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### Background

Considering the diverse backgrounds of stroke researchers, it is unsurprising that stroke clinical trials often report different outcomes. To address this heterogeneity in measurements, core outcome sets (COS) aim to increase reproducibility and transparency in clinical trial results. The first patient-centered COS for stroke clinical trials was published by Salinas et al. in 2016. Therefore, it is the aim of our study to measure the adoption of outcomes as recommended by Salinas et al. in stroke clinical trials in the years since its inception.

### Methods

- A stroke-specific COS was identified by searching the COMET database.
- Stroke clinical trials from between 1/1/1991 and 6/26/2023 were pulled from ClinicalTrials.gov.
- A total of 93 studies were included in our final sample after applying the inclusion criteria described by Salinas et al.
- In a blind, duplicate fashion, two researchers (WC, PC) extracted outcomes for each included study from ClinicalTrials.gov database, an electronic clinical trial registry.
- The presence of an outcome was recorded as 'yes' or 'no' along with other trial characteristics.
- Results were then analyzed via RStudio.

### Results

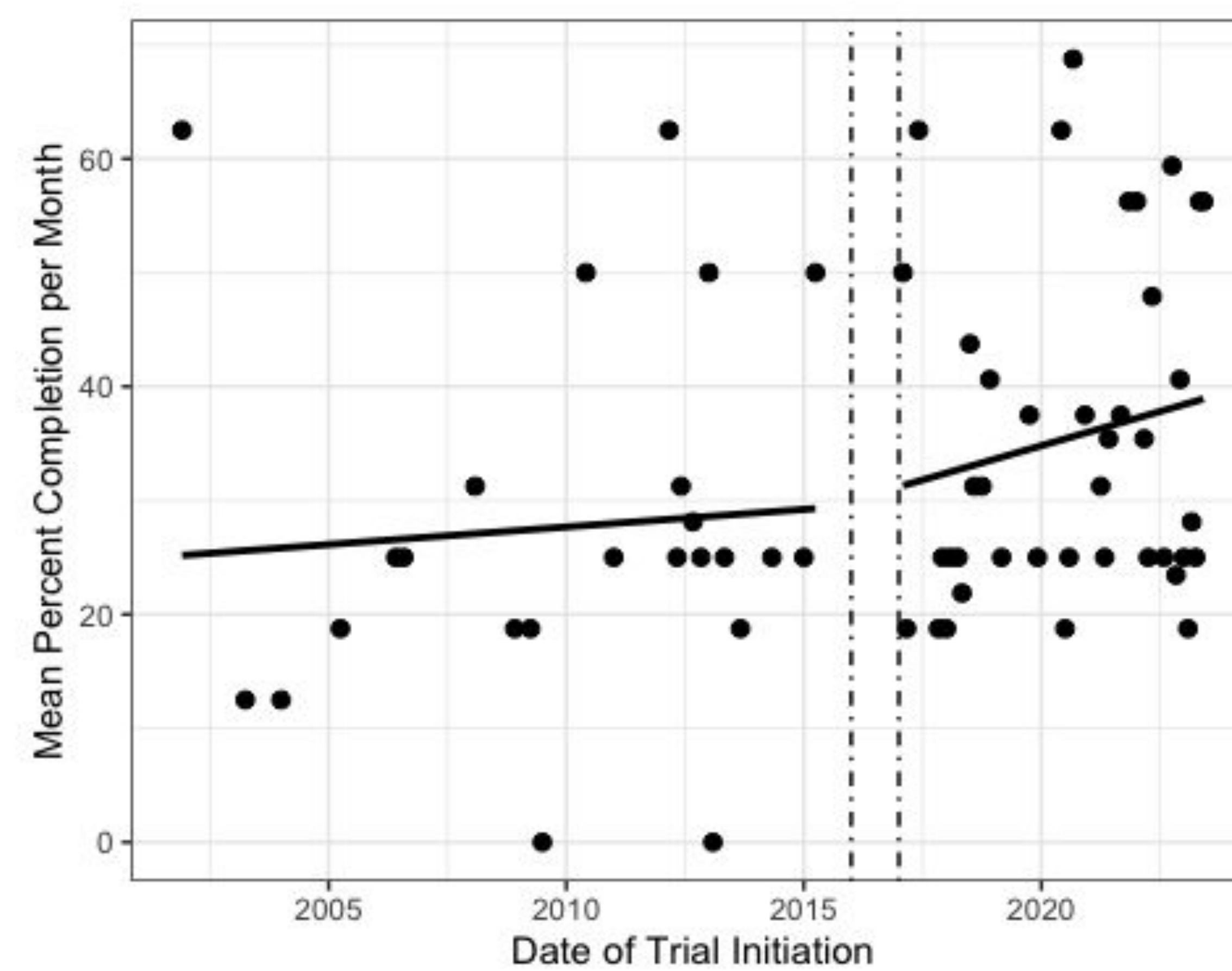
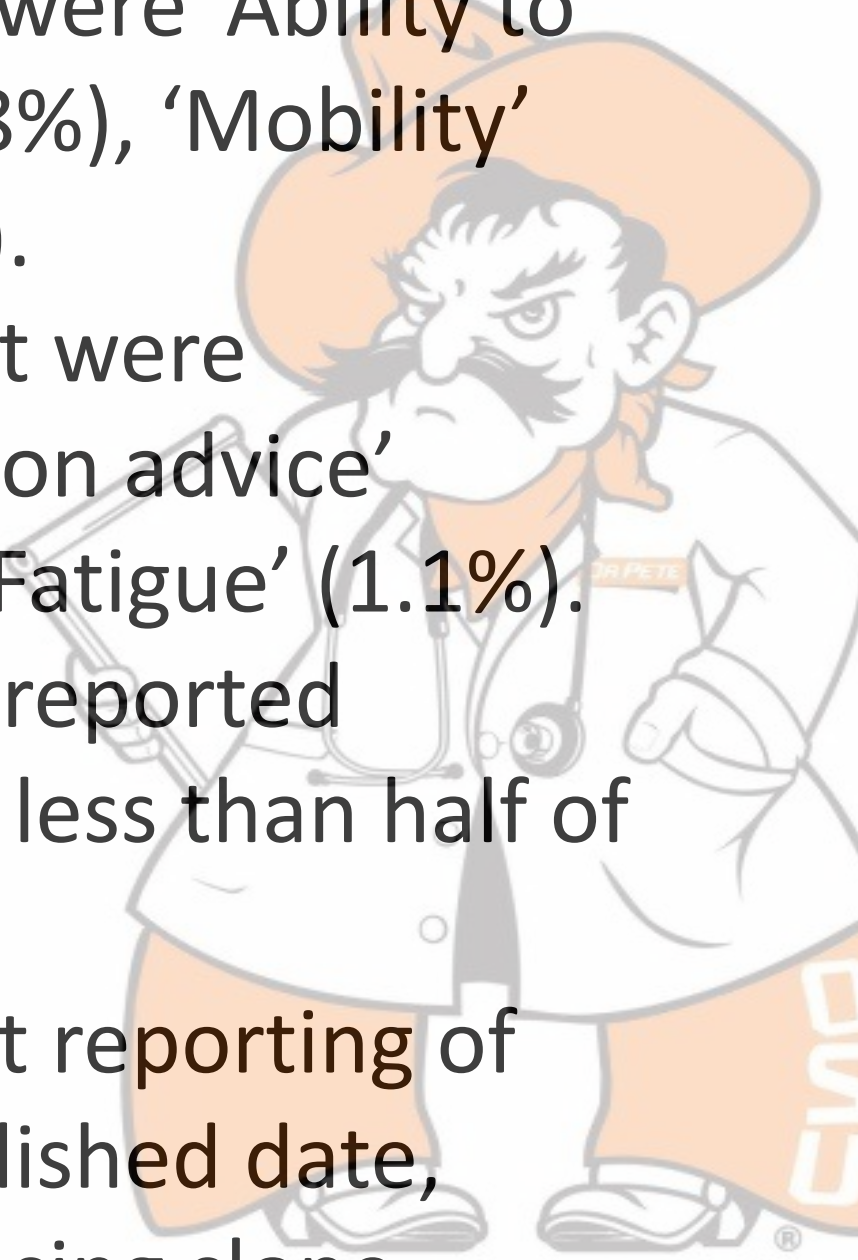


Figure 1. Interrupted Time Analysis

- The most reported outcomes across 93 evaluated stroke clinical trials were 'Ability to return to usual activities' (97.8%), 'Mobility' (96.8%), and 'Survival' (91.4%).
- Outcomes mentioned the least were 'Adherence to smoking cessation advice' (0.0%), 'Feeding' (0.0%), and 'Fatigue' (1.1%).
- Overall, 9-of-12 solely patient-reported outcomes were mentioned by less than half of clinical trialists.
- Figure 1 illustrates inconsistent reporting of outcomes before the COS published date, followed by a minimally increasing slope, ultimately indicating poor uptake and reporting of outcomes suggested by the COS.



### Discussion

Although the uptake of recommended measurements has increased in stroke clinical trials, the COS is regarded as having a statistically non-significant impact on standardized outcome measurements. The use of patient-reported outcomes was limited, with variability in outcome reporting before the COS publication. This study suggests the need for increased adoption of COS measures and expanded collection of PROs in future trials to improve patient-centered care and outcomes.

### References



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Group	Outcome Set Domain and Item	N = 93
Survival and Disease Control	Survival, n (%)	
	Yes	85 (91.4)
	No	8 (8.6)
	Self-report of New Stroke after Admission, n (%)	
Yes	17 (18.3)	
No	76 (81.7)	
Acute Complications	Adherence to Smoking Cessation Advice, n (%)	
	No	93 (100.0)
	Symptomatic ICH after Thrombolysis, n (%)	
	Yes	69 (74.2)
No	24 (25.8)	
Patient-Reported Health Status	Cognitive and Psychiatric Functioning: Global Cognitive Function, n (%)	
	Yes	3 (3.2)
	No	90 (96.8)
	Cognitive and Psychiatric Functioning: Mood, n (%)	
	Yes	25 (26.9)
	No	68 (73.1)
	Motor Functioning: Mobility, n (%)	
	Yes	90 (96.8)
	No	3 (3.2)
	Motor Functioning: Self Care and Grooming, n (%)	
	Yes	27 (29.0)
	No	66 (71.0)
	Motor Functioning: Feeding, n (%)	
	No	93 (100.0)
	Motor Functioning: Ability to Return to Usual Activities, n (%)	
	Yes	91 (97.8)
No	2 (2.2)	
Non-Motor Functioning: Pain and Other Unpleasant Sensations, n (%)		
Yes	22 (23.7)	
No	71 (76.3)	
Non-Motor Functioning: Fatigue, n (%)		
Yes	1 (1.1)	
No	92 (98.9)	
Social Functioning: Ability to Communicate, n (%)		
Yes	2 (2.2)	
No	91 (97.8)	
Social Functioning: Social Participation, n (%)		
Yes	3 (3.2)	
No	90 (96.8)	
General Health Status, n (%)		
Yes	27 (29.0)	
No	66 (71.0)	
Health Related Quality of Life, n (%)		
Yes	29 (31.2)	
No	64 (68.8)	

Characteristic	N = 93 <sup>a</sup>	F-statistic <sup>b</sup>	p-value <sup>c</sup>	η <sup>2</sup>
Continent		2.84	0.01	0.17
Africa	17.65 (NA)			
Asia	29.41 (12.50)			
Australia	45.10 (18.91)			
Europe	27.45 (15.60)			
Multiple	35.29 (19.36)			
North America	27.81 (15.36)			
South America	54.41 (5.63)			
Funding Type		1.71	0.08	0.2
Hospital	30.28 (13.72)			
Industry	23.11 (7.10)			
Multiple With Industry	40.72 (16.37)			
Multiple Without Industry	31.14 (16.99)			
Private, Multiple Without Industry	47.06 (33.28)			
Private, Not Listed	17.65 (5.88)			
University, Government	23.53 (23.53)			
University, Multiple Without Industry	44.12 (29.12)			
University, Not Listed	29.41 (13.34)			
Recruitment Status		1.22	0.3	0.09
Active, but No Recruiting	29.41 (8.32)			
Completed	27.94 (15.24)			
Not Yet Recruiting	32.35 (17.51)			
Recruiting	34.48 (14.97)			
Suspended	23.53 (NA)			
Terminated	25.00 (14.87)			
Unknown Status	41.18 (17.51)			
Withdrawn	23.53 (NA)			
Enrollment Number		2.96	0.004	0.3

### Acknowledgments

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