

## **Mental health changes in patients starting Orkambi treatment? A first-year follow up**

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**Objectives:** Some case reports and studies propose a worsening mental health status in some individuals starting treatment with the new CFTR modulating drugs. It is therefore of importance to follow up and explore how mental health is affected in CF-patients using these medications. The aim of this study was to longitudinally investigate mental health, with regard to indicators of anxiety and depression, and its association with lung function, in CF-patients during their first year of Orkambi treatment.

**Methods:** Patients at Stockholm CF-centre, Sweden, have consecutively since August 2018 in connection to their annual check-up started with Orkambi. As a part of their first year Orkambi follow up patients who are +12 years of age complete questionnaires measuring indicators of anxiety and depression. The questionnaires are completed at baseline, and at 3- and 12 months follow up. Youths (12–17 yrs) complete Becks Youth Inventory (BYI-II) anxiety (BAI-Y) and depression (BDI-Y). Adults ( $\geq 18$  yrs) complete Patient Health Questionnaire (PHQ-9) and General Anxiety Disorder 7-item scale (GAD-7). Data collection is ongoing. Multi-level modelling will be used to fit models to data.

**Preliminary results:** In total 46 individuals (11 youths, 35 adults) have initiated the data collection. Until December 2019 39% of the sample had fulfilled the data collection, 46% of the total sample had participated in the data collection until the 3 months follow up. The majority of the remaining participants will fulfill the data collection during spring 2020. Data will be analyzed as close to the ECFS conference to ensure a high representativeness. Results will be presented at the conference.

**Conclusions:** The results from the present study will increase knowledge of possible effects of the CFTR modulators on mental health. This knowledge will help CF care to develop an adequate level of psychological follow up and support to the group of patients starting treatment with these medications.