Parental Motivation to Join A Randomized Control Trial For Surgical Treatment of Obstructive Sleep Apnea in Children

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Background

- Randomized control trials (RCT) are the gold standard for clinical evidence to generate new knowledge and inform clinical practice.
- Within pediatric otolaryngology (ENT), the recruitment to RCTs of surgical methods may be limited by caregiver motivation to participate, logistical concerns, or other barriers to enrollment.
- No previous study has investigated the willingness, motivation, and barriers of caregivers enrolling in RCTs for pediatric ENT surgeries.

Objective

- To better understand family and caregivers' willingness, motivation and barriers to participation in pediatric ENT RCTs.

Eligibility

- Participants were recruited from a tertiary care pediatric otolaryngology clinic at Oregon Health and Science University between November 2021 and June 2022

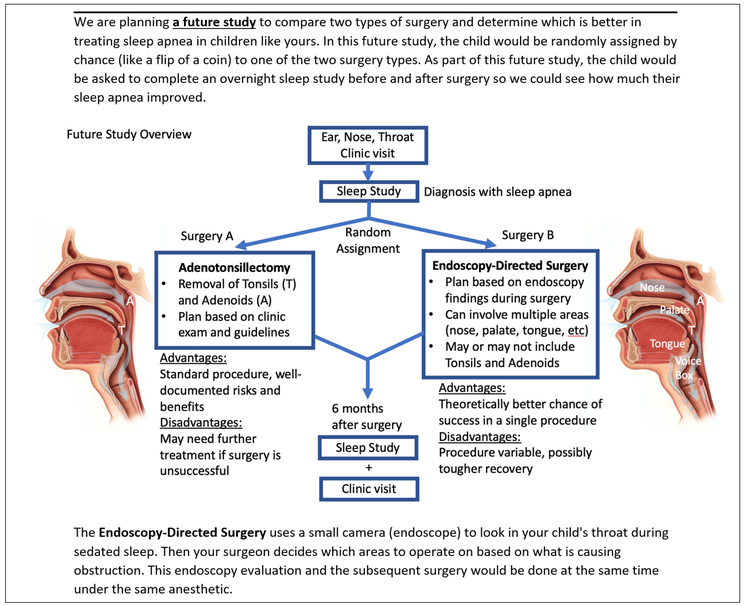
Inclusion criteria:
- Age 2-18 years with suspected OSA desiring surgical treatment
- Clinically small tonsils (Brodsky score 1+ or 2+) OR Down syndrome.

Exclusion criteria:
- Neuromuscular disorder
- Craniofacial anomaly not associated with Down syndrome
- Genetic abnormality,
- Subglottic or tracheal stenosis
- Tracheostomy dependence.

Methods

- Caregivers of children being seen in clinic visits or in the pre-operative area prior to surgery were asked to complete a short survey
- Caregivers were provided a description of a hypothetical RCT where their children would be randomized to either AT or DISE-directed surgery for OSA and answered questions about willingness and motivation to enroll in a hypothetical RCT.

Figure 1. Information page provided to participant parents explaining the hypothetical RCT.



Results

Table 1. Participant baseline characteristics.

Demographics	
Total N	25
Age (years)	8.2 ± 4.8
Sex	16F; 9M
Comorbidities	
Down Syndrome	3
Subjective Measures	
OSA-18	66.8 ± 18.4
Polysomnography*	
Total AHI	8.9 ± 6.2
oAHI	7.7 ± 5.8
LSAT	90 ± 4.2%

* Polysomnography data only available for 20/25 patients.

Would you be willing to participate in a study comparing outcomes of removal of tonsils and adenoids vs endoscopy-directed surgery, if the choice of surgery was determined by chance (e.g. flipping a coin)?

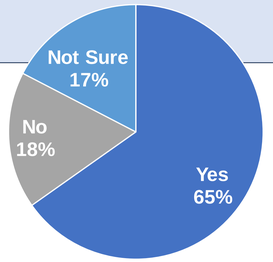


Figure 2. Participant self-reported motivation and confidence.

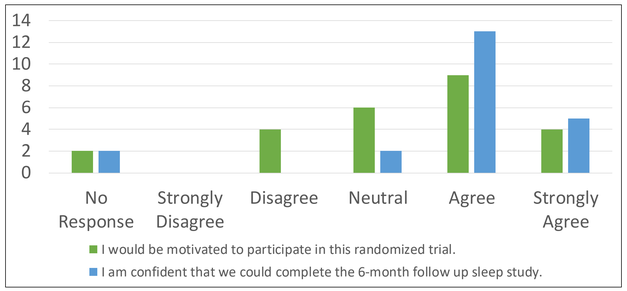
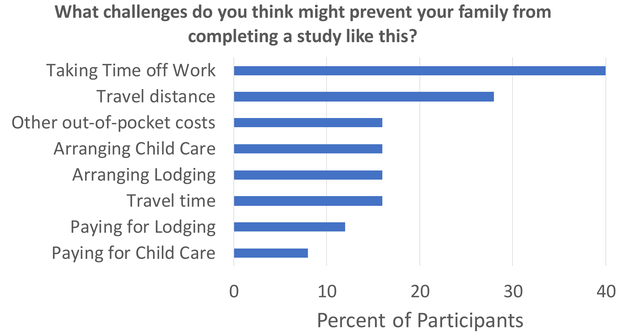


Figure 3. Participant self-reported barriers to completion



Conclusions

- A majority of caregivers surveyed were willing and motivated to participate in an RCT comparing AT versus DISE-directed surgery for treatment of pediatric OSA.
- Understanding motivating and limiting factors to enrollment may help with RCT recruitment and retention.
- These results will help inform future study design to increase participation in pediatric ENT RCTs.

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