

INPLASY

Current state of therapies for sleep disturbances in dementia - a systematic review

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202510097

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 January 2025 and was last updated on 23 January 2025.

INTRODUCTION

Review question / Objective How effective are recent pharmacological and non-pharmacological interventions for sleep disturbances, published since 2020, in improving sleep outcomes among patients with dementia compared to control groups, and what implications do these findings have for future treatment guidelines.

Rationale In 2020 Cochane published a study on pharmacotherapies for sleep disturbances in patients with dementia (McCleery J et. al. 2020) with only one intervention reaching moderate certainty evidence. The authors concluded that there were a lack of distinct evidence for recommendation for treatment of sleep disturbances for dementia patients. Therefore this review aims to look for new studies published since 2020 in the hopes of finding new evidence to help the patients and clinicians. To find as much new evidence as possible non-pharmacological interventions are included as well.

McCleery J, Sharpley AL. Pharmacotherapies for sleep disturbances in dementia. Cochrane Database of Systematic Reviews 2020, Issue 11. Art. No.: CD009178. DOI: 10.1002/14651858.CD009178.pub4.

Condition being studied The main condition being studied is sleep disturbances in patients with dementia.

METHODS

Search strategy ("therapy" OR "treatment" OR "medication" OR "pharmacotherapy" OR "intervention" OR "melatonin" OR "antipsychotics" OR "antidepressants" OR "benzodiazepines" OR "light therapy" OR "phototherapy" OR "bright light therapy" OR "neurostimulation" OR "TMS" OR "z-drugs" OR "psychotherapy" OR "Cognitive Behavioral Therapy" OR "CBT" OR "CBT-I" OR "biofeedback" OR "orexin receptor antagonist" OR "PARO" OR "music therapy" OR "aromatherapy" OR "aroma therapy" OR "cannabis" OR "anticonvulsants" OR "stimulant" OR

"antihistamines" OR "Solriamfetol" OR "Aripiprazole" OR "Haloperidol" OR "Olanzapine" OR "Pericyazine" OR "Quetiapine" OR "Clozapine" OR "Prochlorperazine" OR "Risperidone" OR "Chlorpromazine" OR "Lurasidone" OR "Pimozide" OR "Asenapine" OR "Trifluoperazine" OR "Amisulpride" OR "Sulpiride" OR "Zuclopenthixol" OR "Flupentixol" OR "Iloperidone" OR "Loxapine" OR "Thiothixene" OR "Droperidol" OR "Clopenthixol decanoate" OR "citalopram" OR "escitalopram" OR "fluoxetine" OR "fluvoxamine" OR "paroxetine" OR "sertraline" OR "duloxetine" OR "venlafaxine" OR "amitriptyline" OR "clomipramine" OR "dosulepin" OR "doxepin" OR "imipramine" OR "lofepramine" OR "nortriptyline" OR "trimipramine" OR "mianserin" OR "trazodone" OR "Adinazolam" OR "Alprazolam" OR "Bentazepam" OR "Bretazenil" OR "Bromazepam" OR "Bromazolam" OR "Brotizolam" OR "Camazepam" OR "Chlordiazepoxide" OR "Cinazepam" OR "Cinolazepam" OR "Clobazam" OR "Clonazepam" OR "Clonazolam" OR "Clorazepate" OR "Clotiazepam" OR "Cloxazolam" OR "Delorazepam" OR "Deschloroetizolam" OR "Diazepam" OR "Diclazepam" OR "Estazolam" OR "Ethyl-carfluzepate" OR "Etizolam" OR "Ethyl-loflazepate" OR "Flualprazolam" OR "Flubromazepam" OR "Flubromazolam" OR "Fluclotizolam" OR "Flunitrazepam" OR "Flunitrazolam" OR "Flurazepam" OR "Flutazolam" OR "Flutemazepam" OR "Flutoprazepam" OR "Halazepam" OR "Ketazolam" OR "Loprazolam" OR "Lormetazepam" OR "Meclonazepam" OR "Medazepam" OR "Metizolam" OR "Mexazolam" OR "Midazolam" OR "Nifoxipam" OR "Nimetazepam" OR "Nitemazepam" OR "Nitrazepam" OR "Nitrazolam" OR "Nordazepam" OR "Norflurazepam" OR "Oxazepam" OR "Phenazepam" OR "Pinazepam" OR "Prazepam" OR "Premazepam" OR "Pyrazolam" OR "Quazepam" OR "Rilmazafone" OR "Temazepam" OR "Tetraazepam" OR "Triazolam" OR "Suvorexant" OR "Lemborexant" OR "Daridorexant" OR "Clonazepam" OR "Lamotrigine" OR "Levetiracetam" OR "Phenobarbital" OR "Gabapentin" OR "Topiramate" OR "Carbamazepine" OR "Diazepam" OR "Acetazolamide" OR "Ativan" OR "Felbamate" OR "Oxcarbazepine" OR "Phenytoin" OR "Pregabalin" OR "Rufinamide" OR "Valproic acid" OR "Zonisamide" OR "Clobazam" OR "Ethosuximide" OR "Perampanel" OR "Primidone" OR "Vigabatrin" OR "Vimpat" OR "Brivaracetam" OR "Zopiclone" OR "eszopiclone" OR "zaleplon" OR "zolpidem" OR "Benadryl" OR "Cetirizine" OR "Brompheniramine" OR "Clemastine" OR "Allegra" OR "Atarax" OR "Clarinet" OR "Loratadine" OR "Chlorpheniramine" OR "Desloratadine" OR

"Fexofenadine" OR "Claritin" OR "Cyproheptadine" OR "Doxylamine" OR "Phenergan" OR "Azelastine" OR "Xyzal" OR "Alavert" OR "Carbinoxamine" OR "Dimenhydrinate" OR "Dramamine" OR "Levocetirizine" OR "Meclizine" OR "Movement therapy" OR "Motor therapy" OR "Kinesiology" OR "Functional movement therapy" OR "Exercise therapy" OR "Active rehabilitation" OR "Movement-based intervention" OR "Physical activity intervention" OR "Gait training" OR "Dance therapy" OR "Neuromuscular re-education" OR "Sensorimotor therapy" OR "Pilates-based therapy" OR "Yoga therapy" OR "Tai Chi" OR "Feldenkrais Method" OR "Proprioceptive training" OR "Physiotherapy" OR "Physical therapy" OR "Manual therapy" OR "Rehabilitation therapy" OR "Therapeutic exercise" OR "Occupational therapy" OR "ADL training" OR "Cognitive rehabilitation" OR "Ergotherapy" OR "Environmental modification" OR "Geriatric occupational therapy" OR "Phytopharmaceuticals" OR "Herbal medicine" OR "Plant-based pharmaceuticals" OR "Medicinal plants" OR "Phytotherapy" OR "Natural remedies" OR "Botanical supplements" OR "Complementary medicine" OR "Traditional herbal remedies" OR "Valeriana officinalis" OR "Lavender oil" OR "Silexan" OR "Chamomile" OR "Lemon balm" OR "Passionflower" OR "Mood stabilizers" OR "Lithium" OR "Mood-regulating agents") AND ("sleep disturbance*" OR "insomnia" OR "sleep disorder*" OR "sleep problem*") AND ("dementia" OR "Alzheimer's" OR "cognitive impairment" OR "neurodegenerative disease" OR "senile dementia" OR "vascular dementia") NOT ("REM" OR "Restless-leg-syndrome" OR "sleep apnea" OR "Caregiver")

(Written after starting analysis).

Participant or population Patients with sleep disturbances and any form of dementia.

Intervention Any pharmacological or non-pharmacological trials to treat sleep disturbances.

Comparator Placebo, cross trails or no exposure.

Study designs to be included Any RCT or Cross Trails.

Eligibility criteria Study Design: Randomized controlled trials (RCTs) or cross-over trials. Participants: Individuals with dementia of any subtype who have been identified as having a sleep problem through subjective or objective measures.

Interventions: Pharmacological and non-pharmacological interventions must be compared with a control group.

Outcomes: Sleep outcomes must be recorded using polysomnography, actigraphy

Publication Date: Studies published since 2020 were included.

Information sources Pubmed/MEDLINE, any publication since 2020.

Main outcome(s)

Total nocturnal sleep time

Sleep efficiency

Nocturnal time awake

Number of nocturnal awakenings

Sleep latency.

Quality assessment / Risk of bias analysis

Cochrane Collaboration's Risk of Bias tool.

Strategy of data synthesis

Comparative Analytical Approach with a adjusted forest plot and Cohens D

(Written after starting analysis).

Subgroup analysis Not part of the analysis.

Sensitivity analysis Not part of the analysis.

Language restriction English.

Country(ies) involved Germany.

Other relevant information This registration happend after starting working on the review in April 2024, but there is a protocol from before starting. Originally it was planned to register with another service, however later it was rejected due to internal policies only focusing on certain kinds of studies. This registration will be as close as possible to the one before starting working on the review. For transparency the old protocol is available on request. Anything new is marked.

Keywords Sleep disturbances in dementia; insomnia in Alzheimer's disease; pharmacological sleep interventions; non-pharmacological therapies; light therapy; music therapy; z-drugs.

Contributions of each author

Author 1 - Duc Viet Pham - Conducted the literature search, performed data extraction and statistical analysis, drafted the manuscript.

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Author 2 - Arnim Quante - Had the idea and developed the concept for the review, helped with literature review, verified literature review, provided

guidance and clinical insight throughout, ensuring alignment with current medical practices, and contributed practical experience in dementia care to enhance the review's clinical relevance.

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