

Assessing the Uptake of Core Outcome Sets in Randomized Controlled Trials for Depression



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INTRODUCTION

Given the medical and financial ramifications of depression, establishing evidenced based treatment options is paramount. However, the lack of standardization between trials complicates comparability. A potential solution is for trialists to follow the depression Core Outcome Set (COS). This COS determined symptom burden, medication side effects, functioning impairments, and absenteeism as the minimum set of outcomes to be measured in RCTs.

METHODS

- An electronic clinical trial registry (ClinicalTrials.gov database) was used to identify phase III/IV RCTs focused on depression.
- Authors screened clinical trial registries of all search results to assess study inclusion.
- Following data screening, data was extracted in a masked, duplicate fashion.
- We determined whether the full depression core outcome set was followed in the trial registry entries.

RESULTS

Of the 224 trial entries assessed:

- No trial satisfied all four outcomes of the COS
- 32 trials (14.29%) used the COS recommended questionnaire, PHQ-9.
- 62 trials (27.7%) measured medication side effects.
- 4 trials (1.8%) used the WHODAS 2.0 questionnaire to measure functioning

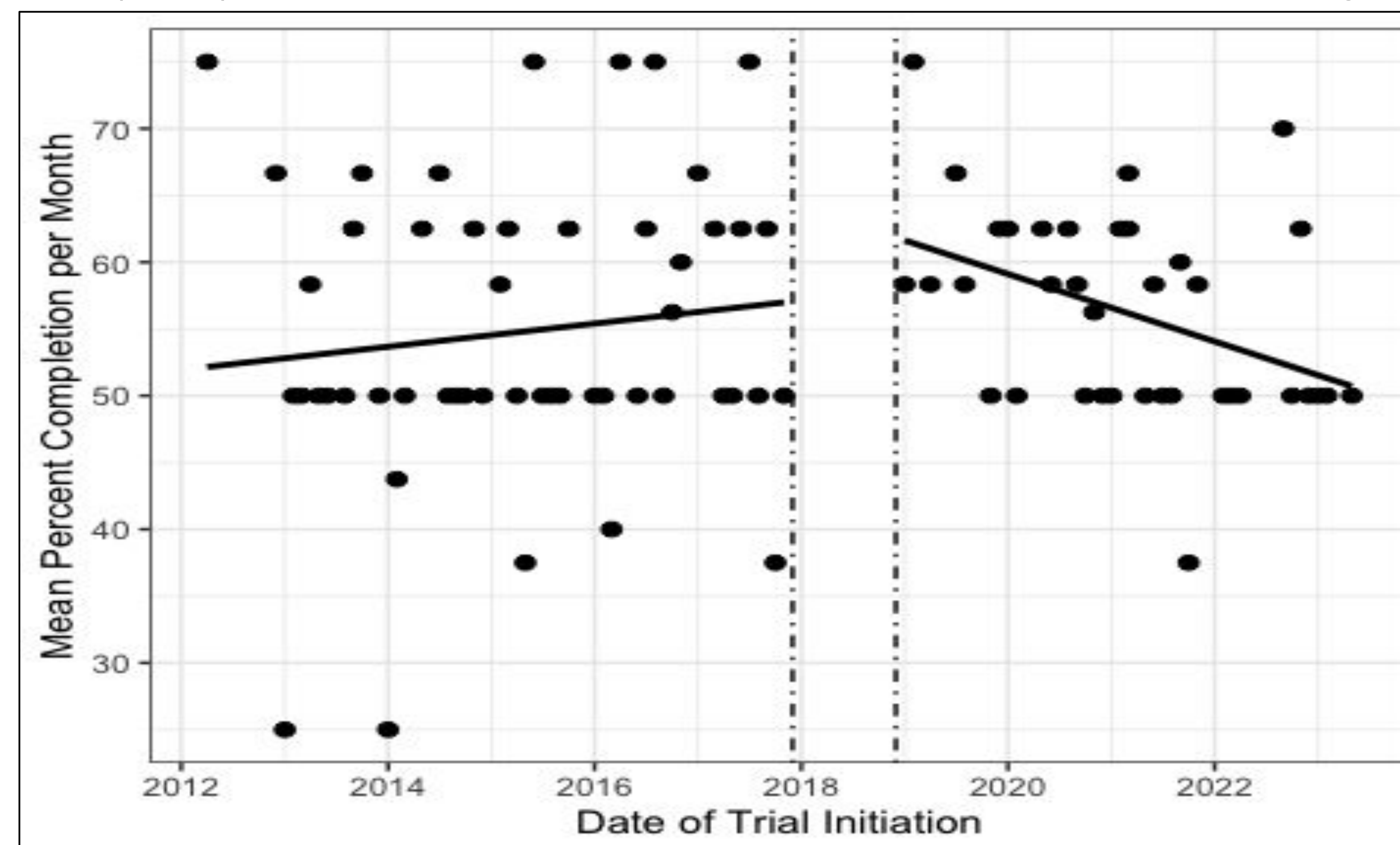


Table 1: Frequency of Outcome Set Uptake

Group	Outcome Set Domain and Item	N = 224
Outcomes	Symptom Burden, n (%)	
	Yes	221 (98.7)
	No	3 (1.3)
	Medication Side Effects, n (%)	
	No	162 (72.3)
	Yes	62 (27.7)
	Functioning, n (%)	
	Yes	213 (95.1)
	No	11 (4.9)
	Absenteeism, n (%)	
	Yes	114 (50.9)
	No	110 (49.1)

Figure 1: Percent of COS being followed by trialists over time

CONCLUSION

- There was not a notable uptake in COS adoption after it was published in 2017.
- Side effects and absenteeism were mentioned less frequently as outcomes by trialists.
- the lack of COS uptake may be of concern given its ability to assist in standardizing clinical trials and ensuring complete reporting of results.

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REFERENCES

