



# SYMPOSIUM

## Large-Scale Multi-centre Trials in Sleep Disorders: Sleep Apnea

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# Large Scale Multicentre Trials in Sleep Apnea

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- Why *RCT's*, why *large scale*, why *multicentre*?
- Important unresolved questions in sleep apnea
- Methodological issues
- Current international trends
- Can capacity for RCTs be enhanced?

# Important unresolved questions in OBSTRUCTIVE SLEEP APNEA

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- Does OSA cause cardiovascular disease?
- Does OSA cause learning difficulties in children?
- Does treatment of OSA reduce accidents?
- Does OSA cause mental illness?
- Is mild OSA worth treating and with what?
- Are ambulatory models of care as effective as current models of hospital-based care?

# The rationale for large, multicentre RCTs in sleep apnea

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- **RCTs establish**
  - Causal relationships (eg OSA *versus* CVD, depression)
  - Level of benefit expected from treatment
- **OSA highly prevalent, chronic disorder**
  - Treatment effects likely small, yet potentially important
  - Therefore large sample size
- **Multi-centre, multi-national, multi-ethnic trials**
  - Increase generalizability of findings

# Methodological issues

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- Measuring the disease accurately
  - should the AHI be laid to rest?
- Will poor long-term adherence to treatments (eg CPAP, oral appliances) sink long-term trials?
- Should symptomatic patients be randomized to placebo or no active treatment?
- Is sham CPAP an appropriate placebo? Do all trials need a placebo?

# “Large-scale” multi-centre RCTs planned or in progress

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- **Neurobehavioural**

- APPLES (USA; n= 1,000)
- CATNAP (USA; n= 270)

- **Cardiovascular**

- MOSAIC (UK, n= 400)
- CANPAP II (Canada, n= 400)
- SAVE (Australia-China; n= 4000)
- Atrial Fibrillation (USA; n=250)
- Spanish trial (n=700)

- **Clinical Management**

- VA trial (USA; n=260)
- SMOSA (Australia; n=200)
- Spanish trial (n= 200?)

# How can the capacity for large-scale RCTs in sleep apnea be increased?

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- National networks
- International co-operation
  - Meta-analyses
  - ***International networks***

# National Sleep Research Networks

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- The Spanish Sleep Disordered Breathing Network
- The Australasian Sleep Trials Network
- The European Sleep Apnea Network
- The CANPAP network

# International Networks

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- Capacity for Mega-RCT(s)  $n = 10,000 +$ 
  - Cardiovascular/ metabolic health
  - Psycho-social health
    - Mental health
    - Accident prevention
    - Productivity/ employment
    - Health Care utilization

