Consort 2010 Statement on Randomised Controlled Trials

Randomised controlled trials (RCTs) can be an invaluable tool in determining the best treatment for patients. However, if undertaken incorrectly they can lead to further confusion. They are the cornerstone of evidence-based medicine. In the early 1990s there was rising concern about the quality of RCTs. The reporting patterns were of variable quality. It was increasingly being recognised that many trials lacked methodology clarity. Another drawback was that trials were not reported in a uniform manner which made subsequent meta-analysis difficult. RCTs are expensive both in terms of time and resources and it is important to maximise the benefits that can accrue. When correctly performed they can lead to significant changes in clinical practice and improved patient care. Negative findings are equally as important as positive findings in this regard.

In 1993 a group consisting of medical journal editors, epidemiologists and methodologists met in Ottawa with the aim of producing a new template for the assessment of the quality of RCTs. Three years later in 1996 the original CONSORT statement was published. It was subsequently revised in 2001. It is now widely accepted by many medical journals. It is a guide for authors when reporting an RCT. In addition it gives guidance to editors and peer reviewers. The term which stands for Consolidated Standards of Reporting Trials was introduced in order to improve the quality of RCTs. The idea behind CONSORT is that the reporting of an RCT should meet a basic uniform standard. CONSORT does not include directives about designing, conducting and analysing trials. It concentrates on reporting what was done and what was found. It has brought about improvements. An assessment of 616 RCTs in 2000 was compared with a corresponding number of RCTs in 2003. It was concluded that the quality of reporting had improved.

Much of the CONSORT directive is commonsense. There is a 25 item checklist and a flow diagram that researchers should adhere to. The checklist relates to the title, abstract, introduction, methods, results and discussion. The flow diagram describes the passage of the participants through the four stages of the trial namely enrolment, allocation, follow-up and analysis. CONSORT urges clarity of reporting which reflects the actual trial design and conduct. Poor reporting allows authors to escape scrutiny of the weak points in their study. The increased scrutiny rewards well conducted trials and penalises those that are poorly carried out.

It should be identifiable from the papers title that it is a RCT. By getting the word randomised into the title one ensures that the paper is correctly indexed. The abstract is very important and should encapsulate the trial design, methods, results with both numbers and percentages and the conclusions. The introduction should set out the background and raise the scientific question that needs to be answered. The Methods and randomisation frequently cause confusion and difficulties for the researchers. CONSORT provides a series of helpful steps. Examples include how the sample size was determined. Eligibility criteria and details about the intervention and control groups need to be provided. The primary and secondary outcomes must be specified.

The CONSORT statement devotes a considerable amount of detail to the randomisation process. It makes reference to the mechanism used to implement the random allocation sequence including who enrolled the patients and who assigned them to interventions. The method by which sample size was determined needs to be recorded. The statistical methods used to calculate the primary and secondary outcomes must be described. In the discussion the trial limitations must be pointed out including potential sources of bias. The generalisability of the trial findings should be commented on. There should a balanced debate about the benefits and harms. The trial registration number and name of registry is required. Information about where the full trial protocol can be accessed should be supplied. The sources of funding and the role of funders must be declared.

CONSORT 2010, the third version, has made some important changes. The new sub-item to clarify the basic trial design. Researchers are asked to document any important changes to the methods after trial commencement. There is a sub-item identifying any changes to the primary and secondary outcomes. The intention to treat analysis has been removed as it proved too vague, it has been replaced with a request for more detailed information about retaining participants in their original assigned groups. Testing for the success of blinding has been removed. It was felt to be potentially misleading as the blinding could be successful but the participants in the trial may correctly guess the treatment limb through supplementary information. For example some treatments have readily recognised benefits or side-effects.

For binary outcomes presentation of both relative and absolute effect sizes is recommended. The need for trial registration is being urged and it is also being demanded by journal editors. A new item on the availability of the trial protocol has been added. This is to ensure that the conduct of the trial adhered to the stated protocol.

The main message is that when the doctor is reading about an RCT one of the first questions to ask of the paper is whether the report conforms to the CONSORT statement. This Q mark increases the reliability of the findings.

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References