

Roberta on the Job

A proof-of-concept study of a customised GPT tool for risk-of-bias assessment of randomised clinical trials

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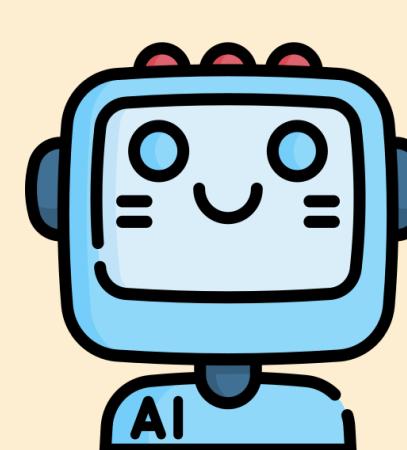
INTRODUCTION



Risk-of-bias (ROB) assessment is a key element of systematic reviews.¹ However, procedures using instruments such as the Cochrane Risk of Bias Tool for Randomised Trials (ROB-2),^{2,3} are known to be:

- challenging to use;⁴⁻⁶
- highly time-consuming;^{4,5,7}
- marred by low inter-rater consistency.⁷⁻⁹

Various attempts have been made to use general-purpose large language models (LLMs) such as ChatGPT (Generative Pre-trained Transformer) for ROB-2 assessment.¹⁰⁻¹³ However, the success of these attempts have been *mixed*, with fair to moderate agreement with human reviewers, hallucinations, and unknown consistency over time.



OUR KEY IDEA

A customised GPT-based tool may have the potential to assist in ROB-2 assessments with greater efficiency and consistency.

Customisation refers to the process of adapting a generic LLM to become more domain-specific, targeting particular operations and using specialised knowledge.^{14,15}

AIM

To develop and assess a simple, customised GPT-based tool for ROB-2 assessment

METHODS

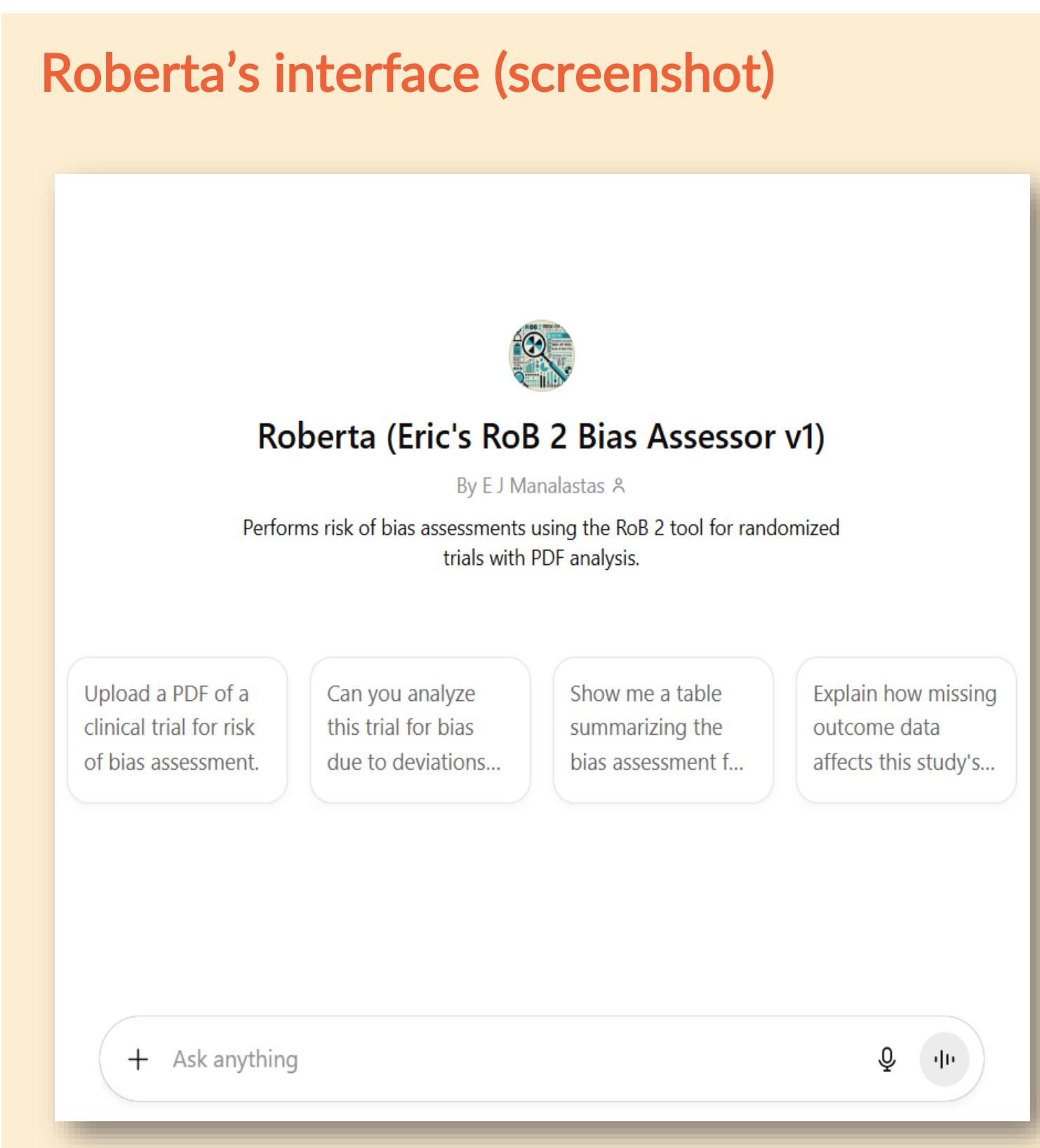
Study design

Proof-of-concept study.

Tool development

A customised GPT for ROB-2 assessment of randomised trials, aligned with Cochrane standards (nicknamed: Roberta)

- **Model:** OpenAI's GPT-4o architecture
- **Customisation:** Retrieval-augmented generation using published guidance documents for the ROB-2 tool.



Testing & evaluation

We tested Roberta on three evaluation criteria:



Speed (time to generate a ROB-2 assessment)



Accuracy (performance against ratings by trained human assessors)



Test-retest reliability (consistency of assessments across time points)

RESULTS

Speed

Evaluation for speed indicated extremely rapid performance.

In tests using 20 clinical trial publications, **average time per ROB-2 assessment was less than half a minute** (M: 25.2 seconds, SD: 4.7).

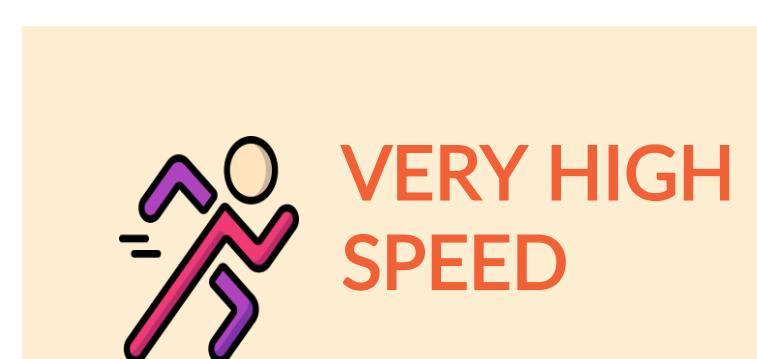
Accuracy

Evaluation for accuracy showed **variation by level of ROB**.

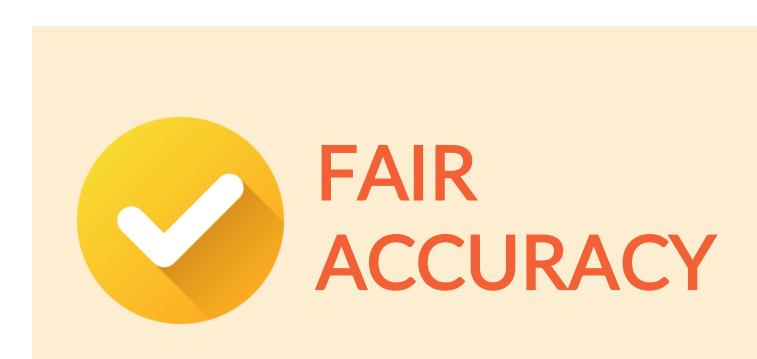
For domains rated by human assessors as **low-risk** and '**some concerns**', high agreement was observed. However, considerable disagreement was observed in domains rated as '**high-risk**', with Roberta ratings being more lenient than human assessors.

Reliability

Evaluation for test-retest reliability indicated **acceptable reliability** across one week (Cohen's kappa = 1.00; perfect consistency) and two weeks (Cohen's kappa = 0.54; moderate consistency).



25.2 seconds
on average to draft a
ROB-2 assessment
vs. human standard
of 28 minutes per
assessment⁵



96%
agreement for
low-risk domains
83%
agreement for
domains with '**some concerns**'



K=1.00
perfect consistency
across one week
K=0.54
moderate consistency
across two weeks

CONCLUSIONS

Preliminary proof-of-concept evaluations suggest a customised GPT tool such as Roberta can support rapid ROB-2 assessments with a fair degree of accuracy and acceptable test-retest reliability, complementing – but not replacing – human review.

Further testing will enhance the utility of LLM-based (including GPT) tools, towards realising the potential of AI to facilitate systematic reviews and evidence synthesis.^{17,18}

Specifically, future tests should:

- Compare the customised GPT versus its base version (i.e. uncustomised GPT)
- Evaluate the customised GPT using the latest models which are rapidly evolving
- Explore the utility of such tools to ROB assessments of non-randomised trials

REFERENCES

1. Viswanathan M, Patino CD, Berkman ND, et al. Recommendations for assessing the risk of bias in systematic reviews of health-care interventions. *J Clin Epidemiol*. 2018;97:26-34. doi:10.1016/j.jclinepi.2017.12.004
2. Higgins J P T, Altman D G, Gøtzsche P C, Jüni P, Moher D, Oxman A D, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials BMJ. 2011; 343:d5288 doi:10.1136/bmj.d5288
3. Sterne JAC, Egger M, Page MJ, et al. Rob 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. 2019;364:k4890. Published 2019 Aug 28. doi:10.1136/bmj.k4890
4. Croker TE, Lam N, Jordão M, et al. Risk-of-bias assessment using Cochrane's revised tool for randomised trials (Rob 2) was useful but challenging and resource-intensive: observations from a systematic review. *J Clin Epidemiol*. 2023;161:39-45. doi:10.1016/j.jclinepi.2023.06.015
5. Minozzi S, Cinquini M, Gianola S, Gonzalez-Lorenzo M, Banzi R. The revised Cochrane risk of bias tool for randomised trials (Rob 2) showed moderate inter-rater reliability and challenges in its application. *J Clin Epidemiol*. 2020;121:10-16. doi:10.1016/j.jclinepi.2020.04.016
6. Savovic J, Weeks L, Sterne JA, et al. Evaluation of the Cochrane Collaboration's tool for assessing the risk of bias in randomised trials: focus groups, online survey, proposed recommendations and their implementation. *Syst Rev*. 2014;3:37. Published 2014 Apr 15. doi:10.1186/2046-4053-3-37
7. Minozzi S, Dwyer K, D'Amore F, Cappiello G. Reliability of the revised Cochrane risk-of-bias tool for randomised trials (Rob 2) following its implementation: a pilot study. *J Clin Epidemiol*. 2022;141:99-105. doi:10.1016/j.jclinepi.2021.09.024
8. Armijo-Olivo S, Ospina M, da Costa BR, et al. Poor reliability between Cochrane reviewers and blinded external reviewers when applying the Cochrane risk of bias tool in physical therapy trials. *PLoS One*. 2014;9:e6920. Published 2014 May 13. doi:10.1371/journal.pone.0096920
9. Higgins J P T, Green S, Avesi A, et al. Testing the risk of bias tool showed low reliability between individual reviewers and agreement was poor across all pairs of reviewer pairs. *J Clin Epidemiol*. 2013;66(9):973-9. doi:10.1016/j.jclinepi.2012.07.005
10. Suster S, Baldwin T, Verspoor K. Zero- and few-shot prompting of generative large language models provides weak assessment of risk of bias in clinical trials. *Res Synth Methods*.
11. Pinto T, Tarwotji J, Jalok, Rupjan Talukdar, Mahreen Shahab, Michael Ling, Dena Zerafandi, *ChatGPT for assessing risk of bias of randomised trials using the Rob 2 tool: A methods study*. *medRxiv* 2023;11.19.22398727; doi: <https://doi.org/10.1101/2023.11.19.22398727>
12. Lai H, Ge L, Sun M, et al. Assessing the Risk of Bias in Randomized Clinical Trials With Large Language Models. *JAMA Netw Open*. 2024;7(5):e2412687. Published 2024 May 1. doi:10.1001/jamanetworkopen.2024.12687
13. Tariq I, et al. Human Versus Artificial Intelligence: Comparing Cochrane Authors' and ChatGPT's Risk of Bias Assessments. *Cochrane Evid Synth Methods*. 2025;3(5):e70044. doi:10.1002/cesm.70044
14. Jiang Z, Liu A, Zhang D, Xiewei Xu, Dai Y. Customization and personalization of large language models for engineering design. *CIRP Ann Manufact Technol*. 2025;74(1):191-195. <https://doi.org/10.1016/cirp.2025.03.009>
15. Chaitanya K, et al. Do large language models meet personalization: perspectives of challenges and opportunities. *World Wide Web*. 2024; 27: 42. doi:10.1007/s11280-024-01274-1
16. Huang J, Li H, Zhao W, et al. Large Language Model-Assisted Risk-of-Bias Assessment in Randomized Controlled Trials Using the Revised Risk-of-Bias Tool: Evaluation Study. *J Med Syst*. 2025;49(1):1-10. doi:10.1007/s10829-024-02631-0
17. Rose C, Bidonde J, Jorgenson M, et al. Using a large language model (ChatGPT) to assess risk of bias in randomised controlled trials of medical interventions: protocol for a pilot study of interrater agreement with human reviewers. *BMC Med Res Methodol*. 2025;25(1):18. Published 2025 Jul 31. doi:10.1186/s12874-025-02631-0
18. Rose C, J. Bidonde, J. Ringstein, M. Jorgenson, G. Berger, A. E. Bergman, D. Meneses-Echazarra, J. F. & Berg, R. C. (2025). Using a Large Language Model (ChatGPT-4o) to Assess the Risk of Bias in Randomized Controlled Trials of Medical Interventions: Interrater Agreement With Human Reviewers. *Cochrane evidence synthesis and methods*, 3(3). e70048. <https://doi.org/10.1002/cesm.70048>