

Participants' flow chart

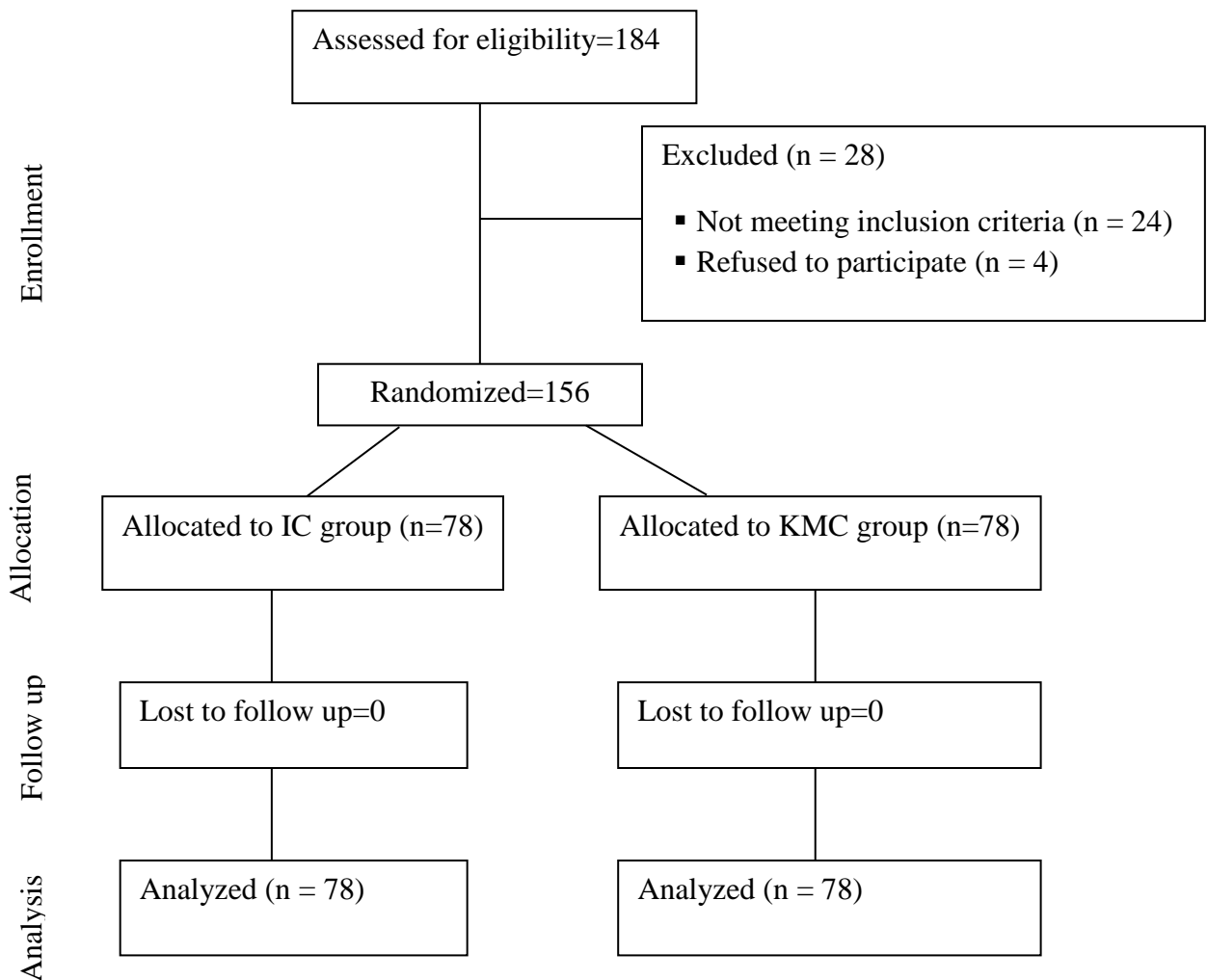


Fig 1: Participants flowchart for the study “The effects of short duration kangaroo mother care on neonatal pain from adhesive tape removal among preterm neonates”

Baseline characteristics of the study participants

Among those neonates involved in the study 77(49.4%) of them were males. The mean GA of the study participants was 33.8(1.8) weeks while their median PA was 5.1(2.4 to 8) days. The mode of delivery for ninety one (58.7%) of the neonates was spontaneous vaginal delivery (SVD). The average first minute Apgar score was 7 (4 to 8) while their fifth minutes Apgar score was 8(5 to 9). The average birth weight of the recruited study participant was 1744.7 ± 380.4

grams. The groups were marginally different in terms mode of feedings and previous KMC experience (**Table 1**).

Table 1: Demographic characteristics of preterm neonates admitted to TASH and GMH

Characteristics	KMC (n=78)	IC (n=78)	P-value
Sex, n (%)			
Male	42(53.9)	35(44.9)	0.26
Female	36(46.2)	43(55.1)	
GA(weeks) †	33.8 (1.9)	33.7 (1.6)	0.88
PA(days)			
Median (IQR)	5.2 (3 to 8.3)	5.1 (2 to 7.2)	0.49
Mode of delivery, n (%)*			
SVD	48(62.3)	43(55.1)	0.36
Cesarean section	29(37.7)	35(44.9)	
1st minute Apgar score*			
Median (IQR)	7(6 to 8)	7(6 to 8)	0.33
5th minute Apgar score*			
Median (IQR)	8(7 to 9)	8(7 to 9)	0.44
Birth weight(gm) †	1792.2(380.9)	1696.5(376.2)	0.12
Hours passed between last feeding and time of data collection (hrs.)*			
Median (IQR)	1.3 (0.5 to 2)	1.2(0.5 to 2)	0.49

Mode of feeding, n (%)^{*φ}

Breastfeeding	47(61)	34 (45.3)	0.05
Cup feeding	18(23.4)	15(20)	0.61
NG tube feeding	27(35.1)	24(32)	0.69
Maintenance fluid	2(2.6)	8(10.7)	0.05

Previous KMC experience, n (%)^{*}

Yes	22 (28.2)	12 (15.6)	
No	56 (71.8)	65 (84.4)	0.05

[^{*} missed values, [†] values in terms of mean (SD), ^φ multiple responses were possible]

Preterm neonates recruited as study participants spent 5.08 (2.42 to 8.04) days in health institutions before the time of data collection and 56 (35.9%) of them were critically ill during admission. One hundred five neonates (67.3%) had been treated with oxygen for about 4(2 to 6.63) days. Among the neonates treated with oxygen, 66 (62.9%) of them were treated with CPAP at least for some time in their life. During the time of data collection, 22 (20.9%) of them were on intranasal oxygen support. None of the preterm neonates recruited for this study had received analgesic drugs at least for 24 hours before the data collection. The groups were not different in terms of their medical characteristics (**Table 2**).

Table 2: Medical characteristics of preterm neonates admitted to TASH and GMH

Characteristics	KMC(n=78)	IC(n=78)	P-value
Length of stay in health institutions since birth (days)*	5.1(3 to 8.3)	5.1 (2 to7.3)	0.44
Critically ill during admission, n (%)			
Yes	24(30.8)	32 (41)	0.18
No	54(69.2)	46 (58.9)	
History of oxygen support, n (%)			
Yes	54 (69.2)	51(65.4)	0.61
No	24 (30.8)	27 (34.6)	
Types oxygen support, n (%) **			
CPAP	30 (55.6)	36 (70.6)	0.11
Prong	13 (24.1)	12 (23.5)	0.95
INO ₂	48 (88.9)	46 (90.2)	0.83
Length of oxygen treatment since admission to the hospitals (days)*	3.5 (2 to 5.7)	4 (1.3 to 8)	0.64
Neonates on INO ₂ support during data collection, n (%)			
Yes	9(16.7)	13(25.5)	0.27
No	45(83.3)	38(74.5)	

(* values in median (IQR), **multiple responses were possible, CPAP= continuous positive airway pressure, INO₂= Intranasal oxygen)

One hundred forty six (93.6%) neonates [IC group=74(94.9%) and KMC group=72(92.3%), $P=0.51$] were exposed to at least one painful procedure before the time of data collection. One hundred five (71.9%) of those neonates were exposed to IV medication administration and 89 (60.9%) of them were exposed to blood drawing. Heel pricks and lumbar punctures were the least commonly performed procedures among the study participants; 4.5% and 0.6% respectively. The types and the numbers of painful medical procedures conducted on the neonates were not significantly different between the groups (**Table 3**).

In both hospitals heuer zinc oxide cloth plaster manufactured by GST Corporation Ltd (India) was used to conduct different procedures. Additionally in GMH, ReliaMed[®] paper surgical tape manufactured by ReliaMed[®] (China) was used during minor procedures like nasogastric tube (NG) tube insertion.

Table 3: Painful medical procedures conducted among preterm neonates admitted to TASH and GMH

Types and frequencies of painful medical procedures conducted on preterm neonates, n (%)	KMC (n=78)	IC (n=78)	P-value
Blood draw			
Once	40 (51.3)	43 (55.1)	0.67
More than once	4 (5.1)	2 (2.6)	
IV medication administration			
Once	24 (30.8)	28 (35.9)	0.31
More than once	24 (30.8)	29 (37.2)	
IV cannula insertion			
Once	23 (29.5)	21 (26.9)	0.53
More than once	5 (6.4)	9 (11.5)	

IV cannula removal

Once	21 (26.9)	13 (16.7)	0.26
More than once	3 (3.9)	5 (6.4)	

NGT insertion

Once	18 (23.1)	13 (16.7)	0.44
More than once	4 (5.1)	7 (8.9)	

Heel prick

Once	2 (2.6)	4 (5.1)	0.44
More than once	0	1 (1.3)	

Lumbar puncture

Once	1(1.3)	0	1
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(Multiple responses were possible) [IV= Intravenous, NGT= Nasogastric tube]

Preterm neonates assigned in both groups were in active sleeping state short before the initiation of the adhesive tape removal and the scores for GA were similar among the groups. Their average baseline PIPP score was 4 ± 3.4 and there was no statistically significant difference between the groups [KMC= 3.9 ± 3.6], IC group= 4 ± 3.3 , $p=0.79$]. The baseline PIPP score of the study participants was not also significantly different between the two hospitals [TASH=4 (0 to 6), GMH =5 (0 to 7), $P=0.2$]. The average baseline HR of the neonates was 139.7 ± 17.3 beats per minute (bpm) [KMC= 139.4 ± 15.9 bpm, IC= 139.9 ± 18.7 bpm, $P=0.82$] and their baseline oxygen saturation was 94% (91 to 96) [KMC= 94% (92 to 96), IC= 94% (91 to 96), $P=0.79$].

Adverse effect of the study

No adverse effect was reported among preterm neonates participated in the study.

Outcome measures

The primary outcome of this study was the level of pain among preterm neonates during adhesive tape removal. The pain level was measured using Premature Infant Pain Profile (PIPP) scale and a difference of 2 points in PIPP score was considered as clinically significant difference. The findings were discussed in terms of mean and standard deviation (SD).

The independent samples t-test showed that preterm neonates in KMC group had lower PIPP scores during adhesive tape removal than that of the neonates kept in the incubator [MD=-2.5, 95% CI (-3.9, -1.2), $P<0.00$] (**Table 4**). Also, compared to their baseline state, the average increment in the PIPP score of neonates in KMC group [MD=7.4, 95% CI (4.7, 10.2), ($P<0.00$)] was lower than that of the neonates in the incubator group [MD=8.1, 95% CI (4.6, 11.5), ($P<0.00$)].

Though the actual HR of neonates assigned in KMC group during adhesive tape removal was lower than that of the neonates in the incubator group, the difference was not statistically significant [MD= -1.3, 95% CI (-7.8, 5.2), $P=0.69$] (**Table 4**). Also, the study participants in KMC group had lower actual oxygen saturation compared to the oxygen saturation of participants in the incubator group. However, the difference was not statistically significant ($P=0.83$) (**Table 4**).

Table 4: The PIPP scores of the study participants during adhesive tape removal

Variables	KMC(n=78)	IC (n=78)	MD (95% CI)	p-value
PIPP score*¥	7.8(4.2)	10.3(4.2)	-2.5 (-3.9, -1.2)	0.00
Scores for PIPP tool components				
GA	1(1)	1(1)		0.55
Alertness state	2(1 to 2)	2(1 to 3)		0.82
Brow bulge	1(0 to 2)	2.5 (1 to 3)		0.00
Eye squeeze	1.5(0 to 3)	2(1 to 3)		0.02
Nasolabial furrow	1.5(0 to 2)	2(1 to 3)		0.00
Heart rate*	1(0 to 2)	1(0 to 2)		0.72
Oxygen saturation*	0(0 to 1)	0(0 to 1)		0.31
Actual HR (bpm)*¥	146.5 (17.4)	148.1(22.8)	-1.3(-7.8, 5.2)	0.69
Actual oxygen saturation (%)*	93(91 to 96)	94(91 to 95)		0.83

[*-Missed values (n=5), ¥: values in mean (SD), bpm (beats per minute)]

The secondary outcome of the study was measuring the feasibility of using KMC for neonatal pain management. It was measured qualitatively by interviewing health care professionals participated in the data collection process of the study.

Health care professionals mentioned that they have noticed the positive effect of KMC on the reduction of neonatal pain. They have also agreed that it is feasible to you use KMC for routine neonatal pain management if the necessary supports are available.