Imperial College London

Objective Randomised Blinded Investigation with optimal medical Therapy of Angioplasty in stable angina (ORBITA)

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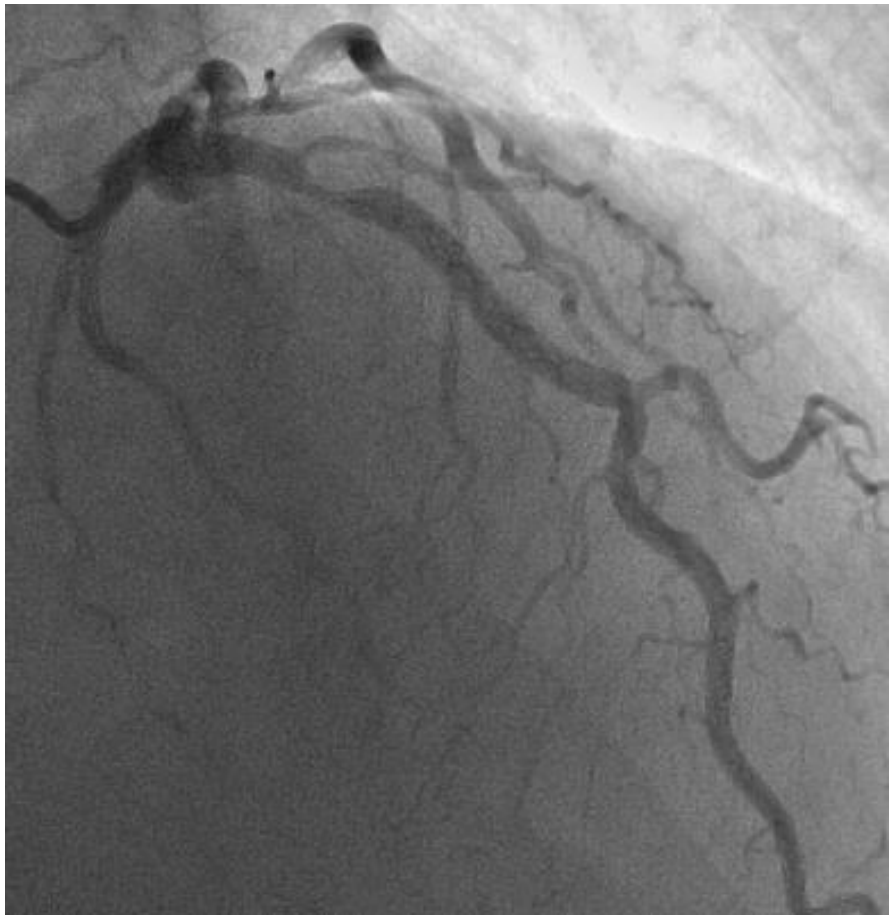
Principal hypothesis:
Symptom relief in stable angina

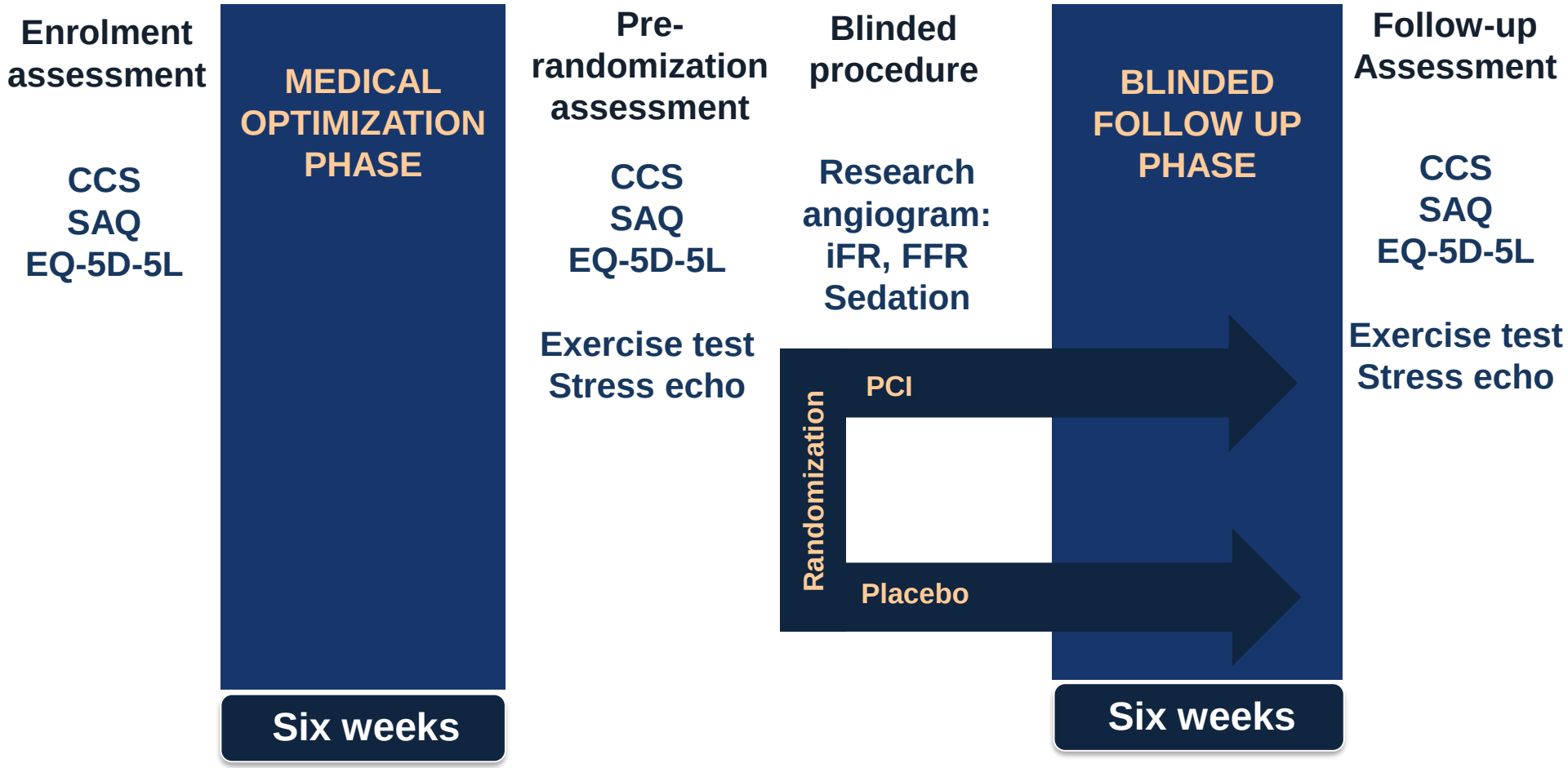
PCI increases exercise time more than placebo procedure

Inclusion criteria



- Stable angina
- One or more ≥ 70% stenosis in a single vessel
- Suitable for PCI

Trial design



Blinding techniques

Patient

Headphones and music
Sedation
Minimum 15 min wait

Both arms:
- DAPT
- Same post-procedural instructions
- Same discharge letter

Clinical team

Standardised handover
Ward team blinded

Both arms:
- Treated as if PCI
- No access to cath report
- Same discharge letter

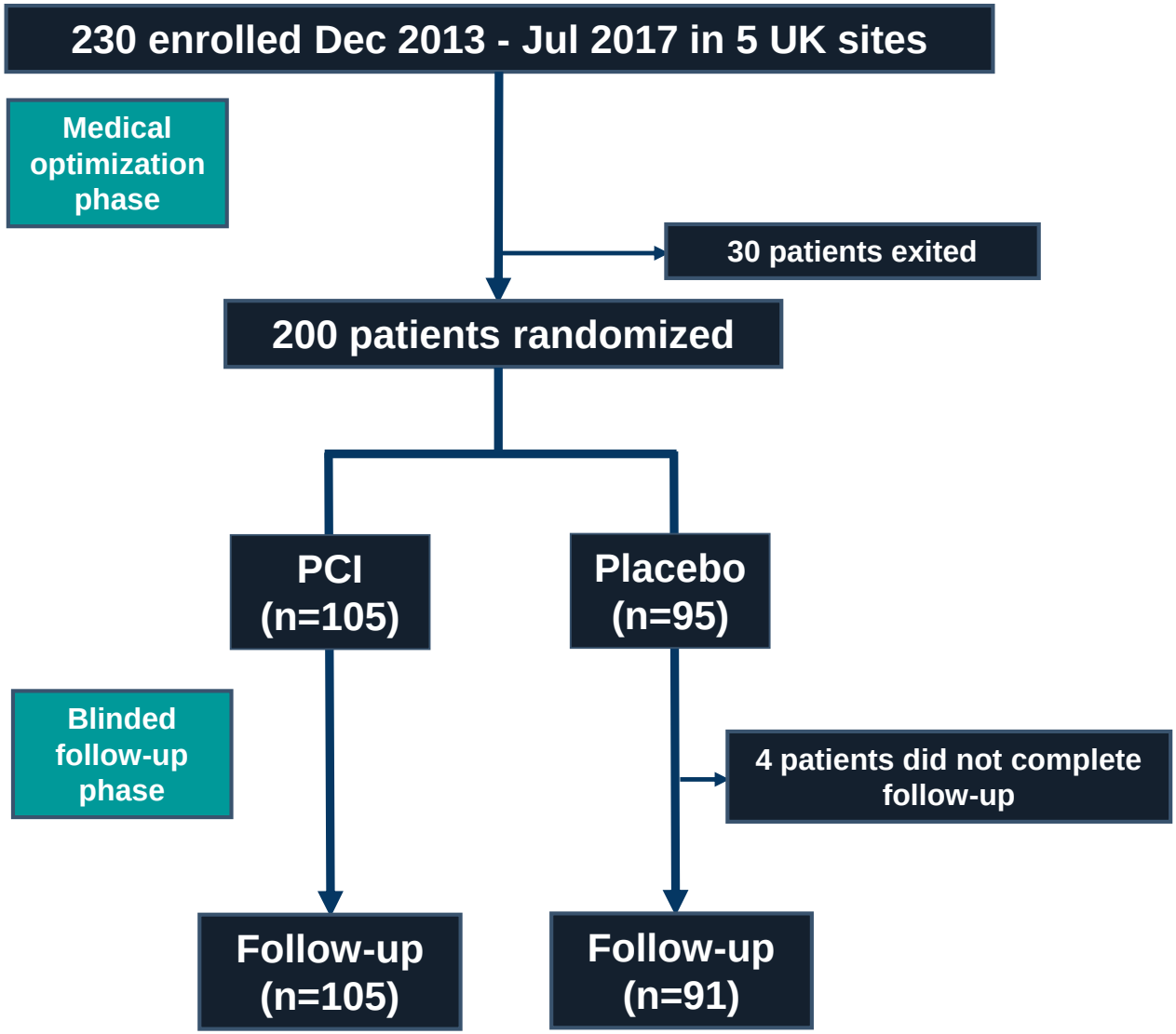
Primary endpoint

Difference in exercise time increment between the arms

Endpoint assessment

Symptoms	assessed by	**blinded** researcher
Exercise test	performed by	2 **blinded** researchers
	interpreted by	2 **blinded** researchers
Stress echo	performed by	2 **blinded** researchers
	interpreted by	2 **blinded** researchers

ORBITA trial



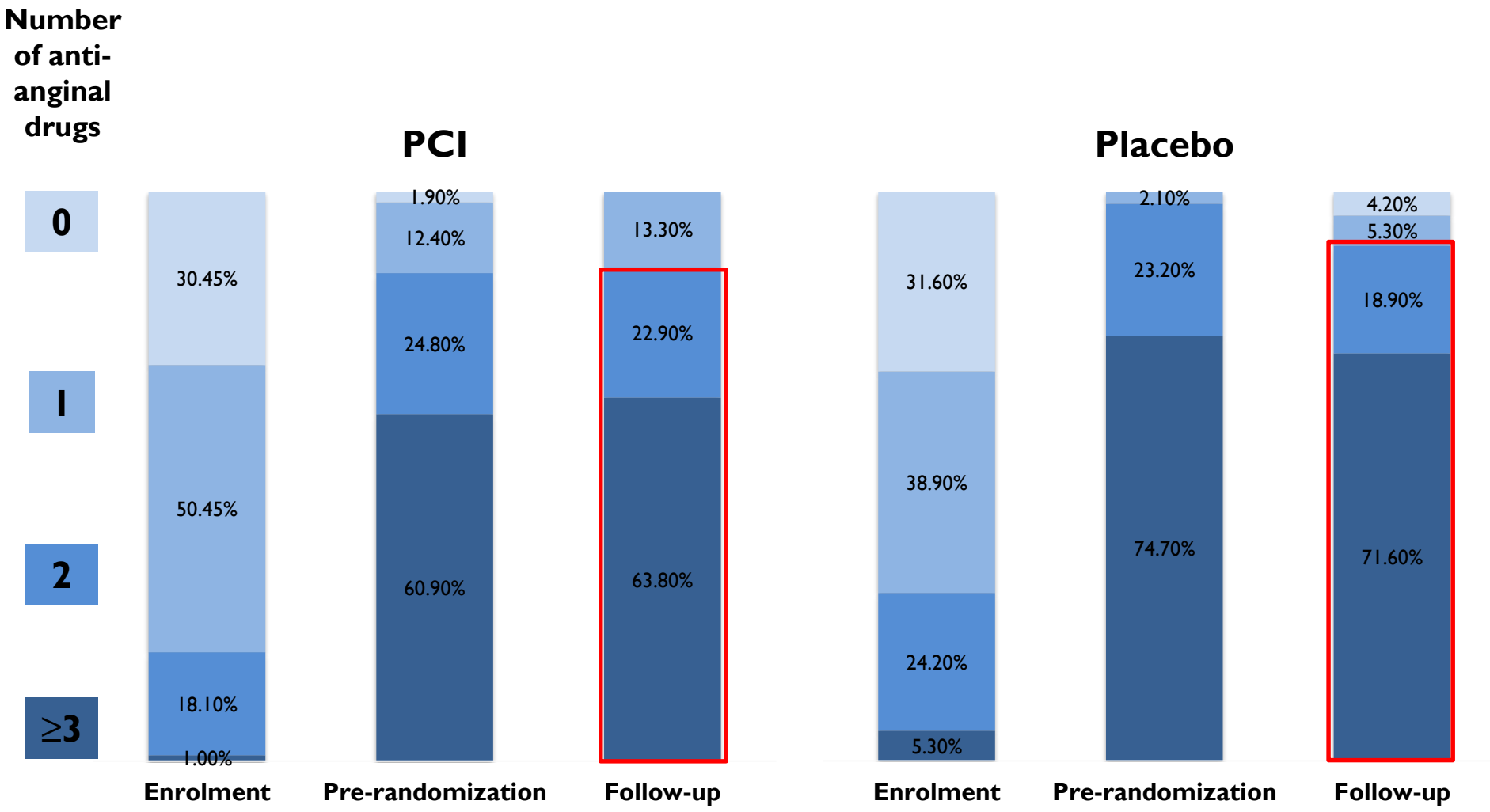
Baseline demographics

	PCI n = 105	Placebo n = 95
Age (yrs)	65.9 (SD 9.5)	66.1 (SD 8.4)
Male	74 (70%)	72 (76%)
Type II diabetes	15 (14%)	21 (22%)
Hypertension	72 (69%)	66 (69%)
Hyperlipidaemia	81 (77%)	62 (65%)
Current smoker	11 (10%)	15 (16%)
Previous MI	5 (5%)	7 (7%)
Previous PCI	10 (10%)	15 (16%)

Baseline demographics

	PCI n = 105	Placebo n = 95
LV systolic function		
Normal	98 (93%)	85 (89%)
Mild	3 (3%)	7 (7%)
Moderate	4 (4%)	3 (3%)
CCS Class		
I	2 (2%)	3 (3%)
II	64 (61%)	54 (57%)
III	39 (37%)	38 (40%)
Angina duration (mo)	9.5 (SD 15.7)	8.4 (SD 7.5)

Medical therapy optimization



Procedural demographics

	PCI n = 105	Placebo n = 95	P
Procedural time (min)	90 (27)	61 (17)	<0.0001
Vessel			
LAD	72 (69%)	66 (69%)	
RCA	17 (16%)	15 (16%)	
Circumflex	9 (9%)	10 (11%)	

Stenosis severity

	PCI n = 105	Placebo n = 95
Area stenosis by QCA (%)	84.6 (SD 10.2)	84.2 (SD 10.3)
FFR	0.69 (SD 0.16)	0.69 (SD 0.16)
iFR	0.76 (SD 0.22)	0.76 (SD 0.21)

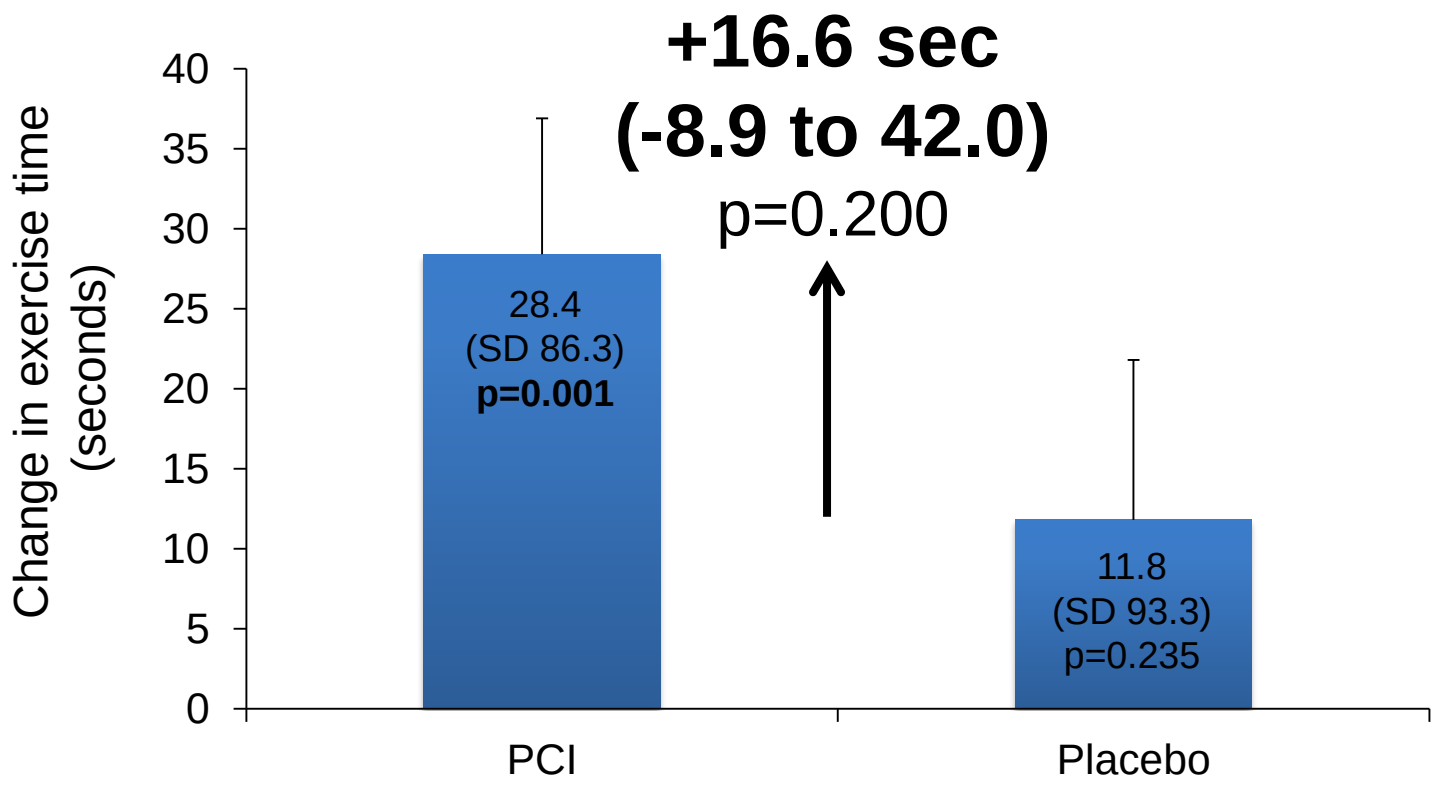
Procedural demographics

	PCI n = 105
Drug eluting stents	138 (100%)*
Stent length (mm)	24 (IQR 18-33)
Stent diameter (mm)	3.1 (SD 0.5)
Post-dilatation	103 (75%)*
FFR post-PCI	0.90 (SD 0.06) p<0.0001
iFR post-PCI	0.95 (SD 0.04) p<0.0001

* Calculated out of 138 stents
p values are for change in pre to post FFR and iFR

Primary endpoint result

Change in total exercise time



Error bars are standard errors of the mean

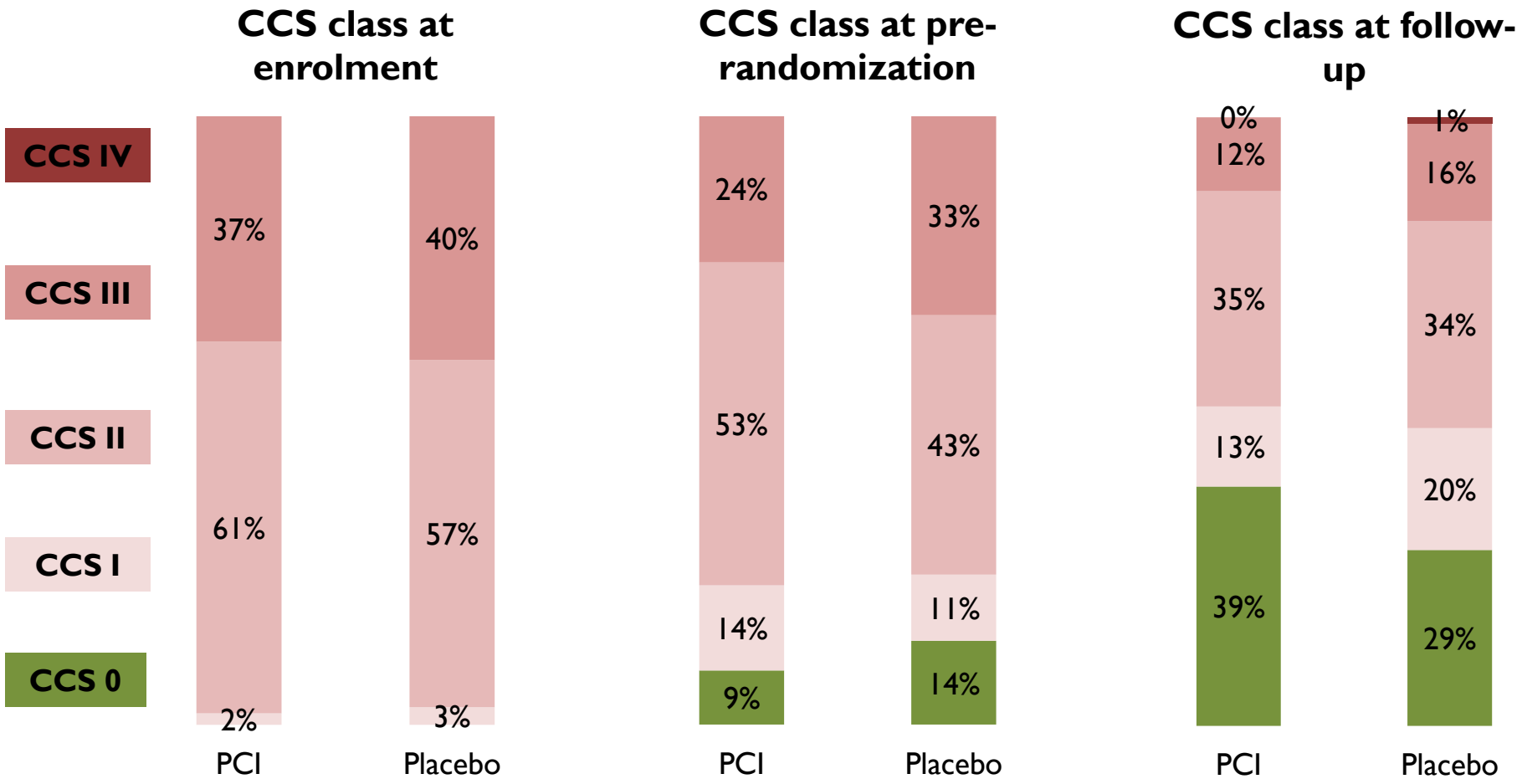
Secondary endpoint results

Blinded evaluation of ischaemia reduction

Peak stress wall motion index score	PCI n = 80	Placebo n = 57
Pre-randomization	1.11 (0.18)	1.11 (0.18)
Follow-up	1.03 (0.06)	1.13 (0.19)
Δ (Pre-randomization to follow-up)	-0.08 (0.17)	0.02 (0.16)
	p<0.0001	p=0.433
Difference in Δ between arms	-0.09 (-0.15 to -0.04) **p=0.0011**	

Secondary endpoint results

CCS class improved in both groups



Secondary endpoint results

No difference in symptom improvement or quality of life

Physical limitation score (SAQ)	
Difference in Δ between arms	2.4 (-3.5 to 8.3) p=0.420
Angina frequency score (SAQ)	
Difference in Δ between arms	4.4 (-3.3 to 12.0) p=0.260
Quality of life (EQ-5D-5L)	
Difference in Δ between arms	0.00 (-0.04 to 0.04) p=0.994

Differences are Δ PCI minus Δ placebo

Adverse clinical events

Adverse clinical event	PCI n = 105	Placebo n = 95
All cause death	0	0
Myocardial infarction	0	0
Cerebrovascular event	0	0
Unplanned revascularization	0	5

Conclusions

- ORBITA is the first placebo-controlled randomized trial of PCI in stable angina
- Area stenosis QCA 84.4%, FFR 0.69, iFR 0.76
- PCI was safe and physiologically effective
- PCI significantly reduced ischemic burden as assessed by stress echo
- In this single vessel, angiographically guided trial there was no difference in exercise time increment between PCI and placebo