pubertal timing in the development of psychosis-related outcomes remains underexplored. This presentation reports new findings on sex differences in the impact of environmental exposures on symptom profiles, as well as female-specific developmental mechanisms shaping mental health outcomes. By elucidating how early adversity interacts with pubertal timing and other sex-specific pathways, this work contributes to improved early identification, prevention, and targeted intervention strategies.

Disclosure of Interest: None Declared

SP072

Stratification and prediction of bipolar disorders using multimodal measures

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doi: 10.1192/j.eurpsy.2026.10320

Abstract: Bipolar disorder (BD) exhibits heterogeneous characteristics, frequent comorbidities, and suboptimal treatment response, negatively impacting health outcomes. Environmental and biological models are being investigated, but overall findings are fragmented. Our study proposes an innovative framework that combines multi-source and multi-site clinical, environmental and neuroimaging data with artificial intelligence tools to create and test predictive diagnostic and stratification models for BD.
Data of healthy controls (HC) and BD were analyzed, including (i) magnetic resonance imaging (MRI) from Human Connectome Project (n>1000 HC) and the STRATIBIP network (n>500 HC, n>500 BD), (ii) environmental data from Italian BD patients (n>200). Normative deep learning models of brain morphology were created using HCP and applied to STRATIBIP for anomaly detection; graph neural networks (GNNs) were applied to brain morphological networks (MBNs) to identify BD brain network markers; in Italian BD, topological data analysis (TDA) was applied to environmental data for outcome stratification.
Normative model application to STRATIBIP showed significant deviations in BD in basal ganglia and hippocampus. In STRATIBIP, BD vs. HC classification based on MBNs reached maximum accuracy with GNNs (68%), overcoming traditional ML methods. In Italian BD, TDA showed key predictive roles of (i) external environment for psychiatric comorbidities, (ii) psychiatric history for episode's polarity.
Using advanced AI, we showed the potential of brain regions and networks as candidate BD biomarkers. We showed that brain alterations in BD are heterogeneous and partly shared with physiological variations. We found that environment plays a pivotal role in predicting BD symptomatology, underscoring the necessity to transition from unifying to multi-dimensional disease perspective.

Disclosure of Interest: None Declared

SP073

Expectation confounds in psychiatric trials: insights from placebo research

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doi: 10.1192/j.eurpsy.2026.10319

Abstract: Randomized-controlled trials (RCTs) are not free of biases. For instance, expectation effects are an important confound in psychiatric RCTs. In this talk, I will explore the relationship between expectation effects, blinding integrity, and estimates of efficacy regarding active treatment and placebo. Proposed methods to mitigate these confounders and enhance the reliability of RCTs across psychiatry will be discussed. I will conclude with suggested research directions and novel approaches to reduce potential confounding by expectation effects.

Disclosure of Interest: N. Huneke Grant / Research support from: I have received funding from the NIHR and MRC.

SP074

Mind the gap: representation and outcomes of individuals with schizophrenia or major depressive disorder not eligible for randomized controlled trials

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doi: 10.1192/j.eurpsy.2026.10318

Introduction: Clinical care guidelines on psychiatric pharmacotherapies are based on evidence derived from randomized controlled trials (RCTs). RCTs typically have strict eligibility criteria, which may lead to situations where evidence on the effectiveness and safety of medications represents only a subset of the real-world population, i.e., unselected patients seen in everyday clinical practice.
Objectives: To quantify the proportion of real-world individuals who would be ineligible for participation in RCTs of schizophrenia or major depressive disorder (MDD), to explore outcomes of eligible versus ineligible individuals, and to compare these rates between schizophrenia and MDD.
Methods: Typical RCT eligibility criteria were applied to real-world populations derived from Finnish and Swedish national registers, in designs mimicking RCTs in terms of duration and inclusion. Proportions of RCT-ineligible individuals were calculated based on any exclusion criteria as well as specific criteria, and risks of outcomes were compared between ineligible versus eligible individuals using Cox regression.
Results: In schizophrenia, 79% of individuals would be ineligible for RCTs, whereas in MDD, the proportion was approximately