D4.1 Study Protocols

PP-2-3-2016 – EU-VIORMED

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

	WP4 – Risk factors for violence and risk assessment tools
Lead contributor	Marco Picchioni (P2 KCL)
	marco.picchioni@kcl.ac.uk
Other contributors	P1 IRCCS-FBF vbulgari@fatebenefratelli.eu cbarattieri@fatebenefratelli.eu gdegirolamo@fatebenefratelli.eu
	P3 MANN
	P4 MUW
	P5 IPIN
	P6 UDUS
	P8 UNIMIB

Due date	30 April 2018
Delivery date	M6
Deliverable type	R
Dissemination level	PU

Document History

Version	**Date**	**Description**
V1.0	23 April 2018	Draft
V1.1	26 April 2018	Comments
V1.2	26 April	Final Version

Publishable Summary

The fundamental objective of the EU-VIORMED project is to improve the quality of forensic care in European countries. This will be achieved by identifying, describing and contrasting areas of best practice in forensic psychiatric care across Europe, with a particular focus on generating new data on violence and self-harm risk assessment.

The present document (D4.1 "Study protocols") present a summary of the study protocol, which has been developed during the first 6 months of the project in the context of WP4 ("Identifying risk factors for violence in patients with SSDs and effective risk assessment tools in forensic psychiatric services") of the EU-VIORMED.

WP4 aims to identify factors associated with the risk of violence to the self and others in patients with Schizophrenia Spectrum Disorders (SSDs), and to assess tools capable of predicting violence risk, to aid risk assessment and support decision-making. To achieve this two clinical studies (Study 1 and Study 2) will be conducted.

The objective of Study 1 is to identify risk factors associated with violence to self and others in patients with Schizophrenia Spectrum Disorders (SSD). The objective of Study 2 is to assess two risk assessment tools capable of predicting risk of violence to assist clinicians in the decision-making process.

The activities concerning the recruitment and evaluation of patients presented here will be carried out in WP4 and WP5 ("Evaluation of effective treatments in forensic psychiatric services"). The outcomes and results of these activities will be reported in the final deliverables, D4.2 "Report of Study 1 and Study 2", due at M30 (April 2019).

Version of the Study Protocol

The complete clinical study protocol should be considered as confidential (Annex 1). The attached version of the Protocol is v1.0, approved by the Coordinator's Ethical Committee (CEIOC) on 13 April 2018 with Opinion n. 16/2018. Should there be further modification to the Protocol, newer versions will be submitted to the EC without delay.

Methods

Study 1 will follow a case-control retrospective design, where forensic patients with SSDs who have a history of interpersonal violence will be compared to non-violent patients with SSDs living in

community-based residential facilities. Study 2 will be a prospective cohort study with 12 month follow-up to test the predictive validity of the leading structured professional clinical judgement risk assessment guide for interpersonal violence, the HCR-20v3 (Douglas et al., 2001), and an entirely new web-based actuarial risk assessment tool (https://oxrisk.com/) for violence to others and self.

With the exception of self-harm and suicide, the definition of violence used in this study is in line with that provided by the World Health Organization (WHO).

Cases will be patients with a primary diagnosis of a schizophrenia spectrum disorder (SSD) (using DSM 5), aged 18-65 years, who are or have been treated in forensic psychiatric units and have committed at least one act of interpersonal violence. Controls will be patients with SSD who have never committed such acts of interpersonal violence.

Researchers have been trained on the clinical study protocol and the use of the main research tools during EU-VIORMED training, held in Vienna on April 5-7 2018.

Patients will be recruited in mental health services and forensic units of the five recruiting centers taking part to the EU-VIORMED project (i.e. P1 IRCCS, P2 KCL, P3 MANN, P4 MUW, and P5 IPIN) during an 8-month period.

Results

The primary outcome of interest of Study 1 will be the ratio of odds of exposure vs. odds of no exposure to a variety of potential sources of violence in cases vs. controls. The primary outcomes of interest of Study 2 will be the assessment of concordance between prediction of risk of violence based on the risk assessment tools scores and observed violent behaviors in forensic patients measured on the MOAS scale .

Repository for primary data

A secure and confidential data capture system is being developed to store study data for analysis and dissemination. Data will be entered through an online system via web-based interface and automatically stored on a dedicated server. The database will be customized by a programming team and all specification (i.e., database variables, validation check, screens) will be agreed between the programmer, the statisticians, and WP leaders. In accordance with the ethical and legal guidelines, each centre will store all relevant documentation and trial records in conformance with the applicable regulatory requirements. Access to stored information will be restricted to authorized personnel only.

Annex 1 – Study Protocol (confidential)