Basic report: ISRCTN6762457

Section 1: Participant Flow

CONSORT 2010 Flow Diagram

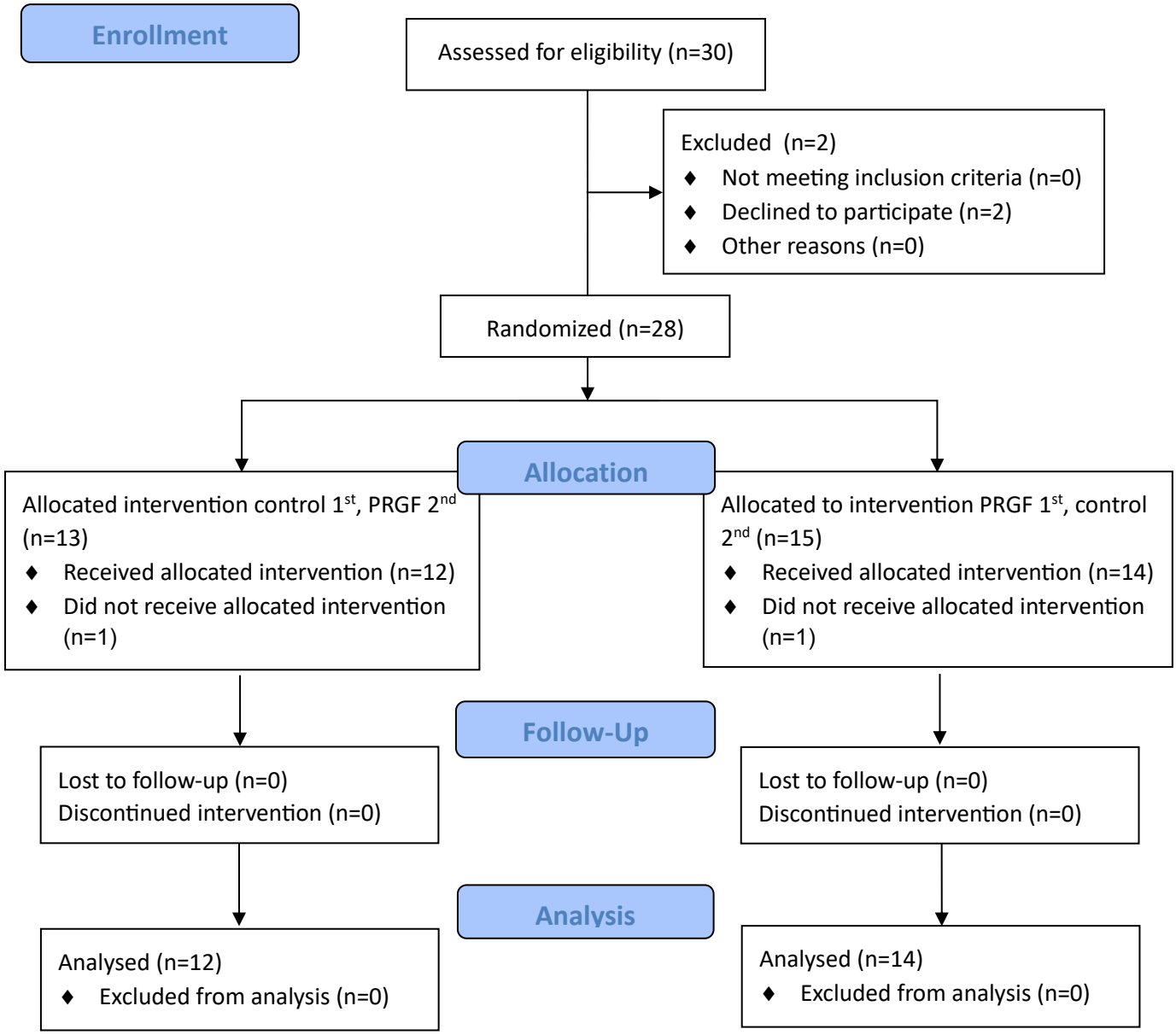

Figure 1. Patient flow through the study. Each participant required treatment on two teeth, one was treated with the control and the other the PRGF treatment, 26 teeth were analysed for each treatment in total.

Section 2: Baseline Characteristics

Table 1: Participant characteristics at baseline

		Intervention: control then PRGF (n=12)	Intervention: PRGF then control (n=14)	All participants (n=26)
Age mean (SD)		42.5 (6.68)	49.14 (8.88)	
Gender n (%):	Male	3 (25%)	5 (35.7%)	8 (30.8%)
	Female	9 (75%)	9 (64.3%)	18 (69.2%)
Ethnicity		White (100%)	White (100%)	White (100%)

Table 2: Tooth site characteristics at baseline, pre treatment[1]

		Treated with control (n=26)			Treated with PRGF (n=26)		
		Treated as first site (n=12)	Treated as second site (n=14)	All control sites (n=26)	Treated as first site (n=14)	Treated as second site (n=12	All control sites (n=26)
% with Bleeding on probing		100%	92.9%	96.1%	100%	100%	100%
Mean pocket probing depth in mm (SD)		3.99 (0.73)	4.77 (1.01)	4.41 (0.96)	4.79 (1.42)	4.28 (1.19)	4.55 (1.32)
Mean Gingival recession depth in mm (SD)		1.31 (0.93)	1.48 (1.05)	1.40 (0.98)	1.63 (1.18)	1.38 (1.06)	1.51 (1.11)
Clinical attachment level in mm		8.58 (2.27)	9.71 (2.33)	9.19 (2.33)	9.50 (3.37)	9.17 (1.85)	9.35 (2.73)
Width of keratinized mucosa in mm		4.58 (1.51)	5.21 (2.15)	4.92 (1.87)	4.86 (2.21)	4.33 (1.44)	4.62 (1.88)
Biotype of gingiva (% thick)		100%	85.7%	92.3%	85.7%	100%	92.3%
Mean Turesky plaque score (SD)		0.58 (0.79)	1.00 (0.88)	0.81 (0.85)	1.00 (0.88)	0.67 (0.78)	0.85 (0.83)
Suppuration n (% yes)		2 (16.7%)	4 (28.6%)	6 (23.1%)	1 (7.1%)	0 (0%)	1 (3.8%)
Mobility grade: n (%)	I	1 (8.3%)	4 (28.6%)	5 (19.2%)	2 (14.3%)	3 (25.0%)	5 (19.2%)
	II	1 (8.3%)	0 (0%)	1 (3.8%)	0 (0%)	0 (0%)	0 (0%)
	III	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	1 (3.8%)
Furcation defect (all grade I) n (%)		2 (16.7%)	1 (7.1%)	3 (11.5%)	0 (0%)	2 (16.7%)	2 (7.7%)

[1]This was a split mouth study, each participant received control and test interventions, the order of delivery (1st or 2nd treatment received) was randomised.

Section 3: Outcome measures

Primary outcome measure: Ability of PRGF to support the predictable regeneration of periodontal tissue as indicated by periodontal measures.

Table 3. Mean periodontal scores for teeth treated with PRGF at baseline, 12 weeks after surgery and the change in these scores.

Table 3. Periodontal scores for teeth treated with PRGF at baseline, 12 weeks after surgery and the change in these scores.

		PRGF (n=26)		
		Baseline mean (SD)	12 weeks mean (SD)	Paired difference after 12 weeks mean (95% CI) p-value[1]
Periodontal Pocket Depth (PPD) (mm)		4.55 (1.32)	2.44 (0.77)	-2.11 (-2.638 to -1.508) p<0.001
Gingival Recession (GR) (mm)		1.51 (1.11)	2.25 (0.94)	0.74 (0.434 to 1.041) p<0.001
Clinical Attachment Level (CAL) (mm)		9.35 (2.73)	6.35 (2.33)	-3.00 (-3.921 to -2.079) p<0.001
		Baseline Median (IQR)	12 weeks Median (IQR)	Related samples difference after 12 weeks (95% CI) test statistic, p-value[2]
Turesky Plaque Index (TPI) (0-5)		1 (0 – 1)	0 (0 – 1)	0 (-0.500 to 0.500) Z -0.146, p=0.884
Width of Keratinised Epithelium (WKE) (mm)		4 (3 – 6)	4 (3 – 6.75)	0 (-0.500 to 0.500) Z 0.574, p=0.566
		Baseline Yes (n)	12 weeks Yes (n)	Related samples difference after 12 weeks test statistic, p-value[3]
Bleeding on Probing (BOP)		26	9	-17 15.059 p<0.001
Suppuration (Supp)		3	0	-3 1.333, p=0.250
		Baseline Yes (n)	12 weeks Yes (n)	Related samples difference after 12 weeks all NS
Mobility (Mob) (grade)	I	5	6	-1
	II	0	1	1
	III	1	0	-1
Furcation (Furc) (grade)	I	2	1	-1
	II	0	0	0
	III	0	0	0
Bony defect[4] (BD) (type)	I	N/A	15	N/A
	II	N/A	14	N/A
	III	N/A	18	N/A
	Missing	N/A	5	N/A
Biotype thick		24	N/A	N/A

[1]paired t test, [2]Wilcoxon signed rank sum, test statistic based on negative ranks, [3]McNemar Test, the exact p-value is computed based on the binomial distribution because there are 25 or fewer records, [4]Bony defect was uncovered at the surgery appointment (12 weeks), NS = non-significant

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Secondary outcome measure:

Determine whether the use of PRGF in periodontal regeneration surgery is more effective than a conventional surgical approach alone in improving clinical attachment loss as indicated by periodontal measures.

Table 4. Between-groups comparison of periodontal parameters

		PRGF (n=26)			Control (n=26)			
		Baseline mean (SD)	12 weeks Mean (SD)	CFB Mean (SD)	Baseline Mean (SD)	12 weeks Mean (SD)	CFB Mean (SD)	Mean difference CFB (95% CI) at 12 weeks p-value[1]
PPD (mm)		4.55 (1.32)	2.44 (0.77)	-2.11 (1.31)	4.41 (0.96)	2.96 (0.96	-1.45 (1.03)	-0.66 (-1.061 to -0.261) p=0.002
GR (mm)		1.51 (1.11)	2.25 (0.94)	0.74 (0.75)	1.40 (0.98)	2.33 (0.96)	0.94 (0.77)	-0.19 (-0.574 to 0.176) p=0.285
CAL (mm)		9.35 (2.73)	6.35 (2.33)	-2.38 (2.94)	9.19 (2.33)	7.65 (2.13)	-1.54 (1.88)	-0.85 (-2.243 to 0.552) p=0.224
		Baseline Median (IQR)	12 weeks Median (IQR)	CFB Median (IQR)	Baseline Median (IQR)	12 weeks Median (IQR)	CFB Median (IQR)	Related samples difference CFB (95% CI) test statistic, p-value[2]
TPI (0-5)		1 (0 – 1)	0 (0 – 1)	0 (-1 – 0.75)	1 (0 – 1)	1 (0 – 1)	0 (-1 – 0.75)	0 (0.000 to 0.500) Z 0.124, p=0.902
WKE (mm)		4 (3 – 6)	4 (3 – 6.75)	0 (0 – 0)	5 (3.25 – 5.75)	4.5 (3 – 7.25)	0 (0 - 1)	0 (-0.500 to 0.500) Z 0.632, p=0.528
		Baseline Yes (n)	12 weeks Yes (n)	CFB (n)	Baseline Yes (n)	12 weeks Yes (n)	CFB (n)	Related samples difference CFB test statistic, p-value[3]
BOP		26	9	-17	23	13	-12	2.286 p=0.125
Supp		3	0	-3	6	1	-5	0.250 p=0.625
		Baseline Yes (n)	12 weeks Yes (n)	CFB (n)	Baseline Yes (n)	12 weeks Yes (n)	CFB (n)	Related samples difference CFB
Mob (grade)	I	5	6	-1	5	6	1	NS
	II	0	1	1	1	1	0	NS
	III	1	0	-1	0	0	0	NS
Furc (grade)	I	2	1	-1	3	3	0	NS
	II	0	0	0	0	0	0	NS
	III	0	0	0	0	0	0	NS
BD (type)	I	N/A	8	N/A	N/A	7	N/A	N/A
	II	N/A	7	N/A	N/A	7	N/A	N/A
	III	N/A	8	N/A	N/A	10	N/A	N/A
	Missing	N/A	3	N/A	N/A	2	N/A	N/A
Biotype thick		24	N/A	N/A	24	N/A	N/A	N/A

[1]paired t test, [2]Wilcoxon signed rank sum, test statistic based on negative ranks, [3]McNemar Test, the exact p-value is computed based on the binomial distribution because there are 25 or fewer records. NS = non-significant

Section 4: Adverse events

Adverse event	Number of Participants affected	Intensity	Likely to be caused by the investigational product
Pain and swelling associated with surgical site	2 (single episode)	Moderate (both)	No (both)