

***Title:***

Interventions that Improve Sleep in Caregivers of Adult Care-Recipients: A Systematic Review

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## **ABSTRACT**

The purpose of the present review was to compile and analyze all interventions aimed at improving the sleep-rest pattern of caregivers of adult care recipients. A database search was performed in PubMed, Embase, Scopus, CINAHL and PsycINFO. Twenty-four papers published between 1998 and 2020 met the inclusion criteria. Informal caregivers can benefit from various types of sleep interventions, including (a) cognitive-behavioral sleep interventions (CBIs), (b) caregiver health interventions (CHIs) and (c) exercise programs. Other types of interventions such as acupuncture, back massage, reflexology, music and heart rate variability biofeedback sessions may have beneficial effects on the sleep of caregivers. Yet, studies on this topic are heterogeneous and often have considerable methodological shortcomings. Few clinical trials have explored sleep problems as a dyadic caregiver-patient relationship. It is necessary to conduct new clinical trials to determine the viability and level of evidence of the various strategies aimed at improving sleep of informal caregivers.

## **KEYWORDS**

Sleep, Caregivers, End-of-life, Adults

Informal and long-term caregiving has been related to serious consequences for the health of caregivers, both at the physical (e.g., fatigue, pain) (Fletcher et al., 2008) and psychological level (e.g., anxiety, depression, stress) (Goren et al., 2014). Moreover, it often leads to a decrease in economic capacity (Evercare & National Alliance for Caregiving, 2007), the loss of social relations and leisure opportunities and an abandonment of self-care (Waligora et al., 2019).

Apart from physical manifestations and psychological impairments, it is estimated that about 30-70% of caregivers have sleep problems (McCurry et al., 2015; Peng & Chang, 2013). The most frequent complaints of caregivers include difficulties falling asleep, getting little sleep because of the continuous interruptions to provide care and daytime fatigue (Etcher, 2014; Maltby et al., 2017; Rowe et al., 2008). Factors such as ageing, female sex and the presence of chronic diseases (van de Straat & Bracke, 2015), combined with the long-term care provided by caregivers, create a fertile ground for the emergence of chronic sleep disorders (McCurry et al., 2015). In caregivers, sleep problems are associated with worse self-reported physical functioning (Spira et al., 2010) and an increase in caregiver overload, depression and anxiety (Byun et al., 2016; McCurry et al., 2015). Sleep-wake disorders also have direct repercussions on the job performed by caregivers: they increase their fatigue (Dhruva et al., 2012), reducing their ability to pay attention to the care recipient (Etcher, 2014), which hampers and/or limits the care they provide. In fact, it has been reported that sleep problems among caregivers of patients with dementia are the first cause of entry of care recipients into a nursing home (Kim & Rose, 2011).

Insomnia is the sleep disorder most highly reported among informal caregivers of adults care recipients (Byun et al., 2016; Kotronoulas et al., 2013). In the context of a dyadic relationship, a combination of predisposing, precipitating and perpetuating factors for both caregivers and care recipients may explain the special vulnerability of caregivers to suffering

from insomnia (McCurry et al., 2015). Insomnia is associated with physical health problems (e.g., hypertension, diabetes and a weakened immune system) and mental health problems (e.g., anxiety and depression); this increases the morbidity and mortality of people who experience sleep deprivation (Morin & Jarrin, 2013; Youngstedt et al., 2017).

In the general population and among older adults, the recommendations for the treatment of insomnia supported by the highest level of evidence include, as first-line interventions, non-pharmacological therapies such as cognitive-behavioral therapy for insomnia (CBT-I) and brief behavioral therapy for insomnia (BBT-I) (Qaseem et al., 2016). Pharmacological therapy is not strongly recommended, since its risks can outweigh its benefits (Sateia et al., 2017). Hence, it is recommended to use this therapy with caution, for a limited time and combined with non-pharmacological therapies (Qaseem et al., 2016).

As regards other types of treatments that can improve sleep, there is evidence that physical exercise reduces sleep latency and improves perceived sleep efficiency and quality (Kredlow et al., 2015). Other therapies for treating insomnia have been described and implemented, such as relaxation therapies or exposure to bright light. Yet, due to the few studies involving this type of interventions, there is not enough evidence available to make any recommendations for the general population (Qaseem et al., 2016).

Despite sleep problems are highly prevalent among informal caregivers of care recipients, few studies have involved interventions targeting caregiver sleep and scarcer are those ones targeting dyadic caregiver-patient sleep jointly. Although McCurry and colleagues aimed that CBT-I, relaxation and mindfulness techniques may be effective for improving caregiver sleep quality in an integrative review (McCurry et al., 2015), to the best of our knowledge there are no systematic reviews analyzing sleep interventions for caregivers in the wide range of modalities applied and considering any disease of the care recipient. Only two systematic reviews and meta-analysis have been carried out in this domain targeting caregivers

of patients suffering from dementia and cancer, respectively. The first one aimed to quantify the extent, nature, and treatability of sleep problems in dementia caregivers (Gao et al., 2019). These authors analyzed 13 interventions studies and reported that behavioral interventions (i.e., hygiene education and stimulus control) and light chronotherapy were significantly associated with better postintervention sleep quality. The other systematic review and meta-analysis synthesized the findings from interventions studies for sleep disturbance in oncology patients and their family caregivers (Langford et al., 2012). In this work, authors highlighted the scarcity of interventions targeting sleep problems among family caregiver (only two clinical trial were collected) and the non-existence of studies regarding both the patient and the family caregiver. Since the mentioned work was released, no literature review in the domain of the caregiver of cancer patient has been published.

## **PURPOSE**

The purpose of this systematic review was to (a) identify the various interventions applied in caregivers of adult care recipients that have resulted in improvement of their sleep-rest patterns and (b) assess their level of scientific evidence in terms of their effectiveness and strength of recommendation. To date, there are no systematic reviews that summarize the evidence about any type of treatment that improve caregivers sleep, irrespective of the type of disease of the adult care recipient.

## **METHOD**

### **Design**

This is a systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Liberati et al., 2009). In compliance with

these guidelines, the protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 15 January 2020 with number CRD42020138878.

### **Study Eligibility**

We followed specific inclusion criteria to select the analyzed review following PICOS approach (Liberati et al., 2009) as follows:

P (Types of participants): familiar and/or informal caregivers of adult care recipients, defined as adults with a chronic illness or disabling condition or an older person who needs ongoing assistance with everyday tasks to function on a daily basis (Family Caregiver Alliance, 2014). Caregivers did not involve with serious physical and/or psychological diseases that might interfere with the results of the interventions.

I (Type of interventions): interventions aimed at improving the sleep-rest pattern as a main or secondary outcome.

C (Types of comparisons): usual care or active treatment.

O (Types of outcome measures): objective and/or subjective sleep-related measure (e.g., sleep questionnaires or objective sleep measures such as actigraphy). Studies that tested interventions in the caregiver or in the caregiver-patient dyad but results were reported separately.

S (Types of studies): Controlled clinical trials. Pilots studies were included.

Concerning reports characteristics, we included those ones written in English with full text access and no limits were set regarding date of publication due to the few studies available.

### **Information sources and search strategy**

The following databases were consulted: PubMed, Embase, Scopus, CINAHL and PsycINFO. We combined the following search terms and medical subject headings (MeSH) to retrieve publications: “Sleep” OR “Insomnia” OR “Circadian” OR “Sleep-Wake disorders”

AND “Caregiver” OR “Famil” OR “Carer” OR “Sibling” OR “Support person” OR “Husband” OR “Spouse” OR “Wife” OR “Wives” OR “Partner” AND “Clinical trial” OR “Treatment” OR “Education” OR “Therapy” OR “Coaching” OR “Management” OR “Intervention” OR “Programm”. The last search took place on 15 September 2020.

### **Study screening**

Two authors independently reviewed the titles and abstracts of the articles included in the searches and selected those that were compatible with the inclusion criteria. After defining which articles to include, we obtained their full text and conducted a second review according to the inclusion criteria and a literature review of their references. Articles that raised doubts about whether they met the inclusion criteria or not were reviewed independently by both authors mentioned above, who agreed on a final decision on them.

### **Data synthesis**

The articles included in the review were analyzed considering study design, study population and setting, sample characteristics, intervention contents and duration, control group description, outcomes and times of measurement. Results were discussed in a descriptive way, using the difference in means of sleep measures as the main outcome variable.

### **Risk of bias assessment**

Three reviewers assessed the methodology followed in the articles selected to determine their risk of bias using the Cochrane risk-of-bias tool for randomized trials (Table 1) (Higgins et al., 2011). This tool makes it possible to assign a risk of bias to each study according to its characteristics.

## RESULTS

### Search results

Figure 1 shows the flow diagram followed to select the articles. We identified 649 articles that could potentially be included in the review. Additionally, 5 records were identified through hand searching from the reference list of included articles. Two researchers reviewed the articles independently. They screened all of them based on their title and abstract to determine whether they met the inclusion criteria. Of them, 51 were eliminated because they were duplicated and other 346 were not relevant for the present review. We selected and read the full text of 150 articles. It was not possible to obtain the full text of nine articles originally selected. Once both researchers had reached a consensus, we included 24 articles in the review.

### Description of the reviewed studies

#### *Design*

Nineteen articles were randomized controlled clinical trials, three of them were quasi-experimental and two articles had a crossover design. Some of those articles describe the randomization method ( $n = 12$ ). Randomized trials mainly included usual care or waiting list condition as a control group, but specific study characteristics are described in Table 2.

#### *Caregivers and care-recipient characteristics and settings*

Some trials ( $n = 12$ ) included a previous calculation of the sample needed to achieve the desired statistical power. Sample sizes ranged between 26 (Park et al., 2020) and 495 participants (Elliott et al., 2010). The mean age of caregivers ranged between 40.3 (Toygar et al., 2020) and 76.2 years (Rose et al., 2009) and most caregivers were female (range from 52% to 100%). Most of them were the wives (up to 100%) or daughters (up to 84%) of the care recipients.



The studies were tested in multiple countries (see Table 2). Most participants were recruited from health centers and community advertisements. The samples included caregivers of patients with dementia ( $n=11$ ), advanced cancer ( $n=8$ ) and other chronic diseases ( $n=5$ ). Those articles involving dementia patients were likely to present care recipients characteristics about the disease, mostly Mini-Mental State Examination and Neuropsychiatric Inventory Questionnaire. However, cancer recipients characteristics were not adequately described, with only three articles describing the disease stage. Other chronic diseases group ( $n=5$ ) differ greatly, but disease information is only available in two articles (Secker & Brown, 2005; Toseland et al., 2004). The mean age of care recipients ranged between 39 (Martín-Carrasco et al., 2016) and 80 years (King et al., 2002). Male patients represented 38.2%-73% of the sample. It is important to highlight that nine articles did not report the care recipient characteristics (i.e., age and sex). Moreover, only in two studies, caregivers had to screen positively for sleep problems (i.e., self-referenced problems initiating/maintaining sleep or nonrestorative sleep in the study by Carter (2006) or a score severe enough to be interfering with their caregiving role measured by the Jenkins Sleep Evaluation Questionnaire in the study by McCurry et al. (1998).

### ***Sleep-related outcome measures***

Only nine of the 24 trials included in this review had sleep-related variables as a main goal. The trials analyzed caregiver sleep using various scales and/or actigraphy. Most of them were not specific for measuring sleep (i.e., subscales of the General Health Questionnaire, GHQ-28) or were self-designed sleep scales. The Pittsburgh Sleep Quality Index (PSQI) and its subscales were the specific sleep measures most widely used. Only three trials (Carter, 2006; Friedman et al., 2012; Rowe et al., 2010) reported the use of actigraphy to measure the objective sleep of caregivers, obtaining their sleep latency, sleep time, sleep efficiency and wake after sleep onset. Follow-up time of the outcome variables ranged from one day after the start of the intervention (Lai et al., 2011) to 12 months in the trials by King et al. (2002), Rowe

et al. (2010) and Toseland et al. (2004) (Table 3). Expectations of the intervention were not included as a variable in any of the studies analyzed.

### ***Intervention characteristics and outcome results***

Intervention characteristics and results obtained throughout the trials are described below according to the type of intervention, theoretical foundation, intervention components, intervention dosage, main goal and sleep-related outcomes in the post-test and follow-up of the studies. Study characteristics and study outcomes are reported in Table 2 and Table 3, respectively. In order to better understand the results, Table 2 presents firstly those articles with sleep-related goals.

### **Cognitive-behavioral sleep interventions (CBIs)**

#### ***Goals***

Three clinical trials involved the administration of CBIs in caregivers with the main goal of improving insomnia and sleep factors that perpetuate or exacerbate sleep disturbances (Carter, 2006; McCurry et al., 1998) or reducing stress (Secker & Brown, 2005). Both articles focused on sleep-related outcomes as a main goal (Carter, 2006; McCurry et al., 1998) were likely to present positive results in terms of sleep.

#### ***Theoretical foundation***

It was based on principles of CBT-I adapted to the role of the caregiver.

#### ***Intervention components***

These therapies included information on patient care and sleep, including cognitive sleep therapy, behavioral sleep therapy (i.e., control of stimuli, relaxation techniques and sleep restriction), education (i.e., sleep hygiene) and information on the disease of the care recipient. Yet, Secker and Brown (2005) did not explain the details of the sleep module administered.

These interventions were especially designed to determine the needs and set targets related to the sleep of caregivers.

### ***Intervention dosage***

Interventions were administered individually (Carter, 2006; McCurry et al., 1998; Secker & Brown, 2005) or in small groups – up to four caregivers – (McCurry et al., 1998) by psychologists (McCurry et al., 1998; Secker & Brown, 2005) or nurses (Carter, 2006). The studies compared the intervention group in CBIs to a waiting-list control group (McCurry et al., 1998; Secker & Brown, 2005) or controls who were asked to set personal goals (Carter, 2006). Interventions took place for 1-2 hours per week for a duration of two (Carter, 2006) to 14 weeks (Secker & Brown, 2005). Follow-up ranged from three months (McCurry et al., 1998) to six months after the intervention (Secker & Brown, 2005).

### ***Sleep-related outcomes***

The authors assessed sleep using the PSQI (Carter, 2006; McCurry et al., 1998) and the anxiety and insomnia subscale of the GHQ-28 (Secker & Brown, 2005). McCurry et al. (1998) also used a sleep diary in the intervention group. After the intervention, the three abovementioned studies showed better scores and significant differences in sleep quality in the intervention group compared to the control group. In the clinical trial conducted by Carter (2006), these differences were significant for sleep latency (actigraphy) only at week five (post-intervention) and only in the PSQI at last (4-month) follow-up; by contrast, in the study by McCurry et al. (1998), differences in the PSQI were significant from the end of the intervention until last (3-month) follow-up. In the intervention group, improvements were observed in sleep efficiency, but these differences were not statistically significant (McCurry et al., 1998). In the study that used the GHQ-28 as a measure of sleep quality (Secker & Brown, 2005), scores of the intervention group significantly improved compared to baseline between post-treatment and follow-up, even though this study was not focus on sleep.

## **Caregiver health interventions (CHIs)**

### ***Goals***

Ten articles involved interventions focused on the general health and education of caregivers with the main goal of improving the overall health of caregivers (Elliott et al., 2010; Ghaffari et al., 2019; Rezaei et al., 2018; Toseland et al., 2004; Xiu et al., 2020), reduce caregiver overload (Elliott et al., 2010; Martín-Carrasco et al., 2016; Martín-Carrasco et al., 2014), improve psychological outcomes (O'Toole et al., 2019; Park et al., 2020) or decrease the stress and promote the adaptation of caregivers (Cohen & Kuten, 2006). Thus, the main aim of these interventions was not to improve the sleep of caregivers per se, but rather to focus on mediating factors which, in turn, have an influence on quality of sleep.

### ***Theoretical foundation***

Although interventions were heterogeneous regarding the session components, cognitive-behavioral principles underlined the designs of these clinical trials. In addition, Xiu et al. (2020) conducted a clinical trial tailoring two active treatments in a dyadic manner: one treatment applied a conventional program based on cognitive-behavioral therapy principles; the other treatment was tailored integrating insights from Daoism, traditional Chinese medicine and Western psychotherapy models. Another clinical trial applied the principles of mindfulness for emotion regulation (O'Toole et al., 2019).

### ***Intervention components***

As we stated above, clinical trials in the category of CHIs included active treatments with the typical components of cognitive-behavioral therapy adapted to caregiver circumstances (i.e., psychoeducation about the care recipient's disease, training in physiological deactivations, emotion management, activity pacing and scheduling, communication skills training, problem-solving strategies and cognitive therapy for coping with negative thoughts and dysfunctional beliefs (See Table 2). The therapy applied by Xiu et

al. (2020) with the aim of restoring a dynamic equilibrium between body, mind and spirit consisted of psychoeducation about wellbeing, mind-body exercises, relaxation techniques and reconstructing the meaning of caregiving.

### ***Intervention dosage***

Interventions were conducted individually (Elliott et al., 2010; Park et al., 2020) in groups of four to 12 people (Cohen & Kuten, 2006; Martín-Carrasco et al., 2016; Martín-Carrasco et al., 2014; Rezaei et al., 2018; Toseland et al., 2004; Xiu et al., 2020), but this was not specified in the study by Ghaffari et al. (2019) or O’Toole et al. (2019). The people in charge of administering the interventions were psychologists/psychiatrists (Martín-Carrasco et al., 2016; Martín-Carrasco et al., 2014; O’Toole et al., 2019), nurses (Park et al., 2020), unspecified expert professionals (Elliott et al., 2010; Ghaffari et al., 2019; Rezaei et al., 2018; Xiu et al., 2020) or social workers (Cohen & Kuten, 2006; Toseland et al., 2004). The number of interventions ranged between seven (Martín-Carrasco et al., 2014) and 18 sessions (Toseland et al., 2004), and each session lasted between 45 m and 3 h. In one study (Park et al., 2020) participants were asked to use the application freely during the 4 weeks of treatment. Post-intervention follow-up ranged from 35-40 days (Ghaffari et al., 2019) to 12 months (Toseland et al., 2004). All the studies included a non-active control group except for those conducted by Park et al. (2020) and Xiu et al. (2020), which compared two interventions (mobile application information vs. handbook information and cognitive-behavioral vs. body-mind-spirit integration, respectively). In the other eight articles that used CHIs as an intervention, the control group received usual care of the clinic where the intervention took place, except for the trial carried out by O’Toole et al. (2019), which used a crossover design.

### ***Sleep-related outcomes***

Most studies analyzed sleep with the insomnia and anxiety subscale of the GHQ-28 (Ghaffari et al., 2019; Martín-Carrasco et al., 2016; Martín-Carrasco et al., 2014; Rezaei et al.,

2018; Toseland et al., 2004), while the study by Elliott et al. (2010) used a self-administered questionnaire that assessed caregivers' self-perceived quality of sleep (i.e., Self-Rated Caregiver Physical and Emotional Health). Some studies used specific sleep questionnaires: the Insomnia Severity Index (Xiu et al., 2020), the PSQI (O'Toole et al., 2019), the Mini Sleep Questionnaire (Cohen & Kuten, 2006) and a specific sleep log-in (Park et al., 2020). As for the results obtained, six of the ten studies reviewed showed improvements in the sleep scores of caregivers from the start of the intervention to last follow-up (Cohen & Kuten, 2006; Elliott et al., 2010; Ghaffari et al., 2019; Martín-Carrasco et al., 2014; O'Toole et al., 2019; Rezaei et al., 2018). By contrast, three studies did not show any significant changes in the sleep measures obtained (Martín-Carrasco et al., 2016; Park et al., 2020; Toseland et al., 2004). One study found an improvement in the post-intervention insomnia assessment, but these measures did not persist at 16-week follow-up (Xiu et al., 2020).

## **Exercise programs**

### ***Goals***

Two articles involved interventions with an exercise program of moderate intensity designed for caregivers, whose main objectives were to decrease the overload and improve the physical symptoms (Hirano et al., 2011) and improve the health and quality of life of caregivers (King et al., 2002). None of them included an improvement of sleep-related outcomes as the main objective.

### ***Theoretical foundation***

Exercise programs as a health behavior for preventing and controlling chronic diseases.

### ***Intervention components***

Both trials prescribed regular exercise with moderate-intensity (3METs, i.e., metabolic equivalents in the study by Hirano et al. (2011), four 30- to 40-minute exercise sessions per

week of primarily brisk walking in a home-based format in the study by King et al. (2002)). The study by Hirano et al. (2011) also asked the caregivers (in both the intervention and control groups) to wear pedometers to record their activity.

### ***Intervention dosage***

Interventions were personalized and administered individually with a frequency of once a week (King et al., 2002) or one to three times a week (Hirano et al., 2011). Caregivers included in the control group received nutritional information (King et al., 2002) or were asked to record their daily activities with a pedometer (Hirano et al., 2011). Follow-up ranged between 12 weeks (Hirano et al., 2011) and 12 months (King et al., 2002).

### ***Sleep-related outcomes***

Sleep outcomes were analyzed with the PSQI (King et al., 2002) and a self-administered questionnaire to assess quality of sleep that considered the following items: light sleep, lying awake in bed, and waking several times during the night (Hirano et al., 2011). Despite the heterogeneous follow-up, caregivers showed an improvement in sleep quality in both trials. However, the study by King et al. (2002) did not find any significant differences in the duration or sleep latency subscales of the PSQI.

## **Other therapies**

### ***Goals***

Nine articles used other types of interventions not included in any of the previous groups. These studies had various objectives, including reducing stress (Cheung et al., 2020; Korn et al., 2009), depression (Korn et al., 2009; Lai et al., 2011; Rose et al., 2009) and anxiety state (Lai et al., 2011; Pinar & Afsar, 2015; Toygar et al., 2020) and improving sleep quality (Friedman et al., 2012; Hasuo et al., 2020; Lai et al., 2011; Pinar & Afsar, 2015; Rose et al., 2009; Rowe et al., 2010; Toygar et al., 2020).

### ***Theoretical foundation***

Complementary and alternative medicine were used in four studies (Cheung et al., 2020; Korn et al., 2009; Pinar & Afsar, 2015; Toygar et al., 2020). Lai et al. (2011) used a psycho-physiological theory for their music intervention. Other theoretical foundations include the psychoneuroimmunology of a negative appraisal of caregiving in the development of sleep disturbances (Rose et al., 2009), the amplitude of the circadian system for improving sleep (Friedman et al., 2012), the combination of factors (such as awakenings) that perpetuate sleep problems as a therapy target (Rowe et al., 2010) and biofeedback as a behavioral therapy that regulates the mind and body (Hasuo et al., 2020).

### ***Intervention components***

Five studies involved interventions in caregivers using acupressure (Cheung et al., 2020), back massages (Pinar & Afsar, 2015), reflexology (Toygar et al., 2020), polarity therapy to achieve relaxation (Korn et al., 2009) and music intervention with nursing presence (Lai et al., 2011). Another two trials exposed caregivers to external objects with electrical stimuli (Rose et al., 2009) or morning bright light (Friedman et al., 2012). In addition, all the caregivers in the study by Friedman et al. (2012) received a 50-minute training session on sleep hygiene over the telephone. The trial conducted by Rowe et al. (2010) used an alert device for awakening the caregiver when the patient left the bed at night. The last trial included used a behavioral intervention based on heart rate variability biofeedback (HRV-BF) with resonant frequency breathing to improve sleep (Hasuo et al., 2020).

### ***Intervention dosage***

Some interventions ( $n=5$ ) adopted a more intensive approach by having daily sessions (the duration ranged from 30-minute to all-night sessions – Nighttime monitoring system – for 2 weeks to 12 months), while others ( $n=4$ ) consisted of less frequent contact, with sessions ranging from 1 session (1 day) to 8 sessions (8 weeks). Those in charge of administering the



interventions were trained unspecified professionals. Control groups were made up of patients in the waiting list condition (Cheung et al., 2020; Pinar & Afsar, 2015), placebo condition (Friedman et al., 2012; Rose et al., 2009; Toygar et al., 2020), a 60-120 minute respite care condition (Korn et al., 2009), patients who listened to recorded music (Lai et al., 2011), were given information about the care recipient's disease (Rowe et al., 2010) or the same HRV-BF sessions but without practicing them at home (Hasuo et al., 2020). The follow-up ranged from 1 day (Lai et al., 2011) to 12 months (Rowe et al., 2010).

### *Sleep-related outcomes*

The authors assessed sleep using the PSQI (Cheung et al., 2020; Hasuo et al., 2020; Korn et al., 2009; Pinar & Afsar, 2015), actigraphy (Friedman et al., 2012; Rowe et al., 2010), the General Sleep Disturbance Scale combined with a sleep diary (Rose et al., 2009) and the Richards-Campbell Sleep Questionnaire (Toygar et al., 2020). The study by Lai et al. (2011) used a visual analog scale to assess sleep quality. Apart from actigraphy, the study by Friedman et al. (2012) used the Epworth Sleepiness Scale, the Global Sleep Assessment Questionnaire and the Blake-Gomez Sleep Hygiene Questionnaire. As for the results, polarity therapy did not show improvements in the sleep of caregivers (Korn et al., 2009), while acupuncture, back massage and reflexology significantly improved the rest of caregivers compared to the control group (Cheung et al., 2020; Pinar & Afsar, 2015; Toygar et al., 2020). The study by Lai et al. (2011) found significant differences in the ease of getting to sleep in the group that underwent a music intervention with nursing presence. Two of the trials that exposed caregivers to external objects did not record significant differences in terms of sleep (Rose et al., 2009; Rowe et al., 2010). However, Rose et al. (2009) described clinically important improvements in sleep latency in the intervention group, with a decrease of 9 minutes in sleep latency. In the trial conducted by Friedman et al. (2012), both groups showed a significant improvement in wake after sleep onset and sleep efficiency measured with actigraphy, insomnia symptoms, sleep

hygiene and sleepiness, probably due to the training in sleep hygiene in both groups, as reported by the authors. In the study that used HRV-BF, the group that also practiced HRV-BF at home showed significantly more improvements in sleep quality than the control group. Overall, those articles that included sleep-related outcomes as a main goal were likely to present positive results in terms of sleep (Friedman et al., 2012; Hasuo et al., 2020; Lai et al., 2011; Pinar & Afsar, 2015; Toygar et al., 2020).

### **Intervention focus**

Importantly, although most studies described the characteristics of the care recipients, only the studies by Friedman et al. (2012) and Xiu et al. (2020) included both caregivers and care recipients in their interventions, considering a dyadic relationship in the onset and persistence of sleep problems. Xiu et al. (2020) administered their caregiver health intervention in parallel to caregivers and care recipients, adapting its contents to the role of participants. By contrast, Friedman et al. (2012) used morning bright light (dim red light in the control group) in the caregiver and patient dyad. Both reported a significant change in their sleep-related outcomes, although these results were not maintained at follow-up in the study by Xiu et al. (2020). However, none of the studies reported a sleep improvement in their intervention groups compared to their controls. Both studies explained these results based on a sleep hygiene session for all caregivers (i.e., in the intervention and control groups) (Friedman et al., 2012) and two-arm active treatments, with a cognitive-behavioral intervention and a body-mind-spirit intervention (Xiu et al., 2020).

### **Risk of bias**

#### *Selection bias*

Although 19 trials were described as randomized trials, eight of them did not report their random sequence generation. Interestingly, in the study by Rowe et al. (2010), two caregivers who had been randomly allocated to the intervention group were switched to the control group following their own request. Also, it should be noted that, in the study conducted by Cohen & Kuten (2006) and Park et al. (2020), subjects in the control group were assigned to the intervention group first but declined to attend the sessions or were not able to use the application. As a result, they were allocated to the control group, which is clearly a potential source of confusion bias, as comparability between groups is lost. Several authors reported the existence of significant pre-treatment differences between the intervention and the control group in some measures (Friedman et al., 2012; Hirano et al., 2011; King et al., 2002; McCurry et al., 1998; Rezaei et al., 2018; Rose et al., 2009; Toygar et al., 2020; Xiu et al., 2020). O'Toole et al. (2019) did not report whether their study groups showed differences between them.

#### ***Performance and detection bias***

The trial conducted by Toygar et al. (2020) was double-blind, whereas the others were not blinded or participant-blinded.

#### ***Attrition bias***

Concerning attrition, the loss of follow-up rates was heterogenous across the studies, ranging between 0% to 63%, with an average of 18% considering all the studies. In many trials, a considerable number of participants dropped out between the start of the intervention and last follow-up (Cohen & Kuten, 2006; Elliott et al., 2010; Martín-Carrasco et al., 2014; O'Toole et al., 2019; Xiu et al., 2020). Only the study by Toseland et al. (2004) did not mention the number of randomized subjects who were lost to follow-up, although it described the use of intention-to-treat analysis. Elliott et al. (2010) and O'Toole et al. (2019) reported that participant who dropped out had a lower educational level and were older and less concerned than completers

at pre-treatment, respectively. This fact introduces a considerable selection bias that limits the internal validity of this study and leads to the fact that the two groups are not interchangeable.

### ***Reporting bias***

Selective outcome reporting was not detected in any of the 24 studies, which all noted significant and non-significant findings.

## **DISCUSSION**

The objective of this systematic review was to explore the diversity and effectiveness of interventions aimed at improving the sleep-rest patterns of caregivers of adult care recipients. We included 24 studies in which interventions varied strongly in duration and content. We identified four types of interventions: cognitive-behavioral sleep interventions (CBIs), caregiver health interventions (CHIs), exercise programs and other interventions (e.g., alternative therapies and use of external devices to improve sleep). Studies in the first two categories were mainly based on the principles of cognitive-behavioral therapy; exercise programs were based on health prevention; and the last category included heterogeneous approaches, such as complementary and alternative therapies and other psycho-physiological approaches. Those interventions were carried out in caregivers of adults care recipients suffering mainly from dementia and cancer. Besides sleep quality, interventions aimed to improve different psycho-physical outcomes, including reducing stress, anxiety and depression, and increasing overall quality of life. Only two interventions had a dyadic focus, applying similar treatments to the caregiver and the care recipient.

In terms of types of intervention, the studies in which CBIs were used led to significant improvements in caregiver sleep, specifically, better self-reported sleep (Carter, 2006; McCurry et al., 1998; Secker and Brown, 2005) and/or objective sleep measured by actigraphy (Carter, 2006). These findings are in line with those of similar studies that have applied CBT-

I to older adults in the general population (Qaseem et al., 2016). Nevertheless, the scarcity and heterogeneity of the clinical trials and methods used to assess the variables makes it difficult to establish a level of recommendation among the caregiver population.

In CHIs, we observed discrepancies in the outcome measures. Specifically, in four trials no differences were found in terms of sleep or the sleep benefits were not maintained over time. A comprehensive analysis of these studies shows that those that included relaxation techniques found sleep benefits in their caregivers (Cohen & Cuten, 2006; Martín-Carrasco et al., 2014; Xiu et al., 2020). By contrast, those that included stress management and coping methods had variable results: improvements were found in two of the three trials that involved managing stress (Elliot et al., 2010; Rezaei et al., 2018) and two of the four trials with coping methods (Rezaei et al., 2018; Xiu et al., 2020). Additionally, two trials included resilience education and emotion regulation, both with beneficial effects on sleep (Ghaffari et al., 2019; O'Toole et al., 2019). Therefore, although the trials included some aspects of CBIs, the fact that they were not designed with the main objective of improving sleep but rather the overall quality of life of caregivers, the lack of education of caregivers about sleep hygiene may have contributed to these results. However, it is known that variables such as stress and anxiety are closely related to sleep (Qaseem et al., 2016; Magee & Carmin, 2010). Thus, interventions that improve these aspects may have a direct or indirect effect on the sleep of caregivers. It should be noted that the heterogeneity of the components of these interventions seriously hindered the possibility of making any comparisons across studies. Therefore, great caution should be exercised when describing the effects of this type of interventions, and it should clearly be explained that their heterogeneity and the few studies on this topic greatly hamper knowledge of their effectiveness.

Regarding exercise programs, there is growing evidence of physical exercise programs that proves that regular exercise can improve sleep quality by increasing sleep efficiency and duration and reducing sleep latency (Kredlow et al., 2015). Two clinical trials in caregivers

that tested this intervention had similar results to those obtained with the general population, increasing the quality of sleep of the subjects (Hirano et al., 2011; King et al., 2002). However, King et al. (2002) did not find significant differences in sleep duration or latency. This may have been due to the fact that this clinical trial included exercise only once a week for caregivers aged 60 years or older. There is recent evidence that physical activity programs in older healthy adults affects sleep quality positively when they are delivered three times a week with a duration of 12 weeks up to six months (Vanderlinden et al., 2020).

As for other types of interventions, caregivers seem to benefit from programs involving acupuncture (Cheung et al., 2020), reflexology (Toygar et al., 2020), back massage (Pinar & Afsar, 2015) and HRV-BF (Hasuo et al., 2020). In the general population, the current evidence does not lead to a clear conclusion on the benefits of these therapies in terms of sleep. Yet, a recent systematic review showed that, regarding insomnia, acupuncture and reflexology are more efficacious in monotherapy and combined with routine care than routine care or no treatment (Yeung et al., 2012). However, the diversity and heterogeneity of therapies and the few clinical trials conducted does not make it possible to draw conclusions backed by sufficient evidence of their effectiveness in sleep problems.

Concerning the type of disease, dementia caregivers seemed to benefit from CBIs, CHIs and exercise programs. We found improvements in sleep quality with exercise programs (Hirano et al., 2011; King et al., 2002) and CBIs (McCurry et al., 1998), along with insomnia symptoms (Ghaffari et al., 2019; Martín-Carrasco et al., 2014) and self-reported sleep (Elliot et al., 2010) with CHIs. Even though we have not carried out a meta-analysis, these results agree Gao et al. (2019), who found better sleep quality in those caregivers who underwent a behavioral intervention. As regard caregivers of cancer patients, benefits were found on sleep quality from CBIs (Carter, 2006), CHIs (Cohen & Kuten, 2006; O'Toole et al., 2019) and other therapies such as massage (Pinar & Afsar, 2015), reflexology (Toygar et al., 2020) and HRV-

BF (Hasuo et al., 2020). CHIs interventions also found insomnia improvements (Xiu et al., 2020) along with sleep latency improvements measured by actigraphy with CBIs interventions (Carter, 2006). These results are in consistently with the ones reported in Langford et al. (2012) systematic review, although this review only includes two articles, one of them reporting sleep quality improvements and other non-controlled one with no significant founds.

Concerning caregivers of patients suffering from other diseases, insomnia improvements were seen for Parkinson's disease caregivers after receiving CBIs (Secker & Brown, 2005) and for caregivers of older adults with a chronic illness (Toseland et al., 2004) and schizophrenia caregivers (Rezaei et al., 2018) after receiving CHIs. Nevertheless, inconsistencies were seen across the studies. For example, both Martín-Carrasco et al. (2016) and Rezaei et al. (2018) use a similar CHIs intervention with schizophrenia caregivers, but only Rezaei et al. (2018) reported changes in insomnia. However, Rezaei et al. (2018) did not report neither caregiver nor care recipient characteristics and disease information. This can result in non-interchangeable groups at baseline. More trials are needed in order to determine which strategies are most effective in caregivers of people with other pathologies other than cancer and dementia.

Finally, the differences in the number and duration of sessions makes it difficult to determine which are the strategies best accepted by caregivers. It should be noted that caregivers reported high percentages of refusal to participate (Carter, 2006; Cohen & Cuten, 2006; Secker & Brown, 2005) and reported having little time to attend sessions (Cohen & Kuten, 2006; Korn et al., 2009). These findings underline the complexity of interventions carried out in caregivers. In fact, there is some evidence suggesting that caregiver-related factors such as caregiver burden and financial status may act as barriers hampering participation and engagement in care management programs (Mavandadi et al., 2017). These caregiver-related factors need to be addressed in future research and considered as potential

stratifying variables when developing the recruitment and program contents of clinical trials to ensure that participants perceive benefits and remain engaged.

As regard the outcome measures used in the studies analysed in this systematic review, only a small proportion of the articles included in this review, nine studies (37.5%) evaluated sleep as a primary outcome. Six studies (25%) evaluated sleep in the context of overall health status and quality of life as a co-primary outcome. The nine articles remainder (37.5%) evaluated sleep disturbance as a secondary outcome. CBI interventions and other type of interventions group most frequently investigated sleep disturbance as the primary outcome of interest. As a result, these interventions were more likely to include a combination of subjective and objective sleep measures to more comprehensively evaluate the impact of these interventions on sleep.

Regarding sleep-related outcome measures, we included studies that reported sleep improvements measured with subscales of general health questionnaires (Ghaffari et al., 2019; Martín-Carrasco et al., 2016; Martín-Carrasco et al., 2014; Rezaei et al., 2018; Secker & Brown, 2005; Toseland et al., 2004) and self-designed scales (Elliot et al., 2010; Hirano et al., 2011; Lai et al., 2011). In addition, concerning the studies that reported specific sleep measures, some of them reported only the PSQI global score (Carter, 2006; Cheung et al., 2020; Korn et al., 2009; McCurry et al., 1998; O'Toole et al., 2019; Pinar & Afsar, 2015) but did not include information about the results obtained across subscales in this instrument. Additionally, we only found one clinical trial that had used a measure of sleepiness (Friedman et al., 2012), which has been proven to be significantly related to caregiver health-related quality of life and daily functioning (Byun et al., 2016).

Except the three clinical trials that applied some or all of the components of CBT-I in their CBIs (Carter, 2006; McCurry et al., 1998; Secker & Brown, 2005), none of these studies used a measure of insomnia as an outcome result. Furthermore, only two of them established a



positive screening for insomnia to include participants in the intervention group (Carter, 2006; McCurry et al., 1998). Considering that insomnia is highly prevalent among informal caregivers, the use of instruments for measuring insomnia would have been desirable and further clinical trials using this kind of measure are warranted in this domain. In addition, only the study conducted by Friedman et al. (2012) used a specific questionnaire to assess sleep hygiene. We consider that assessing sleep habits may provide important insight of the benefit of behavioral interventions focused on sleep problems such as insomnia in this population. The model for the development of chronic sleep disturbances among caregivers proposed by McCurry et al. (2015) considers these sleep-related behaviors and habits as perpetuating factors of sleep disturbances.

The use of objective sleep-related measures was scarce in the studies included in this review. Specifically, only three studies used actigraphy (Carter, 2006; Friedman et al., 2012; Rowe et al., 2010). The gold standard for measuring sleep is polysomnography, which is increasingly being used to explore the impact of behavioural treatments on sleep (Prados et al., 2020). Although actigraphy does not measure sleep itself, the current algorithm of analyses made by these devices can provide feasible and valuable information about insomnia-related parameters (e.g., sleep latency, duration and efficiency, wake after sleep onset and time in bed) and information related to the state of the circadian system of participants that polysomnography is unable to provide (Krystal & Edinger, 2008).

As we stated above, the development of sleep problems among caregivers includes factors related both to the caregiver and the care recipient (e.g., nighttime awakenings and an irregular sleep schedule), creating a “perfect storm” (McCurry et al., 2015). However, few interventions have considered the dyadic relationship between the sleep problems of the caregiver and the care recipient (Friedman et al., 2012; Xiu et al., 2020). In both studies, caregivers seemed to benefit from the intervention, although these results were not maintained

at follow-up (Xiu et al., 2020). Further research is needed concerning interventions aimed at improving sleep quality in both caregivers and care recipients.

The main limitations of this study are the few interventions conducted and the complexity of assessing them. In fact, the populations of caregivers, the interventions (many of them focused not on sleep improvement but on improvement of quality of life and/or other variables), the methods and the follow-up period are very diverse, which makes them difficult to assess. In addition, most studies included have poor quality or high risk of bias. All this introduces several biases: selection biases derived from the randomization method, the differences in sample size, the small sample size or differential dropout rate described by some studies; and information or classification biases derived from the differences in the follow-up period to measure the outcome, the variability in the definition of the outcome or the use of different measures (e.g., self-reported questionnaires vs. actigraphy).

In addition, all caregivers and care recipients were adults and the pathologies and care needed (i.e., quality and quantity) differed greatly. In addition, no common criteria were found along the articles included in this review in order to identify care recipient's factors such as type and stage of disease, dementia-related behaviors, physical function, time after diagnosis of cancer, type of chemotherapy, etc. that have been related to impaired sleep in caregivers (Byun et al., 2016; McCurry et al., 2015; Peng & Chang, 2013). This may have led some caregivers to have more sleep problems than others at baseline (i.e., groups were not interchangeable at baseline). Based in our two main diseases present in this review, sleep problems have been described in up to 72% cancer caregivers (Maltby et al., 2017) and up to 70% dementia caregivers (Peng & Chang, 2013). In another hand, in some trials, caregivers had to screen positively for certain sleep-related factors, such as anxiety and depression; this may also have resulted in differences in the effect size obtained in the improvements related to such variables and sleep quality itself when compared to the other studies included in this review that did not

include the requirement of having this clinical impairment in their criteria. This may also limit the extrapolation of the results obtained in these studies to the general caregiver population. Further research is warranted targeting clinically homogenous population and based on the specific needs of participants. In addition, interventions protocols should include a baseline assessment including all those predisposing, precipitating and perpetuating factors that play a significantly role in the phenomenology of sleep problems of caregiver-care recipient dyad.

In conclusion, caregivers can benefit from various types of interventions to improve their sleep, including CBIs, CHIs and exercise programs. It is more than necessary to conduct further studies on this subject in a standardized way to determine the efficacy of these programs and estimate the effectiveness of the strategies that have the greatest impact on the sleep of caregivers and care recipients. Future interventions should try to link the sleep of patients with that of the caregiver, proposing interventions that act jointly on the caregiver-care recipient dyad. This would allow changes in sleep to be more effective and long-lasting. Moreover, combining objective measures of sleep quality with a subjective assessment may contribute to our understanding of the treatment effects through complex sleep-related phenomena.

#### **DECLARATION OF CONFLICTING INTERESTS**

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**Table 1. Risk of bias assessment**

<b>Author</b>	<b>Random sequence generation (Selection bias)</b>	<b>Allocation concealment (Selection bias)</b>	<b>Treatment provider / participant blinding (Performance bias)</b>	<b>Outcome assessor blinding (Detection bias)</b>	<b>Incomplete outcome data (Attrition bias)</b>	<b>Selective reporting (Reporting bias)</b>
Carter (2006)	n/a	Unclear risk	High risk	High risk	Low risk	Low risk
Cheung et al. (2020)	Low risk	Low risk	High risk	Low risk	Low risk	Low risk
Cohen & Kuten (2006)	n/a	High risk	High risk	High risk	High risk	Low risk
Elliott et al. (2010)	Unclear risk	Unclear risk	Unclear risk	Unclear risk	High risk	Low risk
Friedman et al. (2012)	Unclear risk	Unclear risk	High risk	High risk	Low risk	Low risk
Ghaffari et al. (2019)	Low risk	Low risk	Unclear risk	Unclear risk	Unclear risk	Low risk
Hasuo et al. (2020)	Low risk	Low risk	High risk	High risk	Low risk	Low risk
Hirano et al. (2011)	Unclear risk	Unclear risk	High risk	High risk	Low risk	Low risk
King et al. (2002)	Low risk	Low risk	High risk	High risk	Low risk	High risk
Korn et al. (2009)	Low risk	Low risk	Low risk	Unclear risk	Low risk	Low risk
Lai et al. (2011)	Unclear risk	Unclear risk	High risk	High risk	Low risk	Low risk

Martín-Carrasco et al. (2016)	Low risk	Low risk	High risk	Low risk	Low risk	Low risk
Martín-Carrasco et al. (2014)	Low risk	Low risk	High risk	Low risk	Low risk	Low risk
McCurry et al. (1998)	Unclear risk	Unclear risk	Low risk	High risk	Unclear risk	Low risk
O’Toole et al. (2019)	High risk	Low risk	High risk	High risk	Low risk	Low risk
Park et al. (2020)	n/a	High risk	Unclear risk	Unclear risk	Low risk	Low risk
Pinar & Afsar (2015)	Low risk	Unclear risk	High risk	High risk	Low risk	Low risk
Rezaei et al. (2018)	Low risk	Low risk	Low risk	Unclear risk	Low risk	Low risk
Rose et al. (2009)	Unclear risk	Unclear risk	Low risk	High risk	Low risk	High risk
Rowe et al. (2010)	Unclear risk	High risk	High risk	High risk	Low risk	Low risk
Secker & Brown (2005)	Low risk	Low risk	High risk	High risk	Low risk	Low risk
Toseland et al. (2004)	Unclear risk	Unclear risk	Low risk	High risk	Low risk	Low risk
Toygar et al. (2020)	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Xiu et al. (2020)	Low risk	Low risk	High risk	High risk	Low risk	Low risk

**Table 2. Study characteristics (sleep-related outcome goals articles in first place)**

<b>Author (Location)</b>	<b>Design &amp; setting</b>	<b>Sample</b>	<b>Outcome goal</b>	<b>Intervention contents</b>	<b>Duration &amp; formats</b>
<b>Cognitive-Behavioral Sleep Interventions (CBIs)</b>					
Carter (2006) (USA)	Quasi- experimental design. Home care setting (oncology clinics)	<i>n</i> = 30 CG of advanced stage cancer patients with symptoms related (57% spouses, 30% adult child, 13% other) CG: 63% females, 53 ± 17 years Patients: n/a	Sleep quality	Sleep Intervention: stimulus control, relaxation, cognitive therapy, SH elements. Control group: Information about body mechanics.	2 x 1h individual sessions (4 weeks)
McCurry et al. (1998) (USA)	Randomized controlled trial. Home care setting (day centers)	<i>n</i> = 36 CG of senile dementia patients (75% spouses, 19% adult child, 6% other) CG: 78% females, 68.7 ± 10.6 years Patients: 56% males, 78.3 ± 7.6 years, disease information n/a	Sleep problems	Sleep hygiene, stimulus control, sleep compression, relaxation techniques and education about the illness and related caregiver issues. Control group: Waiting list condition.	6 group sessions (6 weeks) or 4 individual sessions (4 weeks)

Secker & Brown (2005) (UK)	Randomized controlled trial. Home care setting (clinics)	$n = 36$ CG of Parkinson's Disease patients (87% spouses) CG: 90% females, $59.1 \pm 12.2$ years Patients: sex n/a, $69.7 \pm 8.2$ years, Hoehn and Yahr stage $3.0 \pm 1.2$	Psychological distress and clinical caseness	Different modules that targeted a specific stressor and/or provided training on a new adaptive coping method. An specific module for sleep improvement. Control group: Waiting list condition.	12-14 individual sessions (14 weeks)
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### Caregiver Health Interventions (CHIs)

Cohen & Kuten (2006) (Israel)	Quasi-experimental design. Home care setting (oncology clinics)	$n = 143$ CG of breast, colon, prostate, gynecological or other cancer patients (49% spouses, 20% adult child, 16% parents, 14% other) CG: 66% females, $53.3 \pm 14.7$ years Patients : n/a. Disease information n/a	Psychological distress and adjustment	Cognitive (education, skills for stressful situations, adaptive patterns) and behavioral techniques (relaxation, guided imagery, deep breathing). Control group: usual support.	9 x 90 min group sessions (9 weeks)
Elliott et al. (2010) (USA)	Randomized controlled trial. Home care	$n = 495$ CG of dementia patients (42% spouses, 58% other) CG: 83.8% females, $62.3 \pm 12.1$ years	Self-reported health, burden and bother	Health education, skills to manage patient behaviors, social support, cognitive strategies for negative emotional responses,	12 individual sessions + 5 group sessions (6 months)



	setting (clinics and adverts)	Patients: 44.3% males, 78.6 ± 9.4 years, Mini-Mental State score 13.4 ± 7.1		strategies for enhancing behaviors and managing stress. Control group: Two check-in telephone calls.	
Ghaffari et al. (2019)	Randomized controlled trial. Home care setting (clinics)	<i>n</i> = 50 CG of Alzheimer's Disease patients (84% adult child, 16% spouses) CG: 80% females, 42.6 ± 6.2 years Patients: n/a	Mental health	Resilience education: disease information, coping strategies and problem solving. Control group: Usual care.	8 x 45min sessions (8 weeks)
Martín-Carrasco et al. (2016)	Randomized controlled trial. Home care setting (psychiatric centers)	<i>n</i> = 223 CG of schizophrenia or schizoaffective disorder patients (74% parents, 6% spouses, 17% siblings, 3% other) CG: 76% females, 59.2 ± 11.4 years Patients: 71.7% males, 38.7 ± 11.1 years, disease information n/a	Caregiver burden	Psychoeducational intervention: education, skills to manage troublesome behaviors, social support, cognitive strategies for enhancing healthy behaviors and managing stress. Control group: Usual support.	12 x 90-120 min group sessions (12 weeks)

Martín-Carrasco et al. (2014) (Spain)	Randomized controlled trial. Home care setting (clinics and day centers)	$n = 238$ CG of dementia patients (49% spouses, 45% adult child, 6% other) CG: 77% females, $61 \pm 13.6$ years Patients: 38.2% males, $77.8 \pm 8.7$ years, Mini-Mental State score $12.3 \pm 8.9$	Caregiver burden, psychological distress and quality of life	Psychoeducational intervention program: information about the clinical course of dementia and training on cognitive and behavioral skills and relaxation techniques. Control group: Usual care.	7 x 90-120 min group sessions (twice weekly)
O'Toole et al. (2019) (Denmark)	Crossover trial. Home care setting (oncology hospital)	$n = 80$ CG of lung, gastrointestinal and gynecological cancer patients (patient relation n/a) CG: 75% females, $47.9 \pm 15.6$ years Patients: 73% males, $58.0 \pm 9.3$ years, 79% stage III-IV cancer.	Psychological and inflammatory outcomes	Psychoeducation and training of emotion regulation skills with mindfulness practices. Control group: Waiting list condition.	8 x 60 min (8 weeks)
Park et al. (2020) (South Korea)	Quasi-Experimental design. Home care setting	$n = 26$ CG of dementia patients (8.3% spouses, 70.8% adult child, 20.8% other) CG: 58.4% females, $54.5 \pm 3.7$ years	Managing behavior and psychological symptoms	Mobile application with information about dementia, communication skills, coping methods and bulletin boards.	Freely (4 weeks)

	(elderly care facilities and neurology clinics)	Patients: n/a. Neuropsychiatric Inventory score 19.83 ± 18.85			Control group: Handbook with information about dementia, communication skills, coping methods and bulletin boards.
Rezaei et al. (2018) (Iran)	Randomized controlled trial. Home care setting (hospital)	<i>n</i> = 100 CG of schizophrenia patients (patient relation n/a) CG: n/a Patients: n/a	Public health and communication skills	Educational sessions: management and information about schizophrenia, family communication skills, coping with emotions and stress management.	10 x 45-60 min group sessions (5 weeks)
Toseland et al. (2004) (USA)	Randomized controlled trial. Home care setting (Health maintenance organizations)	<i>n</i> = 105 CG of older adults with a chronic illness and daily living impairments (100% spouses) CG: 69.2% females, 68.7 years Patient: 68.8% males, 72.8 years. Activity of Daily Living score 18.8	Perceived health status, burden, emotional well-being and social support.	Health Education Program: multicomponent program that includes emotion-focused and problem-focused coping, strategies, education and support. Control group: Usual care.	8 x 2 h group sessions (8 weeks) and 10 x 2 h group sessions (10 months)

Xiu et al. (2020) (China)	Randomized controlled trial. Home care setting adverts)	<i>n</i> = 157 CG of lung cancer patients (69.4% spouses, 17.2% adult child, 5.1% parents, 8.3% siblings) CG: 52.2% females, 53.9 ± 12.18 years Patients: 40.1% males, 60.0 ± 9.54 years, 83.4% stage III-IV cancer.	Quality of life	Intervention 1 (CBT): Dyads received relaxation techniques, coping patterns, cognitive and behavioral strategies to manage anxiety and depression, dysfunctional attitudes, plans of pleasurable activities.  Intervention 2 (I-BMS): Dyads received psychoeducation about wellbeing, mind-body exercises, relaxation techniques and reconstructing meanings of caregiving.	8 x 3h group sessions (8 weeks) and 2 follow-up group sessions
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### Exercise programs

Hirano et al. (2011) (Japan)	Randomized controlled trial. Home care setting (n/a)	<i>n</i> = 36 CG of dementia patients (patient relation n/a) CG: 67.7% females, 73.7 ± 4.4 years Patients: sex n/a, 76.9 ± 6.0 years, Neuropsychiatric Inventory score 15.0 ± 12.0	Quality of life	Regular exercise with moderate-intensity (3METs) + pedometer.  Control group: No prescription of exercise + pedometer.	3 times a week (12 weeks)
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King et al. (2002) (USA)	Randomized controlled trial. Home care setting (adverts and organizations)	$n = 100$ CG of dementia patients (53% spouses, 47% adult child) CG: 100% females, 63 years Patients: sex n/a, 80 years, Revised Memory and Behavior Problems Checklist score $9.5 \pm 7.2$	Quality of life	Home-based, telephone-supervised, moderate-intensity, individualized exercise training. Control group: Nutrition recommendations by the American Heart Association and similar organizations.	Once a week for 30-40 min (12 months)
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#### Other therapies

Friedman et al. (2012) (USA)	Randomized controlled trial. Home care setting (adverts)	$n = 59$ CG of dementia patients (relation n/a) CG: 66.7% females, $68.8 \pm 12.7$ years Patients: 57.4% males, $77.9 \pm 8.1$ years, Mini-Mental State score $29.2 \pm 1.1$ .	Sleep	Dyads were exposed to bright light phototherapy + Sleep hygiene therapy. Control group: dim red light phototherapy + Sleep hygiene therapy.	60 min daily (2 weeks) Sleep hygiene 1 x 50 min
Hasuo et al. (2020) (Japan)	Pilot randomized controlled trial. Home care	$n = 69$ CG of advanced cancer patients (82.6% spouses, 14.5% adult child, 2.9% parents) CG: 66.7% females, $64.5 \pm 10.5$ years Patients: n/a. Disease information n/a	Sleep	Intervention 1: Sessions for heart rate variability with resonant frequency breathing at the medical institution and at home.	Intervention 1: 30 min daily (5 weeks)

	setting (hospital)			Intervention 2: Sessions for heart rate variability with resonant frequency breathing at the medical institution.	Intervention 2: 3 x 30 min (5 weeks)
Lai et al. (2011) (Taiwan)	Crossover trial. Home care setting (n/a)	<i>n</i> = 34 CG of head, neck, lung, hematological, gastrointestinal or genitourinary cancer patients (38.2 spouses, 38.2% parents, 23.5% adult child) CG: 100% females, 44.9 ± 9.0 years Patients: n/a. 88.2% stage I-II cancer	Blood volume pulse amplitude, heart rate variability, depression, anxiety and sleep quality	Music intervention with nursing presence (MINP): consisted of an erhu (Chinese instrument) and recorder performance. Control group: Prerecorded music.	1 x 30 min each intervention
Pinar & Afsar (2015) (Turkey)	Randomized controlled trial. Hospital setting (oncology clinics)	<i>n</i> = 44 CG of cancer patients (52.3% spouses, 47.7% parents) CG: 63.6% females, 42.3 years Patients: n/a. Disease information n/a	Anxiety, cortisol level, blood pressure, pulse rate and sleep quality	Evening back massage that consisted of a combination of effleurage, petrissage, friction and tapotement. Control group: Caregivers rested in a room in silence and were not allowed to do activities.	7 x 15 min (1 week)

Rose et al. (2009) (USA)	Pilot randomized controlled trial. Home care setting (care providers or support groups)	$n = 39$ CG of Alzheimer's disease or other dementia patients (100% spouses) CG: 65.8% females, $71.9 \pm 7.78$ years intervention group; $76.2 \pm 5.6$ years control group (statistical differences) Patients: sex n/a, $76 \pm 7.2$ years, Global Deterioration Scale moderately severe or severe 63.1%	Sleep disturbance, depressive symptoms and subjective appraisal	Caregivers received a small amount of cranial electrical stimulation by a device. Control group: Same device but without electrical stimulation.	60 min per day (4 weeks)
Rowe et al. (2010) (USA)	Randomized controlled trial. Home care setting (adverts)	$n = 53$ CG of Alzheimer's disease or other dementia patients (51% spouses, 38% adult child). CG: 82% females, $62 \pm 11.9$ years Patients: 44% females, $78.39 \pm 7.68$ years, Mini-Mental State score 13.67	Worry and sleep	Nighttime monitoring system installed at home. Control group: Educational material unrelated to any study goals.	Daily (12 months) Outcome measures: 9 points x 7-day intervals

Toygar et al. (2020) (Turkey)	Randomized controlled trial. Hospital setting (oncology unit)	$n = 66$ CG of cancer patients (43.4% spouses, 24.2 % adult child, 22.7% parents, 10.6% other) CG: 84.9% females, $40.1 \pm 13.3$ years Patients: n/a. Disease information n/a	Sleep and anxiety	Reflexology sessions applying pressure to the reflex points. Control group: Caregivers received reflexology rubbing the foot surface without any deep stimulation.	3 x 30 min (1 week)
Cheung et al. (2020) (China)	Randomized controlled trial. Home care setting (health centers)	$n = 207$ CG of older family patients (patient relation n/a) CG: sex n/a, $59.3 \pm 11.7$ years Patients: sex n/a, > 65 years, need for medical assistance 56.4%	Stress and stress-related symptoms	Training and practice of self-administered acupressure by the participant at home Control group: Waiting list condition.	Training: 2 weeks Practice: 30 min per day x 6 weeks (8 weeks)
Korn et al. (2009) (USA)	Randomized controlled trial. Home care setting (tribes)	$n = 42$ CG of dementia patients (59.5% adult child, 9.5% spouses, 31% other) CG: 90.5% females, 57.1% >50 years Patients: sex n/a, 57.1% >70 years. Disease information n/a	Stress, depression and quality of life	Polarity therapy: pressure on energy points and biofields to help achieve physiological relaxation. Control group: Respite care for the care recipient and activities for the caregiver.	8 x 50 min (8 weeks) Control: 8 x 60-120 min (8 weeks)

CG: Caregivers.



**Table 3. Study outcomes**

<b>Author</b>	<b>Outcomes: time-points</b>	<b>Outcomes: Measures</b>	<b>Post-intervention</b>	<b>Follow-up</b>
<b>Cognitive-Behavioral Sleep Interventions (CBIs)</b>				
Carter (2006)	Baseline	Pittsburgh Sleep Quality Index - global score	NS	p < 0.05
	Post-intervention	Actigraphy: Latency	p < 0.05	NS
	Follow-up: 2, 3, 4 months	Duration	NS	NS
		Efficiency	NS	NS
		Wake after sleep onset	NS	NS
McCurry et al.	Baseline	Pittsburgh Sleep Quality Index - global score	p < 0.05	p < 0.05
	Post-intervention			
	Follow-up: 3 months			
Secker & (2005)	Baseline	General Health Questionnaire subscale: anxiety and insomnia	p < 0.05	p < 0.05
	Post-intervention			
	Follow-up: 6 months			

### Caregiver Health Interventions (CHIs)

Cohen & Kuten	Baseline	Mini Sleep Questionnaire	p < 0.01	p < 0.01
	Post-intervention			
	Follow-up: 4 months			
Elliott et al.	Baseline	Self-Rated Caregiver Physical and Emotional Health questions:	p < 0.01	n/a
	Post-intervention	self-reported caregiver sleep		
Ghaffari et al.	Baseline	General Health Questionnaire subscale: anxiety and insomnia	p < 0.001	n/a
	Post-intervention			
Martín- ayo et al. (2016)	Baseline	General Health Questionnaire subscale: anxiety and insomnia	NS	NS
	Post-intervention			
	Follow-up: 8 months			
Martín- ayo et al. (2014)	Baseline	General Health Questionnaire subscale: anxiety and insomnia	p < 0.05	p < 0.05
	Post-intervention			
	Follow-up: 4 months			

O'Toole et al.	Baseline	Pittsburgh Sleep Quality Index - global score	p < 0.05	n/a
	Mid-treatment: 4 weeks			
	Post-intervention			
	Follow-up: 3, 6 months			
Park et al.	Baseline	Sleep diary: sleep efficiency	NS	NS
	Post-intervention			
	Follow-up: 6 weeks			
Rezaei et al.	Baseline	General Health Questionnaire subscale: anxiety and insomnia	p < 0.001	n/a
	Post-intervention			
Toseland et al.	Baseline	General Health Questionnaire subscale: anxiety and insomnia	NS	NS
	Post-intervention			
	Follow-up: 12 months			
Xiu et al.	Baseline	Insomnia Severity Index	Both groups p < 0.05	NS
	Post-intervention			
	Follow-up: 8, 16 weeks			

### Exercise programs

Hirano et al.	Baseline	Self-related quality of sleep (light sleep, lying awake in bed, sleeping but still waking several times)	p < 0.05	n/a
	Post-intervention			
King et al.	Baseline	Pittsburgh Sleep Quality Index - global score	n/a	n/a
	Post-intervention	Sleep quality	p < 0.05	
		Sleep latency	NS	
		Sleep duration	NS	
		Sleep efficiency	n/a	
		Sleep disturbances	n/a	
		Sleep medication	n/a	
Daytime dysfunction	n/a			

### Other therapies

Cheung et al.	Baseline	Pittsburgh Sleep Quality Index - global score	p < 0.05	p < 0.01
	Post-training (week 2)			
	Post-intervention			
	Follow-up: 12 weeks			

Friedman et al.	Baseline	Actigraphy: Wake after sleep onset	Both groups $p < 0.05$	n/a
	Post-intervention	Time in bed	NS	
		Total sleep time	NS	
		Sleep efficiency	Both groups $p < 0.05$	
		Epworth Sleepiness Scale	Both groups $p < 0.05$	
		Blake-Gomez Sleep Hygiene Questionnaire	Both groups $p < 0.001$	
		Global Sleep Assessment Questionnaire	Both groups $p < 0.01$	
Hasuo et al.	Baseline	Pittsburgh Sleep Quality Index - global score	Both groups $p < 0.05$	n/a
	Post-intervention	Sleep quality	$p < 0.001$ favoring Intervention 1	
		Sleep latency	NS	
		Sleep duration	NS	
		Sleep efficiency	NS	
		Sleep disturbances	NS	
		Sleep medication	NS	
		Daytime dysfunction	NS	

Korn et al.	Baseline	Pittsburgh Sleep Quality Index - global score	NS	n/a
	Post-intervention			
Lai et al. (2011)	Baseline	Visual analogue scale: ease of getting to sleep, sleep quality, ease	Ease of getting to	n/a
	Post-intervention	of awakening from sleep and daytime function.	sleep p < 0.01	
Pinar & Afsar	Baseline	Pittsburgh Sleep Quality Index - global score	p < 0.01	n/a
	Post-intervention			
Rose et al.	Baseline	Pittsburgh Sleep Quality Index - global score	n/a	n/a
	Post-intervention	Sleep quality	NS	
		Sleep latency	n/a	
		Sleep duration	n/a	
		Sleep efficiency	NS	
		Sleep disturbances	n/a	
		Sleep medication	n/a	
		Daytime dysfunction	NS	
		General Sleep Disturbance Scale	NS	
Sleep diary: Bedtime, sleep latency, awakenings, wake-up time	NS			

Rowe et al.	Baseline	Actigraphy: Sleep time	n/a	NS
	Follow-up: 2, 3, 4, 5, 6, 8, 10 and 12 months	Wake after sleep onset	n/a	NS
		Sleep latency	n/a	NS
		Sleep diary	n/a	NS
Toygar et al.	Baseline	Richards-Campbell Sleep Questionnaire	p < 0.001	n/a
	Post-intervention			

NS: nonsignificant

**Figure 1. Flow diagram of the review process according to PRISMA guidelines**

