Novel by Upper Airway Respiratory Muscle Training to Treat OSA in Chronic SCI

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Study Protocol: This pilot/feasibility study randomized 24 Veterans with SCI/D and OSA to receive 3 months of daily treatment with a validated set of oropharyngeal and RMT (intervention arm) versus sham therapy (control arm). All enrolled participants completed sleep-related questionnaires, pulmonary function testing, tongue strength (Fmax) and fatigability (T-50) assessment at night-time and in the morning after sleep, and maximal inspiratory and expiratory muscle force assessment. At the end of three months, participants underwent sleep-related questionnaires, pulmonary function testing, and Fmax, T50, and respiratory muscle force measurement and each participant in the treatment arm underwent a semi-structured telephone interview, asked about issues related to acceptability of intervention.

Statistical Data Analysis: One of the pre-specified primary outcome was the recruitment rate, calculated as the proportion of those invited to fill in a screening questionnaire that consent to the trial. The practicalities of recruitment was assessed descriptively. Refusal and dropout from the study protocol were recorded. The feasibility, acceptability, and appropriateness of data collection strategies were assessed descriptively and through item response rates. Data were collected and overall screening rates, eligibility rates (e.g., rates of OSA, CSA, and SCI/D levels) were calculated, written informed consent rates, randomization rates, intervention completion rates, and attrition rates. The acceptability and feasibility of combined oropharyngeal and RMT were assessed by a short semi-structured telephone interview which was conducted with all study participants after completion of study during which they were be asked how they felt about the processes of recruitment and randomization. The content of the semi-structured interviews was summarized and potential modifications to the oropharyngeal and RMT intervention were identified.