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| **Mental health and sleep quality in children receiving Elexacaftor/Tezacaftor/Ivacaftor therapy** |
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| **Introduction/Aim:** Elexacaftor/tezacaftor/ivacaftor (ETI) is a combination CFTR (Cystic Fibrosis Transmembrane Conductance Regulator) modulator for individuals with CF (Cystic Fibrosis) and at least one *F508del CFTR* variant. Despite its therapeutic benefits, concerns have been raised about adverse mental health outcomes observed in the adolescent and adult population. ETI became available for children aged 6-11yrs in Australia on May 1st, 2023. The effects of ETI on mental health and sleep among this age group have not been previously reported. We aimed to evaluate the impact of ETI on mental health, sleep, and behaviour outcomes in children aged 6-11yrs. **Method:** 111 children aged 6-11yrs were recruited from the CF Clinic at the Queensland Children’s Hospital. Sleep, behavioural and mental health outcomes were measured using parent reported Paediatric Symptom Checklist (PSC) and Sleep Disturbance Scale for Children (SDSC) before commencing ETI (baseline)and after 1-month of therapy. **Results:** Baseline questionnaires were completed by N=98 caregivers. N=66 caregivers completed the 1-month post ETI questionnaires. Results in table below reported as median (25th-75th%). No statistically significant differences were observed between PSC baseline and 1-month scores when examined as an entire cohort (difference 0 [95%CI -2,2], p=0.79) and as matched data (difference 0 [95%CI-2,2], p=0.84). Similar results were seen for SDSC scores as an entire cohort (difference 0 [95%CI-2,3], p=0.77) and as matched data (difference -0.5 [95%CI-4,2], p=0.94). When comparing matched data (baseline and 1-month post) for the PSC, there were six instances where scores became abnormal and five where scores became normal. Similarly, for the SDSC, four instances became abnormal, and five instances became normal.

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|  | Baseline*(n=98)* | Abnormal (%) | Matched Baseline *(n=66)* |  Abnormal (%) | 1-month post*(n=66)* | Abnormal (%) |
| PSC | 10 (5-14) | 23 (23.5%) | 9.5 (5-12) | 11 (16.7%) | 9.5 (6-13) | 12 (18.2%) |
| SDSC | 38.5 (33-46) | 18 (18.4%) | 38 (34-45) | 12 (18.2%) | 39.5 (33-47) | 11 (16.7%) |

**Conclusion:** Our preliminary data suggest there are no significant changes in mental health and sleep scores in the first month of ETI therapy in children 6-11yrs. A larger longitudinal study is planned to address this question more fully. **Key Words:** Cystic Fibrosis, Elexacaftor/tezacaftor/ivacaftor, Paediatric, Mental Health, Sleep Disturbance**Grant Support:** This work has been supported by the Cystic Fibrosis Foundation (USA) and Child Health Foundation (AUS). |