

PEER REVIEW HISTORY

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ARTICLE DETAILS

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| TITLE (PROVISIONAL) | Protocol for Process Evaluation of SMART Mental Health Cluster Randomized Control Trial : An intervention for management of Common Mental Disorders in India |
| AUTHORS | Mukherjee, Ankita; Daniel, Mercian; Kallakuri, Sudha; Kaur, Amanpreet; Devarapalli, Siddhardha; Raman, Usha; Thornicroft, Graham; Essue, Beverley; Praveen, D; Sagar, Rajesh; Kant, Shashi; Saxena, Shekhar; Patel, Anushka; Peiris, David; Maulik, Pallab |

VERSION 1 – REVIEW

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| REVIEWER | Sampogna, Gaia University of Campania Luigi Vanvitelli |
| REVIEW RETURNED | 10-Jan-2022 |

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| GENERAL COMMENTS | <p>This is an interesting study protocol on an integrated community and primary healthcare worker intervention for management of Common Mental Disorders in India.</p> <p>The paper is clear and well organized. The topic is timely and innovative.</p> <p>Authors should consider to include a flow-chart summarizing the main steps of the project (in order to make the paper clearer).</p> <p>In the final part of the discussion, authors should report some practical expected benefits related to the implementation of this complex intervention. Have you considered also to evaluate the acceptability by participants? Do you think that this should have an impact on the dissemination of the intervention?</p> <p>Do you think that the intervention should have any "side-effects"?</p> <p>I think that also an antistigma component is included in the intervention, why this is relevant? Could you discuss on the role of stigma on help-seeking delay (even quoting some recent papers on the same topic).</p> |
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| REVIEWER | Zapata-Ospina, Juan Pablo Universidad de Antioquia |
| REVIEW RETURNED | 21-Jan-2022 |

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| GENERAL COMMENTS | <p>ABSTRACT:</p> <ul style="list-style-type: none"> - The abstract seems long to me and even so, it is not enough to describe the methods. I suggest rewriting it. <p>INTRODUCTION</p> <ul style="list-style-type: none"> - Given that the definition of CMD is not entirely homogeneous (Goldberg's definition includes somatic symptoms for example) and that the authors in previous lines speak of depression, anxiety, and addictions, I suggest defining which are the disorders that will be included under "CMD". - I think reading the introduction makes it clear that this is a protocol |
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| | <p>for further analysis in the context of a clinical trial. Perhaps for a non-specialist reader, the title may be misleading and expect to read some of the essay. That is why I suggest clarifying the title better. Maybe “Protocol for Process Evaluation of an integrated community and primary healthcare worker intervention for management of Common Mental Disorders in India: [ANALYSIS FROM or ANALYSIS OF or ADDITIONAL ANALYSIS FOR or UNDERSTANDING] The Systematic Medical Appraisal, Referral and Treatment (SMART) Mental Health Cluster Randomized Control Trial”</p> <p>METHODS</p> <ul style="list-style-type: none"> - REAIM (RE-AIM) must be written consistently - Table 2: abbreviations and acronyms must be defined - The methods are consistent with the research question. - For the quantitative component, I see it necessary to pre-specify what will be considered "appropriate" to perform a multilevel model <p>FORM:</p> <ul style="list-style-type: none"> - There are some typographical errors |
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| REVIEWER | Buitrago Ramírez, Francisco Centro de Salud La Paz |
| REVIEW RETURNED | 18-Feb-2022 |

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| GENERAL COMMENTS | <p>In this paper, the authors outline the protocol for an ambitious process evaluation of the SMART Mental Health, a Cluster Randomized Control Trial designed to reduce psychiatric morbidity due to common mental disorders (stress, depression, anxiety and self-harm) in high risk individuals in India, where many of them cannot access adequate health care.</p> <p>The intervention, in SMART Mental Health, comprises an anti-stigma campaign and a technology enabled mental health service intervention delivered through task sharing. Accredited Social Health Activists (ASHAs) and PHC doctors participate in the project. The capacities of ASHAs and PHC doctors will be enhanced, by providing training in identifying and managing stress, depression, or suicide risk using a technology enabled decision support system.</p> <p>The authors present a detailed description of quantitative and qualitative methods used to evaluate implementation fidelity, identify facilitators of and barriers to implementation of the intervention, as well as perceptions about effectiveness and acceptability of intervention components by different stakeholders.</p> <p>They also consider the possible appearance of variations in outcomes and unexpected consequences across sites, and present the measures that would be adopted to explain any adaptations to the intervention during the study and their possible impact on the outcomes.</p> <p>In my opinion, the manuscript elaborates in a detailed and convincing way the evaluation process of SMART Mental Health and should be published in the BMJ Open.</p> |
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VERSION 1 – AUTHOR RESPONSE

REVIEWER: 1

1. Authors should consider including a flow-chart summarizing the main steps of the project (in order to make the paper clearer).

Author Response: Flowchart added.

2. In the final part of the discussion, authors should report some practical expected benefits related to the implementation of this complex intervention.

Author Response: Since we have been advised to remove the conclusion section from the protocol, we have not made any concluding comments related to practical benefits.

3. Have you considered also to evaluate the acceptability by participants? Do you think that this should have an impact on the dissemination of the intervention?

Author's Response: Yes. The process evaluation will be evaluating acceptability of intervention components by participants (objective2). Understanding perceptions about acceptability of the intervention components will be helpful in making necessary changes for any future dissemination and scale-up of the intervention.

4. Do you think that the intervention should have any "side-effects"?

Author's Response: We do not expect our intervention to have any adverse effects for participants.

5. I think that also an anti-stigma component is included in the intervention, why this is relevant?

Could you discuss on the role of stigma on help-seeking delay (even quoting some recent papers on the same topic).

Author Response: In the introduction (pg3) we have briefly discussed stigma as an important demand side barrier in accessing mental healthcare and how our past work has demonstrated the importance of an anti-stigma campaign in addressing this barrier

REVIEWER 2

1. The abstract seems long to me and even so, it is not enough to describe the methods. I suggest rewriting it.

Author Response: Abstract has been re-written to provide more clarity on methodology.

2. Given that the definition of CMD is not entirely homogeneous (Goldberg's definition includes somatic symptoms for example) and that the authors in previous lines speak of depression, anxiety, and addictions, I suggest defining which are the disorders that will be included under "CMD".

Author Response: Added line defining CMDs for the project on pg 3.

3. I think reading the introduction makes it clear that this is a protocol for further analysis in the context of a clinical trial. Perhaps for a non-specialist reader, the title may be misleading and expect to read some of the essay. That is why I suggest clarifying the title better. Maybe "Protocol for Process Evaluation of an integrated community and primary healthcare worker intervention for management of Common Mental Disorders in India: [ANALYSIS FROM or ANALYSIS OF or ADDITIONAL ANALYSIS FOR or UNDERSTANDING] The Systematic Medical Appraisal, Referral and Treatment (SMART) Mental Health Cluster Randomized Control Trial"

Author Response: Title changed to Protocol for Process Evaluation of SMART Mental Health Cluster Randomized Control Trial: An intervention for management of Common Mental Disorders in India

4. REAIM (RE-AIM) must be written consistently

Author Response: Corrections made

5. Table 2: abbreviations and acronyms must be defined

Author Response: Abbreviations and acronyms defined

6. For the quantitative component, I see it necessary to pre-specify what will be considered "appropriate" to perform a multilevel model

Author Response: For the process evaluation, usage analytics data on specific parameters from the mHealth platform will be the main quantitative data source (Details on pg 15). Data analysis for

process evaluation will primarily use descriptive statistics.
A separate outcome analysis of trial data is planned which is outside the scope of this protocol.
Multilevel modelling will be undertaken for outcome analysis.

7. There are some typographical errors
Author Response: Typographical errors corrected.