**Evaluation of Quality of an Intervention Study**

This form is used to extract relevant data on effectiveness from your study and to rate the quality of the published study (for item interpretation see guide)

Citation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Authors: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Patient Characteristics** (age, sex, disorder, co-morbidity/important co-variates)

1.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sample Size \_\_\_\_\_\_\_\_\_\_\_\_\_

Interventions (Describe type, timing, frequency, equipment, provider, progression etc.)

1.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Outcome Measures** (Type and when evaluated)

Primary:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Secondary:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Results**:

Outcomes (absolute change, significance)

Primary: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Secondary:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Describe any any effect mediators (things that altered the outcomes achieved.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Describe any complications or adverse events that were reported

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Evaluation of Study Design**

|  |  |  |  |
| --- | --- | --- | --- |
| **Evaluation Criteria** | **Score** | | |
| **Study question** | 2 | 1 | 0 |
| 1. Was there relevant and sufficient background work cited that led to a clear research question? |  |  |  |
| **Study design** |  |  |  |
| 2. Was a comparison group used? |  |  |  |
| 3. Was patient status at more than 1 time point considered? |  |  |  |
| 4. Was data collection performed prospectively? |  |  |  |
| 5. Were patients randomized to groups? |  |  |  |
| 6. Was allocation concealed? |  |  |  |
| 7. Were patients blinded to the extent possible? |  |  |  |
| 8. Were treatment providers blinded to the extent possible? |  |  |  |
| 9. Was an independent evaluator used to administer outcome measures? |  |  |  |
| **Subjects** |  |  |  |
| 10. Did sampling procedures minimize sample/selection biases? |  |  |  |
| 11. Were inclusion/exclusion criteria defined? |  |  |  |
| 12. Was an appropriate enrollment obtained? |  |  |  |
| 13. Was appropriate retention/follow-up obtained? |  |  |  |
| **Intervention** |  |  |  |
| 14. Was the intervention applied according to established principles? |  |  |  |
| 15. Were biases due to the treatment provider minimized (i.e. attention, training)? |  |  |  |
| 16. Was the intervention compared to an appropriate comparator? |  |  |  |
| **Outcomes** |  |  |  |
| 17. Was an appropriate primary outcome defined? |  |  |  |
| 18. Were appropriate secondary outcomes considered? |  |  |  |
| 19. Was an appropriate follow-up period incorporated? |  |  |  |
| **Analysis** |  |  |  |
| 20. Was an appropriate statistical test(s) performed to indicate differences related to the intervention? |  |  |  |
| 21. Was it established that the study had significant power to identify treatment effects? |  |  |  |
| 22. Was the the size and clinical importance of the treatment group differences reported? |  |  |  |
| 23. Were missing data accounted for and considered in analyses? |  |  |  |
| 24. Were treatment benefits, adverse events and costs/implementation considerations addressed? |  |  |  |
| **Recommendations** |  |  |  |
| 25. Were the conclusions/clinical recommendations supported by the study objectives, analysis and results? |  |  |  |
| Total Quality Score (Sum of above) = |  |  |  |
| The total score can be reported out of 100% -- total sum/25 x 100% |  | | |

© Joy MacDermid 2013

Notes: