

## **Expériences sur patients adultes vivant avec une insomnie liée à la dépression : un protocole d'examen systématique qualitatif**

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# I. Méthodologie et informations relatives à l'étude

**Période :** 1er septembre au 15 décembre 2017

**Chef de projet :** Søren Holm Pallesen, Docteur en médecine et physiothérapie

**Méthode :**

Cette étude a été réalisée conformément à la méthodologie JBI (Joanna Briggs Institute) pour les examens systématiques de données qualitatives et présenté conformément à la déclaration PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses).<sup>21-23</sup>. L'examen systématique est enregistré dans la base de données en ligne PROSPERO (CRD42021276048).

**Lieux & mesures :**

Vingt-deux produits ont été sélectionnés pour être testés dans deux EHPAD lors de la première phase. Ils ont d'abord été testés au Danemark dans la municipalité d'Aarhus, dans l'EHPAD Demens Centrum, puis 16 produits ont été sélectionnés pour être testés dans l'EHPAD Augustenborggade.

Des paramètres tels que les habitudes de sommeil, l'environnement de travail et la fréquence d'utilisation ont été mesurés. Les produits ont été divisés en un paquet « actif » et un paquet « calme », les produits PROTAC étant intégrés au paquet « calme ».

**Population étudiée :**

Cette étude a pris en compte des patients souffrant de dépression, définie selon la Classification internationale des maladies (CIM-8 à CIM-10) ou par le manuel "Diagnostic et Statistique des troubles Mentaux" (DSM-III à DSM-5), âgés de plus de 18 ans, et qui présentent ou ont présenté des symptômes d'insomnie (p. ex. problèmes de maintien du sommeil, réveils matinaux précoces, latence d'endormissement, mauvaise qualité du sommeil). Les populations hospitalisées et ambulatoires ont été prises en compte, quelle que soit la gravité de leur dépression.

Au total, 27 utilisateurs ont participé au projet, ce qui a produit un grand nombre de données quantitatives et qualitatives. Au total, plus de 3 000 entrées ont été effectuées sur une période de 30 jours, avec des mesures avant et après utilisation des produits objets de l'étude.

## II. Résultats

- Dans l'ensemble, les initiatives du projet pilote ont permis de réduire l'agitation psychologique et motrice de 60 % et de contribuer à l'amélioration du confort et à la réduction des comportements agressifs et extravertis.

- Le paquet "Calme" a entraîné une réduction totale de 23 % de l'agitation psychologique et motrice. Cela s'est traduit par une diminution des conflits (réduction de 40 %), une diminution des tentatives de sortie (31 %) et une augmentation de la tranquillité nocturne (33 %).

L'amélioration des habitudes de sommeil s'est traduite par de plus longues périodes de sommeil profond et une diminution des sorties du lit.

- L'environnement de travail s'est considérablement amélioré au cours de la période, et les technologies ont réduit le risque général de violence de 29 %. À Augustenborggade, les menaces de violence ont chuté de 40 %, tandis que le nombre de rapports de violence à DemensCentrum a diminué dans les mêmes proportions.

## III. Comment atteindre ce résultat ?

Les données qualitatives montrent clairement que les produits d'intégration sensorielle aident à se sentir calme, ainsi qu'à réduire le nombre de conflits quotidiens entre les usagers et le personnel.

Ces produits doivent être intuitifs à utiliser, car le temps et les ressources sont des paramètres clés de la vie quotidienne dans un EHPAD.

Concrètement, cette étude a permis de recommander aux EHPAD de la municipalité d'Aarhus cinq des produits testés à la fois dans l'ensemble Active Package et Calm Package, à savoir :

- Protac MyFit® (gilet à balles)
- Protac Granulate Blanket™ (couette à balles)
- Animaux en fibre de verre
- Chaises à bascule
- Animaux « endormis »

Protac MyFit®



Protac Granulate Blanket™



## IV. Étude intégrale en Anglais

# Experiences of adult patients living with depression-related insomnia: a qualitative systematic review protocol

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### ABSTRACT

**Objective:** The objective of this review is to identify and synthesize the best available evidence on how adult patients experience living with depression-related insomnia. In particular, the review will examine the experiences related to pharmacological and non-pharmacological interventions to improve sleep.

**Introduction:** Approximately 80% to 90% of patients with depression have insomnia, which is associated with substantial personal and social costs. Despite these costs, insomnia is often underdiagnosed and viewed as a symptom that disappears when depression abates. However, research indicates that insomnia and depression are overlapping but distinct disorders. Thus, it is important to treat both disorders simultaneously, as improving sleep may, in turn, ease core symptoms of depression. Optimal care and treatment rely on patients' experiences of insomnia and their attitudes toward treatment options. Therefore, it is important to synthesize evidence of patients' experiences of living with insomnia, and the experiences of pharmacological and non-pharmacological sleep interventions, to understand the consequences of insomnia and to optimize sleep interventions.

**Inclusion criteria:** This systematic review will synthesize qualitative studies exploring how adults with depression experience living with insomnia and how they experience pharmacological or non-pharmacological sleep interventions. Both inpatient and outpatient populations will be considered.

**Methods:** Databases to be searched include MEDLINE, Embase, CINAHL, PsycINFO, Cochrane Database of Systematic Reviews, Cochrane CENTRAL, SveMed+, Scopus, and Web of Science Core Collection. Google Scholar and ProQuest Dissertations and Theses will be searched for unpublished studies. Studies in English, German, Danish, Swedish, and Norwegian will be included. Databases will be searched from their inception to the present date. All studies will be screened against the inclusion criteria and critically appraised for methodological quality. Findings will be pooled using meta-aggregation, and a ConQual Summary of Findings will be presented.

**Systematic review registration number:** PROSPERO CRD42021276048

**Keywords:** depression; experiences; insomnia; intervention; protocol

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### Introduction

Depression is a global public health concern affecting 280 million people worldwide.<sup>1</sup> In 80% to 90% of cases, depression is accompanied by

insomnia.<sup>2,3</sup> Insomnia is characterized by sleep maintenance problems, sleep onset latency, multiple awakenings, or early morning awakening, resulting in a generally poor sleep quality.<sup>4–7</sup> The consequences of insomnia affect both the individual and society, and may lead to an impaired ability to concentrate, poor memory, social isolation, substance abuse, work absenteeism, increased risk of hospitalization, and higher risk of accidents and

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suicide.<sup>3,6</sup> Despite the seriousness of these consequences, insomnia is often trivialized, underdiagnosed and given little interdisciplinary attention in mental health settings.<sup>8,9</sup> This may be explained by insomnia typically being viewed as a core symptom of depression that will resolve with the use of antidepressants and disappear as depression abates.<sup>4,8</sup> However, insomnia symptoms are known risk factors for both incident and recurrent depression episodes.<sup>2,8</sup>

Insomnia symptoms often predate depression onset and are among the most common residual symptoms to persist after a clinical depression episode, despite treatment with antidepressants.<sup>2</sup> Therefore, it has been suggested that depression and insomnia may constitute two overlapping but distinct disorders.<sup>2,8</sup> However, given the assumption that insomnia may contribute to the onset and maintenance of depression, providing treatment and care for both disorders simultaneously is important, as enhancing sleep may ease the core symptoms of depression by improving patients' mood and overall quality of life.<sup>2</sup>

Health care professionals customarily use pharmacological treatment for both disorders, possibly accompanied by general sleep hygiene recommendations.<sup>6</sup> Benzodiazepines and Z-drugs are often prescribed, but guidelines recommend these drugs for short-term use only.<sup>10-12</sup> Unfortunately, these drugs are often prescribed long term, as alternative evidence-based, non-pharmacological sleep interventions are not made routinely available in many mental health settings.<sup>11,12</sup> This may leave patients with a potential risk of developing dependency problems and daytime sedation, both of which can have a deep and wide-reaching negative impact on patients' health and quality of life.<sup>10</sup> Furthermore, pharmacological sleep interventions are known to have limited long-term efficacy.<sup>10,11</sup>

Non-pharmacological sleep interventions, defined as behavioral and psychological interventions targeting sleep disturbances (eg, light therapy, weighted blankets, and cognitive behavioral therapy for insomnia [CBT-I]),<sup>10</sup> could be considered as alternatives, as they are predominantly without side effects, cause no medical drug interactions, and often have long-term efficacy compared with pharmacological treatment of insomnia.<sup>10-12</sup> A series of pharmacological and non-pharmacological interventions for insomnia have been evaluated.<sup>12,13</sup> Because of its

clinical effectiveness and safety, CBT-I is now recommended as a first-line, non-pharmacological sleep intervention for insomnia<sup>14</sup>; however, CBT-I is not yet available in many mental health settings.<sup>10,13,14</sup> Furthermore, the European guideline recommendations are based on evidence from patients with chronic insomnia,<sup>14</sup> limiting the applicability of CBT-I for other patient groups.<sup>8,13</sup>

It might be assumed that experiences and treatment preferences vary between people with insomnia living with or without depression because of the greater vulnerability depression causes in the individual.<sup>3,8</sup> For instance, according to a qualitative interview study, sleep in depression is experienced as an escape from waking life; accordingly, failure to achieve good sleep may contribute to the core symptoms of depression by worsening fatigue, negative thinking, attention difficulties, and inactivity.<sup>3</sup> These symptoms may challenge participation and adherence in different non-pharmacological sleep interventions, such as CBT-I, due to daytime fatigue or cognitive impairments, as reported in another qualitative interview study.<sup>15</sup> Therefore, patients' experiences of living with insomnia and their current well-being may affect how they perceive participation in different treatment options.

Knowledge of this issue may assist health care professionals in providing effective treatment for patients with depression-related insomnia.<sup>16</sup> Some patients with depression-related insomnia may opt for cognitive strategies to address their sleep problems, while others may prefer to receive medication or combination therapy.<sup>10,11</sup> But, most importantly, safe, effective, and patient-centered approaches in the care and treatment of insomnia in mental health settings are warranted.

To optimize the care and treatment of insomnia, it is important that health care professionals include patients' experiences with insomnia, and their preferences and attitudes toward available treatment options, in their clinical decisions, as gaps and different preferences in the treatment and care for patients with depression-related insomnia have been identified. For instance, a study examining psychiatric inpatients and their experiences of insomnia showed that sleep difficulties were not discussed with staff but endured by patients silently.<sup>17</sup> Furthermore, patients experienced a lack of consistency in nursing practices as they observed differences in the help received.<sup>17</sup> Another qualitative interview study

showed that living with a lack of access to social support during night hours was central to increased suicidal thoughts and behaviors.<sup>3</sup>

Other studies, including two qualitative interview studies and a systematic review and meta-synthesis, have examined patients' experiences with different pharmacological or non-pharmacological sleep interventions targeting insomnia symptoms.<sup>11,15,18</sup> One of the interview studies indicated patients' preference for non-pharmacological treatment because taking medication induced a feeling of powerlessness; contrary to CBT-I where specific tools are provided, in pharmacological treatment, the medication just has to be taken.<sup>15</sup> Results from the systematic review and meta-synthesis indicated that patients found it empowering when doctors trusted them to take hypnotics appropriately, while other patients preferred self-help strategies due to fear of the side effects.<sup>11</sup> Yet, most patients would like to learn more about sleep and insomnia, as well as behavioral strategies to address these issues.<sup>11</sup> The first interview study showed that patients only preferred selected elements of CBT-I because they had difficulty learning cognitive methods (eg, restructuring negative thoughts) due to cognitive problems as a result of sleep loss.<sup>15</sup> The second interview study showed that patients who tried a combination of wake and light therapy experienced a rapid but temporary effect that prompted hope for recovery.<sup>18</sup>

Optimal care and treatment rely on patients' experiences with insomnia and their preferences and attitudes towards the treatment options available to them. Therefore, it is important that health care professionals have a deeper understanding of patients' experiences of living with insomnia and their experiences of pharmacological and non-pharmacological sleep interventions aimed to improve sleep. Synthesis of the current knowledge may advance health care professionals' understanding of depression-related insomnia; it may also enhance knowledge and improve the availability of the range of relevant treatments for patients with depression who are also experiencing insomnia.

Most systematic reviews addressing depression-related insomnia have focused on randomized clinical trials of pharmacological or non-pharmacological interventions for insomnia.<sup>2,10,19</sup> To the best of our knowledge, two narrative reviews exist on patients' experiences with and perspectives on primary insomnia (ie, sleep problems that cannot be connected to an

existing psychiatric, medical, or environmental cause).<sup>6,20</sup> Another systematic review has been conducted on the perspectives on sleep problems and their treatment in people with serious mental illnesses.<sup>8</sup> This latter review included no qualitative studies of populations with depression.<sup>8</sup> No systematic reviews have been conducted of qualitative studies investigating patients' experiences of depression-related insomnia and sleep interventions. A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and *JB I Evidence Synthesis* was conducted and no current or in-progress systematic reviews on the topic were identified. Therefore, the objective of this systematic review of qualitative evidence is to evaluate and synthesize the best available evidence on how adult patients experience living with depression-related insomnia. In particular, the review will examine the experiences related to pharmacological and non-pharmacological sleep interventions to improve sleep.

## Review question

What are the experiences of adult patients living with depression-related insomnia? In particular, what are the experiences related to pharmacological and non-pharmacological interventions to improve sleep?

## Inclusion criteria

### Participants

This review will consider studies that include patients with depression, defined according to the International Classification of Diseases (ICD-8 to ICD-10) or the Diagnostic and Statistical Manual of Mental Disorders (DSM-III to DSM-5), aged  $\geq 18$  years, and who experience or have experienced symptoms of insomnia (eg, sleep maintenance problems, early morning awakenings, sleep onset latency, poor sleep quality). Both inpatient and outpatient populations will be considered, regardless of the severity of their depression. Some studies will likely not have defined the diagnosis of the included population and solely characterize patients as, for example, psychiatric inpatients or outpatients with insomnia symptoms. In these cases, studies will be included if they clearly state that participants receive antidepressants in either a hospital unit or outpatient clinic treating depressive disorders. Authors will be contacted to seek confirmation on the assumed diagnosis.



Studies concerning patients with hypersomnia and patients with diseases directly influencing sleep quality, such as pain issues, restless legs syndrome, or sleep apnea, will be excluded.

### *Phenomenon of interest*

The phenomenon of interest is patients' experiences of living with depression-related insomnia and the experiences of pharmacological and non-pharmacological sleep interventions aimed to improve sleep. All studies concerning patients' experiences, perspectives, beliefs, attitudes, priorities, preferences, and perceptions of insomnia, insomnia symptoms, or pharmacological or non-pharmacological sleep interventions will be included. In this review, pharmacological sleep interventions include use of benzodiazepines (eg, lorazepam, diazepam, temazepam), Z-drugs (eg, zolpidem, zopiclone), and melatonin. Antidepressants and antipsychotics with a sedative effect will be excluded, as indication for their use may be depression, psychotic symptoms, or sleep problems. Non-pharmacological sleep interventions include behavioral (eg, CBT-I, sleep restriction therapy, relaxing training, stimulus control), psychological (eg, cognitive therapy), and complementary and alternative interventions (eg, weighted blankets, exercise, light therapy, aromatherapy, acupuncture, music therapy) targeting sleep disturbances.

### *Context*

The context of this review is both inpatient and outpatient mental health care facilities for populations with a diagnosis of depression.

### *Types of studies*

This review will consider studies that focus on qualitative data, including, but not limited to, designs such as phenomenology, grounded theory, ethnography, and action research.

### **Methods**

The proposed systematic review will be conducted in accordance with the JBI methodology for systematic reviews of qualitative evidence and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.<sup>21-23</sup> The systematic review is registered in PROSPERO (CRD42021276048).

### *Search strategy*

The search strategy will aim to identify both published and unpublished studies. An initial limited search of MEDLINE (PubMed) and CINAHL (EBSCO) was undertaken in collaboration with a research librarian (KRS) to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles, were used to develop a full search strategy for MEDLINE (PubMed; see Appendix I). The search strategy, including all identified keywords and index terms, will be adapted for each included information source. The reference lists of all studies selected for critical appraisal will be screened for additional studies.

Studies published in English, German, Danish, Swedish, and Norwegian will be included. Studies in other languages will be excluded and reported in the final review. All studies published from the inception of the database to the present with no time limitations will be included.

The databases to be searched include MEDLINE (PubMed), Embase, CINAHL (EBSCO), PsycINFO (ProQuest), Cochrane Database of Systematic Reviews, Cochrane CENTRAL, SveMed+ (Karolinska Institutet, Stockholm, Sweden), Scopus, and Web of Science Core Collection. Sources of unpublished studies (eg, dissertations or theses) to be searched will include Google Scholar and ProQuest Dissertations and Thesis (ProQuest).

Searches will be repeated just before the final analyses and any further studies identified will be assessed for eligibility.

### *Study selection*

Following the search, all identified citations will be collated and uploaded into EndNote v.20 (Clarivate Analytics, PA, USA) and duplicates removed. All citation details will be imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia).<sup>24</sup> Titles and abstracts will then be screened by two independent reviewers (STK and MK) against the inclusion criteria for the review. Potentially relevant studies will be retrieved in full. The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers (STK and MK). Reasons for exclusion of full-text studies will be recorded and reported in the systematic review. Any disagreements that arise between the



reviewers at each stage of the study selection process will be resolved through discussion or with a third reviewer (MB). The results of the search will be reported in full in the final systematic review and presented in a PRISMA flow diagram.<sup>22</sup>

### *Assessment of methodological quality*

Eligible studies will be critically and independently appraised by two reviewers (STK and CNL) for methodological quality using the standardized JBI critical appraisal checklist for qualitative research.<sup>21</sup> Following critical appraisal, studies that do not meet a certain quality threshold will be excluded. Studies that rate “no” or “unclear” for five or more of the 10 questions (50% or greater) contained in the critical appraisal checklist will be excluded. Studies that rate “no” or “unclear” for one to five questions will be discussed at a meeting where the two reviewers (STK and CNL) will determine whether these studies will be included. Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer (MB). Authors of articles will be contacted to request missing or additional data for clarification, where required. The results of critical appraisal will be reported in narrative format and in a table.

### *Data extraction*

Data will be independently extracted from studies included in the review by two reviewers (STK and MB) using the standardized JBI data extraction tool.<sup>21</sup> The data extracted will include specific details about the populations, context, culture, geographical location, study methods, and phenomenon of interest relevant to the review objective. Verbatim findings of the author's analytic interpretation of the results or data and their supportive illustrations (eg, direct quotes from patients) will be extracted and assigned one of the three levels of credibility: unequivocal (U), credible (C), or not supported (NS).<sup>23,25</sup> Findings will be identified by repeatedly reading the results section of each included study. For consistency, findings from all included studies will be extracted at the same level (ie, subtheme level).<sup>23</sup> The independently extracted findings will then be compared between the two reviewers. Any disagreements that arise between the reviewers will be resolved through discussion or in consultation with the rest of the review team.

### *Data synthesis*

Qualitative research findings will be synthesized using JBI SUMARI and following JBI qualitative evidence synthesis methodology.<sup>23</sup> This will involve the aggregation or synthesis of findings to generate a set of statements representing that aggregation through assembling the findings rated according to their credibility, and categorizing the findings based on similarity in meaning. These categories will then be synthesized to produce a single comprehensive set of synthesized findings that may be used as a basis for evidence-based practice. The experiences of living with insomnia and the experiences of both pharmacological and non-pharmacological sleep interventions will be synthesized together. The extracted findings will be read repeatedly (by STK and MB) to inductively develop the sets of categories and synthesized findings. These findings and categories will be discussed between STK and MB until an agreement is reached. Only unequivocal and credible findings will be included in the synthesis.

### *Assessing confidence in the findings*

The final synthesized findings will be graded according to the ConQual approach for establishing confidence in the output of qualitative research syntheses and presented in a Summary of Findings.<sup>25</sup> The Summary of Findings will include the major elements of the review (eg, the synthesized finding, type of research, dependability, credibility rankings, and ConQual score) and details of how the ConQual score was developed. Included in the Summary of Findings will be the title, population, phenomenon of interest, and context of the review conducted. Each synthesized finding from the review will then be presented along with the type of research informing it, scores for dependability and credibility, and the overall ConQual score.<sup>25</sup>

### *Acknowledgments*

This systematic review is one of three studies that count toward a PhD degree for STK.

### *Funding*

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in performing the analysis, interpretation of data, or in the decision to submit the results.

### Author contributions

STK, PV, ERL, and MB designed the study. STK, PV, ERL, KRS, MK, CNL, and MB drafted the manuscript. STK, MB, and KRS developed the search strategy. KRS performed the literature search.

### Availability of data

Data from the final review will be available from the corresponding author on request.

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## Appendix I: Search strategy

### MEDLINE (PubMed)

Date searched: October 7, 2021

Search number	Query	Results retrieved
#1	("Depressive Disorder"[Mesh] OR depression[Tiab] OR depressive[Tiab] OR depressed[Tiab])	498,014
#2	("Sleep Initiation and Maintenance Disorders"[Mesh] OR insomnia[Tiab] OR "Sleep"[Mesh] OR sleep[Tiab])	217,187
#3	("Qualitative Research"[Mesh] OR qualitative[Tiab] OR Interview*[Tiab] OR "Focus Groups"[Mesh] OR "focus group*[Tiab] OR "Attitude to Health"[Mesh] OR Experience*[Tiab] OR Perspective*[Tiab] OR ethnograph*[Tiab] OR "grounded theor*[Tiab] OR "Grounded Theory"[Mesh] OR phenomenolog*[Tiab] OR "action research"[Tiab] OR narrativ*[Tiab] OR "case stud*[Tiab] OR "Narration"[Mesh])	2,387,108
#4	(cancer[Title] OR "restless legs syndrome"[Title] OR fibromyalgia[Title] OR apnea[Title] OR apnoea[Title] OR "randomized controlled study"[Title] OR "randomised controlled study"[Title] OR "randomized controlled trial"[Title] OR "randomised controlled trial"[Title] OR epidemiologic*[Title])	1,233,720
#5	(#1 AND #2 AND #3) NOT #4 Limited to Danish, English, German, Norwegian, Swedish	5514