## Additional file 1: CONSORT 2025 checklist of information to include when reporting a randomised trial

*Early outcomes of prenatal and infancy home visiting in Germany: a secondary analysis of a randomised controlled trial*

| Section / Topic | No | CONSORT 2025 checklist item description | Reported on page no. |
|---|---|---|---|
| **Title and abstract** | | | |
| Title and structured abstract | 1a | Identification as a randomised trial | p. 1 |
| Title and structured abstract | 1b | Structured summary of the trial design, methods, results, and conclusions | pp. 2–3 |
| **Open science** | | | |
| Trial registration | 2 | Name of trial registry, identifying number (with URL) and date of registration | pp. 3, 5 |
| Protocol and statistical analysis plan | 3 | Where the trial protocol and statistical analysis plan can be accessed | p. 5 |
| Data sharing | 4 | Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed | p. 17 |
| Funding and conflicts of interest | 5a | Sources of funding and other support and role of funders | p. 17 |
| Funding and conflicts of interest | 5b | Financial and other conflicts of interest of the manuscript authors | p. 17 |
| **Introduction** | | | |
| Background and rationale | 6 | Scientific background and rationale | pp. 4–5 |
| Objectives | 7 | Specific objectives related to benefits and harms | pp. 2, 5 |
| **Methods** | | | |
| Patient and public involvement | 8 | Details of patient or public involvement in the design, conduct and reporting of the trial | n.a. |
| Trial design | 9 | Description of trial design including type of trial, allocation ratio, and framework | pp. 5–6 |
| Changes to trial protocol | 10 | Important changes to the trial after it commenced including outcomes or analyses not prespecified, with reason | p. 10 |
| Trial setting | 11 | Settings and locations where the trial was conducted | p. 5 |
| Eligibility criteria | 12a | Eligibility criteria for participants | pp. 5–6 |
| Eligibility criteria | 12b | Eligibility criteria for sites and for individuals delivering the interventions | p. 7 |
| Intervention and comparator | 13 | Intervention and comparator with sufficient details to allow replication | pp. 6–7 |
| Outcomes | 14 | Prespecified primary and secondary outcomes, measurement variable, metric, aggregation, and time point | pp. 7–8; Additional file 2 |
| Harms | 15 | How harms were defined and assessed | n.a. |
| Sample size | 16a | How sample size was determined, including all assumptions | p. 9 |
| Sample size | 16b | Explanation of any interim analyses and stopping guidelines | n.a. |
| Randomisation: sequence generation | 17a | Who generated the random allocation sequence and the method used | p. 6 |
| Randomisation: sequence generation | 17b | Type of randomisation and details of restriction | p. 6 |
| Allocation concealment mechanism | 18 | Mechanism used to implement the random allocation sequence and conceal the sequence | n.a. |

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|---|---|---|---|
| Implementation | 19 | Whether personnel enrolling or assigning participants had access to the allocation sequence | p. 6 |
| Blinding | 20a | Who was blinded after assignment to interventions | p. 6 |
| Blinding | 20b | If blinded, how blinding was achieved and similarity of interventions | n.a. |
| Statistical methods | 21a | Statistical methods used to compare groups for primary and secondary outcomes | p. 9 |
| Statistical methods | 21b | Definition of who is included in each analysis, and in which group | pp. 9–10 |
| Statistical methods | 21c | How missing data were handled in the analysis | p. 9 |
| Statistical methods | 21d | Methods for additional analyses, distinguishing prespecified from post hoc | pp. 9–10 |
| **Results** | | | |
| Participant flow | 22a | Numbers randomly assigned, received intended intervention, and analysed for primary outcome | pp. 10, 26 |
| Participant flow | 22b | Losses and exclusions after randomisation, with reasons | pp. 10, 26; Additional file 2 |
| Recruitment | 23a | Dates defining recruitment and follow-up periods | p. 6 |
| Recruitment | 23b | If relevant, why the trial ended or was stopped | n.a. |
| Intervention and comparator delivery | 24a | Intervention and comparator as actually administered, adherence/fidelity | pp. 6–7 |
| Intervention and comparator delivery | 24b | Concomitant care received during the trial for each group | pp. 7, 13 |
| Baseline data | 25 | Table showing baseline demographic and clinical characteristics for each group | pp. 27–28 |
| Numbers analysed, outcomes, and estimation | 26 | For each outcome by group: participants analysed, available data, results, effect size and precision; binary outcomes absolute and relative effect size | pp. 10–12, 29–31; Additional file 2 |
| Harms | 27 | All harms or unintended events in each group | n.a. |
| Ancillary analyses | 28 | Other analyses performed, including subgroup and sensitivity analyses, distinguishing prespecified from post hoc | pp. 10–12; Additional file 2 |
| **Discussion** | | | |
| Interpretation | 29 | Interpretation consistent with results, balancing benefits and harms, and considering other evidence | pp. 12–14 |
| Limitations | 30 | Trial limitations, sources of bias, imprecision, generalisability, and multiplicity | p. 14 |