The Good Night Project

Behavioural Sleep Interventions for Children with ADHD: A Randomised Controlled Trial

Hetaf Abdullah I Alammar

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The candidate confirms that the work submitted is hear own and that appropriate credit has been given where reference has been made to the work of others.

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Abstract

The Good Night Project is an evidence-based project aimed to design, implement and evaluate an RCT of behavioural interventions to improve sleep for children aged 5-12 years with ADHD and their primary caregivers in the Kingdom Saudi Arabia. The project was developed by systematically reviewing the literature. From the available, high quality literature using an RCT design (n=4), a group of behavioural interventions were identified using the behaviour change techniques taxonomy BCTs (Chapter two). Health professionals and caregivers were asked to rank these interventions from the most important interventions to the less important interventions using a Delphi method in two rounds (Chapter three). Their recommendations were considered when preparing the final version of the intervention. The 34-page Good Night Project was developed as a guide, translated from English to Arabic. Sleep habits cards and a video clip were also available to help children and their caregivers to promote sleep hygiene. The intervention, using these materials, was delivered by the psychologists to the caregivers in three sessions over three weeks, with each session lasting for three hours. The project was completed in the Kingdom of Saudi Arabia using a randomised controlled trial (RCT) design (Chapter four). Due to the high attrition rate, the number of participants who dropped out (n=61) which is more than 80% of the eligible participants, the study aim has been changed to examine the feasibility of the project instead of the efficacy (Chapter four). The results indicated that the Good Night Project is not feasible at this stage due to high attrition rate, although there is some tentative evidence of positive outcomes for those who completed the intervention. Thus, a further study is required using focus groups or experience-based co-design in order to explore factors that affect parents' ability to complete the

intervention. Following this, a further feasibility study is recommended taking into account the changes indicated to improve acceptability. General discussion about the project including summary of the results, implication for practice and for future research and contribution to knowledge including behavioural change interventions, culturally adapting interventions and sleep in children with ADHD are considered (Chapter five).

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Abbreviations

ADHD	Attention Deficit Hyperactivity Disorder
ASD	Autism Spectrum Disorder
AW	Dr Anna Weighall
BCT Taxonomy	Behaviour Change Techniques Approach
Clinical trial.gov	Database for the registration of randomised controlled trial protocol
CSHQ	The Children's Sleep habit Questionnaire
DSM-5	The Diagnostic and Statistical Manual of Mental Disorders – the fifth version
FDA	The Food and Drug Administration
GRADE	The Grading of Recommendations Assessment, Development, and Evaluation approach
HA	Miss Hetaf Alammar
HN	Dr Hannah Nash
IK	Dr Ian Kellar
JB	Miss Jane Blackwell
NDDs	Neurodevelopmental disorders
PROSPERO	Database for the registration of systematic review protocol
PRISMA	An evidence-based checklist for reporting in systematic reviews and meta-analyses.
RCT	Randomised Controlled Trial
RLS	Restless Leg Syndrome
Revman5	The software used for preparing and maintaining Cochrane Reviews.

Conferences presentations and publications

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Chapter 1 General overview

"And of His signs is your sleep by night and day and your seeking of His bounty. Indeed in that are signs for a people who listen"

The Qura'an, Ar-Rroom, ayah 23

1.1 Introduction

1.1.1 Normal and abnormal sleep in school aged children

Typically developing children of school age with normal sleep require 9–11 hours of sleep every day, but a period of 7–8 hours of sleep is considered as acceptable according to the National Sleep Foundation (Hirshkowitz et al., 2015), and there is considerable individual variation in sleep needs. Although available evidence about parents knowledge of their children's sleep is limited (eight studies in both clinic and community samples), a recent systematic review found that parents (n = 1155) were not aware of the importance of sleep in child development (McDowall, Galland, Campbell, & Elder, 2017).

Sleep is related to many aspects of a child's development. It plays an important role in daily functions and is found to affect a child's quality of life, cognitive functioning, psychological well-being and physical health (Chorney, Detweiler, Morris, & Kuhn, 2007; Craig, Weiss, Hudec, & Gibbins, 2017; Galland et al., 2015; Knight & Dimitriou, 2017; Lee et al., 2014; Patel & Hu, 2008; Virring, Lambek, Jennum, Møller, & Thomsen, 2014; Yurumez & Kilic, 2016). A meta-analysis reviewed 11 studies with around 25,000 children and adolescents found that, there is a significant relationship

between lack of sleep and obesity in young people (Fatima & Mamun, 2015). A four-year longitudinal study showed that, children with sleep disturbances during pre-school have shown a significant impact on psychological well-being (e.g., aggressive symptoms, attention deficit, social problems, somatic complaints and anxiety when they were in school age according to the Child Behaviour Checklist (CBCL) (Simola, Liukkonen, Pitkäranta, Pirinen, & Aronen, 2014). Another longitudinal study assessed over 8,000 children eight times, from birth to 11 years using a questionnaire completed by parents about sleep patterns and sleep duration, and found that those with ADHD has shorter sleep durations and wake after sleep onset 'WASO' than those without the disorder (Scott et al., 2013).

Nearly a third of school aged children have sleep difficulties reported by themselves or their parents (Mindell & Owens, 2015; Stores, 2009). Commonly reported sleep related issues include irregular sleep and wake up time which lead to different sleep duration, late bedtime, sleep anxiety and the need of their parents to be with them and high consume of caffeine during the day which may affect sleep (Meltzer, 2017; Mindell & Owens, 2015). The increased prevalence of screen-based technologies (e.g., mobile phones, video games, iPads and computers) have also been found to affect children's sleep duration and quality. A systematic review found that there is a significant negative effect of using screen-based technologies and poor sleep in school aged children (Hale & Guan, 2015). It has also been found that some groups of children may be at increased risk of sleep difficulties (e.g., children with neurodevelopmental disorders including children with Attention Deficit Hyperactivity disorder ADHD and Autism Spectrum Disorder ASD) (Stores, 2014).

1.2 Attention Deficit Hyperactivity disorder (ADHD)

1.2.1 Defining ADHD

ADHD is a neurodevelopmental disorder that is common in children and adults worldwide. According to the Diagnostic and Statistical Manual of Mental Disorders, the fifth edition (DSM 5), ADHD can be defined as "a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development, with symptoms present prior to age 12 years, in two or more settings. There is clear evidence that the symptoms interfere with, or reduce the quality of, social, academic, or occupational functioning'' (American Psychatric Association, 2013, p. 59). Two recent studies have shown that ADHD affects not only the affected child's quality of life, but that of their parents and siblings (Lee et al., 2016; Peasgood et al., 2016).

ADHD can be diagnosed when the symptoms have been observed in the past 6 months as the following three main types:

- *Inattentive type*, which is more common in primary school children and can be clearly observed in girls more than boys and in older children more than younger children.
- *Hyperactivity and impulsivity type*, which is more common in preschool and less common in adolescents, although some symptoms could still present (e.g., impulsivity).
- *Combined type of the Inattentive type and hyperactivity and impulsivity type* which can be seen in younger children more than older children and adolescents (American Psychatric Association, 2013; Weyandt, 2017).

The combined type of the Inattentive type and hyperactivity and impulsivity is the most common followed by inattentive type, and the less common is the hyperactivity and impulsivity type (Díaz-Román, Hita-Yanez, & Buela-Casal, 2016).

1.2.2 Prevalence of ADHD

ADHD is common in most cultures but prevalence rates vary; from 2%–5% of children in the United Kingdom (National Health Service, 2016), 4.8% in Germany (Huss, Hölling, Kurth, & Schlack, 2008), 3-5% in France (Lecendreux, Konofal, & Faraone, 2011), 5.9% in South Korea (Park et al., 2015) to 7%–8% of children in the United States (Barkley, 2013). The prevalence of ADHD in Arab countries is reported to be even higher, one study systematically reviewed 22 articles with nearly 30,000 children and found that ADHD occurred in 1.3%–16% of children in Arab countries (Alhraiwil, Ali, Househ, Al-Shehri, & El-Metwally, 2015).

According to the National Survey of Children's Health in the United States, the prevalence of ADHD is increasing from 7.8% in 2003 to 11% in 2011 (Visser et al., 2014). A number of factors may explain differences in prevalence rates in different countries (e.g. cultural factors, different versions of the DSM and the methodological ways of assessing the disorder). Cultural factors may play a significant role in recognizing the symptoms then seeking diagnosis (American Psychatric Association, 2013). Parents may be more aware of the differences between normal behaviours and abnormal behaviours that may need an intervention (Visser et al., 2014). In addition, a systematic review and meta-analysis has reported that, there is an increase in the ADHD diagnosis following each version of the DSM which may include changes in criteria that can lead to more frequent diagnoses (Thomas, Sanders, Doust, Beller, & Glasziou, 2015). Also, Lecendreux (2011) highlighted the role of methodological aspects of each

study (e.g., source of data collection (parents, teachers and/or the children) and the way of data collection (e.g., clinical interviews or phone interviews) rather than the cultural issues when conducting the epidemiological studies of the prevelance of ADHD (Lecendreux et al., 2011).

1.2.3 Comorbidities with ADHD

ADHD often co-occurs with other disorders. Common disorders in children with ADHD found in recent studies including learning disorders (e.g., Dyslexia), anxiety disorder, mood disorders, eating disorders and oppositional defiant disorder (Craig et al., 2017; Larson, Russ, Kahn, & Halfon, 2011; Yoshimasu et al., 2012; Yürümez & Kılıç, 2016). Moreover, significant sleep-related difficulties have been observed in children with ADHD by parents and reported in a recent study (Fawkes et al., 2015), reviews and meta-analysis (Cortese, Faraone, Konofal, & Cndreux, 2009; Gregory & Sadeh, 2015). It is important to explore the nature and role of sleep difficulties in children with ADHD, given the crucial role of sleep in child development.

1.3 Sleep difficulties in children with ADHD

Sleep difficulties are common in children who have ADHD. However, opinion is divided as to whether these are behavioural (could cause symptoms similar to ADHD or they come as a result of ADHD) (Corkum, Tannock, Moldofsky, Hogg-Johnson, & Humphries, 2001; Knight & Dimitriou, 2017). On the other hand, sleep difficulties could be also physiological (e.g., sleep disordered breathing, snoring, motor restlessness) which requires medical interventions (e.g., a surgical intervention) (Wood

et al., 2011), not behavioural (e.g., sleep hygiene and behavioural interventions) (Cortese et al., 2005; Silvestri et al., 2009).

1.3.1 Prevalence

It has been estimated that around half of children with ADHD have sleep difficulties (Stores, 2014). The most common type of sleep difficulty reported by parents is insomnia, which is experienced by 30%–50% of children on ADHD medication (Barkley, 2013). Another study indicated that around 44% of children with ADHD have restless leg syndrome (RLS) or its symptoms (Cortese et al., 2005).

1.3.2 Nature of sleep difficulties in children with ADHD and its subtypes

Available literature concluded that, the nature and extent of sleep difficulties may vary in children with ADHD. A meta-analysis reviewed 16 subjective and objective studies showed that children with ADHD had significant sleep difficulties, such as bedtime resistance, sleep onset, night and morning awakenings, sleep disordered breathing and daytime sleeplessness, compared with healthy control groups (Cortese et al., 2009). A review of the literature indicated that around 44% of children with ADHD have restless leg syndrome (RLS) or its symptoms (Cortese et al., 2005). A recent study found that the most common sleep difficulties in children with ADHD are excessive daytime sleeplessness, insomnia, periodic limb movement, sleep-related breathing disorders and varying amount of sleep every day (Craig et al., 2017). Parasomnias, including bedwetting, were also observed in children with ADHD (Knight & Dimitriou, 2017). A recent study compared sleep in children with ADHD, children with Autism spectrum disorder (ASD) and healthy controls and found that more than half of the sample with ADHD slept 45 minutes less than the control group and needed more time

to fall asleep (Heijden, Stoffelsen, Popma, & Swaab, 2017). Moreover, sleep duration seems to be shorter in children with ADHD compared to the control (Knight & Dimitriou, 2017; Peasgood et al., 2016).

Objectively using Actigraphy and video-polysomnography, a study indicated that, both school aged children (5-11 years) with and without ADHD sleep less than eight hours (Knight & Dimitriou, 2017). A recent meta-analysis objectively compared sleep in children with ADHD and in those without and found that children with ADHD exhibited lighter sleep (stage 1) than the controls. (Díaz-Román et al., 2016). Moreover, children with ADHD showed more sleep cycles than controls (Virring, Lambek, Thomsen, Møller, & Jennum, 2016). When using video-polysomnography, a study found that periodic leg movement disorder and restless legs syndrome (RLS) were the two most common sleep disorders in their sample (Silvestri et al., 2009). Conversely, one study compared children with ADHD, without medication (n = 25) and healthy controls (n = 25), and did not find sleep difficulties in the objective assessments and sleep diaries, sleep difficulties were only found in the parents reports especially for bedtime resistance and sleep duration (Corkum et al., 2001).

As reported previously, ADHD can be diagnosed as three main types: inattentive type, hyperactivity and impulsivity type and combined type of the Inattentive type and hyperactivity and impulsivity type (American Psychatric Association, 2013). The nature and extent of sleep difficulties may vary in the different subtypes of ADHD. When looking at each particular subtype, sleep difficulties in children with ADHD were found to be more common in the inattentive type than in the combined type (Becker, Froehlich, & Epstein, 2016; Virring, Lambek, Jennum, Moller, & Thomsen, 2017). This might be due to two reasons; first, stimulants, which are used to treat inattention that have side effects that affect sleep, including insomnia (Kidwell, Van Dyk, Lundahl, & Nelson, 2015; Santosh, 2017; Stein, Weiss, & Hlavaty, 2012), and second, poor sleep

has a negative effect on cognitive functioning including attention (Galland et al., 2015; Knight & Dimitriou, 2017; Lee et al., 2014). Moreover, inattentive type showed less movement disorders during sleep compared with combined type and they reported daytime sleepiness (CHIANG et al., 2010; Corkum, Moldofsky, Hogg-Johnson, Humphries, & Tannock, 1999; Mayes et al., 2009).

On the other hand, hyperactivity and impulsivity subtypes reported more sleep difficulties according to the CSHQ overall score in general and bed bedtime resistance in particular (Vaidyanathan, Shah, & Gayal, 2016). When compared subtype of ADHD with healthy control, children with combined type showed more sleep difficulties in general (Mayes et al., 2009) and in particular breathing related disorders and early morning awaking when compared with inattentive subtypes (Wagner & Schlarb, 2012). Moreover, children with ADHD (the combined type) in Chiang et al. (2010) reported more difficulties in sleep-wake time, talking during sleep and nightmares. In addition, sleep difficulties related to the movement (e.g., periodic limb movements during sleep followed by restless leg syndrome) have been observed in hyperactivity impulsivity and combined type (Silvestri et al., 2009)

Overall, sleep difficulties are common in children with ADHD. The extent of these difficulties can be variable across studies and this may depend upon the type/severity of ADHD and on the assessments used in each study and whether subjective/objective measures were used.

1.3.3 The relationship between sleep difficulties and ADHD symptoms

The relationship between sleep difficulties and ADHD is unclear and potentially complex. The direction of the relationship is difficult to ascertain. For example, there

are two possible explanations for the relationship between sleep and ADHD divided as the following:

1. Sleep difficulties can cause symptoms similar to those seen in ADHD.
2. ADHD may cause sleep difficulties (this explanation would include medication side effects and poor sleep hygiene and/or parents psychological wellbeing).

There is a good amount of evidence to suggest that sleep difficulties can cause symptoms similar to those seen in ADHD. For example, sleep difficulties have been associated with emotional (e.g., anxiety, phobia and depression) and behavioural problems (e.g., hyperactivity and impulsivity) (Chervin, Dillon, Bassetti, Ganoczy, & Pituch, 1997; Dagan et al., 1997; Dollinger, Molina, & Monteiro, 1996; Paavonen et al., 2002; Sadeh, Gruber, & Raviv, 2002). Moreover, sleep difficulties have been found to affect cognitive function including attention (Knight & Dimitriou, 2017; Lee et al., 2014; Owens, 2009). It seems that lack of sleep may cause symptoms similar to ADHD which could lead to debate about diagnosis of ADHD in children (Knight & Dimitriou, 2017; Merten, Cwik, Margraf, & Schneider, 2017; Thomas, Sanders, et al., 2015).

On the other hand, ADHD may cause sleep difficulties. There is clear evidence that some ADHD medications affect sleep from a randomised, double-blind, crossover trial that compared the effects of methylphenidate and atomoxetine (which are commonly used to treat ADHD symptoms) on sleep difficulties in children with ADHD. Actigraphy results showed that both drugs significantly affect sleep onset latency, with methylphenidate having the greatest negative effect (Sangal et al., 2006). Although children with ADHD medication (stimulants) showed better functioning at school according to teachers' reports, parents reported more sleep difficulties in the same children (Craig et al., 2017).

Similarly, parenting related issues (poor sleep hygiene and/or parents psychological wellbeing) might also cause sleep difficulties in children with ADHD; but equally caring for a child with ADHD might result in less effective parenting and higher levels of parental stress. Negative parenting practices (e.g., inconsistency in the daily routine and lack of sleep hygiene) could also result in sleep difficulties such as bedtime resistance (Noble, O'Laughlin, & Brubaker, 2011; Sciberras, Mulraney, et al., 2017; Stores, 2014) and sleep anxiety (Sciberras, Song, Mulraney, Schuster, & Hiscock, 2017). Inconsistency in the daily routine and the lack of sleep hygiene could be due to the high level of ADHD symptoms in caregivers (Gray, 2017; Mokrova, O'Brien, Calkins, & Keane, 2010; Peasgood et al., 2016). Another study suggested that psychological well-being of parents including coping with a child with ADHD may make it more difficult to maintain regular routines (Thomas, Lycett, Papadopoulos, Sciberras, & Rinehart, 2015).

Once again, the direction of the relationship between ADHD and sleep problems is unclear and likely to be interactive and bi-directional.

1.3.4 The role of comorbidities

Comorbidities are found in 59-87% of children diagnosed with ADHD which therefore would result in delayed sleep phase (Cuesta & Delrio-Hortega, 2016; Tsai, Hsu, & Huang, 2016). Evidence available on sleep difficulties in children with ADHD with\without comorbidities is mixed. Some evidence suggested that sleep difficulties in general were found more common in children with a comorbid psychiatric disorder than in those with pure ADHD (Mindell & Owens, 2015; Virring, Lambek, Jennum, Moller, & Thomsen, 2017). In addition, Cuesta & Delrio-Hortega (2016) suggested that comorbidities play a significant role in increasing delayed sleep phase. Moreover,

depression and anxiety have been found to be common in children with ADHD which would result in bedtime resistance (Efron et al., 2016; Mayes et al., 2009). Additionally, children with ASD and ADHD reported different difficulties related to cognitive ability and psychological wellbeing including sleep difficulties (Liu, Hubbard, Fabes, & Adam, 2006; Park et al., 2012). In addition, a review of the literature looked at the role of comorbidities in children with ASD and sleep difficulties and concluded that comorbidities contribute to sleep difficulties (Hollway & Aman, 2011). Comorbidities were divided into two main parts; internalizing difficulties (e.g., anxiety and depression) and externalizing difficulties (e.g. attention deficit, hyperactivity and impulsivity) with more emphasis on the role of internalising behaviours in causing sleep difficulties.

In contrast, no differences in sleep difficulties rate, nature and severity of sleep difficulties in children with pure ADHD and ADHD with comorbidities found (Thomas, Lycett, et al., 2015; Vaidyanathan, Shah, & Gayal, 2016). Moreover, no relationship has been found between sleep difficulties in children with ADHD and age or gender or comorbidities. A possible explanation for sleep difficulties in children with ADHD without comorbidities could be due to other factors (e.g., parents' psychological wellbeing) which affects the management of bedtime routine (Thomas, Lycett, et al., 2015).

Overall, there is some evidence that sleep difficulties reported in children with ADHD have been found to be behavioural (Corkum et al., 2001). Also, it appears that anxiety and depression symptoms may have a significant role in sleep difficulties prevalence which would be clearly observed in bedtime resistance, sleep anxiety, night time wakings and sleep onset delay (Efron et al., 2016; Hollway & Aman, 2011; Mayes et al., 2009). Thus, teaching children how to develop sleep hygiene and the use of behavioural modification to manage their fears would help children to fall asleep easily and reduce bedtime resistance which therefore would improve sleep quantity and

quality (Palermo & Owens, 2008). However, providing sleep routine would be affected by parents' ability to manage the child due to the parents' psychological wellbeing in general (Stores, 2014), and depression and stress in particular (Al-Balushi et al., 2017; Theule, Wiener, Tannock, & Jenkins, 2013). Therefore, it is important to consider helping both children and their caregivers when planning to improve sleep for children with ADHD using behavioural change interventions.

1.3.5 Measuring sleep difficulties

Sleep in children can be assessed using subjective measures (e.g., questionnaires) and objective measures (PSG andActigraphy) measurements. A variety of validated and low cost questionnaires are available in English, such as a brief sleep problem screening questionnaire and a semi-structured interview that were used to collect data on sleep history and problems (Montgomery, Stores, & Wiggs, 2004). In addition, the Children's Sleep Habits Questionnaire (CSHQ), can be also used to assess sleep duration, quality and difficulties (Owens, Spirito, & McGuinn, 2000). CSHQ has been translated into multiple languages and widely used to assess sleep in children including Arabic language (Abou-Khadra, Amin, Shaker, & Rabah, 2013). It consists of 33 items and is divided into the following subscales: bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, night waking, parasomnias, sleep-disordered breathing and daytime sleepiness. In addition, a sleep diary completed by parents can help in understanding bedtime routine and sleep/wake time and be used with the objective assessments (Jan et al., 2008a; Stores, 2014).

On the other hand, sleep can be objectively measured using polysomnography and Actigraphy (Jan et al., 2008a; Mindell & Owens, 2015; Stores, 2014). Polysomnography (PSG) is known as the gold standard when assessing sleep duration,

quality and disorders, however, it is expensive, requires specific equipments with trained staff and is time consuming (Ancoli-Israel et al., 2003; Kosmadopoulos, Sargent, Darwent, Zhou, & Roach, 2014; Mindell & Owens, 2015). PSG can be used in a sleep laboratory or home settings and can provide an overview of sleep disorders such as sleep apnoea or narcolepsy (Stores, 2014). Actigraphy, is the second objective option to record sleep/wake time for around 7 days and can be used with sleep diary in order to understand sleep patterns (Mindell & Owens, 2015). Although objective measures (e.g. Actigraphy and polysomnography) are more reliable, time consuming and expensive compared to the subjective ones (self-reported measurement) (Ancoli-Israel et al., 2003), parents of children with chronic disorders are at high risk of psychological difficulties, which could affect parents' responses to the subjective measurements (e.g., overestimate sleep difficulties) (Lach et al., 2009; Stores, 2014), therefore, it is important to use a combination of methods where possible.

1.3.6 Management of sleep difficulties

There are a range of approaches currently used to manage sleep difficulties in children with ADHD, and they vary depending upon the service the child is referred to, the severity of the sleep difficulties, and whether there is a physical cause (e.g., OSA). Sleep difficulties can be managed using pharmacological interventions or/and non-pharmacological interventions. An Australian study aimed to identify the management of sleep disturbances by paediatricians and found that paediatricians used both non-pharmacological treatment (behavioural techniques) and pharmacological (melatonin, clonidine and antihistamines) for both healthy children and children with different disorders such as ADHD who have severe sleep disturbances (Heussler et al., 2013).

1.3.6.1 Pharmacological treatment

Pharmacological interventions for sleep difficulties are commonly used. Although no medication has been approved by the Food and Drug Administration (FDA) in the US for children who have sleep difficulties, the supplement melatonin is widely used to treat insomnia (The National Institute for Health and Care Excellence (NICE), 2013). Melatonin has been used to treat insomnia in adults, healthy children and children with neurodevelopmental disorders with sleep onset delay (Reiter & Korkmaz, 2008). Multiple studies (Cuesta & Delrio-Hortega, 2016; Hoebert, van der Heijden, van Geijlswijk, & Smits, 2009; Van der Heijden, 2007; Weiss, Wasdell, Bomben, Rea, & Freeman, 2006) have shown that melatonin is effective and safe for long-term use to treat sleep onset latency in children with ADHD, but some side effects such as dizziness, bedwetting, headache and excessive morning sedation were reported during melatonin treatment (Hoebert et al., 2009; Mindell & Owens, 2015).

A recent review summarized the effect of using melatonin for children with ADHD and ASD and suggested that melatonin has a positive effect in helping children in sleep onset delay. The dose of melatonin is depending on some factors (e.g., children age, weight and if the children take stimulant medication for their ADHD) (Cuesta & Delrio-Hortega, 2016). Moreover, following receiving a melatonin, both subjective and objective assessments have shown that sleep latencey decreased for around 40 minutes and total sleep time increased for about 20 minutes in group of children with neurodevelopmental disorders and sleep diffculties (Gringras et al., 2012). Although multiple studies about the role of using melatonin in improving sleep have shown positive results, the methodology of each study needs to be taken with caution. A recent systematic review evaluated the available evidence that examine the efficacy of pharmacological interventions for insomnia in children with ADHD and revealed that

there is limited high quality evidence available (Anand et al., 2017). The majority of the included studies either reported small sample size or suffer limitation in the methodology (e.g., type of assessment used). Ayyash, Preece, Morton, & Cortese (2015) suggested that melatonin is promising and safe in improving sleep in children with neurodevelopmental disorders in general and children with ADHD in particular, however, the overall sample size were small (n=45), and children with ADHD were seven (n=7/45) and only sleep diary was used to report sleep problems nature and severity which could not be enough to detect changes in sleep following having melatonin.

Another medication can be prescribed for sleep difficulties in children with ADHD and ASD is antipsychotic (risperidone). Antipsychotic (risperidone) is used for children with ADHD in general (Amor et al., 2014; Betts et al., 2014) which helps in aggressive symptoms and improves sleep (Mindell & Owens, 2015). Also, ADHD medications (stimulants) can also be adjusted to reduce the negative effects on sleep (Kidwell, Van Dyk, Lundahl, & Nelson, 2015; Stein, Weiss, & Hlavaty, 2012; Stores, 2014) which would be another pharmacological option to manage sleep difficulties in children with ADHD.

It seems that, there are three main options to manage sleep difficulties in children with ADHD using pharmacological interventions: melatonin, antipsychotic (risperidone) and the management of ADHD medication (e.g., stimulant) to decrease sleep difficulties. Although there was an improvement in sleep onset and sleep duration observed when using the supplement melatonin in children with ADHD, it seems however that available evidence did not find a significant role of melatonin in improving children's behaviours, cognitive functions and quality of life (Mayes et al., 2009; Van der Heijden, 2007).

Although sleep services in Saudi Arabia started since more than 25 years. Almeneessier and BaHammam (2017) have discussed available services including sleep specialists, equipment available, health professionals' and medical students' awareness of sleep medicine and medications availability. They conclude that sleep services do not meet the increase demand and population development (Almeneessier & BaHammam, 2017). Evidence on using melatonin for Saudi children with sleep difficulties seems to be limited. A study with ten children with intellectual disability and 70% with comorbidities (e.g., visual impairment and/or epilepsy) with severe sleep problems (e.g., sleep onset delay) have been prescribed melatonin for about a year. The majority of children (n=8/10) had a positive effect in sleep duration and sleep onset time according to the parents reports with no negative side effects reported. Some parents reported improvement in children's daily behaviours although no assessment for behaviours was used (Jan, 2000).

From the available evidence, it seems that sleep difficulties in children with neurodevelopmental disorders in Saudi Arabia are discussed with child psychiatrists due to the availability of child mental health services in Saudi Arabia. Dr Alrahili (2017) compared services and medication availability for children with ADHD and ASD in Canada and Saudi Arabia and stated that; general services (pharmacological and non-pharmacological interventions) for children with ADHD Saudi Arabia seem to be less common compared to Canada. He argued that psychiatrists in Saudi Arabia tend to prescribe antipsychotic (risperidone) for children with ADHD due to medication availability. When the child is under 6 years, there is no alternative medication in Saudi Arabia for this age group (e.g., Adderall or Dexedrine) for children from 3 years old. Therefore, it seems that Antipsychotic (risperidone) has been used in Saudi Arabia for children with ADHD due to the important role of risperidone in managing ADHD symptoms (e.g., impulsive behaviours) (Mindell & Owens, 2015) and due to the fact

that there is no alternative medications that are available in Saudi Arabia compared to Canada (Dr_alrahili., (2017, Jul 19)). From the available evidence, it seems that melatonin is rarely prescribed for Saudi children with ADHD and sleep difficulties.

1.3.6.2 Non pharmacological treatment (Behavioural modification and sleep hygiene)

Sleep difficulties can also be managed using behavioural modification and sleep hygiene, which is important and recommended for children with neurodevelopmental disorders including ADHD and typically developing children (Knight & Dimitriou, 2017). Sleep hygiene can be defined as "a set of sleep-related behaviours that expose persons to activities and cues that prepare them for and promote appropriately timed and effective sleep'' (Jan et al., 2008a, p. 1344). There are four main components of sleep hygiene: sleep environment (including room temperature and level of noise), bedtime routine, regular sleep and wake up time that is consistent every day and some simple physical activities that help in good sleep (Weiss, 2010). Parenting consistency during bedtime plays a significant role in reducing bedtime resistance (Sciberras, Mulraney, et al., 2017). Additionally, behavioural modification and sleep hygiene can manage bedtime resistance, sleep onset which would lead to improve daily functions and mothers' psychological wellbeing (Hiscock et al., 2015a; Stores, 2014). A randomised, controlled trial (RCT), conducted with over 200 children and their families in Australia found that children in the behavioural intervention group compared to the control group (usual care) show a significant improvement in sleep and ADHD symptoms following receiving a behavioural intervention for their sleep difficulties (n = 244) (Hiscock et al., 2015a). Additionally, a recent study used behavioural intervention and sleep hygiene for 23 school-aged children with ADHD and found that the behavioural sleep intervention contributed to the significant reduction of CSHQ and ADHD scores (Peppers, Eisbach,

Atkins, Poole, & Derouin, 2016). A more detailed systematic review of the literature about behavioural interventions and sleep hygiene in children with neurodevelopmental disorders is presented in chapter 2.

1.4 ADHD in Saudi Arabia

The research outlined in this thesis (chapter three and four) was conducted in Saudi Arabia.

In Saudi Arabia, estimates of the prevalence of ADHD is higher than in other countries but vary between regions and sittings (hospitals and school sittings), around 11.6% in primary schools in Jeddah City (Homidi, Obaidat, & Hamaidi, 2013), 13.2% in the Ministry of Health child and adolescent psychiatric clinics in the three cities of Riyadh, Dammam and Buraidah (Al-Habeeb, Qureshi, & Al-Maliki, 2012), 8% in a community setting study in Riyadh City (Al-Modayfer 2015), 2.7% in the Asir region (Alqahtani, 2010) and 3.5% in female primary school children (Jenahi, Khalil, & Bellac, 2012). ADHD seems to be more common in the early stage of primary school. Several studies showed that ADHD is more prevalent in children under nine years old (Albatti, 2017; Alqahtani, 2010; Taleb & Farheen, 2013) and among children with uneducated mothers (Albatti, 2017; Taleb & Farheen, 2013). In sum, the prevalence of ADHD in Saudi Arabia could be higher than that in other countries and could be vary between regions and cities. This could be due to the differences in the way of assessing and evaluating the disorder, cultural factors of recognizing the normal and abnormal behaviours including parents awareness of ADHD (American Psychatric Association, 2013; Visser et al., 2014).

As a result of high prevalence rates, the National Project for ADHD was approved by the Council of Ministers in 2009 to help those suffering from ADHD within multiple ministries (The Council of Ministers in Saudi Arabia, 2009). One of the recommendations was that services should continue to be delivered by government and private charity organizations and institutions. Funding was also made available for research, in patient care, diagnosis as well as educational, behavioural and medical interventions; all of which should be done in coordination with the Ministry of Health, the Ministry of Education and the Ministry of Social Development (see appendix A for more details about the project).

1.5 Aim and overview of the thesis

1.5.1 Thesis aim

Overall, there is some evidence that sleep difficulties reported in children with ADHD all types (inattentive type, hyperactivity and impulsivity type and combined type of the Inattentive type and hyperactivity and impulsivity type) have been found to be external (behavioural) (Corkum et al., 2001). Also, it appears that anxiety and depression symptoms would have a significant role in sleep difficulties prevalence which would be clearly observed in bedtime resistance, sleep anxiety, night time wakings and sleep onset delay (Efron et al., 2016; Hollway & Aman, 2011; Mayes et al., 2009). Thus, teaching children how to develop sleep hygiene and the use of behavioural modification to manage their fears would help children to fall asleep easily and reduce bedtime resistance which therefore would improve sleep quantity and quality (Palermo & Owens, 2008). However, providing sleep routine may be affected by parents' ability to manage the child due to the parents' psychological wellbeing (Stores,

2014). Therefore, behavioural change interventions for both children and their caregivers will be considered when plaining to improve sleep for children with ADHD. Although there is some evidence that behavioural change interventions can improve sleep in children with ADHD but it is not clear whether this has any additional effect on ADHD symptoms. The prevalence of ADHD is raised in Saudi Arabia and as such it is important to trial a behavioural change intervention for sleep in this context. There are some cultural differences between Saudi Arabia and other countries that need to be considered when preparing the behavioural intervention (e.g., religion, culture and language). Thus, the present project aimed to develop, implement, and evaluate the efficacy of an RCT of a behavioural change intervention for children aged 5–12 years with ADHD and sleep difficulties, and their primary caregivers, (women) in Saudi Arabia. The study aims to address the following questions:

1. To what extent can a behavioural change intervention improve sleep difficulties in children with ADHD?
2. To what extent do intervention-induced changes in sleep for children account for any changes in ADHD symptoms, Sleep disorders for caregivers and Depression and Anxiety and Stress Scale (DASS) for caregivers.

In order to answer these questions, the trial will test the following hypothesis:

Compared to the control group and over time (at the baseline, post intervention and two months follow up assessments), children and caregivers in the intervention group would have a statistically significant reduction in the overall scores of the following six outcomes:

Primary outcomes (targeted children – completed by parents)

1. Sleep difficulties (The Children's Sleep Habits Questionnaire (CSHQ).

2. Parent ratings of behavioural problems (Conner's Rating Scale Score – Parents' version).

Secondary outcomes (subjective measures – targeted primary caregivers)

1. Mother's sleep difficulties (Sleep disorders for caregivers).

2. Mother's psychological wellbeing (Depression, Anxiety and Stress Scale (DASS) for Caregivers).

Secondary outcomes (subjective measures – completed by teachers)

1. Teacher's rating of behavioural problems (Conner's Rating Scale Score – Teachers' version).

Secondary outcome – objective Actigraphy

Activity monitor (ActiGraph)

This outcome records the physical activity in order to provide sleep duration in seven days at baseline and seven days after a month of randomization to measure change. It will be used as an objective measure with some participants.

Activity monitor diary – completed by parents

This outcome records sleep/wake time and related information in seven days at baseline and seven days after a month of randomization to measure change. It will be used with some participants to support Activity monitor (ActiGraph) measure.

1.5.2 Thesis Overview

This thesis consists of five chapters. Chapter one has provided an overview of the literature related to ADHD and sleep. Chapter two is a systematic review and meta-analysis of behavioural change interventions for sleep difficulties in children with

neuro-developmental disorders including ADHD. Chapter three presents a Delphi study which informed the development of the Good Night Project, a behavioural sleep intervention for Saudi children with ADHD. Chapter four discusses the development of the intervention and presents the findings of a feasibility study of the Good Night Project. Chapter five concludes by summarising the main findings of the thesis, research limitations and recommendations for future research.

Chapter 2 : A systematic review and meta-analysis of behaviour change interventions for sleep difficulties in children with neuro-developmental disorders

2.1 Introduction

Neurodevelopmental disorders (NDDs) are a group of conditions underpinned by disrupted development of the nervous system. NDDs are heterogeneous in nature and severity, and can result in impairments that range from very specific limitations of learning and cognition to global motor, social and/or intellectual impairment. Such disorders include intellectual disability, communication disorders, autism spectrum disorder (ASD), Attention Deficit Hyperactivity Disorder (ADHD), specific learning disorders, and neurodevelopmental motor disorders including cerebral palsy. Co-occurring disorders are common. Sleep difficulties and disorders are often co-morbid with neurodevelopmental disorders, and significantly more prevalent than in typically developing children (Gregory & Sadeh, 2016).

Sleep plays a vital role in child development, promoting physical health (Irwin, 2015), emotional wellbeing (Goldstein & Walker, 2014) and cognitive development (Rasch & Born, 2013), however, the relationship between sleep and neurodevelopmental disorders has not been studied systematically and is far from clear. Sleep difficulties in this population often persist into adolescence and beyond, and can negatively affect parental wellbeing (Meltzer & Mindell, 2007) and family life (Meltzer & Mindell, 2014). The aetiology of sleep problems in children with NDDs are more complex than in typically developing children (which are usually behaviourally based)

with a combination of neurological, psychiatric, pharmacological and behavioural origins. Furthermore, sleep difficulties may occur because parents have not effectively encouraged positive sleep habits from birth (Stores, 2009); unintentionally reinforced negative behaviours before sleep and/or lacking effective strategies for managing these behaviours appropriately (Stores, 2014).

Poor sleep has been shown to affect quality of life for children with NDDs and their families (Sung, Hiscock, Sciberras, & Efron, 2008), affecting their relationships (Stores, 2009). Daytime dysfunction due to abnormal or reduced sleep patterns is crucial to explore in children with neurodevelopmental disorders given that poor sleep may exacerbate existing difficulties in learning, social interaction and communication.

Effective evidence-based interventions to improve sleep in NDD are crucial but are so far lacking. There are several different approaches to the management of sleep difficulties in children, including the use of medications or behavioural interventions. Parental preference for intervention type varies depending upon the child's psychiatric profile (Williams, Sears, & Allard, 2004). Whereas parents of typically developing children tend to favour behavioural interventions, parents of children with underlying neurodevelopmental disorders including ADHD and Autism Spectrum Disorder (ASD) with ADHD are more likely to find pharmacological interventions acceptable. Interestingly, parents of children with ASD (where ADHD is not co-occuring) are more likely to consider behavioural intervention (Williams et al., 2004). Those who prefer a non-pharmacological approach are generally more concerned about the side-effects of medications than those in favour of medication (Chan, Rappaport, & Kemper, 2003), which is likely to affect adherence to treatment (Horne R, 2005).

There are several existing published reviews of the efficacy of behavioural intervention techniques to improve children's sleep habits (Brown, Kuo, Phillips, Berry, & Tan, 2013; McDaid & Sloper, 2008; Meltzer & Mindell, 2014; Vriend, Corkum,

Moon, & Smith, 2011). These reviews evidence from a wide range of research methodologies, including pre and post treatment measures (McGinnis, Bocknek, Beeghly, Rosenblum, & Muzik, 2015), concurrent multiple baseline designs across participants (Weiskop, Richdale, & Matthews, 2005) and randomised controlled trials (Montgomery et al., 2004). In contrast to previous reviews, this review focuses exclusively on RCTs designed to test the efficacy of behaviour change techniques in managing sleep difficulties, and employs an established taxonomy based on interdisciplinary consensus (Michie et al., 2013).

The primary aim of this review is to characterise the behaviour change techniques (BCTs) employed in order to establish existing best practice for addressing sleep difficulties specifically in school-aged children diagnosed with neuro-developmental disorders. The review focusses on studies that compare active and inactive treatment groups with sleep-related outcome measures. The use of highly stringent criteria ensures that the conclusions drawn are based on the very highest quality evidence available making clear any gaps in the current evidence base. Evidence-based recommendations for researchers and health-care providers are made regarding the content required for effective intervention design.

2.2 Methods

We evaluated the effect of behavioural sleep interventions for children with neuro-developmental disorders using a systematic review and meta-analysis. This review followed the PRISMA 2009 statement (see appendix B) and is registered in PROSPERO. The registration number is CRD42015017331. No previously published protocol was available.

2.2.1 Eligibility criteria

RCTs of behavioural sleep interventions for children who had been diagnosed with neuro-developmental disorders were eligible for this review. The population was children aged between 2 – 14 years. Included papers were in written in English and published between January 2004 and March 2017. Eligible trials reported at least one self-report sleep outcome and included a behavioural intervention with comparator groups (active or inactive groups). We included only full studies that were peer reviewed and excluded conference abstracts, books, non-RCT designs and studies with adults.

2.2.2 Information sources

Systematic electronic searches were conducted across four databases: the Cochrane Library, Embase, Ovid MEDLINE, and PsycINFO between October 2014 and March 2017, with the final search of the databases conducted on 01-03-2017. A combination of relevant keywords were used including sleep difficulties, disorder, children and behaviour interventions (table 1 shows the full list of search terms). Previous reviews and references lists of the included and excluded studies were also hand searched.

Table 1 Search terms, which were used in the review

# ▲	Searches
1	(ADHd or Attention deficit hyperactivity disorder).mp.
2	(Development$ adj disorder&).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
3	(sleep adj3 (disorder$ or problem$ or difficult$)).tw.
4	(Child$ or School age or Paediatric or Student* or boy* or girl* or Primary or Elementary).mp.
5	disorder$.tw.
6	disable$.tw.
7	(Sleep$ or Bedtime or Dipriv$ or Disturb$ or Habit$ or Insomnia or hygiene or Night$).tw.
8	(Behavio?r adj7 (intervention$ or therap$ or treat$ or strateg$ or modif$ or program* or techneq*)).tw.
9	parent$.mp.
10	(Disorder$ or difficult$).mp. or syndrom$.tw. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
11	3 or 7
12	2 or 5 or 6 or 10
13	8 or 9
14	1 or 12
15	4 and 11 and 13 and 14

2.2.3 Study selection

In total, 15,828 articles were found via electronic search and twenty articles were identified from other sources. After discounting duplicates, three reviewers (HA), (IK) and (HN) screened the abstracts of 9,891 articles. Another reviewer (JB) independently screened 5% of these articles to establish whether the screening process was reliably by examining the percentage of agreement over inclusion and exclusion of the studies in the review. The website random.org was used to randomly select the 5% of the articles. The percentage agreement over retrieval for full-text screening was 98.66%. Disagreement was resolved by discussion between the review authors.

Following the abstract screening, 9,797 articles were excluded, with the remaining 94 full-text articles retrieved and assessed for eligibility. Of these, 90 were excluded by all the reviewers, indicating 100% agreement. The most common reason for exclusion was that the study was not an RCT. The decisions for inclusion and exclusion of these studies were further checked by the remaining review authors (AW), (IK) and (HN). Only four studies met the criteria for inclusion in this review.

Figure 1. Flow diagram for identification of relevant studies

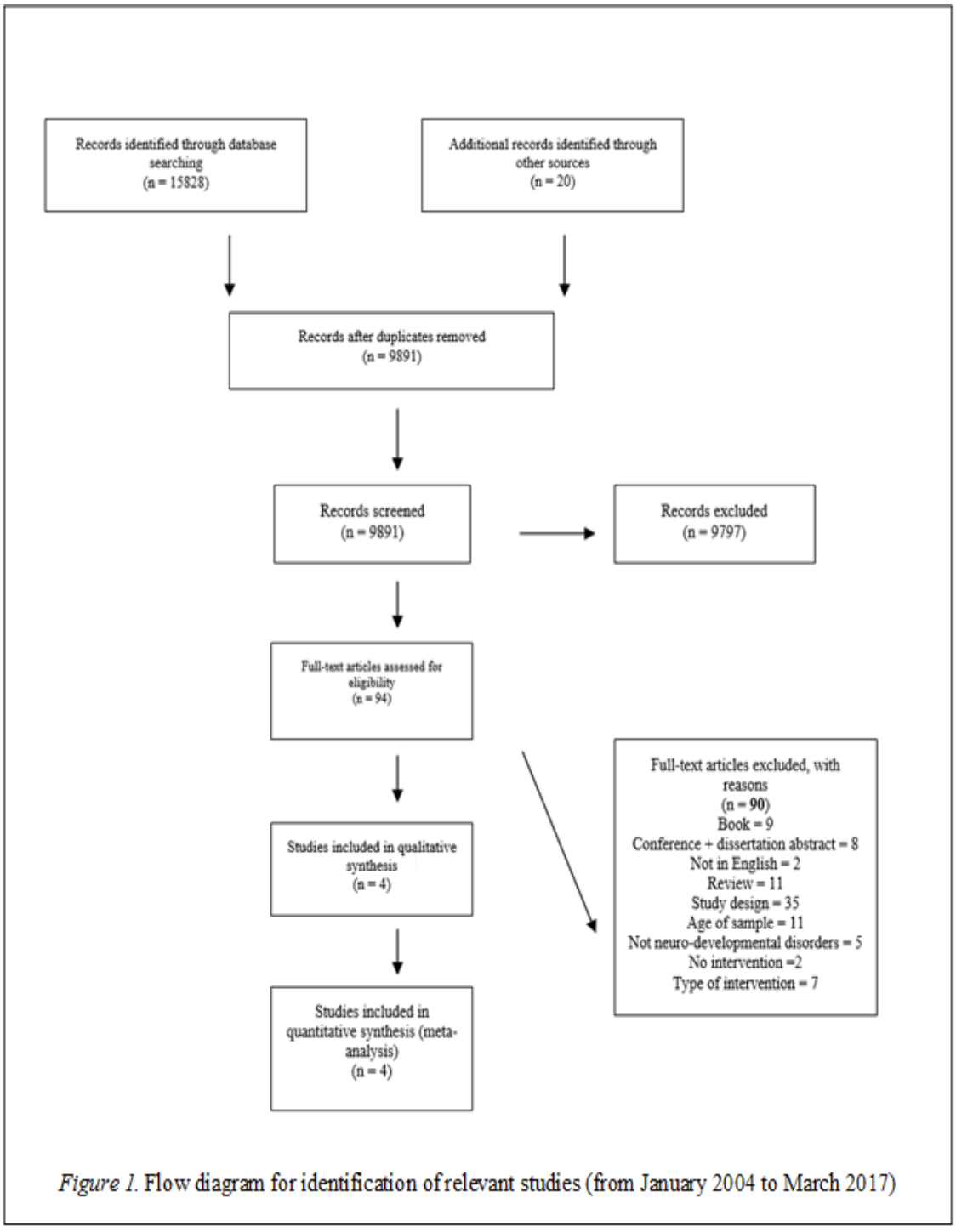


Figure 1. Flow diagram for identification of relevant studies (from January 2004 to March 2017)

2.2.4 Data extraction and assessment of bias

Two reviewers (HA) and (JB) independently extracted the data using a form adapted from a previous review (McDaid & Sloper, 2008). Data extracted included publication details, number of participants, mean age, the nature of the intervention, and sleep related outcomes measures. We contacted the authors to provide more data/details where insufficient information was provided.

Three reviewers (HA), (IK) and (JB) independently assessed the papers in accordance with the Cochrane Risk of Bias Tool that uses the following criteria; random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting. Any disagreement was resolved by discussion.

Publication bias was not assessed as there was an insufficient number of the studies included in the meta-analysis (Higgins JPT, 2011).

2.2.5 Behaviour change technique coding

Two researchers (HA and IK) independently coded the four trials using the BCT Taxonomy (v1) (Michie et al., 2013), and noted the reasons for each coding for discussion. One researcher (AW) checked the coding. Any disagreement was resolved by discussion (between HA, IK and AW).

2.2.6 Summary measures

We used Revman5 (The Nordic Cochrane Centre, 2014) to conduct the meta-analysis. A random effect size model with 95% confidence intervals was used and effect

sizes were calculated to look at the efficacy of the interventions to reduce sleep difficulties and reduce the disorder's symptoms. Data for the meta-analysis was double extracted by two researchers (HA and IK), and the results checked by a third researcher (AW).

2.2.7 Summary of findings and quality of evidence assessment

Quality of evidence of the trials was assessed according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach (2004) using GradPro Software. (HA) assessed the quality of evidence and (IK and AW) checked the assessment.

2.3 Results

Four studies met the inclusion criteria. Two studies were conducted in Australia (Hiscock et al., 2015a; Sciberras, Fulton, Efron, Oberklaid, & Hiscock, 2011), one in England (Montgomery et al., 2004) and one in the United States (Johnson et al., 2013). Information was extracted across nine categories: sampling – interventions – delivery methods - intervention length – comparators - BCT taxonomy - sleep outcome measures – bias and findings. The characteristics of the included studies are presented in Table 2.

Table 2 Characteristics of randomised controlled trials included in the review

Study (year), country	Number of participants	Age	Type of disorder	Sleep difficulties	Interventions	duration of the interventions	Comparator	Outcomes	Length of follow up
Montgomery et al (2004) England	66	2-8	Severe LD	Night waking and/or settling problems	Two intervention groups versus one control (face-to-face and booklet treatment)	6 weeks	No intervention for six weeks	A brief sleep problem screening questionnaire, a semi-structured interview and Sleep diaries	Six-month follow-up
Sciberras et al (2011) Australia	27	5-14	ADHD	At least one sleep disorder (sleep onset association disorder, limit setting disorder, delayed sleep phase, primary insomnia, or anxiety related insomnia)	Brief (a single session) versus extended (two sessions) + written material	2 weeks	Single 45-minute session (brief)	(CSHQ)	Two and five months follow-up
Johnson et al (2013) United Stated	40	2-6	ASD	Bedtime resistance problems - delayed sleep onset - sleep association problems - night-time awakenings	Two intervention groups (behavioural parent-training programme versus Psychoeducational programme)	8 weeks	Psychoeducational programme	Objective measures (actigraphy) Composite sleep of the modified version of the Simonds and Parraga Sleep Questionnaire	Two measurements after the baseline; at week four and eight of the intervention
Hiscock et al (2015) Australia	244	5-12	ADHD and ASD or Asperger disorder	Parent reported moderate to severe sleep difficulties; and met the American Academy of Sleep Medicine diagnostic criteria for at least one sleep disorder	One intervention group versus one control group	2 weeks	Usual care from their child's pediatrician	Objective measures (actigraphy) (CSHQ)	Three + six-month follow-up

Note. LD = Learning Disability, ADHD = Attention Deficit Hyperactivity Disorder, ASD = Autism Spectrum Disorders, CSHQ = Children sleep habits questionnaire

2.3.1 Sampling

The review involved 377 participants, aged between 2 and 14 years, and consisted of 74 females and 296 males as reported. The review also included a range of neuro-developmental disorders; Autism Spectrum Disorder, Down's syndrome and ADHD. Sleep difficulties experienced by the children occurred before sleep, during sleep and in the morning following sleep. They included bedtime resistance; the need for a parent to be present to help the child to fall asleep, primary insomnia; waking during the night; anxiety related insomnia and early morning waking.

2.3.2 Interventions

All included studies used behaviour change techniques, but there were variations in the format, content and duration; and the comparator groups used as detailed below.

2.3.3 Delivery methods

Different intervention formats were used in the trials reported in this review. These were:

1. Face-to-face approaches and booklets (Montgomery et al., 2004)

2. A behavioural parent-training programme designed for the family's needs and the child's sleep difficulties versus the Psychoeducational programme for the families who had received a recent diagnosis (Johnson et al., 2013).

3. A brief intervention (a single session) or extended (two sessions or three if the problems still exist) with written materials for the two groups and a follow-up call for the extended group was provided (Sciberras et al., 2011).

4. Participants were provided with sleep hygiene and behavioural strategies in two bi-weekly sessions then after two weeks, families then received a follow-up phone call (Hiscock et al., 2015a).

2.3.4 Intervention length

Length of the interventions varied from study to study, but ranged from a minimum of two weeks to eight weeks. Two studies were carried out in two weeks (Hiscock et al., 2015a; Sciberras et al., 2011), while one lasted six weeks (Montgomery et al., 2004) and one was carried out in eight weeks (Johnson et al., 2013).

2.3.5 Comparators

Different comparator group designs were used such as usual care (Hiscock et al., 2015b), active treatments (Sciberras et al., 2011), two comparators, active and crossover to active treatment (Montgomery et al., 2004) and providing general information on the disorder then crossover to active treatment (Johnson et al., 2013).

2.3.6 Behaviour Change Techniques

2.3.6.1 Intervention

Table 3 shows common techniques that were used in the intervention groups. Four techniques (4.1 Instruction on how to perform behaviour, 12.1 restructuring the physical environment, 12.2 restructuring the social environment and 14.3 remove rewards) were used in four studies. In addition, four techniques (2.3 Self-monitoring of Behaviour, 2.4 Self-monitoring of outcome(s) of behaviour, 8.7 graded task and 10.3 non-specific rewards) were used in three studies out of four.

2.3.6.2 Comparator

Trials that applied an active comparator (Montgomery et al., 2004; Sciberras et al., 2011) did not differ in techniques provided. They differed in the number of sessions that were used: brief (a single session) versus extended (two sessions) (Sciberras et al., 2011) or the method of delivering the interventions (booklet versus face to face in the parents' home) (Montgomery et al., 2004). The trial that used a psychoeducational group (Johnson et al., 2013) covered different topics aiming to provide general information on the disorder and no codable BCT techniques were used.

Instruction on how to perform behaviour (4.1) was the most common technique in both intervention and comparator groups. Excerpts relating to the BCTs from the comparator and the attendant BCTs coded are presented in table 4.

Table 3 List of Behavioural change techniques taxonomy BCTs used in the review – intervention groups.

BCTs	Study			
	1	2	3	4
1.1. Goal setting (behaviour)		*		*
1.2. Problem solving		*		*
1.3. Goal setting (outcome)	*			
2.3. Self-monitoring of behaviour	*	*		*
2.4. Self-monitoring of outcome(s) of behaviour	*	*		*
4.1. Instruction on how to perform the behaviour	*	*	*	*
4.2. Information about Antecedents	*	*		
5.2. Salience of consequences	*			*
6.1. Demonstration of the behaviour		*		
7.1. Prompts/cues	*	*		
7.7. Exposure		*		
7.8. Associative learning		*		
8.7. Graded tasks	*		*	*
10.2. Material reward (behaviour)			*	*
10.3. Non-specific reward	*	*		*
10.6. Non-specific incentive	*	*		
12.1. Restructuring the physical environment	*	*	*	*
12.2. Restructuring the social environment	*	*	*	*
12.6. Body changes	*			*
14.3. Remove reward	*	*	*	*

Note. 1 = Montgomery (2004), 2 = Johnson (2013), 3 = Sciberras (2011) and 4 = Hiscock (2015)

Table 4 List of Behavioural change techniques taxonomy BCTs used in the review – control groups

Study	BCTs
1	Booklet
Difference is in the way of delivering the intervention:	4.1. Instruction on how to perform the behaviour
	Face to face
	4.1. Instruction on how to perform the behaviour
2	Discuss other treatment options available for child
Topics covered were not aimed to change behaviours – they were descriptive.	11.1. Pharmacological support
3	Single 45 min (brief)
	4.1. Instruction on how to perform the behaviour
	Two sessions extended (extended) + follow up phone call + third session if problems still present
	4.1. Instruction on how to perform the behaviour
	Written material in both groups
	4.1. Instruction on how to perform the behaviour
4	Control – usual care

Note. 1 = Montgomery (2004), 2 = Johnson (2013), 3 = Sciberras (2011) and 4 = Hiscock (2015)

2.3.6.3 BCTs for specific age groups and specific neurodevelopmental disorders

When looking at BCT techniques components in relation to the age group, the results indicated that two studies focused on children with ASD and learning disorders who were in age between 2-8 years (Johnson et al., 2013; Montgomery et al., 2004). In addition, two studies were conducted by the same team in Australia in children with ADHD with and without comorbidities (Hiscock et al., 2015a; Sciberras et al., 2011). However, BCT techniques in the four studies did not differ between the most important and less important techniques. Thus, the Good Night Project will focus on the techniques that were used with children with ADHD with more emphasis on the most common techniques as these report large effect sizes according to the meta-analysis conducted (see figure 4 Meta-analysis for the efficacy of using behavioural sleep interventions in reducing sleep difficulties).

Table 5 BCTs taxonomy components for younger children (2-8) years with ASD and LD

BCT	Example
1.3. Goal setting (outcome)	Setting realistic expectations, indicating the advantages to the whole family when children sleep well
4.2. Information about Antecedents	Introduce concepts of antecedent, behaviour and consequence model
6.1. Demonstration of the behaviour	Training sessions - Sleep manual – Modelling – Role playing
7.1. Prompts/cues	How behaviour scan be triggered by events that precede them, and encouraged (or discouraged) by providing appropriate reinforcement;

	management strategies such as ignoring, consistency and reward systems.
7.7. Exposure	For children with severe and specific fears, teach parents how to implement systematic exposure
10.6. Non-specific incentive	Introduce concept of reinforcement and teach contingent implementation of reinforcement

Table 6 BCTs taxonomy components for children with ADHD with-without comorbidities

BCT	Example
1.1. Goal setting (behaviour)	Develop daily schedule and bedtime schedule and routine
1.2. Problem solving	Problem-solve if things go wrong
2.3. Self-monitoring of behaviour	Sleep diary in the intervention
2.4. Self-monitoring of outcome(s) of behaviour	Sleep diary in the intervention
4.1. Instruction on how to perform the behaviour	Booklet delivered treatment, sleep manual, written material - sleep as a learned behaviour - importance of clear routines - face to face sessions - training sessions - modelling - role playing
5.2. Salience of consequences	Setting realistic expectations, indicating the advantages to the whole family when children sleep well
8.7. Graded task	Sleep onset association disorder was managed by removing the sleep association and checking the child at increasing time intervals (i.e. graduated extinction) to encourage self-settling.

10.3. Non-specific reward	Introduce concept of reinforcement and teach contingent implementation of reinforcement - rewarding compliance - reinforce suggested strategies
12.1. Restructuring the physical environment	Gradually decreasing the physical contact between child and parent during the episode
	Sleeping in the parents' bed: (ii) returning the child to bed as needed using the settling techniques
	Appropriate surroundings
	how to deal with possible physical causes of sleep disturbance
	Putting children down to sleep while awake but drowsy - Removal of bottles
	Develop daily schedule and bedtime schedule and routine.
	Introduce faded bedtime routines and review bedtime routine.
	Healthy sleep hygiene
12.2. Restructuring the social environment	Gradually decreasing the physical contact between child and parent during the episode
	Sleeping in the parents' bed: (ii) returning the child to bed as needed using the settling techniques
	" Develop daily schedule and bedtime schedule and routine
	" Introduce faded bedtime routines and review bedtime routine limit setting disorder was managed by ignoring child protests

12.6. Body changes	Removal of daytime nap - Bedtime fading - Relaxation techniques
14.3. Remove reward	Ignoring child protests

2.3.7 Sleep outcome measures

Subjective and objective measures were used in the included trials. However, the emphasis was placed on self-reported measures. The child sleep habits questionnaire (CSHQ) was the most frequent, subjective method used (Hiscock et al., 2015b; Sciberras et al., 2011). A number of other questionnaires such as a brief sleep problem screening questionnaire, a semi-structured interview and Sleep diaries were used to collect data on sleep history and problems (Montgomery et al., 2004) . One objective measure, Actigraphy, was also used in two studies (Hiscock et al., 2015a; Johnson et al., 2013).

A six-month follow-up measurement was used in two of the four studies (Hiscock et al., 2015a; Montgomery et al., 2004), one of which additionally included a follow up after 3 months (Hiscock et al., 2015b). One trial included two and five months follow-up measures (Sciberras et al., 2011). Finally, one trial followed up at week four and eight of an eight week intervention (Johnson et al., 2013).

2.3.8 ADHD measures that were used in included studies

Both studies included in the meta-analysis and focused on children with ADHD (Hiscock et al., 2015a; Sciberras et al., 2011) were conducted by the same team in Australia with different sample. Sciberras et al., (2011) is considered as a pilot study of

(Hiscock et al., 2015a) which was the large trial. Both studies used ADHD rating scale IV (DuPaul et al., 1998). The scale is available in two versions, one is for parents at home and one is for teachers at school. It consists of 18 items that measure ADHD symptoms in individuals aged between 4-20 years in accordance with the Diagnostic and Statistical Manual of Mental Disorders, the fourth edition (Frances, 1994). Using the same assessment allowed us as reviewers to make sure that the two assessments include similar items and subcategories which would allow a clear comparison. The research team decided to include analysis of the teachers' version of the ADHD questionnaire only from Hiscock et al., (2015) due to the point that teachers were blinded to the children's allocation which would decrease bias.

2.3.9 Bias

All trials were assessed for risk of bias using the Cochrane Risk of Bias tool. All trials had a low risk of bias for random sequence generation. Two trials had a low risk of bias for blinding of participants and personnel (Hiscock et al., 2015a; Montgomery et al., 2004) and allocation concealment (Johnson et al., 2013; Montgomery et al., 2004). Two trials were not clear in terms of blinding of outcome assessment (Johnson et al., 2013; Sciberras et al., 2011). Two trials had a low risk of bias (Montgomery et al., 2004; Sciberras et al., 2011) and two had a high risk of bias (Hiscock et al., 2015a; Johnson et al., 2013) for incomplete outcome data. Three trials were not clear in terms of selective reporting (Johnson et al., 2013; Montgomery et al., 2004; Sciberras et al., 2011). (See figure 2: Risk of bias summary: judgements about each risk of bias item for each included study and Figure 3 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies).

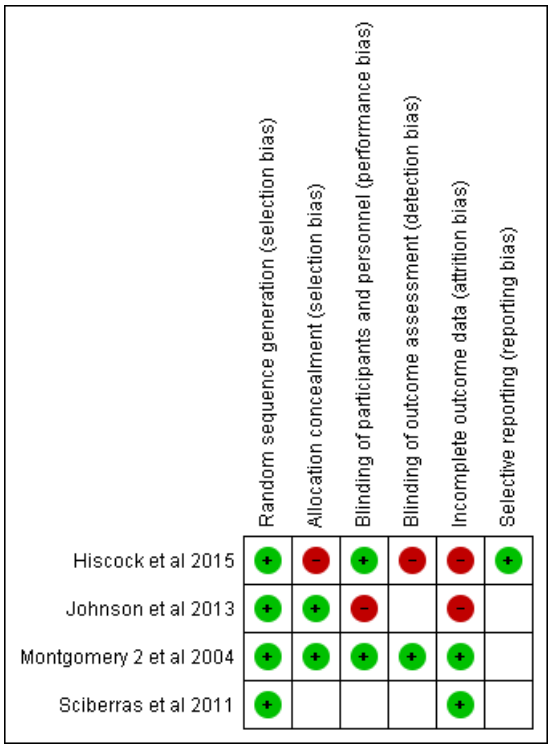


Figure 2. Risk of bias summary: judgements about each risk of bias item for each included study.

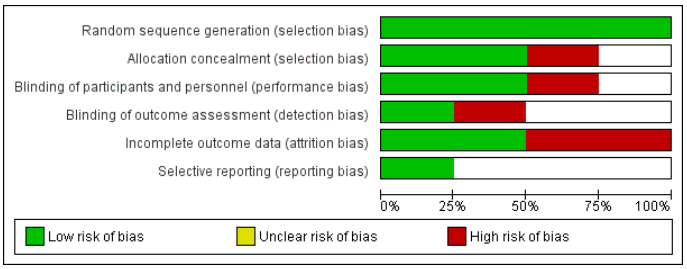


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

2.3.10 Findings

The quality of evidence for improving sleep difficulties was rated as high quality according to the GRADE approach (see table 5 for summary of findings and quality of evidence assessment table). In contrast, the evidence supporting symptom reduction in ADHD was rated as low quality.

All children who received interventions experienced an improvement in their sleep patterns, and reduction in sleep difficulties. Furthermore, follow-up measures indicated that reductions in sleep difficulties were maintained in two studies (Hiscock et al., 2015a; Montgomery et al., 2004). More than half of the child participants exhibited positive responses at the follow-up stage (Sciberras et al., 2011). However, there were no significant differences observed between the intervention and comparator groups in terms of parent mental health (Hiscock et al., 2015b).

Table 7 Summary of findings and quality of evidence assessment table

Behavioural interventions for sleep difficulties in children with neuro-developmental disorders

Patient or population: patients with [Sleep problems in children with neuro-developmental disorders]
Settings: Hospitals and clinics
Intervention: Behavioural interventions
Comparison: Comparator

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Comparator	Corresponding risk Behavioural interventions				
Sleep Sleep difficulties Follow-up: 0-6 months	The mean sleep ranged across control groups from 5.75 to 55.25	The mean sleep in the intervention groups was 0.87 lower (1.46 to 0.29 lower)		266 (4 studies)	⊕⊕⊕⊕ high[1,2,3,4]	
Disorder's symptoms ADHD Follow-up: 5-6 months	The mean disorder's symptoms ranged across control groups from 9 to 27.8	The mean disorder's symptoms in the intervention groups was 0.01 higher (0.94 lower to 0.97 higher)		197 (2 studies)	⊕⊕⊖⊖ low[3,5,6,7]	

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
CI: Confidence interval;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Parents in the experiment by Hiscock et al, (2015) knew which group their children belonged to and this could have led to a detection bias and this study consisted of more than 60% of the sample included in the review.
[2] the small sample size 266
[3] Publication bias was not assessed as there was insufficient number of the studies included in the meta-analysis (less than ten studies) as reported in the Cochrane handbook for systematic reviews of interventions (Higgins and Green, 2011).
[4] The standardised mean difference (95% confidence intervals) in sleep was -0.87 which means almost -0.9 (large effect size)
[5] The teachers version was subjected to meta-analysis from (Hiscock et al, 2015) because they were blinded to which group the students were belongs to, this subject to lower risk of bias.
[6] 1 trial favours intervention, the other favours the minimal intervention.
[7] the small sample size 197

2.3.10.1 Efficacy in reducing sleep difficulties

Four trials (Hiscock et al., 2015b; Johnson et al., 2013; Montgomery et al., 2004; Sciberras et al., 2011) reporting data from 266 participants were included in a meta-analysis to evaluate the efficacy of behaviour change interventions in the reduction of sleep difficulties (see figure 4). High quality evidence indicated a significant, large effect size in post treatment outcome measures between the two groups (The standardised mean difference (95% confidence intervals) in sleep was -0.87 [-1.46, -0.29].

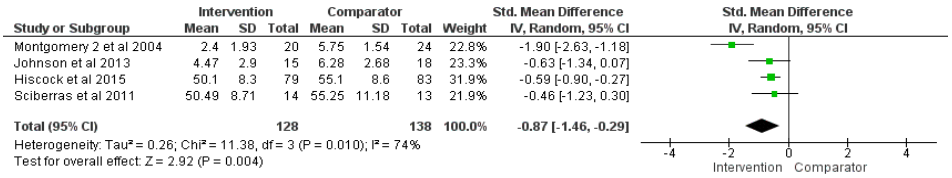


Figure 4. Meta-analysis for the efficacy of using behavioural sleep interventions in reducing sleep difficulties

2.3.10.2 Efficacy in reducing disorder symptoms

Two trials (Hiscock et al., 2015a; Sciberras et al., 2011) reporting data from 197 participants were included in a meta-analysis to evaluate the efficacy of behaviour change interventions in terms of ADHD symptom reduction, and the results are shown in Figure 5. Parent and teacher versions of the outcome measure was available for one study and in this case the teachers' version was subjected to meta-analysis (Hiscock et al., 2015a) because they were blinded to which group the students were belong to, resulting in lower risk of bias. No significant effect was found between the two groups (intervention versus comparator) The standardised mean difference (95% confidence

intervals) in ADHD symptoms was 0.01 [-0.94, 0.97]. However, it must be noted that the evidence for this lack of effect was assessed as low quality.

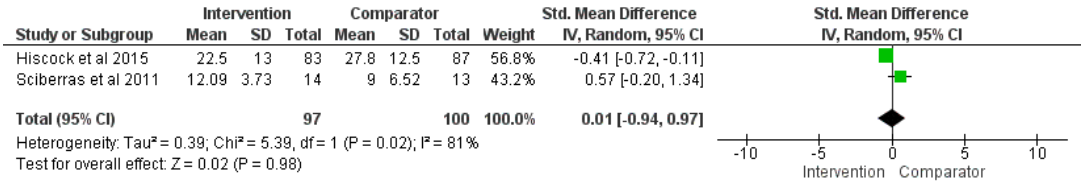


Figure 5. Meta-analysis for the efficacy of using behavioural sleep interventions in reducing ADHD symptoms.

2.4 Discussion

2.4.1 Justification for the choose of RCTs design and exclude other designs

In order to look at the high quality and gold standard clinical research, studies with an RCT design were chosen for inclusion in this systematic review. Participants in the RCT designs were randomly allocated to one of each group (intervention versus control, which was either active or non-active). This decreases the bias and increases the chance of each participant to be allocated for one of two groups equally. In addition, any change observed in an RCT design can be attributed to the effect of the intervention (Thiese, 2014). In contrast, non RCT design (quasi-experimental design) were excluded due to possible bias which could lead to decrease the quality of the studies included and affect conclusions drawn when applying the GRADE assessment of the quality of evidence (Guyatt et al., 2008). Pre and post intervention studies were excluded due to the lack of control group which means that changes in the outcomes over time may not be related to the intervention (Thiese, 2014). The researcher therefore screened interventions that were conducted by non RCT design e.g., (Allen, 2013; Austin, Gordon, & O'Connell, 2013; Didden, de Moor, & Curfs, 2004; Knight, 2014) and it seems that no new techniques were used in the excluded studies that differ from the four included studies.

2.4.2 Sleep difficulties

Behaviour change interventions were found to have a large and positive effect in reducing the severity of sleep difficulties in children with neuro-developmental disorders, when post-intervention severity is measured compared with the control

(Hiscock et al., 2015b; Johnson et al., 2013; Montgomery et al., 2004; Sciberras et al., 2011). This result is consistent with other randomised controlled trials that use behavioural intervention in other populations, such as children with behavioural insomnia (Paine & Gradisar, 2011), typically developing children (Moore, Friman, Fruzzetti, & MacAleese, 2007) and trials with both children with ADHD and typically developing children (Corkum et al., 2016) . Other studies have also found efficacy of behavioural sleep interventions in children with a variety of disorders, by comparing results from before and after intervention (Malow, 2014; Moss, Gordon, & O'Connell, 2014; Storch, 2008) and with a concurrent multiple baseline design across participants (Weiskop et al., 2005). Thus, based on the 4 RCTs comprising 377 participants (74 females and 296 males), there is high quality evidence that behaviour change techniques can moderately improve the sleep outcomes of children.

Crucially, improvements in sleep were maintained at both 3 and 6 month follow-up (Hiscock et al., 2015a). These results are consistent with other studies that found improvements maintained in the following 2, 3 and 12 months post-intervention (Moss et al., 2014; Weiskop et al., 2005). However, there were no significant differences between the intervention and control groups with respect to parental mental health (Hiscock et al., 2015a). This result is consistent with another study who did not find a statistically significant change in the level of stress felt by parents post-intervention and during the follow-up sessions (Moss et al., 2014). This is notable but unsurprising given that the intervention did not include any techniques for the parents that specifically focus on improving mental health or reducing stress. These results, therefore, need to be interpreted with caution. Parents in (Hiscock et al., 2015b) (more than 60% of the sample in the current review) knew which group their children belonged to (intervention group or control group ‘usual care’). This could have led to a detection bias.

The outcomes of this review indicate that the BCTs identified in this review have potential for inclusion in future interventions. Effective strategies seem to focus on providing primary caregivers with instructions on how to achieve targeted behaviour then reward children, managing the physical and social environment and ignoring negative behaviours.

2.4.3 ADHD symptoms

Paradoxically, this review found a lack of evidence for effects of behaviour change interventions on ADHD symptoms. However, it is important to note that only two trials collected data on symptom reduction and were thus included in the meta-analysis (Hiscock et al., 2015b; Sciberras et al., 2011), thereby reducing the power to detect an effect. The complexity of ADHD and its symptoms make it difficult to observe and classify behavioural improvements. Seventy percent of children with ADHD have a comorbid psychiatric disorder such as anxiety, conduct disorder and some autistic symptoms (Mayes et al., 2009), which can complicate management of ADHD symptoms through behaviour change interventions.

Furthermore, measurement issues arose in relation to the outcome of ADHD symptoms. One included only primary caregiver ratings from the ADHD Rating Scale IV, which may not have been blinded (Sciberras et al., 2011); the other included both teacher and parent report on the same scale and the teacher rating was included in the meta-analysis (Hiscock et al., 2015b). Moreover, the evidence derived from the studies that examined this outcome was rated as low quality, meaning that any conclusion about lack of efficacy in this domain are tentative at best. This review highlights the importance of rigorously assessing the impact of sleep interventions disorder

symptomology. This is crucial to determine the cost effectiveness of interventions in the future.

2.4.4 Limitations of this review.

There are four main limitations to note with respect to this review. First, the review focuses on randomised controlled trials in order to ensure that the current best evidence is evaluated and synthesised. Whilst this is a justified approach, evidence from studies using less rigorous designs that may have provided indication as to the efficacy of other behaviour change techniques is necessarily excluded. Second, the number of children who were measured using objective measures was less than children who were measured using subjective measures. This might be due to the cost of using objective measures for all children included in each study. Parental report is well accepted as measure of children's sleep problems and the relationship between subjective parental report and objective measures is considered to be conservative but reliable (Honomichl, Goodlin-Jones, Burnham, Gaylor, & Anders, 2002; Minde et al., 1993). However, it does pose a risk of bias. Underreporting of sleep problems can occur because parents are not always aware of the extent of the sleep problem (Minde et al., 1993). Third, the review is limited by the lack of studies and small numbers of participants included in the studies Only one study out of four included a large sample size which was more than 200 participants (Hiscock et al., 2015a). As such, this meta-analysis may fall foul of a small study effect, whereby a systematic bias towards treatment exists, and may distort the meta-analysis (Nüesch et al., 2010). Finally, this review focuses on behaviour change interventions thus we cannot compare these to other interventions that can be used to aid sleep difficulties in children with neuro-developmental disorders.

2.4.5 Conclusions

This review was designed to update current knowledge regarding the efficacy of behaviour change interventions to manage sleep difficulties in children who have been diagnosed with different neuro-developmental disorders, and describe what behaviour change techniques are employed in such interventions. RCTs were chosen in the current review synthesise the best available evidence. Four studies conducted between 2004 until 2015 provided high quality evidence for a positive effect of behavioural interventions on sleep. The limited number of trials, the small number of behaviour change techniques employed, and the low quality of evidence pertaining to symptom reduction suggest that further high quality trials are needed to examine the efficacy of behavioural change interventions in improving both sleep itself and disorder symptoms in this population.

2.5 Reflections on the results of the systematic review

This chapter has systematically reviewed available evidence that aimed to improve sleep in children with neurodevelopmental disorders since 2004 using non-pharmacological (behavioural interventions and sleep hygiene). The available evidence has been evaluated using GRADE approach to rate the quality of included evidence. Although the available and high quality literature related to sleep results have shown a positive large effect size according to the meta-analysis, all the four studies conducted in western countries (the UK, the US and Australia) in English language. When there is a plan to implement a similar project in different settings or countries, there are some points need to be considered (e.g., language, culture and beliefs) of the new setting

(Boergers & Koinis-Mitchell, 2010) especially for a variable that may be affected by culture (e.g., sleep and its related habits including sleep and wake up time in addition to duration of sleep) (Airhihenbuwa, Iwelunmor, Ezepue, Williams, & Jean-Louis, 2016; Bernal, Jiménez-Chafey, & Domenech Rodríguez, 2009; Boergers & Koinis-Mitchell, 2010). Therefore, due to the aim of this thesis to conduct an efficacy study of using behavioural change interventions for Saudi children with ADHD and sleep difficulties, it is important to consider the views and recommendations of health professionals who work in area related to ADHD and sleep in Saudi Arabia in addition to primary caregivers' needs to help in designing the appropriate and culturally sensitive intervention. Thus, the next chapter will focus on involving health professionals and primary caregivers in designing the Good Night Project that will be implemented in Saudi Arabia using a Delphi method in multiple rounds.

Chapter 3 : Behavioural Sleep interventions for Saudi children with ADHD: A Delphi study

3.1 Introduction

Recent reviews have shown that behavioural sleep interventions are effective in managing sleep difficulties in children (Gregory & Sadeh, 2016; Meltzer & Mindell, 2014). Such interventions have been widely used with normally developing children (Paine & Gradisar, 2011; Rigney et al., 2015), and children with disorders, such as anxiety (Clementi & Alfano, 2014) Angelman Syndrome (Allen, 2013), and intellectual disability (Priday, Byrne, & Totsika, 2017). A recent systematic review and meta-analysis of randomized controlled trials suggested that behavioural sleep interventions can have a large impact on improving sleep difficulties in children with neurodevelopmental disorders (see chapter two), (ALammar, Blackwell, Kellar, Nash, & Weighall, 2017).

Behavioural sleep interventions have been delivered to the caregivers in different formats, such as written materials (Montgomery et al., 2004; Sciberras et al., 2011), face-to-face approaches (Montgomery et al., 2004), a behavioural parent-training programme (Johnson et al., 2013), either as a brief intervention (a single session) or an extended programme (two sessions or three if the problems still exist) (Sciberras et al., 2011).

Interventions have been implemented in several settings and countries worldwide, such as the UK (Montgomery et al., 2004), Australia (Hiscock et al., 2015a), the USA (Johnson et al., 2013), and Canada (Corkum et al., 2016). However, no

study has been conducted in Saudi Arabia, although Saudi Arabia has a high prevalence of ADHD (Al-Habeeb et al., 2012; Al-Modayfer 2015; Alqahtani, 2010; Homidi et al., 2013; Jenahi et al., 2012). In the event that such a study would be done in Saudi Arabia, there may be some cultural differences to consider in the way the intervention is delivered; the content and language would need to be adjusted to the culture of the family and childhood.

Existing evidence-based interventions can be appropriately adapted to different settings, minority groups, and cultures. Cultural adaptation can be defined as "the systematic modification of an evidence-based treatment (EBT) or intervention protocol to consider language, culture, and context in such a way that is compatible with the client's cultural patterns, meanings, and values" (Bernal et al., 2009, p. 361). Systematic reviews which focused on using cultural educational interventions for minority groups, found that using such interventions are effective with different groups, such as asthma (Bailey et al., 2009) and type 2 diabetes patients (Hawthorne, Robles, Cannings-John, & Edwards, 2010). A meta-analysis that summarized 76 studies reveled that culturally adapted mental health interventions are effective with a moderate effect size d = .45 (Griner & Smith, 2006).

This study set out to develop an intervention called "The Good Night Project" which aims to train primary caregivers of children with Attention Deficit Hyperactivity Disorder ADHD in Saudi Arabia to manage sleep difficulties. The development process sought health professionals' insights and to understand primary caregivers' needs in respect to existing behavioural interventions that have been reported in previous systematic reviews (see Chapter Two), (ALammar et al., 2017). The main aim of this Delphi study is to achieve consensus among a panel of stakeholders (health professionals and primary caregivers) on priorities around sleep to help the research team develop the intervention.

3.2 Methodology

This study was part of a PhD study examining the efficacy of behavioural interventions to manage sleep difficulties in children with Attention Deficit Hyperactivity Disorder (ADHD) in Saudi Arabia. The Delphi study had two versions of a questionnaire (the first was for health professionals and the second was for primary caregivers). Both Delphi processes were conducted in two rounds, and each round gave participants one month to respond. The health professionals completed their version online using the Bristol Online Survey tool (BOS, 2017). The primary caregivers' version was a paper-based written questionnaire, administered by sending the questionnaires to the school where there are classes for children with ADHD.

3.2.1 Ethics statement

Ethical approval was received from the Psychology Research Ethics Committee, University of Leeds (reference no: 16-0016; date approved: 17 January 2016), and all participants provided information sheet that explained the study aim, duration and stages, and participants gave their informed consent (completed online or in a written form). Participants were not compensated for taking part in this study.

3.2.2 Sample

Participants for this study were health professionals who specialised in disciplines related to children, ADHD or sleep, such as psychologists, psychiatrists, occupational therapists, family practitioners and paediatricians, as well as primary caregivers for

children diagnosed with ADHD attending private centres or primary school classes for ADHD children in Riyadh, Saudi Arabia.

3.2.3 Procedure

The study consisted of six stages to reach the consensus on intervention content priorities:

3.2.3.1 Stage 1: Identify the interventions

Items included in this study were a list of intervention content from a recent systematic review and meta-analysis the research team conducted (see chapter two), (ALammar et al., 2017). Intervention content items were divided as follows: learn about sleep processes, normal sleep in children, sleep cycles, common sleep problems in ADHD children, managing children's sleep difficulties, sleep hygiene and how to manage primary caregivers sleep difficulties and related stress.

3.2.3.2 Stage 2: Invitations

The 66 participants were contacted via the following methods: 42 health professionals were invited to take part in this study via email, if they agreed to take part in the two rounds, the researcher sent them the link to the questionnaire.

24 written questionnaires were distributed in private centres for children with neurodevelopmental disorders and in ADHD classes in Aljawdah Primary School in Riyadh, Saudi Arabia.

3.2.3.3 Stage 3: Delphi survey: round one

Round one lasted one month. It started on 28 January 2016 and ended on 28 February 2016. A reminder was sent two weeks after each round began if the researcher

had not yet received a response from the participant. The reminder was sent via email for the health professionals or via email or SMS to the participant's mobile phone number depending on their preference (primary caregivers).

Health professionals were asked to provide detail of what undergraduate degree they had undertaken. Primary caregivers were asked whether they had ever sought help for their children's sleep difficulties and whether they preferred pharmacological or non-pharmacological interventions to manage sleep difficulties. Also, whether they prefer their children to sleep more hours or have good quality of sleep.

In both versions in round one, participants were asked to evaluate the importance of each piece of intervention content on a scale from one to ten. One indicated that the item is not important, and ten indicated that including the content in the programme is very important. Moreover, participants were asked to rank the importance of including a written guide, bedtime stories and videos. Additionally, participants were asked to make suggestions as to possible further intervention content that could be ranked in the next round, and for suggestions regarding the number of sessions and their length. Details of the questions asked are given in table 8. See appendix C that reports the questionnaires for both versions (health professionals and primary caregivers).

Table 8 Questionnaire contents for each group

	Health professionals	Primary caregivers
General questions	Provide detail of their undergraduate degree	Whether they had ever sought help for their children's sleep difficulties. Whether they preferred pharmacological or non-pharmacological interventions to manage sleep difficulties. Whether they prefer their children to sleep more hours or have good quality of sleep.
	Questions asked to both groups	
Number of sessions and hours recommended	Number of sessions recommended Number of hours each session should last	
Ranking questions	Participants were asked to evaluate the importance of each piece of intervention content on a scale from one to ten. One indicated that the item is not important, and ten indicated that including the content in the programme is very important.	
Additional suggestions	Participants were asked to make suggestions as to possible further intervention content that could be ranked in the next round.	

3.2.3.4 Stage 4: Study team synthesis

Mean rank and standard deviation for each item were calculated. The research team also discussed the additional intervention content that the participants suggested, to determine if they should be included or excluded, and provided a reason for the inclusion or exclusion of each item. The most common reason for exclusion of an item was the suggested intervention was already part of the intervention available for ranking. (See table 9 that lists the suggestions).

3.2.3.5 Stage 5: Delphi survey: round two

Round two started on 7 March 2016 and ended on 7 April 2016. A reminder was sent two weeks after each round began if the researcher had not yet received a response from the participant. The reminder was sent via email or via SMS to the participant's mobile phone number. After round one was complete and the results had been analysed, participants received the mean rank for each item and were asked to re-evaluate their responses accordingly and provide a reason if they disagreed with the ranking.

3.2.3.6 Stage 6: study team synthesis Results summary and consensus outcome

Data received after round two in both versions were combined to reach the consensus for each item. Consensus for inclusion was defined as items that had a mean rank of 9 or higher on one or both versions should be included in the final programme. At this stage, the results were summarized and level of consensus was determined for each item.

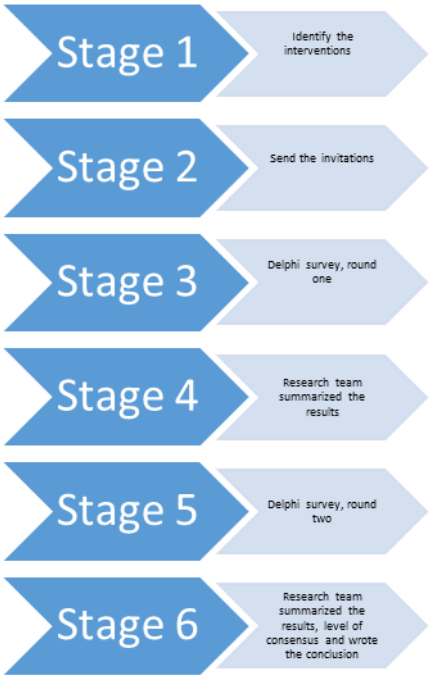


Figure 6. Flowchart of the steps of the study

3.3 Results

3.3.1 Sample

3.3.1.1 Health professionals

Forty-two health professionals from children sleep or ADHD-related disciplines were invited. Eighteen completed the questionnaire. Health professionals from different discipline were invited because they all work as a team to help children with ADHD. The breakdown of health professional backgrounds was eight psychologists, two psychiatrists, two occupational therapists, two paediatricians, a respiratory therapist and two family physicians.

3.3.1.2 Primary caregivers:

The questionnaire was distributed in ADHD classes at Aljawdah Primary School and in private centres for children with neurodevelopmental disorders in Riyadh, Saudi Arabia. Nineteen caregivers participated in the first round. Nine of them indicated an interest in completing round two and provided their contact details. Only four caregivers completed round two.

3.3.2 Primary caregiver's views responses to general questions

Eighty-five percent of caregivers prefer their children to sleep well than to sleep more hours. In contrast, 15% prefer they sleep more hours. In addition, 95% prefer non-pharmacological treatments to pharmacological. Thirty-five percent of the participants sought help for their children's sleep difficulties. Sixty-five percent of them either did not seek help or their children did not have significant sleep difficulties.

3.3.3 Number of sessions recommended

Primary caregivers recommended between one and ten sessions be included in the final programme. The average number was three sessions. In contrast, health professionals suggested between two and twelve sessions. The average was four sessions.

3.3.4 Number of hours each session should last

Primary caregivers suggested that each session should last between two and four hours. In contrast, health professionals suggested between one and five hours. The average for both versions was three hours.

Table 9 Intervention content importance ranking: round one

Item	Caregivers' version		Professionals' version	
	M (SD)	IQR	M (SD)	IQR
Workshop sessions to help primary caregivers to:				
Understand the sleep process	6.63 (3.31)	3.75	7.0 (2.89)	6
Understand normal sleep	7.68 (3.21)	2.5	7.44 (2.71)	4.5
Understand sleep cycles	7.58 (3.08)	3.75	7.17 (2.69)	0
Understand the most common sleep problems ADHD children experience	8.95 (2.24)	0	9.78 (0.42)	.5
Manage children's sleep problems	7.83 (2.95)	1	9.5 (0.69)	4.75
Learn about sleep hygiene	7.88 (2.74)	1	9.17 (1.34)	4.25
Manage primary caregivers' stress	8.89 (2.51)	2.75	8.28 (1.73)	.75
Manage primary caregivers' sleep problems	6.47 (3.7)	3	7.53 (2.43)	7.5
Written guide to help primary caregivers manage sleep problems at home	8.89 (2.49)	1.75	8.56 (2.03)	.5
Bedtime stories	7.13 (3.07)	1.75	7.56 (2.29)	5
Videos to help primary caregivers manage bedtime routines	8.63 (1.9)	2.75	8.11 (2.16)	3

Note. M = mean, SD=standard deviation, IQR interquartile range

Table 10 Intervention importance ranking: round two

Item	Caregivers' version		Professionals' version	
	M (SD)	IQR	M (SD)	IQR
Workshop sessions to help primary caregivers to:				
Understand the sleep process	5.5 (2.6)	.5	6.4 (2.47)	6
Understand normal sleep	8.0 (2.12)	2	6.73 (2.64)	4.5
Understand sleep cycles	7.5 (1.8)	2	7.4 (1.93)	0
Understand the most common sleep problems ADHD children experience	8.75 (1.3)	0	9.87 (0.34)	.5
Manage children's sleep problems	7.75 (1.79)	0	9.87 (0.34)	4.75
Learn about sleep hygiene	8.0 (1.87)	1	8.93 (1.53)	4.25
Manage primary caregivers' stress	9.75 (0.43)	1.5	8.27 (1.48)	.75
Manage primary caregivers' sleep problems	8.5 (1.5)	.5	8.13 (1.31)	7.5
Written guide to help primary caregivers manage sleep problems at home	7.0 (3.46)	0	8.67 (1.49)	.5
Bedtime stories	8.0 (2.12)	0	7.6 (1.54)	5
Videos to help primary caregivers manage bedtime routines	9.25 (0.43)	1	8.27 (1.12)	3

Note. M=mean rank, SD=standard deviation, IQR interquartile range

3.3.5 Additional intervention content suggested in round one

Different interventions were suggested in both versions and discussed by the research team. Primary caregivers suggested adding behavioural modification techniques workshop that can be used for children with ADHD in general to help in managing sleep difficulties. In addition, the children should take showers before bedtime, and their caregivers should spend at least ten minutes with them before they go to sleep. Also, one session should be designed to discuss problems primary caregivers face and possible solutions. One caregiver suggested that massaging children before sleep needs to be included in the programme.

In the health professional version, an occupational therapist suggested that adding some sleep tips that are related to primary caregivers' culture could encourage them to follow the instructions they receive. For instance, sleep habits in Islam may need to be mentioned when talking about sleep habits.

Following the discussion, the research team concluded that all the suggestions were variants of interventions already in the ranking process, or were not interventions except with regards to consider the participants' culture.

Table 11 Additional suggestions from each group

Additional suggestions	
Health professional	Primary caregivers
Health professional suggested adding some sleep tips that are related to primary caregivers' culture could encourage them to follow the instructions they receive. For instance, sleep habits in Islam may need to be mentioned when talking about sleep habits.	Primary caregivers suggested adding behavioural modification techniques workshop that can be used for children with ADHD in general to help in managing sleep difficulties. Children should take showers before bedtime, and their caregivers should spend at least ten minutes with them before they go to sleep. One session should be designed to discuss problems primary caregivers face and possible solutions. Massaging children before sleep needs to be included in the programme.

Note. Additional suggestions by health professional and primary caregivers

3.3.6 Delphi Survey round 2 results: Behavioural sleep interventions for Saudi children with ADHD (The Good Night Project)

The research team elected to use a cut off of a mean rank of 9 or higher from the second round of either of the panels. The final items were: workshop sessions to understand the most common sleep problems ADHD children experience, manage children's sleep problems, learn about sleep hygiene, help primary caregivers manage their own stress and help primary caregivers manage their own sleep problems; a written guide to help primary caregivers manage sleep problems at home; and videos to help primary caregivers manage bedtime routines.

Following the previous systematic review of the literature, and after conducting this Delphi study in order to prepare the intervention based on the available literature and according to health professionals' views and primary caregivers' needs, the research team decided that the intervention (the Good Night Project) should consist of three sessions over three weeks (one session each week), and each session should last for three hours. The intervention includes workshop sessions taken from a translated guide containing the highly ranked intervention content, a video clip, culturally sensitive sleep habits cards and relaxation techniques. The intervention will be delivered to primary caregivers by trained psychologists working in each centre or hospital. Psychologists have been chosen to deliver the intervention due to the nature of the project (behavioural) and due to the RCT design which require the researcher to be blinded to the project stages (children's allocation to the group and the delivery of the intervention).

3.3.6.1 Workshop sessions taken from the translated guide

We elected to base the workshop sessions around a culturally sensitive handbook, which we generated from existing materials that contained relevant content (Barkley, 2013; Mindell & Owens, 2015; Stores, 2014; Weiss, 2010) in order to achieve the following aims:

To understand the most common sleep difficulties experienced by ADHD children (Stores, 2014).

1. To manage sleep difficulties in school aged children (Mindell & Owens, 2015).
2. To become aware of sleep hygiene (Mindell & Owens, 2015; Weiss, 2010).
3. To help primary caregivers to manage their stress and look after themselves (Barkley, 2013).
4. To teach primary caregivers relaxation technique (Ibrahim, 1998)

In addition to the workshop sessions, a written guide to help in managing sleep difficulties at home will be distributed on completion of the programme. Each session will begin with a short discussion of the sleep difficulties experienced by the caregivers and their children. The second and third sessions will open with a short discussion about any progress made and any challenges faced, after which feedback was given.

3.3.6.2 Video

A video clip will be presented in the second session (Alhammoud, 2017). The aim of the video is to teach primary caregivers sleep hygiene and give them some tips on how to prevent and manage sleep difficulties (Weiss, 2010). The content of the video will be translated into Arabic.

3.3.6.3 Sleep habits cards

In order to prepare a material that helps in delivering sleep habits in general, sleep hygiene and sleep habits in Islam, the research team have decided to include them as cards. This will give the primary caregiver and her child the opportunity to spend time together while preparing for the bedtime, discuss about sleep hygiene in general and sleep hygiene in Islam and colour the cards after discussing them. Delivering the behaviours to children with ADHD by the cards are effective and suitable for children with ADHD due to the nature of the disorder (e.g., short attention) (ALammar, 2011). The content of the sleep habits cards were taken from (BaHammam, 2011; Mindell & Owens, 2015; Raising Children Network, 2011). Three examples of the cards are shown below (a card related to sleep hygiene, a card related to dealing with the fears and cards related to applying sleep habits in Islam). A full copy of the sleep habits cards can be found in appendix E.

Figure 7. Sleep habits cards in terms of sleep hygiene

Figure 8. sleep habits cards in terms of applying sleep habits in Islam

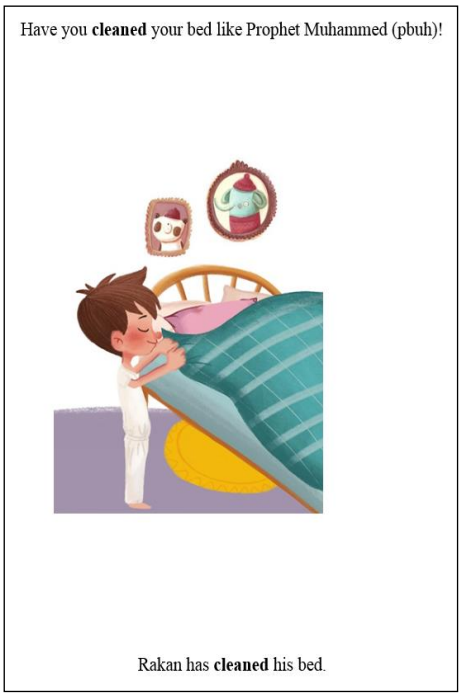
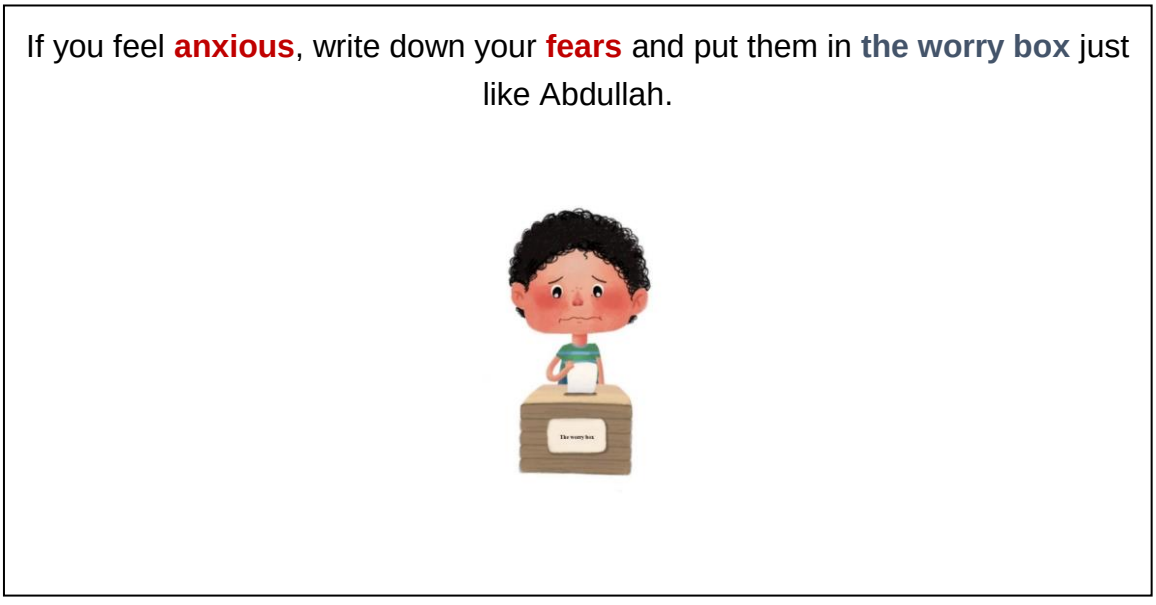


Figure 9. Sleep habits cards in terms of applying sleep habits in Islam



3.3.6.4 Relaxation technique

In order to reduce primary caregivers stress, they will be taught about how to practice relaxation technique exercise (Ibrahim, 1998). Available literature indicated that parents of children with chronic disorders are high risk of some psychological difficulties (e.g., depression and stress) (Al-Balushi et al., 2017; Theule et al., 2013), which would affect their wellbeing and parenting in general including sleep hygiene delivery which could lead to the difficulties in managing bedtime resistance (Stores, 2014). Therefore, it is assumed that improving caregivers' psychological wellbeing would benefit both caregivers and their children which would result in providing appropriate sleep hygiene. When children with ADHD receive appropriate and consistent sleep hygiene, their sleep quality and quantity would be improved which could decrease bedtime resistance (Jan et al., 2008b). Thus, primary caregivers will be taught about how to practice relaxation technique exercise, deep breathing and progressive muscle relaxation and how to manage the environment around them when practicing this technique in order to reduce their stress and anxiety symptoms (Ibrahim, 1998). Teaching primary caregivers how to practice relaxation technique is expected to improve their psychological wellbeing. In turn this may enable parents to feel more able to provide the appropriate sleep hygiene context in the home, thus improving sleep and quality of life for their children and their family.

Table 12 BCTs components of the relaxation technique can be divided as the following

BCTs	Example from the relaxation technique
1.1. Goal setting (behaviour)	Set the goal of practising deep breathing and relaxation technique
4.1. Instruction on how to perform the behaviour	Primary caregivers have been given instructions on how to preform deep breathing and progressive musicale relaxation
8.7. Graded tasks	Preform deep breathing and progressive musicale relaxation starting from the feet to the forehead
12.1. Restructuring the physical environment	The physical environment includes room temperature, light and level of noise.
12.2. Restructuring the social environment	The social environment includes finding an appropriate place to practice relaxation technique without children being around.
12.6. Body changes	Take off shoes, comfortable cloth , focus on muscle change and deep breathing

BCTs behavioural change techniques

3.4 Discussion

The present study was designed to help the research team on designing a project which aims to train primary caregivers of children with ADHD in Saudi Arabia to manage sleep difficulties. A Delphi method was used in order to ensure stakeholder priorities were followed in terms of intervention content, based on the health professionals' views and the primary caregivers' needs.

Following this study, the intervention project will be translated into the Arabic language. It will consist of three sessions over three weeks (one session per week). Culturally sensitive cards about sleep habits including sleep habits in Islam will be added to the written guide. Sleep habits in Islam will be mentioned in the text of the cards which will be adapted to the Islamic culture. Including sleep habits in Islam further supports considering cultural issues when making an intervention adaptation. Two models assume that cultural values, beliefs, religious and spiritual practices are important domains to consider when adapting interventions to be fitted to other societies (Bernal, Bonilla, & Bellido, 1995). Additionally, including these domains could promote commitment of the caregivers to the intervention itself (Lau, 2006).

The Good Night Project aimed to improve sleep and psychological wellbeing for both children with ADHD and sleep difficulties and their primary caregivers. Hiscock et al., (2015) provided sleep intervention that targeted children and measured parents' psychological wellbeing without providing an intervention for parents. In contrast, the Good Night Project aims to target both children with ADHD and sleep difficulties in addition to the primary caregivers' psychological wellbeing. Stores (2014) indicated that parents of children with neurodevelopmental disorders may not provide the

appropriate sleep hygiene due to their psychological wellbeing. Thus, the Good Night Project would consider improving caregivers' psychological wellbeing which would contribute in providing the appropriate sleep hygiene for children which therefore could result in improving children's behaviours including ADHD symptoms. See figure 10 that presents the sequences of the main aim of the Good Night Project.

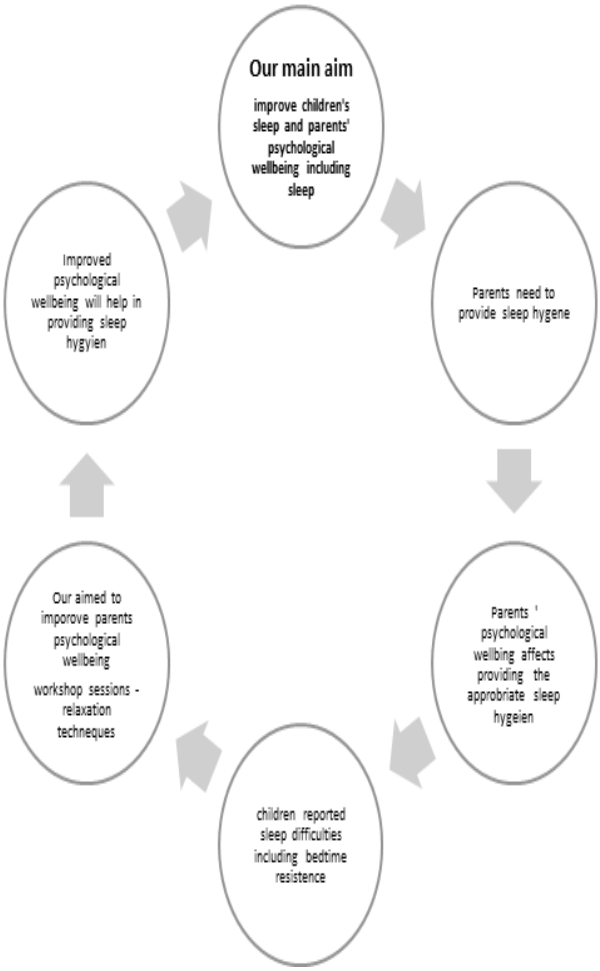


Figure 10 the sequences of the main aim of the Good Night Project.

This study has a number of strengths. The intervention content ranked in this study was developed based on a recent systematic review and meta-analysis of a randomized controlled trial (see Chapter Two), (ALammar et al., 2017) ensuring that the intervention is evidence based. Additionally, participants in Delphi process included

health practitioners from various backgrounds which gave multiple opinions from a range of clinical perspectives (eight psychologists, two psychiatrists, two occupational therapists, two paediatricians, a respiratory therapist and two family physicians) in addition to primary caregivers of children with ADHD in Riyadh, Saudi Arabia. Furthermore, the behavioural interventions included in the final programme were highly ranked by both sets of stakeholders ensuring the intervention aligns with their priorities.

A number of limitations should be considered. This Delphi study was limited to two rounds. A conclusion on the final draft of the intervention was drawn following the second round, and discussion among the research team members was held in order to design the Good Night Project. This was due to limited time available to the whole project. Another limitation was that, the caregivers did not provide multiple opinions, due to the small sample size of round two (the caregivers' version), caregivers = 4. An additional limitation was that primary caregivers were all from one city, Riyadh, the capital of the Kingdom of Saudi Arabia while the Good Night Project will be implemented in multiple cities within the Kingdom. Caregivers were chosen to be based in Riyadh due to the network that the researcher had at that stage which make it easy to distribute the questionnaires while the researcher was based in England when this research took place. In Delphi studies, there is no definition of the level of the agreement between the experts (Keeney, McKenna, & Hasson, 2010), therefore, a mean rank of 9 or higher in one or two versions was considered when reporting the consensus in the current study.

A number of important implications for future research need to be considered. Practitioners suggested that, when modifying interventions to fit them to different cultures, both language and religion must be considered. Primary caregivers would benefit from being in a group therapy programme which might allow them to help and support other caregivers (Hartman, Radin, & McConnell, 1992). It is important that

future research using a Delphi study includes primary caregivers from multiple cities within the Kingdom of Saudi Arabia. This would allow examination of the different feedback, needs and opinions provided from different cities especially if the planned intervention will be implemented in different cities.

3.5 Conclusion

The purpose of the current study was to determine the behavioural interventions that can be used to manage sleep difficulties in Saudi Arabian children who have been diagnosed with ADHD, based on the health practitioners' perspectives and primary caregivers' needs. This research extends our knowledge of the importance of considering caregivers' needs, opinions, and cultures when adapting an intervention to be implemented in a specific society.

3.6 Reflection on chapter three, cultural adaptation of sleep interventions

Recent research has emphasised the role of considering culture and beliefs when adapting an intervention to be delivered to specific racial group (Barrera Jr, Castro, Strycker, & Toobert, 2013). A meta-analysis of culturally sensitive interventions focused on mental health disorders (number of studies = 76) have shown that culturally sensitive interventions have a medium effect size d = .45 (Griner & Smith, 2006). In addition, culture has a crucial role in sleep in general (Airhihenbuwa et al., 2016; Boergers & Koinis-Mitchell, 2010), and in children with medical illness in particular (Boergers & Koinis-Mitchell, 2010). Thus, considering health professionals' views and

primary caregivers' needs was an important step into designing the Good Night Project. This chapter aimed to involve stakeholders to rank the available behaviour change techniques (BCT) that were found in the literature to help parents of children with ADHD to improve sleep (see chapter two), (ALammar et al., 2017). This study has started from the available evidence about behaviour change techniques in the literature in addition to considering the views and needs of the targeted population. This will inform cultural adaptions to the intervention for a Saudi setting. The next chapter will focus on implementing and evaluating the Good Night Project that was developed based upon the evidence from the systematic review and the Delphi, and conducted in the Kingdom of Saudi Arabia.

Chapter 4 The Good Night Project: Behavioural sleep interventions for children with ADHD: a feasibility study of a randomised controlled trial.

''If you have built castles in the air, your work need not be lost; that is where they should be. Now put the foundations under them''

Henry David Thoreau (Thoreau, 1854)

4.1 Introduction

4.1.1 General overview

Sleep difficulties in children with ADHD can be managed pharmacologically (e.g., melatonin) (Cuesta & Delrio-Hortega, 2016; Mindell & Owens, 2015; The National Institute for Health and Care Excellence (NICE), 2013; Weiss et al., 2006) or non-pharmacologically (e.g., sleep hygiene and behavioural modifications). The previous chapter found that the majority of primary caregivers of children with ADHD (95%) prefer non-pharmacological interventions compared to pharmacological interventions (e.g., melatonin). Additionally, the majority of them (85%) ranked the quality of sleep as more important than the duration (see chapter three). A randomised, controlled trial (RCT), conducted in over 200 children and their families in Australia (Hiscock et al., 2015a), found that children in the intervention group compared to the control group (usual care) show a significant improvement in sleep and ADHD following a behavioural intervention for their sleep difficulties (n = 244). However, the results of this study need to be taken with caution, as the parents were aware of the children's

allocation to treatment arm (intervention or control) which might have led to a detection bias. This was one of four studies included in a recent systematic review and meta-analysis (see chapter two), (ALammar et al., 2017) that concluded that behavioural sleep interventions have the potential to improve sleep for children with neurodevelopmental disorders. However, it was less clear, due to the poorer quality of the subset of studies that have looked at this question, whether improvement of sleep will also improve ADHD symptoms. A recent study implemented sleep hygiene and behavioural modification in 23 school age children and indicated that there is a significant reduction in the total score on both CSHQ and ADHD assessment following receiving the interventions (Peppers et al., 2016) suggesting that improving sleep might have a positive effect on symptoms. However, no studies have examined the provision of behaviour change techniques to improve outcomes for primary caregivers of children with ADHD, despite the fact that parents of children with ADHD are at high risk of stress, lack of sleep and psychological wellbeing (Gallagher, Phillips, & Carroll, 2009; Lee, 2013; Thomas, Lycett, et al., 2015), which may affect the efficacy of behavioural interventions for their children (Stores, 2014). Furthermore, managing sleep in the mothers of children with developmental disorders may have a positive effect on them, their families in general (Chu & Richdale, 2009) and mothers' psychological well-being in particular (Stores, 2014).

4.1.2 The differences between feasibility, pilot and efficacy studies

In order to justify the purpose of conducting a feasibility study, three terms need to be defined, firstly, feasibility studies, secondly, pilot studies and finally, efficacy studies. According to the National Institute for Health Research (NIHR), "feasibility studies are pieces of research done before a main study in order to answer the question

"Can this study be done?" They are used to estimate important parameters that are needed to design the main study. For instance: standard deviation of the outcome measure, which is needed in some cases to estimate sample size; willingness of participants to be randomised; willingness of clinicians to recruit participants; numbers of eligible patients, carers or other appropriate participants, characteristics of the proposed outcome measure (and in some cases feasibility studies might involve designing a suitable outcome measure); follow-up rates; response rates to questionnaires; adherence/compliance rates; availability of data needed or the usefulness and limitations of a particular database; and, time needed to collect and analyse data'' (The National Institute for Health Research, 2018). In addition, Bowen et al, (2009) reported multiple points worth considering when conducting a feasibility study for instance;

- Is there a need and demand to conduct the study?
- Can the study fit with the resources available and culture?
- What might affect the project progress?
- Will the participants be able to complete all study stages (Bowen et al., 2009).

Moreover, feasibility studies are the first and fundamental step into conducting a main trial with more flexible methodology aiming to examine the procedure of the main study and should provide a descriptive analysis due to the small sample size available (Arain, Campbell, Cooper, & Lancaster, 2010).

In contrast, pilot studies ''are a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It resembles the main study in

many respects, including an assessment of the primary outcome. In some cases, this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or, at the end of the pilot study, the data may be analysed and set aside, a so-called external pilot'' (The National Institute for Health Research, 2018). Finally, efficacy studies which can be defined as "the extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials'' (The National Institute for Health Research, 2018).

4.1.2.1 Practice guidance available for feasibility studies

Before designing an intervention, it is important to follow available guides that focus on the process of developing interventions, e.g., the guide developed by (Craig et al., 2008). According to Craig et al. (2008), designing an intervention starts with a feasibility study that would help in examining the basic components of the study (e.g., test the study process including participants and their ability to be involved in the study) see figure 11 process of developing an intervention. Also, to be able to conduct a feasibility study it is suggested to follow a guide that explains the most important components that need to be covered. Bowen et al. (2009) focus on eight important components when conducting a feasibility study (e.g., whether the study is suitable to be implemented in a specific sitting, country and group of people). Moreover, the importance of a feasibility study would be increased when there is a plan to transfer an intervention to be implemented in a different country with a variable that would be affected by culture (e.g., sleep and its related habits including sleep and wake up time in addition to duration of sleep) (Airhihenbuwa et al., 2016; Bernal et al., 2009; Boergers & Koinis-Mitchell, 2010). Thus, the need of a feasibility study will be increased when there is a plan to implement an intervention that was designed for different group of

people and specific sittings. Therefore, a feasibility study would help in examining whether the intervention can be implemented in different sitting, language and culture. The feasibility study would also help to see whether this intervention fits with the available resources (financial resources, personnel and assessments), see figure 12 components of feasibility study).

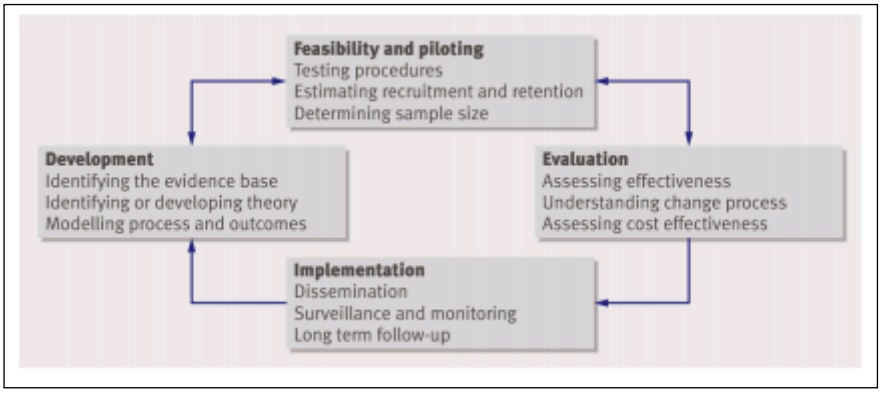


Figure 11 Process of developing an intervention, taken from (Craig et al., 2008, p. 6)

Area of focus	The feasibility study asks …	Sample outcomes of interest
Acceptability	To what extent is a new idea, program, process or measure judged as suitable, satisfying, or attractive to program deliverers? To program recipients?	• Satisfaction • Intent to continue use • Perceived appropriateness
Demand	To what extent is a new idea, program, process, or measure likely to be used (i.e., how much demand is likely to exist?)	• Fit within organizational culture • Perceived positive or negative effects on organization • Actual use • Expressed interest or intention to use • Perceived demand
Implementation	To what extent can a new idea, program, process, or measure be successfully delivered to intended participants in some defined, but not fully controlled, context?	• Degree of execution • Success or failure of execution • Amount, type of resources needed to implement
Practicality	To what extent can an idea, program, process, or measure be carried out with intended participants using existing means, resources, and circumstances and without outside intervention?	• Factors affecting implementation ease or difficulty • Efficiency, speed, or quality of implementation • Positive/negative effects on target participants • Ability of participants to carry out intervention activities • Cost analysis
Adaptation	To what extent does an existing idea, program, process, or measure perform when changes are made for a new format or with a different population?	• Degree to which similar outcomes are obtained in new format • Process outcomes comparison between intervention use in two populations
Integration	To what extent can a new idea, program, process, or measure be integrated within an existing system?	• Perceived fit with infrastructure • Perceived sustainability
Expansion	To what extent can a previously tested program, process, approach, or system be expanded to provide a new program or service?	• Costs to organization and policy bodies • Fit with organizational goals and culture • Positive or negative effects on organization • Disruption due to expansion component
Limited efficacy	Does the a new idea, program, process, or measure show promise of being successful with the intended population, even in a highly controlled setting?	• Intended effects of program or process on key intermediate variables • Effect-size estimation • Maintenance of changes from initial change

Figure 12 Components of feasibility study, taken from (Bowen et al., 2009, p. 8).

Therefore, it is important to conduct a feasibility study aiming to examine whether the main study (the Good Night Project) is feasible and can be implemented in Saudi Arabia considering the following points;

- In terms of the feasibility components:

Centres, primary caregivers, nature of the randomized controlled trial RCT, time and funds, psychologists and psychiatrists, ethical approval and the sample size.

- In terms of the summary of the findings:

Children's age, nature of sleep difficulties, outcomes, subjective and objective (Actigraphy) assessments.

4.1.3 Aim of this study

The present study aimed to develop, implement, and evaluate the efficacy of an RCT of a behavioural change intervention for children aged 5–12 years with ADHD and sleep difficulties, and their primary caregivers, (women) in Saudi Arabia. The study aims to address the following questions:

1. To what extent can a behavioural change intervention improve sleep difficulties in children with ADHD?
2. To what extent do intervention-induced changes in sleep for children account for any changes in ADHD symptoms, Sleep disorders for caregivers and Depression and Anxiety and Stress Scale (DASS) for caregivers.

In order to answer these questions, the trial would test the following hypothesis:

Compared to the control group and over time (at the baseline, post intervention and two months follow up assessments), children and caregivers in the intervention group would have a statistically significant reduction in the overall scores of the following six outcomes:

Primary outcomes (targeted children – completed by parents)

- Sleep difficulties (The Children's Sleep Habits Questionnaire (CSHQ).
- Parent ratings of behavioural problems (Conner's Rating Scale Score – Parents' version).

Secondary outcomes (subjective measures – targeted primary caregivers)

- Mother's sleep difficulties (Sleep disorders for caregivers).
- Mother's psychological wellbeing (Depression, Anxiety and Stress Scale (DASS) for Caregivers).

Secondary outcomes (subjective measures – completed by teachers)

Teacher's rating of behavioural problems (Conner's Rating Scale Score – Teachers' version).

Secondary outcome – objective Actigraphy

Activity monitor (ActiGraph)

This outcome records the physical activity in order to provide sleep duration in seven days at baseline and seven days after a month of randomization to measure change. It will be used as an objective measure with some participants.

Activity monitor diary – completed by parents

This outcome records sleep/wake time and related information in seven days at baseline and seven days after a month of randomization to measure change. It will be used with some participants to support Activity monitor (ActiGraph) measure.

4.2 Methods

This study follows the CONSORT checklist (see appendix D) (Schulz, Altman, Moher, & Group, 2010).

4.2.1 Ethics and translation permission

The trial has been funded by Shaqra University in Saudi Arabia. It has been granted ethical approval by the Psychology Research Ethics Committee University of Leeds on [25/07/2016] (ethics reference 16-0195) and by the Ministry of Health in Saudi Arabia on [30/11/2016] (ethics reference 16-356E). Paper assessments and personal information were kept in locked cabinets at the hospitals and centres while the trial was ongoing, after which they were moved by the researcher to the University of Leeds, where they again were kept in locked cabinets. A "desktop anywhere" application provided by the University of Leeds was used to write and save data inside and outside the UK, while the researcher was in Saudi Arabia. Online data and questionnaires were provided via the Bristol Online Survey, and only the research team had access to the data. A signed consent form was obtained from the participants after they have been given the information sheet and received a full explanation of the study. Translation permissions from English into Arabic were granted from the publishers for the following three resources (Barkley, 2013; Mindell & Owens, 2015; Stores, 2014).

4.2.2 Trial design

The study was a randomised, controlled, parallel-group trial. The participants were divided randomly into two groups (intervention versus control 'usual care'). It is

registered in the National Institutes of Health **https://clinicaltrials.gov/** and the registration number is NCT02871674.

4.2.3 Participants

4.2.3.1 Eligibility criteria

The participants were primary caregivers of children aged 5–12 years who had been diagnosed with ADHD by a psychiatrist in Saudi Arabia, using the criteria taken from the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Children with co-occurring Autism Spectrum Disorder (ASD) were also included. Sleep difficulties were defined as a total score of over 41 in the Children's Sleep Habits Questionnaire (CSHQ). Primary caregivers were able to speak Arabic in order to understand the intervention and answer the assessments.

4.2.3.2. Exclusion criteria

Children were excluded from the study if they met any of the following criteria:

1. They had received behavioural interventions for their sleep difficulties.
2. They had been previously diagnosed as having an intellectual disability (IQ < 70).
3. They had obstructive sleep apnoea (OSA), according to the three items in the CSHQ.

4.2.4 Study setting

The data were collected from Child Development & Behaviour Centres supervised by the Ministry of Health, in addition to special needs centres supervised by the Ministry of Social Development, in Saudi Arabia. Ten cities were included in the study in five regions as the following:

1. The Central (Riyadh, Buraidah and Al Kharj).
2. The Western (Makkah and Jeddah),
3. The Southern, Aseer (Khamis Mushait).
4. The Eastern region. (Ad Dammam, AL Khobar, Hafr Albatin and Alahsaa).

The study was conducted from October 2016 to May 2017 which was during the academic year. This period included health practitioners training, recruitment and randomisation of the participants, implementation of the interventions and undertaking pre, post intervention and follow-up measures. The researcher visited each centre for two hours and trained the psychologists on how to implement the project and gave them all the materials.

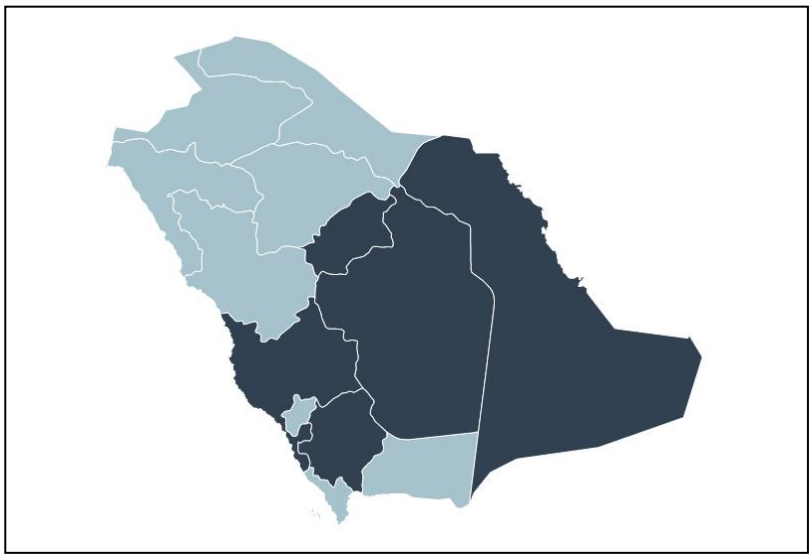


Figure 13. Study regions (five regions)

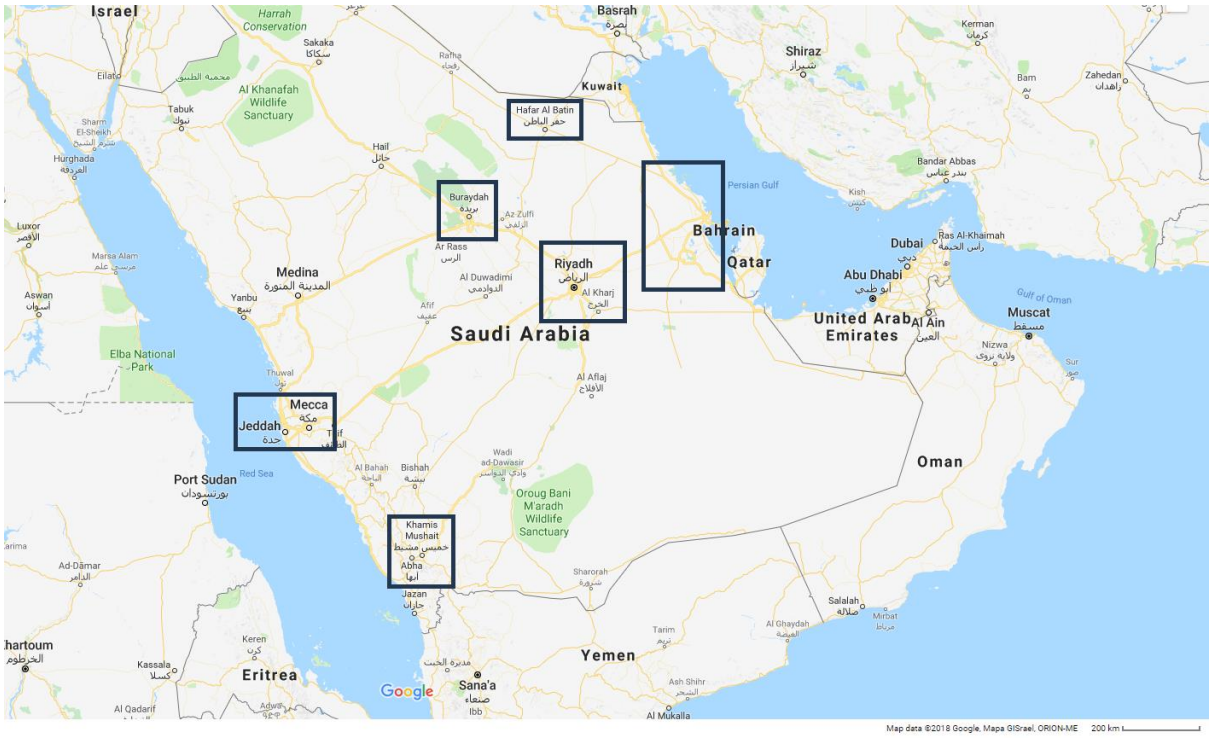


Figure 14. Study cities (10 cities)

4.2.5 Recruitment

1. Participants (primary caregivers) were recruited using the following methods:

2. Psychiatrists and psychologists who work in the included hospitals and centres introduced this study to primary caregivers.

3. Advertising materials were posted in the hospitals and centres included in the study.

4. Information sheets, baseline assessments and consent form were sent to each primary caregivers who have a child with ADHD diagnosis in each centre included in the study.

4.2.6 Intervention

The behavioural interventions were designed on the basis of following sources. Firstly, a systematic review conducted by the research team examined the best evidence on the behavioural interventions that can be used to manage sleep difficulties in children with neurodevelopmental disorders (see chapter two), (ALammar et al., 2017). Secondly, following the result of the systematic review, a Delphi study, which aimed to identify behavioural interventions that can be used to manage sleep difficulties in Saudi Arabia in accordance with professionals' views and primary caregivers' priorities, and which was also conducted by the research team (see chapter three). Participants were asked to rank the importance of the following interventions: learn about sleep processes, normal sleep in children, sleep cycles, common sleep problems in ADHD children, managing children's sleep difficulties, sleep hygiene and how to manage primary caregivers sleep difficulties and related stress. In addition, participants were asked to rank the importance of including a written guide, bedtime stories and videos. They were also asked to decide how many sessions the targeted programme should include and to suggest additional items to be included. Based on the systematic review and the Delphi results, evidence-based practice resources that help in understanding and managing sleep difficulties were translated into Arabic by the researcher (Barkley, 2013; Mindell & Owens, 2015; Stores, 2014; Weiss, 2010).

On the basis of these sources, the intervention consists of three sessions over three weeks (one session each week), and each session lasted for three hours. The intervention included workshop sessions taken from the translated guide, a video clip, sleep habits cards and relaxation technique. The intervention was delivered to primary caregivers by a trained psychologist working in each centre or hospital, see table 11 training timeline.

Workshop sessions

1. Workshop sessions were taken from the translated guide by the researcher (Barkley, 2013; Mindell & Owens, 2015; Stores, 2014; Weiss, 2010), to achieve the following aims:

2. To understand the most common sleep difficulties experienced by ADHD children (Stores, 2014).

3. To manage sleep difficulties in school aged children (Mindell & Owens, 2015).

4. To become aware of sleep hygiene (Mindell & Owens, 2015; Weiss, 2010).

5. To help primary caregivers to manage their stress and look after themselves (Barkley, 2013).

6. To teach primary caregivers relaxation technique (Ibrahim, 1998).

A written guide to help in managing sleep difficulties at home was distributed on completion of the programme. Each session began with a short discussion of the sleep difficulties experienced by the caregivers and their children. The second and third sessions were opened with a short discussion about any progress made and any challenges faced, after which feedback was given.

Video

A video clip was presented in the second session (Alhammoud, 2017). It aimed to teach primary caregivers sleep hygiene and give them some tips on how to manage sleep difficulties (Weiss, 2010). The content of the video was also translated into Arabic.

Sleep habits cards

Following some recommendations given from health practitioners in the Delphi study (see chapter three), sleep habits cards were included in the intervention. The aims of them were:

1. To give the primary caregiver and her child the opportunity to spend time together while preparing for the bedtime.

2. To support discussion about sleep hygiene in general and sleep hygiene in Islam.

3. To colour the cards after discussing them to help the child relax and engage with the material.

The content of the sleep habits cards was adapted from existing literature and interventions (BaHammam, 2011; Mindell & Owens, 2015; Raising Children Network, 2011). Three examples of the cards are shown below (a card related to sleep hygiene, a card related to the dealing with the fears and cards related to the applying of sleep habits in Islam). A full copy of the sleep habits cards can be found in appendix E.

Figure 15. Sleep habits cards, in terms of sleep hygiene card

You can depend on **yourself** in managing your **fears**. But if you **cannot**, you are allowed to wake your mum up **ONE** time like **Muteb** with his mum **Nourah**. Use this card.

Figure 16. Sleep habits cards, in terms of managing the fears card

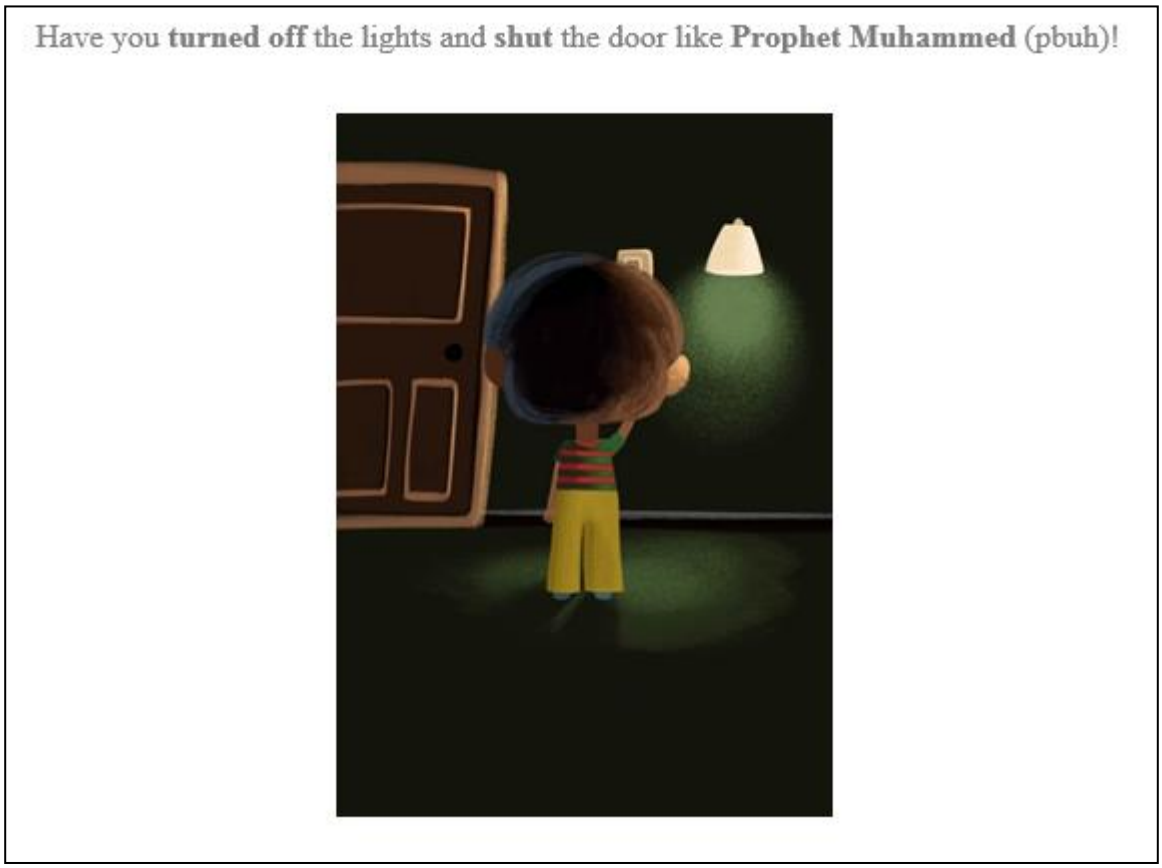


Figure 17. Sleep habits cards, in terms of applying sleep habits in Islam

Relaxation technique

In order to reduce primary caregivers stress and anxiety symptoms, they were taught about how to practice relaxation technique exercise, deep breathing and progressive muscle relaxation. They were also taught when to use it and how to manage the environment around them when practicing this technique (Ibrahim, 1998).

4.2.6.1 Behaviour Change Techniques BCT Taxonomy

After systematically reviewing four studies in chapter two (ALammar et al., 2017), the BCT taxonomy (Michie et al., 2013) was applied in order to characterise the techniques used in the interventions included in the meta-analysis. The results suggested that the common techniques used with the intervention group can be divided as the following; four techniques were used in the four studies, (4.1 Instruction on how to perform behaviour, 12.1 restructuring the physical environment, 12.2 restructuring the social environment and 14.3 remove rewards). In addition, four techniques (2.3 Self-monitoring of Behaviour, 2.4 Self-monitoring of outcome(s) of behaviour, 8.7 graded task and 10.3 non-specific rewards) were used in three studies out of four. Therefore, the Good Night Project consists of 11 components of the BCT taxonomy. The 11 components were chosen based on the systematic review and meta-analysis, see chapter two, (ALammar et al., 2017) with more focus on the most common techniques used in addition to the techniques taken from two studies that were conducted with children with ADHD (Hiscock et al., 2015a; Sciberras et al., 2011).

The 11 components can be divided as the following; (1.1. Goal setting (behaviour), 1.2. Problem solving, 4.1. Instruction on how to perform the behaviour, 5.2. Salience of consequences, 8.7. Graded tasks, 10.2. Material reward (behaviour), 10.3. Non-specific reward, 12.1. Restructuring the physical environment, 12.2. Restructuring the social environment, 12.6. Body changes, 14.3. Remove reward). Table 10 shows BCT components in each intervention components (workshop sessions taken from a translated and written guide, sleep habits cards, video and relaxation technique).

Table 13 BCTs components of the intervention used in the project

BCT	Workshop sessions	Sleep habits cards	Video	Relaxation technique
1.1. Goal setting (behaviour)	*	*	*	*
1.2. Problem solving	*	*	*	
4.1. Instruction on how to perform the behaviour	*	*	*	*
5.2. Salience of consequences	*			
8.7. Graded tasks	*		*	*
10.2. Material reward (behaviour)	*	*		
10.3. Non-specific reward	*			
12.1. Restructuring the physical environment	*	*	*	*
12.2. Restructuring the social environment	*	*	*	*
12.6. Body changes	*	*		*
14.3. Remove reward	*		*	

Note. BCT = Behavioural change technique

Table 14 BCTs components and examples of the workshop sessions + the translation guide used in the project

BCT	Example
1.1. Goal setting (behaviour)	To learn about managing sleep difficulties in school aged children
1.2. Problem solving	Questions and answer between caregivers and professional
4.1. Instruction on how to perform the behaviour	Sleep in school aged children – presentation from the second chapter of the guide
5.2. Salience of consequences	Consequences of the lack of sleep (chapter one from the guide).
8.7. Graded tasks	Preform deep breathing and progressive musicale relaxation starting from the feet to the forehead
10.2. Material reward (behaviour)	At the end of the sessions, a translated guide and sleep habits cards will be given to the caregivers.
10.3. Non-specific reward	
12.1. Restructuring the physical environment	When practicing the relaxation technique and deep breathing in a group sitting
12.2. Restructuring the social environment	Teach caregivers leaving the child's room to help him/her sleep alone
12.6. Body changes	Practice relaxation technique and deep breathing together
14.3. Remove reward	Teach caregivers how to ignore bedtime resistance

Note. BCT = Behavioural change technique

Table 15 BCTs components and examples of the sleep habits cards used in the project

BCT	Examples
1.1. Goal setting (behaviour)	Sleep hygiene
1.2. Problem solving	Wake his/her up mother once a night using a card provided
4.1. Instruction on how to perform the behaviour	Manage the fears dependently
	Positive reinforcement
10.2. Material reward (behaviour)	
12.1. Restructuring the physical environment	Turn the light off
12.2. Restructuring the social environment	Spend the time in bed and read a book
12.6. Body changes	Sleep positioning

Note. BCT = Behavioural change technique

Table 16 BCTs components and examples of the video used in the project

BCT	Example
1.1. Goal setting (behaviour)	help the child sleep alone
1.2. Problem solving	parents gradually remove themselves from the child's room to help him/her sleep alone
4.1. Instruction on how to perform the behaviour	Teach the child how to sleep alone
8.7. Graded tasks	parents gradually remove themselves from the child's room to help him/her sleep alone
12.1. Restructuring the physical environment	A child's bedroom environment (level of noise, light)
12.2. Restructuring the social environment	parents leave the child's room to help him/her sleep alone
14.3. Remove reward	Decreasing the light during the night

Note. BCT = Behavioural change technique

Table 17 BCTs components and examples of the relaxation technique can be divided as the following

BCTs	Example from the relaxation technique
1.1. Goal setting (behaviour)	Set the goal of practising deep breathing and relaxation technique
4.1. Instruction on how to perform the behaviour	Primary caregivers have been given instructions on how to preform deep breathing and progressive musicale relaxation
8.7. Graded tasks	Preform deep breathing and progressive musicale relaxation starting from the feet to the forehead
12.1. Restructuring the physical environment	The physical environment includes room temperature, light and level of noise.
12.2. Restructuring the social environment	The social environment includes finding an appropriate place to practice relaxation technique without children being around.
12.6. Body changes	Take off shoes, comfortable cloth , focus on muscle change and deep breathing

BCTs behavioural change techniques

Table 18 Training timeline

Session	30 minutes	30 minutes	30 minutes	30 minutes	30 minutes	30 minutes
First session	Give each caregiver a code to be used instead of the names on the questionnaires Complete baseline assessments Conner's rating scale (parents' version) - DASS -Sleep disorders for primary caregivers if they did not complete them. Give each primary caregiver Conner's rating scale (teacher's version)	Let each caregiver talk about what is the most important sleep difficulties from her perspective and she faces	First chapter from the guide: Sleep disorders in children with ADHD Presentation (Stores, 2014)	Second chapter from the guide: Sleep in school aged children Presentation (Mindell & Owens, 2015)		Give each caregiver the sleep habits' cards Questions' time Confirm the next session (date and time) Remind them to bring Conner's rating scale (teacher's version) baseline
Second session	Let the caregivers talk about their practices during the week and give them feedback Collect Conner's rating scale (teacher's version) baseline	Second chapter from the guide: Sleep in school aged children Presentation (Mindell & Owens, 2015) Video (sleep problems in children) (Weiss, 2010)				Questions' time Confirm the next session (date and time)
Third session	Let the caregivers talk about their practices during the week and give them feedback	Third chapter from the guide: Just for parents, how to take care of yourself? Presentation (Barkley, 2013)	Relaxation technique group exercise (Ibrahim, 1998)	-Complete post intervention assessments -Give them the Conner's rating scale (teacher's version) for post intervention		Questions' time Confirm the follow up session for each caregiver Remind them to bring Conner's rating scale (teacher's version) - post intervention (next session)

Note. Each session divided to 6 parts, each part divided to 30 minutes

4.2.7 Control group

Caregivers in the control group received usual care. They attended their usual appointments with the psychiatrists and they did not receive any sleep intervention.

4.2.8 Outcomes

Demographic data obtained from all participants. It consisted of the following information: the city and the centre (where the intervention took place), child's age, nationality, primary caregivers contact details, whether the child has another disorder and if they are taking any medications.

Data on sleep (duration/quality/disturbance) was collected using validated questionnaire instruments. Data on ADHD symptoms was assessed via validated questionnaires to be completed by primary caregivers and teachers. The outcomes were divided as follows.

4.2.8.1 Primary outcomes (targeted children)

1. The Children's Sleep Habits Questionnaire CSHQ (Owens et al., 2000). This is used widely to assess sleep, pre and post intervention, and focuses on measurement of the following subscales: bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, night waking, parasomnias, sleep-disordered breathing and daytime sleepiness. Higher scores indicate increased sleep difficulties. Due to the nature of this intervention (non-pharmacological, behavioural intervention) there is a need to use an assessment that capture change in sleep (sleep time, wake up time and sleep duration) in addition to sleep difficulties in children before, during and after sleep. Therefore, CSHQ,

the Arabic version has been chosen to assess sleep and its changes in the Good Night Project. The changes can be observed in the overall score in addition to the sub-scores categories which divided into eight subcategories: bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, night waking, parasomnias, sleep-disordered breathing and daytime sleepiness. Additionally, CSHQ was used in the four studies included in the systematic review and meta-analysis (see chapter two) (ALammar et al., 2017). Using a similar assessment would enable a comparison between the available literature and the current study. Owens (2000) suggested that a score of 41 indicated that there are sleep difficulties according to their study on the reliability and validity of CSHQ for school aged children.

2. Conners' Parent Rating Scale-48 (CPRS-48) (Albuhairy, 2011). This scale consists of 48 items that focus on five subscales: conduct problems, learning disabilities, psychosomatic disorders, impulsivity and hyperactivity and anxiety. It focuses on children aged 3–17 years. Higher scores indicate increased behavioural difficulties from parents' perspective.

4.2.8.2 Secondary outcomes (subjective measures – targeted primary caregivers)

1. The Sleep Disorders Scale for primary caregivers (Ahmad, 2013). This scale consists of 36 items that focus on sleep difficulties in adults, and is divided according to the following subscales: insomnia, hypersomnia, circadian rhythm sleep disorders, sleep terrors and sleepwalking. Higher scores indicate increased sleep difficulties.

2. The Depression Anxiety Stress Scales DASS (Taouk, Lovibond, & Laube, 2001). This is designed to measure negative emotions in adults, according to three subscales: depression, anxiety and stress. Higher scores indicate increased depression, anxiety and stress. DASS assessment has been chosen to assess primary caregivers' psychological wellbeing due to following reasons:

1. DASS would capture several psychological well-being outcomes (depression, anxiety and stress symptoms).
2. DASS is used in Saudi Arabia in hospital sittings when implementing an intervention in the psychiatric units and was recommended by a psychologist in Saudi Arabia with more than ten years of experience.
3. DASS has been translated and validated assessment into Arabic language for adults' psychological wellbeing. (Moussa, Lovibond, Laube, & Megahead, 2017).
4. Parents of children with chronic disorders are at high risk of psychological difficulties, in general, (Lach et al., 2009; Stores, 2014) and, more specifically, depression (Al-Balushi et al., 2017) and stress (Theule et al., 2013), so providing interventions for the parents would be beneficial to help them to improve their psychological well-being. Using DASS would allow assessing parents'

psychological wellbeing before, after the intervention in addition to two months follow up to see whether there is any change in parents' psychological wellbeing.

5. It is one of the assessments included in the systematic review, see chapter two (Alammar, 2017). In particular DASS was used in (Hiscock et al., 2015a) with more than 200 parents. Although Hiscock et al., (2015) did find an improvement in parents' psychological wellbeing using DASS assessment following implementing behavioural sleep intervention in their study. This would be due to the point that there were no techniques were provided in their programme which targeted parents to observe changes according to DASS assessment. Therefore, the Good Night Project includes some techniques for parents to see whether providing specific techniques would be observed in parents' psychological wellbeing.

4.2.8.3 Secondary outcomes (subjective measures – completed by teachers)

1. Conner's Teachers Rating Scale-28 (CTRS-28) (Albuhairy, 2011). This scale consists of 28 items that focus on three subscales: Conduct problems, Hyperactivity, Inattentive and Passive. It focuses on children aged 3–17 years. Higher scores indicate increased behavioural difficulties at school.

Data was collected at three time points: baseline, post intervention and at a follow-up of 2 months. Teachers' assessments were completed at baseline and post intervention. All participants in each group had an appointment with psychologists two months after the post intervention assessments in order to complete the final assessments (follow up assessment).

4.2.8.4 Secondary outcome – objective measures - Actigraphy

- **Activity monitor (ActiGraph)**

This outcome records the physical activity in order to provide sleep duration in seven days at baseline and seven days after a month of randomization to measure changes. It will be used as an objective measure with some participants.

- **Activity monitor diary – completed by parents**

This outcome records sleep/wake time and related information in seven days at baseline and seven days after a month of randomization to measure change. It will be used with some participants to support Activity monitor (ActiGraph) measure.

4.2.8.5 CSHQ and Actigraphy, a comparison

The Children's Sleep Habits Questionnaire CSHQ (Owens et al., 2000). This is used widely to assess sleep, pre and post intervention, and focuses on measurement of the following subscales: bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, night waking, parasomnias, sleep-disordered breathing and daytime sleepiness. Higher scores indicate increased sleep difficulties. CSHQ is a validated, widely used and paper based. It gives an overview of sleep patterns, sleep difficulties in children. It is considered as cheap and subjective assessment which is commonly and easy to use by parents.

Although CHSQ has shown many advantages, it is a subjective assessment which its result could be affected by other factors (e.g., parents' psychological wellbeing). However, Actigraphy is an objective assessment which is more accurate but it will not reflect behavioural problems (e.g., bedtime resistance, sleep anxiety). Thus, CSHQ would be the appropriate primary outcome due to the nature of this intervention

(non-pharmacological, behavioural intervention), paper based and cheap in cost and parents are familiar with complete this kind of assessments. The use of both subjective and objective measures will provide reliable data on sleep in different aspects (subjectively and objectively).

Actigraphy has been chosen to be a secondary outcome. It is an expensive device and the researcher had only small number of them (n=6), which will not allow to measure all children included objectively. In addition, Actigraphy is considered as medical device in the United States and the European Union.

4.2.9 Sample size

The meta-analysis of RCTs that was conducted by the research team (see chapter 2), (ALammar et al., 2017) showed an effect size of -0.87 [-1.46, -0.29], (95% confidence intervals), which implies a sample size of 60, G*Power 3.1 was used to determine sample size.

4.2.10 Assignments to interventions

Participants were randomly and equally assigned (ratio 1:1) to either the intervention or the control group (usual care) by a member of the study team (IK) who was not involved in data collection. Randomization allocated participants from a list of participants' codes using The Random Number Service (Haahr, 2017). Trained psychologists enrolled participants, assessed the measures and delivered the intervention.

4.2.11 Blinding

The researcher (IK) who undertook randomisation was blinded to any detail regarding the participants, having only been supplied with participant codes. The researcher (HA) was blinded to allocation and intervention delivery until after the follow up assessments, then was aware of the allocation at the analysis stage. However, participants and staff were not blinded due to the nature of the intervention. Participants were asked to hide the intervention form their children's teachers. The outcomes assessors were the psychologists who will deliver the intervention, so they were not blinded to the assessment.

4.3 Result

4.3.1 The revised aim, completed outcomes and completed analysis

This PhD project started in October 2014. Its aim was to conduct an efficacy study. The efficacy study design has been chosen due to the available literature with a large effect size on the role of using behavioural sleep intervention to improve sleep for children with neurodevelopmental disorders (see chapter two), (ALammar et al., 2017). In October 2017 and after the data collection has been completed, the project team have decided to convert the study aim and analysis plan from presenting an efficacy study to a feasibility study. This was due to the sample size that was available at analysis stage for the RCT (chapter four). 74 children were found to be eligible to participate in the RCT and were randomly allocated to one of two group, intervention and control (usual care). At the analysis stage 13 children completed the project and 61 dropped out at different stages for different reasons. Result and discussion sections in this chapter present and fully discuss the feasibility components of the Good Night Project from the available data and assessments. However, there were no accessibility question due to the study aim which was (an efficacy study) not (a feasibility study). Therefore, it is important to clarify the following points after converting the study aim from an efficacy study to a feasibility study:

- **Outcomes**, all the planed outcomes remain after changing the study aim except using Actigraphy as a secondary objective measures. Actigraphy could not be used due to multiple reasons (see the discussion section: outcomes, objective measure (Actigraphy).
- **Original analysis:** Analysis of variance (ANOVA) was planned to compare means of each outcome at three time points, baseline, post intervention and two

months follow up. Analysis of variance can be defined as "an extensive group of tests of significance which compare means on a depending variable. There may be one or more independent (grouping) variables or factors'' (Howitt & Cramer, 2007, p. 685).

- **Completed analysis,** a feasibility study does not require result analysis (Arain et al., 2010). Thus, a descriptive analysis will be conducted in order to look at the mean and standard deviation for each outcome and each group of children who completed the project and who dropped out.

4.3.2 Practitioners, participants and recruitment

84 health practitioners from 42 centres and hospitals within the Kingdom of Saudi Arabia agreed to take part in the project and received the materials and the training. Two thirds of them were psychologists due to the behavioural nature of the intervention, and one third from other disciplines.

560 invitations were sent via 42 centres, hospitals and schools included within the Saudi Arabia. After primary caregivers have shown an interest in taking part in the study and completed the baseline assessment (CSHQ), they received a phone call informing them whether they met the eligibility criteria or not. If they met the criteria, they were randomly allocated, and if they were in the intervention group, they were given an appointment to start the training. If they were in the control group they were given an appointment / invited to complete the assessments. Figure 18 includes recruitment details and participants' timeline.

258 children were screened and in total, 184 were excluded. 163 were excluded because they did not meet the inclusion criteria and 21 declined to take part. 74 children were randomly allocated to the intervention group or the control group (usual care). 13

participants completed the project until the analysis stage, 8 in the intervention and 5 in the control. 3 were from the central region, Riyadh 1 and Alkharj 2, 10 from Western region, Jeddah 6 and Makkah 4.

61 participants dropped out at different stages from different cities and settings (centres, hospitals and schools). 9 participants dropped out from the Ministry of Health hospital settings due to family issues. From the Ministry of Labour and Social Development 42 participants dropped out. 7 Dropped out due to centre issue (centres were no longer interested in the project), 32 due to family issue and 3 due to the time that could change sleep habits (month of Ramadan). 9 participants dropped out from a centre from the Ministry of Education due to school issues. See table 19; number of eligible children 74, who completed 13, who dropped out 61, in each region, city, and sitting.

4.3.3 Participants' timeline

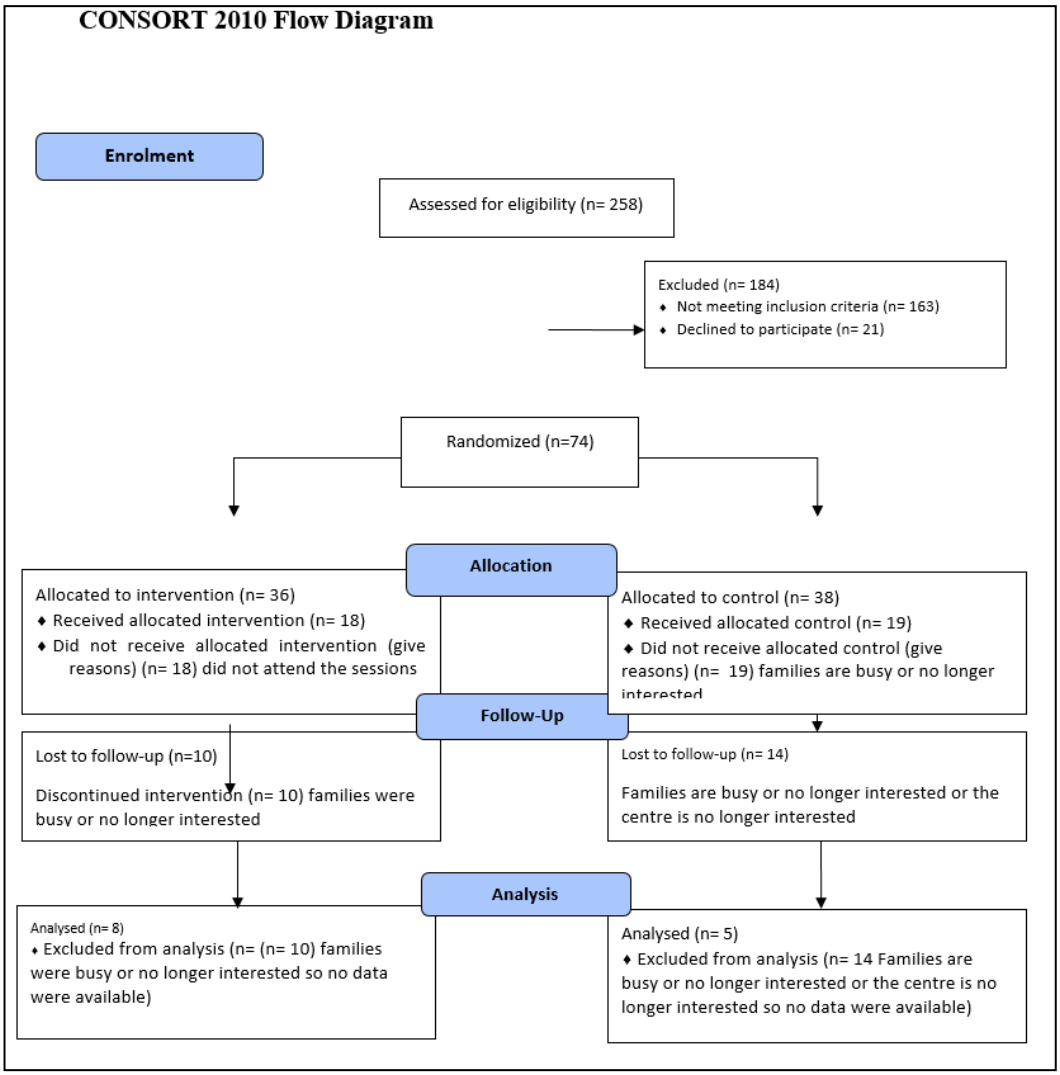


Figure 18. Participants' timeline

Table 19 Number of eligible children (74), who completed (13), who dropped out (61), in each region, city, and sitting

Region	City	Sitting (N of centres)	Eligible participants	Completed	Dropped out	Reason (n of participants)
Central	Riyadh (the capital)	Ministry of Health (1)	3	0	3	B (3)
		Ministry of Labour and Social Development (6)	32	1	31	A (7) B (24)
	Alkharj	Ministry of Labour and Social Development (1)	3	2	1	B
Alqassim	Buraidah	Ministry of Health (1)	0	0	0	0
Eastern	Dammam	Ministry of Health (1)	0	0	0	0
		Ministry of Labour and Social Development (1)	7	0	7	B
	Alkhobar	Ministry of Education (1)	9	0	9	A
	Alahsaa	Ministry of Health (1)	1	0	1	C
	Hafr Albatin	Ministry of Labour and Social Development (1)	3	0	3	C
Western	Jeddah	Ministry of Labour and Social Development (1)	6	6	0	N/A
	Makkah	Ministry of Health (1)	0	0	0	0
		Ministry of Education (1)	4	4	0	N/A
Southern	Khamis Mushait	Ministry of Health (1)	6	0	6	B
			74	**13**	**61**	

Note. dropped out due to: Centre issue (A), family issue (B), due to the time that could change sleep habits (Ramadan) (C). N/A not applicable

4.3.4 Sample characteristics, general overview, age, gender, comorbidity and medications

4.3.4.1 The allocation stage: baseline assessment (all participants, n = 74)

At the allocation stage, data of 74 children (36 intervention – 38 control) were available for general overview and data analysis. Children who were eligible and received allocation were in age between 5-12 years. Age mean was eight. 92% of the

sample was boys. Almost 70% of the sample was diagnosed with pure ADHD. 24% of the sample was diagnosed with ADHD in addition to ASD. 6% were diagnosis with ADHD and learning disorders or speech disorders. 64% of the children included in the study did not take medication. 36% were prescribed either one or more than one medications.

4.3.4.2 The analysis stage, baseline assessment (participants completed, n = 13)

At the analysis stage, data of 13 children (8 intervention – 5 control) were available for general overview and data analysis. Children completed the project were in age between 5-9 years. Age mean was seven. 77% of the sample was boys. 70% of the sample was diagnosed with pure ADHD. 30% of the sample was diagnosed with ADHD in addition to ASD. Almost 60% of the children included in the study did not take medication. 40% were prescribed either one or more than one medications.

4.3.4.3 The allocation stage, baseline assessment (participants dropped out, n = 61)

At the allocation stage, data of 61 children who dropped out (28 intervention – 33 control) were available for general overview and data analysis. Children who dropped out were in age between 5-12 years. Age mean was eight. 95% of the sample was boys. Almost 70% of the sample was diagnosed with pure ADHD. 23% of the sample was diagnosed with ADHD in addition to ASD. 7% were diagnosis with ADHD and learning disorders or speech disorders. Almost 64% of the children included in the study did not take medication. 36% were prescribed either one or more than one medications.

Table 20 Sample characteristics (total number, age, gender and diagnosis)

	Completed the project			Dropped out			Overall		
Variable	**Intervention**	**Control**	**N**	**Intervention**	**Control**	**N**	**Intervention**	**Control**	**N**
Total number	8 (62%)	5 (38%)	13	28 (46%)	33 (54)	61	36 (49%)	38 (51%)	74
Age	5-9 years		Mean = 7	5-12 years		Mean = 8	5-12 years		Mean = 8
Gender	Boys 5 (63%) Girls 3 (37%)	Boys 5 (100%) Girls 0	Boys 10 (76%) Girls 3 (23%)	Boys 26 (93%) Girls 2 (7%)	Boys 32 (97%) Girls 1 (3%)	Boys 58 (95%) Girls 3 (5%)	Boys 31 (86%) Girls 5 (14%)	Boys 37 (97%) Girls 1 (3%)	Boys 68 (96%) Girls 6 (4%)
Diagnosis	ADHD = 9 (70%) ADHD + Comorbidities = 4 (30%) ADHD + ASD = 4			ADHD = 42 (66%) ADHD + Comorbidities = 19 (31%) ADHD + Speech disorders = 2 (3%) ADHD + ASD = 14 ADHD + Learning disorders = 3			ADHD = 51(69%) ADHD + Comorbidities = 23 (31) ADHD + Speech disorders = 2 ADHD + ASD = 18 ADHD + Learning disorders = 3		

Table 21 Medications were prescribed can be divided as the following

Variable	Completed the project	Dropped out	Over all
Medication	No medication = 8 (62%) One or more medication = 5 (38%) Antipsychotic (Risperidone) = 2 Methylphenidate (Ritalin) = 1 Non-stimulant (Strattera) Antidepressant (Faverin) = 1 Omega3 = 1	No medication = 39 (64%) One or medication = 22 (36%) Antipsychotic (Risperidone) = 9 (41%) Methylphenidate (Ritalin) – (Concerta) = 4 (18%) Non-stimulant (Strattera) = 1 (5%) Non-stimulant (Strattera) + Antipsychotic (Risperidone) = 4 (18%) Methylphenidate (Ritalin) + Antidepressant (Cipralex) = 2 (9%) Methylphenidate (Concerta) + Antipsychotic (Risperidone) = 2 (9%)	No medication = 47 (64%) One or medication = 27 (36%) Antipsychotic (Risperidone) = 11 (41%) Methylphenidate (Ritalin) – (Concerta) = 5 (19%) Non-stimulant (Strattera) = 1 (4%) Non-stimulant (Strattera) + Antipsychotic (Risperidone) = 4 (15%) Methylphenidate (Ritalin) + Antidepressant (Cipralex)= 2 (7%) Methylphenidate (Concerta) + Antipsychotic (Risperidone) = 2 (7%) Non-stimulant (Strattera), Antidepressant (Faverin) = 1 (4%) Omega3 = 1 (4%)

4.3.4.4 Sleep characteristics in children with ADHD in the Good Night Project

4.3.4.4.1 Overall score, participants who completed the project, n = 13

The overall score of the CSHQ at the baseline assessment for both groups were in between 43 to 71. The mean score was 58.

4.3.4.4.2 Overall score, participants who dropped out, n = 61

The overall score of the CSHQ at the baseline assessment for both groups were in between 41 to 76. The mean score was 52.

4.3.4.4.3 Sleep duration, sleep time and wake up time, participants who completed the project, n = 13

Children, who participated in the Good Night Project and completed the project until analysis stage n=13, sleep between 5-10 hours every day with an overall average of 7 hours. They go to their beds between 7 pm to 12 am but on average they go at 10 pm. Wake up average time was at 5 am. However, average sleep time in the intervention group was 6 hours and the control group was 7.5 as reported. It seems that children in the intervention group slept fewer hours than control group.

4.3.4.4.4 Sleep duration, sleep time and wake up time, participants who dropped out, n = 61

Children, who were eligible for the project, received the allocation then dropped out, sleep between 5-12 hours every day with an overall average of 9 hours. However, average sleep time in the intervention group was 10 hours and the control group was 9 as reported. Children go to their beds between 6 pm to 2 am but in average they go at 8 pm. Wake up average time was at 6 am.

Table 22 Sleep duration, sleep time on average and wake up time for two groups (completed and dropped out, intervention and control)

Item	Duration	Average	Duration	Average
	Who completed, n =13		Who dropped out, n =61	
Sleep duration (hours)	5-10	7	5-12	9
Intervention group	5-9	6	7-13	10
Control group	7-8	7.5	5-12	9
Wake up time	3-7 am	5 am	5-9 am	6 am
Sleep time	7 pm – 12 am	10 pm	6pm-2am	8 pm

4.3.4.4.5 Nature of sleep difficulties in children with ADHD according to the CSHQ, children who completed the project (n = 13)

Caregivers reported that nearly half of children tend to go to their bed at the same time every day, fall asleep in other's beds and need more than 20 minutes to fall asleep. They also reported that, the majority of their children get the enough time of sleep. However, 50% of children do not sleep the same amount every day. In addition, caregivers reported that 70% of children struggle at bedtime, need their parents to be with them and afraid of sleeping alone and have trouble in sleeping away. 30% of children are afraid of sleeping in the dark and half of them wake up once a day and move to others bed. Caregivers also reported that, half of children move a lot during sleep. In addition, a quarter of them wet their beds. When children wake up in the morning, 40% of them wake up in a negative mood, take long time to be alert and have hard time getting out of bed. Caregivers also reported that half of the children sleep while they are in the car and a quarter of them sleep while watching the TV. Children in

the study do not have sleep disorders breathing. Caregivers who report that their children have sleep disorder breathing were excluded from the study and referred to a specialist.

4.3.4.4.6 Nature of sleep in children with ADHD according to the CSHQ in children who did not complete the intervention (n = 61)

Caregivers reported that half of children tend to go to their bed at the same time every day. 40% fall asleep in other's beds and need more than 20 minutes to fall asleep. They also reported that, the majority of their children (70%) get the enough time of sleep. However, 30% of children do not sleep the same amount every day. In addition, caregivers reported that 60% of children struggle at bedtime, 50% need their parents to be with them and afraid of sleeping alone and have trouble in sleeping away. 40% of children are afraid of sleeping in the dark. Caregivers also reported that, around 30% them wake up once a day and move to others bed and move a lot during sleep. In addition, 20% of them wet their beds. When children wake up in the morning, nearly 40% of them wake up in a negative mood, 30% take long time to be alert and have hard time getting out of bed. Caregivers also reported that 40% of the children sleep while they are in the car and nearly a third of them sleep while watching the TV. Children in the study do not have sleep disordered breathing. Caregivers who report that their children have sleep disorder breathing were excluded from the study and referred to a specialist.

Table 23 Sleep items subscales taken from the CSHQ in two groups (children who completed and who dropped out)

Sleep subscale	Completed, n= 13	Dropped out, n= 61
Bedtime Resistance	Nearly half of children tend to go to their bed at the same time every day.	Half of children tend to go to their bed at the same time every day.
	70% of children struggle at bedtime, need their parents to be with them and afraid of sleeping alone and have trouble in sleeping away.	60% of children struggle at bedtime, 50% need their parents to be with them and afraid of sleeping alone and have trouble in sleeping away
Sleep Onset Delay	50% Falls asleep in 20 minutes	60% Falls asleep in 20 minutes
Sleep Duration	50% of children do not sleep the same amount every day.	30% of children do not sleep the same amount every day.
Sleep Anxiety	70% of children need their	50% of children need their

	parents to be with them and afraid of sleeping alone and have trouble in sleeping away. 30% of children are afraid of sleeping in the dark	parents to be with them and afraid of sleeping alone and have trouble in sleeping away. 40% of children are afraid of sleeping in the dark.
Night Wakings	Half of them wake up once a day and move to others bed.	30% them wake up once a day and move to others bed.
Parasomnias	25% wet their beds.	20% wet their beds
	40% of them wake up in a negative mood, take long time to be alert and have hard time getting out of bed.	Nearly 40% of them wake up in a negative mood, 30% take long time to be alert and have hard time getting out of bed.
	Half of children move a lot during sleep.	30% of children move a lot during sleep.

Sleep Disordered Breathing	No sleep disordered breathing was reported due to the behavioural nature of the study	
Daytime Sleepiness	Half of the children sleep while they are in the car and a quarter of them sleep while watching the TV.	40% of the children sleep while they are in the car and nearly a third of them sleep while watching the TV.

The differences between children in the intervention group with ADHD with and without ASD in CSHQ overall results and subcategories results

Table 24 Age, gender, medication, duration of sleep, sleep and wake up time

	Children with ADHD (n=5)	**Children with ADHD + ASD (n=3)**
Age	7	6
Gender	Male = 3 Female = 2	Male = 2 Female = 1
Medication	Risperdal = 2	Ritalin = 1 Omega 3 = 1
Duration of sleep	9.30 hours	6.30 hours
Sleep time	8 pm	11 pm
Wake up time	5.30 am	5.30 am

Table 24 shows that children with ADHD and ASD (n=3) reported that they sleep fewer hours compare to children with ADHD (n=5). In terms of medications, two children out of five with ADHD were prescribed Risperdal and a child with ADHD and ASD was prescribed Ritalin. Duration of sleep for children with ADHD and ASD seems to be lower compare with children with ADHD.

Table 25 Mean scores of the overall results of the CSHQ

	Baseline	Post intervention	Two months follow up
Children with ADHD (n=5)	55	55	52
Children with ADHD + ASD (n=3)	64	60	51

Table 25 shows that children with ADHD and ASD (n=3) reported severe sleep difficulties according to the CSHQ overall results compare to children with ADHD (n=5). Moreover, children with ADHD and ASD (n=3) have shown more improvement in their sleep within time from the baseline, to the second assessment to the final assessment (two months follow up).

Table 26 Mean results of each subcategories of the CSHQ at three time points in children with and without ASD

		1	2	3	4	5	6	7
Baseline	Children with ADHD (n=5)	11	2	4	8	6	13	14
	Children with ADHD + ASD (n=3)	14	2	7	9	7	11	14
Post intervention	Children with ADHD (n=5)	10	2	4	7	4	10	14
	Children with ADHD + ASD (n=3)	13	2	6	9	6	9	14
Two months follow up	Children with ADHD (n=5)	9	2	10	9	6	11	12
	Children with ADHD + ASD (n=3)	8	2	11	12	6	7	11

1. Bedtime Resistance 2. Sleep Onset Delay 3. Sleep duration 4. Sleep anxiety 5.Night wakings 6. Parasomnia 7. Daytime sleepiness

Sleep Disordered Breathing items have been removed due to the eligibility criteria that have been chosen in this study: (children who reported that they have Sleep Disordered Breathing exclude from the study).

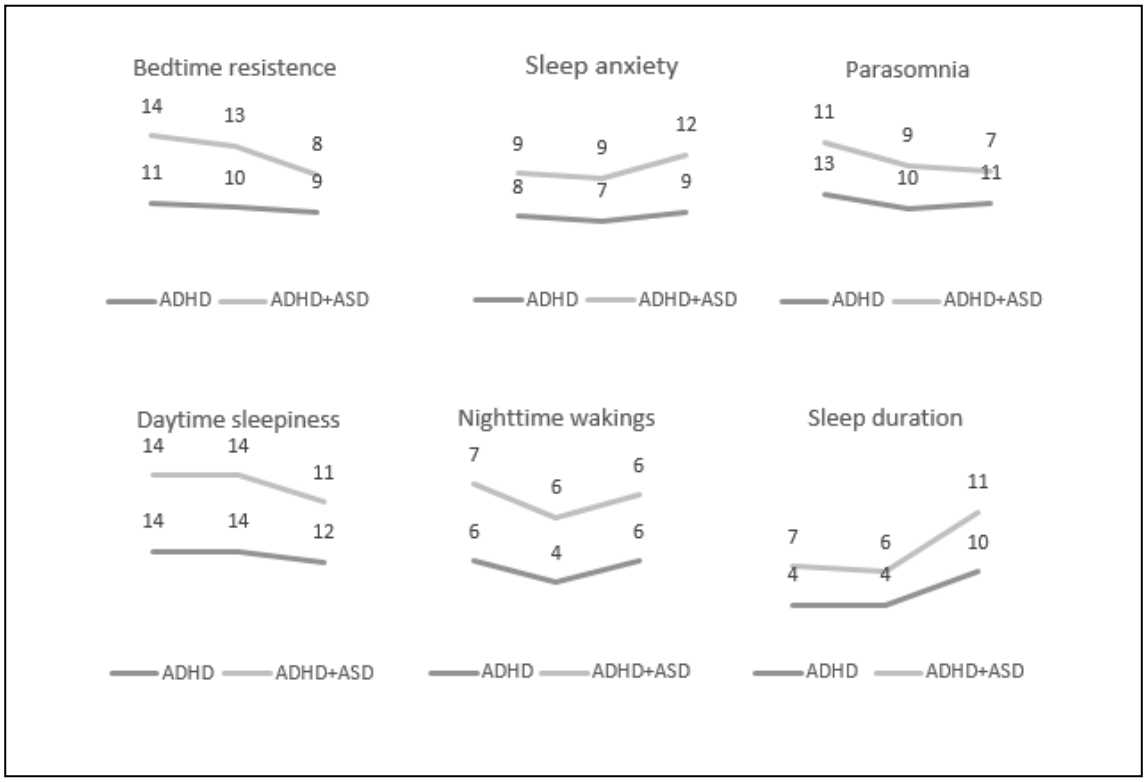


Figure 19 CSHQ subscales. There was no change reported in sleep onset delay in both groups at all time points (mean score was 2, see table 26).

When looking at each subscale from CSHQ, it seems that there were three subscales (bedtime resistance, daytime sleepiness and parasomnia) that have shown a decrease in the mean result of the subscale which indicated that there is an improvement. On the other hand, there were three subscales (sleep anxiety, sleep duration and night time wakings) have shown either a decrease or no change was reported between the baseline and post intervention assessments. Then, an increase in the mean result between post intervention assessment and after two months follow up. The mean result in the subscale sleep onset delay was 2 at three time points which would be difficult to be assertive about whether there was an improvement in any of the groups within time in this specific subscale.

Table 27 Descriptive statistics of the baseline assessment for children and their caregivers who completed the project n= 13 and dropped out n = 61

	Completed the project			Dropped out		
Assessment	Intervention Baseline *M (SD)*	Control Baseline *M (SD)*	N	Intervention Baseline *M (SD)*	Control Baseline *M (SD)*	N
CSHQ	*60.75 (10.24)*	52.5 (4.20)	Intervention = 8 Control = 4 Total = 12	*50 (7.5)*	*53 (7.3)*	Intervention = 28 Control = 33 Total = 61
Conner's - P	45.75 (21.85)	65.25 (21.93)	Intervention = 4 Control = 4 Total = 8	*42 (12.5)*	*56 (28)*	Intervention = 9 Control = 17 Total = 26
ADHD	14.75 (4.06)	17 (5.92)	Intervention = 8 Control = 5 Total = 13	*13.88 (2.97)*	*15.64 (5.74)*	Intervention = 9 Control = 17 Total = 26
SDC	63.75 (12.62)	61.2 (24.05)	Intervention = 8 Control = 5 Total = 13	*64.6 (15)*	*62 (10.9)*	Intervention = 5 Control = 14 Total = 19
DASS	44.17 (31.43)	47.4 (37.02)	Intervention = 6 Control = 5 Total = 11	*32.5 (12.4)*	*30 (14.6)*	Intervention = 6 Control = 14 Total =
Conner's – T	38.25 (13.48)	42.50 (3.54)	Intervention = 4 Control = 2 Total = 6	No teachers' assessments were available		

Note. Descriptive statistics of the baseline assessments.

Table 28 Descriptive statistics of the six outcomes at three time points, children who completed the project (n = 13)

	Intervention			Control			
	Baseline *M (SD)*	Post Intervention *M (SD)*	2 months follow up *M (SD)*	Baseline *M (SD)*	Post intervention *M (SD)*	2 months follow up *M (SD)*	N
CSHQ	*60.75 (10.24)*	*53.88 (8.56)*	*51.75 (6.32)*	52.5 (4.20)	61.25 (12.69)	56 (7.26)	Intervention = 8 Control = 4 Total = 12
Conner's – P	45.75 (21.85)	31 (18.57)	37 (19.1)	65.25 (21.93)	55 (28.58)	37 (19.20)	Intervention = 4 Control = 4 Total = 8
ADHD	14.75 (4.06)	11.75 (4.92)	*N/A*	17 (5.92)	12.60 (7.64)	*N/A*	Intervention = 8 Control = 5 Total = 13
SDC	63.75 (12.62)	60 (12.69)	*N/A*	61.2 (24.05)	63.4 (14.05)	*N/A*	Intervention = 8 Control = 5 Total = 13
DASS	44.17 (31.43)	40 (29.73)	*N/A*	47.4 (37.02)	32.20 (32.17)	*N/A*	Intervention = 6 Control = 5 Total = 11
Conner's – T	38.25 (13.48)	32.75 (18.57)	*N/A*	42.50 (3.54)	45 (4.24)	*N/A*	Intervention = 4 Control = 2 Total = 6

Notes. N= number of participants. CSHQ = The Children's Sleep Habits Questionnaire. Conner's-P = Conner's Rating Scale Score – parents' version. ADHD= ADHD sub-scale from Conner's Rating Scale. SDC = Sleep disorders for caregivers. DASS = Depression and Anxiety and Stress Scale for caregivers. Conner's – T = Conner's Rating Scale Score – teachers' version. N/A = not applicable due to incomplete data.

4.3.5 Primary outcomes

4.3.5.1 The Children's Sleep Habits Questionnaire (CSHQ)

CSHQ scores are available at three time points, baseline, post intervention and at two months follow up (N = 12, Intervention = 8, Control = 4). The intervention group at the baseline (M = 60.75, SD = 10.24), post intervention (M = 53.88, SD = 8.56), and at two months follow up (M = 51.75, SD = 6.32), control group at the baseline (M = 52.5, SD = 4.20), post intervention (M = 61.25, SD =12.69), and at two months follow up (M = 56, SD =7.26).

The results of CSHQ (intervention group) indicated that there is a decrease in the score from the baseline to the post intervention and from the post intervention to the follow up assessment. In contrast, the control group showed an increase in the overall score of the CSHQ from the baseline to the post intervention assessment. However, the control group has shown a decrease between the post intervention assessment to the follow up. The figure 20 showed that the intervention group has shown a reduction in the score between the baseline and the two month follow up assessment. In contrast, the control group has shown an increase in the score between the baseline and the two month follow up assessment.

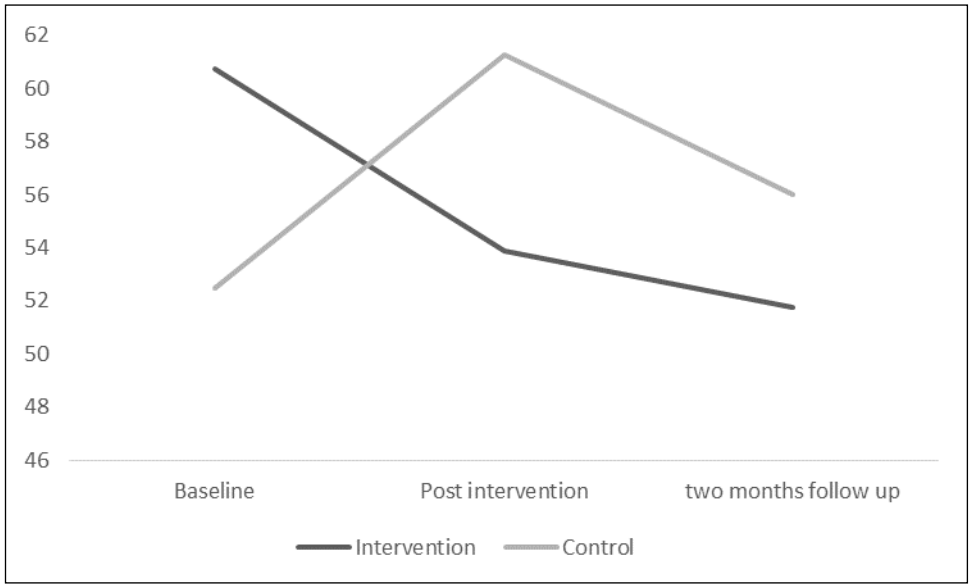


Figure 20. CSHQ scores result, intervention and control at baseline, post intervention and at two months follow up.

4.3.5.2 Conner's Rating Scale - parents' version

Conner's Rating Scale - parents' version scores are available at three time points, baseline, post intervention and at two months follow up (N = 8, Intervention = 4, Control = 4). The intervention group at the baseline (M = 45.75, SD = 21.85), post intervention (M = 31, SD = 18.57), and at two months follow up (M = 37, SD = 19.1), control group at the baseline (M = 65.25, SD = 21.93), post intervention (M = 55, SD =28.58), and at two months follow up (M = 37, SD = 19.20).

The result of the Conner's Rating Scale - parents' version indicted that there is a reduction in both groups (intervention and control) between the baseline and the post intervention assessment. The control group showed additional reduction in the two months follow up assessment, in contrast, an increased reported in the intervention group at the two months follow up assessment.

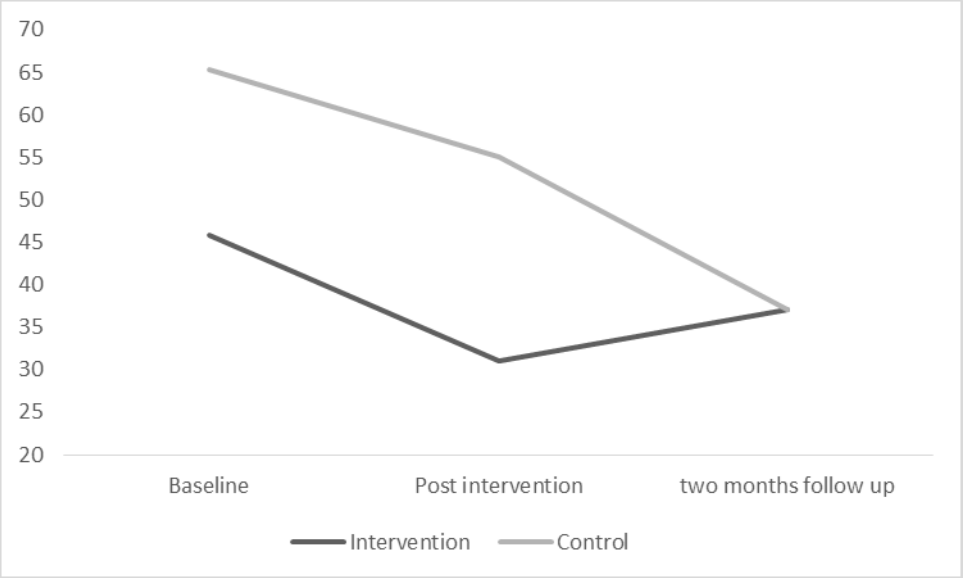


Figure 21. Conner's Rating Scale - parents' version scores result, interventions and control at baseline, post intervention and at two months follow up.

4.3.5.3 ADHD score from Conner's Rating Scale

ADHD score from Conner's Rating Scale scores are available at two time points, baseline and post intervention, (N = 13, Intervention = 8, Control = 5).The intervention group at the baseline (M = 14.75, SD = 4.06) and post intervention (M = 11.75, SD = 4.92), control group at the baseline (M = 17, SD = 5.92) and post intervention (M = 12.60, SD = 7.64).

The result of ADHD score from Conner's Rating Scale in both groups (intervention and control) have shown a reduction in the ADHD score from the baseline to the post intervention assessment (see figure 22).

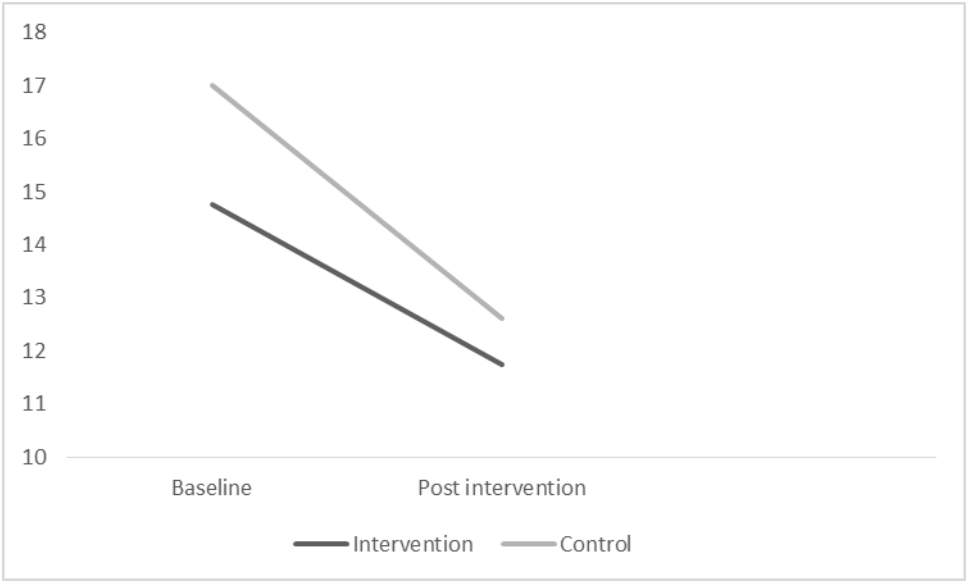


Figure 22. ADHD scores result from Conner's Rating Scale, interventions and control at baseline and post intervention.

4.3.5.4 Sleep for primary caregivers

Sleep for primary caregivers scores are available at two time points, baseline and post intervention, (N = 13, Intervention = 8, Control = 5). The intervention group at the baseline (M = 63.75, SD =12.62), and the post intervention (M = 60, SD = 12.69), control group at the baseline (M = 61.2, SD = 24.05), and the post intervention (M = 63.4, SD = 14.05).

The result of sleep for adults indicted that intervention group showed a reduction in overall score between baseline and post intervention assessment. In contrast, an increase reported in the control group between the baseline and the post intervention assessment(see figure 23).

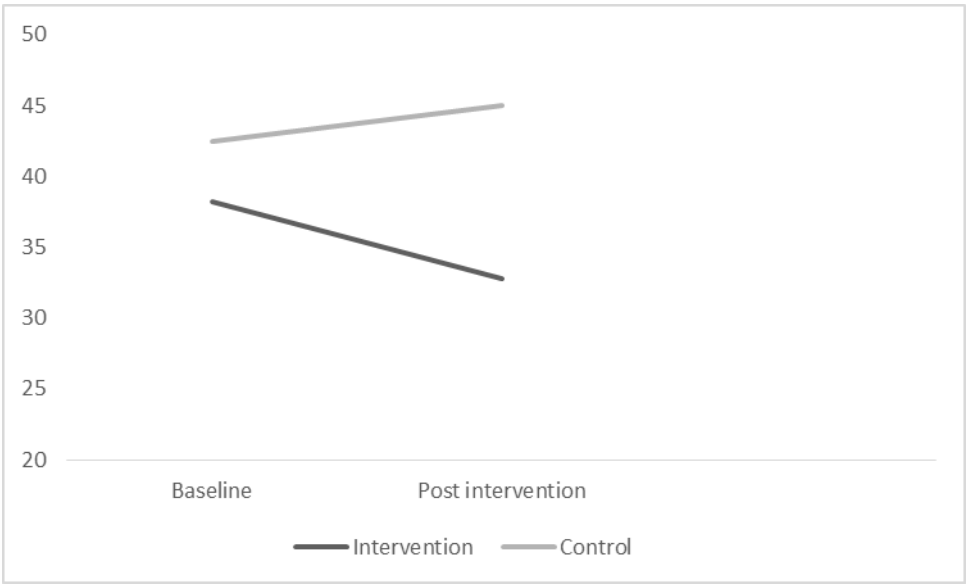


Figure 23. Sleep disorders scores result for primary caregivers, interventions and control at baseline and post intervention.

4.3.5.5 Depression, Anxiety and Stress Scale (DASS) for caregivers

Depression, Anxiety and Stress Scale (DASS) for caregivers scores are available at two time points, baseline and post intervention (N = 11, Intervention = 6, Control = 5). The intervention group at the baseline (M = 44.17, SD = 31.43), and the post intervention (M = 40, SD =29.73), control group at the baseline (M = 47.4, SD = 37.02), and the post intervention (M = 32.20, SD = 32.17).

Intervention group showed a reduction in the score between the baseline to the post intervention assessment. However, the control group showed an increase from the baseline to the post intervention assessment (see figure 24).

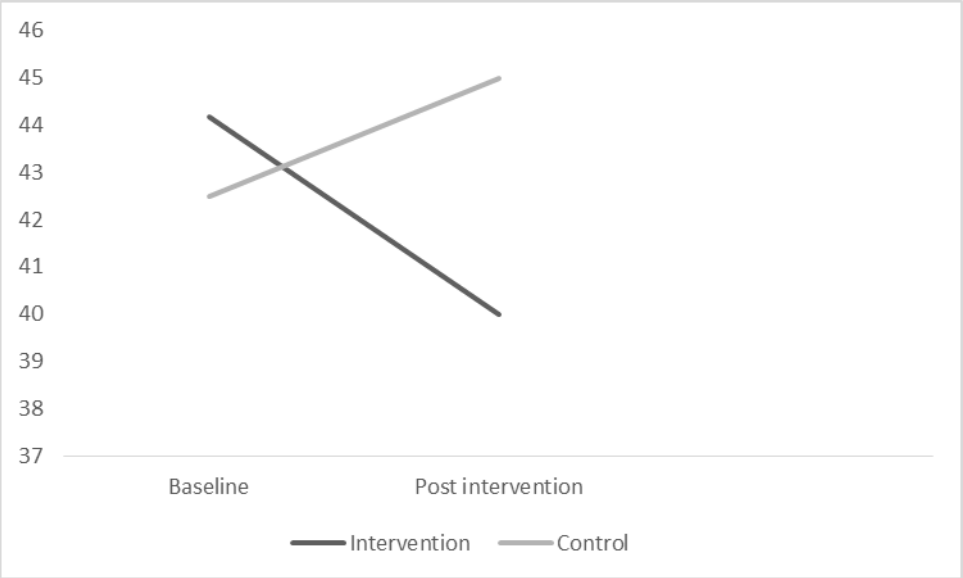


Figure 24. DASS scores result for caregivers, interventions and control at baseline and post intervention.

4.3.5.6 Conner's rating scale– Teachers' version

Conner's rating scale – teachers' version scores are available at two time points, baseline and post intervention, (N = 6, Intervention = 4, Control = 2). The intervention group at the baseline (M = 38.25, SD = 13.48), and the post intervention (M = 32.75, SD = 18.57), control group at the baseline (M = 42.50, SD = 3.54), and the post intervention (M = 45, SD = 4.24).

The results of Conner's rating scale – teachers' version indicted that intervention group sowed a reduction in the score from the baseline to the post intervention assessment. In contrast, the control group showed an increase between the baseline assessment to the post intervention assessment (see figure 25).

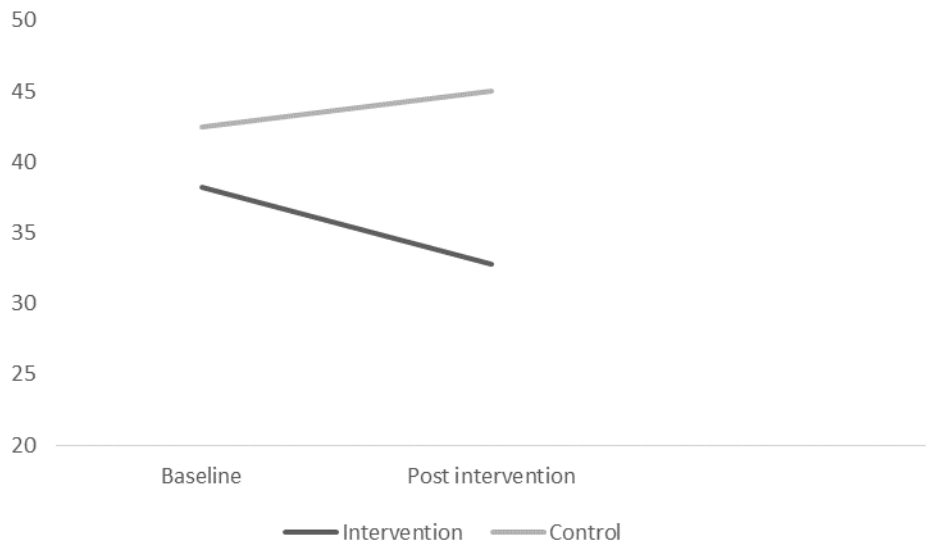


Figure 25. Conner's rating scale– Teachers' version scores result, interventions and control at baseline and post intervention.

4.4 Discussion

This RCT aimed to design, implement and evaluate the feasibility of behavioural sleep interventions in managing sleep difficulties and decreased ADHD symptoms following participation in the Good Night Project in Saudi Arabia using an RCT design. There are several points worth considering following implementation of the Project. These points were observed by the researcher and reported by the psychologists and caregivers who were involved. The points can be categorized as follows: firstly, feasibility of the study components; Centres, Primary caregivers, Nature of the Randomized controlled trial RCT, Time and Funds, Psychologists and psychiatrists , Ethical Approval, Sample size, and secondly, Summary of the Findings for both caregivers and children who completed the project (n=13) and caregivers and children who dropped out (n=61) (Children's age, Nature of sleep difficulties, Outcomes (Subjective and Objective (Actigraphy) assessments)).

4.4.1 Feasibility of the study components

4.4.1.1 Centres, cities and regions

Centres were keen to participate in the project due to their understanding of the importance of the research. They also were looking forward to improving their services. Only a minority of these centres completed the final stage of the project (n=4). Some of them were busy with their own goals and apologized for not completing the project after a few months of agreeing to take part. A few centres agreed to take part if there was an admission fee paid by each participant. This needs to be considered when applying for a grant when planning to conduct another feasibility study. More than half of the centres

included in the study are in Riyadh (the capital city). It seems, however, that most of the centres in Riyadh stopped collaborations at early stages because they were busy with their own goals. Centres outside the capital (Riyadh) showed more commitment in completing the project than centres in the capital.

It seems that participants who completed the project were in schools or centres sittings supervised by the Ministry of Education or the Ministry of Labour and Social Development. This might be due to the point that both caregivers and schools/centres team (head of the centre and all the team including psychologists) were aware of the workshops and group therapy that are conducted in order to help caregivers dealing with their children. In contrast, participants from Ministry of Health seem to receive individual sessions with follow up appointments in an individual sitting. They were not aware of group support and group therapy in multiple sessions in hospital settings. Moreover, participants who completed were typically from the western region (n=10) and central region (n=3). All centres who had participants who completed were keen to improve their services at different levels (head of the centre and all the team including psychologists). Therefore, it is important to consider minimising the number of session to one session with follow up sessions after around three to four weeks when planning to implement the project again in the Ministry of Health (hospital sittings).

4.4.1.2 Primary caregivers

A few primary caregivers in the intervention group completed the project and suggested to implement the project in multiple cities within the Kingdom (intervention group n = 8). Psychologists reported that primary caregivers who are not educated were more likely to follow the guidance and collaborate with the centre to provide better services for their children. Primary caregivers who participated in this intervention were

not compensated for taking part in the project other than receiving the translation guide and the sleep habits cards. Compensation could encourage participants to complete the training and the assessments at all time points. Also, the intervention should be offered to the control group, using a wait-list control group design. This may encourage them to complete the assessments at three time points, as controls were less likely to complete than those in the intervention condition, possibly because they do not receive any benefit. Also, primary caregivers who work could not leave their jobs to attend the training, although they were given a letter to provide it to their workplace. Primary caregivers who did not complete the project reported that they were busy with other tasks, commitments, and children. A psychiatrist reported that some primary caregivers might increase or decrease responses in the paper assessments to keep the benefits that they might already have (e.g., financial assistance from the Ministry of Social Development; acceptance of their children in a specific centre). Therefore, anything that can reduce the intervention burden on caregivers would likely increase completion rates.

4.4.1.3 Nature of the Randomized controlled trial RCT

Although the researcher was blinded to the intervention delivery, which could decrease the bias, and the intervention reached multiple users, it seems that the RCT needs a large team to facilitate the trial. The researcher was in England following the training and during implementation. Being a primary investigator in a different country—with different normal business days—could affect the progress of the project.

4.4.1.4 Time and Funds

The data collection period for Saudi students who are funded by the Ministry of Education in Saudi Arabia is 3 months during their entire degree program, whether for a

master's degree or PhD. This period cannot be expanded, although study designs may be different.

This study lasted from October 2016 to May 2017. The team then agreed to stop adding any more participants because Ramadan in 2017 started at the end of May, and might change sleep habits for both children and their parents. During Ramadan, the majority of families sleep at dawn or in the morning following sunrise. Parents are flexible in terms of sleep\wake up time. Also, in the last semester, summer holiday date in Saudi Arabia was changed to be started a month in advance. This decision was made on short notice by the Ministry of Education. The change affected the study's progress as the primary schools and day care centres for special needs closed 1 month before the actual date. Additionally, one more task that consumed time during the study was the translation of the guide from English into Arabic. The guide is 34 pages long and divided into three chapters. Translating the guide and checking its accuracy consumed time, and the researcher needed assistance to complete the tasks before the trial started.

4.4.1.5 Psychologists and psychiatrists

A few centres welcomed the researcher to implement the programme. Psychologists, however, were busy with other tasks. Some of them received training and materials, but they could not complete the research due to their other responsibilities. When planning to conduct a pilot study, it is important to consider a compensation for all personnel involved in the project. Additionally, a contract should be drawn up before agreeing to take part in the project.

4.4.1.6 Ethical Approval

This research is collaboration between two countries: the United Kingdom and Saudi Arabia; this means that approval is needed from each country. Ethical approval from each source required at least 3 months prior to beginning the research ‘’research involving living human participants or the personal data of living human participants requires ethical approval’’ according to the University of Leeds Research Ethics Policy (University of Leeds, 2018). Also, each hospital in Saudi Arabia requires its own approval, depending on which site is supervising it (e.g., Ministry of Health, a specific University hospital, or Ministry of National Guard), which might affect the study’s progress. To prevent delay, a suggestion was made by the research team to avoid including any hospital that required a separate or lengthy ethical approval process in order to include more hospitals.

4.4.1.7 Sample size

The meta-analysis of RCTs that was conducted by the research team (see chapter 2) (ALammar et al., 2017) showed an effect size of -0.87 [-1.46, -0.29], (95% confidence intervals), which implies a sample size of 60, G*Power 3.1 was used to determine sample size. This contrasts with the findings of the sample size which found a high attrition rate which implies, this small sample size would result in an underpowered efficacy trial. A few parents completed the project (n = 13). More than 80% of the sample (n = 61) dropped out and did not complete the project although they completed the baseline assessments, met the inclusion criteria and agreed to take par and received allocation. This could be due to multiple reasons, first, no compensation was given to take part in the project other than receiving the translation guide and the sleep habits cards. Second, Parents who work could not leave their jobs to attend the training,

although they were given a letter to provide to their workplace. Third, parents reported that they were busy with other tasks, commitments, and children. Fourth, another explanation for the incomplete data might be due to the psychological well-being of the caregiver when they completed the baseline assessments. Multiple studies indicated that psychological well-being (stress, mood and lack of sleep) of the caregiver could be affected by being primary caregivers for children with chronic conditions such as developmental disorders (Gallagher et al., 2009; Lee, 2013).

4.4.2 Summary of the Findings

4.4.2.1 Sample characteristics

4.4.2.1.1 Children and their primary caregivers who completed the project n = 13 (results are at the baseline)

One interesting finding is that all children included in the study and completed the project, n=13 were nine years old or younger. This means that all of them were at the early stages of primary school. In Saudi Arabia, year one in primary school starts when the child is seven years old. The eligibility criteria in this study were children should be in primary school which is between 5-12 years, and children who completed the project were 9 years or younger. This would mean that children who are in the earlier school years might be at high risk of sleep difficulties which could be difficult to be managed by their caregivers then require an intervention. This could be one of the points worth considering to distinguish between children who completed and who dropped out.

4.4.2.1.2 Children and their primary caregivers who were eligible, received allocation then dropped out n = 61

Children who were eligible, received allocation then dropped out were in age between 5-12 years which was different than children who completed the project who

were 9 years old or younger which is in the early years of primary schools in Saudi Arabia. Nearly 15% of the children who dropped out were prescribed Antipsychotic (Risperidone) which is one of the medication that can be used in order to help children with ADHD to have better sleep (Mindell & Owens, 2015). Also, 10% (n=10) of children who dropped out were prescribed Antipsychotic (Risperidone) in addition to another medication (either stimulant or non-stimulant), (see Table 21 Medications that were prescribed). Additionally, when looking at sample characterises in participants who completed and who dropped out the results showed that a third of the children who dropped out (n=19) were diagnosed with comorbidities in addition to ADHD. Nearly 70% without comorbidities still reported sleep difficulties which could support the result taken from a recent study that indicated that sleep disturbances in children with ADHD are not related to comorbidities and can be reported with pure ADHD (Virring et al., 2016). Therefore, when studying sleep or planning to improve sleep in children with ADHD, it is important to consider differential effects in children with and without comorbidities, also, children with and without medication with different kind of medications.

4.4.2.2 Sleep duration

4.4.2.2.1 Children and their primary caregivers who completed the project n = 13 (results are at the baseline)

The average sleep duration reported in the current study was seven hours, and this is in the acceptable range in accordance with the National Sleep Foundation which indicates that school aged children require 9–11 hours of sleep every day but that a period of 7–8 hours of sleep is acceptable for school age children (Hirshkowitz et al., 2015). However, when looking at the duration times of each particular group, the results

indicated that children in the intervention group slept six hours which is 90 minutes less than the children in the control group who slept 7.5 hours, which is not in the accepted range for the intervention group. These different results are in line with studies that found that children with ADHD sleep the acceptable number of hours every day (Knight & Dimitriou, 2017; Yurumez & Kilic, 2016); however, this finding is in contrast to that of (Heijden et al., 2017) who found that children with ADHD slept 45 minutes less than those in the control group. Furthermore, the 90 minute difference reported in each group could have been due to the randomisation used to allocate the children to the intervention or the control group (usual care). The difference also could be due to the normal variation as a result of the small sample size.

4.4.2.2.2 Children and their primary caregivers who were eligible, received allocation then dropped out n = 61

The average sleep duration reported for children who dropped out in both groups (intervention and control) (n=61) was 9 hours and this is in the required range for school aged children in accordance with the National Sleep Foundation which indicates that school aged children require 9–11 hours of sleep every day (Hirshkowitz et al., 2015). When looking at the duration times of each particular group for children who dropped out, the results indicated that, children in the intervention group slept 10 hours which is 60 minutes more than the children in the control group who slept 9 hours. The difference between groups could be due to the normal variation as a result of the small sample size.

4.4.2.3 Nature of sleep difficulties

4.4.2.3.1 Children and their primary caregivers who completed the project n = 13 (results are at the baseline)

The overall results of the CSHQ from the baseline assessment suggest that sleep difficulties in children with ADHD in this study are behavioural in nature. Most difficulties reported were related to struggling at bedtime, needing their parents to be with them and being afraid of sleeping alone. This result seems to be consistent with other research, which found that the most common sleep difficulties reported in children with ADHD are (a) having difficulty falling asleep and (b) refusing to go to their beds (Corkum et al., 2001; Cortese et al., 2009; Gray, 2017; Sung et al., 2008). In addition, these difficulties may be related to the inconsistency and sleep hygiene provided by parents (Gray, 2017; Sciberras, Mulraney, et al., 2017).

Another important finding was that half of the children did not sleep the same amount of time every day, needed more than 20 minutes to fall asleep and moved a lot during sleep. In addition, a quarter of them wet their beds, and nearly half of them awakened in a negative mood, took a longer time to become alert, had a hard time getting out of bed and seemed tired during the day. These results are in agreement with the findings of Craig et al. (2017), which showed that the most common sleep difficulties reported by parents of children with ADHD are excessive daytime sleepiness, insomnia, periodic limb movements in sleep and lack of daily consistency in sleep. Furthermore, parasomnias including bedwetting were also found by (Knight & Dimitriou, 2017).

However, the nature of sleep difficulties (behavioural difficulties) found in this study needs to be interpreted with caution. All assessments used in this study were subjective assessments. Although they are standardized tests, caregivers' responses to

the measures might be affected by any contemporaneous life circumstances when completing the questionnaires. In fact, parents of children with chronic disorders are at high risk of psychological difficulties which may affect their perceptions of their child's behaviour (Lach et al., 2009; Stores, 2014). There was no objective assessment used to capture sleep stages, sleep and wake-up times using Actigraphy or polysomnography, although (Corkum et al., 2001) did not find sleep difficulties in their objective assessments.

4.4.2.3.2 Children and their primary caregivers who were eligible, received allocation then dropped out n = 61

Similar to children who completed the project, children who dropped out have shown similar nature of sleep difficulties which is behavioural in nature. However, children who dropped out have shown less difficulties in each particular subscales compared with those who completed the project which would indicate that children who completed would have severe sleep difficulties which affect their life and require an intervention. This may have motivated continued engagement with the intervention.

4.4.2.4 Subjective and objective outcomes of children and their primary caregivers who completed the project n = 13

4.4.2.4.1 subjective assessments (a comparison between baseline, post intervention and if available follow up)

The key finding from this study was that there is an effect on CSHQ in the sleep intervention group (a reduction in sleep difficulties score as measured by CSHQ) versus the control group's 'usual care' at three time points. This change was observed in the intervention group between the baseline and the post-intervention assessment and between the baseline and the two-month follow-up assessment. These results seem to be

consistent with other research by (Montgomery et al., 2004), who found that, at the post-intervention and follow-up assessments, a statistically significant change in means was reported in the composite sleep disturbance scores over time. This result is also in line with (Peppers et al., 2016), who found an improvement in both CSHQ and ADHD scores following a behavioural intervention for sleep difficulties, although this study was not an RCT design.

Another important result was that both groups (intervention and control 'usual care') showed a decrease in the score over time on the Conner's Rating Scale overall score and its ADHD subscale. This could be explained by the services that both groups received. Thus, improving sleep in children with ADHD did not improve ADHD symptoms. This result is in line with the meta-analysis in chapter two (ALammar et al., 2017) which found that, using behavioural sleep intervention for children with ADHD, improved sleep significantly, but did not contribute to the improvement of ADHD symptoms. However, the quality of evidence in the meta-analysis (ADHD outcome) was low, which might affect the conclusion drawn. The result found in this project (chapter two and four) which indicated that behavioural sleep intervention did not contribute to the improvement in ADHD score are in contrast to the majority of findings detailed in previous literature. A recent RCT found that an improvement in ADHD scores was observed in parents' reports following sleep intervention; however, it was not observed in the teachers' reports (Hiscock et al., 2015a), although the teachers were blinded to the children's allocation for the intervention or the control group (usual care) while the parents were not which might lead to a detection bias.

Additionally, there was a decrease in the overall scores, (which indicated an improvement in caregivers' sleep and psychological wellbeing) in the intervention group compared to the control group, on two assessments of the caregivers sleep and well-being (Sleep for Adults and DASS). This could be due to the fact that parents of

children with chronic disorders are at high risk of psychological difficulties, in general, (Lach et al., 2009; Stores, 2014) and, more specifically, depression (Al-Balushi et al., 2017) and stress (Theule et al., 2013), so providing interventions for the parents would be beneficial to help them to improve their psychological well-being.

Furthermore, the intervention group showed a decrease in the overall results and the control group showed an increase in the overall results according to the figure 19 and 20 on two assessments (Sleep for Adults and DASS). This would be explained by the improvement of sleep following participation in the Good Night Project which led to the improvement of the parents' sleep and a decrease in the mothers' DASS, which might have benefitted both the child and the family. This finding corroborates previous literature which found that receiving training contributed to decreasing both children and their caregivers' stress (Vander Stoep et al., 2017). Whilst not conclusive due to the small sample size, the results suggest that the Good Night intervention has potential to improve wellbeing in the parents of children with ADHD.

4.4.2.4.2 Outcomes, objective Measure (Actigraphy)

According to the user guide, the ActiGraph wGT3X-BT is considered to be a medical device in the United States and the European Union . The device could not be used without an internal approval from Saudi Arabia. Children who were involved and completed the project were not in hospital settings to use the device. They were in centres for children with additional needs. So it was not possible to use this measure at this stage.

4.4.2.5 A comparison between participants who completed (n=13) and participants who dropped out (n=61) at the baseline stage

It appears that children who completed the study have shown a significant and severe sleep difficulties which affect their life and require an intervention compared to those who dropped out at different stages. This would be explained by multiple points: first, nearly 15% of children who dropped out (n=9) were prescribed Antipsychotic (Risperidone) and 10% (n=6) of children who dropped out were also prescribed Antipsychotic (Risperidone) in addition to another medication (either stimulant or non-stimulant), (see Table 21 Medications were prescribed). In total 25% of children who dropped out were prescribed Antipsychotic which is one of the medication that can be used in order to help children with ADHD to have better sleep (Mindell & Owens, 2015) and this would lead to decrease sleep difficulties then decrease the demand of receiving sleep interventions.

Another point is duration of sleep in each group (who completed and dropped out) and each particular group (intervention and control 'usual care'). When comparing children who completed the project (n=13) and children who dropped out (n=61), the results showed that, children who completed the project slept fewer hours (average sleep duration = 7 hours) than children who dropped out (average sleep duration = 9 hours). When looking at each particular group, children in the intervention group (who completed n= 8) slept in total 6 hours compared to children in the intervention group (who dropped out, n=28) who slept in total 10 hours. Additionally, when looking at children in the control group the results revealed that, children who completed (n=5) slept 7.5 hours compared children in the control group who dropped out (n=33) who slept 9 hours. According to the National Sleep Foundation, school aged children require 9–11 hours of sleep every day but a period of 7–8 hours of sleep is acceptable (Hirshkowitz et al., 2015). Thus, children who completed the project sleep the

acceptable duration (control group = 7.5 hours) and less than the acceptable hours (intervention group = 6 hours). In contrast, children who dropped out sleep the required hours for school age children which is 9 hours for both groups (in particular, 10 hours for the intervention and 9 hours for the control.

Another point worth considering is the total mean score of the assessments for caregivers and children who completed and dropped out. CSHQ that assesses sleep and DASS that assesses psychological wellbeing for caregivers (Depression, Anxiety and Stress) revealed a high score in both groups in children and their caregivers who completed compared with those who dropped out. Children who completed reported a mean score in the intervention group 60.75 (10.24) the control group 52.5 (4.20). Whereas children who dropped out seem to sleep better and have less sleep difficulties, according to the overall score of CSHQ mean score for the intervention group 50 (7.5) and the control group 53 (7.3). Moreover, caregivers who dropped out seem to have better psychological wellbeing in accordance with DASS scores which revealed a mean score of 32.5 (12.4) for the intervention group and 30 (14.6) for the control group. Whereas caregivers who completed have shown worse mean scores in DASS, intervention group mean score 44.17 (31.43) control group mean score 47.4 (37.02). Three assessments (Conner's for parents, ADHD score taken from Conner's and Sleep for Adults Scale) have shown less mean scores for participants who dropped out compared to those who completed (see table 18 descriptive statistics of the baseline assessment for children and their caregivers who were eligible and received allocation n = 74, completed n= 13, dropped out n = 61), however, they seem to be in the same range compared with differences reported in both CSHQ and DASS.

The nature of sleep difficulties in both groups (who completed and dropped out) is similar with less severity reported in those who dropped out compared with those who completed the project. This would indicate that children who completed the project slept

fewer in average with a greater difficulties reported which have a negative effects on their lives which would require an intervention, it may indicate that parents of children with more severe sleep problems are more highly motivated to complete the intervention because it is more beneficial to them. However, the difference reported needs to be taken with caution, given the small numbers of participants who completed. The difference observed might be due to the natural variation due to the small sample size.

4.4.2.6 Sleep difficulties in children in the intervention group with and without ASD according to the CSHQ

It seems that children with ADHD and ASD reported severe sleep problems and slept fewer hours than children with just the diagnosis of ADHD. This could be explained by the role of comorbidities that could lead to more sleep difficulties (Cuesta & Delrio-Hortega, 2016; Efron et al., 2016; Liu et al., 2006; Mayes et al., 2009; Mindell & Owens, 2015; Virring et al., 2017). Another important explanation in this study could be related to the medication used in each particular group. Two children out of five with ADHD were prescribed Risperdal which could contribute in improving sleep (Mindell & Owens, 2015). On the other hand, a child with ADHD and ASD were prescribed Ritalin which would affect sleep quality and quantity. Moreover, children with comorbidities ADHD + ASD (n=3) have shown more improvement in their sleep within time from the baseline, to the second assessment to the final assessment (two months follow up) although a child has been taken Ritalin which negatively affects sleep. Therefore, it seems that the improvement observed in children with comorbidities would be related to the Good Night Project.

4.5 Limitations of the Current Study

This study was limited by the absence of objective methods (e.g. Actigraphy) to provide accurate data on sleep and wake-up time. All outcome assessments used in this study were subjective. Although they are standardized tests, caregivers' responses to the assessments might be affected by any contemporaneous life circumstances when completing the questionnaires. Moreover, parents of children with chronic disorders are at high risk of psychological difficulties (Lach et al., 2009; Stores, 2014), and this could affect assessments results. Using an objective measure (e.g., Actigraphy) is required when implementing a similar project to record the actual progress in sleep and wake-up time. The Actigrphy (The ActiGraph wGT3X-BT) could not be used with the current sample due to the device nature (is considered to be a medical device in the United States and the European Union). This means that it needs an internal approval from Saudi Arabia. Children who were involved and completed the project were not in hospital settings in order to use the device. They were in centres for children with additional needs and school sittings. Another limitation was that this study was limited to semester dates due to the fact that parents are generally less consistent in their bedtime routines on non-school nights (Sciberras, Mulraney, et al., 2017).

4.6 Recommendations for Future Research

Due to the high attrition rate n=61, it is recommended that the Good Night Project could be implemented in a university hospital setting where there was significant buy-in from the leadership. Additionally participants from the university

hospital might be aware of the importance of the research, were involved in previous researches and, consequently, help to complete the project.

Objective measures for sleep (e.g., Actigraphy) are highly recommended in order to provide objective and more accurate data to assess sleep and wake-up time (ActiGraph Software Department., 2015). The objective measure is not related to any other life circumstances which would affect parents' psychological wellbeing including their responses to the subjective assessment (Stores, 2014).

It is recommended that, in future research, compensation should be given to the participants in both groups in order to encourage them to complete the training and the assessments at all time points. Participants could be keen to complete the project when there is a compensation. Also, the intervention should be provided for the control group after the study stages completed in order to encourage them to complete the assessments at three time points. Moreover, compensation should be also given to the centres and psychologists in order to encourage them to complete the study stages and reduce the incomplete data caused by centres.

The literature suggests that stimulants affect sleep in children with ADHD. In contrast, 60% of the sample in this study who completed the project did not take medication at all, and 92% did not take stimulants but their parents still reported sleep difficulties. A suggestion for future research might be assessing sleep in children with ADHD using objective assessments together with subjective measures. Additionally, including both children who take and do not take stimulants might help in exploring the nature of sleep difficulties in children with ADHD and whether they are intrinsic or extrinsic.

It seems that participants who completed the project were in schools or centres sittings supervised by the Ministry of Education or the Ministry of Labour and Social

Development. No participants completed the project from the Ministry of Health (hospital sittings). This might be due to the point that both caregivers and schools/centres team (head of the centre and all the team including psychologists) were aware of the workshops, group therapy that are conducted in order to help caregivers dealing with their children. In contract, participants who were from Ministry of Health seem to receive individual sessions with follow up appointments. Therefore, the Good Night Project might be modified to be fitted with hospital sittings (one session followed by follow up sessions after few weeks in an individual sitting). The project therefore might be worked in this way which is usually provided by the Ministry of Health (hospital sittings) rather than group therapy in multiple sessions.

The Delphi study (chapter three) did not highlight the caregivers' needs, and understanding these could help when designing the project. Thus, using different methods such as a focus group and experience-based co-design (Bate & Robert, 2006) might be required in order to understand participants' needs and what is possible for them when they will be part of an intervention.

After exploring the participants' needs using focus group and/or experience-based design, it is recommended to conduct another feasibility study of the subsequent co-designed intervention, considering the results and recommendations taken from the current study.

4.7 Conclusion

The present study was designed to determine the feasibility of behavioural sleep interventions for Saudi children who have been diagnosed with ADHD. The following points were considered with respect to the feasibility aspects of the study; centres,

primary caregivers, nature of the randomized controlled trial RCT, time and funds, psychologists and psychiatrists, ethical approval, sample size, summary of the findings for both participants who completed and who dropped out (children's age, nature of sleep difficulties, outcomes (subjective and objective (Actigraphy) assessments).

This feasibility study demonstrated that the Good Night Project is not feasible for children with ADHD and their primary caregivers in its current form. This is reflected in the high attrition rate. It seems that the Delphi study (chapter three) did not explore participants' needs, barriers and facilitations. The failure to addressing them stopped families being fully involved in the project and complete all the stages. Therefore, it is important to consider conducting further study using focus group or experience-based co-design in order to explore participants' needs and what is possible for them when they will be part of an intervention.

Chapter 5 : General discussion

5.1 Introduction

Sleep research for children has progressed rapidly because of an emerging knowledge about the crucial role of sleep in children's development including quality of life, cognitive functioning, psychological well-being and physical health (Chorney et al., 2007; Craig et al., 2017; Galland et al., 2015; Knight & Dimitriou, 2017; Lee et al., 2014; Patel & Hu, 2008; Virring et al., 2014; Yurumez & Kilic, 2016). Sleep difficulties have been found to affect children in general and children with neurodevelopmental disorders (e.g., children with ADHD and ASD) in particular (Mindell & Owens, 2015; Stores, 2014). It has been suggested that sleep difficulties in children with ADHD may be intrinsic (physiological) in nature (Cortese et al., 2005; Silvestri et al., 2009). On the other hand, sleep difficulties in children with ADHD could be extrinsic (behavioural). The second assumption (that sleep difficulties are predominantly behavioural would lead to two different explanations:

1. Sleep difficulties in children with ADHD could come as a result of ADHD (e.g., medication side effects and parents related issues (poor sleep hygiene and/or parents psychological wellbeing) (Craig et al., 2017; Gray, 2017; Noble et al., 2011; Peasgood et al., 2016; Sangal et al., 2006; Sciberras, Song, et al., 2017; Thomas, Sanders, et al., 2015).

2. Sleep difficulties might cause symptoms similar to ADHD (e.g., cognitive function including attention deficit, emotional problems including anxiety, phobia and depression in addition to behavioural problems including hyperactivity and impulsivity

(Chervin et al., 1997; Dagan et al., 1997; Dollinger et al., 1996; Knight & Dimitriou, 2017; Lee et al., 2014; Owens, 2009; Paavonen et al., 2002; Sadeh et al., 2002).

Therefore, improving sleep in children would benefit both children's sleep and their caregivers' sleep and psychological well-being (Stores, 2014). Thus, this project aimed to design, implement and evaluate the feasibility of behavioural sleep interventions for children diagnosed with ADHD in the Kingdom of Saudi Arabia. The design and the implementation of the project considered existing studies, language, religion and culture when adapting this intervention. This process has been followed in order to see whether the Good Night Project is feasible, acceptable and suitable to be implemented as a large trial.

The thesis has been completed in three phases:

- **First phase**: (*chapter two*), a systematic review and meta-analysis of behaviour change interventions for sleep difficulties in children with neuro-developmental disorders

- **Second phase**: (*chapter three*), behavioural sleep interventions for Saudi children with ADHD: a Delphi study.

- **Third phase**: (*chapter four*), a feasibility study of a randomised controlled trial (The Good Night Project: Behavioural sleep interventions for children with ADHD).

This chapter focuses on synthesising the key findings of the thesis in relation to the research questions, contribution to the knowledge including: behaviour change interventions, culturally adapting interventions and sleep in children with ADHD, implications of findings for future research and practice and research limitations.

5.2 Summary of key findings in relation to the research questions

5.2.1 Phase one: Systematic Review.

There is some evidence that behavioural sleep interventions can improve sleep in children with ADHD (Hiscock et al., 2015a). The systematic review and meta-analysis discussed in chapter two (ALammar et al., 2017) aimed to characterise the behaviour change techniques (BCTs) employed in order to establish existing best practice for addressing sleep difficulties specifically in school-aged children diagnosed with neuro-developmental disorders. Only four studies met the stringent inclusion criteria (number of children = 377), which indicates limited high quality research in area, and a paucity of RCTs to assess relevant interventions.

After systematically reviewing these four studies (ALammar et al., 2017), the behaviour change techniques (BCTs) (Michie et al., 2013) were identified in order to establish existing best practice for addressing sleep difficulties specifically in school-aged children diagnosed with neuro-developmental disorders. This is the first time, to our knowledge, that the Behaviour Change Taxonomy has been applied in the domain on developmental sleep disorders, and using BCTs to characterise existing intervention proved a useful approach. The review revealed that effective strategies focused on providing primary caregivers with instructions on how to achieve targeted behaviour then reward children, managing the physical and social environment and ignoring negative behaviours.

The included studies were assessed using the GRADE approach (Atkins et al., 2004), and the quality of the evidence for managing sleep difficulties in children with neuro-developmental disorders was judged to be high, and indicated a large and positive effect

of behaviour change interventions. In contrast, low quality evidence found no evidence for a corresponding reduction in ADHD symptoms in two of the four included trials that reported this outcome. As such, this review reveals clear and positive evidence for the role of behaviour change interventions to improve sleep in children with neurodevelopmental disorders, but does not enable us to conclude that such interventions have a corresponding effect in the reduction of ADHD symptoms in this context. The use of GRADE was innovative in the field and proved useful in drawing appropriate and evidence based conclusions.

5.2.2 Phase two, a Delphi study.

Following the systematic review of the literature, chapter two (ALammar et al., 2017), a Delphi study was conducted in order to achieve consensus among a panel of stakeholders (health professionals and primary caregivers) on priorities to help the research team to design the intervention. Other factors were also considered when designing the project (e.g., language, culture and religion of the participants), (chapter three). Both health professionals and primary caregivers were asked to rank the most important behavioural interventions that could be used to manage sleep difficulties in two rounds, with each round lasting for one month. This Delphi study extends our knowledge of the importance of considering cultural values, beliefs, religious and spiritual practices when adapting interventions to be fitted to specific societies (Bernal et al., 1995) more specifically when it is related to a topic that is affected by the culture (e.g., sleep) (Airhihenbuwa et al., 2016; Boergers & Koinis-Mitchell, 2010).

5.2.3 Phase three, the feasibility study.

The third phase was the feasibility study using a randomised controlled trial design that aims to see whether the project is feasible to be conducted as a large trial (chapter four). The Project was conducted in Saudi Arabia in five regions in ten cities. Multiple settings were included (schools, centres and hospitals) where children with ADHD receive medical, behavioural and educational services (n=42).

The key finding of the intervention indicated that the Good Night Project is not feasible for children with ADHD and their primary caregivers at this stage and in its form. This is due to the small sample size who completed the project (n = 13/74) who were eligible and received allocation to the groups (intervention and control). It seems that the Delphi study did not sufficiently identify factors that might prevent or encourage participants to complete the project. The failure to address potential barriers stopped families being fully involved and completing the project. Thus, it is recommended to conduct further study using focus group or experience-based co-design (Bate & Robert, 2006) in order to explore factors that affect parents ability to complete the project. However, results of this project has provided an important insight into behavioural sleep interventions for Saudi children with neurodevelopmental disorders in general and children with ADHD in particular. This finding is contrary to a recent systematic review of the feasibility of behavioural interventions to improve sleep in children with neurodevelopmental disorders which has suggested that this kind of intervention is feasible and acceptable to be used for wide range of neurodevelopmental disorders including ADHD and ASD (Rigney et al., 2018). Additionally, using behavioural interventions to improve sleep would help identifying whether children with ADHD have been received over diagnosis of ADHD (Knight & Dimitriou, 2017; Merten et al., 2017; Thomas, Sanders, et al., 2015).

5.3 Contribution to knowledge

The Good Night Project has been contributed to knowledge in several aspects and can be divided into three main points: to the behaviour change techniques taxonomy BCTs, culturally adapting interventions and sleep in children with ADHD.

5.3.1 Behaviour change interventions for sleep in children with ADHD

Behavioural sleep interventions that can be used for children with neurodevelopmental disorders have been characterise using BCT taxonomy (Michie et al., 2013), see chapter two (ALammar et al., 2017). Characterising the innervations was divided into children age (younger and older children), condition (e.g., ADHD, ASD, and LD) and group (intervention and control, usual care). This would contribute to the growing BCT taxonomy literature. Available literature on BCT taxonomy usually focus on promoting adult physical activity, diabetes management and consuming healthy food (Howlett, Trivedi, Troop, & Marie Chater, 2015; Presseau et al., 2015; Samdal, Eide, Barth, Williams, & Meland, 2017). However, chapter two (ALammar et al., 2017) has focused on using BCT taxonomy to improve sleep in children with neurodevelopmental disorders which would be to the best of our knowledge the first study in this field.

5.3.2 Culturally adapting interventions

The Good Night Project used a novel approach aiming to consider culture when adapting the behavioural sleep interventions due to the importance role of the culture in evidence based practices in general (Bernal et al., 2009) and in sleep research in particular (Airhihenbuwa et al., 2016; Boergers & Koinis-Mitchell, 2010), more specifically, in children with different disorders (Boergers & Koinis-Mitchell, 2010). In

addition, whilst behavioural sleep interventions have been conducted in western countries in English language (see chapter two), (ALammar et al., 2017), there was no Arabic guide available that aims to help Arabic language speakers to improve sleep for children with ADHD population. Therefore, the translated guide from English into Arabic language is the first guide to help in improving sleep in Arabic school aged children in general and in children with ADHD in particular. Additionally, the protocol of this study including explanation of the process of an RCT design has also been translated into Arabic raising awareness of this approach internationally. Another consideration was the religion of the participants. Religions and beliefs of the participants play a significant role when designing an intervention (Bernal et al., 2009; Boergers & Koinis-Mitchell, 2010). Additionally, chapter three (the Delphi study) focused on involving local health practitioners and mothers of children with ADHD in designing the project and all views and needs were considered and discussed.

5.3.3 Sleep and ADHD

Sleep research for children with ADHD has progressed rapidly due to the crucial role of sleep in children's development. Research available focused on reporting sleep difficulties in this population using subjective and objective measures (Becker, Froehlich, & Epstein, 2016; Virring, Lambek, Jennum, Moller, & Thomsen, 2017). Also, management of sleep difficulties using pharmacological treatment and non-pharmacological treatment (Cuesta & Delrio-Hortega, 2016; Hiscock et al., 2015a).

The Good Night Project therefore has provided an overview of sleep difficulties for Saudi children who are diagnosed with ADHD with and without comorbidities and their caregivers' psychological wellbeing including (sleep difficulties, depression, anxiety and stress). The project also developed behavioural interventions that were designed based on the high quality evidence considering the culture of the participants. The project also examined the feasibility of conducting such interventions in order to help children with ADHD and their caregivers to improve sleep and psychological wellbeing. Moreover, multiple locations (ten cities in five regions) and settings (schools, day care centres and hospitals, n = 42) within Saudi Arabia have informed recommendations to improve the feasibility of future interventions in this context. A large number of practitioners from different disciplines (psychiatry, psychology, occupational therapy and nursing) (n = 84) received training on conducting a research based on an RCT design within the Kingdom in two languages Arabic and English. Moreover, the mixed methods used in this project (systematic review and meta-analysis, Delphi study and RCT design) have contributed to the field of behavioural sleep interventions for children with ADHD.

5.4 Implications of findings for future research and practice

5.4.1 Implications for future research

The Good Night Project could be adjusted to fit the UK context and be conducted to examine the feasibility of the project to help children with ADHD and their family to have better sleep and better psychological wellbeing.

The Good Night Project could be modified for children with other neurodevelopmental disorders. Behavioural problems during bedtime such as bedtime resistance which have been reported in the literature can be managed by teaching tips on how to have better sleep with less behavioural problems during bedtime (see chapter two), (ALammar et al., 2017).

Exploring sleep in children with ADHD and their parents and siblings can elucidate the environmental factors affecting sleep for both children and their parents. In addition, parents of children with chronic disorders are at high risk of psychological difficulties; thus, providing interventions for the parents would help them to improve their psychological well-being which therefore would contribute in providing the appropriate management for their children.

In future research, when conducting another feasibility study in a Saudi setting, the following points need to be considered; compensation should be given to participants to encourage them to complete the training and the assessments at all time points. Additionally, it is recommended to offer the intervention for the control group when they complete the assessment at the three time points. This would encourage them to complete the study stages. The objective measures for sleep (e.g., Actigraphy) are highly recommended to be used to provide objective data to assess sleep\wake time. Objective measures for sleep would allow exploration of whether sleep difficulties reported by mothers are accurate or whether mothers' responses to the subjective assessments are related to different life circumstances.

The researcher suggests that the Ministry of Education in Saudi Arabia should specify funds and data collection time based on each study design (e.g., after the first year).

5.4.2 Implications for practice

The translated guide from English into Arabic language is the first guide to help in improving sleep for school age children in general and in children with ADHD in particular. Therefore, it is recommended to seek permission from the publishers in order to print the guide and make it available in different settings where children with ADHD receive services (e.g. hospitals, schools and centres).

All the children who completed the project were aged 9 years old or younger (see chapter four). Moreover, sleep difficulties observed in this study were behavioural in nature. Thus, a suggestion for caregivers of children in the earlier stage of the primary school with and without ADHD is to teach children how to develop sleep hygiene and a bedtime routine to prevent any sleep difficulties that may happen in the future. Also, using behavioural sleep interventions could be the first choice before prescribing medication for sleep difficulties according to the parents' preference (see chapter three).

5.5 Limitations

This project is subject to a number of limitations. First, the small number of staff in this project who could have assisted in training the psychologists and travelled to deliver the materials. More personnel would give the researcher more time to provide more support to each centre. The study was also limited by funding and available time. The funds available for the study did not enable the researcher to provide compensation for the participants. Therefore this points need to be considered when planning to

conduct future projects. This project was also limited by the absence of objective methods (e.g., Actigraphy) to provide accurate data on sleep and wake-up time. The Actigraphy (The ActiGraph wGT3X-BT) could not be used with the current sample due to the device nature (is considered to be a medical device in the United States and the European Union), which means that this medical device requires an internal approval from Saudi Arabia. Children who completed the project were not in hospital settings in order to use the device (where the internal approval has been received). They were in schools or centres for children with additional needs. Also, all outcome assessments used in this study were subjective measures. Although they are standardized tests, caregivers' responses to the assessments might be affected by any contemporaneous life circumstances when completing the questionnaires. Moreover, parents of children with chronic disorders are at high risk of psychological difficulties (Lach et al., 2009; Stores, 2014), and this would affect assessments results (e.g., overestimate of sleep difficulties). Using an objective measure (e.g., Actigraphy) would have improved the rigour of the data collected enabling recording of the actual progress in sleep and wake-up duration. Therefore, Actigraphy should be included when possible in future projects. Another limitation was that this study was limited to semester dates due to the fact that parents are generally less consistent in their bedtime routines on non-school nights (Sciberras, Mulraney, et al., 2017). The final and the most important limitation was that, this study was not designed as a feasibility study, it was designed as an efficacy study and there were no accessibility questions. However, due to the small sample size, the research team decided to present the result as a feasibility study using the available data.

5.6 Conclusion

The Good Night Project is an evidence-based intervention designed by systematically reviewing the literature and by involving health practitioners and primary caregivers in Saudi Arabia using a Delphi study. Other factors, such as the language and the religion of the participants, were also considered when designing and adapting the intervention. The key strength of the Good Night Project is the multiple settings (schools, day-care centres and hospitals) involving in multiple cities (n=10) and regions (n=5) within the Kingdom of Saudi Arabia. Moreover, multiple outcomes were used that focused on both children and their caregivers. The main finding of this project indicates that, the Good Night Project is not feasible in its current form. This is reflected in the high attrition rate. However, the data collected provides insight into how the intervention could be adapted to be more viable. Although the conclusion on the efficacy of behavioural sleep interventions for Saudi children with ADHD cannot be made at this stage due to small sample size, the research provides a basis for further research to improve sleep in Saudi children with neurodevelopmental disorders in general and children with ADHD in particular. Therefore, it is recommended to conduct further study using focus group or experience-based co-design in order to explore participants' needs and what is possible for them when they will be part of an intervention. This thesis presents a valuable framework and culturally sensitive materials for future development of an effective intervention to improve sleep for Arabic children with ADHD.

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Appendices

Appendix A The National Project for Attention Deficit Hyperactivity Disorder (ADHD)

According to The Council of Ministers in Saudi Arabia, the project which was approved by the Council of Ministers in 2009 sought that provision of services should continue at both government and private charity organizations and institutions (The Council of Ministers in Saudi Arabia, 2009). It also sought improvement of performance in handling and dealing with those suffering from ADHD, as well as coordination and evaluation of services and fostering their efficiency as follows:

A.1 Ministry of Health:

Adequate numbers of specialized centres, with qualified staff and cadres, should be dedicated for diagnosis and treatment of ADHD cases.

Provide support for field studies to determine the extent of prevalence of ADHD. Develop future plans to provide care for those affected with this disorder based on the results of such field studies.

Provide adequate information and knowledge to concerned families regarding the nature of this disorder and educate them as to how to deal with it.

Apply best methods to control symptoms associated with developmental disorders whether by therapeutic or behavioural intervention.

Organize local and regional conferences and symposiums that aim to spread awareness and knowledge of those disorders as well as methods of their diagnosis and treatment.

A.2 Ministry of Higher Education & Universities:

1. Some scholarships at the Bachelor and Master Degree levels should be dedicated to specialize in ADHD. At the bachelor and post university diploma levels specialties should be in patient care. While at the Master and PhD levels specialties should be in diagnosis as well as educational, behavioural and medical rehabilitation; all of which should be done in coordination with the Ministry of Health, the Ministry of Education and the Ministry of Social Development.
2. Provide support for scientific research in ADHD and encourage university educators to conduct studies and researches in the detection, diagnosis and provision of care to this group of patients.
3. Prepare, regulate and develop suitable diagnostic and assessment at colleges and universities and provide facilities to identify patients with ADHD.

A.3 Ministry of Education:

Adopt early intervention programmes to serve children with ADHD. Such programmes should take over the education of affected children and initiate early intervention right from nursery age.

Admission of children with ADHD from both sexes to public education programmes, where females would be admitted to girls' education and males to boys education facilities. They will be diagnosed by a multidisciplinary team and enrol then in public education with other normal children unless they have other associated disorders. Each child will be given individual courses designed to suit his/her specific capabilities and needs.

If the candidate has other disorders in addition to ADHD, he/she shall be admitted together with candidates who have similar disorders. Example: children having ADHD together with learning difficulty who are admitted to learning difficulty programmes and provided with care for ADHD as part of their educational programmes.

This group of students who are admitted to public education programmes should be given all needed facilities to ensure their success in their educational programmes particularly those related to exams, as well as consideration to their cognitive, mental, expressive and writing capabilities.

Adopt and preparation an conduction of educational workshops and permutations as well as general guidelines for public and educational staff (teachers and trainers from both sexes) so as to enlighten them regarding this group of students and deal with then at classrooms and schools.

A.4 Ministry of Labour and Social Development:

Provide care for those with ADHD from both sexes at vocational rehabilitation centres in accordance with admission controls applied at those centres.

Provide financial aid (grants) for each case as per conditions and requirements applied at the Ministry.

Urge and encourage charity societies to provide special services to those with ADHD.

Encourage establishment of private charity societies which shall provide care to those with ADHD.

A.5 Private Sector:

Provide financial support to charity societies which provide care to those with ADHD as well as provide financing to their studies and researches.

Encourage entities and individuals who provide care to this group, through sponsoring and supporting scientific conferences and forums organized in this regard.

Chambers of commerce in the Kingdom should participate through enlightening businessmen as to this group with ADHD.

Appendix B : PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Appendix C : Behavioural Sleep interventions for Saudi children with ADHD: first round questionnaires

Health professionals' version

Please provide detail of your undergraduate degree

Psychiatry	Psychology	Occupational therapy	Nursing	Paediatrics	family medicine	Other, please specify

Please specify number of sessions recommended in the project

……

Please specify number of hours each session should last

……

Please evaluate the importance of each piece of intervention content on a scale from one to ten. One indicated that the item is not important, and ten indicated that including the content in the programme is very important.

Learn about sleep processes

The item is not important									The item is very important
1	2	3	4	5	6	7	8	9	10

Learn about normal sleep in children

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about sleep cycles

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about common sleep problems in ADHD children

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about managing children’s sleep difficulties,

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about sleep hygiene

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about how to manage primary caregivers sleep difficulties

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about how to manage primary caregivers stress

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Written guide to help primary caregivers manage sleep problems at home

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Bedtime stories

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Videos to help primary caregivers manage bedtime routines

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Please make any suggestions as to possible further intervention content that could be ranked in the next round

……

……

……

……

……

Behavioural Sleep interventions for Saudi children with ADHD: A Delphi study

First round – primary caregivers' version

Would you prefer to be contacted to complete the second and final round?

Yes	No

If you state yes, what method would you prefer to receive round two questionnaire?

Paper version	Electronic version

If you have chosen Electronic version, could you provide your email otherwise the questionnaire will be sent with your son.

……

Please provide your mobile phone to remind you to complete the questionnaire

……

Have you ever sought help for your child's sleep difficulties?

……

What would you prefer pharmacological or non-pharmacological interventions to manage sleep difficulties?

……

Would you prefer your child to sleep more hours or have good quality of sleep?

……

Please specify number of sessions recommended in the project

……

Please specify number of hours each session should last

……

Please evaluate the importance of each piece of intervention content on a scale from one to ten. One indicated that the item is not important, and ten indicated that including the content in the programme is very important.

Learn about sleep processes

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about normal sleep in children

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about sleep cycles

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about common sleep problems in ADHD children

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about managing children's sleep difficulties,

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about sleep hygiene

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about how to manage primary caregivers sleep difficulties

The item is not important									**The item is very important**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Learn about how to manage primary caregivers stress

The item is not important								**The item is very important**	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Written guide to help primary caregivers manage sleep problems at home

The item is not important								**The item is very important**	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Bedtime stories

The item is not important								**The item is very important**	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Videos to help primary caregivers manage bedtime routines

The item is not important								**The item is very important**	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Please make any suggestions as to possible further intervention content that could be ranked in the next round

……

……

……

……

……

Appendix D : CONSORT 2010 checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org

Appendix E : Sleep Habits Cards

Do you know that around **50** of school-aged children who are participating in this intervention in the Kingdom are preparing for ***SLEEP*** now?

Let us see what they are doing!

Join us and prepare yourself by answering these questions before saying **GOOD NIGHT** to your family!

Have you worn your **pyjamas**?

Nawwaf has worn his **pyjamas.**

Have you **brushed** your teeth?

Walaa has **brushed** her teeth.

Have you used **the toilet**?

Faisal has used **the toilet.**

Have you started **reading** a book?

Munerah has started **reading** a book.

Have you **cleaned** your bed like Prophet Muhammed (pbuh)!

Rakan has **cleaned** his bed.

Have you **turned off** the lights and **shut** the door like **Prophet Muhammed** (pbuh)!

Now, recite the name of Allah and lie **on your** right **side like Prophet Muhammed (pbuh)!**

Yara has **said** Bismillah and **laid** on her right side.

If you feel **anxious**, you can take a **deep breath** just like Muhammed. He is feeling **better** now.

You can depend on **yourself** in managing your **fears**. But if you **cannot**, you are allowed to wake your mum up **ONE** time like **Muteb** with his mum **Nourah**. Use this card.

If you feel **anxious**, write down your **fears** and put them in **the worry box** just like Abdullah.

Now, **enjoy** colouring!