

INSPECT-SR: a tool for assessing trustworthiness of RCTs



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Management group: Calvin Heal, George Antoniou, Ella Flemyng, Lisa Bero, Jamie Kirkham

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Disclaimer


I am not accusing anyone of fraud or other forms of misconduct. A study might be 'problematic' or 'untrustworthy' due to honest errors. **I recommend you don't accuse anyone of fraud**

Declaration of interest

I am Stats Editor for BJOG, Cochrane Gynaecology and Fertility, Fertility and Sterility, Journal of Hypertension. I undertake integrity investigations for various journals, and sometimes I am paid for this.

Ivermectin for COVID-19

Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines

 Bryant, Andrew MSc^{1*}; Lawrie, Theresa A. MBBCh, PhD²; Dowswell, Therese PhD²; Fordham, Edmund J. PhD²; Mitchell, Scott MBChB, MRCS³; Hill, Sarah R. PhD¹; Tham, Tony C. MD, FRCP⁴

Bryant et al., 2021

Risk ratio for death:

0.38 (95% CI 0.19 to 0.73)

15 trials

Evidence of benefit

Meta-analysis of Randomized Trials of Ivermectin to Treat SARS-CoV-2 Infection

Andrew Hill,¹ Anna Garratt,² Jacob Levi,³ Jonathan Falconer,⁴ Leah Ellis,⁵ Kaitlyn McCann,⁵ Victoria Pilkington,⁶ Ambar Qavi,⁵ Junzheng Wang,⁵ and Hannah Wentzel⁵

Hill et al., 2021

Risk ratio for death:

0.49 (95% CI 0.28 to 0.86)

12 trials

Evidence of benefit

Ivermectin for COVID-19

- SRs widely covered in media and social media.
- Used by antivax groups

Our Systematic Review...

Our peer-reviewed study clearly shows that ivermectin prevents and treats Covid-19 and has the potential to save and improve countless lives.

- 2.6 million views
- Ranked 7th of 20 million articles of a similar age.



Read More

A just-published, peer-reviewed study already clearly shows that ivermectin prevents and treats Covid-19 and has the **potential to save and improve countless lives in the UK and worldwide right now.**

The strength of evidence for ivermectin has this week been supercharged by publication of a gold standard review of 24 randomised trials conducted in 15 countries among more than 3400 people worldwide proving infections fall and deaths are dramatically reduced when ivermectin is administered. Published in the American Journal of Therapeutics the most rigorous statistical standards were applied by world-leading researchers biostatistician Mr Andrew Bryant and medical doctor and researcher Dr. Tess Lawrie.



- Tweeted by 45388**
- Blogged by 13**
- On 17 Facebook pages**
- Picked up by 102 news outlets**

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General

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	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	
1	Name	initials	Sex	Age	Fever	Fatigue	Dyspnea	Sore thro.	other symptoms	HGB (gm/dl)	CRP before	CT description	CO-RAD	symptoms date	PCR	CRP at discharge	GRADE
149	AZM	F	65	yes	yes	no	no	no		12.40%	44	UN GGO	4		08/06/2020		8 moderate
150	AAE	F	49	yes	no	yes	yes	cough		9.70%	32	SCATTERED RED CON	4		11/06/2020		8 moderate
151	AEG	M	54	yes	no	no	yes	cough		12.50%	44	NAD	1		07/06/2020		5 mild
152	OES	M	24	yes	no	no	no	myalgia		15.00%	32	NAD	1	23/5/2020			5 mild
153	FFA	F	39	yes	no	no	yes	cough		11.80%	44	GGO+CON	5		11/06/2020		8 moderate
154	FHA	F	38	yes	no	no	no	cough, diarrhea		13.90%	44	SEGMENTAL CON	3	15/5/2020			10 moderate
155	FMM	F	54	yes	yes	yes	yes	cough		12.50%	44	GGO	5	18/6/2020			12 moderate
156	FT	M	60	no	no	yes	no	no		14.40%	44	GGO	5		08/06/2020		6 moderate
157	FMM	M	67	yes	no	no	yes	no		13.50%	42	GGO+SEGMENTAL CON	4		02/06/2020		6 moderate
158	MES	M	62	yes	yes	yes	no	cough		12.60%	45	GGO	5	16/6/2020			6 moderate
159	MHS	F	60	yes	no	no	yes	cough		12.70%	46	GGO+CP	5	18/5/2020			8 moderate
160	MAE	M	25	yes	no	yes	yes	cough		14.60%	12	NAD	1	26/5/2020			5 mild
161	MSA	M	28	yes	yes	no	yes	cough		13.50%	23	NAD	1	22/5/2020			5 mild
162	FSA	M	30	no	no	no	no	cough		13.30%	48	GGO	5	20/6/2020			10 moderate
163	MAE	M	27	yes	no	no	yes	joint pain		14.70%	33	GGO	4	30/5/2020			12 moderate
164	MAA	M	68	no	yes	no	yes	cough, diarrhea		14.00%	44	GGO	5	14/5/2020			10 moderate
165	MAN	M	42	yes	no	no	yes	cough		13.00%	42	GGO	5	18/6/2020			8 moderate
166	MK	M	48	yes	yes	no	yes	no		14.60%	44	GGO+CP+HEAL	5		03/06/2020		8 moderate
167	MMA	M	26	yes	yes	no	yes	cough		13.50%	24	UN SEGMENTAL CON+GGO	3	18/5/2020			8 moderate
168	MMR	M	28	yes	yes	no	yes	headache, chest pain		14.20%	38	NAD	1		12/05/2020		5 mild
169	HAA	F	52	yes	no	yes	yes	cough		9.20%	43	CON WITH CAVITATION	2		05/06/2020		8 moderate
170	WES	M	42	yes	no	yes	yes	cough		13.90%	43	GGO+CP	5		07/06/2020		8 moderate
171	WSA	F	26	yes	no	yes	yes	cough, diarrhea		12.80%	15	NAD	1		10/06/2020		6 mild
172	WHO	M	45	yes	no	yes	yes	no		13.30%	44	UN GGO	4	17/5/2020			8 moderate
173	YHA	M	43	yes	no	yes	yes	cough, abd pain, diarrhea		13.80%	42	GGO+CO+HEAL	5	25/5/2020			8 moderate
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192	MMA	M	26	yes	yes	yes	yes	cough		13.50%	24	UN SEGMENTAL CON+GGO	3	18/6/2020			8 moderate
193	MRL	M	28	yes	yes	yes	yes	cough		14.10%	46	NAD	1		05/06/2020		5 mild

- Data from one of the ivermectin RCTs.

Initials	Sex	Age	HGB
AAE	F	49	9.70%
AEG	M	54	12.50%
OES	M	24	15.00%
FFA	F	39	11.80%
FHA	F	38	13.90%
FMM	F	54	12.50%
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MK	M	48	14.60%
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FFA	F	39	11.80%
FHA	F	38	13.90%
FMA	F	54	12.50%
FTE	M	60	14.40%
FSA	M	67	13.50%
MRL	M	28	14.10%

- Here is a snapshot from the data (easier to see)
- Look at this for a minute – can you see any problems?

Initials	Sex	Age	HGB
AAE	F	49	9.70%
AEG	M	54	12.50%
OES	M	24	15.00%
FFA	F	39	11.80%
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FMA	F	54	12.50%
FTE	M	60	14.40%
FSA	M	67	13.50%
MRL	M	28	14.10%

- There are repeated sequences

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Clipboard: Cut, Copy, Paste, Format Painter

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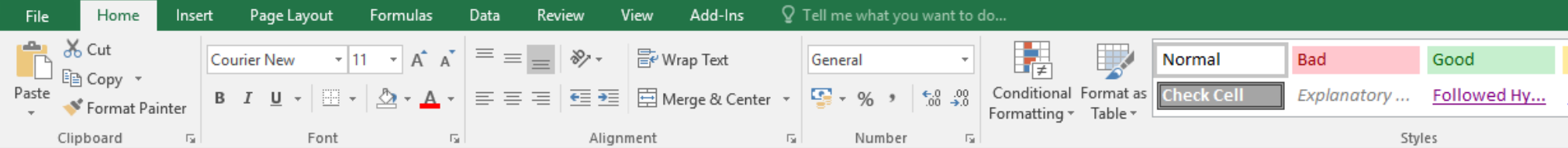
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191	MKE	M	48	yes	yes	yes	yes	no		14.10%	46	GGO+CP+HEAL	5	03/06/2020		9 moderate
192	MMA	M	26	yes	yes	yes	yes	cough		13.50%	24	UN SEGMENTAL CON+GGO	3	18/6/2020		8 moderate
193	MRL	M	28	yes	yes	yes	yes	cough		14.10%	46	NAD	1	05/06/2020		5 mild



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	Name initial	Sex	Age	Fever	Fatigu	Dyspne	Sore thro	other symptoms		HGB (gm/dl)	CRP befor	CT description	CO-RAD	symptoms date&+ve PCR	CRP at discharge	GRADE
149	AZM	F	65	yes	no	no	no	no		12.40%	44	UN GGO	4	08/06/2020		8 moderate
150	AAE	F	49	yes	no	yes	yes	cough		9.70%	32	SCATTERED RED CON	4	11/06/2020		8 moderate
151	AEG	M	54	yes	no	no	yes	cough		12.50%	44	NAD	1	07/06/2020		5 mild
152	OES	M	24	yes	no	no	no	myalgia		15.00%	32	NAD	1	23/5/2020		5 mild
153	FFA	F	39	yes	no	no	yes	cough		11.80%	44	GGO+CON	5	11/06/2020		8 moderate
154	FHA	F	38	yes	no	no	no	cough, diarrhea		13.90%	44	SEGMENTAL CON	3	15/5/2020		10 moderate
155	FMM	F	54	yes	yes	yes	yes	cough		12.50%	44	GGO	5	18/6/2020		12 moderate
156	FT	M	60	no	no	yes	no	no		14.40%	44	GGO	5	08/06/2020		6 moderate
157	FMM	M	67	yes	no	no	yes	no		13.50%	42	GGO+SEGMENTAL CON	4	02/06/2020		6 moderate
158	MES	M	62	yes	yes	yes	no	cough		12.60%	45	GGO	5	16/6/2020		6 moderate
159	MHS	F	60	yes	no	no	yes	cough		12.70%	46	GGO+CP	5	18/5/2020		8 moderate
160	MAE	M	25	yes	no	yes	yes	cough		14.60%	12	NAD	1	26/5/2020		5 mild
161	MSA	M	28	yes	yes	no	yes	cough		13.50%	23	NAD	1	22/5/2020		5 mild
162	FSA	M	30	no	no	no	no	cough		13.30%	48	GGO	5	20/6/2020		10 moderate
163	MAE	M	27	yes	no	no	yes	joint pain		14.70%	33	GGO	4	30/5/2020		12 moderate
164	MAA	M	68	no	yes	no	yes	cough, diarrhea		14.00%	44	GGO	5	14/5/2020		10 moderate
165	MAN	M	42	yes	no	no	yes	cough		13.00%	42	GGO	5	18/6/2020		8 moderate
166	MK	M	48	yes	yes	no	yes	no		14.60%	44	GGO+CP+HEAL	5	03/06/2020		8 moderate
167	MMA	M	26	yes	yes	no	yes	cough		13.50%	24	UN SEGMENTAL CON+GGO	3	18/5/2020		8 moderate
168	MMR	M	28	yes	yes	no	yes	headache, chest pain		14.20%	38	NAD	1	12/05/2020		5 mild
169	HAA	F	52	yes	no	yes	yes	cough		9.20%	43	CON WITH CAVITATION	2	05/06/2020		8 moderate
170	WES	M	42	yes	no	yes	yes	cough		13.90%	43	GGO+CP	5	07/06/2020		8 moderate
171	WSA	F	26	yes	no	yes	yes	cough, diarrhea		12.80%	15	NAD	1	10/06/2020		6 mild
172	WHO	M	45	yes	no	yes	yes	no		13.30%	44	UN GGO	4	17/5/2020		8 moderate
173	YHA	M	43	yes	no	yes	yes	cough, abd pain, diarrhea		13.80%	42	GGO+CO+HEAL	5	25/5/2020		8 moderate
174	YRA	M	62	no	no	yes	yes	cough		13.00%	46	GGO+CP	5	15/6/2020		7 moderate
175	AAE	F	49	yes	no	yes	yes	cough		9.70%	32	SCATTERED RED CON	4	11/06/2020		7 moderate
176	KHEG	M	54	yes	no	yes	yes	cough		12.50%	48	NAD	1	07/06/2020		5 mild
177	OESM	M	24	no	no	yes	yes	myalgia		15.00%	32	NAD	1	23/5/2020		5 mild
178	FFA	F	39	yes	no	yes	yes	cough		11.80%	44	GGO+CON	5	11/06/2020		6 moderate
179	FHA	F	38	yes	no	yes	yes	cough, diarrhea		13.90%	38	SEGMENTAL CON	3	15/5/2020		6 moderate
180	FMA	F	54	yes	yes	yes	yes	cough		12.50%	44	GGO	5	18/6/2020		9 moderate
181	FTE	M	60	no	yes	yes	yes	no		14.40%	46	GGO	5	08/06/2020		9 moderate
182	FSA	M	67	yes	yes	yes	yes	no		13.50%	44	GGO+SEGMENTAL CON	4	02/06/2020		9 moderate
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188	MAE	M	27	yes	yes	yes	yes	joint pain		14.70%	33	GGO	4	30/5/2020		10 moderate
189	MAE	M	78	yes	yes	yes	yes	cough, diarrhea		14.00%	44	GGO	5	14/5/2020		8 moderate
190	MAE	M	42	yes	yes	yes	yes	cough		13.00%	44	GGO	5	18/6/2020		8 moderate
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193	MRL	M	28	yes	yes	yes	yes	cough		14.10%	46	NAD	1	05/06/2020		5 mild

- Blocks of data are repeated
- This is not authentic data
- One possible explanation – it has been fabricated, by copying and pasting blocks of data into a spreadsheet.
- This analysis was done by Nick Brown
- [Nick Brown's blog \(steamtraen.blogspot.com\)](http://steamtraen.blogspot.com)
- Similar problems with other ivermectin RCTs!

Systematic reviews: Fake data to patient care pipeline

1

**Attempt to identify all RCTs
on the review topic**

- Problematic trials will be included

2

**Critically appraise study
methodology, include in
meta-analysis**

- Assess risk of bias
- But do not consider authenticity
- Many (not all) fake trials report sound methods

3

**Make conclusions,
recommendations, on
basis of evidence**


- SRs seen as gold standard
- Included in guidelines
- Influence patient care

Vitamin K and the Prevention of Fractures

Systematic Review and Meta-analysis of Randomized Controlled Trials

*Sarah Cockayne, MSc; Joy Adamson, PhD; Susan Lanham-New, PhD; Martin J. Shearer, PhD, MRCPATH;
Simon Gilbody, DPhil; David J. Torgerson, PhD*

Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta- analysis, and Trial Sequential Analysis to Inform Clinical Guidelines

 Bryant, Andrew MSc^{1,2}; Lawrie, Theresa A. MBBCh, PhD²; Dowswell, Therese PhD²; Fordham, Edmund
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Psychological therapies for the management of chronic pain (excluding headache) in adults (Review)


Williams ACDC, Fisher E, Hearn L, Eccleston C

Vitamin K and the Prevention of Fractures

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Psychological therapies for the management of chronic pain (excluding headache) in adults (Review)

Williams ACDC, Fisher E, Hearn L, Eccleston C

3 out of 5 trials subsequently identified as **fake**.

Suggested impressive benefit on mortality due to **fraudulent** trials.

3 trials from one investigator suggested to be **implausible** (huge effects, no attrition), 2 **retracted**.

EDITORIAL

When beauty is but skin deep: dealing with problematic studies in systematic reviews

Stephanie L Boughton, Jack Wilkinson, Lisa Bero

Managing potentially problematic studies

<https://bit.ly/3SsJO9E>

EDITORIAL

When beauty is but skin deep: dealing with problematic studies in systematic reviews

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- Do not include problematic studies in the systematic review.

EDITORIAL

When beauty is but skin deep: dealing with problematic studies in systematic reviews

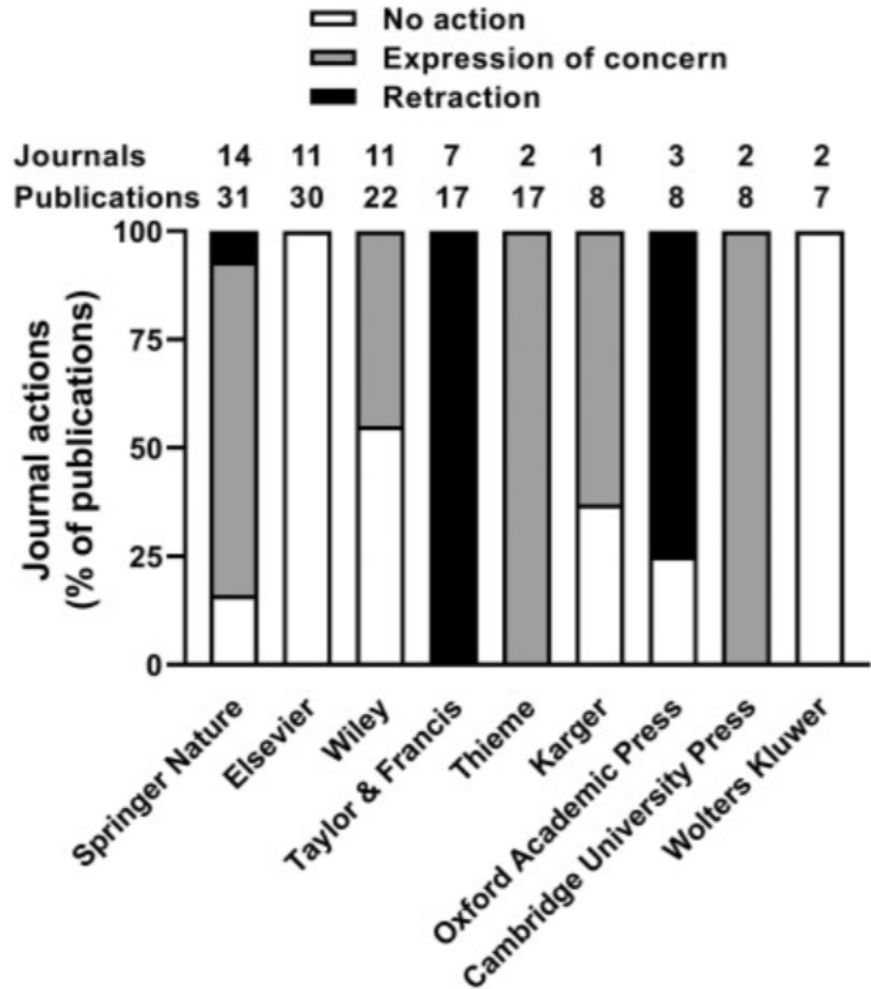
Stephanie L Boughton, Jack Wilkinson, Lisa Bero

Managing potentially problematic studies

<https://bit.ly/3SsJO9F>

- Do not include problematic studies in the systematic review.
- But how can we identify problematic studies in the first place?

Can't we just use retraction status?



It typically takes a long time for problematic studies to be retracted

Many are never retracted

Example (left): outcome 5 years after reporting 172 problematic clinical trials from one research group

So we cannot rely on retraction status alone as an indicator of trustworthiness

Do we need a tool to identify fraud and misconduct?

Our view: it is neither necessary nor desirable to develop a “diagnostic test for fraud”

Legal consequences, harms

What matters is the trustworthiness of a study (example)

A trustworthiness tool should help the user make a judgement about a study's trustworthiness, and to articulate a basis for that judgement

Wilkinson and Tovey 2025, JCE:
doi.org/10.1016/j.jclinepi.2025.111670

Table I. Patients' characteristics.

	Group A (minimal stimulation) (<i>n</i> = 58)	Group B (CC) (<i>n</i> = 55)	<i>p</i> Value
Age (years)	27.7 ± 2.4	26.8 ± 2.3	0.57
Duration of infertility (years)	1.88 ± 0.7	2.14 ± 0.8	0.71
BMI (kg/m ²)	24.9 ± 2.3	25.3 ± 2.6	0.62
Waist-to-hip ratio	0.8 ± 0.04	0.8 ± 0.05	0.38
Menstrual cycle			
Oligomenorrhea	54 (93.1%)	51 (92.7%)	0.43
Amenorrhea	4 (6.9%)	4 (7.3%)	0.61
Hyperandrogenism	26 (44.8%)	23 (41.8%)	0.74
LH (mIU/mL)	12.9 ± 2.3	13.4 ± 2.4	0.52
FSH (mIU/mL)	5.6 ± 1.1	5.7 ± 1.3	0.72
LH/FSH ratio	2.6 ± 1.1	2.6 ± 1.2	0.42
Testosterone (ng/mL)	0.94 ± 0.21	0.92 ± 0.24	0.77
SHBG (nmol/L)	33.62 ± 3.6	35.53 ± 3.1	0.48
Fasting glucose (mg/dL)	91.6 ± 1.5	89.7 ± 1.4	0.76
Fasting insulin (μU/mL)	10.7 ± 2.7	11.2 ± 3.1	0.57
Fasting glucose/insulin ratio	7.7 ± 3.7	7.2 ± 3.6	0.33
Ovarian volume (mL)	11.3 ± 2.5	11.4 ± 2.4	0.22

BMI, Body mass index; CC, clomiphene citrate; FSH, follicle-stimulating hormone;

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Health and Care Research

INveStigating ProBlEmatic Clinical Trials in Systematic Reviews

Aim: To develop a tool for identifying problematic randomised controlled trials in the context of health systematic reviews.



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Aim: To develop a tool for identifying problematic randomised controlled trials in the context of health systematic reviews.

Stage 1: Assemble list
of checks for
problematic studies
(previous studies, new
survey of 71 experts):
76 checks identified



INveStigating ProBlEmatic Clinical Trials in Systematic Reviews

Aim: To develop a tool for identifying problematic randomised controlled trials in the context of health systematic reviews.

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76 checks identified

Stage 2: Apply list of checks to 95 RCTs in 50 Cochrane Reviews (feasibility, impact)

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Aim: To develop a tool for identifying problematic randomised controlled trials in the context of health systematic reviews.

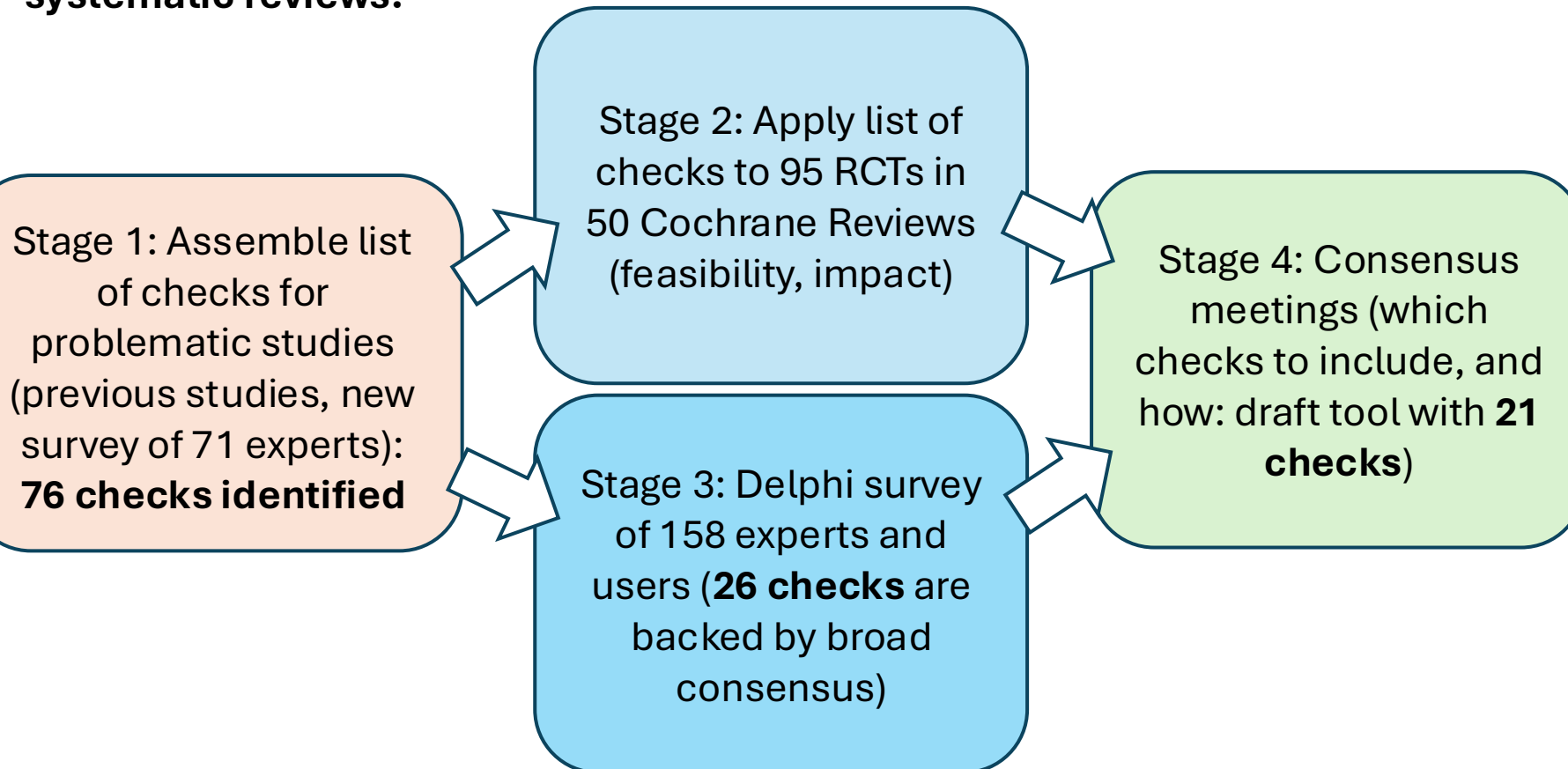
Stage 1: Assemble list of checks for problematic studies (previous studies, new survey of 71 experts):
76 checks identified

Stage 2: Apply list of checks to 95 RCTs in 50 Cochrane Reviews (feasibility, impact)

Stage 3: Delphi survey of 158 experts and users (**26 checks** are backed by broad consensus)

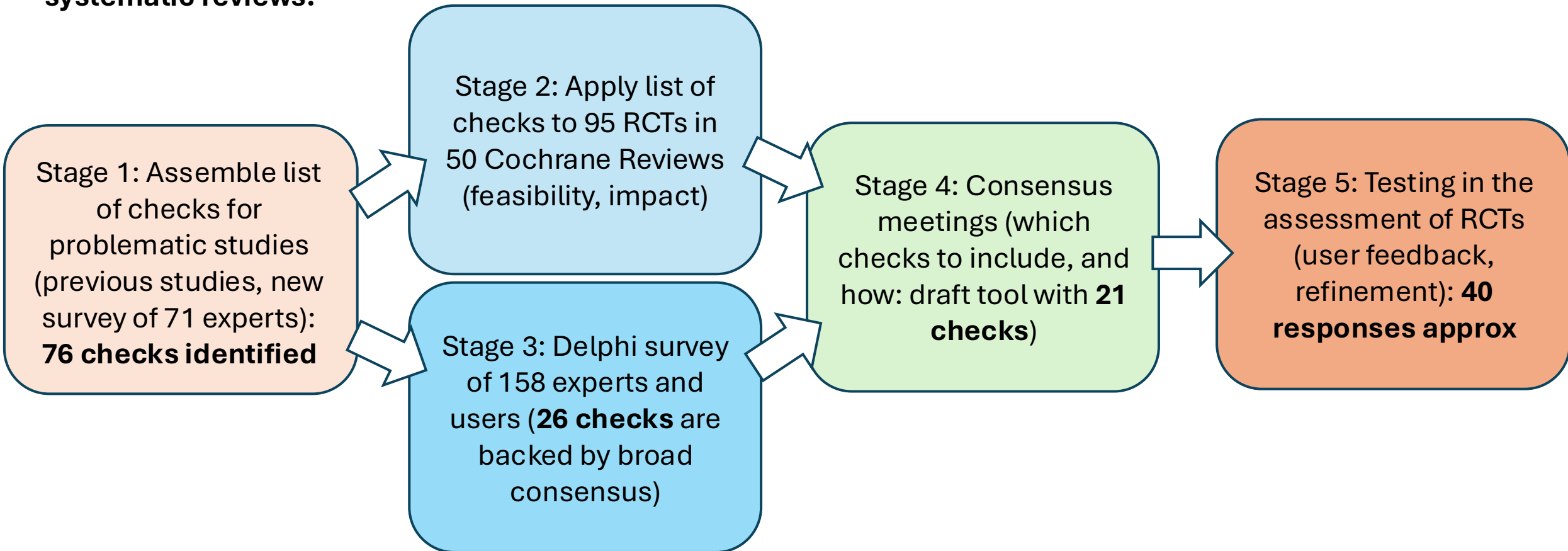
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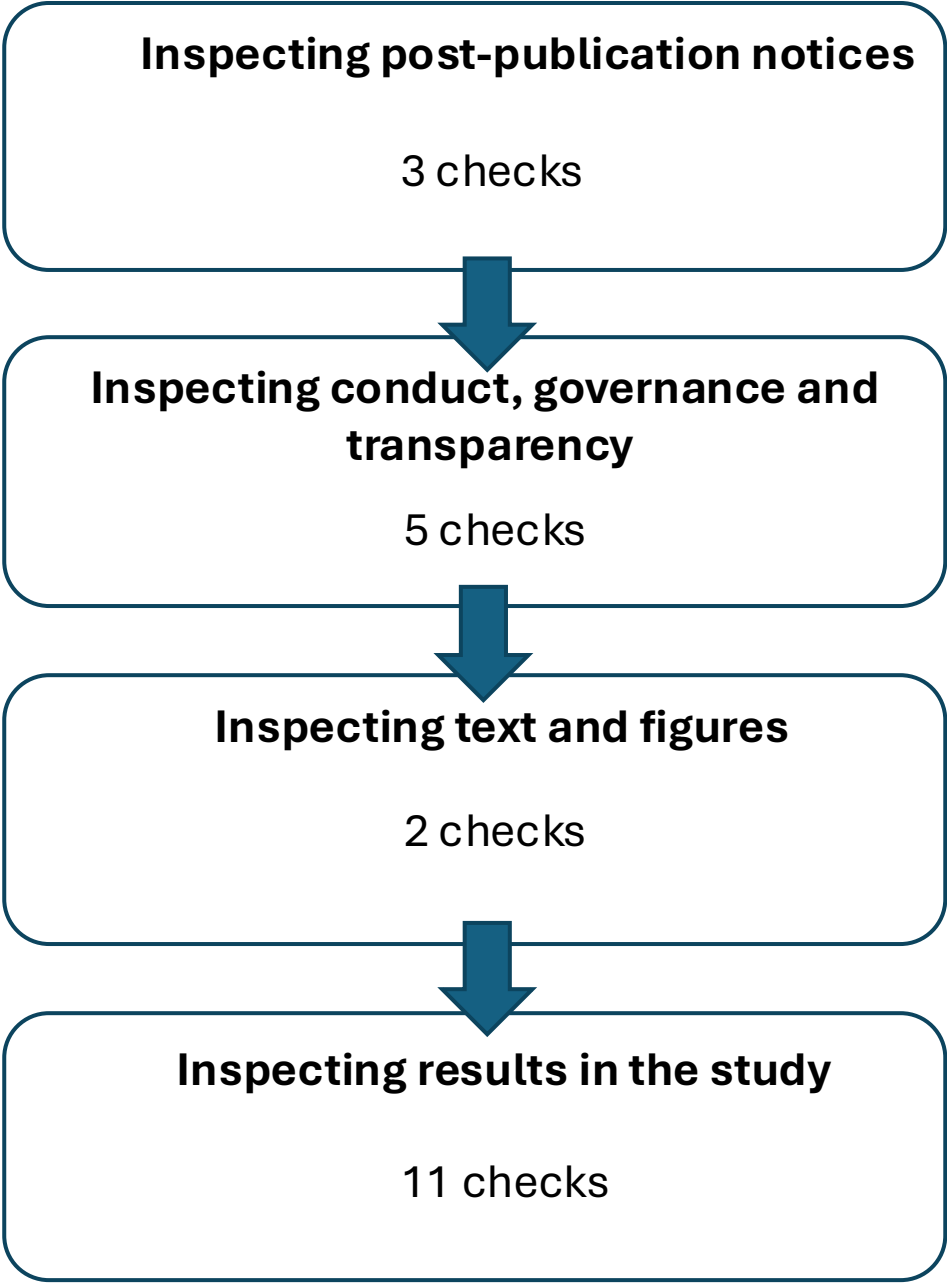
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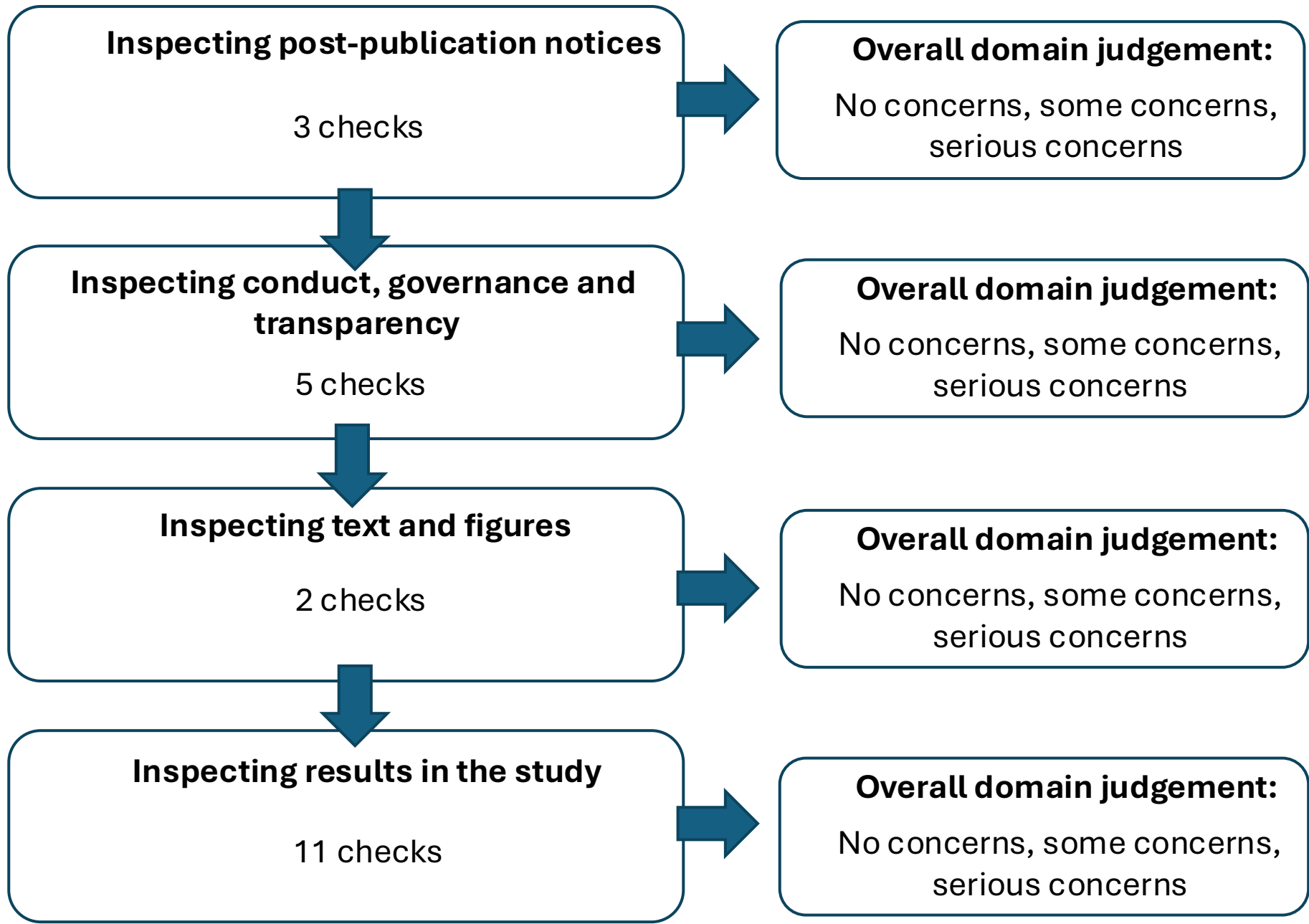


INveStigating ProBlEmatic Clinical Trials in Systematic Reviews

Aim: To develop a tool for identifying problematic randomised controlled trials in the context of health systematic reviews.







Inspecting post-publication notices
3 checks



Overall domain judgement:
No concerns, some concerns,
serious concerns

Inspecting conduct, governance and transparency
5 checks



Overall domain judgement:
No concerns, some concerns,
serious concerns

Inspecting text and figures
2 checks



Overall domain judgement:
No concerns, some concerns,
serious concerns

Inspecting results in the study
11 checks

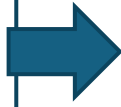


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Overall study judgement:
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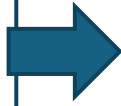
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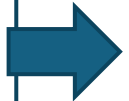


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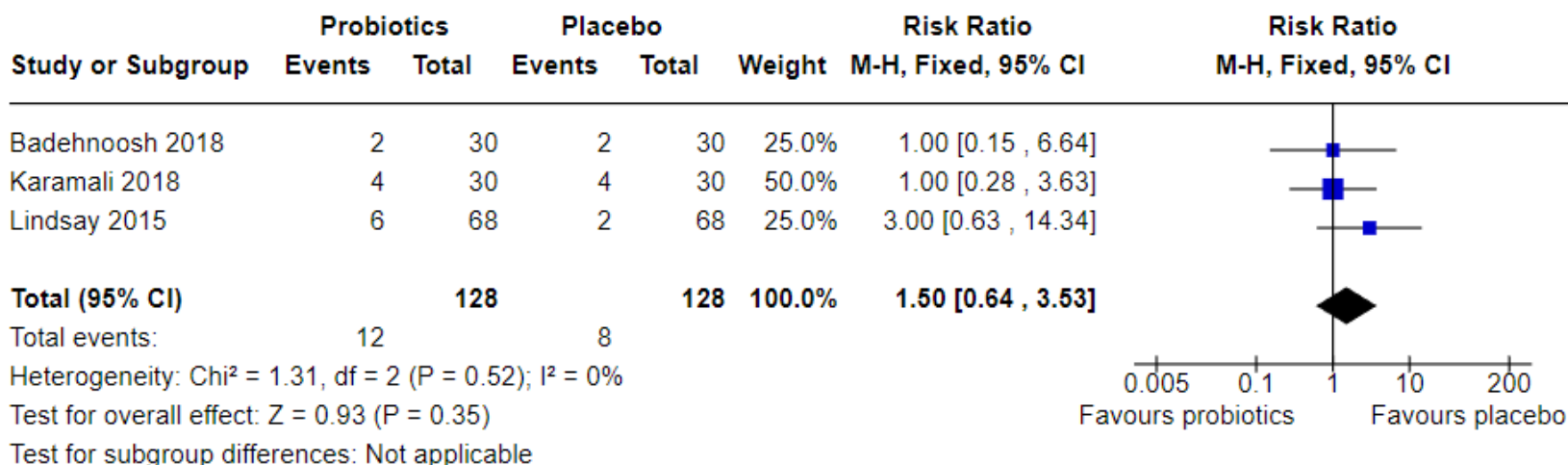
Probiotic treatment for women with gestational diabetes to improve maternal and infant health and well-being

✉ Karaponi AM Okesene-Gafa, Abigail E Moore, Vanessa Jordan, Lesley McCowan, Caroline A Crowther

Authors' declarations of interest

Version published: 24 June 2020 Version history

<https://doi.org/10.1002/14651858.CD012970.pub2>



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias): All outcomes	Blinding of outcome assessment (detection bias): All outcomes	Incomplete outcome data (attrition bias): All outcomes	Selective reporting (reporting bias)	Other bias
Ahmadi 2016	+	?	+	+	+	?	+
Badehnoosh 2018	+	?	+	+	+	?	+
Hajifaraji 2017	+	?	+	+	+	?	+
Jafarnejad 2016	+	?	+	+	+	?	+
Karamali 2016	+	?	+	+	+	?	+
Karamali 2018	+	?	+	+	+	?	+
Kijmanawat 2019	+	?	+	+	+	?	+
Lindsay 2015	+	+	+	+	+	?	+
Nabhani 2018	+	?	+	+	+	?	+

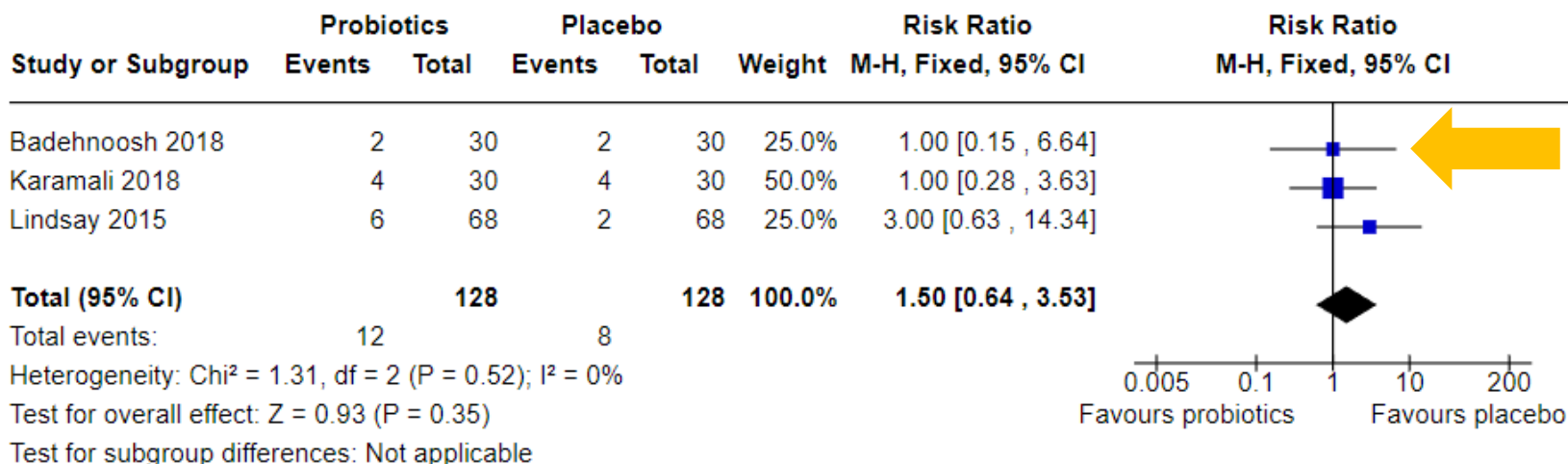
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Karamali 2018	+	?	+	+	+	?	+
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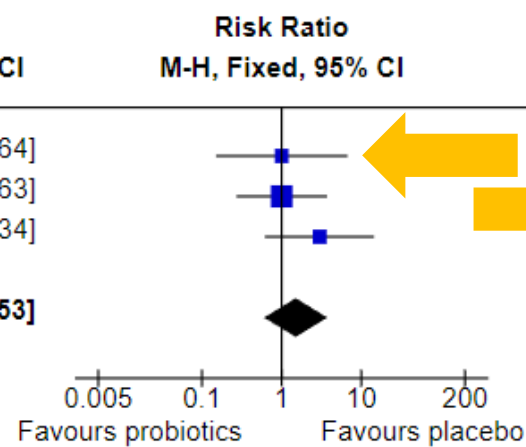
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Study or Subgroup	Probiotics		Placebo		Weight	Risk Ratio
	Events	Total	Events	Total		M-H, Fixed, 95% CI
Badehnoosh 2018	2	30	2	30	25.0%	1.00 [0.15 , 6.64]
Karamali 2018	4	30	4	30	50.0%	1.00 [0.28 , 3.63]
Lindsay 2015	6	68	2	68	25.0%	3.00 [0.63 , 14.34]
Total (95% CI)		128		128	100.0%	1.50 [0.64 , 3.53]
Total events:	12		8			
Heterogeneity: Chi ² = 1.31, df = 2 (P = 0.52); I ² = 0%						
Test for overall effect: Z = 0.93 (P = 0.35)						
Test for subgroup differences: Not applicable						



Ahmadi 2016
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Jafarnejad 2016	+	?	+	+	+	?	+
Karamali 2016	+	?	+	+	+	?	+
Karamali 2018	+	?	+	+	+	?	+
Kijmanawat 2019	+	?	+	+	+	?	+
Lindsay 2015	+	+	+	+	+	?	+
Nabhani 2018	+	?	+	+	+	?	+

Inspecting post-publication notices

Does the study have an associated retraction?

This study has recently been **retracted**.

RETRACTED ARTICLE: The effects of probiotic supplementation on biomarkers of inflammation, oxidative stress and pregnancy outcomes in gestational diabetes

Both the journal editorial team and the external statistical reviewer were unable to confirm the integrity of the trial design and the main outcome of the external review was that the article's conclusions are unreliable. Therefore, as the editorial team no longer have confidence in the reported conclusions the decision has been made to retract the article.

Does consideration of other studies from members of the research team highlight causes for concern?

Search on last author on Retraction Watch database: <http://retractiondatabase.org/>

Author(s):	<input type="text" value="Asemi, Zatollah"/>	Country(s):	<input type="text"/>
Title:	<input type="text" value="Type to search"/>		
Reason(s) for Retraction:	<input type="text"/>		
Subject(s):	<input type="text"/>	Article Type(s):	<input type="text"/>
Journal:	<input type="text"/>		
Publisher:	<input type="text"/>		
Affiliation(s):	<input type="text"/>		
Notes:	<input type="text"/>		
URL:	<input type="text"/>		

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Publisher:	<input type="text"/>		
Affiliation(s):	<input type="text"/>		
Notes:	<input type="text"/>		
URL:	<input type="text"/>		

Retraction or Other Notices
Title/Subject(s)/Journal — Publisher/Affiliation(s)/Retraction Watch Post URL(s)
50 Items Displayed Out of 72 Item(s) Found

Inspecting conduct, governance and transparency

Are there important inconsistencies between the publication and the registration documents?

- Retrospective registration, with **various inconsistencies** (e.g. recruitment period 6 months vs 1 month)
- Description of the control arm differs between paper and registration (later changed to match):

Description - English

Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 6 weeks orally.

Control group: Placebo (Tak Gen Zist, Tehran, Iran), daily, for 6 weeks orally.

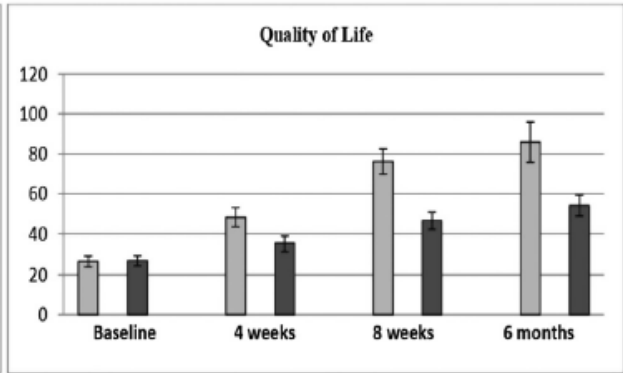
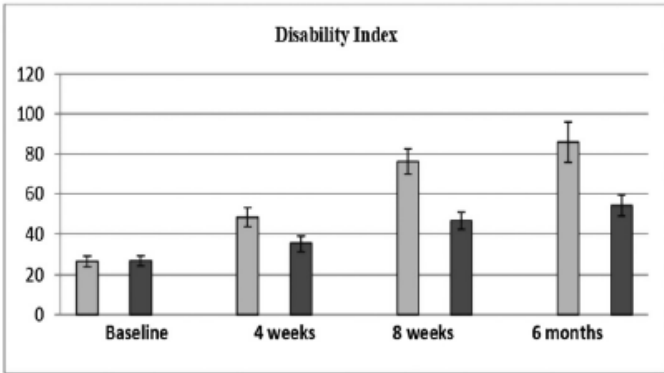
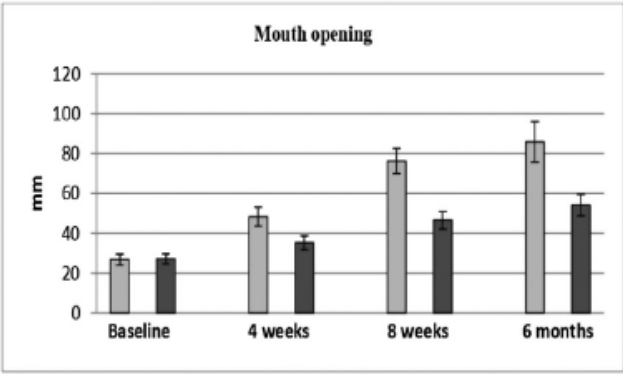
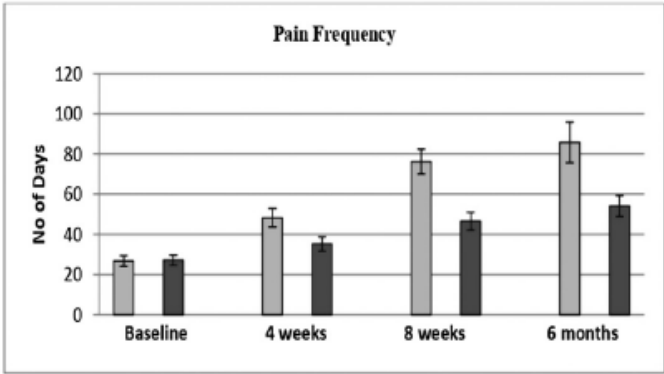
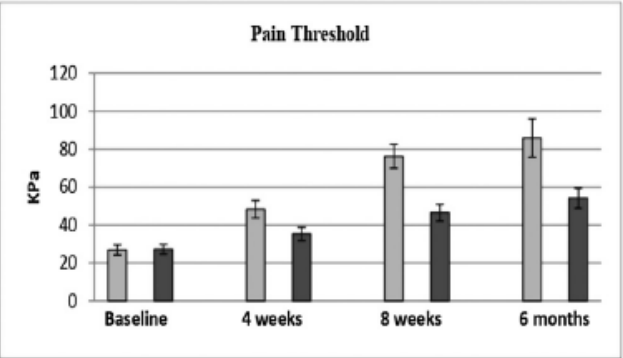
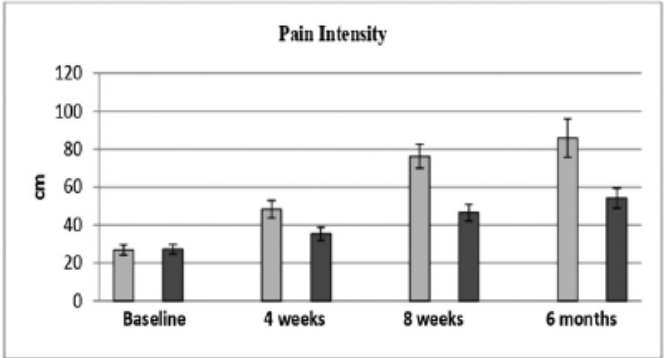
Description - Persian

گروه کنترل: پلاسبو (باریج اسانس، کاشان، ایران)، روزانه، به صورت خوراکی برای 6 هفته

گروه کنترل: پلاسبو (تک ژن زیست، تهران، ایران)، روزانه، به صورت خوراکی برای 6 هفته

Inspecting text and figures

Is there evidence of manipulation or duplication of figures?



Active Laser Group
 Placebo Laser Group

Inspecting results in the study

Are the means and variances of integer data impossible?

1-min Apgar score	8.93 ± 0.25	8.96 ± 0.18	.561
5-min Apgar score	9.93 ± 0.18	9.96 ± 0.18	.561
Newborns' hyperbilirubinemia (%)	8 (26.7)	2 (6.7)	.080 ^b
Newborns' hospitalization (%)	8 (26.7)	2 (6.7)	.080 ^b
Newborns' hypoglycemia (%)	3 (10.0)	2 (6.7)	>.999 ^b

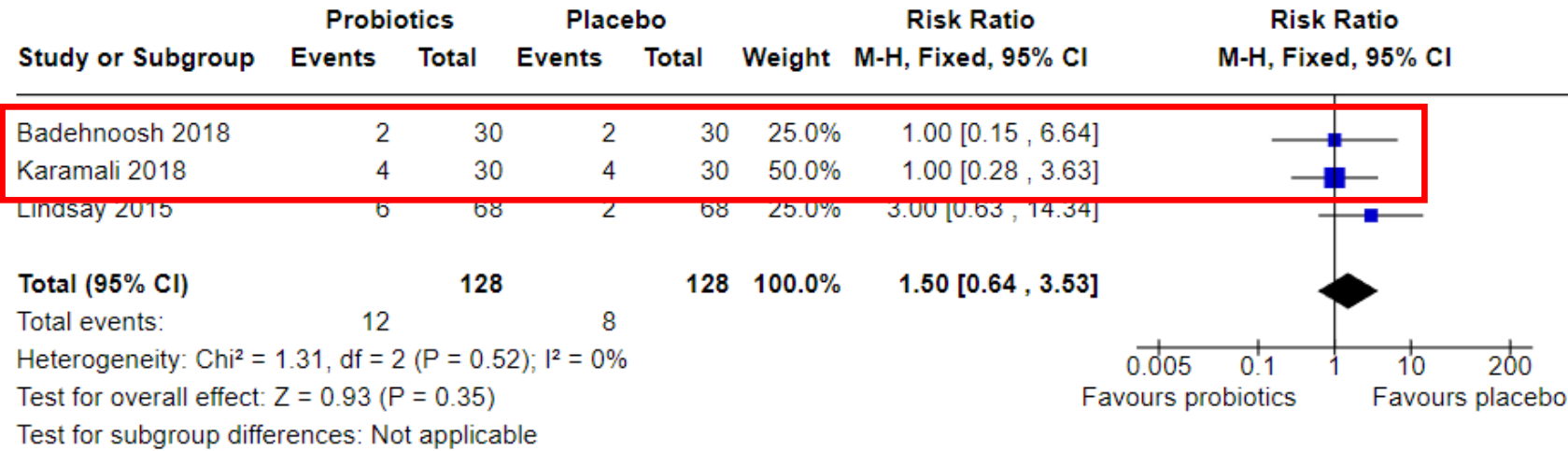
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Newborns' hypoglycemia (%)	3 (10.0)	2 (6.7)	>.999 ^b

- Apgar score is a variable which only takes **integer values** (1,2,3,4,5,6,7,8,9,10).
- The highlighted values **cannot occur** for the group sizes in the study.
- 'GRIM' and 'GRIMMER'

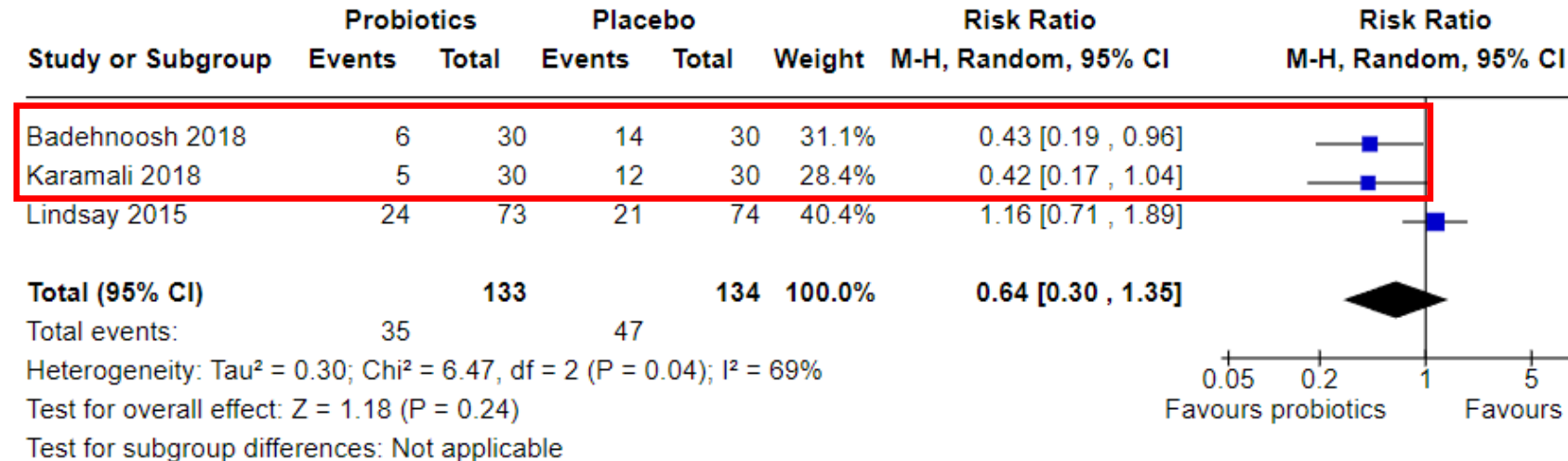
Hypertensive disorders



Are any outcome data, including estimated treatment effects, implausible?

- Karamali 2018 is another trial from same group.

Caesarian deliveries



- Almost identical risk ratios in the two studies (2 here, several other outcomes have identical effect estimates).

Domain	Check	Result
Inspecting post-publication notices	<i>Does the study have an associated retraction?</i>	Yes , this article has been retracted
	<i>Do other studies by the research team highlight causes for concern?</i>	Yes , the senior author has more than 50 notices on Retraction Watch
Inspecting conduct, governance, and transparency	<i>Are there important inconsistencies between the publication and the registration documents?</i>	Yes , various discrepancies, including recruitment dates and description of control intervention
Inspecting text and figures	<i>Is there evidence of manipulation or duplication of figures?</i>	NA , no figures in the manuscript
Inspecting results in the study	<i>Are the means and variances of integer data impossible?</i>	Yes , there are impossible means and variances for Apgar scores
	<i>Are any outcome data, including estimated treatment effects, implausible?</i>	Yes , results essentially identical in another RCT from this team, across multiple measures

Applying the draft INSPECT-SR tool would lead to **serious concerns** about the study's trustworthiness.



🔔 Follow this preprint

INSPECT-SR: a tool for assessing trustworthiness of randomised controlled trials

Jack Wilkinson, Calvin Heal, Ella Flemyng, Georgios A. Antoniou, Tony Aburrow, Zarko Alfirevic, Alison Avenell, Virginia Barbour, Vincenzo Berghella, Dorothy V. M. Bishop, Esmée M Bordewijk, Nicholas J. L. Brown, Jana Christopher, Mike Clarke, Darren Dahly, Jane Dennis, Patrick Dicker, Jo Dumville, Helen Frankish, Andrew Grey, Steph Grohmann, Lyle C. Gurrin, Jill A. Hayden, James A.J. Heathers, Kylie E Hunter, Ian Hussey, Lukas Jung, Emily Lam, Toby J. Lasserson, Sarah Lensen, Tianjing Li, Wentao Li, Jianping Liu, Elizabeth Loder, Andreas Lundh, Gideon Meyerowitz-Katz, Ben W. Mol, Florian Naudet, Anna Noel-Storr, Neil E. O'Connell, Lisa Parker, Rita F. Redberg, Barbara K. Redman, Rachel Richardson, Anna Lene Seidler, Kyle Sheldrick, Emma Sydenham, Madelon van Wely, Colby J. Vorland, Rui Wang, Stephanie Weibel, Matthias Wjst, Lisa Bero, Jamie J. Kirkham

doi: <https://doi.org/10.1101/2025.09.03.25334905>

Upcoming online training workshops:

- **April 30th** 6pm-8pm (London time, UK)
<https://www.trybooking.com/uk/GATM>
- **May 15th** 11am-1pm (London time, UK)
<https://www.trybooking.com/uk/GDRW>


- INSPECT-SR is now available
- Endorsed by Cochrane:
<https://www.cochrane.org/authors/methods-cochrane>
- An editable template and detailed guidance document are provided: <https://osf.io/b74wj>



Retracted: Randomized controlled trial of elevation of the fetal head with a fetal pillow during cesarean delivery at full cervical dilatation

 [Correction\(s\) for this article](#) ▾

 [Retraction\(s\) for this article](#) ▾

Subrata L. Seal, Alok Dey, Sannyashi C. Barman, Gourisankar Kamilya, Joydev Mukherji,
Joseph L. Onwude 

- RCT retracted – National Institute for Health and Care Excellence (NICE) subsequently reversed recommendation of this device.
- Royal College of Obstetrics and Gynaecology retracted Scientific Impact Paper
- See <https://doi.org/10.1111/1471-0528.18004>

- INSPECT-SR would have flagged problems ahead of retraction
- E.g. Numerical anomalies in the abstract and results

Results

Overall, 120 women were assigned to each group. Major uterine wound extensions occurred in 6 (5.0%) women in the Fetal Pillow group and 39 (32.5%) in the control group (relative risk 0.23, 95% confidence interval 0.11–0.48).

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Can you spot any problems in this RCT dataset?

	A	B	C	D	E	F
1	Surname and Name	Sex	Birthdate	Eye	Date of Surgery	Age at Surgery
2	Alison Green	M	05/06/1976	RE	11/08/2008	32
3	Jared Friedman	F	13/04/1997	LE	13/04/2015	17
4	Jessica Cohen	M	21/03/1976	RE	28/12/2008	32
5	Sara Young DDS	F	12/05/1964	LE	03/04/2010	45
6	Whitney Douglas	M	26/01/1974	RE	02/01/2009	34
7	Daniel Watkins	M	13/11/1987	RE	03/11/2006	18
8	Jennifer Johnson	M	05/08/1952	RE	31/07/2010	57
9	Tara Thompson	M	16/06/1999	RE	16/06/2017	18
10	Jennifer Dixon	M	30/11/1977	RE	14/03/2007	29
11	Susan Howe	M	19/04/1955	LE	04/04/2005	49
12	Daniel Mccarthy	F	11/10/1989	LE	30/04/2009	19
13	Bianca Boyd	M	07/11/1951	RE	02/05/2005	53
14	Lisa Kaufman	M	23/11/1996	RE	23/11/2014	17
15	Michael Stephen	M	06/10/1972	RE	21/07/2005	32
16	Robert Hill	F	05/08/1982	RE	18/08/2008	26
17	Caleb Grant	F	28/02/1971	RE	28/10/2008	37
18	Shawn Mccarty	F	28/02/1956	RE	31/05/2006	50
19	Jennifer Callahar	M	13/11/1975	RE	12/04/2006	30
20	Alexis Cortez	F	11/05/1954	LE	21/11/2008	54
21	Daniel Robertsor	M	05/11/1954	RE	21/07/2006	51
22	Susan Howe	F	22/09/1954	RE	11/06/2008	53
23	Vanessa Moore	F	01/10/1952	RE	13/05/2010	57
24	Brittany Poole	M M	15/10/1954	LE	31/07/2007	52
25	Angela Cunningh	F	06/06/1991	RE	06/06/2009	18
26	Joseph Robinson	M	07/10/1981	LE	02/10/2006	24
27	Jordan Reid	F	02/11/1983	LE	14/06/2005	21
28	Jordan Dunlap	M	01/04/1980	LE	05/02/2006	25
29	Dr. Susan Townse	M	19/04/1984	RE	14/09/2006	22
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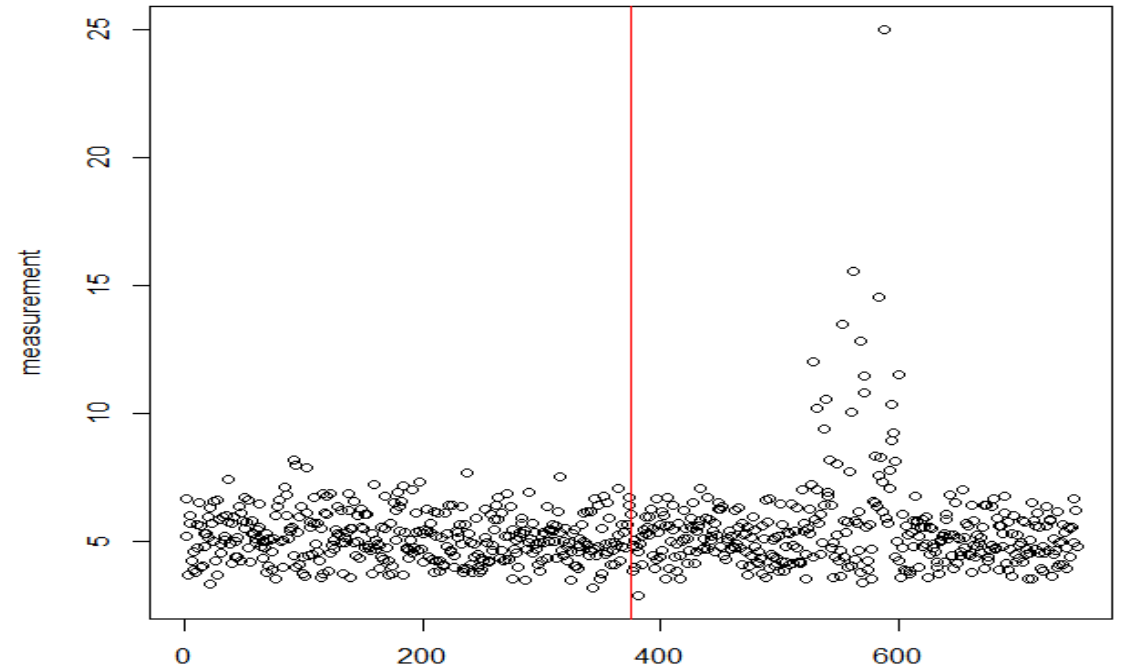
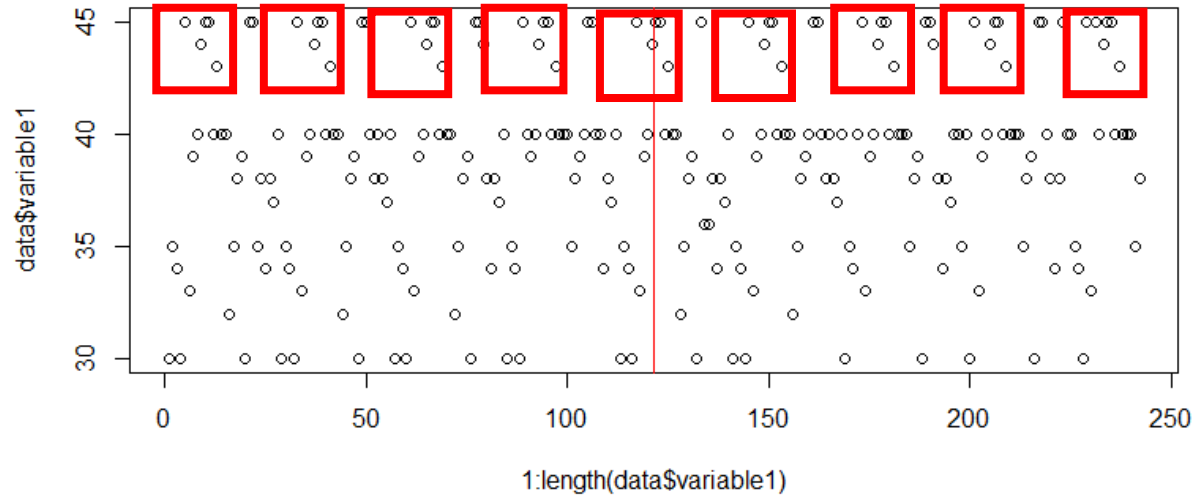
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- This dataset was actually created using artificial intelligence (ChatGPT)
- No correspondence between name and sex at all (e.g. Alison, Jessica, Whitney, Jennifer, Bianca all Male).
- Multiple eyes per person (fine), but we have people with two right eyes, people with different birthdays for each eye, and one person with five eyes (see M Wjst <https://tinyurl.com/3dmz fz8r>)
- Easy to spot **if we can see the underlying data**
- There is a real risk that LLMs will be used by lone fabricators and paper mills to produce more ambitious (convincing?) forgeries.

Individual participant data



- How to assess IPD when available?
- IPD Integrity tool (Hunter 2024: <https://doi.org/10.1002/jrsm.1738>)
- INSPECT-IPD – an extension to INSPECT-SR, is in development (Heal <https://doi.org/10.64898/2026.02.06.26345217>)





INSPECT-AI

INveStigating ProblEmatic Clinical Trials with AI

Start investigating, Goutham

Upload clinical trial PDFs to run automated integrity checks against INSPECT-SR tool.

 Start INSPECT-AI

Open INSPECT-SR Tool

Avenell and colleagues, University of Aberdeen,
Vorland, Indiana University

Received: 27 September 2024 | Revised: 6 December 2024 | Accepted: 9 December 2024

DOI: 10.1111/apa.17549

ORIGINAL ARTICLE



Closed-loop automated oxygen control in late preterm and term, ventilated infants: A randomised controlled trial

Ourania Kaltsoyianni^{1,2} | Allan Jenkinson^{1,2} | Christopher Harris^{1,2} | Eleanor Jeffreys² | Oishi Sikdar² | Anne Greenough¹ | Theodore Dassios^{1,2}

¹Women and Children's Health, School of Life Course Sciences, Faculty of Life Sciences and Medicine, King's College London, London, UK

²Neonatal Intensive Care Centre, King's College Hospital NHS Foundation Trust, London, UK

Correspondence
Theodore Dassios, Neonatal Intensive Care Centre, King's College Hospital NHS Foundation Trust, Denmark Hill, London SE5 9RS, UK.
Email: theodore.dassios@kcl.ac.uk

Funding information
National Institute for Health Research (NIHR) Biomedical Research Centre; Guy's and St Thomas' NHS Foundation Trust; King's College London

Abstract

Aim: To compare the time spent above the target oxygen saturation range ($SpO_2 > 96\%$) and the duration of supplemental oxygen between ventilated infants receiving closed-loop automated oxygen control (CLAC) or manual oxygen control in late preterm and term ventilated infants.

Methods: Infants were randomised to receive CLAC or manual oxygen control from recruitment and within 24 h of mechanical ventilation until successful extubation.

Results: Forty infants with a median (IQR) gestational age of 37.4 (35.9–38.5) weeks were studied at a corrected postmenstrual age of 37.6 (36.0–38.7) weeks. In infants randomised to CLAC ($n = 18$) the time spent above the target oxygen saturation range was reduced by 20% ($p < 0.001$), and the time spent in the target range (92%–96%) was increased by 32% ($p < 0.001$) and the time spent in hyperoxia was reduced ($p = 0.003$). CLAC reduced the time spent in hypoxemia ($SpO_2 < 85\%$) ($p = 0.017$) and there were fewer manual adjustments to the inspired oxygen concentration (FiO_2) ($p < 0.001$). There was no significant difference in the duration of supplemental oxygen ($p = 0.271$).

Conclusion: CLAC in ventilated infants born at or near term was associated with reduced time spent in hyperoxemia, more time spent in the target oxygen range, and fewer manual adjustments to the FiO_2 .

Check for updates

0

EOC/Correction Notices

0

PubPeer Comments

Expression of Concern & Correction Notices

No Concerns Found

SEARCH METHOD
DOI-based lookup

DOI (USED FOR SEARCH)
[10.1111/apa.17549](https://doi.org/10.1111/apa.17549)

TITLE
Closed-loop automated oxygen control in late preterm and term, ventilated infants: A randomised controlled trial

PubPeer Community Comments

No PubPeer Comments Found

This publication has no comments on PubPeer

Does the study have an associated expression of concern or other relevant post publication notice?

INSPECT-AI Suggestion: No

Yes

No

Unclear

N/A

Comments

No comments on webpage either

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✓ Q1.3 Research team concerns

Ctrl + /

Do other studies by the research team highlight causes for concern (retraction, expression of concern, relevant post-publication notices)?

7

Authors with No Mentions

0

Authors with Some Mentions

> Authors without Mentions in Retraction Watch (7)

Do other studies by the research team highlight causes for concern (retraction, expression of concern, relevant post-publication notices)?

INSPECT-AI Suggestion: No

Yes

No

Unclear

N/A

Clear

Comments

No concerns

Save comment

What's next?



- First-time users report median time of 45 minutes per RCT
- Can this be reduced with AI-assisted tools? (INSPECT-AI project)
- INSPECT-SR has been designed for RCTs, primarily in systematic review context
- Adaptations for journal context (INSPECT-JR), other study designs (e.g. NRSIs), and when IPD available (INSPECT-IPD)

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