Appendix 3. Assessments of bias risk for the patient comprehension outcome among interventions to improve patient comprehension in informed consent for medical and surgical procedures using Cochrane's risk-of-bias (RoB) 2.0 tool

Study	Domain 1: Risk of Bias Arising from Randomization Process	Domain 2: Risk of Bias Due to Deviations from Intended Intervention to Improve Patient Comprehension	Domain 3. Risk of Bias Due to Missing Outcome Data for Patient Comprehension Outcome	Domain 4. Risk of Bias in Measurement of Patient Comprehension Outcome	Domain 5. Risk of Bias in Selection of Reported Patient Comprehension Result	Overall Risk of Bias for the Patient Comprehension Outcome*
Alsaffar 2016	H†	S‡	S	S	S	High
Aremu 2011	S	S	L§	S	S	Some
Armstrong 2010	L	S	L	S	S	Some
Baenninger 2018	S	S	L	L	L	Some
Bennett 2009	H¶	S	S	S	S	High
Bethune 2018	S	L	L	L	S	Some
Borello 2016	S	S	L	L	S	Some
Bowers 2015	L	S	L	S	S	Some
Brandel 2017	H	S	H	S	S	High
Choi 2015	S	S	S	S	S	High
Clark 2011	S	S	L	L	S	Some
Cornoiu 2011	H	H	S	S	S	High
Egekeze 2016	S	L	L	L	L	Some
Ellett 2014	S	S	S	S	S	High
Finch 2009	S	S	S	S	S	High
Fink 2010	S	S	S	L	L	Some
Fraval 2015	L	S	L	S	S	Some
Gangol 2010	H	S	S	H	S	Some
Goldberger 2011	H	H	S	S	S	High
Gordon 2017	L	S	S	L	L	Some
Gyomber 2010††	L	H	L	S	S	High
Ham 2016	S	S	L	S	S	Some
Heller 2008	S	S	S	S	S	High
Hong 2009	S	S	S	S	S	High
Huber 2012	L	S	L	S	L	Some
Johnson 2011	H¶	S	S	L	S	High
Karan 2011	S	S	S	S	S	High
Karan 2014	H¶	S	S	L	S	High
Kesänen 2016	L	L	S	L	L	Some
Khan 2013	L	H	S	S	S	High
Kim 2018	S	S	L	H	S	High
Kinman 2017	L	S	L	L	S	Some
Kostick 2018	L	L	S	L	L	Some
Lattuca 2018	S / S**	S	L	L	L	Some
Lin 2018	L	S	L	L	L	Some
Mishra 2010	S	S	L	L	S	Some
Pallett 2018	S	S	L	L	L	Some
Sharma 2018	S	S	H	L	S	High
Shukla 2012	S	S	S	S	S	High
Siu 2015	S	S	S	H	S	High
Smith 2012	H	S	S	S	S	High

Straessle 2011	L	S	L	L	S	**Some**
Tait 2009	S	S	L	L	S	**Some**
Tait 2014	S	S	S	L	S	**Some**
Tipotsch-Maca 2016	S	S	L	S	S	**Some**
Vo 2018	S	L	L	L	S	**Some**
Wilhelm 2009	H	S	S	S	S	**High**
Winter 2016††	L	H	L	L	L	**High**
Wollinger 2012	L	L	S	L	S	**Some**
Wong 2016	S	S	L	L	S	**Some**
Wysocki 2012	L	S	S	S	S	**Some**
Zhang 2017	L	S	L	L	S	**Some**

* RoB 2.0 can be utilized to assign 'low risk,' 'some concerns,' or 'high risk' of bias per study outcome. Overall risk-of-bias judgments for a given outcome are based on risk-of-bias assessments in 5 separate domains for that outcome. When any of the 5 domains is determined to have a high risk of bias, the overall risk of bias for that outcome is considered to be high. Only when all 5 domains are determined to have a low risk of bias can the overall risk of bias for that outcome be considered low. When multiple domains are determined to have some risk of bias, and no domains a high risk of bias, reviewers use their discretion to assign 'some concerns' or 'high risk' of bias to the outcome overall. For this review, studies that had some concerns for bias in all 5 domains were considered to have an overall high risk for bias for that outcome. Studies with ≤4 domains with some concerns for bias were considered to have some risk for bias for that outcome overall. This cutoff was selected to reflect a reasonable balance between study rigor and practical feasibility. Specific domains were not prioritized in determining overall bias risk since each had similar bearing on the results.

† H: high risk of bias in the given domain

‡ S: some concerns for bias in the given domain

§ L: low risk of bias in the given domain

¶ For non-randomized controlled trials, we automatically counted potential risk of bias arising from randomization process as high

** Additional RoB 2.0 guidelines were followed for cluster randomized trials, which divide domain 1 into domain 1a (risk of bias arising from randomization process) and 1b (risk of bias arising from the timing of identification and recruitment of participants in a cluster randomized trial)

†† Additional RoB 2.0 guidelines were followed for crossover trials, which includes additional signaling questions in domains 1, 2, and 5