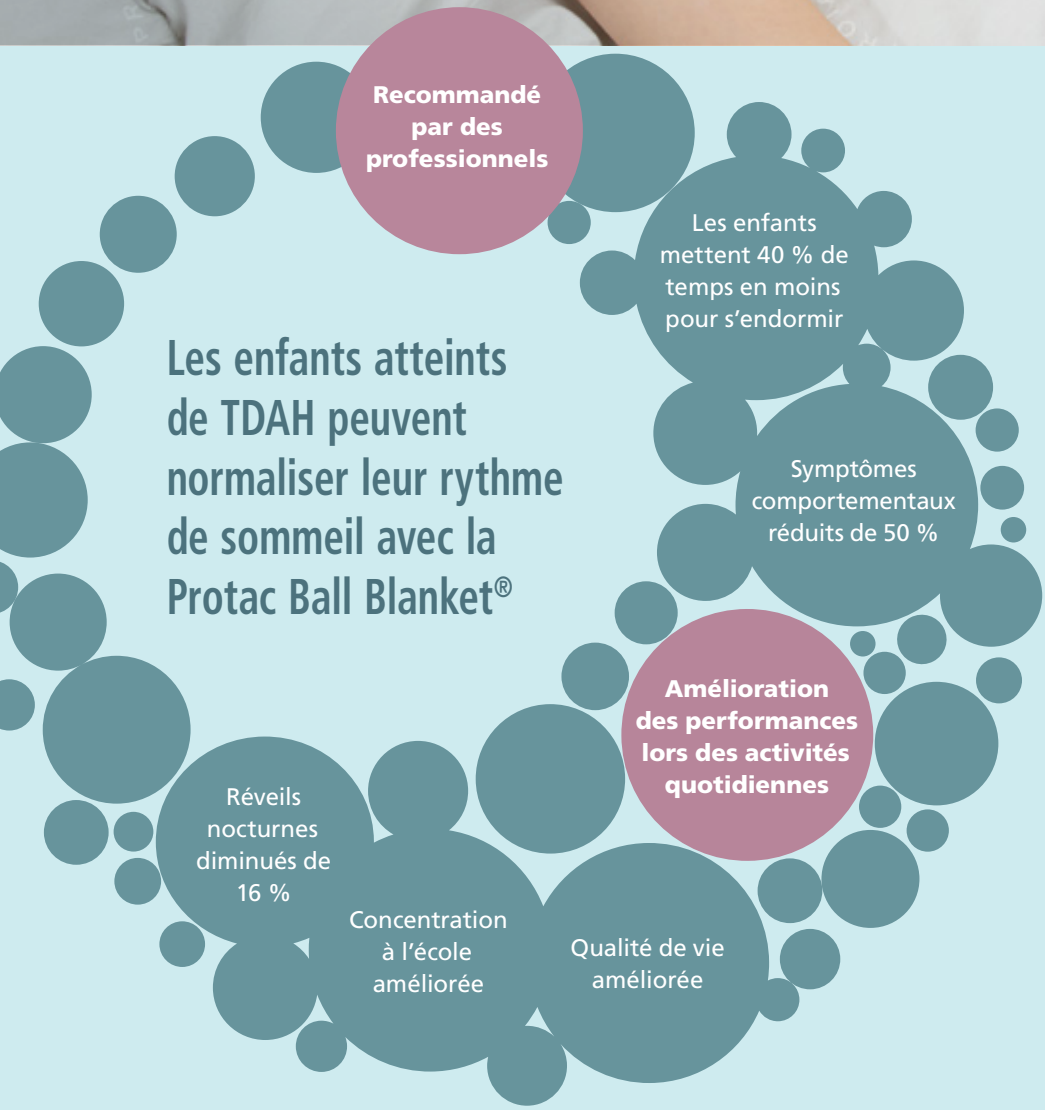
Dormir avec une Protac Ball Blanket® a un effet positif sur le bien-être des enfants souffrants de TDAH



Par Jakob Kehlet, journaliste

Environ 70 % de tous les enfants atteints de TDAH souffrent de troubles du sommeil. Avec la couverture Protac Ball Blanket® près de la moitié de ces enfants normalisent leur rythme de sommeil, s'endorment plus rapidement et se réveillent moins la nuit.

L'effet positif des couvertures Protac Ball Blanket® a été scientifiquement prouvé deux fois par des pédopsychiatres danois. L'objectif de ces projets de recherche était de voir si la couverture a un effet sur le sommeil des enfants. Plusieurs des résultats sont positivement significatifs, dit Allan Hvolby, pédopsychiatre et auteur principal des deux projets de recherche en 2010 et 2020.

Le premier projet a montré que le temps nécessaire pour endormir les enfants TDAH a diminué de 40 %. De cette façon, ils ont mis le même temps à s'endormir que les enfants du groupe témoin sain. Le projet-2020 confirme ces résultats et montre aussi qu'un sommeil de qualité améliore la qualité de vie au quotidien et la concentration à l'école.

Environ 70 % de tous les enfants atteints de TDAH souffrent de troubles de sommeil. Avec la couverture Protac Ball Blanket®, presque la moitié d'entre eux retrouvent un rythme de sommeil normalisé.

Projet de recherche 2020*

- Confirme que l'utilisation de la couverture Protac Ball Blanket® réduit de 40 % le temps qu'il faut pour s'endormir.
- L'école a remarqué une réduction de l'hyperactivité de 20 % et les symptômes comportementaux ont presque diminué de moitié.
- Les parents ont également remarqué une réduction de l'hyperactivité de 20 %.
- Les enfants ont généralement amélioré leur qualité de vie de 30 %.
- L'expérience a duré huit semaines.

Projet de recherche 2010**

- L'utilisation de la couverture Protac Ball Blanket® réduit le temps qu'il faut pour s'endormir de 40 %.
- L'école a remarqué une amélioration de 10 % de la concentration des enfants.
- Les soirées, où les enfants passaient plus de 30 min à s'endormir est tombé de 19 % à 0 %.
- L'expérience a duré quatre semaines.

** "Utilisation de Protac Ball Blanket® dans le traitement des troubles du sommeil chez les enfants ayant TDAH. Effets sur la qualité de vie et le fonctionnement quotidien." Allan Hvolby, pédopsychiatre. L'article a été publié dans le Journal of Sleep Medicine & Disorders en 2020.*

*** "Utilisation de Protac Ball Blanket® dans les troubles du sommeil lié à TDAH", Niels Bilenberg, professeur en psychiatrie infantile et Allan Hvolby, pédopsychiatre. L'article a été publié dans Nordic Journal of Psychiatry en 2011.*

Plus d'informations sur les deux projets de recherche sur le site www.cree.fr. Les articles peuvent également être demandés en contactant CREE.

La couverture Protac Ball Blanket® réduit le temps d'endormissement et le nombre de réveils.

Les enseignants des enfants remarquent que les enfants sont remarquablement plus concentrés à l'école et que les symptômes comportementaux sont réduits de moitié.

Moins d'hyperactivité et d'inattention

Pour de nombreux enfants atteints de TDAH, il est difficile de se concentrer à l'école. D'anciens projets de recherche ont montré une relation claire entre un mauvais sommeil et des troubles d'apprentissage.

C'est pourquoi une attention particulière aux symptômes typiques du TDAH, l'hyperactivité et l'inattention, a été donnée dans ce projet. Les parents et les enfants ont évalué l'enfant en utilisant un modèle de test scientifique pendant le projet.

Les deux projets nous montrent une amélioration remarquable concernant l'hyperactivité et l'inattention. En 2010 de 10 % et en 2020 de 20 %. Cette différence peut être expliquée par le fait que le deuxième projet a duré deux fois plus longtemps que le premier et l'effet du bon sommeil a eu plus de temps pour fortifier l'enfant.

De plus, les enseignants ont remarqué une diminution de la moitié des symptômes comportementaux.

Amélioration du fonctionnement quotidien et de la qualité de vie

Les parents ont également observé des améliorations notables au cours des projets. Outre le bon sommeil, ils ont également remarqué une réduction de l'inattention de 20 %. On note aussi que le niveau de fonctionnement quotidien s'améliore de 30 %. C'est d'une importance capitale pour la qualité de vie de toute la famille et pour le développement de l'enfant.

"Une bonne nuit de sommeil donne aux enfants plus d'énergie pendant la journée", dit le pédopsychiatre Allan Hvolby.

Témoignages

Mère d'un garçon de 12 ans avec TDAH :

"Toute notre vie de famille a changé. Il pouvait se détendre jusqu'à ce qu'il s'endorme et il semblait beaucoup plus à l'aise pendant la journée".

Père de deux garçons de 9 ans atteints de TDAH :

"Plus il y a de sommeil pendant la nuit, plus il y a d'énergie pendant la journée. Les garçons ont plus de ressources mentales pour les défis quotidiens maintenant".

Mère d'une fille de 10 ans avec TDAH

"Maintenant, elle se couche sous la couverture quand elle en ressent le besoin. Son sommeil est plus calme et elle se sent bien mieux pendant la journée".

La Protac Ball Blanket® favorise le calme, le sentiment de sécurité et le bon sommeil.

Faits sur la Protac Ball Blanket®

- La Protac Ball Blanket® est remplie de balles de 5 cm donnant des pressions profondes et dynamiques pour stimuler le sens du toucher ainsi que les sens en lien avec la position des muscles et des articulations.
- Le mouvement et la pression des balles a un effet calmant et procure une sensation de sécurité pour les enfants avec des troubles de l'intégration sensorielle, par ex. TDAH.
- Protac Ball Blanket® est agréée CE conformément au règlement (UE) 2017/745 et aux dispositifs médicaux de classe I 93/42/EC et certifié STANDARD 100 par OEKO-TEX® n° 2076-310 DTI.

Une bonne nuit de sommeil permet une meilleure qualité de vie et des ressources supplémentaires pour les défis de la vie quotidienne.

Les projets de recherche impliquant des produits Protac

Réduire le besoin de contention dans les unités psychiatriques
L'ergothérapeute Charlotte Andersen prouve que l'application systématique de l'intégration sensorielle réduit le besoin de contention dans les unités psychiatriques. Le projet a montré une diminution de 38 % du besoin de contention et une diminution de 46 % du besoin de médication forcée.

Dépression et insomnie dans les unités psychiatriques
L'étudiante en doctorat et infirmière Sanne Toft Kristiansen fait des recherches sur l'effet de la couverture Protac Ball Blanket® sur l'insomnie liée à la dépression dans les unités psychiatriques. Sanne étudiera si cette couverture peut être une alternative non pharmacologique pour les patients.

Difficultés de traitement sensoriel chez les jeunes écoliers
Ann Nielsen, étudiante en doctorat et ergothérapeute, fait des recherches sur l'effet du gilet Protac MyFit® pour les enfants de 6 à 12 ans en mettant l'accent sur leur participation aux activités scolaires, leur concentration, leur capacité d'apprentissage et leur concentration pendant la journée scolaire. L'arrière-plan de ce projet est la thèse d'Ann qui a documenté que 21 % des élèves de l'école primaire ont des problèmes sensoriels.

Démence
Un projet pilote montre que les produits Protacs ont un effet calmant sur les patients atteints de démence. Les troubles physiques et psychiatriques ont diminué de 60 % et les troubles du sommeil et le bien-être général ont été améliorés.

Voir plus de projets de recherche et de cas sur www.cree.fr

Outre la couverture Protac Ball Blanket®, Protac produit également d'autres produits d'intégration sensorielle pour le jour et la nuit. Tous les produits sont labellisés CE conformément au règlement (UE) 2017/745 et 93/42 / CE sur les dispositifs médicaux de classe I et tous les produits contiennent des balles spécialement conçues. Tous les produits stimulent le sens du toucher et le sens des muscles et des articulations et ont un effet calmant sur le corps et l'esprit.

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Use of Ball Blanket in attention-deficit/ hyperactivity disorder sleeping problems

ALLAN HVOLBY, NIELS BILENBERG

Hvolby A, Bilenberg N. Use of Ball Blanket in attention-deficit/hyperactivity disorder sleeping problems. Nord J Psychiatry 2010; Early Online, 1–6.

Objectives: Based on actigraphic surveillance, attention-deficit/hyperactivity disorder (ADHD) symptom rating and sleep diary, this study will evaluate the effect of Ball Blanket on sleep for a sample of 8–13-year-old children with ADHD. *Design:* Case–control study. *Setting:* A child and adolescent psychiatric department of a teaching hospital. *Participants:* 21 children aged 8–13 years with a diagnosis of ADHD and 21 healthy control subjects. *Intervention:* Sleep was monitored by parent-completed sleep diaries and 28 nights of actigraphy. For 14 of those days, the child slept with a Ball Blanket. *Main outcome measures:* The sleep latency, number of awakenings and total length of sleep was measured, as was the possible influence on parent- and teacher-rated ADHD symptom load. *Results:* The results of this study will show that the time it takes for a child to fall asleep is shortened when using a Ball Blanket. The time it takes to fall asleep when using the Ball Blanket is found to be at the same level as the healthy control subjects. Teacher rating of symptoms show an improvement in both activity levels and attention span of approximately 10% after using the Ball Blankets. *Conclusions:* The results of this study show that the use of Ball Blankets is a relevant and effective treatment method with regard to minimizing sleep onset latency. We find that the use of Ball Blankets for 14-days improves the time it takes to fall asleep, individual day-to-day variation and the number of awakenings to a level that compares with those found in the healthy control group. Furthermore, we find that the use of Ball Blankets significantly reduces the number of nights that the ADHD child spends more than 30 min falling asleep from 19% to 0%.

• *ADHD, Sleep, Treatment.*

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Attention-deficit/hyperactivity disorder (ADHD) is the most common problem presented to Child and Adolescent Mental Health Services (CAMHS). The disorder affects 3–5% of all school-aged children (1). The core symptoms of the disorder—inattention, hyperactivity and impulsivity—are associated with a high rate of comorbidity (e.g. oppositional defiant disorder, anxiety and depression; 2–4), as well as academic underachievement, poor social relations and sleep disturbances. Sleep difficulties was even included in the diagnostic criteria for ADHD in the DSM III (5) and are often included in ADHD rating scales, e.g. Conners' Rating Scale for parents (6).

It has been theorized that sleep deprivation in children with ADHD could be a result of a primary sleep disorder, or that it could be related to dysregulation of arousal mechanisms as implicated in the aetiology of ADHD (7). We know that sleep difficulties with no explanatory cause can be mistaken for ADHD (8), and that the kind of symptoms observed in primary sleep disorders—such as sleep-related breathing disorders or periodic limb movement disorders—can often be mistaken for ADHD, as they are very similar to core symptoms of ADHD. These disorders are found to be related to hyperactivity and inattentiveness (9–14), and the very treatment of the sleep disorders has reduced—or even cured—both hyperactivity and inattentiveness (15, 16). It has also been proposed that an unstable sleep schedule could be the result of biological immaturity, or it could be a dysfunction somehow related to inattentiveness. Likewise, it has been suggested that instability of the sleep–wake system may play a role in the irregularity of the arousal level (17).

Sleep problems are furthermore interesting because learning difficulties are rather frequent in children with ADHD (15), and several studies have documented a link between sleep disorder and learning difficulties (18–23).

Parents of children with ADHD often report that their child has sleep difficulties. Little need for sleep, difficulties

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falling asleep, restless sleep, frequent awakenings and fatigue in the morning are often reported problems (24–26). The children themselves also report sleep difficulties more often than children without ADHD (27). Self-report studies show that more than half the children with ADHD report subjectively experienced sleep difficulties (24, 28, 29). This could be of great theoretical importance in the clinical work.

Recent studies point out that the majority of sleep difficulties found with reference to ADHD may result from a mix-up of comorbidity and medical treatment. Comparing children with ADHD against clinical controls, Mick et al. (30) found no significant sleep difficulties in children with ADHD when comorbidity (anxiety, oppositional defiant disorder and depression) and treatment with stimulants were taken into account, but only few studies have addressed this possible connection, and the picture is far from clear.

However, other studies have documented a higher degree of insomnia and more individual variation in time to sleep latency in medically naïve children with ADHD compared with children with other psychiatric diagnoses and healthy children (29, 31–35). It is difficult to judge the extent and nature of sleep problems in children with ADHD because the range of studies addressing this issue suffer from methodological problems (e.g. too small sample sizes, wavering diagnostic criteria and different status of medication and comorbidity; 4).

From clinical practice, we know that parents of children with ADHD are alarmed by their child's sleeping problems and the difficulties this causes in the family setting. The ADHD-diagnosed children themselves even report sleep difficulties more frequently than children without ADHD. More than half the children with ADHD claim to have sleep difficulties (25, 27, 28). In a study using actigraphy, Hvolby et al. (35) found increased sleep onset latency and an increased day-to-day variability in the sleep–wake pattern of children with ADHD compared with children without ADHD.

The design of the Ball Blanket (Fig. 1) is based on the American occupational therapist and psychologist, A. Jean Ayres's, theories of sensory integration (36). It works because the weight from the loose balls inside the blanket press certain points of the body, stimulating both the sensation of touch and the sense of muscle and joint. The many sensory impressions transmit inhibitory impulses to the central nervous system. This increases the sense of the body and its limits, and it provides confidence. The Ball Blanket has been used in psychiatric inpatient wards for some years as a tranquillizing method and has, in non-scientific and unpublished works, diminished the use of medical tranquilisers.

The Ball Blanket is produced with balls of various sizes and weights. The blanket with plastic balls provides most weight and pressure, and provides therefore the strongest stimulation of the sensory system. The Ball Blanket with a mixture of plastic and polystyrene balls is a somewhat lighter blanket for those who need slightly milder stimulation of the sensory system. The blanket with polystyrene balls provides the lightest stimulation of the sensory system. For this project, the Ball Blanket (adult size 140 × 200 cm) with 50-mm plastic balls and a weight of 7 kg has been used. For more information, see www.protac.dk

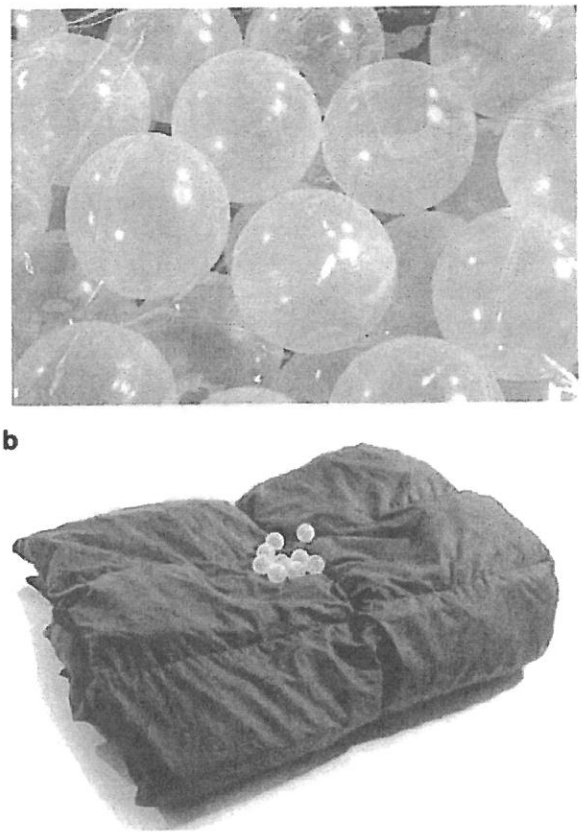

Figure 1. The Ball Blanket.

Aims

Based on actigraphic surveillance, ADHD symptom rating (ADHD-RS; 37) and sleep diary, this study will evaluate the effect of Ball Blankets on sleep in a sample of 8–13-year-old ADHD children. The sleep latency, number of awakenings and total length of sleep will be measured, as will the possible influence on parent- and teacher-rated ADHD symptom load.

Methods

Participants

A total of 21 children (19 boys and two girls) aged 8–13 years, with an average age of 10.0 years, were involved. All had been referred to a child and adolescent

psychiatric department and diagnosed with ADHD. Fourteen children were medicated with methylphenidate, two with dexamphetamine sulphate and two with atomoxetine. One child was treated with a combination of methylphenidate and atomoxetine and two children were not medicated. Three children got melatonin at bedtime. All medications remained unchanged during the test period.

None of the participating children had been referred for sleeping problems nor did they have major sensory-motor handicaps (blindness, deafness and paralysis), autism and psychosis. All had an estimated full-scale IQ above 80.

Psychiatric comorbidity is shown in Table 1.

Diagnostic measures

Each participant in the referred group was subjected to thorough clinical assessment. The diagnostic evaluations were based on face-to-face parent interviews and a clinical assessment, and the hyperkinetic disorder (ADHD) was diagnosed in accordance with the ICD-10 Classification of Mental and Behavioural Disorder.

Table 1. Descriptive characteristics of children and parents.

	ADHD	Healthy control
Age (*s*)	10.0 (1.7)	9.8 (0.4)
Gender		
Male	19	20
Female	2	1
Family type		
Two-parent family*	17	16
Other	4	5
Social class		
Self-employed	3	1
Salary-earner	16	19
Student	2	0
Transfer income	0	0
Unknown	0	1
Psychiatric comorbidity		
Anxiety disorder	2	
Learning disability	4	
PDD-NOS	1	
Oppositional defiant disorder	1	
Conduct disorder	1	
Tourettes Syndrome	1	
Somatic diagnoses		
Asthma	1	0
Medication		
Stimulants	16	(dose interval 5–74 mg)
Atomoxetin	2	(dose interval 25–40 mg)
Stimulant + atomoxetin	1	
Melatonin	3	(dose 3 mg)
Alternative medicine	1	

ADHD, attention-deficit/hyperactivity disorder; *s*, standard deviation; PDD-NOS, pervasive developmental disorder—not otherwise specified.
*Two parents in the family. Two biological parents or one biological parent and his/her cohabiting partner.

Sleep

To obtain an objective view of the sleep pattern, actigraphs (Basic Mini Motionlogger, Ambulatory Monitoring Inc., New York)—a wrist-watch-sized activity sensor worn on the dominant wrist—was used. Actigraphy is an established and well-reputed method of sleep examination. Findings are consistent with those obtained by the polysomnographic methods, with an agreement rate of 95% (38). Sleep recording took place in the children's own home, which is an additional advantage, as the children's sleep does not seem to have been negatively affected (39).

The children wore the actigraph for a consecutive period of 28 nights (40). Surveillance took place in three consecutive periods; first 7 nights without the Ball Blanket to obtain the baseline sleeping pattern, then 14 nights using the Ball Blanket and finally 7 nights without the blanket.

When uploaded to the computer, the accumulated data was analysed according to the Actigraphic Scoring Analysis Program (41). Study of frequency and pattern of movement permits detection of basic sleep–wake patterns. The variables generated were 'sleep onset latency' (time between parents noting lights out and actigraphically measured first sleep onset), 'number of wakes after sleep onset', 'length of each wake' and 'total duration of sleep' (actual sleep time, excluding sleep latency and wakes after sleep onset).

During the same 7–14–7 night period, a sleep diary was completed by the parents to provide a subjective assessment of sleep–wake patterns and to provide more accurate actigraphical measurements. Parents were instructed to observe and specify their children's sleeping and waking states (bedtime, lights out, observed wakes and times the child woke up). Thus we were able to calculate sleep onset latency (time between parents noting lights out and actigraphically measured first sleep onset). Also, parents and teachers rated the load of inattentive and hyperactive/impulsive symptoms on the ADHD-RS at the end of each period.

As a control group, 21 matched children were sampled from a Danish actigraphic norm-population (42).

Results

The results of this study (Table 2) show that sleep onset latency was reduced when using the Ball Blankets. Without the use of Ball Blankets, the average sleep onset latency was 23.1 min, which fell to 14.0 min when using the Ball Blanket—a fall of 39.4%. The time it took for the child to sleep can furthermore be seen as being at the same level as sleep onset latency for healthy control children—whilst the time increases—to 20.5 min—when the blanket is removed.

There is likewise an improvement in the average of individual longest sleep onset latency. The difference between the longest and shortest individual sleep onset

Table 2. Actigraphic sleep parameters.

	Before Ball Blanket	With Ball Blanket	After Ball Blanket	Healthy controls	*P*-value
		$n = 21$		$n = 21$	
Sleep onset latency (minutes), mean (*s*)	23,1 (9.4)	14,0 (6.1)	20.5 (11.7)	14.2 (10.0)	$P < 0.002$
Average of longest sleep onset latency (minutes), mean (*s*)	44.7 (27.2)	32.1 (14.2)	38.8 (19.6)	25,3 (17,1)	ns
Difference between longest and shortest individual sleep onset latency (minutes), mean (*s*)	36.9 (24.8)	30.2 (14.6)	29.8 (15.7)	20.8 (20.0)	ns
Number of awakening (number), mean (*s*)	7,7 (5.6)	6,1 (3.8)	6,4 (4.6)	7,8 (4,8)	ns
Average time awake (minutes), mean (*s*)	3,3 (1.5)	3,6 (1.7)	3,2 (3.3)	2,9 (1,6)	ns
Total sleep time (minutes), mean (*s*)	510 (50.3)	524 (26.4)	487 (117)	579 (32,6)	ns
Sleep onset latency (average) >30 min (%)	19.0%	0%	19.0%	4.8%	$p = 0.035^*$
(n = total number of nights in each group)	(n = 130)	(n = 243)	(n = 107)	(n = 147)	
Sleep onset latency >30 min (%)	27.7%	14.8%	33.6%	12,4%	$P < 0.003^*$
Sleep onset latency <15 min (%)	38.5%	68.7%	47.7%	na	$P < 0.001^*$

s, standard deviation; ns, not significant (significance level $P < 0.01$).
Actigraphic sleep parameters in minutes averaged for each child, and fraction of children with an average sleep onset latency >30 min.
Data analysed with one-way analysis of variance (ANOVA).
*Chi-squares with two degrees of freedom.

latency and the average number of awakenings during the night was between 18% and 28%.

An interesting find is that the proportion of children that spent longer than 30 min on average falling asleep; 19% spent more than 30 min on average falling asleep before and after using the Ball Blanket, whilst no children had an average of more than 30 min when using the blanket.

Likewise, the proportion of single nights when more than 30 min were spent falling asleep fell from 27.7% to 14.8% when using the blanket, which is the same level as the healthy control children. At the same time, the proportion of single nights during which the child fell asleep within 15 min rose from 38.5% to 68.7%.

Table 2 shows that the sleep parameters described deteriorate again when the Ball Blanket is not used.

Parents' evaluation of the sleep is shown in Table 3. Parents experience that their child falls asleep more quickly, even if the subjective effect is small than with the actigraph measurement. Likewise, parents evaluate that the sleep onset latency falls from an average of 36.7 min to 26.9 min, which is an improvement of 26.7%.

Parents have a tendency to overestimate the length of time it takes to go to sleep, both in the period with and without the use of the Ball Blanket. However, as the table shows, this phenomenon is found at the same level in the healthy control group.

In Tables 4a and 4b, the ratings of ADHD symptoms are shown from teachers and parents respectively. Teacher ratings show a non-significant improvement in both activity level and attention—approximately 10% from before the Ball Blanket is used to scoring after 14 nights with the Ball Blanket. The tables also show a continued, further improvement in both parameters in the week after the Ball Blanket has been removed again.

Parent rating shows the same tendency, though with a smaller improvement in activity and attention, but with an improvement in behavioural disturbance symptoms of 13%.

Discussion

Previous studies found that non-medicated children with ADHD had longer sleep onset latency, and that

Table 3. Parental versus actigraphic estimated sleep onset latency.

Sleep onset latency	Before Ball Blanket	With Ball Blanket	After Ball Blanket	Healthy controls	*P*-value
Actigraphic measure, mean (*s*)	23.1 (9.4)	14.0 (6.1)	20.5 (11.7)	14.2 (10.0)	$P < 0.002$
Parental estimation, mean (*s*)	36.7 (21.6)	26.9 (9.4)	31.8 (16.9)	24.8 (11.1)	$P < 0.01$
Difference (between actigraphic and parent est.), mean (*s*)	13.6 (21.5)	12.9 (8.2)	11.3 (16.8)	10.6 (9.9)	$P < 0.01$
Number of parents who overestimate (%)	76.5%	93.8%	86.7%	75.0%	ns

s, standard deviation; ns, not significant (significance level $P < 0.01$).
Parents' estimation (by sleep diary) of sleep onset latency (time between *parents noting* lights out and *parents noting* first sleep onset), compared with the objectively (actigraphically) measured sleep onset latency (time between *parents noting* lights out and *actigraphically* measured first sleep onset).
*Data analysed with three-way analysis of variance (ANOVA), adjusted for gender and family type.

Table 4a. Attention-deficit/hyperactivity disorder (ADHD) rating scale (score (standard deviation))—rated by teachers.

	Without Ball blanket	With Ball blanket	Without Ball blanket after	Difference	*P*-value*
Hyperactivity	14.6 (7.9)	13.1 (7.3)	12.5 (6.8)	10.5%/14.4%	ns
Inattention	12.8 (6.6)	11.5 (6.7)	10.8 (6.2)	10.2%/15.6%	ns
Total	27.4 (14.2)	24.6 (14.1)	23.3 (12.6)	10.2%/15.0%	ns
Behaviour	6.2 (5.8)	6.4 (6.4)	5.6 (4.9)	–/9,7%	ns

*Wilcoxon Rank sign test.

significantly more children with ADHD spend more than 30 min (on average) falling asleep (35). An increased intra-individual day-to-day variability in sleep onset latency in children with ADHD compared with healthy children and children with other psychiatric diagnoses has also been documented (16).

Previous studies (8–11, 35) show a relationship between sleep difficulties and an increased magnitude of ADHD symptoms, inattention and hyperactivity. Treatment with Ball Blankets appears therefore to improve sleep and this study has furthermore shown a small decrease in the severity of ADHD symptoms, as evaluated by both teachers (approximately 10% improvement), and by parents (approximately 6%). In both evaluations, the improvement appears to continue even when use of the Ball Blanket has stopped.

In accordance with other studies (31–33, 35), we found poor correspondence between parental recordings of sleep problems and the objective measurements (actigraphy). We found disagreement both with and without the use of Ball Blankets. Corkum et al. (43) claims that the lack of correspondence between objective and subjective measurements of especially sleep onset latency, which is the most frequently reported problem area, is related to the children's problematic behaviour around bedtime. In addition, the individually based day-to-day variation in the sleep pattern of children with ADHD found in this study may well contribute towards making the problem appear greater than it really is. These phenomena may play an important role in parents' experiences of their child's problems falling asleep. Parents may recall "worst case" scenarios.

Other studies have highlighted the importance of sleep in relation to learning difficulties, behaviour, concentration and motor skills disturbances. Treating sleep problems in children with ADHD is therefore relevant (9–14, 18–23).

The results of this study show that the use of Ball Blankets is a relevant and effective method of treatment with regard to reducing sleep onset latency

We find that the use of Ball Blankets for 14 days improves sleep onset latency, individual day-to-day variation and number of awakenings to a level comparable with those found in the healthy control group.

We furthermore find that the use of Ball Blankets significantly reduces the number of nights in which the ADHD child spends more than 30 min falling asleep from 19% to 0%.

The weakness in this study is the relatively small study group and the short length of time in which the Ball Blanket was used. It is conceivable that a longer period using the Ball Blanket would give more significant results, especially with regard to improving ADHD symptoms. The present study has not included possible differences between subtypes of ADHD. This study has not examined whether medication with central stimulating medicine has any effect on the results.

As far as we are aware, this is a unique study that demonstrates that the Ball Blanket can be a good alternative when treating sleep difficulties in children with ADHD and a supplement to medical treatment for its core symptoms.

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The author has no obligations to Protac regarding this manuscript.

Table 4b. Attention-deficit/hyperactivity disorder (ADHD) rating scale (score (standard deviation))—rated by parents.

	Without Ball blanket	With Ball blanket	Without Ball blanket after	Difference	*P*-value*
Hyperactivity	15.1 (5.9)	14.2 (5.5)	14.1 (5.9)	6.0%/6.6%	ns
Inattention	12.5 (6.4)	11.7 (5.9)	11.5 (5.8)	5.6%/8.0%	ns
Total	27.6 (12.0)	25.9 (11.2)	25.6 (11.3)	6.2%/7.2%	ns
Behaviour	8.4 (5.9)	7.3 (5.1)	7.3 (4.7)	13.1%/13.1%	ns

*Wilcoxon Rank sign test.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Research Article

The Application of Ball Blankets in the Treatment of Sleeping Difficulties in Children with Attention Deficit/Hyperactivity Disorder. Effect on Quality of Life and Daily Functioning

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Abstract

Sleeping difficulties are often associated with Attention Deficit Hyperactivity Disorder (ADHD). Both children with ADHD and their parents report sleeping difficulties more often than healthy controls. The purpose of this study was to examine the effect of weighted Ball Blanket on sleep onset latency, number of awakenings and duration of sleep, severity of ADHD symptoms, daily level of functioning and Quality of Life in a group of children with both ADHD and actigraphy-verified sleeping difficulties.

Material and Methods: The study investigated 36 children between 8 and 13 years of age diagnosed with ADHD. The participants were recruited after referred to an outpatient child and adolescent psychiatric department. The participants slept with a Ball Blanket for 8 weeks and sleep, Quality of Life and daily functioning were measured.

Results: The use of a Ball Blanket over a period of 8 weeks improved sleep, in particular sleep onset latency and reduced the score on core symptoms of ADHD. The daily level of functioning and the Quality of Life were increased. The Ball Blanket was the only new intervention in the group during the 8 weeks period.

Conclusions: We conclude that the Ball Blanket might be an effective non-pharmacologic treatment of sleep problems in ADHD.

INTRODUCTION

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most common psychiatric conditions in children; 3-6% of school-aged children are affected by attention deficit dysfunction, inattention and impulsivity [1]. Furthermore, ADHD are often associated with comorbid conditions, such as anxiety, depression and behavioural disorders [2-5]. ADHD are also commonly associated with sleeping difficulties [6] and Parents of children with ADHD often report a range of sleeping difficulties in their children like little need for sleep, difficulty falling asleep, unsettled sleep, numerous awakenings and increased morning fatigue [7-9]. Children with ADHD also report sleeping difficulties more often than children without ADHD such as prolonged sleep onset latency, frequent night awakenings, restless sleep and sleep-disordered breathing [10-12], and more than half of children with ADHD report subjective sleeping difficulties [8,13-15]. Furthermore, sleeping difficulties in their children form a significant stress factor, and are often a cause of worry for parents [16,17].

Studies have shown increased instability in sleep-waking patterns with regard to sleep onset latency, length of sleep and real sleep time in ADHD individuals compared to controls [18,19]. Hvolby [20], found a significant positive correlation between sleep onset latency and high scores on the ADHD-RS in a group of healthy children. Additionally, another study found that treatment of sleep rhythm disturbances drastically reduced ADHD symptoms in a child referred for ADHD assessment [21].

In some clinical populations, sleeping difficulties have been associated with various comorbid conditions, e.g. anxiety and behavioural disorders [22,23], and psychiatric comorbidity was found associated with more severe sleeping difficulties [24]. Especially internalizing or autistic disorder lead to higher sleep problem score [25]. Whereas other studies have not been able to prove this hypothesis that comorbidity rather than ADHD is associated with sleeping difficulties [19,26]. However, there might be an increased risk of developing depression as a result of sleeping disturbance [27].

The core symptoms of ADHD - inattention, impulsivity and

hyperactivity - are strikingly similar to those seen in primary sleep disorders, such as sleep-related breathing disorders and periodic limb movement disorder. Evidence is indicating that these sleep disorders are related to hyperactivity and inattention [28,33]. Additionally, treatment of the sleep disorders has been found to simultaneously improve symptoms of ADHD [34]. Some studies have shown that non-medicated children with ADHD have more sleep problems compared to other children [19,26], and that sleep problems can worsen the symptoms of ADHD and also behavioural problems [35,36]. An earlier study has shown that children with sleeping difficulties tend to present learning disabilities more often than other children [37]. And sleeping problems is associated with poor executive functions [38]. and individuals with poor sleep are shown to have altered connectivity in the frontostriatal network [39], which is associated with executive functioning deficits [40]. In the light of a possible connection between ADHD symptoms and sleep disorders it would make sense to target existing sleeping difficulties in individuals with ADHD regardless of their status as the primary diagnosis or an artefact of medical treatment [11,21,36].

Previous studies have shown that sleep hygiene and melatonin can relieve sleeping problems (41+42), and behavioural interventions have shown positive effect on both ADHD symptoms, Quality of Life (QoL) and daily functioning [43].

Only one previous study has dealt with the possible effect on sleep in particular difficulties falling asleep, using Ball Blanket [44]. They found that application of a Ball Blanket for two weeks could reduce sleep onset latency in a group of children with ADHD to the level of healthy controls. In that study was showed a small but non-significant drop in the severity of ADHD symptoms evaluated by teachers (approx. 10% improvement), who were blind to the fact that the child was using a ball blanket. Also the parents reported an approx. 6% improvement. Both groups reported continued improvement in ADHD symptoms even after stopping using Ball Blankets.

A Ball Blanket is a weighted blanket whose design is based on the American occupational therapist and psychologist A. Jean Ayres' theories of sensory integration [45]. The effect of the ball blanket is based on the weight of loose balls inside the blanket that creates pressure on certain body points, stimulating both the sensation of touch and muscle and joint senses. Ball Blankets have been used in psychiatric inpatient wards for some years as a tranquillising method, and according to non-scientific or unpublished work, application of these blankets is connected to reduced use of medical tranquilisers.

The actigraph unit is a wrist worn activity monitor (Basic Mini Motionlogger, Ambulator Monitoring Inc., New York). In the present study actigraphs are used with the purpose to differentiate between sleep and waking states, and data is analysed using an algorithm developed to perform this differentiation in the Actigraphic Scoring Analysis Program. Actigraphy is a precise and recognised method for sleep evaluation and, despite the fact that no EEG measurements are performed, the method has demonstrated 90% agreement with polysomnography measurements including sleep onset latency [46,47].

The method also has the advantage of being less invasive to the child's sleep as measurements can be taken in the child's usual environment, which is important because children with ADHD are known to be more sensitive to sleep measurement than their control counterparts [48].

The aim of this study was to investigate whether use of a Ball Blanket in treatment of actigraphy-verified sleeping difficulties was able to improve sleep onset latency as well as to reduce ADHD symptoms, improve daily level of functioning and QoL in a group of children with ADHD. Treatment of sleeping difficulties in children with ADHD can help reduce ADHD core symptoms, improve daily level of functioning and improve QoL.

MATERIAL AND METHOD

Included were children aged 8-13 years referred to outpatient Child and Adolescent Psychiatric Department and received a clinical diagnosis based on the ICD-10 criteria for Hyperkinetic Disorder (DF 90.0) and Hyperkinetic Behavioural Disorder (DF90.1) [49].

Additionally, these diagnoses were subsequently verified with the clinical interview Kiddie-SADS [50], Danish version to ensure the fulfilment of the DSM-IV criteria for ADHD combined subtype. Furthermore, all participants underwent cognitive evaluation with WISCIV [51].

All children who were enrolled in the study presented prolonged sleep onset latency, verified by an actigraph unit prior to the study.

Inclusion criteria

1) ADHD-combined type, 2) Age 8-13 years, 3) average sleep onset latency > 25 minutes and at least 4 of 7 days with sleep onset latency > 30 minutes, 4) None of the participants were receiving any treatment for sleeping problems.

Exclusion

Participants with major sensory-motor handicaps (paralyses, deafness and blindness), psychoses, autism or a total IQ of < 70.

Intervention

For this project a Ball Blanket size 140 x 200 cm with 50 mm plastic balls and a weight of 7 kg were used and were free of charge for the participants of the study. The participants were asked to use the Ball Blanket every night for 8 weeks. Parents were asked to register the use of the Ball Blanket in a sleep diary.

MEASURES

Evaluation of sleep

To clarify sleep patterns, actigraphy and sleeping diaries completed by the parents were used. Actigraphy was used to get an objective evaluation of sleep onset latency, number of nightly awakenings and length of sleep. Actigraphic measurements were performed over 7 consecutive nights [52], at baseline before the Ball Blanket was used, and again for 7 consecutive days after 8. weeks' use of the Ball Blanket . Parents entered information on bedtime, lights out and time falling asleep into a sleeping diary. The sleeping diary was completed in connection with the

objective sleep registration (actigraphy) at baseline and again at follow up and was used to verify sleep onset latency.

Evaluation of ADHD symptoms

The ADHD-Rating Scale questionnaire (ADHD-RS) [53], Danish version was used to evaluate the severity of ADHD symptoms, based on DSM-IV criteria. The questionnaire consists of 18 items describing inattention, hyperactivity and impulsivity scored on a scale of 0 ("not present") to 3 ("present to a large extent"). 8 items evaluate behavioural problems on a scale of 0-3. The questionnaire is age and sex standardised for the Danish population. Questionnaires were given to the parents and to the child's main teacher/social educator.

Level of functioning

One of the methods used to describe the child's level of functioning and quality of life was the Dundee - Difficult Times of the Day Scale (D-DTODS) [54]. This scale evaluates the child at 10 different times during the day on a scale of 1-4 (1 representing "no problems" and 4 "many difficulties").

In addition, the child's QoL was evaluated, using the Weiss Functional Impairment RatingScale (WFIRS) [55]. The WFIRS is a parent questionnaire and evaluates the well-being of the child in 6 everyday domains - family, learning and schooling, life skills, the child's self-perception, social activities and risk behaviour. Scores are ranging from 0 to 3 (0 indicating "never or not at all", and 3 indicating "very often and very much").

DATA ANALYSIS

Means and standard deviations are reported for all outcomes. Pre and post scores are tested for significant changes using a non-parametric Wilcoxon signed-rank test. Linear regression with bootstrapped error estimates is used to test the association between time-to-sleep improvements (difference between pre and post time-to-sleep measured using the Actigraph) and change in QoL and D-DTODS. Regression estimates are controlled for pre measurements of QoL and D-DTODS.

RESULTS

The study included a total of 36 children aged between 8 and 13 years with ADHD and actigraphy-verified sleep onset latency (average age 10 years and 2 months (Table 1), who were referred to an outpatient Department of Child and Adolescent.

This study show that sleep can be improved by using a Ball Blanket (Table 2).On average, sleep onset latency measured by actigraphs improved from 30.6 minutes to 18.9 minutes, which is an improvement of 38.2% ($p < 0.001$)

Sleep onset latency registered by parents using a sleep diary improved from 41.1 minutes to 29.8 minutes on average, which is an improvement of 27.5% ($p < 0.01$) 13 of the 36 children spent more than 30 minutes on average falling asleep before using the ball blanket, whereas no children spent more than 20 minutes on average falling asleep while using the Ball Blanket. Likewise, the number of nightly awakenings measured by actigraphy was reduced by 16% (ns).

In five of the children a prolongation of sleep onset latency was found. All five children had measured sleep onset latency of more than 25 minutes both before and during the use of the Ball Blanket. ADHD symptoms as evaluated on the ADHD-RS improved both at school and at home (Table 3).

At school, the symptom ratings for inattention and impulsivity/hyperactivity fell by approx. 20%, while ratings for behavioural symptoms almost halved.

At home, as reported on the ADHD-RS, fewer symptoms of inattention and impulsivity/hyperactivity were also seen, with an improvement of approx. 20%, although the effect on behavioural symptoms was lower, with an improvement of only 14%. ($p < 0.01$-0.001)

The daily level of functioning measured by D-DTODS increased markedly by 30% ($p < 0.001$), likewise there was a change of the more general evaluation of QoL, where we found an 11% higher evaluation of QoL ($p < 0.01$)

DISCUSSION

Sleeping problems can resemble the symptoms of ADHD, and disprove ADHD as the correct diagnosis [21,30], and in some cases improving sleep can reduce symptoms [43]. It therefore seems highly relevant to attempt to target any existing sleeping problems before introducing medical treatment for ADHD, especially in case of severe sleeping difficulties. This study shows that sleep can be improved by using a Ball Blanket.

Table 1: Descriptive characteristic of children and parents.

			Numbers	Daily Dose interval
Age		10 years 2 month (8.1 – 12.8)		
Gender	Boys		32	
	Girls		4	
Parent Social class	Self employed		3	
	Salary-earner		30	
	Student		3	
Family type:				
	Two-parent family*		29	
	Single-parent		7	
Medication:				
	Stimulants		24	(interval 5-72 mg a day)
	Atomoxetin		2	(interval 26-60 mg a day)
	Omega n-3 fatty Acid		6 **	
	No medication		10	

*Two parents in the family. Two biological parents or one biological parent and his/her cohabiting partner.
** In combination with medicine or no medical Treatment

Table 2: Sleep parameters, minutes (mean).

	Before use of Ball Blanket	After 8 weeks use of Ball Blanket	p-value*
Sleep onset latency measured with actigraph	30.6 (15,0)	18.9 (12,1)	p<0,001
Sleep onset latency, parent estimate	41,1 (19,9)	29,8 (12,5)	p<0,01
Number of awakenings, numbers	8.1 (4.8)	6.8 (4.3)	ns
*_Wilcoxon sign rank test			

Table 3: Attention-Deficit Hyperactivity Disorder Rating Scale Scores (ADHD-RS), Quality of Life (QoL) and Dundee – Difficult Times of the Day Scale (D-DTODS) Mean Scores, (SD.)

	Before Use of Blanket	After 8 weeks of Blanket use	p-value **
ADHD-RS School: total score			
Inattention	13,1 (6,8)	11.0 (5.9)	p<0,001
Hyperactivity/impulsivity	15,0 (5,1)	13,0 (5.6)	p<0,001
Behaviour	7,5 (6.9)	5,7 (5.9)	p<0,01
ADHD-RS Home: total score			
Inattention	14.1 (6.3)	11,6 (6.5)	p<0,001
Hyperactivity/impulsivity	12,4 (6,2)	10.0 (5.8)	p<0,01
Behaviour	8,0(5.6)	5,9 (4,6)	p<0,01
QoL total score	43.8 (20,6)	38.8 (20.9)	P<0,01
D-DTODS total score	19.3 (4.7)	13.4 (4.8)	p<0.001
** Wilcoxon sign rank test			

As found in Hvolby et al. [44], this present study shows that use of Ball Blankets can improve sleep - in particular improve sleep onset latency - for children with ADHD in medical treatment for ADHD. At the same time, the study shows fewer ADHD symptoms, fewer behavioural problems, especially in relation to school but also at home, and improved QoL and daily functioning when using the Ball Blanket. A relation also found by Hiscock et al. [43].

Importantly, this study raises the hope that the behavioural problems often seen in relation to ADHD and sleeping problems [4,36] can be effectively improved - especially in relation to school.

In agreement with Hvolby et al. [19], this study has shown that there is a difference between the parents' evaluation of sleep and the measurements shown using actigraphy. Sleep onset latency is often perceived longer by parents than measured by actigraphy. Furthermore, we found that only 64% of the parents experienced an improvement in their child's sleep when using a Ball Blanket, while the actigraph unit measured improvements in sleep in 86% of the participants.

This difference could be related to the child's difficult behaviour around bedtime. However, it could also be a consequence of the substantial day-to-day variations that typify the sleeping patterns of children with ADHD [18,19].

We found that the use of a Ball Blankets over a period of 8 weeks improved sleep, in particular sleep onset latency, and that the improved sleep seemed to reduce the core symptoms of ADHD (inattention, impulsivity/hyperactivity), the daily level of functioning and also quality of life.

It seems relevant to treat sleeping problems in children who are already in medical treatment for ADHD because - as this study has shown - it could help further reduce symptoms and improve daily level of functioning.

CONCLUSION

Based on this study, it can be concluded that the Ball Blanket can be an effective method for treating sleeping difficulties, especially sleep onset latency in children with ADHD. Despite some promising results, we cannot with certainty conclude a direct relation between better sleep and the positive changes found in daytime symptoms. More studies will be needed to examine the effect of sleep improving on ADHD symptoms, QoL and daily level of functioning.

LIMITATIONS

This study has a number of weaknesses. It is a relatively small study and we did not make an power calculation before including participants. The study was not controlled, and the patients were not randomised to a Ball Blanket. .The children were used as their own controls (sleep pattern before and after using ball blanket) and it is a limitation that we did not use a control group. We were not able to compare children with and without medication. However, the participants did not change their medication or other treatment during the study, neither for ADHD nor sleeping difficulties.

In this study, we did not diagnose any primary sleep disorders, e.g. sleep apnoea or Restless Leg Syndrome, although these sleep disorders are seen in children with ADHD [28-33]. We included a clinically referred group of children diagnosed with ADHD, but we did not consider or adjust for any comorbidity. This study included children aged 8-13, and it is not possible on the basis of this study to make any conclusion regarding the effect of sleep

treatment using ball blankets for younger children, adolescent or adults.

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Trials

STUDY PROTOCOL Open Access

The efficacy of ball blankets on insomnia in depression in outpatient clinics: study protocol for a randomized crossover multicentre trial

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Abstract

Background: Depression affects approx. 4% of the global population and is often accompanied by insomnia. Medications used to treat insomnia can have side effects such as development of tolerance and addiction. The Protac Ball Blanket™ (PBB) is a non-pharmacological supplement to sedatives and hypnotics, but evidence for the efficacy of PBB is needed before the treatment is implemented. The objective of this trial is to test the efficacy of PBB on insomnia caused by depression in a randomized controlled design.

Methods: This study is a multicentre, randomized crossover trial with planned inclusion of 45 patients. The randomization procedure is permuted-block randomization with varying block sizes. Patients are allocated into either a sequence "AB" or "BA" each lasting 4 weeks (28 nights). Patients randomized to the "AB" sequence receive treatment A (Protac Ball Blanket™) in the first 2 weeks and switch to treatment B (treatment as usual) in the second period, whereas patients who are randomized to the BA sequence receive treatment B in the first period and treatment A in the second period. The participants will serve as their own control in this design. The primary outcome is changes in total sleep time. Secondary outcome measures are changes in sleep onset latency, number of awakenings, wake after sleep onset, and use of sedatives and hypnotics. Furthermore, quality of sleep, insomnia severity status, and self-reported symptoms of depression, anxiety, interpersonal sensitivity, and neurasthenia will be measured. A paired, two-sided *t* test to compare the means of the differences in the outcomes will be performed.

Discussion: This clinical trial will assess the effect of PBB on depression-related insomnia. The outcomes are of high interest as the PBB is a potential non-pharmacological supplement to medical treatment of patients with insomnia due to depression.

Trial registration: ClinicalTrials.gov Identifier: NCT03730974. Registered on 5 November 2018.

Keywords: Insomnia, Depressive disorder, Outpatients, Weighted blankets, Actigraphy, Crossover studies

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Background

Depression affects approximately 4% of the global population and is associated with significant morbidity and mortality. Evidence-based treatment of the condition is therefore an important clinical and public health issue [1, 2]. Unfortunately, some symptoms of depression are difficult to manage such as for instance insomnia. Insomnia occurs in the majority of patients with depression [2] and is characterized as problems with initiating sleep, several wake ups, early morning awakening, reduced total sleep time, and daytime dysfunction [3–5], all causing poor sleep quality. The relationship between insomnia and depression is complex. Whether insomnia is part of depression or a separate entity is still debated [6–8]. Insomnia in this trial is addressed as a diagnostic symptom of depression [9]. Possible reasons for insomnia in depression are anxiety, impaired stress regulation, substance abuse, poor sleep hygiene, or ruminations [4, 10]. In both inpatient and outpatient psychiatry, medicine is often used to treat insomnia, but pharmacological treatment has side effects and, importantly, in case of benzodiazepines, there is a risk of drug tolerance and addiction [11] as well as somnolence during day-time. Increased attention on investigating the known and unknown benefits of non-pharmacological treatment options for insomnia due to depression is therefore highly relevant. Non-pharmacological treatments include cognitive behavioural therapy, which has proven effects on insomnia [12–14]. Cognitive behavioural therapy for insomnia (CBT-I) typically includes sleep restriction, stimulus control, cognitive therapy, sleep hygiene, and relaxation training [12–14]. Unfortunately, sleep restriction with formal cognitive restructuring to target hyperarousal, dysfunctional behaviours, and maladaptive beliefs, thoughts, and attitudes is limited to patients without severe cognitive problems who are mentally able to participate in therapy sessions [14, 15]. Participation may therefore be problematic for a number of patients with depression, due to decreased energy and difficulties concentrating and remembering, and in some cases psychotic symptoms. Therefore, additional non-pharmacological treatment options are needed.

The Protac Ball Blanket™ is an option that can be used in all patients including patients with severe cognitive deficits due to depression. It has been shown to decrease sleep disturbances in children with ADHD [16]. Further, it has been used in adult psychiatric inpatient settings in Denmark since the early 1990s for patients suffering from depression, anxiety, agitation, manic episodes, and psychosis. From a clinical perspective, the blanket has been found to enhance the patient's awareness of the body and its physical delimitation which relieves restlessness, stress, and anxiety and provides a sense of security and calm in mind and body, which for some resolves in improved sleep quality. The theory underlying the reasons for using the PBB for calming purposes is based on theories of Sensory Integration [16–18]. It is hypothesized that the deep pressure stimulation and the sensory inputs from the weight of the blanket are providing sensory input to the Proprioceptive System located in our muscles and joints. This provides us with a sense of body awareness and the movement of the loose plastic balls in the blanket which provide sensory input to the Tactile System reduces the body's physiological level of arousal and stress, which might improve sleep. Clinical experiences support the use of PBB in depression, but to our knowledge, there are no studies on the exact effects of the blanket and the appropriateness of using PBB in insomnia among adults with depression. Two published dissertations on sleeping problems due to dementia or sense of touch and sense of movement issues in children indicate calming effects of using ball blankets [18, 19]. Overlap in symptoms between these conditions and depression, i.e., anxiety and sleep disturbances, suggest an effect in depression. Currently, ball blankets are used as a non-evidence-based treatment option among adults with depression. However, lack of evidence limits the use in the adult population or may expose some to a useless treatment. Further, if ball blankets are beneficial for a proportion of patients with depression, the lack of data on adult patients hampers further development and improvement of the PBB for the benefit of patients.

An important goal in the treatment of depression is to increase the total sleep time, minimize the sleep onset latency, and improve quality of sleep, and at the same time minimize the use of sedatives [1, 8, 20]. We hypothesize that PBB will extend sleep durations, minimize the sleep onset latency, reduce the number of awakenings, reduce wake after sleep onset, reduce the need for sedatives, improve the quality of sleep, and reduce the self-reported symptoms in patients with insomnia due to depression.

Methods/design

Objectives

The objective is to investigate the efficacy of PBB on insomnia caused by depression in a randomized controlled design.

Hypotheses

The use of PBB on patients with insomnia due to depression will

Primary goal

1. Extend the total night-time sleep and

Secondary goals

2. Reduce sleep onset latency
3. Reduce the number of awakenings
4. Reduce wake after sleep onset

5. Reduce the need for sedatives
6. Improve the quality of sleep
7. Reduce the self-reported symptoms of patients with depression

Trial design and study setting

This multicentre trial has a randomized 2-sequence, 2-period, 2-treatment crossover design. The rationale for choosing a crossover design is as follows:

1. Traditionally, the recruitment of depressed patients for research trials is heavily challenged due to the nature of depression, and by choosing a crossover design, we can achieve the same precision as a parallel group trial with a lower sample size [21].
2. We further expect easier recruitment and fewer drop-outs as all patients get to try the PBB intervention compared to a parallel group design.

We are not including a washout period in the trial design for one reason:

1. The clinical nature and mechanism of the PBB is unlikely to have a residual effect that persists into the subsequent period, as PBBs only cause effect when patients are exposed to the product.

The data collection period lasts 4 weeks (28 nights in total) with planned inclusion of 45 patients. The study protocol adheres to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines [22].

The trial takes place in two outpatient settings, The Mood Disorders Clinic, Aarhus University Hospital Psychiatry, Central Denmark Region, and in the Mental Health Department Odense – University Clinic, Mental Health Service, Region of Southern Denmark. Both hospitals are public university hospitals. In Denmark, public hospitals containing outpatient clinics are free of charge and treat all patients in need of urgent treatment of depression.

Eligibility criteria

Patients will be recruited through their primary contact in the clinics. The project manager (PhD student and psychiatric nurse (STK)) and three research assistants (two psychiatric nurses and a medical student) will perform the interventions.

Inclusion criteria

1. Participants: Patients with first depressive episode or with recurrent depressive disorders according to ICD-10 (F32–33) or F32–33 in combination with anxiety disorders F40–41.2 (males and females, aged ≥ 18 years) who receive outpatient treatment in The Mood Disorders Clinic, Aarhus University Hospital Psychiatry, Denmark, and in the Mental Health Department Odense – University Clinic, Mental Health Service, Region of Southern Denmark.
2. Participants must
   - Experience poor sleep and have a Global Pittsburgh Sleep Quality Index Score ≥ 5 [3, 5, 14].
   - Report one or more of the following:
     (a) Sleep onset latency ≥ 31 min, occurring ≥ 3 nights a week, for ≥ 14 days, [14, 23]
     (b) Wake time after sleep onset of ≥ 31 min occurring ≥ 3 nights a week for ≥ 14 days, [14, 23]
     (c) Early morning awakenings ≥ 3 nights a week for ≥ 14 days [14, 23].

In this trial, early morning awakening is defined as the final morning awakening with a wake-up time ≥ 1 h prior to desired wake up time [14, 24, 25].

Exclusion criteria

- Patients that, according to ICD-10 criteria, have been depressed > 2 years
- Patients suffering from hypersomnia (ICD-10: F51.13)
- Patients with harmful use of or dependence on psychoactive drugs (ICD-10: F10–19)
- Patients with diseases directly influencing sleep quality (such as severe chronic pain issues, sleep apnoea)
- Patients who report breathing issues during the eligibility PSQI interview
- Patients with Circadian Rhythm Sleep-Wake Disorders (ICD-10; G47.20–47.26)
- Participation in other research interventions during the intervention period.

Intervention

The intervention is the 7-kg Protac Ball Blanket™ Flexible cotton 200 cm filled with loose quit plastic balls. The blanket is characterized by the movement of the plastic balls, which provides a changing sensory stimulation. For more information, see www.protac.dk.

Treatment as usual in this trial refers to the regular duvet each patient usually uses when sleeping at home. Information (e.g. size, weight, material) on each of the patient's duvets will be registered before inclusion for the purpose of describing the average duvets used as control blanket in this trial.

Actigraphy

Actigraphy will be used as an instrument to objectively evaluate sleep in this trial.

The devise used is a Motionlogger Micro Watch (Version 1.99.5.1.) from Ambulatory Monitoring Inc. New York, USA. It is a portable device that is the size of a large wristwatch. The actigraph is an accelerometer that detects the intensity and the amount of movements as a function of time [26]. Movements are monitored continuously and stored within the device. Subsequent analysis of frequency and patterns of movement by means of validated algorithms permits detection of sleep-wake patterns. For this trial, movements will be sampled in 1-min epochs. The data activity collection modes are Zero Crossing (ZC) and Proportional Integrating Measure (PIM) [26, 27]. All movements that are scored above a preset threshold using the algorithm Cole-Kripke scoring algorithm are scored as "awake" and those that are below this threshold are scored as "sleep". The algorithm correctly distinguished sleep from wakefulness 88% of the time when compared to polysomnography [27].

All patients will be asked to wear the actigraph on the wrist of their non-dominant hand for the consecutive 4 weeks (28 nights in total) in their own home environments. As the device is waterproof, patients are instructed to wear the actigraph 24 h a day, including when taking showers. Patients are instructed to press the event-marker as they go to bed, wake up, and when they get out of bed at the start of the next day. These starts and stop intervals will be registered in sleep diaries as patients will be able to visually see if they forgot the registration.

STK and an experienced sleep scientist will perform the scoring and analysis of actigraphic records. The degree of agreement between raters will be calculated and reported using the Intraclass Correlation Coefficient. Data will be analysed using the MotionLogger Analysis Software program Action-W (AW2) (Version 2.7.2).

The pertinent sleep variables chosen for this trial are total sleep time after sleep onset (in minutes) (TST), sleep onset latency (SOL), number of awakenings, and wake after sleep onset (WASO) (for definitions of variables, see the "Outcomes" section).

The practicalities of the trial

Figure 1 outlines the participant timeline, and Fig. 2 shows the standard protocol items recommended by SPIRIT: Schedule for enrolment, intervention, and assessments. Additional file 1 presents The Standard

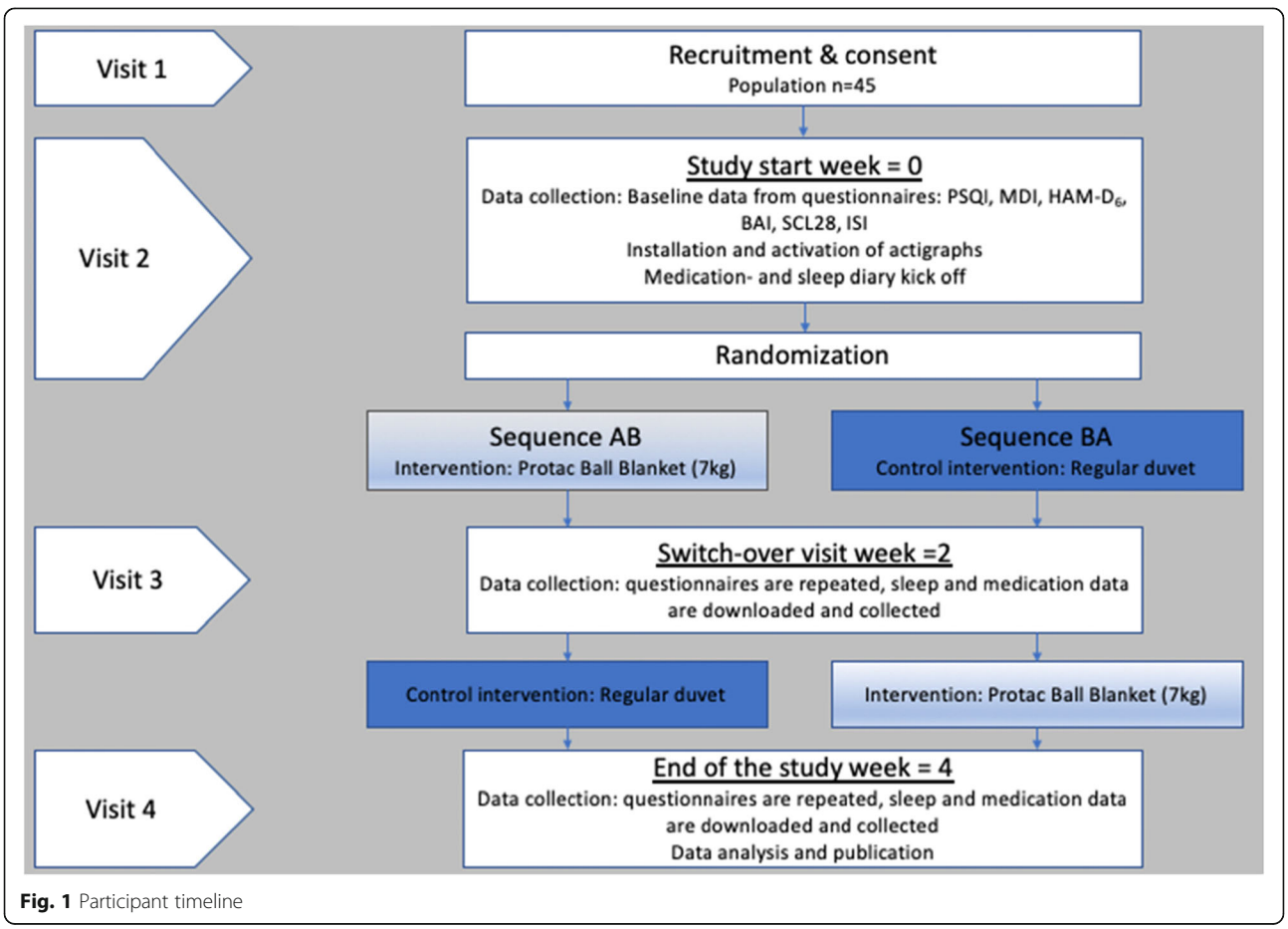

Fig. 1 Participant timeline

STUDY PERIOD					
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT**	$-t_1$	Baseline 0	2 weeks (t_1)	4 weeks (t_2)	Year 2022 (t_3)
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Activation of actigraphs		X			
[Intervention AB: Protac Ball Blanket, Flexible (7kg]					
[Intervention BA: Regular duvet: Treatment as usual]					
Cross-over			X		
ASSESSMENTS:					
[Socio-demographic and medical variables]	X				
[Total nighttime sleep (TST)]					
[Sleep onset latency (SOL)]					
[Number of awakenings (NA)]					
[Wake after sleep onset (WASO)]					
[PRN "When nessary" medication]					
[Sleep quality (PSQI)]		X	X	X	
[Insomnia Severity Index (ISI]		X	X	X	
[Hamilton Depression Scale (HAM-D_6]		X	X	X	
[Major Depression Inventory (MDI)]		X	X	X	
[Beck Anxiety Index (BAI)]		X	X	X	
[Patient Reported Outcomes (SCL-28)]		X	X	X	
Data analysis					X
Knowledge dissemination					X

Fig. 2 Study schedule for enrolment, intervention, and assessments

Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.

The participant timeline (Fig. 1) shows patients will meet with data collectors four times in total. Initially for the purpose of recruitment and written consent (visit 1), the second visit (Visit 2) consists of the installation and activation of actigraphs. Baseline data will be gathered using six validated questionnaires (see the "Data collection methods" section for further details). Patients will be introduced to the sleep and medication diary (Table 2) presented as a supplementary material. Data from sleep diaries will be used to aid the process of scoring sleep-wake stages, when analyzing patients' actigraphic sleep records. Subsequently, patients are randomized into either (1) sequence "AB" or (2) sequence "BA" each lasting 4 weeks. Patients randomized

to the AB sequence receive treatment A (Protac Ball Blanket™, Flexible, 7 kg) in the first 2 weeks (14 nights) and switch to treatment B (treatment as usual = regular duvet) in the second period, whereas patients that are randomized to the BA sequence receive treatment B in the first period and treatment A in the second period. This means that participants will serve as their own controls.

In both sequences, patients receive general sleep advice prior to participation [4]. The rationale behind this is to avoid behavioural irregularities between periods in order to make comparison of data possible. Patients are recommended to avoid major variations in their sleep-wake patterns from day to day during the trial. But also to avoid major variations in their sleep environment and nicotine, caffeine, alcohol and food consumption directly before bed. Patients are also advised to limit daytime naps to a maximum of 30 min.

The third visit (visit 3) at day 15 consists of a switch-over visit to either receive the intervention or treatment as usual. All six questionnaires will be repeated. Data concerning sleep and medication will be downloaded from actigraphy and collected from diaries for the first 2-week period (14 days and nights). The procedures will be repeated at the end of the study (week four = day 29) at visit 4.

The investigators allow a + 7-day non-compliance with the scheduled visit dates (2 weeks apart) in case patients experience relapse or become ill, which can hinder a physical meeting. The allocated treatment will be discontinued in all cases of patient requests, hospitalization, and alcohol or drug abuse. Patients may withdraw from the trial for any reason. The investigators may withdraw the patient from the study if the patient is unwilling or unable to wear the actigraph, as the analysis of the primary outcome data depends on these measures.

In case patients experience intolerable adverse events and other unintended effects of trial interventions or trial conduct, the reasons will be recorded in the patient's Case Report Form (CRF) and securely stored in REDCap. All serious adverse events will be reported to the Danish Scientific Ethics Committee, in the final article, and also to Protac A/S.

The overall protocol adherence is secured by STK and the three research assistants. Individual training of research assistants is completed before study initiation. In order to secure full data completion, we have registered all questions from questionnaires as "required" in the REDCap (REDCap 8.5.22 2019 Vanderbilt University) system. Hereby, the system will immediately remind us of any missing data when patients are present. REDCap (Research Electronic Data Capture) is a secure browser-based, metadata-driven EDC software solution and workflow methodology for designing clinical and research databases. All data from this trial will be securely stored in REDCap.

Outcomes

Primary outcome measure

1. Changes in total night-time sleep (TST) after sleep onset measured by actigraphy [time frame: 4 weeks = 28 days]. The investigators will detect the change in total night-time sleep in minutes (i.e. actual sleep time, excluding sleep latency and wakes after sleep onset) by comparing the means of the difference in total sleep time for each participant between the two periods (A and B). The night-time sleep frame is defined as sleep occurring during a 12-h night interval (21:00 to 08:59 h). The investigators designate the first sleep episode after 2100 h as the first nocturnal sleep episode; if the individual is already asleep at that time, the bedtime will be moved earlier to the first epoch of wake prior to sleep onset [26].

Secondary outcome measures

1. Changes in sleep onset latency (SOL) will be measured by actigraphy [time frame: 28 days]. The investigators will measure patients' sleep onset latency in minutes (time between registered bedtime in sleep diaries and first sleep onset measured by actigraphy) and compare the means of the difference for each participant between the two periods (A and B).
2. Changes in number of awakenings measured by actigraphy [time frame: 4 weeks = 28 days]. The investigators will measure the number of awakenings between first sleep onset and the last wake up time registry and compare the means of the difference between periods (A and B) for each participant.
3. Changes in wake after sleep onset (WASO) will be measured by actigraphy [time frame: 4 weeks = 28 days]. The investigators will measure patients' total time awake between initial sleep onset and the final morning awakening (WASO) in minutes and compare the means of the difference between periods for each participant.
4. Daily use of sedatives and hypnotics will be measured by medication registration use in sleep diaries [time frame: 4 weeks = 28 days]. The investigators will measure the change in total use of per need sedatives and hypnotics in mg by comparing the means of the difference for each participant between periods.
5. Quality of sleep measured by questionnaire using the Pittsburgh Sleep Quality Index (PSQI) [time frame: data will be collected at baseline (visit 2), after 2 weeks (visit 3), and after 4 weeks (visit 4)].

The investigators will measure and report the change in quality of sleep between period A and B. For each participant, the difference between the PSQI measured at the first and the last visit (2 weeks apart) of the exposure period will be subtracted from the difference between the PSQI measured at the first and the last visit (2 weeks apart) of the control period. The total Pittsburgh Sleep Quality Index Score between 0 and 21, with "0" indicating no difficulty and "21" indicating severe difficulties, is reported. Because there will be less than 30 days between assessment at visit 3 and visit 4 and the standard PSQI is a retrospective 30-day instrument, we will use a modified version of the PSQI in which the patients will only be asked about their subjective sleep quality during the past 14 days.

6. Symptoms of depression will be measured by the self-reported Hamilton Depression Rating Scale ($HAM\text{-}D_6$). Data will be collected at baseline, after 2 weeks, and after 4 weeks. The investigators will measure the change in self-reported symptoms of depression between periods. For each patient, the difference between the scores measured at the first and last visit (2 weeks apart) of the exposure sequence will be subtracted from the difference between the scores measured at the first and last visit (2 weeks apart) of the control period. The total sum scores between 0 and 50 will be reported, where higher values represent worse outcome.
7. Insomnia Severity Status will be measured by questionnaire using the Insomnia Severity Index (ISI). Data will be collected at baseline, after 2 weeks, and after 4 weeks. The investigators will measure the change in patients' insomnia severity status between periods. For each patient, the difference between the scores measured at the first and last visit (2 weeks apart) of the exposure period will be subtracted from the difference between the scores measured at the first and last visit (2 weeks apart) of the control period. The total scores between 0 and 28 will be reported, where higher values represent worse outcomes.
8. Patients self-reported symptoms of depression measured by questionnaire using the Major Depression Inventory (MDI) [time frame: data will be collected at baseline (visit 2), after 2 weeks (visit 3), and after 4 weeks (visit 4)]. The investigators will measure the change in self-reported symptoms of depression between periods. For each patient, the difference between the scores measured at the first and last visit (2 weeks apart) of the exposure period will be subtracted from the difference between the scores measured at the first and last visit (2 weeks apart) of the control period. The total score between 0 and 50 is reported, where higher values represent worse outcomes.
9. Symptoms of anxiety will be measured by questionnaire using the Beck Anxiety Index (BAI). Data will be collected at baseline (visit 2), after 2 weeks (visit 3), and after 4 weeks (visit 4).The investigators will measure the change in self-reported symptoms of anxiety between periods. For each patient, the difference between the scores measured at the first and last visit (2 weeks apart) of the exposure period will be subtracted from the difference between the scores measured at the first and last visit (2 weeks apart) of the control period. The total score between 0 and 63 for each visit is reported, where higher values represent worse outcomes.
10. Patient-reported outcomes concerning interpersonal sensitivity, neurasthenia, anxiety, and depression will be measured by questionnaire using The Self-Reported Symptom State Scale (SCL-28) [time frame: data will be collected at baseline (visit 2), after 2 weeks (visit 3), and after 4 weeks (visit 4)]. The investigators will measure the change in self-reported symptoms between period A and B or B and A. For each patient, the difference between the scores measured at the first and last visit (2 weeks apart) of the exposure period will be subtracted from the difference between the scores measured at the first and last visit (2 weeks apart) of the control period. Sub scales are combined to compute a total score. The range for each sub scale is: Interpersonal Sensitivity 0–32, Neurasthenia 0–28, Anxiety 0–32, and Depression 0–24. Both total score and sub scale scores will be reported. The total score ranges between 0 and 112, where higher value represents worse outcomes. Because of an overlap in one question between the sub scales anxiety and depression question, number 31 is only considered in the total sum scores.

Sample size

The power calculation is based on data from a pilot study ($N = 8$) as we have not identified any studies investigating the effects of ball blankets on TST in depressed patients.

The main outcome will be changes in total night-time sleep with and without PBB estimated by the means of the differences between the periods for each participant. The null hypothesis is that there is no change in sleep duration. In the pilot study, the mean sleep duration appeared normally distributed and the mean sleep duration without a ball blanket was 420 min. The standard deviation of the difference between the sleep duration with

and without a ball blanket was 42 min. Based on the potential clinical gains, we aim to be able to detect a change in total sleep duration of 20 min. Assuming that the differences in sleep duration with and without a ball blanket is normally distributed, we performed power calculations for a paired t test, and with an alfa = 0.05 and power = 0.80 the minimum required sample size is $N = 37$. To take into account dropout rates, we aim to include 45 patients.

Recruitment

Patients will be recruited through dedicated teams of nurses, doctors, and psychologists at each hospital. STK or research assistants will participate in weekly treatment conferences in order to help the nurses identify participants according to the eligibility criteria. When potential participants are identified, the primary contact nurse will perform the first contact. She will briefly inform them about the project and hand out the leaflet "Ball blankets as a treatment option for sleep disturbances". In cases where patients show interest, the primary contact nurse will ask for oral permission for STK or one of the research assistants to make contact with them by phone. The contact nurse will also ask for permission to pass on the following information to STK or the research assistants from their medical journal before signing the written consent for participation: their phone number, ICD-10 diagnosis, actual medication prescriptions, and symptoms of sleep disturbances. Shortly after, STK or the research assistants will contact the patient and go over the inclusion criteria on the phone in order to verify the patients' ability to participate. Further, patients will receive oral information on the aim, methods, benefits, and consequences of participation by phone and will be asked for permission to receive written patient participation material by e-mail. This enables the patients to read the material in quiet surroundings in cooperation with a relative. The material is concisely and precisely formulated in order to be easily understood by patients with potential cognitive deficits. Three to 5 days later, STK or one of the research assistants will make contact with the patients in order to confirm or disconfirm their interest in arranging a meeting. At a meeting, oral information on the project will be repeated and questions will be answered for the purpose of gaining written consent. Before signing the consent, each patient will be given a 1-week period for deliberation. The consent will give STK or the research assistants the right to gather the relevant information necessary for the analyses, i.e. medication use and diagnosis. The information will be given by STK or the research assistants in a quiet and undisturbed meeting room at the hospital in the presence of a relative. No further information from patients' medical journal will be gathered after the signing of the written consent unless patients inform us of changes in diagnosis or medication prescriptions. The written consent will be uploaded and stored in REDCap.

If the inclusion rate is unexpectedly low, additional outpatient clinics from other university hospitals will be included.

Allocation

The randomization procedure is permuted-block randomization with varying block sizes of 4, 6, and 8 generated by an independent service provider using REDCap for randomization, meaning detailed information on blocking is unavailable to those who enrol participants and assign interventions. STK and the research assistants have access to the randomization module in REDCap as data will be entered and stored in REDCap. STK and the research assistants will be informed of allocation sequences by pressing the randomization button in REDCap. The allocation sequence is not concealed from the outcome assessors (STK and the research assistants).

Blinding

The administration of blankets will be performed in a randomized order but blinding of the patients and operators is not possible. The data analyses will be performed blinded to the sequence ("AB" or "BA", described above).

Data collection methods

The following data will be collected for the purpose of the research and recruitment:

1. From hospital records: Name, phone number, personal identification number from the Danish Civil Registration System (CPR number), diagnosis, medication prescriptions.
2. From actigraphy (Motionlogger Micro Watch from Ambulatory Monitoring Inc. NY): Total sleep time, sleep onset latency, number of awakenings, wake after sleep onset.
3. From diaries: The use of sleep and anxiety medications, bedtime and time of getting out of bed, number of awakenings and duration, wake after sleep onset and daytime naps including lengths registered in minutes.
4. From six validated questionnaires: The Global PSQI Score using The Pittsburgh Sleep Quality Index (PSQI), the insomnia severity score using the Insomnia Severity Index (ISI), depressive symptoms using the Major Depression Inventory (MDI) and 6-item Hamilton Rating Scale for Depression ($HAM\text{-}D_6$), patients' self-reported symptoms using the Self-reported Symptom State Scales (SCL-28)

and anxiety symptoms using the Beck Anxiety Index (BAI) [3, 25, 28–30].

Data management

All data will be securely stored in REDCap. Using the function "identifier" in REDCap enables the full trial dataset to be anonymized when exported to the Stata IC15 and MotionLogger Analysis Software programs. Sleep data from actigraphy will not include any personal identifiers. Sleep data will be stored under the allocated ID number from REDCap.

The trial will be conducted in adherence to the Declaration of Helsinki - Ethical principles for medical research involving human subjects.

Statistical methods

Paired, two-sided analyses will be performed. If the differences in the measures between the exposure and control periods for each patient are normally distributed, as we expect, we will use a Student's t test to test the null hypotheses of no differences. For the non-normal distributions, non-parametric tests, e.g. Wilcoxon signed-rank tests or Fisher's exact tests will be used.

All data with or without protocol violation will be included in the analysis with complete outcome data for all randomized participants. Because the analyses are based on the differences between period A and B or B and A for each patient, we will perform complete case analysis (i.e. participants with missing actigraphic data from one of the periods will be removed from the analysis). An intention to treat analysis will be performed, i.e. patients that in one or both of the periods use an "incorrect", non-study blanket will be kept in the analyses in their randomized sequence group. We will not account for missing data by imputation.

The level of statistical significance will be set to 5%.

The randomization will determine whether the participants will begin or end with a PBB. The baseline characteristics of these two groups will be presented in a table. Baseline information on sleep will be based on The Pittsburgh Sleep Quality Index (PSQI) and the Insomnia Severity Index (ISI) and not collected via actigraphy.

There will be no wash-out period in this trial because the PBB are expected to have no residual effect persisting in the subsequent periods. This assumption is based on the biological mechanisms of the ball blanket and on clinical experience, but there are no studies to corroborate this expectation. This aspect of the design, however, is expected to lead to bias toward the null, i.e. that the study will not overestimate a potential effect of PBB. The assumption of no carry-over effect in the data will be ruled out in a preliminary test. The sum of the TST values will be calculated for the time period when using PBB and when using patients' own duvets for each participant. This will be compared across the sequence groups by means of an independent t test. If this test yields a statistically significant result, the usual test for differences between the effects of treatment A or B will not be applied [31].

Data will be analysed using Stata IC15 (Stata Corp, College Station, TX, USA).

Data monitoring

No data monitoring committee (DMC) will be established for this trial. Further, no interim analysis will be performed due to the short duration of the trial and a minimal intervention risk.

Discussion

This trial has some limitations. First, we use the PSQI four times during the trial. For the purpose of screening for eligibility and again at visits 2, 3, and 4. However, PSQI is a retrospective 30-day instrument and there will be less than 30 days between assessments at visits 3 and 4 (14 days to be precise) [3]. However, there will be no overlap in the recall periods between visits, as patients are asked about their sleep quality during the past 14 days at these particular two visits using a modified version of the PSQI. This is not expected to cause any bias to the results and interpretations of these as a duration of 2 to 3 weeks is often recommended clinically to differentiate transient from persistent sleep-wake disorders [3]. Most importantly, the PSQI with a 1-month recall period will be used as suggested when screening for eligibility and again at visit 2, which will enable us to separate the transient sleep-wake problems from the persistent sleep-wake problems when recruiting patients for this trial [3].

Second, remission in the underlying depression condition may occur during the trial. In order to minimize the chance of remission and to ensure a constant intensity during both periods (AB and BA), we have chosen a short intervention period. The condition is less likely to develop radically compared to when there are long treatment periods.

Third, patients in outpatient clinics are often in need of acute treatment. Therefore, period effects may occur due to newly introduced medication or medication adjustments during the trial period. Nevertheless, patients will not be excluded from the study due to these conditions as recruitment will then become almost impossible. Besides, such conditions will be equally distributed between sequence groups A-B and B-A due to the randomization. In order to interpret the results critically, we register medication prescriptions at baseline and again in sleep diaries if any changes are made during the trial period.

In summary, this is a randomized crossover multicentre trial testing the efficacy of Protac Ball Blankets™ on insomnia in depression treated in an outpatient setting. An easy identification of the included patients by clearly defined inclusion criteria, together with the multicentre design, supports the broad clinical relevance of the study results. Because both treatments are evaluated for the same individual, the treatment effect can be estimated based on an average of within-individual differences. Hereby, the crossover design removes between-patient variation and patients can indicate clear preferences for PBB vs regular duvets. The outcome of this trial is of high interest as the PBB may be a potential non-pharmacological supplement to medical treatment of patients with insomnia due to depression.

Trial status

Recruitment of participants began on November 21, 2019, and will be completed in May 2021. The manuscript reports protocol version 5, October 9, 2019.

The results will be submitted for publication in an international peer-reviewed open access journal in Spring 2022. Authors will have to meet the principles of the Vancouver Declaration. The results will be presented at both national and international conferences, fairs, and hospitals. Furthermore, the results will be presented at national and international business collaboration meetings by means of Protac A/S contacts. An e-mail will inform the patients about test results if requested.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-020-04638-y.

Additional file 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

Additional file 2. Sleep and medication diary.

Abbreviations

AMI: Ambulatory Monitoring Inc.; BAI: Beck Anxiety Index; HAM-D6: 6-Item Hamilton Rating Scale for Depression; ISI: Insomnia Severity Index; MDI: Major Depression Inventory; PBB: Protac Ball Blanket™; PIM: Proportional Integrating Measure; PSQI: The Pittsburgh Sleep Quality Index; SCL-28: Self-reported Symptom State Scales; SOL: Sleep onset latency; TST: Total sleep time; WASO: Wake after sleep onset; ZC: Zero Crossing

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Authors' contributions

STK: Developed the idea, searched the literature, and drafted the protocol in collaboration with ERL. STK conducted the power calculation in collaboration with Morten Frydenberg (statistician at Aarhus University). STK framed the intervention and control treatment, planned the study and data collection, and planned the analysis in close collaboration with ERL, MB, and PV. STK and ERL raised the funds. STK and ERL conducted a pilot study at Aarhus University Hospital, Risskov $N = 8$ prior to the final draft of the protocol. ERL, PV, and MB revised and approved the protocol. STK registered the trial at ClinicalTrials.gov, obtained ethical approvals, and developed the REDCap database. STK is responsible for patient recruitment and information materials. Materials are all revised by ERL, MB, and PV. STK and ERL are responsible for the overall conducting and completion of the trial. STK and three research assistants employed at the outpatient clinics are responsible for the inclusion, randomization of patients in REDCap, protocol adherence, data collection and monitoring, data management, and data protection. STK, ERL, and PV will perform the analysis in collaboration with a statistician at Aarhus University. STK will draft the final report. PV, MB, and ERL will critically read the final report and thereby have the final authority over the report submitted for publication. All contributors have approved this protocol version submitted to BMC Trials for publication. All authors have read and approved the final manuscript.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

The protocol was approved by the Danish Scientific Ethics Committee (1-10-72-204-18), the Innovation Fund Denmark (7038-00157B), and the Data Protection Agency internally at Aarhus University (2016-051-000001, 1159) before patient enrolment. The trial is registered at the ClinicalTrials.gov database (NCT03730974). The Protac Ball Blanket™ is CE registered.
In case of protocol amendments, all relevant parties will be notified.
We identify no risk, pain or discomfort involved in participating in the trial. Full informed consent will be obtained from all study participants before participation in this trial. The model consent forms are available from the corresponding author on request. This trial does not involve collecting biological specimens, why additional consent provisions are not needed. Participation is completely voluntary, and patients can withdraw from the project at any time. Participation or dropout will have no influence on the usual treatment offered in the psychiatric outpatient clinics. Patients will not receive any payment for participating in the trial. Patient confidentiality will be protected before, during, and after the trial. Data will be entered and securely stored in REDCap. Data will be accessed through secure VPN connections at Aarhus University when analysed by STK. Data will be fully anonymized before being shared with an internal statistician at Aarhus University. The datasets analysed during the current study will be available from the corresponding author on reasonable request. After trial completion, data will be stored at the Danish Data Archive.
A co-operation agreement has been produced and signed in collaboration with the legal department at Aarhus University and Protac A/S, Skanderborg, ensuring (1) that Aarhus University owns the final dataset, (2) the company will have no access to the dataset, and (3) all results will be published regardless of whether the results turn out positive or negative.

Consent for publication

Not applicable.

Competing interests

This is an industry-supported trial. The company Protac A/S covers 50% of STK's salary in collaboration with The Innovation Fund Denmark, who covers the remaining 50%. However, trial sponsors and funders have no role in the study design; the collection, management, analysis, and interpretation of data; the writing of the report; and the decision to submit the report for publication.

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