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Plain English results summary

Obstructive Sleep Apnea (OSA) occurs in up to 10% of the general population and is characterised by repetitive pauses of breathing during sleep due to obstruction of the upper airway. Approximately 35% of patients with (OSA) have most of these events when sleeping on their back, which is called Positional OSA or POSA. Devices that discourage patients with POSA from sleeping on their backs have shown promise. The Nightbalance Sleep Position Trainer (SPT) (Previous name/version was Lunoa SPT 1.0) discourages patients with POSA from sleeping on their backs by delivering a vibration via a small device, which is worn in a chest strap during sleep. Each time the patient rolls to his/her back, the device prompts the patient to roll over onto his/her side.
The purpose of the research study was to investigate the safety, efficacy and cost effectiveness of the SPT device in patients with POSA by comparing it to the gold standard treatment for OSA, Positive Airway pressure (PAP). In this study, participants used one of the treatments (SPT or PAP) for 3 months and then switched to the other treatment for 3 months. Which device the participant used first in the study was determined by chance. Safety was measured by evaluating how many adverse events occurred during the study. Efficacy was to be measured by the number of times participants stopped breathing during each treatment and the average number of hours per night that the participants used the assigned treatment. Other measures to be evaluated during the study included OSA symptoms and Quality of Life (QoL). Once the study was completed, a calculation of the device cost and health outcomes was to occur. The study was to include data from 150 participants with POSA from France, Germany, and the UK. Participants were made up of two treatment groups:
1)patients with POSA who were not being treated (or previously treated) (Target: N=95) and
2)patients with POSA who were not using their PAP device regularly (less than 3 hours a night) (Target: N=55).
A total of 14 participants were consented across three sites (no sites in the UK were initiated or enrolled participants) before the study was terminated. A total of 9 participants completed the study, 3 were screen failures, and 2 withdrew. Due to the study being terminated and there being a limited number of participants, the main efficacy and other health outcome measures as noted above were not analyzed.
15 adverse events (AEs) were reported throughout the study, 2 of which were serious adverse events (SAEs). The SAEs involved hospitalizations, but both were resolved and unrelated to the study and/or devices. There were 3 device deficiencies reported throughout the study. All deficiencies were related to issues with the Lunoa SPT data not properly being transmitted to the web portal.
Several factors contributed to the decision to end the trial early, including the ongoing PAP-device recall that limited the participants' use of their own devices and the availability of loaned devices.