

## PREPARING MANUSCRIPTS AND RESPONDING TO REFEREES' REPORTS: INSIDE THE EDITORIAL BLACK BOX

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### INTRODUCTION

This chapter describes how the peer review process works and presents suggestions to authors of manuscripts. It is based upon the experiences of scientists and clinicians who have many years of experience as editors of prominent addiction journals. The task of the editor is to publish manuscripts appropriate to the journal and to assist would-be authors in the production of suitable material. Many of the problems facing authors writing for scholarly peer-reviewed journals in the addiction field are similar to those in other fields. Therefore, it is recommended that readers consult one or more of the full-length books that have already been published in this general area. Literally hundreds of books have been published, as can be seen by searching amazon.com or PubMed for 'scientific writing'. For example, a search of amazon.com on 3 October 2003 produced 188 results, many of which were relevant. A short list of recent books is provided at the end of this chapter in Appendix 6.1.

### TRIAGE: THE FIRST SELECTION

The author's quest to find a suitable publication outlet ends with a letter stating 'I am pleased to inform you that your manuscript is acceptable for publication ...'. The first step is to get the manuscript into the peer-review system.

This is not the inevitable consequence of submitting to a peer-reviewed journal. Some journals state formally that they operate a system of 'triage' whereby the editor or his or her assistants decide which submitted articles will be entered into the peer review process. In practice, it is likely that all journals have such a system to protect the profile of the journal and to avoid bothering authors and peer reviewers with a long and laborious process where a negative result can be predicted (see Box 6.1). Thus, if something is received that clearly has no hope of acceptance it may be rejected without review. Here, the difference between journals is quantitative rather than qualitative: in the journals of highest impact in science and medicine generally, it may be more than half of the submissions that are rejected at this stage. In contrast, in very specialised journals such as those in the addiction field, it may be a fairly rare occurrence for submissions to be rejected without review. Nevertheless, this rate can be as high as 10% for some journals.

### Box 6.1 REASONS FOR REJECTION BY TRIAGE

- The submission is outside the scope of the journal (e.g., it is about an abused drug but it is not relevant in any discernible way to abuse of or dependence on it)
- The manuscript type is not appropriate (e.g., a case report is submitted to a journal that does not publish case reports)
- Clear ethical problems such as apparent violation of current generally accepted standards for the treatment of human or animal subjects
- The article is poorly organized
- The report is purely descriptive, has no hypotheses, or reaches no conclusions
- Major methodological weakness
- There appears to be nothing new in it
- Instructions to Authors are flagrantly ignored in some way not covered by the above

Note: the editor has a duty to referees as well as to authors, and tries not to waste their time by requesting reviews of work that has no chance of acceptance for one or more of the reasons above.

There are some aspects of manuscript preparation that are so easy that everyone should get them right. To ensure your manuscript has the best chance at triage (and beyond), make sure you do all these things as set out in the Instructions to Authors that every journal provides. Follow all advice and recommendations to the letter, format your submission precisely as requested, check to make sure that all sections are complete, and that no tables, figures, or figure legends are missing. Check the reference list to ensure that all cited references are in it, and no others. Check the accuracy of each citation. Look in the journal to see exactly how they are styled. Then check them over again, after you have made the corrections, until no more errors can be found. This sort of work is tedious but does not need expensive resources, profound knowledge of the subject or outstanding intellectual ability.

If the editor sees at a glance that you do not even get these straightforward, mechanical things right, he or she may well develop a jaundiced view about your capability to deal with more complex matters. Try to look at the manuscript as an editor might. If you do not bother to do the easier things required of an author, the editor might reasonably conclude that you will not be able to do complex revisions either and you may not be given the opportunity to revise and resubmit.

## COMMUNICATION WITH MORE EXPERIENCED WRITERS

Would-be authors may seek the advice of more experienced colleagues at almost any stage of the publication process. When planning a publication, discussion with colleagues after a presentation of the work at a seminar in the home institution may yield some tips as to the type of journal that may be interested in the study. Subsequently, during preparation of the manuscript, it may be appropriate to seek the advice of local colleagues on technical aspects such as statistical analyses. When a manuscript exists in a complete form, it can often be immensely helpful to ask somebody to read through it and make comments and suggestions. People are very often willing to help if authors make clear they value an expert opinion on aspects such as coverage of the literature, clarity, style, language and validity of conclusions. If there is no person in the author's own institution, it is possible to approach outsiders and ask if they would be willing to comment. Both people whom you know personally and others who have published in the area are likely to feel flattered and pleased that you value their opinion and may well provide advice. The manuscript that cannot be improved has yet to be written, and even experienced authors often seek the opinions of colleagues because after working on a manuscript for months, through revision after revision, it can be difficult to spot the little problems that spring to the attention of a new reader.

## WRITING IN A FOREIGN LANGUAGE

It is an unavoidable fact that many authors have to write in a language other than their own, and to convey complex scientific ideas with clarity and precision can be a difficult task even in one's native language. Authors may therefore find it worthwhile to seek the assistance of colleagues with more experience of writing in the chosen language and, if possible, enlist a native speaker of the language to correct the manuscript. If that is not possible, it may be necessary to obtain the assistance of a professional translator to suggest corrections. Journals provide varying amounts of assistance in the correction of errors after accepting a manuscript for publication, but they cannot do anything to assist reviewers of poorly written manuscripts. A fuller consideration of language issues may be found in Chapter 3.

## THE PEER REVIEW PROCESS: SELECTION OF REFEREES

The next step for the editor is selection of referees who will advise him or her of the strengths and weaknesses of the work and recommend whether or not it should be accepted, reconsidered after revision, or rejected outright. Referees are also expected to make constructive suggestions for improving the manuscript in a report that can be sent to the authors.

The criteria used for selecting referees are diverse and probably few if any journals have tightly defined procedures. Box 6.2 shows the main criteria used by editors to identify referees. The number of referees varies within and between journals, but most commonly there are two referees. The editors of some journals may work with only one referee but this seems to be increasingly rare. Occasionally, three or more referees

are used, depending upon the journal and the editor's perception of the complexity and significance of the work. For example, multi-disciplinary manuscripts may require more than two referees to ensure sufficient expertise. Similarly, if a study seems likely to have major practical impact, for example upon policy or treatment, the editor may wish to be especially certain that it is assessed thoroughly. If the two referees selected initially disagree about the paper it is a common practice to turn to a third person for additional advice.

### **Box 6.2** SOME METHODS USED BY EDITORS TO IDENTIFY REFEREES

- Recognised expertise in the specific field of the manuscript as noted in the journal's database of previous referees and authors
- Previous invitations to referee for the journal have resulted in thorough, well-written, polite reviews submitted in a timely manner
- Record of recent publications in the field as determined by searches of databases such as MEDLINE and PsycINFO

The following criteria are used to *exclude* reviewers from consideration:

- Persons who are known to have a very close connection to the authors or to have a conflict of interest with the authors will be avoided
- People who are currently refereeing another manuscript for the same journal or have refereed one within a set period (e.g., three months) will be avoided
- Excessive praise or criticism of the reviewer's work in the manuscript to be assessed

Note: different bulleted points will be used in combination to reach a decision on whom to invite and there will inevitably be appreciable variations between journals with respect to the use of these different methods of selection.

For all reports, regardless of whether they are quantitative or qualitative, each journal has its own set of instructions for referees; journals differ with respect to the attributes of their 'ideal' manuscripts. There will sometimes be a requirement for referees to complete a questionnaire as part of the review, with ratings of the manuscript according to criteria such as importance and likely impact on the field, as well as technical competence. The referees are usually also asked to make a recommendation on the fate of the manuscript, and to justify it in confidential comments to the editor. Finally, referees are in all cases expected to produce a report that the editor will forward to the authors. The main purposes of this report are (1) to make suggestions enabling the author to improve the manuscript and (2) to list criticisms that the referee believes need to be addressed if the report is to be published. The report to the authors should not include specific recommendations for acceptance or rejection of the manuscript because that decision is in the hands of the editor.

The task of the editor is to reconcile sometimes conflicting reports from different referees and to make a personal judgement based on a variety of other considerations. The task is made more difficult if the reviews contain conflicting recommendations for publication. Referees are also asked to act according to ethical guidelines that are presented and discussed elsewhere in this book (see Chapters 7 and 8 and ISAJE's ethical guidelines at Appendix B).

## CRITERIA FOR EVALUATION OF MANUSCRIPTS

If the journal has published its Instructions to Referees, or put them on a website, they will give you an idea about the features that both editors and referees will look at. Some desirable features of highly-rated studies are probably shared among many journals.

If it is a *quantitative* study, the criteria include the use of a sufficiently large and suitably representative sample of the population under study, a high response rate among invited participants, valid measures, absence of procedural biases and minimal confounding of one independent variable with another, and the use of appropriate controls. Similarly, referees will look for as full a description of the methods as allowed by the space available, with referencing of earlier publications that provide more detail and establish the validity of the methods and measuring instruments (where applicable). Results must be described in a clear and logical sequence, with all necessary information presented. No more detail should be provided than can be covered in the discussion section. The discussion should bring out the importance of all the main findings, indicate how the work advances the state of knowledge and understanding in the relevant sub-field. Additionally, alternative interpretations of the data may be given, thus acknowledging limitations of the study. Referees pay attention to all the preceding points, and to many others.

In quantitative research, one of the common problem areas is the data analysis where several mistakes occur repeatedly. These include:

- failure to deal adequately with confounding variables;
- claims to have shown something without performing a (statistical) test that supports it directly and unequivocally;
- failure to control for multiple comparisons;
- drawing inappropriate conclusions from non-significant associations or differences: we probably all realise that lack of significance means only that we have failed to find an effect and does not prove that no effect exists, but we don't always remember this in our enthusiasm to explain how our results fail to support the ideas of a scientist whose theory we dislike.

Authors developing reports of randomised controlled trials may wish to follow the CONSORT (Consolidated Standards of Reporting Trials) checklist, which includes 22 items considered essential to judge the reliability or relevance of the findings (presented in Appendix 6.2 to this chapter in slightly abbreviated form).

The criteria for the evaluation of *qualitative* reports vary depending on the type of data and methods of analysis (e.g., participant observation and ethnography, qualitative interviews, content analysis, textual analysis, discourse analysis, ethnography and conversation analysis). The following issues should be addressed in most types of qualitative report (see also Cuba and Cooking 1994; Mäkelä 1990; Medical Sociology Group of the British Sociological Association 1994).

- Clear criteria for the selection of data or subjects should be given. The material should therefore be carefully positioned in the social and cultural space. For example, different genres of fiction represent different segments of the culture.
- A detailed account should be presented of where and when data were collected or which existing data sets were used. In studies based on fieldwork, the relation between the fieldworkers and the subjects should be described, and possible influence of the data collection on the phenomenon under study should be discussed. Ideally, the researcher should keep careful records of the data and offer them for independent examination.
- The way the analysis was done should be stated clearly with indication of whether reliability was assessed, for instance by replicating the analysis.
- Themes, concepts and categories derived from the data should be described. The interpretation process should be divided into short steps, with rules of classification and interpretation specified.
- Steps taken to guard against selectivity in the use of data should be outlined; exceptions and deviant cases should be discussed. Ideally, the reader should be able to apply the same classifications, take the same analytic steps and reach the same kind of results with another dataset.
- Data must be presented systematically so that quotations, field notes and so on are easily identifiable.
- There should be enough primary evidence to show a relation between evidence and conclusions, but presentation of too many illustrations is to be avoided; the focus should be on the most representative ones.

## COMMON PROBLEMS WITH MANUSCRIPTS

All parts of a manuscript are open to criticism from the title onwards. The first requirement for gaining the confidence of an editor or a referee is to describe the findings objectively and in a sober style without the use of hyperbolic language. If your data are good, they will speak for themselves. It is always better for the reader to find that the results themselves are stronger than you claim, instead of being obscure

and unconvincing in relation to your description. Every 'data not shown' statement may raise the suspicions of referees that the authors are trying to hide something. If there really is not enough space to show important data graphically or in tabular form, then give some examples of the more important of such results in the text (with means, standard errors or other indicator of variance and numbers of subjects, if it is a quantitative study).

The discussion section is the most difficult part of a manuscript to write, and it often shows. Sometimes the opening paragraph is only a summary of the results, which is not satisfactory. One approach is to decide which are the main new findings, mention only them, and summarise two or three important conclusions that follow from them. It is also common to find that the discussion does not focus on the aims as stated in the introduction, and sometimes discusses issues on which no background was given. A failure to place findings in the context of previous knowledge means that the case for publication is not made. Referees and editor want to know what is new, what is confirmatory, and of any important failures to confirm previous findings. Instead, authors may attempt to extract too much from their data, in the sense of trying to address too many different issues. The effect of this error is to dilute strong conclusions with weakly supported ones, giving an overall unfavourable impression leading to rejection.

The discussion should also consider alternative interpretations of the study and acknowledge major limitations. These may arise from methodological weaknesses; or unexpected findings that could not be pursued to a firm conclusion, due to practical limitations such as the project period coming to an end, or a financial constraint (these reasons do not need to be stated). If the referees discover these weaknesses they will consider themselves smart and are likely to make sure you know it; if you show that you are aware of the limitations and understand the implications, they will perceive you as smart and honest, which counts for a lot.

Don't waste time and space discussing 'trends' that are not statistically significant; if the effect is not there, its implications do not need discussing. Remember there are more than enough 'significant' effects that do not replicate and there is no need to create new myths. If it is believed that a real and important difference was undetected due to lack of statistical power, what needs to be done is a new experiment, and then there may be something to discuss.

Particular but somewhat different problems are associated with reviews and theoretical articles. If a review claims to be comprehensive, it is now common practice to state in it the way that the literature search was carried out, and to define criteria for including articles. Articles that do not claim to be comprehensive but rather argue for a particular theoretical viewpoint or set of ideas are frequently less comprehensive. In such cases authors often cite publications that support their own position in a rather uncritical manner, and they may refer to few or no articles that oppose it. Editors may then firmly but politely ask the author to state the assumptions made and ensure that the article makes clear to readers where issues are controversial. Alternatively, where the intention is to let a distinguished writer express a personal view based on his or

her selective citation of the literature, it should be made clear that a case is being made for a theory and that a balanced assessment of the state of the field is not being attempted.

Finally, remember you are writing a scholarly paper and not running a campaign! Do not enter into politics and polemics. For example, if your main finding is that a widely used intervention is less favourable than another which lacks some sort of official approval for general use in your country, make the case for their relative merits and if appropriate argue for a policy change, but don't abuse the politicians and don't keep repeating the argument in more and more florid and emphatic language. Political battles are not won in the pages of academic journals.

## THE EDITOR'S DECISION

The much-anticipated and sometimes feared letter from the editor finally arrives on the corresponding author's desk, together with the statements from the referees.

The editor will often need to reach a decision based upon the balance between innovation and quality of work. The perfect manuscript would have important new ideas with far-reaching importance backed up by sound data obtained by means of thoroughly validated methods. In reality, such manuscripts are seen only rarely, if ever, and the editor and the referees have to make judgements. If the approach to a problem is highly novel or the study is a potential stimulus for further valuable work, a manuscript may be accepted with data that are less than wholly convincing. On the other hand, if there is not very much that is really new, but the study is the first one to address a particular methodological weakness of previous work, then clear data of high quality will probably be essential.

The referees' reports and recommendations inevitably and appropriately influence the editor's decision but they are not the sole determining factors. Editors may study a manuscript in varying amounts of detail and may have concerns that are not reflected in referees' reports. These concerns may relate to any of the whole range of issues that the referees also address, but especially to the appropriateness of the subject matter for the journal; whether there are any ethical problems; and whether the importance of work is sufficient to justify publication in his or her journal rather than in a publication of lesser status that may be struggling to fill its pages. Studies may be technically competent and presented well, but may be unimportant because they merely confirm well-known facts or because they focus on apparently trivial issues.

When the reports of referees are in agreement with each other, the editor will most frequently accept the recommendations made. It is a brave editor indeed who would overturn the opinions of two independent experts, not least because referees will soon stop assisting an editor who consistently ignores the advice given. When referees disagree, the editor may seek to sort out the matter by studying the manuscript and coming down in support of one or other referee; this is the ideal method if the editor can reach a clear view because a decision is obtained quickly and the valuable time of another expert is not required. However, sometimes referees reach opposing conclusions

on the basis of equally well-argued cases and then the editor may feel it is essential to obtain advice from a third person. This is especially likely to occur if the work is outside the editor's main area of expertise.

When a third referee reaches a definite view supporting one or the other of the earlier referees, then the way forward is clear, but this does not always happen. If the first referee supports publication strongly and the second referee recommends rejection, the third referee quite often says the manuscript is weak but may reach publication standard after major revision; in such cases the contribution of the third referee may swing the decision one way or the other depending upon the journal's needs at the time. If the journal is trying to raise the standard of published items, such marginal manuscripts will probably be rejected, whereas if the study is in a field that is under-represented in the journal, the editor may wish to include it. An editor may also seek to publish the article but in a shorter form that reflects its lesser merits.

The abusive referee is a particular annoyance to editors. The most commonly identified, although happily quite rare, form of abuse occurs when a referee attempts a review of the author instead of the manuscript. It is one thing, and perfectly acceptable, to state that an argument is constructed poorly and is unconvincing, that it is presented badly, or does not take account of previous knowledge; it is quite another thing to assert that the author is stupid, careless or ignorant. Editors have a duty to alter or remove such inappropriate remarks from a referee's report, so that unnecessary distress is not caused and the author will be encouraged to improve the manuscript. If the referee is young and inexperienced, the editor may also explain the problem with the report, whereas a senior person will more likely not be invited to review again.

A particularly difficult situation arises if the review process generates suspicion that the author has engaged in scientific misconduct and unethical behaviour. Such misconduct may be either minor or major in nature and the editor typically has available a range of sanctions to apply. These may include refusing to consider further work from the author, reporting the matter to the author's institution or employer, and publishing a statement in the journal to alert the scientific community to the issue. The availability of a code of practice by which editors can abide in such circumstances is very helpful (see Appendix B for the ethical practice guidelines, developed by the International Society of Addiction Journal Editors). Editors are also wary of trying to resolve contentious ethical issues because they do not have the resources to conduct a full investigation; equally important, they cannot simply brush the matter aside by refusing to publish suspect material but must take reasonable steps to ensure that appropriate action is taken. These and other related issues are discussed in greater detail in Chapters 7 and 8, which deal with ethical considerations in scientific publishing.

## RESPONDING TO REFEREES' REPORTS: GENERAL RULES OF CONDUCT

Authors who achieve immediate acceptance of a manuscript as submitted are rare indeed. Revisions are almost always required prior to acceptance, and in many cases a final decision cannot be reached until the revised version has been assessed. Therefore, the way in which authors respond to the reports of referees and to the editor can have a major influence upon the outcome. If editors invite resubmission, it means they are expecting to receive the manuscript back again.

An invitation to resubmit is not a half-hearted and cowardly way of saying the work is unpublishable, but rather an implicit suggestion that the editor remains interested in the paper and that it is likely to be accepted if the author is responsive to the questions and recommendations of the reviewers. In such cases, it is nearly always worth resubmitting unless there is some clear and unavoidable requirement with which you cannot possibly comply. Some guidance for authors on how to navigate through this maze successfully is now given.

The overriding aim of the response is to engender trust among editors and referees. Authors should never claim to have made changes that in fact they have not done. If the covering letter says all requested changes have been made and an editor or referee checks two or three points at random and finds nothing much has changed, they may reject the manuscript without looking carefully at the rest of it. If you have made major changes by rewriting whole sections of the manuscript, state that is the case and identify the sections. Alternatively, if just a few words have needed to be inserted or deleted, make clear which words were changed so that referees can see what has been done. If you were asked to shorten something, you should almost always do so and perhaps state by how much (i.e. by how many words or pages). Don't try to fool the editor by printing the new version in smaller type or by other stylistic changes.

Be polite, even if you feel that the referees have not understood your intentions. When you have been through all the points of criticism, you should have an idea of the changes you think are appropriate. Will they be enough?

If after reading the reports, you have concluded that none of the recommendations is worth accepting and you don't want to make any changes, it is commonsense to take a break from the job and look at it again on another day! It is simply not realistic to expect editors and referees to accept that *none* of the changes they request and the criticisms they make are well founded. Referees spend anything from an hour to a full day preparing their reports. If you dismiss all this effort out of hand you will get nothing published. You must therefore aim to make changes to deal with as many as possible of the points raised, and preferably with a clear majority of them.

### THE COVERING LETTER: MAKE LIFE EASIER FOR THE EDITOR

After completing the changes to the manuscript, write a detailed reply to the referees. It is worth spending a significant amount of time getting your reply to referees as near perfect as you can. Sometimes constructing the letter may take nearly as long as doing

the revisions, but it will not take as long as botching the job and then being obliged to reformat the manuscript for another journal in order to start the whole process over again. Nevertheless, it is best to keep this reply as short as possible. Typical successful replies will be in the range of 1-3 single-spaced pages. If the referee makes a point in just three lines and you need a page to rebut it, it is likely you have not got straight to the heart of the matter and your reply will probably not be convincing (it is best to write the minimum needed to refute the criticism).

If the referee cannot understand a point that you made in the manuscript, it may be because he or she is lacking in intellectual capacity (as we often think when we encounter such comments on our own work). However, if one person does not follow what you have written, the same may apply to others. Referees are all published research workers and are often the very people whom you might hope would read your paper; if a referee cannot understand your point, try to analyse your text to see how the misunderstanding may have arisen. Then make changes to ensure it will not happen again.

Do remember that if a referee asks a question, other readers may want to know the answer to it too. The answer should therefore usually be contained in the revised manuscript and not in the covering letter. The latter need only refer to the sections of the manuscript where the question is addressed. Save the referees' time and they will love you; don't get them to read the answer to a question in the letter and then refer them to the manuscript where they have to read the answer over again to check if it is really there!

If possible, reply in numbered sections that correspond with numbered points of referees. Explain the revisions you made to deal with most of the criticisms and also explain why you did not deal with the rest. Describe briefly each change you made, referring to the relevant page or paragraph in the revised manuscript. Try not to respond in a combative, overly-assertive style. If there are major and important changes recommended that you are sure are wrong, then present a concise, logically-argued rebuttal. If there are minor changes requested that you feel don't really improve matters, do them anyway because it helps a lot if you can truthfully claim to have dealt with the majority of points. At all stages, remember that although referees and editors may appear to be distant, self-opinionated and arrogant, they are also human beings with their own feelings, emotions and problems. If you want acceptances, make life easy for them by writing clearly, and don't antagonise them by criticisms or by gratuitous insults however unwise and misguided you think they may be.

It is sensible to maximise and stress agreements with what referees write and to acknowledge their contribution when they have made suggestions that improve the manuscript. Don't build minor disagreements into major issues. You probably only need to make minor changes to accommodate them, and then mention the changes in the cover letter, instead of wasting time arguing and putting the referee's back up in the process. However, it is not necessary or appropriate to minimise disagreements to the point of dishonesty; they should be dealt with by logical rebuttal in the cover letter and, sometimes, by acknowledging and discussing the point in the manuscript.

Perhaps the most difficult case occurs when you feel that a referee shows a bias towards a theoretical approach that differs from yours, and therefore undervalues the work. Here you can explain in the cover letter that there are different approaches to the problem (state what these are), that yours is equally valid, that there is a genuine difference of opinion and that you have a different but scientifically legitimate point of view. However, this strategy is probably unwise unless you have a strong case and there is no other way to deal with the issue. In the end the editor will have to decide and what one person perceives as objective and unbiased looks very different from another viewpoint.

At the end of the day, the editor wants to have papers to publish. The number of acceptances rather than of rejections is therefore the mark of success and of an editor's job well done. Authors, editors, referees and publishers must all work together to ensure the production of a journal of high quality that achieves its intended objectives.

### **ACKNOWLEDGEMENTS**

I would like to thank Klaus Mäkelä and Kerstin Stenius for assistance with drafting the material about qualitative research.

## APPENDIX 6.1

### GENERAL PUBLICATIONS ON SCIENTIFIC AND MEDICAL PUBLISHING

This is a very short selection from the huge number of publications. Many additional works may be found by searching biomedical databases such as PubMed or on-line booksellers.

Albert T, 2000. *The A-Z of Medical Writing*. BMJ Books. ISBN 0727914871.

American Medical Association *Manual of Style*, 1998. 9th ed. edited by C. Iverson. Williams & Wilkins. ISBN 0683402064.

American Psychological Association, *Publication Manual*, 2001. 5th ed. American Psychological Association. ISBN 1557987904.

British Medical Association,  
<http://www.bma.org.uk/ap.nsf/Content/LIBReferenceStyles>. This is a useful website established by the British Medical Association, giving general guidance on resources for people publishing in the biomedical field (accessed 3 October 2003).

Huth EJ, 1990. *How to Write and Publish Papers in the Medical Sciences*. 2nd ed. Williams & Wilkins. ISBN 0683042718.

McInerney DM, 2001. *Publishing your psychology research*. Sage. ISBN 0761973370.

Peat J, 2002. *Scientific writing*. BMJ Books. ISBN 0727916254.

Richardson P, 2002. *A guide to medical publishing and writing*. Quay Books. ISBN 1856422224.

## APPENDIX 6.2

### CHECKLIST OF ITEMS TO INCLUDE WHEN REPORTING A RANDOMISED TRIAL

This section consists of a slightly shortened version of the checklist of Moher et al. (2001).

<b>TITLE AND ABSTRACT</b>	How participants were allocated to interventions (e.g., 'random allocation', 'randomised', or 'randomly assigned').
<b>INTRODUCTION</b>	Scientific background and explanation of rationale.
<b>METHODS</b>	
<i>Participants</i>	Eligibility criteria for participants and the settings and locations where the data were collected.
<i>Interventions</i>	Precise details of the interventions intended for each group and how and when they were actually administered.
<i>Objectives</i>	Subjective objectives and hypotheses.
<i>Outcomes</i>	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).
<i>Sample size</i>	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.
<i>Randomisation</i>	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).
<i>Allocation concealment</i>	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.
<i>Implementation</i>	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.
<i>Blinding</i>	Whether or not participants, those administering the interventions, and those assessing the outcomes were aware of group assignment.
<i>Statistical analysis</i>	Statistical methods used to compare groups for primary outcome; methods for additional analyses, such as subgroup analyses and adjusted analyses.

## RESULTS

- Participant flow* 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.
- Recruitment* Dates defining the periods of recruitment and follow-up.
- Baseline data* Baseline demographic and clinical characteristics of each group.
- Numbers analysed* 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%).
- Outcomes and estimation* For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g. 95% CI).
- Ancillary analyses* Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.
- Adverse events* All important adverse events or side effects in each intervention group.

## DISCUSSION

- Interpretation* 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.
- Generalisability* External validity of the trial findings.
- Overall evidence* General interpretation of the results in the context of current evidence.

Reference: Moher, D., Schulz, K.F., Altman, D.G., for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001; 357; 1191-94.

