Appendix 2. Interpretation of the checklist items used to judge integrity risk in the TRACT checklist. Derived from Mol et al. 2022 [1]

DOMAIN	*Checklist Item*	*Interpretation*
Governance	1a	Absent or retrospective registration of RCTs. This is relevant for RCTs commencing after 2010
	1b	Discrepancy of >15% between the intended sample size in the trial registration compared to the actual sample size achieved in the RCT[1]
	1c	Absent or vague description of research ethics or apparent concerns regarding ethics[2]
Author Group[3]	2a	Number of authors ≤3 or low author to study size ratio
	2b	Other studies of authors have been retracted not on request of the authors[4]
	2c	Large number of RCTs published in a short time frame by one author/in one institute[5]
Plausibility of Intervention Usage	3a	Insufficient or implausible description of allocation concealment (e.g. two interventions but only one placebo)[6]
	3b	Unnecessary or illogical description of methodological standards (e.g. use of sealed envelopes in a placebo-controlled trial)
Timeframe	4a	Fast recruitment of participants within the study time (especially single centre studies)
	4b	Short or impossible time frame between ending recruitment/follow up and submission of the paper (take into account time to outcome e.g. live birth, pregnancy outcome etc.)[7]
Drop-Out Rates	5a	Zero participants lost to follow up or no reasons mentioned for loss of follow up[8]
	5b	Ideal number of losses to follow up resulting in perfectly rounded number in each group (e.g. groups of 50 or 100)
Baseline Characteristics	6a	No or few baseline (<5) characteristics presented
	6b	Implausible patient characteristics judging from common sense, the literature and local data (e.g. similar standard deviations for completely different characteristics with different means and distributions)
	6c	Perfect balance for multiple baseline characteristics or significant/large differences between baseline characteristics
		Important prognostic factors are not reported as baseline characteristics
Outcomes	7a	Effect size that is much larger than in other RCTs regarding the same topic[9]
	7b	Conflicting information between outcomes (e.g. more ongoing pregnancies than clinical pregnancies)
		Change in primary outcome from registration to publication

Reference:

[1] Mol BW, Lai S, Rahim A, et al. Checklist to assess Trustworthiness in RAndomised Controlled Trials (TRACT checklist): concept proposal and pilot. Res Integr Peer Rev 2023; 8(1): 6.

[1]If registration is retrospective, then by definition the RCT sample size will the same as the registered number
[2]Obtaining proof of ethics approval (or similar) may be useful to guide the rating of this item
[3]Consider using publisher services such as Scopus or Clarivate to identify authors and their publications
[4]Consider checking http://retractiondatabase.org/RetractionSearch.aspx
[5]This 'number' is subjective based on the field of study, author or author group, number of recruitment centres, and timeframe
[6]Consider if the interventions and control/placebo are explained sufficiently enough to be repeated in another experiment
[7]The recruitment time frame is from the date of the first recruited patient to the date of the last recruited patient
[8]Especially in cases of long follow up (e.g. multiple months) and/or multiple cycles of or long-lasting interventions
[9]Consider utilising meta-analyses if available