

BACKGROUND

Pragmatic clinical trials (PCTs) are **interventional studies** that incorporate design elements which reflect how the investigational therapy would be applied under **real-life circumstances** [1,2]. For example, they recruit patients based on relatively few selection criteria, employ flexibility in the delivery of and adherence to the allocated treatment, and avoid subjecting participants to any follow-up procedures that go beyond standard practice.

As such, PCTs are considered to be **sources of real-world evidence** [3]. However, since the **PCT label is mostly self-assigned**, it may be inappropriately used by researchers. The objective of this study was to evaluate whether **oncology trials** that call themselves pragmatic are actually pragmatic.

METHODS

- **Systematic literature review** in PubMed and Embase
- **Inclusion** of cancer trials self-labelled as pragmatic
- **Exclusion** of studies of complementary therapies or system-level interventions
- Assessment of degree of pragmatism using **PRECIS-2 tool** [4]
- Article selection and review performed by **two different reviewers** blinded to each other's work
- Differences in interpretation resolved through **consensus**

RESULTS

- **38 publications** were included in the analysis (figure 1)
- Studies encompassed **12 different cancer domains**
- **71% were RCTs**
- **84.2% were open-label trials**
- **68.4% took place in a single country**
- **None** were sponsored by **commercial parties**
- **65.8%** had been **published in the last five years**
- **Overall PRECIS-2 scores**
 - **Average: 3.2** (standard deviation: 0.6)
 - **Median: 3.3** (interquartile range: 2.9-3.6)
 - **Score per domain:** see table 1
- For **97.4%**, one or more PRECIS-2 domains **could not be appraised**
- **'Eligibility'** and **'Primary outcome'** were the **most frequently appraisable domains**
- **'Organization'** was the **least frequently appraisable domain**
- **'Primary analysis'** was the domain with the **highest average and median score**
- **'Follow-up'** was the domain with the **lowest average and median score**

Figure 1: flowchart of publication selection process

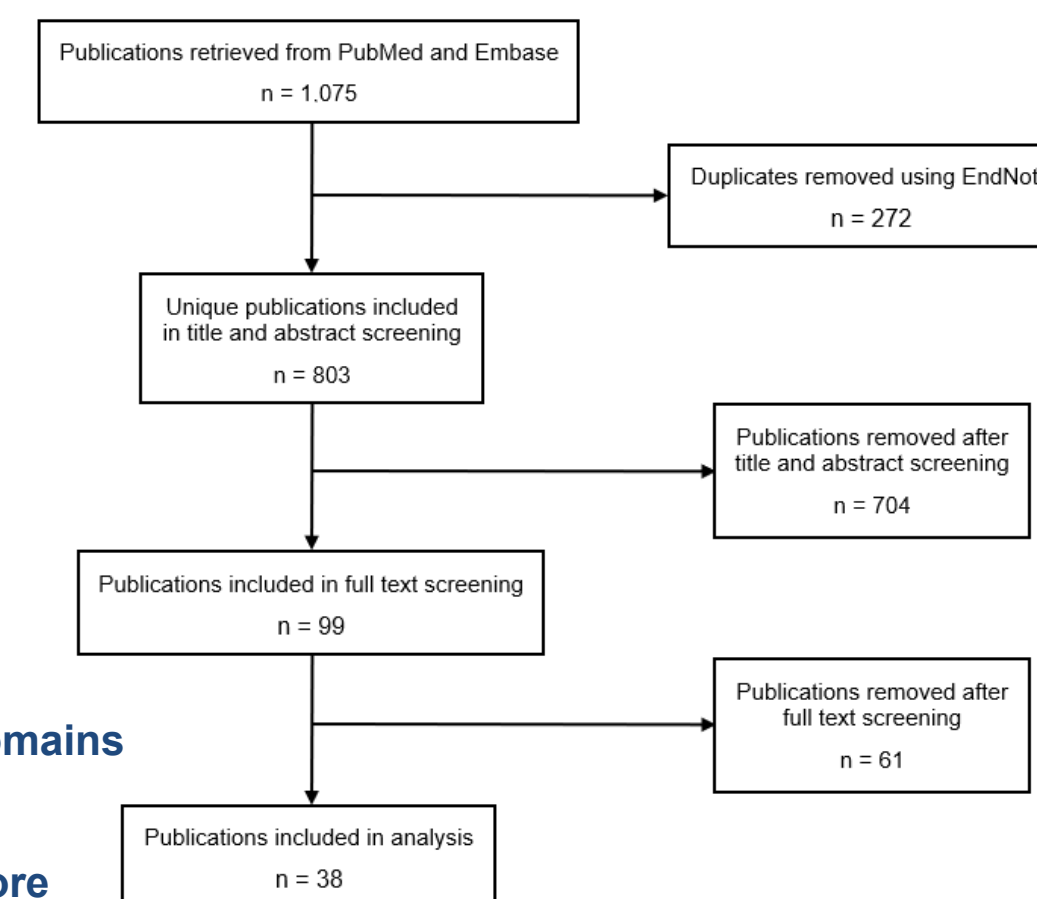


Table 1: mean and median PRECIS-2 scores for each domain*

and median es for each		PRECIS-2 domains							
		Eligibility	Recruitment	Setting	Organization	Flexibility- delivery	Flexibility- adherence	Follow-up	Primary outcome
Mean score (SD)	2.9 (1.0)	3.4 (1.0)	3.2 (1.2)	2.8 (1.3)	3.5 (0.9)	3.3 (1.2)	2.7 (1.1)	3.1 (1.3)	4.3 (1.1)
Median score (IQR)	3 (2-4)	3 (3-4)	3 (3-4)	3 (2-4)	4 (3-4)	3 (2-4)	3 (2-3)	3 (2-4)	5 (4-5)

*Calculated after excluding studies for which individual domains could not be appraised due to lack of reported information

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ABBREVIATIONS

IQR: Interquartile range
PCT: Pragmatic clinical trial
RCT: Randomized controlled trial
SD: Standard deviation

REFERENCES

- [1] Patsopoulos (2011)
- [2] Ford and Norrie (2016)
- [3] Zuidgeest *et al.* (2017)
- [4] Loudon *et al.* (2015)

CONCLUSIONS

- Few cancer trials with published results call themselves pragmatic
- Sponsorship of PCTs featuring anticancer therapies is dominated by non-commercial parties
- Self-labelled PCTs in the field of oncology are generally not very pragmatic in practice
- Pragmatism is difficult to assess due to lack of reported information on PRECIS-2 domains