

Study Protocol

"From Silence to Empowerment: Addressing Sexual Challenges in Rural Karachi, Pakistan with the Revolutionary PLISSIT Model"

Abstract:

Objectives: To solve the sexual health problems among young women aged 20-39 years by using a PLISSIT model in rural Sindh Karachi Pakistan.

Material and Methods This Quasi-experiment will carry in the primary health care center of Sindh Karachi, Pakistan. One primary healthcare center will be randomly selected as an intervention group and another center will be selected as control from all primary healthcare centers in Karachi. Intervention and control groups both will have socio-demographic characteristics. The population will be post-married women of age 20 to 39 years. Eligible participants will be randomly selected into control or intervention groups by applying the Balanced Blocked Randomizing method. For estimating sample size a confidence level of 95%, with a power of 80%, and with a dropout rate of 15%, will be used in open epi online software. This led to about 40 participants in each group of intervention and the control group will be the sample size. An adapted questionnaire (tool) called the female sexual functioning index (FSFI) from an Iranian study will be used in the study. Permission has been taken through email from the corresponding author. The questionnaire of FSFI is a validated and reliable measurement for assessing female sexual problems.

Analysis Plan: For the statistical analysis, SPSS version 20 will be used and data will be shown in the form of mean and standard deviation. For the comparison of scores between and within the groups, the Pair T-test and repeated measure of variance (ANOVA) will be used. The results will be considered significant for all statistical analyses if $P < 0.05$.

KEYWORDS: Sexual Health, PLISSIT model, Pakistan

Introduction

Sexual health is the core component of health, which can be measured through the scale of the sexual functioning health index. The word sex or sexuality cannot be discussed openly in a rural community because of the sensitivity and taboo. People often feel discomfort and embarrassment when exploring a certain sexual issue (Liang et al., 2019). Developing countries are almost lagging in addressing sexual concerns although the matter is internationally highlighted (Chen et al., 2020). In less developing countries, there is insufficient awareness and information, which leads to sexual problems and reproductive problems. Therefore specific interventional programs and workshops are needed to assess the sexual problems and practices in the community (Akbari et al., 2013). According to one study, there is a high level of stress and anxiety in pregnant women having sexual problems, therefore these women should be emotionally encouraged and enhance their knowledge regarding sexual problems (Liu et al., 2013). A study has been conducted in Turkey on postpartum women the results showed that most postpartum women have sexual problems and these problems significantly raise with the increase of age (Acele & Karaçam, 2012). The sexual health association in 2008 acknowledged that sexual health is the core component of the human being. Still, unfortunately, policymakers and lawmakers have ignored the complexity of sexual health. Governments should know their responsibility in promoting sexual health (Gruskin & Kismödi, 2020). According to WHO, Female sexual dysfunction (FSD) is classified into four domains the first is desire, the second is arousal, the third is orgasm, and the fourth is sexual pain (Petit-Steeghs et al., 2020). The rate of female sexual dysfunction is more prevalent among women in developing as compared to developed countries. The finding of an Iranian study revealed that about 31 to 51 % of Iranian women have sexual health problems (Moreira et al., n.d.)

(Safarinejad, 2006). Despite the high prevalence of sexual problems, primary health care services could not be managed properly. Knowledge and skill-building program need incorporation into rural healthcare for better management.

Study Purpose

This study will be conducted to assess the efficacy and practicability of the PLISSIT model for addressing sexual problems among women of age 20 to 39 years in rural health centers in Sindh Karachi, Pakistan.

Significance

WHO indicated that the incorporation of sexual health programs education and counseling into primary health care centers is the way forward to combat sexual problems, (Chen et al., n.d.). At the community level and in the rural health centers sexual health education has constantly ignored. Community midwives, LHVs, and LHWs are unskilled in sexual education and counseling. For proper addressing sexual health problems, the implementation of the PLISSIT model in the rural health center is the right option for the improvement of sexual health (Ayaz, 2013). In a session of sexual education and counseling, perceive values, and behaviors are discussed openly. the patient should be encouraged to start the discussion openly and elaborate on their problems (Robinson et al., 2011). Many studies have been conducted on the efficiency of the PLISSIT model, their results showing that there is marked improvement observed in sexual health (Keshavarz et al., 2020). Therefore, this PLISSIT model will be sufficient and feasible for rural health centers in Sindh Karachi Pakistan.

Operational definition

The female sexual function index (FSFI) score will be used in the study for assessing sexual health problems among women. The total FSFI will be computed by totaling the mean score of all domains. The maximum score on the scale is 36 and the minimum score is two. Score higher than 28 showings improvement in sexual functioning.

Literature Review

Despite the high occurrence of sexual problems, sexual health has been grossly ignored in rural healthcare. These centers lack skilled professionals to incorporate sexual education and practices in these centers. (Cheema et al., 2020). According to one study conducted in 28 less-developed countries, a finding of the study revealed that sexual dysfunction is increasing with increase of age 26% in 20 years and 39% in 50-year-old women (Safarinejad, 2006).

Protection of sexual and reproductive health needs investment in health services and education. Tunisia country has initiated sexual health service program for unmarried girls, while Iran had also launched a premarital program for young one having sexual problems (Dejong et al., 2005). To address sexual problems and concerns an effective model is suggested by the literature called the PLISSIT model (permission, little information, special suggestion, and intensive therapy) this model has a complete solution to all sexual problems(Aragie & Abate, 2021).

In a study conducted in Korea on gynecologic cancer patients, the finding of this study showed improvement in sexual health hence this study is an evidence base thus showing the PLISSIT model is effective for addressing sexual issues. (Assistant Professor, 2011). In Egypt a study has been conducted on women with dyspareunia, the findings of this study revealed significant mean differences in pre and post-intervention of the PLISSIT model, the score of FSFI in multiple domains for desire, the arousal, orgasm, satisfaction, and the pain the ($p < 0.005$)(Robinson et al.,

2011). Ayaz and Kubaily have done a study among turkey patients with stoma bags. The findings of the study revealed that there is improvement observed in patient satisfaction with the PLISSIT model (Ayaz, 2009). Thus, above all studies showed that sexual health could be improved through sexual education.

The PLISSIT model is comprised of four stages the permission phase (p) little information phase (LI) special suggestion phase (SI) and the intensive therapy phase (IT). In the permission stage, a friendly discussion will be initiated, and a trusted relationship is built up gradually then sexual issues and practices would be addressed. The second phase will be the information phase in which clients will be updated about sexual practices and behaviors through skills and knowledge (Kazemi et al., n.d.). The third level is the suggestion phase, in which problem-specific suggestions will be given to a patient. In the third level, specific suggestions are given to the patient for specific problems if the patient has. The fourth level is intensive therapy in which patients need intensive treatment and intervention. This is also called the referral phase because patients are referred in this phase (Ayaz, 2009). Therefore, the PLISSIT model is considered effective for resolving sexual issues. Community health workers and midwives need to be updated in knowledge and skill for assessing sexual problems therefore PLISSIT model is recommended for implementation at the community level in the primary health centers. Therefore, we are hypothesizing that this model will be sufficient for addressing sexual issues in the primary health center in Sindh Karachi, Pakistan.

Research questions

The study aims to answer the following questions

- A. What are the current sexual problems among women (aged 20 to 39 years) in rural areas of Sindh Karachi, Pakistan?
- B. Is the PLISSIT model effective for addressing sexual problems among women of age 20 to 39 years in rural health centers in Sindh Karachi, Pakistan?

Study design

The study design will be a Quasi-experimental in a rural health center in Sindh Karachi, Pakistan.

Study population and study setting

This Quasi-experiment will carry out in the primary health care center of Sindh Karachi, Pakistan. One primary healthcare center will be randomly selected as an intervention group and another center will be selected as control from all primary healthcare centers in Karachi. Intervention and control groups both will have socio-demographic characteristics. The population will be post-married women of age 20 to 39 years. All methods will be carried out in accordance with the International Code of Medical Ethics. This is an educational intervention hence No harm will be given to the study participant, participant health will be our first consideration.

Sample and sampling

Written informed consent will be obtained from all eligible study participants and all eligible participants will be randomly selected into control or intervention groups by applying the Balanced Blocked Randomizing method.

For estimating sample size a confidence level of 95%, with a power of 80%, and with a dropout rate of 15%, will be used in open epi online software. This led to about 40 participants in each group of intervention and the control group will be the sample size

Ethical consideration

All methods will be carried out in accordance with the International Code of Medical Ethics. This is an educational intervention hence No harm will be given to the study participant, participant health will be our first consideration. Eligible participants will be informed about the aim of the study and will assure that confidentiality would be sustained by means of codes rather than names. Written informed consent will be obtained from all the study participants who take participation in the study. Privacy, confidentiality, and anonymity of the participant will be ensured throughout the study through a coding system.

Inclusion Criteria

Those women will be included in the study, if they are currently living with their husbands and are married for the past five years; have self-reported sexual issues, and willingness to participate in the study.

Exclusion Criteria

- 1) Those women will be excluded from the study who are not living with their husbands because of any issues.
- 2) Those women will also be excluded from having some psychological issues like depression, anxiety, stress, or gynecological issues that may cause sexual problems.

Study variables

Independent variables of the study will be the practices, knowledge, and counseling given in the intervention, that's will give through the questionnaire.

While dependent variables of the study will be the FSFI score of post intervention in both the control and intervention groups.

Data collection tool

An adapted questionnaire (tool) called the female sexual functioning index (FSFI) from an Iranian study will be used in the study. Permission has been taken through email from the corresponding author. The questionnaire of FSFI is a validated and reliable measurement for assessing female sexual problems. The FSFI questionnaire consists of 19 questions regarding sexual problems. The questionnaire will be in English language and will be used during interviewing the participants. The study tool has two parts; first part contains questions related to demographics, socioeconomic, education, and income. The second part of the study tool has 19 questions. These 19 questions will be classified into six domains. The domain of desire has (two questions), a domain of arousal has (four questions), a domain of lubrication has (four questions), a domain of orgasm has (three questions), and the domain of satisfaction has (three questions), and domain of pain having (three questions). For the calculation of each domain score sum of all scores within each domain will add and then will multiply with a certain coefficient. Each domain has a minimum score of 0 to 6. A higher score indicates better functioning for that domain. Then total score of FSFI will be computed by totaling a mean score of all domains. The total minimum score for FSFI is two while maximum is 36.

Data collection procedure

The investigator will screen the eligible participants, then these participants about the study's purpose, and will ask about their willingness to participate. If agreed to participate an informed consent will be signed. Then data collection will start and all the selected women that come to primary health centers for sexual problems will be interviewed about demographics (age, income, education level, occupation, reproductive history (marriage duration, number of children, and parity). To assess sexual problems, the participants will be interviewed through the FSFI questionnaire. The investigator will ask about participants' relationship status, reproductive health factors, partner age, sexual debut age, and when they are pregnant. The study tool will also ask for awareness and previous infections of HIV or any STIs. The tool will also ask about contraception i.e. if yes whether Hormonal or condom use. The level of education, age, and income will be converted into ordinal variables.

Study Rigor

The study tool will be thoroughly checked by two research experts for content validity and pilot testing. CVI will be calculated and will be modified if required further modification. Pilot testing will be applied to 10% of participants of the total sample size.

Data Analysis Plan

The mean score of FSFI in each domain will be calculated and then this score will be compared between the intervention group and control group. These FSFI scores will be calculated at three levels before the counseling, 2 and 4 weeks after the counseling. For the statistical analysis, SPSS version 20 will be used and data will be shown in the form of mean and standard deviation. For the comparison of scores between and within the groups, the Pair T-test and repeated measure of

variance (ANOVA) will be used. For all statistical analyses, the results will be considered significant if $P < 0.05$.

Strengths and limitations of this study

The study will be the developer to the best of our knowledge in identifying women with both sexual and reproductive health issues in rural Sindh Karachi Pakistan. This Quasi-experimental approach will provide a more inclusive research result as little is known about their sexual health issues. Limiting the study is only rural Sindh area of Karachi Pakistan rather than the majority of all provinces of Pakistan

Declarations

consent to participate

All methods and process will be carry out in accordance with the International Code of Medical Ethics. This is an educational intervention hence No harm will be given to the study participant, participant health will be our first consideration.

Publication Consent

Not applicable

Availability of data and materials

Original datasets will be offered upon reasonable request to the corresponding author.

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