

Protocol for Investigating the Effect of Kegel Exercises on Pelvic Floor Muscle Disorders and Quality of Life among Pregnant and Postnatal Women in Ho, Ghana

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ABSTRACT

Introduction: Pelvic floor disorders (PFD) are common presenting gynecological complaints that adversely affect quality of life, including sexual health among women.

Study Objective: To examine the effect of Kegel exercises on the disorders of pelvic floor muscles among Ghanaian pregnant women in the third trimester and in women after delivery in Ho.

Methods: The study will be conducted in the Volta Regional Hospital of Ghana. Pregnant women in the third trimester will be invited to participate in this study through a simple random sampling technique. Through a screening of pregnant women with pelvic floor disorders, structured questionnaires will be used to collect data from 435 pregnant women of the Volta Regional Hospital and those who qualify will be followed up till 6 weeks postnatal. Participants will be grouped into control and intervention groups. 104 participants from the screening will be recruited for the interventional study; 52 for the intervention and 52 controls.

Analysis: Statistical analysis will be performed using SPSS version 21. The results will be enumerated into means and proportions at 95% CI and presented in tables, charts or graphs. Independent t-test will be used to analyse the effect of treatment. $P < 0.05$ will be considered statistically significant.

Expected Outcome: Evidence from this study will inform practice and care of pregnant women. It will also help implementation of interventions regarding pelvic floor muscle disorders.

Keywords: Pelvic floor muscle disorders; Kegel exercises; Effect; Pregnancy; Postnatal; Ghana

BRIEF SUMMARY

Pregnancy is known to weaken the pelvic floor muscles resulting in disorders. The study investigates the effect of Kegel exercises on women's health in Ghana.

INTRODUCTION

Pelvic floor muscle disorders are public health issues impeding on the quality of life of women of reproductive health. It is estimated that eleven percent of all women would require surgery at least once in their life for one pelvic floor muscle

disorders. Of these, at least one in three will need a second, or next, surgery as a result of reoccurrence [1,2]

In a study carried by Mason, Glenn [3] in the UK, they reported the efficacy of antenatal PFE in the primary prevention of postpartum stress incontinence but the study only focused on primiparous women. Though they also reported significant improvement in pelvic floor functions among the study group, they were not able to use the required power estimation due to high lost to follow up. In Africa where birth rates are high, it is

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Received: March 15, 2020; Accepted: March 27, 2020; Published: April 3, 2020

Citation: Torgbenu EL, Aimakhu CO, Morhe EKS (2020) Protocol for Investigating the Effect of Kegel Exercises on Pelvic Floor Muscle Disorders and Quality of Life among Pregnant and Postnatal Women in Ho, Ghana. Clinics Mother Child Health 17:345. DOI: 10.35248/2090-7214.20.17.345

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appropriate we examine if similar effects of Kegel exercises will be achieved among both primiparous and multiparous as well.

Most of the studies on pelvic floor disorders carried out among Sub-Saharan Africans reported varied prevalence and focused mainly on Nigeria [4-6]. Studies on effects of pelvic floor muscle training or exercises were lacking in Africa. All these studies focused on prevalence of pelvic floor disorders and therefore, studies aimed at investigating the effect of Kegel exercise on pelvic floor muscle disorders are required.

In fact, one study in Egypt by El-Shamy and El Fatah [7] on the effect of antenatal pelvic floor muscle exercise reported only on the mode of delivery. They also involved only participants who were able to contract the PFM. Though the study recommended Kegel exercises as a safe and inexpensive strategy for increasing vaginal delivery rates, their findings did not look at the effect among women with pelvic floor disorders.

Pelvic floor disorders are common debilitating affecting quality of life, especially in women, but hitherto their pathogenesis has not been well understood [8]. Some pregnant women may develop PFD as a result of the weakening of the pelvic floor muscles. Weakness of the pelvic floor muscle [PFM] can decrease the muscle strength and consequently could result in urinary and faecal incontinence [9] among pregnant and puerperal women. Incontinence among pregnant women are major source of psychological trauma and stigmatization and therefore, it is prudent that studies aimed at diagnosing the menace are encouraged among Africans to help plan management of the condition. These may impede on pregnant women participation in the society and hence studies focusing on exposing the menace are required. The conditions are also associated in varying degree, with clinical, electrophysiological and histological features of chronic partial denervation in the muscles of the pelvic floor, especially in the puborectalis and levator ani muscles, and in the external anal and periurethral striated sphincter muscles [8, 10]. Subsequently, pelvic floor disorders may result in pelvic girdle pain. This pain according to Elden, Ladfors [11] is a common complaint among pregnant women worldwide, and it causes severe pain in one third of the affected women. They added that, strenuous work, previous low back pain, and previous pelvic girdle pain are known risk factors[11]. Though pelvic floor disorder is not a life threatening condition, it is a source of severe morbidity and psychological distress to the patient, who is often socially withdrawn and stigmatized [1]. It is true that pregnancy must not hinder or impede the quality of life of women especially due to pelvic floor disorders, therefore disorders emanating from weakness of the pelvic floor muscles require attention to prevent any impediment on the social and health status of the pregnant women.

It is therefore based on this that this study seeks to find answers to the following questions:

- 1) What disorders of the pelvic floor muscles are prevalent among pregnant women who are in the third trimester and during postnatal women?
- 2) What will be the effect of Kegel's exercises on the quality of life of pregnant women diagnosed with PFDs in Ho, Ghana?

This current study will be the first of its kind to investigate the effect of Kegel exercise on pelvic floor disorder specifically, urinary incontinence and pelvic floor muscle weakness among Ghanaian pregnant women. It is likely to inform policy regarding the antenatal care pregnant women receive in the country.

METHODS

Study setting

The study site will be carried out at the antenatal unit of the Volta Regional Hospital in Ghana which is the Teaching Hospital of the University of Health and Allied Sciences, Ho which serves the twenty-nine (29) different health facilities in the Municipality. These smaller health centres include Community-Based Health Planning and Services (CHIPS) compounds, polyclinic and private clinics located in the Volta Region of the Southern Ghana. The Regional Hospital serves all the 29 districts of the Volta Region and it is the only referral hospital in the region. The Ho municipality is located on 6.6023° N, 0.4844° E.

Study design and approach

The study which is projected to span a period of nine months of data collection is divided into two phases. These are:

A cross-sectional study will be employed for the collection of data at various antenatal clinic and the maternity wards of the Volta Regional Hospital to establish the prevalence and factors associated with pelvic floor disorders among Ghanaian pregnant women.

The second phase will be a randomized controlled trial. This will involve the incorporation of Kegel exercises in the strengthening of Pelvic floor muscles among two groups of pregnant women. Participants will be randomized into two groups. Participants will either be in the study or control groups through simple randomization as they arrive in the hospital seeking healthcare. Pregnant women in their third trimester of pregnancy will be recruited. The process will include the identification of pregnant women and they will be screened for any of the pelvic floor muscle disorders and weaknesses. Participants for this study will include pregnant women in the third trimester and will be followed up till 6 weeks postnatal.

Inclusion criteria

The inclusion criteria will be:

All pregnant women who are in their third trimester.

Pregnant women who have registered with the facility and are on attending antenatal visits. Participant at the time of conducting the study should have registered for antenatal clinic at the Out-patient department (OPD) or with their designated antenatal clinics in the locality and have their records with the facility.

Pregnant women who are residents of the region where the study is being carried out and should be living in the area. This is to help with the follow up during the second stage of the study.

Participants who will be recruited to participate in the interventional study are those identified with pelvic floor weakness during the screening stage of the study.

Exclusion criteria

The exclusion criteria will be

Pregnant women with high risk for pre-term labour

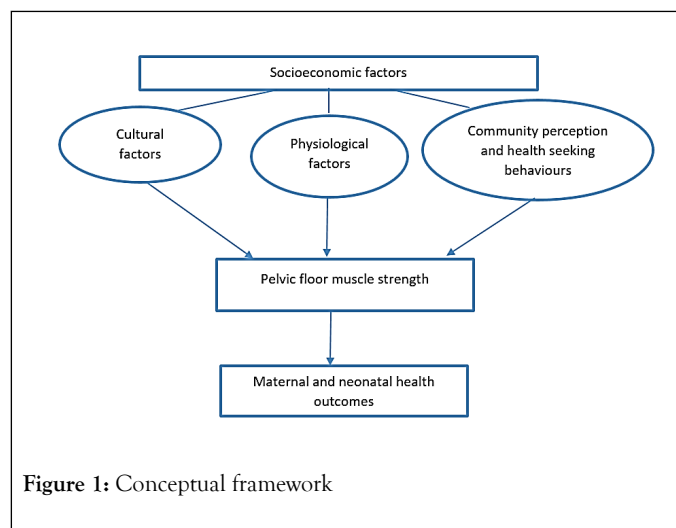
Pregnant women who may be experiencing pain during pelvic floor muscle contractions.

Pregnant women with ongoing urinary tract infections (UTI) or any nerve disease condition (neurological conditions) that could interfere with participation and outcomes.

Pregnant women without pelvic floor disorder will be excluded from participating in the interventional study.

Conceptual framework

This study is guided by a conceptual framework (Figure 1).



This framework indicates that cultural practices, physiological factors and prevailing attitudes in the community as well as health seeking behavior and diverse risk factors all impact the strength of the pelvic floor muscles during and after pregnancy. Based on this framework, we would expect that the Kegel exercises consequently may increase the strength of the pelvic floor muscles and affect labour, thus influencing maternal and neonatal health outcomes.

Sampling/ Participants Recruitment

Before the recruitment of the participants for the study, two (2) interviewers will be trained and informed adequately on the skills of making women talk comfortably about their pelvic floor disorders. This will be to enhance the quality of measurements. All pregnant women who meet the inclusion criteria will be screened for pelvic floor disorders by the principal investigator. Those women with the disorder will constitute the sample for the interventional group of the study. Participants will be recruited from the antenatal clinic (ANC) of the hospital once they meet the inclusion criteria and have given informed consent to participate. Data for the study will be collected from

the out-patient department of the antenatal and follow-up will be made after delivery at the postnatal clinics of the Volta Regional Hospital of Ghana for the second measurement six-weeks after delivery. Screening for participants with pelvic floor muscle disorders will be done using the World Health Organization quality of life (WHOQOL-Bref) questionnaire and the pelvic floor muscle questionnaire [12] The principal investigator and the trained research assistant will administer the questionnaire to recruit the participants and those who will be identified with the disorder of the pelvic floor muscles will be recruited to participate in the interventional phase of the study.

Sample size

The Antenatal Unit of the Volta Regional Hospital sees 75-100 pregnant women daily. Averagely, the Regional Hospital sees a total of 2,450 woman monthly and 29400 pregnant women annually.

Using the Slovin’s formula for sample size estimation

$$n = \frac{N}{1 + N(e)^2}$$

Where n is the required sample size

N is the population size

e is the level of precision

A 95% confidence level will be used.

This formula will be used to derive the sample size with the values of each term in the formula given as;

N=29400, e=0.05

Therefore, n=394.63

With a non-response rate of 10%, the sample size to be recruited from the Volta Regional Hospital will be 395+40=435.

Thus, 435 participants will be recruited for the study from the Volta Regional Hospital, Ho-Ghana.

Sample size for the intervention phase

In calculating the sample size for the interventional study, the power calculation will be considered for the purpose of determining the number of cases that will form the study and the control groups required. The power calculation will be calculated only by the prevalence of pelvic floor disorders. In accordance with the reports by Dinc, Beji [13] 43.2% of pregnant women presented with pelvic floor disorders in the study group and 71.4% presented among the control group.

Accordingly, the sample size (comparing two proportions) for the study will be calculated as follows: p1= 0.432 (intervention group), p2= 0.714 (control group) with 95% confidence interval, α =0.05, β =0.20, and power at 80% (1B), using the formula:

$$n = [(Z_{\alpha/2} + Z_{\beta})^2 \times \{p1(1 - p1) + (p2(1 - p2))\}] / (p1 - p2)^2$$

where , n is the number of sample size required in each group
 $Z_{\alpha/2}$: This depends on level of significance, for 5% this is 1.96
 Z_{β} : This depends on power, for 80% this is 0.84

Therefore,

$$n = \frac{[(1.96 + 0.84)^2 \times \{0.432(1 - 0.432) + (0.714(1 - 0.714))\}]}{(0.432 - 0.714)^2} = 44.28$$

Hence, the sample size per group will be 45 and the total sample size required is 90.

Accounting for lost to follow up in each group, 15% will be added and the total number will be 104 [52 in each group]

MEASUREMENTS AND INTERVENTION

Control and interventional groups

One hundred and four (104) participants will be recruited from the screening of pregnant women for the interventional study. Two groups of fifty-two (52) participants each will be generated from the point of data collection. Pregnant women who presented with pelvic floor disorders will be randomized into the two groups; the control and the intervention group. Both the control and the intervention groups will be similar in that, participants will both present with the pelvic floor disorder. This will be to aid comparison between the two groups and to help draw conclusion of the effect of the Kegel exercises on the treatment of pelvic floor disorders.

The control group

The control group will be pregnant women in the third trimester of pregnancy with pelvic floor disorders. Pregnant women in the control group will only be given instruction about pelvic floor muscle training. They will also be allowed to follow the routine antenatal care as provided by the midwives. Measurement for the effect of the exercises for the comparison with the interventional group will be done at the beginning of the study (28 weeks of pregnancy), and at 6 weeks postnatal by the trained research assistant. It is expected that, those women who might have suffered injury during the delivery process will have enough time to heal before the second measurement is done. The perineometer will be used to measure the strength of the pelvic floor muscle at the third trimester of pregnancy and at 6 weeks postnatal visit.

The intervention group

The intervention group are also pregnant women in the third trimester of pregnancy who present with pelvic floor disorders. They will receive more intensive interaction and well monitored Kegel exercises in addition to the usual antenatal care provided in the hospital. Women in this group will receive pelvic floor muscle training (PFMT) twice weekly with 45 minute per session plus prescribed home exercise programmes (HEP) in between sessions. Participants will be assessed at baseline for the risk of pregnancy, and at 6 weeks after delivery (the end of the intervention). Individuals recruited must not be receiving any form of physiotherapy prior to the study and during the study.

The principal investigator will administer the intervention. The investigator will instruct participants individually on the Kegel exercises and will teach them how to perform the exercises effectively. Measurement for the strength of the pelvic floor muscles will also be done at two points during the study: the beginning of the study, and the last measurement will be done at 6 to 8 weeks postnatal. One research assistant (female physiotherapist) will be trained by a specialist women’s health physiotherapist to do the pelvic floor muscle strength measurements for all the participants.

Data Collection tool

The characteristics and data to be collected is presented in (Table 1)

Table 1: Demographic data collection form

PARTICIPANT INFORMATION	PRENATAL	POSTNATAL
AGE		
CODE		
HOSPITAL NUMBER		
STAGE OF PREGNANCY		
DURATION OF SYMPTOMS		
BMI		
HEIGHT		
WEIGHT		
PELVIC FLOOR DISORDER SCORE		
MULTIPLE PREGNANCIES?		
QUALITY OF LIFE SCORE		
PERINEOMETER SCORE		
1ST READING		
2ND READING		
OXFORD MUSCLE TESTING		
1ST		
2ND		
BIRTH INFO		
WEIGHT OF BABY AT BIRTH		
GESTATIONAL AGE		

 MODE OF DELIVERY

 EPISIOTOMY (YES/NO)

The study will use two (2) standardized data collection tools. The pelvic floor questionnaire (PFQ) will be used to assess the prevalence and type of pelvic floor muscle disorder (PFD) [14] and the impact of PFD on the quality of lives of the pregnant women before and after the end of PFMT program will be assessed using the World Health Organization Quality of Life Questionnaire. The modified pelvic floor questionnaire (PFQ) is an interviewer-administered pelvic floor measurement tool which assesses all pelvic floor symptoms including bladder, bowel, and sexual function and prolapse symptoms, symptom severity, impact on quality of life and bothersomeness in women with pelvic floor disorders [15]. It classifies PFD into four main domains: bladder 19 functions, bowel functions, prolapse and Sexual functions. This measuring tool assesses all aspects of pelvic floor function including condition-specific quality of life issues in a reproducible and valid fashion. It is suitable for clinicians and researchers. Due to its easy application and clinical relevance, the questionnaire can be integrated in routine clinical assessment as an alternative to time-consuming self-administered separate bladder, bowel and sexual dysfunction questionnaires.

The quality of life of pregnant women will be measured using the World Health Organization Quality of Life (WHOQOL) – BREF questionnaire. WHOQOL-BREF [16,17] is a patient reported outcome measure used to assess the quality of life within six (6) contextual areas including the individual's quality of life, activities of daily living, the general health, life participation, mental health and social life relationships. It is a self-report questionnaire which consists of 26 items and addresses four (4) main QoL domains including physical health (7 items), psychological health (6 items), social relationships (3 items) and the environment (8 items). The other two items measure the overall QoL and general health. Each item is rated on a 5-point Likert scale (low score of 1 to high score of 5) to determine a raw item score. Subsequently, the mean score for each domain is calculated, yielding a mean score for each domain that is between 4 to 20. Finally, this mean domain score is multiplied by four in order to transform the domain score into a scaled score, with a higher score indicting a higher QoL.

Piloting and pre-testing

A pre-piloted interview schedule will be used to ensure that the key questions which will be asked address the issues appropriately. The questionnaire will be pre-tested in Accra Regional Hospital which is also a tertiary facility.

Data analysis

Statistical analysis will be performed using SPSS version 21. The results will be presented into means and proportions for the quality of life and the pelvic floor muscle weakness for the pre- and postnatal visits at 95% CI and presented in charts or graphs.

Descriptive statistics will be performed to estimate the prevalence of the pelvic floor disorders among pregnant women.

Binary and multivariate logistic regression will be used to determine the socio-demographic factors of pregnant women with PFDs. Comparison between different groups regarding categorical variables will be tested using chi-square test.

Ordinal logistic regression will be used to determine the effect of pelvic floor disorder on the quality of life of pregnant women.

An independent t-test will be used to compare the means for the pelvic floor measurements pre- and postnatal. The effect of Kegel exercises on the pelvic floor muscle weakness among pregnant women as well as the effect of the Kegel exercises on the quality of life of pregnant women will then be estimated.

$P < 0.05$ will be considered statistically significant for test of associations and correlation for the current study.

Dependent Variables

The primary dependent variable is pelvic floor muscle disorder (presence or absence) and the quality of life and they will be measured using the Pelvic Floor Questionnaire (PFQ) and World Health Organization Quality of Life-BREF Questionnaire (WHOQOL-BREF) respectively.

Explanatory Variables

The main independent variable is the effect of PFMT (Kegel exercises) on the strength of pelvic floor muscles and this will be measured using the perineometer reading for the pelvic muscle strength measurement. The other control variables will include both extrinsic factors such as parity, history of previous hysterectomy, co-morbidities, occupation, socioeconomic status, educational levels, and the intrinsic factors will be the age of the participant, the gestational age, and the age at first pregnancy.

Ethical consideration

The Ethics Board at the University College Hospital, Ibadan, Nigeria and Ghana Health Service Ethical review committee approved the study protocol. Written authorization letter will be sent to the hospital to seek for approval to conduct the study.

Expected Outcome

The expected outcomes of pelvic floor disorders measurement among Ghanaian pregnant women will be to quantify the extent of the condition and then will aid planning and strategies to develop interventions will be cost effective and appropriate to tackling the condition. In the situation where the prevalence of the condition is low, the interventional stage will provide a better way of increasing pelvic floor muscle strengths and this will be included in antenatal care sessions. Pregnant women will be taught to practice this simple but highly effective exercises throughout the continuum of the pregnancy period which it is expected will be able to shorten the second stage of labour and hence reduce maternal death as well as safeguard the safety of the newborn baby.

Subsequently, the investigator is also expecting that Ghana Health Service will deploy more physiotherapists engaged in reproductive health rehabilitation to assist in the implementation of Kegel exercises to women of childbearing age to strengthen pelvic floor muscles in preparation for childbirth. Despite the proven effect of the pelvic floor muscle exercises, Ghana is yet to offer these services to expectant mothers and it is expected that the outcome of this research will inform this decision as appropriate considering the setting of the study. Additionally, it is also expected that the evidence from this study will improve upon the practice of physiotherapy in reproductive health conditions in the future which will help the entire community, antenatal care, health care workers, physiotherapists and women during pregnancy as well as postnatal.

It is also anticipated that, there will be a number of publications and media campaigns will emerge from this study. The investigators will be available to spearhead the education on the condition and the interventional strategies and to tell the story of how this long-time proven technique of Dr. Kegel in 1948 was implemented in Ghana to assist pregnant women through the period of gestation. The lead investigator will be ready with materials and soundbites about the procedure and practice. This will bring to bear the role of the healthcare providers engaged in the management and care of maternal health. A collaborative effort between the Ministry of Health and Ghana Health Service will be established to render special training to midwives and community health nurses on the Kegel exercises techniques to assist them prescribe the appropriate skills to expected mothers at the focus antenatal care sessions to help achieve the best results required. Strategies will be developed to enable the implementation of the study aim across the whole country to help achieve the best outcomes.

LIMITATIONS

The study may have potential limitations. First, since the study is a cross-sectional study and participants will be recruited at the third trimester, it will not be able to establish causality. Participants who may be recruited for the intervention study will only be pregnant women with pelvic floor muscle weaknesses. A large prospective study researching the condition among pregnant women from the onset of pregnancy to delivery will be appropriate to study the pattern and trajectory of the condition. Another limitation may be that participants for the study may have different gestational periods which is likely to affect the outcome of the interventions.

CONCLUSIONS

In conclusion, Kegel exercises are effective treatment for weakened pelvic floor muscles and are appropriate to prevent the discomfort and disability encountered during the period of pregnancy thereby increasing the quality of lives of women in gestation. Therefore, it calls for its implementation as a routine exercise regimen for pregnant women.

Conflict of Interest

None

AUTHORS' CONTRIBUTIONS

ELT, COA, and EKSM conceptualized the study. ELT drafted the manuscript under the supervision of COA and EKSM. ELT, COA, and EKSM, reviewed and made inputs into the intellectual content and agreed on its submission for publication. All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS

The authors acknowledge sincerely the support of the staff of Pan African University of Life and Earth Sciences Institute (Including Health and Agriculture), Pan African Commission and the Professors of University College Hospital (UCH), University of Ibadan, Nigeria. The authors will also like to dedicate this study to the loving memory of the Late Professor A. O. Fawole who made tremendous input into the conceptualization of the project idea.

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