Telehealth - OSAHS

Telehealthcare interventions in the management of Obstructive Sleep Apnoea Hypopnoea Syndrome

Systematic review protocol

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Summary

Informed by the preliminary phases of the Medical Research Council’s (MRC) framework for the design and evaluation of complex interventions, this systematic review forms essential background work underpinning a programme of research to develop, refine and pilot a telehealth intervention to address the clinical review needs of people who are diagnosed with Obstructive Sleep Apnoea Hypopnoea Syndrome and who are using Continuous Positive Airway Pressure (CPAP) therapy and living remotely to centralised Sleep Medicine services.

We will identify, and quality assess and synthesise the published and unpublished evidence for telehealthcare interventions that are designed to deliver clinical care for people with OSAHS remotely compared to usual face to face care.
**Introduction**

Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAHS) entered the mainstream medical literature approximately 30 years ago and has only been given a higher profile by the general public over the last 10 years. It is one of a number of sleep disordered breathing conditions that is increasingly recognised. It is a major public health problem as an important cause of morbidity and mortality (1-5). The most recent epidemiological data reports the incidence of OSAHS as 3–7% of middle-aged men and 2–5% of women (2-4). Population datasets to estimate OSAHS prevalence in the United States and other countries did not start to emerge until the 1990’s (4) and a review by Won et al in 2008 concluded that the accumulated results of several population-based studies across various global regions and ethnic groups show a similar prevalence rate of OSAHS despite differences in study designs and methodologies used (5).

**OSAHS is a common condition**

The rising prevalence of OSAHS is directly related to obesity (1, 4, 6) with an estimated 25% prevalence of obesity reported in a large cross sectional observational study in England 2011 (7). A significant minority of affected individuals, however, are non obese (2, 6, 8). Other contributory factors that can narrow the upper airway are; an enlarged tongue, enlarged tonsilar tissue, excess soft tissue in the pharynx and retro or microagnathia (9, 10).

OSAHS is defined as a condition during sleep where there is repeated collapse or closure of the pharyngeal airway resulting in apnoic and or hyponoeic episodes that can range from mild to moderate to severe depending on how many episodes of these occur per hour of sleep. The symptomatic consequences of OSAHS are numerous and sufferers may report a combination of excessive daytime somnolence, loud and disruptive snoring, a sensation of nocturnal choking and gasping, poor and unrefreshing sleep, mood changes, impaired alertness (sometimes when driving), morning headaches, nocturia and decreased libido (2, 3, 6, 10-13).

**OSAHS has associated morbidity and mortality**

There are no European collective statistics available on associated morbidity and mortality (2). The quality of life (QOL) of individuals with OSAHS can very often be impaired as a result of these symptoms (14, 15). Excessive daytime somnolence caused by OSAHS can be severe enough to affect concentration and cognitive functioning. Reported adverse effects on work related performance are common, and may include including falling asleep whilst working and work related accidents particularly driving related accidents that may result in loss of employment and earnings (16, 17).

OSAHS has been implicated as a condition that poses an increased risk of road traffic accidents. The European Working Group report on Obstructive Sleep apnoea published in 2013 reported on two recent meta analysis of published literature, that estimate the increased risk for vehicle accidents is 2 to 3 times greater than for the general population (16, 17). The 2014 British Thoracic Society position statement on driving and OSAHS gives clear guidance to specialist teams in secondary care about advising those with sleep disorders (18). The individual who holds a current driving licence is solely responsible for ensuring their fitness to drive; however, clinicians should highlight the risks if excessive sleepiness is impairing driving prior to referral to secondary care for further investigation.
Treatment and the on-going management/follow-up of OSAHS

Following diagnosis of OSAHS the majority of individuals will be established on fixed Continuous Positive Airway Pressure (CPAP) therapy following a trial of auto titration therapy to establish therapeutic pressure setting (1, 11). During the initial CPAP auto titration phase mask fit issues and potential side effects will be resolved. A fixed pressure dedicated CPAP unit will then be supplied to the patient and ongoing management and review will be agreed upon. Some individuals may find fixed CPAP pressure difficult to tolerate and it may be appropriate to leave these patients on auto titration as a long term management strategy. Guidelines recommend that patients using CPAP therapy should be seen periodically for clinical review of their compliance with therapy, replacement of disposables such as masks, filters and hoses and to check that their CPAP units are working correctly. Annual review is offered in many centres however many individuals who are well controlled with established long term compliance can be seen on a less regular basis (3, 11).

Current guidelines recommend that patients using CPAP must have rapid access to skilled clinician follow-up including equipment maintenance; this includes availability of medical advice where services are run primarily by nonmedical personnel. Facilities for appropriate trouble-shooting, such as home overnight monitoring and auto-titrating machines, and telephone support within working hours and answer phone support service are also recommended (1).

The potential of telehealth to support clinical review of people with OSAS using CPAP

Telehealthcare solutions to support the clinical review of patients with a diagnosis of OSAHS who are using CPAP therapy have significant potential to deliver person centred, safe, and effective care that is closer to home (19). There are also potential benefits for patients and clinicians in terms of reduced travel, fuel consumption and environmental impact in terms of reduced carbon emissions (20). It has the potential to deliver equivalent clinical care for people living in remote and rural areas and this can have a significant impact on time taken off work to travel to sleep centres to undergo diagnostic and treatment invent interventions.

Aim of the systematic review

We aim to systematically review the published and unpublished literature for randomised controlled trials to evaluate the application of a telemedicine-based approach in CPAP therapy management, particularly focusing on the utility of teleconsultation, the acceptability, feasibility and clinical effectiveness of using telehealthcare to manage OSAHS compared to traditional face to face care.

Outcomes

Primary outcomes

Process outcomes:

The number of patients with a diagnosis of OSAHS who are using CPAP who have received a teleconsultation review

Recorded adherence with prescribed CPAP therapy via teleconsultation compared to usual care.

Clinical outcomes:

Current control
Improvement in daytime somnolence and self recorded Epworth sleepiness score.

Quality of sleep

Quality of life

*Future risk* (e.g. of RTA’s, CV complications)

**Secondary outcomes**

**Satisfaction/acceptability**

Patient and clinician acceptability and satisfaction with teleconsultation review in the ongoing management of this condition.

The benefits and drawbacks of the use of Telehealthcare in OSAHS

**Health Economics**

Health service resource use compared to usual face to face care

**Plan of investigation**

We will follow the procedures described in the Cochrane Handbook for Systematic Reviews of Interventions.

**Identification of studies**

We will search electronic databases, scan reference lists of included studies, identify unpublished studies using a PICOS search strategy (see table 1). Search methods for identification of studies will include electronic searches, and trials will be identified using the Cochrane Airways Group Specialised Register of trials, which is derived from systematic searches of bibliographic databases including the Cochrane Central Register of Controlled Trials (CENTRAL, MEDLINE, EMBASE, CINAHL, AMED and British Nursing Index and hand searching of respiratory journals. Search dates will be from 1995-2015. These dates have been chosen as the earliest literature on telehealth interventions in sleep medicine appears in 2000 and we looked back to 1995 to ensure that we captured all of the literature published on the subject. Our search terms are detailed in Appendix 1.

Unpublished and ongoing work and research in progress will be identified by searching key Internet-based relevant databases – UK Clinical Research Network Study Portfolio and the meta Register of Controlled Trials, [www.clinicaltrials.gov](http://www.clinicaltrials.gov); [www.controlledtrials.com](http://www.controlledtrials.com). In addition, to extend our search for published, unpublished and on-going studies, we will contact an international panel of experts in this field.

Only published and unpublished work in the English Language will be considered in this review. In addition, we will search for any qualitative studies associated with included trials to add context to our interpretation of trial data.

All records in the Specialised Register coded as ‘sleep apnoea’ were searched using the following
terms: telehealth* or telemonitoring* or teleconsultation* or teleclinics* or telecare* or telehealthcare* or remote review. An additional search of CENTRAL will be conducted using the search strategy in Appendix 1. The most recent searches were carried out in March 2015. We searched reference lists from retrieved articles to identify other relevant reports. In addition, we contacted authors of included studies to identify any additional published or unpublished studies which fulfilled the inclusion criteria.

Table 1: PICOS search strategy

<table>
<thead>
<tr>
<th>Definitions</th>
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<tbody>
<tr>
<td>Population</td>
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<tr>
<td>People with a diagnosis of OSAHS on CPAP therapy</td>
</tr>
<tr>
<td>Sleep apnoea is defined as a condition in which a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep (1, 13).</td>
</tr>
<tr>
<td>Intervention</td>
</tr>
<tr>
<td>The application of teleconsultation via video conference link in the management of people with a diagnosis of OSAHS</td>
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<tr>
<td>This will include the use of telehealth to review patients using CPAP therapy remotely:</td>
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<tr>
<td>- via video consultation</td>
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<tr>
<td>- telemonitoring and remote consultation</td>
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<tr>
<td>We will exclude telephone calls with telemonitoring and also telemonitoring without remote consultation</td>
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<tr>
<td>Context</td>
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<tr>
<td>Community based</td>
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<tr>
<td>The patient will be in the community and the Health Care practitioner may be based in primary or secondary care.</td>
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<td>Comparator</td>
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<tr>
<td>Usual face to face clinical care</td>
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<td>Normally delivered face to face but may include some telephone calls</td>
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<tr>
<td>Outcomes</td>
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<tr>
<td>Primary outcome:</td>
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<tr>
<td>Outcomes of interest are clinical (measure of sleepiness, quality of sleep and quality of life), risk of complications (including RTAs) and process outcomes (including number of reviews and adherence to CPAP)</td>
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<tr>
<td>Secondary outcomes:</td>
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<tr>
<td>Patient/clinician acceptability and satisfaction with teleconsultation.</td>
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<tr>
<td>The benefits and drawbacks of the use of Telehealthcare in OSAHS</td>
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</table>
| Health service resource use compared to usual face to
| Study design | Randomised controlled trials (RCTs), quasi-RCTs and controlled clinical trials (CCT). |

**Selection of studies**

Following an initial sift and rejection of obviously unrelated abstracts the titles and abstracts of trials identified from the searches will be checked by two investigators who will not be masked to study details. In order to ensure that we do not overlook potentially eligible trials we will consider any trial in which OSAHS, CPAP therapy and telehealthcare methods are explicitly mentioned in the abstract.

The full text of all potentially eligible studies will be retrieved and independently assessed against the inclusion criteria (see above) by two reviewers. The reviewers will decide which of the studies fit the inclusion criteria: any disagreements will be resolved by discussion, with a third researcher brought in to arbitrate if needed.

To ensure transparency, the process of selection will be summarised using a PRISMA flow diagram (Appendix 2) [Moher, 2009 #2466].

**Dealing with lack of information**

If after the full text assessment it is still unclear whether a study fulfils the inclusion criteria, or if we require clarification of any details relating to the intervention or data we will attempt to contact authors by email for further relevant information. If we fail to make contact/retrieve this, we will list the respective study as “potentially relevant study”.

**Dealing with duplication**

Multiple papers may be published for a number of reasons including translations, results at different follow-up period or reporting of different outcomes. We will treat a study with multiple reports as a single study, but draw on and make reference to all the relevant publications.

**Assessment of methodological quality**

We will assess and document the methodological quality of included controlled trials following the Cochrane approach using the methods detailed in section six of the Cochrane Handbook for Systematic Reviews of Interventions. Intervention studies will be assessed using the Cochrane Effectiveness and Practice Organisation of Care (EPOC) guidelines. We propose to concentrate on using the following seven domain-based parameters to assess quality: adequate sequence generation, allocation concealment; blinding of participants and personnel, blinding of outcomes, incomplete outcome data addressed, free of selective reporting and free of other bias. We will grade each parameter of trial quality: A - low risk of bias; B - moderate risk of bias; C - high risk of bias and an overall assessment for each controlled trial using the same three criteria will be made. We will assess the agreement of reviewers on methodological quality assessment and resolve disagreements by discussion, with a third researcher brought in to arbitrate if needed.
Data extraction
Two reviewers will extract data using a customised data extraction form which will initially be piloted to ensure the form is easily and consistently interpreted and captures all relevant information. We will resolve any disagreements by discussion between reviewers; in the case of consensus not being reached, a third reviewer will become involved and, if necessary, arbitrate.

In order to compile a detailed descriptive summary, two reviewers will independently extract data, using the headings ‘telehealth care setting’, ‘telehealth mode of delivery’, ‘aspects of holistic care addressed by telehealth intervention’, ‘duration and components of telehealth intervention’.

Data synthesis
Based on our preliminary scoping work, we anticipate that we will identify a limited number of eligible trials with substantial heterogeneity so that meta-analysis will not be appropriate. We therefore plan to undertake a narrative synthesis by developing a matrix of what has been shown to be effective or ineffective and the elements of the interventions under the headings of setting, mode of tele healthcare delivery, aspects addressed during clinical review.

Project management
This programme of work will carried out by Phyllis Murphie as part of a PhD supervised by Dr Hilary Pinnock and Professor Brian McKinstry.

Research environment and project management
Within the Usher Institute of Population Health Sciences and Informatics of The University of Edinburgh there is an on-going programme of qualitative and quantitative work underway involving social scientists, clinicians, epidemiologists, trialists and statisticians providing access to in-house methodological expertise.
Research team
The research team who will actively work on the review are:

Phyllis Murphie
Dr Stuart Little
Dr Hilary Pinnock
Professor Brian McKinstry

Library facilities will be provided by Marshall Dozier
Statistical advice will be provided by the Usher Institute of Population Health Sciences and Informatics of The University of Edinburgh.

Lay Advisory Group – Lay advisory advice will be sought from the Scottish Association of Sleep Apnoea patients support group.

Timetable

<table>
<thead>
<tr>
<th>February – March 2015</th>
<th>Develop and agree search strategy</th>
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<tr>
<td></td>
<td>Database searching</td>
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<td>Data collection from all sources</td>
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<td>Preliminary data analysis</td>
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<td>April – May 2015</td>
<td>Selection of papers</td>
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<td></td>
<td>Contact authors/experts</td>
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<td>June 2015</td>
<td>Data extraction</td>
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<td></td>
<td>Quality assessment</td>
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<tr>
<td>July 2015</td>
<td>Final data analysis</td>
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<td></td>
<td>Write report</td>
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<td></td>
<td>Prepare abstracts and write papers</td>
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</table>
Implementation potential

The underlying purpose of the study is to establish essential background work for the development, piloting and evaluation of a telehealthcare intervention to address future clinical review of patients who have OSAHS and are being treated with CPAP therapy. This systematic review will clarify the evidence base underpinning the intervention.

Dissemination

We will share our findings with fellow investigators planning intervention studies, present abstracts at international conferences; disseminate findings within our professional spheres of influence. A paper will be published in a peer reviewed journal.
References

18. BTS position statement driving and Sleep apnoea (1).pdf. 2014.
20. Murphie P, L C. Telemedicine – the Good, the Bad & the Future? by @murphieRNC & @Louisefclark. 2014.
Appendix 1: Search strategy

Search terms for Cochrane library, CINAHL, LILACS, British Nursing Index (BNI), , ISI Web of Science (1995-2015)

(“Obstructive Sleep Apnoea Hypopnoea Syndrome” or “Sleep Apnoea Syndrome” or “Sleep disordered breathing” or “CPAP therapy” or “Nasal CPAP”)
AND
(telehealth stud* or telecare stud* telemedicine stud* or ehealth stud*or telehealthcare stud* or telemonitoring stud* or clinical trial or controlled clinical trial or randomised controlled trial or quasi-randomised clinical trial)
AND
(“quality of life” or “health related quality of life”)

Appendix 2 - PRISMA 2009 Flow Diagram

Records identified through database searching (n = 2410)

Additional records identified through other sources (n = 4)

Records after duplicates removed (n = 1959)

Records screened (n = 1963) → Records excluded (n = 2121)

Full-text articles assessed for eligibility (n = 40) → Full-text articles excluded, with reasons (n = 34)

Studies included in qualitative synthesis (n = 6)

Studies included in quantitative synthesis (meta-analysis) (n = )