Selective Reporting in Clinical Trials:
A feasibility study for examining discrepancies between trial protocols and trial reports submitted to journals

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Selective Reporting

BMJ

RESEARCH

Frequency and reasons for outcome reporting bias in clinical trials: interviews with trialists

"When I take a look at the data I see what best advances the story, and if you include too much data the reader doesn't get the actual important message, so sometimes you get data that is either not significant or doesn't show anything, and so you, we, just didn't include that". *Smyth et al., 2011*

BMJ 2011; 342:c7153.

Aims and Objectives

Aims: To conduct a further interview study in real-time with trialists, to characterize reasons for biased reporting and to provide guidance.

Feasibility study objectives (The BMJ):

1) To understand the processes involved in comparing pre-specified outcomes from protocols and reported outcomes in initial manuscript submissions
2) To document the frequency and types of outcome discrepancies between pre-specified outcomes in protocols and submitted papers
3) To review any discussions around discrepancies identified in trial registries, manuscripts or correspondence with editors and peer reviewers

Methodology

Trial Registry

Protocol

Initial submission

Peer review

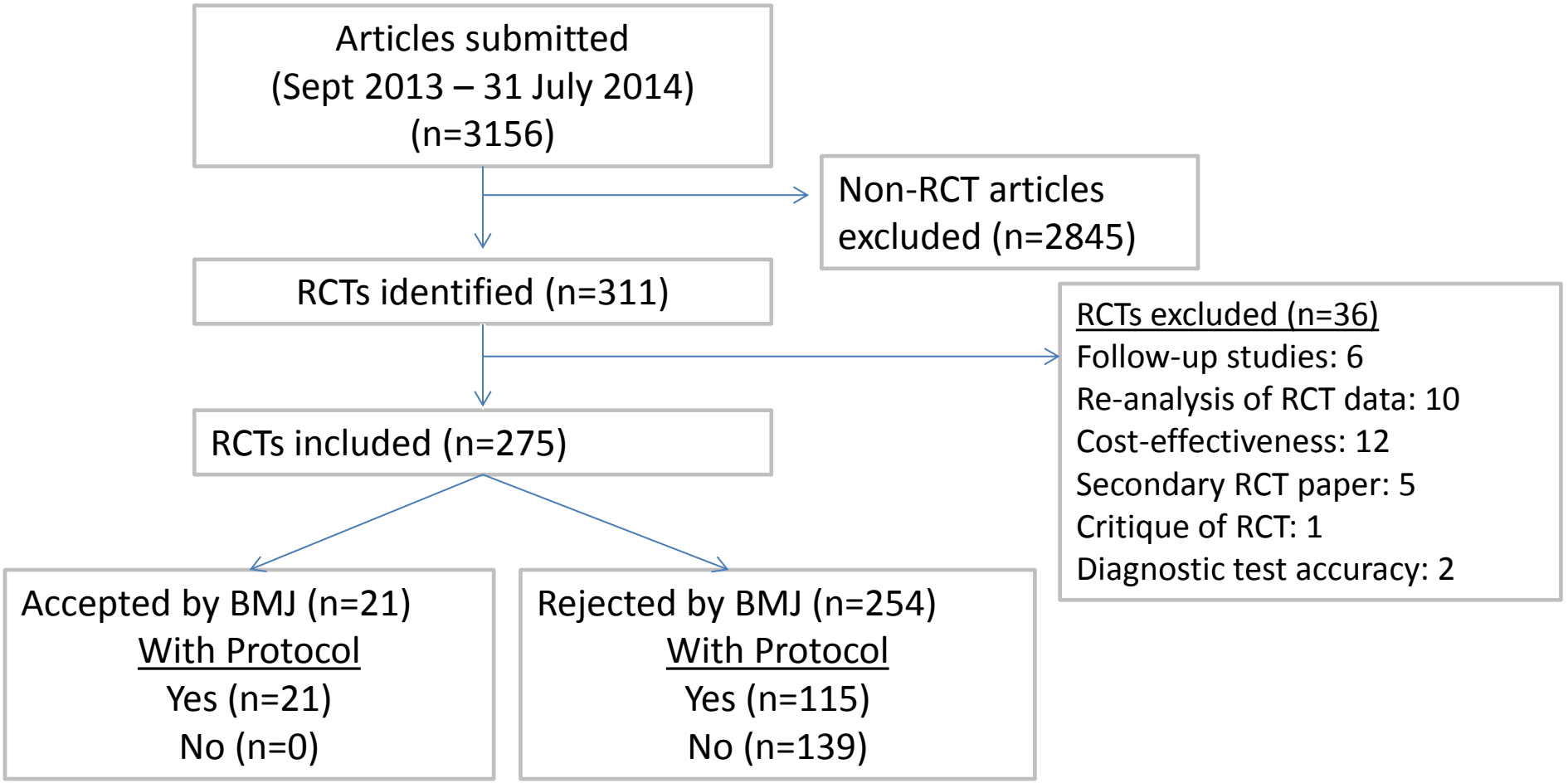
Publication

Methodology – outcome matrix

Outcomes	Trial Registry	Protocol	Initial Report	Final Report
Depression symptoms (SCL-D13)	x [P]	X [P]	x	x
Depression diagnosis (PHQ-9)	X	x	X [P]	X [P]
Quality of life (EQ5D)		x		
Quality of life (WHOQoL BREF)		x	X	x
Quality of life(DQoL)		x		x
Angina(SAQ)		x		x
Anxiety (GAD-7)		x	X	x
Self-efficacy (SEQ)		x	x	x

[Primary outcome]

Eligibility of studies



Trial Characteristics

Characteristic		Accepted by BMJ (N=21) (%)	Rejected by BMJ (N=21) (%)
Trial design:	Parallel Cluster Crossover Factorial	16 (76) 4 (19) 0 (0) 1 (5)	17 (81) 3 (14) 1 (5) 0 (0)
Multicentre/ Single Centre:	Multicentre Single Centre	18 (86) 3 (14)	15 (71) 6 (29)
Trial Sample Size:	<100 100-999 >1000	1 (5) 14 (67) 6 (29)	4 (19) 13 (62) 4 (19)
Duration of Trial:	<12 months 12 - 24 months >24 months Unclear	8 (38) 12 (57) 1 (5) 0 (0)	10 (48) 9 (43) 1 (5) 1 (5)
Source of Funding:	Commercial Non-commercial Both Not stated	0 (0) 15 (71) 5 (24) 1 (5)	0 (0) 18 (86) 3 (14) 0 (0)

Trial Registration / Protocols

"In accordance with the ICMJE Recommendations, BMJ will not consider reports of clinical trials unless they were registered prospectively before recruitment of any participants"

Characteristic		Accepted by BMJ (N=21)	Rejected by BMJ (N=21)
Trial Registration	All trials were registered (majority with clinicaltrials.gov or ISRCTN register)		
Prospective / Retrospective	Prospective Retrospective Unclear	19 (91%) 1* (5%) 1 (5%)	10 (48%) 10 (48%) 1 (5%)
Protocol Published?	Yes No	14 (67%) 7 (33%)	11 (52%) 10 (48%)

* Trial registered before ICMJE recommendation

Main Results – protocol vs. initial submission

	Accepted by BMJ	Rejected by BMJ
Studies with no discrepancies	4/21	2/21
Pre-specified outcome (not reported)	27% (89/333)	19% (63/335)
Reported (but no pre-specified)	11% (31/275)	14% (45/317)
Downgrading an outcome	3*	0
Upgrading an outcome	0	0

*No reasons for these downgrades were provided

Editorial Impact on Discrepancies (published)

- 14 of 17 trials: *some* outcomes discrepancies were identified during peer review.

Following peer review:

  - Unreported outcomes reduced from 27% to 21% (published manuscript)

  - Reported but not pre-specified outcomes remained similar (11%)

- Reporting of the reason for discrepancies was rare.

Conclusions

- Discrepancies are common between trial documents
- Reporting of reasons for discrepancies is rare

Future Work

- MRC MRP grant application has been submitted:
    - Interview trialists during the peer review process to further understand the reasons for such discrepancies
    - Provision of guidance to prevent and minimise bias as a result of selective reporting
- Partner journals (The BMJ, BMJ Open, PLoS Medicine, PLoS ONE)