Processes involving clusters

Recruitment of clusters: How are clusters sampled and recruited? Who agrees to participate?

Delivery to clusters: What intervention is actually delivered to each cluster? Is it the intended intervention?

Response of clusters: How is the work of the intervention and trial implemented in and adopted by clusters?

Processes involving target population

Recruitment and reach of individuals: Who actually receives the work of the intervention in each setting? Are they representative?

Delivery to individuals: What intervention is delivered in each cluster? Or what behaviour change has occurred because of the intervention?

Response of individuals: How does the target population respond?

Maintenance: How and why are these processes sustained over time (or not)?

Effectiveness: What are the effects on the primary and secondary outcomes?

Unintended consequences: change in other outcomes which may be perverse, harmful or beneficial?

Theory: What theory has been used to develop the intervention? Can a theory be considered to interpret the effects of the intervention?

Context: What is the wider context in which the trial is being conducted (e.g., organisation of healthcare, financial and non-financial incentives affecting the processes being examined)?