

## W05-01 - RATIONALE AND DESIGN OF AN RCT COMPARING "EMC-STRATEGY" WITH TAU IN PATIENTS WITH MAJOR DEPRESSION - THE EMC TRIAL

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**Introduction:** For Major Depression, current guidelines recommend treatment durations of 3-8 weeks until optimisation in case of insufficient outcome. Many retrospective studies indicate that improvement (HAMD-17 decrease  $\geq 20\%$ ) occurs usually within 10-14 days and that non-improvement after 14 days of treatment is highly predictive for poor clinical outcome.

**Methods:** In level 1 of the EMC trial, non-improvers after 14 days of antidepressant treatment will be randomised to "early medication change" (EMC) strategy or treatment according to current guidelines (TAU). EMC schedules treatment optimisations on day 15 and day 29 in case of non-improvement. TAU schedules a medication change after 28 days in case of non-response (HAMD-17 decrease  $< 50\%$ ). Both interventions will last 42 days. In levels 2 and 3, EMC strategies will be compared with TAU strategies in improvers on day 14, who experience a stagnation of improvement during the course of treatment. The EMC trial is a multi-centre, multi-step, randomised controlled trial investigating for the first time prospectively, whether non-improvers after 14 days of antidepressant treatment with EMC are more likely to attain remission on treatment day 56 compared to patients with TAU. The trial is funded by the German Federal Ministry of Education and Research (BMBF), will be conducted in cooperation with the BMBF supported Interdisciplinary Centre for Clinical Trials (IZKS) Mainz and at six trial sites in Germany.

**Results/conclusions:** If the EMC strategy leads to significantly more remitters, consecutive revision of guidelines, clinical practice and research settings for the treatment of MD can be expected.