Background

Over 500 000 PCIs per year for stable angina

- **Primarily for angina relief**

Size of angina relief beyond placebo unknown

- **Unblinded PCI +96 seconds** (NEJM 1992)
- **Single drug +55 seconds** (JACC 2004)

Principal hypothesis:
Symptom relief in stable angina

PCI increases exercise time more than placebo procedure

Primary endpoint

Difference in exercise time increment between the arms

For patients to be willing to participate in this first placebo-controlled trial of PCI, duration must long enough for full hemodynamic effect but not so long as to inhibit recruitment

Sample size calculation

To detect 30 sec,

at 80% power,

within-arm SD 75 sec,

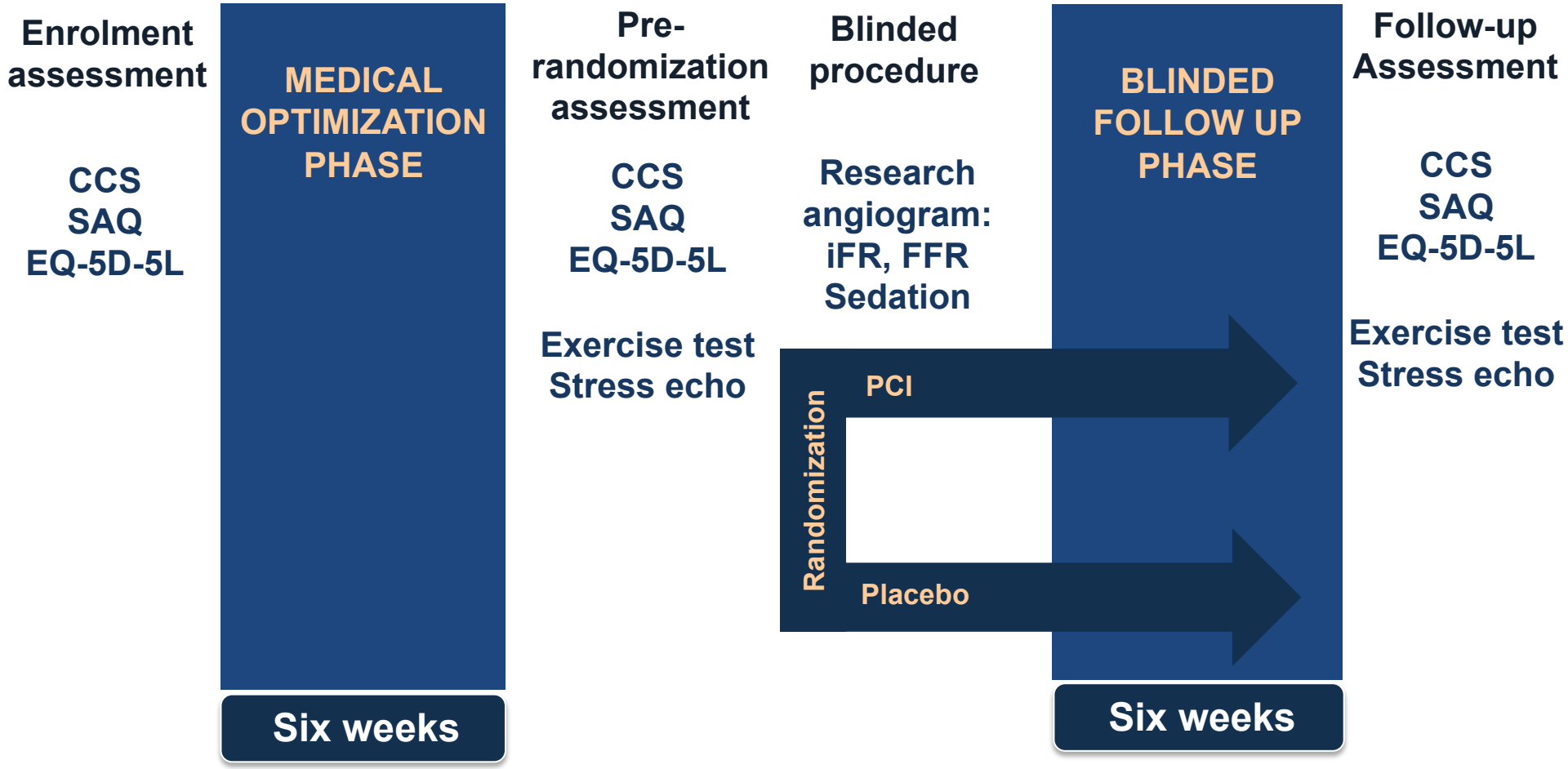
needs 200 randomized patients

This sample size is comparable to other trials assessing *this question.*

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

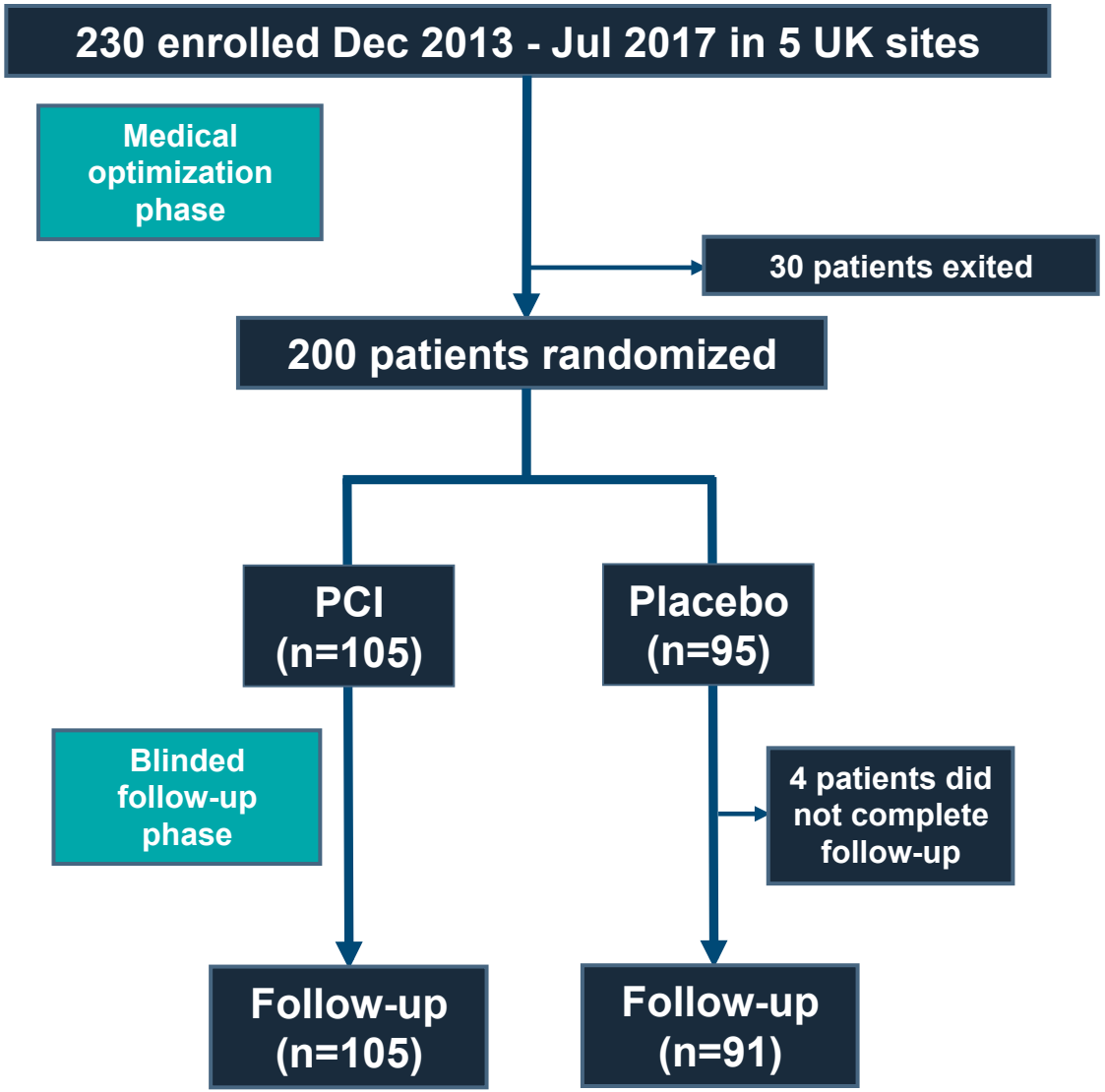
Both arms:
- DAPT
- Same post-procedural instructions
- Same discharge letter

Clinical team

Standardised handover
Ward team blinded

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

ORBITA trial

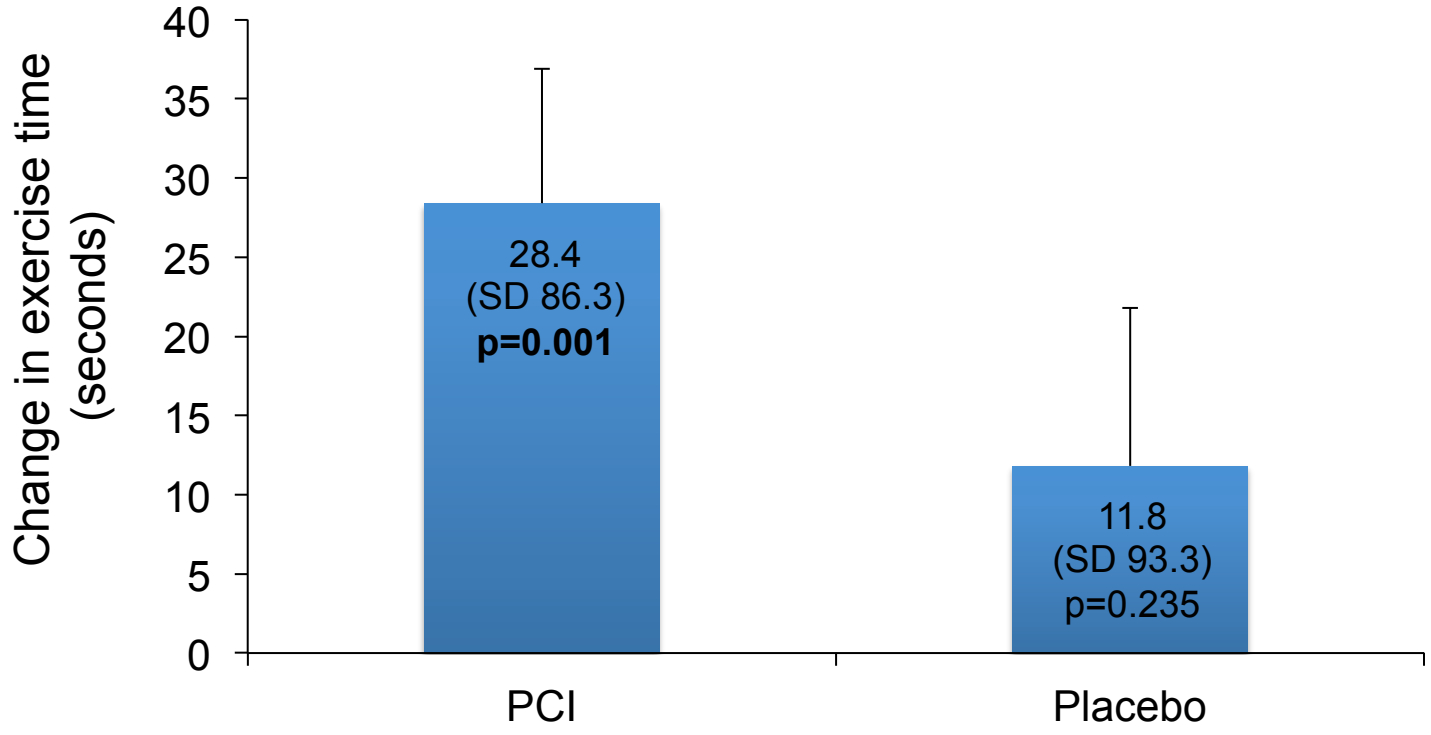


Stenosis severity

	PCI n = 105	Placebo n = 95	P
Area stenosis by QCA (%)	84.6 (SD 10.2)	84.2 (SD 10.3)	0.781
FFR	0.69 (SD 0.16)	0.69 (SD 0.16)	0.778
iFR	0.76 (SD 0.22)	0.76 (SD 0.21)	0.751

Primary endpoint result

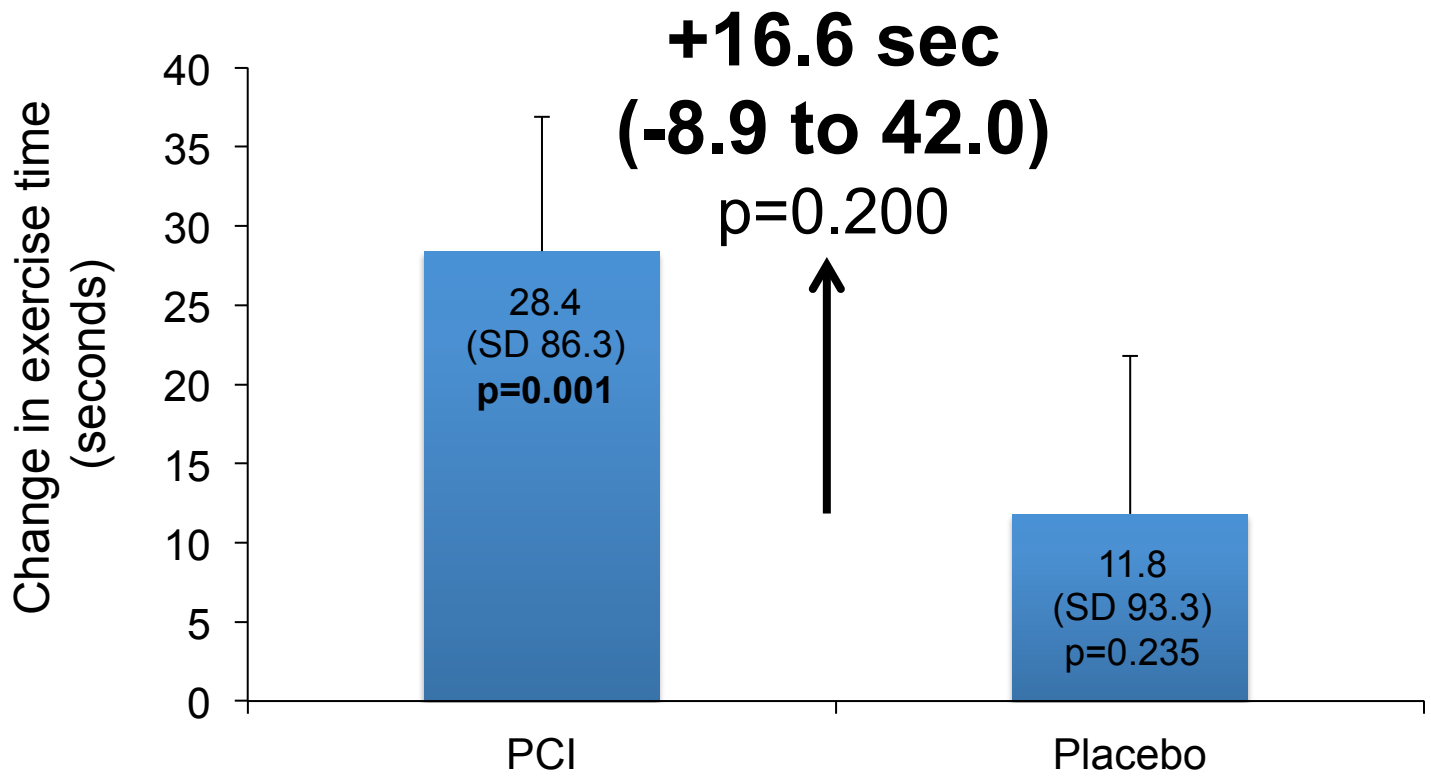
Change in total exercise time



Error bars are standard errors of the mean

Primary endpoint result

Change in total exercise time



Error bars are standard errors of the mean

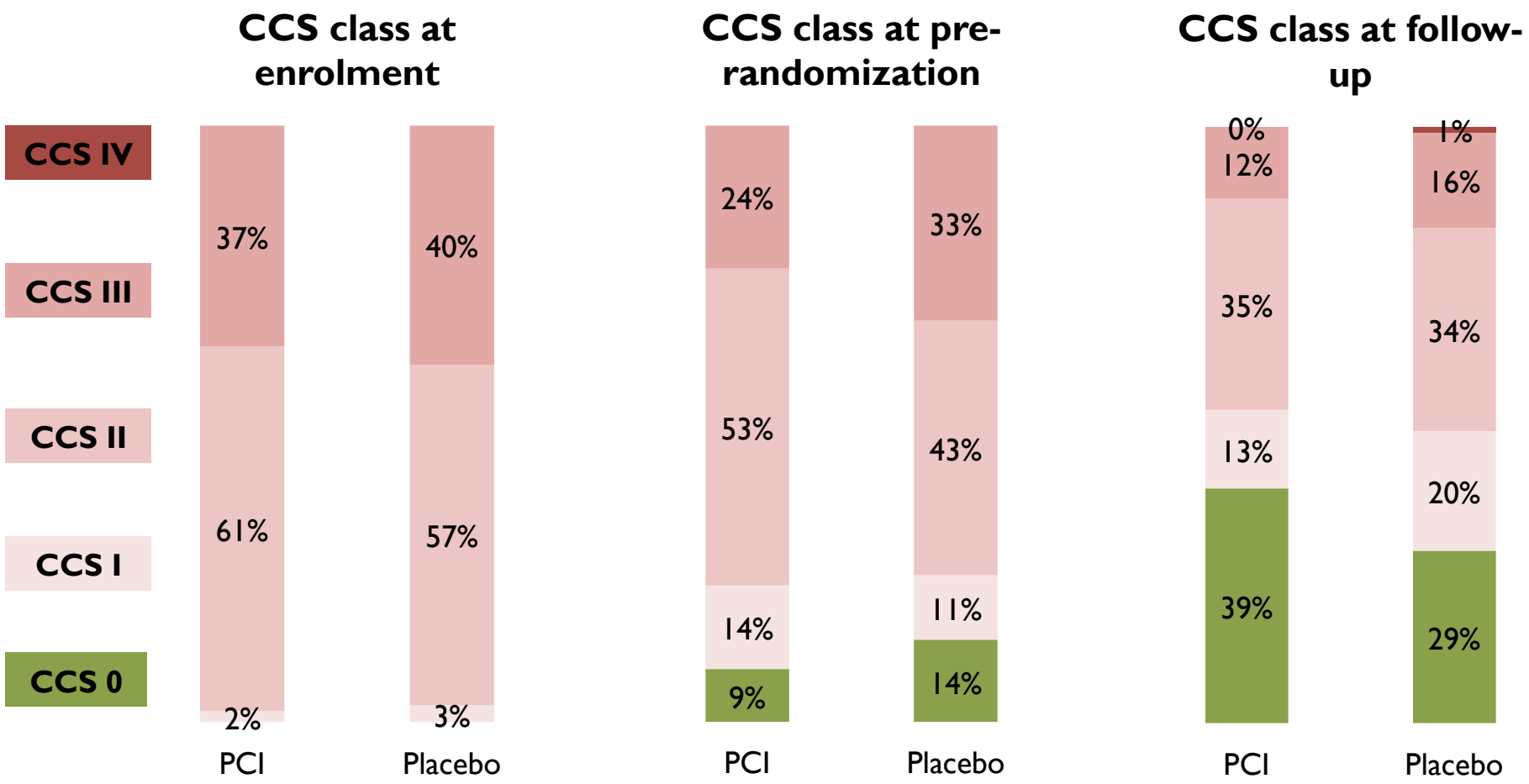
Secondary endpoint results

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



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

ORBITA in context

- Single vessel
  - To allow complete revascularization
- PCI guided by angina + angiogram
  - In line with common practice
- Focus is on symptomatic relief
  - Not risk or events
- Intensive medical therapy
  - In line with Guidelines