Quality Rating Scale – Coding Notes

Treatment Quality
The aim of this section is to ensure that in the report a clear account of the treatment is given and that there is evidence that the investigators took steps to ensure that the treatment was delivered as intended by trained and competent personnel. Each item is therefore a judgement about whether this has been achieved.

Item #	Question and Items	Score & Coding Notes
1 1 part	**Has a clear rationale for the treatment been given and an adequate description of its content?**	
	Treatment Content / Setting The aim of this item is to make a judgment of the quality of the treatment in the trial by ascertaining whether a coherent rationale is given e.g. reference to the relevant evidence base for the treatment. Another consideration is whether an adequate description of the treatment content is given such that there may be sufficient information to stratify studies for example.	**2 - Adequate:** A clear rationale for the treatment has been reported along with an adequate description of its content. **1 - Partial:** Either a clear rationale or a description of the content of the treatment is reported. **0 - Inadequate:** Neither the rationale for treatment or the treatment content are adequately reported.
2 1 part	**Has the total treatment duration been reported?**	
	Treatment duration Total treatment duration includes both number of treatment sessions and duration of each session. Issues relating to the actual number of sessions attended i.e. attrition is dealt with in a later section.	**Reviewer decides.** **1 - Reported** **0 - Unknown**
3 2 parts	**Is there a treatment manual that describes the active components of treatment?**	
	Manualisation Treatment manuals should clearly prescribe the active components of the treatment and ideally proscribe activities that should not be included within the treatment. Trials with more than one treatment arm should demonstrate that manuals were utilised for each of the treatments where appropriate, e.g. for relaxation training and coping skills training but not for treatment as usual.	**2 - Adequate:** there is reference to use of a manual that describes the active components of the treatment of study. If more than one treatment arm, manuals were used for all the appropriate treatments. **1 - Partial:** In trials with more than one treatment arm, the use of a manual is described but not for all the treatments that would be expected to be manualised. **0 - Inadequate:** no evidence that a manual has been used, but reference is made to various principles.
	Adherence to the manual Treatment manuals are also considered essential as they provide a benchmark for various checks of validity e.g. whether therapists are adhering to the treatment under study and whether patients are doing what is required of them.	**1 - Adequate:** there is evidence that the investigators have checked adherence to the manual during the period of study via direct observations, tape recording or supervisory processes that explicitly state adherence to the manual. **0 - Inadequate:** no evidence of adherence checks reported.
4 1 part	**Have the therapists been appropriately trained in the relevant procedures for this trial?**	
	Therapist training The important issue here is not just whether the therapists have the appropriate qualifications and experience *per se,* as a multidisciplinary team may implement the treatment. Of importance is whether the therapists involved have been trained appropriately to conduct the particular treatment of the trial.	**2 - Adequate:** there is documentation of explicit training for the treatment of the trial. **1 - Partial:** the general level of therapist training is reported and is adequate (professionally qualified) but there is no mention of explicit training for the trial. **0 - Inadequate:** there is no convincing evidence that the therapists have an adequate level of training (e.g. graduate level) or explicit training for the trial.

Item #	Question and Items	Score & Coding Notes
5 1 part	**Is there evidence that the patients have actively engaged in the treatment?**	
	Client Engagement This item assesses whether the investigators took steps to check that the patients actively engaged in the therapy and complied with the instructions of the treatment e.g. checks for evidence of skills practice, reviews of homework.	**1 - Adequate:** documented that evidence of engagement was sought e.g. checks on homework were made, skills practice in sessions. **0 - Inadequate:** no evidence that checks were made on level of engagement.

Quality of study design and methods
The aim of this section is to ensure that investigators made attempts to ensure that the design of the study was appropriate for its aims and that rigorous methodological efforts were made to reduce the potential for bias. Each item is a judgement about whether this has been achieved.

Item #	Question and Items	Score & Coding Notes
1 2 parts	**Are the inclusion and exclusion criteria clearly specified?**	
	Sample Criteria This item explores the context of the patient selection and allows the generalisability of the trial to be examined. Detailed information of the sample can also be used for stratifying in meta-analyses.	**1 - Adequate:** the inclusion and exclusion criteria are clearly specified and there is evidence of adherence to the criteria. **0 - Inadequate:** criteria not clearly specified.
	Evidence that the criteria have been met It is equally important to check for evidence that the inclusion and exclusion criteria have been met.	**1 - Adequate:** clear evidence is reported that the criteria have been met. **0 - Inadequate:** no evidence that any criteria have been met.
2 2 parts	**Is there evidence that CONSORT guidelines for reporting attrition have been followed?**	
	Attrition It is considered essential that good quality trials follow the CONSORT guidelines for reporting attrition i.e. “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”. It should be noted that this criteria automatically biases against pre-CONSORT trials i.e. prior to and during 1996.	**2 - Adequate:** documented evidence that the CONSORT guidelines have been followed. **1 - Partial:** a reasonable account of how attrition was dealt with is given, but without reference to CONSORT. **0 - Inadequate:** there is no documented evidence or insufficient evidence reported of how attrition was dealt with.
	Rates of attrition It is also important to ascertain whether final sample could be biased due to differential dropout rates between the treatment groups.	**1 - Adequate:** there is evidence that any differential rates of attrition were **not** statistically significant. **0 - Inadequate:** there is insufficient evidence that differential rates of attrition have not resulted in significant bias.
3 2 parts	**Is there a good description of the sample in the trial?**	
	Sample Characteristics This criteria is concerned with there being an adequate description of the actual sample obtained in terms of demographic information, concurrent treatments, treatment history, gender, diagnosis, site of pain and chronicity.	**1 - Adequate:** there is a good description of the sample in the trial detailing areas such as demographic details, treatment history etc. **0 - Inadequate:** insufficient information is reported to allow adequate comparisons to be made.
	Group equivalence Good descriptions of the sample characteristics and testing are essential for ascertaining whether there is equivalence between the treatment groups.	**1 - Adequate:** there is evidence that the groups are broadly equivalent shown by testing or examination of reported data. **0 - Inadequate:** either equivalence of groups is not reported or there is evidence of non-equivalence.

Item #	Question and Items	Score & Coding Notes
4 4 parts	**Have adequate steps been taken to minimise biases?**	
	Randomisation This item examines the steps taken to ensure that each participant of the trial has an equal chance of being allocated to the different treatment arms. In particular, it asks for evidence that an adequate method of randomisation has been used e.g. random number table or computerised random number generator (CONSORT, 1996).	**2 - Adequate:** a convincing method for generating a random allocation sequence is reported that used an independent person not involved in enrolment or allocation of participants. **1 - Partial:** a convincing method of randomisation is reported but this did not involve an independent person. **0 - Inadequate:** randomisation is mentioned but there is not an adequate description of the methods used.
	Allocation bias Were steps taken to ensure that the allocation sequence of patients to the treatment arms was concealed so that investigators could not have biased it? Ideally, an independent person should make assignment; alternatively, assignment can be enclosed in sequentially numbered, opaque sealed envelopes (CONSORT, 1996).	**1 - Adequate:** an adequate method is reported that removes the potential biases of investigators e.g. use of an independent person or sequentially numbered opaque sealed envelopes. **0 - Inadequate:** there is not an adequate description of attempts to deal with potential allocation bias.
	Measurement bias In order to reduce the risk of measurement bias a third party who is blind to the patient's study group should be responsible for the collection of data.	**1 - Adequate:** a convincing effort to reduce bias in outcome measurement is reported e.g. 3rd party blind data collection. **0 - Inadequate:** efforts to reduce measurement bias are not reported or are insufficient e.g. outcomes collected by therapist.
	Treatment expectations It is impossible for participants to be blind to the treatment they are receiving therefore it is imperative that steps are taken to check for equivalence in treatment expectations.	**1 - Adequate:** credible checks for equivalence in treatment expectations are reported. **0 - Inadequate:** checks have not been reported or are insufficient.
5 3 parts	**Are the outcomes that have been chosen justified, valid and reliable?**	
	Justification of outcomes This item is concerned with whether the outcomes measures that have been chosen encompass the aims of the treatment and are therefore justified with regard to those aims.	**2 - Adequate:** all of the outcome measures are justified. **1 - Partial:** most of the outcome measures are justified. **0 - Inadequate:** most or all of the measures used are not justified.
	Validity of outcomes for context A report stating that measures with known validity were used is not sufficient as measures cannot be said to be valid *per se*, only that they have validity in a particular context. This item therefore requires an informed judgement as to whether the measures chosen are valid given the context of the study population and the treatments implemented.	**2 - Adequate:** all of the outcome measures are valid given the context of the study. **1 - Partial:** most of the measures are valid. **0 - Inadequate:** most or all of the measures are not valid given the context of the particular study.
	Reliability and sensitivity to change It is important that the outcome measures chosen have both good reliability (generally defined as $r \geq 0.8$) and sensitivity to change.	**2 - Adequate:** all the outcome measures chosen were shown to be reliable and sensitive to change. **1 - Partial:** most of the measures were reliable and sensitive to change. **0 - Inadequate:** most of the measures were not reliable or sensitive to change.

Item #	Question and Items	Score & Coding Notes
6 1 part	**Has there been a measure of any sustainable change between the treatment and control groups?**	
	Follow up This item examines whether attempts have been made to measure sustainable changes between the treatment and control groups e.g. over a period of at least 6 months.	**1 - Adequate:** follow up measurements for at least 6 months are reported. **0 - Inadequate:** the follow up period was inadequate to measure sustainable change e.g. less than 6 months.
7 5 parts	**Are the statistical analyses adequate for the trial?**	
	Has a power calculation been used? The report must state that power calculations were calculated a priori.	**Reviewer decides.** **1 - Yes** **0 - No**
	Has a sufficient sample size, based on the power calculation been obtained?	**Reviewer decides.** **1 - Yes** **0 - No**
	Has the data analysis been adequately planned to assess the hypothesis and aims of the trial?	**Reviewer decides.** **1 - Yes** **0 - No**
	Is there adequate reporting of summary statistics? The means, standard deviations and numbers should be reported for the variables. The proportions or frequencies should be reported for dichotomous variables.	**Reviewer decides.** **1 - Yes** **0 - No**
	Did the analysis include an intention to treat analysis? It is important to account for any potential biases in rates of attrition by performing an intention to treat analysis as well as an analysis per protocol.	**Reviewer decides.** **1 - Yes** **0 - No**
8 1 part	**Has a good, well-matched alternative treatment group been used?**	
	Control group This item is concerned with the quality of the control condition in the trial and the efforts made to ensure that as many features as possible have been controlled for.	**2 - Adequate:** an active alternative treatment group has been used that is well matched in terms of structural features of the treatment and its meaningfulness. **1 - Partial:** an active alternative treatment group has been used but it is not matched for structural features e.g. bibliotherapy. **0 - Inadequate:** a poor control group has been used that merely controls for the duration of time e.g. waiting list control.