

**SEXUAL COUNSELING FOR PREGNANT WOMEN BASED ON THE PILSET MODEL: QUASI-EXPERIMENTAL CLINICAL TRIAL PROTOCOL**

**ASESORAMIENTO SEXUAL PARA MUJERES EMBARAZADAS BASADO EN EL MODELO PILSET: PROTOCOLO DE ENSAYO CLÍNICO CUASIEXPERIMENTAL**

**ACONSELHAMENTO SEXUAL DE GESTANTES BASEADO NO MODELO PILSET: PROTOCOLO DE ENSAIO CLÍNICO QUASE-EXPERIMENTAL**

<sup>1</sup>Emanuely Vieira Pereira

<sup>2</sup>Luan Layzon Souza Silva

<sup>3</sup>Lilian de Carvalho Araújo

<sup>4</sup>Vanessa Silva Gaspar

<sup>5</sup>Natália Gondim de Almeida

<sup>6</sup>Saiwori de Jesus Silva Bezerra dos Anjos

<sup>7</sup>Paulo Renato Alves Firmino

<sup>8</sup>Ana Virginia de Melo Fialho

<sup>1</sup>Universidade Estadual do Ceará (UECE), Fortaleza-CE, Brasil. ORCID: <https://orcid.org/0000-0003-1457-6281>

<sup>2</sup>Faculdade São Francisco do Ceará (FASC), Iguatu-CE, Brasil. ORCID: <https://orcid.org/0000-0001-9700-8153>

<sup>3</sup>Universidade Estadual do Ceará (UECE), ORCID: <https://orcid.org/0009-0005-6086-4841>

<sup>4</sup>Universidade Estadual do Ceará (UECE), Fortaleza-CE, Brasil. ORCID: <https://orcid.org/0000-0003-4119-2283>

<sup>5</sup>RN at New York Oncology Hematology (EUA), ORCID: <https://orcid.org/0000-0002-7254-4360>

<sup>6</sup>Universidade Estadual do Ceará (UECE), Fortaleza-CE, Brasil, ORCID: <https://orcid.org/0000-0001-7559-8471>

<sup>7</sup>Universidade Federal do Cariri (UFCA), Juazeiro do Norte-CE, Brasil, ORCID: <https://orcid.org/0000-0002-3308-2650>

<sup>8</sup>Universidade Estadual do Ceará (UECE), Fortaleza-CE, Brasil, ORCID: <https://orcid.org/0000-0002-4471-1758>

**Corresponding Author**

**Emanuely Vieira Pereira**

Avenida Agricultor Damião Quirino da Silva, nº 319, Bairro Mons. Fco. Murilo de Sá Barreto, Juazeiro do Norte-CE, Brasil. CEP:63038-802, +55(88)99980-9919

e-mail: [emanuely.v.p@gmail.com](mailto:emanuely.v.p@gmail.com).

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**ABSTRACT**

Objective: To describe the study protocol for analyzing the effects of the Sexual Counseling Intervention, based on the Permission, Limited Information, Specific Suggestions, Intensive Therapy (PLISSIT) model, on the sexual function and sexual quality of life of pregnant women. Method: Quasi-experimental clinical trial protocol. Participants will be pregnant women registered and followed up by Family Health teams, who have a sexual partner and are up to 18 gestational weeks at the first data collection. High-risk pregnant women or those using medications that may impact sexual function will be excluded. Participants will be allocated to an intervention and a control group. The primary outcome will be the improvement in sexual function and sexual quality of life scores in the Intervention Group, compared by applying validated questionnaires. The research was registered in the Brazilian Registry of Clinical Trials and approved by the Research Ethics Committee. Expected Results: The implementation of sexual counseling based on the PLISSIT model in prenatal care, with an interprofessional and collaborative nature, can be carried out by trained health professionals, favoring a group approach, timely access and management of sexual complaints, and referral to sexual therapy when necessary, with a positive impact on the sexual function and quality of life of pregnant women.

**Keywords:** Women's Health; Sexuality; Sexual behavior; Sexual Counseling; Prenatal Care; Pregnancy.

**RESUMEN**

Objetivo: Describir el protocolo de estudio para analizar los efectos de la Intervención de Asesoramiento Sexual, basada en el modelo Permiso, Información Limitada, Sugerencias Específicas, Terapia Sexual (PLISSIT), en la función sexual y calidad de vida sexual de gestantes. Método: Protocolo de ensayo clínico cuasi-experimental. Participarán gestantes registradas y seguidas por equipos de Salud de la Familia con pareja sexual y, hasta, 18 semanas de gestación, en la primera recolección de datos. Serán excluidas las gestantes de alto riesgo o aquellas que utilicen medicamentos que puedan impactar la función sexual. Las participantes serán asignadas a un grupo de intervención y a un grupo de control. El resultado principal será la mejora en las puntuaciones de función sexual y de calidad de vida sexual en el Grupo Intervención, comparadas mediante la aplicación de cuestionarios validados. La investigación fue inscrita en el Registro Brasileño de Ensayos Clínicos y aprobada por el Comité de Ética en Investigación. Resultados esperados: La implementación del asesoramiento sexual basado en el modelo PLISSIT en la atención prenatal, de carácter interprofesional y colaborativo, puede ser realizada por profesionales de la salud capacitados, favoreciendo un enfoque grupal, el acceso y manejo oportuno de las quejas sexuales y la derivación a terapia sexual cuando sea necesario, con una repercusión positiva en la función sexual y la calidad de vida de las gestantes.

**Palabras clave:** Salud de la Mujer; Sexualidad; Comportamiento sexual; Asesoramiento Sexual; Atención Prenatal; Embarazo.

**RESUMO**

Objetivo: Descrever o protocolo de estudo para analisar os efeitos da Intervenção de Aconselhamento Sexual, baseada no modelo Permissão, Informação Limitada, Sugestão Específica, Terapia Sexual na função sexual e qualidade de vida sexual de gestantes. Método: Protocolo de ensaio clínico quase experimental. Participarão gestantes cadastradas e acompanhadas por equipes de Saúde da Família com parceiro/a sexual e, até, 18 semanas gestacionais, na primeira coleta de dados. Serão excluídas gestantes de alto risco ou em uso de medicamentos que podem impactar a função sexual. As participantes serão alocadas em grupo de intervenção e controle. O desfecho principal será a melhoria nos escores de função sexual e de qualidade de vida sexual no Grupo Intervenção comparados pela aplicação de questionários validados. A pesquisa foi inscrita no Registro Brasileiro de Ensaio Clínicos e aprovada pelo Comitê de Ética em Pesquisa. Resultados esperados: A implementação do aconselhamento sexual baseado no modelo Permissão, Informação Limitada, Sugestão Específica, Terapia Sexual no pré-natal, de caráter interprofissional e colaborativo, pode ser realizado por profissionais de saúde capacitados, favorecendo abordagem grupal, acesso e manejo oportuno de queixas sexuais e encaminhamento à terapia sexual quando necessário, com repercussão positiva na função sexual e qualidade de vida das gestantes.

**Palavras-chave:** Saúde da Mulher; Sexualidade; Comportamento sexual; Aconselhamento Sexual; Cuidado Pré-Natal; Gravidez.



## INTRODUCTION

Pregnant women experience changes that can negatively impact sexual function<sup>(1-2)</sup> and sexual quality of life, which, consequently, affect the conjugal relationship<sup>(3)</sup>. However, difficulties are observed in addressing aspects of sexuality in prenatal care<sup>(4)</sup>, resulting from cultural factors, limitations in the training process regarding gender and sexuality<sup>(5)</sup>, competence in promoting sexual and reproductive health<sup>(6)</sup>, and the lack of qualification among health professionals to perform sexual counseling<sup>(7)</sup>.

Sexual counseling has a preventive nature, enabling reflection for the modification of harmful behaviors through person-centered listening focused on the feelings, perceptions, and conflicts of the individual/couple. When combined with multidisciplinary services, it can contribute to different social sectors, constituting a field of action for health professionals, provided they are qualified to address it<sup>(7)</sup>.

Evidence demonstrates that sexual counseling contributes to the improvement of sexual response by promoting access to knowledge and attitudes related to physical and psychological changes and factors intervening in sexual function, enabling adaptive behaviors<sup>(8)</sup>. In contrast, its absence can perpetuate myths, taboos, and false beliefs, which, along with physical changes, concerns about risks, and fluctuations in sexual interest, result in reduced sexual activity<sup>(9)</sup>.

Sexuality education in prenatal care allows for clarifying doubts, reducing fears, anxieties, myths, taboos, and prejudices, contributing to the maintenance of sexual health<sup>(4,10)</sup>, which is considered a relevant aspect of sexual quality of life<sup>(3)</sup>.

From the perspective of care aimed at behavior modification, sexual counseling based on the Permission, Limited Information, Specific Suggestions, Intensive Therapy (PLISSIT) model constitutes a technique for addressing human sexual function composed of four elements (Permission, Limited Information, Specific Suggestions, and Intensive Therapy), which facilitate dialogue between the health professional and the person, enabling access and interventions in response to sexual complaints<sup>(11-12)</sup>. This model has been applied in research with women of reproductive age<sup>(11)</sup>, those undergoing oncological treatment<sup>(13)</sup>, and during pregnancy, where it has demonstrated efficacy in improving sexual function<sup>(14-16)</sup>.

However, previous research in the registries of the Brazilian Registry of Clinical Trials and previous literature reviews<sup>(1,10)</sup> have not evidenced studies that have implemented sexual counseling for pregnant women based on this model, which justifies the realization and originality of this research, with a view to contributing to the interprofessional approach and comprehensiveness in addressing sexual health in prenatal care.

A study evidenced that educational interventions specific to sexuality during pregnancy were effective in improving sexual

function and sexual satisfaction<sup>(14)</sup>. Nevertheless, there is a scarcity in the Brazilian literature regarding the evaluation of the impact of sexual counseling interventions on the sexual function and sexual quality of life of pregnant women.

In this regard, the objective was to describe the study protocol for analyzing the effects of the sexual counseling intervention based on the PLISSIT model on the sexual function and sexual quality of life of pregnant women.

## METHODS

This is a quasi-experimental clinical trial protocol, prepared in accordance with the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement, which constitutes a checklist for drafting non-randomized studies<sup>(17)</sup>. It was approved by the Research Ethics Committee under Opinion No. <omitted for blind review> and registered in the Brazilian Registry of Clinical Trials (ReBEC) <omitted for blind review>.

The study population will include all pregnant women registered and followed up in two Basic Health Units (UBS) in the urban area of a municipality in the Central-South Region of Ceará, Brazil, during the data collection period. Recruitment criteria include pregnant women registered and followed up by Family Health teams (eSF) who have a sexual partner and a Gestational Age (GA) of up to 18 weeks at the first data collection.

Pregnant women will be excluded if they: are receiving high-risk prenatal care, whose

pregnancy resulted from sexual violence or are experiencing intimate partner violence; have a psychiatric disorder and are using medications (selective serotonin reuptake inhibitors, antipsychotics, antiepileptics, anxiolytics, antidepressants, and hypotensive agents) because these can affect female sexual response<sup>(18)</sup>; are reclassified as high-risk<sup>(19)</sup>; have absences from two or more educational intervention sessions; give birth during the intervention or data collection; experience death or miscarriage; or change their address, altering their link to the eSF.

Sampling will be intentional consecutive and convenience-based, by applying the criteria mentioned above. On the days of prenatal or dental appointments, women will be invited to participate in the research, at which time the first data collection will be carried out, and they will be informed about the two subsequent collections. For the Intervention Group (IG), reminders will be sent by Community Health Agents via invitations a week beforehand, and a telephone contact will be made the day before each intervention.

The selection of the UBSs was convenience-based, as they are field sites for the extension activities of the University <omitted for blind review>. To mitigate the biases of non-randomization, participants will be selected from the same neighborhoods, the allocation to groups will be non-matched, and the selection criteria are directed toward healthy pregnant women, excluding factors that intervene in sexual function.



Data collection will preferably take place in the nursing office, where questions will be clarified without influencing the responses. Participation will be voluntary upon signing the Informed Consent Form.

The data collectors will identify and allocate the participants, and they will be blinded to the planning, execution of the intervention, and data analysis. The nurses will be blinded to

the planning, execution of the intervention, and data analysis. The professionals working in the intervention will be blinded to the Control Group, data collection, and analysis of the instruments. For impartiality in data analysis, the principal investigator will not participate in data collection or the intervention.

The interventions to be applied are shown in Table 1:

**Table 1** – Interventions implemented at the study sites. Fortaleza, Ceará, Brazil, 2023-2024.

Intervention component	Intervention group	Control group
Profile of people included	Pregnant women at usual risk, up to 18 weeks of gestational age, who have a sexual partner.	Pregnant women at usual risk, up to 18 weeks of gestational age, who have a sexual partner.
Intervention strategy	Sexual counseling based on the PLISSIT Model (Permission, Limited Information, Specific Suggestions, Intensive Therapy).	Individual sexual health education using the Ministry of Health's Low-Risk Prenatal Care Manual, offered during the prenatal consultation.
Data collection instruments	FSFI (Female Sexual Function Index), QS-F (Sexual Quotient - Female), SQoL-F (Sexual Quality of Life - Female) transcribed into an online form; field diary for recording non-participant observation.	FSFI, QS-F, SQoL-F transcribed into an online form.
Who will perform data collection?	Scholarship holders and nursing students previously trained by the principal investigator.	Scholarship holders, nursing students, and residents previously trained by the principal investigator.
Who will apply the interventions?	Psychologist and sexual therapist in a group activity, in a reserved room at the UBS (Basic Health Unit).	Nurse working in the eSFs (Family Health teams), in an individual consultation, according to routine.
Number of intervention sessions	Five (5).	According to the routine schedule of prenatal care by gestational trimester.
Time between data collections	Baseline/Follow-up (T0) (before the first data collection); Four weeks after the intervention (at the last intervention session) (T1); and Three months after the last week of the intervention (T2).	Baseline/Follow-up (T0) (before the first data collection); Four weeks after the intervention (at the last intervention session) (T1); and Three months after the last week of the intervention (T2).

Source: research data, 2024.

The instruments will be reapplied on the last day of the intervention and three months after the last intervention session, considering the possibility that the effect may still be present<sup>(20)</sup>.

In the IG, group sexual counseling will be applied once a week, consisting of five meetings of up to 120 minutes, based on the PLISSIT

model. This model is composed of four elements: The PLISSIT model for sexual counseling is structured into four progressive elements to address sexual concerns. First, P (Permission) is granted, where the professional "permits" the patient to express any concerns about sexuality, taking into account the physiological aspects of the sexual response<sup>(12)</sup>.

This initial phase is crucial as it aims to demystify taboos and prejudices that might limit sexual activity. The second element, LI (Limited Information), involves providing clarification on the physiology of sexual response and the anatomy of the genitalia, including guidance on erogenous zones. Next, SS (Specific Suggestions) involves giving counseling and suggestions for changes in sexual behavior based on the physiology of sexual response. Guidance is also provided on altering attitudes so the woman can maintain a positive outlook toward negative situations, which, in turn, impacts the conjugal and sexual relationship. Finally, IT (Intensive Therapy/Sexual Therapy) involves referral for sexual therapy with a specialist if severe sexual conflicts are identified<sup>(12)</sup>.

The intervention script was developed from July to October 2023 through meetings between the principal investigator and the sexual therapist, both possessing theoretical expertise on the subject. The first author conducted literature reviews<sup>(1,10)</sup> and empirical research<sup>(2,21)</sup>, and the sexual therapist has experience in individual and couples sexual therapy. Both also have experience in sexuality education during pregnancy linked to the "Sexuality, function, practices, and sexual positions" extension project since 2019, with contributions from the actively observing psychologist, which provided theoretical-practical support for constructing the scripts. These scripts were reviewed by three researchers.

For data collection, forms for sociodemographic, reproductive, and affective-

sexual characterization will be applied. To assess sexual quality of life, the Questionnaire on Sexual Quality of Life – Female (SQoL-F)<sup>(22)</sup> will be used, and to assess sexual function, the Female Sexual Function Index (FSFI)<sup>(23)</sup> and the Sexual Quotient – Female version (QS-F)<sup>(24)</sup> will be employed. During the intervention, non-participant observation will be used, conducted by a psychologist with records in a field diary.

Participants who drop out of the follow-up will have their data excluded, given the necessity of completing the follow-up for comparative analyses. The scholarship holders and volunteer collectors will be trained for instrument application, including simulation of form completion and conducting a pre-test. The principal investigator will be responsible for safeguarding the research data for a minimum of five years. Furthermore, any necessary changes to the research protocol will be communicated to the ethics committee and ReBEC. Questions will be resolved before and during the research execution.

The field diary data will be transcribed into a notepad, forming the textual corpus for processing in the *Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires*® software version 0.7 alpha 2, and presented in figures (descending hierarchical classification, word cloud). The data will be subjected to Content Analysis<sup>(25)</sup>.

The quantitative data will be exported from the online form into a Microsoft Office Excel® spreadsheet version 2010. Subsequently, a double-check will be performed to identify and



correct possible typing errors. The database will be exported for grouping, organization, and computerization in the RStudio® Software - online version (Cloud).

The Shapiro-Wilks test<sup>(25)</sup> will be conducted to identify the distribution of the variables. For statistical analysis, all variables of interest will be classified. Descriptive statistics (mean, standard deviation, relative and absolute frequency) and inferential statistics of the data obtained between the IG and CG at each time point (pre and post) will be used, applying parametric or non-parametric statistical tests as characterized by the variables and data normality.

For bivariate data analysis, considering the possibility of normal data distribution, the following will be used: Paired Student's t-test for comparing the same group; Student's t-test for independent samples to compare results between groups at the collection time points; Fisher's Exact Test for categorical data; In case of non-normality, the Wilcoxon test and the Mann-Whitney U test will serve as alternatives to the paired t-test and the independent samples t-test, respectively<sup>(25)</sup>.

If non-normality is identified, the Spearman's correlation test and the non-parametric tests: Pearson's Chi-squared, Wilcoxon-Mann-Whitney U, or Kruskal-Wallis<sup>(26)</sup> will be used.

To evaluate the effects of the intervention on sexual function and sexual quality of life, the scores of the SQoL-F, FSFI, and QS-F instruments between the IG and CG

will be compared at each collection time point, applying the Analysis of Variance (ANOVA) for repeated measures, or the Friedman ANOVA followed by Post-hoc tests, with values of  $p < 0.05$  considered statistically significant. Regression will be performed with variables resulting from the bivariate analysis with  $p < 0.01$ <sup>(25)</sup>. Cohen's d will be applied to identify the effect size, considered small if  $(0.20 \leq d < 0.50)$ , medium if  $(0.50 \leq d < 0.80)$ , and large if  $(d \geq 0.80)$ , or, alternatively, Hedges' g as a correction for Cohen's d, which reduces evaluation bias in small samples<sup>(27)</sup>.

The results will be presented descriptively and in figures, tables, and charts, and will be confronted and discussed with findings from scientific research to validate the results. Furthermore, the study will comply with Resolutions No. 466/2012 and 510/2016 of the National Health Council, which establish the guidelines and norms for research involving human subjects.

Pregnant women will be exposed to minimal risks of embarrassment, shame, and anxiety during data collection and intervention. To mitigate these, privacy will be safeguarded, and questions regarding the secrecy and confidentiality of the information will be clarified.

In cases of psychological harm or situations of sexual violence, women will be referred to the Women's Reference Center and/or for psychotherapeutic follow-up within the municipal health network.

Participant data will be coded using letters and numbers corresponding to the data collection time, which will ensure anonymity and confidentiality. The results will be disseminated to the scientific community, health professionals, patients, and the general community through scientific means and will serve to plan health education actions.

## EXPECTED RESULTS

It is expected that this research will contribute to research and clinical care in sexual health directed at pregnant women, allowing for scientific advancement in sexuality education within the healthcare landscape. The originality of applying sexual counseling based on the PLISSIT model to Brazilian pregnant women is highlighted as a strength.

It is believed that the application of sexual counseling based on the PLISSIT model during prenatal care can be implemented by health professionals, provided they are previously trained. By allowing for a group approach, timely access and management of sexual complaints, it will contribute to the improvement of sexual function and quality of life of pregnant women. In this sense, it is necessary to train prenatal professionals to apply the PLISSIT model individually or in a group setting.

Furthermore, compared to the routine approach performed during prenatal consultations, sexual counseling based on the PLISSIT Model will enable an improvement in the sexual function and sexual quality of life of

pregnant women, as evidenced by the comparison of data obtained from the questionnaires at the three data collection time points.

Therefore, it is suggested that the sexual counseling protocol can be used as an innovative tool for sexuality education based on collaborative interprofessional practices during prenatal care, and in future research to evaluate its effects on the sexual function and sexual quality of life of pregnant women in primary health care or other sexual health care settings. The necessity of developing protocols directed at pregnant transgender men is also highlighted.

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Nothing to declare.

#### **Authorship criteria (authors' contributions)**

All authors contributed to the conception and/or planning of the study; to the obtaining, analysis and/or interpretation of the data; as well as to the writing and/or critical review and final approval of the published version.

**Scientific Editor:** Ítalo Arão Pereira Ribeiro. Orcid: <https://orcid.org/0000-0003-0778-1447>

