cognitive remediation. However, only few if any data are available regarding
the impact of the group factor as an unspecific mechanism of change regard-
ing 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 out-
come 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 so-
lution 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 supple-
ment 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 neu-
transmission, 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 in-
itial 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 Phases 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 cog-
nitive 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 32.3; 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 cogni-
tive stimulation through at-home CCT; and determine the role of motiva-
tion 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 imple-
mentation of at-home CCT across multiple centres and several countries
is feasible.
Secondary outcome measures: i) Symptom severity-Positive and Negative Syndrome Scale (Kay et al., 1987); ii) Functioning-General Assessment of Functioning (Endicott et al., 1976), World Health Organization Disability Scale (WHOO, 2012) and Satisfaction Life Domains Scale (Carlson et al., 2009), and only at follow-up (T2) iii) Suicidal Behaviour and iv) Hospitalizations.

Power calculations: To reach a power of $\beta=0.80$ and detect a between-group difference of two points on the SAI-E total scores, which is considered to be clinically meaningful - effect size of 0.33-, the estimated sample size at the end of the study is $n=126$.

Statistics: Student’s T-test and Mann-Whitney U tests were used as appropriate to compare between-group differences before- and after-treatment, i.e., the changes from baseline to post-treatment scores.

The protocol of the study is registered at ClinicalTrials.gov (NCT04104347).

Results: n=49 subjects have been assessed at baseline so far (26 males, age: 47.0±10.2 years, diagnosis of schizophrenia -F20-ICD10-, n=36, 73.5%).

Fifteen individuals (MCT: n=8; controls: n=7) have completed the treatment and the post-treatment assessment (T1).

‘After-treatment-T1 - baseline-T0’ scores difference means/medians between-group differences (MCT vs. PSE) were: SAI-E total insight 1.00 vs. -2.00, p=0.050; SAI-E illness awareness 0.62±2.20 vs. -0.43±1.62, p=0.316; SAI-E symptom relabelling 0.37±3.38 vs. -1.86±2.34, p=0.167; SAI-E treatment compliance 0.00 vs. 0.00, p=0.05; SAI-E self-certainty 1.62±2.97 vs. 0.00±2.44, p=0.298 and BCIS Composite Index -1.13±5.62 vs. -2.17±3.49, p=0.698.

Discussion: This is the first RCT testing the effect of group MCT on insight (as primary outcome) in a sample of unselected patients with SSD in comparison with psychoeducation. Two main findings emerged from the results. First, MCT appears to improve clinical and cognitive insight in SSD. Second, MCT was shown to be superior to PSE in changing insight. Whether the above MCT-related insight improvement is maintained at longer-term and whether this has an impact on clinical and social outcomes are yet to be established, which will be properly looked at in this trial.