Otolaryngology–Head and Neck Surgery (2008) 138, 283-288

ORIGINAL RESEARCH—SLEEP MEDICINE

# A randomized crossover trial of conservative snoring treatments: Mandibular repositioning splint and nasal CPAP

**Stuart Robertson, MRCS, Maria Murray, RDN, David Young, PhD, Richard Pilley, PhD,** and **John Dempster, FRCS,** Kilmarnock and Glasgow, Scotland, United Kingdom

**OBJECTIVE:** To compare the effectiveness of a mandibular repositioning splint (MRS) and nasal continuous positive airway pressure (CPAP) device as first-line treatments for disruptive snoring.

**STUDY DESIGN:** Prospective randomized crossover trial.

**SUBJECTS AND METHODS:** Twenty snorers received 3 months of treatment with both an MRS and nasal CPAP. Snoring Outcomes Survey (SOS), Snoring Bed Partner Survey, and Epworth questionnaires were completed serially. Changes in questionnaire scores were analyzed with a general linear statistical model and by analysis of variance.

**RESULTS:** There was a significant difference between the three preference outcomes for the mean SOS changes ($P = 0.003$). The mean SOS change was significantly greater for those who preferred MRS to CPAP (mean score difference, 27.15). Eight snorers chose final long-term MRS treatment, five chose nasal CPAP, and seven chose neither.

**CONCLUSION:** The majority of disruptive snorers can be managed effectively with conservative treatments and therefore avoid surgery.



Patients with disruptive snoring are commonly referred to secondary care ENT services for treatment. The high failure rate and postoperative morbidity rate of snoring surgery make conservative first line treatment attractive.[1] Indeed, there is no published clinical evidence to support the use of surgery over conservative treatments in the first line management of disruptive snoring. Conservative treatment options include continuous positive airway pressure (CPAP) devices and mandibular repositioning splints (MRS).[2-4]

The relative efficacy of CPAP and MRS has been evaluated in snorers with obstructive sleep apnoea hypopnea syndrome (OSAHS).[5] National guidelines advocate the use of an MRS for mild to moderate OSAHS, but CPAP is recommended for severe OSAHS.[4] However, the majority of patients referred to ENT with disruptive snoring do not have OSAHS.[6] By definition, apneic and nonapneic snorers differ in terms of the degree of anatomic airway obstruction present. It is therefore incorrect to assume that the treatment of choice for both snoring populations should be the same in the absence of supporting clinical evidence.

The principal aim of this study was to determine the relative efficacy of a custom-moulded MRS and a nasal CPAP device as first-line treatments for nonapneic snorers referred to a secondary care ENT service. Secondary aims were to determine how many snorers could be managed effectively with conservative first line treatment and therefore avoid surgical intervention and whether any side effects were associated with either treatment.

## METHODS

### Ethical Considerations

Formal ethical approval was obtained from the Local Research Ethics Committee in January 2005. A cohort of 50 patients referred to our ENT service for investigation and treatment of disruptive snoring were given appointments to attend a dedicated snoring clinic. Snorers who failed to attend were offered a second appointment.

### Clinical Assessment and Recruitment

All snorers were assessed by the principal author and a structured history and examination performed in accordance with national guidelines to identify patients at risk of having OSAHS.[4] Patients with risk factors for OSAHS were referred for formal sleep study investigation. Inclusion criteria for trial participation were 1) the presence of sufficient dentition for an MRS, 2) living with a partner on a regular basis, and 3) no evidence of OSAHS on clinical assessment.[4] All eligible snorers and their partners were given

Received August 30, 2007; revised October 30, 2007; accepted November 5, 2007.

0194-5998/$34.00 © 2008 American Academy of Otolaryngology–Head and Neck Surgery Foundation. All rights reserved.
doi:10.1016/j.otohns.2007.11.004

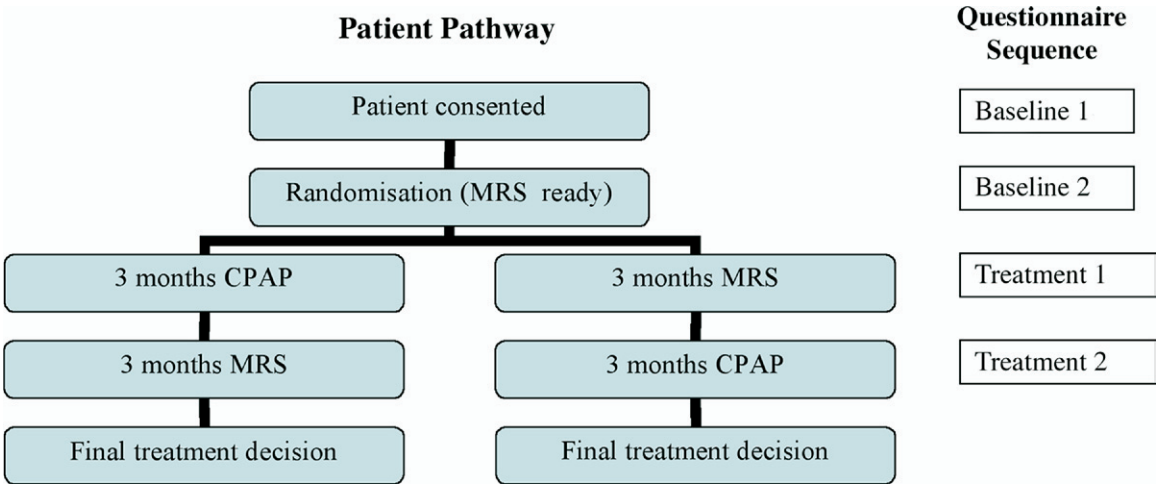


**Figure 1** Trial pathway and questionnaire sequence.

formal information sheets on the study. Informed consent was then obtained from participating couples. Each snorer received a consecutive 3-month trial of a MRS and nasal CPAP device (Fig 1). Snorers were randomized to the order of treatment as detailed below.

## Randomization Process

Based on previous snoring research conducted by the principal author in the west of Scotland, it was anticipated that recruitment rates from a cohort of 50 snorers would be less than 60%.[7] Thirty sealed brown opaque envelopes (15 marked internally with "CPAP" and 15 with "MRS") were prepared by the principal author and given to an ENT secretary (S.J.M.) to shuffle thoroughly. The shuffled envelopes were then numbered sequentially from 1 to 30 by the principal author and stored in the ENT Department secretarial office (all witnessed by S.J.M.).

## Clinical Pathway

Snorers progressed through the trial as shown in Figure 1. It was anticipated that the length of time required to make patients' MRS would vary depending on the complexity of individual patient dentition and their attendance at consecutive orthodontic clinic appointments. To ensure that progress through the trial was not interrupted, randomization of each snorer was not undertaken and treatment did not commence until that patient's MRS was ready for use. When each MRS was ready, the principal author opened the next numerically labeled envelope in the ENT office and recorded the treatment assigned on a datasheet (all witnessed, signed, and dated by S.J.M.). Between June 2005 and June 2006, each snorer then commenced a 3-month trial of the treatment assigned on randomization (treatment 1). After completing treatment 1, each snorer returned his or her MRS or CPAP device and "crossed over" to the other treatment for a further 3 months (treatment 2). No blinding of subjects or researchers was possible or attempted because of the nature of this study. Three month follow-up data collection was completed in January 2007.

## CPAP Device

The CPAP device used was the ResMed S7 Lightweight (ResMed Ltd, Oxfordshire, UK). Air was delivered via a standard nasal mask. Patients were shown how to vary the ramping time for comfort. Ramping pressure and treatment pressure were set at 4 cm and 10 cm water pressure, respectively, so that all patients received the same initial CPAP treatment protocol. Patients who chose to continue with long-term CPAP treatment after completing this trial were shown how to vary treatment pressure for maximal comfort and treatment efficacy.

## MRS Design

All patients received a clinical and radiographic examination before splint construction. Dentition was surveyed to assess bone support, gingival health, tooth mobility, and the presence of advanced restorations. Once dentally fit, upper and lower impressions were cast in dental stone. Each MRS (Fig 2) was manufactured from thermoformable plastics resin sheets (supplied by Erkodur, Erkodent, Germany) bonded together by cold-curing polymethyl methacrylate resin (Wright-Cottrell, Dundee, UK). Each MRS was de-

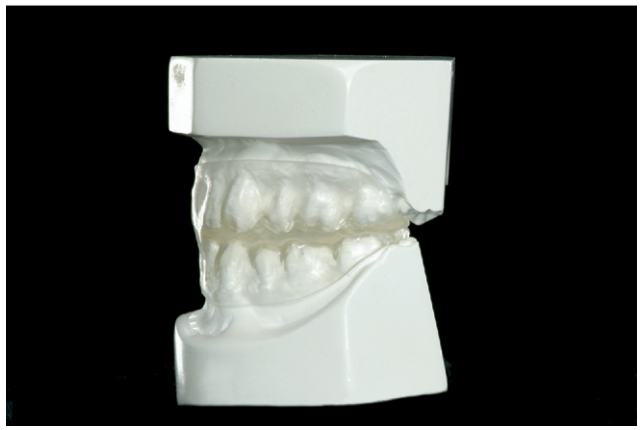

**Figure 2** Custom-molded thermoplastic MRS device.

**Table 1**
**Details of 30 nonparticipants**

| | |
|---|---|
| Refused to participate | 11 |
| Failed to attend | 7 |
| Insufficient dentition | 7 |
| Diagnosed with OSAHS | 1 |
| Discomfort during molding | 1 |
| Currently dieting | 1 |
| No partner | 2 |

signed to advance the mandible by holding the upper and lower incisors in an edge-to-edge position making sure the center line was coincident.

## Outcome Measures

*Questionnaire scores.* The effects of disruptive snoring on snorers' partners are well recognized.[8,9] Accordingly, it was decided that to determine the relative efficacy of MRS and CPAP, feedback from both the snorer and partner should be obtained. The Epworth Sleepiness Score and the Snoring Outcomes Survey (SOS) Questionnaire/Bed Partner Survey (SBPS) were completed by snorer and partner at four separate time points: 1) at the time of initial informed consent (baseline 1), 2) at the time of randomization (baseline 2), 3) after completion of treatment 1, and 4) after completion of treatment 2.

The SOS has been shown to be valid, reliable, and sensitive to clinical change after treatment in snoring populations.[10] An increase in SOS or SBPS score is associated with a reduction in perceived snoring severity. The Epworth questionnaire is widely used in sleep disordered patients as a validated method of assessing patients' perception of daytime fatigue or sleepiness. A reduction in Epworth score is associated with a reduction in subjective daytime sleepiness.[4] All questionnaires were either completed at clinic with the principal author or by return of post.

*Decision on long-term treatment.* After completing treatment 2, each snorer was asked to choose a long-term treatment preference (MRS, CPAP, or neither). Snorers who chose neither were sent a further clinic appointment to discuss other treatment options. Snorers who chose either long-term MRS or CPAP treatment were contacted by telephone in October 2007 to collect compliance data after 12 months of treatment.

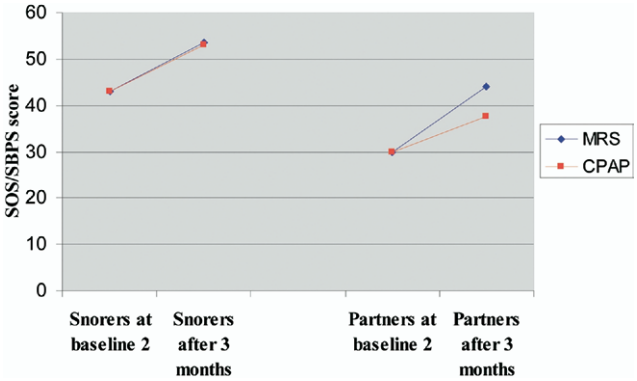


**Figure 3** Mean SOS/SBPS score changes for snorers and partners.

## Statistics

Tables of descriptive statistics were produced to summarize the changes in SOS and Epworth scores for each treatment. The reliability of the data was investigated with a comparison of the questionnaire results at recruitment with those at randomization by computing 95% confidence intervals for the mean differences in the scores. The changes in scores for each questionnaire were analyzed by treatment with a general linear model that included a factor for the order of treatment that corresponded with the cross-over design of the study. Comparison of the changes in questionnaire scores with the stated preference of treatment by patients (MRS, CPAP, or neither) were done with analysis of variance. All analyses were done with Minitab statistical software (Version 14, Minitab, Coventry, UK) with a significance level of 5%.

# RESULTS

## Trial Recruitment

From the 50 snorers referred for investigation and treatment of disruptive snoring, 20 participated in the trial. Reasons for exclusion are detailed in Table 1. One patient satisfied the referral criteria (SIGN) for sleep study investigation who subsequently confirmed a diagnosis of OSAHS. This patient was excluded from the trial. After 2 weeks of CPAP

**Table 2**
**Changes in questionnaire scores with treatment (CI, confidence interval)**

| | Treatment | Snorers (n) | Mean score change (CI) | Partners (n) | Mean score change (CI) |
|---|---|---|---|---|---|
| SOS/SBPS change | MRS | 20 | 10.5 (3.5, 17.5) | 20 | 14 (3.9, 24) |
| | CPAP | 19 | 10 (3.9, 16.1) | 18 | 7.6 (−1.2, 16.4) |
| Epworth change | MRS | 20 | −2.2 (−4.1, −0.2) | 20 | −0.8 (−2.3, 0.7) |
| | CPAP | 19 | −3.3 (−5.8, −0.9) | 18 | −1.9 (−4.1, 0.3) |

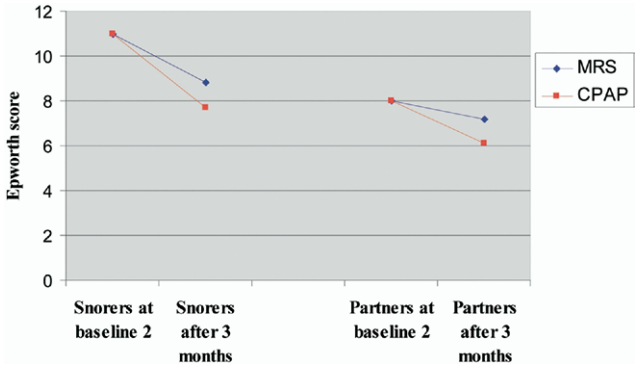


**Figure 4** Mean Epworth score changes for snorers and partners.

treatment (as treatment 2), one patient refused to continue and demanded to be given back their MRS. Questionnaire scores for CPAP treatment were therefore not collected for this couple (Table 2). This snorer subsequently chose long-term MRS treatment. Another couple ended their relationship during the trial and questionnaire scores for the partner could not be collected after the snorer completed CPAP treatment. This snorer subsequently chose long-term MRS treatment.

## Questionnaire Scores

The mean Epworth scores of snorers and partners at baseline 2 were 11 and 8, respectively. The mean SOS and SBPS scores at baseline 2 were 43 and 30, respectively. An improvement in mean questionnaire scores from baseline 2 occurred after both MRS and CPAP treatment (Table 2). As shown in Figures 3 and 4, there was no significant difference between the mean changes in SOS ($P = 0.863$), SBPS (0.479), or Epworth scores for snorers ($P = 0.174$) or partners ($P = 0.484$) between treatments. There was also no significant effect of cross-over for SOS ($P = 0.758$), SBPS ($P = 0.624$) or Epworth ($P = 0.492$ for snorers, $P = 0.772$ for partners).

Changes in questionnaire scores in relation to final treatment choice are shown in Table 3. There was a significant difference between the three preference outcomes for mean SOS changes ($P = 0.003$). The mean SOS change was significantly greater for those choosing long-term MRS treatment in comparison with those choosing CPAP (mean difference, 27.15; confidence interval, CI = 9.38 to 44.92), Fig 5). There was no evidence of any difference between the three preference outcomes for mean SBPS changes ($P = 0.119$) or Epworth changes ($P = 0.197$ for snorers, $P = 0.821$ for partners).

## Questionnaire Reliability

There was no significant difference between questionnaire scores for patients or partners at baseline 1 and baseline 2 (Table 4). This represents a control period as no treatment occurred during this time and confirms the reliability of both questionnaires.

## Final Treatment Choices

After completing the trial, 8 of 20 snorers chose final long-term MRS treatment, 5 chose nasal CPAP, and 7 chose not to continue either treatment. A telephone interview in October 2007 confirmed that seven of the eight snorers who chose MRS treatment and four of the five snorers who chose CPAP were still using their chosen treatment after 12 months. The snorer who discontinued CPAP treatment had found it to be ineffective after 9 months and requested a further clinic appointment to discuss surgical treatment options. The snorer who discontinued MRS treatment had done so after 8 months in order to undergo restorative dental work unrelated to MRS usage. This dental work has recently been completed. The patient has asked to be fitted with a new MRS and is currently awaiting splint manufacture.

## Adverse Effects of Treatments

Table 5 presents the side effects of each treatment as specified by snorers. One of the patients with temperomandibular joint (TMJ) discomfort was subsequently diagnosed with TMJ disk displacement. This condition was treated conservatively. After recovery and splint adjustment, this patient has recommenced MRS treatment.

**Table 3**
**SOS, SBPS, and Epworth score changes as per final treatment choice**

| Treatment choice | n | Questionnaire | Mean score change after MRS | Mean score change after CPAP |
|---|---|---|---|---|
| MRS | 8 | SOS | 22.75 | 6.50 |
| | | SBPS | 26.50 | 0.13 |
| | | Epworth (snorer) | −4.25 | −5.38 |
| | | Epworth (partner) | −1.38 | −3.38 |
| CPAP | 5 | SOS | −4.40 | 14.40 |
| | | SBPS | 2.20 | 15.00 |
| | | Epworth (snorer) | 0.20 | −3.80 |
| | | Epworth (partner) | −0.20 | −2.80 |
| Neither | 7 | SOS | 7.14 | 2.71 |
| | | SBPS | 0.00 | 0.00 |
| | | Epworth (snorer) | −1.43 | −0.86 |
| | | Epworth (partner) | −0.57 | −0.14 |

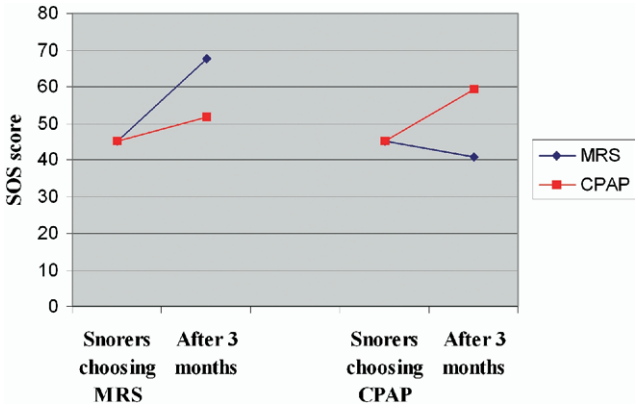


**Figure 5** Mean SOS score changes for snorers vs final treatment choice (MRS or CPAP).

## DISCUSSION

The improvement in SOS, SBPS, and Epworth scores reported by patients in this trial demonstrates that both MRS and CPAP are effective snoring treatments. The greatest improvement in snoring severity (as defined by the SOS questionnaire) was reported by the snorers who chose long-term MRS treatment. However, it is clear that while conservative treatments may be effective, they are not always tolerable and some patients will be unable to comply with either MRS or CPAP. Such patients should be offered referral for an opinion on surgical snoring treatments.

Thirteen (65%) of the 20 patients in this trial chose long-term conservative snoring treatment. After 1 year of conservative treatment, 11 of these patients were still compliant with treatment. The authors therefore propose that at least one-half of snorers referred to ENT can be managed effectively with conservative treatments. Long-term follow-up on this trial cohort is ongoing.

The authors accept that the final number of participants in this trial was small and comparable numbers of snorers chose each of the three final treatment preference choices. The recruitment rate for this trial was also low although 22 of the 30 patients excluded were excluded for reasons unrelated to suitability for either MRS or CPAP treatment (Table 1). Although pain and malocclusion are recognized long-term complications of MRS usage,[3] the incidence of such side effects in this trial population was low (Table 5).

**Table 4**
**Mean questionnaire changes from Baseline 1 to Baseline 2 (CI, confidence intervals)**

| | Questionnaire | Mean score change (95% CI) |
|---|---|---|
| Snorers | SOS | −1 (−3.5, 1.5) |
| | Epworth | 0.65 (−1.0, 2.3) |
| Partners | SBPS | −0.85 (−4.6, 2.9) |
| | Epworth | 0.3 (−0.9, 1.5) |

**Table 5**
**Incidence of side effects specified by snorers (n = 20)**

| Treatment | Side effect | n |
|---|---|---|
| MRS | TMJ discomfort | 3 |
| | Toothache | 2 |
| | Minor gingival bleeding | 2 |
| CPAP | Dry nose/mouth | 5 |
| | General discomfort | 15 |

All snorers receiving long-term MRS treatment at our center are seen on a 3-month basis for the first year to check for such complications.

## CONCLUSION

This study presents level 1 evidence to support the argument that the first-line treatment of disruptive snoring should be conservative. At least one-half of snorers referred to ENT can be managed effectively with conservative treatments and therefore avoid surgery. The authors propose that snorers should first be offered an MRS. If MRS treatment is ineffective or unsuitable because of insufficient dentition, patients should be offered a trial of nasal CPAP. If CPAP is ineffective, then snorers should be given the opportunity to discuss surgical treatment options with an otolaryngologist.

## ACKNOWLEDGMENT

The authors wish to thank Ms Sarah-Jane Mackie (SJM), ENT Secretary for her assistance with the randomization process (see Methods section).

## AUTHOR INFORMATION

From the Departments of Otolaryngology–Head and Neck Surgery (Mr Robertson and Mr Dempster) and Orthodontics (Dr Pilley and Mrs Murray), Crosshouse Hospital, Kilmarnock, and the Department of Statistics and Modelling Science (Dr Young), Strathclyde University, Glasgow, UK.

Presented at AAO-HNS annual meeting, Washington, DC, September, 2007.

Corresponding author: Mr Stuart M Robertson, MRCS, Specialist Registrar, Department of Otolaryngology–Head and Neck Surgery, Crosshouse Hospital, Kilmarnock, Scotland, United Kingdom KA2 OBE.

E-mail address: stuart@glasgow.org.

## AUTHOR CONTRIBUTION

**Stuart Robertson**, trial design, data collection, manuscript composition, AASHNS podium presentation; **Maria Murray**, splint manufacture; **David Young**, statistical analysis; **Richard Pilley**, trial design, splint manufacture, manuscript appraisal; **John Dempster**, trial design, manuscript appraisal.

## FINANCIAL DISCLOSURE

None.

## REFERENCES

1. Jones TM, Earis JE, Calverley PMA, et al. Snoring surgery: a retrospective review. Laryngoscope 2005;115:2010–5.
2. Pancer J, Al-Faifi SA, A-Faifi M, et al. Evaluation of variable mandibular advancement appliance for treatment of snoring and sleep apnea. Chest 1999;116(6):1511–8.
3. Schmidtnowara W, Lowe A, Wiegand L, et al. Oral appliances for the treatment of snoring and obstructive sleep apnea: a review. Sleep 1999;18(6):501–10.
4. Scottish Intercollegiate Guidelines Network (SIGN) Guideline 73. Management of obstructive sleep apnoea/hypopnoea syndrome in adults, 2003:8–19.
5. Engleman HM, McDonald JP, Graham D, et al. Randomized crossover trial of two treatments for sleep apnoea/hypopnea syndrome. Am J Respir Crit Care Med 2002;166:829–55.
6. Lim PVH, Curry AR. The role of history, Epworth Sleepiness Scale Score and body mass index in identifying non-apnoeic snorers. Clin Otolaryngol 2000;25:244–8.
7. Robertson S, Loughran S, MacKenzie K. Ear protection as a treatment for disruptive snoring: do ear plugs really work? J Laryngol Otol 2006;120:81–4.
8. Beninati W, Harris CD, Herold DL, et al. The effect of snoring and obstructive sleep apnoea on the sleep quality of bed partners. Mayo Clin Proc 1999;74(10):955–7.
9. Cartwright RD, Knight S. Silent partners: the wives of sleep apnoeic patients. Sleep 1987;10:244–8.
10. Glikich RE, Wang P. Validation of the snore outcomes survey for patients with sleep-disordered breathing. Arch Otolaryngol Head Neck Surg 2002;128:819–24.

# APPENDIX

**CONSORT Statement 2001 - Checklist**
**Items to include when reporting a randomized trial**

| Paper section and topic | Item | Descriptor | Reported on page # |
|---|---|---|---|
| TITLE & ABSTRACT | 1 | How participants were allocated to interventions (*e.g.*, "random allocation," "randomized," or "randomly assigned"). | 1 |
| INTRODUCTION Background | 2 | Scientific background and explanation of rationale. | 1 |
| METHODS Participants | 3 | Eligibility criteria for participants and the settings and locations where the data were collected. | 1,2 |
| Interventions | 4 | Precise details of the interventions intended for each group and how and when they were actually administered. | 2 |
| Objectives | 5 | Specific objectives and hypotheses. | 1 |
| Outcomes | 6 | Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors). | 2,3 |
| Sample size | 7 | How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules. | 2 |
| Randomization – Sequence generation | 8 | Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification). | 2 |
| Randomization – Allocation concealment | 9 | Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned. | 2 |
| Randomization – Implementation | 10 | Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups. | 2 |
| Blinding (masking) | 11 | Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated. | 2 |
| Statistical methods | 12 | Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses. | 3 |
| RESULTS Participant flow | 13 | Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons. | 2, Fig1 |
| Recruitment | 14 | Dates defining the periods of recruitment and follow-up. | 2,3 |
| Baseline data | 15 | Baseline demographic and clinical characteristics of each group. | 4 |
| Numbers analyzed | 16 | Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%). | 4 |

**(Continued)**

| Paper section and topic | Item | Descriptor | Reported on page # |
|---|---|---|---|
| Outcomes and estimation | 17 | For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval). | 4 |
| Ancillary analyses | 18 | Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory. | 4 |
| Adverse events | 19 | All important adverse events or side effects in each intervention group. | 4,5 |
| DISCUSSION<br>Interpretation | 20 | Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes. | 5 |
| Generalizability | 21 | Generalizability (external validity) of the trial findings. | 5 |
| Overall evidence | 22 | General interpretation of the results in the context of current evidence. | 5 |

www.consort-statement.org