Appendix B

.. Criteria for evaluating the quality of randomized controlled trials, according to the US Preventive Services Task Force 12

Quality rating	Criteria
Good	 All of the following criteria must be met for a study to merit a "good" grading: Intervention and control groups were comparable Comparable groups were maintained over the study, with follow-up available for a minimum of 80% Interventions were clearly defined Valid and reliable measurement instruments were used and were applied equally to both groups Outcome was clearly defined and measurable, and all relevant outcomes were considered Researchers were blinded to intervention allocation Intention-to-treat analysis was employed, if applicable There was appropriate attention to confounders in the analysis
Fair	 The presence of any of the following criteria will result in a "fair" grading: Minor differences between the intervention and control groups were identified, or group demographic characteristics were not reported Intervention was clearly defined but was not measurable (e.g., administration of probiotic without documentation of dose) Outcome was clearly defined but was not measurable (e.g., presence of diarrhea, with no explicit definition) No difference was detected (a negative study) but study had insufficient power
Poor	The presence of any of the following fatal flaws will result in a "poor" grading: • There were major differences between the intervention and control groups • There was significant loss to follow-up (> 20%) • Interventions were not clearly defined • Outcomes were not clearly defined (e.g., gastrointestinal symptoms without specification) • Major confounders were not accounted for