INPLASY PROTOCOL

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Nutraceutical treatment for antidepressant induced sexual dysfunctions: a systematic review

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Review question / Objective: **What are the effects of nutraceutical treatments for anti-depressant-induced sexual dysfunctions when added to standard care?**
Condition being studied: **Anti-depressant induced sexual dysfunctions.**
Information sources **We will search the following electronic databases: Web of Science, Embase, and PsycINFO, and CENTRAL (Cochrane Controlled Register of Trials).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 November 2021 and was last updated on 15 November 2021 (registration number INPLASY2021110051).

INTRODUCTION

Review question / Objective: **What are the effects of nutraceutical treatments for anti-depressant-induced sexual dysfunctions when added to standard care?**

Condition being studied: **Anti-depressant induced sexual dysfunctions.**

METHODS

Participant or population: **Patients with depression and antidepressant induced sexual dysfunction.**

Intervention: **Nutraceuticals, defined as "any natural substance such as food or a part of them, a vitamin, a mineral or a herb with beneficial effects for human health", added to standard care, regardless of**

dosage and pharmaceutical form, alone or in combination, i.e. fatty acids, vitamins, minerals, amino acids, probiotics, etc.

Comparator: Placebo or any other nutraceutical.

Study designs to be included: Randomized trials (RCTs) that assessed primary outcome at minimum 4 weeks (published in English language in peer-reviewed journals, both parallel and crossover group design).

Eligibility criteria: Inclusion criteria: Adults in treatment with antidepressant (agomelatine, amisulpride, amitriptyline, amoxapine, atomoxetine, bupropion, buspirone, citalopram, clomipramine, desipramine, desvenlafaxine, dothiepin, doxepin, duloxetine, escitalopram, fluoxetine, fluvoxamine, imipramine, isocarboxazid, ketamine, lofepramine, maprotiline, mianserin, milnacipran, mirtazapine, moclobemide, nefazodone, nortriptyline, paroxetine, phenelzine, protriptyline, reboxetine, selegiline, sertraline, sulpride, tianeptine, tranylcypromine, trazodone, trimipramine, venlafaxine, vilazodone, vortioxetine), affected by antidepressant induced sexual dysfunctions. Exclusion criteria: People who do not suffer by any psychiatric disorders who have any sexual disfunction not induced by antidepressant medication.

Information sources: We will search the following electronic databases: Web of Science, Embase, and PsycINFO, and CENTRAL (Cochrane Controlled Register of Trials).

Main outcome(s): Primary outcomes will be change or post-treatment differences, in the severity of identified sexual dysfunctions (assessed by self (self-rated measures) or interviewer (interviewer-rated measures), or both.

Quality assessment / Risk of bias analysis: AR and a second reviewer will independently assess the risk of bias using the Cochrane Risk of Bias tool, considering how the sequence was generated, how allocation was concealed, the integrity of blinding at the outcome, completeness of outcome data, selective reporting, and other biases.

Strategy of data synthesis: We will provide a narrative synthesis of the findings from the included studies. Continuous outcomes will be measured with standardized mean differences (SMDs) and 95% confidence intervals (CIs). Dichotomous outcomes will be measured with risk ratios (RRs) and 95% CIs.

Subgroup analysis: We will provide a narrative synthesis of findings according to the types of and nutraceutical treatments and the outcome measures.

Sensitivity analysis: No sensitivity analyses are planned.

Language: English and Italian.

Country(ies) involved: Italy.

Keywords: Anti-depressants; sexual dysfunction; Systematic review; Narrative synthesis; nutraceutical treatments.

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Conflicts of interest: Dr. Aguglia E is/ has been a consultant and/or a speaker and/or has received research grants from Allergan, Angelini, Doc Generici, FB-Health, Janssen, Lundbeck, Otsuka, Fidia, Recordati.