## S37. CROSS-CULTURAL DIFFERENCES IN PANSS ITEM RATINGS: COMPARISONS OF SIX GEO-CULTURAL REGIONS

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**Background:** While schizophrenia is observed in different parts of the world across countries, ethnicities, and races, research indicates cultural factors play significant roles in the phenomenology of this illness. Cultural norms and values affect manifestations of this pathology; more specifically, they affect how symptoms are expressed, experienced, and interpreted. Given that culture affects manifestations of schizophrenia, cultural factors should be considered in the assessment of its symptoms in clinical trials. This study explores the differences and patterns in the Positive and Negative Syndrome Scale (PANSS) item ratings across different geocultural regions. Identifying such patterns can give insights into culturally sensitive assessment practices and aid in developing more effective rater training and data surveillance that consider unique cultural factors.
**Methods:** Data were obtained from an international group of raters from 37 different countries, representing 6 geocultural regions across 13 different studies. As part of the rater training and qualification process for each of these studies, raters viewed and scored the 30-item PANSS based on a video-recorded PANSS interview that was administered using the Structured Clinical Interview-Positive and Negative Syndrome Scale (SCI-PANSS). Raters were deemed qualified if their scores fell within the defined acceptable item score ranges. Given the cultural diversity of the raters, the acceptable passing score ranges for each country were determined by a combination of expert opinion scores, group modal scores, and clinical analyses. Only the scores from raters who achieved qualification on their first scoring attempt were analyzed. The number of raters per geocultural regions included: Asia Pacific, n = 397; Eastern Europe, n = 412; Latin America, n = 88; Middle East/Africa, n = 29; North America, n = 339; and Western Europe, n = 129.
**Results:** A Shapiro-Wilk test for normality was conducted on the scores for each PANSS item and found all significantly different from a normal distribution (all ps < .0001). A Kruskal-Wallis test for rank-ordered differences was conducted for each item for the influence of region on item score. Most items showed a significant influence of region on score after a Bonferroni correction was applied; most ps < .0001 with the following exceptions: N1, p < .001; G15, p < .05; P2, P7, N6, N7, G1, G6, G10, G12, and G13 were not significant. The most significant cross-regional differences were found with P1, P3 and P6, and these items were analyzed further with a post hoc Dunn test to understand cross-regional patterns. On P1, Asia Pacific and Eastern Europe were significantly lower than Latin America, North America, and Western Europe (all ps < .0008) but not Mideast/Africa. On P3, Western Europe were significantly lower than all other regions (all ps < .0005); Asia Pacific were significantly lower than Eastern Europe, North America, and Western Europe (all ps < .006). On P6, Asia Pacific and Eastern Europe were significantly lower than all other regions (all ps < .03).
**Discussion:** The present study suggests that ratings of schizophrenia symptoms are influenced by cultural factors. Cultural beliefs and behaviors seem to influence interpretations of schizophrenia pathology. Given that the PANSS is not standardized for cross-cultural contexts, it is important to consider cultural factors when using this scale in clinical studies. In addition, when developing rater training and data surveillance programs, adjustment of acceptable item score ranges for key PANSS items highlighted above for different geocultural region is recommended. Future studies should explore country-level patterning of ratings of the PANSS.

## S38. EXPERT RATERS RELIABLY ASSESS PSYCHOMOTOR SLOWING IN PSYCHOSIS, BUT SELF-REPORT DOES NOT

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**Background:** Motor abnormalities frequently occur in schizophrenia along with hallucinations, delusions, and negative symptoms. Psychomotor slowing (PS) is one of these motor abnormalities and is characterized by reduced levels of spontaneous gross motor activity as measured by actigraphy, slowed gait and slowing in fine motor tasks. Several reports indicated that 30–50% of schizophrenia patients are suffering from PS. Moreover, PS is associated with multiple disadvantages such as sedentary behavior, cardiometabolic risks and predicts poor treatment outcome and long-term cognition deficits. Therefore, there is a need to accurately and reliably evaluate PS in clinical settings.
In the current study, we anaylized how the gold-standard actigraphy corresponds to either self-report or expert ratings.
**Methods:** In the present study, we evaluated the motor behavior of 23 patients suffering from schizophrenia spectrum disorders and 17 healthy controls using 3 distinct methods. (i) An observer rating scale: The Salpêtrière Retardation Rating Scale (SRRS), which is a 15 Items-scale ranging from 0 to 60 points measuring PS. A higher score indicates severe impairment. (ii) A self-report Questionnaire: the International Physical Activity Questionnaire (IPAQ), in which the participant report their physical activity. It is a 7 Items-scale, which estimates the weekly metabolic commitment to walk and to perform physical activities of moderate and vigorous intensities. The higher the score, the more active was the person during the last week. (iii) the gold-standard actigraphy, which measures the gross motor activity of the participants for 24h by wearing an actiwatch on the non-dominant arm. It integrates all movements of a subject whithin 24 hours into one parameter.
**Results:** Both the physical activity measured with wrist activity ($t(35) = 3.901$, $p < .005$; controls: m = 349099, sd = 112853; patients: m = 228072, sd = 74639) and the observer rated SRRS-score ($t(38) = -15.235$, $p < .001$; controls: m = .41, sd = .62; patients: m = 26.30, sd = 6.96) differed between patients and controls. However, self-reported physical activity did not differ between both groups ($t(38) = 1.452$, $p = .155$; controls: m = 4502, sd = 6103; patients: m = 2241, sd = 3727).
There is a trend for a negative correlation between the SRRS-score and the objective activity level, measured by actigraphy, in patients ($r = -.378$, $p = .100$). This suggests that patients with the highest SRRS scores indeed presented also the lowest level of global activity. There is also a positive correlation between the objective activity level and the self-reported activity in patients yet lacking statistical significance ($r = .337$, $p = .147$). However, there is no correlation between SRRS and IPAQ ($r = .204$, $p = .349$) in patients.
**Discussion:** In this study, we demonstrated that the expert ratings (SRRS) correspond well to the gold standard actigrahpy, even though this association is not significant yet. Thus, expert raters seem to rate PS correctly in patients. However, the self-report (IPAQ) neither corresponds well with the expert ratings nor the actigraphy. Thus, in evaluating PS in psychosis, researchers should not rely on self-report exclusively. Finally, this finding also suggests that patients may not perceive their physical inactivity correctly in case this was due to psychomotor slowing.

## S39. THE IMPACT OF THE GROUP FACTOR ON OUTCOME IN GROUP THERAPY: FINAL RESULTS OF RCT INCLUDING 127 SCHIZOPHRENIA OUTPATIENTS

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**Background:** Today, some evidence-based group therapy approaches focusing different treatment goals are available for the treatment of schizophrenia patients, e.g. psychoeducation, social skills training, CBTp or

cognitive remediation. However, only few if any data are available regarding the impact of the group factor as an unspecific mechanism of change regarding outcome in schizophrenia patients. Does the participation in goal-oriented groups per se affect therapy outcome?
**Methods:** To bridge this gap, a cognitive remediation group approach (Integrated Neurocognitive Therapy, INT) developed in our lab has been compared with control patients not participating in therapy groups (Treatment as Usual, TAU). A total of 127 schizophrenia outpatients has been randomly assigned to INT (N=65) or TAU (n=62). INT was conducted twice a week over 15 weeks therapy duration. A comprehensive test battery was assessed before and after therapy as well as at 1-year follow up in both comparison groups. The group factor was assessed by the newly developed questionnaire "Experience and Behavior in Therapy groups EBIT", a brief questionnaire including 13 items.
**Results:** The therapy group showed significantly better effects in EBIT outcome compared to controls regarding the global score (mean of all EBIT items) (GLM: F=4.23, p=.02) as well as regarding empirical 2-factor solution using factor analysis: factor 1 (affect and communication skills) (GLM: F=3.70; p=.03) and factor 2 (eye contact during communication) (F=3.35, p=.04). Additionally, EBIT scores are significantly associated with improvement in cognition and negative symptoms after treatment but not with positive symptoms.
**Discussion:** First of all, the group factor can be identified and measured using a brief questionnaire. Additionally, the group factor has a supplement positive effect on cognition and negative symptoms.

## S40. COMBINING PHARMACOTHERAPY OF BI 425809 WITH COMPUTERISED COGNITIVE TRAINING IN PATIENTS WITH SCHIZOPHRENIA: INITIAL EXPERIENCE OF A LARGE-SCALE MULTICENTRE RANDOMISED CLINICAL TRIAL

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**Background:** There are currently no approved medications for cognition in patients with schizophrenia. BI 425809, a glycine transporter 1 inhibitor, increases glycine in the synaptic cleft and may improve glutamatergic neurotransmission, synaptic neuroplasticity, and cognition. Pharmacotherapies targeting neuroplasticity may require concurrent cognitive stimulation, and often the surroundings of patients with schizophrenia provide only a low level of cognitive demand. At-home computerised cognitive training (CCT) should increase the level of cognitive stimulation for these patients. Combining CCT with pharmacotherapy could therefore improve cognition in patients with schizophrenia. CCT studies are currently limited in scale and are associated with challenges, such as patient compliance.
This ongoing study explores whether at-home CCT combined with BI 425809 could improve cognition, as compared with patients on at-home CCT and placebo, in patients with schizophrenia. Here, we provide an initial reflection on the experiences and challenges associated with setting up this large-scale clinical trial, in addition to an update on recruitment trajectories.
**Methods:** This is a Phase II, double-blind, placebo-controlled, parallel group trial in patients with schizophrenia on stable antipsychotic therapy, across ~50 centres in 6 countries. Recruitment commenced in June 2019. Patients (aged 18–50 years) must demonstrate compliance with CCT during a 2-week run-in period; this means completing at least 2 hours/week (i.e. 4 hours total during screening). Only CCT-compliant patients are randomised (1:1) to BI 425809 or placebo once daily on top of CCT for 12 weeks. The target duration for at-home CCT is ~30 hours, across 3–5 sessions (2.5 hours total) per week. The primary endpoint is change from baseline in neurocognitive composite score of the Measurement and Treatment Research to Improve Cognition in Schizophrenia Consensus Cognitive Battery after 12 weeks of treatment. Novel exploratory endpoints include the Virtual Reality Functional Capacity Assessment Tool to assess daily functioning and the Balloon Effort Task to assess motivation in cognitive performance and, its association with patients' willingness to comply with at-home CCT.
**Results:** To date, 32 patients have been screened and 11 randomised (21 patients failed screening, primarily due to non-compliance with CCT run-in). The last patient out is planned for December 2020 and results are expected in Q1 2021. Patients randomised so far (n=11; 82% male) have a mean age of 33 years; those who failed screening (n=21; 67% male) have a mean age of 36 years. Mean MCCB total scores for the two groups are 30.9 and 22.3; Positive and Negative Syndrome Scale (PANNS) total scores: 71.3 vs 77.9; and PANNS negative symptom scores: 20.5 vs 20.3, for the randomised and screen failure patients, respectively.
**Discussion:** It is expected that the results of this trial will help to: indicate if there is an enhanced benefit of combining pharmacotherapy with cognitive stimulation through at-home CCT; and determine the role of motivation in CCT compliance and performance in patients with schizophrenia. The main reason for screen failures was non-compliance with CCT run-in, underscoring the relevance of coaching and motivational accompaniment to promote adherence to CCT. The results will indicate if large-scale implementation of at-home CCT across multiple centres and several countries is feasible.

## S41. RANDOMISED CONTROLLED TRIAL OF METACOGNITIVE TRAINING COMPARED WITH PSYCHOEDUCATION IN PATIENTS WITH SCHIZOPHRENIA SPECTRUM DISORDERS: EFFECTS ON INSIGHT

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**Background:** Insight in schizophrenia spectrum disorders (SSD) has been linked with positive outcomes. However, the effect size of previous treatments on insight has been relatively small to date. The metacognitive basis of insight in SSD has led to speculation that metacognitive training (MCT) may improve insight and clinical outcomes in SSD.
**Methods:** Design: Single-center, assessor-blind, parallel-group, randomised controlled trial (RCT).
Sample: Participants are recruited from the outpatient clinic of Hospital Universitario Fundación Jiménez Díaz (Madrid, Spain) over June-December 2019. Inclusion criteria: i) age: 18–64 years, both inclusive, at the study inception; ii) diagnosis: SSD based on the Mini International Neuropsychiatric Interview (Sheehan et al., 1998) and iii) IQ>70 according to the Wechsler Adults Intelligence Scale-IV (Wechsler, 1981). Those with organic and drugs-induced psychosis, poor level of Spanish and/or lack of cooperativeness are excluded.
Intervention: Participants are randomised to receive eight weekly group sessions of MCT or group psychoeducation (PSE) and they will be assessed at: T0) at baseline; T1) after treatment and T2) at 1-year follow-up, although follow-up data are not available yet.
Co-primary outcome measures: clinical and cognitive insight dimensions, which will be measured by the Schedule for Assessment of Insight (Expanded version) (SAI-E) (Kemp & David, 1997), and the Beck Cognitive Insight Scale (BCIS) (Beck et al., 2004), respectively.