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Practitioner Allegiance Risk Scale (PARS-6): Development of a Theory-Informed Instrument for Screening Investigator Allegiance-Related Risk Across Intervention Research

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Abstract

Background

Researcher allegiance — a personal, professional, financial, or cultural relationship between an investigator and the intervention under study — is a recognised but inconsistently screened source of potential bias in intervention research. Allegiance effects are well documented in psychotherapy outcome research, where reviews have found that researcher allegiance explains a substantial proportion of outcome variance in some analyses — a finding that, while contested in subsequent reviews, has never been definitively refuted. We did not identify a broadly used, structured instrument specifically designed to document investigator allegiance-related characteristics during systematic-review data extraction across intervention fields.

Methods

This paper describes the theoretical grounding and development of PARS-6 (Practitioner Allegiance Risk Scale) Version 2.0 — a theory-informed, six-item candidate instrument developed for use during data extraction in systematic reviews of intervention research. Instrument development followed a structured process comprising: (1) theoretical model specification across three allegiance-related risk pathways; (2) item generation from documented allegiance-risk constructs anchored to the published literature; (3) operational definition of each item with behavioural anchor statements; (4) a four-step decision tree distinguishing confirmed absence (0) from unreported information (U); (5) a confidence rating layer (High/Moderate/Low) applied to each item score; (6) a bidirectional allegiance frame acknowledging both pro- and anti-intervention allegiance; and (7) an embedded inter-rater reliability documentation record. Each item is scored independently by at least two trained reviewers following a mandatory calibration exercise, with disagreements resolved by discussion or third-party adjudication.

Results

The development process yielded six items — each scored on a three-option decision rule (present/confirmed absent/unreported) with a mandatory confidence rating (High/Moderate/Low) — producing an Allegiance Risk Index (ARI) ranging from 0 to 6. The ARI is a descriptive count of documented allegiance-related characteristics; it is not a measure of bias occurrence or magnitude. PARS-6 records documented investigator allegiance-related characteristics; it does not determine whether allegiance bias occurred, quantify bias magnitude, establish study validity, or justify study exclusion. The six items address: tradition affiliation, funding source, COI disclosure, comparator disadvantaging, intervention development role, and prior public advocacy. For the MBM Lifespan Series application, a prespecified threshold of ≥ 4 documented items triggers a sensitivity analysis; this threshold is provisional and should not be generalised without prospective justification. A reflexive worked example applying PARS-6 to the development team produced an Allegiance Risk Index of 1/6,

illustrating transparent self-application. An illustrative composite worked example demonstrates PARS-6 application across a hypothetical study context; cross-study applicability and reliability require empirical assessment across multiple systematic reviews and intervention fields. Initial content-validity evidence was developed through a theory-to-item construct map anchoring each item to the published allegiance-bias literature. Independent expert assessment, inter-rater reliability studies, construct validity testing, and criterion-related validation remain necessary before PARS-6 can be considered validated.

Conclusions

PARS-6 Version 2.0 is a theory-informed candidate instrument for use in systematic-review data extraction and other evidence-synthesis contexts. Independent studies should evaluate its content validity, feasibility, inter-rater reliability, construct validity, criterion-related validity, threshold calibration, and performance across intervention fields. To the authors' knowledge, based on targeted literature review rather than formal systematic search, no prior allegiance screening instrument has combined a theoretical model, confidence ratings, bidirectional allegiance framing, a responsible reporting framework, and an ethics statement. PARS-6 is freely available under CC0 licence at doi.org/10.17605/OSF.IO/NY94H. Research teams applying PARS-6 are invited to register their application at forms.gle/rfJJVpyceF77DzVz9 to contribute to prospective validation of the Allegiance Risk Index.

Plain Language Summary

Researchers who study treatments they personally practise, financially benefit from, or publicly advocate for may unconsciously produce more favourable results — a phenomenon called investigator allegiance bias. This is well documented in psychotherapy research but no standard tool exists to screen for it across all research fields. PARS-6 (Practitioner Allegiance Risk Scale) is a six-item instrument that produces an Allegiance Risk Index (ARI) — a structured score of allegiance-relevant relationships between investigators and the interventions they study. Reviews that apply PARS-6 can test whether removing studies meeting the prespecified ARI sensitivity-analysis threshold changes their conclusions. PARS-6 is theoretically grounded, field-agnostic, freely available, and is the first allegiance screening tool to include confidence ratings, bidirectional allegiance framing, and an ethics statement. It is released as a living instrument with an open application registry for ongoing validation.

Introduction

Investigator allegiance — the personal, professional, financial, or cultural alignment between a researcher and the intervention they study — is a construct extensively discussed in psychotherapy outcome research and less consistently operationalised in systematic reviews of intervention research. The phenomenon is well established in psychotherapy outcome research, where allegiance has been found

to predict effect size direction and magnitude across hundreds of comparative trials. Despite this evidence base, no structured, validated instrument exists for screening allegiance bias across research fields — leaving systematic reviewers without a standard tool for documenting or adjusting for this source of between-study variance. The consequence is an inconsistency gap: two review teams examining the same evidence base may reach different conclusions about allegiance-related characteristics using informal, undocumented approaches — with limited basis for reconciliation.

Existing approaches to allegiance assessment have been informal and study-specific. Munder et al. 2013 [2]; Munder et al. 2011 [3] coded allegiance narratively from study descriptions — a valid but non-standardised approach that cannot be replicated consistently across review teams. Standard risk-of-bias tools (RoB 2 [10], ROBINS-I [11]) address methodological conduct within studies but explicitly exclude investigator allegiance from their scope. Conflict of interest disclosure requirements (ICMJE [15]) address financial relationships but not experiential or reputational allegiance. The result is a systematic gap in evidence synthesis methodology: allegiance-relevant relationships are acknowledged in principle but screened in practice only when reviewers choose to address them — and without a standard instrument for doing so.

PARS-6 (Practitioner Allegiance Risk Scale) was developed to close this gap. This paper reports the development of PARS-6 Version 2.0 — a theory-informed, six-item candidate instrument designed for adaptation across intervention research fields, producing an Allegiance Risk Index (ARI) for use during data extraction in systematic reviews of intervention research. The aims of this paper are: (1) to describe the three-pathway theoretical model underpinning item selection; (2) to present operational definitions, behavioural anchor statements, and decision rules for each item; (3) to establish content validity through theoretical construct mapping; (4) to demonstrate applicability through reflexive and external worked examples; and (5) to establish the infrastructure — an application registry, calibration exercise, and living instrument framework — for prospective criterion validity development.

1. Purpose, Scope, and User Specification

1.1 Purpose

PARS-6 is a structured screening instrument that measures allegiance-relevant relationships between investigators and the interventions they study. It produces an Allegiance Risk Index (ARI) — a documentable, auditable summary of the structural conditions associated with allegiance-related bias in the published literature.

Critical distinction — Allegiance versus Bias

PARS-6 measures allegiance — the documented presence of personal, professional, financial, or cultural relationships between investigators and the intervention under study. It does not measure bias directly. High PARS-6 scores indicate the presence of structural conditions associated with allegiance-related risk in the existing literature. They do not confirm that bias occurred in any specific study Leykin & DeRubeis

2009 [9]. A researcher whose study meets the prespecified ARI threshold may still produce unbiased findings — for example, where methodological safeguards such as pre-registration, independent outcome assessment, and rigorous blinding are in place, or where the study findings are unfavourable to the intervention despite the researcher's personal investment. A researcher can have high allegiance (4/6) and produce unbiased findings. A researcher can have zero documented allegiance-related characteristics and produce biased findings through other mechanisms — for example, inadequate blinding, selective outcome reporting, or publication pressure independent of personal investment in the intervention. This distinction is fundamental to appropriate interpretation of PARS-6 scores.

Non-stigmatisation statement

A high PARS-6 score does not constitute evidence of misconduct, dishonesty, or reduced scientific value. It documents allegiance-relevant relationships that should be considered in sensitivity analysis. PARS-6 documents allegiance-relevant relationships. It does not adjudicate — it makes no judgment about whether bias occurred, whether findings are invalid, or whether any researcher acted inappropriately.

1.2 Primary User Specification

PARS-6 Version 2.0 is designed for use by trained systematic review data extractors — researchers who have completed the PARS-6 calibration exercise, read this manual in full, and are working within a preregistered systematic review protocol.

PARS-6 is NOT designed for:

- • **Journal peer reviewers** assessing individual manuscripts for publication
- • **Research integrity officers** investigating misconduct allegations
- • **Clinicians** evaluating whether to trust a specific published study
- • **Meta-analysts** without completing the calibration exercise first

Users outside the intended context should consult the PARS-6 application guidance at osf.io/ny94h before applying the instrument.

1.3 Scope of Application

PARS-6 is applicable across various intervention research fields:

- • **Contemplative and mind-body interventions** (mantra, meditation, yoga, prayer, mindfulness)
- • **Pharmacological research** (drug trials, vaccine research)
- • **Surgical and device research** (operative techniques, medical devices)
- • **Psychotherapy and behavioural interventions** (CBT, psychodynamic, EMDR)
- • **Nutritional and lifestyle interventions** (dietary, exercise, sleep)

Note

PARS-6 is most informative in research areas where the intervention has an identifiable tradition, developer, or organisational promoter. In research areas where the intervention has no such origin (e.g., generic pharmacological agents with no commercial sponsor), some items may be systematically unreportable. See Section 5 *for cross-field application guidance.*

1.4 Scope of Inference — Study Design Considerations

The allegiance effects most clearly documented by Luborsky et al. 1999 [1] and Munder et al. 2013 [2]; Munder et al. 2011 [3] are those detected in comparative trial designs where the researcher's preferred treatment is one of two or more conditions. In single-arm and pre-post studies — which constitute a substantial proportion of the contemplative science literature — the allegiance mechanism operates differently: rather than tipping the balance between conditions, allegiance may influence outcome measure selection, reporting thresholds, attrition handling, and publication decisions.

PARS-6 captures the structural antecedents of allegiance risk regardless of study design. However, the functional impact of a given PARS-6 score may differ between comparative and non-comparative designs. In comparative studies, allegiance may operate through comparator selection and differential dosing (Item 4); in single-arm designs, Item 4 is scored U and the allegiance pathway operates primarily through tradition affiliation and prior advocacy rather than comparator structuring. This distinction should be noted when interpreting sensitivity analyses in mixed-design systematic reviews.

2. Theoretical Model — Three Pathways of Allegiance Bias

PARS-6 is grounded in a three-pathway model of allegiance bias transmission. The three pathways are theoretically independent — a researcher may have experiential allegiance without institutional allegiance, or reputational allegiance without either. PARS-6 captures all three pathways simultaneously, enabling systematic reviewers to distinguish between types of allegiance risk rather than treating all allegiance as equivalent.

Pathway	Mechanism	PARS-6 Items	Theoretical Basis
Pathway 1 — Experiential	Researchers who personally practice an intervention develop embodied knowledge that predisposes them toward positive interpretation of ambiguous findings.	Items 1, 5	Luborsky et al. 1999 [1]; Munder et al. 2013 [2]; Munder et al. 2011 [3]; Leykin & DeRubeis 2009 [9]
Pathway 2 — Institutional	Researchers embedded in organisations that promote, deliver, or fund an intervention face structural incentives — career advancement, continued funding, institutional reputation — that create systematic pressure toward favourable findings.	Items 2, 3, 4	Bhandari et al. 2004 [4]; Ridker & Torres 2006 [5]
Pathway 3 — Reputational	Researchers who have publicly advocated for an intervention face cognitive dissonance pressure — the documented human tendency to interpret evidence in ways consistent with prior public commitments.	Items 4, 6	Festinger 1957 [6]; Pronin et al. 2002 [7]; Greenwald 1980 [13]

** Item 4 (Comparator Disadvantaging) loads onto both Pathway 2 and Pathway 3 because comparator disadvantaging may reflect either institutional structural incentives or reputational commitment to the intervention's superiority — mechanisms that are theoretically distinct but observationally indistinguishable from published information alone.*

2.1 Bidirectional Allegiance

PARS-6 Version 2.0 acknowledges that allegiance bias can operate in two directions:

Pro-intervention allegiance

The researcher wants the intervention to succeed. This is the primary direction screened by PARS-6 Items 1–6.

Anti-intervention allegiance

The researcher wants the intervention to fail. A committed sceptic — a pharmacologist who believes a practice is pseudoscience, or a researcher with financial ties to a competing intervention — has allegiance risk in the opposite direction.

Version 2.0 addresses anti-intervention allegiance through the Direction field in the scoring record. Systematic reviewers should apply equivalent scrutiny to studies where anti-intervention allegiance is plausible — including studies funded by competing industries, conducted by researchers with documented opposition to the tradition, or published in journals with editorial positions against the intervention type. A full Anti-Allegiance Module is designated for development in PARS-6 Version 3.0.

3. The Six Items — Operational Definitions and Anchor Statements

3.1 Item Selection Rationale

The six items were selected on three criteria: (1) each must be documentable from publicly available information without access to unpublished materials; (2) each must capture an investigator-intervention relationship that is structurally independent of study quality; and (3) each must be theoretically anchored to one or more of the three allegiance-related risk pathways specified in Section 2.

3.2 Content Validity Mapping

Item	Theoretical Construct	Evidence Base	Pathway	Precedent
1 — Tradition affiliation	Experiential allegiance	Luborsky 1999; Munder 2013 [1,3]	P1	ICMJE [15]; ROBINS-I [11]
2 — Funding source	Financial allegiance	Bhandari 2004; Ridker 2006 [4,5]	P2	ICMJE [15]; CONSORT
3 — COI disclosure	Institutional allegiance	ICMJE 2019 [15]	P2	ICMJE [15]; RoB 2 [10]
4 — Comparator disadvantaging	Institutional + reputational	Munder 2013 [2]	P2 + P3	ROBINS-I [11]
5 — Development role	Experiential + institutional	Leykin & DeRubeis 2009 [9]	P1 + P2	FDA disclosure
6 — Prior public advocacy	Reputational allegiance	Festinger 1957 [6]; Pronin 2002 [7]	P3	Norcross 2011 [14]

3.3 Scale Type

PARS-6 employs a cumulative risk scoring approach — each item contributes equally to a total Allegiance Risk Index (ARI) ranging from 0 to 6. This design reflects the theoretical assumption that each allegiance-relevant relationship constitutes an independent and additive source of risk, PARS-6 uses an unweighted item count for transparency and ease of application. The count is not a clinical prediction score, and its item weights, threshold, measurement properties, and association with study outcomes have not yet been empirically established. PARS-6 yields a structured, transparent summary of potential investigator-allegiance risk to support prespecified sensitivity analyses and interpretation; it is not a determination that allegiance bias occurred.

The equal weighting of items is a deliberate simplification — it prioritises feasibility and inter-rater reliability over differential weighting, which would require empirical calibration data not yet available for allegiance risk in systematic reviews. Differential weighting is designated for investigation in PARS-6 Version 3.0 validation studies.

3.4 Item Definitions, Anchor Statements, and Field-Adaptive Guidance (see Additional file 2 — Scoring Reference Table)

Item 1 — Tradition Affiliation (Pathway 1 — Experiential)

Score	Anchor Statement
1 — Present	Author self-identifies as practitioner in paper, registry, institutional profile, or any publicly available source; OR author's publication record demonstrates a sustained identity association with the tradition predating the study.
0 — Confirmed absent	After completing all four steps of the decision tree (Section 4.2), no tradition affiliation is identified AND the paper includes an explicit COI statement with no tradition affiliation declared.
U — Unreported	Author information is insufficient to determine affiliation status after completing all four decision tree steps. Score U when no COI statement is present and no biographical information is publicly available.

Field-adaptive guidance

In pharmacological and device research, score Item 1 as 1 when an author has a foundational intellectual or professional identity associated with the intervention that predates the study. In contemplative research, this includes tradition membership, practice initiation, and lineage association. In surgical research, this includes being the operative technique's originator.

Item 2 — Funding Source (Pathway 2 — Institutional)

Score	Anchor Statement
1 — Present	Study received funding, in whole or in part, in the past 36 months from an organisation with a financial or institutional interest in the intervention's adoption, commercialisation, or favourable evaluation. Include: research grants, salary support, equipment provision, free intervention delivery, or in-kind support from tradition-promoting organisations.
0 — Confirmed absent	Funding source is explicitly disclosed as independent of any tradition-promoting or commercially interested organisation AND no contrary evidence is found in decision tree Steps 1–4.
U — Unreported	No funding statement is present in the paper or trial registration record.

Temporal window

The 36-month window is consistent with ICMJE COI disclosure standards [15], FDA disclosure requirements, and CONSORT financial disclosure guidance.

Item 3 — COI Disclosure (Pathway 2 — Institutional)

Score	Anchor Statement
1 — Present	Author COI disclosures (or their documented absence) indicate a financial, employment, advisory, equity, or organisational relationship with the intervention, its developer, or a commercial entity promoting it in the past 36 months.
0 — Confirmed absent	Explicit COI statement declares no such relationships AND no contrary evidence is found in decision tree Steps 1–4.
U — Unreported	No COI statement is present in the paper.

Organisational sub-classification for Item 1 (record in notes field only —does not modify score)

Occasional participant · Volunteer/informal member · Formal member · Office-holder/board member · Employed or contracted. This sub-classification documents the nature of affiliation for future validation research and does not affect the scoring of Item 1 or another item.

Item 4 — Comparator Disadvantaging (Pathway 2 + 3)

Score	Anchor Statement
1 — Present	The study design, comparator selection, or dosing of the comparator condition appears structured in a way that disadvantages the comparator relative to standard practice in the field. Includes: underdosed active comparators, non-standard comparator protocols, or waitlist controls where active comparators exist.
0 — Confirmed absent	Comparator is consistent with field-standard practice as documented in contemporaneous clinical guidelines or systematic reviews.
U — Unreported	Insufficient comparator detail to assess adequacy; or no comparator (single-arm study — score U, not 0).

Note

Item 4 requires a clinical or methodological judgment about comparator adequacy and is the item most likely to generate inter-rater disagreement. All Item 4 disagreements should default to third-party adjudication rather than resolution by discussion alone.

Item 5 — Intervention Development Role (Pathway 1 + 2)

Score	Anchor Statement
1 — Present	One or more authors played a direct role in developing, formalising, certifying, or commercialising the specific protocol or technique being evaluated. Score 1 if this relationship creates ongoing professional dependency, loyalty, or reciprocal obligation.
0 — Confirmed absent	No author played a development role AND no contrary evidence found in decision tree Steps 1–4.
U — Unreported	Training history and development role are not publicly available after completing all four decision tree steps.

Field-adaptive guidance: In contemplative research: writing or formally formalising the practice manual, training and certifying teachers, or holding a recognised teaching lineage position with formal authority over the practice. Note: receiving initiation or practising the tradition is captured by Item 1 — not Item 5. In pharmacological research: postdoctoral fellowship or formal mentorship under the intervention's inventor. In psychotherapy research: certification in the modality being tested. In surgical research: training as the operative technique's primary apprentice.

Item 6 — Prior Public Advocacy (Pathway 3 — Reputational)

Score	Anchor Statement
1 — Present	Author(s) have a documented public record — publications, talks, media appearances, or organisational leadership — of advocating for the intervention's efficacy prior to the study's commencement of data collection. 'Prior' means before data collection began, regardless of publication date. When the data collection start date is not available, use the study registration date as reference. If no registration date exists, use the paper's submission date as a conservative proxy. Document which reference date was used in the IRR record.
0 — Confirmed absent	No public advocacy record found in decision tree Steps 1–4 AND no mention of prior advocacy in the paper itself.
U — Unreported	Insufficient publicly available information to determine advocacy history.

Advocacy sub-classification for Item 6 (record in notes field only): Promotional advocacy (public talks, media appearances, social media, and popular-press publications promoting the intervention to non-academic audiences) vs Implementation advocacy (clinical guideline committees, policy bodies, government advisory panels, and professional society position statements recommending adoption). This distinction does not modify the item score but should be documented in the IRR record for future validation studies.

Important limitation

Self-reported perceived influence (as used in some COI instruments) is not used in PARS-6 Item 6. The bias blind spot literature (Pronin et al., 2002 [7]; Scopelliti et al., 2015 [8]) demonstrates that people systematically underestimate their own biases while accurately perceiving bias in others. Self-reported perceived influence is therefore potentially inversely correlated with actual allegiance risk in the most affected researchers. PARS-6 uses only documentable public advocacy records, not self-assessment.

4. Scoring, Application, and the Allegiance Risk Index

4.1 The Allegiance Risk Index (ARI)

The PARS-6 total score represents the study's Allegiance Risk Index (ARI) — a structured, documentable summary of the allegiance-relevant relationships present in the investigator team at the time of study conduct. The ARI ranges from 0 (no documented allegiance-relevant relationships) to 6 (all six allegiance-relevant relationship types documented).

The ARI is not a continuous measure of bias magnitude. It is an ordinal index of structural allegiance risk. A score of 4/6 does not mean twice the bias of 2/6 — it means four independent allegiance-relevant relationship types are documented.

4.2 Four-Step Decision Tree — Scoring Each Item

For each item, reviewers must complete all four steps before assigning a score. A score of 0 (confirmed absent) requires active confirmation — not merely failure to find evidence of presence.

Application workflow (Fig. 1). Figure 1 summarises the PARS-6 workflow for use during systematic-review data extraction. At least two trained reviewers independently assess each item using the defined evidence sources and decision rules, record the score and confidence rating, reconcile disagreements according to the protocol, and report both documented items and unreported information. The resulting ARI may be used to trigger a prospectively specified sensitivity analysis; it must not be interpreted as proof that allegiance bias occurred.

- • **Step 1** Read the full published paper including title page, methods, acknowledgements, COI disclosure, and author affiliations.
- • **Step 2** Check the trial registration record (ClinicalTrials.gov, ISRCTN, or equivalent) for any additional COI or affiliation disclosures.
- • **Step 3** Check the corresponding author's institutional profile page and any publicly available biographical information.
- • **Step 4** If the item remains unresolvable after Steps 1–3, score as U (unreported). Only after completing all four steps should an item be scored 0 (confirmed absent).

4.3 Confidence Rating Layer

Each item score is accompanied by a mandatory confidence rating:

Rating	Definition	Example
H — High	Information explicitly stated in the paper, trial registry, or author's own institutional profile.	Author states 'I am an initiated TM practitioner' in the COI statement.
M — Moderate	Information inferred from multiple indirect sources that consistently point in the same direction.	Author's institutional affiliation, publication record, and acknowledgements all suggest tradition membership, though none states it explicitly.
L — Low	Information inferred from a single indirect source with no corroborating evidence.	Author's institution is located in a region strongly associated with the tradition, but no personal affiliation information is publicly available.

Note

A PARS-6 score of 4/6 where all four triggered items are rated H (High confidence) is methodologically very different from a 4/6 where two items are rated L (Low confidence). Report confidence ratings alongside item scores in supplementary materials.

4.4 Threshold and Sensitivity Analysis

For the MBM Lifespan Series application, a prespecified threshold of ≥ 4 documented items triggers a sensitivity analysis; this threshold is provisional and should not be generalised without prospective justification. The threshold was selected on the following theoretical basis: score for the MBM Lifespan Series application, the protocol prespecified an ARI threshold of ≥ 4 documented items as a trigger for sensitivity analysis. This operational threshold is provisional, is not a validated risk category, and should not be generalised to other reviews without prospective justification — the simultaneous presence of allegiance-relevant relationships across multiple pathways, creating conditions under which allegiance effects documented in the literature are most likely to manifest.

Threshold calibration note

The ≥ 4/6 threshold is provisional. It was set by the development team rather than derived from empirical calibration. It should be treated as provisional pending reliability and criterion validity data from the PARS-6 Application Registry. Research teams with field-specific reasons to prefer a different threshold may preregister an alternative before applying PARS-6.

Small review calibration

When > 50% of included studies score ≥ 4/6, the sensitivity analysis should be supplemented with a narrative statement acknowledging that the evidence base itself is substantially allegiance-affected. In

reviews with fewer than ten included studies, individual study ARI scores should be presented in the main results table rather than supplementary materials.

4.5 Author Coverage Protocol

PARS-6 is applied to the first author and corresponding/senior author as a minimum. When the data extraction or statistical analysis team differs from listed authorship and this information is available, PARS-6 should additionally be applied to those authors.

Team Allegiance Note: When all listed authors share the same institutional affiliation with a tradition-affiliated organisation, append to the PARS-6 record: 'Team-level allegiance: all authors share institutional affiliation with organisation. Individual ARI scores may underestimate team-level allegiance risk.' This note is qualitative and does not modify the numeric ARI.

4.6 Historical Allegiance Guidance

PARS-6 screens allegiance-relevant relationships as they existed at the time of study conduct — not at the time of systematic review data extraction. When evidence suggests that an allegiance-relevant relationship has ended since the study was conducted, this should be noted in the PARS-6 record but does not change the item score. The allegiance risk documented by PARS-6 reflects the conditions under which the study was conducted.

4.7 Multi-Publication Study Guidance

PARS-6 is applied once per study — not once per publication. When a study appears in multiple publications (protocol, primary outcomes, secondary outcomes, follow-up), PARS-6 is applied to the primary outcomes paper. The score applies to all publications from the same study. If allegiance-relevant relationships change across publications, the higher score applies across all publications from that study.

4.8 Missing Author Information Protocol

When author biographical information is unavailable after completing all four decision tree steps, all items should be scored U rather than 0. The total score should be reported as U/6 (meaning: insufficient information to score — not equivalent to 0) rather than 0/6. Studies with three or more U scores should be flagged as 'insufficient information to assess allegiance risk' — a distinct category from low-allegiance (0–3/6) and high-allegiance (≥ 4/6) studies.

5. Cross-Field Application Guide

Field	Most Relevant Items	Rarely Applicable	Special Considerations
Contemplative / spiritual	1, 4, 5, 6	2 (financial — often underdisclosed; verify tradition-specific funding)	Cultural allegiance — Item 1 should note ethnic or religious background. Writing or formalising the practice manual, or training and certifying teachers, is the primary Item 5 trigger. Receiving initiation alone is captured by Item 1.
Pharmacological / device	2, 3, 6	1, 5 (tradition not applicable)	Industry funding is primary pathway. Item 5 should include patent royalties and inventor relationships.
Surgical / procedural	2, 4, 6	1, 5	Inventor allegiance is primary. Item 2 should include device company equity and consultancy fees.
Psychotherapy / behavioural	1, 3, 5, 6	2 (financial — often underdisclosed; verify tradition-specific funding)	Developer allegiance is primary — same researcher develops and tests the manual. Item 5 is frequently triggered.
Nutritional / lifestyle	2, 3, 6	1, 5	Industry funding and commercial product allegiance dominant. Item 1 rarely applicable.

6. Inter-Rater Reliability, Calibration, and Embedded IRR Record

6.1 Pre-Application Calibration Exercise

Before applying PARS-6 independently, all reviewers must complete a calibration exercise using the worked examples provided at osf.io/ny94h. A calibration set of four published studies with reference ARI scores spanning 0/6 to 4/6 is deposited at doi.org/10.17605/OSF.IO/YVZP4. Reviewers whose calibration scores total calibration ARI differs from the reference ARI by ≥ 2 points should discuss their interpretation with the review PI before beginning independent scoring. This calibration exercise must be documented and reported in the methods section of any systematic review applying PARS-6.

6.2 Embedded IRR Documentation Record

The following fields must be completed for each included study scored with PARS-6:

Field	Entry
Study identifier	
Screener 1 name + ARI	/6
Screener 2 name + ARI	/6
Items with disagreement	
Resolution method	□ Discussion - □ Third-party adjudication
Final agreed ARI	/6
Confidence ratings (H/M/L per item; N/A for U-scored items)	Item 1: ☐ Item 2: ☐ Item 3: ☐ Item 4: ☐ Item 5: ☐ Item 6: ☐
Allegiance direction	□ Pro-intervention - □ Anti-intervention - □ Mixed - □ Indeterminate
Team allegiance note	
Date of reconciliation	

7. Worked Examples

7.1 Reflexive Worked Example — MBM Lifespan Series Development Team

In its first application (MBM Lifespan Series, Vol II), PARS-6 was applied reflexively to the development team itself. The lead author (BG) has a documented personal and cultural familiarity with the contemplative tradition from which the primary intervention is drawn.

Item	Score	Confidence	Rationale
1 — Tradition affiliation	1	H	Lead author documents personal practice familiarity in competing interests statement.
2 — Funding source	0	H	No external funding. Self-funded. Explicitly declared.
3 — COI disclosure	0	H	No financial or employment relationship with tradition-promoting organisation.
4 — Comparator	U	N/A	Not applicable to a systematic review protocol paper.
5 — Development role	0	N/A	No development role identified. BG received initiation in HKMM Japa — a tradition affiliation signal already captured by Item 1 — but did not write the HKMM manual, train teachers, or certify practitioners. Initiation is not equivalent to development role under Item 5.
6 — Prior advocacy	0	H	No prior public advocacy for the intervention tradition documented.
ARI Total	1/6		Low allegiance risk. Safeguard: independent statistician (Walsh, TCD) with zero tradition connection.

7.2 Illustrative Composite Example — Hypothetical Intervention Study

The following demonstrates PARS-6 application to a published external study: The following illustrative example uses a composite hypothetical study to demonstrate PARS-6 application. All details are fictional; the example is designed to illustrate typical evidence patterns rather than to score any specific real study.

Item	Score	Confidence	Decision Tree Notes
1 — Tradition affiliation	1	M	Author institutional affiliation and publication record indicate sustained engagement with contemplative research tradition. No explicit self-identification statement found (Step 1 and 2 incomplete — Step 3 profile consulted).
2 — Funding source	U	N/A	No funding statement present in paper (Step 1). No trial registration found (Step 2). Score U.
3 — COI disclosure	U	N/A	No COI statement present in paper. Score U.
4 — Comparator	U	M	Pre-post design — no comparator arm. Score U. (Note: U not 0 — single-arm studies score U on Item 4.)
5 — Development role	0	L	No evidence of development role found in Steps 1–3. Low confidence given limited author information available.
6 — Prior advocacy	U	N/A	Insufficient publicly available biographical information to determine advocacy history.
ARI Total	1 + 4U/6		One confirmed allegiance-relevant relationship; four items unreportable. Sensitivity analysis not triggered by numeric threshold but unreportable items should be noted narratively.

Discussion

7.1 Principal Findings

PARS-6 Version 2.0 addresses a gap that has been acknowledged but not systematically addressed in the evidence synthesis literature: the absence of a structured, theory-informed instrument for documenting investigator allegiance-related characteristics during data extraction in systematic reviews of intervention research. The existing allegiance literature — anchored by Luborsky et al. 1999 [1] and Munder et al. 2013 [2]; Munder et al. 2011 [3] — has documented the phenomenon comprehensively in psychotherapy research but has not produced a transferable screening tool. PARS-6 proposes a structured approach to making this transfer operational..

7.2 Theoretical Contribution

The three-pathway model of allegiance bias — experiential, institutional, and reputational — is the foundational theoretical contribution of this paper. Prior allegiance research has treated researcher allegiance as a unidimensional construct, typically operationalised as the researcher's declared preferred treatment in a comparative trial. The three-pathway model extends this conceptualisation in two important ways. First, it distinguishes between allegiance pathways with different structural origins — personal practice, organisational embedding, and public commitment — each of which may operate through different mechanisms and with different magnitudes. Second, it enables construct validation: if

the three pathways are theoretically independent, items loading onto different pathways should not necessarily correlate with each other, and future validation studies can test this prediction empirically.

7.3 The Allegiance Risk Index

The naming of the PARS-6 total score as the Allegiance Risk Index (ARI) is a deliberate contribution to the field's nomenclature. Unnamed constructs cannot be synthesised across reviews, mandated by journals, or entered as moderators in meta-regression. The ARI provides a citable, reportable, and eventually synthesisable output that is absent from all prior allegiance measurement approaches. The ARI should be understood as an ordinal index of structural conditions — not a continuous measure of bias magnitude. A score of 4/6 does not imply twice the bias of 2/6; it implies four independent allegiance-relevant relationship types are present and documented.

7.4 Comparison With Prior Approaches

Prior approaches to allegiance screening have been informal, ad hoc, and study-specific. Munder et al. 2013 [2]; Munder et al. 2011 [3] coded allegiance from descriptions of researcher affiliation and study framing — a valid but non-standardised approach that cannot be replicated consistently across review teams. RoB 2 [10] and ROBINS-I [11] address methodological conduct within studies but explicitly exclude investigator allegiance as a bias domain. ICMJE [15] COI declaration requirements address financial relationships but not experiential or reputational allegiance. PARS-6 addresses all three pathways systematically, with standardised decision rules, calibration requirements, and a documented IRR record. It is complementary to — not competing with — existing tools.

7.5 Limitations

Four limitations of PARS-6 Version 2.0 should be stated explicitly. First — criterion validity: PARS-6 has not been validated against a criterion measure of bias. The ≥ 4/6 threshold is theoretically derived, not empirically calibrated. Until criterion validity data accumulate through the PARS-6 Application Registry, the ARI should be interpreted as an indicator of structural risk, not a confirmed predictor of biased findings. Second — item overlap: Items 1 (tradition affiliation) and 5 (development role) may capture partially overlapping constructs, both representing forms of experiential allegiance rooted in personal practice and training. Similarly, Items 3 (COI disclosure) and 6 (prior public advocacy) may partially overlap, both reflecting reputational and institutional commitment to the intervention. Future validation studies should examine inter-item correlations to determine whether these item pairs contribute independent information. Third — information asymmetry: PARS-6 relies on publicly available information. Researchers with allegiance-relevant relationships who have not disclosed them publicly will receive lower ARI scores than their actual allegiance risk warrants. This limitation is inherent to any instrument relying on disclosed information and cannot be fully resolved without mandatory author self-disclosure. Fourth — single-arm study applicability: The allegiance mechanism documented in the psychotherapy literature operates most clearly in comparative trials. The functional impact of a given ARI score may differ in single-arm and pre-post studies, as noted in Section 1.4.

7.6 Future Directions

Three priority directions for PARS-6 development are designated for Version 3.0. First — criterion validity study: a meta-epidemiological study examining whether ARI scores predict effect size inflation across a large sample of included studies from completed systematic reviews, using the PARS-6 Application Registry as the data source. Second — Anti-Allegiance Module: a parallel six-item module screening anti-intervention allegiance — financial ties to competing industries, documented scepticism, and institutional opposition — which the current instrument does not address. Third — unpublished study extension: application of PARS-6 to registered-but-unpublished trials to examine whether high-allegiance research teams are disproportionately represented among non-publishing registrants, addressing the most consequential and least visible form of allegiance-related bias.

8. Reporting Standards and Responsible Use

8.1 PARS-6 Minimal Reporting Standard (PARS-6 MRS; see Additional file 1 — Quick Reference Card)

Systematic reviews applying PARS-6 are invited, but not required, to register their application at forms.gle/rfJJVpyceF77DzVz9 and report the following minimum information as part of that registration:

- • The number of included studies scored
- • The number of reviewers who scored each study and whether calibration was completed
- • The inter-rater agreement statistic (Cohen's κ or percentage agreement) for the ARI total score
- • The distribution of ARI scores across included studies (range, mean or median)
- • The number and proportion of studies scoring ≥ 4/6
- • The results of the sensitivity analysis comparing pooled estimates with and without studies meeting the prespecified ARI sensitivity-analysis threshold
- • Item-level scores for individual studies in supplementary materials

8.2 Standardised Citation Language

When reporting PARS-6 application, authors are encouraged to use the following standard language:

"Allegiance bias was screened using PARS-6 Version 2.0 (Practitioner Allegiance Risk Scale; Gopurala et al., 2026), a six-item instrument that produces an Allegiance Risk Index (ARI) ranging from 0 to 6. Studies scoring ≥ 4/6 on the ARI were subject to prespecified sensitivity analysis (PARS-6 preregistration: doi.org/10.17605/OSF.IO/NY94H)." *PARS-6 yields a structured, transparent summary of potential investigator-allegiance risk to support prespecified sensitivity analyses and interpretation; it is not a determination that allegiance bias occurred.*

When PARS-6 is used as a continuous moderator in meta-regression:

"ARI score (0–6) was entered as a continuous moderator to examine whether allegiance-relevant relationships predicted effect size magnitude."

8.3 Responsible Reporting Framework

PARS-6 scores assigned to published studies should be reported at the study level — not attributed to individual researchers by name in published systematic reviews. The recommended reporting format is: 'Of [N] included studies, [X] scored ≥ 4/6 on the ARI (range [Y]–[Z]/6). Studies scoring ≥ 4/6 were subject to prespecified sensitivity analysis.'

PARS-6 should not be cited as grounds for post-publication criticism of individual researchers. Research integrity concerns should be reported through the journal's established post-publication peer review mechanisms or the relevant national research integrity body. Research teams that identify concerns beyond allegiance screening should follow established research integrity reporting pathways rather than PARS-6.

8.4 Taxonomy Positioning

Within the Cochrane risk-of-bias taxonomy, allegiance effects most directly influence detection bias (systematic differences in how outcomes are measured or interpreted) and reporting bias (selective reporting of outcomes based on their results). PARS-6 operates upstream of these bias domains — it identifies the structural conditions that make detection and reporting bias more likely. PARS-6 is therefore complementary to — not a replacement for — RoB 2 [10] and ROBINS-I [11], which assess methodological conduct within these bias domains.

8.5 Contraindications — When NOT To Use PARS-6

PARS-6 is not appropriate:

- • As a substitute for standard risk-of-bias tools (RoB 2 [10], ROBINS-I [11], and GRADE [12]) which address methodological conduct and evidence certainty
- • When the intervention has no identifiable tradition, developer, or organisational promoter
- • To exclude studies from meta-analysis without first completing standard risk-of-bias assessment
- • As grounds for manuscript rejection in peer review without full disclosure of scoring rationale
- • When applied by users who have not completed the calibration exercise

9. Ethics Statement

PARS-6 is applied to publicly available information about researchers and their institutional relationships. It does not require informed consent from the researchers being scored, as it draws exclusively from information they have voluntarily placed in the public domain through publication, registration, and institutional affiliation.

Users are encouraged to apply PARS-6 with the same professional courtesy they would wish to receive: scoring conservatively when evidence is ambiguous, reporting scores at the study level rather than naming individual researchers, and acknowledging in publications that PARS-6 scores reflect structural conditions rather than confirmed misconduct.

Research teams who identify that a living researcher has been scored are not obligated to inform that researcher, but may choose to do so as a courtesy and to enable correction of any factual errors in the scoring record.

PARS-6 should never be applied with the intent to damage a researcher's reputation. It is a transparency tool. It documents. It does not judge.

10. Validation Status, Living Instrument Declaration, and Registry

10.1 Pre-Publication Criterion Validity Statement

PARS-6 Version 2.0 is published as a theoretically grounded, operationally specified instrument prior to formal criterion validity testing. The existing allegiance literature (Luborsky et al.1999 [1]; Munder et al., 2013 [2]) provides strong theoretical support for the construct PARS-6 measures, but does not constitute validation of PARS-6 specifically.

Criterion validity — evidence that ARI scores predict effect size inflation — will be examined as application data accumulate through the PARS-6 Application Registry. Pending this validation, PARS-6 scores should be interpreted as indicators of structural allegiance risk, not confirmed predictors of biased findings.

10.2 Living Instrument Declaration

PARS-6 is released as a pre-validation, living candidate instrument. Version 2.0 reflects the developers' current best judgment on item selection, scoring rules, provisional threshold specification, and operational guidance based on theoretical rationale and theory-informed development. The threshold of ≥ 4/6 will be subject to empirical review as application data accumulate.

Version changelog:

- • **Version 1.0 (July 2026)** Developed as 'PARS-6: A Six-Item Instrument for Screening Allegiance Bias in Intervention Research.' It included six preliminary items, basic scoring rules, and a reflexive illustrative example. It was not validated or formally published and has been superseded.
- • **Version 2.0 (August 2026)** Major theory-informed revision. Changes include: (1) an explicit three-pathway conceptual model; (2) reframing from screening ‘allegiance bias’ to documenting ‘investigator allegiance-related risk’; (3) operational item definitions and permitted evidence sources; (4) present/confirmed-absent/unreported response rules; (5) item-level confidence recording; (6) a four-step evidence-review process; (7) dual-reviewer scoring and adjudication; (8) field-adaptation

guidance; (9) responsible-reporting and non-stigmatisation safeguards; (10) clarification that the ARI is a descriptive, unweighted count; (11) explicit handling of unreported items; and (12) an agenda for independent empirical evaluation.ramework, ethics statement, Allegiance Risk Index nomenclature, living instrument declaration, and PARS-6 Application Registry.

10.3 PARS-6 Application Registry

Users are invited, but not required, to deposit completed application metadata in the PARS-6 registry at forms.gle/rfJJVpyceF77DzVz9 (also accessible via the PARS-6 OSF page: doi.org/10.17605/OSF.IO/NY94H) by submitting: (1) the intervention field; (2) the number of studies scored; (3) the distribution of ARI scores; (4) the proportion of studies scoring ≥ 4/6; and (5) whether sensitivity analyses changed the direction or significance of pooled estimates.

Registry data may inform future empirical assessment of threshold performance and field-specific applicability for the ARI. A voluntary application registry may support future research on feasibility, scoring distributions, reliability, and validity. Registry participation is not a requirement for use of the instrument and does not constitute validation.

10.4 Version 3.0 Development Priorities

The following extensions are designated for development in Version 3.0:

- • **Anti-Allegiance Module** Full six-item anti-intervention allegiance screening mirroring the current pro-allegiance items
- • **Empirical provisional threshold specification** Criterion validity study examining whether ARI scores predict effect size inflation across fields
- • **Differential item weighting** Investigation of whether some allegiance-relevant relationships predict bias more strongly than others
- • **Unpublished study extension** Application of PARS-6 to registered-but-unpublished trials to examine whether high-allegiance teams are disproportionately represented among non-publishing registrants

10.5 Dissemination and Adoption Strategy

Following criterion validity development through the Application Registry, PARS-6 will be submitted for consideration as a recommended screening instrument to the EQUATOR Network and Campbell Collaboration Methods Group. The instrument is freely available under CC0 licence at OSF (doi.org/10.17605/OSF.IO/NY94H) and has been preregistered before application in the MBM Lifespan Series systematic review (PROSPERO: CRD420261334284), constituting the first prospective application of PARS-6 in a formally registered systematic review.

Declarations

Competing Interests

The lead author (B.G.) has a documented personal and cultural familiarity with contemplative practice traditions relevant to the mantra-based meditation interventions examined in the MBM Lifespan Series systematic review programme. This relationship is disclosed in the manuscript and was scored under PARS-6 Item 1 in the reflexive worked example. No financial, employment, advisory, equity, or organisational competing interests are declared. All co-authors declare no competing interests.

Competing Interests Statement:

The lead author (BG) has a documented personal and cultural familiarity with contemplative practice traditions, including the primary intervention studied in the MBM Lifespan Series (HKMM Japa). This relationship is scored under PARS-6 Item 1 in the reflexive worked example (Section 7.1). No financial, organisational, or advocacy-related competing interests are declared. All co-authors declare no competing interests. The reflexive internal application (Section 7.1) produced ARI 1/6 — Item 1 only. An external application may produce ARI 2–3/6, depending on whether prior advocacy (Item 6 — the MBM Lifespan Series itself constitutes advocacy for HKMM research) is assessed against the full published record — demonstrating the instrument's sensitivity to its own developers' allegiance-relevant relationships.

Funding Statement:

This work received no external funding. Instrument development was conducted as part of the MBM Lifespan Series systematic review programme (PROSPERO: CRD420261334284), which is self-funded by the principal investigator.

Author Contribution

Balaganesh Gopurala (B.G.) conceptualised the study, developed the theoretical model, designed all six items, drafted the main manuscript text, conducted the reflexive and illustrative worked examples, developed the scoring framework and decision tree, and led all revisions. Om Vrishank Gopurala (O.V.G.) served as independent screener and data extractor, contributed to calibration and inter-rater reliability procedures, and reviewed the manuscript. Suryaprathap Gopurala (S.G.) contributed to the health equity and policy translation framework referenced in the instrument's development context, reviewed the manuscript critically for intellectual content, and approved the final version. Cathal Walsh (C.W.) provided independent statistical oversight, reviewed the instrument and scoring framework for methodological rigour, and reviewed the manuscript. All authors approved the final manuscript and agree to be accountable for all aspects of the work.

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Data Availability Statement:

The PARS-6 instrument (Version 2.0), scoring record, IRR documentation template, and calibration set (upon deposit) are publicly available under CC0 1.0 Universal licence at doi.org/10.17605/OSF.IO/NY94H. No other datasets were generated or analysed during this study.

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Figures

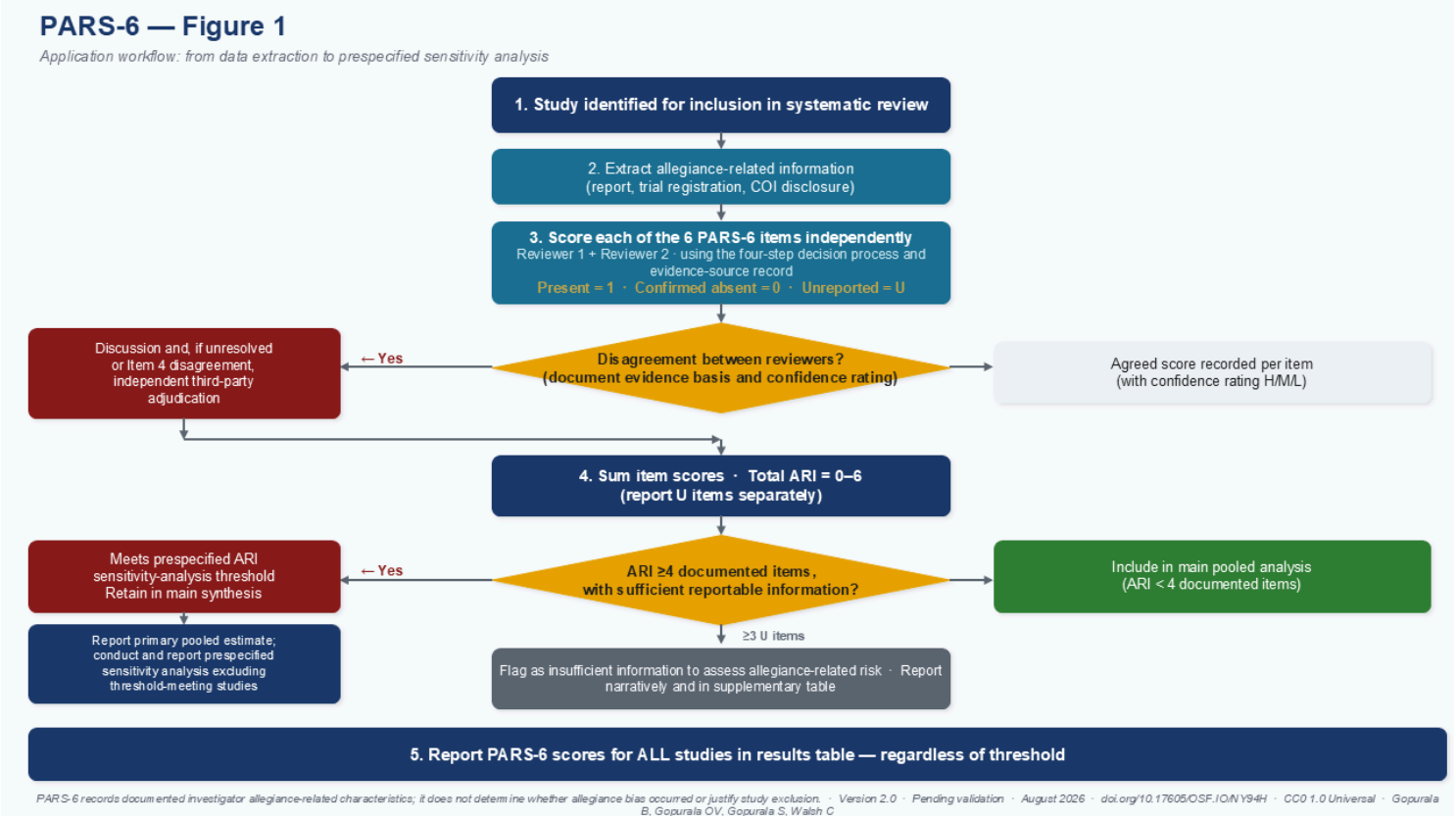


Figure 1

Legend not included with this version.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AppendixA.docx
- PARS6AppendixCScoringTable.docx
- PARS6AppendixBQRC.docx