A SYSTEMATIC REVIEW OF RANDOMISED INTERVENTION STUDIES OF NON-PHARMACOLOGICAL INTERVENTIONS AIMED TO IMPROVE INSOMNIA OR SLEEP QUALITY FOR INDIVIDUALS WITH PSYCHOSIS

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CONTRIBUTING AUTHORS ROLES AND SUPPORT

CONTRIBUTION OF AUTHORS

The search strategy will be developed by a single author (CJR), who will subsequently run all literature searches in selected databases and save search results to Endnote to be made available to research group. Primary (CJR) and a secondary reviewer (NH) will contribute to the selection process by reviewing titles for exclusion of true negative articles independently and blinded. These will be compared, and any conflicts will be further reviewed for consensus decision, continuing to abstract review stage by both (CJR) and (NH) if in question. The abstracts of remaining articles will be reviewed by (CJR) independently to identify those that meet the predefined inclusion criteria. The quality assessment of all articles selected for inclusion will be independently completed by (CJR). Following this the secondary reviewer (NH) will complete a 10% independent and blinded crosscheck of abstracts and articles to confirm consistency of selection process. The review process will be periodically monitored, and consultation will occur regularly with at least one of the supervising senior members of the team, with experience in conducting systematic reviews (PBJ, JKA or AL).

SUPPORT

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INTRODUCTION

CURRENT KNOWLEDGE AND RATIONALE

SLEEP DISRUPTIONS IN PSYCHOSIS

Sleep disturbances and disorders have frequently been documented in patients with schizophrenia. Originally describing the disorder as dementia praecox, Kraepelin observed that 'During the whole development of the disease the *sleep* of the patients is frequently disturbed even when they are lying quiet'. He went on to suggest in the Treatment of Symptoms, that 'care for sleep' is among the most important requisites (Kraepelin, 1907, 1919). The current literature reflects that sleep disorders are common in people with psychotic disorders and have been heavily studied in schizophrenia particularly. Insomnia has been found to occur in patients with schizophrenia in 30-80% of cases, depending on psychotic symptomology (Cohrs, 2008) and sleep disturbances in some form are reported in almost all individuals with psychotic disorders at some point in the course of the illness (Chouinard, Poulin, Stip, & Godbout, 2004; Pandi-Perumal & Kramer, 2010; Waters, Ree, & Chiu, 2017). These disturbances are associated with the onset of psychosis, wax and wane in parallel with psychotic symptoms, and are associated with neurocognitive deficits, reduced quality of life and lower daily function (Davies, Haddock, Yung, Mulligan, & Kyle, 2016; Pandi-Perumal & Kramer, 2010; Waters et al., 2017). Sleep disturbances have also been shown to exist in the prodromal phase of psychosis and the presence of nightmares in early life may be an indicator of early risk for psychosis (Lunsford-Avery et al., 2013; Thompson et al., 2015; Zanini et al., 2015).

Extensive research conducted using both subjective (self-report, sleep diaries and questionnaires) and objective (actigraphy and polysomnography) measures, has provided evidence that individuals with psychotic disorders experience disruptions in specific sleep domains. The most consistently replicated findings reflect an increase in sleep latency (SL) (the time it takes to fall asleep), reduced total sleep time (TST) (the actual time spent sleeping), reduced sleep efficiency (SE) (the percentage of sleep divided by time spent in bed), increased awakenings after sleep onset and increased disturbing dreams or nightmares. Although it had previously been thought that these disturbances were a consequence of symptoms, more recent research lends strong evidence to sleep disturbances and psychotic symptoms having a bidirectional relationship. Although sleep disorders in schizophrenia and other psychotic disorders would seem to be an intrinsic feature and are similarly recorded in untreated patients (Chouinard et al., 2004), the neuroleptic effects of some antipsychotics can either reduce or exacerbate these difficulties. Co-occurring hypersomnia has an increased prevalence following anti-psychotic treatment and can occur concurrently with insomnia but to date has received little attention in the research. (Chouinard et al., 2004; Cohrs, 2008; Krystal, 2013; Pandi-Perumal & Kramer, 2010; Waters et al., 2017).

INTERVENTIONS FOR INSOMNIA AND SLEEP DISRUPTIONS IN PSYCHOSIS

Insomnia is the most common sleep disruption in individuals with psychosis, and as previously mentioned has a prevalence of 30%-80% (Cohrs, 2008), which is well above the range in the general population of 10%-48% (Buysse, 2013; Morin & Benca, 2012; Morphy, Dunn, Lewis, Boardman, & Croft, 2007; NICE, 2015). Notwithstanding the high prevalence of insomnia and other sleep disruptions in schizophrenia and other psychotic disorders, NICE guidelines for schizophrenia have no specific advisements for the treatment of sleep in this population. However, the NICE guidelines for long-term insomnia (>4 weeks in duration) recommend the following approaches (NICE, 2015):

- Identifying and managing underlying causes of sleep disruption
- Refer to psychological services IAPT
- Sleep hygiene education and regular exercise
- Cognitive behavioural treatment
- Referral to a sleep clinic where possible

The compiled evidence of the four expert opinion articles that set the foundation for the NICE guidelines make clear that although hypnotic drugs have good evidence for treating short-term insomnia they are not recommended for long-term insomnia (>4 weeks), and the strongest evidence supports the use of cognitive behavioural therapy (CBT) for chronic and secondary insomnia (Budur, Rodriguez, & Foldvary-Schaefer, 2007; Buysse, 2013; Falloon, Arroll, Elley, & Fernando, 2011; NICE, 2015; Ramakrishnan & Scheid, 2007).

The first randomised controlled trial examining the effectiveness of a treatment for insomnia in patients with current psychotic experiences and a diagnosed psychotic disorder was the Better Sleep Trial (BEST) (Freeman et al., 2015). This trial compared the use of CBT plus standard care vs. standard care alone and showed a large effect size (d=1.9) on reductions in insomnia. An impressive 96% (n=22/23) of the treatment group no longer had insomnia at week 12, in contrast to 4% (n=1/26) in the control group (Freeman et al., 2015).

Given the high prevalence of insomnia and other sleep disruptions in individuals with a psychotic disorder, and the impact of these on daytime function, severity of symptoms, likelihood of relapse and risk of suicide (Davies et al., 2016; Krystal, 2013; Waite et al., 2016; Waters et al., 2017), one might expect that interventions to improve this critical area of recovery would have been well explored in this population. However, this research is still far from robust and requires methodologically rigorous examination of well-evidenced treatments for insomnia and sleep disruptions to determine the viability, acceptability and effectiveness in this profoundly impacted community.

OBJECTIVES OF REVIEW

This study aims to systematically review the effectiveness of non-pharmacological interventions to improve insomnia or sleep quality in individuals with psychosis. Secondary outcomes such as cognition, daily function, quality of life or symptoms will be included where they have been utilised in the studies.

METHODS

REVIEW QUESTIONS

PRIMARY RESEARCH QUESTION:

What is the reported effectiveness in randomised intervention studies of non-pharmacological interventions aimed to reduce long-term insomnia (>4 weeks) or improve sleep quality in individuals with psychosis?

SECONDARY RESEARCH QUESTIONS:

1) What outcome measures were used to measure sleep quality or insomnia (objective and/or subjective) in experimental studies, specifically randomised intervention studies, conducted in those with psychosis?
2) Of the studies examining non-pharmacological interventions to improve sleep or reduce insomnia in individuals with psychosis, how many included cognitive outcome measures, what areas of cognition (e.g. attention, memory, executive function, social & emotional) were measured and what tests were used?
3) What was the effect size of changes to outcomes measured relating to; cognition, daily function, quality of life or symptoms?

OUTCOME VARIABLES

PRIMARY OUTCOME(S)

- Insomnia OR Sleep quality (with consideration of variation on definition) (e.g. Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI), Sleep Condition Indicator (SCI-8), Sleep Diaries, Actigraphy and Polysomnography)

SECONDARY OUTCOMES

- Daily Function or Social Recovery (e.g. the Social and Occupational Functioning Assessment Scale (SOFAS), Work and Social Adjustment Scale (WSAS), Global Assessment of Functioning (GAF), relationship status, and working status)
- Psychotic symptoms
- Depressive symptoms
- Cognition OR cognitive function OR cognitive improvement

INCLUSION CRITERIA

Experimental studies must meet the following criteria to be eligible for inclusion.

SCOPE

Published peer reviewed journal articles. Any RCTs registered but not yet published will be described but not included in analysis unless pre-publication articles are made available. In which case this will be noted as 'Not yet peer reviewed'.

PARTICIPANTS/POPULATION

Individuals with mental health diagnosis of primary psychosis.

TYPES OF INTERVENTIONS

Non-pharmacological sleep interventions:

- Cognitive behavioural therapy (CBT)/cognitive behavioural therapy for insomnia (CBT-I)
- Sleep hygiene
- Sleep restriction
- Exercise
- Relaxation therapy
- Stimulus control therapy
- Temporal control measures
- Mindfulness

Interventions divided into categories as follows:

- Psychological or behavioural treatments
- Psychological or behavioural therapies in combination with pharmacological therapies
- Other

TYPES OF STUDY TO BE INCLUDED

The parameters for these are reviewed manually:

- Randomised Controlled Studies
- Randomised Controlled Trials (RCTs)
- Randomised Intervention Studies

DATE RANGE

No specific starting date to January 2022

SPECIES

Human

LANGUAGE

No specific language restrictions, will obtain translations to English where feasible.

SEARCH TERMS, STRATEGIES AND INFORMATION SOURCES

SEARCH TERMS

The following search terms were used and adapted based on database requirements, with each group of search terms joined by the boolean operator AND, while searching in 'all text' where possible and noted if not:

1. Intervention* OR CBT OR "cognitive behavio?r* therap*" OR "cognitive therap*" OR "behavio*ral therap*" OR "sleep hygiene" OR "sleep restrict" OR exercis* OR "relax* therap*" OR "stimulus control" OR "stimulus control therap*" OR "temporal control measure" OR mindful*
2. Sleep* OR insomnia
3. Psychosis OR "psychotic disorder*" OR schizophrenia

SEARCH STRATEGIES BY DATABASES

The following three databases will be searched and specific variation necessary in the context of each are detailed below:

1) APA PsycINFO, EBSCO
   - (TX = all text) Expanders - Apply equivalent subjects
   - TX(Intervention* OR CBT OR "cognitive behavio?r* therap*" OR "cognitive therap*" OR "behavio*ral therap*" OR "sleep hygiene" OR "sleep restrict" OR exercis* OR "relax* therap*" OR "stimulus control" OR "stimulus control therap*" OR "temporal control measure" OR mindful*)

     AND
   - TX(Sleep* OR insomnia)

     AND
   - TX(Psychosis OR "psychotic disorder*" OR schizophrenia)
   - Filters Applied:
     i. Date range: no starting date to January 2022
     Source Types: Academic Journals
     ii. Population Group: Excluding Animals
     iii. Language(s): No restrictions

2) Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R)
   - (Af=all fields)
   - Af(Intervention* OR CBT OR cognitive behavio?r* therap* OR cognitive therap* OR behavio*ral therap* OR sleep hygiene OR sleep restrict OR exercis* OR relax* therap* OR stimulus control OR stimulus control therap* OR temporal control measure OR mindful*)

     AND

- Af(Sleep* OR insomnia)

AND

- Af(Psychosis OR "psychotic disorder*" OR schizophrenia)
- Filters Applied:
    i. Specific year range: 1946 to January 2022
    ii. Article types: adaptive clinical trial OR comparative study OR clinical study OR clinical trial, all OR controlled clinical trial OR equivalence trial OR evaluation study OR pragmatic clinical trial OR randomized controlled trial OR validation study
    iii. Species: Humans (manually excluding animal studies)
    iv. Language(s): No restrictions

3) Ovid Embase
    - (Af=all fields)
    - Af(Intervention* OR CBT OR "cognitive behavio?r* therap*" OR "cognitive therap*" OR "behavio*ral therap*" OR "sleep hygiene" OR "sleep restrict*" OR exercis* OR "relax* therap*" OR "stimulus control" OR "stimulus control therap*" OR "temporal control measure" OR mindful*)

AND

    - Af(Sleep* OR insomnia)

AND

    - Af(Psychosis OR "psychotic disorder*" OR schizophrenia)
    - Filters Applied:
        i. Specific year range: 1974 to January 2022
        ii. Species: Humans (manually excluding animal studies)
        iii. Language(s): No restrictions
4) Web of Science
    - (ALL= All Fields)
    - ALL(Intervention* OR CBT OR "cognitive behavio?r* therap*" OR "cognitive therap*" OR "behavio*ral therap*" OR "sleep hygiene" OR "sleep restrict" OR exercis* OR "relax* therap*" OR "stimulus control" OR "stimulus control therap*" OR "temporal control measure" OR mindful*)

AND

    - ALL(Sleep* OR insomnia)

AND

    - ALL(Psychosis OR "psychotic disorder*" OR schizophrenia)
    - Filters Applied:
        i. Date range: 1900 to January 2022
        ii. Species: Humans (manually excluding animal studies)
        iii. Language(s): No restrictions

ADDITIONAL INFORMATION SOURCES AND STRATEGIES OF RETRIEVAL

The primary author (CJR) will use the search criteria previously described to search the following study registries for studies in process but not yet published:

1. ClinicalTrials.gov
2. EU Clinical Trials Registry
3. ISRCTN Registry

4. World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP)

Trial registry searches often require search criteria that is simplified compared to those completed in the primary literature databases. These searches will be adjusted as necessary to increase the likelihood of picking up qualifying studies.

If a study is discovered that fits our inclusion criteria, we will contact the research team and request any available data and/or pre-publication results they are willing to share.

After screening all studies and identifying studies that fit our criteria for inclusion, the primary author (CJR) will review the references within these studies for published research not already included. This process will be repeated for any studies that are found to meet inclusion criteria.

DATA EXTRACTION AND CODING

DATA EXTRACTION

All literature searches will be completed by Camice J Revier (CJR) in selected databases beginning in November 2021 and updated in February 2022 prior to final analysis, to pick up any articles recently published. Search results will be saved to Endnote and made available to the research group accompanied by an Excel spreadsheet covering data extraction and coding, as described below. Primary author will move any duplicates from searches to a duplicate folder in Endnote, while retaining a record of their retrieval from the relevant searches. Primary (CJR) and secondary reviewer (NH) will screen titles for exclusion of true negative articles independently and blinded, noting the exclusion in Endnote. These conclusions will be compared, and any conflicts will be reviewed for consensus decision. If in question the articles will be included in the abstract review stage by both (CJR) and (NH). The abstracts of remaining articles will be reviewed by (CJR) independently to identify those that meet the predefined inclusion criteria. The quality assessment of all articles selected for inclusion will be completed by (CJR) using Cochrane's Grading of Recommendations Assessment, Development and Evaluation (GRADE) methods (Dijkers, 2013). Following this (NH) will complete a 10% independent and blinded crosscheck of abstracts and articles to confirm consistency of selection process. The data extraction Excel spreadsheet will be utilised to collect all relevant information from the articles selected for inclusion.

DATA EXTRACTION TABLE

The following columns have been designed and incorporated into the data extraction table in Excel spreadsheet to allow the researchers to efficiently describe, organise and review the data extracted from the selected source papers:

- Author Year
- Title
- Search Engine / Source
- Journal
- Issue
- Pages
- DOI
- Primary Research Question
- Secondary Research Question (s)
- Study Design (i.e. randomised clinical trial (RCT), randomised controlled study, randomised intervention study, or pragmatic clinical trial)
- Intervention
- Intervention Category: 1 = psychological or behavioural treatments, 2 = psychological or behavioural + pharmacological therapies or 3 = other
- Frequency of Intervention (in days)
- Duration of Intervention (in weeks)
- Duration of follow-up period (in weeks)
- Primary outcome measure – Sleep or Insomnia
- Sleep or insomnia effect size (measure type & confidence interval)
- Secondary outcome measure(s) - Daily Function/Social Recovery & Quality of Life Measures
- Daily function/Social Recovery & Quality of Life Measures effect size (measure type & confidence interval)
- Secondary outcome measure(s) - Symptoms (psychosis and depression)
- Symptoms effect size (measure type & confidence interval)
- Secondary outcome measure(s) – Cognitive
- Cognitive measure(s) effect size (measure type & confidence interval)
- Sample Size
- Duration of Study
- Context of Study (i.e. country, location & sites)
- Key Conclusions
- Important Quotes (page number)
- Risk of Bias (RoB 2) Score
- GRADE Score
- CJR's Notes
- Secondary Reviewer's Notes

Description and Related Measures for Category Variables

Category Variable	Likely Responses
Study Design	i.e. randomised clinical trial (RCT), randomised controlled study, randomised intervention study, or pragmatic clinical trial
Intervention	e.g. cognitive behavioural therapy (CBT), cognitive behavioural therapy for insomnia (CBT-I), Sleepio, sleep hygiene, sleep restriction, exeercise, relaxation therapy, stimulus control therapy, temporal control measures, mindfulness, etc.
Intervention Category	1 = psychological or behavioural treatments, 2 = psyhcological or behavioural + pharmacological therapies or 3 = other
Primary outcome measure(s)	e.g. Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI), Sleep Condition Indicator (SCI-8), Sleep Diaries, Actigraphy and Polysomnography
Seocndary outcome measure(s) - Daily Function/Social Recovery Related	e.g. Global Assessment of Functioning (GAF), Social and Occupational Functioning Assessment Scale (SOFAS), The Warwick-Edinburgh Mental Well-being Scale (WEMWBS), Work and Social Adjustment Scale (WSAS), Time USe Survey (TUS), relationship status and working status
Secondary outcome measure(s) - Symptoms (psychosis and depression)	e.g. Psychosis - Psychotic Symptom Rating Scales (PSYRATS), Positive and Negative Symptom Scale (PANSS), Clinical Assessment Interview for Negative Symptoms (CAINS), Brief Negative Symptom Scale (BNSS), Scale for the Assessment of Positive Symptoms (SAPS), Scale for the Assessment of Negative Symptoms (SANS), Negative Symptom Assessment-16 (NSA-16), and Clinical Global Impression Schizophrenia (CGI-SCH). Depression - Beck Depression Inventory-II (BDI-II), Center for Epidemiologic Studies Depression Scale (CES-D), Geriatric Depression Scale (GDS), Hospital Anxiety and Depression Scale (HADS), and Patient Health Questionnaire-9 (PHQ-9)
Secondary outcome measures - Cognitive	e.g. learning and memory, attention, executive function, working memory, and social & emotional (NOTE: List the specific testing method)

RISK OF BIAS

RISK OF BIAS (QUALITY) ASSESSMENT

The risk of bias assessment scores will be included in the data extraction form. We will use Cochrane's risk of bias tool (RoB 2) to evaluate risk of bias for RCTs. The domains that will be included and assessed are as follows: random sequence generation, allocation concealment, blinding, attrition, selective reporting, and other sources of bias. For each domain all studies will be rated as; low, high or unclear risk of bias (if a clear judgment cannot be made based on information available, and the study authors are unable to be contacted). For each domain allocation we will provide a statement to support this conclusion. The primary reviewer (CJR) will conduct risk of bias assessments and the secondary reviewer will conduct the risk of bias assessment on 10% of the studies. Any disagreements will be resolved via discussion and if necessary, an additional member of the research team will review the conclusions to assist in resolving these. The risk of bias review process will be periodically monitored and consultation will occur regularly with at least one of the supervising senior members of the team with experience in conducting systematic reviews (PBJ, JKA or AL).

DATA SYNTHESIS AND ANALYSIS

STRATEGY FOR DATA SYNTHESIS

Results from included studies will be presented individually and aggregate descriptive statistics and a complementary narrative synthesis using methods adopted from Cochrane's 'Data Synthesis and Analysis' (Ryan, 2013). The specific components of the strategies applied will depend on the number and heterogeneity of studies meeting inclusion. The studies will be described using the variables detailed in the data extraction table. They will be grouped based on intervention category and within this intervention type. Where necessary, and possible, the data will be transformed using RevMan to increase the ability to compare and contrast findings from eligible studies. It is not intended to undertake a meta-analysis.

ANALYSIS OF SUBGROUPS OR SUBSETS

Results from individual studies will be presented stratified by study type and in tiered by quality.

REMAINING CONTEXT AND REVIEW STATUS

COUNTRY OF REVIEW TEAM

United Kingdom

REFERENCE AND/OR URL FOR PUBLISHED PROTOCOL

N/A

KEYWORDS

Insomnia, sleep, sleep duration, sleep quality, total sleep time, sleep latency, sleep fragmentation, intervention(s), daily function, functional outcomes, mental health, psychosis, psychotic disorder(s), schizophrenia, cognition, cognitive function.

DETAILS OF ANY EXISTING REVIEW OF THE SAME TOPIC BY THE SAME AUTHORS

None

ANTICIPATED OR ACTUAL START DATE

5th August 2021

ANTICIPATED COMPLETION DATE

30th December 2021

STATUS OF REVIEW

Stage of review at time of registration	**Started**	**Completed**
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality assessment)	No	No
Data analysis	No	No

FUNDING SOURCES/SPONSORS

None

CONFLICTS OF INTEREST

None known

COLLABORATORS

None

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