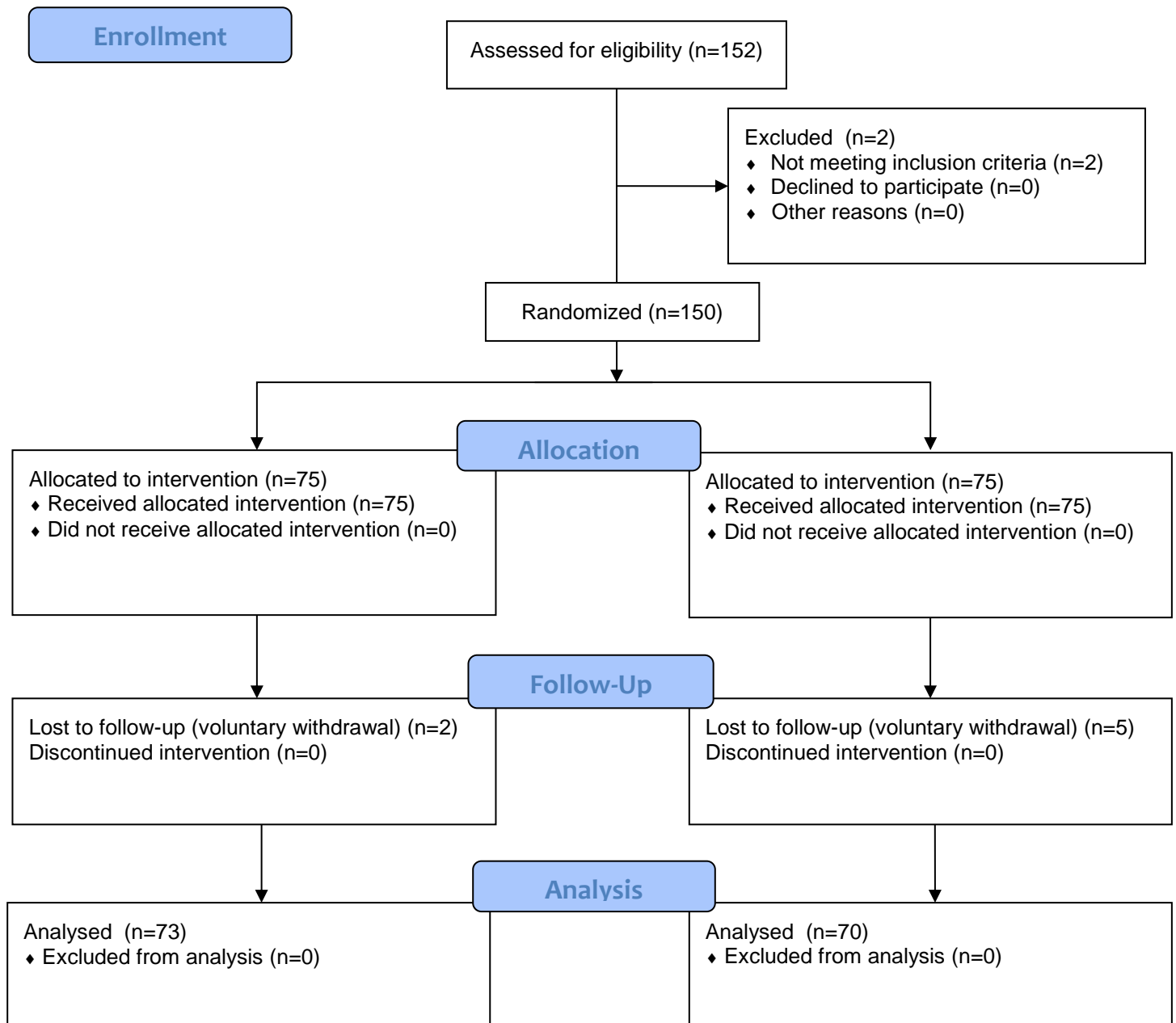


Participant Flow



Baseline characteristics

Demographics Summary			
Demographic/ Statistic or Category	Negative Control (n=75)	Gingivitis Treatment Toothpaste (n=75)	Overall (n=150)
Age (Years)			
Mean (SD)	43.88 (11.05)	46.24 (10.56)	45.06 (10.84)
Min.-Max.	21 - 65	26 - 68	21 - 68
Race			
Caucasian	75 (100%)	75 (100%)	150 (100%)
Sex			
Female	47 (63%)	49 (65%)	96 (64%)
Male ^b	28 (37%)	26 (35%)	54 (36%)
Smoker			
No	62 (83%)	65 (87%)	127 (85%)
Yes	13 (17%)	10 (13%)	23 (15%)

Outcome measures (Intent-to-Treat (ITT) Population)

Efficacy Results, Analysis of Covariance Summary ^a Modified Gingival Index				
Treatment	N	Adj. Mean (SE)	Treatment Difference (SE)	2-sided P-value ^c
Week 4				
Negative Control	66	1.87 (0.007)	0.05 (0.010)	<0.001
Gingivitis Treatment Toothpaste	70	1.82 (0.007)		
Week 12				
Negative Control	70	1.88 (0.007)	0.06 (0.010)	<0.001
Gingivitis Treatment Toothpaste	73	1.82 (0.007)		
^a ANCOVA model included baseline and treatment as fixed effect(s). ^b Percent Change versus Negative Control = 100 x ((Negative Control - Gingivitis Treatment Toothpaste)/ Negative Control) ^c 2-sided p-value comparing treatments using analysis of covariance.				

Efficacy Results, Analysis of Covariance Summary ^a Number of Bleeding Sites				
Treatment	N	Adj. Mean (SE)	Treatment Difference (SE)	2-sided P-value ^c
Week 4				
Negative Control	66	49.07 (1.618)	9.56 (2.256)	<0.001
Gingivitis Treatment Toothpaste	70	39.51 (1.571)		
Week 12				
Negative Control	70	47.82 (2.095)	10.77 (2.933)	<0.001
Gingivitis Treatment Toothpaste	73	37.05 (2.052)		
^a ANCOVA model included baseline and treatment as fixed effect(s). ^b Percent Change versus Negative Control = 100 x ((Negative Control - Gingivitis Treatment Toothpaste)/ Negative Control) ^c 2-sided p-value comparing treatments using analysis of covariance.				

Efficacy Results, Analysis of Covariance Summary ^a Extended Turesky Modified Quigley-Hein Index				
Treatment	N	Adj. Mean (SE)	Treatment Difference (SE)	2-sided P-value ^c
Week 12				
Negative Control	70	4.02 (0.026)	0.11 (0.036)	0.004
Gingivitis Treatment Toothpaste	73	3.92 (0.025)		
^a ANCOVA model included baseline and treatment as fixed effect(s). ^b Percent Change versus Negative Control = 100 x ((Negative Control - Gingivitis Treatment Toothpaste)/ Negative Control) ^c 2-sided p-value comparing treatments using analysis of covariance.				

Adverse events

There were no AEs/ADEs neither observed nor reported in this study.