



## Appendix A1. CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6,7
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8,11
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	9
Participants	4a	Eligibility criteria for participants	8,9
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9,10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10, 11,12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	15
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	9
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	11
Allocation concealment mechanism	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	11
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11
	11b	If relevant, description of the similarity of interventions	9,10

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13,14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13,14
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	15
	13b	For each group, losses and exclusions after randomisation, together with reasons	15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	15
	14b	Why the trial ended or was stopped	15
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16,17
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16,17
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19,20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	20,21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	18,19,20,21
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	8
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org). Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340: c332. Creative Commons Attribution CC BY 2.0.<sup>22</sup>

## **Appendix A2. Semi-structured conversation model**

### **Scenarios for opening intervals of the medication blister/ medication event monitoring system (MEMS):**

1. The electronic device was opened on the planned day of methotrexate administration.
2. The electronic device was opened more than 24hours before the planned day of methotrexate administration.
3. The electronic device was opened more than 24hours after the planned day of methotrexate administration.

Additionally, the planned day of methotrexate administration might have changed after a regular consultation with a rheumatologist or physician assistant.

### **Communication strategies:**

- Related to implementation of the medication regimen in daily life
- Related to cognitive capacity (see "Information" in the semi-structured conversation model)
- Related to medication necessity
- Related to concerns about medication-intake

See Figure A2 for the schematic semi-structured conversation model for proving electronic monitoring feedback.

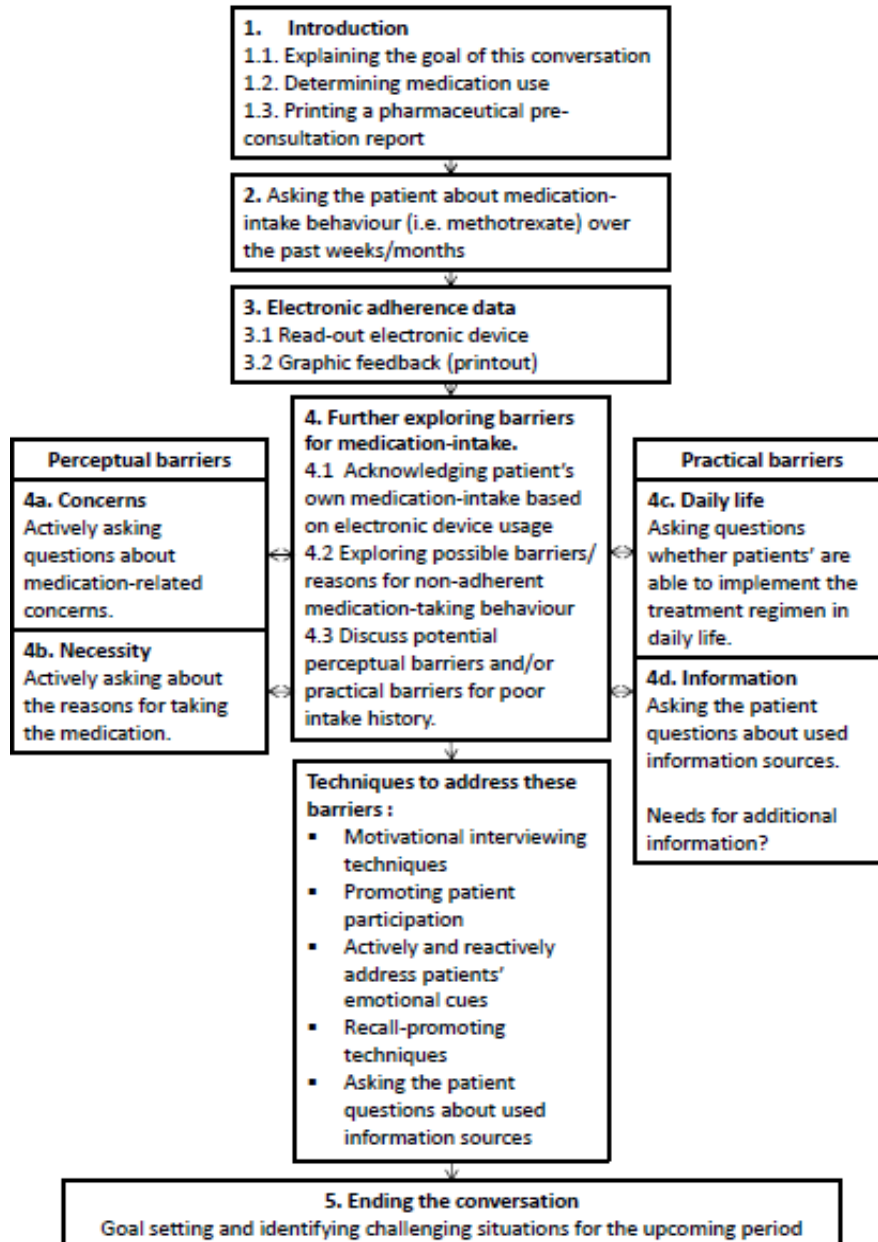


Figure A2. Semi-structured conversation model for providing electronic monitoring feedback.

## Appendix A3. Quality assessment of the audio recordings

<b>Scoring on content of the audio recordings</b>		<b>Total (N=27)</b>
1	Mean duration of an electronic monitoring feedback session, mean (SD) in minutes	8.3 (6.3)
2	Electronic adherence data available, N (%)	25 (93.6)
3	Discussion of electronic adherence data during electronic monitoring feedback session, N (%)	25 (93.6)
4	Asking the patient about medication-intake behaviour (ie methotrexate) over the past weeks/months, N (%)	22 (81.5)
5	Actively asking questions about medication-related concerns, N (%)	13 (48.1)
6	Actively asking about the reasons for taking the medication , N (%)	5 (18.5)
7	Asking questions whether patients' are able to implement the treatment regimen in daily life, N (%)	21 (77.8)
8	Asking the patient questions about used information sources, N (%)	15 (55.6)
9	Asking about the acknowledgement of patient's own medication-intake based on electronic device usage, N (%)	5 (18.5)
10	If applicable; poor medication-intake was discussed during the electronic monitoring feedback session, N (%)	15 (55.6)
<b>Scoring a practitioner's competence for behaviour change counselling</b>		
11	Mean behaviour change counselling index, BECCI (range 0-4), mean (SD)	1.6 (0.70)

Table A3. Quality assessment of the audio recordings.