INPLASY PROTOCOL

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Conflicts of interest: None declared.

Content comparison of quality-of-life measures used in economic evaluations of sleep disorder interventions: a systematic review

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Review question / Objective: 1. To identify the different contexts and populations in which quality-of-life instruments have been used in the published literature of economic evaluations in sleep health research. 2. To compare the content of these quality-of-life instruments by linking them to meaningful concepts.

Information sources: An initial search will be limited to MEDLINE, National Health Service Economic Evaluation Database (NHS EED) and the Cost-Effectiveness Analysis Registry to identify articles on the topic. The text words used in the titles and abstracts and the index terms used to describe the articles were used to develop a full search strategy in MEDLINE, PsycINFO, ProQuest, Cochrane, Scopus, CINAHL, Web of Science and Emcare. The search strategy will be adapted for each database and/or information source. A systematic search will be conducted in the following electronic bibliographic databases from inception until June 2023. The searches will be re-run just before the final analyses and further studies retrieved for inclusion.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 May 2023 and was last updated on 15 May 2023 (registration number INPLASY202350068).

INTRODUCTION

Review question / Objective: 1. To identify the different contexts and populations in which quality-of-life instruments have been used in the published literature of economic evaluations in sleep health research. 2. To compare the content of these quality-of-life instruments by linking them to meaningful concepts. Rationale: Multiple quality-of-life instruments have been applied in economic evaluations of sleep interventions with varying conclusions. Establishing the content and concepts covered by such quality-of-life instruments is essential for determining the most suitable for application in economic evaluations of sleep interventions.

Condition being studied: Sleep disorders.

METHODS

Participant or population: Inclusion: people with sleep disorders ((e.g., insomnia, obstructive sleep apnoea, restless leg syndrome etc.)for whom quality of life was measured using an instrument within an economic evaluation.

Intervention: All interventions designed to diagnose, treat or relieve the effects of sleep disorders. Such interventionsshould be presented within the context of a full economic evaluation applied in sleep health research such ascost-utility analysis, cost-effectiveness analysis or cost-consequences analysis.

Comparator: These will be any comparators/controls to the interventions, including placebo, treatment as usual, or variationsof the main intervention. Such comparators should be presented within the context of a full economicevaluation applied in sleep health research such as cost-utility analysis, cost-effectiveness analysis or cost consequences analysis.

Study designs to be included: Observational studies, randomised controlled trials and modelled populations analysed within an economicevaluation

context.

Eligibility criteria: Studies that met the following inclusion criteria will be considered: 1) measured quality of life (QoL) and/or health-related QoL (HRQoL) as the primary or secondary outcome; 2) used a preference-based generic and/or preference or non-preference-based sleepspecific QoL instrument; 3) study design was a full economic evaluation applied in sleep health research, in particular a costutility analysis, cost-effectiveness analysis (CEA) or cost-consequences analysis, and 4) published in peer-reviewed journals in the English language from conception to 31st March 2023. Studies were excluded if: 1) they were not related to a primary sleep disorder (e.g., insomnia, obstructive sleep apnoea, restless leg syndrome etc.), 2) QoL/HRQoL was measured using an instrument specifically designed for the study, or 3) they were published as dissertations, commentaries, conference papers or review articles or studies for which the full-text article could not be obtained.) measured QoL and/or healthrelated QoL (HRQoL) as the primary or secondary outcome; 2) used a preferencebased generic and/or preference or nonpreference-based sleep-specific QoL instrument; 3) study design was a full economic evaluation applied in sleep health research 25, in particular a CUA, cost-effectiveness analysis or costconsequences analysis, and 4) published in peer-reviewed journals in the English language from conception to 31st March 2023.

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Main outcome(s): Quality of life measures or instruments, including preference-based and non-preference-based generic and sleep-specific instruments. Additional outcome(s): Content coverage of domains/dimensions of the health-related quality of life instruments.

Data management: Data will be extracted from studies using a standardised data extraction tool. Extracted data included specific details about the intervention/s and comparator/s examined, study population/participants and context, study methods, results for resource use, and cost and cost-effectiveness measures. Two review authors will extract data independently with any differences identified resolved through discussion (with a third author where necessary). Missing data will be requested from study authors.

Quality assessment / Risk of bias analysis:

Two independent reviewers will assess the quality of eligible studies against the JBI **Critical Appraisal Checklist for Economic** Evaluation, a standardised critical appraisal instrument. Since economic evaluation studies often employ various cost perspectives and report distinctive health economic measures in different contexts and regions, the European Network of Health Economic Evaluation Databases (EURONHEED) checklist will be used to assess further generalisability and transferability of included studies. The critical appraisal results will be reported in narrative form and tabulated. Following the critical appraisal, studies that did not meet an agreed quality threshold will be excluded based on whether HRQoL and/or QoL were measured empirically.

Strategy of data synthesis: The findings will be presented in a narrative form, including tables and figures where appropriate.

Subgroup analysis: The results will be presented according to whether the healthrelated quality of life instruments are (i) preference-based or non-preference-based and (ii) whether they are generic or sleepspecific.

Sensitivity analysis: Results will be analysed according to study participants' ages, gender and country of study to see if the study conclusions are robust. Results between instrument subgroups will also be compared, e.g. (i) generic versus sleepspecific quality of life instruments and (ii) preference versus non-preference-based quality of life instruments.

Language restriction: Only publications reported in English will be included.

Country(ies) involved: Australia.

Keywords: Quality of life, sleep health, sleep disorder, insomnia, obstructive sleep apnoea, preference-based instruments, economic evaluation.

Dissemination plans: The review will be submitted to a Q1 journal.

Contributions of each author:

Author 1 - Billingsley Kaambwa. Author 2 - Taylor-Jade Woods. Author 3 - Andrea Natsky. Author 4 - Norma Bulamu. Author 5 - Christine Mpundu-Kaambwa. Author 6 - Kelly Loffler. Author 7 - Alexander Sweetman. Author 7 - Alexander Sweetman. Author 8 - Peter Catcheside. Author 9 - Amy Reynolds. Author 10 - Robert Adams. Author 11 - Danny Eckert.