

SPIRIT 2025 Checklist – GRACE Pilot RCT (Completed)

| Item No. | Description | Location in Manuscript |
|----------|--|------------------------------|
| 1a | Title identifies design and protocol | Title page |
| 1b | Structured summary including WHO items | Structured Abstract |
| 2 | Protocol version and date | Declarations 4.9 |
| 3a | Names, affiliations, roles | Title page |
| 3b | Sponsor name/contact | Title page |
| 3c | Role of sponsor/funder | Declarations 4.5 |
| 3d | Trial oversight committees | Methods 2.1 |
| 4 | Trial registration + URL | Title page; Declarations 4.8 |
| 5 | Protocol + SAP availability | Methods 2.9 |
| 6 | Data sharing statement | Methods 2.9 |
| 7a | Funding sources | Declarations 4.5 |
| 7b | Conflicts of interest | Declarations 4.4 |
| 8 | Dissemination policy | Methods 2.10 |
| 9a | Background and rationale | Introduction |
| 9b | Explanation of comparator | Methods 2.6 |
| 10 | Objectives | Abstract + Introduction |
| 11 | Patient and public involvement | Methods 2.1 |
| 12 | Trial design | Methods 2.1 |
| 13 | Setting | Methods 2.2 |
| 14 | Eligibility criteria | Methods 2.3 |
| 15 | Interventions | Methods 2.6 |
| 16a | Outcomes and timing | Figure 2; Methods 2.7-2.8 |
| 16b | Pilot progression criteria | Methods 2.9; Table 3 |
| 17a | Sequence generation | Methods 2.5 |
| 17b | Allocation concealment | Methods 2.5 |
| 17c | Implementation | Methods 2.5 |
| 18a | Blinding | Methods 2.1 |
| 18b | If unblinded, rationale | Methods 2.1 |
| 19 | Data collection methods | Methods 2.7-2.8 |
| 20 | Data management | Methods 2.7 |
| 21 | Statistical methods | Methods 2.9 |

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| 22 | Interim analyses | Not applicable (pilot) |
| 23a | Data Monitoring Committee | Added statement (no DMC needed) |
| 23b | Harms | Methods 2.11 |
| 23c | Auditing | Not applicable |
| 24 | Ethics approval | Declarations 4.1 |
| 25 | Protocol amendments | Added statement |
| 26a | Consent | Methods 2.5 + 2.11 |
| 26b | Consent for ancillary studies | Not applicable |
| 27 | Confidentiality | Methods 2.7 |
| 28 | Conflicts of interest | Declarations 4.4 |
| 29 | Access to data | Methods 2.9 |
| 30 | Post-trial care | Standard care; not applicable |
| 31 | Dissemination | Methods 2.10 |
| 32 | Protocol versioning | Declarations 4.9 |
| 33 | Supplementary materials | Supplement tables + Figure 2 |
| 34 | Biological specimens | Not applicable |