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Prevalence and treatment of sleep-disordered breathing in Down's syndrome

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/10/2022	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Controlled prospective trial of the effectiveness of continuous positive airway pressure therapy in adults with Down's syndrome

Study objectives
Continuous positive airway pressure (CPAP) use in Down's syndrome (DS) adults with obstructive sleep apnoea/hypopnoea syndrome (OSAHS)/sleep-disordered breathing (SDB) improves sleepiness and quality of life more effectively than lifestyle measures alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, 28/02/2011 and substantial amendment on 17/05/2011, ref: 11/MRE00/3

Study design
Repeated measures parallel-arm controlled intention to treat study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep disordered breathing, obstructive sleep apnoea, Down's syndrome

Interventions
All participants with a diagnosis of sleep apnoea on home sleep study will be randomised to either the Lifestyle group or the CPAP Group. Participants allocated to the Lifestyle Group will receive written lifestyle advice on diet, exercise, sleep hygiene and sleeping position. Participants allocated to the CPAP Group will receive CPAP at the optimal pressure to treat their symptoms, along with written lifestyle advice as per the Lifestyle Group. Participants in both groups will be followed up at 1 week & at 1 month after randomisation. After 1 month, the Lifestyle Group will be offered CPAP, with additional follow ups at 1 week and 1 month after

commencing CPAP. Both groups will then be followed at 3 months and 6 months after randomisation. At 6 months, participation in the study is complete, and all participants will be encouraged to remain on CPAP.

Participants in both limbs will have anthropometric measures, cognitive function tests, health questionnaires, carer questionnaires and documentation of healthcare contact at baseline (randomisation), 1 month, 3 months & 6 months. All participants will complete and return a monthly diary recording health care contact, caffeine intake, medication, health questionnaires and a carer questionnaire.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Change in Subjective Sleepiness: Epworth Sleepiness Scale (ESS) recorded at baseline, 1 week and monthly thereafter (averaged over 1, 3, and 6 months).
2. Change in health related quality of life: EQ-5D (measured at measured at baseline, 1, 3 and 6 months) valued using UK population tariffs. This will be used to estimate the cost per quality-adjusted life year (QALY) gained by providing CPAP in comparison to lifestyle measures. The analysis will incorporate health care utilisation, including hospital visits and GP visits during the trial (recorded by monthly diary) and 3 months prior to trial entry (obtained via GP letter and review of patient records).

Secondary outcome measures
1. Objective changes in emotional and behavioural function: Modified DBC-A - measured at baseline and monthly thereafter
2. Health status (quality of life): SF-12, SAQLI - baseline, 1, 3, 6 months
3. Cognitive function: All tests deleted, replaced with Arizona Cognitive Test Battery (ACTB) (Added 31/05/2011)
4. Adverse events: Side effects associated with CPAP usage, such as dry mouth - baseline and monthly thereafter, + 1 week after commencing treatment
5. Compliance with CPAP: Average hours of use per night from in-built machine timeclocks - baseline, 1, 3, 6 months
6. Carer burden: Modified CBI, GHQ-12, open-ended qualitative comments about the experience of caring - baseline and monthly thereafter

Previous secondary outcome measures:
3. Cognitive function: Leiter-R, BPVSII, Raven Matrices, DSQIID - baseline, 1, 3, 6 months

Overall study start date
01/02/2011

Completion date
31/12/2014

Eligibility

Key inclusion criteria

For the prevalence study:
1. Age greater than or equal to 16 years, either sex
2. A clinical diagnosis of Down's syndrome

Additionally, for CPAP evaluation:
3. A clinical diagnosis of OSAHS (greater than or equal to 10 obstructive apnoeas hour on multichannel sleep study and symptoms of excessive daytime sleepiness or Epworth Sleepiness Scale [ESS] greater than or equal to 9)
4. Ability to give informed consent and comply with protocol (participant and/or relative/carer, as appropriate)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
68

Total final enrolment
28

Key exclusion criteria
1. Previous exposure to CPAP therapy
2. Arterial oxygen saturation less than 90% on room air
3. Participants with forced expiratory volume in one second (FEV1) less than 60%
4. Participants with chronic heart failure or recent myocardial infarction (heart attack)
5. Participants with known moderate or severe dementia
6. Participants with severe behavioural problems that would preclude sleep studies or CPAP treatment
7. Inability to give informed consent AND relative/carer unable or unwilling to give informed consent
8. Inability to comply with the protocol

Date of first enrolment
01/02/2011

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Sleep Medicine
The Royal Infirmary of Edinburgh
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Sponsor information

Organisation
University of Edinburgh and NHS Lothian (UK) - Joint Sponsorship

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Sponsor type
University/education

Website
http://www.ed.ac.uk/home

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZH/4/549)

Funder Name
Fondation Jerome Lejeune (France) (ref: R41361-195RSP)

Funder Name
Added 08/10/2013:

Funder Name
Baily Thomas Charitable Trust (ref: TRUST/RNA/AC/TM/2634-5178)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Validation of pictorial Epworth sleepiness scale in adults with Down syndrome	01/02/2020	18/12/2020	Yes	No
Results article		12/11/2020	27/10/2022	Yes	No