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Effect of pelvic floor muscle training among pregnant black African population on the risk of postpartum urinary incontinence, a single blind randomized control trial

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EFFECT OF PELVIC FLOOR MUSCLE TRAINING AMONG PREGNANT BLACK AFRICAN POPULATION ON THE RISK OF POSPARTUM URINARY INCONTINENCE, A SINGLE BLIND RANDOMIZED CONTROL TRIAL

By

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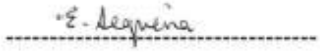

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DEDICATION

I dedicate this dissertation to my family and friends for their prayers and constant support throughout the period of the study.

To my dear wife Fidelis Muthoni, I deeply appreciate your support and encouragement. I shall be forever grateful for your understanding, concern, and care and for you always creating a conducive environment for intense academic output. Thank you darling!

To my daughter Anne Wairimu, your smile always warms my heart and your sense of humour gives me strength. You are indeed awesome!

ABSTRACT

TRIAL REGISTRATION

The study was registered at the Pan African Clinical Trial Registry and a unique identification number issued PACTR201407000850309.

BACKGROUND

Pelvic Floor Muscle Training (PFMT) in the antenatal period has been found to be an effective primary prevention intervention in the Caucasian population in reducing the risk of postpartum Urinary Incontinence.

OBJECTIVE

This study was primarily designed to determine the effect of PFMT introduced in the second trimester amongst pregnant black African population on the risk of six weeks postpartum Urinary Incontinence.

Secondary objectives included investigating the risk of postpartum Urinary Incontinence, the effect of mode of delivery on the risk of six weeks postpartum Urinary Incontinence and determining contributory factors in this population on the risk of postpartum Urinary Incontinence.

STUDY DESIGN

The study was a single blind Randomized Control Trial.

INTERVENTION

PFMT was conducted by a Physiotherapist and a Continence Nurse from recruitment to 37 completed weeks of gestation, with the control group receiving standard Antenatal care.

ASSESSMENT OF URINARY INCONTINENCE STATUS

Data collection was done primarily by administering a validated questionnaire (ICIQ-UI Short Form) at recruitment in the Antenatal clinic and in the postpartum period at the six week postnatal visit.

MAIN FINDINGS

Intention to treat analysis was undertaken using the SPSS Statistics 17.0 software package. The primary outcome of the study was an estimate of the risk of 6 week postpartum Urinary Incontinence as a proportion for the treatment and control groups. The risk in the treatment group was found to be 6% while in the control group was 36%. The Risk Ratio was found to be 0.17 (95% Confidence Interval; 0.04, 0.69) and the Relative Risk Reduction was found to be 83%.

Comparison of proportions was done using the Chi-square test to compare the two groups for any statistically significant difference. X^2 (1) = 9.07, P= 0.003 which was considered statistically significant. The null hypothesis was rejected.

There was a statistically and clinically significant difference in the risk of postpartum Urinary Incontinence between PFM trained pregnant black African population and those given standard Antenatal Care.

LIST OF TERMS, ABBREVIATIONS AND SYMBOLS USED

ANC	Antenatal Clinic
AKU	Aga Khan University
AKUH	Aga Khan University Hospital
BMI	Body mass index
C.I.	Confidence Interval
DR	Doctor
EA	East Africa
ICIQ-UI-SF	International Consultation on Incontinence Questionnaire – Urinary Incontinence – Short Form
MD	Doctor of Medicine
MRCOG	Member of the Royal College of Obstetrics and Gynaecology
NHS	National Health Service, United Kingdom
O.R.	Odds Ratio
PFM	Pelvic Floor Muscles
PFMT	Pelvic Floor Muscle Training
R	Pearson Product Moment Correlation Coefficient
RCT	Randomized Controlled Trial
SPSS	Statistical package for the social sciences
UI	Urinary Incontinence
UK	United Kingdom

ACKNOWLEDGEMENT

First of all, I am grateful to my supervisors Prof. Zulfiqarali Premji, Dr. Evan Sequiera, Dr. Johnstone Miheso and Dr. Charles Muteshi, whose scholarly advice, help and constant encouragement have contributed significantly to the completion of this study.

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I am appreciative of the services of Mr. George Ong'ete who assisted in the proofreading and editing of my paper and to Ms. Faustina Mandu who assisted with formatting and other technical aspects.

My very deep gratitude to Mr. Lawrence Gichini and Mrs. Victoria Musyoka who were instrumental in designing and implementing the PFMT regimen employed in this study.

Thank you all

DECLARATION

I declare this dissertation does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university and that to the best of my knowledge it does not contain any material previously published or written by another person except where due reference have been made in the text.

(Signature of candidate)

26/06/2015

Date

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Chapter 1: INTRODUCTION

Urinary incontinence was defined as the complaint of any involuntary leakage of urine. Studies have shown that urinary incontinence, arising during pregnancy and childbirth, may often fail to resolve. A systematic review found that during the first 3 months postpartum, the pooled prevalence of any postpartum incontinence was 33% (95% confidence interval (CI) 32–36%) in all women (1).

Epidemiological studies on Urinary Incontinence during pregnancy and postpartum list numerous variables associated with the condition. The risk factors can broadly be divided into modifiable and non-modifiable categories. Some, like race, chronic diseases, and maternal age are non-modifiable risk factors. Modifiable risk factors include smoking, obesity, constipation, pelvic floor muscle training, use of perineal warm packs during delivery, aiming at normal weight before pregnancy, and regaining pre-pregnancy weight postpartum and should be promoted to prevent urinary incontinence in association with pregnancy and the postpartum period (2).

The black population appears to have a lower predisposition to urinary incontinence during pregnancy and the postpartum period when compared to the white population (3). In addition to racial variation in the prevalence of urinary incontinence in women, race appears to play a role in the distribution of types of incontinence in incontinent women. In a study of 200 consecutive patients with urinary incontinence who were subject to a comprehensive physical exam and urodynamic testing, significant differences were found in the distributions of stress urinary incontinence, urge incontinence, and mixed incontinence between African-American and Caucasian patients (4).

Similar results were obtained in a study by Graham and Mallet, who examined urodynamic findings in 183 African-American and 132 Caucasian women with urinary incontinence. African-American women had a significantly lower prevalence of stress urinary incontinence and higher prevalence of urge incontinence than Caucasian women (5).

Chapter 2: LITERATURE REVIEW

Continence depends upon an intricate reflex pathway which involves both anatomical and physiologic components (6, 7). The lower urinary tract system consists of the urinary bladder and urethra and has two roles, namely, storage of urine and voiding at appropriate times.

Control of the detrusor and urethral sphincter muscles in these two mutually exclusive states is dependent upon both local spinal reflexes and central cerebral control. Central coordination occurs at the pontine micturition centre, which receives input from higher centres responsible for switching between the two states. These higher centres include the peri-aqueductal gray area of the midbrain, hypothalamus, and cortical areas such as the medial prefrontal cortex.
The frequency of micturition in a person with a bladder capacity of 400 to 600 mL is once every 3 to 4 hours, with the implication that for more than 99.8% of the time, the bladder is in a storage phase. Normal voiding usually takes 20 to 30 seconds.

"Switching to a voiding phase is initiated by a conscious decision determined by the perceived state of bladder fullness and an assessment of the social appropriateness of doing so (8)."

The parietal area and the thalamus receive and coordinate urinary bladder muscle afferent stimuli while the frontal area and basal ganglia produce inhibitory signals. Peripheral coordination occurs at the sacral spinal cord level S2-S4. Sympathetic efferent fibres from the hypogastric nerve (spinal level T11-L2) mediate alpha-adrenergic contractions of the urethral smooth muscle and relaxation of the detrusor muscle to allow urine storage during the filling phase. The pudendal nerve (spinal level S2-S4) augments the External Urethral Sphincter closure via cholinergic stimulation. A fascial and muscular urethral support provides a "hammock" which compresses the urethra when there is increased abdominal pressure or when the pelvic muscles are contracted (9).

Detrusor afferent stimuli mediated by stretch receptors indicate the need to void; these signals are processed at the pontine micturition centre. There is parasympathetic activation via the pelvic nerve through the sacral micturition centre. The end result is contraction of the detrusor muscle mediated by the parasympathetic system and preganglionic inhibition of sympathetic system which leads to urethral relaxation. The primary parasympathetic muscarinic subtypes in the human bladder are M2 and M3, and although a majority of receptors are M2, M3 receptors predominate in the mediation of detrusor muscle contractions (10). A variety of other neurotransmitter systems in the urothelial lining of the bladder play an as yet not wholly defined role in mediating urinary bladder contraction and relaxation via afferent signalling (11).

2.1 Anatomy of the Detrusor Smooth Muscle

The Detrusor smooth muscle is covered by a specialized mucosa known as the uroepithelium. There is a glycosaminoglycan layer over the mucosa which inhibits bacterial adherence.

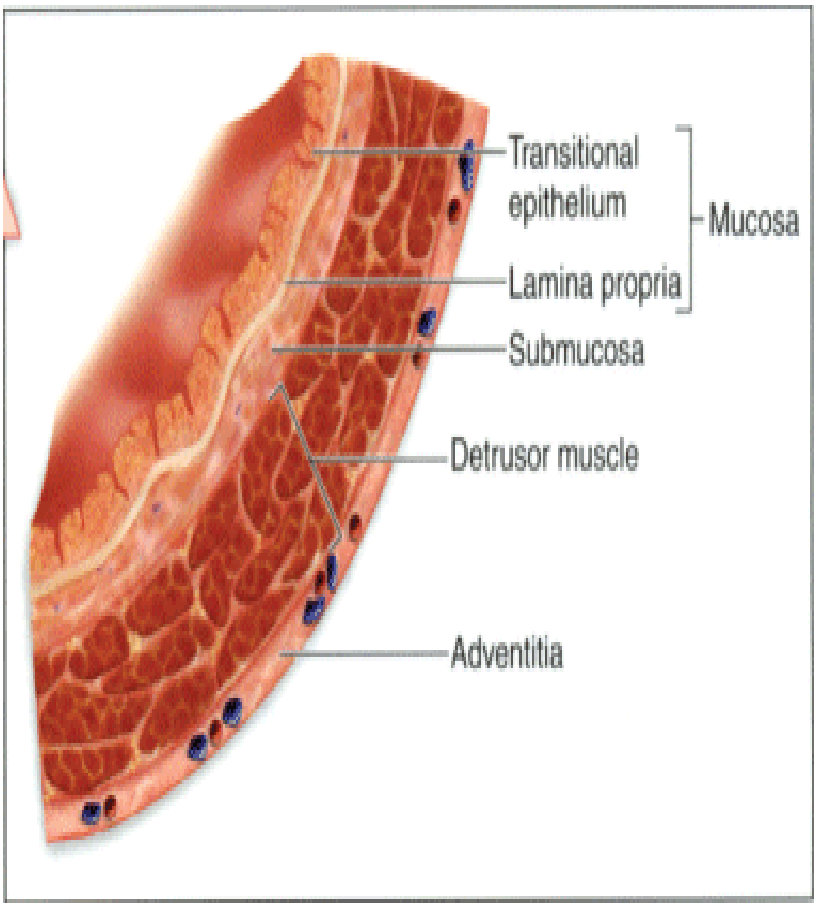


Figure 1: Cross section of the Detrusor Smooth Muscle
Source: McGraw-Hill © 2008

2.2 Anatomy of the Female Urogenital Sphincter

The Urogenital Sphincter can be divided into three anatomical components, namely:

- Sphincter Urethrae
  Proximal two thirds of urethra- Circumfrential slow twitching muscle contributing to continence at rest.
- Urethrovaginal Sphincter
- Compressor urethrae
  Distal third of the urethra- fast twitching muscle, which contributes to brisk contraction when continence is challenged by sudden rise in intra abdominal pressure.

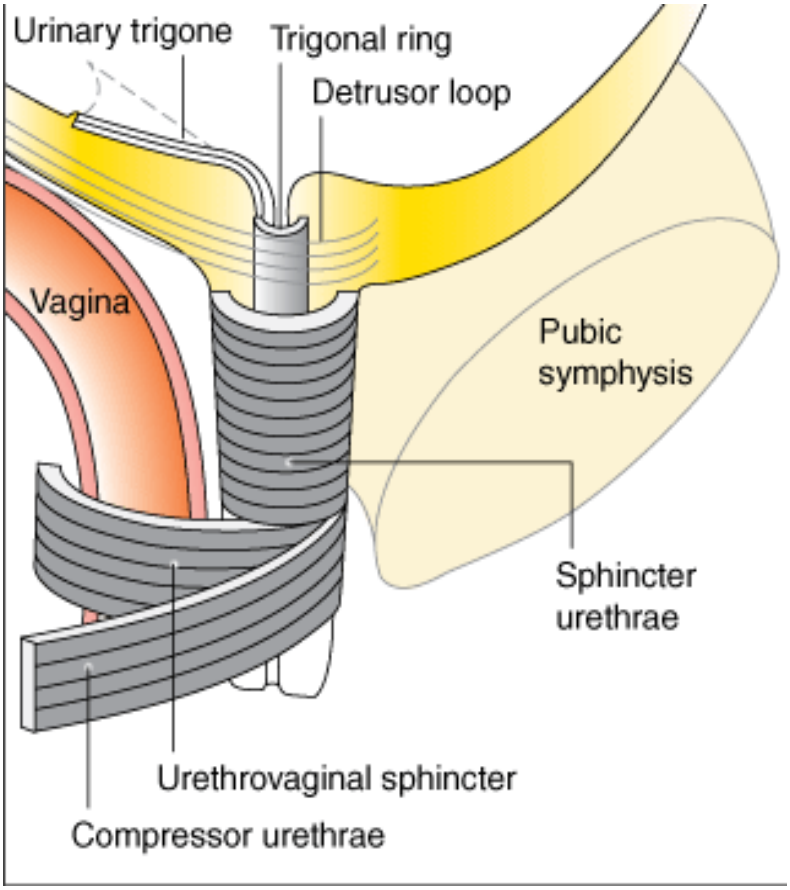


Figure 2: Anatomy of the Female Urogenital Sphincter (9).

Any anatomical or physiological alteration of any part of this intricate and elaborate system may thus predispose to urinary incontinence.

2.3 Classification

Stress urinary incontinence is characterized by loss of small amounts of urine during physical activity or intra-abdominal pressure (coughing, sneezing jumping, lifting, exercise); can occur with minimal activity, such as walking or rising from a chair, and the patient usually can predict which activities will cause leakage.

Urge urinary incontinence is characterized by loss of urine preceded by a sudden and severe desire to pass urine; patient typically loses urine on the way to the toilet. The loss of urine may also be stimulated by a change in body position (i.e., from supine to upright) or with sensory stimulation (e.g., running water, hand washing, cold weather, arriving at the front door). The pathophysiology relates to detrusor over-activity (uninhibited bladder contractions) caused by irritation within the bladder or loss of inhibitory neurologic control of bladder contractions. Volume of urine loss is variable, ranging from minimal to flooding (if entire bladder volume is emptied). Frequency and nocturia are common. Symptoms of urgency may also occur without urinary loss, which is known as overactive bladder.

Mixed urinary incontinence involving involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.

Temporary incontinence noted due to transient factors such as constipation, and urinary tract infection.

Functional incontinence caused by non-genitourinary factors. These include cognitive or physical impairments that result in the patient's inability to void independently.

Overflow incontinence noted with over distension of the bladder caused by impaired detrusor contractility or bladder outlet obstruction leading to urine leakage by overflow.

Obstetric Fistulae, common in Sub Saharan Africa usually due to ischaemic necrosis after obstructed labour, or as a complication of surgery (hysterectomy, colporrhaphy, caesarean section)

Congenital anomalies.

2.4 Pathophysiology

The exact pathophysiology of urinary tract dysfunction during pregnancy and postpartum is not clear. Elevated relaxin levels (12), an increased glomerular filtration rate, increased urinary bladder neck mobility, the gravid uterus and altered connective tissue composition may all play a role. There is an association between maternal age, parity, delivery and the development of stress urinary incontinence. Women lose 1 % of striated urethra muscle per year, leading to a reduction in urethral pressure (13). The development of stress urinary incontinence after vaginal delivery is thought to be a consequence of muscular and neuromuscular injuries of the pelvic floor as well as damage to the suburethral fascia. Damage to the levator ani has been well documented following vaginal delivery and is thought to be associated with the subsequent development of lower urinary tract symptoms (14).

A variety of hypotheses have been suggested for why PFMT might help prevent urinary incontinence. For example, trained muscle might be less prone to injury, and previously trained muscle might be easier to retrain after damage as the appropriate motor patterns are already learned. It may be that previously trained muscle has a greater reserve of strength so that injury to the muscle itself, or its nerve supply, does not cause sufficient loss of muscle function to reach the threshold where reduced urethral closure pressure results in leakage. During pregnancy, training the pelvic floor muscles might help to counteract the increased intra-abdominal pressure caused by the growing fetus, the hormonally mediated reduction in urethral closure pressure, and the increased laxity of fascia and ligaments in the pelvic area (15).

Chapter 3: JUSTIFICATION FOR THE STUDY

The public health impact of urinary incontinence cannot be assessed in terms of years of life lost or overall mortality. Nevertheless, there is little doubt that urinary incontinence has a considerable impact on patients' health, well-being, and overall quality of life.
Fitzgerald and colleagues sent a urinary incontinence questionnaire to 2000 women who were randomly selected from a population of 4000 employed women. The response rate in this study was 57%. Defining urinary incontinence as "the accidental loss of urine at least monthly," including incontinence both with and without associated increased intra-abdominal pressure or urgency, they found a urinary incontinence prevalence rate of 17.6% in women less than 50 years old. In this study, fewer than half of affected women reported urinary incontinence as a problem to their health care provider, underscoring the consistent finding that urinary incontinence was an underreported and undertreated condition (16).

A crucial limitation identified in a systematic review on Prevalence of postpartum urinary incontinence is the dearth of studies on prevalence of urinary incontinence in developing countries (1). This study will add to the body of scientific knowledge that will help in establishing the aforementioned prevalence.

A Cochrane review has shown that pregnant women without prior urinary incontinence who were randomised to intensive antenatal PFMT were less likely than women randomised to no PFMT or usual antenatal care to report urinary incontinence up to six months after delivery (about 30% less; risk ratio (RR) 0.71, 95% CI 0.54 to 0.95) (15). 22 Randomized Controlled Trials were included in this review. Majority of the study sites were in Europe, and overall in settings with a predominantly non-African population and so the results may not be generalisable to a black African population. (appendix I).

This study was designed to investigate the external validity of the Cochrane findings amongst the pregnant black African population. Of note, PFMT as an intervention has been found to be beneficial and does not have harm.

The aforementioned Cochrane review recommended further investigations on the effect of antenatal PFMT on mode of delivery and other delivery outcomes (15). Long term follow-up was recommended to determine whether benefit of PFMT persists for beyond one year (15).

Chapter 4: HYPOTHESIS

4.1 Research Question

Does PFMT in the pregnant black African population have an effect on the risk of postpartum urinary incontinence?

4.2 Null Hypothesis

There is no difference in the risk of postpartum Urinary Incontinence between PFM trained pregnant black African population and those given standard Antenatal Care.

4.3 Alternate Hypothesis

There is a statistically significant difference in the risk of postpartum Urinary Incontinence between PFM trained pregnant black African population and those given standard Antenatal Care.

Chapter 5: OBJECTIVES

5.1 Primary Objective

To determine effect of PFMT introduced in the second trimester amongst pregnant black African population on the risk of six weeks postpartum Urinary Incontinence.

5.2 Secondary Objectives

i. To investigate the risk of postpartum urinary incontinence in the study population.
ii. To investigate the effect of mode of delivery on the risk of postpartum Urinary Incontinence.
iii. To investigate contributory factors in this population on the risk of postpartum Urinary Incontinence

Chapter 6: METHODOLOGY

6.1 Study design

The study design was a single blinded randomized controlled trial.

6.1.1 Random Sequence Generation

Screening of the prospective study participants was done using the inclusion and exclusion criteria before randomization. The randomization was done using a computer generated random sequence (SPSS version 17.0). Each patient was assigned to one of two groups. The first group received PFMT as per the study protocol. The second group received the standard Antenatal care offered at the Aga Khan University Hospital, Nairobi. The randomization schedule specified the group to which each prospective patient would be allocated upon enrolment in the trial.

6.1.2 Random Sequence Concealment

The random allocation sequence was kept in sequentially numbered opaque envelopes in the custody of the Antenatal Clinic Team Leader. Assignment of the study participants to either the exercise group or the control group was done by a midwife delegated by the Antenatal Clinic Team Leader, according to the randomization schedule.

The principal investigator was blinded to the random sequence generation, and the allocation of participants to either of the two groups.

6.1.3 Blinding of participants and personnel

It was not feasible to blind the study participants to the intervention that is PFMT. The physiotherapist and the credentialed continence nurse conducting the PFMT were blinded to the random sequence generation and allocation and first came into contact with the study participants at the first scheduled training session.

6.1.4 Blinding of outcome assessment

A research assistant oversaw the outcome assessments at the 6 week postnatal visit. She did not have access to the randomization schedule. The principal investigator, the physiotherapist and the continence nurse conducting the PFMT were blinded to this process.

6.2 Study Period

TIME PERIOD	ACTIVITY
January-April 2014	Proposal development
May-June 2014	Ethical and budget approval
July 2014-May 2015	Data collection
May 2015	Data Analysis
June 2015	Results presentation

6.3 Study Population and setting

The Aga Khan University hospital, Nairobi, one of the largest not-for-profit hospitals in Kenya with a bed capacity of 280 beds, and postgraduate medical education programmes in various disciplines, was the setting of the study.

Study population included the pregnant patients attending the Antenatal Clinic at the Aga Khan University Hospital, Nairobi, which runs from Tuesday to Friday.

6.4 Eligibility criteria

6.4.1 Inclusion criteria

Black African descent
18 years and above as determined by age of birth
First ongoing pregnancy with a singleton foetus
Between 14-24 weeks of pregnancy as determined by a first trimester ultrasound scan.

6.4.2 Exclusion criteria

Pre-existing urinary incontinence of any type
Severe medical illness requiring recurrent hospital admissions, or affect compliance with training regimen
Obstetrical conditions likely to lead to preterm delivery, for example, severe Preeclampsia and Preterm Prolonged Rupture of Membranes

History suggestive of neurological conditions, for example, myasthenia gravis
History suggestive of collagen disorders, for example, Ehlers-Danlos Syndrome
Diabetes Mellitus but not Gestational Diabetes Mellitus

6.5 Intervention

The selected participants were trained by a physiotherapist and a credentialed Stoma Wound and Continence Nurse, who has further served at the standardization committee of the International Continence Society. Four training sessions were held. Training venue was at two locations, the AKUH, Nairobi Physiotherapy department and at the AKUH, Nairobi Antenatal Clinic. The first session encompassed general patient education on postpartum urinary incontinence. An educational video on PFMT downloaded from the NHS website (http://www.nhs.uk/video/Pages/how-and-when-should-i-do-pelvic-floor-exercise.aspx) was given in DVD format in addition to a video which detailed the anatomical muscles targeted in PFMT (http://www.anatomyzone.com/category/tutorials/reproductive/Pelvic Floor Tutorial). The next three sessions included supervised PFMT. Participants were trained on how to identify Pelvic Floor Muscle contractions with instructions to pass a stream of urine with a full bladder then abruptly stop the flow of urine (inward lift and squeeze around the urethra, vagina and rectum) (17).
The goal was to achieve three sets of 10 contractions with holding periods of 10 seconds (in sitting, kneeling or standing positions) per day. This regimen was repeated up to three times in a week. The first two training sessions were one to one sessions taught by the physiotherapist and the continence nurse, followed by subsequent two PFMT group sessions. The one to one training sessions were done by either the physiotherapist or the continence nurse. The two trainers standardized the training regimen such that each patient was taken through the same standardized training session for all the four sessions. Each group training session had five to ten patients in attendance. The interval between the training sessions varied from one to two weeks, which was dependent upon patient recruitment into the study and the availability of the trainers.

"There is a lack of evidence of the effect of vaginal cones and electrical stimulation to prevent UI in association with pregnancy. This is confirmed in a Cochrane review; there was no difference between cones and PFMT (RR 1.01, 95 % CI 0.91–1.13) or electro-stimulation (RR 1.26, 95 % CI 0.85–1.87) (2, 18)." Thus neither electrical stimulation nor vaginal cones were in-cooperated in the study protocol in addition to PFMT.

6.6 Duration of Intervention

This was from recruitment to 37 completed weeks of gestation.

6.7 Control Group

These patients received standard antenatal care.

6.8 Data collection procedure and tools

Baseline data was collected by the principal investigator and a research assistant at the Antenatal Clinic using the data collection forms (Appendix III) at recruitment. This included the patient's age, Gravidity, BMI at ANC booking, history of smoking before pregnancy, Cultural PMFT practices, Past Medical and Surgical History and an assessment of urinary continence by administering a validated questionnaire (ICIQ-UI Short Form). The collected data was then counterchecked for correct entry by the principal investigator and then entered into an MS-Excel data base.

The exit interview was done exclusively by the research assistant. Data collected included the mode of delivery, an assessment of urinary continence by administering a validated questionnaire (ICIQ-UI Short Form) and any form of PFMT during the pregnancy for study participants in the control arm.

6.9 Data storage

The raw data in this study was filed in folder files which were then stored in a lockable filing drawer at the supervisor's secretary office. All the data sheets were checked to confirm completeness before being filed. The raw data was furthermore de-identified and stored electronically in encrypted and password protected formats in the hard drive of the principal investigator's laptop computer and a Transcend Storejet ® 1 Terabyte external hard disk drive.

6.10 Assessment of Urinary Incontinence Status

Data collection was done primarily by administering a validated questionnaire (ICIQ-UI Short Form) at recruitment in the Antenatal clinic and in the postpartum period at the six week postnatal visit at the Aga Khan University Hospital, Nairobi.

This questionnaire achieved a Cronbach's alpha coefficient of 0.92, showing a very high level of internal consistency and reproducibility, well above the recommended Cronbach's alpha coefficient of 0.7 (19).

6.11 Sample Size Calculation

A Cochrane review found that pregnant women without prior urinary incontinence who were randomized to antenatal PFMT were less likely than women randomized to no PFMT or usual antenatal care to report urinary incontinence up to six months after delivery (about 30% less; risk ratio (RR) 0.71, 95% CI 0.54 to 0.95, combined result of 5 trials) (15). Of these five trials, only one, Gorbea 2004 (20) had the primary outcome assessed at six weeks postpartum, in addition to only recruiting nulliparous women and excluding women with multiple pregnancy and women with pre-existing urinary incontinence at the time of recruitment. The findings of this study (20) were used for sample size calculation.

Sample Size Calculation

$$\text{m (size per group)} = C \times \frac{\pi 1(1-\pi 1)+\pi 2(1-\pi 2)}{(\pi 1 - \pi 2)^2}$$

where C = 7.9 for 80% power and 10.5 for 90% power, π 1 and π 2 were the proportion estimates.
π 1 = 16/34 and
π 2 = 6/38 For a 80% power, we have

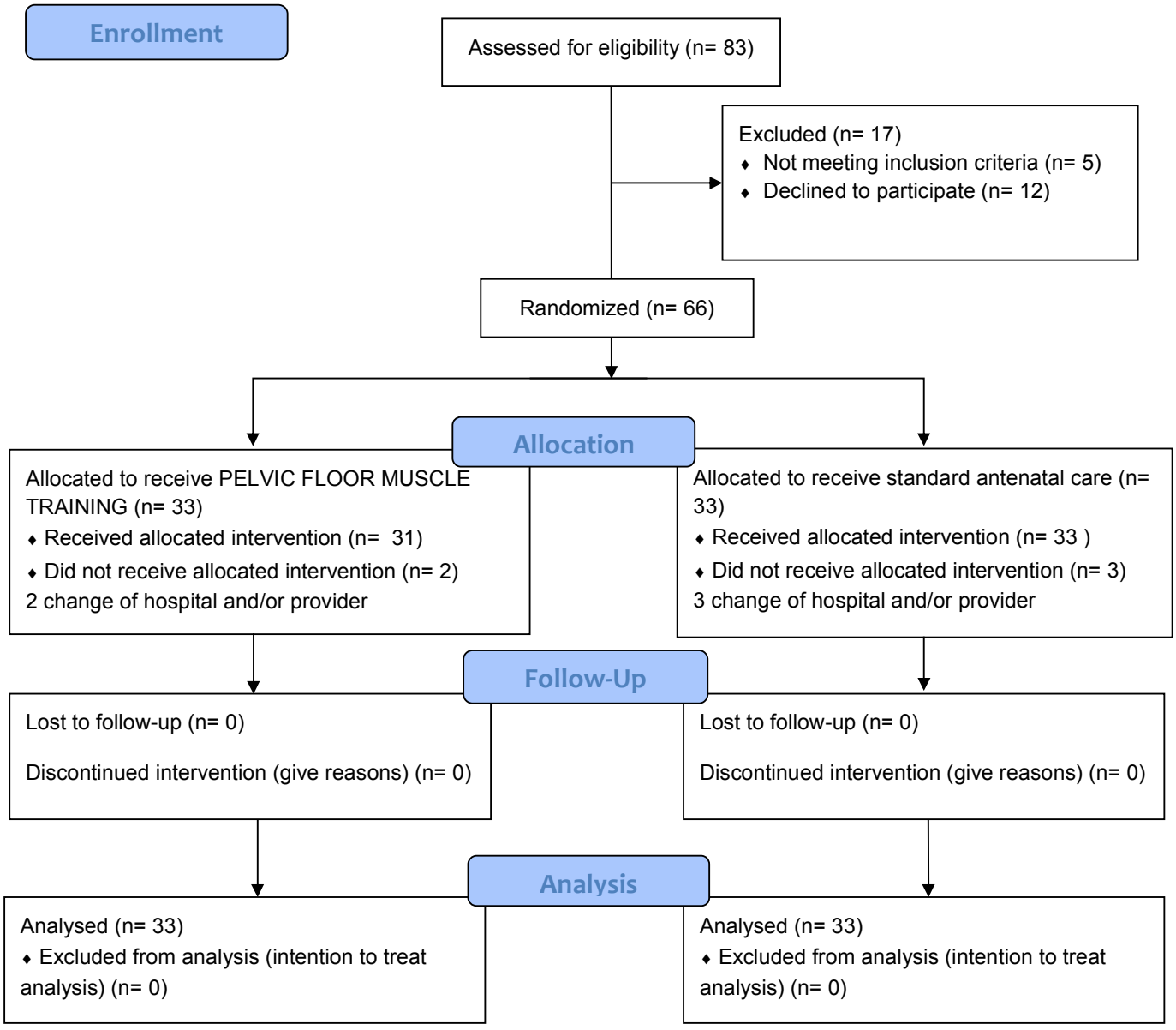
$$\text{m (size per group)} = 7.9 \times [0.47 (1 - 0.47) + 0.16 (1 - 0.16)]/(0.47-0.16)^2$$
$$= 31.53$$

32 X 2 = 64 patients in total (21).

33 X 2 = 66 patients were recruited, taking into account an expected negligible loss to follow-up proportion at 6 weeks postpartum.

Chapter 7: DISCUSSION OF STUDY FINDINGS

7.1 Trial Flow Diagram



7.2 Main Study Findings

Descriptive statistics were used to compare patients' characteristics in terms of age, BMI, pre-pregnancy smoking status, mode of delivery, and cultural PFMT practice. The mean and standard deviation was calculated for Age and BMI, while proportions were calculated for pre-pregnancy smoking status, mode of delivery and cultural PFMT practice.

Baseline Characteristics of the Study Participants *		
	PFMT (n = 33)	NO PFMT (n = 33)
Age — years	27.8 ± 3.1	27.6 ± 3.3
BMI †	26.3 ± 4.8	27.1 ± 4.7
English Proficiency	33 (100)	33 (100)
Pre-pregnancy smoking status —no. (%)	1 (3)	2 (6)
Obstetrical outcomes Spontaneous Vertex Delivery — no. (%)	20 (61)	21 (64)
Operative Vaginal Delivery — no. (%)	0 (0)	1 (3)
Cesarean delivery — (%)	13 (39)	11 (33)
Cultural PFMT practice (%)	0 (0)	0 (0)

Table 1: Baseline Characteristics of the Study Participants

* Plus–minus values are means ± Standard Deviation
† The body-mass index is the weight in kilograms divided by the square of the height in meters.

All patients recruited and randomized had full proficiency in English as a communication language and thus translation of the study information leaflets and interview questionnaires to Kiswahili was not required.

Data analysis was undertaken using the SPSS 17.0 with the input of the statistician who was involved from the initial development of the proposal.

Data was analysed on an intention to treat basis where the participants who did not fully comply with the study protocol were included in the final analysis in the groups they there randomized to.

The primary outcome of the study was an estimate of the risk of 6 week postpartum Urinary Incontinence as a proportion for the treatment and control groups. The risk in the treatment group was found to be 6% while in the control group was 36%. Risk Ratio = 0.17 (95% Confidence Interval; 0.04, 0.69) P= 0.003.
The Relative Risk Reduction was derived as a percentage = (1 - 0.17) * 100
= 83%

Comparison of proportions was done using the Chi-square test to compare the two groups for any statistically significant difference. X^2 (1) = 9.07, P= 0.003 which was considered statistically significant. The null hypothesis was rejected.

There was a statistically and clinically significant difference in the risk of postpartum Urinary Incontinence between PFM trained pregnant African population and those given standard Antenatal Care.

The severity of Urinary Incontinence was assessed by the ICIQ-UI-SF score. A score of 0 was assessed as no urinary incontinence. A score of 3-7 was assessed as slight UI. A score of 8-14 was assessed as moderate UI. A score of 15-21 was assessed as severe UI.

The two patients in the PFMT intervention group who reported symptoms of 6 week postpartum Urinary Incontinence had an ICIQ-UI-SF score of 4 and 6 respectively. They were both classified as having slight or mild Urinary Incontinence.

There were twelve patients in the control group who reported symptoms of 6 week postpartum Urinary Incontinence. Eight had an ICIQ-UI-SF score 3-7 and four had an ICIQ-UI-SF score of 8-14 respectively. Thus 66.7% of the 6 week postpartum Urinary Incontinence was classified as slight or mild and 33.3% was classified as moderate in the control group. The primary outcome of the study and the main focus of the data analysis was absence (ICIQ-UI-SF score 0) or presence (ICIQ-UI-SF score of 3 and above) of the 6 week postpartum UI.

Sixty four patients in the study had live births at term. One patient in the control group had a stillbirth at 36 weeks gestation secondary to severe preeclampsia and placental abruption, while one patient in the PFMT group delivered a live female infant at 32 weeks gestation with a birthweight of 1745 grams after premature labour secondary to Preterm Premature Rupture of Membranes. She had received 3 training sessions. Intention to treat analysis was employed and data from these 2 patients was analysed.

Three patients in the control group practised some form of PFMT during the antenatal period. One of these patients received PFMT from a physiotherapist who was also her husband. The other two received PFMT after attending child birth classes offered by midwives called Lamaze. Intention to treat analysis was employed and data from these three patients was analysed as part of the control group data.

7.3 Analysis for Secondary Objectives

None of the patients recruited in this study gave a positive response as to ever have had cultural PFMT practices and thus this factor was not analysed.

Summary of Study Findings *					
		PFMT n=33	No PFMT n=33	Odds Ratio (95% CI)	P Value
6 week postpartum UI	Present	2	12	0.11(0.00,0.51)	0.003
	Absent	31	21		
Obstetrical outcomes	Vaginal Delivery	20	22	0.40 (0.11,1.53)	0.191
	Cesarean Delivery	13	11		
Age		27.8 ± 3.1	27.6 ± 3.3	1.49 (0.56,3.94)	0.42
B.M.I.		26.3 ± 4.8	27.1 ± 4.7	2.06 (0.99, 4.26)	0.05
Pre-pregnancy smoking status —no. (%)		1 (3)	2 (6)	1.92 (0.16, 22.89)	0.61

Table 2: Summary of Study Findings

* Plus–minus values are means ± Standard Deviation

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

Analysis for the secondary objectives suggested there to be no trend towards a difference on the effect of mode of delivery on the risk of six weeks postpartum Urinary Incontinence. The study was not sufficiently powered to detect a difference for this secondary objective.

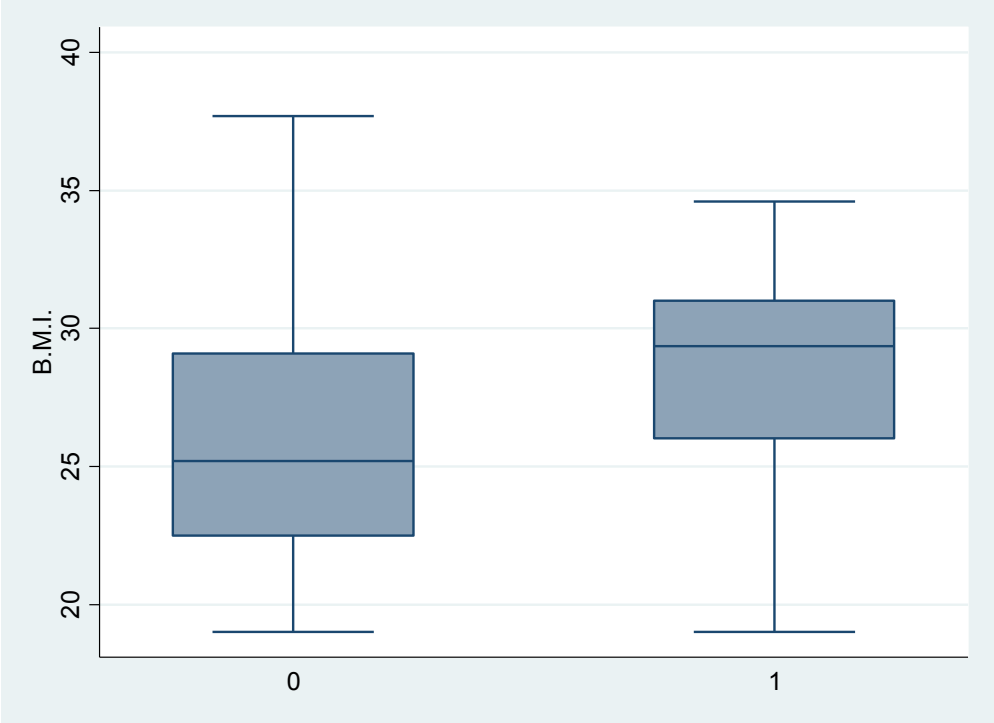
7.4 Logistic Regression

	CRUDE O.R. (95% C.I.), P Value	**ADJUSTED O.R. (95% C.I.), P Value**
PFMT	0.11 (0.00, 0.51) P= 0.003	0.088 (0.15, 0.52) P= 0.007
AGE	1.49 (0.56, 3.94) P= 0.42	2.60 (0.77, 8.77) P= 0.12
B.M.I.	2.06 (0.99, 4.26) P= 0.05	2.74 (1.09, 6.89) P= 0.03
PRE-PREGNANCY SMOKING	1.92 (0.16, 22.89) P= 0.61	3.04 (0.11, 81.39) P= 0.51
MODE OF DELIVERY	0.40 (0.10, 1.62) P= 0.20	0.20 (0.03, 1.19) P= 0.08

Table 3: Logistic Regression; Crude and Adjusted Odds Ratio for PFMT, age, B.M.I., pre-pregnancy smoking and mode of delivery

Logistic regression showed positive correlation between increasing B.M.I. and risk of 6 weeks postpartum UI, which was statistically significant (P value= 0.03) and a negative correlation between PFMT and the risk of 6 weeks postpartum UI which was statistically significant (P value= 0.007).

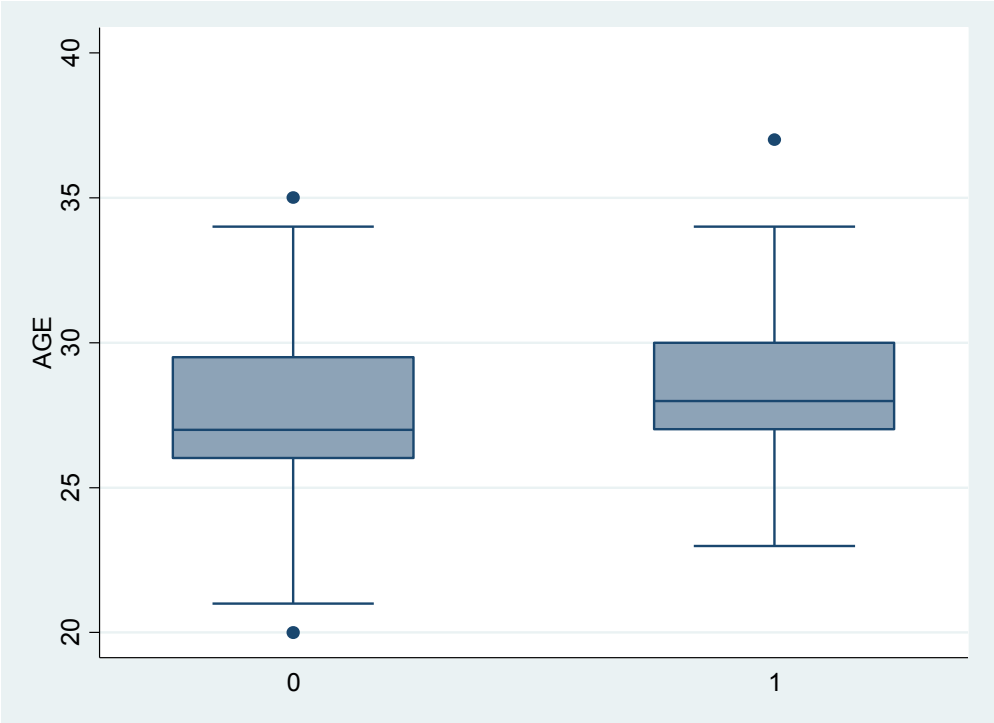
Graph box B.M.I., over (6 weeks postpartum UI)



0= No 6 weeks postpartum Urinary Incontinence noted
1= 6 weeks postpartum Urinary Incontinence noted

The adjusted Odds Ratio after logistic regression though not statistically significant, increased for pre-pregnancy smoking and age in relation to the risk of 6 weeks postpartum UI. The study was not sufficiently powered to detect a difference for these secondary objectives.

Graph box age, over (6 weeks postpartum UI)



0= 6 week postpartum UI absent
1= 6 week postpartum UI present

7.5 Study limitations

The main study limitation identified included a short follow-up duration period of only six weeks in the postpartum period. A longer follow-up duration of up to six months postpartum would have provided a more accurate determination of whether the benefit of PFMT persisted beyond six weeks in the postpartum period in the study population.

Sample size calculation was found to be greatly affected by the postpartum duration to primary outcome assessment. A retrospective analysis of the sample size using the findings of this study revealed the sample size of 66 patients to have been adequate.

$$m \text{ (size per group)} = C \times \frac{\pi 1(1-\pi 1)+\pi 2(1-\pi 2)}{(\pi 1 - \pi 2)^2}$$

where C = 7.9 for 80% power and 10.5 for 90% power, π 1 and π 2 were the proportion estimates.
π 1 = 0.36 and
π 2 = 0.06 For a 80% power, we have

$$m \text{ (size per group)} = 7.9 \times [0.36 (1 - 0.36) + 0.06 (1 - 0.06)]/(0.36-0.06)^2$$
$$= 25.17$$

26 X 2 = 52 patients in total (21).

Another limitation identified was a limited study budget. An exercise diary was to be issued to patients in the intervention arm of the study, but this was not feasible due to the study budget constraints. Patients were to be encouraged to make an entry each day the patient performed the PFMT. Weekly reminders for performing the PFMT were sent via email and Short Message Service (SMS). The individual compliance to the PFMT regimen was self-reported, as opposed to being formally assessed from the exercise diary entries. The mean self-reported compliance rate was 89%, with a standard deviation of 11%.

7.6 Data dissemination

The data was presented to the faculty board of examiners and disseminated to health practitioners. Results of the study will be submitted for publication in a peer review journal of Obstetrics and Gynaecology at a later date. The findings will be submitted to scientific conferences in the future.

Chapter 8: ETHICAL CONSIDERATIONS

The study was performed following approval from the department of Obstetrics and Gynaecology, and Ethical and scientific review Committee at the Aga Khan University, EA.

Patients were recruited after having signed an informed consent, which clearly stated that it was a research study being conducted and that their personal information was kept confidential with use of number identifiers.

All the study participants received the standard antenatal care regardless of the group they are randomized to. It was clearly stated that they could not be denied care if they declined to participate in the study.

An explanation on the study procedure was given to the patient both verbally and using a written form. It was also made clear there no monetary benefit to the patient arising from participation in the study, but that the results could be used to change local practice in the future. There was no added expenses to the patient for participating in the study.

The patients voluntarily signed the consent form and were recruited at the antenatal clinic.

The patients were free to withdraw from the study at any stage and still be accorded standard care.

Chapter 9: STUDY BUDGET

2 printing paper reams, cost per ream Ksh. 400	Ksh. 800
33 DVDs: Cost per DVD Ksh. 25	Ksh. 825
Transport reimbursement at Ksh. 200 per participant, for 33 participants, for 2 group sessions	Ksh. 13,200
PFMT sessions: Cost per session Ksh. 500, Each of the 33 selected participants to receive 4 sessions	Ksh. 66,000
Allowance for Research Assistant	Ksh. 10,000
Total	Ksh. 90,825

Chapter 10: Conclusion and Recommendations

PFMT has been shown to be an effective primary prevention intervention in reducing the risk of postpartum urinary incontinence for up to six months to one year after delivery predominantly in the Caucasian population. This study aimed to explore the effect of PFMT in the Black African population and investigate contributing and alleviating factors to the risk of postpartum urinary incontinence in the same population.

Postpartum Urinary Incontinence should be assessed for every patient using a validated tool as the risk in the black African population may be as high as in the Caucasian population. A prevalence study of postpartum UI in the black African population is recommended. ICIQ-UI short form was successfully used in this population and can be used as a screening tool at the 6 weeks postpartum review for Urinary Incontinence.

Primary outcome of the study was an estimate of the risk of 6 week postpartum Urinary Incontinence as a proportion for the treatment and control groups. The main conclusion of this study is that antenatal PFMT in the black African population leads to a clinically significant Relative Risk Reduction of 83% in the risk of postpartum Urinary Incontinence at the 6 weeks postpartum period and is thus recommended from the second trimester of pregnancy until 37 completed weeks of gestation.

Increasing B.M.I. at ANC booking was found to have a positive correlation with 6 weeks postpartum urinary incontinence which was statistically significant and thus a normal B.M.I. in the pre-conception period is recommended.

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Appendix I

NAME OF STUDY	METHODS	PARTICIPANTS	SETTINGS
Bø 2011	RCT	105 primigravid women	Norway
Chiarelli 2002	RCT	720 postnatal mums	Australia
Dannecker 2004	RCT	144 primigravid women	Germany
Dias 2011	RCT	87 primigravid women	Brazil
Dinc 2009	RCT	92 gravid women	Turkey
Dumoulin 2004	RCT	64 postnatal women	Canada
Ewings 2005	RCT	234 postnatal mums	UK
Gaier 2010	RCT	127 primigravid women	Italy
Glazener 2001	RCT	747 postnatal mums	New Zealand, UK
Gorbea 2004	RCT	75 primigravid women	Mexico
Hughes 2001	RCT	1169 primigravid women	UK
Ko 2011	RCT	300 gravid women	China
Meyer 2001	RCT	107 gravid women	Switzerland
Mørkved 2003	RCT	301 gravid women	Norway
Reilly 2002	RCT	268 gravid women	UK
Sampselle 1998	RCT	72 primigravid women	USA
Skelly 2004	RCT	Women with antenatal UI	Canada
Sleep 1987	RCT	1800 postnatal mums	UK
Stafne 2011	RCT	855 gravid women	Norway

Stothers 2002	RCT	86 gravid women	Canada
Wilson 1998	RCT	230 postnatal mums	New Zealand
Woldringh 2007	RCT	264 gravid women	The Netherlands

Appendix II: Informed consent for antenatal PFMT trial

This document is to be read to or by each prospective participant in a language she understands.

Principal investigator: **Dr. Samuel Ngugi**

I am Dr. Samuel Ngugi, a Resident at the Aga Khan University Hospital in the Obstetrics and Gynaecology department. I am conducting a research study to determine the effect of Pelvic Floor Muscle Training (PFMT) among pregnant African population on the incidence of postpartum urinary incontinence.

You are being requested to participate as part of the antenatal population at the hospital. The collection of information will happen over a 6 month period.

Purpose

This is an interventional study, which means that some participants will be selected to receive routine antenatal care, and other participants will be selected to receive antenatal PFMT.

Your routine antenatal care during the study period will not be affected regardless of your decision to participate in this study.

The reason we are performing this study is because we would like to obtain information that would be useful in determining the effect of antenatal PFMT in the pregnant African population on incidence of postpartum urinary incontinence. Other studies done among the Caucasian population have shown benefit of PFMT in reducing the incidence of postpartum urinary incontinence.

Procedures

The following is a description of the information we would like to collect as part of this study:

If you agree to participate, basic medical and reproductive history will be taken, and questionnaire administered which attempts to elicit urinary incontinence related symptoms. One group will receive routine antenatal care, and another group will be selected to receive antenatal PFMT. Selection will be done in a randomised manner with equal probability in being selected into either of the two groups.

Your medical care will be the one routinely performed at this institution.

Risks and discomforts

You are not expected to have any additional risks by participating in this study.

Benefits

Participating in this study will not be of direct benefit to you. The knowledge obtained by this study will improve our understanding of the utility of antenatal PFMT among the pregnant African population.

Compensation

You will receive no direct compensation for participating in this study. In case new protocols are developed as a result of this study, you will not receive monetary or other benefits from the development of such protocols.

Confidentiality

Any information you provide during the study will be kept strictly confidential. Your full name will not appear on any study document and only the principal investigator and the research assistants will have access to the information you provide. I shall take full responsibility for your confidentiality.

Right to refuse

You are free to choose whether or not you wish to participate. If for any reason, you are not eligible for the study, or decide not to participate, you will receive normal care and standard treatment and medication before, during and after pregnancy. You will suffer neither penalties nor loss of any benefits should you decide not to participate.

Who to contact

If you have any questions you may ask now or later during your follow up. If you wish to ask questions later, you may contact the responsible doctor caring for you at the time of your routine antenatal follow up. You can also reach Dr. Samuel Ngugi (Principal Investigator) through Tel. 0722591677.

Your Contacts

You will be requested to provide your telephone and email contact. This shall only be used to remind you of any PFMT sessions and for filling of the incontinence questionnaire.

This proposal has been reviewed and approved by the Aga Khan University EA research committee, whose task is to make sure that research participants are protected from harm.

Certificate of Consent for Participants to Sign

Assessment of antenatal PFMT among the pregnant African population on postpartum urinary incontinence

Participant's
name.....

I have (been) read the information sheet concerning this study and I understand what is required of me if I take part in the study. All my questions and doubts have been answered by you. I agree to take part in this study.

Participant's
signature.....Date.....

If not able to sign: print name of Independent Witness, date and signature of Witness (if possible, this person should be selected by the participant and should have no connection to the research team)

Witness
name.....

Witness
signature.....Date.....

Name of
Researcher.....

Researcher's
signature.....Date.....

Appendix III: *criteria for enrolment to the study*

Assessment of antenatal PFMT among the pregnant African population on postpartum urinary incontinence

Participant's eligible for participating in this study should fulfil all of the following criteria:

1. Black African descent.
2. First ongoing pregnancy with a singleton foetus.
3. 18 years and above by date of birth
4. Between 14-24 weeks of pregnancy by first trimester ultrasound scan
5. Informed Consent to participate in the study.

Appendix IV: *Data Collection Questionnaires*

Assessment of antenatal PFMT among the pregnant African population on postpartum urinary incontinence

Patient Identifier:

STUDY NUMBER						
FILE NUMBER						

Patient Contacts:

Tel No and email.....

Age (yrs) .....

Gravidity: Para .....+.....

BMI at ANC booking: .....

History of smoking before pregnancy

Mode of delivery

Cultural PMFT practices

Past Medical and Surgical History

Initial number

ICIQ-UI Short Form

CONFIDENTIAL

DAY MONTH YEAR

Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth:

DAY MONTH YEAR

2 Are you *(tick one)***:** Female ☐ Male ☐

3 How often do you leak urine? *(Tick one box)*

never about once a week or less often	☐ 0
two or three times a week about once a day	☐ 1
several times a day all the time	☐ 2
	☐ 3
	☐ 4
	☐ 5

4 We would like to know how much urine <u>you think</u> leaks.
How much urine do you <u>usually</u> leak (whether you wear protection or not)?
(Tick one box)

none a small amount	☐ 0
a moderate amount	☐ 2
a large amount	☐ 4
	☐ 6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**

not at all — a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 When does urine leak? *(Please tick all that apply to you)*

never – urine does not leak leaks ☐
before you can get to the toilet leaks ☐
when you cough or sneeze leaks ☐
when you are asleep ☐
leaks when you are physically active/exercising leaks ☐
when you have finished urinating and are dressed ☐
leaks for no obvious reason leaks all the time ☐
☐

Thank you very much for answering these questions.

Appendix IV: *AKU, Nairobi Health Research Ethics Committee approval letter*

THE AGA KHAN UNIVERSITY

Faculty of Health Sciences
Medical College

Ref: 2014/REC-25(v2)
22nd August 2014

Dr. Samuel Ngugi
Resident, Department of Obstetrics and Gynecology
Aga Khan University-EA, Nairobi

Dear Dr. Ngugi,

Re: EFFECT OF PELVIC FLOOR MUSCLE TRAINING AMONG PREGNANT BLACK AFRICAN POPULATION ON THE RISK OF POSTPARTUM URINARY INCONTINENCE, A SINGLE BLIND RANDOMIZED CONTROL TRIAL

The Aga Khan University, Nairobi Health Research Ethics Committee (REC),in a meeting held on 11th August 2014 reviewed your proposal, as submitted to the Research Support Unit (RSU) on 30th June 2014. The committee records that this is a well-articulated protocol. Further, minor typographic errors were noted and it is recommended that they are addressed prior to commencing the study. The in-text comments will be emailed to you.

The committee has granted approval for this project based on core ethical standards which have been fully instituted in the protocol. This proposal is also in compliance with the Aga Khan University Research Ethics Regulations. You are authorized to conduct this study from **15th August, 2014**. This approval is valid until **14th August, 2015.**

The study should be conducted in full accordance with all the applicable sections of the R&EC guidelines and you should notify the R&EC immediately of any changes that may affect your research project. You should report any unanticipated problems involving risks to the participants to the R&EC. You must provide an interim report before expiration of the validity of this approval and requested extension if additional time is required for study completion. As the principal investigator you must advise the R&EC when this study is finished or discontinued and a final report submitted to the RSU. Further approval from the Hospital should be sought before publishing the results. If you have any questions, please contact Research Support Unit - kamanda.ciru@aku.edu or 020-366 2148.

Sincerely,

Dr. Amyn Lakhani
Chair, Health Research Ethics Committee, AKU (N)

3rd Parklands Avenue, off Limuru Road, P. O. Box 30270, GPO 00100, Nairobi, Kenya
Tel: +254 20 366 2107/2109; Fax: + 254 20 374 4035
Email: medicalcollege.enquiries@aku.edu

Appendix V: ***Pan African Clinical Trial Registration letter***

SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

SOUTH AFRICAN COCHRANE CENTRE

PO Box 19070, Tygerberg, 7505, South Africa;
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Tel: +27 21 938 0438; Fax: +27 21 938 0836
E-mail: cochrane@mrc.ac.za

THE SOUTH AFRICAN COCHRANE CENTRE

THE COCHRANE COLLABORATION

25 July 2014

To Whom It May Concern:

RE: Effect of pelvic floor muscle training among pregnant black African population on the risk of postpartum urinary incontinence, a single blind randomized controlled trial

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201407000850309**

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email, post or fax) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

PACTR
PAN AFRICAN CLINICAL TRIALS REGISTRY