# CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial

| Section/Topic                | Item No | Checklist item                                                                 | Reported on page No |
|-----------------------------|---------|---------------------------------------------------------------------------------|---------------------|
| **Title and abstract**      | 1a      | Identification as a pilot or feasibility randomised trial in the title           | 1                   |
|                             | 1b      | Structured summary of pilot trial design, methods, results, and conclusions      | 2                   |
|                             |         | (for specific guidance see CONSORT abstract extension for pilot trials)          |                     |
| **Introduction**            |         |                                                                                 |                     |
| Background and objectives   | 2a      | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | 3-4                 |
|                             | 2b      | Specific objectives or research questions for pilot trial                        | 4-5                 |
| **Methods**                 |         |                                                                                 |                     |
| Trial design                | 3a      | Description of pilot trial design (such as parallel, factorial) including allocation ratio | 5                   |
|                             | 3b      | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | NA                  |
| Participants                | 4a      | Eligibility criteria for participants                                           | 6                   |
|                             | 4b      | Settings and locations where the data were collected                             | 6-7                 |
|                             | 4c      | How participants were identified and consented                                   | 6                   |
| Interventions               | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 8-14                |
| Outcomes                    | 6a      | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | 15-18               |
|                             | 6b      | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | NA                  |
|                             | 6c      | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | 19                  |
| Sample size                 | 7a      | Rationale for numbers in the pilot trial                                        | 5                   |
|                             | 7b      | When applicable, explanation of any interim analyses and stopping guidelines     | NA                  |
| Randomisation:              |         |                                                                                 |                     |
| Sequence generation         | 8a      | Method used to generate the random allocation sequence                           | 7                   |
|                             | 8b      | Type of randomisation(s); details of any restriction (such as blocking and block size) | 7                   |
| Allocation concealment      | 9       | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 7                   |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 7 |
|----------------|----|-------------------------------------------------------------------------------------------------------------------------|---|
| Blinding       | 11a| If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 5,6 |
|                | 11b| If relevant, description of the similarity of interventions | NA |
| Statistical methods | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | 18 |
| Results        | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | 18 |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective | Figure 1 |
|                | 13b | For each group, losses and exclusions after randomisation, together with reasons | NA |
| Recruitment    | 14a | Dates defining the periods of recruitment and follow-up | NA |
|                | 14b | Why the pilot trial ended or was stopped | NA |
| Baseline data  | 15 | A table showing baseline demographic and clinical characteristics for each group | NA |
| Numbers analysed | 16 | For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group | NA |
| Outcomes and estimation | 17 | For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group | NA |
| Ancillary analyses | 18 | Results of any other analyses performed that could be used to inform the future definitive trial | NA |
| Harms          | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | NA |
|                | 19a | If relevant, other important unintended consequences | NA |
| Discussion     | 20 | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | NA |
| Limitations    | 21 | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | NA |
| Generalisability | 22 | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence | NA |
| Interpretation | 22a | Implications for progression from pilot to future definitive trial, including any proposed amendments | NA |
| Other information | 23 | Registration number for pilot trial and name of trial registry | 1 |
| Registration   | 24 | Where the pilot trial protocol can be accessed, if available | NA |
| Protocol       | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Consortium of Multiple Sclerosis |
|   | Ethical approval or approval by research review committee, confirmed with reference number |
|---|--------------------------------------------------------------------------------------------|
| 26 |                                                                                             | 22

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