D5.1 – Study protocol for systematic review 1 and 2

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European Study on Risk Factors in Mental Disorder and Forensic Care: a multicenter study

	[WP5 – WP "Evaluation of treatment effectiveness"]
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V0.3	24.04.2018	Revision & Final version

Publishable Summary

Deliverable 5.1 “Study protocol for systematic review 1 and 2” represents the outcomes of the activities carried out in the context of WP5 “Evaluation of treatment effectiveness” of the EU-VIORMED.

There are a growing number of reviews and reports examining the pharmacological and non-pharmacological management of aggression in individuals with SSDs. However, very few of these have specifically examined the management of aggression in forensic units, or the efficacy of treatments specifically targeted at forensic patients. The analysis of effective treatments of aggression will rely on existing research using systematic reviews and meta-analyses. Thus, in order to identify effective treatment of aggression in forensic units, we will conduct systematic reviews of the existing literature on the pharmacological and non-pharmacological treatments of aggression in samples of patients with schizophrenia spectrum disorders living in forensic settings.

The aim of this systematic review and meta-analysis is to estimate efficacy of pharmacological treatments and of non-pharmacological interventions for aggressive behaviors and violence in subjects suffering from schizophrenia spectrum and other psychotic disorders. Results from these reviews and meta-analyses will help clarify the most effective treatments of aggression suitable in forensic settings and so assist policy makers and clinicians in services planning.

The present document represent the framework of activities concerning the systematic reviews and meta-analysis to be carried out in the context of WP5, which will be reported in the final deliverables, D5.2 and D5.3, due at M15 (January 2019).

Methods

We will systematically search for studies in the following databases: PubMed, PsycINFO, and Cochrane Library. We will also explore reference lists of relevant systematic reviews published in this topic. No language restrictions will be applied. Any standard psychopharmacological treatment and any non-pharmacological treatment will be included. Two authors will perform the preliminary screening based on titles and abstracts, to include potentially relevant articles. After the first screening, studies will be retrieved in full text to check eligibility according to inclusion/exclusion criteria. A structured sheet will be used for data extraction from each study included: year of publication; country; inclusion criteria; setting; sample size; tested (non-)pharmacological treatments; study duration; main findings. Two authors will conduct independently data extraction, and any differences will be resolved by consensus with other co-authors. If some data remain unclear, one investigator will contact corresponding authors of included studies, to obtain relevant information. In cases of doubt, we will

invite a member of the Steering Committee into the discussion. Further, we will use full Cochrane Collaboration's tool for risk of bias assessment also including evaluation of double blind, and evaluating strength, quality of evidence and recommendations. Study quality will be assessed using a four-point "strength of reporting" scale, derived from the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement checklist (Vandenbroucke et al., 2007). Differences between treatment and control groups will be pooled generating standardized mean difference with 95% confidence interval (95% CI), based on random effects model, for continuous outcomes, and relative risk with 95% CI according to the random effects model for categorical outcomes. Statistical significance will be set at $p<0.05$ and results will be summarized using conventional forest plots. Heterogeneity will be estimated using the I^2 index, with values of 25%, 50%, and 75%, taken to indicate low, moderate, and high levels of heterogeneity, respectively.

When writing the protocol we considered the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement (Moher et al., 2009). For interpretation our findings we will use the GRADE approach (GRADE Working Group 2004).

In general, we plan to publish our strongest findings in the highest impact general medical journals, maximizing the potential for influencing different areas of clinical practice. For other papers we will target leading specialty journals (such as British Journal of Psychiatry or International Journal of Forensic Mental Health). We plan to publish in open access journals (or in articles with open-access format), as we would hope to reach the professionals in the widest possible way. We plan to publish at least two papers from these reviews and meta-analyses in high-ranking journal reporting the main findings. Further, smaller papers reporting details which are not feasible for the two main papers are planned.

Results

Collection of studies started

Discussion

Data collection and analyses not yet finished.

Conclusion

Data collection and analyses not yet finished.

Repository for primary data

The complete protocols are available as attachment and on the PROSPERO online database at:

1. Systematic review 1 (Pharmacological treatment)

   http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018087421

2. Systematic review 2 (Non-pharmacological treatment)

   http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018087427