

Evaluating a Digital, Patient Centred Diagnostic Pathway for Sleep Apnoea: A Pan European Randomised Trial from the ESADA-Sleep Revolution network

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Background:

The EU funded Sleep Revolution Project aims to transform the diagnosis and treatment of obstructive sleep apnoea (OSA) through AI supported, home based technologies and greater patient engagement—the Sleep Revolution Care (SRC) diagnostic pathway.

Aims and objectives:

To compare standard care (SC) with SRC regarding technical feasibility, diagnostic outcomes, and staff time required for OSA evaluation.

Methods:

Patients were randomised to SRC or SC across 23 centres in 13 European countries within the ESADA network (an ERS endorsed Clinical Research Collaboration) (cross over, randomised order design). SC followed local protocols using polygraphy (PG) or polysomnography (PSG). SRC included three nights of self applied PSG (NOX SAS), app based symptom assessment, and an activity watch (Withings). SRC PSG incorporated semi automated EEG scoring. The primary endpoint was non inferiority in total staff time (SC vs. SRC).

Results:

Of 965 participants (35% female, age 48±12 y, BMI 30±6 kg/m², AHI 26±23/h, ESS 9±5), 506 were assigned to SC and 459 to SRC. Median staff time was higher in SRC (185 [125–240] min) than SC (120 [80–185] min), not meeting the predefined 30 min non inferiority margin. Sleep physician time, however, was similar (29.5 vs. 29.7 min). When SC used PSG, total staff time equalled SRC (180 min; non inferiority achieved). Self applied PSG was highly feasible, with 90.3% obtaining at least one valid night and 61.7% of patients obtaining three valid nights. OSA was diagnosed in 84% (SC) and 85% (SRC), with SRC identifying more severe OSA (37% vs. 32%).

Conclusions: Multi night, self applied PSG is feasible for routine OSA assessment and matches staff time requirements of standard single night PSG. SRC enables a patient centred, scalable diagnostic pathway for OSA aiming to better detect treatable traits in OSA.