living, in their capacity to form and maintain interpersonal relationships, and in their work productivity.
**Objectives:** We present data from the trial to assess the impact of the symptoms of the depressive episode on the patient`s functional abilities in daily living.
**Methods:** Adult patients (≥18 years) suffering from a major depressive episode of mild to moderate severity according to ICD-10 were included. Further inclusion criterion was a total score of 19 – 34 points in the Montgomery-Åsberg-Depression Rating Scale (MADRS). Randomised patients took 80 mg Silexan, 50 mg Sertraline, or placebo once daily over 8 weeks. Functional impairment was assessed using the change of the Sheehan Disability Scale (SDS total score) between baseline and week 8, changes of each SDS single item "work" (item 1), "social life/leisure activities" (item 2), and "family life/home responsibilities" (item 3), as well as the number of lost (DL) and underproductive days (DU). The scientific questions if the active treatment groups are superior to placebo in improving functional impairment was investigated as secondary objectives, which were analysed descriptively using an analysis of covariance model with factors for treatment and centre and the baseline value as covariate.
**Results:** The full analysis set consisted of 498 patients. The changes of the SDS total score differed by 2.40 ($p<0.001$) points (adjusted mean difference) in favour of Silexan compared to placebo and by 0.82 ($p=0.267$) points in favour of Sertraline compared to placebo. The mean differences between Silexan and placebo were 0.98 points for item 1, 0.65 for item 2, and 0.78 for item 3 ($p<0.05$, each). Compared to placebo, both DL ($p=0.055$) and DU ($p=0.011$) occurred less frequently with Silexan. In the primary efficacy endpoint of the trial, the change of the MADRS total score, Silexan was significantly superior to placebo ($p<0.01$).
**Conclusions:** With Silexan treatment, patients with a major depressive episode coped better with work, social life, or family responsibilities and had fewer lost or underproductive days.

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## EPP649

## Top-line Results from ESCAPE-LTE: An Open-Label Extension Study to Assess Long-term Safety of Esketamine Nasal Spray in Treatment Resistant Depression

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**Introduction:** ESCAPE-LTE was a phase 4, long-term, open-label extension (OLE) study for patients (pts) with treatment resistant depression (TRD) who were continuing esketamine nasal spray (ESK-NS) treatment following ESCAPE-TRD. ESCAPE-TRD was a randomised, phase IIIb trial comparing the efficacy and safety of ESK-NS versus quetiapine extended release (Q-XR), when both were flexibly dosed alongside an ongoing selective serotonin/serotonin-norepinephrine reuptake inhibitor (SSRI/SNRI), in pts with TRD. The study demonstrated that ESK-NS significantly increased the probability of achieving remission at Week 8, and of being relapse-free through Week 32 after remission at Week 8, versus Q-XR (Reif *et al.* NEJM 2023; 389 1298–309).
**Objectives:** To assess the long-term safety, tolerability and efficacy of ESK-NS alongside an SSRI/SNRI in pts with TRD. Here, the study design of ESCAPE-LTE is described; top-line results will be reported in the poster.
**Methods:** ESCAPE-LTE was a single-arm, 2-year OLE to ESCAPE-TRD in 14 countries. Pts eligible for ESCAPE-LTE were those who completed ESK-NS treatment in combination with an SSRI/SNRI in ESCAPE-TRD through to the end of the study (Week 32), continued to benefit from the ESK-NS treatment regimen and for whom commercial ESK-NS was not accessible in their country. The starting dose of ESK-NS was based on the pts' dose (28 mg [≥65 years and adults of Japanese ancestry], 56 mg or 84 mg) and frequency (weekly or biweekly) at completion of the maintenance phase (Week 32) of ESCAPE-TRD. Investigators were able to change the dose and frequency within label recommendations during the OLE based on clinical judgment.
The primary objective was to assess the long-term safety and tolerability of ESK-NS. The secondary objective was to assess the long-term efficacy of ESK-NS based on the proportion of pts being relapse-free at Week 104 (or end-of-study).
The primary endpoints were the number of pts who developed treatment-emergent adverse events, and suicidal ideation and behaviour, assessed by the Columbia-Suicide Severity Rating Scale (C-SSRS). Safety assessments also included body weight and vital sign measurements and clinical laboratory tests. The secondary endpoint was no relapse until the end of the prospective observation at Week 104 (or end-of-study); relapse was defined as a worsening of depressive symptoms as indicated by a total Montgomery-Åsberg Depression Rating Scale (MADRS) score of ≥22 at two consecutive assessments; hospitalisation for worsening depression, suicide prevention or attempt; or any other event assessed by the investigator to be indicative of relapse.
**Results:** 183 pts were enrolled in the ESCAPE-LTE. Top-line study results will be reported in the poster.

**Conclusions:** Results from the ESCAPE-LTE will provide evidence for the long-term safety, tolerability and efficacy of ESK-NS as a treatment for pts with TRD.

**Disclosure of Interest:** None Declared

## EPP650

### Male Depression – Are gender-related personality traits associated with the severity of depressive symptoms?

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**Introduction:** Higher prevalence & incidence rates of depressive disorder in women compared with men are among the recurring findings from epidemiologic & clinical studies. The literature suggests that this is not due to a lower need for treatment of depression in men. In the context of the concept 'male depression' (MD), it is often argued that men tend to have so called 'non-typical' depressive symptoms. These symptoms (such as aggressiveness, irritability, alcohol use, risk-taking & antisocial behavior) are rarely considered in the diagnosis of depressive disorders, which may lead to underdiagnosis. With regard to the occurrence of 'non-typical' depressive symptoms and the concept MD, the importance of masculine personality traits is often discussed. The topic of the session is the extent to which gender-related personality traits such as masculine, feminine, androgynous & undifferentiated are associated with the occurrence and severity of 'non-typical' and 'typical' depressive symptoms in women and men with a depressive disorder.
**Objectives:** The results of a study in a clinical setting will be presented. The aim of the study was to investigate whether above mentioned gender-related personality traits are associated with increased severity of depressive symptoms and whether there are differences between women & men.
**Methods:** Depressive symptoms (GMDS & BDI II) and gender-related personality traits (GEPAQ) were assessed in female & male patients (≥ 18 years) with an unipolar depressive disorder (ICD-10). Participants were recruited from inpatient settings & day clinics of specialized psychiatric-psychotherapeutic hospitals in Germany. The multicenter study with a cross-sectional design has been completed. Data from the clinical sample were analyzed using multiple linear regression analysis.
**Results:** Multiple linear regression analysis: criteria variable **GMDS** & predicting variable **GEPAQ** (**masculine** pt) b-coefficient women = -1.36 (n.s.) & b-coefficient **men** = **-1.48** ($p \leq .01$); criteria variable GMDS & predicting variable GEPAQ (feminin pt) b-coefficient women = .12 (n.s.) & b-coefficient men = .79 (n.s.); criteria variable **BDI II** & predicting variable **GEPAQ** (**masculine** pt) b-coefficient women = -1.72 (n.s.) & b-coefficient **men** = **-4.23** ($p \leq .01$); criteria variable BDI II & predicting variable GEPAQ (feminin pt) b-coefficient women = .95 (n.s.) & b-coefficient men = .-24 (n.s.)
**Conclusions:** Gender-related personality traits are associated with the occurrence and severity of 'non-typical' & 'typical' depressive symptoms. They should be considered in the diagnosis & treatment of depression. Gender differences have also been identified. In men, the expression of masculine personality traits does not lead to an increase in depressive symptoms, especially not in 'non-typical' depressive symptoms, as was originally thought. Based on these and other recent findings, the concept of MD can be critically discussed.

**Disclosure of Interest:** None Declared

## EPP651

### Retrograde autobiographical amnesia following electroconvulsive therapy in patients treated for depression - a mixed-methods systematic review with meta-analysis and thematic meta-synthesis

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**Introduction:** Electroconvulsive therapy (ECT) is a treatment received by approximately 1.4 million people worldwide annually, depressive disorder being the most prevalent indication. Retrograde autobiographical amnesia (RAA) refers to difficulties in retrieving memories of past events. Despite being the most commonly reported side effect of ECT, its nature, duration and impact on patients' lives remains uncertain.
**Objectives:** (1) Assessing RAA severity in patients treated with ECT for depression compared with other treatment methods. (2) Assessing RAA severity in patients treated with right unilateral (RUL) vs bilateral (BL) ECT for depression. (3) Assessing overall RAA severity (pre-post effect) following an acute course of ECT. (4) Summarising patients' lived experiences of RAA following ECT for depression.
**Methods:** This systematic review was registered prospectively with PROSPERO (CRD42024445105). Seven databases were searched for eligible articles. Quantitative and qualitative studies assessing RAA in patients treated with ECT for depression published since 1985 were included. Abstract, full-text screening and data extraction were done in duplicates and independently. Quantitative data were meta-analysed using random effects model and qualitative data were analysed using thematic meta-synthesis.
**Results:** Of initial 6126 records, 22 quantitaive and 20 qualitative studies were included. ECT caused significantly greater RAA compared with other treatments (SMD -0.73, 95% CI -1.31; -0.15, I2=54%, Figure 1). BL treatment caused significantly greater RAA than RUL (SMD -0.29, 95% CI -0.57; -0.01, I2=32%, Figure 2). The pre-post effects were big for RUL (SMD -0.77, 95% CI -1.15; -0.38, I2=93%, Figure 3) and BL ECT (SMD -1.16, 95% CI -1.79; -0.52, I2=93%). The main effect moderator was RAA assessment tool. Few studies reported delayed effects of ECT on RAA. Four analytical themes were identified from qualitative data: (1) Uncertainty regarding the cause, nature and severity of memory loss may cause distress for patients, undermine the quality of information provision and post-ECT care. (2) Ambiguous testimonies – perception of