MASTER THESIS

An ACT-based intervention among patients suffering from chronic pain and insomnia: A Pilot Study

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Abstract

Background

Chronic pain and insomnia are both highly prevalent and have both numerous negative consequences. On top of that, chronic pain and insomnia often co-occur, and insomnia is the most common sleep disorder associated with chronic pain. Cognitive Behavioral Therapy for insomnia (CBT-I) is the most used method to treat insomnia but the use of Acceptance and Commitment Therapy (ACT) in treating insomnia grows. Until now, few studies have examined ACT in chronic pain patients with insomnia. Therefore, the aim of the present study is to investigate whether an ACT-based intervention leads to improvements in insomnia severity, dysfunctional beliefs and attitudes and objective and subjective sleep quality.

Methods

This research consists of a pilot study with 11 participants (M=46 years, SD = 10.58) who suffer from chronic pain and insomnia. The participants were selected based on their insomnia score and on a semi-structured interview with a sleep expert at Roessingh, a centrum for rehabilitation. They received a five-week ACT-based intervention, which included components of sleep restriction/stimulus control, the comparison of subjective and objective measures based on a sleep diary and ballistocardiograph (Withing's sleep analyser) and Acceptance and Commitment Therapy. The sleep diary and ballistocardiograph were used in the intervention week 1, 3 and 5 to measure objective and subjective sleep parameters. The sleep diary was filled in in the morning and evening, and included numerical rating scales for pain intensity, fatigue, and daytime activities. The Dysfunctional Beliefs and Attitudes for Sleep (DBAS) questionnaire and the Insomnia Severity Index (ISI) were also used. The assessment of the DBAS took place at the baseline and at the end of the last intervention week. The assessment of the ISI took place at the beginning and end of each of the three intervention weeks. The participants stayed one week at home after every intervention week. No measurements were taken when the participants were at home.

Results

The results of the present study showed that an ACT-based intervention is a promising method to treat insomnia in chronic pain patients. A significant decrease was found between pre-test and post-test in sleep-related dysfunctional beliefs and attitudes. Furthermore, a large significant decrease was found between the baseline and the end of the first intervention week. Additionally, a significant decrease was found between the baseline and the end of the last intervention week. There was no improvement found in objective sleep parameters as well as subjective sleep parameter during week 1, 2 and 5. A correlation was found between objective and subjective total sleep time and objective and subjective total time in bed. There was no correlation found between pain intensity and sleep quality.

Conclusion

This pilot study indicates that the participation in the ACT-based intervention decreases dysfunctional beliefs and attitudes about sleep and insomnia severity, even though only data from 11 participants was used. Although, it is unclear which component of the intervention is responsible for these findings.

Keywords: ACT-based intervention, sleep quality, Insomnia, Dysfunctional beliefs and attitudes, Chronic pain

Introduction

Chronic pain, usually defined as pain that persist longer than three months, is a complex and distressing problem that has a profound impact on individuals and society (Mills, Nicolson & Smith, 2019). It can lead to a complete stop of the previous life, the formation of a new identity and a new definition of what normal life is with pain (Ojala, 2015). Furthermore, its economic costs are driven by a decreased productivity, absenteeism, and early retirement (Breivik, Eisenberg & O'Brien, 2013). In general, the prevalence of chronic pain ranges from 10% to over 40%, depending on the definition of chronic pain and the population studied (Neville, Peleg, Singer, Sherf & Shvartzman, 2008). A literature review has shown that moderate to severe general chronic pain among Dutch adults can be estimated at 18% (Bekkering et al., 2011).

Contrary to protective acute pain, chronic pain occurs to be a dysfunction of the pain system (Andersen, Araujo, Frange & Tufik, 2018). Moreover, it is not only negatively affecting the physical health of patients, but also their mental health, daily activities, family and social relationships, and their interactions in the workplace (Dueñas, Ojeda, Salazar, Mico & Failde, 2016). The biopsychosocial model of pain, which is widely accepted as the most heuristic perspective to understand chronic pain, views pain as the result of dynamic interaction among physiologic, psychological, and social factors, which perpetuates and may even worsen the clinical presentation (Gatchel, Pen, Peters, Fuchs & Turk, 2007).

Chronic pain is associated with numerous negative consequences. For example, in a study by Ojala et al. (2014), participants reported that the pain dominated their life, removing everything else and raising itself to be the most important aspect of life. Moreover, chronic pain conditions are associated with strikingly low quality of life (Lamé, 2005), psychological disorders, such as depression and anxiety (Lerman et al., 2015), and an increased risk for social isolation (Karos et al., 2020) and suicidality (Racine, 2018). Furthermore, Breivik et al. (2006) found that people with chronic pain have difficulty to maintain an independent lifestyle and function normally due to their pain. In addition, Breivik et al. (2006) stated as one of the most notable results that two-third of the people with chronic pain were less able or unable to sleep due to the pain. In fact, a great amount of research shows that sleeping problems are one of the most reported issues in adults living with chronic pain (Smith & Haythornthwaite, 2004; Jank, Gallee, Boeckle, Fiegl & Pieh, 2017; Keilani, Crevenna & Dorner, 2018).

Insomnia is the most common sleep disorder associated with chronic pain (Mathias, Cant & Burke, 2018). More precisely, insomnia frequently occurs in patients with chronic

pain with the prevalence of co-occurrence ranging between 50% and 88% (Baker, McBeth, Chew-Grahm & Wilkie, 2017). Insomnia is characterized by dissatisfaction of sleep quantity or quality and is associated with symptoms like difficulty in initiating sleep, maintaining sleep and early-morning awakening with the inability to return to sleep. Acute or short-term insomnia lasts less than 3 months and it is defined as chronic when it occurs at least 3 nights per week for at least 3 months (American Psychiatric Association, 2013). Furthermore, the estimates of the prevalence of insomnia depend on the criteria used to define insomnia, but approximately 30% of adults report one or more symptoms of insomnia (Roth, 2007).

There are models of insomnia that describe how insomnia occurs and maintains. The behavioural model, also known as the 3P model, describes a set of predisposing, precipitating, and perpetuating factors that may contribute to the development and maintenance of insomnia (Levenson, Kay & Buysse, 2015). Two examples for predisposing factors, that make an individual more susceptible to insomnia are advanced age and female gender (Soares, 2005; Patel, Steinberg & Patel, 2018). Precipitating factors, that coincide with the onset of insomnia are for example major stressors like a divorce (Benca, 2007). Perpetuating factors are behaviours and beliefs that maintain insomnia, such as increasing time in bed to "catch" up on sleep (Levenson, Kay & Buysse, 2015;). Another often used model, the cognitive model of insomnia, focuses on cognitive processes. According to the model, the central cognitive processes that ensure the maintenance of insomnia, are selective attention and monitoring, distorted perception of sleep and daytime deficits, erroneous beliefs, and counterproductive safety behaviours. These processes cause an escalation of excessive and increasingly catastrophic worry along with the associated physiological arousal and emotional distress (Harvey, 2002). All in all, the 3P model, the cognitive model and several other models of insomnia contribute all something unique to the understanding of the aetiology of insomnia (Perlis, Smith & Pigeon, 2005).

Insomnia is, just as chronic pain, associated with numerous negative consequences and a lot of them are the same. Insomnia is an important cause of reduced quality of life, is associated with substantial morbidity and mortality, and is a significant economic burden on society (McArdle, 2020). Moreover, people with insomnia have a higher risk to develop depression and anxiety compared to people with no sleep difficulties (Baglioni et al., 2011; Chen, 2017). Furthermore, daytime symptoms that are associated with insomnia are sleepiness, fatigue, depressed mood, lack of energy, impaired cognition, memory problems, irritability, psychomotor dysfunction, and a decreased alertness and concentration (Szentkirályi, Madarász & Novák, 2009).

The direction of the sleep-pain relationship is frequently debated (Babiloni et al., 2020). In general, there is strong evidence that sleep disturbance and chronic pain have a bidirectional relationship (Affleck, Urrows, Tennen, Higgins & Abeles, 1996; McCracken & Iverson, 2002). However, some studies indicate that changes in sleep were a stronger predictor of changes in pain than the other way around. In a critical review by Finan, Goodin and Smith (2013) the prospective and experimental research between 2005 and 2013 on the association of sleep and pain was examined. In short, the results indicate that sleep impairments can reliably predict new incidents and exacerbations of chronic pain. They found that sleep impairments are a stronger, more reliable predictor of pain than the other way around. Additionally, they found that sleep disturbance may impair key processes, such as endogenous pain inhibition, that contribute to the development and maintenance of chronic pain. Since 2013, more research has been performed and support the previous conclusion that sleep is a stronger predictor of pain, than pain is of sleep (Agmon & Armon, 2014; Anderson et al., 2018; Koffel et al., 2016).

Multiple studies investigated sleeping problems in chronic pain patients. Keilani, Crevenna and Dorner (2018) have shown that 38.8% of the chronic pain patients needed more than 30 minutes to fall asleep, 63.6% reported sleep fragmentation, 30.6% slept less than 5 hours a night and 60.3% reported no recovering effect of sleep. Chronic pain patients report poorer sleep quality, more symptoms of disruptive sleep, poorer daytime functioning, spend more time in bed and show lower sleep efficiency than patients without chronic pain (Lunde, Pallesen, Krangnes & Nordhus, 2010). Furthermore, some studies support that sleep continuity, sleep architecture and sleep fragmentation are significantly worse in persons with chronic pain compared to healthy controls. Especially disruptions of sleep continuity (e.g., sleep efficiency) are common in chronic pain patients (Bjurstrom & Irwin, 2016; Mathias, Cant & Burke, 2018).

Dysfunctional beliefs play a role in the maintenance of pain and insomnia. Dysfunctional beliefs and attitudes in chronic pain patients interfere with pain, disability, and mood (Barbosa et al., 2018). For example, the beliefs that one is disabled, and that activity should be avoided because pain signifies damage was positively associated with physical disability (Jensen et al., 1994). In the case of insomnia, dysfunctional beliefs about sleep may lead to increased arousal and attention toward sleep-related threats, preventing sleep onset and exacerbating sleep difficulties (Theadom & Cropley, 2008). The unrealistic sleep beliefs that nothing can be done about poor sleep may heighten sleep-related performance anxiety and make sleep more difficult to achieve (Carney & Edinger, 2006). The change of

dysfunctional beliefs and attitudes is associated with improvements in subjective sleep report and improvement in daytime impairment (Eidelman et al., 2016).

Measurements of sleep

In clinical literature a common characteristic of insomnia is the discrepancy between subjective reports of sleep and objective measurements (Lund et al., 2013). An individual with insomnia tends to overestimate their sleep disturbances compared with objective measures of sleep (Ouellet & Morin, 2006). Harvey and Tang (2012) investigated the possible mechanisms of misperception in insomnia patients and the results show that three mechanisms can explain the discrepancy between subjective and objective findings in insomniacs: (1) sleep being misperceived as wake (2) worry and selective attention toward sleep-related threats and (3) the presence of brief awakenings.

However, sleep quality is a complex phenomenon that is difficult to define and measure objectively. It includes quantitative aspects of sleep, such as sleep latency, as well as purely subjective aspects such as restfulness of sleep. The exact elements of sleep quality and their relative importance may vary between individuals (Buysse, Reynolds, Monk, Berman & Kupfer, 1989). In fact, objective sleep quality and quantity are not included as formal criteria for the diagnosis of insomnia; because of multiple reasons, such as a large variability in sleep needs in the general population and the absence of empirically validated cut-offs for objective sleep parameters defining pathology (Castelnova et al., 2019). However, the best practice is to include both subjective and objective measures when examining sleep quality in adults (Landry, Best & Liu-Ambrose, 2015). Subjective sleep quality is mainly evaluated using sleep diaries and/or questionnaires (Crivello, Barsocchi, Girolami & Palumbo, 2019). Polysomnography is the golden standard for sleep assessment and diagnosis of sleep, but it is a costly, highly specialized procedure, which can only be used as a short-term monitoring with substantial burdens to the participant (Fonseca, Den Teuling, Long & Aarts, 2018). Alternatives are movement, respiration and heart rate sensors used in home sleep monitoring, such as actigraphy (Park & Choi, 2019) or ballistocardiography (Giovangrandi, Inan, Wiard, Etemadi & Kovacs, 2011).

Treatment for insomnia

There are several therapies for insomnia, including pharmacological treatment, cognitive behavioural therapy (CBT-I), which is the most used one, and third-wave cognitive behavioural psychotherapies (CBT).

Pharmacological treatment is one possible way to treat insomnia and includes an approved list of medications (e.g. Flurazepam, Triazolam or Zaleplon) (Lie, Tu, Shen & Wong, 2015). Nevertheless, treatment with these medications is associated with a wide range of side effects, including residual daytime sedation, drowsiness, dizziness, light-headedness, and lack of coordination (Roach et al., 2020). Also, sleep medication is more a short-term solution (Lie, Tu, Shen & Wong, 2015).

The first wave of psychotherapy for insomnia included single component treatments that took a strictly behavioural focus (e.g., sleep restriction) and as the field of psychotherapy moved towards a focus on patterns of thinking during the second wave, insomnia treatments followed with cognitive therapy and shortly after, with cognitive behavioural therapy (Taylor, Hailes & Ong, 2015). Cognitive behavioural therapy for insomnia has the goal to change sleep-related behaviours and thoughts to target factors that cause insomnia to persist over time (Mitchell, Gehrman, Perlis & Umscheid, 2012). The components of Cognitive Behavioural Therapy for Insomnia (CBT-I) are stimulus control therapy, sleep restriction, relaxation, cognitive therapy and sleep hygiene (Taylor & Pruiksma, 2014). Although multiple studies support the effectiveness of CBT-I (Mitchell, Gehrman, Perlis & Umscheid, 2012; Van Straten, 2018), attrition and suboptimal adherence may diminish its impact (Matthews, Arnedt, McCarthy, Cuddihy & Aloia, 2013).

Acceptance and commitment therapy (ACT) is one of the third-wave CBT for insomnia. The third wave is a collection of new therapies that has been developed to continue the tradition of behaviour therapy but adopt a different approach to internal experiences and cognitions compared to the therapies of the second wave (Taylor, Hailes & Ong, 2015). Traditional cognitive interventions focus on changing the content of thoughts but the focus in ACT lies on changing the contact in which thoughts (and other private experiences) relate to behaviour. ACT focuses on the increase of psychological flexibility, clarifying the client's values and asks them to make commitments to move toward behavioural changes that are consistent with their values (Hayes, Strosahl & Wilson, 1999). The six core processes of ACT are: Contact with the present moment, Acceptance, Defusion, Self-as-context, values and committed action (Harris, 2009). A study by Dalrymple et al. (2010) showed that some

people do not respond to cognitive behavioural therapy for insomnia and that acceptance and commitment therapy has the potential to help in such a situation.

A growing amount of research support the effectiveness of ACT on sleep quality and insomnia (Salari, 2020) and dysfunctional beliefs and attitudes (Lappalainen et al., 2019; Zakiei & Khazaie, 2019; Rafihi-Ferreira et al., 2020). Few studies have been added in literature that examine the effect of Acceptance and Commitment Therapy (ACT) specifically in chronic pain patients with insomnia (McCracken, Williams & Tang, 2011; Daly-Eichenhardt, Scott, Howard-Jones, Nicolaou & McCracken, 2016; Zetterqvist, 2018). In the systematic review by Salari (2020) evidence was found that ACT has a significant effect on primary and comorbid insomnia and sleep quality evidence in studies that have been published in 2012-2020. A study by Lappalainen et al. (2019) investigated an internet-delivered self-help ACT and the results showed a significant improvement in quality and duration of sleep and sleep-related dysfunctional belief and attitude, also during the 6 month follow up. In another study by Zakiei & Khazaie (2019) sleep quality, dysfunctional beliefs and attitudes towards sleep, emotion regulation and experiential avoidance improved over time. Furthermore, the results of an empirical evaluation of an acceptance-based behavioural treatment for insomnia and chronic pain showed an overall satisfying degree of feasibility with regards to retention, treatment compliance and completion of planned assessments (Zetterqvist).

Considering, that chronic pain and insomnia are both highly prevalent, have both numerous negative consequences and cooccur often, the present study aims to examine further whether ACT has the potential to improve insomnia severity, dysfunctional thinking, and sleep quality in patients suffering from chronic pain and insomnia. Furthermore, subjective sleep parameter as well as objective sleep parameter will be included in the present study.

Following research questions are formulated:

1.) Does the participation in the ACT-based sleep intervention lead to a decrease in sleep-related dysfunctional beliefs and attitudes?
2.) Does the participation in the ACT based sleep intervention lead to a decrease in insomnia severity?

3.) Does the participation in the ACT-based sleep intervention lead to an improvement of subjective sleep quality?
4.) Does the participation in the ACT-based sleep intervention lead to an improvement of objective sleep quality?
5.) What is relation between subjective and objective sleep parameters?
6.) What is the relation between sleep quality and pain?

Methods

Participants

A total of 18 individuals were registered to participate in the study between mid-July 2020 and November 2020. To participate in the study, participants had to meet four inclusion criteria. First, the participants had to be diagnosed with chronic pain. Second, the participants must have scored high in the subscale "insomnia" of the Symptom Checklist (SCL-90) which had to be confirmed by a psychologist after a semi-structured interview at Roessingh. Third, they had to be present at Roessingh for at least another six weeks, and finally, the participants needed to be older than 18 years.

In total, seven people were excluded from the research, four were excluded after the semi-structured interview and three were excluded during the first week of intervention at the Roessingh research centrum (e.g., through the pandemic and personal circumstances), which resulted in a total of 11 participants that took part in current research. Due to the COVID-19 pandemic it was not possible to get access to existing raw data of a control group at the Roessingh research centrum. Therefore, it was not possible to compare the results of the intervention group with a control group. The Ethics Committee of the University of Twente approved the Sleep Study and written informed consent was obtained from all participants (request number, 201052).

All 11 participants suffered from one or more of the following types of chronic pain: chronic abdominal pain, chronic hip pain, chronic back pain, chronic knee pain, whiplash syndrome, fibromyalgia, or arthrosis. In this study, the mean age of the participant sample was 46 years (SD = 10.58). Females (90.9%) and participants with a low education (72.7%) were in the majority. Table 1 summarizes the demographic characteristics of the sample.

Tabel 1

Demographic characteristics of the sample

Characteristics	**Category**	**Total (n, %)**
Age (mean, sd)		45.63 (10.58)
Gender (n (%))		
	Female	10 (90.9)
	Male	1 (9.1)
Education(n (%))		
	Low	8 (72.7)
	Moderate	2 (18.2)
	High	1 (9.1)
Medication use (n (%))		
	Yes	4 (36.4)
	No	7 (63.6)
Work situation (n (%))		
	Employed	10 (90.9)
	Unemployed	1 (9.1)
Current living situation (n (%))		
	Living with parents	1 (9.1)
	Living with partner/husband	10 (90.9)
	Living alone	0 (0.0)
Children (n (%))		
	Yes	9 (81.8)
	No	2 (18.2)
HADS* (mean, sd)		
	HADS-A	11.45 (3.45)
	HADS-D	10.36 (2.73)

*Note: Hospital Anxiety and Depression Scale

Design and Procedure

Data was collected at Roessingh, centrum for rehabilitation, in the department of pain rehabilitation. In general, the sleep expert at Roessingh checks the scores of the subscale "Insomnia" (SCL-90) of every patient. If a patient scored high on the subscale, the patient was invited to an interview. During the semi-structured interview, the sleep expert and sometimes also the researcher (depending on the COVID-19 restrictions and the approval of the participant) asked questions about the sleeping problems of the patients and verified inclusion and exclusion criteria for the ACT-based sleep intervention. After potential participants were screened with the criteria, they got an oral explanation of the study and received all necessary information about the study on paper as well as a consent form to

participate in the study. When the patient gave their consent by filling in the consent form, the patient was invited to make an appointment for their first sleep intervention session.

Figure 1 shows an outline of the design of the study, with T0 as the screening phase for potential participants. All questionnaires were in Dutch to make it more comfortable for the participants. A pre-test/post-test design was performed to examine whether the ACT-based intervention led to an improvement in sleep-related dysfunctional beliefs and attitudes. The pre-test (T1) was conducted at the beginning of week one before the first sleep intervention session and the post-test (T2) was conducted at the end of week five after the last sleep intervention session. Furthermore, six measurement points were made to determine if the ACT-based intervention led to a decrease in the insomnia severity (ISI).

In order to examine whether the ACT-based intervention lead to an improvement of the subjective sleep quality, the participants were asked to fill in their sleep diary (in paper form) just before they went to bed each night and as soon as they woke in the morning between Monday evening and Friday morning in Week 1, 3 and 5. While they were at home in Week 2 and 4, they did not have to keep a diary or answer questionnaires for this study.

The objective sleep quality was examined using the Withings Health Mate (sleep analyser). The participants received an anonymous email address and password that they used to install the Health Mate app (that was required to use the Withings Health Mate). In the participants bedroom, the mat was placed under the mattress at chest level and plugged into the main outlet. The researcher and sleep expert helped the participants with the installations.

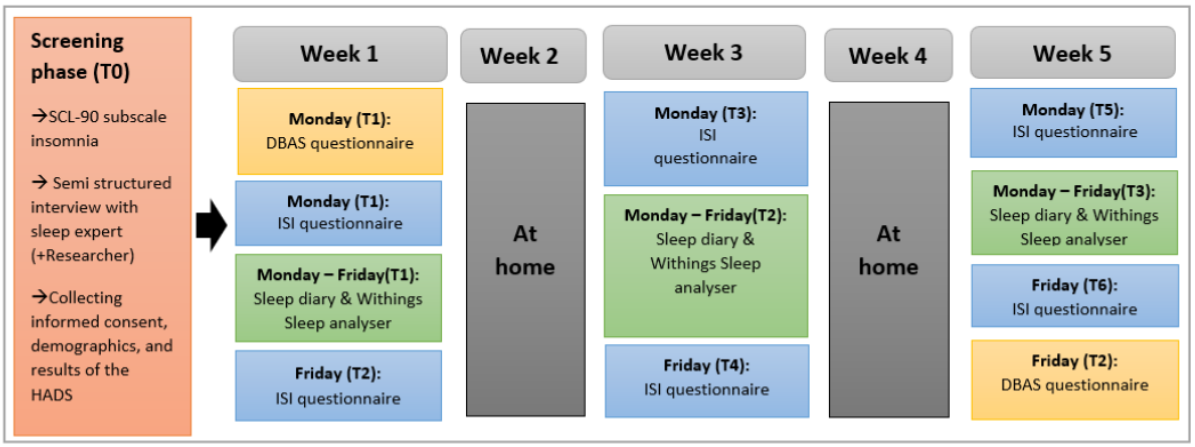

Figure 1 Study Design

Measuring Instruments

Depression and Anxiety

The Hospital Anxiety and Depression Scale (HADS) is used to measure levels of symptoms of depression (HADS-D) and anxiety (HADS-A) (Zigmond & Snaith, 1983). The questionnaire takes 2 to 5 minutes to complete and consists of 14 items, seven questions for anxiety and seven questions for depression. Each item is answered on a four-point (0-3) response category and anxiety and depression are scored separately. For both scales, a score of 0 to 7 indicate non-cases, scores of 8 to10 are defined as mild, scores of 11 to 14 are defined as moderate and scores of 15 to 21 are defined as severe (Stern, 2014). The Dutch version of the HADS was used in this study (Pouwer, Snoek & van der Ploeg, 1997). Cronbach's alpha for HADS-A varied from .68 to.93 (mean .83) and for HADS-D from .67 to .90 (mean .82) (Bjelland, Dahl, Tangen Haug & Neckelmann, 2002). This is in accordance with the findings in present study, HADS-A and HADS-D (Cronbach's alpha 0.81 and 0.68, respectively).

Dysfunctional Beliefs and Attitudes about Sleep

The self-reported 25-item questionnaire that is used in present study is part of the 30-item questionnaire Dysfunctional Beliefs and Attitudes about Sleep (DBAS) (Morin, 1993). Different versions of the questionnaire exist e.g., DBAS-SF or DBAS-16. The original DBAS is a 30-item self-report questionnaire designed to identify and assess various sleep/insomnia-related cognitions (e.g., beliefs, attitudes, expectations, appraisals, attributions) (Morin, Vallières & Ivers, 2007). The questionnaire in the present study used 23 items of the original DBAS-30 questionnaire with items such as "I need eight hours of sleep to feel good". The items that were removed were mostly referring to the age of the patients, e.g "I feel that insomnia is basically the result of aging and there isn't much that can be done about this problem". Furthermore, there were two items that are added to the questionnaire that are not part of the original DBAS-30 questionnaire. The added items were: "Smoking helps me to relax better." and "When I sleep anywhere else, I know that I will have a poor night's sleep.". In this sample, the pre-test reported a Cronbach's alpha of .82 while the post-test showed a value of .92.

Insomnia

In the present study, a ballistocardiograph and a sleep diary were used to measure the sleep of the patients and the questionnaire Insomnia Severity Index (ISI) was used to measure the severity of insomnia. The ballistocardiograph that is chosen to detect the objective sleep quality is the Withing's Sleep Analyzer. Its pneumatic sensors measure respiratory rate, heartbeat via ballistocardiography and body movements across the mattress while a sound sensor identifies audio signals specific to snoring and cessation of breathing episodes (Withings, 2020). The sleep parameter that are measured are Total Time in Bed (TIB), Total Sleep Time (TST), Sleep efficiency (SE), Wake after Sleep Onset (WASO), Number of Awakenings, Sleep Onset Latency (SOL), Sleep Stages and whether a night was restorative or not. Furthermore, a sleep score (0-10) is estimated by the Withing's Sleep Analyzer based on the following six key parameters: Duration, Regularity, Time to fall asleep, Depth, Interruptions and Time to get up. Furthermore, if a night was restorative or not depends on the depth of the sleep (proportionality of the Sleep Stages Light, Deep and REM). A ballistocardiograph was chosen because it is an inexpensive and user-friendly method that can be used for long-term sleep monitoring. Figure 2 shows the Withing's Sleep Analyzer and Withing's Health Mate app. Ballistocardiography (BCG) is based on the measurement of the body motion generated by the ejection of blood at each cardiac cycle (Giovangrandi, Inan, Wiard, Etemadi & Kovacs, 2011). It does not require attaching electrodes on patient's body surface and has therefore the advantage of not disturbing the subject's ordinary sleep behaviours in collecting data (Inan et al., 2014).

A sleep diary was used to collect quantitative data about sleep quality of the participants. The sleep diary included a morning section and an evening section with a total of 10 questions to assess the sleep quality of the participants. The questions collect information about TIB, TST, sleep efficiency and number of awakenings. In the present study the TIB consisted of the time in which the participant goes to bed until the moment that they get up. The TST consists of the time the participants try to fall asleep until the moment that they wake up. The sleep onset latency and wake after sleep onset were not measured in current study. Therefore, the TST is an overestimation of the actual TST. Furthermore, the sleep diary contains two questions that estimate the perceived sleep score of last night's sleep and how restful they woke up. Another question which was included asks the participants whether they could fall asleep quickly. They could answer with yes, no, quite fast and I don't know. Sleep diaries are less dependent on the memory of the patient because they are often

filled in just after waking up. Sleep diaries are therefore suited to detect alterations in sleep over shorter periods of time (Aili et al., 2017).

Furthermore, the Insomnia Severity Index (ISI) is used to detect the nature, severity, and impact of insomnia in patients (Morin, 1993). In present study, the questionnaire consists of seven-items that assesses the dimensions severity of sleep onset, sleep maintenance and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. Every item is rated on a different five-point Likert scale (0 = not at all/ 4 = very much or 0 = Very satisfied / 4 = Very dissatisfied) and the total score ranges from 0 to 28. The total score is divided into absence of insomnia (0-7), subthreshold insomnia (8-14), moderate insomnia (15-21) and severe insomnia (22-28) (Morin, Belleville, Bélanger & Ivers, 2011). Past research shows clearly that the ISI is a reliable and valid instrument to measure insomnia severity (Bastien,Vallières, Morin, 2001). In this sample, the ISI reported a mean Cronbach's alpha of .50 between all measurement points of the ISI.

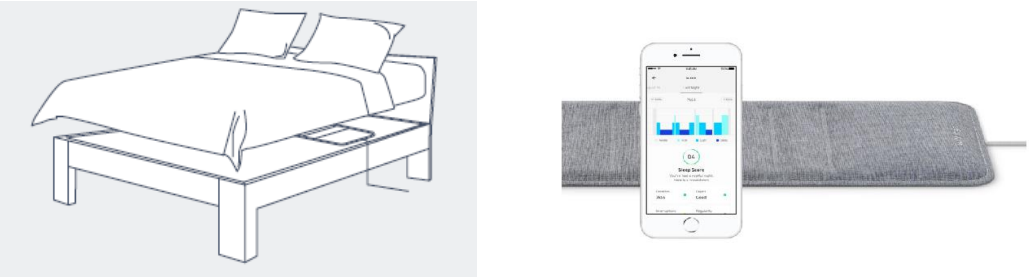

Figure 2: Withings Sleep Analyzer

Daytime activities, Fatigue and Pain intensity

The evening section of the sleep diary includes tracking daytime data about coffee after 4 p.m., alcohol consumption, exposure to direct daylight, exercising, sport, medication, naps, worries and stress. The response formats for these questions were multichotomous (Yes, No, A little), dichotomous (Yes or No) or time frames. These questions were added to assess compliance with the recommended sleep hygiene. Furthermore, the evening and morning section include questions about the fatigue of the participants. In the evening part of the diary, the participants are asked to estimate how tired they were during the day and how tired they are mentally and physically in the present moment. In the morning section of the diary, the participants are asked to estimate how fatigued they woke up. Furthermore, the

participants are asked to report their pain intensity in the morning and evening. A numeric rating scale is used for the fatigue and pain questions.

ACT-based sleep intervention

At the end of 2019, several caregivers were trained at Roessingh to get knowledge about sleep and sleep disorders. Currently, a standard ACT-based intervention is used to treat chronic pain patients with insomnia in the pain department at Roessingh. The individual face-to-face session with the sleep expert lasted 60 minutes. Since the participants slept at Roessingh during their intervention weeks, it was always possible to easily contact the sleep expert if the patient had any questions. The ACT-based intervention sessions focussed on the six core processes of ACT but included the comparison of subjective and objective sleep measures, sleep hygiene recommendations, sleep restriction and stimulus control as well. At the beginning of a session, the participants described how they perceived their sleep quality and compared it to the Withing's Sleep Analyzer data. The structure of a session was open as long as all important components of the respective session were discussed. Table 2 summarizes the content of the ACT-sessions. In general, it was the purpose not to overload the participants, therefore the participants are not overburdened with homework, especially not in the period that they were at home.

Table 2

Overview of the content of the screening phase and the three ACT-based intervention sessions

	Content
Screening phase	- Checking the SCL-90 subscale insomnia from every patient - Semi structured interview: gathering information on how the participant is currently experiencing his/her sleep (symptoms of insomnia, sleep quality and thoughts and beliefs about sleep) - Explanation of the use of the Withing's sleep analyser and the sleep diary - Explanation of what to expect when taking part in the intervention as well as from the sleep expert

Session one	- Sleep hygiene recommendations - Implementing sleep restriction (restricted time allowed in bed, improving sleep efficiency) - Implementing stimulus control (strengthen association between bed and sleep) - Introduction of the Acceptance and Commitment therapy 1. How can ACT help to treat insomnia? 2. Explaining the six core processes: Contact with the present moment, Acceptance, Defusion, Self-as-context, values and committed action → psychological flexibility 3. encouraging the patients to embrace all kind of thoughts and feelings instead of trying to get rid of them or avoid them, accept them as products of the mind (learning about acceptance and experiencing avoidance) - Homework: observe feelings, thoughts, and experiences in relation to insomnia → exercising mindfulness, practise acceptance
Session two	- Reviewing sleep pattern (Withing's data) and discuss it - Continuing sleep hygiene, sleep restriction and stimulus control - Discussing homework - Repeat homework for the next session + identify core values and commit to the values and related behaviour - Repetition of what was discussed in session one in relation to the six core processes of ACT
Session three	- Reviewing sleep pattern (Withing's data) and discuss it - Discussing homework - Repetition of the six core processes of ACT - Summary of the last weeks

Data analysis

All statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS) version 25. In order to answer the first research question, whether the ACT-based sleep intervention led to a decrease in sleep-related dysfunctional beliefs and attitudes, it was first, analysed whether the difference of the pre-test (T1) and post-test (T2) was normally distributed. The Shapiro-Wilk test was used since the sample size is smaller than 50 (Ghasemi & Zahediasl, 2012). The Shapiro-Wilk test showed that the difference between pre-test (T1) and post-test (T2) was not normally distributed ($p = .001$). Therefore, the non-parametric Wilcoxon signed rank test was conducted to investigate whether a significant change between pre-test and post-test can be concluded.

In order to answer the second research question whether the ACT-based sleep intervention led to a decrease in insomnia severity, it was first analysed whether all differences of the pre-test and post-test (T1-T6) are normally distributed. The Shapiro-Wilk

test showed that all possible differences were normally distributed, except for T2-T5 ($p = .05$). Only one difference was not normally distributed, therefore multiple paired T-tests were conducted to analyse whether the mean scores differ between the different measurement points (T1-T6) and for T2-T5 an exception was made, and the non-parametric Wilcoxon signed rank test was used.

To answer the third and fourth research question whether the ACT-based sleep intervention led to an improvement in subjective sleep quality and objective sleep quality, multiple repeated measures ANOVA and Friedman tests were run. Therefore, multiple Shapiro Wilk test were first used to determine the differences between week 1, 3 and 5 for the Sleep parameter total sleep, sleep score, sleep efficiency, wake after sleep onset, number of awakenings and total time in bed were significant. The Shapiro Wilk test was not significant for the variable's objective and subjective total sleep, objective sleep score, subjective and objective Number of Awakenings. Thus, repeated measures ANOVA was used for those variables. First, the Mauchly's test of Sphericity was used to examine whether Sphericity can be assumed ($p > .05$). The Friedman test was used for the rest variables.

Furthermore, in order to answer the fifth research question what the relation between the objective and subjective sleep parameter is, multiple Shapiro-Wilk tests were first run to check for the assumption of normality. The assumption of normality was not violated for any of the variables. Therefore, multiple Pearson's correlation analyses are used. The same method was used for the sixth research question.

Results

The first research question investigated if the ACT-based sleep intervention led to a decrease in sleep-related dysfunctional beliefs and attitudes of the participants. The Wilcoxon signed rank test indicated that the median post-test (T6) ranks were statistically significantly lower than the median pre-test (T1) ranks, $Z = -2.93$, $p < .003$. Thus, a significant decrease of the total scores of sleep-related dysfunctional beliefs and attitudes can be concluded. The greatest change in thinking throughout the intervention occurred in the following items: (1) A few bad nights of sleep have serious consequences for my health (2) When I am tired or lethargic during the day it is because of a previous bad night (3) I cannot get control over my sleep (4) I think my sleep is only going to get worse and (5) I have no control about my worrying thoughts during the night (Appendix, table 2).

Table 2 indicates the total mean scores and the standard deviations of every measurement point of the Insomnia Severity Index during the intervention. Furthermore, the most important decreases between T1 and T6 are shown.

Table 2

Mean, Standard deviation and decrease in insomnia severity over the six measurement moments

	T1 (n = 11)	**T2** (n = 10)	**T3** (n = 8)	**T4** (n = 11)	**T5** (n =10)	**T6** (n =10)
M (SD)	16.36(2.58)	13.20(2.48)	15.00(4.44)	15.00(4.38)	13.50(4.52)	12.40(4.50)
T1	-	$p < .000$*	$p < .305$	$p < .242$	$p < .050$*	$p < .023$*
T2		-	$p < .321$	$p < .168$	$p < .523$	$p < .393$
T3			-	$p < .586$	$p < .217$	$p < .033$*
T4				-	$p < .175$	$p < .004$*
T5					-	$p < .185$
T6						-

*Note: * $p < 0.05$*

Table 3 shows how the number of participants per subscale of the Insomnia Severity Index changed between baseline and post-test.

Table 3

Number of participants per subscale of the Insomnia Severity Index (ISI) at baseline and post-test

ISI subscale	**Baseline (n = 11)**	**Post-test (n = 10)**
Absence of insomnia	0	3
Subthreshold insomnia	3	3
Moderate insomnia	8	4

Severe insomnia	0	0

Below, Table 4 summarizes the total mean scores, mean scores and standard deviation of the sleep parameter that were measured with the sleep diary. No significant differences were found for subjective parameter between the total mean scores of weeks 1, 3 and 5.

Table 4.

Total mean score, mean scores per week, standard deviation and changes in subjective sleep parameter over week 1,3 and 5

Sleep Diary	**M (SD)**				
	Week 1	**Week 3**	**Week 5**	**Total**	***p****
Total Sleep Time (min)	511.26 (74.09)	521.82 (62.34)	512.87 (58.74)	514.83 (62.05)	.734
Total Time in Bed (min)	537.00 (53.40)	531.56 (55.22)	522.03 (54.97)	528.73 (53.72)	.614
Sleep efficiency	94.45(6.76)	97.85 (2.05)	96.48(4.71)	96.25(3.32)	.277
Perceived Sleep Score (0-10)	6.19 (.91)	5.95 (1.12)	5.87 (1.10)	5.98 (1.60)	.651
Number of awakenings	3.16 (1.68)	3.22 (1.74)	2.77 (1.27)	2.96 (1.05)	.594
Did you fall asleep quickly? (%)	Yes (22.5) Quite fast (42.5) No (30.0) Not sure (5.0)	Yes (17.5) Quite fast (50.0) No (30.0) Not sure (2.5)	Yes (23.7) Quite fast (36.8) No (34.2) Not sure (5.3)	Yes (21.2) Quite fast (43.2) No (31.4) Not sure (4.2)	.508
Did you wake up rested? (%)	Yes (10.0) Moderately (30.0) No (60.0)	Yes (0.0) Moderately (57.5) No (42.5)	Yes (7.7) Moderately (41.0) No (51.3)	Yes (5.9) Moderately (42.9) No (51.3)	.355

*Note: * $p < 0.05$*

Table 5 summarizes the sleep parameter that were based on the Withing's sleep analyser. No significant differences were found for the objective sleep parameter between the total mean scores of week 1, 3 and 5.

Table 5.

Total mean score, mean scores per week, standard deviation and changes objective sleep parameter over week 1,3 and 5

Ballistocardigraph	**M (SD)**				
	Week 1	**Week 3**	**Week 5**	**Total**	***p****
Total Sleep Time (min)	492.38 (63.17)	474.31 (72.00)	460.61 (60.26)	473.45 (56.13)	.234
Total Time in Bed (min)	562.62 (77.54)	537.72 (86.03)	522.33 (64.83)	537.80 (62.71)	.103
Sleep Efficiency (%)	87.94 (5.09)	87.97 (7.72)	88.11 (5.20)	88.10 (5.25)	.529
Withings Sleep Score (0-10)	8.26 (1.05)	7.93 (1.30)	7.70 (1.72)	7.97 (12.6)	.237
Number of awakenings	2.86 (2.20)	2.36 (1.79)	1.93 (1.41)	2.37 (1.66)	.530
Sleep Onset Latency (min)	30.40 (13.23)	31.71 (14.46)	32.70 (14.20)	31.46 (11.11)	.760
Wake after Sleep Onset (min)	36.16 (33.87)	34.29 (42.51)	25.04 (21.12)	30.73 (26.61)	.761
Restorative Night (Sleep Depth, %)	Good (45.7) Moderate (22.9) Bad (31.4)	Good (36.4) Moderate (30.3) Bad (33.3)	Good (44.4) Moderate (22.2) Bad (33.3)	Good (42.3) Moderate (25) Bad (32.7)	.705
Light Sleep (%)	57.01 (13.54)	57.75 (17.26)	58.53 (16.56)	57.5	.844
REM Sleep (%)	22.02 (7.58)	18.59 (7.62)	19.05 (8.58)	20.4	.421
Deep Sleep (%)	20.96 (9.15)	23.65 (12.75)	22.41 (13.32)	20.0	.060

*Note: * $p < 0.05$*

The correlation between the subjective and objective sleep parameter was analysed using the Pearson's correlation analyses, which is summarized in Table 6. A positive correlation is found between Objective Total Sleep Time and Subjective Total Sleep Time (r

= .794 , p = .000) and between Objective Total Time in Bed and Subjective Total Time in Bed (r = .929, p = .003).

Table 6

Correlation Coefficients for the sleep parameters derived from the sleep diary and ballistocardiograph

	1	2	3	4	5	6	7	8	9
Objective TTiB	-								
Subjective TTiB	.929**	-							
Objective TST	.874**	.804**	-						
Subjective TST	.911**	.963**	.794**	-					
Objective AWK	-.666*	-.727*	-.620*	-.758**	-				
Subjective AWK	.255	.114	.282	.050	.055	-			
Objective SE	-.135	-.143	.357	-.137	.158	.158	-		
Withings SS	.296	.219	.282	.144	-.520	-.484	.116	-	
Subjective SS	.233	.202	.236	.141	-.400	-.314	.028	.108	-

*Note: * p<0.001,** p<0.05, TTiB = Total Time in Bed, TST = Total Sleep Time, AWK = Awakenings, SE = Sleep efficiency, SS = Sleep Score*

During the intervention weeks the total mean score of morning pain was M = 6.22, SD = 1.539 and the total mean score of Evening Pain was M = 6.21, SD = 1.537. Below, Table 7 shows that a positive correlation was found between total sleep quality and total morning pain (r = .698, p = .017).

Table 7

Correlation Coefficients for pain intensity and perceived sleep quality in week 1, 3, 5 and total

		Sleep Quality		
	(Week 1)	(Week 3)	(Week 5)	(In total)
Morning pain	.212	.321	.236	.698*
Evening pain	.183	.273	-.083	.521

Note: *p<0.05

Finally, no changes were found in the daytime activities of the participants in between week 1, 3 and 5. During the intervention weeks, no participant drank alcohol, more than half of the total answers were positive for coffee/energy drinks after 4pm (58.1%) and 29.9% of the total answers were positive for medication use. The percentages for the item "Exposed to direct daylight" (69.2%), "Enough Exercise" (94%) and "Finished the day relaxed" (89.7%) stayed high during the intervention weeks. Furthermore, 60.7 % of the total answers were positive for physical activities/sports during the day and 32.5% of the total answers were positive for naps during the day. The stress level (11.1%) and worry level (17.1%) during the day stayed low (Table 1, Appendix). The fatigue level after waking up, fatigue during the day and mental fatigue decreased but not significantly. Only the physical fatigue decreased significantly during the intervention weeks (Table 2, Appendix)

Discussion

The key findings of this research are that sleep related dysfunctional beliefs and attitudes and insomnia severity decreased in chronic pain patients, while no significant differences are found for the subjective and objective sleep parameter. This means that the total time of sleep, time in bed, awakenings, sleep onset latency, wake after sleep onset, sleep efficiency, waking up rested, perceived sleep quality, Withing's sleep score and sleep depth of the participants did not change during the intervention. In the following section the main findings will be discussed and compared with previous studies. Additionally, the components of the intervention that could have played a role in the improvements that are found are discussed.

The present data shows that sleep related dysfunctional beliefs and attitudes significantly decreased after the five-week intervention, which is in line with a small but growing amount of research in the influence of an ACT based intervention on dysfunctional beliefs and attitudes in adults with insomnia (Lappalainen et al., 2019; Zakiei & Khazaie, 2019; Rafihi-Ferreira et al., 2020). However, to the best of my knowledge, present study is the first to investigate the influence specifically in chronic pain patients with insomnia.

The participants had a mean ISI score of 16.36 (T1), which is indicative of clinically significant insomnia. Their score decreased to a mean ISI score of 12.40 (T6), which is indicative of subthreshold insomnia, after participation in an ACT-based intervention. These findings are in line with the first systematic review that focused on the effect of ACT-based interventions on insomnia in high quality studies (Salari, 2020) and with the small number of

studies on chronic pain patients with insomnia (Wiklund et al., 2018; Zetterqvist, 2018). Even though the strongest statistical decrease for ISI scores was found in the first week, it cannot be concluded that a one-week ACT-based intervention is enough. Six participants of the nine participants, who had no missing data, had lower ISI scores at the end of the intervention compared with the end of the first intervention week. Furthermore, at the end of intervention three participants showed an absence of insomnia, which was not found in the end of the first week.

Few studies exist that combined sleep restriction/stimulus control, sleep diary and core processes of ACT related exercises like in the present study and presented a good overview of the sessions in their published study (Zetterqvist, 2018; Rafihi-Ferreira et al., 2020). Zetterqvist (2018) examined the effect of an ACT-based intervention in chronic pain patients (n = 16) with clinical insomnia (20.19 ± 3.78). At the post-test and follow-up, the mean ISI score of the participants decreased significantly below the cut-off score (post-test, 10.75 ± 5.23; 3-month follow-up 11.20 ± 6.71) (Zetterqvist, 2018). In another study by Rafihi-Ferreira et al. (2020) the ACT-based intervention showed a significant positive impact on insomnia severity and sleep-related dysfunctional beliefs and attitudes in adults with insomnia. These findings support the results of the present study and confirm the promising potential that ACT-based intervention has in improving sleep in chronic pain patients. However, the question arises which component of the ACT-based sleep intervention led to an improvement in the outcome measures in the present study.

The present study included two components of cognitive behavioural therapy for insomnia, sleep restriction and stimulus control. Previous research has shown that both components are effective interventions for insomnia (Vincent, Lewycky & Finnegan, 2008). Large treatment effects were found for sleep restriction therapy versus control on insomnia severity and self-reported sleep continuity at post-treatment (Maurer et al., 2021). Even though, no significant changes are found in the objective sleep parameter in the present study, it can be observed that total sleep time and total time in bed worsened, sleep efficiency stayed the same, the number of awakenings decreased and the mean wake after sleep onset decreased by 15 minutes. This could be the result of sleep restriction, considering that the goal of sleep restriction is to improve sleep efficiency and reduce wakefulness during the night (Maurer et al., 2021). However, the results were not significant and numerous studies show that sleep restriction improved both, sleep quality and insomnia severity (Maurer et al., 2021). The question arises how sleep restriction could have decreased insomnia severity, but not sleep quality.

Another component of the present study was the use of the Withing's sleep analyser data. In terms of the objective sleep parameters, the participants in the present study averaged 7.53 hours of sleep per night, which is good, and they had a mean sleep efficiency score of 0.88 which is also defined as good sleep efficiency. Furthermore, the participants had an average Withings sleep score of 79.7, which is also defined as good. Considering the good results of these objective sleep parameters, it could be assumed that the participants in the present are good sleeper. However, the results of the correlation analysis showed that objective and subjective total sleep time and objective and subjective total time in bed are positively correlated, but the other sleep parameters not. The subjective sleep parameters were clearly worse than the objective sleep parameter. It is not uncommon that individuals who report insomnia do not exhibit disturbed sleep according to objective measures (Lund et al., 2013). This mismatch between objective and subjective measures that is found in the present study, support the use of the Withing's sleep analyser data as a control for the subjective perception of the participants sleep.

Few studies exist that focus only on the effect of the behavioural experiment, comparison between subjective and objective measures, on insomnia severity and dysfunctional beliefs and attitudes. In a study by Tang and Harvey (2006) the effect of an one-week behavioural experiment was compared to the effect of a verbal explanation, which consists of simply being told about the discrepancy. The behavioural experiment was associated with greater reduction in insomnia severity and sleep-related anxiety and distress than the verbal explanation (Tang & Harvey, 2006). Based on these findings, Quintiliani et al. (2020) recently explored the usefulness of this behavioural experiment further in a primary-care setting. The behavioural experiment was assumed to help the patients with insomnia to identify eventual sleep misperceptions and reappraise related dysfunctional beliefs in a one-session psychoeducational intervention. The results showed a significant reduction of dysfunctional beliefs and attitudes about sleep, an improvement of subjective perception of sleep and a reduction of insomnia severity mean score, which fell below the cut off score at the post-test (Quintiliani et al., 2020). The findings support that correcting sleep misperception may have played a beneficial role in decreasing insomnia severity and sleep-related dysfunctional beliefs and attitudes in the present study. Furthermore, this could be an explanation for the strong statistical decrease that is found in the first week for insomnia severity. However, the long-term effect of this behavioural experiment is unclear (Quintiliani et al., 2020).

The main component of the intervention in the present study was ACT. No processes of ACT are measured in present study, and no control group is used, which makes it difficult to define what specifically about the ACT component could have led to the decrease in insomnia severity and dysfunctional beliefs and attitudes. However, in a preliminary retrospective study of chronic pain patients with clinical insomnia, psychological flexibility was found to be a significant predictor of insomnia severity, problems with sleep and rest, sleep efficiency and fatigue (McCracken, Williams & Tang, 2011). In line with these findings, Daly-Eichenhardt et al. (2016) found that the psychological flexibility processes such as cognitive fusion and committed action are significant correlated with insomnia severity and sleep interference. Furthermore, the results of an ACT intervention, which included ACT sessions similar to those in the present study but without sleep restriction/stimulus control and objective measures, showed improved experiential avoidance, sleep quality, dysfunctional beliefs and attitudes about sleep, sleep problems acceptance, and difficulties in emotion regulation compared to a control group (Zakiei & Khazaie, 2019). The ACT component of the present study could have improved insomnia severity and dysfunctional beliefs and attitudes through increasing psychological flexibility, bearing in mind that the patients learned about the six core processes of psychological flexibility and did exercises related to them. In summary, all of the three components could play a role in the improvement of insomnia severity or sleep-related dysfunctional beliefs. More research is needed to determine how each component of the ACT-based intervention effect sleep-related outcome measures.

Furthermore, something that was noticed when comparing the present study with previous studies, is that the present study included less ACT sessions than most ACT interventions for insomnia (Salari et al., 2020). The number of treatment sessions that are reported in previous studies varied between 6 and 8 sessions, normally including one core process of ACT per session (Salari et al., 2020). More importantly the studies that are similar to the present study and its ACT-based intervention include more ACT sessions and found improvements in sleep quality (Zetterqvist, 2018; Rafihi-Ferreira et al., 2020). The question arises whether the ACT-based invention should have been longer to find more improvements in sleep.

Furthermore, it was anticipated that insomnia severity would decrease more at each of the six measurement points of the ISI. Contrary to the expectations, no significant decrease was found in the middle of the intervention compared with the baseline. One explanation for the increase in sleeping problems could have been an increase of the experience of pain

among participants in the middle of the intervention, which conversely could increase sleeping problems according to past research (Affleck, Urrows, Tennen, Higgins & Abeles, 1996; McCracken & Iverson, 2002). In a study conducted by Kowal et al. (2011) nearly one third of the patients reported increased pain severity on global rating at the end of a three-week CBT oriented chronic pain management program. One explanation was that they were only starting to implement various pain management strategies and had not yet masters or consistently applied them (Kowal et al., 2011). In fact, of the seven participants who had higher ISI scores in the in middle of the intervention compared with the end of the first intervention week, five reported higher pain intensity compared with the start of the intervention.

Finally, a positive correlation was found between pain intensity and perceived sleep quality in the present study. These findings are in contradiction with a great number of previous studies (Finan, Goodin & Smith, 2013). An explanation is that even though the pain numeric rating scale is a valid and reliable scale to measure pain intensity, it only measures one component of the pain experience, and therefore does not capture the complexity and idiosyncratic nature of the pain experience (Hawker, Mian, Kendzerska & French, 2011). In ACT-based interventions pain acceptance and pain disability is often used (Daly-Eichenhardt et al. 2016; Zetterqvist, et al., 2018). Furthermore, the sample is small, the variability of the sample may also play a role in those results.

Strength and Limitations

One strength of the present study is that a novel method was applied to treat insomnia. This study is one of the few to examine whether an ACT-based intervention can improve insomnia severity and sleep quality among patients suffering from chronic pain. Also, it is, to the best of my knowledge, the first to examine whether an ACT-based intervention can improve sleep-related dysfunctional beliefs and attitudes in chronic pain patients with insomnia. Insomnia is highly prevalent in chronic pain patients which makes it important that the treatment for insomnia will be further developed. Therefore, the present study has an added value for researchers and therapists in developing and enhancing the treatment of people with chronic pain and insomnia.

In addition, subjective and objective sleep instruments are used. Two questionnaires with a pre-test/post-test design are used, as well as a sleep diary and ballistocardiography. Diary methods are characterized by repeated sampling of behaviours and experiences in

people's natural environments, they therefore aim to reduce memory biases and increase the ecological validity of self-reports (Schneider & Stone, 2016). The subjective and objective measures could be compared and are integrated in the intervention, which gives an insight in possible discrepancy between the two.

An additional strength is that the research was conducted in a clinical setting. The sample in the present study was not restricted to individuals without co-morbidities. The present study consisted of participants that have chronic pain and insomnia. By not excluding patients with co-morbid conditions, the present study reflects real-life patients better, considering that chronic pain and insomnia often co-occur.

A major limitation of the present study is clearly the missing control group. As result of lacking a control group, it is unclear whether the reduction in sleep-related dysfunctional beliefs and attitudes and insomnia severity were caused by the ACT-based sleep intervention, or due to other variables, such as the normal recovery over time. Therefore, no conclusion with a high degree of certainty can be drawn. An additional major limitation of the present study is the small sample size, which limited the reliability and generalizability of the results. There is a chance that the present sample has a greater sampling variability due to its small size, which can lead to bias. For example, most of the patients are female and have a low education.

Another limitation is that the sleep parameter wake after sleep onset was not included in the subjective sleep parameters that are measured in the present study. The participants were asked to estimate the number of awakenings but not the estimation in minutes. Furthermore, the subjective sleep onset latency was measured with yes/quite fast/no/I don't know response. Even though, the results give an insight whether the participants did fall asleep quickly or not, the sleep efficiency can be estimated better when measure wake after sleep onset in minutes and the results can better be compared with previous research results.

Moreover, the study was carried out during the COVID-19 pandemic, which was the cause of not including the data of a control group. Additionally, the COVID-19 pandemic caused one participant to stop during the screening phase with the treatment at Roessingh. Not to mention the possibility that the COVID-19 pandemic influenced the results of the current study. For example, one participant described in the open comments in her sleep diary how COVID-19 influenced her daily life currently.

Future Recommendations

The findings in the present study should be replicated with a larger sample and include one or more control groups. An appropriate sample size would provide more reliable and generalizing results of the present study. In terms of possible control groups, future research should conduct a randomized control trail with three groups, a group just like in the present study, chronic pain patients with insomnia that follow an ACT-based intervention, a group with chronic pain patients that receive only the behavioural experiment and a group with chronic pain patients that received sleep restriction and stimulus control. In this way the effectiveness of the ACT component of the present study could be appropriately validated. A follow up should be included to investigate the persistent effects of the treatments. Another option would be to repeat the ACT-based intervention with more individual sessions or added group sessions compared with a control group.

Furthermore, considering that the aim in treatment of both, chronic pain, and insomnia, is to help patients to cope with their pain and sleeping problems in an accepting way, future research should use methods that measure pain acceptance or pain willingness and a sleep problem acceptance instead of focusing only on measuring pain intensity and the decrease in insomnia severity.

The present study has no data from the time the patients spend at home during the intervention weeks and in terms of future research, there are some reasons why filling this knowledge gap is important. First of all, during the time the patients spend at Roessingh, they will also be prepared for the time after the treatment, which means they will be confronted about questions and problems that could occur when they resume their life at home. By measuring sleep quality at home, the sleep expert and the patient could use the data to identify possible problems in the time that they are at home or more important, only occur at home. In this way the patients are possible better prepared for the time after the treatment.

Additionally, future research should investigate more in the measurement of quality of life in chronic pain patients with insomnia. Abbasi et al. (2018) found evidence that patients with chronic lower-back pain have higher prevalence of insomnia, lower quality of life, and worse sleep quality compared to a control group, which were selected from the attendants of the same clinic. In another study by Dragioti et al. (2018) the results show that older adults with pain who reported clinical insomnia were more likely to experience pain more frequently, with an increased pain intensity and had a lower quality of life compared with

those that reported no clinically significant insomnia. Despite of the low amount of research into this subject, the findings show that chronic pain patients with insomnia might have a higher risk of experiencing low quality of life. It is important to examine quality of life in this target group further since health is defined as a state of complete physical, mental, and social well-being and not only as the absence of disease (WHOQOL, 1997). Therefore, upcoming research should not only measure the change in the frequency and severity of insomnia in chronic pain patients with questionnaires, such as the Insomnia severity index, but should also examine whether acceptance and commitment therapy leads to an improvement of quality of life in chronic pain patients with insomnia.

Some chronic pain patients in the present had mild or moderate anxiety or depression scores. Multiple studies confirm the strong relationship between insomnia and chronic pain (Finan et al., 2013), and their underlying possible mechanisms are frequently debated (Babiloni et al., 2020). Early research shows that within this target group greater levels of anxiety and depression are found compared to chronic pain patients who do not have trouble with sleeping (Hester & Tang, 2008). Recent studies show that anxiety symptoms (Dunietz et al., 2018) and depressive symptoms (Generaal, Vogelzangs, Penninx & Dekker, 2017) might partially mediate the relationship between insomnia symptoms and pain. However, more research is needed to investigate how depression and anxiety contributed to the relationship between insomnia and chronic pain (Babiloni et al., 2020). This could be achieved by adding a pre-test/post-test design with questionnaires such as the hospitality anxiety and depression scale in future research.

Practical implications

The patients also follow a multidisciplinary treatment for pain besides the ACT-based intervention at Roessingh. It is important that the patients are not overloaded during the ACT-based intervention, therefore it is important that the ACT-based intervention consists of the most important elements to help chronic pain patients with insomnia. The question arises whether all components of the ACT-based intervention are necessary. In general, it cannot be said that one component was more important than the other in the present study without the data of a control group and methods that measure outcomes that are associated with the respective intervention component.

However, some recommendations can be given to optimise the ACT-based intervention. First of all, the behavioural experiment should be used only in the first week, based on the results of previous studies, or should be used at the beginning and end of the

intervention. This would provide more time for ACT exercises in the sessions. Secondly, wake after sleep onset (min) and sleep onset latency (min) need to be included in the sleep diary. Furthermore, some questions in the sleep diary are overlapping. Therefore, some questions can be deleted. Thirdly, it would be ideal to integrate more sessions in the intervention weeks to do more ACT exercises. However, it is not certain whether this fits in the general planning. An alternative would be the use of an ACT online coaching that provides different ACT exercises online. In a study by Lappalainen et al. (2019) an unguided internet-delivered ACT was found to be effective in treating symptoms of insomnia. The intervention included 6 modules based on the processes of ACT and each module consisted of text, experiential audio exercises and video clips aiming to enhance psychological flexibility (Lappalainen et al., 2019). Ideally the ACT-online coaching would include an online sleep dairy to relieve the patient from organising sleep diary and online exercises separately.

Conclusion

Despite some non-significant results and limitations, the current study gathered new information about subjects which was limited in amount or not existent prior to this study. The present study provides an insight in the potential of an ACT-based intervention in treating insomnia in chronic pain patients. The ACT-based intervention for insomnia improves insomnia severity and dysfunctional beliefs and attitudes in chronic pain patients. More specifically, the patients might deal with their sleeping problem in a more accepting and non-judgemental way after the intervention. The results of this pilot study can be used as a basis for the planning of larger studies with control groups on this topic.

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Appendix

Table 1

Daytime activities Week 1, 3 and 5

		Mean percentage (%)	***p****
Coffee/Energy drinks after 4 pm	Yes	58.1	.135
	No	41.9	
More than 2 glasses of alcohol	Yes	0	1.00
	No	100	
Medication use	Yes	29.9	.369
	No	70.1	
Exposed to direct daylight	Less than an hour	30.8	.522
	Between 1 and 4 hours	56.4	
	More than 4 hours	12.8	
Enough exercising	Yes	94	1.00
	No	6	
Sport	Yes	60.7	.156
	No	39.3	
Naps	Yes	32.5	.846
	No	67.5	
Stress	Yes	11.1	.939
	A little bit	49.6	
	No	39.3	
Worrying	Yes	17.1	.417
	A little bit	47.9	
	No	35	
Finished the day relaxed	Yes	89.7	.368
	No	10.3	

Note: * Friedman testresults

Table 2

Mean, Standard deviations, and differences between the fatigue level between week 1, 3 and 5

Fatigue	**Week 1**	**Week 2**	**Week 3**	**W1-W2**	**W2-W3**	**W1-W3**
How tired did you wake up?	6.0 (1.8)	6.0 (1.7)	6.5 (1.6)	p < .677	p <.168	p <.645
How tired did you feel during the day?	7.2 (1.6)	6.7 (1.4)	6.2 (1.6)	p <.074	p <.138	p <.059
How tired do you feel mentally right now? (Evening)	7.4 (1.3)	6.9 (1.3)	6.5 (1.5)	p <.153	p <.441	p <.169
How tired do you feel physically right now? (Evening)	7.5 (1.0)	7.1 (0.8)	6.5 (1.3)	p <.153	p <.066	p <.012*

Note: * p<0.05

Dagboek

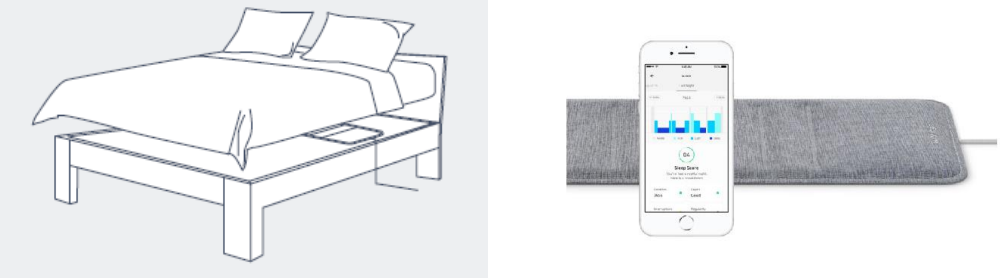
Slaapmonitoren bij mensen met chronische pijn met en zonder slaapproblemen

Gegevens Healthmate app
Emailadres:
Wachtwoord:

Het slaapboekje bestaat uit drie verschillende onderdelen:

1. Op de eerste en laatste dag van het hele onderzoek vult u de vragenlijst “Hoe denk je over slaap?” in.
2. Het slaapboekje bevat een dagboek. Het dagboek vult u elke avond en ochtend in. Deze vragenlijst bestaat uit 19 vragen in de avond en 12 vragen in de ochtend. Het invullen van het dagboek duurt ongeveer 5 minuten per keer.
3. Elke maandag en donderdag vult u een slaapinventarisatie vragenlijst (ISI) in.

Het is van belang dat de onderdelen van het slaapboekje op het juiste moment worden ingevuld om de resultaten beter te kunnen analyseren en fouten te verkomen.



Figuur 1: Slaapsensor

1.Vragenlijst ‘Hoe denk je over slaap’

Hieronder vind je een aantal overtuigingen over slaap en slapeloosheid. Geef aan in hoeverre je het eens of oneens bent met iedere overtuiging. Er is geen goed of fout antwoord.

	Helemaal oneens	Helemaal eens
1. Ik heb acht uur slaap nodig om me goed te voelen.	O O O O O	
2. Haal ik de acht uur niet, dan moet ik dat inhalen door de volgende nacht langer te slapen, of door overdag te dutten.	O O O O O	
3. Een paar slechte nachten slaap heeft ernstige gevolgen voor mijn gezondheid.	O O O O O	
4. Mijn slapeloosheid zit in mijn genen. Ik heb daar echt pech mee.	O O O O O	
5. Wanneer ik ergens anders slaap, slaap ik sowieso slecht.	O O O O O	
6. Met een slaappil slaap ik zeker weten beter dan zonder slaappil.	O O O O O	
7. Als ik slecht geslapen heb zien anderen dat aan me.	O O O O O	
8. Als ik de volgende dag een belangrijk iets te doen heb, kan ik beter eerder dan later naar bed.	O O O O O	
9. Door uit te slapen in het weekend slaap ik meer en voel ik me beter.	O O O O O	
10. Als ik niet kan inslapen is het het beste om in elk geval in bed te blijven liggen.	O O O O O	
11. Als ik niet kan inslapen probeer ik nog harder mijn best te doen in slaap te vallen.	O O O O O	
12. Eén slechte nacht vormt altijd het begin van een reeks slechte nachten.	O O O O O	
13. Ik kan zelf geen controle uitoefenen op mijn slaap.	O O O O O	
14. Wanneer ik moe of futloos ben overdag, komt dat door een voorafgaande slechte nacht.	O O O O O	
15. Mijn slapeloosheid heeft een enorme impact op mijn leven.	O O O O O	
16. Ik kan niet goed omgaan met mijn slapeloosheid.	O O O O O	

17. Door mijn slapeloosheid kan ik niet gelukkig zijn. Het belemmert mij in de dingen die ik wil doen.	O O O O O
18. Ik moet net zo goed kunnen slapen als anderen. Bijvoorbeeld als mijn partner.	O O O O O
19. Na een slechte nacht heb ik gegarandeerd een slechte dag. Ik functioneer dan amper.	O O O O O
20. Ik heb geen invloed op mijn (pieker)gedachten.	O O O O O
21. Ik weet nooit van te voren of ik wel of niet goed zal slapen.	O O O O O
22. Als ik slecht geslapen heb, is het beter voor mij sociale verplichtingen af te zeggen.	O O O O O
23. Een glas alcohol is een goede manier om lekker te slapen.	O O O O O
24. Ik denk dat mijn slaap alleen nog maar slechter wordt. Ik geloof niet dat mijn slaap ooit goed wordt.	O O O O O
25. Roken helpt me beter te ontspannen.	O O O O O

<u>Hoe zou jij een goede nacht definiëren? Wanneer vind je dat je goed geslapen hebt?</u>

<u>Hoe zou jij een slechte nacht definiëren? Wanneer vind je dat je slecht geslapen hebt?</u>

Heb je problemen met slapen? Zo ja, wat voor problemen heb je dan?

---

2. Slaapinventarisatie vragenlijst (ISI)

Onderstaande vragen gaan over **hoe u uw slaap ervaart.**

Om te antwoorden hoeft u alleen het cijfer te omcirkelen bij het antwoord dat het best op u van toepassing is. Dus vindt u bijvoorbeeld dat u over het algemeen enigszins moeite heeft met inslapen, komt dit er als volgt uit te zien:

Voorbeeld

	Niet	Een beetje	Matig	Ernstig	Zeer ernstig
Moeite met inslapen	0	(1)	2	3	4

Beantwoord alle uitspraken. Omcirkel slechts één antwoord bij elke uitspraak!

Het is mogelijk dat u per ongeluk het verkeerde antwoord omcirkelt of bij nader inzien toch een ander antwoord wilt geven. Als dat het geval is, kruis dan het foute antwoord duidelijk door en omcirkel het juiste antwoord.

1. Geef de ernst van uw slaapprobleem aan gedurende de afgelopen twee weken:

	Geen	Een beetje	matig	ernstig	Zeer ernstig
a.) Moeite met inslapen	0	1	2	3	4
b.) Moeite met doorslapen	0	1	2	3	4
c.) Problemen met te vroeg wakker worden	0	1	2	3	4

2. Hoe tevreden bent u met uw huidige slaappatroon?

Zeer tevreden	Tevreden	Neutraal	Ontevreden	Zeer ontevreden
0	1	2	3	4

3. In hoeverre beïnvloeden uw slaapproblemen uw dagelijks functioneren? (bijvoorbeeld vermoeidheid, concentratie, geheugen en stemming)

	Geen negatieve invloed	Een beetje	Enigszins	Veel	Zeer veel negative invloed
	0	1	2	3	4

4. Hoe opvallend zijn de dagelijkse gevolgen van uw slaapproblemen voor anderen?

	Helemaal niet opvallend	Een beetje	Enigszins	Erg	Heel erg opvallend
	0	1	2	3	4

5. Hoe ongerust bent u over uw huidige slaapproblemen?

	Helemaal niet ongerust	Een beetje	Enigszins	Erg	Heel erg ongerust
	0	1	2	3	4

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4. Dagboek

Maandag avond

In de avond (als je in bed gaat liggen)

Datum:
Tijdstip dat je naar bed bent gegaan:

1. Ga je direct slapen nadat je dit dagboek hebt ingevuld, of ga je eerst nog wat anders doen (tv kijken, boek lezen etc)?
☐Ik ga direct slapen na het invullen van dit dagboek
☐Ik ga eerst nog wat anders doen
➔ Vul dan hier later op de avond het tijdstip in van het moment dat je daadwerkelijk klaar bent om te gaan slapen:

_____uur

2. Heb je na 16.00 uur vanmiddag nog koffie of andere cafeïne-houdende dranken gedronken?
☐ Ja
➔ Hoe laat heb je je laatste kop koffie of andere cafeïne-houdende drank gedronken?

Om _____ uur
☐ Nee

3. Heb je vandaag meer dan 2 glazen alcohol gedronken?
☐ Ja
☐ Nee

4. Hoeveel ben je blootgesteld aan direct daglicht (dus in de buitenlucht) vandaag?
☐ < 1 uur
☐ 1-4 uur
☐ > 4 uur

5. Heb je na 18.00 uur ‘s avonds nog buiten gewandeld/ gefietst?
☐ Ja→ hoeveel minuten in totaal?

____ minuten
☐ Nee

6. Heb je vandaag voor je gevoel voldoende lichaamsbeweging gehad?
☐ Ja
☐ Nee

7. Heb je nog gesport vandaag (min 30 min intensieve beweging)?
☐ Ja
☐ Nee

8. Indien je een fitbit of een andere stappenteller gebruikt:

Hoeveel stappen heb je vandaag in totaal gezet?

_____ stappen

9. Heb je vandaag nog medicatie gebruikt die van invloed kan zijn op je slaap (betablokkers, slaapmedicatie, ontspanningsmiddelen)?

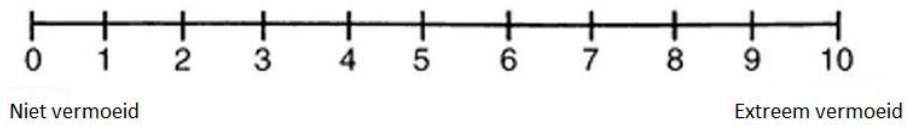
☐ Ja→ Welke medicatie heb je gebruikt?

_____
_____

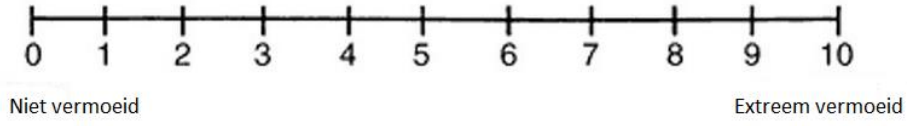
☐ Nee

10. Heb je overdag nog dutjes gedaan?
☐ Ja
☐ Nee

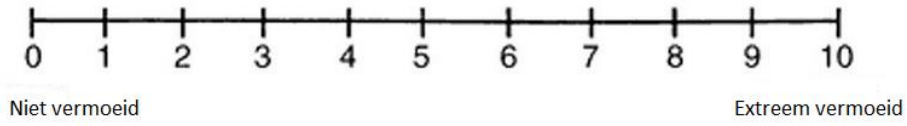
11. Hoe moe voelde je je vandaag op een schaal van 1-10? Waarbij 1 niet moe is en 10 extreem moe.



12. Hoe moe voel je je *mentaal* op dit moment op een schaal van 1-10? Waarbij 1 niet moe is en 10 extreem moe.



13. Hoe moe voel je je *fysiek* op dit moment op een schaal van 1-10? Waarbij 1 niet moe is en 10 extreem moe.



14. Heb je veel stress gehad vandaag?

☐ Ja
☐ Nee
☐ Beetje

15. Heb je je overdag veel zorgen gemaakt?
☐ Ja
☐ Nee
☐ Beetje

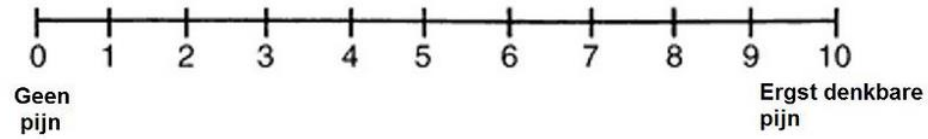
16. Heb je je dag ontspannen afgerond?

☐ Ja
☐ Nee

17. Heb je een zware maaltijd gegeten 2 uur of minder voordat je naar bed bent gegaan?
☐ Ja
☐ Nee

18. Heb je op dit moment ergens lichamelijke pijn?
☐ Ja
☐ Nee

Indien ja: Waar heb je pijn:
Wat is je pijnscore op een schaal van 0-10:



19. Heb je nog andere opmerkingen die betrekking kunnen hebben op je slaap vannacht?

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Dinsdag ochtend

(vlak voordat je op gaat staan)

Datum:
Tijdstip van invullen:

1. Viel je snel in slaap gisteravond?
☐Ja
☐Redelijk snel
☐Nee
☐ Weet ik niet meer

2. Hoe laat ben je wakker geworden vanmorgen?

Om_____ uur

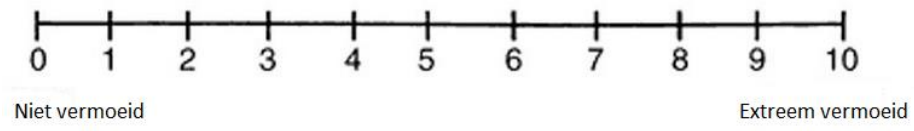
3. Wat was de reden dat je wakker bent geworden (wekker, uit jezelf, kinderen, etc)?
_____
_____
_____
_____
_____
_____

4. Wat voor cijfer geef je je slaap vannacht?

_____

5. Werd je uitgerust wakker?
☐ Ja
☐ Redelijk
☐ Nee

6. Geef met een streepje op onderstaande schaal aan hoe vermoeid je wakker werd op een schaal van 0-10?



7. Heb je een goede of een slechte nacht gehad?

_____

Waarom vind je dat?

_____
_____
_____
_____
_____
_____

8. Ben je vannacht nog een keer wakker geworden?

☐ Ja → Hoe vaak ben je wakker geweest?

_____ keer

☐ Nee

☐ Weet ik niet meer

9. Ben je nog uit bed geweest vannacht?

☐ Ja

☐ Nee

☐ Weet ik niet meer

10. Heb je 's nachts liggen piekeren?

☐ Ja

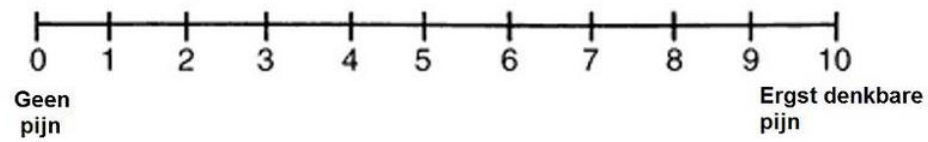
☐ Nee

11. Heb je op dit moment ergens lichamelijke pijn?

☐Nee

☐Ja → Waar heb je pijn:_____

Wat is je pijnscore op een schaal van 0-10:



12. Heb je nog andere opmerkingen over je slaap vannacht?

_____
_____
_____
_____
_____
_____