

Table 1

Key questions to be answered when working with the PICOT framework (population, intervention, comparator, outcome, and time frame) in a clinical research design

Component	Related questions
Population	<ul style="list-style-type: none">-What is the target population?-Is the target population narrow or broad?-Is the target population vulnerable?-What are the eligibility criteria?-What is the most appropriate recruitment strategy?
Intervention	<ul style="list-style-type: none">-What is the intervention? (treatment, diagnostic test, procedure)-Is there any standard of care for the intervention?-Is the intervention the most appropriate for the study design?-Is there a need for standardizing the intervention?-What are the potential side effects of the intervention?-Will potential side effects be recorded?-If there is no intervention, what is the exposure?
Comparator	<ul style="list-style-type: none">-How has control intervention been chosen?-Are there any ethical concerns related to the use of placebo?-Has a sham intervention been considered?-Will statistical analyses be adjusted for multiple comparisons?
Outcome	<ul style="list-style-type: none">-What is the primary outcome?-What are the secondary outcomes?-Are the outcomes exploratory, explanatory or confirmatory?-Have surrogate and clinical outcomes been considered?-Are the outcomes validated?-Have safety outcomes been considered?-How are the outcomes going to be measured?-Will the dependent and independent variables be numerical, categorical or ordinal?-Will be enough statistical power to measure secondary outcomes?
Time frame	<ul style="list-style-type: none">-Is the study designed to be cross-sectional or longitudinal?-How long will the recruitment phase take?-What is the time frame for data collection?-Have frequency and duration of the intervention been specified?-How often will outcomes be measured?-Which strategy will be used to prevent/decrease dropouts?
