

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	What are the factors that contribute to the development of sexual dysfunction in breastfeeding women? A systematic scoping review protocol
AUTHORS	Fuentealba-Torres, Miguel; Cartagena-Ramos, Denisse; Sierra, JC; Lara, Lúcia; Okano, Sérgio; Berra, Thaís; Alves, Luana; Leite, Ana Carolina; Yamamura, Mellina; Silva, Isília; Nascimento, Lucila; Arcêncio, Ricardo

VERSION 1 – REVIEW

REVIEWER	Marjan Khajehei Westmead hospital, Australia
REVIEW RETURNED	03-Apr-2018

GENERAL COMMENTS	<p>Thank you for designing this systematic review on sexual function of breastfeeding women!</p> <p>This is an important topic that has been understudied and needs a sophisticated systematic approach to discover risk factors and assist with eth improvement of their sexual function.</p> <p>My comments are as follows:</p> <ul style="list-style-type: none">- The authors have indicated four research questions in Table one including “sexual behaviour of breastfeeding women”, “aspects related to the sexuality of breastfeeding women”, “types of sexual dysfunction in breastfeeding women” and “factors contributing to their sexual dysfunction”. The first two questions (sexual behaviour and sexuality) are very broad and consist of a variety of features (as the authors have mentioned in the definition of sexuality in Table 2). For example, human sexuality is the way people experience and express themselves sexually. It involves biological, erotic, physical, psychological, emotional, social, cultural and spiritual feelings. It also include orientations, identity and behaviours. Each of these is a broad topic and has its own definitions and subcategories. Sexual behaviour means a person’s sexual practices that has three components: attraction, motivation and performance. Again, each one is a wide-ranging topic by itself. Thus, in general, I believe the research questions for this systematic review have not been defined properly and correctly. In addition, the introduction does not provide enough background literature on the issue,
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	<p>what is known about the topic and what are the gaps in the literature and why this systematic review is required.</p> <ul style="list-style-type: none"> - Table 2: <ul style="list-style-type: none"> • It needs to provide definition of ‘sexual behaviours’ and “risk factors” as well. • It will also be better if the authors use the ‘American Psychiatric Association’ or ‘DSM-V’ definitions for sexual dysfunction. • Definition of ‘breastfeeding women’ does not indicated categories of breastfeeding: exclusive breastfeeding and partial breastfeeding. - Exclusion criteria indicates that studies focusing on the sexuality of pregnant women will be excluded. But, what about those cohort studies that recruited pregnant women and followed them up until after birth? Will they be considered? - On page 10, the section “Collating, summarizing and reporting data”, the authors have mentioned they will use SPSS to analyse quantitative data. However, there is no explanation of which statistical tests they will use for each research question. The specific tests and p value level need to be indicated.
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REVIEWER	ANA KATHERINE GONÇALVES UNIVERSIDADE FEDERAL DO RIO GRANDE DO NORTE
REVIEW RETURNED	03-Jun-2018

GENERAL COMMENTS	<p>Dear Author</p> <p>After reading the article and evaluating the paper personally, we feel that despite the interesting subject there is some sloppy proofreading of the manuscript and in general, the instructions to authors concerning the systematic review, the protocol was not entirely followed.</p> <p>At first, the Abstract does not follow the standard systematic review style.</p> <p>The purpose of the systematic review is to explore the factors that contribute to the development of sexual dysfunction in nursing mothers. This objective is too broad and non-specific to generate a systematic review of good quality. Additionally, the design of the studies used to answer this question was not mentioned. Primary and secondary outcomes were not reported, as well as the risk of bias.</p> <p>Furthermore, The PROSPERO (Trial registration number International Prospective Register of Systematic Review) is not mentioned.</p> <p>The introduction must include Description of the condition; Description of the intervention and How the intervention might work. The methods must include a register in the PROSPERO; Criteria for considering studies for this review, Types of studies, Types of participants; Types of interventions; Types of outcome measures; Search methods for identification of studies; Data collection and analysis.</p> <p>Finally, we suggest the evaluation of the quality of evidence through the GRADE (Grading of Recommendations Assessment, Developing and Evaluation).</p> <p>Generally, before the systematic review, the authors set about their</p>
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	<p>task very methodically following, step by step, an advance plan called a protocol. The protocol describes the steps that will be followed when preparing a review. It is essential that each review is approached rigorously and with careful attention to detail. Plan carefully, and document everything. Thus, we suggest remaking this systematic review</p> <p>Best wishes</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Marjan Khajehei

Institution and Country: Westmead hospital, Australia

Please state any competing interests or state 'None declared': No conflict of interest

Please leave your comments for the authors below

Please see the attached file for my comments. Thank you!

Reviewer: 2

Reviewer Name: ANA KATHERINE GONÇALVES

Institution and Country: UNIVERSIDADE FEDERAL DO RIO GRANDE DO NORTE

Please state any competing interests or state 'None declared': NONE DECLARED

Please leave your comments for the authors below

Dear Author

After reading the article and evaluating the paper personally, we feel that despite the interesting subject there is some sloppy proofreading of the manuscript and in general, the instructions to authors concerning the systematic review, the protocol was not entirely followed.

At first, the Abstract does not follow the standard systematic review style.

The purpose of the systematic review is to explore the factors that contribute to the development of sexual dysfunction in nursing mothers. This objective is too broad and non-specific to generate a systematic review of good quality. Additionally, the design of the studies used to answer this question was not mentioned. Primary and secondary outcomes were not reported, as well as the risk of bias. Furthermore, The PROSPERO (Trial registration number International Prospective Register of Systematic Review) is not mentioned.

The introduction must include Description of the condition; Description of the intervention and How the intervention might work.

The methods must include a register in the PROSPERO; Criteria for considering studies for this review, Types of studies, Types of participants; Types of interventions; Types of outcome measures; Search methods for identification of studies; Data collection and analysis.

Finally, we suggest the evaluation of the quality of evidence through the GRADE (Grading of Recommendations Assessment, Developing and Evaluation).

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It is essential that each review is approached rigorously and with careful attention to detail. Plan carefully, and document everything. Thus, we suggest remaking this systematic review

Reviewers' comments:

We appreciate the comments of the reviewers. Below, we describe the changes made based on your comments highlighting the text in blue. We also inform that to characterize this revision protocol in a more adequate way, we have formulated the title in the form of a question:

What are the factors that contribute to the development of sexual dysfunction in breastfeeding women: a systematic scoping review protocol.

REVIEWER 1 (R1)

Thank you for designing this systematic review on sexual function of breastfeeding women!

This is an important topic that has been understudied and needs a sophisticated systematic approach to discover risk factors and assist with the improvement of their sexual function.

My comments are as follows:

The authors have indicated four research questions in Table one including “sexual behaviour of breastfeeding women”, “aspects related to the sexuality of breastfeeding women”, “types of sexual dysfunction in breastfeeding women” and “factors contributing to their sexual dysfunction”. The first two questions (sexual behaviour and sexuality) are very broad and consist of a variety of features (as the authors have mentioned in the definition of sexuality in Table 2). For example, human sexuality is the way people experience and express themselves sexually. It involves biological, erotic, physical, psychological, emotional, social, cultural and spiritual feelings. It also includes orientations, identity and behaviours. Each of these is a broad topic and has its own definitions and subcategories. Sexual behaviour means a person's sexual practices that has three components: attraction, motivation and performance. Again, each one is a wide-ranging topic by itself. Thus, in general, I believe the research questions for this systematic review have not been defined properly and correctly. In addition, the introduction does not provide enough background literature on the issue, what is known about the topic and what are the gaps in the literature and why this systematic review is required.

We appreciate these comments and believe they help improve our research protocol.

In relation to the first question of our review "What are the sexual behaviors of the breastfeeding women?" We agreed to delimit the concept of "sexual behavior" For this study, we have used the theoretical referential of sexual behavior¹ which explains that "sexual performance" is a component of "sexual behavior". As a result, we replaced the concept of the original question "sexual behavior" with the concept of "sexual performance". We consider that this change will help us to investigate "sexual behavior" in a more specific way.

From this change, we rephrased our original question in this way: What happens to female sexual performance in the course of breastfeeding?

In relation to second question of our review "What are the aspects related to the sexuality in breastfeeding women?" We agreed that the "aspects related to the sexuality of women who breastfeed" can be very broad, we delimited the concept "aspects related to sexuality", by "biological and psychosocial aspects." We understood that with this change, we will be able to investigate in a more specific way the available literature.

From this change, we have reformulated our original question and we have developed the following question: What are the biological and psychosocial aspects that interfere with the sexual function of breastfeeding women?

Regarding the third and fourth questions of our review (What are the types of sexual dysfunctions in breastfeeding women?). We agree with the observations of the opinion. For this reason, we have agreed to merge these two questions with the purpose of focusing our scoping review in a clearer and more specific way.

From these changes, we have asked the following question: What are the sexual dysfunction problems in breastfeeding women?

R1: Table 2: It needs to provide definition of 'sexual behaviours' and "risk factors" as well.

We appreciate the comments. We included a definition of all the concepts that are going to be investigated in the Scoping Review. According to the suggestions, we replaced the concept of "sexual behaviors" by "Sexual Performance".

In the present review we did not include "risk factors for sexual dysfunction in nutritious women", because there is not robust evidence to show risk exposures in the literature.

We report that the definitions for each concept are described in table 2.

R1: It will also be better if the authors use the 'American Psychiatric Association' or 'DSM-V' definitions for sexual dysfunction.

Thanks for your comment. We took this definition to the table 2.

R1: Definition of 'breastfeeding women' does not indicated categories of breastfeeding: exclusive breastfeeding and partial breastfeeding.

We appreciate this observation. Just read our comments above.

R1: Exclusion criteria indicates that studies focusing on the sexuality of pregnant women will be excluded. But, what about those cohort studies that recruited pregnant women and followed them up until after birth? Will they be considered?

We appreciate this observation. We consider this fourth criterion of inclusion:

4. Cohort studies with focus on the sexuality of breastfeeding women, who have followed up from pregnancy to post-delivery, will also be included.

R1: On page 10, the section "Collating, summarizing and reporting data", the authors have mentioned they will use SPSS to analyse quantitative data. However, there is no explanation of which statistical tests they will use for each research question. The specific tests and p value level need to be indicated.

We appreciate this observation. We have redefined the form of quantitative data analysis. Because it is a revision of the "Scoping Review" type, we will not be able to perform statistical tests due to the diversity of studies that are going to be included. Reason why, we agreed to analyze the results of quantitative studies in a narrative form based on the identification of result categories. We are going to use the SPSS program for the descriptive analysis of the characteristics of the literature considering absolute frequencies and percentages.

REVIEWER 2 (R2)

Dear Author

After reading the article and evaluating the paper personally, we feel that despite the interesting subject there is some sloppy proofreading of the manuscript and in general, the instructions to authors concerning the systematic review, the protocol was not entirely followed.

R2: At first, the Abstract does not follow the standard systematic review style.

We appreciate your comment. In this opportunity, we have not written a summary using the standard style for systematic reviews because our proposal is to develop a protocol of a Systematic scoping review.

However, we have made improvements to our summary and we have highlighted the importance of carrying out a literature review due to the lack of primary studies of sexual dysfunction in breastfeeding women. This lack allowed the development of a classic systematic review as well as the use of meta-analysis.

R2: The purpose of the systematic review is to explore the factors that contribute to the development of sexual dysfunction in nursing mothers. This objective is too broad and non-specific to generate a systematic review of good quality.

We appreciate this observation. The objective of our study was intentionally formulated broadly. To formulate the objective, we have followed Levac's guidelines², for the development of Scoping Studies. Were objectives formulated using a three-component structure suggested by the author.

Original article: The research questions were discussed by the authors and, from a consensus, three research questions were elaborated, articulated with the purpose of the review. The questions were of a broad nature, structured from three components: 1) the definition of the concept to be researched, 2) the target population, and 3) the results of interest in health.²

However, we have made adjustments to the original objectives, which were made based on the suggestions of the reviewers. These adjustments are found in table 1.

R2: Additionally, the design of the studies used to answer this question was not mentioned.

We appreciate this observation. The design of the studies used to answer this question is detailed in the inclusion criteria.

Original text:

Inclusion criteria:

1. Literature in English, Spanish or Portuguese, focused on the research questions detailed in table 1.
2. Literature focusing on sexual dysfunction in the breastfeeding women population, including: qualitative or quantitative empirical studies; studies of literature review, regardless of the method used; and brief communications of ongoing studies.
3. Gray literature focusing on sexual dysfunction in the breastfeeding women population, including: annals of congresses, conferences of organizations or societies; academic dissertations, theses, books, book chapters, and government documents.
4. Cohort studies focused on the sexuality of nutritious women, who have followed up from pregnancy to post-delivery, will also be included.

R2: Primary and secondary outcomes were not reported, as well as the risk of bias.

We appreciate this observation. As it is a Systematic Scoping Review, for us it is not possible to define a priori the primary and secondary results that will be analyzed in this review.^{2,3} For this reason, we will carry out a comprehensive mapping of the available scientific literature, including gray literature.

Original text:

A Systematic Scoping Review contributes to the clarification of knowledge gaps in lightly researched phenomena by performing a comprehensive mapping of available scientific literature, including the gray literature.^{2,3}

In relation to the evaluation of the risk of bias, for us this type of analysis is not possible. According to the recommendations of the "Cochrane Public Health Group"⁴ and the group "Scoping Studies",^{2,5} the risk of bias is not made in this type of review.

R2: Furthermore, The PROSPERO (Trial registration number International Prospective Register of Systematic Review) is not mentioned.

We appreciate this observation. For us it is not possible to make this type of registration, because the PROSPERO registry was not created to register reviews of type "Scoping Review". Currently, the PROSPERO registration system warns in its online instruction manual, "Scoping Review records will not be accepted."⁶

R2: The introduction must include Description of the condition; Description of the intervention and How the intervention might work.

We appreciate this observation. In the introduction, we have described the condition of "breastfeeding woman". The definition of this condition is found in table 2.

Literature suggests that breastfeeding women may be at increased risk of developing sexual dysfunction.^{7–11} Despite the lack of systematic reviews and lack of empirical studies, which makes it impossible to identify associated factors, risk factors or predictive factors for the development of DSF in breastfeeding women, exploratory studies suggest that hyperprolactinemia, hypoestrogenism and the context of motherhood influence the female sexual response and make mothers more vulnerable to the development of sexual dysfunctions.^{11–15}

Because it is a Systematic Scoping Review, it is not possible to include intervention in the introduction and it is also not possible to include how this intervention can work, because our review does not propose to evaluate the effect of clinical interventions in the sample, as is usual in reviews.⁴

R2: The methods must include a register in the PROSPERO; Criteria for considering studies for this review, Types of studies, Types of participants; Types of interventions; Types of outcome measures; Search methods for identification of studies; Data collection and analysis.

We appreciate all these comments. Next we answer each one of them:

1. Being a Systematic Scoping Review, we can not make PROSPERO record because this record was not created for Systematic Scoping Review.⁶
2. The criteria for considering the studies for this review are detailed on page 8 of the original manuscript.

3. The types of studies that we will include in our review are detailed on page 8 of the original manuscript.
4. The types of participants that we will include in our review are detailed on page 8 of the original manuscript.
5. Because we are dealing with a Systematic Scoping Review, we do not consider types of interventions nor do we consider types of outcome measures.^{2–4}
6. The method of systematic search for the identification of the literature is detailed on page 6 of the original manuscript. In addition, search strategies are detailed in supplementary file 2 of the original manuscript.
7. The form of information collection is detailed on page 8, 9 and 10 of the original manuscript. In addition, data extraction matrices are detailed in supplementary file 4 and 5 of the original manuscript.
8. Analysis of detailed data on page 10.

R2: Finally, we suggest the evaluation of the quality of evidence through the GRADE (Grading of Recommendations Assessment, Developing and Evaluation).

We appreciate this observation. Because it is a Systematic Scoping Review, for us it is not possible to use the suggested GRADE, because this instrument was developed to be applied in classical systematic reviews (by the Cochrane Corporation). However, we declare on page 9 of the original article, that we will use the MMAT instrument to map the quality of quantitative, qualitative and / or mixed primary studies.¹⁶

Original text:

The quality of the empirical studies included in the review will be evaluated using the Mixed Methods Appraisal Tool (MMAT).¹⁶ This instrument was developed to evaluate the methodological quality of empirical studies included in systematic reviews, conducted through qualitative, quantitative and mixed methods. Subsequently, the evidence of methodological quality of the scope of the literature will be presented, including the evidence of studies that present low scores in the quality evaluation, which will not be excluded from the sample analyzed.

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VERSION 2 – REVIEW

REVIEWER	Dr Marjan Khajehei Westmead Hospital, Sydney, Australia
REVIEW RETURNED	29-Jun-2018
GENERAL COMMENTS	Thank you for amending the protocol! It looks more sophisticated now. I wish you all the best with conducting your study.