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| **Title** |  |
| **Background and rationale** |  |
| **Aim** |  |
| **Primary Objectives** |  |
| **Secondary Objectives** |  |
| **Tertiary/correlative Objectives** |  |
| **Hypotheses** |  |
| **Study design** |  |
| **Population and setting** |  |
| **Interventions** |  |
| **Outcomes and measures** |  |
| **Study procedures** |  |
| **Statistical considerations** |  |
| **Feasibility** |  |
| **Significance** |  |
| **Funding** |  |
| **Risks** |  |