CONSERVE-CONSORT Extension Checklist

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| **CONSERVE – CONSORT Extension: 08/11/21** | | | | | |
| Item | Item Title | Description | | | Page |
| I. | Extenuating Circumstances | Describe the circumstances and how they constitute extenuating circumstances. | | | 6 |
| II. | Important Modifications | 1. Describe how the modifications are important modifications. 2. Describe the impacts and mitigating strategies, including their rationale and implications for the trial. (see below) 3. Provide a modification timeline. | | | 6 |
| III. | Responsible Parties | State who planned, reviewed and approved the modifications. | | | 7 |
| IV. | Interim data | If modifications were informed by trial data, describe how the interim data were used, including whether they were examined by study group, and whether the individuals reviewing the data were blinded to the treatment allocation. | | | N/A |
| CONSORT Number and Item | | For each row, if important modifications occurred check “direct impact” and/or “mitigating strategy” and describe the changes in the trial manuscript or supplement. Check “no change” for items that are unaffected in the extenuating circumstance. | | | Page |
| No Change | Impact\* | Mitigating Strategy\*\* |
| 1 | Title and abstract | X |  |  | N/A |
| 2 | Introduction | X |  |  | N/A |
| 3 | Methods: Trial Design |  | X | X | 6 |
| 4 | Methods: Participants | X |  |  | N/A |
| 5 | Methods: Interventions |  | X | X | 6 |
| 6 | Methods: Outcomes | X |  |  | N/A |
| 7 | Methods: Sample Size | X |  |  | N/A |
| 8-10 | Methods: Randomization | X |  |  | N/A |
| 11 | Methods: Blinding | X |  |  | N/A |
| 12 | Methods: Statistical methods | X |  |  | N/A |
| 13 | Results: Participant flow |  | X | X | 6 |
| 14 | Results: Recruitment |  | X | X | 6 |
| 15 | Results: Baseline data | X |  |  | N/A |
| 16 | Results: Numbers analyzed | X |  |  | N/A |
| 17 | Results: Outcomes and estimation | X |  |  | N/A |
| 18 | Results: Ancillary analyses | X |  |  | N/A |
| 19 | Results: Harms | X |  |  | N/A |
| 20 | Discussion: Limitations |  | X | X | 12 |
| 21 | Discussion: Generalizability |  | X | X | 12 |
| 22 | Other information: Registration | X |  |  | N/A |
| 23 | Other information: Protocol | X |  |  | N/A |
| 24 | 24 Other information: Funding | X |  |  | N/A |