Supplementary information – online resource 2

Pharmacological Treatment for Pedophilic Disorder and Compulsive Sexual Behavior Disorder - a Review

Drugs

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Risk of bias table

Reference	Overall risk-of-bias-judgment	Comments	Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result
Bancroft et al 1974	High	Due to lack of pre-specified study plan	Randomization process described as a williams square design to adjust for carryover effects. Low	Describes the off-site preparation of identical interventions by a pharmacist, with treating staff blinded to the intervention Low	Probably not, although not explicitly stated, other than that one participant withdrew after 3 days and was replaced Low	Probably not because the assessors were blinded. A crossover trial is at risk of carry-over effects. Some concern	No pre-specified plan for analysis is described Unclear
Tennent et al 1974	High	Due to lack of pre-specified study plan	Randomization process described as a williams square design to adjust for carryover effects. Low	Describes the off-site preparation of identical interventions by a pharmacist, with treating staff blinded to the intervention An initial liquid preparation was changed to tablets after the first six weeks due to dosing difficulties and was applied to all three preparations. Low	Three participants dropped out, and were replaced Unclear	Probably not because the assessors were blinded. A crossover trial is at risk of carry-over effects. Some concern	No pre-specified plan for analysis is described Unclear
Cooper et al 1981	High	No pre-specified study plan, ambiguity about handling of missing data and unblinded data collectors.	Describes random allocation of treatment order Low	Describes placebo pills to be identical with the active treatment Low	Corrections with analysis of variance applied to account for missing data, but extent not reported Unclear	Although outcomes were based on self-report, answers were elicited from participants from unblinded assessors. A crossover trial is	No pre-specified plan for analysis is described Unclear

						at risk of carry-over effects. High	
Wincze et al 1986	High	No randomization of treatment assignment, inconsistent length of interventions and analysis of results.	No randomization, interventions applied in the same order for all participants, albeit with different durations of the active treatments. High	Varying durations of active treatment were applied (30-56 days), and the rationale and identity of the decision maker for this is not described. High	For unclear reasons, one out of five assessment domains (Nocturnal penile tumescence) had missing data for one participant. Low	Probably not, because there was a double-blind procedure. Reversal design is at risk of carry-over effects. Some concern	No formal statistical analysis High
Hucker et al 1988	High	Drop-out and lack of pre-specified plan for statistical analysis.	Assignment of intervention in parallel groups provided by remote pharmacist Low	Describes staff and participants to be unaware of what was being given Low	Out of 18 participants, 7 dropped out. Although groups appear to be similar in size (5 vs 6), group allocation and reasons for discontinuation is not reported for five participants. High	Probably not, because there was a double-blind procedure Low	No pre-specified plan for statistical analysis described. It was inferred from hormonal assays that one participant assigned active treatment had not been taking the assigned medication and was therefore excluded from analysis. High
McConaghy et al 1988	High	No blinding	Described as random allocation Low	No procedure for allocation concealment employed, and intervention obvious (imaginal desensitization w/wo i.m. injections). High	20% drop-out after 3-5 injections. Data for all participants reported, but methods for handling missing data unclear Unclear	Unblinded participants and data collectors. Treatment response not defined. High	No pre-specified plan for statistical analysis described. High

Cooper et al 1992	High	Deficient randomization	Treatment order reported as "quasi-randomized", but participants were all at the same time on either placebo or one of four active treatments High	All involved staff described as blinded. Low	Three participants dropped out during the initial placebo run-in phase. No other missing data reported, and no serious adverse events causing discontinuation Likely low	Participants and staff blinded to treatment allocation. All treatments dispensed as identical capsules. Treatment switching is at risk of carry-over effects. Some concern	Deviations from the initial plan for analysis due to low recruitment are reported, but not described in detail. Unclear
Kruesi et al 1992	High	Inadequate placebo-control and rater bias in assessing outcome.	Only randomization between active treatments and not placebo. High	Assessors were unblinded to whether participants were assigned placebo and only blinded to choice of active treatment. High	Out of 15 participants entering the placebo phase, 7 were excluded from analysis. High	Assessors were unblinded to whether participants were assigned placebo and only blinded to choice of active treatment. High	Only per-protocol analysis was reported, as 7 participants were excluded. No pre-specified plan for analysis is described. High
Bradford et al 1993	High	Some concerns due to deviation from intended intervention and unclear description of pre-planned analyses	Described as random allocation to either placebo or active treatment after a placebo-run in phase Low	Treatment phase was changed for one participant, Unclear	Two participants dropped out, with reasons stated Low	Treatment phase changed for one participant. Crossover design is at risk of carry-over effects. Unclear	Preplanned statistical analyses are mentioned, but not described in detail. Unclear
Schober et al 2005	High	No randomization, blinding broken.	No randomization High	Blinding broken and active treatment was reinstated for three participants. High	No missing data. Low	Participants and raters were blinded to the treatment phase, but protocol was identical for all participants.	No pre-specified analysis plan described. Participants act as their own control, but both within-case

						High	and group mean results are reported. Unclear
Wainberg et al 2006	Low	Methods and reporting are generally adequate. Low	Described as randomized. Low	Double-blinding. Low	Two of 28 participants dropped out, but groups were analyzed by intention to treat. Low	Probably not because there was a double-blind procedure Low	Pre-specified protocol described, but none provided. Likely low
Landgren et al 2020	Low	Methods and reporting are generally adequate Low	Block randomization by independent personnel. Low	No deviations described. Low	Two participants with some missing data, one lost to last follow-up with reasons stated. Low	Mix of self-report and objective measures, and a double-blind procedure. Low	A pre-specified trial protocol is provided. Low