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Feasibility of Paula Exercise as an Adjunct to Pelvic Floor Muscle Training in Women with Post-Fistula Repair Incontinence: A Pilot Randomized Controlled Trial

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Abstract

Background

Post-fistula repair incontinence (PFRI) is a common and distressing complication after successful vesicovaginal fistula (VVF) repair. Conservative management, particularly pelvic floor muscle training (PFMT), is preferred, yet many women struggle with correct voluntary contraction. Paula exercise (PE), which targets circular/ring muscles, has shown promise for urinary incontinence but has not been evaluated in women with PFRI.

Objective

To conduct a pilot randomized controlled trial examining the effect of PE (added to PFMT) versus PFMT alone on urine leakage, pelvic floor strength (PFS), and quality of life (QoL) in women with PFRI, and to assess feasibility and adherence.

Methods

Thirty women with PFRI (> 3 months post-repair) were randomized 1:1 to PE + PFMT or PFMT alone for 4 weeks at two Nigerian fistula centers. Primary outcome was urine leakage (1-hour pad test); secondary outcomes were PFS (perineometer) and QoL (Hausa-translated Incontinence Quality of Life questionnaire). Outcomes were assessed at baseline and 4 weeks by a blinded assessor. Within-group changes were analyzed with paired t-tests or Wilcoxon signed-rank tests; between-group differences used independent t-tests or Mann-Whitney U tests ($\alpha = 0.05$).

Results

Both groups showed non-significant reductions in urine leakage and no significant change in PFS. QoL improved significantly within both groups (PE: median 18.18 to 34.09, $p < 0.05$; PFMT: $p = 0.001$). No statistically significant between-group differences were observed for any outcome. Adherence was 100% with no adverse events or dropouts.

Conclusions

In this short-duration pilot trial, adding PE to PFMT conferred no clear advantage over PFMT alone for urine leakage or PFS, although both approaches improved QoL. Larger, longer trials are warranted to determine the clinical value of PE for PFRI in low-resource settings.

Trial Registration Number: PACTR201906515532827

Registration date: 13 June 2019

Registry: Pan African Clinical Trials Registry

Introduction

Vesicovaginal fistula (VVF) is an abnormal communication between the bladder and the vagina that results in continuous leakage of urine [1, 2]. It most commonly arises from prolonged obstructed labour, during which the fetal head compresses maternal pelvic tissues, producing ischaemic necrosis and subsequent fistula formation [1, 3]. VVF accounts for approximately 90% of all obstetric fistulas and remains a major cause of female morbidity in low- and middle-income countries, with substantial residual burden even in some high-income settings [4, 2, 5]. Globally, more than two million women are estimated to live with untreated obstetric fistula; in Nigeria alone, 20 000 new cases occur annually, adding to a backlog of 400 000–800 000 unrepaired cases, with the highest incidence concentrated in the north-western states [6, 7].

Although surgical closure of the fistula is successful in the majority of cases [1, 8, 3], a substantial proportion of women reported as 24–50% continue to experience involuntary urine leakage after anatomical repair [9, 10]. This condition, termed post-fistula repair incontinence (PFRI), is defined as involuntary leakage of urine, especially on exertion, following confirmed fistula closure [11, 9]. Stress urinary incontinence is the predominant subtype [12, 9]. Persistent leakage produces vaginal encrustation, recurrent infection, social stigma, progressive weakening of the pelvic floor muscles (PFM), and marked deterioration in quality of life and mental health [8, 10]. The functional failure after anatomical success remains a source of frustration for both surgeons and patients [1, 10].

Conservative management is widely recommended as first-line therapy for PFRI [13, 10]. Surgical re-intervention is reserved for refractory cases because further procedures risk additional tissue damage [11, 14]. Physiotherapy, principally pelvic floor muscle training (PFMT), constitutes the cornerstone of conservative care for urinary incontinence [15, 16]. However, evidence specific to PFRI is limited and derives largely from small programme evaluations of PFMT [17, 18, 10]. Effective PFMT requires individualised instruction and supervised practice [19]. In most Nigerian VVF centres, trained physiotherapists or continence nurses are scarce, patient volumes are high, and many women with weakened pelvic floors are unable to isolate a correct PFM contraction even when given detailed verbal cues; instead they recruit abdominal, gluteal or adductor muscles, potentially aggravating leakage [19, 20]. Consequently, there is a clear need for an alternative or adjunctive technique that is simpler to teach, suitable for group delivery, and capable of rehabilitating the pelvic floor indirectly.

Paula exercise (PE), also known as circular or ring-muscle exercise, was developed by [21] on the premise that all body sphincters function as an interconnected system whose activity is mutually influenced by spinal oscillations. Contraction and relaxation of accessible circular muscles (for example, the peri-ocular muscles) are hypothesised to facilitate recovery of damaged sphincters, including the urethral sphincter and pelvic floor [15, 22]. Randomised trials in women with stress urinary incontinence have reported comparable short- and medium-term efficacy of PE relative to conventional PFMT for leakage reduction and quality-of-life improvement [15, 22, 23, 24]. A systematic review, however, noted important methodological limitations: suboptimal dosing of the PFMT comparator, high attrition (28%),

and the fact that nearly all existing PE trials were conducted by a single research group [16]. These shortcomings underscore the necessity for independent evaluation in diverse populations and clinical contexts.

To date, PE has never been examined in women with PFRI or any form of post-pelvic-floor surgery, nor has it been tested in a low-resource African setting. The present pilot randomised controlled trial was therefore designed to investigate the effect of PE (administered as an adjunct to PFMT) versus PFMT alone on urine leakage, pelvic floor strength and quality of life among women with PFRI, while simultaneously assessing feasibility, adherence and safety of the intervention.

Materials and Methods

Study design

This was a single-blind (outcome-assessor blinded), two-arm pilot randomized controlled trial with a pretest–posttest design. Eligible participants were randomly allocated in a 1:1 ratio to either the intervention group (Paula exercise [PE] plus pelvic floor muscle training [PFMT]) or the control group (PFMT alone). The total study period was two calendar months, comprising a 4-week enrolment phase followed by a 4-week supervised and home-based intervention phase.

Study setting

Recruitment and delivery of the interventions took place in the physiotherapy departments of two public hospitals in north-western Nigeria: Murtala Muhammad Specialist Hospital (MMSH), Kano State, and Jahun General Hospital (JGH), Jigawa State. Both centres provide specialised care for women with obstetric fistula and post-fistula repair complications.

Participants

Women attending the vesicovaginal fistula (VVF) clinics of MMSH or JGH who had post-fistula repair incontinence (PFRI) were screened for eligibility. Inclusion criteria were: (1) written informed consent; (2) PFRI lasting more than 3 months after successful VVF repair (to allow adequate tissue healing); (3) documented urine leakage of ≥ 1 g on a 1-hour pad test; (4) absence of urinary tract infection; (5) age ≤ 50 years; (6) absence of faecal incontinence or previous rectal surgery; and (7) no concurrent pelvic-floor rehabilitation programme.

After eligibility confirmation, a standardised cough-stress test was performed to classify the type of incontinence (stress, urge, or overflow/functional). Women were considered to have stress urinary incontinence if leakage coincided with coughing.

Sample size

Forty women with PFRI were initially identified from outpatient records. After screening against the inclusion criteria, 30 eligible participants (19 from MMSH and 11 from JGH) were enrolled and randomised.

Randomisation and blinding

Simple randomisation (1:1 ratio) was performed by an independent individual who was not involved in recruitment, intervention delivery, or outcome assessment. Allocation was concealed until baseline assessments were completed. Outcome assessments were conducted by a trained researcher who remained blinded to group assignment throughout the study.

Interventions

Both exercise programmes were delivered by the principal investigator and a research assistant (a physiotherapist with postgraduate training in women's health physiotherapy). All sessions were conducted in the morning and adhered to the Consensus on Exercise Reporting Template (CERT) checklist. No specialised equipment was required for either intervention.

Paula exercise (intervention group)

The PE protocol was adapted from previously published studies and modified for monitoring feasibility in a low-resource setting. Participants sat comfortably on a chair with a backrest and relaxed for 2 minutes. They were taught to contract (squeeze) the peri-ocular muscles, hold the contraction for 5 seconds, and then relax for 3 seconds (one exercise cycle). Each daily session consisted of 40 cycles. During the first week, exercises were performed under direct supervision. For the remaining three weeks, participants continued the same protocol at home and recorded sessions and any adverse events in an activity logbook. Adherence was monitored by daily telephone calls. Group supervised sessions were repeated at weeks 2 and 4.

Pelvic floor muscle training (Control)

PFMT followed standard clinical guidelines. Participants began in a supine position with knees semi-flexed, relaxed for 2 minutes, and then performed maximal voluntary pelvic-floor contractions (as if stopping the flow of urine or elevating the vagina) while avoiding contraction of the abdominal, gluteal, or adductor muscles. Each contraction was held for a count of 7 and followed by a relaxation of 3 counts (one cycle). Visual biofeedback with a mirror was provided. After mastery in the supine position, the same sequence was performed in sitting. Forty cycles were completed once daily. The first week was

supervised; the subsequent three weeks were home-based with logbook documentation and daily telephone monitoring. Group supervised sessions occurred at weeks 2 and 4.

Participants in the intervention arm performed PE in addition to the PFMT protocol described above. Usual medical or surgical care unrelated to pelvic-floor rehabilitation was permitted in both groups. No participant withdrew or discontinued the exercises because of adverse events.

Outcome measures

All outcomes were assessed at baseline (before randomisation) and at the end of the 4-week intervention by the blinded assessor.

• Primary outcome urine leakage (UL)

Quantified by the International Continence Society 1-hour pad test. Participants emptied the bladder, drank 500 mL of water, and wore a pre-weighed pad. After 15 minutes of sitting, they performed a standardised set of activities (10 coughs, 10 squats, 10 jumps, and 10 minutes of brisk walking). The pad was re-weighed; a gain of ≥ 1 g was considered diagnostic of incontinence, and any reduction after intervention was regarded as improvement.

• Secondary outcomes

Pelvic floor strength (PFS) was measured with a Peritron perineometer (NEEN HealthCare, UK). With the participant supine and knees semi-flexed, the vaginal probe was inserted to the level of the hymen. Three maximal 2–3-second contractions were recorded (10-second rest intervals), and the average value (cm H_2O) was used. – Quality of life (QoL) was assessed with the Incontinence Quality of Life (I-QoL) questionnaire (22 items covering Avoidance and Limiting Behaviour, Psychosocial Impact, and Social Embarrassment subscales). The instrument was translated into Hausa by the Language Department of Bayero University, Kano, and back-translated for validation. Total scores were transformed to a 0–100 scale; higher scores indicate better QoL.

Data analysis

Data were entered into Microsoft Excel and analysed with SPSS version 26. Descriptive statistics (means, standard deviations, medians, inter-quartile ranges, frequencies, and percentages) summarised baseline characteristics. Within-group changes were examined with paired t-tests (normally distributed continuous data) or Wilcoxon signed-rank tests (non-normally distributed data). Between-group differences at post-intervention were assessed with independent t-tests or Mann–Whitney U tests as appropriate. Statistical significance was set at $p < 0.05$.

Ethical considerations and trial registration

Ethical approval

was obtained from the Human Research Ethics Committees of the Ministries of Health of Kano and Jigawa States. Written informed consent was obtained from every participant. The trial was registered with the Pan African Clinical Trials Registry (PACTR201906515532827).

Results

Recruitment, randomisation and feasibility

Forty women with post-fistula repair incontinence (PFRI) were screened. Ten did not meet the inclusion criteria, leaving 30 eligible participants who were randomised 1:1 to the Paula exercise plus pelvic floor muscle training (PE + PFMT) group (n = 15) or the PFMT-only group (n = 15). No participant withdrew from the study. All 30 women completed the 4-week intervention and both assessment visits, yielding a 100% retention rate (Fig. 1).

Baseline characteristics

The two groups were comparable on demographic and clinical variables (all $p > 0.05$) except for baseline urine leakage, which was higher in the PFMT group (Table 1). The overall mean age was 29.93 ± 9.40 years. Most participants were married (66.7%), although more than one-third (36.7%) reported living without their husbands. Stress urinary incontinence predominated (90%). Median baseline urine leakage for the whole cohort was 11.45 g (IQR 23.94). Median baseline quality-of-life (QoL) scores indicated a substantial negative impact of leakage on daily life (PE + PFMT: 18.18; PFMT: 14.77).

Within-group changes

Neither group showed statistically significant reductions in urine leakage or improvements in pelvic floor strength after 4 weeks (Table 2).

- Urine leakage: PE + PFMT median change from 4.53 g to 4.50 g ($Z = -0.284$, $p = 0.776$); PFMT median change from 21.61 g to 12.50 g ($Z = -1.591$, $p = 0.112$).
- Pelvic floor strength: PE + PFMT mean increase from 38.79 ± 17.51 to 43.96 ± 22.90 cm H_2O ($t = 2.018$, $p = 0.063$); PFMT mean increase from 41.98 ± 15.00 to 46.35 ± 17.59 cm H_2O ($t = 1.904$, $p = 0.078$).

In contrast, both groups demonstrated statistically and clinically meaningful improvements in QoL:

- PE + PFMT: median score rose from 18.18 to 34.09 ($Z = -2.726$, $p = 0.006$, $r = 0.70$).
- PFMT: median score rose from 14.77 to 28.40 ($Z = -3.411$, $p = 0.001$, $r = 0.88$).

Between-group comparisons

At the end of the intervention there were no statistically significant differences between the PE + PFMT and PFMT-only groups on any outcome (Table 3):

- Urine leakage: U = 1.556, p = 0.120
- Pelvic floor strength: t = − 0.321, p = 0.750
- Quality of life: U = 0.581, p = 0.561

Adherence and safety

Adherence to the prescribed exercise regimen was 100% in both arms, supported by daily telephone monitoring and activity logbooks. No adverse events (including vaginal bleeding, pain or medical emergencies) were recorded during the 4-week period.

Table 1
Baseline demographic and clinical characteristics

Variable	**PE + PFMT (*n* = 15)**	**PFMT (*n* = 15)**	**Combined (*n* = 30)**	***P***
Age (years), Mean ± SD	27.93 ± 8.60	31.93 ± 10.03	29.93 ± 9.40	0.251
Weight (kg), Mean ± SD	52.80 ± 16.15	48.73 ± 10.50	50.77 ± 13.54	0.422
Height (m), Mean ± SD	1.52 ± 0.05	1.50 ± 0.06	1.51 ± 0.05	0.255
BMI (kg/m²), Mean ± SD	22.96 ± 7.07	21.68 ± 4.24	22.32 ± 5.76	0.553
PRT (months), Mean ± SD	12.07 ± 26.65	11.67 ± 9.75	11.87 ± 19.72	0.957
SBP (mmHg), Mean ± SD	122.33 ± 15.50	129.73 ± 23.00	126.03 ± 19.63	0.311
DBP (mmHg), Mean ± SD	83.13 ± 15.21	81.80 ± 12.62	82.47 ± 13.75	0.796
Marital status, *n* (%)				0.508
Married	4 (26.7)	5 (33.3)	9 (30.0)	
Separated	5 (33.3)	6 (40.0)	11 (36.7)	
Divorced	6 (40.0)	4 (26.7)	10 (33.3)	
TOI, *n* (%)				0.559
Stress	14 (93.3)	13 (86.7)	27 (90.0)	
Urge	1 (6.7)	2 (13.3)	3 (10.0)	
UL (g), median (IQR)	4.53 (11.45)	21.61 (35.3)	11.45 (23.94)	0.008
PFS (cm H_2O), mean ± SD	38.79 ± 17.51	41.98 ± 15.00	40.39 ± 16.10	0.597
QoL score, median (IQR)	18.18 (20.46)	14.77 (32.73)	17.04 (19.60)	0.552

PE, Paula exercise; PFMT, Pelvic floor muscle training; UL, Urine leakage; TOI, Type of incontinence; PFS, Pelvic floor strength; QoL, Quality of Life; DBP, Diastolic blood pressure; SBP, Systolic blood pressure

Table 2
Within-group changes from baseline to 4 weeks

Outcome	Group	Pre-intervention	Post-intervention	Test statistic	*P*
UL (g), Median (IQR)	PE + PFMT	4.53 (11.45)	4.50 (16.52)	$Z = -0.284$	0.776
	PFMT	21.61 (35.3)	12.50 (26.98)	$Z = -1.591$	0.112
PFS (cm H_2O), Mean ± SD	PE + PFMT	38.79 ± 17.51	43.96 ± 22.90	$t = 2.018$	0.063
	PFMT	41.98 ± 15.00	46.35 ± 17.59	$t = 1.904$	0.078
QoL score, Median (IQR)	PE + PFMT	18.18 (20.46)	34.09 (27.27)	$Z = -2.726$	0.006
	PFMT	14.77 (22.73)	28.40 (26.13)	$Z = -3.411$	0.001

PE, Paula exercise; PFMT, Pelvic floor muscle training; PFS, Pelvic floor strength; QoL, Quality of Life

Table 3
Between-group comparisons at 4 weeks

Outcome	PE + PFMT (*n* = 15)	PFMT (*n* = 15)	Test statistic	*P-value*
UL (g) Mean ± SD	10.69 ± 13.07	19.29 ± 16.17	1.556^U	0.120
PFS (cm H_2O) Mean ± SD	43.96 ± 22.90	46.35 ± 17.59	0.321^t	0.750
QoL score Mean ± SD	33.70 ± 16.03	32.02 ± 16.54	0.581^U	0.561

UL, Urine leakage; PFS, Pelvic floor strength; QoL, Quality of Life; U = Mann Whitney U test, t = Student t-test,

After four weeks of training, both PE + PFMT and PFMT alone produced clear, statistically significant improvements in quality of life, with large effect sizes. Reductions in urine leakage and gains in pelvic floor strength were observed numerically but did not reach statistical significance, most likely reflecting the short intervention period and the modest sample size of this pilot trial. Critically, the addition of Paula exercise conferred no measurable advantage over PFMT alone on any outcome. The complete absence of drop-outs and adverse events, together with perfect adherence, indicates that both protocols are feasible and acceptable in a low-resource Nigerian setting.

Discussion

This pilot randomised controlled trial represents, to the best of our knowledge, the first investigation of Paula exercise (PE) delivered as an adjunct to conventional pelvic floor muscle training (PFMT) in women living with post-fistula repair incontinence (PFRI). After four weeks of supervised and home-based training, both the PE + PFMT and the PFMT-only arms achieved statistically significant and clinically meaningful improvements in incontinence-related quality of life. In contrast, neither group demonstrated statistically significant reductions in objectively measured urine leakage or gains in pelvic floor muscle strength. Most importantly, the addition of PE produced no incremental benefit over PFMT alone on any primary or secondary outcome. Complete adherence and the total absence of adverse events further indicate that both protocols are feasible, safe and culturally acceptable within a low-resource Nigerian fistula-care setting.

The lack of statistically significant change in urine leakage warrants careful interpretation. Earlier randomised trials conducted by [23, 24, 15] consistently reported significant reductions in 1-hour pad-test leakage after 12 weeks of either PE or PFMT in women with uncomplicated stress urinary incontinence. Several interrelated factors may account for the divergent results observed here. First, the intervention duration in the present study was only one-third as long as the programmes previously evaluated. Neuromuscular adaptation and hypertrophy of the pelvic floor musculature generally require progressive, supervised training over at least 8–12 weeks [16]. A four-week exposure is therefore likely to be insufficient for detectable physiological change, particularly in a population whose pelvic floor has already been compromised by prolonged obstructed labour and subsequent major reconstructive surgery. Second, residual scarring, fibrosis, urethral shortening and partial denervation are common sequelae of obstetric fistula repair [12, 11]. These anatomical and neurological alterations may reduce the responsiveness of the pelvic floor to both direct (PFMT) and indirect (PE) training stimuli. Third, baseline urine leakage was substantially higher in the PFMT-only arm, creating an imbalance that, despite randomisation, may have attenuated the ability to detect between-group differences and introduced regression-to-the-mean effects within that arm.

Pelvic floor strength, quantified by perineometry, likewise failed to improve significantly in either group. This finding is consistent with the earlier observation of Liebergall-Wischnitzer et al. (2005) that neither PE nor PFMT produced measurable changes in perineal muscle strength after a full 12-week programme. Several explanations are plausible. Strength gains may lag behind functional or quality-of-life improvements; the measurement technique itself may be less sensitive in the presence of post-surgical vaginal scarring and altered tissue compliance; or the training dosage (40 contractions once daily) may have been inadequate to elicit hypertrophy within the short time frame. The near-significant p-values (0.063 and 0.078) suggest that a longer intervention or a larger sample might have revealed modest strength gains, but such speculation requires confirmation in adequately powered trials.

In marked contrast to the objective continence and strength outcomes, both groups experienced large improvements in quality of life, with effect sizes of r = 0.70 (PE + PFMT) and r = 0.88 (PFMT alone). These

gains align with previous PE trials [15, 23, 24] and with the broader literature demonstrating that even modest or non-significant reductions in leakage can produce substantial enhancements in perceived well-being, social participation and emotional health [25]. The dissociation between objective leakage/strength measures and patient-reported quality of life underscores the multidimensional nature of incontinence-related quality of life and reinforces the necessity of including validated patient-reported outcome measures as co-primary endpoints in future incontinence trials. It is also possible that the structured exercise regimen itself irrespective of the specific technique conferred psychological benefits through increased self-efficacy, daily routine, peer support during group sessions, and the simple experience of active self-management after years of passive suffering.

The feasibility and safety data are among the most encouraging findings of this pilot. Adherence reached 100% and no adverse events were recorded results that compare favourably with the approximately 27% attrition reported in earlier PE studies [24]. Several design features likely contributed to this high retention: daily telephone monitoring, the simplicity and non-invasiveness of the peri-ocular component of PE, the provision of activity logbooks, the culturally acceptable nature of equipment-free exercise, and the two scheduled group sessions that fostered peer support. These elements are particularly relevant in low-resource fistula centres where trained physiotherapists or continence nurses are scarce, patient volumes are high, and many women struggle to isolate a correct pelvic floor contraction even when given detailed verbal instruction [19, 20]. The demonstrated feasibility of group-based delivery therefore holds practical promise for scale-up.

Several methodological limitations must be acknowledged. The pilot sample size of 30 participants was intentionally modest and under-powered to detect small-to-moderate between-group differences; the study was designed primarily to assess feasibility and generate preliminary effect-size estimates rather than to provide definitive comparative efficacy data. The four-week intervention period is substantially shorter than the 8–12 weeks typically required for neuromuscular adaptation of the pelvic floor [26]; consequently, the absence of statistically significant improvements in urine leakage and pelvic floor strength should be interpreted with caution and may not reflect the true potential of either intervention over a longer timeframe. Despite randomisation, a clinically relevant baseline imbalance in urine leakage existed between arms and may have influenced the magnitude of observed change. Classification of incontinence subtype relied on the cough-stress test rather than multichannel urodynamics; while practical and reasonably accurate in resource-limited settings, the cough test is less precise [12]. Finally, the absence of a no-treatment or delayed-treatment control arm precludes estimation of the natural history of PFRI over four weeks.

Taken together, the findings indicate that both PE + PFMT and PFMT alone are safe, highly acceptable and capable of improving quality of life within a short time frame in women with PFRI. However, the addition of Paula exercise did not yield superior effects on urine leakage or pelvic floor strength under the conditions tested. Larger, adequately powered randomised trials with stratified randomisation (to balance baseline leakage severity), longer intervention and follow-up periods (minimum 12 weeks), and the inclusion of both objective and patient-reported endpoints are now warranted. Such trials should also

explore whether progressive dosing, biofeedback-enhanced PFMT, or longer-term maintenance programmes can amplify the modest numerical improvements observed here. Until more definitive evidence is available, clinicians working in low-resource fistula centres may reasonably offer either PE + PFMT or PFMT alone as feasible first-line conservative options, while prioritising quality-of-life assessment and long-term support for this vulnerable population.

Given the promising feasibility, safety, and quality-of-life findings of this pilot, there is clear need for larger, adequately powered randomised controlled trials of at least 12 weeks' duration, incorporating stratified randomisation to balance baseline leakage severity, progressive exercise dosing, and longer-term follow-up. Only such trials can definitively establish whether the addition of Paula exercise offers clinically meaningful advantages over pelvic floor muscle training alone for women living with post-fistula repair incontinence.

Conclusion

This pilot randomised controlled trial provides the first evidence on the feasibility and preliminary effects of Paula exercise delivered as an adjunct to pelvic floor muscle training in women with post-fistula repair incontinence in a low-resource African setting. Both interventions proved safe, highly acceptable, and associated with complete adherence and retention, while producing statistically significant and clinically meaningful improvements in incontinence-related quality of life within only four weeks. However, the addition of Paula exercise conferred no measurable incremental benefit over pelvic floor muscle training alone for objectively measured urine leakage or pelvic floor strength under the conditions tested.

These findings carry direct practical relevance for fistula centres in Nigeria and similar resource-constrained environments, where specialist physiotherapy capacity is limited and many women struggle to isolate correct pelvic-floor contractions. Either protocol can therefore be offered as a feasible, equipment-free, first-line conservative option that prioritises patient-reported well-being while awaiting more definitive evidence.

Larger, adequately powered trials with stratified randomisation, progressive dosing, and a minimum 12-week intervention and follow-up period are now essential to determine whether Paula exercise ultimately adds clinical value for this highly vulnerable population.

Declarations

Conflict of Interest Statements

We declare no conflict of interest.

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Author Contribution

SUA and SMH contributed to the conceptualization and design of the study. SMH, SUA, and IUL were responsible for developing the research questions and the pilot study. SUA and SMH arranged and prepared the exercise interventions. SUA drafted the preliminary manuscript, while IUL prepared and edited the final manuscript. All authors contributed to discussions on the study design and development of the protocol. All authors read and approved the final version of the manuscript.

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Data Availability

All data supporting the findings of this study are available within the paper.

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Figures

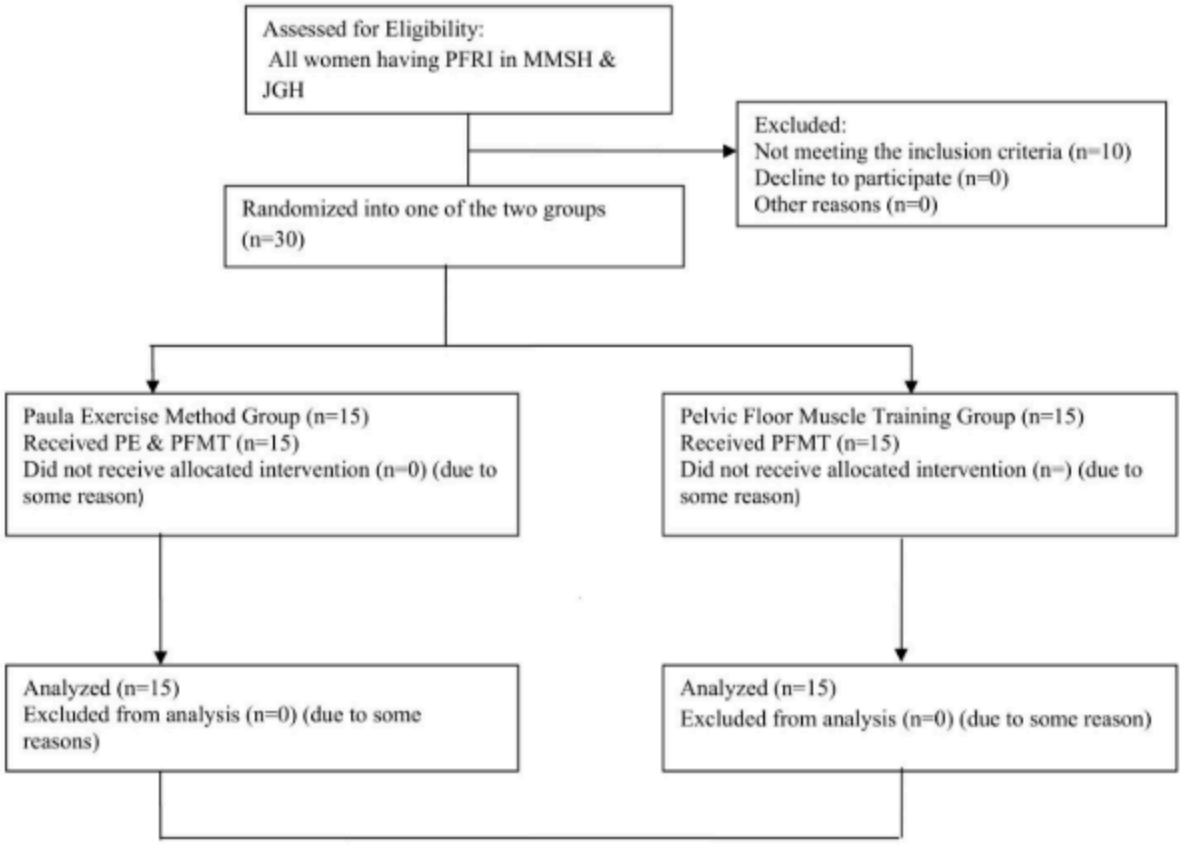


Fig.1: Study flow diagram

Figure 1

See image above for figure legend.