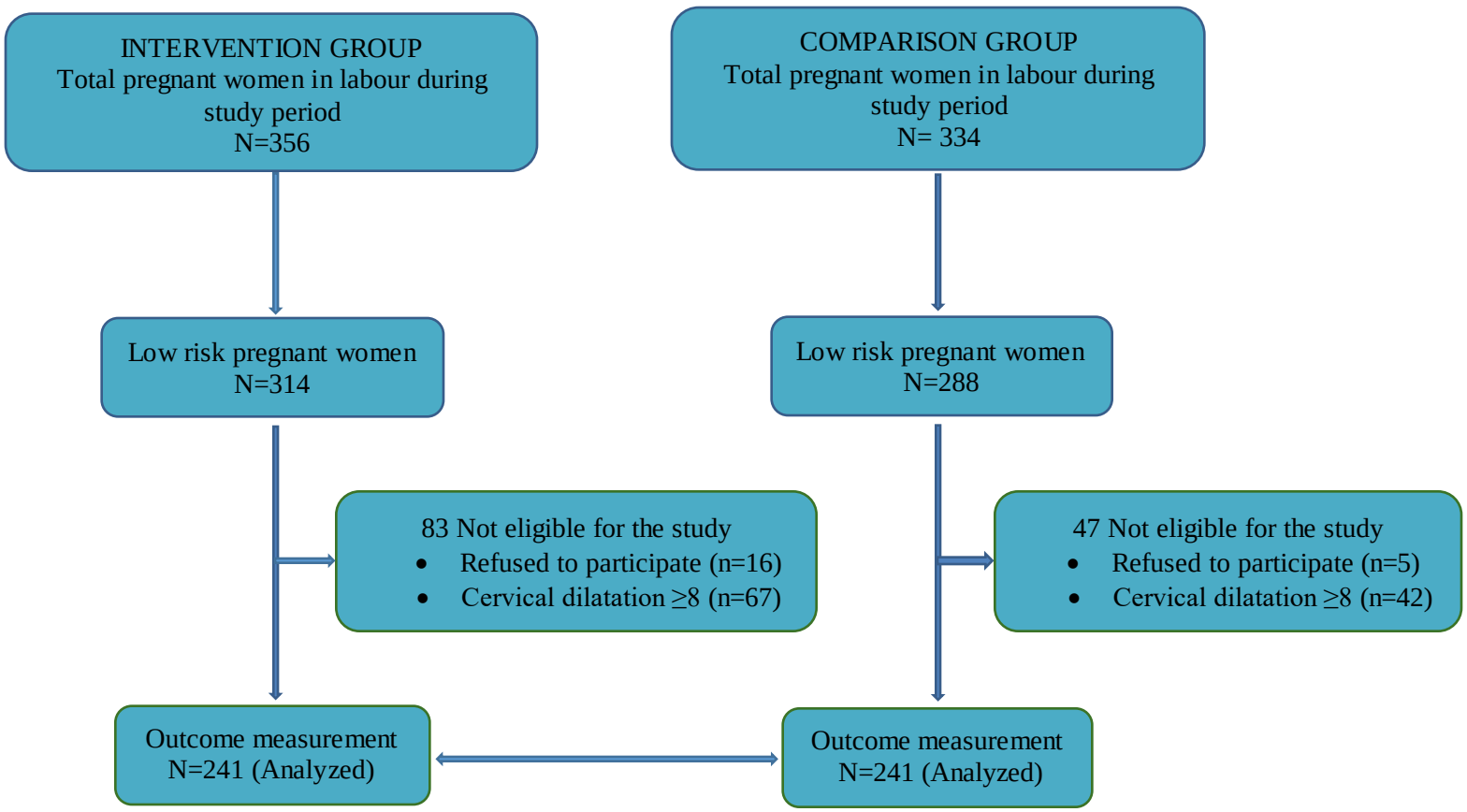
Participant selection and recruitment

All women in labor were screened at admission with risk assessment tool to rule out high risk women, those who met the inclusion criteria (low-risk women) were recruited for follow up in the study. Study participants were informed on the aim and the need of this study in the society. The researcher further informed participants on ethical issues such as sharing of the information to the authorities and assuring the safety of the interventions. A signed informed consent was obtained from participants who understood and agreed to participate in the study. A numbered blue sticker was put on the partograph of selected participants for easy identification. The same process of recruiting was repeated until the sample size was achieved.

At the intervention site, low-risk women were monitored by using LCG (experimental tool) while high risk women were not included in the study and therefore continued with usual labour monitoring by using composite partograph. At the comparison site, low-risk women were included in the study and monitored by using composite partograph (comparison tool) while those who had high risk were not included in the study and therefore continued with usual monitoring by using composite partograph.

Figure 1: Flow chart of study participant recruitment



Results

Maternal demographics of study participants

During the three-month study period, 356 deliveries were conducted at the intervention site and 334 deliveries were conducted at the comparison site. Low-risk pregnant women represented 88% and 86% of all women who delivered at the intervention and comparison sites respectively. The two groups had no statistical differences in demographic characteristics. Table number 1 summarizes the maternal demographics.

Table 1: Maternal demographics of study participants, N=482

Variables	WHO Labour Care Guide (N=241)	WHO composite partograph (N=241)	Overall % N=482 (%)	P value
Maternal Age (mean ± SD)	27.4±4.0	27.3±4.4	27.3±4.2	0.058
20-24	63 (26.14)	77 (31.95)	140 (29.05)	
25-29	100 (41.49)	75 (31.12)	175 (36.31)	
30-34	78 (32.37)	89 (36.93)	167 (34.65)	
Maternal education				
Primary incomplete	23 (9.54)	73 (29.29)	96 (18.92)	0.141
Primary complete	73 (30.29)	52 (21.58)	125 (25.93)	
Secondary	102 (42.32)	103 (42.74)	205 (42.53)	
College/University	43 (17.84)	13 (5.39)	56 (11.62)	
Marital status				
Married, living together	230 (95.44)	222 (92.12)	452 (93.78)	0.131
Single, Divorced	11 (4.56)	19 (7.88)	30 (6.22)	
Occupation				
Sales services	87 (36.1)	135 (56.02)	222 (46.06)	0.061
Domestic service	45 (18.67)	63 (26.14)	108 (22.41)	
Clerical services	42 (17.43)	2 (0.83)	44 (9.13)	
Managerial services	58 (24.07)	8 (3.32)	66 (13.69)	
Agriculture	9 (3.73)	33 (13.69)	42 (8.71)	

Parity (Median, IQR)	1 (0-2)	2 (0-3)		
0	115 (47.72)	98 (40.66)	213 (44.19)	0.129
1-2	73 (30.29)	64 (26.56)	137 (28.42)	
>2	53 (21.99)	79 (32.78)	132 (27.39)	

Maternal and Clinical Characteristics of Study Participants at Admission

By mode of birth, majority (88.9% and 86.7%) of study participants in the intervention and comparison group respectively had spontaneous vaginal birth. Vacuum vaginal birth accounted for 0.8% in the intervention group and 2.1% in the comparison group. Those who were HIV positive were 2.9% and 5.8% in the intervention and comparison group respectively.

About admission status, 98% of study participants both in the intervention and comparison group were admitted from home. The average gestational age at labour was 39 weeks and 1 day for both participants in the intervention group and the comparison group. The average cervical dilation at admission was higher for participants at the intervention group (4.3cm) as compared to participants at the comparison group (3.9cm). More than ninety percent of participants in both groups had intact membranes on admission**.** Furthermore, head station of more than half of the participants in the intervention group was at negative one. The proportion of low-risk pregnant women (participants) whose head position at admission showed occiput anterior, was 84.4% for the intervention group and 67.5% in the comparison group. Statistically, there was no difference between the two groups in terms of clinical characteristics.

Comparison of Maternal Outcomes, Mode of Delivery and Labour Process

At 5% level of significance, there was no statistically significant association between partograph type and maternal outcomes. Table number 2 highlights details of the compared maternal outcomes.

Table 2: Comparison of maternal outcomes, mode of delivery and Labour process between "Labor Care Guide" and "composite partograph" N=482

Variable	Labour Care Guide (N=241) n	proportion (95% CI)	Composite Partograph (N=241) n	proportion (95% CI)	χ^2	p-value
Post-partum Hemorrhage	18	0.1(0.0-0.1)	20	0.1(0.1-0.1)	0.11	0.74
Perineal trauma	35	0.1(0.1-0.2)	31	0.1(0.1-0.2)	0.28	0.60
Severe perineal trauma	5	0.02(0.0-0.0)	6	0.02(0.0-0.0)	0.09`	0.76
Maternal death	1		0			
Mode of delivery						
Cephalic vaginal birth	216	0.9(0.9-0.9)	209	0.9(0.8-0.9)	1.42	0.49
Caesarean section	25	0.1(0.1-0.1)	27	0.1(0.1-0.2)		
Duration of first stage	9.15±3.4		9±2.4			
Up to 12hrs	200	0.8(0.8-0.9)	222	0.9(0.9-1.0)	9.21	0.002
More than 12 hours	41	0.2(0.1-0.2)	19	0.1(0.1-0.1)		
Duration of second stage (minutes)	N=216	21.5±11.2	N=214	27.4±12.3		
Less than 30	191	0.9(0.8-0.9)	150	0.7(0.6-0.8)	22.01	<0.001
Above 30	25	0.1(0.1-0.2)	64	0.3(0.2-0.4)		
Need for Augmentation						
yes	14	0.1(0.0-0.2)	32	0.1(0.1-0.2)	7.79	0.005
No	227	0.9(0.9-1.0)	209	0.9(0.8-1.0)		
Admitted before criteria for initiation of Partograph						
Yes	121	0.5(0.4-0.6)	80	0.3(0.3-0.4)	14.34	<0.001
No	120	0.5(0.4-0.6)	161	0.7(0.6-0.7)		
Number of vaginal examinations						
<= 2	149	0.6(0.6-0.7)	158	0.7(0.6-0.7)	0.73	0.39
> 2	92	0.4(0.3-0.5)	83	0.3(0.3-0.4)		

Comparison of Newborn Outcomes

Results shows that the p-values for all newborn components, were above 0.05, therefore, we fail to reject the null hypothesis. From the results shown in table number 3, it implies that at 5% level of significance, there is no statistically significant association between newborn outcomes and partograph type.

Table 3: Comparison of newborn outcomes between "Labor Care Guide" and "Composite Partograph" N=482

Variable	Labour Care Guide (N=241) n	proportion (95% CI)	Composite Partograph (N=241) n	proportion (95% CI)	χ^2	p-value
Condition of baby						
Live birth	231	1.0 (0.9-1.0)	235	1.0 (1.0-1.0)	0.97	0.33
Fresh still birth	10	0.0 (0.0-0.1)	6	0.0 (0.0-0.0)		
Apgar score at 1 minute						
< 7	22	0.1 (0.1-0.1)	18	0.1 (0.0-0.1)	0.6	0.45
≥7	219	0.9 (0.9-0.9)	223	0.9 (0.9-1.0)		
Apgar score at 5 minutes						
< 7	20	0.1 (0.1-0.1)	15	0.1 (0.0-0.1)	0.7	0.41
≥7	221	0.9 (0.0-1.0)	226	0.9 (0.9-1.0)		
Need for NICU admission						
No	229	1.0 (1.0-1.0)	228	1.0 (1.0-1.0)	0.1	0.80
Yes	12	0.1 (0.0-0.1)	13	0.1 (0.0-0.1)		
Newborn Birth Weight (BWT)						
Very Low BWT(<1500g)	5	0.0 (0.0-0.0)	3	0.0 (0.0-0.0)	0.9	0.82
Low BWT (1500 to<2500g)	21	0.1 (0.1-0.1)	19	0.1 (0.1-0.1)		
Normal BWT (2500-4000g)	210	0.9 (0.8-0.9)	212	0.9 (0.8-0.9)		
High BWT (>4000g)	5	0.0 (0.0-0.0)	7	0.0 (0.0-0.1)		

Adverse event: No advent event reported as this study did not involve invasive procedure

Outcome measures: Maternal and Newborn outcomes: mode of delivery, Post-Partum Hemorrhage, labour augmentation, duration of labor, maternal death, Apgar score, admission to Neonatal Intensive Care Unit and perinatal death.