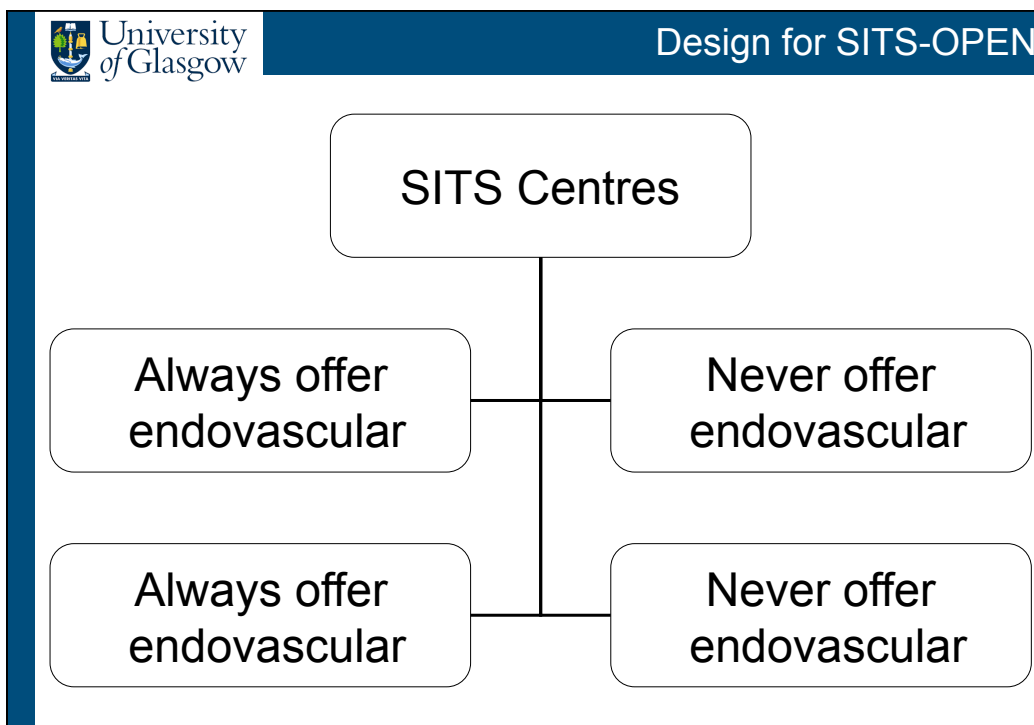



University of Glasgow

Central adjudication of modified Rankin scale

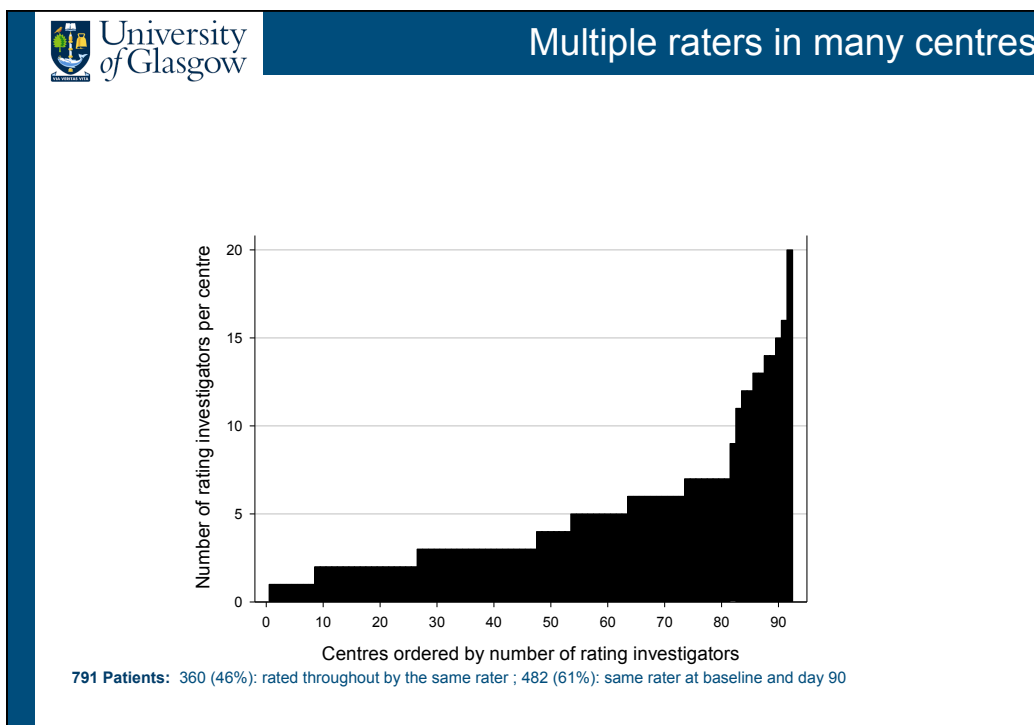
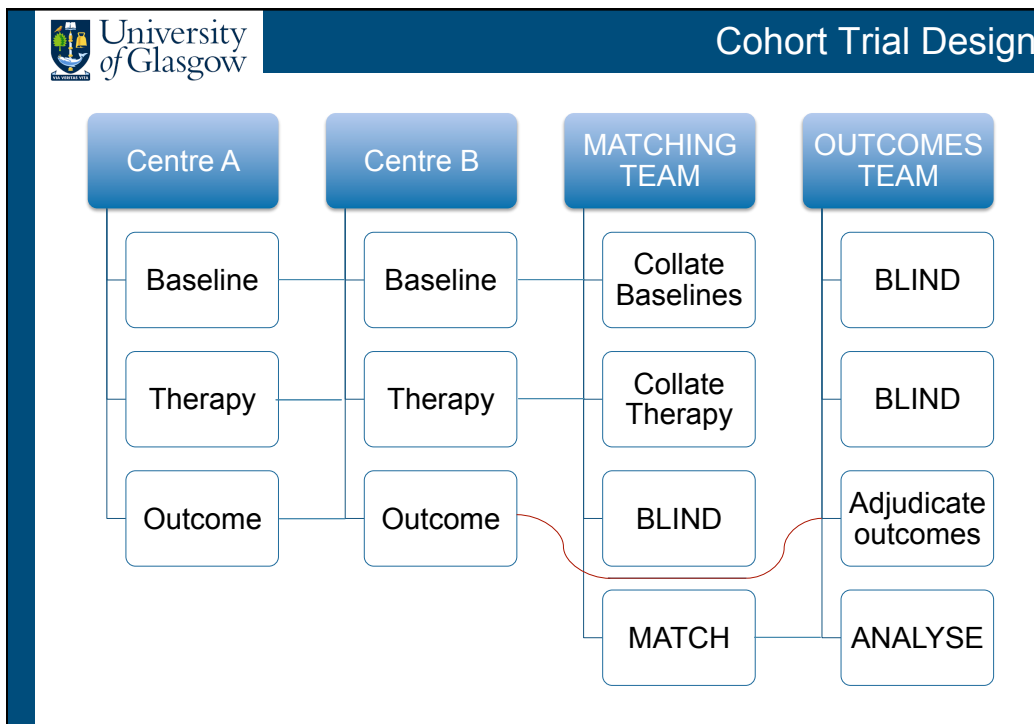
Kennedy Lees
University of Glasgow

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colleagues at First University Hospital Beijing
Chief Scientist Office, National Institute of Health

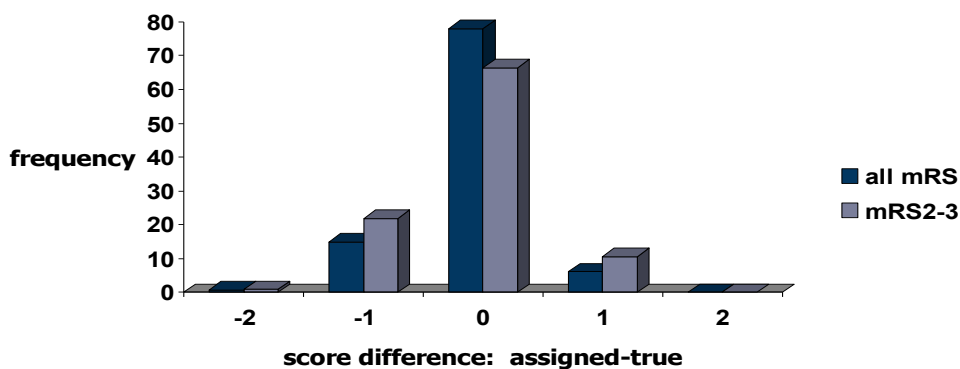


- **Variation in case mix, eg from referral pattern**
- **Variation in outcome after adjusting for baseline prognosis**
- **Selective enrolment**
- **Investigator prejudice, influencing scoring of outcome**
- **Inherent (cultural?) bias in assessment of outcome**

- **Variation in referral case mix**
Use propensity score methods to match populations
- **Variation in outcome after adjusting for baseline prognosis**
Use intracluster correlation coefficient, assume cluster design
- **Selective enrolment**
Remains an issue, but matching and adjustment methods help
- **Investigator prejudice, influencing scoring of outcome**
Blinded assessment is essential, by independent committee
- **Inherent (cultural?) bias in assessment of outcome**
Standardised interview assessed by independent committee



25-30% clinically relevant misclassification



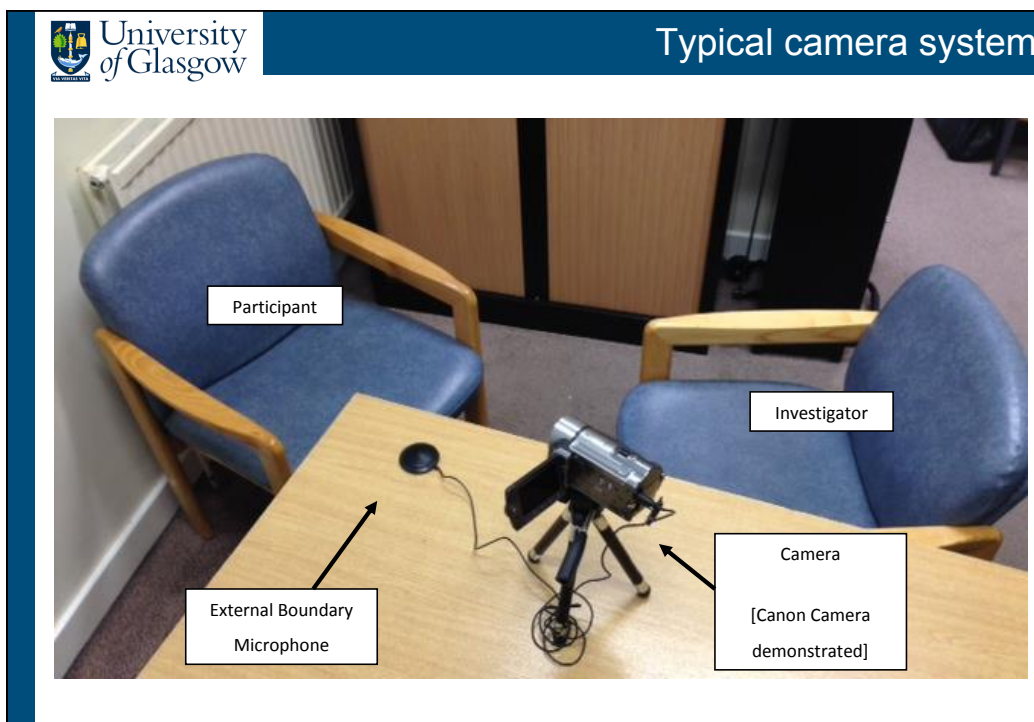
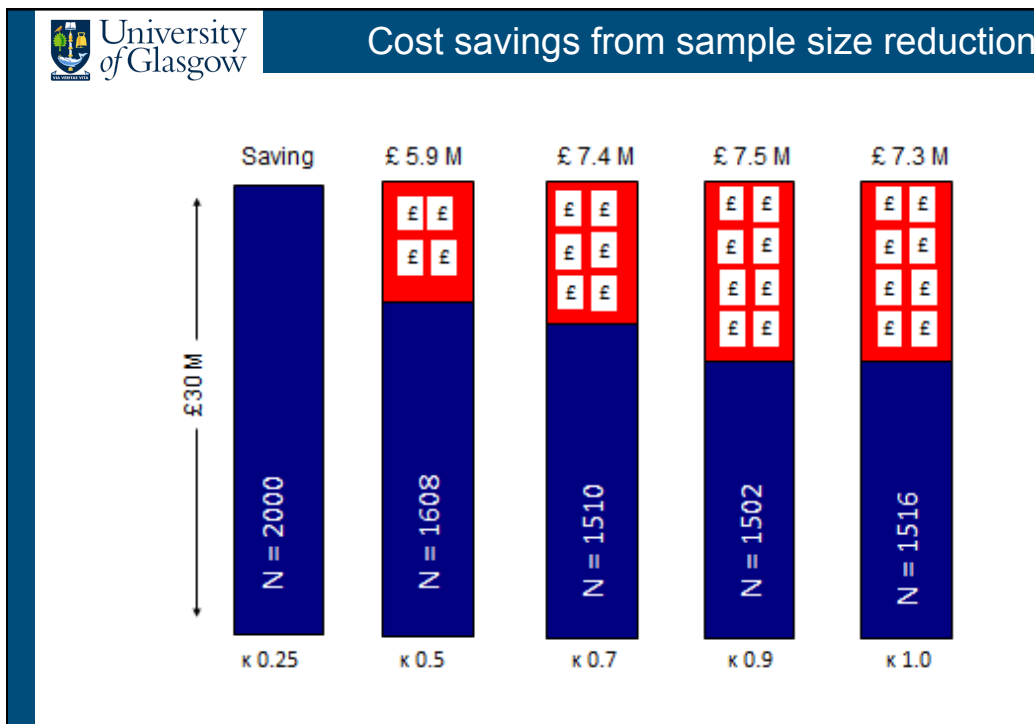
Effect of improving reliability

Sample size reductions of up to 25% feasible

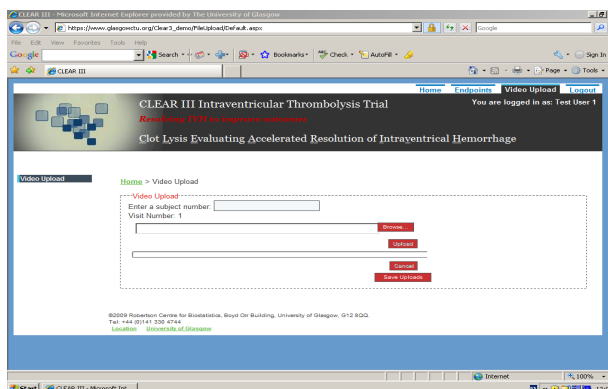
Typical kappa of 0.25 to 0.5, or 0.5 to 0.7

Limited/no advantage if kappa is already 0.9

Multiple mRS assessments can save approx 10% sample



Easy to record & submit Rankin for central review

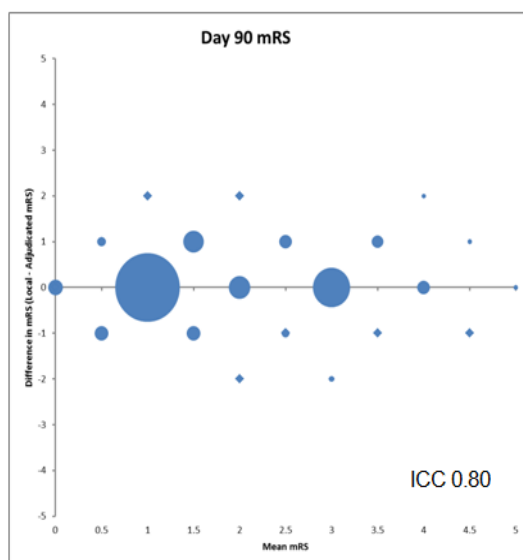


Technical failures?

Reason (n)	Day 30 (Total n = 296)	Day 90 (Total n= 267)
Poor Audio	5	2
Duplicate Clip uploaded in error	1	5
Camera Malfunction – data lost	5	-
Incorrect (assessory) File type uploaded in error	2	-
Incomplete Assessment (battery failure)	1	1
Committee Unable to reach consensus	2	1
Total	16	9

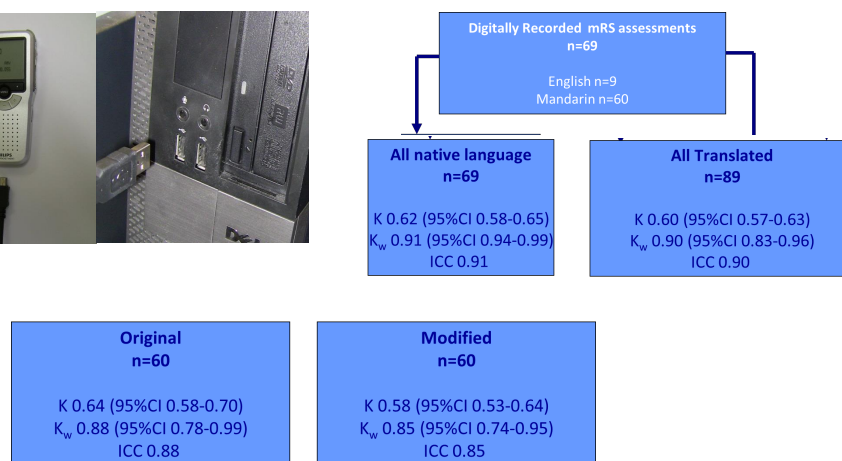
- Revised camera selection improves function, audio and battery issues – near foolproof, and easily checked
- Local score is always retained as backup
- Turnaround time is short in real trial (eg CLEAR-III), permitting valid reinterview

- File size with modern HD cameras
- Upload time
- Battery status
- Video file conversion software
- iPad / MAC / PC compatibility
- Translation
- Editing for anonymity pre-distribution
- Security of cameras



Local Score

	0	1	2	3	4	5
0	15	7	4			26
1	13	63	20	5		102
2		11	31	12		54
3		6	7	36	11	1
4			1	3	10	1
5					3	1
Total	28	83	63	67	24	3
Total						258



Conclusion:
Foreign languages readily and reliably handled by translation

- **Blinding guaranteed**
- **Mitigates national- or centre-specific scoring bias**
- **Statistical advantage from multiple scoring**
 - Spearman-Brown Prophecy**
 - Expanding number of assessors per patient from 1 to 4 reduces sample size by 9.8%**
- **Stored data facilitate sponsor & regulatory validation**