MDSG GUIDE FOR RESULTS SECTION

The methods suggested below can be adapted to suit your review. Examples are provided in italics.

- Activate all the RevMan headings.
- Insert RevMan links to study IDs, tables, figures and analyses throughout.

Description of studies

Results of the search

The search retrieved 97 articles. Seventeen studies (22 articles) were potentially eligible and were retrieved in full text. Ten studies (15 articles) met our inclusion criteria. Five studies were excluded and two are ongoing. See study tables: Characteristics of included studies, Characteristics of excluded studies, Characteristics of studies awaiting classification.

Include a PRISMA flow chart – insert as figure

Included studies

No text is needed directly under this heading. Insert four subheadings (as below) and briefly summarise important points. Include full details of individual studies in Characteristics of included studies table (not here).

Study design and setting

Ten parallel-design randomised controlled trials (RCTs) were included in the review. All were single-centre studies conducted in outpatient clinics in China.

Participants

The studies included XX women in the intervention groups and XX in the control groups. All were women with infertility; 30-60% of women in all studies also had pelvic pain. The mean participant age was 34 years (range 22-42). Most women had unexplained infertility.

Interventions

- *5/10 studies compared XX versus placebo*
- *7/10 compared XX versus YY*
- *Co-treatments included XXX. The studies varied in initial dose of YY used.*

Outcomes

- *3/10 studies reported live birth.*
- *10/10 reported ongoing pregnancy*
- *10/10 reported miscarriage*
- *8/10 reported multiple pregnancy*
- *7/10 reported ovarian hyperstimulation syndrome (OHSS).*

Excluded studies

Only studies that initially appeared eligible should be listed as excluded studies (i.e. if you had to read the full-text publication in order to determine that it was ineligible)

Five studies were excluded from the review, for the following reasons:

- *3/5 were not RCTs*
- *2/5 reported no comparisons of interest*

Risk of bias in included studies

Allocation (Selection bias)
Address both generation of random sequence and allocation concealment under this heading. Use separate paragraphs or subheadings.

Five studies were at low risk of selection bias related to sequence generation, as they used computer randomisation or a random numbers table. The other five studies did not describe the method used and were at unclear risk of this bias.

Four studies were at low risk of selection bias related to allocation concealment….etc

Blinding of participants and personnel
Consider the degree to which blinding is likely to influence specific outcomes.

We did not consider that blinding was likely to influence findings for the primary review outcome (live birth). However for adverse effects and subjective secondary outcomes (quality of life), blinding status could potentially affect findings. 6/10 studies described use of a double-dummy placebo identical to the intervention and were thus deemed to be at low risk of performance bias …etc..

Blinding of outcome assessors
8/10 studies described blinding of outcome assessors and we judged them to be at low risk of detection bias..etc.

Incomplete outcome data
8/10 studies analysed all or most (>95%) women randomised and we judged them to be at low risk of bias. Two studies were considered to be at high risk of attrition bias: in one there was a differential drop out rate in the two groups (18% versus 5%) and the other stated that results were reported per protocol.

Selective reporting
Protocols were available for 6/10 studies, of which 5/6 reported all prespecified outcomes. The sixth reported a number of outcomes not stated in the protocol. Among four studies where protocols were not available, all four reported outcomes that were not clearly prestated in the methods section and two failed to report adverse events as an outcome. In summary, we judged five studies to be at low risk of bias, two at unclear risk and three at high risk of bias.

Other potential sources of bias
In one study there were substantial baseline differences in age between the two groups and the risk of bias was deemed high. We found no potential sources of within-study bias in the other nine studies.

Do not include funding source, power calculations, ethics approval or early stopping in this section, as they do not affect internal validity. These issues should be reported in the Characteristics of Included Studies table.

Effects of interventions

- Summarise the main findings of the review, directly addressing the review objectives
- Separate primary and secondary outcomes
- Use the same order of comparisons and outcomes and numbering system as in your Methods section and data tables
- Include all pre-specified comparisons, outcomes and planned subgroup analyses: if no relevant data were found, report this.
- Report quality of evidence for each outcome (from 'Summary of findings' table)
- Use this type of format for presenting results: OR 1.5, 95% CI 1.2 to 1.8, P=0.02, 5 RCTs, 345 women, I^2=24%, low-quality evidence
- If there are multi-arm studies, take care to avoid double-counting of controls.
- Do not describe the results of individual studies unless there is only one study in the comparison.
- Report all prespecified sensitivity and subgroup analyses at the end of each comparison. If there were too few studies to conduct the analyses, state this.
- Report any post-hoc analyses at the end of each comparison, noting that they were not prespecified and require extra caution in interpretation
- Report the results of funnel plots *E.g. Funnel plots for the primary outcomes (Live birth and ongoing pregnancy) did not suggest reporting bias*
- Acknowledge any substantial statistical heterogeneity detected and explore it (e.g. by means of sensitivity analyses)

How to format your findings:

1. Comparison of treatment A versus Treatment B

Primary outcomes

1. 1 Live birth

Treatment A was associated with an increased live birth rate compared to treatment B (OR 3.2, 95% CI 1.2-4.7, P=0.001, 5 RCTs, 435 women, I^2= 21%, low-quality evidence). (Link to graph/figure here). There was no evidence of an effect in the subgroup of women who had a poor prognosis (OR 1.5, 95% CI 0.6 to 1.9, 2 RCTs, 60 women, I^2=37%, moderate quality evidence). Sensitivity analysis excluding poor quality studies did not affect the statistical significance of the main analysis for this outcome.

1.2 Adverse events

Treatment A was associated with….etc

Secondary outcomes

1.3 Clinical pregnancy

2. Comparison of Treatment A versus treatment C

Primary outcomes

2. 1 Live birth

2.2 Adverse events

Secondary outcomes

2.3 Clinical pregnancy

Discussion

No text is needed directly under this heading

Summary of main results

Briefly summarise the main findings and outstanding uncertainties, balancing important benefits against important harms. Express results in the most consumer-friendly way possible. Refer to quality of evidence (from SoF table) .

Overall completeness and applicability of evidence

This section addresses the external validity of the review.

- Did the included studies answer the review question?
- Were relevant participants, interventions and outcomes investigated?
- Do the review findings support current practice?
- Comment on studies that measured outcomes but had no 'usable' data

Quality of the evidence

This section addresses the internal validity of the review.

- How robust are the conclusions?
- Summarise number of studies, sample sizes, their key methodological limitations, and consistency/inconsistency of the results.

Potential biases in the review process

Comment on the strengths and limitations of the review process

- Were all relevant studies identified?
- Could review authors' methods have introduced bias?

Agreements and disagreements with other studies or reviews

How do review findings fit into the wider research context?

Authors' conclusions

Implications for practice

- Do not go beyond the evidence reviewed, mention risk of bias
- Do not make recommendations for practice
- If there is no statistically significant effect, say 'there is no evidence of effect'
- Do not interpret no evidence of effect as evidence of no effect.
- Consider clinical as well as statistical significance
- If relevant, summarise the likely benefits and risks/costs of the intervention and for whom it should be considered.

Implications for research

- Which questions have been well answered (no further trials needed)
- Which questions remain unanswered (further trials needed)
- Whether further trials in selected populations are warranted
- Identify any new research areas (dose modification, combined therapies etc).

Differences between protocol and review

Describe any change to Methods from protocol to review (eligibility criteria, outcomes studied etc.). State when changes were made and why.