ICMR School of Public Health, National Institute of Epidemiology, Chennai, India

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Concept paper for an intervention study– [insert title here]

Insert name of primary investigator here

Background *[This section should have linked references]*

- Provide state-of-the art information on disease/health condition. Avoid general statements and provide quantified data when available[1].
- Spell out what is known and unknown for drug/treatment options or interventions for that specific disease/health condition[2]
- Specify (1) information that is needed for improving clinical/ public health management of the disease or health condition (2) why the currently available information is insufficient. [3-5]

Objectives

- Needs to be stated quantitatively for the primary outcome (Make it clear whether you propose to *estimate a quantity* or whether you propose to *test a hypothesis*)
- Clearly distinguish secondary from the primary objectives

Proposed methods

[Use SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 Statement *(www.spirit-statement.org)*]

Study participants

- Eligibility criteria for the participants (Inclusion and exclusion criteria)

Study design

- Describe the type of study in one short bullet (spelling out key features, e.g., randomized; blinding)

Interventions

- Provide details of the drug(s) [Name, dosage, frequency] or nature of other forms of intervention(s)

Operational definitions

- Provide information regarding the key definitions
- Define primary & secondary outcomes {Use standard guidelines); Spell out any new definitions}

Sample size

- Briefly mention your sample size and the main assumptions you used to calculate it. This should contain enough information for the reader to redo the calculations to check the estimate.

Randomization, sequence allocation & allocation concealment

- Describe the type of randomization, methods to generate and implement the allocation

Blinding (masking)

- Describe the level and type of masking

Data collection

- Explain shortly who will collect what kind of data, what the timeline is and what quality assurance mechanism will be used.

Analysis plan

- Summarize the primary (specifically for primary outcomes) as well as additional analyses that you plan to carry out. Mention laboratory analysis if they will be part of the study.

Human participants protection

- Mention key measures taken to ensure the protection of human subjects in your study

Expected benefits

- Describe the expected output (e.g., reports) that this study will generate and the timeline.
- Describe the expected outcome: How this study will influence management of disease/health condition studied

References *[As per standard guidelines (refer to www.icmje.org), not more than 5]*

1. United Nations, Title, 2011
2. WHO, Title, Place 2011
3. X, Y, Z *et al*. Achieving the programme objectives. IndiaInternational. 2011;12:22-26
4. Govt. of India, Title, Place 2010
   Govt. of Tamil Nadu, Title, Place, 2011

Budget *(Optional)*

- Staff (Salary and per diem):A XX,XXX
- Transport: A XX,XXX
- Supplies (e.g., laboratory reagents, stationary and others): A X,XXX
- Miscellaneous: A XX,XXX

Total amount needed: A X,XX,XXX

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