

Appendix 1.

Extension to the CONSORT statement

<p><i>The column on the left-hand side is selected CONSORT elements. The column on the right represents the coding extensions specific for this study. All of these additional items are rated on three-point scales.</i></p>	
<p>2a Scientific background and explanation of rationale</p>	<ul style="list-style-type: none"> • <u>Scientific background</u> (maximum score = 3) include the use of <ol style="list-style-type: none"> 1) Educational instruments. Score = 1.0 <i>Example: Simulation-based medical education, use of assessment instruments with validity evidence.</i> 2) Educational concepts. Score = 1.0 <i>Example: Deliberate practice, self-directed learning.</i> 3) Educational theories. Score = 1.0 <i>Example: Cognitive load theory, developmental frameworks.</i> • <u>Explanation of rationale</u> is the clinical rationale or justification for conducting the study. Maximum score = 3. <ol style="list-style-type: none"> 1) Clinical background. Score = 1.5. <i>Example: "laparoscopic surgery has long learning curves and complications occurs more frequently with inexperienced surgeons."</i> 2) Justification of the use of intervention. Score = 1.5. <i>Example: "Simulation-based training has been shown to be useful for initial training and may therefore reduce the number of complications..."</i>
<p>2b Specific objectives or hypotheses</p>	<ul style="list-style-type: none"> • <u>Objectives or research question</u> (maximum score = 3) include specifications of <ol style="list-style-type: none"> 1) Setting and population (Each = 0.5) 2) Intervention and control (Each = 0.5) 3) Outcome measures (Each = 0.1) • <u>Hypotheses</u> are proposed effects or mechanisms of action. <ol style="list-style-type: none"> 1) Score = 3 if stated clearly as a hypothesis <i>Example: Our hypothesis was that...</i> 2) Score 1.5 if potential mechanisms of actions are stated but not explicitly called a hypothesis <i>Example: "Simulation-based training has previously shown improved operative performances and may therefore also reduce complications..."</i> 3) Score=0 if no mechanism of action is proposed or no specific hypothesis is suggested.

	<p>Example: Effective communication is difficult. We aimed to explore if a simulated patient programme improved students' confidence in...</p>
<p>5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</p>	<ul style="list-style-type: none"> • <u>Description of the use of the intervention and control</u> (maximum score = 3) include <ol style="list-style-type: none"> 1) Detailed description of the type of intervention and control conditions. Score = 1 <i>Example: Type of simulation or type of learner interaction.</i> 2) Detailed description of instructions/information available to participants. Score = 1 <i>Example: Verbal or written instructions available prior to and during the intervention and additional resources such as textbooks, web-based learning material etc.</i> 3) Detailed description of the supervision/ assessment/ feedback provided, the amounts available and the qualifications/training of the persons providing supervision/ assessment /feedback. Score = 1. <i>Example: How much feedback was provided, how was it provided, by whom and for how much time?</i>
<p>Interpretations</p>	<ul style="list-style-type: none"> • <u>Interpretation of results</u> (maximum score = 3) includes <ol style="list-style-type: none"> 1) Reported consistent with the observed results (Score = 1.5). <i>Example: "These significantly higher performance-scores suggest that simulation-training of junior surgeons may lead to superior performance in the OR".</i> 2) Integration of results and interpretation into existing educational theory. (Score = 1.5) <i>Example: "These results are consistent with cognitive load theory suggesting that..."</i>