CONSORT 2010 Checklist and Participant Flow Diagram

2026-08-19

1 CONSORT 2010 Checklist

Section/topic	CONSORT item	Requirement	Manuscript location	Status/notes
Title and abstract	1a	Identify the study as a randomized trial in the title.	Title	Complete
Title and abstract	1b	Provide a structured summary of trial design, methods, results, and conclusions.	Abstract	Complete
Title and abstract	2a	Scientific background and explanation of rationale.	Background	Complete
Title and abstract	2b	Specific objectives or hypotheses.	Background / End of Introduction	Complete
Methods: trial design	3a	Description of trial design, including allocation ratio.	Methods / Study design	Complete
Methods: trial design	3b	Important changes to methods after trial com- mencement, with reasons.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Methods: participants	4a	Eligibility criteria for participants.	Methods / Study population	Complete
Methods: participants	4b	Settings and locations where the data were collected.	Methods / Study population	Complete

Section/topic	CONSORT item	Requirement	Manuscript location	Status/notes
Methods: interventions	5	The interventions for each group with sufficient details to allow replication.	Methods / Interventions	Complete
Methods: outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when assessed.	Methods / Outcomes	Complete
Methods: outcomes	6b	Any changes to trial outcomes after trial commencement, with reasons.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Methods: sample size	7a	How sample size was determined.	Methods / Sample size	[NEEDS COMPLETION]
Methods: sample size	7b	When applicable, explanation of any interim analyses and stopping guidelines.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Methods: randomisation sequence generation	8a	Method used to generate the random allocation sequence.	Methods / Randomization	Block randomization, block size 4; exact sequence generation method [NEEDS COMPLETION]
Methods: randomisation sequence generation	8b	Type of randomisation; details of any restriction such as blocking and block size.	Methods / Randomization	Complete

Section/topic	CONSORT item	Requirement	Manuscript location	Status/notes
Methods: allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence, concealing the sequence until interventions were assigned.	Methods / Allocation concealment	Complete
Methods: implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Methods: blinding	11a	If done, who was blinded after assignment to interventions and how.	Methods / Blinding	Complete
Methods: blinding	11b	If relevant, description of the similarity of interventions.	Methods / Blinding	Over-encapsulation; complete
Methods: statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes.	Methods / Statistical analysis	Complete
Methods: statistical methods	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses.	[NEEDS COMPLETION]	[NEEDS COMPLETION]

Section/topic	CONSORT item	Requirement	Manuscript location	Status/notes
Results: participant flow	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome.	Results / Participant flow	Complete
Results: participant flow	13b	For each group, losses and exclusions after randomization, together with reasons.	Results / Participant flow	Complete for loss to follow-up; exclusions [NEEDS COMPLETION] if any
Results: recruitment	14a	Dates defining the periods of recruitment and follow-up.	Methods / Study period or Results / Recruitment	[NEEDS COMPLETION]
Results: recruitment	14b	Why the trial ended or was stopped.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Results: baseline data	15	A table showing baseline demographic and clinical characteristics for each group.	Results / Baseline characteristics	Complete
Results: numbers analysed	16	For each group, number of participants included in each analysis and whether the analysis was by original assigned groups.	Results / Analysis	Complete

Section/topic	CONSORT item	Requirement	Manuscript location	Status/notes
Results: outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision.	Results / Outcomes	Complete
Results: outcomes and estimation	17b	For binary outcomes, presentation of both absolute and relative effect sizes.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Results: ancillary analyses	18	Results of any other analyses performed, including subgroup and adjusted analyses, distinguishing pre-specified from exploratory.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Results: harms	19	All important harms or unintended effects in each group.	Results / Adverse events	Complete
Discussion: limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and multiplicity of analyses.	Discussion / Limitations	Complete
Discussion: generalizability	21	Generalizability of the trial findings.	Discussion / Limitations or Conclusion	Complete

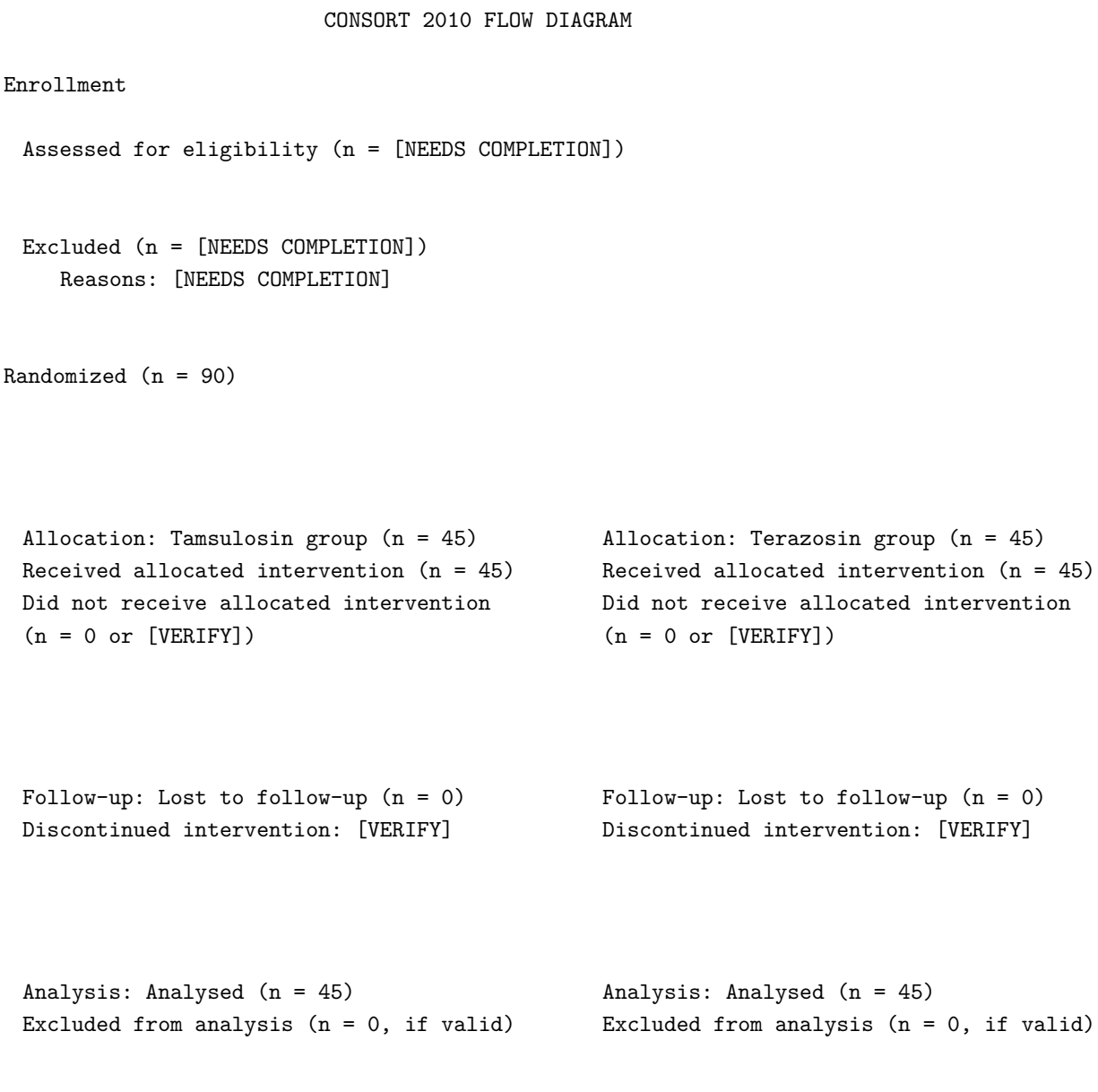
Section/topic	CONSORT item	Requirement	Manuscript location	Status/notes
Discussion: interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	Discussion / Conclusion	Complete
Other information: registration	23	Registration number and name of trial registry.	Abstract / Methods / Declarations	Complete; registration date [NEEDS COMPLETION]
Other information: protocol	24	Where the full trial protocol can be accessed, if available.	[NEEDS COMPLETION]	[NEEDS COMPLETION]
Other information: funding	25	Sources of funding and other support, role of funders.	Declarations / Funding	Complete

Notes for submission

- Trial design: double-blind randomized clinical trial, 1:1 allocation.
- Participants: 90 total; 45 tamsulosin and 45 terazosin.
- Follow-up: all participants completed follow-up; loss to follow-up was 0.
- Setting and year: 2024, centers affiliated with Arak University of Medical Sciences.
- Ethics approval: IR.ARAKMU.REC.1400.227.
- Trial registration: IRCT20201006048950N3.
- Interventions: tamsulosin 0.4 mg once daily; terazosin 2 mg once daily.
- Outcomes: USSQ, IPSS, QoL, and adverse events.
- Randomization: block randomization, block size 4.
- Allocation concealment: sequentially numbered opaque sealed envelopes.
- Blinding: over-encapsulation; patient and assessor blinding.
- Statistics: SPSS; Shapiro-Wilk, independent t-test, Mann-Whitney U, chi-square.
- Any manuscript-specific item not provided in the source text remains marked [NEEDS COMPLETION].

References: CONSORT guidance and flow diagram structure are based on the official CONSORT materials and reporting-guideline index pages S1, S2, and the CONSORT 2010 statement S3. Trial-specific facts were taken only from the information you supplied and are grounded in the user-provided study details [U1].

2 CONSORT 2010 Participant Flow Diagram



All numerical entries are based only on the information provided by the authors. Bracketed entries require verification before submission.

References: Flow-diagram structure follows the official CONSORT materials S1, S2, S3.