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OPEN PEER REVIEW

Effectiveness of an Internet-Based Transdiagnostic Unified Protocol Intervention for the Treatment of Depressive and Anxiety Disorders in Women with Threatened Abortion: A Feasibility Study

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

More about open peer review: brieflands.com/knowledgebase/opr

Contents

1 **Original submission** Referee 1, Editor-in-Chief 2
2 **Revision 1** Editor-in-Chief 5
Authors' reply to reviewers 6
Reviewer and editor comments 15

1 Original submission

2 comments · 6 Jun 2024 – 1 Jul 2024

Referee 1 Reviewer

MAJOR REVISION 6 Jun 2024

I've reviewed your paper and offered constructive feedback to enhance its impact. Kindly consider my suggestions to improve clarity and effectiveness. Best wishes.

Abstract:
1. Provide more detail on the selection criteria for participants, including demographic information such as age, gestational age, and previous mental health history, to enhance the study's reproducibility and generalizability.
2. Provide more detail on the selection criteria for participants, including demographic information such as age, gestational age, and previous mental health history, to enhance the study's reproducibility and generalizability.
3. Provide effect sizes with confidence intervals to enable readers to assess the magnitude and precision of treatment effects more accurately.
4. Provide practical recommendations for clinicians working with pregnant women experiencing anxiety and depressive symptoms, based on the study findings and clinical experience.

background
• Define threatened abortion (TA) clearly, specifying the gestational period during which it occurs and the diagnostic criteria used in clinical practice.
• Provide a brief explanation of the physiological processes and potential causes of TA to enhance readers' understanding of the condition.
• Expand the review of literature to include recent epidemiological data on the prevalence of TA and its associated complications.
• Include studies investigating the psychological impact of TA on women's mental health, particularly focusing on anxiety and depressive symptoms.
• Provide a more detailed discussion of the risk factors associated with TA, including maternal age, medical history, lifestyle factors, and environmental stressors.
• Discuss the mechanisms through which these risk factors contribute to the development of TA, considering both biological and psychosocial perspectives.
• Emphasize the psychological consequences of TA on maternal mental health, highlighting the prevalence of anxiety and depressive symptoms in affected women.
• Include evidence from longitudinal studies to elucidate the long-term effects of TA on maternal well-being and quality of life.
• Provide a rationale for employing psychotherapy as an intervention for women with TA, drawing on theoretical frameworks and empirical evidence supporting the efficacy of psychological interventions in perinatal mental health.
• Discuss the potential benefits of psychotherapy in mitigating the psychological distress associated with TA and preventing the onset of more severe psychiatric disorders.
• Introduce internet-based psychotherapeutic interventions as a novel approach to addressing perinatal mental health issues, including depression and anxiety during pregnancy.
• Summarize the advantages of internet-based Cognitive Behavioral Therapy (iCBT) and the Unified Protocol (UP) in terms of accessibility, acceptability, and effectiveness in diverse populations.

method
• Provide more detailed descriptions of the development process of the iCBT-Specific and transdiagnostic

treatment programs, including the rationale for specific intervention components and adaptations made for the TA population.
• Clarify how potential participants were screened for eligibility and ensure consistency in the application of inclusion and exclusion criteria across recruitment sites.
• Justify the choice of effect size and statistical power used in the sample size calculation, considering the specific aims and hypotheses of the study.
• Provide references or empirical evidence supporting the selected effect size estimate to enhance the credibility of the sample size determination.
• Clarify the rationale for selecting the Mini-International Neuropsychiatric Interview (MINI), Brief Symptom Inventory-18 (BSI-18), System Usability Scale (SUS), and Client Satisfaction Questionnaire (CSQ-8) as outcome measures.
• Provide information on the psychometric properties and validation status of the Persian versions of these measures to ensure their suitability for use in the study population.
• Specify the statistical methods used for data analysis, including descriptive statistics, repeated measures analysis, and analysis of covariance (ANCOVA).
• Include information on ethical approval obtained from relevant institutional review boards and provide assurance of compliance with ethical guidelines for research involving human participants.

Results
1. Provide a concise summary of the demographic characteristics of the study population, highlighting key findings such as the mean age, educational background, and gestational age.
2. Consider presenting demographic data in a descriptive narrative rather than within a table to enhance readability.

Discussion
• Be more specific when discussing the feasibility, acceptability, and effectiveness of the two treatment methods. Provide detailed descriptions of the assessment criteria used and how they were measured.
• Critically evaluate the strengths and limitations of the study, including aspects such as study design, sample size, follow-up procedures, and potential biases.
• Discuss any unexpected or contradictory findings and provide possible explanations or interpretations based on existing literature.
• Compare and contrast the methodologies, findings, and implications of previous studies with the present study to contextualize your findings better.
• Offer specific recommendations for future research based on the limitations identified in the current study.
• Suggest potential areas for further investigation, such as exploring alternative treatment modalities, conducting longitudinal studies, or expanding the sample population to enhance generalizability.
• Summarize the key findings of the study concisely and emphasize their significance in the broader context of mental health treatment.

Editor-in-Chief MAJOR REVISION 1 Jul 2024

Thank you for submitting your manuscript for consideration for publication in the Iranian Journal of Psychiatry and Behavioral Sciences. Your paper has been evaluated by external peer reviewers. Please revise your manuscript according to the reviewers' comments.

After revision, authors are obliged to upload a Word file containing the reviewers' comments and their point-by-point responses to all comments.

Besides, please pay attention to the word count limitation:
Word count limits are declared in this link: http://kowsarpub.com/en/index.php/services/for-authors/895-word-count

We look forward to receiving your revised manuscript. Thank you for sending your work to the Iranian Journal of Psychiatry and Behavioral Sciences. The revised text must be highlighted in the full manuscript file.

2

Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Editor of IJ Psychiatry and Behavioral Sciences

Thank you for chancing us to revise the manuscript ID:147292 "Effectiveness of an Internet-based Transdiagnostic Unified Protocol Intervention for the Treatment of Depressive and Anxiety Disorders in Women with Threatened Abortion: A Feasibility Study."

We revised the paper based on the valuable comments of the Reviewer. We addressed all comments point by point and answered clearly the concerns. We also highlighted the changes with yellow color.

I hope we could address all of your recommendations.

With warm personal regards,

Corresponding Author

Reviewer 1

به نام خدا
با تشکر از زحمات تون

پاسخ: ممنون از پیشنهادات ارزشمندتان که منجر به غنی تر شدن این مقاله شد.

لطفا سال و مکان مطالعه در چکیده ذکر شود.

پاسخ: سال و مکان در چکیده گذاشته شد.

کلید واژه مش باشد.

پاسخ: کلید واژه ها چک شد طبق مش می باشد.

معیارهای ورود و خروج ذکر شوند.

پاسخ: معیار های ورود خروج در قسمت شرکت کنندگان (3.1) ذکر شده است و به صورت هایلایت مشخص شد.

درمان شناختی رفتاری درمانی روتین برای اختلالات خلقی هستند چرا در این مطالعه درمان دوم بر این درمان برتری دارد؟_

پاسخ: نتایج این مقاله نشان داده است که هر دو درمان iUP و iCBT-Specific treatments از سهولت و مقبولیت در حد متوسط به بالا برای زنان تهدید به سقط برخوردار هستند. این دو مدل از نظر سهولت و مقبولیت بر یکدیکر برتری ندارند. همچنین، هیچ یک از دو درمان iUP و iCBT-Specific treatments از نظر اثربخشی بر یکدیگر برتری نداشتند. بخشی از نتایج به شرح زیر است:

Results: Both the iUP and iCBT-Specific models demonstrated high acceptability, and the average feasibility of treatment was above average for both models. In terms of acceptability and feasibility of treatment for women with TA, neither model proved to be superior (all p > 0.05). Also, in terms of improving depression and anxiety, there was no significant difference in the effectiveness of iUP and iCBT-Specific treatments (respectively p =0.146, Eta=0.027 and p =0.221, Eta=0.019)

حجم مقاله کمتر شود.

پاسخ: از قسمت بحث کم شد.

منابع 2024 و 2025 اضافه شوند.

پاسخ: دو منبع 10 و 11 تغییر یافت و جدید تر شد(با سالهای 2022 و 2024 جایگزین شد)

بحث طولانی است باید به نتایج مطالعه به ترتیب و نیز به شواهد همسو و ناهمسو اشاره شود.

پاسخ: قسمت بحث تعدیل شد و به دنبال نتایج مطالعه، مطالعات همسو و ناهمسو اشاره شد. نتایج همسو و ناهمسو هایلایت شد.

:Reviewer 2
With thanks and appreciation for your time and effort in writing the manuscript. Please find .my comments below
Response: Thank you for valuable comments. We improved the paper according you .suggestions

Comment 1: Are the patients randomly assigned between the two groups? In this case, the .type of study is not semi-experimental

Response: The design of this research is semi-experimental and of pre-test-post-test .type with a control group and the available samples were selected

Paul et.al (2015) in their books (Chapter 7: None experimental Research) defined :quasi-experimental research as below [1]

The prefix *quasi* means "resembling." Thus quasi-experimental research is research that resembles experimental research but is not true experimental research. Although the independent variable is manipulated, participants are not randomly assigned to conditions or orders of conditions (Cook & Campbell, 1979).[2]

Research Methods in Psychology - 2nd Canadian Edition Paul C. Price, Rajiv Jhangiani, & .1 I-Chant A. 2015

Cook, T. D., & Campbell, D. T. (1979). *Quasi-experimentation: Design & analysis issues .2 .in field settings*. Boston, MA: Houghton Mifflin

.Comment 2: Please describe the method of random allocation completely

Response: As explained in the previous questions, random allocation method was not .performed in quasi-experimental studies

Comment 3: Incomplete reporting of results in the abstract: The results do not provide information on the specific statistical tests or models used for comparing between two .groups, especially effect sizes, coefficients (%95 CI), and p-values

.Response: We have added specific statistical tests and models

.Comment 4: Please express the location of the study completely

:Response: We explained the location of the study as below

Pregnant patients, both inpatients and outpatients, were selected from a public hospital and two private obstetrics and gynecology clinics collaborating with this project, as described in the participants section (3.1)

Comment 5: Incomplete reporting of results: The result section provides incomplete results. It mentions some findings without giving any effect sizes or coefficients (%95 CI), especially .the results of the ANCOVA model

.**Response:** The results were presented in a more detailed explanation

Comment 6: Have the measurements been repeated twice (before and after the intervention)? Please check the Table 3. Here, the RM ANOVA model seems inappropriate, and .independent and paired t-tests (or their non-parametric equivalents) are more appropriate

Response: Thank you for your attention. Yes, our measurement was before and after the intervention. In Table 3, ANOVA was typed incorrectly. We used paired t-tests to compare the averages within the group, and we used ANCOVA to compare the two groups (between .groups)

Comment 7: The interpretation provided for the results of the ANCOVA model is not correct and needs to be modified, especially the interpretation provided for the groups. Please check them completely and present the results of the ANCOVA model including the estimated .regression coefficients (%95 CI) and p-values in a table

Response: We apologize for the mistake. The interpretation provided for the results of the ANCOVA model was modified and the description was made more complete in the .text

:Reviewer 3

با سلام و عرض ادب

با تشکر از شما بابت ارسال مقاله به مجله متاسفانه طي بررسي صورت گرفته در پژوهش هاي گذشته مشخص شد " Effectiveness of the internet-based Unified Protocol transdiagnostic intervention for the treatment of depression, anxiety and related disorders in a primary care setting: a randomized controlled trial" مقالات مشابه با پژوهش شماانجام شده است و در بیان مسئله توجیه نشده تفاوت مطالعه شما با مطالعات گذشته و مشابه در چیست؟

پاسخ: با تشکر از سوالی که مطرح کردید، فولتکس مقاله پیشنهادی بدقت مطالعه شد. مطالعه ما به چند دلیل از مقاله ی مشابه ذکر شده Timulak و همکاران (2020) متفاوت است.

Timulak L, Richards D, Bhandal-Griffin L, Healy P, Azevedo J, Connon G, Martin E, Kearney A, O'Kelly C, Enrique A, Eilert N, O'Brien S, Harty S, González-Robles A, Eustis EH, Barlow DH, Farchione TJ. Effectiveness of the internet-based Unified Protocol transdiagnostic intervention for the treatment of depression, anxiety and related disorders in a primary care setting: a randomized controlled trial. Trials. 2022 Aug 31;23(1):721. doi: 10.1186/s13063-022-06551-y. PMID: 36045387; PMCID: PMC9429701.

1. **همانطور که در ضرورت تحقیق آورده شده است، مطالعه ی ما اولین تحقیقی است که محتوای آنلاین درمان فراتشخیصی را برای زنان باردار ایرانی مبتلا به اختلال اضطرابی تهیه می کند و سهولت آن را ارزیابی میکند. سپس، درمان آنلاین UPرا با درمان سی بی تی آنلاین مقایسه می کند.**
2. **شرکت کنندگان مطالعه ما زنان باردار ایرانی فراتشخیصی در معرض تهدید به سقط هستند اما مطالعه Timulak و همکاران در مرکز مراقبت بهداشتی دوبلین ایرلند است.**

A Dublin-based primary care psychology service which is part of .the Health Service Executive (HSE) in Ireland

3. **شرکت کنندگان ما زنان تهدید به سقط با تشخیص اختلال افسردگی و یا اضطراب با مصاحبه بالینی بود اما Timulak و همکاران، بزرگسالان با علایم اضطراب و یا افسردگی براساس معیار پرسشنامه Overall Anxiety Severity and Impairment Scale (OASIS)بود.**
4. **شرایط ورود/خروج هم با مطالعه ی ما متفاوت است. مطالعه ی ذکر شده بزرگسالان بالای 18 سال که نمرات اضطراب بالای 8 بر اساس پرسشنامه ذکر شده داشتند وارد مطالعه شدند To be eligible, participants will have to have a score of ≥ 8 on the Overall Anxiety and Severity Impairment Scale (OASIS) and/or a score of ≥8 on the Overall Depression Severity and Impairment Scale (ODSIS)**

درصورتیکه مطالعه ی ما معیار ورود زنان باردار تهدید به سقط با تشخیص اختلال اضطرابی و افسردگی بر اساس مصاحبه بالینی ساختاریافته بود.

5. **نوع مداخله: در مطالعه ما ، درمان آنلاین UP با درمان سی بی تی آنلاین مورد مقایسه قرار گرفت در صورتیکه در مطالعه ی ذکر شده UP با گروه کنترل مورد مقایسه قرار گرفت.**
6. **ابزارهای مورد استفاده هم در دو مطالعه کاملا متفاوت است. در مطالعه ما از پرسشنامه های**

Brief Symptom Inventory (BSI-18) ,Client Satisfaction Questionnaire (CSQ-8) and the System Usability Scale (SUS) استفاده شد در صورتیکه در مطالعه ی ذکر شده، ابزارهای مورد استفاده OASIS , ODSIS,WSAS,GAD-7,PHQ-9 می باشد.

:Reviewer 4

I've reviewed your paper and offered constructive feedback to enhance its impact. .Kindly consider my suggestions to improve clarity and effectiveness. Best wishes

:Abstract

Provide more detail on the selection criteria for participants, including .1 demographic information such as age, gestational age, and previous mental health .history, to enhance the study's reproducibility and generalizability

Response: **Thanks for your attention, we have added these items to the abstract section.**

2. Provide effect sizes with confidence intervals to enable readers to assess the magnitude and precision of treatment effects more accurately.

Response: **We added the effect sizes with confidence intervals.**

3. Provide practical recommendations for clinicians working with pregnant women experiencing anxiety and depressive symptoms, based on the study findings and clinical experience.

Response: **We have added your suggestion to this section.**

Background

- Define threatened abortion (TA) clearly, specifying the gestational period during which it occurs and the diagnostic criteria used in clinical practice.

Response: **We added your suggestion**

- Provide a brief explanation of the physiological processes and potential causes of TA to enhance readers' understanding of the condition.

Response: **We added your suggestion**

- Expand the review of literature to include recent epidemiological data on the prevalence of TA and its associated complications.

Response: **: We added your suggestion**

- Include studies investigating the psychological impact of TA on women's mental health, particularly focusing on anxiety and depressive symptoms.

Response: **: We added your suggestion**

- Provide a more detailed discussion of the risk factors associated with TA, including maternal age, medical history, lifestyle factors, and environmental stressors.

Response: **We added your suggestion**

- Discuss the mechanisms through which these risk factors contribute to the development of TA, considering both biological and psychosocial perspectives.

Response: **We explained it**

- Emphasize the psychological consequences of TA on maternal mental health, highlighting the prevalence of anxiety and depressive symptoms in affected women.

Response: We added your suggestion.

- Include evidence from longitudinal studies to elucidate the long-term effects of TA on maternal well-being and quality of life.

Response: We added your suggestion

- Provide a rationale for employing psychotherapy as an intervention for women with TA, drawing on theoretical frameworks and empirical evidence supporting the efficacy of psychological interventions in perinatal mental health.

Response: We provided a rationale for employing psychotherapy

- Discuss the potential benefits of psychotherapy in mitigating the psychological distress associated with TA and preventing the onset of more severe psychiatric disorders.

Response: They were mentioned in references 15-20

- Introduce internet-based psychotherapeutic interventions as a novel approach to addressing perinatal mental health issues, including depression and anxiety during pregnancy.

Response: They were mentioned in references 21-29

- Summarize the advantages of internet-based Cognitive Behavioral Therapy (iCBT) and the Unified Protocol (UP) in terms of accessibility, acceptability, and effectiveness in diverse populations.

Response: We have added a study of accessibility and feasibility

Method

- Provide more detailed descriptions of the development process of the iCBT-Specific and transdiagnostic treatment programs, including the rationale for specific intervention components and adaptations made for the TA population.

Response: We provided more detail of the development of the therapies

- Clarify how potential participants were screened for eligibility and ensure consistency in the application of inclusion and exclusion criteria across recruitment sites.

Response: Screening of participants for eligibility was determined by clinical interview and marked for each entry on recruitment sites. Also, the duration of each person's treatment session is specified on the site.

• Justify the choice of effect size and statistical power used in the sample size calculation, considering the specific aims and hypotheses of the study.

Response: Empirical evidence to estimate the effect size was selected to increase the validity of the sample size determination based on the same study (reference 37).

• Provide references or empirical evidence supporting the selected effect size estimate to enhance the credibility of the sample size determination.

Response: We used G*Power software to determine the sample size taking into account the findings of a study by Shafirizi et al (reference 37).

• Clarify the rationale for selecting the Mini-International Neuropsychiatric Interview (MINI), Brief Symptom Inventory-18 (BSI-18), System Usability Scale (SUS), and Client Satisfaction Questionnaire (CSQ-8) as outcome measures.

Response: As explained in the method, we used the Mini-International Neuropsychiatric Interview (MINI), to diagnose depression and anxiety disorder and enter the study and used the other instruments as outcomes. Brief Symptom Inventory-18 (BSI-18), System Usability Scale (SUS), and Customer Satisfaction Questionnaire (CSQ-8) are tools that have recently been used in similar articles and they effectiveness and acceptance (references 23-24-36-37).

• Provide information on the psychometric properties and validation status of the Persian versions of these measures to ensure their suitability for use in the study population.

Response: The Persian validity of the questionnaires was added.

• Specify the statistical methods used for data analysis, including descriptive statistics, repeated measures analysis, and analysis of covariance (ANCOVA).

Response: Descriptive statistics were used to check the frequency distribution, mean and standard errors of the mean. Also, we used paired t-tests to compare the averages within the group, and we used ANCOVA to compare the two groups (between groups).

• Include information on ethical approval obtained from relevant institutional review boards and provide assurance of compliance with ethical guidelines for research involving human participants.

Response: The ethical approval code is in the acknowledgement section.

Results

1. Provide a concise summary of the demographic characteristics of the study population, highlighting key findings such as the mean age, educational background, and gestational age.

Response: A brief summary of the demographic characteristics of the study population such as average age, educational background and gestational age was given in the text.

Consider presenting demographic data in a descriptive narrative rather than within a table .2
.to enhance readability

.Response: The descriptive narrative was more complete in the results section

Discussion

Be more specific when discussing the feasibility, acceptability, and effectiveness of the two • treatment methods. Provide detailed descriptions of the assessment criteria used and how .they were measured

Response: In the discussion section, the two treatment methods of .the studies were explained in more detail and highlighted

Critically evaluate the strengths and limitations of the study, including aspects such as • .study design, sample size, follow-up procedures, and potential biases

Response: The strengths and limitations of the study are placed in the last part of the .discussion and highlighted

Discuss any unexpected or contradictory findings and provide possible explanations or • .interpretations based on existing literature

Response: The results of study 24 are similar to our results, and study 44 is .inconsistent with our results, which is given in the discussion section

Compare and contrast the methodologies, findings, and implications of previous studies • .with the present study to contextualize your findings better

:Response
.We compared the methodologies, finding and implications of previous studies •

:Response
Suggest potential areas for further investigation, such as exploring alternative treatment • modalities, conducting longitudinal studies, or expanding the sample population to enhance .generalizability

Response: We improved the suggestion and that it is highlighted at the end of the .discussion section

Summarize the key findings of the study concisely and emphasize their significance in the • .broader context of mental health treatment

.Response: We did it

2 Revision 1

1 comment · 14 Sep 2024

Editor-in-Chief

ACCEPT 14 Sep 2024

We have completed our review of your manuscript and are pleased to inform you that it is being considered for publication in the IJPBS. Note that the publication of your article will only be finalized upon your cooperation with the editorial process.
Thank you for your fine contribution. On behalf of the Editors of IJPBS, we look forward to your continued contributions to the Journal.