Appendix E. Quality Assessment Form

Study Design

1. Did the study employ a group design?

Group designs may include randomized controlled trials, prospective or retrospective cohorts, case-control studies.

NOTE: Assess studies that include 2 groups but which we will report on as case series as group design studies.

+ = yes

- = no

2. Were the groups randomly assigned?

+ = yes

- = no

3. Was there an appropriate comparison group?

The comparison group should accurately represent the characteristics of the intervention group in the absence of the intervention. Specifically, factors that are likely to be associated with the intervention selected and with outcomes observed should be evenly distributed between groups, if possible. These factors may include, for example, age, IQ, severity, etc.

+ = yes

- = no or not reported (NR)

NA

4. If an RCT, was randomization done correctly?

+ = yes

- = no or not reported (NR)

NA for all non-RCTs

Considerations:

Was the approach to randomization described? Were random techniques like computer-generated, sequentially numbered opaque envelope used?

Were technically nonrandom techniques, like alternate days of the week used?

Participant Ascertainment/Inclusion

1. Was a systematic diagnostic confirmation approach used within the study?

+ = yes

- = no or not reported (NR)

Considerations: Does the study indicate confirmation of an ASD diagnosis (e.g. reports diagnosis within study [not necessary to indicate specific tool used], review of medical records to confirm diagnosis, etc.)

2. Was the sample clearly characterized (e.g., information provided to characterize participants in terms of impairments associated with their ASD, including cognitive or language levels)?

+ = yes

- = no or not reported (NR)

Considerations:

Study must report at minimum a measure of language, cognition, or intellectual disability.

How reproducible is the study in terms of the sample participants? Do the authors provide enough information that you could recreate the study population in a new study?

3. Were inclusion and exclusion criteria clearly stated?

+ = yes
- = no or not reported (NR)
Considerations:
Did the authors report this information?

4. Do the authors report attrition?
+ = yes
- = no
NA
Considerations:
Do they report loss to follow-up and/or drop-out?

Intervention

1. Was the intervention fully described?
+ = yes
- = no or not reported (NR)
Considerations:
Is there sufficient detail to allow replication of the intervention?
Does the study describe the dosage, formulation, timing, duration, intensity, etc. of the intervention?

2. For behavioral studies, was treatment fidelity monitored in a systematic way?
+ = yes
- = no or not reported (NR)
NA

3. Did the authors measure and report adherence to the intended treatment process?
+ = yes
- = no or not reported (NR)
NA
Considerations:
Does the study report number of hours of treatment or treatment sessions or time period receiving therapy (planned vs. actually received)? Do they provide pill count data for pharmacologic interventions?

4. Did the authors report differences in OR hold steady all concomitant interventions?
+ = yes
- = no or not reported (NR)

Outcome Measurement

1. Did outcome measures demonstrate adequate reliability and validity (including interobserver reliability for behavior observation coding)?
+ = yes
- = no or not reported (NR)
Considerations:
If the study used an established measure, has validity been established previously and do the authors provide a reference?
If the study used a new measure, was validity established?
For interobserver coding, was reliability and /or validity tested?

2. Were the primary & secondary outcomes clearly specified a priori?
+ = yes
- = no or not reported (NR)
Considerations:
Was there a "called shot?"

3. Were outcome data collected from sources appropriate to the target outcome (e.g. parent report, teacher report, direct behavior observation)?
+ = yes
- = no or not reported (NR)
Considerations:
Ex: Parent report for home-focused outcomes, teacher report for academic/school-focused, etc.

4. Were outcomes coded by individuals blinded to the intervention status of the participants?
+ = yes
- = no or not reported (NR)

Analysis

1. Was an appropriate statistical analysis used?
+ = yes
- = no
1a. For RCT's, was there an intent-to treat analysis?
+ = yes
- = no
NA
Considerations:
Does the study report ITT analyses or last observation carried forward or note that all subjects were included in the final analyses?

1b. Did the study correct for multiple testing?
+ = yes
- = no
NA

1c. For observational studies, were potential confounders and effect measure modifiers captured?
+ = yes
- = no
NA

1d. For observational studies, were potential confounders and effect measure modifiers handled appropriately?
+ = appropriate analysis
- = inappropriate analysis
NA
Considerations:

Confounders are variables that are associated both with the intervention and the outcome and that change the relationship of the intervention to the outcome. These are variables that we would control for in analysis.

Effect measure modifiers are variables that we think of as stratifying, in that the relationship between the intervention and outcome is fundamentally different in different strata of the effect modifier. Observational research should include an assessment of potential confounders and modifiers, and if they are observed, analysis should control for or stratify on them.

Was the candidate variable selection discussed/noted? Was the model-building approach described?

Were any variables unrelated to the studied variables that could have altered the outcome handled appropriately?

Were any variables not under study that affected the causal factors handled appropriately?