

## Baseline characteristics

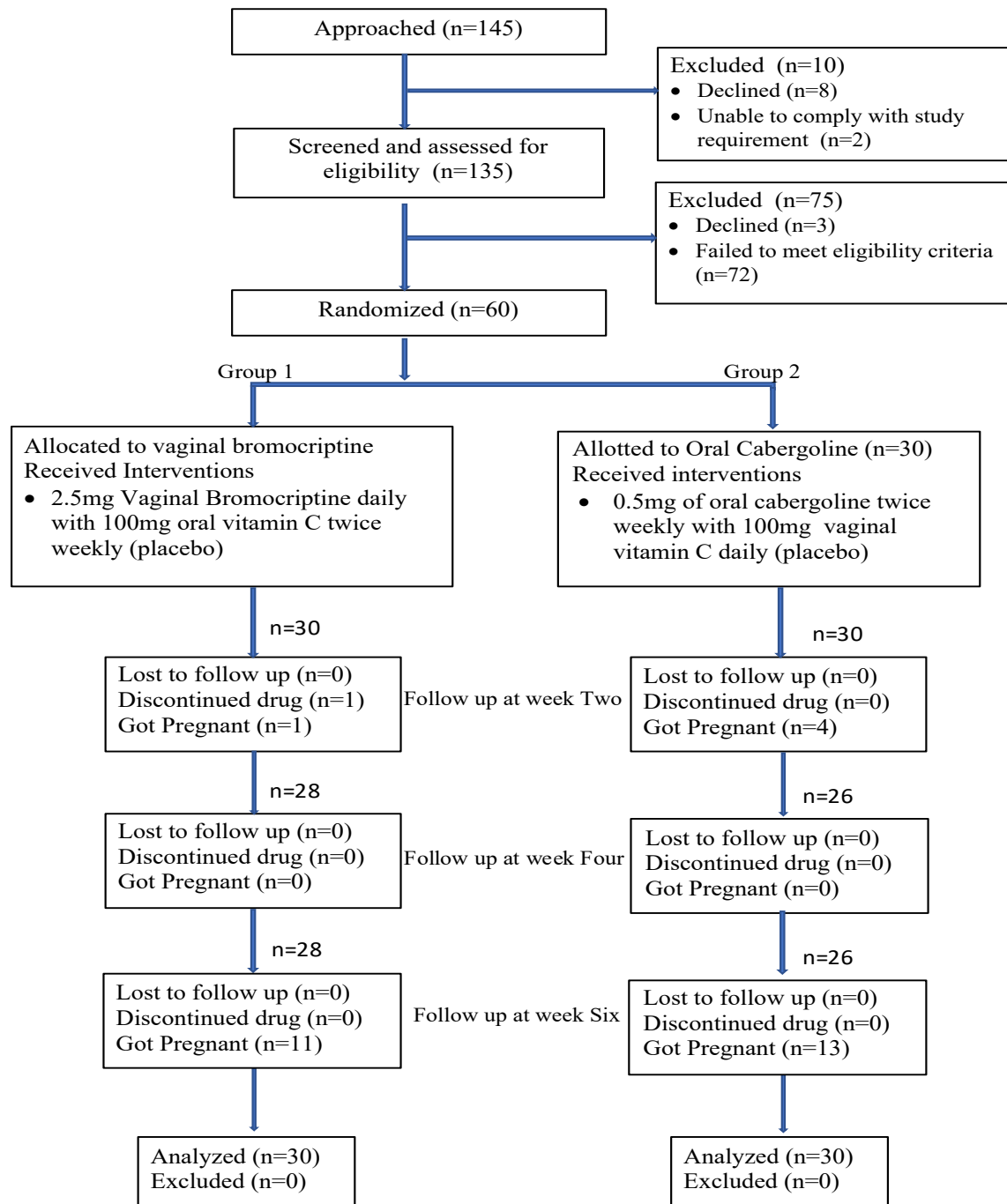
• Table 4.1: Sociodemographic Characteristics and body mass index

		Group 1 Vaginal Bromocriptine (n=30)	Group 2 Oral Cabergoline (n=30)
<b>Age (years)</b>	18-25	9 (30.0%)	10 (33.4%)
	26-35	17 (56.7%)	16 (53.3%)
	36-45	3 (10.0%)	3 (10.0%)
	>45	1 (3.3%)	1(3.3%)
<b>Monthly household Income (₦)</b>	< 30,000	19 (63.3%)	16 (53.3%)
	30,001-50,000	4 (13.3%)	2 (6.7%)
	50,001-100,000	2 (6.7%)	2 (6.7%)
	100,001-200,000	2 (6.7%)	4 (13.3%)
	>200,000	3 (10.0%)	6 (20.0%)
<b>Religion</b>	Muslim	17 (56.7%)	14 (46.7%)
	Christian	13 (43.3%)	16 (53.3%)
<b>Tribe</b>	Hausa	14 (46.7%)	12 (40.0%)
	Yoruba	7 (23.3%)	8 (26.6%)
	Igbo	4 (13.3%)	5 (16.7%)
	Other	5 (16.7%)	5 (16.7%)
<b>Level of Education</b>	No Formal	2 (6.7%)	1 (3.3%)
	Islamic	3 (10.0%)	2 (6.7%)
	Primary	8 (26.7%)	3 (10.0%)
	Secondary	7 (23.3%)	9 (30.0%)
	Tertiary	10 ((33.3%)	15 (50.0%)
<b>Parity</b>	Nullipara	9 (30.0%)	10 (33.3%)
	Multipara	19 (63.3%)	18 (60.0%)
	Grandmultipara	2 (6.7%)	2 (6.7%)
<b>Body Mass Index (kg/m<sup>2</sup>)</b>	Underweight	0 (0.0%)	3 (10.0%)
	Normal	9 (30.0%)	12 (40.0%)
	Overweight	11 (36.7%)	4 (13.3%)
	Grade 1 obesity	7 (23.3%)	5 (16.7%)
	Grade 2 obesity	1 (3.3%)	6 (20.0%)
	Morbid obesity	2 (6.7%)	0 (0.0%)

**Table 4.2: Comparison of the mean of baseline characteristics in both study groups**

	<b>Group 1 Vaginal bromocriptine (n=30)</b>	<b>Group 2 Oral Cabergoline (n=30)</b>	<b>P Value</b>
<b>Age in years</b>	28.2	28.3	<b>0.939</b>
<b>BMI in kg/m<sup>2</sup></b>	27.7	27.6	<b>0.916</b>
<b>Parity</b>	2.0	2.0	<b>0.816</b>
<b>Baseline serum prolactin levels in ng/ml</b>	49.8	49.2	<b>0.911</b>

## Participant flow (PRISMA flow diagram)



## Adverse events

• Table 4.8: Specific side effects experienced in both study groups

		Nausea n (%)	Vomiting n (%)	Headache n (%)	Fainting n (%)	Vaginal discharge n (%)
<b>Group 1</b> <b>Vaginal</b> <b>Bromocriptine</b> <b>N=30</b>	Yes	12 (40.0)	2 (6.7)	1 (3.3)	2 (6.7)	7 (23.3)
	No	18 (60.0)	28 (93.3)	29 (96.7)	28 (93.3)	23 (76.7)
<b>Group 2</b> <b>Oral</b> <b>Cabergoline</b> <b>N=30</b>	Yes	10 (33.3)	1 (3.3)	0 (0.0)	1(3.3)	2 (6.7)
	No	20 (66.7)	29 (96.7)	30 (100.0)	29 (96.7)	28 (93.3)
<b>X<sup>2</sup></b>		0.287 (df=1)	0.357 (df=1)	1.403 (df=1)	0.351 (df=1)	3.433 (df=1)
<b>P value</b>		<b>0.5920</b>	<b>0.550</b>	<b>0.236</b>	<b>0.550</b>	<b>0.064</b>

## Outcome measures

• Table 4.9: Symptom resolution at the end of the study in each study group.

Symptoms resolved at the end of the study		Group 1 Vaginal Bromocriptine	Group 2 Oral Cabergoline	$\chi^2$	P Value
<b>Had at least one symptom resolved at the end of the study</b>	Yes	22 (73.3%)	27 (90.0%)	3.413 ( <i>df</i> =1)	<b>0.065</b>
	No	8 (26.7%)	3 (10.0%)		
<b>Inability to conceive</b>	Yes	12 (40.0%)	17 (56.7%)	0.834 ( <i>df</i> =1)	<b>0.636</b>
	No	18 (60.0%)	13 (43.3%)		
<b>Amenorrhoea</b>	Yes	2 (15.4%)	2 (25.0%)	0.197 ( <i>df</i> =1)	<b>0.986</b>
	No	11 (84.6%)	6 (75.0%)		
<b>Oligomenorrhoea</b>	Yes	2 (40.0%)	3 (33.3%)	1.044 ( <i>df</i> =1)	<b>0.623</b>
	No	3 (60.0%)	6 (66.7%)		
<b>Galactorrhoea</b>	Yes	9 (81.8%)	8 (66.7%)	0.199 ( <i>df</i> =1)	<b>0.982</b>
	No	3 (18.2%)	4 (33.3%)		
<b>Decreased libido</b>	Yes	10 (71.4%)	11 (91.7%)	0.779 ( <i>df</i> =1)	<b>0.682</b>
	No	4 (28.6%)	1 (8.3%)		
<b>Other</b>	Yes	2 (100.0%)	0 (0.0%)	1.017 ( <i>df</i> =1)	<b>0.188</b>
	No	0 (0.0%)	0 (0.0%)		

## RESULT SUMMARY

The level of significance was set at 0.05 for this study. The prolactin normalization rate (73.3% vs. 76.7%,  $p=0.508$ ), percentage drop in serum prolactin (58.4% vs 62.2%,  $p=0.357$ ) and symptom resolution rate (73.3% vs 90.0%,  $p=0.065$ ) was higher in the cabergoline treated patients than in the bromocriptine treated patients but not statistically significant. More side effects were recorded in patients who took bromocriptine (53.3% vs. 40.0%,  $p=0.310$ ), this difference was however not statistically significant.

**Conclusion:** The vaginal route of bromocriptine administration was demonstrated to have comparable effectiveness and side effect profile to the more expensive and less readily available cabergoline.