APPENDIX 15F: CLINICAL STUDY CHARACTERISTICS: PHARMACOLOGICAL INTERVENTIONS

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1.1 CHARACTERISTICS OF STUDIES INCLUDED IN THE META-ANALYSIS

BATTAGLIA1999

Bibliographic reference	Battaglia, J., Wolff, T. K., Wagner-Johnson, D. S., *et al.* (1999) Structured diagnostic assessment and depot fluphenazine treatment of multiple suicide attempters in the emergency department. *International Clinical Psychopharmacology*, *14*, 361–372.
Methods	Allocation: double-blind randomisation Follow-up period: 6 months N lost to follow-up: 5 out of 58 (8.6%) for repetition data
Participants	Total N: 58 N used in analysis: experimental 30, control 28 Setting: Dallas, TX, US Inclusion criteria: (i) aged 18 to 65 years; (ii) receiving treatment for suicide attempt that occurred within 30 days prior to study entry; (iii) at least two prior attempts; (iv) able to read English; (v) not allergic/hypersensitive to fluphenazine; (vi) no tardive dyskinesia; (vii) no history or neuroleptic malignant syndrome; (viii) no narrow angle glaucoma; (ix) not schizophrenic; (x) no terminal illness with less than 1 year's life expectancy; (xi) not pregnant or of childbearing age without effective birth control; (xii) no current/expected continued treatment with medications having psychotropic effects. Gender: female 44% (n=28) Profile: repeaters 100% (n=58); substance abuse 79% (n=45); mood disorder 35% (n=20); anxiety disorder 29% (n=17) Source of participants: patients presenting to a psychiatric hospital, screened for history of suicide attempts
Interventions	Experimental: low dose (12 mg) fluphenazine decanoate Control: ultra low dose (1.5 mg) fluphenazine decanoate Therapist: none Type of therapy offered: drug therapy Length of treatment: 6 months
Outcomes	Included: (i) repetition; (ii) suicide (review authors contacted trialist for this information) Excluded: (i) adverse effects; (ii) drug and alcohol use
Notes	Repetition data from: self report

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	'Participants...were randomized' (p. 363) Probably done, but method unclear
Allocation concealment?	Unclear	No details given
Blinding?	Yes	Participants, personnel and outcome assessors
Incomplete outcome data addressed?	Unclear	Of the 58 randomised participants, 53 completed 1 month and 23 completed 6 months. Reasons were given for dropouts. However, the authors did not report any ITT analysis. Data likely to be more reliable

		at 1 month.
Free of selective reporting?	Unclear	Suicide data were obtained from the trial investigators, reducing the risk of bias
Free of other bias?	Yes	No apparent other sources of bias

HALLAHAN2007

Bibliographic reference	Hallahan, B., Hibbeln, R. J., Davis, J. M., *et al.* (2007) Omega-3 fatty acid supplementation in patients with recurrent self-harm: single-centre double-blind randomised controlled trial. *British Journal of Psychiatry, 190,* 118–22.
Methods	Allocation: computer generated list (double blind). Code revealed to researchers only after data collection was complete Follow-up period: 12 weeks N lost to follow-up: 0 out of 49 (0%) for repetition data (although 13 did not complete the study)
Participants	Total N: 49 N used in analysis: experimental 22, control 27 Setting: Dublin, Ireland Inclusion criteria: (i) presenting acutely with self-harm; (ii) at least one previous episode; (iii) no current history of addiction, substance abuse, psychosis or eating disorder; (iv) not currently receiving psychotherapy; (v) no known history of dyslipidaemia; (vi) no involvement in any treatment, diet or illness known to interfere with lipid or n-3 EFA [essential fatty acid] metabolism; no weight loss greater than 10% over the previous 3 months; (vii) not taking supplements containing n-3 EFAs or consuming fish more than once per week; (viii) not changes to, or introduction of, psychotropic medication during the previous 6 weeks; (ix) living inside greater Dublin area. Gender: female 65% (n=32) Profile: mean age 30.6 years; repeaters 100% (n=49); alcohol misuse 41% (n=20); personality disorder 82% (n=40); taking psychotropic medication 53% (n=26) Source of participants: patients presenting to hospital after self-harm
Interventions	Experimental: EPAX 5500 plus usual psychiatric care: four capsules containing 305 mg eicosapentaenoic acid (EPA) and 227 mg docosahexaenoic acid (DHA). Total dose equalled 2128 mg per day of EPA plus DHA. Control: placebo plus usual psychiatric care: four capsules per day consisting of 99% corn oil and a 1% EPA/DHA mixture Therapists: n/a Type of therapy offered: experimental – drug therapy; control – placebo Length of treatment: 12 weeks
Outcomes	Included: (i) repetition; (ii) suicide; (iii) suicidal ideation; (iv) depression (measured in two ways); (v) compliance Excluded: (i) aggression; (ii) impulsivity; (iii) stress; (iv) adverse effects
Notes	Repetition data from: self-report Adherence encouraged by weekly telephone calls and determined by pill counts

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Yes	'An independent colleague dispensed either active or placebo capsules according to a computer-generated list' (p. 119)

		Probably done
Allocation concealment?	Yes	No specific details about allocation concealment given, however, colleague called 'independent'. Probably done
Blinding?	Yes	Both participants and personnel were blinded. Outcome assessors unclear
Incomplete outcome data addressed?	Yes	
Free of selective reporting?	Unclear	No reason to suspect that all outcomes were not measured; however, in the absence of the trial protocol, cannot be certain.
Free of other bias?	Yes	No suggestion of other sources of bias

HIRSCH1982

Bibliographic reference	Hirsch, S., Walsh, C. & Draper, R. (1982) Parasuicide: a review of treatment interventions. *Journal of Affective Disorders*, *4*, 299–311.
Methods	Allocation: randomly allocated, double-blind, placebo controlled trial Follow-up period: 12 weeks N lost to follow-up: 0 out of 114 (0%) for repetition data
Participants	Total N: 114 N used in analysis: experimental 76, control 38 Setting: London, UK Inclusion criteria: (i) not taking antidepressant or antipsychotic medication; (ii) GHQ score of over 20 Gender: not specified Profile: aged 16 to 65 years Source of participants: patients who were admitted to a hospital after deliberate self-poisoning
Interventions	Experimental: antidepressants – either 30 to 60 mg mianserin or 75 to 150 mg nomifensine Control: placebo Therapist: none Type of therapy offered: experimental – drug therapy; control – placebo Length of treatment: 6 weeks
Outcomes	Included: (i) repetition; (ii) suicide. Excluded: (i) GHQ score; (ii) depression; (iii) life events; (iv) compliance.
Notes	Repetition data from: not specified Depression and compliance outcomes excluded due to inability to collect unpublished data

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	'[R]andomised' (p. 307)
Allocation concealment?	Yes	Randomly allocated, double-blind trial
Blinding?	Yes	Randomly allocated, double-blind trial
Incomplete outcome data addressed?	Unclear	No details given

Free of selective reporting?	No	Authors claim various outcomes, such as GHQ and depression, are n's, but report no numerical data.
Free of other bias?	Yes	No suggestion of other sources of bias

LAUTERBACH2008

Bibliographic reference	Lauterbach, E., Felber, W., Müller-Oerlinghausen, B., *et al.* (2008) Adjunctive lithium treatment in the prevention of suicidal behaviour in depressive disorders: a randomised, placebo-controlled, 1-year trial. *Acta Psychiatrica Scandinavica*, *118*, 469–479.
Methods	Allocation: randomly allocated, double-blind, placebo controlled trial Follow-up period: 12 months N lost to follow-up: 69% for repetition data
Participants	Total N: 167 N used in analysis: experimental 84, control 83 Setting: Germany Inclusion criteria: (i) suicide attempt within 3 months prior to the first drug administration; (ii) occurrence of suicide attempt within the context of a depressive spectrum disorder; (iii) minimum age of 18 years; (iv) ability to complete screening and baseline assessment; (v) ability to understand and provide written informed consent. Gender: female 58% (n = 96) Profile: mean age 39 years; MDD as main diagnosis 76%; adjustment disorder 19.2%; another depressive disorder (mainly dysthymia) 4.8% Source of participants: patients presenting to the emergency department following a suicide attempt at one of five study centres
Interventions	Experimental: lithium 200 mg per week Control: placebo Therapist: none Type of therapy offered: experimental – drug therapy; control – placebo Length of treatment: 3 to 4 weeks
Outcomes	(i) repetition; (ii) suicide
Notes	Repetition data from: self-report. High drop out rate (60%); maintenance treatment for 12 months may imply self-selection bias because those who remain are less likely to self-harm.

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Yes	
Allocation concealment?	Yes	
Blinding?	Yes	Personnel and participants blinded. Unclear for outcome assessors
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Yes	
Free of other bias?	Unclear	The lithium group had a higher incidence of personality disorders as well as a higher number of subjects with multiple suicide attempts whereas individuals in the

		placebo group had a higher score in the SIS.

MONTGOMERY1979

Bibliographic reference	Montgomery, S., Montgomery, D., Jayanthi-Rani, S., *et al.* (1979) Maintenance therapy in repeat suicidal behaviour: a placebo controlled trial. In: *Proceedings of the 10th International Congress for Suicide Prevention and Crisis Intervention*. Ottawa, Canada, pp. 227–229.
Methods	Allocation: random allocation in double-blind trial Follow-up period: 6 months N lost to follow-up: 7 out of 37 (19%) for repetition data
Participants	Total N: 37 N used in analysis: experimental 18, control 19 Setting: Maidstone, UK Inclusion criteria: (i) documented history of two or more episodes of self-harm; (ii) not experiencing overt depression or schizophrenia; (iii) no organic illness Gender: female 70% (n=26) Profile: aged 18 to 68 years, mean age 35.3 years; repeaters 100% (n=37). Source of participants: patients admitted to a general hospital following a suicidal act
Interventions	Experimental: 20 mg intramuscular flupenthixol decanoate; 4 weekly for 6 months Control: placebo Therapist: none Type of therapy offered: experimental – drug therapy; control – placebo Length of treatment: 6 months
Outcomes	Included: (i) repetition; (ii) compliance Excluded: (i) adverse effects
Notes	Repetition data from: not specified

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	'Patients were randomly allocated' (p. 227) No further details given
Allocation concealment?	Yes	Described as a double-blind trial
Blinding?	Yes	'Patients and raters remained blind to actual treatment' (p. 227) No further details given, but probably done due to medication and placebo being delivered by injection at identical intervals. Outcome assessors: no details given
Incomplete outcome data addressed?	No	37 patients entered the trial. There were seven dropouts – reasons given for some of the dropouts (such as two for parkinsonian side effects), which caused removal of patients 'to preserve blindness'. Otherwise, there were three dropouts for placebo and two for active treatment (roughly equivalent)

Free of selective reporting?	Yes	No reason to suspect that all outcomes were not measured
Free of other bias?	Yes	No suggestion of other sources of bias

1.2 CHARACTERISTICS OF EXCLUDED STUDIES

MONTGOMERY1983

Reason for exclusion	Borderline personality disorder population. This study has been reviewed in narrative manner for completeness.

VERKES1998

Reason for exclusion	Borderline personality disorder population. This study has been reviewed in narrative manner for completeness.

ZISOOK2010

Reason for exclusion	Schizophrenia population and unclear if they have had self-harm episodes.

References of excluded studies

Montgomery, S. A., Roy, D. & Montgomery, D. B. (1983) The prevention of recurrent suicidal acts. *British Journal of Clinical Pharmacology*, *15*, 183S–188S.

Verkes, R. J., van der Mast, R. C., Hengeveld, M. W., *et al.* (1998) Reduction by paroxetine of suicidal behavior in patients with repeated suicide attempts but not major depression. *American Journal of Psychiatry*, *155*, 543–547.

Zisook, S. K. (2010) Augmentation with citalopram for suicidal ideation in middle-aged and older outpatients with schizophrenia and schizoaffective disorder who have subthreshold depressive symptoms: a randomized controlled trial. *Journal of Clinical Psychiatry*, *71*, 915–922.