Evaluation of an online writing tool based on the CONSORT : a randomized controlled trial

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Context

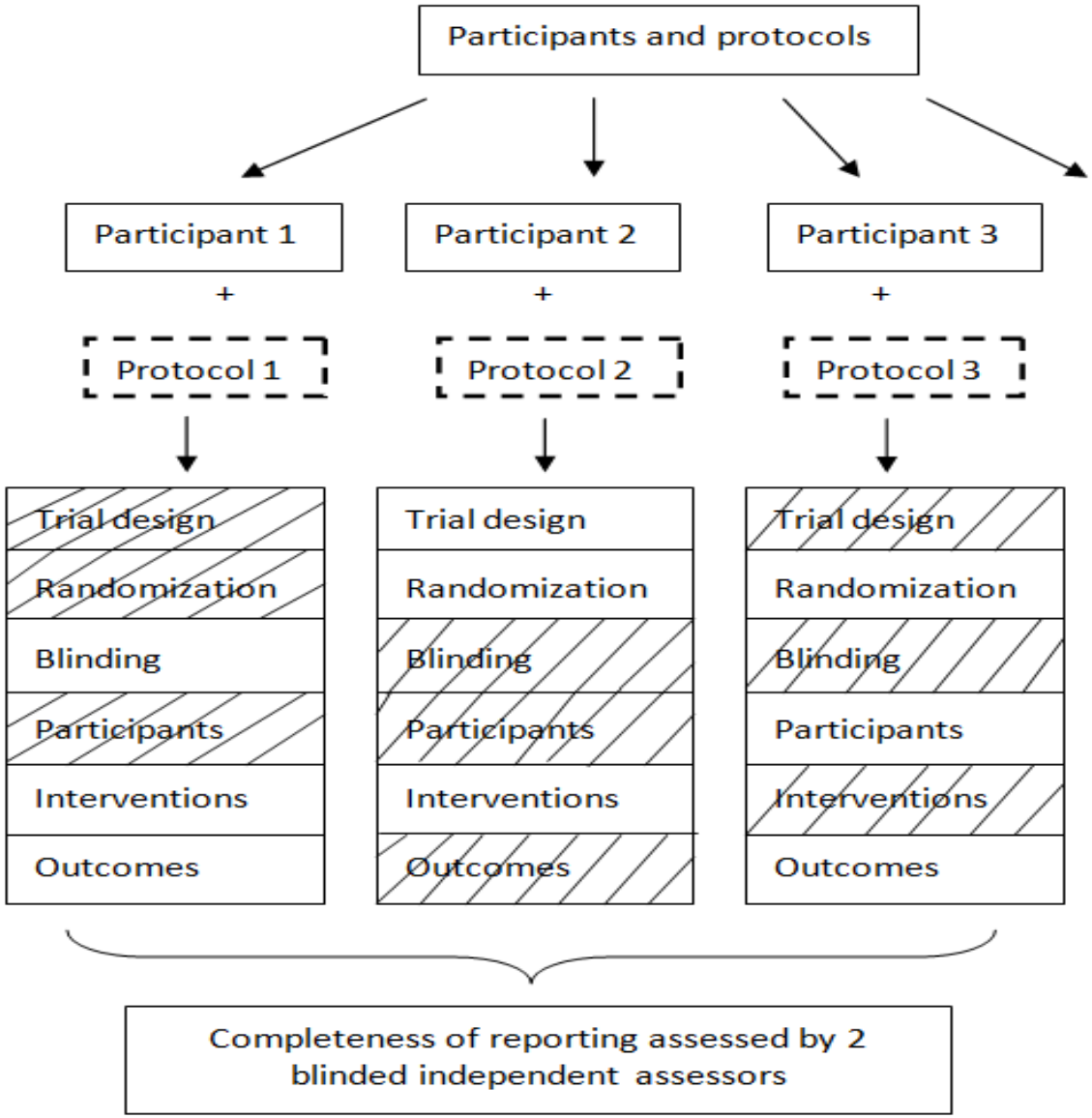
- Despite the existence of the CONSORT guidelines for randomized controlled trials (RCTs) since 1996, inadequate reporting remains[1,2,3]
  - >30% of trial interventions with insufficient descriptions
  - >50% of planned study outcomes not reported

- Objective: To develop and evaluate the impact of a CONSORT based online writing tool on the completeness of reporting in manuscript drafts

1. *Glasziou P et al. Lancet. 2014*
2. *Chalmers I et al. Lancet. 2009*
3. *Glasziou P et al. BMJ.2008*

Methods: Study design

- "Split-manuscript" randomized controlled trial design (derived from a split-body design)
- Methods section was splitted into 6 "domains"
  - Trial design
  - Randomization
  - Blinding
  - Participants
  - Interventions
  - Outcomes
- Unit of randomization: domain (3 with the tool and 3 without
- The randomization sequence was computer generated and the sequence secured by a computer interface



Masters and doctoral students asked to write the methods section of an RCT based on a study protocol

= Control

= Experimental tool

Methods: Development of the writing tool

- The theory behind the development of this writing tool was to enforce the use of the guidelines as of the writing of the first draft instead of simply waiting until the submission of the article to journals.
- The tool included the CONSORT item as well as further elaboration of what the writer should include in order to properly report this item.
- The information for this further elaboration was taken from the corresponding explanation and elaboration publication of the CONSORT statement.
- The tool was also developed to take into account the guidelines for reporting randomized controlled trials with non pharmacologic treatments.
- Finally, examples of adequate reporting were provided for the writers

Methods: Development of the writing tool

INTERVENTIONS (Pharmacological treatment)

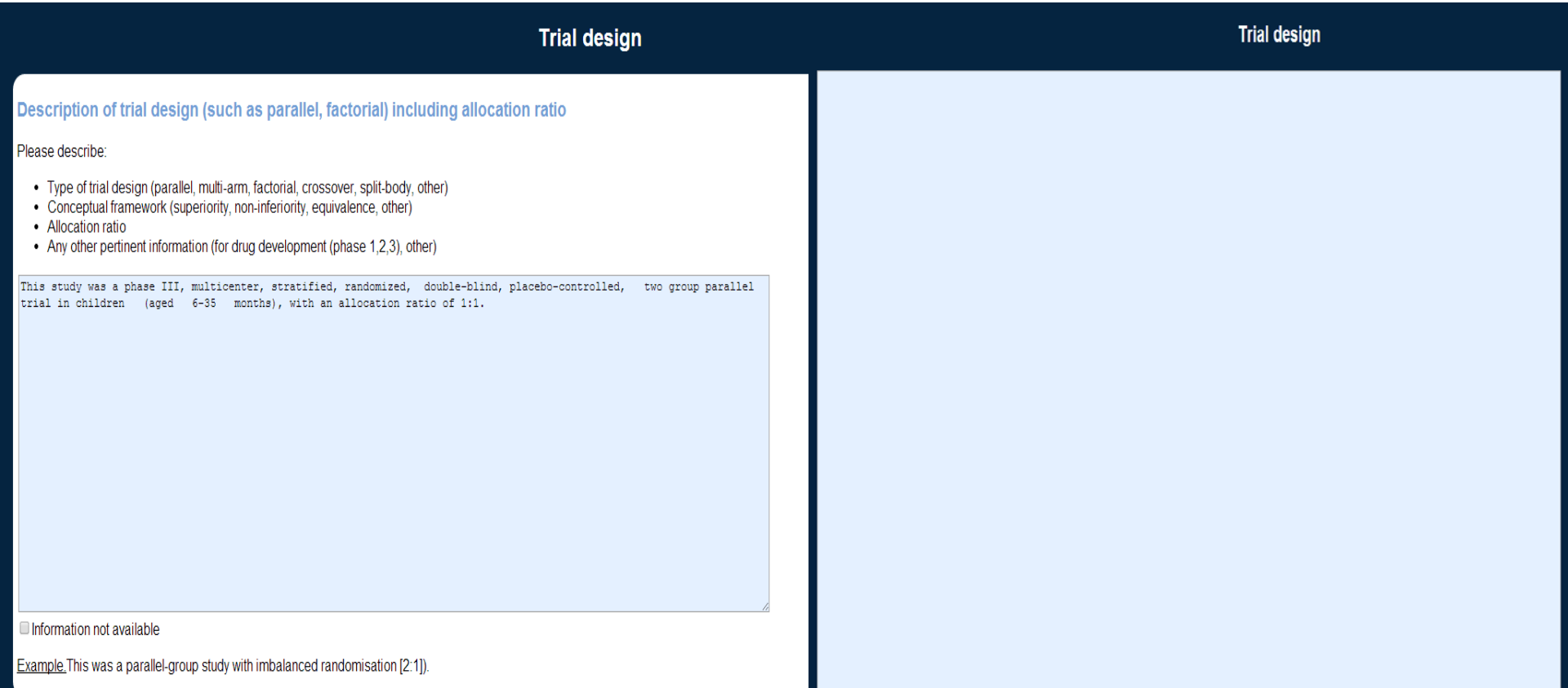
The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

- Please provide a detailed description of the experimental intervention including the:
  - Medication name
  - Mode of administration
  - Dose and duration
  - …

- Please provide a detailed description of the control intervention:
  - …

Methods: Interventions

- Four hours to write the methods section of an RCT based on a study protocol for articles published in the NEJM or JCO in 2013
- Example: domain “trial design”, experimental and control interventions



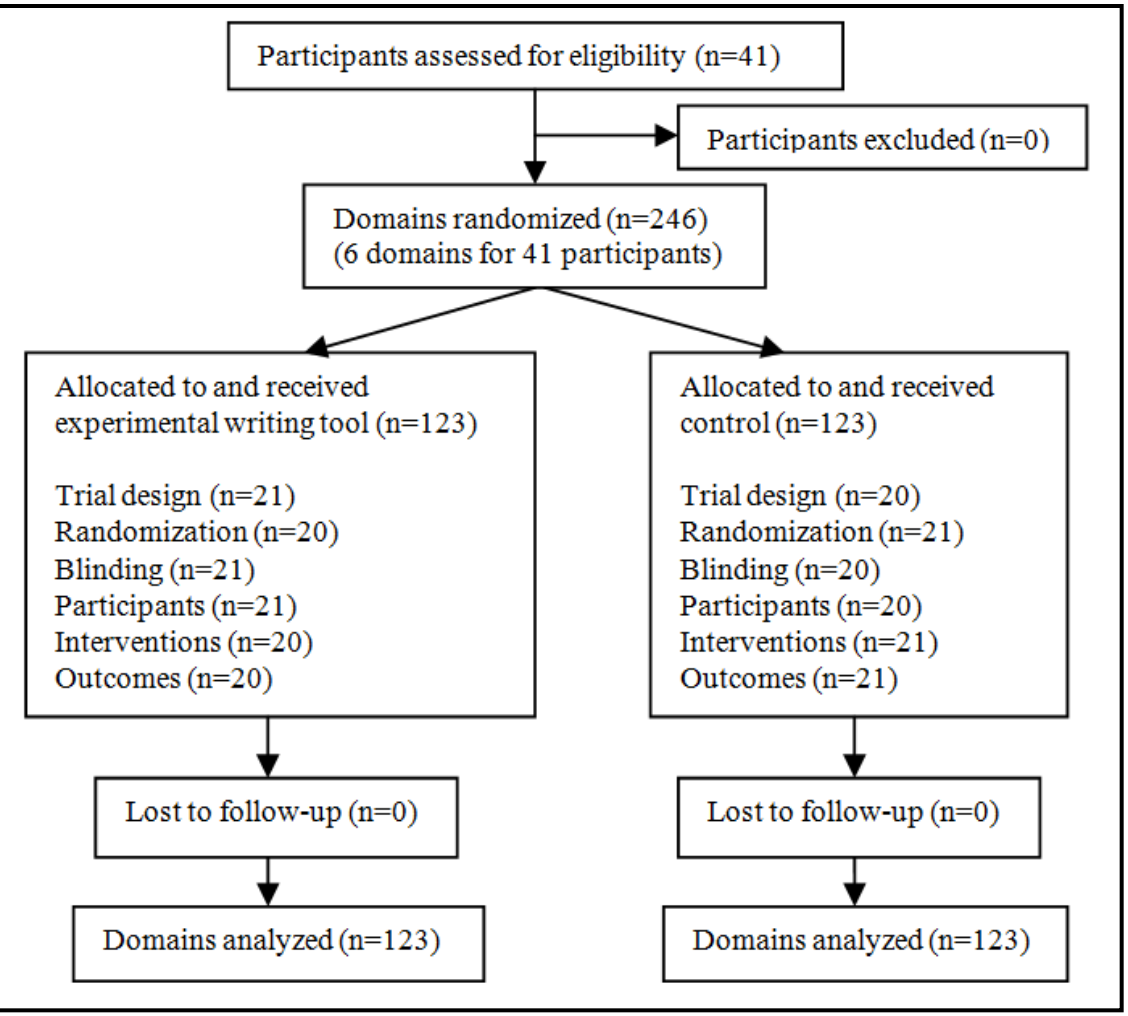
Outcomes and statistical analyses

- Outcomes:
  - Primary: average score for completeness of reporting
  - Secondary: scores for completeness of reporting by domain, average score for completeness of reporting essential elements

Outcome assessment: 2 independent outcome assessors blinded to treatment assignments according to checklist of items reported and not reported, followed by consensus

- Statistical analyses:
  - Paired t-tests for the average completeness of reporting scores (primary and one secondary outcome respectively)

Results



Population

Forty-one masters and doctoral students participated in this study

Protocol characteristics

41 different protocols

-19 medications-based trials

-22non pharmacological trials

Results: average overall scores

	Writing tool scores (0-10)	Control scores (0-10)	Mean difference (95% CI)	p-value
Completeness of reporting score	7.1 +/- 1.2	5.0 +/- 1.6	2.1 (1.5-2.7)	<0.01
Completeness of reporting score for essential elements	7.8 +/- 1.6	6.4 +/- 2.3	1.4 (0.4-2.3)	0.01

n=41 (mean+/- s.d.)

Results: scores by domain

Domain	Writing tool scores (0-10)	Control tool scores (0-10)	Mean difference (95% CI)	p-value*
Trial design	8.1 +/- 2.3	2.7 +/- 1.9	5.4 (4.1-6.7)	<0.01
Randomization	8.4 +/- 2.4	4.6 +/- 2.9	3.8 (1.1-4.4)	<0.01
Blinding	6.9 +/- 2.0	6.2 +/- 2.3	0.7 (-0.7-2.0)	0.50
Participants	6.7 +/- 2.0	4.5 +/- 2.4	2.2 (0.8-3.6)	<0.01
Interventions	7.1 +/- 1.5	5.3 +/- 2.0	1.8 (0.7-2.9)	<0.01
Outcomes	6.1 +/- 2.1	6.4 +/- 3.0	-0.3 (-2.0-1.3)	0.43

n=20 or 21 (mean +/- s.d.), *Wilcoxon tests

Conclusion

- A simple Writing Aid tool could improve of completeness of reporting

- Implications for future research:

  - To expand and improve the tool

  - to incorporate all CONSORT items and items for CONSORT extensions

Extra slides for explanation if necessary

Example: completeness of reporting score

Protocol	Key element to report	Keyword or phrase	Weight	Evaluation	Score	Total score
x	Methods to generate the sequence	Computer generated	1.5	Reported	1.5	7.25
		Minimization	1.5	Reported	1.5	
	Randomization ratio	1 to 1	1	Not reported	0	
	Restriction method(s)	Site	0.5	Reported	0.5	
		Visit 1 MMSE score	0.25	Not reported	0	
		Mild or moderate	0.25	Reported	0.25	
	Mechanism of allocation concealment	IVRS (interactive voice response system)	3.5	Reported	3.5	
	Who generated the allocation sequence	Information not available: who generated the allocation sequence	0.5	Not reported	0	
	Who enrolled the patients and assigned the interventions	Information not available: who enrolled patients, who assigned the interventions	0.5	Not reported	0	
	How the allocation list was kept secret	Information not available: how the allocation list was kept secret	0.5	Not reported	0	

Generic for the type of protocol

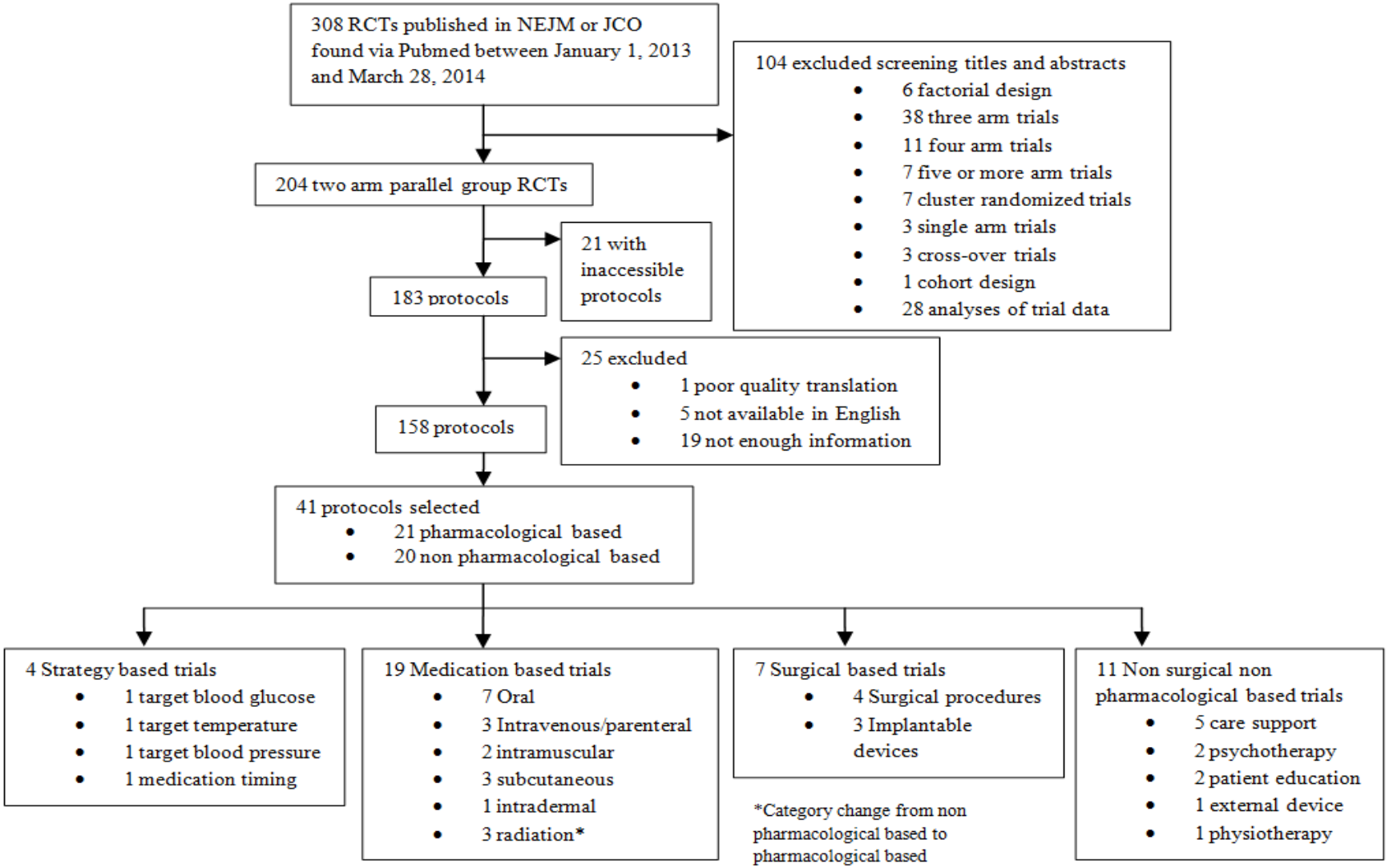
Specific to the protocol

Example: scoring system for the completeness of reporting essential items

Pharmacological therapy

Essential element to report	Weight
TD: Type of trial design (parallel, etc)	10
Randomization: Sequence generation	5
Randomization: Allocation concealment	5
Blinding: participants	5
Blinding: outcome assessors	5
Participants: Inclusion and exclusion criteria	10
Intervention: Medication name	2.5
Intervention: Dose and duration of administration	2.5
Intervention: Number and timing of medication administration	2.5
Intervention: Name or type of control treatment	2.5
Outcomes: Presentation of primary outcome	5
Outcomes: Time frame for the primary outcome	5

Flowchart for selecting study protocols



Discussion

- Strengths:
  - Randomized controlled trial
  - Unique study protocols, describing a large variety of interventions
    - Different types of pharmacological treatments (oral, subcutaneous, intravenous, other), strategy based treatments, surgical procedures, care support, psychotherapy, patient education and more)
    - Real protocols

- Limitations:
  - Study population not representative (students, many without experience)
  - Context (4 hours to write, use of study protocols by other researchers)
  - Control tool still provided structure to writer reports
  - Protocols only representative of RCTs published in NEJM and JCO