

What minimal detectable effect size is in your power - An inverted sample size formular for survival data

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Results: There are 33 REMSs in Italy. As of 31st December 2021, 573 in-patients are hosted in REMSs. The most frequent diagnosis is schizophrenia (33%), followed by personality disorders (32%) and substance abuse (21.4%). 80% of the crimes committed involve violence towards human beings. As of 25th March 2022, the REMSs waiting lists include 605 individuals, 42 of whom were already imprisoned and 561 released. The average waiting time for admittance is about 10 months. Positioning on the waiting list follows the exclusive chronological criterion (date of sentence) and is not related to any clinical risk criteria whatsoever. It is estimated that one third of waiting patients remain without adequate care.

Conclusions: Rethinking the admittance criteria to REMSs is crucial. The use of alternative safety measures, the improvement of community mental health services and a real integration between both legal and health systems in terms of management of the offending psychiatric patient are among ways suggested to avoid breaking the dream of deinstitutionalisation.

Disclosure of Interest: None Declared

Guidelines/Guidance / Mental Health Policies

EPP0854

Hyperprolactinemia in patients taking antipsychotics: the importance of a shared approach between psychiatry and endocrinology

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Introduction: Hyperprolactinemia is a commonly encountered adverse effect of antipsychotic medication. Short and long-term repercussions of high prolactin, such as amenorrhea, sexual dysfunction, osteopenia and increased cardiovascular risk carry significant burden and may compromise therapeutic adherence. Despite its serious practical implications, hyperprolactinemia is still underscreened and its management neglected.

Objectives: To review current clinical guidelines regarding the management of hyperprolactinemia associated with the use of antipsychotics, reflecting upon the importance and need to share the management of this risk with an endocrinology expert.

Methods: We performed a literature review to identify clinical guidelines containing specific recommendations for antipsychotic-induced hyperprolactinemia (British Association of Psychopharmacology [BAP], NICE, Maudsley Prescribing Guidelines, Royal Australian and New Zealand College of Psychiatrists), published over the last ten years, with a particular focus on its physical risks.

Results: Most guidelines do not recommend routine monitoring of prolactin levels in asymptomatic patients. NICE and BAP guidelines have suggested measuring the baseline prolactin level, but have not specified follow-up monitoring, while Maudsley guidelines have. Management strategies depend on factors such as sex, age, as well as the clinical manifestations that ensue. Different treatment strategies have been described, such as decreasing the

dose of the antipsychotic, switching antipsychotics, adding aripiprazole or adding dopaminergic agonists. Referral to an endocrinology specialist should be made if the aetiology is unclear, prolactin levels continue to rise despite some intervention, the hyperprolactinaemia is severe (>3000 mIU/L) or there is suspected/confirmed pituitary adenoma. Further physical implications of having hyperprolactin are to be dressed by the endocrinology expert, namely those on bone metabolism, gonadal function and cancer risk.

Conclusions: Given the widespread use of antipsychotics and the need to have psychotic patients stabilized (sometimes with a lack of effective alternative), early detection and shared management of hyperprolactinemia are instrumental towards assisting both clinician's and patients' decision-making, be it towards lowering prolactin levels or managing its risk without compromising the antipsychotic's efficacy.

Disclosure of Interest: None Declared

EPP0855

What minimal detectable effect size is in your power – An inverted sample size formula for survival data

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Introduction: Power calculations are widely used in the conduct of clinical trials and are often required in funding applications and approvals. There is a recent debate on the role of power calculations in observational studies on existing data with (Hernán J Clin Epidemiol 2022; 144 203-205) and (Moris and Smeden J Clin Epidemiol 2022; 142 261-263) emphasizing the need for planning for all study types without risking discarding imprecise but otherwise relevant studies. In the current study, we construct a graph useful in the planning of a wide range of studies with survival data. We map the minimal detectable effect (MDE) for any possible number of events with a dichotome exposure varying the proportion assigned to the exposure groups.

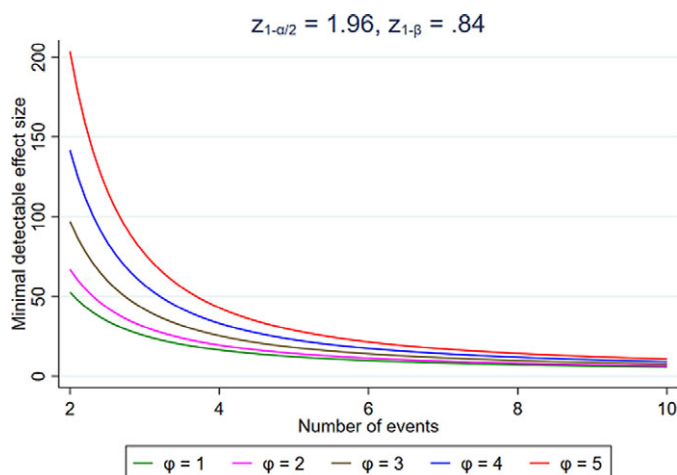
Objectives: To provide a visual tool relating the sample size, more precisely the number of events, and the MDE for survival data in unbalanced designs.

Methods: The visualization is based on the formulas used by Stata's power logrank function by (Schoenfeld Biometrics 1983; 39 499-503) and (Freedman Statistics in medicine 1982; 1 121-129), and the MDE is mapped as a function of the number of events. Furthermore, we apply this to an ongoing project on data from the Danish national registers, comparing the risk of developing polycystic ovary syndrome (PCOS) associated with treatment with valproic acid in a population with bipolar disorder or epilepsy.

Results: Preliminary results (Fig. 1) show, as expected, that a larger sample size is required to obtain an MDE close to one. Also, the MDE increases when the assignment among groups is skewed. Moreover, we find a relevant minimal detectable HRR of 1.78 for developing PCOS in a population of 13,839 patients with bipolar disorder or epilepsy, exposed to valproic acid versus those not exposed to valproic acid, with a total of 203 cases of PCOS.

Fig. 1 shows the minimal detectable effect size as a function of the number of events, with $\alpha = 0.05$ and a power of $1 - \beta = 0.8$, for various assignment ratios $\varphi = P_T/P_C$, where P_T and P_C are the proportions of patients assigned to the treatment group and the control group, respectively.

Image:



Conclusions: The current visualization and corresponding calculation can be used to guide decisions in the design phase of both observational studies as well as in clinical trials. For observational studies, the sample size, or equivalently, the number of events, could well be fixed, and the MDE may help assess the clinical relevance of conducting the study as in the example with PCOS data. The curves can also provide insight into which efforts might lower the MDE, e.g., whether a small increase in sample size or a different assignment proportion would be most beneficial based on a given sample size.

Disclosure of Interest: None Declared

EPP0856

Older adults' mental health during humanitarian crisis

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Introduction: A humanitarian crisis is defined as a singular event or a series of events that are threatening in terms of health, safety or wellbeing of a community or group of individuals, and require action that is usually urgent and often non-routine. Examples of such crisis are wars, natural disasters, epidemics and forced immigration. There is an urgent need of an international commitment to planning for humanitarian emergencies that include individual and community psychosocial support for older adults with mental health conditions. The current lack of inclusion for these older adults in humanitarian response is dramatic and constitute a clear violation of their Human Rights.

Objectives: The World Psychiatric Association Section of Old Age Psychiatry and the International Psychogeriatric Association are working together since 2020 to promote the older adults' Human Rights. Articles, position statements, seminars, symposia and congress were produced. The ultimate common goal is to support the adoption of an UN Convention on the Human Rights of the Older Persons that include the promotion and protection of the mental health of these persons.

Methods: Input to the Independent Expert on Older Adults at the OHCHR who prepared official reports presented during the UN General Assembly in 2022.

Publication of articles, organization of seminars, symposia and congress

Results: The main documents published will be presented as well the template of the next Position statement on Older Adult's mental health during Humanitarian Crisis

Conclusions: Humanitarian actors must provide assistance in accordance with the principles of humanity, neutrality and impartiality. Promoting and ensuring compliance with these principles are essential elements of effective humanitarian coordination, in respect of the Human Rights principles, in particular when vulnerable people such older adults with mental health conditions are involved.

Disclosure of Interest: None Declared

EPP0857

Promoting occupational justice policies in mental health organizations: A model based on the experiences of mental health rehabilitation consumers and employees

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Introduction: Occupational justice (OJ) regards the human right to be engaged in meaningful life occupations (work, leisure, learning, house management etc.). It highlights the idea that all society members should be able to actively participate in all occupations as equals. Yet, people with mental health problems remain at the margins of society and struggle to fully participate in life activities. At the same time, such participation has been shown to lead to better functional abilities, higher quality of life, and better illness management among this population. It provides routine, connectedness, belonging, purpose, and identity. Moreover, impaired occupational participation due to mental health problems has resulted in functional impairment, symptomatic deterioration, loss of social roles, and a reduced sense of competence. Despite the importance of such participation, it is unclear in many mental health rehabilitation service organizations how to design policies that will achieve better occupational participation for their consumers.

Objectives: To better understand the OJ concept and to create a conceptual model pertaining to the challenges and solutions, which may serve policy makers as a theoretical basis for enhancing OJ based policies.

Methods: We conducted a qualitative phenomenological study that included in-depth interviews with mental health rehabilitation