate (one rating as WEAK), or weak (two or more WEAK ratings). Thomas and co-workers assessed the validity and reliability of this tool through an iterative process and test-retest reliability, respectively. Based on the results, kappa values of 0.74 and 0.6 were achieved for the agreement between the two reviewers (19). Two authors (MA and ZKH) independently reviewed each study for quality and bias, and the evaluations were compared and discussed between authors.

Data Extraction

Descriptive information of all studies was presented in Table 3 and showed the study characteristics, participants, intervention(s), methods, and results. The data extraction from relevant studies was performed using a CONSORT checklist, which included quality factors related to the RCTs designs and key factors such as trustworthiness and generalizability (20).

Results

After removing duplicates, titles and abstracts of the 1946 papers were evaluated independently by MA and PA in terms of inclusion and exclusion criteria. Full texts of 20 studies were considered separately by FF, ZKH, and MA for further review, and probable differences in the perception were discussed. Out of these 20 studies, 15 were excluded. In reviewing the quality of articles, three articles were of high quality, and three papers were of medium quality.

Study Characteristics

The studies were published in international peer-reviewed journals between 2001 and 2016. All studies were conducted in a single country. Four of the six studies were conducted in Europe (two in the UK, one in Sweden, and one in the Netherlands), one in Australia, and one in Asia (Taiwan). All studies contained well-defined and clinically relevant descriptions for the review. The study population included pregnant women in the first or second trimester of pregnancy who participated in the AAST procedure. All studies were designed with one or more interventions to reduce anxiety and improve the information level. Various outcome measurements were

Table 2. Quality Assessment of Each Study Using the EPHPP Quality Assessment Tool for Quantitative Studies

Author (Ref)	Selection Bias	Study Design	Confounders	Blinding	Data Collection Methods	Withdrawals and Dropouts	Overall Quality Score
Hewison et al (21)	Moderate	Strong	Strong	Moderate	Strong	Moderate	Strong
Bekker et al (22)	Moderate	Strong	Strong	Moderate	Weak	Strong	Moderate
Nagle et al (23)	Moderate	Strong	Strong	Weak	Strong	Moderate	Moderate
Hwa et al (24)	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong
Bjorklund et al (25)	Weak	Strong	Strong	Moderate	Strong	Strong	Moderate
Beulen et al (26)	Strong	Strong	Strong	Moderate	Strong	Strong	Strong

Table 3. Description of Included Studies

Author, Country (Ref)	Gestational Age	Study Participants	Interventions	Outcome variables/ Measurement tool	Results
Hewison, England (21)	12 wk	Case group (n=359) Control group (n=420)	A video was sent to the intervention group at their home before a visit for their admission to the hospital. All women in both groups also were provided with information about screening in the form of a leaflet before admission.	Information about Down syndrome screening, concerns about abnormalities in the infant, and anxiety. Concerns about screening tests and more common concerns about pregnancy and delivery. / Multiple-choice questions to measure knowledge, concerns, and anxiety, HAD scale.	Using Down syndrome screening video increases knowledge; however, it has no impact on the rate of screening uptake, concern about abnormalities in the baby, and anxiety.
Bekker, England (22)	14-15 wk	Case group (n=50) Control group (n=56)	This study aimed to evaluate decision analysis as a strategy that facilitates decision-making concerning antenatal diagnosis for Down syndrome in women with a positive maternal serum screening result. Routine consultation was provided for the control group.	Decision on the test, perception of the risk, Subjective expected utility, Information, Quality of consultation, decisional conflict, anxiety, and perceived effectiveness and directivity of consultation information. / STAI, Decisional Conflict Scale, IDM, multiple-choice items about prenatal tests for Down syndrome.	In the intervention group, higher levels of informed decision-making, more real perceived risk, and lower levels of decisional conflict were observed. Moreover, the intervention did not impact knowledge, subjective utility, reduction, or increased anxiety levels.
Nagle, Australia (23)	≥12 wk	Case group (n=167) Control group (n=171)	The effectiveness of a decision aid for prenatal testing of fetal abnormalities was compared to a pamphlet in supporting women's decision-making. The decision aid was a 24-page booklet with a worksheet that provided information about the tests. This decision aid consisted of four scenarios of other women's experiences.	Informed choice and decisional conflict. Anxiety, depression, views on the pregnancy/ fetus, and appropriateness of the resource. / The MMIC, DCS, the short version of the State, and The Edinburgh Postnatal Depression Scale.	Women in the intervention group were more likely to make informed decisions. The majority of women in the intervention group had a "good" level of knowledge. There was no difference in anxiety, depression, or acceptability measures.
Hwa, Taiwan(24)	15-21 wk	Case group (n=96) Control group (n=97)	Researchers provided comprehensive individual genetic counseling about serum screening for Down syndrome for women in the experimental group; however, the control group offered routine care.	The perceived level of understanding of serum screening for Down syndrome and independent decision-making for serum screening. Levels of anxiety and depression. / Multiple choice questions modified based on earlier reports, The STAI, and TDQ.	A higher perceived level of perception of antenatal serum screening for Down Syndrome was observed in participants of the experimental group. A more significant number of women in the experimental group decided to make decisions on their own whether to undertake screening tests. Levels of anxiety and depression did not vary between the two groups.
Bjorklund, Sweden (25)	<11 wk	Case group (n=184) Control group (n=206)	Doctors provided information about prenatal screening for both groups at about ten weeks of gestation, and the different methods were clarified. The intervention group watched a video explaining medical facts and interviews with parents who reflected on their values, choices, and experiences.	Worry and anxiety. / STAI, the Cambridge Worry Scale (Two single questions were selected).	No difference was found between the groups in state and trait anxiety. Regarding concerns about the probable abnormalities in the baby and the labor, no differences were observed between the groups. The women stated that watching the video increased their worry rather than decreasing it.
Beulen, Netherlands (26)	<22 wk	Case group (n=130) Control group (n=131)	Standard pregnancy care was provided for the control group. In addition, they gained access to a web-based multimedia decision aid on prenatal testing. According to IPDAS standards, the web-based multimedia decision aid was developed. Researchers designed infographics, 2D and 3D animations for this decision aid to enlighten the prenatal testing process, the risk concept, the difference between low-risk and high-risk outcomes, and the important characteristics and test procedures of existing prenatal tests.	Informed decision-making concerning prenatal testing. Secondary outcomes: knowledge, attitudes, prenatal test utilization, value-consistency, decisional conflict, decision regret, and anxiety/ the Multidimensional Measure of Informed Choice, DCS the DRS, the six-item short form of the state scale of the STAI	Women in the intervention group obtained significantly higher scores on the knowledge scale. No significant difference was in the proportions of women with positive or negative attitudes toward undertaking prenatal tests. Maternal age, high educational level, and access to web-based multimedia decision aid are the most significant independent predictors of informed decision making. No statistically significant differences were found in decisional conflict, decision regret, or anxiety.

HAD: Hospital anxiety subscale and depression; STAI: Short-form state-trait anxiety inventor; IDM: Informed decision-making; MMIC: Multidimensional measure informed choice; DCS: Decisional conflict scale; STATE: Spielberger state-trait anxiety inventory; TDQ: Taiwanese depression questionnaire; DRS: decision regret scale; IPDAS, International Patient Decision Assistance;

used in the studies; however, the majority included one or more of the following criteria: knowledge, satisfaction, anxiety, depression, decision-making involvement, informed choice, and concern. Randomization was on served in all studies. Randomization methods in these studies included the use of sealed and opaque envelopes (22,25), the use of even or odd file numbers (21), and computer-generated randomization (23,26). In one study, the randomization method was not described (24). The Allocation Concealment mechanism was described in two studies (21,23). Only in one study was participant blinding performed (22), and except for two studies (22,23), other studies did not comment on the blinding of the researcher or participants. However, based on the EPHPP quality assessment tool, these articles received a moderate score in the blinding section. No single study indicated that pregnant women in the control or intervention groups received similar treatment information, except for the intervention. The number of pregnant women who participated in these studies varied widely from 2000 (21) to 117 pregnant women (22). The gestational age of women enrolled in the studies ranged from less than 11 weeks to 21 weeks. In some studies, there was a long interval from data collection to publication, as in two studies; there was more than a 4-year interval (22,24). The only difference between the two groups in all studies was the intervention performed. Anxiety was measured in all studies, and the full (24,25) or short forms of (22,23,26) State-Trait Anxiety Inventory (STAI) tool was frequently used. Only one of the three studies measured state anxiety (23). STAI is a validated, 40-item questionnaire to measure "state anxiety" (20 items) that is a temporary condition of anxiety, and "trait anxiety" (20 items) which refers to a more general long-standing quality of anxiety. Respondents' scores for each scale are rated on a 20-80 ranking base; higher scores are positively associated with higher anxiety levels (27). State anxiety varies gradually; however, trait anxiety does not fluctuate (10). The short version of the STAI is also valid (28). Comparison between studies can be facilitated by extensive use of STAI. Other forms of validated scales were also used in other studies; for instance, the Cambridge Worry Scale (25) and the Hospital Anxiety and Depression Scale (HADS) (21). In one of the studies (25), only two questions were taken from the Cambridge Concern Scale to measure anxiety during pregnancy. In addition, two more studies measured depression (23,24). Only two studies measuring and comparing the level of anxiety and concern were among their primary outcomes (21,25). In other studies, it was categorized as their secondary outcomes.

Results Based on the Type of Intervention

Decision Aids

Decision aids are the interventions designed to help patients with specific and informed choices, provide information about the risks, benefits, and consequences of current choices, and help to clarify the congruence between patients' decisions and personal values (29).

Face-to-Face Decision Aid Sessions

In one study, during a counseling session, while taking advantage of a decision tree representing the options and consequences of diagnostic tests, researchers continued to discuss and consult with pregnant women to find out whether they decide to perform diagnostic tests or wish to have a child with Down syndrome (22). Their intervention was a decision analysis to help pregnant women with high-risk AAST outcomes decide. Although this intervention left no effect on reducing or increasing anxiety, knowledge, and mental well-being, it led to higher informed decision-making, more real perceived risk, and lower decision conflict.

Distance Decision Aids Sessions

The other two studies used indirect decision aids with a 24-page booklet (23) and web-based multimedia (26). There was no change in anxiety and depression levels and acceptance of performing tests among women to whom the booklet was posted to their home compared to the control group. However, the intervention group made a more informed decision and profited from a good knowledge level. Anxiety in pregnant women who had access to web-based multimedia did not differ from women in the control group. Despite achieving higher scores on the knowledge scale, there was no difference in decisional conflict and decision regret among women in the intervention group compared to those in the control group.

Consultations

One study examined the effectiveness of counseling (24). The women in the intervention group were provided with comprehensive individual genetic counseling on serum screening for Down syndrome, and the control group received routine care. Anxiety and depression did not vary between these two groups; yet, participants in the experimental group had a higher perception of prenatal serum screening for Down syndrome and made more informed decisions.

Audiovisual Information

Two studies investigated the use of videotapes information (21,25). One study indicated that Down syndrome screening videos could improve knowledge without increasing concern, anxiety levels, and uptake rate (21). Another study, which investigated the effect of watching an educational video showing a description of medical facts and interviews with parents about their values, choices, and experiences associated with screening tests on the intervention group, found no difference between state and trait anxiety. Furthermore, no difference was observed between these two groups regarding concern

about the possibility of a complication in the baby and labor. Women stated that watching the video increased their anxiety rather than reducing it (25).

Discussion

This systematic review demonstrates that interventions to provide information about AAST can improve pregnant women's knowledge and satisfaction level and impact their ability to make informed choices. However, it was revealed that they did not affect reducing anxiety levels. Only in two studies, investigating pregnant women's anxiety and concern was one of the primary objectives. In these studies, screening tests were predominantly provided rather than helping pregnant women reduce anxiety and concern in AAST.

There was heterogeneity among the studies regarding the intervention type and the outcome measured. A variety of interventions (from personal counseling to Information and Communication Technology interventions) were employed. Conclusion criteria and clinical settings widely varied among studies. There are significant socio-cultural differences in countries that offer private health systems instead of public health systems, leading to complications in comparisons throughout the investigations. Diverse screening methods (first-trimester screening, second-trimester screening, and non-invasive prenatal testing) were used, which affected the intervention content and gestational age to access the intervention. Most studies lacked detailed information on specific methodological issues such as randomization. Few studies had used computer-generated randomization, which is the current gold standard. To ensure robust methodological studies, RCTs should follow the guidelines outlined in the CONSORT statement (30). The sample size in all studies seemed sufficient to demonstrate the effect size. In only one study, participants were kept blinded (22). Lack of blindness can lead to bias in cases where the results may be influenced by participants, caregivers, or evaluators aware of what intervention has been proposed to the patient (31). If participants distinguish that they receive additional information and are asked to complete a questionnaire, there is a risk that they strive to gain knowledge compared to the control group.

On the other hand, women in the control group may be disappointed in not receiving any additional information and may become demoralized to acquire knowledge. Overall, blinding patients are considered so challenging. Another significant issue is determining dropout rates. In most studies, the authors described both the numbers and reasons for withdrawals and dropouts. Anyway, only Hwa and colleagues (24) analyzed data according to intention-to-treat and therefore considered scores for all participants in the analysis - including the dropouts. Similar to selection bias, we assume that dropouts may also affect anxiety and worry levels. It should be noted that in some studies, there was an interval between data collection and publication. This may cause the figures to be obsolete at the time of publication.

Women's satisfaction is best achieved when their expectations are met rather than merely raising their knowledge level. Accordingly, it is crucial to be aware of the pregnant women's expectations from their information before initiating the intervention. The most positive outcomes occur when the caregiver uses decision support techniques (16). In decision-making, helping individuals recognize their preferences and the probable advantages and disadvantages is crucial (32) since informed patients are required for effective health care (33). Pregnant women can be less involved and stressed out in decision-making and benefit from increased personal well-being by improving their knowledge level.

Taking prenatal screening tests can cause stress and increase anxiety and concern in all women (10). A systematic review found that the preparation of individuals for medical interventions was associated with reduced anxiety. They stated that the types of information provided looked so beneficial in this area consisting of two parts: 1. Instructions concerned with relaxation techniques include receiving specific information about methods, describing their feelings and/or the feelings they might experience, and techniques to help them cope with "health threats"; 2. Information provided on women's demands while making an informed choice regarding tests. Knowledge may not reduce anxiety to the extent that it improves decision-making. Successful studies in increasing knowledge have not reported an increase in anxiety. Anxiety is undoubtedly elevated in women who receive positive screening results. Yet, there is no evidence that the negative screening results have a beneficial effect on anxiety (34).

We need to have the means to identify why some women experience extremely high anxiety levels, preventing them from making effective and thoughtful decisions. Subsequently, we are expected to examine the complex feelings, including anxiety, excitement, nervousness, and delight, that indicate pregnant women's experiences of pregnancy and prenatal care. To address these intricate issues, we propose that future studies apply a combination of qualitative and quantitative perspectives on the concern and anxiety of pregnant women in the AAST process. It is unfortunate that, according to our study, from 2000 to 2020, no RCT studies were conducted with psychological or educational-psychological intervention to reduce or prevent pregnant women's anxiety in the AAST procedure; Based on the findings of this systematic review, we recommend such studies to researchers and hope that this issue will be put on top of health policy makers' agenda in different countries.

Strengths and Limitations

This review's strength includes a systematic and rigorous approach to identifying and evaluating studies on

reducing pregnant women's anxiety and concern in the AAST process. Their inclusion provided medium and high-quality studies. However, it can be assumed that some articles were missed out despite implementing a comprehensive and precise search strategy for peer-reviewed literature within the main databases. Another positive aspect of this study is the application of standard instruments through most of the included studies. Despite all its advantages, one of the limitations of this study was concerned with the majority of interventions performed in developed countries (four in European countries), which weakens the generalizability of the results. The small number of available studies examining the effect of an intervention on reducing the anxiety and concern of pregnant women in the AAST process can be considered another limitation.

Conclusions

This systematic review showed that most of the interventions mainly involved providing information to pregnant women on antenatal anomaly screening. Even though those interventions could improve both the knowledge and satisfaction level of pregnant women and influence their ability to make informed choices, none of them could effectively reduce the anxiety and concern of pregnant women involved. Of all these studies, there was no study designing a psychological intervention to reduce the stress and anxiety of pregnant women at this stage of pregnancy. Future studies should prioritize psychological or educational-psychological interventions to reduce the anxiety and concern of pregnant women in the AAST process.

Authors' Contribution

MA, ZKH, FF, SH ideated the study. MA, ZKH, FF, and PA identified and evaluated the potential studies. MA and PA drafted the paper. ZKH, FF, and SH revised the draft paper. All authors approved the final copy of the manuscript.

Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

The study protocol has been approved by the Ethics Committee of the Tehran University of Medical Sciences, Tehran, Iran (Code: IR. TUMS. FNM.REC.1397.099).

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