

RESULTS

The participant's flow pattern is displayed on the chart below.

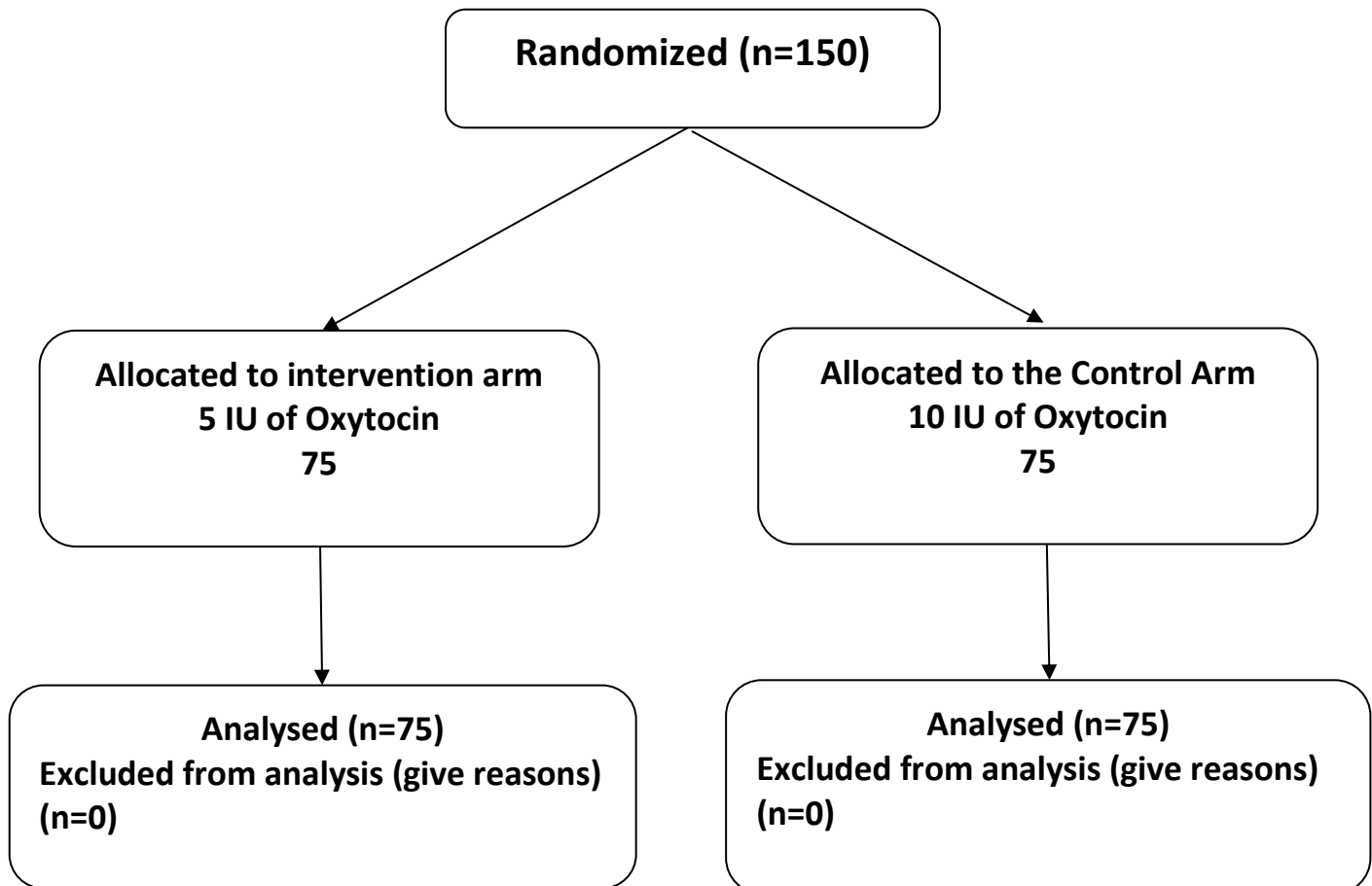


FIGURE 1: PARTICIPANT'S FLOW CHART.

A total of 150 women were randomized to the study between 20 May 2020 and 30 November 2020. All participants were included in the primary and secondary analysis

on an intention to treat basis. Of the 150 women randomized, 75 received 5 I.U. of intravenous oxytocin and 75 received 10 I.U. of intravenous oxytocin.

The demographic constitution of both trial arms was similar as shown in table 1. The mean age was 29 years and 96% of the women had at least a secondary level of education. About a third of the population was obese, with a similar percentage also being nullipara (30%). Almost half of the women were at 39 weeks of gestation (48.7%).

TABLE 1: DEMOGRAPHIC ATTRIBUTES OF PARTICIPANTS.

ATTRIBUTE	5 I.U. ARM	10 I.U. ARM		P-VALUE
	N (%) or Mean (SD)	N (%) or Mean (SD)	TOTAL N (%)	
Age	29.07 (5.3)	29.4 (5.7)		0.712
Educational status				
Primary	4 (5.3)	2 (2.7)	6 (4.0)	0.401
Secondary	32 (42.7)	40 (53.3)	72 (48.0)	
Tertiary	39 (52.0)	33 (44.0)	72 (48.0)	
Total	75	75	150	
BMI				
<30	51 (68.0)	54 (72.0)	105 (70.0)	0.593
≥30	24 (32.0)	21 (28.0)	45 (30.0)	
Total	75	75		

Parity				
Nullipara	28 (37.3)	17 (22.7)	45 (30.0)	0.145
Primipara	22 (29.3)	28 (37.3)	50 (33.3)	
Multipara	25 (33.3)	30 (40.0)	55 (36.7)	
Total	75	75		
Gestational age				
Early term(37–38wks)	21 (28.0)	20 (26.7)	41 (27.3)	0.928
Full-term (39wks)	17 (22.7)	19 (25.3)	36 (24.0)	
Late-term (40 – 41 wks)	37 (49.3)	36 (48.0)	73 (48.7)	
Total	75	75		

Table 2 displays the delivery attributes of the study participants. There was no statistically significant difference between both groups. The mean birth weight for the low dose arm and the high dose arm was 3.39 ± 0.44 kg and 3.32 ± 0.36 kg, respectively. The mean difference of 0.06 kg did not attain statistical significance. Though more women in the 5 IU arm had episiotomy/tears/lacerations compared to the 10 I.U. arm (40% vs 29.3%), this was not statistically significant. The pre-delivery and post-delivery haemoglobin concentration for both groups were similar (11.39 vs 11.41 g/dl and 11.13 vs 11.13 g/dl). The same relationship was found for the haematocrit.

TABLE 2: DELIVERY ATTRIBUTES OF PARTICIPANTS

ATTRIBUTE	5 I.U. ARM	10 I.U. ARM		P-VALUE

	N (%) or Mean (SD)	N (%) or Mean (SD)	TOTAL N (%)	
Birth Weight	3.39 ± 0.44	3.32 ± 0.36	0.061	0.350
Episiotomy/Tears/Lacerations				
Yes	30 (40.0)	22 (29.3)	52 (34.7)	0.170
No	45 (60.0)	53 (70.0)	98 (65.3)	
Total	75	75		
Pre-Delivery Haemoglobin Concentration	11.39 ± 0.96	11.41 ± 1.07	-0.025	0.879
Post-Delivery Haemoglobin Concentration	11.13 ± 0.98	11.13 ± 1.05	-0.007	0.968
Pre-Delivery PCV	33.79 ± 2.79	33.88 ± 3.10	-0.093	0.847
Post-Delivery PCV	33.03 ± 2.93	33.12 ± 3.06	-0.093	0.849

OUTCOME MEASURES

The median postpartum blood loss for the 5 IU arm was 258mls (IQR=217). This was different from the median postpartum blood loss of the 10 I.U. arm (245mls (IQR=191)), though this difference was not statistically significant (P = 0.3359). The occurrence of PPH > 500 ml (16% vs 14.7%) and PPH > 1000 ml (1.3% vs 2.7%) was similar for both groups. The haemoglobin concentration change, though not statistically significant, was higher in the 10 I.U. group. It was 0.02 g/dl more than the 5 I.U. arm. But the

haematocrit change was the same at 0.76 for both groups. The use of additional uterotonics and blood transfusion showed no significant difference between the arms. No patient in the study arms reported the occurrence of nausea and vomiting.

TABLE 3: PRIMARY AND SECONDARY OUTCOME MEASURES OF PARTICIPANTS.

ATTRIBUTE	5 I.U. ARM	10 I.U. ARM		P-VALUE
	N (%) or Mean (SD)	N (%) or Mean (SD)	TOTAL N (%) or Mean Difference	
PRIMARY OUTCOME				
Mean Postpartum Blood Loss (ml)	330.56 ± 216	312.24 ± 229	18.32	0.616
Median Postpartum Blood loss	258(217)	245(191)	0.9259	0.3359
LOGBLOOD LOSS	2.44 ± 0.25	2.41 ± 0.27	0,03	0.396
SECONDARY OUTCOMES				
PPH >500mL Yes	12 (16.0)	11 (14.7)	23 (15.3)	0.821

No	63 (84.0)	64 (85.3)	127 (84.7)	
Total	75	75		
Severe PPH				
>1000ml	1 (1.3)	2 (2.7)	3 (2.0)	1.000
Yes	74 (98.7)	7 (97.3)	147 (98.0)	
No	75	75		
Total				
Haemoglobin concentration change	0.261 ± 0.751	0.280 ± 0.87	-0.019	0.888
PCV Change	0.760 ± 2.204	0.76 ± 2.546	0.000	1.000
Additional Uterotonic				
Yes	2 (2.7)	3 (4.0)	5 (3.3)	0.683
No	73 (97.3)	72 (96)	145 (96.7)	
Total	75	75		
Blood transfusion				
Yes	0 (0.0)	1 (1.3)	1 (0.7)	1.000
No	75 (100.0)	74 (98.7)	149 (99.3)	
Total	75	75		
Nausea				
Yes	0 (0.0)	0 (0.0)	0 (0.0)	
No	75 (100.0)	75 (100.0)	150 (100)	

Total	75	75		
Vomiting				
Yes	0 (0.0)	0 (0.0)	0 (0.0)	
No	75 (100.0)	75 (100.0)	150 (100)	
Total	75	75		

Table 4 shows the result of a multivariate linear regression analysis of the oxytocin dose and other risk factors on the primary study outcome. The model showed a coefficient of determination of 14%. There was no significant relationship between the oxytocin dose given and the amount of postpartum blood loss. Of all the variables entered in the model, only the presence of episiotomy/tears/lacerations showed a significant association with the amount of postpartum blood loss ($P < 0.0001$).

TABLE 4: LINEAR REGRESSION ANALYSIS OF POSTPARTUM BLOOD LOSS AND VARIABLES

VARIABLE	COEFFICIENT	P-VALUE	CORRELATION COEFFICIENT (r^2)
Study Group	-1.326	0.9700	0.14
Parity	-5.590	0.7349	
Birth Weight	37.225	0.4249	
Gestational Age	-9.375	0.5582	
Height	-3.870	0.2542	
Weight	0.807	0.6202	
Episiotomy/Tears/lacerations	157.594	0.0001	
Constant	1080.542	0.2029	