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INSOMNIA: TREATMENT NEEDS, EFFECTIVENESS, AND EXPERIENCES

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INSOMNIA: TREATMENT NEEDS, EFFECTIVENESS, AND EXPERIENCES

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Do but consider what an excellent thing sleep is; it is so inestimable a jewel that, if a tyrant would give his crown for an hour's slumber, it cannot be bought; of so beautiful a shape is it, that though a man lie with an Empress, his heart cannot beat quiet till he leaves her embracements to be at rest with the other: yea, so greatly indebted are we to this kinsman of death, that we owe the better tributary, half of our life to him: and there is good cause why we should do so: for sleep is that golden chain that ties health and our bodies together.

— Thomas Dekker (The Gull's Hornbook, 1609)

ABSTRACT

Background and aim: The sleep-wake disorder insomnia reduces daytime functioning and quality of life and increases the risk for mental and physical illness. Most people with insomnia who seek treatment do so in primary health care (PHC). Although the recommended first-line treatment is cognitive behavioral therapy for insomnia (CBT-I), the most common treatment remains hypnotics. The aims of this thesis were to investigate the need for treatment for sleep difficulties in the general population (study I), evaluate whether a nurse-led group treatment for insomnia is more effective than treatment as usual in improving insomnia in PHC (studies II and III), and to explore patients' experiences of the group treatment (study IV).

Material and methods: Study I was a telephone survey investigating factors associated with self-reported need for treatment for sleep difficulties. Participants were 1115 people randomly selected from the general population of Sweden. Studies II and III were based on a randomized controlled trial (n = 165) that investigated the effects of a group treatment program for insomnia. The 10-week program (seven sessions) was based on the techniques of CBT-I and led by district nurses in routine PHC. The control condition was treatment as usual. Patient-reported outcome measures were used to assess outcomes at baseline and post-treatment. Additionally, patients who received group treatment were assessed 1 year after group treatment. In study IV, patients' experiences of the group treatment were explored via five focus group interviews that were transcribed and analyzed with qualitative content analysis.

Results: Study I showed that 12.5% of the general population reported a need for treatment for sleep difficulties. Difficulty initiating sleep was the factor most strongly related to need for treatment. Other important factors were nonrestorative sleep, mental disorders, and fatigue. Study II showed that the nurse-led group treatment for insomnia was more effective than treatment as usual in reducing insomnia severity, improving sleep, and reducing patients' use of hypnotics. Study III showed that the group treatment was more effective than treatment as usual in improving the daytime symptomatology of insomnia (fatigue, depressive symptoms, psychological distress, health-related quality of life, general daytime functioning, specific daytime symptoms, and dysfunctional beliefs). All improvements found after group treatment in studies II and III were sustained 1 year later. In study IV, the qualitative analysis revealed four themes that described patients' experiences: involvement and trust open the door for change, competence arising from deeper understanding, struggling with vulnerability and failure, and tailoring treatment to individual needs.

Conclusions: Many people in the general population feel that they need treatment for sleep difficulties. An important factor behind this need is difficulty initiating sleep, followed by nonrestorative sleep, mental health problems, and fatigue. Nurse-led group treatment can effectively improve insomnia, is feasible to implement in routine PHC, and has the potential to increase patients' access to recommended first-line treatment (CBT-I). Patients' experiences of group treatment illuminate what motivated them to change, what helped them improve, and the challenges they faced.

LIST OF SCIENTIFIC PAPERS

This thesis is based on the following four papers, which will be referred to in the text by their Roman numerals:

- I. Sandlund C, Westman J, Hetta J. Factors associated with self-reported need for treatment of sleeping difficulties: a survey of the general Swedish population. *Sleep Med.* 2016 Jun;22:65-74.
- II. Sandlund C, Hetta J, Nilsson GH, Ekstedt M, Westman J. Improving insomnia in primary care patients: A randomized controlled trial of nurse-led group treatment. *Int J Nurs Stud.* 2017 Jul;72:30-41.
- III. Sandlund C, Hetta J, Nilsson GH, Ekstedt M, Westman J. Impact of group treatment for insomnia on daytime symptomatology: Analyses from a randomized controlled trial in primary care. *Int J Nurs Stud.* 2018 Sep;85:126-35.
- IV. Sandlund C, Kane K, Ekstedt M, Westman J. Patients' experiences of motivation, change, and challenges in group treatment for insomnia in primary care: a focus group study. *BMC Fam Pract.* 2018 Jul;19(1):111.

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LIST OF ABBREVIATIONS

ANOVA	Analysis of variance
APC	Academic Primary Health Care Centre
CBT	Cognitive behavioral therapy
CBT-I	Cognitive behavioral therapy for insomnia
CI	Confidence interval
DBAS	Dysfunctional Beliefs and Attitudes about Sleep
DSM	Diagnostic and Statistical Manual of Mental Disorders
EEG	Electroencephalogram
FSS	Fatigue Severity Scale
GHQ	General Health Questionnaire
ICD	International Statistical Classification of Diseases
ICSD	International Classification of Sleep Disorders
ISI	Insomnia Severity Index
MADRS-S	The Montgomery-Asberg Depression Rating Scale Self-Assessment
OR	Odds ratio
P	Probability value
PHC	Primary health care
RCT	Randomized controlled trial
REM	Rapid eye movement
SD	Standard deviation
SF-36	Short Form Health Survey, 36-item version
TAU	Treatment as usual
USI	Uppsala Sleep Inventory
Z-drugs	Benzodiazepine receptor agonists; most start with the letter "Z," such as zopiclone and zolpidem

INTRODUCTION

The sleep-wake disorder insomnia includes both night- and daytime symptoms and affects several domains of daily life and functioning. When people need treatment for insomnia, they seek primary health care (PHC). In 2007, when I started to work in PHC, it quickly became clear to me that insomnia was a main concern for many patients. It was also clear that we had limited options for helping and treating patients with insomnia and that more could be done to meet their needs. The projects in this doctoral thesis arose from a desire to improve care for these patients.

The thesis includes epidemiological, clinical, and qualitative studies that focus on treatment needs and group treatment for insomnia. I hope the results will contribute to improving care for patients with insomnia by increasing knowledge about and understanding of what makes people feel they need treatment for sleep difficulties, how insomnia can be effectively treated in PHC, and patients' experiences of treatment.

1 BACKGROUND

1.1 INSOMNIA

1.1.1 Sleep

Sleep is essential to our health, well-being, and survival, and we spend almost a third of our lives asleep. While we sleep, heart rate, blood pressure, breathing, and brain temperature decrease (1, 2) and glucose, lipid, and energy metabolism are regulated (3). Levels of growth hormone increase (4) and thyroid-stimulating hormone decrease (5). Cortisol levels, regulated by the circadian rhythm, rise in the middle of the night and peak during the morning (6). Moreover, sleep consolidates memory (7) and prepares us to function socially and emotionally (8).

The nature of sleep is dynamic and complex. It is characterized by behavioral and physiological changes that occur cyclically in two distinct states: rapid eye movement (REM) sleep and non-REM sleep (9). Non-REM sleep is divided into three stages, defined by different patterns of activity in the brain visible on an electroencephalogram (EEG). Stage 1 is the transition from wakefulness to sleep, in which brain-wave activity gradually slows. Stage 2 includes low brain-wave activity of mixed frequency and the appearance of sleep spindles, bursts of swaying brain activity (sigma waves). Stage 3 is defined by the occurrence of high-amplitude, low-frequency brain-wave activity, called delta activity or slow-wave sleep. REM sleep is characterized by an EEG pattern similar to that of wakefulness and involves vivid dreams, loss of muscle tone, and rapid eye movements. Non-REM and REM sleep occur in cycles of approximately 60 to 120 minutes, during which sleep gradually moves from shallow (stages 1 and 2), to deep (stage 3), to REM sleep (9). The first hours of sleep include mainly deep sleep, and the last hours, shallow and REM sleep (1, 2, 9).

How we sleep depends on two main factors that interact to regulate sleep and wakefulness: the homeostatic process and the circadian rhythm (10). The homeostatic process is driven by the duration of wakefulness: the longer a person has been awake, the stronger the drive for sleep. Prolonged wakefulness and one or more nights of insufficient sleep create recovery sleep, which is characterized by more slow-wave sleep (deep sleep) the following nights (11, 12). The circadian rhythm is controlled by the circadian clock, located in the suprachiasmatic nucleus of the hypothalamus. The circadian clock regulates the rhythm of sleep and wakefulness in an approximation of the 24-hour clock. It activates and deactivates systems that promote wakefulness, temperature change, and hormone release. Light and darkness (10, 13), and other environmental signals, such as meal times, social interactions, and daily routines, help to regulate this rhythm (10).

However, sleep needs and sleep patterns vary from person to person, and across the lifespan (14). As a part of normal aging, circadian rhythms and sleep homeostasis become less stable (15). With increasing age, shallow sleep increases and REM sleep and slow-wave

sleep decrease (15, 16). These age-related changes contribute to older adults' advanced sleep timing; shorter sleep duration; and increased frequency of daytime naps, number of nocturnal awakenings, and time spent awake during the night (15, 17). In women, sleep is affected by hormonal changes related to menstruation, pregnancy, and menopause (18).

Occasional sleepless nights are something most people have experienced as a normal response to a perceived or actual stressor, such as worry, medication, or medical symptoms (19). But if sleep difficulties occur frequently and persistently and if the difficulties are accompanied by daytime symptoms and impaired daytime functioning (i.e., daytime symptomatology), the person may have developed the sleep-wake disorder insomnia.

1.1.2 The sleep-wake disorder insomnia

Insomnia disorder is included in several classification and diagnosis systems: the International Statistical Classification of Diseases and Related Health Problems (ICD-10) (20), the International Classification of Sleep Disorders (ICSD-3) (21), and the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (22).

In 2011, when the randomized controlled trial (RCT) in this thesis was initiated, the prevailing DSM criteria were those of DSM-IV (23). DSM-IV distinguished primary insomnia (not directly caused by a psychiatric or a physical disorder) from secondary insomnia (related to or caused by a psychiatric or a physical disorder). However, the most recent criteria, those of DSM-5, reflect a shift in the prevailing view of insomnia. These criteria consider the relationship between insomnia and other health problems to be interactive and bidirectional. Today, insomnia is viewed as a disorder that requires independent clinical attention, which means that a person has insomnia not only if it occurs as an independent condition, but also if it occurs together with another psychiatric or somatic condition (e.g., depression, pain) or together with another sleep disorder.

The DSM-5 diagnostic criteria for insomnia disorder (22, p. 362):

- a) A predominant complaint of dissatisfaction with sleep quantity or sleep quality with one or more of the following sleep difficulties: difficulty initiating sleep, difficulty maintaining sleep, and early morning awakenings.
- b) The sleep difficulties cause significant distress or impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning.
- c) The sleep difficulties occur at least 3 nights per week.
- d) The sleep difficulties have been present for at least 3 months.
- e) The sleep difficulties occur despite adequate opportunity for sleep (e.g., adequate time and circumstances for sleep and a safe, quiet, and dark bedroom).
- f) The symptoms are not better explained by and do not occur exclusively during the course of another sleep-wake disorder (e.g., hypersomnolence disorder; narcolepsy; breathing-related sleep disorders such as obstructive sleep apnea; circadian rhythm

- sleep-wake disorders such as delayed sleep-wake phase and shift work; parasomnias such as sleepwalking, sleep terrors, and nightmares; and restless legs syndrome).
- g) The symptoms cannot be attributed to the effects of a substance (e.g., drug abuse and medication).
 - h) Coexisting mental disorders and medical conditions do not adequately explain the predominant complaint of insomnia.

The ICSD-3 uses similar criteria but further states that the patient must report daytime symptoms such as fatigue, lack of energy, mood disturbance, difficulty concentrating, and worry about sleep as a result of the sleep difficulties. According to the ICD-10 criteria for non-organic insomnia, symptoms also include an excessive focus on sleep and worry about the negative consequences of poor sleep.

The clinical diagnosis of insomnia is based on the patient's own experiences of symptoms, a medical and psychiatric examination, laboratory testing if indicated, and the patient's sleep history (e.g., trigger factors, sleep-wake schedule, sleep environment, and circadian factors). Objective measures (e.g. polysomnography) are indicated if sleep-related breathing disorder, periodic limb movement disorder, or narcolepsy is suspected; if the insomnia diagnosis is uncertain; or if the patient does not respond to treatment (24, 25).

1.1.3 Etiology of insomnia

The prevailing framework of insomnia is mainly based on theories explaining the disorder from psychological, neurobiological, and behavioral perspectives (26-31). The theories all resemble each other in that they posit that an interaction between predisposing and precipitating factors creates sleep difficulties, but that perpetuating factors are necessary for the development and maintenance of insomnia.

1.1.3.1 Predisposing factors

Factors that predispose people to develop insomnia include a family history of and a propensity for stress-related sleep disturbance (27, 32). Studies suggest that genetics can play a role in people's vulnerability to insomnia. For example, people who have a close biological relative with insomnia are at increased risk of developing the disorder (33). The pathway may involve an elevated stress response that raises the risk for poor sleep and for a negative reaction to poor sleep (34). Moreover, a genetic component linked to hyperactivity of the arousal system may cause an imbalance in sleep-wake regulation and hypoactivity in sleep-inducing systems (35).

1.1.3.2 Precipitating factors

Components of a person's environment, health situation, and/or psychosocial situation can prompt the onset of sleep difficulties (27, 36). A stressful life event (37), mental health problems (38), and physical health problems (38) are examples of common precipitating factors. It is not necessarily the number of stressful events, but rather a lack of control over stressful events that precipitates insomnia (39). Moreover, in order for a person to develop

insomnia, the person must perceive the sleep difficulties or their consequences as problematic (29).

1.1.3.3 Perpetuating factors

Insomnia is perpetuated by a vicious cycle of hyperarousal, emotional distress, and dysfunctional behaviors that commonly is caused by worry about sleep and about the consequences of poor sleep (26-31). Such worry contributes to increased attention to poor sleep and to daytime impairments. It leads to calculating the amount of sleep obtained and how many hours can be obtained if the person falls asleep quickly, awareness of bodily sensations, and signs of tiredness that could affect daytime activities (26). The increased attention to symptoms may result in a reduced ability to discriminate sleep from wakefulness (26, 40). People with insomnia tend to underestimate their total sleep time and misperceive sleep prior to awakening as time spent awake (41). Worry, brief awakenings, and monitoring the clock during the night are factors that contribute to misperception of sleep (42, 43).

Misperception of sleep further increases worry, which induces behaviors that are intended to avoid sleeplessness and daytime symptoms. Examples of such behaviors include taking hypnotics, canceling planned activities after a poor night's sleep, attempting to avoid unpleasant thoughts when trying to sleep (26), and extending time spent in bed (going to bed early, sleeping later in the morning, and sleeping during the day) (44). Irregular sleep habits, the attention focused on insomnia symptoms, and direct attempts to control sleep further increase arousal, which puts the person at risk for maintaining poor sleep or even worsening it (28).

Worry and the use of unsuccessful behaviors reinforce beliefs and attitudes about sleep that fail to help the person cope with insomnia (26). Examples include unrealistic expectations of sleep need and sleep patterns, for example a strong belief that getting less than eight hours of uninterrupted sleep will result in poor functioning the next day. Sleep-related rumination tends to dominate the person's thoughts during the day and the night and thus serves to perpetuate insomnia by creating hyperarousal and emotional distress (30, 45).

1.1.4 Consequences of insomnia

Living with insomnia can affect health via physical and mental illnesses, cognitive decline, and reduced quality of life. Insomnia is associated with an increased risk for several somatic diseases, such as cardiovascular disease (46), diabetes (47), and obesity (48). Poor sleep (short, mistimed, or disturbed sleep) may link insomnia and these disorders (48, 49). Moreover, poor sleep is related to adverse changes in health-related behaviors, such as smoking, high-risk alcohol consumption, and physical inactivity (50). Additionally, poor sleep increases vulnerability to chronic pain by modifying pain habituation and sensitivity to pain (51).

Insomnia is also closely related to psychiatric disorders (52), particularly depression (53). Even though sleep disturbance can be a symptom of depression, studies show that insomnia is

often comorbid with depression rather than secondary to it (54) and that insomnia increases the risk of developing depression (55-57) and anxiety (58). Moreover, insomnia is involved in the development of burnout (59) and the maintenance of emotional exhaustion in people with burnout (60).

Additionally, studies show that insomnia is associated with reduced quality of life (61, 62) and a number of factors that are important to people's ability to manage their daily lives. Examples include fatigue and depressed mood (63, 64); increased sensitivity to stress (65); and impaired daytime functioning (63, 64), memory (66), attention (66), alertness (66), problem-solving (66), and social and emotional functioning (67). Moreover, insomnia is related to increased health care use and decreased work performance (68, 69).

In agreement with these findings, qualitative studies show that people can experience living with insomnia as a 24-hour problem that affects several domains of their daily lives and functioning (70), leading them to feel that they are just struggling through, are isolated and feel like an outsider, and that insomnia is an obstruction to their desired self. Moreover, they could experience impairments in cognitive, emotional, and physical functioning on a daily basis along with limited work performance, social participation, and life aspirations (71).

From a societal perspective, insomnia is costly. For instance, in 2015, the direct and indirect annual cost of insomnia in the United States was approximately a hundred billion dollars (72). Most costs were related to increased health care use, impaired workplace performance, and increased risk for accidents (e.g., workplace accidents, car accidents, and falls).

1.1.5 Prevalence and course of insomnia

Population-based studies show that approximately 20% to 30% of the adult general population report they have sleep difficulties (73), and that about 10% meet the criteria for insomnia (74, 75). The prevalence of sleep difficulties increases with age, but insomnia is most prevalent in people of middle age (40 to 49 years) (74). Both sleep difficulties and insomnia are more common in women than in men (74, 76, 77), and these sex differences are already apparent in early adolescence (78). Moreover, insomnia is a growing public health problem, as its prevalence is increasing (79-82).

Insomnia is characterized by persistence (54, 83-87). One population-based study found that 75% of people with insomnia still had the disorder 12 years later (88). Another study that followed PHC patients for a year found that 69% of the 474 who reported insomnia symptoms at baseline still reported such symptoms a year later, regardless of whether or not they had sought treatment during the year (86). That study also showed that persistent insomnia was associated with the use of hypnotics.

1.1.6 Treatment-seeking and clinical presentation

PHC is the level of care people commonly turn to when they seek treatment for insomnia symptoms (89). Sleep difficulties and insomnia are thus common in PHC patients. For

instance, one study from Norway found that approximately 56% of patients visiting PHC reported sleep difficulties, and that 54% of all patients met the criteria for insomnia (90). Similar studies from other countries, including the United States (91), Canada (92), Italy (93), Germany (94), and Malaysia (95), have estimated that 26% to 60% of PHC patients met the criteria for insomnia.

People seeking treatment for insomnia in PHC typically have severe insomnia (96), including daytime symptoms and impaired daytime functioning (64, 97, 98). Factors associated with treatment-seeking for insomnia include fatigue, psychological distress, physical discomfort, and reduced work performance (89); daytime sleepiness (99); and short sleep duration (99, 100). Moreover, insomnia is highly comorbid with other physical and mental health problems that prompt people to seek care (96, 100). For example, approximately half of patients visiting PHC who have insomnia also have anxiety, depressive symptoms, and/or general physical health problems (95, 101). Higher levels of education (100) and higher socioeconomic status (102) are also associated with seeking treatment for sleep difficulties.

However, several studies have found that many people do not seek treatment for their insomnia (86, 89, 103-105). For example, one study that used surveys and medical records to follow PHC patients for a year found that 72% of those with persistent insomnia symptoms ($n = 474$) had not consulted PHC for advice or medication for insomnia during that year (86). People with insomnia can wait to seek care because they feel resigned and hopeless about being taken seriously and receiving effective help (70). They also commonly think they should be able to cope with insomnia by themselves and often try to do so (91, 106, 107), for instance by self-medicating with alcohol or over-the-counter drugs (e.g., herbal medicines) (103, 108, 109).

1.2 TREATMENT OF INSOMNIA

1.2.1 Clinical guidelines

During the past decade, several guidelines have been published that provide clinical recommendations for the treatment of adults with insomnia. All of them recommend cognitive behavioral therapy for insomnia (CBT-I) as the first-line treatment (25, 110-115).

In 2010, the Swedish Council on Health Technology Assessment (SBU) published a national report that provided insomnia treatment guidelines (111). The 2017 European Sleep Research Society's guidelines are among the most recent and most comprehensive (25). They are based on a systematic review of meta-analyses of diverse insomnia treatments (pharmacological and non-pharmacological) and treatment formats (e.g., individual, group, and Internet). The review found high-quality evidence that CBT-I results in sustainable improvements in sleep variables, regardless of a person's age or comorbid conditions (e.g., chronic pain, cancer, chronic obstructive pulmonary disease, and depression). The guidelines state that even if insomnia is comorbid with another disorder, the recommended treatment for the insomnia is CBT-I (25).

If CBT-I is unavailable or has not improved the person's insomnia symptoms, the recommendation is short-term treatment (≤ 4 weeks) with benzodiazepines, benzodiazepine receptor agonists (“Z-drugs”), or sedating antidepressants (25, 113-116). Treatment longer than 4 weeks is not recommended because there is not enough evidence to support it and because of potential side effects, which include fatigue, sleepiness, and rebound insomnia (i.e., worsening of sleep after discontinuation of hypnotics) (117, 118). Hypnotics can also impair cognitive performance (119, 120) and, by reducing time spent in slow-wave sleep, they can impair sleep quality (121). If used over the long term, they can thus worsen sleep and daytime symptoms. Additionally, hypnotics increase the risk for falls and fractures in older adults (> 65 years) (122). Guidelines further state that clinicians should take the circumstances of each patient and available treatment options into account when applying the guidelines.

1.2.2 Cognitive behavioral therapy for insomnia

Cognitive behavioral therapy (CBT) is an umbrella term for cognitive and behavioral psychotherapies that focus on behaviors: both inner cognitive processes and behaviors that can be observed. The content of CBT varies by diagnosis, but all forms of CBT share a similar approach to treatment (123). CBT-I is CBT specific to insomnia. Its history started with the introduction of insomnia-specific behavioral techniques, including stimulus control in the early 1970s (124) and sleep restriction in the late 1980s (12). Cognitive techniques for treating insomnia were introduced in the early 1990s (31). These techniques, together with educational components, still constitute the basis of multi-component CBT-I.

CBT-I aims to treat insomnia by targeting the perpetuating factors that are involved in the disorder. Specifically, CBT-I aims to re-establish conditions for sleep and support people in overcoming sleep-inhibitory mechanisms such as worry and sleep performance (the attempt to force sleep to come) (28). It also aims to help people develop a feeling of being in control of their sleep, thereby reducing the emotional distress caused by insomnia (125). The overall aims of CBT-I and of insomnia treatment in general are to improve sleep, improve daytime functioning, reduce daytime symptoms, and alleviate suffering (110, 112, 125). However, the recommendation that CBT-I should be the first-line treatment for insomnia is based on its effects on objective and/or subjective measurements of sleep (i.e., sleep onset latency, total sleep time, time awake after sleep onset, sleep efficiency, number of awakenings during the night, and sleep quality).

The first large meta-analysis to show that cognitive and/or behavioral techniques effectively improve sleep (more than no treatment at all) was published in 1994 (126). It included 59 studies on individually delivered treatments (i.e., treatments delivered face-to-face) that were conducted between 1974 and 1993. Individual treatment remains the most common format (25). However, group formats have the advantage of allowing one provider to treat many patients at the same time. Two meta-analyses show that group CBT-I effectively improves sleep onset latency, sleep efficiency, and time awake after sleep onset (127, 128). They included mainly the same studies (a total of 12 studies). Studies that compare group CBT-I

and individually delivered CBT-I show somewhat inconsistent results. Two studies have found that both treatment formats have similar effects on sleep outcomes (129, 130), but another showed that individual CBT-I was more effective than group CBT-I in improving sleep (131).

Whereas there is evidence that CBT-I improves sleep, less is known about whether it improves daytime functioning and reduces daytime symptoms. The assumption that improved sleep leads to improvements in the daytime symptomatology of insomnia remains largely unexplored. The majority of insomnia treatment studies do not include outcomes related to daytime symptomatology (25, 113), and the few studies that have investigated the effects of CBT-I on such outcomes have had inconsistent results. For example, a meta-analysis of five studies found a very low grade of evidence that CBT-I improved daytime functioning better than hypnotics (132). A systematic review of 18 studies found small to moderate effects on subjective measures of daytime symptoms such as cognitive functioning, but few of the effects were statistically significant (133). Another meta-analysis of 47 studies found that individual CBT-I (but not group or self-help treatments) reduced depressive symptoms but not fatigue (134). Nevertheless, a few individual studies show that group CBT-I can reduce fatigue and anxiety and improve mood, mental functioning, and general daytime functioning (135). Moreover, they show that group CBT-I can reduce specific daytime symptoms, such as sleepiness, difficulty concentrating, impaired work performance, muscle aches, stress, arousal, and anxiety (136).

1.2.2.1 Components of CBT-I

The educational components of CBT-I aim to increase knowledge about sleep, what can be expected from sleep, and one's own ability to impact sleep. They typically include information about normal sleep processes, sleep regulation, normal variations in sleep, sleep at different ages, sleep need, sleep misperception, and the function of sleep (137, 138). Educational components may also include sleep hygiene recommendations (139). There is no consensus about which information should be included in sleep hygiene recommendations, but recommendations typically include advice to keep the bedroom cool and dark (e.g., avoid daylight and blue light from electronic devices); avoid nicotine, caffeine, and alcohol; and avoid heavy meals and intensive exercise close to bedtime (140).

Examples of behavioral techniques in CBT-I include stimulus control and sleep restriction. Stimulus control is based on the theory that the bed and bedroom no longer function as stimuli for sleep. Instead, the environment is associated with sleeplessness and behaviors incompatible with sleep, such as rumination, worry, anxiety, frustration, watching television, working on the computer, eating, and so on. Stimulus control aims to strengthen the association between bed and sleep and include instructions, such as: go to bed only when sleepy, avoid using the bed for activities other than sleep and sex, and get up from bed if sleepless (124). Sleep restriction is based on the theory that people with insomnia spend too much time in bed in an attempt to get more sleep, which leads to a decreased period of wakefulness during the day and variations in the timing of sleep and wakefulness, which in

turn may lead to fragmented sleep. Sleep restriction aims to consolidate sleep and establish a consistent sleep-wake schedule. Patients are instructed to limit their time in bed to the actual amount of time they spend asleep (but not less than 5 hours) and then gradually extend their time in bed by 15 to 30 minutes a week until they experience sleep as restorative (12).

The most common cognitive technique in CBT-I is cognitive restructuring (141). This technique is based on the theory that a strong and rigid trust in certain beliefs and attitudes can contribute to maintaining emotional distress and maladaptive behaviors. It can thus perpetuate insomnia by creating mental and physical hyperarousal and by disturbing sleep-regulating processes, for example by irregular sleep habits (26, 31). Examples of dysfunctional beliefs and attitudes related to insomnia include: “When I don't get a proper amount of sleep on a given night, I need to catch up the next day by napping or on the next night by sleeping longer,” “After a poor night's sleep, I know that it will interfere with my daily activities on the next day,” and “When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before” (142). Cognitive restructuring aims to change the course of such thoughts by recognizing them, arguing against them, and finding more nuanced ways of thinking, thus reducing sleep-interfering arousal and emotional distress (31, 143).

1.2.3 Management of insomnia in primary health care

1.2.3.1 PHC

PHC is designed to be the first level of care in the health care system and is characterized by a broad and long-term perspective on patients' health, an individually tailored approach, and continuity of care. PHC centers are located close to where people live and work, and in Sweden, as in many countries, PHC is publicly funded. The mission of PHC is to provide care for common physical and mental health problems, prevent disease, promote health, refer patients to specialist care if necessary, and ensure that the population has access to appropriate and cost-effective care (144). PHC centers are staffed by physicians, nurses, and sometimes other professionals, such as physical therapists, occupational therapists, psychologists, and medical social workers. These professionals often work in teams to meet patients' needs.

Two of the largest groups are physicians specialized in family medicine and district nurses, registered nurses who have completed a specialist education in PHC. Nurses are typically the first point of contact for patients seeking PHC. They work in partnership with patients to provide nursing, which refers to actions and/or interventions that aim to promote health, prevent illness, restore health, and alleviate suffering (145). Moreover, nursing aims to strengthen patients' ability to take control over their lives (146).

District nurses work in collaboration with other health care professionals. They also work independently to provide nursing and motivational support for self-care and support for health behavioral change (147). Examples of interventions provided by PHC nurses (e.g.,

district nurses) include group interventions for patients with diabetes (148, 149) and obesity (150).

1.2.3.2 Common treatments for insomnia in PHC

Hypnotics are the most common treatment for insomnia in PHC (111, 151, 152). Zopiclone and zolpidem (“Z-drugs”) are typical, as are antihistamines and antidepressants (113, 153). One study from Norway found that 16% of patients visiting PHC used hypnotics, and that 5.5% used them on a daily basis (90). Although guidelines do not recommend treatment with hypnotics for longer than 4 weeks, studies show that long-term treatment with hypnotics is common in PHC patients. For instance, one UK study found that 95% of patients who were prescribed hypnotics (benzodiazepines or non-benzodiazepines) during a 6-month period had used these drugs for 4 weeks or more (154). Other studies have found that PHC patients can use hypnotics for years (155-157), sometimes despite inadequate effects on insomnia (156).

Sleep hygiene recommendations are another common treatment for insomnia that is provided in PHC, often together with hypnotics (153, 158-160). For instance, a Swedish survey of PHC physicians found that 94% often provided patients with sleep hygiene recommendations (111). Similarly, a study from the United Kingdom found that 88% gave their patients advice about sleep hygiene, although they found it insufficient to improve insomnia (161). Indeed, a review of non-pharmacological treatments for insomnia conducted by the American Academy of Sleep Medicine (162) concluded that sleep hygiene recommendations are insufficient as a single treatment for insomnia. Moreover, a review of sleep hygiene recommendations found that although the recommendations are theoretically reasonable, knowledge regarding individual components of sleep hygiene is limited to acute effects tested in a laboratory on normal sleepers, not in people with insomnia in everyday settings (163).

1.2.3.3 Dissemination of CBT-I in PHC

CBT-I is not yet in widespread routine use in PHC and is not available to the majority of PHC patients. Sleep researchers have been drawing attention to this problem since 2009, but little concrete progress has been made (164, 165). One possible barrier to the dissemination of CBT-I in PHC is insufficient knowledge about insomnia. For instance, PHC professionals tend to view insomnia as a symptom rather than an independent disorder and may focus on treating symptoms of mental health problems rather than treating insomnia (159, 161, 166). Other possible barriers to disseminating CBT-I based interventions in PHC could be a lack of clear and feasible guidelines on how to manage insomnia (166) and a shortage of time during consultations (106). Moreover, there seems to be a mismatch in the treatment preferences of PHC professionals and patients. Studies show that professionals can experience patients' great trust in medication as a barrier to recommending non-pharmacological treatments (107, 161, 166, 167). However, other research indicates that the majority of PHC patients prefer treatments other than medication (91, 168, 169). One study showed that 80% of patients who had been treated with hypnotics

wanted non-pharmacological treatment, but only 9% had been offered such treatment (169). Another study showed that approximately 50% of long-term users of hypnotics wanted to discontinue their use but needed information and advice on how to do it (168).

The Swedish Council on Health Technology Assessment (SBU) reported in 2010 that the main reason CBT-I is not available to PHC patients seems to be the scarcity of professionals who can provide it (111). The report suggested that more CBT-I providers should be trained to increase access to the treatment. Since then, the number of psychologists or psychotherapists in PHC has increased, at least in some parts of Sweden. However, lack of professionals trained in CBT-I is still a barrier to access in Sweden (170) and elsewhere (25, 171, 172). Prompted by the lack of psychologists and psychotherapists, British (164) and American (173) sleep researchers have suggested using stepped care models to increase access to adequate treatment for insomnia in PHC. Stepped care models propose self-help treatments (e.g., books) and manual-guided group CBT-I delivered by ordinary PHC professionals (e.g., nurses) as a lower level of treatment. If patients do not improve, they should be stepped up to a higher (more intensive) level of treatment: individual CBT-I delivered by a psychologist, psychotherapist, or sleep medicine specialist. However, criticisms include potential difficulty identifying patients best suited to each treatment level and ensuring that treatment begins at the appropriate level of care (174).

1.2.3.4 Previous research on CBT-I in PHC

The scientific evidence for CBT-I mainly comes from studies conducted in contexts outside PHC, which included participants other than PHC patients (people from the general population recruited via media, psychiatric clinics, and sleep clinics). Most of these studies excluded people who took hypnotics or had physical and/or mental illnesses (175). Moreover, in most studies, CBT-I was delivered by professionals who are relatively rare in PHC, such as psychologists, psychotherapists, and sleep medicine specialists (176).

An April 2018 literature search found six studies that aimed to investigate CBT-I based interventions to treat insomnia in routine PHC (177-182). All studies had an RCT design; included patients with insomnia; and measured sleep outcomes (i.e., sleep onset latency, time awake after sleep onset, total sleep time, sleep efficiency, and number of nocturnal awakenings). Some studies measured hypnotic drug use (177, 179, 182) and most measured an outcome or outcomes related to the daytime symptomatology of insomnia, including health-related quality of life (177, 179, 182); depression (177, 180); fatigue, sleepiness, and anxiety (177); and pain (181). Those who provided the treatments were trained in CBT-I. Training ranged from 2 days to 6 weeks.

Three studies investigated nurse-led, strictly manual-guided group CBT-I, which means that the intervention was didactic, manualized, followed a standardized format, and used prepared material (e.g., Power Point slides). The control condition was treatment as usual (TAU). Two of these studies were conducted in the United Kingdom. One included 139

(178), and the other, 209 patients with insomnia (179). The third was conducted in Sweden and included 66 patients (177).

The other studies were led by social workers (181, 182), psychologists (181), and physicians (180). One of these, undertaken in the United Kingdom, compared individual CBT-I with TAU in 209 patients with insomnia who had used hypnotics for more than a month (182). Another, from Germany, also included patients who used hypnotics regularly ($n = 80$) (180). That intervention consisted of a self-help program based on CBT-I techniques and stepwise reduction of hypnotics, and the control condition was stepwise reduction of hypnotics only. Finally, a study from the United States included patients who had insomnia and osteoarthritis pain. The intervention was group CBT for insomnia and osteoarthritis pain ($n = 122$), and the control condition was education about sleep and pain ($n = 123$) (181).

When the RCT included in this thesis started, only three of the reviewed studies were published (178, 179, 182). However, the results of all previous studies show that CBT-I based treatment in PHC can improve insomnia severity and sleep variables (i.e., sleep onset latency, time awake after sleep onset, and sleep efficiency). None of the studies provided evidence that the treatment improved the daytime symptomatology of insomnia. There is thus a need to develop and evaluate ways to increase access to effective treatments for insomnia in PHC.

Only a few studies had explored people's experiences of insomnia treatment. One explored experiences of sleep restriction therapy (183), and two explored experiences of Internet CBT-I (184, 185). To the best of my knowledge, no studies had explored PHC patients' experiences of multi-component CBT-I delivered in a group treatment format. Qualitative explorations have the potential to evaluate treatments from the patient's perspective and can shed light on important information about treatment that is not captured in quantitative studies (186, 187). There is thus also a need for qualitative explorations of patients' experiences of insomnia treatment in PHC.

1.3 THE RATIONALE FOR THIS THESIS

Sleep difficulties and insomnia are common in the population, increase the risk for mental and physical illness, and reduce daytime functioning and quality of life. PHC provides first-level care, and people turn to PHC when they seek treatment for insomnia. Research has focused on those who seek treatment for insomnia. Less is known about those who do not seek treatment despite having insomnia and about what makes people feel they have a need for treatment (study I).

CBT-I has been the recommended first-line treatment since 2008. Nevertheless, in PHC, insomnia is commonly treated with hypnotics and/or sleep hygiene recommendations, and CBT-I is not widely available to PHC patients. A main motivation for this thesis project was to bring CBT-I based treatment to more PHC patients. District nurses are one of the largest groups of professionals in PHC and are specially trained in patient education and in supporting health-related behavioral change. They are thus potentially well-suited to deliver treatment based on the techniques of CBT-I. If nurse-led group treatment can effectively improve insomnia (study II), then educating district nurses to provide it would expand the pool of professionals who can treat the high proportion of patients with insomnia who present in PHC.

Guidelines that call for CBT-I to be the treatment of choice for insomnia are based on studies showing that CBT-I improves sleep. Less is known about how effective it is in improving the daytime symptomatology of insomnia, which plays an important role in health and wellbeing (study III). Finally, CBT-I has mainly been evaluated in quantitative studies; only a few studies explore patients' experiences of such treatment. None seem to have investigated multi-component CBT-I delivered in the form of group treatment (study IV).

2 AIMS

2.1 GENERAL AIM

The overall aim of this thesis was to investigate the need for treatment for sleep difficulties in the general population and evaluate a nurse-led group treatment program for insomnia delivered in PHC.

2.2 SPECIFIC AIMS

The specific aims of this thesis were to:

- Study I Investigate factors associated with self-reported need for treatment for sleep difficulties in the general population.
- Study II Evaluate whether nurse-led group treatment for insomnia delivered in PHC is more effective than treatment as usual in decreasing insomnia severity, improving sleep, and reducing hypnotic drug use.
- Study III Evaluate whether nurse-led group treatment for insomnia delivered in PHC is more effective than treatment as usual in improving the daytime symptomatology of insomnia.
- Study IV Explore patients' experiences of nurse-led group treatment for insomnia delivered in PHC.

3 MATERIAL AND METHODS

This thesis includes four studies (Table 1). Study I was a national cross-sectional telephone survey investigating the self-reported need for treatment for sleep difficulties in the general population. Studies II and III were based on an RCT that compared whether a nurse-led group treatment for insomnia in PHC was more effective than TAU. Study IV was a focus group study exploring patients' experiences of the group treatment.

Table 1. Overview of the studies included in this doctoral thesis.

	Aim	Design	Participants	Data collection	Data analysis
I	Investigate factors associated with self-reported need for treatment for sleep difficulties in the general population	National cross-sectional survey	1115 adults randomly selected from the general population of Sweden	Telephone interviews	Descriptive and analytical statistics
II	Evaluate whether nurse-led group treatment for insomnia delivered in primary health care is more effective than treatment as usual in decreasing insomnia severity, improving sleep, and reducing hypnotic drug use	Randomized controlled trial	165 adult primary health care patients with insomnia	Patient-reported outcome measures (questionnaires and sleep diaries); assessments pre- and post-treatment and 1 year after group treatment	Descriptive and analytical statistics
III	Evaluate whether nurse-led group treatment for insomnia delivered in primary health care is more effective than treatment as usual in improving the daytime symptomatology of insomnia.	Randomized controlled trial	165 adult primary health care patients with insomnia	Patient-reported outcome measures (questionnaires); assessments pre- and post-treatment and 1 year after group treatment	Descriptive and analytical statistics
IV	Explore patients' experiences of nurse-led group treatment for insomnia delivered in primary health care	Focus group study	17 adult primary health care patients who had participated in the group treatment	Five focus group interviews	Qualitative content analysis

3.1 STUDY DESIGN AND PARTICIPANTS

3.1.1 Study I

3.1.1.1 Study design

The aim of study I was to investigate factors associated with self-reported need for treatment for sleep difficulties in the general population. In this cross-sectional study, data from a survey conducted by Statistics Sweden were analyzed to investigate self-reported need for treatment for sleep difficulties. Telephone interviews were conducted with a randomly selected sample of the adult general population in Sweden derived from the Swedish Register of the Total Population. The survey was initiated by the Swedish Council on Health Technology Assessment and researchers at Karolinska Institutet in 2008 to investigate sleep difficulties in the general population (111). In study I, the main outcome was people's response to the question "Do you think you need treatment of some kind for sleep difficulties?" ("yes" or "no"). Those who responded "yes" were considered to have a self-reported need for treatment for sleep difficulties, which was the dependent variable in the study.

3.1.1.2 Participants

As shown in Figure 1, 1550 people were included in the survey, and 1128 (72.8%) completed the telephone interview. The 1115 who responded to the outcome question in this study were included in the analyses. They were 18 to 84 years old (mean age 49.4 years; standard deviation [SD] 17.7), 583 (52.3%) were women, and 532 (47.7%) were men.

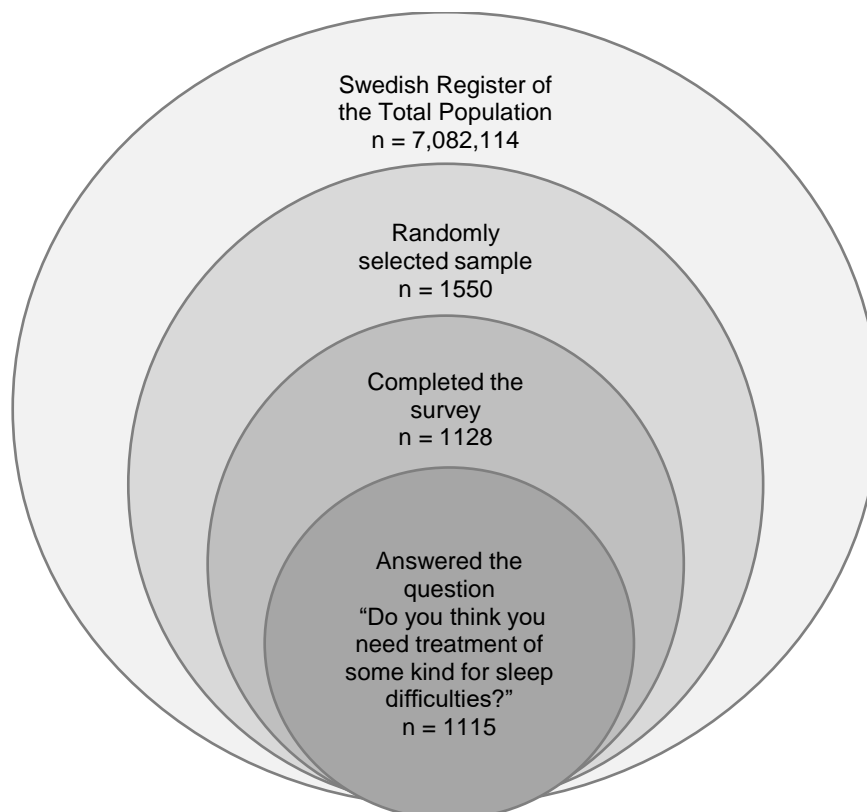


Figure 1. Target population and sampling frame (study I).

3.1.2 Studies II and III

3.1.2.1 Study design

Studies II and III were based on an RCT conducted at seven PHC centers in Stockholm, Sweden, from 2011 to 2014. The aim of study II was to evaluate whether nurse-led group treatment for insomnia delivered in PHC is more effective than TAU in decreasing insomnia severity, improving sleep, and reducing hypnotic drug use. The aim of study III was to evaluate whether nurse-led group treatment for insomnia delivered in PHC is more effective than TAU in improving the daytime symptomatology of insomnia. The group treatment (intervention) was based on the techniques of CBT-I and included seven 2-hour sessions over the course of 10 weeks. TAU (control condition) was expected to consist of hypnotics and/or sleep hygiene recommendations. Patients were assessed pre- and post-treatment. Additionally, the patients who participated in group treatment (intervention group) were assessed 1 year post-treatment.

3.1.2.2 Participants

Patients seeking care at any of the participating PHC centers were included in the study if they were 18 years or older, were interested in participating in group treatment for insomnia, and met the DSM-IV diagnostic criteria for insomnia (23). In line with the DSM 5 diagnostic criteria, patients with both "primary" and "secondary" insomnia were included, but not patients with severe untreated somatic and/or mental illness. Moreover, patients were excluded if they were experiencing a stressful life event (e.g., a life-threatening illness), had bipolar disorder, regularly worked night shifts, scored less than 7 points on the Insomnia Severity Index (ISI) (31), and/or had difficulty participating in the group treatment program or completing forms because of language or cognitive problems. They were also excluded if they had symptoms indicating a sleep disorder other than insomnia (see section 1.1.2 in the background).

To confirm the patient's insomnia diagnosis and assess whether the patient met the other eligibility criteria, the participating nurses conducted a structured screening assessment of patients who were referred to the study by their PHC physician. In an individual 45-minute interview, the nurse used a standardized diagnostic manual, "Structured diagnostic interview for sleep disorder according to DSM-IV" (23), and a semi-structured interview guide (31). If the nurses found the patient eligible, they obtained the patient's written informed consent and then phoned an independent administrator at the Academic Primary Health Care Centre, Stockholm County Council, who randomized the patient into intervention group or control group.

The 165 patients included in the RCT were 20 to 90 years of age (mean age 54 years), and most were women (72.7%). Approximately half were employed (52.7%) and one third (32.7%) were retired. They had experienced insomnia symptoms for a mean of 16 years. Moreover, many had coexisting physical and mental health problems, such as cardiovascular disease (27%), pain problems (24%), anxiety (12%), and depression (10%). A description of

the baseline characteristics of the intervention group and the control group is provided in the results section (section 4.2.1).

3.1.2.3 Intervention

Groups of four to seven patients met for seven 2-hour sessions over the course of 10 weeks. Six sessions took place weekly. The final session took place 4 weeks after the last weekly session. The group treatment (Table 2) was based on the rationale for and general principles of CBT-I (31, 125, 162, 188, 189), CBT-I interventions in previous insomnia treatment studies (136, 179) and self-help books (138, 190, 191), and the author's (C.S.'s) experiences of leading insomnia groups in routine PHC. The group treatment program included educational components and information about techniques. The patients were encouraged to apply the techniques as homework between the sessions, and their experiences of the techniques formed the basis for group discussions. At the end of treatment, each patient created an individual program to help them maintain improvements and to prevent or manage relapse.

Table 2. Overview of the group treatment program for insomnia.

Session	Educational components	Techniques introduced and applied as homework
1	Sleep and sleep regulation Arousal	Individual treatment goals Relaxation Sleep diary
2	Theoretical framework of insomnia Individual analysis of perpetuating factors Intrusive thoughts and worry	Worry time and problem solving Paradoxical intention Sleep efficiency
3	Sleep hygiene Sleep habits	Sleep hygiene Stimulus control Sleep restriction Stepwise reduction of hypnotics
4	Cognitive restructuring Stress	Recognizing dysfunctional beliefs and attitudes about sleep and daytime impairments Stress management
5	Cognitive restructuring Daytime impairments Physiological and psychological effects of hypnotics	Arguing against dysfunctional beliefs and attitudes and formulating more helpful thoughts Coping with daytime impairments
6	Review of techniques Risk analysis Relapse prevention	Individual program for maintaining improvements and preventing relapse
7	Evaluation of individual program Risk analysis Relapse prevention	Problem solving Revision of individual program for maintaining improvements and preventing relapse Evaluation of individual treatment goals

3.1.2.4 Nurse training

The group treatment sessions were led by eight district nurses at seven PHC centers. The nurses had worked as registered nurses for 8 to 35 years (median 29 years) and had been district nurses for 1 to 26 years (median 15 years). None of them had any formal training in CBT.

Nurse training consisted of a 16-hour course provided by C.S. at the Academic Primary Health Care Centre or at the nurses' PHC center. Training included information about the theoretical framework for understanding development and maintenance of insomnia (section 1.1.3). It also included information about how the nurses should perform a structured assessment of insomnia using a semi-structured interview guide (31) to explore insomnia symptoms (e.g., duration, frequency, and severity of symptoms), sleep history (e.g., trigger factors, sleep habits, sleep pattern, and sleep environment), current and previous somatic and mental health problems, treatments, substance use and medications, and symptoms of sleep disorders other than insomnia. Nurses were also trained in how to assess insomnia by using structured assessments such as the manual "Structured diagnostic interview for sleep disorder according to DSM-IV," ISI, sleep diaries, and the Montgomery-Asberg Depression Rating Scale Self-Assessment (MADRS-S) (192, 193).

Moreover, the nurses were trained in how to deliver the group treatment on the basis of the semi-structured treatment manual. The manual outlined the content of each session, including the information the nurses should give to the patients and which techniques they should introduce. To help the nurses feel confident in starting insomnia groups, the manual provided a great deal of detail and included supporting materials the nurses could use with patients. However, the manual was intended to be used as a guide for treatment, and the nurses were encouraged to use their own nursing skills to adapt the treatment to the individual patients.

To record which patients attended the sessions and ensure that the nurses had provided information in accordance with the manual, C.S. e-mailed or phoned each nurse after each group treatment session. This contact also gave the nurses the opportunity to discuss any questions or concerns they had.

3.1.3 Study IV

3.1.3.1 Study design

The aim of study IV was to explore patients' experiences of the nurse-led group treatment for insomnia delivered in PHC. Participants were patients who had taken part in the group treatment. Five focus group interviews (194) were conducted during the last treatment session and analyzed with qualitative content analysis (195).

3.1.3.2 Participants

Seventeen patients participated in the focus group interviews. All were women, and their median age was 57.9 years (25–75 years). Nine were employed and eight were retired. They had participated in the control group in the RCT (studies II and III), and thus met the criteria for insomnia as well as the other eligibility criteria. The focus group participants had been offered the group treatment after the post-treatment assessment and had thus been waiting 3 to 4 months for group treatment. Five patients (four women and one man) were not able to participate in the last group treatment session and thus did not take part in the interviews.

3.2 DATA COLLECTION AND MATERIAL

3.2.1 Study I

Trained interviewers from Statistics Sweden conducted computer-assisted telephone interviews to collect data. They used an interview guide developed by researchers with expertise in sleep medicine. The interview included the question “Do you think you need treatment of some kind for sleep difficulties?” (“yes” or “no”). The outcome variable (dependent variable), self-reported need for treatment for sleep difficulties, was based on the responses to this question (yes = coded 1, and no = coded 0). Moreover, the interview included questions about sociodemographic characteristics, sleep problems, daytime symptoms, interference of sleep difficulties with daily life, persistence of sleep difficulties, physical and mental disorders, perceived general health, health care consultations, and use of prescribed hypnotics.

For some questions, the response alternatives were simply “yes” or “no,” whereas for others, responses were provided on a Likert scale, for example, “never or less than once a month” (= 1) to “daily or almost daily” (= 5). For the analyses, responses were collapsed and dichotomized to indicate “minor problems” (response 1 to 3, coded 0), or “major problems” (response 4 or 5, coded 1). Moreover, some variables were collapsed to create new variables. For instance, the variable “insomnia disorder” was based on the DSM-IV criteria for insomnia and included “major difficulty initiating sleep” and/or “major problems to maintain sleep” and “moderate to severe sleep difficulties that interfered with daily life” (recall period 1 month). This variable was dichotomized into “insomnia” (coded 1), and “no insomnia” (coded 0).

3.2.2 Studies II and III

Data on sociodemographic and clinical characteristics were collected by the nurses during the structured screening assessment. Patient-reported outcome measures were collected before treatment (baseline), directly after treatment (post-treatment), and 1 year after group treatment (1 year post-treatment). Questionnaires and sleep diaries were sent home to patients, together with a postage-paid return envelope. The measures chosen to assess the outcomes are listed below.

Study II

Outcomes	Measures
Insomnia severity (main outcome)	ISI (31, 196, 197). This 7-item scale assesses the severity of sleep disturbance, how much sleep disturbance interferes with daily life and functioning, the noticeability of these impairments to others, worry and distress resulting from sleep disturbance, and general sleep satisfaction/dissatisfaction. Responses are provided on a Likert-scale (0–4). The total score ranges from 0 to 28, and higher scores indicate more severe problems.
Sleep diary variables	14-week sleep diary. The diary covered sleep onset latency, time awake after sleep onset, total sleep time, sleep efficiency, number of nocturnal awakenings, and sleep quality (31, 198).
Clinically important insomnia outcomes	ISI and sleep diaries. Variables derived from the ISI and sleep diaries included an ≥ 8 -point reduction in total ISI score (minimally important difference) (197), a total ISI score of ≤ 11 (no clinical insomnia) (197), sleep onset latency of ≤ 30 min. (considered normal) (199), time awake after sleep onset of ≤ 30 min. (considered normal) (199), and a baseline to post-treatment increase of ≥ 30 min. in total sleep time (200).
Hypnotic drug use	Questionnaire that included the question “How often do you use hypnotic drugs?” Possible answers were “never” = 0, “a few times a year” = 1, “a few times a month” = 2, “a few times a week” = 3, “almost daily” = 4, and “daily” = 5. Responses were dichotomized into no or occasional use (0–2) and regular use (3–5).

Study III

Fatigue severity (main outcome)	The Fatigue Severity Scale (FSS) (201, 202). The scale assesses the interference of fatigue in various aspects of life (e.g., motivation, exercise, physical functioning, work, family, and social life). FSS consists of nine statements, and responses are provided on a Likert scale (1–7). Total score ranges from 0 to 63, and higher scores indicate more severe problems.
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Psychological distress	The General Health Questionnaire (GHQ-12) (203, 204). This is a 12-item questionnaire with responses provided on a Likert scale (0–3). Total score ranges from 0 to 36, and higher scores indicate more severe problems.
Depressive symptoms	MADRS-S (192, 193, 205). This instrument includes nine items with responses provided on a Likert scale (0–6). Total score ranges from 0 to 54. The higher the score, the more severe the symptoms.
Health-related quality of life	The Short Form Health Survey (SF-36) (206). This instrument covers eight domains of health (four physical and four mental). It includes two summary scores or subscales (physical functioning and mental functioning). Total score or summary score ranges from 0 to 100, and higher scores indicate better health/functioning.
General daytime functioning	This variable was assessed with one item on the ISI in which patients were asked to rate the degree (0–4) to which sleep difficulties interfered with general daytime functioning (e.g., work, spare time, concentration, memory, and mood). Responses range from 0 to 4, and higher scores indicate more severe problems.
Specific daytime symptoms	Uppsala Sleep Inventory (USI-27) (207) and ISI. Patients were asked to rate their degree of worry about sleep (ISI) and their degree of daytime sleepiness, daytime bodily tiredness, and difficulty concentrating (USI-27). Responses range from 0 to 4, and higher scores indicate more severe problems.
Dysfunctional beliefs	The 16-item Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS-16) (142). Responses are provided on a 100-mm horizontal line (0 = strongly disagree to 100 = strongly agree). Higher scores indicate greater trust to dysfunctional beliefs. For the analyses, the 16 items were grouped into a 4-theme structure of beliefs: “attributions of the causes and appraisals of the consequences of insomnia,” “issues of worry and helplessness about insomnia,” “unrealistic sleep expectations,” and “trust in hypnotic drugs.”

3.2.3 Study IV

Focus group interviews were used to collect data because they are useful for gaining an understanding of people's experiences of a shared phenomenon (Kitzinger 2005). The interviews took place at the end of the last group treatment session (session seven). The groups selected to participate in the study were those five treatment groups that took place between 2013 and 2015. The focus groups included three or four patients ($n = 17$). Each interview took approximately 70 minutes and was audio recorded and transcribed verbatim. A semi-structured interview guide with open-ended questions (developed by C.S., M.E., and J.W.) was used in the interviews, and probing questions were asked to deepen the discussion (194, 208).

The interviews started with opening questions, such as "Can you tell me about how it was before you started the group treatment?" and "Can you tell me about a night, how it was, how it felt, how it affected you during the day, and what you did so you could sleep?" The following questions then guided the interviews: 1) "How do you experience your sleep after the treatment?" 2) "Is there anything special that helped you?" 3) "What changes have you made?" 4) "What was it that got you to make these changes?" 5) "Was there something that didn't work so well?" 6) "Was there something about the treatment that you thought was hard? That didn't fit you? Why do you think that was?" and 7) "What do you think could be done to improve this program?" To enrich the discussion, probing follow-up questions such as the following were used: "What did you do then?" "What could have helped you to act or feel otherwise?" "What do you think that was due to?" and "Tell me more about that."

3.3 DATA ANALYSIS

3.3.1 Statistical analyses

In studies I, II, and III, statistical analyses were performed with IBM SPSS (version 22, IBM Corp., Armonk, NY, USA). The significance level in all analyses was 5% (two-tailed). Standard descriptive statistics such as frequency, mean, and standard deviation (SD) were used to summarize outcomes and sociodemographic and clinical characteristics. To compare groups (e.g., study I: self-reported need for treatment vs. no need for treatment, insomnia vs. no insomnia; studies II and III: intervention vs. control group), Student's *t*-test was used for continuous and normally distributed data, Mann-Whitney U-test was used for responses provided on ordinal scales and for non-normally distributed data, and Pearson's χ^2 or Fisher's exact test was used for categorical variables.

In study I, logistic regression with odds ratios (ORs) and 95% confidence intervals (CIs) was used to investigate the relationships between the dependent variable (self-reported need for treatment) and explanatory variables (demographic and clinical factors). The Hosmer-Lemeshow goodness-of-fit test was used to test whether the values predicted by the logistic regression models significantly differed from observed values ($P > 0.05$).

The analyses in studies II and III applied the principles of intention-to-treat. This means that all patients who were randomized into the RCT were included in the analyses and analyzed in accordance with their treatment assignment. To handle missing data, analyses employed the last observation carried forward method (i.e., missing post-treatment data were replaced with the patient's baseline data) (209).

For continuous and normally distributed data, paired t-tests were used to investigate differences within groups from baseline to post-treatment. To analyze differences in change from baseline to post-treatment between the intervention and the control group, analysis of variance (ANOVA) for repeated measurements (General Linear Model; group * time) was used (studies II and III). If data were on an ordinal scale, the Mann-Whitney U test was used to compare delta values (the differences from baseline to post-treatment) between groups (study III). In study II, some continuous variables were non-normally distributed (sleep onset latency, time awake after sleep onset and number of nocturnal awakenings). Both parametric and non-parametric tests were performed on these data, and both tests resulted in the same *P* values. The results of the parametric tests were thus presented.

To analyze the pattern of changes in the outcomes over time in the intervention group (baseline, post-treatment, and 1 year post-treatment), ANOVA for repeated measurements was performed if data were continuous (studies II and III), McNemar's test if the data were categorical (study II), and Friedman's test (baseline, post-treatment, and 1 year post-treatment) and Wilcoxon signed-rank test if the data were ordinal (post-treatment and 1 year post-treatment) (study III).

In study II, effect size was calculated using Cohen's *d* (standardized mean difference between groups divided by the standard deviation). An effect size of 0.2 was considered a small effect, 0.5 a medium effect, and 0.8 a large effect (210).

3.3.2 Qualitative analysis

The transcribed text from the focus group interviews was analyzed with qualitative content analysis as described by Graneheim and Lundman (195, 211). The analytical process in study IV is described in Figure 2. The first author (C.S.) and the second author conducted the initial analysis independent of each other before proceeding further with the analytical process. All authors were involved in an ongoing discussion and reflection throughout the analysis until consensus was reached. The approach to the text was inductive, which means that the authors' ideas about the patients' experiences of group treatment emerged from the text (212).

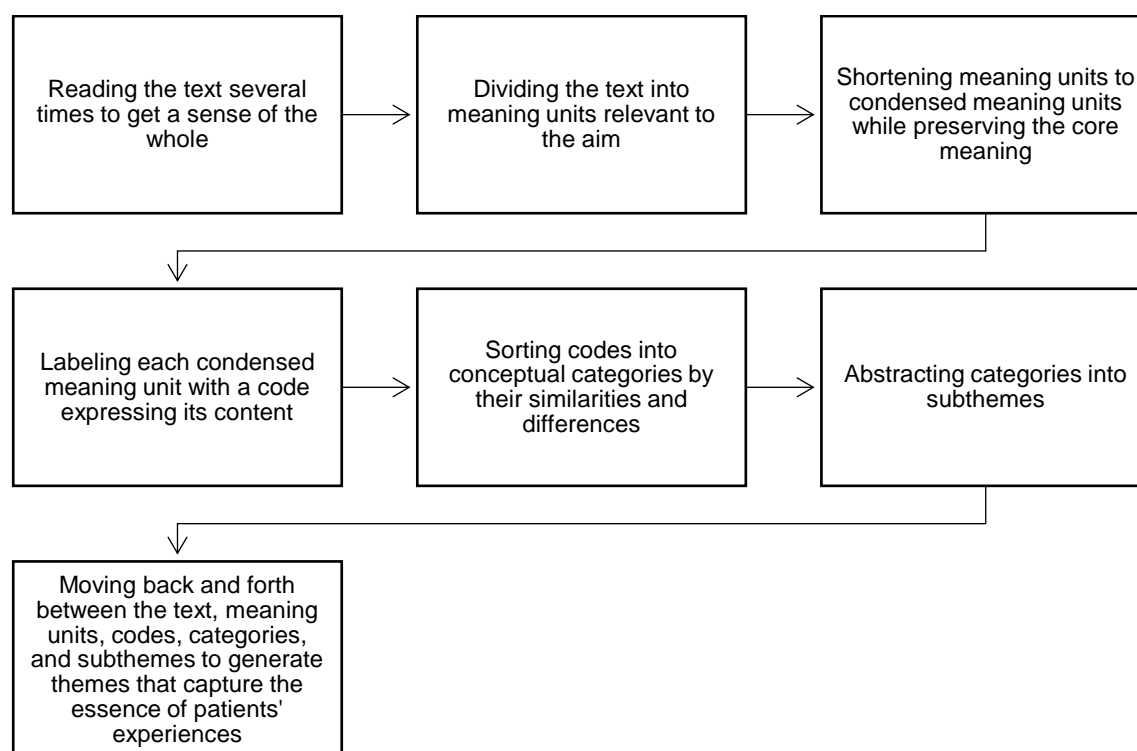


Figure 2. The analytical process guided by qualitative content analysis.

The table below (Table 3) provides an example of the way the analytical process moved from meaning units through condensed meaning units to codes and categories, and subsequently, subthemes and themes.

Table 3. Example of the analytical process.

Meaning unit	Condensed meaning unit	Code	Category	Subtheme	Theme
<i>You got your body to cooperate purely physically. It wasn't just up here, instead the physical, too, that got you to understand, your body to understand.</i>	You got your body to cooperate purely physically	Body cooperates	Trusting your body and its ability to sleep	Trusting in own efficacy	Competence arising from deeper understanding
	Bodily experiences make you understand	Bodily experiences	Learning by doing	Obtaining knowledge and making it your own	

3.4 ETHICAL CONSIDERATIONS

The clinical studies included in this thesis were conducted in accordance with the Declaration of Helsinki (213), a statement of ethical principles for medical research involving human subjects. Ethical approval for all four studies was obtained from the Regional Ethical Review Board in Stockholm (study I, Dnr 2014/256-31/5; studies II and III, Dnr 2011/194-31/1; and study IV, Dnr 2013/484-32). The ethical approval for study IV was obtained as a supplement to the ethical approval for studies II and III (the RCT). Studies II and III followed the Consolidated Standards of Reporting Trials (214), and study IV followed the Consolidated Criteria for Reporting Qualitative Research (215).

Participation in the studies was voluntary, and all participants provided their informed consent. Participants in each study received written and verbal information about the study and were informed that the results would be published. They were ensured that the information collected would be treated confidentially and that no information that could be related to an individual person would be published. Moreover, all were informed that they had the right to stop participating at any point without providing a reason and without any consequences to their care.

4 MAIN RESULTS

4.1 STUDY I

4.1.1 Factors associated with self-reported need for treatment for sleep difficulties

Of the 1115 participants in this study, 139 (12.5%) answered “yes” to the outcome question “Do you think you need treatment of some kind for sleep difficulties?” Of those 139, 69.8% had consulted a physician at some point because of their sleep difficulties, and 36.7% used prescribed hypnotics weekly.

Logistic regression analyses showed that sociodemographic factors were associated with self-reported need for treatment for sleep difficulties. Women (OR 1.46; CI 1.02–2.10; reference group = men), 60- to 69-year-olds (OR 1.93; CI 1.08–3.47; reference group = 18- to 29-year-olds), people on sick leave (OR 18.15; CI 7.21–45.70; reference group = employed), people who were retired (OR 2.62; CI 1.75–3.94; reference group = employed), and people who were unemployed (OR 3.19; CI 1.39–7.34; reference group = employed) had significantly increased odds of reporting a need for treatment for sleep difficulties.

Moreover, all specific sleep complaints measured in the study were significantly associated with self-reported need for treatment for sleep difficulties. Difficulty initiating sleep was the sleep complaint most strongly associated with need for treatment (OR 19.91; CI 13.15–30.16), followed by nonrestorative sleep (OR 16.41; CI 10.89–24.73), early morning awakening (OR 6.03; CI 4.06–8.97), and difficulty maintaining sleep (OR 5.97; CI 4.04–8.81). Of daytime symptoms, difficulty concentrating was the symptom most strongly associated with need for treatment (OR 15.55; CI 8.63–27.99), followed by fatigue (OR 12.36; CI 8.06–18.96), depressed mood (OR 11.58; CI 6.95–19.32), and feeling easily irritated (OR 10.06; CI 5.83–17.36). Need for treatment for sleep difficulties was also associated with poor general health (OR 13.37; CI 7.59–23.56), mental disorder (i.e., psychiatric disorder, depression, and/or burnout) (OR 9.79; CI 6.54–14.67), and several physical disorders, especially fibromyalgia (OR 8.31; CI 3.46–19.97). However, the strongest associations with self-reported need for treatment for sleep difficulties were observed for general insomnia symptoms, such as perceiving sleep difficulties as a major problem in daily life (OR 70.87; CI 37.36–134.46), perceiving that sleep difficulties interfere with daily life (OR 37.41; CI 20.50–68.27), and meeting the diagnostic criteria for insomnia disorder (OR 22.97; CI 14.61–36.12). Moreover, some differences were found between women and men who reported a need for treatment. For instance, women were more likely to have insomnia disorder (OR 2.31; CI 1.15–4.65), perceive sleep difficulties as a major problem in life (OR 2.33; CI 1.16–4.69), and extend their sleep on weekends ($P = 0.01$).

Logistic regression models were conducted to identify the factors most strongly associated with self-reported need for treatment for sleep difficulties (Table 4). All three models were adjusted for age and sex. The first model (Model 1) included specific sleep complaints. In the second model (Model 2), specific daytime symptoms were added to the sleep complaints that

were significant in Model 1. Difficulty initiating sleep was the factor most strongly associated with self-reported need for treatment in Model 1 and in Model 2. In the final model (Model 3), mental and physical disorders were added to the sleep complaints and the daytime symptoms that were significantly associated with self-reported need for treatment for sleep difficulties in Model 2. In the final model, difficulty initiating sleep remained the factor most strongly associated with self-reported need for treatment after taking other factors into account. Nonrestorative sleep, mental disorder, and fatigue were also significantly associated with need for treatment in the final model.

Table 4. Odds ratios (ORs) and 95% confidence intervals (CIs) of the association between self-reported need for treatment for sleep difficulties by explanatory factors after stepwise inclusion of these factors in three models (210, p. 69).

Self-reported need for treatment by explanatory factors		Model 1	Model 2	Model 3
Sleep complaints		OR (CI)	OR (CI)	OR (CI)
Difficulty initiating sleep	No	1 (Reference)	1 (Reference)	1 (Reference)
	Yes	7.64 (4.64–12.60)	7.47 (4.46–12.52)	6.29 (3.67–10.78)
Early morning awakening	No	1 (Reference)		
	Yes	1.29 (0.75–2.23)		
Difficulty maintaining sleep	No	1 (Reference)	1 (Reference)	1 (Reference)
	Yes	2.06 (1.23–3.43)	1.78 (1.03–3.07)	1.52 (0.85–2.72)
Nonrestorative sleep	No	1 (Reference)	1 (Reference)	1 (Reference)
	Yes	6.77 (4.10–11.17)	3.67 (2.08–6.49)	3.70 (2.05–6.69)
Daytime symptoms				
Fatigue	No		1 (Reference)	1 (Reference)
	Yes		2.95 (1.54–5.65)	2.95 (1.53–5.68)
Depressed mood	No		1 (Reference)	1 (Reference)
	Yes		2.46 (1.08–5.57)	1.94 (0.85–4.42)
Easily irritated	No		1 (Reference)	
	Yes		2.01 (0.84–4.80)	
Difficulty concentrating	No		1 (Reference)	
	Yes		1.65 (0.65–4.18)	
Mental and physical disorders				
Mental disorder	No			1 (Reference)
	Yes			3.01 (1.59–5.67)
Joint pain	No			1 (Reference)
	Yes			1.16 (0.64–2.10)
Gastrointestinal disorder	No			1 (Reference)
	Yes			1.07 (0.60–1.90)
Hypertension	No			1 (Reference)
	Yes			1.26 (0.64–2.47)
Asthma	No			1 (Reference)
	Yes			0.88 (0.45–1.74)
Heart disease	No			1 (Reference)
	Yes			1.54 (0.67–3.54)
Urogenital disorder	No			1 (Reference)
	Yes			1.73 (0.75–3.97)
Diabetes	No			1 (Reference)
	Yes			1.78 (0.72–4.42)
Fibromyalgia	No			1 (Reference)
	Yes			1.81 (0.50–6.54)
Sex				
Men		1 (Reference)	1 (Reference)	1 (Reference)
	Women	0.84 (0.53–1.34)	0.71 (0.43–1.17)	0.67 (0.40–1.13)
Age				
Continuous variable		1.01 (0.10–1.03)	1.02 (1.01–1.03)	1.01 (0.10–1.03)
Hosmer-Lemeshow				
P value		0.18	0.67	0.48

4.1.2 Insomnia and no need for treatment

More than one-third (37.7%) of people who met the criteria for insomnia disorder ($n = 114$) reported no need for treatment for sleep difficulties ($n = 43$). Further investigation of this group showed that significantly fewer of those who did not need treatment than those who did ($n = 71$) reported difficulty initiating sleep ($P = 0.001$), fatigue ($P = 0.022$), depressed mood ($P = 0.001$), easily irritated ($P = 0.033$), difficulty concentrating ($P = 0.004$), persistent sleep difficulties ($P = 0.002$), poor general health ($P = 0.032$), and mental health problems ($P < 0.001$). Moreover, fewer experienced sleep difficulties as an overall problem in life ($P < 0.001$), used hypnotics weekly ($P < 0.001$), and had consulted a physician because of sleep difficulties ($P < 0.001$). Additionally, the people who said they did not need treatment reported shorter sleep onset latency (49 min [SD 44.3] vs. 72 min [SD 70.5]; $P = 0.04$) and approximately 1 hour more of sleep on weeknights (6.42 hours [SD 1.5] vs. 5.38 hours [SD 1.6]; $P = 0.001$) than those who said they needed treatment.

4.2 STUDIES II AND III

4.2.1 Flow of patients through the trial

The physicians assessed 218 patients eligible to participate in the study. Of those 218, the nurse was unable to contact 11 to invite them to the structured screening assessment, 31 declined to participate, and 11 met the exclusion criteria and were excluded from the study.

Of the 165 patients included in the RCT, 90 were randomized to group treatment for insomnia (intervention group) and 75 to TAU (control group). The post-treatment dropout rate was the same in both groups: 20%. The majority of the dropout took place before treatment (eight in the intervention and four in the control group). In the intervention group, six patients dropped out during ongoing treatment. In accordance with the principles of intention-to-treat (209), those who completed the baseline assessment were included in the analyses (intervention group = 82, control group = 71). In the intervention group, 54 of those 72 who participated in group treatment completed 1 year follow up assessments 9 months after group treatment. Figure 3 shows the flow of patients through the trial.

4.2.2 Baseline characteristics

The distribution of sociodemographic and clinical variables was equal (non-significant, $P > 0.05$) in the intervention group and the control group at the time of randomization. These variables included sex, age, educational level, employment status, marital status, health problems, medications, and duration of insomnia symptoms. Hypnotics were used by 72.2% in the intervention group and 66.7% in the control group ($P = 0.439$). One exception to the equal distribution was gastrointestinal problems, which were more prevalent in the intervention than control group ($P = 0.021$). Moreover, outcomes assessed at baseline were similar in the two groups, except that depressive symptoms (total MADRS-S score) were more severe in the intervention than in the control group ($P = 0.037$).

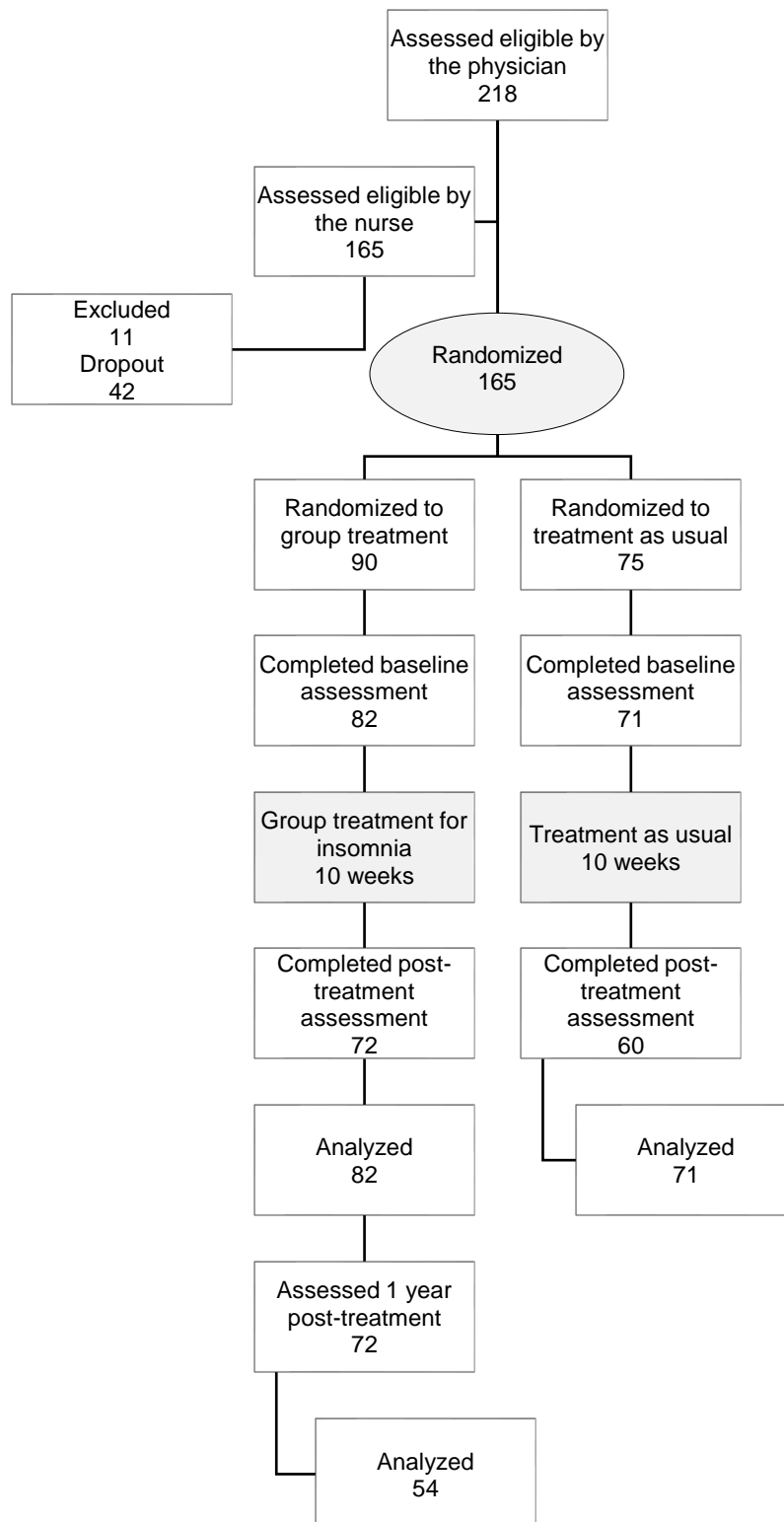


Figure 3. Flow of patients through the trial (studies II and III).

4.2.3 Effects of treatment on insomnia severity, sleep, and hypnotic drug use

Study II showed that insomnia severity (total ISI score), the main outcome of the study, decreased significantly more ($P < 0.001$) after group treatment than after TAU (Table 5). The effect size was large: 1.23 (Cohen's d).

Moreover, all measured sleep variables improved significantly more in the intervention than in the control group (Table 5). The effect sizes for sleep variables were small (total sleep time, time awake after sleep onset, number of nocturnal awakenings, and sleep quality) to medium (sleep onset latency and sleep efficiency).

Significantly more patients in the intervention group than in the control group had results after treatment that are considered clinically important insomnia outcomes (i.e., an ≥ 8 -point reduction in total ISI score, a total ISI score of ≤ 11 , sleep onset latency of ≤ 30 min., time awake after sleep onset of ≤ 30 min., and a baseline to post-treatment increase of ≥ 30 min. in total sleep time). Additionally, significantly fewer patients reported regular use of hypnotics (a few times a week to daily) after group treatment than after TAU (Table 6).

Table 5. Insomnia severity (ISI) and sleep diary variables at baseline and post-treatment in the intervention group ($n = 82$) and the control group ($n = 71$).^{a, b} (216, p. 37).

Variables	Intervention group	Control group	Analysis of variance
	Mean (SD)	Mean (SD)	Group * time
Insomnia severity (ISI total score)			
Baseline	18.41 (4.4)	17.01 (4.4)	
Post-treatment	10.74 (4.4)	16.55 (5.1)	$P < 0.001$
Sleep onset latency (min.)			
Baseline	68.10 (45.5)	58.21 (37.9)	
Post-treatment	39.45 (27.1)	56.98 (38.6)	$P < 0.001$
Total sleep time (min.)			
Baseline	358.90 (65.9)	355.04 (60.3)	
Post-treatment	384.21 (56.2)	360.81 (60.1)	$P = 0.008$
Time awake after sleep onset (min.)			
Baseline	90.05 (62.3)	83.46 (53.3)	
Post-treatment	55.54 (57.5)	76.85 (49.1)	$P < 0.001$
Sleep efficiency (%)			
Baseline	70.5 (13.1)	72.7 (12.2)	
Post-treatment	81.3 (11.8)	74.1 (11.3)	$P < 0.001$
Number of nocturnal awakenings			
Baseline	2.28 (1.4)	2.13 (1.2)	
Post-treatment	1.69 (1.1)	2.10 (1.1)	$P = 0.002$
Sleep quality (1-5)			
Baseline	2.76 (0.6)	2.91 (0.6)	
Post-treatment	3.26 (0.7)	3.01 (0.7)	$P < 0.001$

^aThe number of patients analyzed varied for certain outcomes, as two patients in the intervention group and four in the control group did not complete the sleep diary. ^bAll analyses employed the last observation carried forward method. Abbreviations: ISI, Insomnia Severity Index; SD, standard deviation.

Table 6. Percentage of patients with clinically important insomnia outcomes and percentage with regular hypnotic drug use (a few times a week to daily) in the intervention group (n = 82) and the control group (n = 71).^{a, b} (216, p. 37).

Variables	Intervention group	Control group	χ^2
	n (%)	n (%)	P
A reduction of ≥ 8 in total Insomnia Severity Index score			
Post-treatment	41 (50.0)	3 (4.2)	0.001
Insomnia Severity Index cutoff ≤ 11			
Baseline	6 (7.3)	6 (8.5)	1.000
Post-treatment	51 (62.2)	10 (14.1)	0.001
Sleep onset latency ≤ 30 minutes			
Baseline	17 (29.3)	18 (26.9)	0.395
Post-treatment	41 (51.2)	18 (26.9)	0.004
Time awake after sleep onset ≤ 30 min.			
Baseline	12 (15.0)	9 (13.4)	0.489
Post-treatment	34 (42.5)	13 (19.4)	0.004
Increased total sleep time ≥ 30 minutes			
Post-treatment	34 (42.5)	12 (17.9)	0.001
Regular hypnotic drug use			
Baseline	44 (53.7)	33 (46.5)	0.419
Post-treatment	23 (28.0)	37 (52.1)	0.003

^aThe number of patients analyzed varied for certain outcomes, as two patients in the intervention group and four in the control group did not complete the sleep diary. ^bAll analyses employed the last observation carried forward method.

4.2.4 Effects of treatment on the daytime symptomatology of insomnia

In study III, several outcomes related to the daytime symptomatology of insomnia were analyzed in the intervention group (group treatment) and control group (TAU). The main outcome was fatigue severity (total FSS score), which decreased significantly more ($P < 0.001$) after group treatment than after TAU (Table 7).

Two measurements of mood also decreased significantly more after group treatment than after TAU (Table 7): level of psychological distress (total GHQ-12 score) and depressive symptoms (total MADRS-S score, both with and without the sleep domain, $P < 0.001$). Moreover, the intervention group's scores on the health-related quality of life (SF-36) mental functioning subscale improved significantly more, but their scores on the physical functioning subscale did not (Table 7), even if two of the domains in the physical functioning subscale did: physical functioning ($P = 0.017$) and physical role limitation ($P = 0.024$). The results regarding the SF-36 domains were included in the supplementary materials published with the electronic version of the manuscript, "Impact of group treatment for insomnia on daytime symptomatology: Analyses from a randomized controlled trial in primary care" (217).

Additionally, group treatment resulted in greater improvements in general daytime functioning and in specific daytime symptoms (worry about sleep, daytime sleepiness, daytime bodily tiredness, and difficulty concentrating) than TAU (Figure 4). This was also true for insomnia-related dysfunctional beliefs, divided into four themes of beliefs (DBAS-

16), which decreased significantly more after group treatment than after TAU (Table 7): “attributions of the causes and appraisals of the consequences of insomnia,” “issues of worry and helplessness about insomnia,” “unrealistic sleep expectations,” and “trust in hypnotic drugs.”

Table 7. Fatigue, mood, health-related quality of life, and dysfunctional beliefs: baseline and post-treatment scores in the intervention group (n = 82) and the control group (n = 71).^{a, b} (217, p. 131).

Variables	Intervention group	Control group	Analysis of variance
	Mean (SD)	Mean (SD)	Group * time
Fatigue severity (FSS)			
Baseline	37.18 (11.9)	35.89 (12.1)	
Post-treatment	31.02 (13.4)	35.73 (12.8)	$P < 0.001$
Mood			
Psychological distress (GHQ-12)			
Baseline	13.74 (6.2)	13.10 (5.7)	
Post-treatment	9.82 (6.2)	11.49 (5.9)	$P < 0.001$
Depressive symptoms ^c (MADRS-S)			
Baseline	13.16 (7.5)	10.79 (6.2)	
Post-treatment	9.11 (6.8)	10.72 (6.3)	$P < 0.001$
Health-related quality of life (SF-36)			
Mental functioning			
Baseline	38.36 (13.2)	41.26 (11.6)	
Post-treatment	44.09 (12.3)	40.79 (12.3)	$P < 0.001$
Physical functioning			
Baseline	44.84 (10.5)	46.19 (11.1)	
Post-treatment	45.46 (10.7)	47.48 (11.6)	$P = 0.558$
Dysfunctional beliefs (DBAS, themes)			
Appraisals of the consequences of insomnia			
Baseline	50.61 (17.7)	52.33 (18.3)	
Post-treatment	44.40 (23.3)	59.38 (22.4)	$P < 0.001$
Worry and helplessness about insomnia			
Baseline	51.49 (19.9)	51.60 (20.1)	
Post-treatment	38.67 (21.3)	49.75 (20.2)	$P < 0.001$
Unrealistic sleep expectations			
Baseline	49.13 (21.0)	45.96 (26.6)	
Post-treatment	37.61 (22.8)	46.51 (23.2)	$P < 0.001$
Trust in hypnotic drugs			
Baseline	44.14 (25.2)	42.80 (26.1)	
Post-treatment	27.37 (25.4)	43.37 (26.5)	$P < 0.001$

^aHigher scores indicate more severe problems or stronger trust in dysfunctional beliefs, except for the variables physical and mental functioning, for which higher scores indicate better functioning. ^bThe number of patients analyzed varied by outcome. ^cIncluding the sleep domain. Abbreviations: SD, standard deviation; FSS, Fatigue Severity Scale; GHQ, General Health Questionnaire; MADRS-S, Montgomery-Asberg Depression Rating Scale – Self; SF-36, Short Form Health Survey (subscales); DBAS, Dysfunctional Beliefs and Attitudes about Sleep scale, 16-item version (themes).

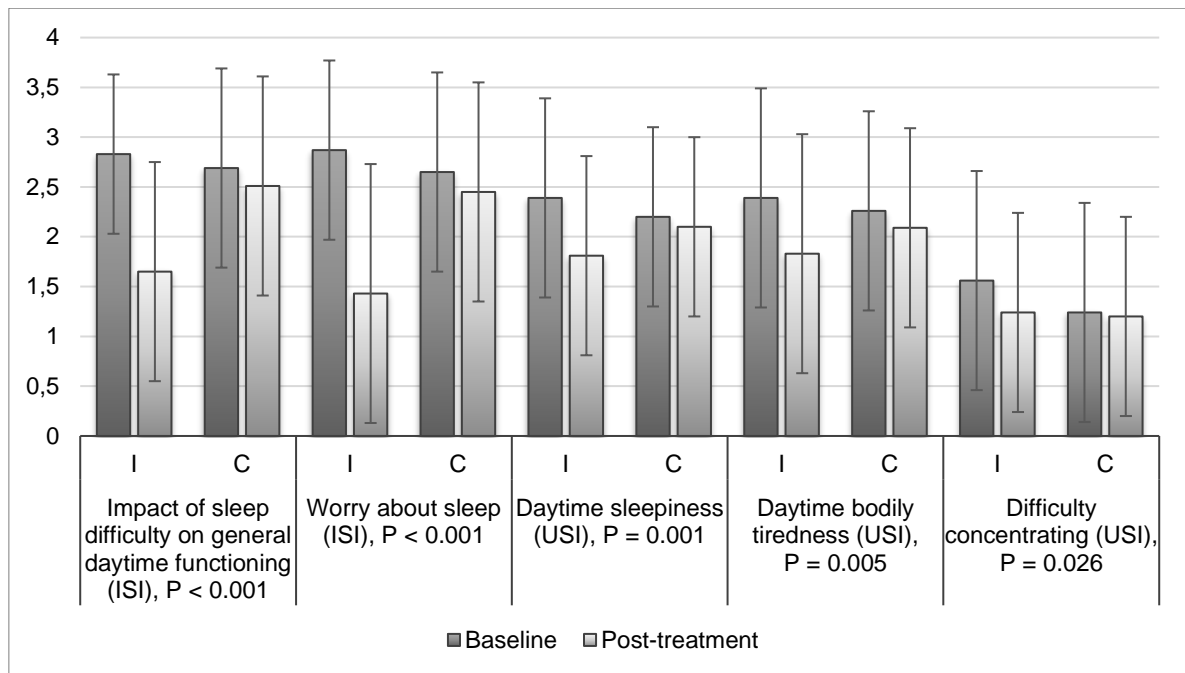


Figure 4. General daytime functioning improved and specific daytime symptoms (mean scores 0–4) decreased significantly more in the intervention group ($n = 82$) than the control group ($n = 71$) from baseline to post-treatment (Mann-Whitney U test based on between-group differences in change from baseline to post-treatment). Abbreviations: I, intervention group; C, control group; ISI, Insomnia Severity Index (item); USI, Uppsala Sleep Inventory scale (item) (217, p. 132).

4.2.5 1 year follow-up of group treatment

Of the 72 patients who participated in group treatment (intervention group), 54 completed all assessments (baseline, post-treatment, and 1 year post-treatment) and were included in the 1-year follow-up of group treatment (Figure 5). The results showed that all the outcomes measured in study II and in study III (except the SF-36 physical functioning subscale and the SF-36 domain bodily pain) improved significantly ($P < 0.05$) from baseline to the 1-year follow-up of group treatment. Some outcomes worsened slightly from post-treatment to 1 year post-treatment: insomnia severity, all sleep variables except total sleep time, psychological distress, depressive symptoms, mental functioning (SF-36 subscale), physical role limitation (SF-36 domain), and “trust in hypnotic drugs.” Some remained the same: hypnotic drug use, total sleep time, physical functioning (SF-36 domain), general health (SF-36 domain), general daytime functioning, specific daytime symptoms, and “attributions of the causes and appraisals of the consequences of insomnia.” Some improved slightly: fatigue severity, “worry and helplessness about insomnia,” and “unrealistic sleep expectations.”

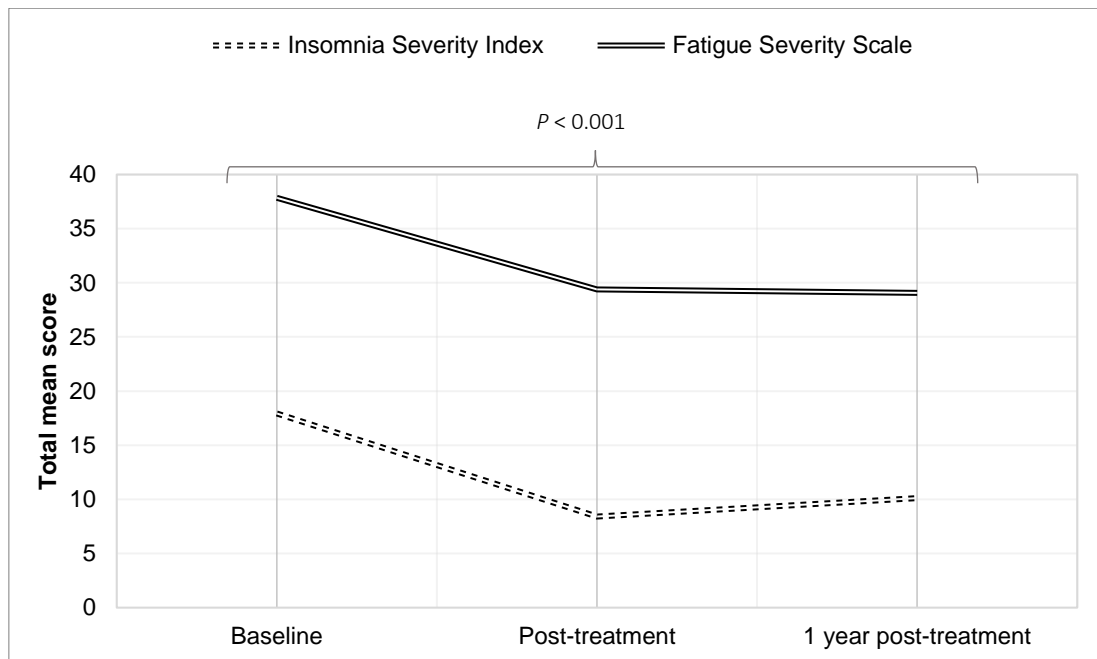


Figure 5. Change in Insomnia Severity Index and Fatigue Severity Scale scores in the intervention group (n = 54) from baseline to 1 year post-treatment.

4.3 STUDY IV

The qualitative content analysis of focus group interviews with patients who had participated in the group treatment revealed 37 categories and 12 subthemes. Four themes that captured the essence of patients' experiences of group treatment emerged from the analysis (Table 8). The theme "Involvement and trust open the door for change" expresses how motivation to engage in treatment arose from patients' own desire for change, from being together with others who shared or understood their struggles, and from feeling emotionally affirmed and trustful. The theme "Competence arising from deeper understanding" denotes how patients obtained knowledge and made it their own, which enabled them to develop functional sleep habits and let go of sleep performance and worry. It also expresses how patients' ability to impact their insomnia increased their trust in their own efficacy and helped them persist in behavioral change. However, treatment was tough, and patients could feel challenged by external circumstances. They could also distrust their own efficacy. The theme "Struggling with vulnerability and failure" emerged from these findings. Patients experienced different life circumstances and adapted the techniques to their needs and abilities by focusing on what felt right for them, and the theme "Tailoring treatment to individual needs" expresses these experiences.

Table 8. Overview of categories, subthemes, and themes that illuminate patients' experiences of group treatment for insomnia.

Categories	Subthemes	Themes
<p>Attracted by a non-pharmacological treatment option</p> <p>Health concerns</p> <p>Hope for change for the better</p> <p>Commitment to oneself</p>	Desiring positive change	Involvement and trust open the door for change
<p>Being pushed forward by meeting in person</p> <p>Commitment to the group</p>	Being together with others pushes you forward	
<p>Feeling understood and less lonely</p> <p>Feeling involvement</p> <p>Trusting authorities</p>	Feeling emotionally affirmed and trustful	
<p>Gaining knowledge via educational components</p> <p>Learning by doing</p> <p>Reflecting on own thinking and behavior</p> <p>Receiving information repeatedly and processing it</p>	Obtaining knowledge and making it your own	Competence arising from deeper understanding
<p>Experiencing the development of routines as helpful</p> <p>Experiencing reducing time in bed as helpful</p> <p>Finding short daytime naps helpful</p>	Developing functional sleep habits	
<p>Being able to dedramatize sleep and insomnia</p> <p>Experiencing sleepiness as less of an enemy and more of an ally</p> <p>Being able to relax and cope with unhelpful thoughts</p>	Letting go of sleep performance and worry	
<p>Feeling trust in yourself and the techniques</p> <p>Trusting your body and its ability to sleep</p> <p>Feeling the power to act</p> <p>Feeling motivated to keep going when you experience that it works</p>	Trusting in own efficacy	
<p>Difficulty letting go of sleep performance and worry</p> <p>Challenged by tiredness, exhaustion, and worries</p> <p>Techniques are tough</p>	Finding treatment tough	Struggling with vulnerability and failure
<p>Circumstances outside your control</p> <p>Techniques interfere with social commitments</p>	Challenged by external circumstances	
<p>Attributing failure to oneself</p> <p>Experiencing feelings of helplessness and failure</p> <p>Feeling that improvements are fragile and the future is uncertain</p>	Distrusting own efficacy	
<p>Techniques don't fit everyone's needs</p> <p>Differing experiences due to differing lives</p>	Experiencing different life circumstances	Tailoring treatment to individual needs
<p>Adapting techniques to fit own needs, abilities, and inclinations</p> <p>Feeling your way forward</p> <p>The leader adapts the techniques to fit the individual</p> <p>Everyone can find something</p>	Focusing on what feels right	

5 DISCUSSION

5.1 MAIN FINDINGS

The overall aim of this thesis was to investigate the need for treatment for sleep difficulties in the general population and to evaluate a nurse-led group treatment program for insomnia delivered in PHC. The findings of this thesis contribute to knowledge about what makes people feel they need treatment for sleep difficulties (study I), the effectiveness of group treatment for insomnia led by nurses in PHC (studies II and III), and patients' experiences of participating in the group treatment (study IV).

Study I showed that 12.5% of a randomly selected sample of the general population reported they needed some kind of treatment for sleep difficulties. Difficulty initiating sleep was the factor most strongly related to need for treatment regardless of age, sex, and other clinical factors (other sleep complaints, daytime symptoms, and physical health problems). Other closely related factors were nonrestorative sleep, mental health problems, and fatigue.

Study II showed that nurse-led group treatment for insomnia delivered in PHC was more effective than TAU in decreasing insomnia severity, improving sleep (i.e., sleep onset latency, total sleep time, time awake after sleep onset, sleep efficiency, number of nocturnal awakenings, and sleep quality), and reducing hypnotic drug use. Study III showed that nurse-led group treatment for insomnia was more effective than TAU in improving the daytime symptomatology of insomnia. More specifically, fatigue severity, depressive symptoms, and psychological distress decreased, and health-related quality of life improved. The impact of sleep difficulties on general daytime functioning decreased, as did specific daytime symptoms (worry about sleep, daytime sleepiness, daytime bodily tiredness, and difficulty concentrating) and dysfunctional beliefs ("attributions of the causes and appraisals of the consequences of insomnia," "issues of worry and helplessness about insomnia," "unrealistic sleep expectations," and "trust in hypnotic drugs"). Additionally, all improvements found after group treatment were maintained 1 year later (studies II and III).

Study IV illuminated patients' experiences of motivation, change, and challenges in the group treatment for insomnia. Motivation to engage in treatment arose from patients' own desire for change, from being together with others who shared or understood their struggles, and from feeling emotionally affirmed and trustful. They obtained knowledge and made it their own, which enabled them to develop more functional sleep habits and let go of sleep performance and worry. Feeling able to impact their insomnia increased patients' trust in their own efficacy and helped them persist in behavioral change. Nevertheless, treatment was sometimes tough. They could feel challenged by external circumstances and could distrust their own efficacy. However, patients adapted the techniques to fit their own needs and abilities by focusing on what felt right for them. Four themes captured the essence of patients' experiences: "involvement and trust open the door for change," "competence arising from deeper understanding," "struggling with vulnerability and failure," and "tailoring treatment to individual needs."

5.2 DISCUSSION OF RESULTS IN RELATION TO PREVIOUS RESEARCH

5.2.1 Factors associated with self-reported need for treatment for sleep difficulties

Study I adds to our knowledge about the self-reported need for treatment for sleep difficulties in a sample of a national population. The results showed that insomnia predicted a self-reported need for treatment, as did various kinds of sleep complaints, daytime symptoms, and physical and mental disorders. Some factors were more closely related to a need for treatment than others, which could mean that some factors were more problematic to cope with than others. For example, difficulty initiating sleep was the factor most strongly associated with self-reported need for treatment, even after other clinical factors related to sleep difficulties were taken into account.

It might be more problematic to cope with difficulty initiating sleep than with other sleep difficulties (frequent awakenings, early morning awakenings, and nonrestorative sleep). Previous studies show that difficulty initiating sleep tends to be more persistent (86) and leads to shorter sleep duration than other sleep difficulties (96). Moreover, difficulty initiating sleep is more closely related to mental health problems (73, 218, 219) and hypnotic drug use than are other sleep complaints (73). Difficulty initiating sleep has also been associated with nonrestorative sleep (220), another strong predictor of the perceived need for treatment for sleep difficulties in study I. However, previous studies show that the main reasons why people seek treatment in PHC for sleep difficulties and insomnia are fatigue and psychological distress (89). Those results are in line with the study I finding that fatigue and mental health problems were also closely related to a need for treatment.

Some differences were observed between women and men who reported that they needed treatment for sleep difficulties (study I). For example, women were more likely to have insomnia disorder and perceive sleep difficulties as a major problem in life. These findings are consistent with those of previous studies showing that women are more vulnerable to insomnia than men (77). Moreover, people aged 60 to 69 and people who were retired were more likely to report a need for treatment for sleep difficulties than people 18 to 29 years and those who were employed (study I). This finding agrees with those of previous studies showing that sleep becomes shorter, more fragmented, and more easily disturbed as people age (17). Studies have also suggested that changes in everyday life, such as lower levels of social and physical activity, irregular sleep habits, more health problems, and more medications may contribute to sleep difficulties in older adults (221).

An additional finding of study I was that 30% of the people who thought they needed treatment for their sleep difficulties had never consulted a physician about these difficulties. This finding is in line with those of previous studies, which show that many people do not seek treatment despite sleep difficulties and insomnia (86, 89, 103-105). Furthermore, although insomnia predicted a need for treatment for sleep difficulties, 38% of those with insomnia reported they did not need any treatment (study I). Fewer of those with insomnia who felt they did not need treatment than those with insomnia who felt they needed treatment

reported difficulty initiating sleep, and fewer reported nonrestorative sleep. Moreover, fewer reported major problems with fatigue, judged their general health as poor, had mental health problems, experienced sleep difficulties as an overall problem in life, and had sought treatment because of sleep difficulties (28% vs. 72%). These findings may indicate that at least some people with insomnia might feel that they can manage on their own. Study I may thus add information about the people who do not seek treatment for insomnia.

5.2.2 Nurse-led group treatment for insomnia in primary health care

5.2.2.1 Results in relation to previous studies of insomnia treatment in PHC

The few studies that have investigated CBT-I based treatment in PHC have similarities to the RCT in this thesis but also differ from it in important ways (177-182). As in the current RCT, in those studies, non-CBT specialists, including nurses, social workers, and physicians, were trained to deliver the interventions, which were conducted in routine PHC, apparently without additional resources such as extra time or money. They differed, however, in that they were designed by psychologists or sleep medicine specialists. In the current RCT, the intervention was designed by nurses for nurses.

The interventions most like the present one (177-179) were similar in content, led by nurses, and had a group treatment format. Moreover, they were strictly manual-guided, which likely meant that the nurses' freedom to adapt the intervention to patients' circumstances was limited. To maintain the flexibility needed to treat patients in real clinical settings, it is important for those who provide clinical interventions to have a certain degree of independence and leeway in their work (222). The present intervention was thus not strictly manual-guided, and group leaders were encouraged to use their professional knowledge and skills to adapt the treatment to the circumstances of individual groups and patients.

The previous studies of CBT-I based treatments in PHC found that treatment had a significant effect on insomnia severity measured by ISI (177, 181) or on sleep quality (179, 180, 182) measured by the Pittsburgh Sleep Quality Index (223). The Pittsburgh index measures aspects of insomnia similar to those measured by ISI. Moreover, they found significant effects on sleep diary variables, including sleep onset latency (177-179, 182) and time awake after sleep onset (177-179). One of the previous studies also found significant effects on sleep efficiency (179), and another, on reduced use of hypnotics (182). Only one of the six studies showed sustained improvements in outcomes related to the daytime symptomatology of insomnia (the SF-36 domains vitality and mental health) (179). The improvements in insomnia severity and sleep outcomes found in study II were comparable to those found in reviews (200) and meta-analyses of CBT-I outside PHC (224, 225).

5.2.2.2 Clinical relevance and interpretation of results

Statistically significant results do not necessarily mean that the patients perceived the improvements as beneficial. Methodological studies have investigated when indicators of insomnia severity (197) and sleep variables (199, 200) become clinically meaningful. Fewer

if any such methodological studies have been conducted on outcomes related to the daytime symptomatology of insomnia.

In study II, 50% of the patients decreased more than 7 points in insomnia severity scores after group treatment (vs. 4% after TAU), and 62% were below the 12-point threshold for clinical insomnia (vs. 14% after TAU). Such treatment outcomes have been considered clinically meaningful as they are related to improved quality of life and reduced depressive symptoms, anxiety, and fatigue (197). Moreover, sleep improved after group treatment, and approximately half of patients had at least one outcome that is considered clinically relevant (199, 200). For example, 51% had a sleep onset latency of 30 minutes or less after group treatment (vs. 27% after TAU) (199). Another indicator of clinical relevance is decreased use of hypnotics (morin 1999). In study II, fewer patients (28%) used hypnotics on a regular basis after group treatment than after usual treatment (52%). This is clinically important because of hypnotics' adverse side effects and limited long-term effects (226, 227).

There are no well-established indicators of the clinical relevance of changes in daytime functioning and daytime symptoms. We therefore could not assess whether the changes found in study III are clinically meaningful or not. However, patients reported improvements across multiple domains of the daytime symptomatology of insomnia, and all improvements were maintained a year after group treatment. It thus seems relevant to discuss the potential relevance of these results.

In study II, most patients were more fatigued than people in the general population (mean FSS score in the general population = 2.3) (228) both before and after group treatment. However, fatigue (measured by mean FSS score) did diminish from 4.13 to 3.45. The suggested cut-off score for fatigue outside the normal range in people with sleep-wake disorders (e.g. insomnia) is ≥ 4 (mean FSS score) (202). Previous studies show that fatigue severity (229), which decreased after group treatment in study III, and insomnia severity (230), which decreased after group treatment in study II, are both strongly associated with depression. Although patients had relatively low depressive symptom scores before treatment, their symptom scores decreased from 13 to 9 (total MADRS-S scores) after group treatment (study III). Similarly, psychological distress decreased after group treatment, from 14 to 10 (total GHQ-12 scores). In the general population, GHQ-12 scores of 11 to 12 are typical (204). Like fatigue, psychological distress is a factor that prompts people to seek treatment for insomnia (89). Health-related quality of life, especially mental functioning (measured by the SF-36 subscale) also improved after group treatment (study III). Mental functioning is commonly the aspect of health-related quality of life that is most affected in people with-insomnia (231).

Group treatment reduced the impact of sleep difficulties on general daytime functioning (study III). Daytime symptoms also decreased (worry about sleep, daytime bodily tiredness, daytime sleepiness, and difficulty concentrating); all are included in the diagnostic criteria for insomnia (ICSD-3). Additionally, patients' beliefs and attitudes about sleep became more nuanced, which in turn could have facilitated and helped maintain other improvements, such

as those related to sleep, fatigue, and mental health. This reasoning is based on the findings of previous studies, which show that dysfunctional beliefs and attitudes about sleep are related to worry, emotional distress, and heightened arousal, all of which serve to maintain insomnia (232), and that reductions in such beliefs are related to sleep improvements after CBT-I (233-235). Moreover, studies show that dysfunctional beliefs and attitudes about sleep modulate the relationship between insomnia and depression and anxiety (236).

5.2.3 Patients' experiences of group treatment

Study IV seems to be the first qualitative exploration of patient's experiences of multi-component CBT-I delivered in a group treatment format. It illuminated patients' experiences of motivation, change, and challenges during treatment. Specifically, it shed light on how patients experienced different degrees of improvement or lack of improvement in insomnia symptoms; how they experienced certain components of the treatment as essential to their motivation, behavioral change, and improvements; and how they experienced challenges related to treatment. Four themes emerged from the qualitative content analysis: "involvement and trust open the door for change," "competence arising from deeper understanding," "struggling with vulnerability and failure," and "tailoring treatment to individual needs."

One essential component of treatment was the environment in which treatment took place (i.e., the group treatment format and the PHC context). Being in a group of people who knew how it could be to live with insomnia (including both other patients and the group leader) made patients feel safe enough to try new behaviors. Feeling support from these people promoted motivation and engagement in treatment. This finding is in line with findings of previous studies showing that a group treatment format (237-239) and a trustful relationship with the treatment provider are important to behavioral change and to achieving improvements (239-242).

Patients' experiences of the group treatment format and their relationship with the group leader reflect so-called common factors in therapy, including alliance with the treatment provider and feeling validated. They also reflect common factors specific to group therapy, sometimes called therapeutic or curative factors, such as being supported by others who share experiences similar to one's own. Common factors—both those relevant to therapy in general and to group therapy in particular—may be the main mechanisms behind behavioral change and improvements that patients experience as a result of therapy (243-246).

Specific factors—factors unique to specific psychological treatments—seem to explain only a small part of treatment effects (247, 248). However, in study IV, patients experienced some factors specific to CBT-I as essential to motivation, behavioral change, and achieving improvements. Knowledge about sleep and insomnia, practicing techniques, and discussing and reflecting during the treatment sessions helped them to achieve a deeper understanding. This deeper understanding made patients feel competent and confident in having strategies that could help them. Moreover, they could experience increased trust in their own ability to

sleep. Because feelings of low control over sleep are related to long-term use of hypnotics (169), it could be that patients' increased trust in their own ability to sleep helped them reduce their use of hypnotics (study II). Patients could experience sleep restriction as particularly helpful to achieving improvements in insomnia (study IV). This finding is in line with those of previous studies showing that sleep restriction is one of the most potent techniques in CBT-I; it reduces the time it takes to fall asleep and the time spent awake during the night (249-251). Moreover, patients experienced power naps as helpful in coping with physical and mental arousal, worry, and fatigue. Daytime napping is generally not recommended for people with insomnia, but a nap shorter than half an hour will probably not interfere with nighttime sleep (163). Patients' experiences of using powernaps are in line with the findings of previous studies showing that scheduled naps of shorter than 30 minutes after a night of poor sleep can increase alertness and performance (252) and reduce stress (49).

Even though patients experienced some aspects of treatment as helpful, they could also experience challenges to engaging in treatment and achieving improvements. They could express feelings of helplessness and failure. Moreover, they could doubt that the treatment would help them or lack confidence that they would be able to use what they learned when they really needed it. Poor confidence in coping skills can make people less motivated to try to change their behaviors and to persist in behavioral change (253). It can also impact people's emotional reactions to difficult situations (254). Some challenges experienced by patients in study IV may have been related to the group treatment format, and these are not often discussed in the literature. For example, even though patients could feel calmed and encouraged by comparing the problems and progress of others to their own, such comparisons could also make them feel they had more severe problems than others and that they had failed. Other challenges were related to patients' life circumstances (e.g., job situation, pain) and some to insomnia itself (e.g., tiredness, fear of sleeplessness). Fatigue, worry about sleep, and lack of confidence in one's ability to sleep are common in people with insomnia (28, 89). Moreover, challenges could be related to specific techniques, especially sleep restriction. The challenges of sleep restriction are well documented, and most side effects of CBT-I are related to this technique (183, 250). The side effects of sleep restriction are most prominent at the beginning of treatment, and include fatigue/exhaustion, extreme sleepiness, reduced motivation/energy, and headache (250). At the beginning of treatment, sleep restriction can also prompt anxiety and catastrophizing about daytime consequences of the technique (183).

Patients could find that the group leader supported them in adapting the techniques to fit their individual life circumstances and needs and that this support helped them overcome some of the challenges they experienced (study IV). The flexible and supportive leadership provided by the nurses was encouraged by the design of the intervention and reflects the values of person-centered care, in which patients are viewed as experts on their own experiences and everyday lives (255, 256). Previous research also shows that a flexible therapist who adjusts the intensity of the techniques used in therapy to the individual patient can positively impact treatment outcomes (257).

Patients' experiences of motivation, change, and challenges in treatment are recognizable in educational theory (258, 259) and in theories of motivation and behavioral change (253, 254). For example, educational theory posits that learning moves from fact-based knowledge to lived experiences and reflection that lead to deeper understanding and subsequently to utilization of knowledge in everyday life (258, 259). According to behavioral theory, feelings of competence are related to motivation and behavioral change (254), and intrinsic motivation (motivation that comes from the person's own goals, and that people feel that they have something to win from a behavior) is important to people's ability to engage in and persist in behavioral change (253). Intrinsic motivation is supported by feelings of autonomy, relatedness, and competence (253), which are reflected in the feelings of involvement, trust, and competence experienced by patients who took part in the group treatment (study IV).

5.3 METHODOLOGICAL CONSIDERATIONS

5.3.1 Study I

The strength of study I was the randomly selected sample from the Swedish Register of the Total Population, which includes demographic data about all people resident in Sweden. The register is maintained by Statistics Sweden, Sweden's official government statistics agency, and is commonly used in epidemiological research (260). The randomization and the telephone survey were conducted by Statistics Sweden, which has expertise in conducting cross-sectional, population-based studies. The dropout rate was relatively low (27.2%). The questions included in the survey were chosen because of their relationship with sleep difficulties and insomnia. They have previously been used in sleep research (74, 207, 261).

The proxy for insomnia disorder used in study I (experiencing major difficulties to initiate sleep and/or maintain sleep and considerable interference of sleep difficulties with daily life; recall period 1 month) is similar to proxies commonly used in other population-based studies of insomnia (75, 262). However, the study I proxy for insomnia did not separate insomnia from other sleep disorders, such as restless legs syndrome and sleep apnea. Restless legs syndrome is common in the general population. It is associated with difficulty initiating sleep (263), the factor most strongly related to need for treatment in study I. In sleep apnea, difficulty initiating sleep is not a typical symptom, but nonrestorative sleep and fatigue are (264), and they were also strongly associated with need for treatment in study I. If information on symptoms such as restless legs, snoring, and excessive daytime sleepiness had been gathered, the results of the logistic regression models might have been different. However, we did include the variable "difficulty maintaining sleep," which can be a symptom of restless legs syndrome and/or sleep apnea. That variable was not significantly associated with need for treatment in the final model (study I).

Finally, although it is not reasonable to expect a telephone survey to cover all possible aspects of a phenomena, it would have been valuable to ask which kind of treatment people thought they needed and about self-medication for sleep difficulties (e.g., herbal medicines and alcohol).

5.3.2 Studies II and III

5.3.2.1 *Strengths and limitations*

A main strength of studies II and III was the RCT design. RCTs are considered the gold standard design for intervention studies as they provide the highest level of evidence about the effects of a treatment (265). The RCT in this thesis had a pragmatic design in that it was adapted to be feasible in routine PHC. Pragmatic trials, in contrast to explanatory trials, aim to investigate whether an intervention has positive effects when it is delivered in real clinical practice. They typically focus on the generalizability of the results and include participants who have the characteristics of patients for which the treatment is intended (266). The present RCT included 165 patients recruited from seven geographically diverse PHC centers. The patients ranged in age from 20 to 90 years, and many had comorbid health problems and medications.

Although the pragmatic design may have strengthened the generalizability of the results of the current RCT, it also conferred some methodological challenges, for instance during the recruitment phase. For example, patients were referred to the study by their physician, who conducted an initial assessment and asked the patient if he or she was interested in participating in the trial. We cannot be sure that the physicians assessed all potentially eligible patients. Moreover, we did not gather information on how many potentially eligible patients' physicians assessed as ineligible for the study, whether physicians asked all potentially eligible patients if they wanted to participate, or how many patients declined to participate and why. Monitoring those factors would have strengthened the results of the RCT.

Objective measures of sleep are not routinely used in PHC to assess sleep disorders (267, 268). Thus, during the recruitment process, no objective measure (i.e., polysomnography or actigraphy) was used to screen patients for sleep disorders other than insomnia (e.g., sleep apnea and restless legs syndrome). Instead, patients who reported symptoms indicative of a sleep disorder other than insomnia were sent back to their physician, who decided whether the patient should be referred to a sleep clinic for further evaluation. However, four patients in the intervention group were diagnosed with a sleep disorder other than insomnia at a sleep clinic during the 1-year follow-up period. The symptoms of these disorders were missed both by the physicians and the nurses during the recruitment process. One had hypersomnia, one had bruxism, one had restless legs syndrome, and one had sleep apnea. Bruxism (269), restless legs syndrome (270), and sleep apnea (271) are often comorbid with insomnia, and at least restless legs syndrome and sleep apnea are often undiagnosed in PHC patients (272, 273). Different sleep disorders require specific treatments, and it was probably more important for patients to receive treatment for those sleep disorders than for insomnia. However, recent research suggests that patients who have sleep apnea comorbid with insomnia can benefit from CBT-I (274). Moreover, during group treatment, patients learned about other sleep disorders, and this prompted some to discuss their symptoms with their group leader and subsequently with their physician.

Studies show that a significant part of the effect of hypnotics can be explained by the placebo effect (226). However, like the RCT that formed the basis for studies II and III, most studies of psychological treatments in clinical settings are not blinded (275, 276). This is a weakness, as without blinding, it is not possible to determine how much of a role the placebo effect may play in the positive results of such treatments. A recent meta-analysis of insomnia treatments in which participants could not tell they were in the placebo group found placebo effects in sleep outcomes for both pharmacological and psychological treatments (277). Even if the placebo effect accounts for part of the positive results of the group treatment, psychological treatment would retain important advantages, as unlike hypnotics, it does not cause adverse side effects, such as tolerance, dependency, hangover, nocturnal confusion, falls, and rebound insomnia.

Information about treatment fidelity was limited. The sessions in the treatment program were not observed or recorded. However, the nurses were contacted after each session to ensure that they had introduced the techniques as planned and that the patients had participated in the session. Moreover, all nurses received the same training, the manual provided guidance for each treatment session, and the nurses were provided with prepared written material about the techniques to give the patients. Thus, even though the treatment manual was semi-structured and the nurses were encouraged to use their professional judgment to adapt treatment to each group and individual, treatment followed a structure, and the patients received the same written material.

The control condition in the current RCT was TAU (the treatment patients would have received if they had not participated in the trial). An alternative to TAU would have been to compare the effectiveness of the current intervention with that of other active control conditions, such as sleep restriction alone. However, choice of control condition should be informed by the objective of a study, and this RCT investigated whether the group treatment was helpful in addition to usual treatment.

As well as being scientifically acceptable, TAU as the control condition is generally considered an ethically sound alternative in that the control group receives current standard treatment (278). The main critique of TAU is that it is difficult to know what treatment patients in the control group actually receive (278-280). However, studies indicate that TAU for insomnia is currently similar around the world: typically hypnotics and sleep hygiene recommendations (113). In the current RCT, 67% of patients in the control group used hypnotics at baseline and this proportion did not change during the assessment period (study II). None of the PHC centers in the current RCT offered group treatment for insomnia to patients in the control group during the assessment period. However, it would have further strengthened the study if we had continuously documented the treatment patients in the control group received between the assessments.

No structured harm assessment was conducted. Previous studies show that one component of the RCT, sleep restriction, can cause extreme sleepiness, especially at the beginning of

treatment (249, 281). Patients were advised to take this into consideration, for instance by avoiding long-distance driving and operating heavy machinery during treatment.

Analyses of the results of the RCT employed an intention-to-treat approach. This means that all patients who were randomized into the study were analyzed in accordance with their treatment assignment, and all patients were included in the analyses, including those in the intervention group who were diagnosed with sleep disorders other than insomnia. The post-treatment dropout rate was 20% in the intervention and in the control group. To avoid attrition bias, missing post-treatment data were replaced with the patient's baseline data. This method (the last observation carried forward-method) is commonly employed in clinical trials but can overestimate results if it is likely that participants will improve on their own without treatment (209). However, analyses of observed data showed slightly better results than the intention-to-treat analyses and were thus not reported.

5.3.2.2 Assessment of insomnia outcomes

Because of the experiential nature of insomnia (21, 22), it was relevant to measure treatment outcomes with patient-reported outcome measures. The measures used in studies II and III are well-established, and most of them are recommended for use in insomnia treatment research (282).

Sleep outcomes were measured by sleep diaries, as objective measures are not recommended in the evaluation of insomnia treatment (283). Sleep diaries reflect the variability of sleep and how people experience sleep in their own environment (200, 284), which may be more important to daytime functioning than objectively measured sleep. For example, studies show that sham negative or positive feedback about sleep quality after objective sleep measurement influenced people's appraisal of their daytime symptoms (e.g., fatigue and sleepiness) (285) and even their objectively measured cognitive functioning (286).

Both ISI (196, 197), used to measure the main outcome in study II, and FSS (202), used to measure the main outcome in study III, have been clinically validated for reliability, internal consistency, and sensitivity to change in patients' symptoms over time. Moreover, they are the instruments most widely used to evaluate the effects of treatment on insomnia severity and fatigue (282). Previous studies recommend that evaluations of insomnia treatments should include measurements of fatigue, but also of daytime functioning, mood, and quality of life (282, 287). In study III, GHQ-12 and MADRS-S were used to measure mood, and the SF-36 was used to measure quality of life.

The GHQ-12 was developed to identify the severity of psychological distress in adult PHC patients (204). It has good psychometric properties (288), and its validity is unaffected by age, sex, or educational level (204). Likert scoring (used in the analyses) is recommended for comparing the severity of psychological distress in groups (204). MADRS-S is a validated instrument, sensitive to changes in the severity of depressive symptoms (205) and previously used in insomnia treatment research (289).

An ethical issue related to the use of MADRS-S arose during data collection. Several months after the post-treatment assessment, when the responses were being registered in the study database, C.S. discovered that one patient had reported suicidal thoughts on MADRS-S. C.S. contacted the patient to ensure that they were under care and discussed the matter with the research group. After this event, responses to the question about suicidal ideation were checked immediately after the patients returned the questionnaires. We also began including MADRS-S as a part of the structured screening assessment that took place before patients were included in the study. However, no additional patients with suicidal thoughts were identified.

SF-36 is one of the most common quality of life measures and is frequently used in insomnia studies (282). To strengthen the results of the two subscales (summary scores) (290, 291), the eight domains that lay behind the subscales were analyzed, and the results were reported.

5.3.3 Study IV

Readers should take certain aspects of qualitative studies into consideration when judging the trustworthiness of the findings. In study IV, the focus group participants had attended the treatment together and were familiar with each other, which may have facilitated group discussions. The groups were small, consisting of three to four patients each. Small group size generally makes it easier for all participants to contribute to the group discussion but can also limit interaction between participants (292). Moreover, all participants were women, and they were probably a highly motivated group of patients, as they had been waiting for group treatment for approximately 3 months and did not drop out even though some of the treatment components were challenging (e.g., sleep restriction).

The focus group interviews were conducted during the last group treatment session, which meant that the patients did not have to return an extra time for the interviews. So that no one would think they needed to skip the last group session in order to avoid an interview, all patients were informed separately that their group would not be interviewed if any of them did not want to take part in the interview.

In qualitative research, researchers need to describe their prior understanding to make readers aware of the metaphorical glasses they wore during data collection, analysis, interpretation, and reporting (293). In study IV, the prior understanding of the authors varied from high to some to none. Two of the authors (C.S. and M.E.) had a great deal of prior understanding because they had worked with group treatment for insomnia for several years. Bias caused by prior understanding is unavoidable and not entirely negative (293, 294), but it was important for the researchers to maintain awareness of their perspective to minimize the impact of prior understanding during data collection and interpretation. To increase the trustworthiness of analyses, K.K., who had low prior understanding of insomnia and no clinical experience, conducted the initial coding independently from C.S. The two then compared their findings. Moreover, all coauthors participated actively in the analytical process, discussing the coding until they reach consensus.

In three focus groups, the group leader and interviewer were different people. In two, however, the interviewer (C.S.) had also led the groups. She thus had a dual role as group leader and researcher. This raises ethical issues because patients depend on their health care providers for care, which puts them in a vulnerable position in the relationship (295). C.S.'s dual role may also have affected the group interaction. However, there is no such thing as an entirely neutral interaction between an interviewer and the person or people they are interviewing (296). The nature of the relationship between the interviewer and the participants is thus important to keep in mind when judging the trustworthiness of the findings of any qualitative study.

One concept commonly used in qualitative studies to ascertain adequate sample size is "data saturation." Data saturation is reached when further data collection no longer adds any new information (297, 298). Repeated interviews are one way to reach data saturation (215), but repeated interviewing is more relevant to grounded theory than to qualitative content analysis. In study IV, we interviewed all five groups that were ongoing at the time of the study. Repeated interviews were not an option. However, another concept used to ascertain adequate sample sizes in qualitative studies is information power: the more information relevant to the study the sample holds, the lower the number of participants needed (298). The current study had a relatively narrow aim, and all participants had experienced the explored phenomenon. Moreover, we judged the dialogues to have been strong because patients expressed a variety of experiences, characterized by both similarities and differences. The sample size of the study may thus have provided adequate information power.

6 IMPLICATIONS FOR HEALTH CARE AND FUTURE RESEARCH

Study I provides health care professionals with a picture of how many people feel they need treatment for sleep difficulties and what typically makes them feel this way. PHC must be prepared to care for the 12.5% of the population who feel they need treatment. Moreover, an increased understanding about what makes people feel they need treatment may be valuable to professionals who encounter and care for patients with insomnia.

Studies II through IV can contribute to the evidence base for the development of future guidelines for the treatment of insomnia in PHC. Studies II and III show that with brief training, nurses can provide group treatment for insomnia that is more effective in improving insomnia than treatment as usual in PHC. The RCT thus adds to the growing body of evidence (177-182) that CBT-I can be provided effectively in PHC by professionals who are not CBT specialists. Training nurses to give the treatment would increase the pool of professionals who can provide CBT-I based treatment to patients. The intervention is also an effective use of resources, as the group format allows one nurse to treat several patients at the same time.

The results may be considered generally applicable in PHC. The intervention was carried out in routine care by ordinary PHC professionals. Participants were people who sought PHC. There were few exclusion criteria, so the participants were representative of PHC patients in general. Additionally, it was feasible to carry out the intervention in PHC with few extra resources (e.g., time for nurse education).

Together with previous research, the effectiveness of the intervention suggests that it is time to implement nurse-led group treatment for insomnia as a treatment option in PHC. Implementing the intervention would increase patients' access to treatment that is in line with clinical treatment guidelines. Moreover, the group treatment can be a useful component of a stepped care model, freeing CBT experts (e.g. psychologists) to devote more time to patients who need them the most.

Study IV can be used to inform plans for implementation, as it provided information about patients' experiences of motivation, change, and challenges in group treatment.

PHC patients are a heterogeneous group with different preferences and life circumstances, so their needs may be best addressed with a broad array of treatment options. Group treatment is one such option. Future research could test brief interventions that include core components of insomnia treatment. Another promising research area is digital treatment. The scientific evidence for various kinds of digital treatment for insomnia is growing (165, 299). However, less is known about how such treatments work for the wide spectrum of patients encountered in PHC. Finally, the overall landscape of PHC is changing rapidly. Recent developments include the growth of virtual PHC, and it may be especially relevant to evaluate treatments delivered in virtual environments.

7 CONCLUSIONS

Many people in the general population perceive that they need treatment for sleep difficulties, and a large proportion of these people have insomnia. Difficulty initiating sleep, but also nonrestorative sleep, mental health problems, and fatigue are factors that make people feel they need treatment for sleep difficulties (study I).

Nurse-led group treatment for insomnia delivered in PHC is more effective than TAU in decreasing insomnia severity, improving sleep, reducing hypnotic drug use, and improving the daytime symptomatology of insomnia. The results suggest that the techniques of CBT-I can be integrated into nursing practice and into routine PHC to provide care for patients with insomnia (studies II and III). Moreover, analyses of focus group interviews illuminate what motivated patients to change, what helped them improve, and the challenges they faced (study IV).

Hopefully, by contributing knowledge about what makes people feel they need treatment for sleep difficulties, the effectiveness of group treatment for insomnia led by nurses in PHC, and patients' experiences of participating in the group treatment, this thesis will contribute to improving care for patients with insomnia.

8 SAMMANFATTNING PÅ SVENSKA

Bakgrund

Sömn är centralt för hälsa och välbefinnande. I befolkningen uppger mellan 20 % till 30 % att de har sömnbesvär och ungefär 10 % uppfyller kriterierna för insomni. Insomni är en sömn- och vakenhetsstörning med särskilda diagnoskriterier. I diagnoskriterierna ingår sömnbesvär, såsom svårigheter att somna eller svårigheter att bibehålla sömnen, men också att sömnbesvären ger dagbesvär såsom trötthet, nedstämdhet och oro, samt nedsatt funktionsförmåga (i arbete eller socialt). För att uppfylla diagnoskriterier för insomni ska sömnbesvären förekomma minst 3 nätter i veckan och ha varat minst 3 månader. Diagnosen är baserad på personens upplevelse av sömn och dagbesvär, samt en klinisk bedömning av att sömnbesvären inte fullt ut kan förklaras av sjukdom eller någon annan sömnstörning, till exempel sömnapné, restless legs, sömngång eller mardrömmar. Studier visar att insomni är relaterat till försämrad livskvalitet samt till en rad faktorer som kan påverka hälsa och välbefinnande negativt, exempelvis trötthet, ökad stresskänslighet, nedsatt minnes- och problemlösnings- och arbetsförmåga. Insomni ökar också risken för att utveckla en rad sjukdomar, såsom hjärtkärlsjukdom, diabetes och depression.

Det finns studier som visar att insomni tenderar att kvarstå när det väl utvecklats. Teorier som förklarar hur insomni utvecklas och vidmakthålls beskriver hur insomni ofta börjar med sömnbesvär som en naturlig respons på oro, stress eller sjukdom. Utvecklingen från enbart sömnbesvär till insomni triggas av en stark oro för sömnbrist och dess konsekvenser. Insomni vidmakthålls sedan av beteenden som att tillbringa mer tid i sängen, försök att prestera sömn, aktivera sig i sängen samt att prioritera ned fysisk och social aktivitet under dagen. Dessa beteenden riskerar att ytterligare försämra sömn och dagfunktion, vilket ger ökad oro och därmed en ökad mental och fysiologisk uppvarvning, vilket i sin tur kan göra det ännu svårare att komma till ro och sova. Föreställningar kring hur sömnen borde vara och tankar som handlar om oro för dagfunktion tenderar att förstärkas med katastroftankar som ”om jag inte får sova en hel natt kommer jag inte fungera imorgon.”

Människor vänder sig i första hand till primärvården för vård och behandling av insomni. Studier visar att mer än hälften av primärvårdens patienter uppger symptom på sömnbesvär och/eller insomni. De som söker primärvård har ofta svåra symtom, i synnerhet dagsymtom såsom trötthet. Studier visar dock att många människor lever med insomni utan att söka vård, vilket har förklarats med att de kan känna att de borde kunna hantera sina sömnbesvär på egen hand och att deras problem inte tas på allvar. Många drar sig också för att söka vård för de känner sig tveksamma till läkemedelsbehandling för sömnbesvären och inte känner till vilka behandlingsalternativ som finns. Det är inte tidigare studerat vad det är som gör att människor i befolkningen upplever att de har ett behov av behandling för sömnbesvär, oavsett om de sökt vård eller ej (studie I).

Den vanligaste behandlingen för insomni i primärvården är sömnmedel av bensodiazepintyp (s.k. Z-läkemedel). Statens beredning för medicinsk utvärdering (SBU) publicerade 2010 en rapport som rekommenderade kognitiv beteendeterapi för insomni (KBT-I) som

förstahandsval vid behandling av insomni. KBT-I är en psykologisk och beteendeförändrande behandling specifikt inriktad på insomni. I behandlingen ingår utbildning om sömn och sömnbesvär samt metoder som syftar till att ge patienten strategier att få fungerande sömnvanor, hantera oro och hantera dagsymtom. Behandlingen kan ha olika upplägg men basen utgörs av sömnrestriktion och stimuluskontroll samt en kognitiv metod, till exempel kognitiv omstrukturering. Det övergripande målet med KBT-I är att patienten ska få bättre sömn men också mindre dagbesvär, såsom minskad trötthet och förbättrad dagfunktion.

SBU konstaterade i sin rapport att få patienter får tillgång till annan behandling än läkemedel. En av slutsatserna var att fler behöver utbildas i kognitiva och beteendeförändrande metoder för att kunna täcka behovet hos den stora andelen patienter med insomni i primärvården. SBU-rapportens resultat och slutsatser 2010 har sedermera bekräftats i flertalet stora systematiska litteraturöversikter och meta-analyser, som har legat till grund för internationella riktlinjer för behandling av insomni. Det vetenskapliga stödet är således starkt för att KBT-I har god effekt på sömn (insomningstid, vakentid under natten, total sömntid, sömneffektivitet, uppvaknanden och sömnkvalitet). Över tid så har KBT-I bättre effekt på dessa variabler än sömnmedel. Behandlingseffekter på dagbesvär är inte lika studerat, varken när det gäller sömnmedel, som är den sedvanliga behandlingen i primärvården, eller KBT-I.

Mycket av det vetenskapliga stödet för KBT-I är också baserat på studier som utförts i andra miljöer än primärvården och som har rekryterat friska deltagare via media och/eller tillämpat strikta exklusionskriterier. Detta innebär att studiernas resultat inte kan betraktas som generaliserbara till primärvårdens heterogena patientpopulation. Dessutom så har, i de flesta studier, KBT-I utförts av professioner som fortfarande är relativt få i primärvården, exempelvis psykologer, psykoterapeuter och specialister i sömnmedicin. För att öka primärvårdens möjligheter att erbjuda KBT-I så är det angeläget att utveckla och utvärdera interventioner som är tillämpbara i klinisk vardag och som ger goda resultat för primärvårdens patientpopulation. Sjuksköterskor och distriktssköterskor har en nyckelroll i primärvården genom att vara en av de största yrkesgrupperna och patientens första kontakt när de söker primärvård. Distriktssköterskor är specialistutbildade för att kunna stödja patienter till egenvård och beteendeförändring och de arbetar ofta framgångsrikt med gruppbehandling inom områden såsom diabetes och levnadsvanor.

Ett sätt att öka möjligheten för primärvården att erbjuda rekommenderad behandling för insomni kan vara att utbilda sjuksköterskor (t.ex. distriktssköterskor) i gruppbehandling baserad på KBT-I och på så sätt göra metoden mer tillgänglig för patienterna (studie II). Insomnibehandling behöver också utvärderas avseende effekter på dagbesvär och inte bara sömnbesvär (studie III). Det saknas studier som utforskar patienters upplevelse av KBT-I baserad gruppbehandling. Att utforska patienters upplevelser av behandling genom kvalitativa studier kan tillföra information som inte fångas i kvantitativa utvärderingar av behandling (studie IV).

Syfte

Det övergripande syftet med denna avhandling var att undersöka behovet av behandling för sömnbesvär i befolkningen och att utvärdera en gruppbehandling för patienter med insomni som leds av distriktssköterskor i primärvården.

Avhandlingen innehåller fyra delstudier:

- I Syftet med studie I var att undersöka faktorer relaterade till att anse sig behöva behandling för sömnbesvär.
- II Syftet med studie II var att undersöka om gruppbehandling baserad på KBT-I som leds av distriktssköterskor i primärvården är mer effektivt än sedvanlig behandling avseende minskad svårighetsgrad av insomni, förbättrad sömn och minskad sömnmedelsanvändning.
- III Syftet med studie III var att undersöka om gruppbehandling baserad på KBT-I som leds av distriktssköterskor i primärvården är mer effektivt än sedvanlig behandling avseende minskade dagbesvär relaterade till insomni.
- IV Syftet med studie IV var att utforska patienternas upplevelse av gruppbehandlingen.

Material och metoder

I studie I analyserades data insamlat genom telefonintervjuer med ett slumpmässigt urval av Sveriges vuxna befolkning i befolkningsregistret. Undersökningen genomfördes av Statistiska Central Byrån under 2008 på uppdrag av SBU och forskare på Karolinska Institutet. Deltagarna i studien ($n = 1115$) tillfrågades om sömnbesvär (svårigheter att somna, svårigheter att bibehålla sömnen, tidiga morgonuppvaknanden, en icke återhämtande sömn), dagbesvär (trötthet, nedstämdhet, koncentrationssvårigheter, irritation), hälsosituation (allmän hälsa, fysiska och psykiska sjukdomar), sömnmedelsanvändning, vårdsökande och sociodemografiska faktorer (ålder, civil status, sysselsättning). Deltagarna tillfrågades också om de ansåg sig behöva någon form av behandling för sömnbesvär (ja eller nej). Utfallsvariabeln i denna studie var "självrapporterat behov av behandling för sömnbesvär". Data analyserades med statistiska metoder (logistisk regressionsanalys) för att undersöka samband mellan självrapporterat behov av behandling för sömnbesvär, kliniska symptom (t.ex. sömnbesvär och dagbesvär) och sociodemografiska faktorer.

Studie II och III baserades på material från en randomiserad kontrollerad klinisk interventionsstudie som genomfördes på sju vårdcentraler i Stockholm mellan 2011 till 2014. Patienter med insomnisymtom som sökte läkare på vårdcentralerna blev inkluderade i studien om de uppfyllde studiekriterier, till exempel diagnoskriterier för insomni samt var 18 år eller äldre. De 165 patienter som inkluderades i studien lottades till gruppbehandling (interventionsgrupp, $n = 90$) alternativt sedvanlig behandling (kontrollgrupp, $n = 75$). Gruppbehandlingen bestod av sju träffar á två timmar under 10 veckor. Gruppbehandlingen var baserad på KBT-I och utfördes av åtta distriktssköterskor inom ramen för deras ordinarie arbete på vårdcentralen. Distriktssköterskorna i studien deltog i en två-dagars utbildning som behandlade ämnen som sömn, sömnreglering, insomni och KBT-I metoder.

Patientrapporterade utfallsmått användes för att utvärdera skillnader i resultat mellan interventionsgruppen och kontrollgruppen. Data samlades in genom att patienterna ombads att fylla i frågeformulär och föra sömndagbok, precis före behandling och efter avslutad behandling. Patienterna i interventionsgruppen följdes upp ett år efter behandling. Statistiska analyser (t.ex. variansanalys för upprepade mätningar) utfördes för att undersöka skillnader mellan interventionsgruppens och kontrollgruppens förändring från före behandling till efter behandling samt förändring över tid i interventionsgruppen (före, direkt efter och 9 månader efter gruppbehandling).

Delstudie II och III baserades på samma RCT, men studierna hade olika fokus och olika utfallsmått. I delstudie II analyserades svårighetsgrad av insomni (Insomnia Severity Index [ISI], primärt utfallsmått), sömn (sömndagbok), och sömnmedelsanvändning (frekvens). I delstudie III analyserades utfall relaterade till dagbesvärskvaliteten vid insomni: trötthet (Fatigue Severity Scale, primärt utfallsmått), psykisk ohälsa (General Health Questionnaire-12), depressiva symtom (Montgomery-Asberg Depression Rating Scale Self-Assessment), hälsorelaterad livskvalitet (Short Form Health Survey-36), allmän dagfunktion i relation till sömnbesvär (enskild fråga i ISI), specifika dagsymtom: oro för sömn, dagsömnighet, kroppslig trötthet, koncentrationssvårigheter (enskilda frågor i ISI och Uppsala Sleep Inventory), samt dysfunktionella tankar och föreställningar relaterade till insomni (Dysfunctional Beliefs and Attitudes about Sleep scale-16).

I studie IV utforskades patienternas ($n = 17$) upplevelse av gruppbehandlingen genom fem fokusgruppsintervjuer. Intervjuerna spelades in på band, transkriberades och analyserades med kvalitativ innehållsanalys.

Resultat

Studie I visade att 12,5 % ($n = 139$) av deltagarna i studien ansåg sig behöva behandling för sömnbesvär. Sociodemografiska faktorer såsom kön och sysselsättning var relaterat till behandlingsbehov. Exempelvis hade kvinnor (OR 1,46; CI 1,02–2,10), personer mellan 60 och 69 år (OR 1,93; CI 1,08–3,47), sjukskrivna (OR 18,15; CI 7,21–45,70), pensionärer (OR 2,62; CI 1,75–3,94), och arbetslösa (OR 3,19; CI 1,39–7,34) signifikant ökad risk för att anse sig behöva behandling. De som uppfyllde diagnoskriterier för insomni hade 23 gånger högre risk (OR) för att anse sig behöva behandling (CI 14,61–36,12). En logistisk regressionsmodell som inkluderade flera kliniskt relevanta faktorer visade att svårigheter att somna (OR 6,29; CI 3,67–10,78), en icke återhämtande sömn (OR 3,7; 2,05–6,69), psykisk ohälsa (OR 3,01; CI 1,59–5,67) och trötthet (OR 2,95; CI 1,53–5,68) var signifikant associerade till behandlingsbehov, oavsett kön, ålder och andra typer av besvär.

Studie II visade att patienter i interventionsgruppen ($n = 82$) förbättrades signifikant jämfört med patienter i kontrollgruppen (sedvanlig $n = 71$) avseende minskad svårighetsgrad av insomni ($P < 0,001$), förbättrad sömn (insomningstid [$P > 0,001$], total sömntid [$P = 0,008$], vakentid under natten [$P < 0,001$], sömneffektivitet [$P < 0,001$], antal uppvaknanden [$P = 0,002$], sömnkvalitet [$P < 0,001$]) samt minskad sömnmedelsanvändning ($P = 0,003$).

I studie III så förbättrades interventionsgruppen signifikant jämfört med kontrollgruppen avseende trötthet ($P < 0,001$), psykiskt välbefinnande ($P < 0,001$), depressiva symptom ($P < 0,001$), samt hälsorelaterad livskvalitet, i synnerhet mental funktionsförmåga ($P < 0,001$). Dessutom förbättrades allmän dagfunktion ($P = 0,001$) och specifika dagsymtom ($P < 0,001 - 0,026$). Dysfunktionella tankar och föreställningar relaterade till insomni minskade i styrka ($P < 0,001$). Samtliga förbättringar som sågs efter gruppbehandlingen (studie II och III) kvarstod vid uppföljning efter ett år ($n = 54$).

Den kvalitativa analysen i studie IV resulterade i fyra teman som belyser patienternas upplevelser av gruppbehandlingen. Det första temat ”engagemang och tillit öppnar dörren för förändring” belyser hur patienternas motivation till att engagera sig i behandlingen uppstod genom en egen önskan om förändring, genom att vara tillsammans med andra som förstod deras situation och engagerade sig i deras förändringsprocess samt genom att känna sig sedd, omhändertagen och bekräftad. Det andra temat ”kompetens genom en djupare förståelse” belyser patienternas upplevelse av att ha fått en djupare kunskap och hur detta låg till grund för att utveckla fungerande sömnvanor och förmåga att släppa sömnprestation och oro. Upplevelsen av att kunna påverka sin insomni stärkte tilliten till den egna förmågan vilket hjälpte dem att kämpa på och fortsätta med behandlingen. I det tredje temat ”kämpar med sårbarhet och misslyckanden” belyses hur behandlingen kunde upplevas som krävande samt hur yttre omständigheter och inre faktorer som trötthet, stress och oro för att inte sova kunde försvåra situationen. De beskrev också att de kunde känna en bristande tilltro till sin egen förmåga att kunna genomföra insomnibehandling. Det fjärde temat ”anpassar behandlingen utifrån individuella behov” belyser hur patienterna valde att ta till sig den information som de tyckte var relevant för dem och hur de anpassade metoderna efter egna behov.

Slutsatser

En stor andel av befolkningen anser sig behöva behandling för sömnbesvär. Svårigheter att somna, men även en icke återhämtande sömn, psykisk ohälsa och trötthet är symtom som kan skapa ett behov av behandling. Gruppbehandling baserad på KBT-I som leds av distriktssköterskor i primärvården är mer effektiv än sedvanlig behandling när det gäller att minska svårighetsgrad av insomni, förbättra sömn, minska sömnmedelsanvändning och minska dagbesvär relaterade till insomni. Dessa resultat ger stöd för att KBT-I och dess metoder kan integreras i distriktssköterskans omvårdnadsåtgärder och i primärvårdens ordinarie verksamhet för att förbättra vården av patienter med insomni. Patienternas upplevelser av gruppbehandlingen belyser vad som motiverade dem till beteendeförändring, vad som gjorde att de förbättrades i sin insomni samt utmaningar och svårigheter de ställdes inför. Detta resultat kan bidra till fortsatt utveckling och utvärdering av insomnibehandling i primärvården (studie IV).

Förhoppningsvis kan denna avhandling bidra till att det i framtiden kommer finnas en möjlighet till stegrade insatser i vården av patienter med insomni och att fler patienter ska kunna erbjudas effektiv behandling med kognitiva och beteendeförändrande metoder på sin vårdcentral.

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