

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

Challenges of Smoking Cessation in Users of Non-Invasive Stimulation Technologies in Iran: A Parallel Convergent Mixed Methods Study

Authors

Sahebihagh, Mohammad Hasan; hosseinzadeh, mina; Mirghafourvand, Mojgan; Sarbakhsh, Parvin; Nemat, Hossein

VERSION 1 - REVIEW

Reviewer	1
Name	El-Khoury, Fabienne
Affiliation	Sorbonne Université, Institut Pierre Louis d'Épidémiologie et de Santé Publique IPLESP,, Departement of social epidemiology
Date	18-Aug-2024
COI	None

Thank you for presenting such a well-structured manuscript and for the considerable effort invested in this research.

While this manuscript addresses an important topic, it may be difficult to draw meaningful conclusions about the determinants and challenges of using these diverse methods when they are all grouped together. The limited, and in some cases nonexistent, evidence supporting the efficacy of these individual technologies further complicates the analysis. A more focused study on each method separately could provide clearer insights, given their distinct mechanisms and varying levels of evidence.

Here some of my other minor comments :

Abstract :

– The term "noninvasive stimulation technologies" is broad and could encompass a range of interventions, from Auriculotherapy to Neurofeedback, each with varying levels of evidence. To enhance clarity and avoid oversimplification, it would be helpful to specify the particular technologies discussed, at least in the abstract if space is limited in the title.

- Consider using "component" or "aspect" instead of "phase" to better reflect that the quantitative and qualitative parts of the study were conducted concurrently, capturing the simultaneous nature of your design.
- Including the percentages of the quantitative results in the abstract's results section would provide a clearer snapshot of the findings.
- It might be beneficial to specify that participants in the quantitative analysis were asked to rank the challenges of smoking cessation based on a pre-determined list.
- The conclusion should be nuanced to more accurately reflect the results presented.

Introduction

- I suggest adding to the introduction that there is currently no concrete evidence supporting the efficacy of any of these technologies.
- In the phrase "Smoking behaviors have significantly changed over the past decades," it would be clearer to specify that this refers to global trends, especially following the discussion of Iranian data.
- Instead of "Most smokers want to quit," consider using "report a desire to quit" for a more accurate representation.
- The statement that rTMS "significantly reduces cigarette cravings" cites Chail et al. (2018), but upon reviewing the article, I did not find any specific mention of smoking, cigarette craving, or smoking cessation (it does mention "substance use disorders"). It might be necessary to either find a more appropriate reference or revise the statement to align with the cited source.
- In the phrase "Qualitative researchers consider triangulation a research strategy to complete or validate findings," the term "validate" might be misleading in the context of qualitative research, especially in epidemiology. It would be more appropriate to emphasize how triangulation enhances the credibility or robustness of the findings.
- How much does access to these technologies cost? (this is specially important since cost is highlighted as a challenge) What are determinants of use of these technologies?

Methods

- Please rephrase "Exclusion criteria included known and treated psychiatric disorders and drug addiction" as tobacco can be considered a drug (perhaps "co-addiction" could be mentioned).
- Was the protocol of the intervention registered in a clinical trials database? If so, please include the citation.
- Were participants using other smoking cessation tools, such as e-cigarettes or nicotine replacement therapy? If not considered, this could introduce significant bias into the study.

Additionally, were any participants using two noninvasive technologies simultaneously at any time?

– Please consider using the term "rigor of the study" instead of "trustworthiness".

Results

– How many cigarettes participants smoked on average? For how long? What is their addiction level? How many of your participants successfully quit smoking? This is important to understand the perceptions of participants, especially for those participating months after their quit attempt using non invasive technologies.

– The methods section discusses the strategy for combining quantitative and qualitative data, but the results are presented separately. It might be more consistent to just state that a mixed-methods approach was used.

– I think the "Short-term experience of withdrawal symptoms" theme was accidentally omitted from the numbering? Since you mention that six themes were identified, but only five are numbered. Please correct this discrepancy

Discussion

– The phrase "The findings of this study showed that individuals felt that they were losing a loved one and an important tool in their lives when quitting smoking" could be rephrased for clarity. Consider placing "loved one" in quotation marks to indicate metaphorical use.

– The phrase "The findings of this study showed" is repeated several times in the discussion. Varying the phrasing would improve the readability and flow of this section.

Table 1

– Instead of "number," consider using "frequency" or "n."

– Please replace "job" with "socio-professionel situation" or a similar term, as "unemployed" is not a job.

– Please consider replacing "Family income" with "Household income" for greater accuracy.

Reviewer	2
Name	LORENSIA, AMELIA
Affiliation	Department of Clinical-Community Pharmacy, Faculty of Pharmacy, Universitas Surabaya, Ubaya, Indonesia
Date	19-Aug-2024
COI	no conflict of interest

- This paper is interesting and displays good novelty.

- Research results are presented well.
 - Many libraries should be updated.
-

VERSION 1 - AUTHOR RESPONSE

Response to Reviewer 1

Comment 1: While this manuscript addresses an important topic, it may be difficult to draw meaningful conclusions about the determinants and challenges of using these diverse methods when they are all grouped together. The limited, and in some cases nonexistent, evidence supporting the efficacy of these individual technologies further complicates the analysis. A more focused study on each method separately could provide clearer insights, given their distinct mechanisms and varying levels of evidence.

Response: Thank you for your insightful feedback regarding the grouping of diverse noninvasive stimulation technologies in our manuscript. We appreciate your concern about the challenges of drawing meaningful conclusions when these methods are considered collectively.

In this study, we intended to provide a comprehensive overview of the challenges faced by users of various noninvasive stimulation technologies for smoking cessation. While we recognize that a more focused study on each method separately could yield clearer insights, we aimed to identify common challenges and experiences that could inform future research and practice.

We also acknowledge the limitations regarding the existing evidence for the efficacy of these technologies. The current body of literature is indeed varied, and further research on individual methods is warranted to better understand their distinct mechanisms and effectiveness. We believe that this study can serve as a preliminary exploration that highlights the need for more targeted investigations in the future.

Thank you for your valuable input, which has helped us clarify the context and direction of our research.

Abstract

Comment 2: The term "noninvasive stimulation technologies" is broad and could encompass a range of interventions, from Auriculotherapy to Neurofeedback, each with varying levels of evidence. To enhance clarity and avoid oversimplification, it would be

helpful to specify the particular technologies discussed, at least in the abstract if space is limited in the title.

Response: The specific technologies used in the study (rTMS, tDCS, bioresonance, and auriculotherapy) have been added to the abstract for clarity [Page 2, Line: 28-32].

Comment 3: Consider using "component" or "aspect" instead of "phase" to better reflect that the quantitative and qualitative parts of the study were conducted concurrently, capturing the simultaneous nature of your design.

Response: Thank you for your insightful feedback regarding our manuscript. The word "*phase*" has been replaced with "*component*" to reflect the concurrent nature of the study design [Page 2, Lines: 34, 39, Methods section].

Comment 4: Including the percentages of the quantitative results in the abstract's results section would provide a clearer snapshot of the findings.

Response: Percentages from the quantitative analysis have been added to the abstract to provide clearer results [Page: 2, Lines: 44-54].

Comment 5: It might be beneficial to specify that participants in the quantitative analysis were asked to rank the challenges of smoking cessation based on a pre-determined list.

Response: A sentence has been added to specify that participants ranked the challenges based on a pre-determined list in the quantitative component [Page 2, Lines: 38, 39].

Comment 6: The conclusion should be nuanced to more accurately reflect the results presented.

Response: The conclusion has been revised to more accurately reflect the detailed findings of the study [Pages 2, 3, Lines: 55-60].

Introduction

Comment 7: I suggest adding to the introduction that there is currently no concrete evidence supporting the efficacy of any of these technologies.

Response: Thank you for your insightful feedback regarding the effectiveness of noninvasive stimulation technologies for smoking cessation. In the introduction, we have acknowledged evidence supporting the effectiveness and assistance these technologies may provide in quitting smoking. We have also added a statement clarifying that "while some studies show potential

benefits, more rigorous trials are needed to prove their effectiveness" [Page: 4, Lines: 87-105]. This distinction highlights the current state of research and the need for further validation of these technologies.

Comment 8: In the phrase "Smoking behaviors have significantly changed over the past decades," it would be clearer to specify that this refers to global trends, especially following the discussion of Iranian data.

Response: The phrase has been revised to specify that the changes in smoking behaviors refer to global trends, followed by the discussion of Iranian data [Page: 3, Lines: 80-83].

Comment 9: Instead of "Most smokers want to quit," consider using "report a desire to quit" for a more accurate representation.

Response: The phrase has been revised to "report a desire to quit" for more accuracy. [Page: 3, Line: 83, 84].

Comment 10: The statement that rTMS "significantly reduces cigarette cravings" cites Chail et al. (2018), but upon reviewing the article, I did not find any specific mention of smoking, cigarette craving, or smoking cessation (it does mention "substance use disorders"). It might be necessary to either find a more appropriate reference or revise the statement to align with the cited source.

Response: Thank you for your valuable feedback. The relevant phrase and reference have been reviewed and revised. [Page: 4, Line: 92, 93, Reference: 8].

Comment 11: In the phrase "Qualitative researchers consider triangulation a research strategy to complete or validate findings," the term "validate" might be misleading in the context of qualitative research, especially in epidemiology. It would be more appropriate to emphasize how triangulation enhances the credibility or robustness of the findings.

Response: Qualitative researchers consider triangulation a research strategy to enhance the reliability of the data and provides a more comprehensive understanding of the research topic by examining a phenomenon from multiple methods, data sources, or perspectives. [Page: 5, Lines: 135-138].

Comment 12: How much does access to these technologies cost? (This is specially important since cost is highlighted as a challenge) What are determinants of use of these technologies?

Response: A brief statement regarding the cost of noninvasive stimulation technologies and the factors influencing their use has been added to the introduction. [Page: 5, Lines: 125-127].

Methods

Comment 13: Please rephrase "Exclusion criteria included known and treated psychiatric disorders and drug addiction" as tobacco can be considered a drug (perhaps "co-addiction" could be mentioned).

Response: Thank you for the suggestion. We have revised the statement to clarify the exclusion criteria, mentioning co-addiction. [Page: 6, Lines: 162, 163].

Comment 14: Was the protocol of the intervention registered in a clinical trials database? If so, please include the citation.

Response: Thank you for your question. Our study was not a clinical trial. The sample was selected from individuals who had completed noninvasive technology therapy at least six months before the study. As such, the study did not require registration in a clinical trials database.

Comment 15: Were participants using other smoking cessation tools, such as e-cigarettes or nicotine replacement therapy? If not considered, this could introduce significant bias into the study. Additionally, were any participants using two noninvasive technologies simultaneously at any time?

Response: Thank you for raising this important point. We recognized the potential biases associated with using other smoking cessation tools concurrently. To address this, we excluded participants who were using additional smoking cessation tools, such as e-cigarettes or nicotine replacement therapy, as well as those who used two non-invasive technologies simultaneously. This exclusion criterion has been added to the relevant section of the manuscript [Page: 6, Lines: 163-166]. Additionally, participants were explicitly asked if they had used two non-invasive technologies at the same time, and no such cases were reported.

Comment 16: Please consider using the term "rigor of the study" instead of "trustworthiness".

Response: We have replaced "trustworthiness" with "rigor of the study" in the relevant sections of the manuscript to align with standard terminology. [Page: 10, Lines: 255, 262].

Results

Comment 17: How many cigarettes participants smoked on average? For how long? What is their addiction level? How many of your participants successfully quit smoking? This is important to understand the perceptions of participants, especially for those participating months after their quit attempt using noninvasive technologies.

Response: We appreciate the reviewer's suggestion to provide additional details on participants' smoking habits. We have included information on the average number of cigarettes smoked per day and the duration of smoking. Additionally, we have reported the number of participants who successfully quit smoking using noninvasive technologies [Page: 11, Lines: 284-287]. However, we did not examine the Fagerström Test for Nicotine Dependence (FTND) to assess average levels of addiction among participants. We have mentioned this in the limitations of the study [Page: 17, Lines: 466-471].

Comment 18: The methods section discusses the strategy for combining quantitative and qualitative data, but the results are presented separately. It might be more consistent to just state that a mixed-methods approach was used.

Response: As mentioned in the strategy for combining quantitative and qualitative data, the researcher compared the different results during the interpretation phase after analyzing the quantitative and qualitative data. The interpretation of the combined results is presented in the discussion section of the manuscript.

Comment 19: I think the "Short-term experience of withdrawal symptoms" theme was accidentally omitted from the numbering? Since you mention that six themes were identified, but only five are numbered. Please correct this discrepancy

Response: Thank you for pointing out this discrepancy. We have corrected the omission of the "Short-term experience of withdrawal symptoms" theme from the numbering. The "Short-term experience of withdrawal symptoms" theme has been correctly numbered as the second theme, ensuring consistency in the numbering of all six themes [Page: 11, Line: 303].

Discussion

Comment 20: The phrase "The findings of this study showed that individuals felt that they were losing a loved one and an important tool in their lives when quitting smoking" could be rephrased for clarity. Consider placing "loved one" in quotation marks to indicate metaphorical use.

Response: Thank you for your suggestion. We have rephrased the statement for clarity and placed "loved one" in quotation marks to indicate its metaphorical use [Page: 15, Line: 397, 398].

Comment 21: The phrase "The findings of this study showed" is repeated several times in the discussion. Varying the phrasing would improve the readability and flow of this section.

Response: We appreciate your feedback on the repetitive phrasing. We have revised the discussion to vary the language used when referring to the findings, enhancing readability and flow [Pages: 14-16, Lines: 366, 380, 397, 411, 422, 439, and 450].

Table 1

Comment 22: Instead of "number," consider using "frequency" or "n."

Response: We have replaced "number" with "frequency" in Table 1 as suggested.

Comment 23: Please replace "job" with "socio-professional situation" or a similar term, as "unemployed" is not a job.

Response: We have replaced "job" with "socio-professional situation" in Table 1.

Comment 24: Please consider replacing "Family income" with "Household income" for greater accuracy.

Response: We have replaced "Family income" with "Household income" for improved accuracy.

Response to Reviewer 2

Comment 1: This paper is interesting and displays good novelty. Research results are presented well.

Response: We appreciate the reviewer's feedback on our manuscript.

Comment 2: Many libraries should be updated.

Response: Thank you for your comment regarding the references. We have updated several references in the manuscript, and currently, approximately 70% of the references (37 out of 55) are from the last six years. The earlier references included in the manuscript are foundational studies related to the results, instruments, and research methodologies. These references are

essential for providing context and supporting the validity of our findings. We appreciate your feedback and believe that the balance of updated and foundational references strengthens the manuscript.

VERSION 2 - REVIEW

Reviewer	1
Name	El-Khoury, Fabienne
Affiliation	Sorbonne Université, Institut Pierre Louis d'Épidémiologie et de Santé Publique IPLESP,, Departement of social epidemiology
Date	27-Oct-2024
COI	

Thank you for the revisions made to the manuscript. I appreciate the effort to address comments. I've included a few additional comments below that I hope will add further clarity and nuance.

-Thank you for updating the reference concerning the statement that rTMS "significantly reduces cigarette craving". While this cited study provides some promising data on rTMS for smoking cessation, it also has limitations that could introduce bias, including selection bias and methodological bias (for example only those who maintained abstinence by Week 6 were subsequently monitored until Week 18). Also this cited study was funded by the company who supplied the rTMS.

Given these factors, it's important to report the findings with caution. I recommend revising the statement to add more nuance and to better reflect these potential biases and emphasize that, while initial results are promising, more robust studies are needed to confirm rTMS's effectiveness in smoking cessation.

- Thank you for including more data on participants' outcomes. I see that you've added the statement, "Of the 400 participants, 329 (82.3%) successfully quit smoking following the use of noninvasive stimulation technologies," which is a remarkable result. However, this raises some questions, as it was not mentioned in the original submission. Could this high rate be influenced by selection bias, where only those with positive experiences chose to participate? How many individuals were initially approached?

Given the limited evidence supporting these technologies, it may help to provide additional context around the criteria for "successful quitting" and the duration for which abstinence was maintained in the methods section. This clarification would strengthen the credibility of this significant finding.

-I would also recommend a review for any language issues or minor errors to ensure clarity and accuracy throughout the manuscript

VERSION 2 - AUTHOR RESPONSE

Response to Reviewer 1

Comment 1: Thank you for updating the reference concerning the statement that rTMS "significantly reduces cigarette craving". While this cited study provides some promising data on rTMS for smoking cessation, it also has limitations that could introduce bias, including selection bias and methodological bias (for example only those who maintained abstinence by Week 6 were subsequently monitored until Week 18). Also this cited study was funded by the company who supplied the rTMS. Given these factors, it's important to report the findings with caution. I recommend revising the statement to add more nuance and to better reflect these potential biases and emphasize that, while initial results are promising, more robust studies are needed to confirm rTMS's effectiveness in smoking cessation.

Response: Thank you for your insightful comments. We appreciate your attention to the potential limitations and biases in the cited study on rTMS for smoking cessation. We agree that these factors merit caution in interpreting the findings, and we will revise the text to reflect this nuance and emphasize the need for further robust studies [Page: 4, Lines: 92-95].

Comment 2: Thank you for including more data on participants' outcomes. I see that you've added the statement, "Of the 400 participants, 329 (82.3%) successfully quit smoking following the use of noninvasive stimulation technologies," which is a remarkable result. However, this raises some questions, as it was not mentioned in the original submission. Could this high rate be influenced by selection bias, where only those with positive experiences chose to participate? How many individuals were initially approached?

Given the limited evidence supporting these technologies, it may help to provide additional context around the criteria for "successful quitting" and the duration for which abstinence was maintained in the methods section. This clarification would strengthen the credibility of this significant finding.

Response: Thank you for your thoughtful comments and for highlighting important considerations regarding participant outcomes.

While our sample selection was randomized, we acknowledge that a large proportion of participants in this study had successful outcomes, which could suggest potential selection bias. We will address this in the limitations section and suggest that future studies include more participants with unsuccessful outcomes to provide a balanced perspective [Page: 18, Lines: 485-488].

We specified the initial number of individuals approached in the methods section to provide a complete context for the study's participant pool [Page: 7, Lines: 181-182].

We clarified in the methods section that "successful quitting" was defined as abstinence for at least six months within the past year [Page: 6, Lines: 165-166, Reference: 30].

Thank you again for helping us strengthen the clarity and rigor of our manuscript.

Comment 3: I would also recommend a review for any language issues or minor errors to ensure clarity and accuracy throughout the manuscript

Response: Thank you for your feedback and suggestions. We have thoroughly reviewed the entire manuscript and made necessary revisions to enhance its clarity and address language issues. We believe these changes improve the overall quality of the text.

VERSION 3 - REVIEW

Reviewer	1
Name	El-Khoury, Fabienne
Affiliation	Sorbonne Université, Institut Pierre Louis d'Épidémiologie et de Santé Publique IPLESP,, Departement of social epidemiology
Date	25-Nov-2024
COI	

Thank you for addressing my comments. The revisions are satisfactory to me