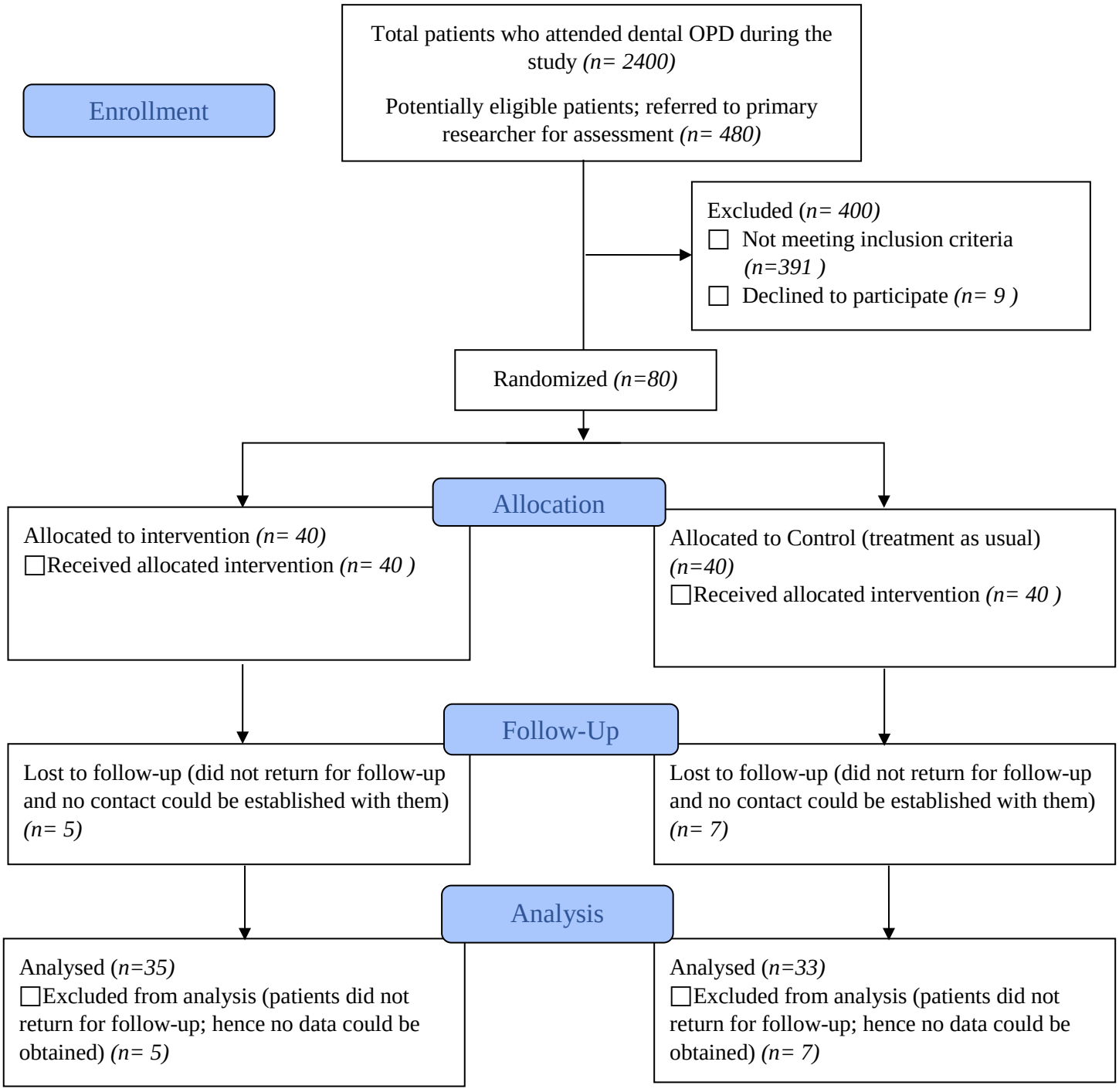
1. Participant Flow



2. Baseline Characteristics

Baseline Characteristics		**Groups**	
Demographic data:		**Control group**	**Experimental group**
Age (mean ± SD)		*33.6 ± 6.3*	*33.2 ± 6*
Sex; count (%)			
	Males	*12 (30%)*	*18 (45%)*
	Females	*28 (70%)*	*22 (55%)*
Ethnicity		*Asian*	*Asian*
Clinical Characteristics:			
Pre-operative pain score (mean ± SD)		*13.1 ± 17.4*	*18.1 ± 12.4*
Teeth included in the study; count (%)			
	Maxillary Central Incisor	*4 (10%)*	*2 (5%)*
	Maxillary Lateral Incisor	*4 (10%)*	*4 (10%)*
	Maxillary Canine	*8 (20%)*	*7 (17.5%)*
	Maxillary 2nd Premolar	*6 (15%)*	*14 (35%)*
	Mandibular Central Incisor		
	Mandibular Lateral Incisor	*3 (7.5%)*	
	Mandibular Canine	*1 (2.5%)*	*2 (5%)*
	Mandibular 1st Premolar	*4 (10%)*	*5 (12.5%)*
	Mandibular 2nd Premolar	*10 (25%)*	*6 (15%)*

3. Outcome Measures

PRIMARY OUTCOME (1a):

Pain intensity (based on Visual Analogue Scale) difference between both the groups; without exclusion of patients who took analgesics.

Self-recorded pain intensity by the patients at 4 hours, 12 hours, day 2, day 3 and day 4 after root canal preparation and intracanal medicament insertion. Pain intensity recorded on a Visual Analogue Scale from 0 to 100. Patients who experienced no or mild pain; and do not require analgesic recorded their pain intensity from 0 to 24. Patients who experienced moderate pain; and require Over-the-counter analgesic recorded pain intensity from 25 to 49. Patients who experienced severe pain; and required use of codeine containing medicine recorded their pain intensity from 50 to 74. Patients who experienced extreme pain, and no medicine was able to relieve their pain recorded pain intensity from 75 to 100.
lower pain score (intensity) is a better outcome as compared to higher pain intensity (score)

Interval	N (33)	Group I Mean Pain Score (SD) (min – max)	N (35)	Group II Mean Pain Score (SD) (min – max)	Mean Difference (P-value)
Pre-op		14.7 ± 18.3 (1 – 90)		20.6 ± 17.3 (2 – 50)	*-5.87 (0.053*)*
4 hours		11.8 ± 18.7 (0 – 70)		8.8 ± 11.1 (0 – 43)	*2.96 (0.329)*
12 hours		9.4 ± 16.7 (0 – 50)		10.3 ± 13.3 (0 – 49)	*-0.92 (0.764)*
Day 2		3.5 ± 7.7 (0 – 30)		5.1 ± 9.2 (0 – 30)	*-1.57 (0.605)*
Day 3		2.6 ± 6.4 (0 – 30)		3.4 ± 6.8 (0 – 25)	*-0.82 (0.786)*
Day 4		1.9 ± 4.7 (0 – 20)		2.7 ± 7.3 (0 – 30)	*-0.72 (0.813)*

** Significant at 0.05*

PRIMARY OUTCOME (1b):

Pain intensity (based on Visual Analogue Scale) difference between both the groups; with exclusion of patients who took analgesics

Interval	N	Group I Mean Pain Score (SD) (min – max)	N	Group II Mean Pain Score (SD) (min – max)	Mean Difference (P-value)
4 hours	26	3.1 ± 5.3 (0 – 23)	32	6.6 ± 8.3 (0 – 24)	*-3.49 (0.146)*
12 hours	26	1.4 ± 3.6 (0 – 15)	26	4.3 ± 6.6 (0 – 20)	*-2.92 (0.245)*
Day 2	26	0.5 ± 1.4 (0 – 5)	25	1.4 ± 3.0 (0 – 10)	*-0.94 (0.712)*
Day 3	26	0.8 ± 2.2 (0 – 9)	25	1.4 ± 3.5 (0 – 12)	*-0.63 (0.803)*
Day 4	26	0.6 ± 1.2 (0 – 9)	24	0.5 ± 2.0 (0 – 10)	*0.08 (0.976)*

SECONDARY OUTCOME (1):

Acute increase in pain score (acute exacerbation of pain) or "flare-up"

An increase of a total of at least 20 pain score points from previous pain score reading indicate that pain has increased significantly and will be reported as "flare-up"

Time Interval	Caoh (%) N= 33	Propolis (%) N= 35	Total (%)
4 hours	4 (12%)	1 (2.8%)	*5 (7.4%)*
12 hours	0 (0%)	4 (11.4%)	*4 (5.9%)*
Day 2	0 (0%)	1 (2.8%)	*1 (1.5%)*
Day 3	0 (0%)	0 (0%)	*0 (0%)*
Day 4	0 (0%)	0 (0%)	*0 (0%)*
Total (%)	*4 (12%)*	*6 (17%)*	*10 (14.8%)*

SECONDARY OUTCOME (2a):

Mean difference of pain scores between different time intervals; without exclusion of patients who took analgesics

Time	Pre-op	4 hours	12 hours	Day 2	Day 3	Day 4
Pre-op	C →	2.97 (p=0.334)	5.30 (p=0.085)	11.18 (p=0.000**)	12.12 (p=0.000**)	12.79 (p=0.000**)
4 hours	11.80 (p=0.000**)	C → ← E	2.33 (p=0.448)	8.21 (p=0.008**)	9.15 (p=0.003**)	9.82 (p=0.001**)
12 hours	10.26 (p=0.001**)	-1.54 (p=0.605)	C → ← E	5.88 (p=0.056)	6.82 (p=0.27)	7.84 (p=0.015**)
Day 2	15.49 (p=0.000**)	3.69 (p=0.217)	5.23 (p=0.80)	C → ← E	0.94 (p=0.760)	1.61 (p=0.601)
Day 3	17.17 (p=0.000**)	5.37 (p=0.72)	6.91 (p=0.21)	1.69 (p=0.574)	C → ← E	0.67 (p=0.828)
Day 4	17.94 (p=0.000**)	6.14 (p=0.40)	7.69 (p=0.10)	2.46 (p=0.410)	0.77 (p=0.796)	← E

*** significant at 0.01, * significant at 0.05*
Estimation parameter= Mean difference (net), Parameter dispersion= standard error of mean
C→ = control group values, ←E = Experimental group values

SECONDARY OUTCOME (2b):

Difference of pain scores between different time intervals; with exclusion of patients who took analgesics

Time	Pre-op	4 hours	12 hours	Day 2	Day 3	Day 4
Pre-op	C →	11.65 (p=0.000**)	13.34 (p=0.000**)	14.27 (p=0.000**)	13.92 (p=0.000**)	14.15 (p=0.000**)
4 hours	14.04 (p=0.000**)	C → ← E	1.69 (p=0.501)	2.62 (p=0.298)	2.27 (p=0.367)	2.5 (p=0.320)
12 hours	16.29 (p=0.000**)	2.25 (p=0.346)	C → ← E	0.92 (p=0.713)	0.58 (p=0.818)	0.81 (p=0.748)
Day 2	19.20 (p=0.000**)	5.16 (p=0.33)	2.91 (p=0.252)	C → ← E	-0.35 (p=0.890)	-0.12 (p=0.963)
Day 3	19.16 (p=0.000**)	5.12 (p=0.035*)	2.87 (p=0.259)	-0.4 (p=0.988)	C → ← E	0.23 (p=0.927)
Day 4	20.10 (p=0.000**)	6.06 (p=0.014**)	0.381 (p=0.138)	0.90 (p=0.728)	0.94 (p=0.717)	← E

*** significant difference at 0.01, * significant at 0.05*
C→ = Control group values, ←E = Experimental group values

OTHER OUTCOME (1a):

Difference of pain scores between males and females
** Significant at 0.05*

Interval	N	Males Mean Pain Score (SD) (min – max)	N	Females Mean Pain Score (SD) (min – max)	Mean Difference (P-value)
4 hours	25	9.8 ± 11.9 (0 – 40)	43	10.4 ± 16.9 (0 – 70)	*-0.6 (0.412)*
12 hours	25	11.6 ± 14.5 (0 – 49)	43	8.8 ± 15.2 (0 – 50)	*2.8 (0.94)*
Day 2	25	7.8 ± 11 (0 – 30)	43	2.3 ± 5.8 (0 – 25)	*5.5 (0.035*)*
Day 3	25	5.8 ± 8.9 (0 – 30)	43	1.40 ± 4 (0 – 20)	*4.4 (0.023*)*
Day 4	25	5 ± 9.2 (0 – 30)	43	0.70 ± 2.1 (0 – 9)	*4.3 (0.020*)*

OTHER OUTCOME (1b):

Difference of pain quality between males and females

Time Interval	Gender	No or mild pain (N)	Moderate pain (N)	Severe pain (N)	Total (N)
4 hours	*Male*	21	4	0	68
	Female	37	3	3	
12 hours	*Male*	19	6	0	68
	Female	36	5	2	
Day 2	*Male*	21	4	0	68
	Female	41	2	0	
Day 3	*Male*	23	2	0	68
	Female	43	0	0	
Day 4	*Male*	23	2	0	68
	Female	43	0	0	

OTHER OUTCOME (2a):

Difference of pain scores between different age groups

Time Interval	20 – 24 (N=6)	25- 29 (N= 10)	30 – 34 (N= 17)	35 – 40 (N= 35)	P - value
	MEAN (SD)				
4 hours	7.1 (9.1)	14.5 (15.1)	14.6 (21.2)	7.4 (12.1)	*0.15*
12 hours	8.3 (14.3)	12.9 (17.9)	13.6 (16.3)	7.4 (13.5)	*0.36*
Day 2	0 (0)	10.6 (13.1)	3.7 (6.9)	3.6 (7.7)	*0.13*
Day 3	1.5 (3.6)	4 (9.6)	1.5 (4.2)	3.7 (6.9)	*0.55*
Day 4	0 (0)	2.1 (6.2)	0.3 (1.2)	3.7 (7.6)	*0.17*

OTHER OUTCOME (2b):

Difference of pain quality between different age groups

Time	Pain severity	20 to 24 (N=6)	25 to 29 (N= 10)	30 to 34 (N= 17)	35 to 40 (N= 35)
4 hours	*No or mild*	6	8	13	31
	Mod	0	2	2	3
	Severe	0	0	2	1
12 hours	*No or mild*	5	7	13	30
	Moderate	1	3	3	4
	Severe	0	0	1	1
Day 2	*No or mild*	6	7	16	33
	Moderate	0	3	1	2
	Severe	0	0	0	0
Day 3	*No or mild*	6	9	17	34
	Moderate	0	1	0	1
	Severe	0	0	0	0
Day 4	*No or mild*	6	10	17	33
	Moderate	0	0	0	2
	severe	0	0	0	0

OTHER OUTCOME (3):

Type of analgesics required by patients during study

Groups	Time Interval	No medication	OTC medication	Narcotic medication
Control Group (Calcium hydroxide/Calcipulpe)	4 hrs	*26 (38%)*	*4 (6%)*	*3 (4%)*
Experimental Group (Propolis)		*32 (47%)*	*3 (4%)*	*0*
Total		**58 (85%)**	**7 (10%)**	**3 (4%)**
Control Group (Calcium hydroxide/Calcipulpe)	12 hrs	*27 (40%)*	*4 (6%)*	*2 (3%)*
Experimental Group (Propolis)		*28 (41%)*	*7 (10%)*	*0*
Total		**55 (81%)**	**11 (16%)**	**2 (3%)**
Control Group (Calcium hydroxide/Calcipulpe)	Day 2	*31 (46%)*	*2 (3%)*	*0*
Experimental Group (Propolis)		*31 (46%)*	*4 (6%)*	*0*
Total		**62 (91%)**	**6 (9%)**	**0**
Control Group (Calcium hydroxide/Calcipulpe)	Day 3	*32 (47%)*	*1 (1.5%)*	*0*
Experimental Group (Propolis)		*34 (50%)*	*1 (1.5%)*	*0*
Total		**66 (97%)**	**2 (3%)**	**0**
Control Group (Calcium hydroxide/Calcipulpe)	Day 4	*33 (48.5%)*	*0*	*0*
Experimental Group (Propolis)		*33 (48.5%)*	*2 (3%)*	*0*
Total		**66 (97%)**	**2 (3%)**	**0**

4. Adverse Events

There were no adverse events associated with this trial