ESM 4. Complete Risk-of-Bias Assessments

Article title: Multimodal Digital Health Interventions versus Standard Perioperative Management in Lung Cancer Surgery: A Systematic Review, Meta-Analysis, and Evidence Gap Map

Journal: Supportive Care in Cancer

Authors: [replace with author names]

Risk of Bias Assessment: Unified Included Evidence Base

Date: 2026-06-13
Assessors: AI-assisted first assessment; independent human second-reviewer confirmation still recommended before submission.
Final included set: 11 controlled studies: 8 RCTs assessed with Cochrane RoB 2.0 and 3 nonrandomized controlled studies assessed with ROBINS-I logic.

RoB 2.0 Domain-Level Assessment for RCTs

Domain Legend

- **D1**: Bias arising from the randomization process
- **D2**: Bias due to deviations from intended interventions
- **D3**: Bias due to missing outcome data
- **D4**: Bias in measurement of the outcome
- **D5**: Bias in selection of the reported result

Rating: L = Low risk, SC = Some concerns, H = High risk

Study	D1	D2	D3	D4	D5	Overall
Sui 2020	SC (randomized 1:1; allocation details limited)	SC (open-label WeChat intervention)	L (n=100/100 reported at analysis)	SC (HADS/QLQ-C30 subjective PROs)	SC (registration/protocol not clearly identified)	**SC**
Jiang 2024	SC (random number table; concealment unclear)	SC (open-label WeChat intervention)	L (0/60 dropout reported)	SC (PaO2 objective; VAS/HRQoL subjective)	SC (no pre-registration found)	**SC**
Xu 2025	L (computer-generated random sequence; allocation concealed)	SC (open-label; DTx vs MM; per-protocol elements)	L (mITT; attrition balanced)	L for objective outcomes; PROs cautious	L (ChiCTR pre-registered)	**SC**
Lv 2025	L (random number table; allocation concealed; single-blind)	L (single-blind design)	L (4/140 dropout; balanced)	L for PFRR; PROs cautious	L (ChiCTR pre-registered)	**L**

Study	D1	D2	D3	D4	D5	Overall
Li 2025	L (computer-generated; allocation concealed)	SC (open-label DTx vs usual care)	SC (small N; attrition affects precision)	SC (objective VO2peak; PROs susceptible)	L (ChiCTR pre-registered)	**SC**
Dai/Jing 2025	L (computer-generated; stratified by site; allocation concealed)	SC (open-label ePRO intervention)	L (dropout balanced; sensitivity analysis reported)	SC (symptom/PRO outcomes; readmission administrative)	L (registered; outcomes match protocol)	**SC**
Patel 2023	L (random permuted blocks; allocation concealed; blinded providers/analysts)	SC (participants could not be blinded to Fitbit/preconditioning)	SC (primary outcome table n=45/50 of 51/51 randomized)	L for LOS/complications; PROs cautious	L (ClinicalTrials.gov NCT03689634)	**SC**
Chen 2026	SC (random number table/envelopes described; some reporting inconsistencies in randomized counts)	SC (patients/nurses not blinded to device training)	L/SC (low attrition; ITT and imputation reported)	SC (objective spirometry/6MWT; QoL subjective)	SC (registration not clearly reported)	**SC**

RoB 2 Summary

- **Low risk**: 1 RCT (Lv 2025)
- **Some concerns**: 7 RCTs (Sui 2020, Jiang 2024, Xu 2025, Li 2025, Dai/Jing 2025, Patel 2023, Chen 2026)
- **High risk**: 0 RCTs

ROBINS-I Assessment for Nonrandomized Controlled Studies

Domain Legend

- **C1**: Bias due to confounding
- **C2**: Bias in selection of participants
- **C3**: Bias in classification of interventions
- **C4**: Bias due to deviations from intended interventions
- **C5**: Bias due to missing data
- **C6**: Bias in measurement of outcomes
- **C7**: Bias in selection of reported results

Rating: L = Low, M = Moderate, S = Serious, C = Critical, NI = No information

Study	C1	C2	C3	C4	C5	C6	C7	Overall
Lee 2024	S (historical control; temporal/cohort confounding likely)	M (single tertiary center; eligibility clear)	L (wearable intervention clearly classified)	M (adherence/counseling intensity may vary)	M (time-point completion needs supplement confirmation)	M (objective activity plus PROs)	M (published tables available)	**Serious**
Tang/Wang 2026	S (retrospective matched design; residual confounding likely)	S (pulmonary-function follow-up n varies markedly)	L (Dignio platform and devices clear)	M (real-world intervention exposure may vary)	S (very sparse outcome denominators at later time-points)	M (objective PFTs, but selective follow-up)	M (tables available, but denominator handling unclear)	**Serious**
Chen 2024 wearable pedometer	S (retrospective single-center comparison; selection bias likely)	S (allocation mechanism unclear)	M (digital multimodality borderline)	M (nurse-led rehabilitation intensity may differ)	M (limited reporting)	S (table formatting inconsistencies; PRO quality concerns)	M (selective reporting cannot be excluded)	**Serious**

Key Observation

The principal bias concern across RCTs is open-label intervention delivery, which is difficult to avoid in digital health trials. Objective outcomes such as spirometry, arterial blood gas, LOS, CPET, and management time are less vulnerable to detection bias than subjective PROs. For nonrandomized studies, confounding, selection bias, and missing/variable follow-up denominators are the main reasons they are synthesized narratively and not pooled with RCTs.