

1 **APPENDIX 15D: PHARMACOLOGICAL INTERVENTIONS**

2 **CHARACTERISTICS OF INCLUDED STUDIES**

3 **BATTAGLIA1999**

**Methods**

Allocation: double-blind randomisation.

Follow-up period: 6 months.

N lost to follow up: 5/58 (8.6%) for repetition data.

Setting: Dallas, USA.

**Participants**

Inclusion criteria: i) aged 18-65 years; ii) receiving treatment for suicide attempt that occurred within 30 days prior to study entry; iii) at least 2 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 life expectancy; xi) not pregnant or of childbearing age without effective birth control; xii) no current/expected continued treatment with medications having psychotropic effects.

Numbers: 58 participants: 30 experimental, 28 control.

Profile: 44% (n=28) female. 79% (n=45) had diagnosis of substance abuse, 35% (n=20) mood disorder, and 29% (n=17) anxiety disorder. 100% (n=58) were repeaters.

Source of participants: patients presenting to a psychiatric hospital, screened for history of suicide attempts.

**Interventions**

Experimental: low dose (12mg) fluphenazine decanoate.

Control: ultra low dose (1.5mg) fluphenazine decanoate.

Therapist: none.

Type of therapy offered: drug therapy.

**Outcomes** Length of treatment: 6 months.  
Included: i) repetition; ii) suicide (review authors contacted triallist for this information).

**Notes** Excluded: i) adverse effects; ii) drug and alcohol use.  
Repetition data from: self report.

1 **Risk of bias table**

Item	Judgement	Description
Adequate sequence generation?	Unclear	Quote: "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 randomized participants, 53 completed 1 month and 23 completed 6 months. Reasons were given for drop outs. 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 was obtained from the trial investigators, reducing the risk of bias.
Free of other bias?	Yes	No apparent other sources of bias.

2 **HALLAHAN2007**

**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: 0/49 (0%) for repetition data.  
Although 13 did not complete the study. Should we mark this as 13/49 even though ITT data for all 49 participants is used for repetition?

**Participants** Setting: Dublin, Ireland.

Inclusion criteria: i) presenting acutely with DSH; 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 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.

Numbers: 49 participants: 22 experimental, 27 control.

Profile: 65% (n=32) female. Mean age of 30.6 years. 100% (n=49) were repeaters. 41% (n=20) had diagnosis of alcohol misuse and 82% (n=40) personality disorder. 53% (n=26) were taking psychotropic medication.

Source of participants: patients presenting to hospital after DSH.

### **Interventions**

Experimental: EPAX 5500 plus usual psychiatric care: four capsules containing 305 mg EPA and 227 mg 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.

Item	Judgement	Description
Adequate sequence generation?	<input type="text" value="Yes"/>	Quote: "An independent colleague dispensed either active or placebo capsules according to a computer-generated list" (p.119)
Allocation concealment?	<input type="text" value="Yes"/>	Probably done. No specific details about allocation concealment given, however, colleague called "independent"
Blinding?	<input type="text" value="Yes"/>	probably done Both participants and personnel were blinded. Outcome assessors unclear.
Incomplete outcome data addressed?	<input type="text" value="Yes"/>	
Free of selective reporting?	<input type="text" value="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?	<input type="text" value="Yes"/>	No suggestion of other sources of bias

1 **HIRSCH1982**

**Methods**

Allocation: randomly allocated, double-blind, placebo controlled trial.

Follow-up period: 12 weeks.

N lost to follow up: 0/114 (0%) for repetition data.

**Participants**

Setting: London, UK.

Inclusion criteria: i) not taking antidepressant or antipsychotic medication; ii) GHQ score of over 20.

Numbers: 114 participants: experimental 76, control 38.

Profile: aged 16 - 65 years.

Source of participants: patients who were admitted to a hospital after deliberate self-poisoning.

**Interventions**

Experimental: antidepressants: either 30-60mg mianserin or 75-150mg 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.

1 **Risk of bias table**

Item	Judgement	Description
Adequate sequence generation?	Unclear	Quote: “randomised” (p.307)
Allocation concealment?	Yes	This was a randomly allocated, double-blind trial.
Blinding?	Yes	This was a randomly allocated, double-blind trial.
Incomplete outcome data addressed?	Unclear	No details given.
Free of selective reporting?	No	Authors claim various outcomes e.g. GHQ and depression are 'ns', but report no numerical data.
Free of other bias?	Yes	No suggestion of other sources of bias.

2 **LAUTERBACH2008**

**Methods**

Allocation: randomly allocated, double-blind, placebo controlled trial.

Follow-up period: 12 months.

% lost to follow up: 69% for repetition data.

**Participants**

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.

Numbers: 167 participants: experimental 84, control 83.

Profile: 76% had a major depressive disorder as the main diagnosis, 19.2% had an adjustment disorder, and 4.8% had another depressive disorder (mainly dysthymia). Mean age: 39

Source of participants: Patients presenting to the emergency department following a suicide attempt at one of 5 study centres.

**Interventions**

Experimental: Lithium 200mg per week

Control: placebo.

Therapist: none.

Type of therapy offered: Experimental: drug therapy; Control: placebo.

Length of treatment: 3-4 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 DSH

1 **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.

1 **MONTGOMERY1979**

<b>Methods</b>	Allocation: random allocation in double-blind trial.  Follow-up period: 6 months.
<b>Participants</b>	N lost to follow up: 7/37 (19%) for repetition data. Setting: Maidstone, UK.  Inclusion criteria: i) documented history of two or more episodes of DSH; ii) not suffering from overt depression or schizophrenia; iii) no organic illness.  Numbers: 37 participants: 18 experimental, 19 control.  Profile: 70% (n=26) female. Aged 18 - 68 years. Mean age of 35.3 years. 100% (n=37) were repeaters.
<b>Interventions</b>	Source of participants: patients admitted to a general hospital following a suicidal act. Experimental: 20mg 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.
<b>Outcomes</b>	Included: i) repetition; ii) compliance.
<b>Notes</b>	Excluded: i) adverse effects. Repetition data from: not specified.

2 **Risk of bias table**

<b>Item</b>	<b>Judgement</b>	<b>Description</b>
Adequate sequence generation?	<input type="text" value="Unclear"/>	Quote: "Patients were randomly allocated" (p.227)
Allocation concealment?	<input type="text" value="Yes"/>	No further details given. Described as a double-blind trial.
Blinding?	<input type="text" value="Yes"/>	Quote: '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?

37 patients entered the trial. There were 7 dropouts - reasons given for some of the dropouts (e.g. 2 for Parkinsonian side effects) which caused removal of patients in order 'to preserve blindness'. Otherwise, dropouts were 3 for placebo and 2 for active treatment (roughly equivalent).

Free of selective reporting?

No reason to suspect that all outcomes were not measured.

Free of other bias?

No suggestion of other sources of bias.

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## 2 **Characteristics of excluded studies**

### 3 **MONTGOMERY1983**

**Reason for exclusion**

Borderline Personality Disorder population. Self-harm outcome does not seem to be the primary outcome.

### 4 **VERKES1998**

**Reason for exclusion**

Borderline Personality Disorder population. Self-harm outcome does not seem to be the primary outcome.

### 5 **ZISOOK2010**

**Reason for exclusion**

Schizophrenia disorder and unclear if they have had self-harm episodes.

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