AĞIRLIKLI YORGAN

BİLİMSEL MAKALELER

İÇERİK

Bu dökümanda ağırlıklı yorganların yenilikçi tamamlayıcı tedavi yöntemi olarak kullanılabilecekleri problemler üzerinde yapılmış bilimsel çalışmaların makaleleleri bulunmaktadır.

SINADA

Ocak.2023

İÇİNDEKİLER

7. **Weighted blanket and sleep medication use among adults with psychiatric diagnosis a population based register study**

   Bu gözlemsel çalışmada, ağırlıklı yorgan kullanımı ile yaygın uyku ilaçlarının kullanımında azalma arasında istatistiksel olarak anlamlı bir ilişki bulunmuştur.

8. **Using weighted blankets in an inpatient mental health hospital to decrease anxiety**

   Bu çalışmaya göre; Ağırlıklı yorgan kullanımı, psikiyatrik bir klinikte bireylerin kaygılarını yönetmelerine yardımcı olmak için güvenli ve potansiyel olarak etkili bir yoldur. Bu çalışma, hasta odaklı olmayan veya travmaları desteklemeyen ilaçlar, tecrit ve fiziksel kısıtlamaların olası bir alternatifini önermektedir.

9. **Intervention with weighted blankets for children with ADHD**

   Dikkat eksikliği ve hiperaktivite bozukluğu olan (DEHB) çocuklarn 25% ile 50%i ciddi uyku sorunları yaşamaktadır. Bu makalede İsviçrede ilaçsız tedavi yöntemi olarak reçetelere yazılan ağırlıklı yorganların verimliliği araştırılmaktadır.

10. **Parents' Experiences of Weighted Blankets' Impact on Children**

    Bu çalışma, Ağırlıklı yorgan kullanan DEHB'li çocukların ebeveynlerinin deneyimlerinden bilgiler sunmaktadır. Ağırlıklı yorgan kullanan çocuklar hızlanmış uykuya dalma süresi, kesintisiz uyku sürekliliği dahil kaliteli uyku deneyimledikleri gözlemlenmiştir. Çocuklar ayrıca artan gevşeme, azalan kaygı ve artan yaşam sevinci göstermişlerdir. Daha iyi bir denge, aile işlevi ve okul ile boş zaman aktivitelerine katılım yoluyla, geliştirilmiş uyku günlük yaşamlarında ustalaşmalarını sağladı.

11. **The effectiveness of weighted blankets on sleep and everyday activities A retrospective follow up study of children and adults with ADHD and Autism**

    Bu çalışmaya göre ağırlıklı yorgan kullanan ADHD ve/veya ASD olan çocuklar ve yetişkinlerde; hızlı uykuya dalma, gece boyunca uyuma ve gündüzleri rahatlama konularında olumlu bir etki gösterdi.

12. **Widespread Pressure Delivered by a Weighted Blanket Reduces Chronic Pain**

    Mevcut çalışma, kronik ağrı şiddetini ve müdahale derecelerini azaltmada ağır bir yorganın, hafif bir yorgana kıyasla daha büyük bir etkisinin olduğunu gösterdi.

13. **Weighted Blankets for Pain and Anxiety Relief in Acutely Injured Trauma Patients**

    Bu çalışma ağırlıklı bir yorganın, akut ağrı ve anksiyete yaşayan travma hastalarında opioid ve anksiyolitik ilaç kullanımını azaltabileceğini göstermiştir.

14. **Weighted Blankets Anxiety reduction in adult patients receiving chemotherapy**

    Bu çalışma, kemoterapi alan hastalarda anksiyeteyi azaltmak için ağırlıklı yorganların kullanımını araştırdı. Ağırlıklı yorganın tamamlayıcı bir tedavi yöntemi olarak kullanılması, çeşitli ağırlıklara sahip kanser hastalarında poliklinik infüzyon ortamında anksiyeteyi azaltabilir.

15. **Weighted Blankets' Effect on the Health of Older People Living in Nursing Homes**

    Bu çalışma, ağırlıklı yorganın, bakım evlerindeki yaşlı insanların yaşam kalitesi, uyku, beslenme, bilişsel fonksiyon, ADL ve ilaç kullanımı gibi sağlık üzerinde bir etkisi olduğunu gösterdi. Ağırlıklı yorganlar, bakım evlerindeki yaşlı insanlar için etkili ve güvenli hayat konforunu artırıcı bir ürün olarak görünmektedirler.

16. **Nursing staff's experiences of how weighted blankets influence resident's in nursing homes expressions of health**

    Elde edilen bulgular, ağırlıklı battaniyenin yaşlı bakım evi sakinlerinin sağlık durumlarında birkaç önemli alanda değişiklik yarattığını göstermektedir. Derin basınç tedavisi, yaşlı bakım evi sakinleri için geliştirilmiş bir alternatif sağlık tedavisi olarak görülebilir. Ancak, herhangi bir tedavinin etkinliği, kişinin özel sağlık ihtiyaçları ve tıbbi geçmişi gibi çeşitli faktörlere bağlı olacaktır.

17. **The use of weighted blankets as a novel approach for treatment of persistent vocalizations in late stage dementia**

    2021 yılında Geriatric Nursing dergisinde yayınlanan makaleye göre, ağırlıklı yorganların geç evre demans hastalarındaki sürekli ses çıkarmalar için umut verici bir ilaçsız tedavi yöntemi olabileceği belirtilmektedir. Ağırlıklı yorganlar sıklıkla derin basınç uygulaması sağlamak için kullanılırlar ve vücut üzerinde sakinleştirici bir etki yaratabilirler. Duyusal entegrasyon teorisi, demans hastalarının duyusal bilgiyi işlemede zorluk yaşayabileceğini ve bu durumun sürekli ses çıkarma gibi davranışsal semptomlara neden olabileceğini öne sürer. Ağırlıklı yorganlar, sinir sisteminin düzenlenmesine ve duyusal yükün azaltılmasına yardımcı olabilecek öngörülebilir ve tutarlı bir duyusal uyaran sağlayabilir.

#1

Ağırlıklı Battaniye Kullanımının Erken Dönemde Uyku Kalitesi Üzerine Etkisi

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Pine Bay Otel - Kuşadası

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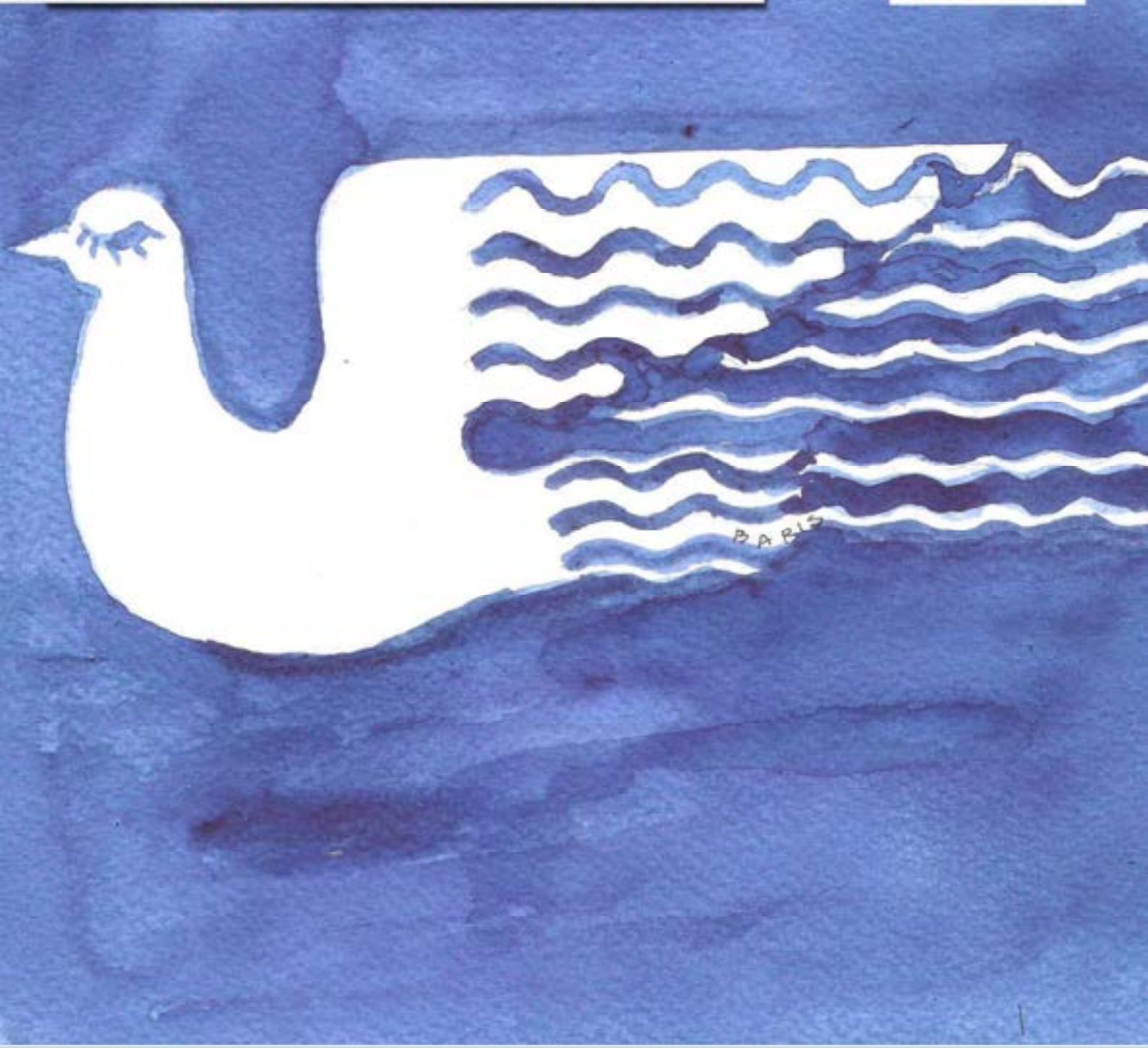

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SÖZEL BİLDİRİ TAM METİNLER

SB13

AĞIRLIKLI BATTANİYE KULLANIMININ ERKEN DÖNEMDE UYKU KALİTESİ ÜZERİNE ETKİSİ

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Giriş

Uyku kalitesinin insan sağlığı ve yaşam kalitesi üzerindeki etkileri günümüzde çok daha iyi anlaşılır hale gelmiştir. Uyku ile ilişkili bozuklukların tanınması ve tedavisinin yanı sıra, uyku hijyeni ve çevresel koşulların düzenlenmesi ile ilgili çok sayıda yaklaşımlar ortaya çıkmaktadır. İnsomni alt tiplerinden psikofizyolojik insomnide daha belirgin olmak üzere, insomniye koşullanma, fatig, anksiyete ve depresyonun sıklıkla eşlik ettiği bilinmektedir. İnsomni tedavisinde bilişsel davranışçı terapi ve farmakolojik tedavilerin yanı sıra, farmakolojik olmayan yöntemler, günümüzde giderek daha fazla tercih edilir hale gelmiştir. Ağırlıklı battaniyelerin, derin bası uyarımı ile anksiyete hissini azalttığı ve böylelikle uyku kalitesini arttırdığına yönelik yeni bilgiler mevcuttur (1). Vücudun çok farklı bölgelerinde aynı anda tendon, kas ve eklemleri uyararak, akupunktur ve masaja benzer bir etki gösterdiği öne sürülmektedir.

Amaç

Çalışmamızda, ağırlıklı battaniye kullanımının psikofizyolojik insomni tanısı alan hastalarda kısa süreli kullanımı sonrasında, sübjektif ve objektif etkilerinin araştırılması hedeflenmiştir.

Yöntem

Çalışmamızda uyku laboratuvarına Ekim 2021 ve Ağustos 2022 tarihleri arasında başvuran ve klinik olarak Uluslararası Uyku Bozuklukları Sınıflamasına (2) göre insomni tanısı alan hastalar değerlendirilmiştir. İlk gece polisomnografi (PSG) tetkikinde altta yatabilecek uyku apnesi gibi ikincil nedenleri dışlanan ve primer psikofizyolojik insomni tanısı konulan hastalar ardışık ve prospektif olarak çalışmaya dahil edilmiştir. Çalışma, özel bir ağırlıklı battaniye üreticisi tarafından finansal olarak desteklenmiştir (CTF Etik kurul onayı alınmış ve tüm hastalardan yazılı onam alınmıştır). Tüm hastalara, hastaların kilosunun □%10'una denk gelecek şekilde 6kg veya 8kg olan battaniyeler verilmiş ve evlerinde en az üç gün süre ile kullanmaları istenmiştir. Hastalar yaklaşık bir haftanın sonunda uyku laboratuvarında tekrar tüm gece PSG tetkiki ile incelenmiş ve ağırlıklı battaniye kullanımının sübjektif etkileri İnsomni Şiddet Skalası (3) ile değerlendirilmiştir.

Bulgular

Çalışmamızda toplam 19 hasta değerlendirildi; ancak burada10 hastanın değerlendirme sonuçları verilmiştir. On hastanın yedisi kadın (%70) ve üçü erkekti (%30). Hastaların yaş ortalaması 50,3±6,8 yıl olarak hesaplandı. Sübjektif olarak değerlendirildiğinde beş hastada (%50) belirgin fayda olduğu izlendi. İnsomni şiddet skalasındaki farklılık ise, fayda gördüğünü ve görmediğini ifade eden iki hasta grubunda istatistiksel olarak anlamlı bulunmadı (p=0.256). Sübjektif olarak uyku kalitesinde fayda görmediğini belirten hastalar sorgulandığında, ağırlıklı battaniyenin önemli dezavantajlarından bir olan vücut sıcaklığındaki artış ve buna bağlı terleme gibi istenmeyen etkilerinin olduğu bilgisi alındı.

İlk ve ikinci gece PSG parametreleri değerlendirildiğinde, uyku etkinliğinin (UE) %50 hastada arttığı izlendi; ortalama UE değerindeki değişim ise anlamlı değildi (p=0.714). Buna karşın, derin NREM (N3) uyku evre süresinde istatistiksel olarak anlamlı bir artış (%7,1±6,0 karşın %9,1±7,4; p=0.040) izlendi. Ek olarak, periyodik ekstremite hareketleri indeksinin de ikinci gece PSG tetkikinde istatistiksel olarak anlamlı bir düzeyde azaldığı görüldü (12,8±20,8/saat karşın 9,0±16,7/saat; p=0.001) görüldü.

Sonuç

Çalışmamızda, ağırlıklı battaniye kullanımının primer psikofizyolojik insomni tanısı alan hastalardaki kısa dönem etkileri araştırılmıştır. Her ne kadar sübjektif veriler açısından istatistiksel olarak anlamlı veriler elde edilemese de, PSG verilerinde derin NREM (N3) uyku evre süresinde anlamlı düzeyde artış izlenmiştir. Daha önce 120 hasta üzerinde yapılan bir çalışmada (1), dört hafta boyunca ağırlıklı battaniye kullananlarda insomni şiddetinin önemli ölçüde azaldığı, uykuyu daha iyi sürdürebildikleri, depresyon ve anksiyete şikayetlerinin de azaldığı bildirilmiştir. Çok yeni tarihli bir diğer çalışmada da (4) 26 genç ve sağlıklı yetişkinde ağırlıklı ve hafif battaniye kullanılarak uyku öncesi tükürük melatonin ve oksitosin hormon düzeyleri karşılaştırılmış, ağırlıklı battaniye kullanan bireylerde uyku öncesi tükürük melatonin konsantrasyonlarının daha yüksek olduğu bildirilmiştir. Bu bilgiler ışığında, ağırlıklı battaniye kullanımının muhtemelen derin bası uyarımı ve melatonin arttırıcı etkileri ile anksiyeteyi azalttıkları ve derin uykuyu arttırdıkları söylenebilir. Özellikle farmakolojik tedaviyi istemeyen hastalar için ağırlıklı battaniyeler, önemli bir tedavi imkanı sunmaktadır.

Çalışmamızda, ek olarak, PSG kayıtlarında periyodik ekstremite hareketleri indekslerinde istatistiksel olarak anlamlı oldukça belirgin bir azalma saptanmıştır. Periyodik ekstremite hareketlerinin de uykuyu sürdürme güçlüğüne neden oldukları göz önüne alındığında, bu mekanizma üzerinden de ağırlıklı battaniyelerin uyku üzerinde olumlu etkileri olduğu söylenebilir. Literatürde, ağırlık battaniye kullanımı ile periyodik ekstremite hareketleri arasındaki ilişkinin bildirildiği bir çalışma izlenmemiştir. Ancak bu önemli veri, ağırlıklı battaniyenin insomninin yanı sıra periyodik ekstremite hareket bozukluğu veya huzursuz bacaklar sendromunda da olası etkilerini göz önüne koymakta olup, bu konuda ileri çalışmalara ihtiyaç duyulmaktadır. Ağırlıklı battaniyenin uyku bozuklukları alanında kullanım alanına sahip olacağı görülmektedir. Çalışmamızda elde edilen verilerimizin daha yüksek hasta sayıları ile ve kontrol grubu karşılaştırmalı çalışmalar ile tekrarlanması, özellikle ağırlıklı battaniyeden fayda görecek alt grupların belirlenmesi açısından faydalı olacaktır.

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#2

A weighted blanket increases pre-sleep salivary concentrations of melatonin in young, healthy adults

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RESEARCH ARTICLE

A weighted blanket increases pre-sleep salivary concentrations of melatonin in young, healthy adults

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Summary

Weighted blankets have emerged as a potential non-pharmacological intervention to ease conditions such as insomnia and anxiety. Despite a lack of experimental evidence, these alleged effects are frequently attributed to a reduced activity of the endogenous stress systems and an increased release of hormones such as oxytocin and melatonin. Thus, the aim of the present in-laboratory crossover study (26 young and healthy participants, including 15 men and 11 women) was to investigate if using a weighted blanket (~12% of body weight) at bedtime resulted in higher salivary concentrations of melatonin and oxytocin compared with a light blanket (~2.4% of body weight). We also examined possible differences in salivary concentrations of the stress hormone cortisol, salivary alpha-amylase activity (as an indicative metric of sympathetic nervous system activity), subjective sleepiness, and sleep duration. When using a weighted blanket, the 1 hour increase of salivary melatonin from baseline (i.e., 22:00) to lights off (i.e., 23:00) was about 32% higher ($p = 0.011$). No other significant differences were found between the blanket conditions, including subjective sleepiness and total sleep duration. Our study is the first to suggest that using a weighted blanket may result in a more significant release of melatonin at bedtime. Future studies should investigate whether the stimulatory effect on melatonin secretion is observed on a nightly basis when frequently using a weighted blanket over weeks to months. It remains to be determined whether the observed increase in melatonin may be therapeutically relevant for the previously described effects of the weighted blanket on insomnia and anxiety.

KEYWORDS
alpha-amylase, cortisol, melatonin, oxytocin, sleep, weighted blanket

1 | INTRODUCTION

Weighted blankets have emerged as a method within the scope of occupational therapy practice to ease conditions such as insomnia and anxiety (Eron et al., 2020; Gee, Peterson, Buck, & Lloyd, 2016). For example, a study involving 120 psychiatric patients found that the use of a weighted blanket during bedtime for over 1 month eased the severity of insomnia more than among patients using a light blanket during sleep (Ekholm, Spulber, & Adler, 2020). In addition, depression and anxiety symptoms decreased significantly in participants using the weighted blanket (Ekholm et al., 2020). However, the potential mechanisms underlying the sleep-improving and anxiolytic effects of the weighted blankets remain unclear. One hypothesis is that weighted blankets may have a calming effect through deep pressure stimulation (Eron et al., 2020). In support of this hypothesis, using a weighted blanket in a supine wake position has been shown to lower electrodermal activity (Mullen, Champagne, Krishnamurty, Dickson, & Gao, 2008), a proxy of sympathetic nervous system (SNS) activity (Miller et al., 1999). Additional mechanisms potentially accounting for the calming effects of deep pressure stimulation may be activation of the oxytocinergic system and reduced physiological and behavioural reactivity to stressors as seen after stimulation of the cutaneous sensory nerves, e.g., unmyelinated C-tactile afferents in the skin (Case et al., 2021; Löken, Wessberg, Morrison, McGlone, & Olausson, 2009; Marshall, Sharma, Marley, Olausson, & McGlone, 2019; Olausson et al., 2002, 2008; Portnova, Proskurnina, Sokolova, Skorokhodov, & Varlamov, 2020; Walker, Trotter, Swaney, Marshall, & Mcglone, 2017).

Oxytocin is produced by the hypothalamic neurons and released into the circulation through the neurohypophyseal system (Uvnäs-Moberg, 1997a). It has several biological effects, e.g., the promotion of labour and breastfeeding, decreasing fear, pain, and stress, and increasing levels of wellbeing and calm (Heinrichs, Baumgartner, Kirschbaum, & Ehlert, 2003; Moberg, Handlin, & Petersson, 2020; Uvnäs Moberg, Handlin, Kendall-Tackett, & Petersson, 2019; Uvnäs-Moberg, Handlin, & Petersson, 2015). However, whether weighted blankets increase the release of oxytocin is unknown.

Melatonin is produced by the pineal gland and plays an essential role in sleep timing (Dawson & Encel, 1993). In addition to ambient light (Brzezinski, 1997), non-photic cues such as physical activity, meal patterns, and social activities can impact the release of melatonin in humans (Mistlberger & Skene, 2005). However, whether weighted blankets alter melatonin release has not been investigated experimentally.

Thus, the primary aim of the present in-laboratory crossover study was to investigate if using a weighted blanket at bedtime results in higher salivary concentrations of melatonin and oxytocin compared with when using a light blanket. In addition, we also examined possible differences in salivary concentrations of the stress hormone cortisol, alpha-amylase activity (a measure of SNS activity [Rohleder, Nater, Wolf, Ehlert, & Kirschbaum, 2004]), subjective sleepiness, and sleep duration.

2 | METHODS

2.1 | Participants

Twenty-six normal-weight young, non-smoking men and women participated in the study (Table 1 for sample characteristics). All of the included women ($n = 11$) were on hormonal monophasic contraceptives to account for the potential confound of the menstrual cycle (Baker & Lee, 2018). A screening interview ensured that the participants reported good general health status. For example, those indicating that they suffered from an acute or chronic disease, including somatic and psychiatric conditions, were not considered to be eligible for study inclusion. A history of weighted blanket use before the study, as well as confirmative answers to either of the following questions, led to exclusion from the study: "Do you sleep uncovered?", "Did or do you have difficulties falling and staying asleep?", "Did or do you suffer from heavy snoring or other sleep-related breathing disturbances?", "Did a medical examination reveal any other sleep disorders?", "Do you habitually sleep less than 7 hours?", "Do you habitually go to bed before 22:00 or later than 24:00 on working days?", "Do you regularly use medications, drugs, or nicotine?", "Do you consume more than five standard units of alcohol or caffeine beverages per day?", and "Did you travel across time zones in the last months, or do you have plans to travel across time zones in the next weeks?". We also excluded subjects in the case of extreme chronotype, as measured by a score of ≤ 30 or ≥ 70 in the Morningness-Eveningness Questionnaire (Horne & Ostberg, 1976).

As the study was partially performed amid the COVID-19 pandemic, the participants were only invited for onsite experimental sessions when they were free of any COVID-19-related symptoms. The regional Ethics Committee approved the study protocol (Dnr 2019–04541), which has been preregistered (https://osf.io/b3qxk). Furthermore, all the participants provided informed consent in written and oral form before partaking in the study.

2.2 | Experimental procedure

All participants underwent two experimental sessions in a randomised and counterbalanced order in our laboratory, as outlined in Figure 1. The day before the first testing session, the participants visited the laboratory for an adaptation night. The adaptation night served to adjust the participants to the experimental setting. In addition, before each experimental night, the participants were asked to habituate to both the light and the weighted blanket, either for three nights at home before the adaptation night or for four nights at home before the second experimental session. On the testing days, the subjects were provided a standardised dinner upon arrival at the sleep laboratory (19:00). Between 19:00 and 21:00, the subjects sat in front of two light-emitting diode boxes (0.4 m distance; each box emitted 300 lux; Wake-up light Philips HF3531, UK) to minimise inter-individual differences in the timing of the dim-light melatonin onset. Between 21:00 and 23:00, the room lights were dimmed to 5 lux. In

TABLE 1 Sample characteristics

Characteristic	Overall	Weighted blanket	Light blanket	*p*-value
Number of men	15	--	--	--
Number of women	11	--	--	--
BMI, kg/m^2[a]	22.3 ± 0.5	--	--	--
Age, years[a]	24.4 ± 0.6	--	--	--
Habitual nighttime sleep duration, hours[a]	8.1 ± 0.9	--	--	--
Baseline values at 22:00				
Salivary alpha-amylase levels, U/mL	--	74.9 ± 13.8	84.5 ± 17.1	0.751[b]
Salivary melatonin levels, pg/mL	--	8.9 ± 1.5	9.4 ± 1.6	0.347[b]
Salivary cortisol levels, mmol/L	--	1.1 ± 0.1	1.1 ± 0.1	0.964[c]
Salivary oxytocin levels, pg/mL	--	1298 ± 184	1487 ± 200	0.230[b]
Karolinska Sleepiness Scale, points	--	5.1 ± 0.3	5.7 ± 0.3	0.096[b]

Data are shown as mean ± SE, unless otherwise stated.
BMI, body mass index.
[a]Assessed/surveyed during the screening session.
[b]Wilcoxon signed-rank test.
[c]Paired Student's *t*-test.

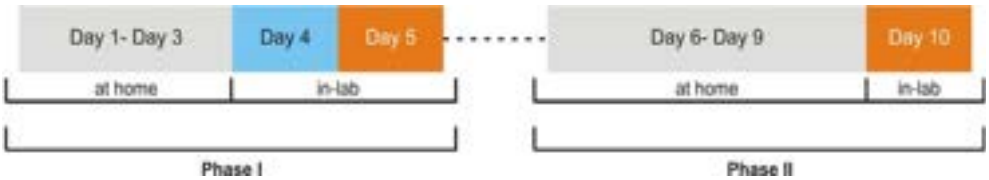

FIGURE 1 Overview of the randomised, counterbalanced within-subjects design. Boxes highlighted in grey illustrate the two at-home adaptation phases (i.e., day 1 to 3 and day 6 to 9); in blue, the sole adaptation night (day 4); and in orange, the two experimental days (days 5 and 10)

one session, the subjects used a weighted blanket (Cura of Sweden, Sundsvall, Sweden) covering the extremities, abdomen, and chest, in a supine position 1 h before and during 8 h of sleep opportunity (scheduled between 23:00 and 07:00). The filling of the weighted blanket consisted of honed glass pearls combined with polyester wadding, corresponding to 12.2% of the participants' body weight. In the other experimental session, the subjects used a light blanket, which weighed 2.4% of their body weight.

To assess the effects of the blankets on melatonin, alpha-amylase, cortisol, and oxytocin, saliva was collected every 20 min between 22:00 and 23:00. Additionally, the participants' subjective sleepiness was assessed every 20 min using the Karolinska Sleepiness Scale (KSS; Gillberg, Kecklund, & Akerstedt, 1994) during the hour before lights off (i.e., 22:00–23:00), and the next morning (i.e., at 07:00 and 08:00, respectively). Sleep duration in each experimental night was recorded with the ŌURA ring (Ōura Health, Oulu, Finland). The ŌURA ring is a commercial multi-sensor wearable that measures multiple physiological variables and shows acceptable accordance with polysomnography-assessed sleep duration (de Zambotti, Rosas, Colrain, & Baker, 2019). For the present study, we focused on total sleep duration as an outcome.

2.3 | Saliva assays

Saliva was collected by passive drool using a Saliva Collection Aid (Salimetrics, State College, PA, USA), stored immediately on ice until 23:00, and then kept at −80°C until analysis. Melatonin saliva tubes were wrapped with aluminium foil to avoid photodegradation (Andrisano, Bertucci, Battaglia, & Cavrini, 2000). Saliva melatonin concentrations were determined by a commercially available immunoassay with luminescence detection (LIA, IBL-International, Hamburg, Germany). Salivary free cortisol was measured using a chemiluminescence immunoassay (CLIA; IBL International, Hamburg, Germany). For alpha-amylase analysis, we applied a quantitative enzyme-kinetic method (Rohleder & Nater, 2009). Finally, salivary oxytocin was measured using an Oxytocin ELISA kit (Enzo Life Sciences, New York, USA).

2.4 | Statistical analysis

Data were analysed using IBM SPSS Statistics 26 (SPSS Inc. Chicago, IL, USA). To account for intra- and inter-individual differences in

baseline salivary concentrations of melatonin, cortisol, oxytocin, as well as alpha-amylase activity, we calculated the difference between the baseline (i.e., 22:00) and post-baseline time points (i.e., 22:20, 22:40, and 23:00). We also baseline-adjusted the subjective sleepiness scores by subtracting the 22:00 KSS score from those measured at 22:20, 22:40, and 23:00. Data distribution was tested using the Kolmogorov–Smirnov test, and comparisons of baseline values between the blanket conditions relied on a paired Student's *t*-test for normally distributed variables and a Wilcoxon signed-rank test for skewed variables.

We applied generalised linear mixed models (GLMMs; assuming a normal distribution with an identity link function) to determine the effects of the following fixed factors on the outcomes: within-subjects factors BLANKET (i.e., weighted vs. light blanket) and TIME. We also investigated possible interactions between BLANKET and TIME. Unless otherwise specified, data are reported as mean ± standard error (SE). Due to sample size restrictions, we did not investigate possible interactions between BLANKET and biological sex.

Ratings of perceived heaviness of the weighted blanket measured on a 100 mm visual analogue scale were assessed after the end of the second experiment. Using Spearman's correlational analysis, we investigated whether the perceived heaviness of the weighted blanket correlated with the change in salivary concentrations of melatonin, oxytocin, cortisol, and alpha-amylase in the weighted blanket condition. Overall, $p < 0.05$ was considered significant.

3 | RESULTS

3.1 | Effects of the weighted blanket on salivary melatonin, cortisol, alpha-amylase, and oxytocin

No baseline differences in any of the salivary factors were found between the blanket conditions ($p \geq 0.230$ as derived from either a Wilcoxon signed-rank test or paired Student's *t*-test; Table 1). The salivary melatonin concentrations rose on average by about 5.8 pg/mL between 22:00 and 23:00 ($p < 0.001$ for TIME). The average increase in salivary melatonin concentrations between 22:00 and 23:00 was greater in the weighted blanket condition (weighted vs. light blanket: 6.6 ± 0.7 vs. 5.0 ± 0.5 pg/mL; $p = 0.011$ for BLANKET; Figure 2a); however, no interaction between BLANKET and TIME was found ($p = 0.855$).

Salivary cortisol concentrations dropped on average by about 0.2 mmol/L between 22:00 and 23:00; however, no significant main effects of TIME ($p = 0.052$) or BLANKET were observed (weighted vs. light blanket: −0.2 ± 0.03 vs. −0.2 ± 0.04 pg/mL from baseline; $p = 0.992$ for BLANKET; $p = 0.950$ for BLANKET*TIME; Figure 2b).

Compared with its activity measured at 22:00, the activity of salivary alpha-amylase was descriptively but not statistically reduced by about 12 U/mL at 22:20, 17 U/mL at 22:40, and 25 U/mL at 23:00 ($p = 0.213$ for TIME). The change in alpha-amylase activity from baseline did not differ between the two blanket conditions (weighted vs. light blanket: −16.5 ± 4.2 vs. −19.5 ± 5.3 U/mL from baseline; $p = 0.665$ for BLANKET); and no interaction was observed ($p = 0.891$ for BLANKET*TIME; Figure 2c).

Compared with the salivary levels measured at 22:00, oxytocin rose by about 315 pg/mL at 22:20; 112 pg/mL at 22:40, and 84 pg/mL at 23:00; however, no significant main effect of TIME was found ($p = 0.453$ for TIME). The change in the salivary oxytocin concentrations from baseline observed until 23:00 was highly variable within and between subjects and did not reach significance between the weighted and light blanket conditions (251 ± 135 vs. 91 ± 104 pg/mL from baseline; $p = 0.384$ for BLANKET; $p = 0.363$ for BLANKET*TIME; Figure 2d).

3.2 | Effects of the weighted versus light blanket on subjective sleepiness before and after sleep

At 22:00, the participants exhibited a lower KSS score during the weighted blanket condition; however, the difference in sleepiness between the blanket conditions did not reach significance ($p = 0.096$ as derived from a Wilcoxon signed-rank test; Table 1). Irrespective of the blanket condition, compared with the baseline, the KSS score was 0.4 ± 0.1 points higher at 22:20, 0.8 ± 0.1 points higher at 22:40, and 1.0 ± 0.2 points higher at 23:00 ($p = 0.004$ for TIME). The KSS score was about 0.2 ± 0.2 points higher during the weighted than the light blanket condition; however, this difference did not reach significance ($p = 0.215$ for BLANKET). Finally, the change in KSS scores from baseline did not vary by TIME between the blanket conditions ($p = 0.498$ for BLANKET*Time; Figure 2e).

The following morning, i.e., after the participants had slept either with a weighted or a light blanket, no differences in the KSS scores were found between the blanket conditions (weighted vs. light blanket: 4.2 ± 0.2 vs. 4.2 ± 0.2 points; $p = 0.936$ for BLANKET; 07:00: 4.8 ± 0.2; 08:00: 3.5 ± 0.2; $p < 0.001$ for TIME; $p = 0.256$ for BLANKET*TIME).

3.3 | Effects of the weighted versus light blanket on total sleep duration

Due to technical problems connecting the ŌURA ring with the mobile application, on 13 of the 52 experimental nights (25% of the experimental nights), total sleep duration estimates were unavailable for the analysis. No significant differences were found when comparing total sleep duration between the blanket conditions (6.83 ± 0.13 vs. 6.84 ± 0.14 h; $p = 0.986$ for BLANKET).

3.4 | Correlation between perceived blanket heaviness and hormone secretion

As suggested by Spearman correlational analysis, the perceived heaviness of the weighted blanket on a visual analogue scale was inversely associated with the change in salivary melatonin concentrations in the

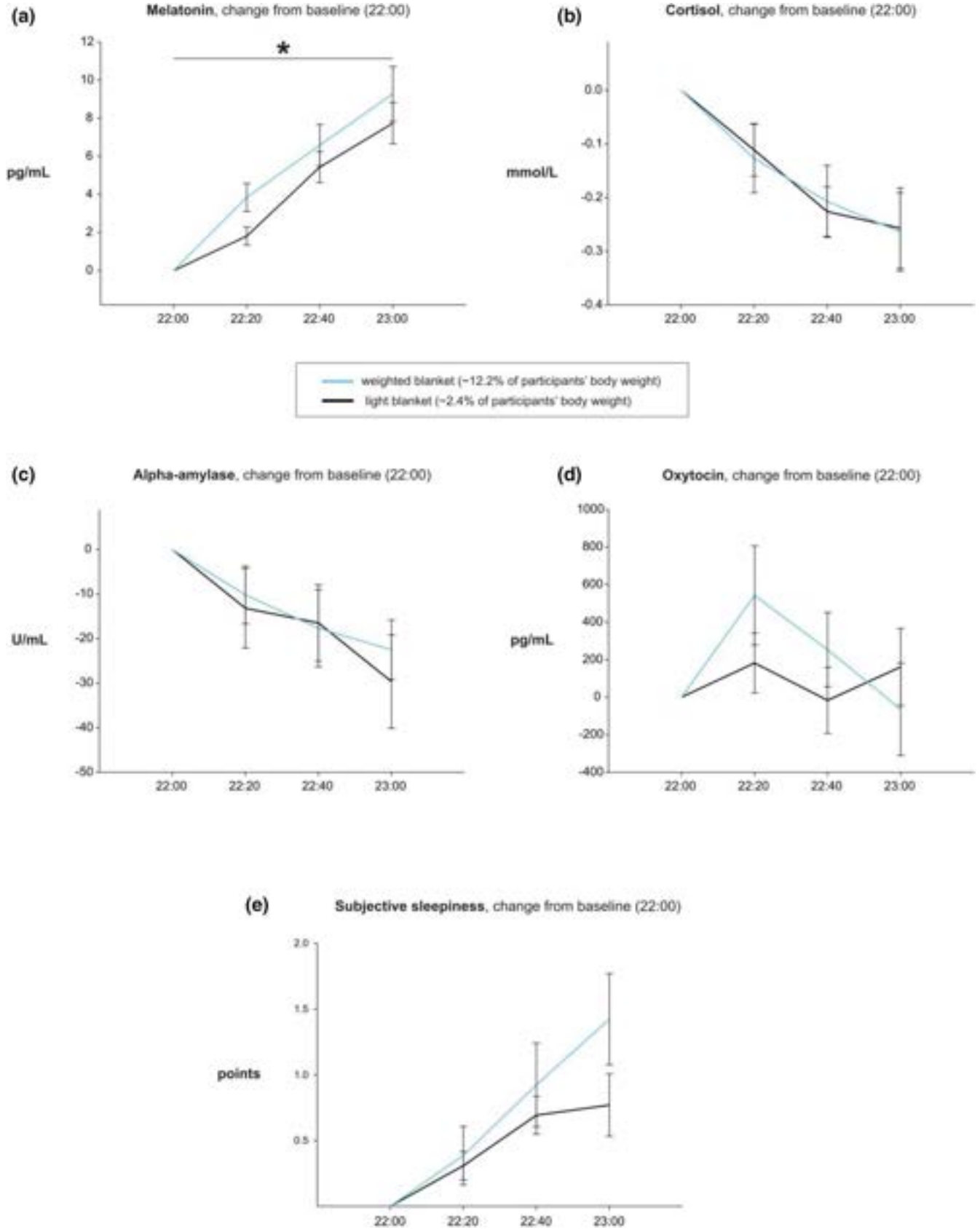

FIGURE 2 Effects of the weighted versus light blanket on salivary (a) melatonin, (b) cortisol, (c) alpha-amylase activity, (d) oxytocin, and (e) subjective sleepiness ratings. $N = 26$ (11 women). For oxytocin, no data from one female subject were available for analysis. *$p < 0.05$ for a main effect of blanket (derived from a generalised linear mixed model using the within-subjects factors blanket and time as fixed factors)

weighted blanket condition (Spearman's rho = −0.384); however, the correlation did not reach significance ($p = 0.064$). No other correlations with perceived heaviness were observed (Spearman's rho; cortisol: −0.190, $p = 0.385$; alpha-amylase: −0.189, $p = 0.388$; and oxytocin: 0.130, $p = 0.565$).

4 | DISCUSSION

In the present experimental study, involving 26 healthy young men and women, we found that using a weighted blanket in bed was associated with a higher increase of salivary melatonin in the hour before sleep than using a light blanket. Some studies suggest that melatonin possesses sleep-promoting and anxiolytic properties (Brzezinski et al., 2005; Madsen, Zetner, Møller, & Rosenberg, 2020; Scheer & Czeisler, 2005). However, whether the observed rise in melatonin accounts for the sleep-promoting and anxiolytic effects of weighted blankets reported previously (Ekholm et al., 2020; Eron et al., 2020; Gee et al., 2016) is unclear.

Our study cannot identify the underlying mechanism for the observed stimulatory effects of the weighted blanket on melatonin. However, one explanation could be that the pressure exerted by weighted blankets activates cutaneous sensory afferents, carrying sensory information via the spinal cord to the nucleus tractus solitarius. This brainstem region has projections to the paraventricular nucleus of the hypothalamus (Saper, Loewy, Swanson, & Cowan, 1976), a brain area hosting parvocellular oxytocinergic neurons. Through their impact on other brain networks, parvocellular oxytocinergic neurons can promote calm and well-being and decrease fear, stress, and pain (Uvnäs-Moberg et al., 2019; Uvnäs-Moberg, 1997b; Eliava et al., 2016). In addition, they also connect to the pineal gland to influence the release of melatonin (Møller, 2021), which could explain the more significant rise in salivary melatonin in the weighted blanket condition. Noteworthy, spinal cord injuries resulting in a total loss of afferent sensory signalling are associated with a complete absence of evening melatonin increase (Verheggen et al., 2012), suggesting a critical role of the peripheral sensory nervous system in regulating the central nervous release of melatonin.

We noticed an initial and transient rise in the circulating oxytocin levels in the weighted blanket condition; however, this effect did not reach statistical significance. Two factors affect the interpretation of these findings. The first concerns the use of commercially available assays for the measurement of plasma oxytocin (including the one used herein), as the presence of multiple immunoreactive products in addition to oxytocin may result in an overestimation of oxytocin (Szeto et al., 2011). Furthermore, oxytocin levels are increased by the oestrogen component of oral contraceptives (McCarthy, 1995), which was used by the women participating in the study and may have affected our ability to detect differences in oxytocin between the blanket conditions.

A previous study found that the one-time use of a weighted blanket resulted in reduced SNS activity (Chen, Yang, Chi, & Chen, 2012). However, in our research, salivary concentrations of the stress hormone cortisol (which dropped before sleep irrespective of the blanket condition) and the mainly sympathetically regulated alpha-amylase (Rohleder et al., 2004) did not differ between the blanket conditions. Hence, our study does not provide compelling evidence that dampening the activity of endogenous stress systems accounts for the sleep-promoting and anxiolytic effects of weighted compared with light blankets. However, we cannot rule out that the activity of endogenous stress systems may have differed between the blanket conditions if saliva had been collected over a more extended period.

While sleepiness increased during the hour before scheduled lights off, we did not find significant differences in subjective sleepiness between the weighted and light blanket conditions before or after one night of sleep. Additionally, the total sleep duration remained unaffected by using a weighted blanket. At first glance, these results may contradict a previous study in which using a weighted metal chain blanket during bedtime over an extended period reduced insomnia severity among patients with psychiatric diagnoses (Ekholm et al., 2020). However, our study involved a highly selected population of healthy young adults without any history of chronic somatic or psychiatric co-morbidities or sleep disorders. Additionally, we investigated the effects of a weighted blanket on sleep only for one night, and sleep was measured with a consumer sleep wearable. Thus, we cannot rule out that weighted blankets may aid sleep in healthy young adults when used over more extended periods or that the effects may have become visible with methods to assess sleep other than the one used in the present study (e.g., polysomnography). In this context, it is also essential to discriminate between the subjective and objective effects of weighted blankets. For example, one study found that children with autism spectrum disorder favoured using weighted blankets, despite a lack of objective changes in their sleep (Gringras et al., 2014).

Several methodological limitations apply to our findings. First, it is unclear whether using different weights of the weighted blanket would have produced similar results. In this context, the perceived heaviness of a weighted blanket, which can vary considerably between subjects with different levels of interoceptive and sensory awareness, could impact the extent to which the blanket affects the salivary secretion of factors such as melatonin. It is also unclear whether similar results would be seen in other populations, e.g., elderly subjects and patients with sleep and neuropsychiatric disorders. Finally, our findings must be confirmed in more extensive studies.

5 | CONCLUSIONS

Our study is the first to suggest that using a weighted blanket may result in a greater release of melatonin at bedtime. However, future studies should investigate whether the stimulatory effect on melatonin secretion remains when using a weighted blanket over more extended periods. It is also unclear whether the observed increase in melatonin is therapeutically relevant.

AUTHOR CONTRIBUTIONS

E.M.S.M., L.T.E., F.A., K.U.V., J.C., and C.B. conceived the study. E.M.S.M., P.X., A.G., J.W., A.A., and A.P.P. contributed to data collection. E.M.S.M., L.E.M.B., A.G., A.A., A.P.P., and C.B. analysed the data. E.M.S.M., A.P.P., K.U.M., J.C., and C.B. interpreted the data. E.M.S.M., A.P.P., and C.B. drafted the paper. L.E.M.B., L.T.E., P.X., A.G., J.W., A.A., F.A., K.U.M., and J.C. provided critical feedback on the draft, and approved it in its final version.

FUNDING INFORMATION

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CONFLICT OF INTEREST

The author F.A. is an employee of Cura of Sweden. None of the remaining authors declare any commercial or financial relationships that could be construed as a potential conflict of interest, nor were they paid by Cura of Sweden for conducting the present experiment.

DATA AVAILABILITY STATEMENT

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to ethical restrictions.

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#3

Positive Effects of a Weighted Blanket on Insomnia

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Research Article

Positive Effects of a Weighted Blanket on Insomnia

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- Blanket

Abstract

Insomnia is a common occurrence and can have a negative impact on physiological, psychological and social well-being. There is a need for simple, effective solutions to increase sleep quality. It has been suggested that weighted blankets and vests can provide a beneficial calming effect, especially in clinical disorders. Hence, we aimed to investigate the effects of a chain weighted blanket on insomnia, using objective and subjective measures. Objectively, we found that sleep bout time increased, as well as a decrease in movements of the participants, during weighted blanket use. Subjectively, the participants liked sleeping with the blanket, found it easier to settle down to sleep and had an improved sleep, where they felt more refreshed in the morning. Overall, we found that when the participants used the weighted blanket, they had a calmer night's sleep. A weighted blanket may aid in reducing insomnia through altered tactile inputs, thus may provide an innovative, non-pharmacological approach and complementary tool to improve sleep quality.

ABBREVIATIONS

ANOVA: Analysis of Variance; ASD: Autism Spectrum Disorders; BMI: Body Mass Index; ISI: Insomnia Severity Index; KSS: Karolinska Sleepiness Scale; PSG: Polysomnography; REM: Rapid Eye Movements; Karolinska Sleepiness Scale; TST: Total Sleep Time; VAS: Visual Analog Scale; WASO: Wake after Sleep Onset

INTRODUCTION

According to most epidemiological studies, up to a third of the population in industrialized countries suffers from poor sleep [1-5]. This problem affects all categories of people from teenagers to the elderly, and is increasing due to modern lifestyles and the associated stressors, especially in cities. The impairment of sleep has short- and long-term effects. It can lead to depression, burn-out, psychosomatic disorders and addictions, as well as other serious health problems (e.g. metabolic, cardiovascular) [3,4,6,7]. It can affect professional lives (e.g. loss in productivity, poor judgments, accidents, inadequate emotional reactions), with great economic consequences. It can also have a negative impact on social and family life. Pharmacological and behavioral (e.g. cognitive, relaxation) methods are commonly used to treat sleep disorders. However, drugs are often addictive or have side effects, and psychological/behavioral methods require long treatment sessions and it may take time to achieve satisfactory results. Hence, there is a need for additional, simpler methods to promote and maintain better sleep.

The application of deep pressure, through for example weighted vests and blankets, has been reported to produce a calming and relaxing effect in clinical conditions such as autism spectrum disorders (ASD), attention-deficit hyperactivity disorder, and pervasive developmental disorders [8-15]. Applying deep pressure has been shown to be beneficial for children with high levels of anxiety or arousal [16] and deep pressure touch may also alleviate anxiety (e.g. in dental environments and bipolar disorder [17,18]). There are also anecdotal reports suggesting that the elderly who suffer from anxiety and dementia may find relief from deep pressure touch and many nursing homes are experimenting with weighted blankets.

A weighted blanket that is more than 10% of a person's body weight has been found to provide beneficial, calming effects [19]. Most of the research on weighted blankets has focused on their use in children with clinical disorders, such as ASD. However, the majority of these studies do not probe sleep objectively. To our knowledge only one study has systematically investigated the use of a weighted blanket during bedtime and this was in children with ASD and severe sleep problems, using some objective measures. The study found no increase in the total sleep time; however, the blanket was favored by both the children and their parents [20].

There is a need for systematic studies into the potential benefits of weighted blankets for sleep, especially for adults and those with insomnia. Hence, the aim of the present study was to investigate whether the use of a weighted blanket may have a

positive impact on adults with sleeping problems, mainly chronic insomnia.

MATERIALS AND METHODS

Intervention

There are several weighted blankets on the market. For this study we used a new type of chain-weighted blanket (Somna AB, Stenkullen, Sweden), currently used both in nursing homes for the elderly and in patients with ASD. The weight is provided by a metal chain construction, which is evenly distributed throughout the blanket and provides constant tactile stimulation across the body. The participant can choose to sleep with the chain or the padding side of the blanket closest to their body (hence provide a different sensation). They can also use an additional quilt, either over or under the blanket. The blanket is weighted without being thick, and the fabric is such that the blanket does not particularly provide additional warmth. Three weights were available (6, 8 or 10 kg) and the participants could select the most comfortable one. The majority of the participants in the present study selected the 8 kg blanket.

Study design

A repeated-measures study was undertaken in two clinical sites in Sweden, over the course of a year. For each participant, the study lasted 4 weeks. There was no control group, as the participants were their own control, with baseline pre-test and post-test measures. The study was approved by the Ethical Committee of the Sahlgrenska Academy in Gothenburg and was conducted according to the Declaration of Helsinki. Written, informed consent was obtained from all the participants before taking part and they were paid for their time. Prior to undertaking the study, an effect size analysis was conducted to ascertain the approximate number of participants required for significant effects. This was based on statistical analyses from objective and subjective results of a previous pilot study on 5 participants. Cohen's d was used to calculate an effect size of 0.75, with a power of 0.8 (ratio 4:1 between type 1: type 2 errors); a minimum of 26 participants was required to gain statistical differences. Hence, we aimed to recruit 30 participants to account for drop-out and technical failures, due to the complexity of the study and its design.

Study population

The inclusion criteria were: participants' of\genders, aged 20-66, complaining of chronic insomnia, which was defined as difficulties in falling asleep and/or maintaining sleep for several nights a week (> 3 days) for more than 3 months, and having feelings of not being refreshed when waking up in the morning. If they were on medication upon entering the study, this was continued throughout the trial period. Otherwise they had to be healthy. The exclusion criteria were presence of illnesses or newly discovered problems (<6 months), for example, sleep apnea, untreated metabolic disorders or high blood pressure. The participants should not have changed any medication in the prior 4 weeks to commencing the study.

Participants were selected by advertising at the sleep clinics and through leaflets on boards. A total of 33 healthy participants complaining of chronic insomnia were recruited for the study; 31 completed the protocol (11 men, 20 women). For further details about the participants, see Table 1. Prior to the study, the participants also completed various questionnaires covering environmental and lifestyle factors, including their health status, irregularity in sleep-wake patterns and life style, variability of sleep during the weekend, the presence of any sleep phase delay or advance, their perception of sleep quality, and if they used any medication.

The level of insomnia per participant was determined according to the 7-item Insomnia Severity Index (ISI) [21], which assesses the nature, severity, and impact of insomnia in their life. Each question is rated from 0 (no problem) to 4 (severe problem), with the total possible score being 28. A score of less than7 reflects no clinically significant insomnia, 8-14 being sub-threshold insomnia, while 15-21 represents moderate insomnia and a score greater than 22 indicate severe insomnia. The 8-item Epworth Sleepiness Scale [22] was used to reflect any daytime consequences of insomnia (i.e. daytime sleepiness). This consisted of a questionnaire with answers ranging from 0 (no chance of dozing) to 3 (high chance of dozing) to give a total out of 24 points.

Procedures

After screening and consent, the eligible participants slept for a week in their habitual environment, which consisted the pre-test baseline period. The following test period followed consisted of two consecutive weeks during which the participant used the weighted blanket every night. They pre-selected a blanket weight, but if they felt that it was too light or heavy, they could change it after no more than two nights into the test. The participant returned the blanket after these two test weeks and slept for one more week in their ordinary, habitual conditions (post-test period).

Methods for studying sleep patterns

The trial design included both objective (physiological) and subjective (self-report) measures.

OBJECTIVE MEASURES

Continuous actigraphy (Actiwatch; Cambridge Neurotechnology Ltd, Cambridge, UK) and comprehensive polysomnography (PSG) recordings, in the participants' own home, were obtained.

The actigraphy watch consisted of an accelerometer that was worn on the same wrist continuously during the 4 week period. Data were stored in the watch unit. Analyses of patterns and frequencies of movements were done by validated algorithms for the recognition of basic sleep-wake patterns. The participants' time-to-bed and waking-up time were reported in their sleep diaries, which defined their sleep periods. The main analyses were conducted on these sleep periods. The variables analyzed included sleep latency, assumed sleep, total wake time, sleep fragmentation index, number of bouts of immobile time and their frequency, as well as the number of sleep bouts and their duration. We did not want to interfere with the ordinary lifestyle and activities of the participants, though we recommended that

Table 1: Details about the participants.

Characteristic	Number	Mean ± SD	Range
Age (all)	31	47 ± 14 years	21-66 years
Males	11	49 ± 15 years	25-60 years
Females	20	43 ± 13 years	21-66 years
BMI (all)	31	25.8 ± 5.2	19.6-45.4
Males	11	27.1 ± 2.9	23.9-30.8
Females	20	25.4 ± 5.8	19.6-45.4
ISI(all)	31	20 ± 5	5-28
Males	11	19 ± 4	11-23
Females	20	20 ± 6	5-28
Epworth(all)	31	6 ± 4	0-12
Males	11	6 ± 3	2-12
Females	20	6 ± 4	0-11
Weight of blanket/weight of participant	31	19% ± 7	12% -38%
Question	**No**	**Occasionally/Yes**	**Often**
Do you take sleep medication?	66%	21%	14%
Do you have an irregular sleep cycle?	66%	21%	14%
Is your sleep different at the weekend?	48%	34%	17%
Do you have a phase delay with sleep?	90 %	10%	
Do you do shift work?	93%	7%	

Abbreviations: BMI: Body Mass Index; ISI: Insomnia Severity Index

they avoid major irregularities, if it meant a large variation in their sleep-wake pattern e.g. going to bed late and getting up late during the weekend. For participants that showed these large irregularities in their routine(defined as exceeding 2 hours deviation for 2 or more days), we restricted the analysis to 5 continuous days/nights for both the pre-test and the test period, which typically did not include weekends where the larger sleeping deviations tended to occur.

The PSG was measured using a 23 channel ambulatory polygraph that recorded electroencephalography (electrical brain activity), electromyography (muscle activity), electrooculography (eye movements), electrocardiography (heart beat), respiratory activity and oxygen content in the blood (pulse oximetry), while a sensor pad, placed under the sheets, recorded body movements and positions during the night (Biosaca; Swedsleep AB, Gothenburg, Sweden). Two comprehensive PSG recordings were completed at home, for each participant: one during the first pre-test (no weighted blanket) week and one at the end of the third week (test period, with the weighted blanket). PSG analysis was done using the REM Logic software (Embla Systems LLC).

Further to conventional PSG analysis a validated automatic system for analyzing body movements [23] was used (U-sleep; Swedsleep AB, Gothenburg, Sweden). Based on the sensor pad it detected specific movements and classified them into four groups according to their duration(from < 5 s to >15 s), representing jerks or twitches, minor or major adjustments, and turns in the bed. The total number and duration of each of these measures were calculated, as well as the distribution per recording hour, with an emphasis on the next-to-last hour prior to waking up. The following measures were gained: wake after sleep onset (WASO; in mins), total sleep time (TST), sleep efficiency, sleep latency, latency to deep sleep and rapid eye movements (REM), number of awakenings, amount of deep sleep and REM, arousal index, number of stage shifts, of sleep cycles, deep and REM sleep, average deep sleep period, and sleep spindles index.

Subjective measures

During the whole experimental period, the participants filled in a sleep/day diary reporting daytime behavior and sleep perception together, with any comments about their night's sleep and any environmental changes of importance. Each morning, they also reported their 'sleep quality' in a visual analog scale (VAS; with the end-anchors 'Very good' and 'Very bad'), as well as on the Karolinska Sleepiness Scale (KSS; 1= very alert to 9 = very sleepy) [24].

At the end of the study the participants reported their subjective feelings about using the weighted blanket in an 8-item VAS questionnaire, containing specific questions about their sleep with the blanket (Table 2), where lower scores indicated more favorable feelings towards the weighted blanket. Two further questions were asked: (i) 'Which side of the blanket is closest to your body most of the time?' and (ii) 'Did you use something else as a cover, in addition to the weighted blanket?' These were to assess how the participants used the weighted blanket.

Data analysis

Statistical studies were made using SPSS (version 22; IBM, Armonk, NY) and Prism (version 6; Graph Pad, La Jolla, CA) where significant differences of $p<0.05$ were accepted. All the analyses have been conducted on normalized data, as most of the variables were not normally distributed. Hence, parametric, interval statistics were carried out on the actigraphy, PSG and U-sleep measures and repeated-measures analysis of variance (ANOVA) tests were used. We compared the pre- and post-test data with the weighted blanket data for each variable using Bonferroni post-hoc corrected-significance tests, which controlled for multiple comparisons. It was not always possible

Table 2: The participants rated their subjective feelings about sleep with the weighted blanket using a visual analog scale for questions 1-8.

	Score between	1	10
1	How do you find sleep with the weighted blanket?	Comfortable	Uncomfortable
2	How is your experienced sleep quality, as compared to having no weighted blanket?	Better	Worse
3	How do you find sleep with regard to the extra weight the blanket adds?	Not difficult	Awkward
4	Is it difficult to move with the weighted blanket?	Not at all	Very
5	Does the blanket affect your temperature in bed?	Not at all	Very
6	Is it easier to settle down to sleep with the blanket?	Very	Not at all
7	Does the blanket give you a sense of security?	Very	Not at all
8	How do you feel in the morning with the blanket?	More rested	More tired

to include all of the participants per measure due to issues such as technical problems. The effects of confounding variables, such as the participant's gender, age, use of medication, were tested as covariates. As the behavioral measures were based on questionnaires, non-parametric, ordinal tests were used for the analysis.

Additional analyses were conducted on a sub-set of participants who rated the weighted blanket favorably, which was based on their subjective assessment scores, where lower scores indicated a higher liking. The criteria for exclusion (participant who disliked the blanket) were defined as a mean score on questions 1-8 of more than 5, a maximum score of 8 or more, and scores of 8 or more on more than two questions.

RESULTS

The mean ISI score for all the participants was 19.5 (±5.3 SD), which indicated insomnia of moderate severity (see Table 1 for further details).The mean Epworth score was 6.1 (±3.7 SD) indicating that the participants had minor issues with sleepiness in the daytime, with further details in Table 1.

OBJECTIVE MEASURES

Actigraphy

The actigraphy was used to determine variables about sleep metrics; therefore only the sleep period was analyzed, with the time-in-bed adjusted according to each participant's sleep diary. Actigraphy was obtained from 27 participants, from a total of 26 different measures, although some of these measures were seemingly redundant (e.g. immobility expressed in minutes compared to immobility as a percentage of time). Significant differences were found in comparing the pre-test period to the test period with the weighted blanket. Specifically, the mean sleep bout time (in mins) significantly increased ($p = 0.035$), when using the weighted blanket. Furthermore, the total activity score during the time in bed ($p < 0.001$) and the average dark activity (activity during the night) ($p = 0.032$) significantly decreased, during weighted blanket use. These measures are shown in Figure 1.

There was an effect on the results from one of the covariates, where significant decreases were found for the sleep latency ($p=0.010$) and time-in-bed ($p=0.009$) during use of the weighted blanket, if the participant used medication. The further analysis on the participants that liked using the blanket (n = 19 subjects included) showed no further additional significant differences in the results.

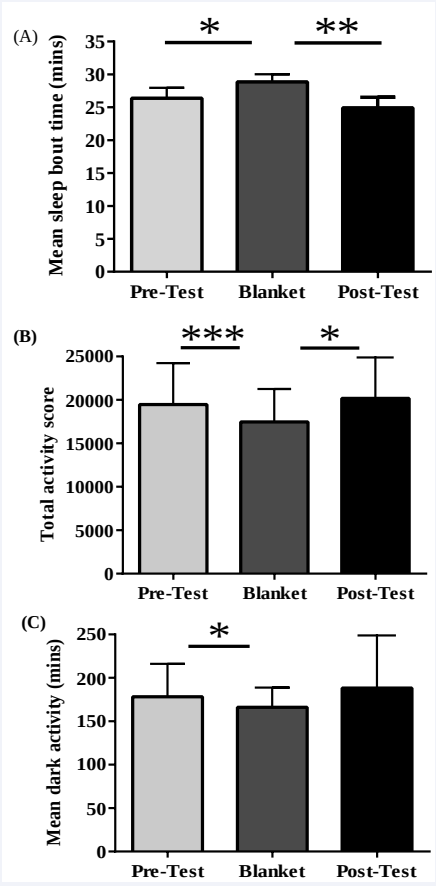

Figure 1 Significant differences between the pre-test and blanket sleep periods from actigraphy measurements.
Significant improvements were found during blanket use for objective actigraphy measures, where there was (A) an increase in the mean sleep bout time, and decreases in (B) the total activity score and (C) the mean dark activity. The asterisks indicate the significance level where * $p < 0.05$ and *** $p < 0.001$.

The post-test actigraphy period was compared to both the pre-test and weighted blanket periods. Due to participant drop-out, only 22 participants completed the post-test, as compared to the 27 who completed the pre-test and weighted blanket periods. There were no significant differences between the pre- and post-

test measures. There was significant decrease between using the weighted blanket and the post-test periods for the mean sleep bout time in mins (p = 0.003), and significant increases in the total activity score (p = 0.018) and mean activity score (p = 0.015).

PSG

A total of 25 participants completed both PSG tests during the pre-test stage and while using the weighted blanket. PSG is a state-of-the-art measure for sleep studies, but the participants often reported that it was disturbing, due to the equipment required. Only one measure gave significant difference during the weighted blanket test, as compared to the pre-test: the spindles index significantly decreased (p =0.003). However considering only the 21 participants (out of the 25 who completed the PSG, i.e. 84%) who liked the blanket, WASO was decreased significantly (p =0.004) and TST increased significantly with the blanket (p =0.016).The effect of confounding variables on the PSG measures was sought, where an effect of gender was found, but this was only for the sleep spindles measure. Here, females had a higher spindles index during use of the weighted blanket, as compared to males (p = 0.024).

Movement analysis

The U-sleep data consisted of 6 measures collected from 23 of the 25 participants who completed the PSG (in 2 subjects there were technical problems with the sensor pad). The mean movements decreased in the next-to-last hour prior to waking up, both in duration (p =0.001) and in number (p = 0.075).No significant effects were found for the confounding variables on the U-sleep measures. A further analysis was run using only the subjects that liked using the weighted blanket (n = 15). Here, the number of movements in the next-to-last hour prior to waking up now showed a very significant decrease (p < 0.001), during blanket use.

Subjective measures

The sleep quality and KSS measures were obtained from 29 participants. There were decreases in both of these measures, meaning a better subjective sleep quality (sleep quality: decreased from 5.9 (pre-test) to 5.5 (during blanket use), p = 0.005; KSS decreased from 5.8 (pre-test) to 5.5 (during blanket use), p = 0.068). The post-test values showed no significant differences with either the pre-test or weighted blanket periods (both the sleep quality and KSS were 5.6).No significant effects were found for the confounding variables on the KSS or sleep quality measures, nor were any further differences found when only the participants that liked using the blanket (n = 20) were analyzed.

In Figure 2, the subjective assessment of using the weighted blanket showed that overall, the participants liked sleeping with the blanket (p =0.035), found easier to settle down to sleep (p = 0.032) and reported a much better quality of sleep (p = 0.004), feeling more refreshed in the morning (p = 0.045). They were not disturbed by the weight of the blanket (p =0.012) and in fact, felt a sense of security (p = 0.042). Furthermore, the weighted blanket did not affect their temperature in bed. The majority of participants (63%) preferred the padding side of the blanket to be closest to their body during sleep. The majority also just used

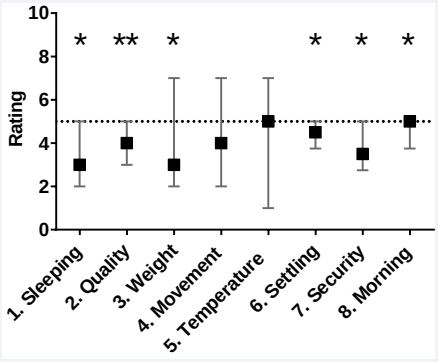

Figure 2 Ratings of subjective feelings about sleep with the weighted blanket. Each participant rated their feelings on VASs for eight items (numbered 1-8, see questions in Table1), where lower numbers are more favorable ratings towards the weighted blanket. The dotted line indicates the level between liking and disliking. The asterisks indicate the questions where there were significant decreases under the dotted line (i.e. significant liking), * p < 0.05, ** p < 0.01.

the weighted blanket (63%), as compared to 30% who used an additional quilt under the blanket and 7% who used a quilt over the blanket.

DISCUSSION

In the present study, a chain weighted blanket was found to be effective at improving sleep quality in recognized insomniacs, both in parameters measured objectively and subjectively. The impact was more pronounced objectively when the participants reported having a positive experience of using the weighted blanket and if they used sleep medication. No adverse effects of using the weighted blanket were found.

Weighted blankets providing a 'cocooning' feeling and are often recommended for young patients with ASD and in the care of agitated elderly people. However, to our knowledge this is the first scientific study on the effect of weighted blankets in insomniacs. The ISI results validated that the selected group had mild-to-moderate insomnia and their Epworth scores, expected to be low in this group of subject, though within the normal range, were also a little elevated (mean = 6, indicating some tendency for daytime consequences), meaning that the blanket could be beneficial for general insomnia and potentially also for mild sleep problems. Based on sensory integration, it has been suggested that deep pressure and consistent sensory input, such as provided by a heavy weight on the body, can reduce physiological levels of arousal [25].A crucial point is that the weight should not be too light or heavy, and the weight must be evenly distributed throughout the fabric to provide constant tactile stimulation distributed across the body, which the current weighted blanket design provided.

There are many weighted blankets and vests on the market with different designs, for example, those with metal chains or covers filled with small plastic balls or pellets. Chain covers and ball quilts may provide different sensations (e.g. tactile, thermal insulation) and have different weights, which need to be adapted individually, as some patients may be more sensitive to stimulation, thus requiring a lesser-weighted blanket. The

effectiveness of a weighted blanket has been found to relate to the mass of a person, where a blanket that weighs more than 10% of the person's body is more beneficial [19]. All of the participants in the current study had a weight of blanket/participant ratio of more than 12% (see Table 1). The longitudinal chain construction of the present weighted blanket may adjust well to the participant's body, where an even weight is delivered over the body from the whole blanket surface, with the longitudinal chain construction adding further pressure points that fluctuate with minor movements producing a stroking-like effect.

There are limitations to the current study design, which include a lack of a control group, the long duration of the study, some missing data, and the inability to provide a placebo weighted blanket. The participants represented their own control (pre- and post-test measures) in our cross-over design and a control group would only have been necessary if the goal was to compare different types of blankets. However, in some tests, we had reduced numbers of participants (e.g. in the PSG), particularly due to technical issues with this equipment-intensive technique. As we calculated that we needed at least 26 participants for significant effects prior to the study, we conducted the study on 31 participants, which allowed for some issues and participant drop-out (which occurred mainly at the week 4 post-test stage).Giving a weighted blanket to control participants without insomnia would have been less meaningful, unless we were interested in looking at a possible negative impact of the blanket. However, the strengths of our design include the use of combined objective and subjective assessments using different, independent methods, and the use of a pre- and post-test baseline.

PSG is the golden standard to study sleep, but it can be cumbersome, disturbing and is limited to a few nights, hence not representative of the subject's habitual night sleep. The PSG did show some beneficial effects of blanket use, including the TST and WASO that were significantly improved in the 21 participants reporting a subjective positive impact of the blanket. Regarding the significant decrease in the spindles index, this may reflect the responsiveness of the brain to stimuli, where a decreased amount suggests a 'loss of contact' with the external environment, hence working as a filter and enhancing sleep continuity [26]. The movement (U-sleep) analysis was based on recordings from the PSG pad; however, the first sleep hours can be disturbed by the PSG. Hence, we used the 'next to last hour' measure to assess sleep, since the last hour is often characterized by a shallow sleep. The participants showed a decrease of movements this next to last hour, which represented a quieter, more restful sleep. Therefore the combination with actigraphy made for a more comprehensive evaluation of the effects of using the weighted blanket over time. The actigraphy showed a number of objective improvements in sleep, including a decrease in movements and an increase in the length of sleep bouts.

Overall, these measures suggest the additional pressure stimulation from the weighted blanket provided a calming effect on the participants, by decreasing agitation and increasing the quality of their sleep. This was demonstrated through a decrease in movements during sleep with the weighted blanket, which were increased in the pre- and post-test periods, and also the subjective increased in sleep quality (measured by the VAS) and KSS (which is a validated instrumental scale). Although these subjective measures are possibly less clinically relevant, it is important to consider the psychological effects of using the weighted blanket (cf. [20]), for example, having a positive attitude. Weighted blankets and deep pressure touch may work well for insomniacs, both through psychological means (e.g. calming and 'cocooning', releasing anxiety [27]) and physiological means (e.g. tactile input that decreases activity of the sympathetic nervous system [28]).As increased sympathetic arousal likely affects sleep quality negatively, reducing it may aid sleep.

CONCLUSION

The weighted chain blanket used in the present study had a positive impact on sleep, both objectively and subjectively, where a number of physiological and behavioral measures were improved during weighted blanket use. When the participants used the weighted blanket, they had a calmer night's sleep, with a decrease in movements. Subjectively, they believed that using the blanket provided them with a more comfortable, better quality, and more secure sleep. In conclusion, a weighted blanket may aid in reducing insomnia through increased tactile and proprioceptive inputs, may provide an innovative, non-pharmacological approach and complementary tool to improve sleep quality.

CONFLICT OF INTEREST

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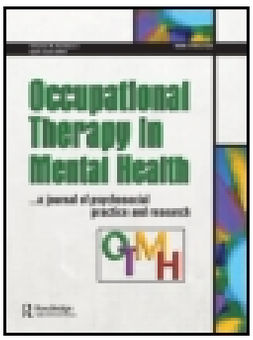
Exploring the Safety and Therapeutic Effects of Deep Pressure Stimulation Using a Weighted Blanket



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Exploring the Safety and Therapeutic Effects of Deep Pressure Stimulation Using a Weighted Blanket

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ABSTRACT. This paper presents the results of a concurrent, nested, mixed methods exploratory study on the safety and effectiveness of the use of a 30 lb weighted blanket with a convenience sample of 32 adults. Safety is investigated measuring blood pressure, pulse rate, and pulse oximetry, and effectiveness by electrodermal activity (EDA), the State Trait Anxiety Inventory-10 and an exit survey. The results reveal that

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the use of the 30 lb weighted blanket, in the lying down position, is safe as evidenced by the vital sign metrics. Data obtained on effectiveness reveal 33% demonstrated lowering in EDA when using the weighted blanket, 63% reported lower anxiety after use, and 78% preferred the weighted blanket as a calming modality. The results of this study will be used to form the basis for subsequent research on the therapeutic influence of the weighted blanket with adults during an acute inpatient mental health admission. doi:10.1300/J004v24n01_05

KEYWORDS. Sensory modulation, weighted blanket, deep pressure touch stimulation, skin conductance, electrodermal activity

INTRODUCTION

The weighted blanket is a therapeutic modality used within the scope of occupational therapy practice (Nackley, 2001; Walker & McCormack, 2002). It has been increasingly employed in acute mental health care settings for crisis intervention, preparatory purposes, and as a purposeful activity, which appears to help the consumer nurture, soothe, and care for himself or herself (Champagne & Stromberg, 2004). When used in this way it is considered a sensory modulation treatment tool aiding in the stabilization and recovery process (Champagne, 2005). While there is no published research on the safety or effectiveness of the therapeutic use of the weighted blanket, anecdotal accounts support that when used in an individualized manner, the weighted blanket appears to facilitate the ability to feel safe, comforted, and grounded in the world (Champagne & Stromberg, 2004; Heller, 2002).

The President's Freedom Commission (Department of Health and Human Services, 2003) was initiated to promote a national focus on increasing options in the areas of treatment, education, employment, assistive devices, and universally designed technology for people with mental illness. National and state mental health organizations, such as the National Association for State Mental Health Program Directors (NASMHPD) and the Department of Mental Health (DMH) support this initiative and advocate the use of more humane, person-centered, and sensory supportive options (Huckshorn, 2004; National Executive Training Institute [NETI], 2003). Although it is well established that no one therapeutic tool is helpful to all consumers, the use of the weighted blanket as a

prevention and/or crisis intervention tool, classifies as a primary and secondary crisis prevention approach (NASMHPD, 1999), which may ultimately help to decrease the need for the use of restraint and seclusion (Champagne & Stromberg, 2004; NETI, 2003). Therefore, given the potential of this humane and recovery supportive treatment option and the importance of engaging in evidence-based practice, it is necessary for occupational therapists to begin studying the safety and effectiveness of the use of the weighted blanket.

Further, when requesting the allocation of resources to introduce a novel treatment modality into clinical practice it is necessary to present empirical evidence demonstrating that its use is within one's scope of practice and that it is both safe and effective. This may be achieved through the application of principles from traditional social science and engineering data analysis. Such an analysis will not only lead to a better understanding of the therapeutic effects of deep pressure, but also will lay the foundation for technological advances in the remote sensing of anxiety (Luharuka, Gao, & Krishnamurty, 2003), and the engineering of new and improved modalities offering deep pressure stimulation. To this end, this paper presents the details of the first clinical study exploring both the *safety* and *effectiveness* of the use of a 30 lb weighted blanket, the heaviest available at the time of the study, with a heterogeneous convenience sample of 32 volunteer adults.

Background Information

Deep Pressure Stimulation (DPS)

One of the qualities offered by the weighted blanket is DPS, which is generally referred to as a form of touch pressure applied to the body providing the feeling of a firm hug, holding, swaddling, or massage (Grandin, 1992). Although there is no published research regarding the use of the weighted blanket, there is a growing body of research supporting the use of DPS for varied therapeutic purposes. Interestingly, when using Grandin's Hug Machine, the use of DPS had a calming influence for adults and children with anxiety, autism, and attention difficulties (Edelson, Edelson, Kerr, & Grandin, 1999; Grandin, 1992). Additionally, DPS applied through the use of the weighted vest, for children with pervasive developmental and attention disorders, influenced an increased ability to focus on fine motor tasks (Fertel-Daly, Bedell, & Hinojosa, 2001; Olson & Moulton, 2004a, 2004b; VandenBerg, 2001), and a decrease in self-stimulatory behaviors (Fertel-Daly et al., 2001).

Foam-padded splints to the arms applying firm pressure appeared to help reduce self-stimulatory and self-injurious behaviors in a child with autism (McClure & Holtz-Yotz, 1991). Wrist weights providing DPS influenced a reduction in self-injurious behaviors by 92% in a child with intellectual disabilities (Hanley, Piazza, Keeney, Blakeley-Smith, & Worsdell, 1998). These studies provide support for the use of DPS modalities for a variety of treatment purposes, such as the facilitation of attention, self-control, and a decrease in anxiety. While providing some evidence of the effectiveness of the use of DPS modalities these studies do not specifically explore the use of the weighted blanket or whether the modalities used are safe.

Measuring Safety and Establishing Guidelines

Safety guidelines established for the use of backpacks have been generalized to the use of the weighted vests and weighted blankets (Olson & Moulton, 2004a; Walker & McCormack, 2002). This includes recommendations according to body weight ratios (5-10%), the distribution of the weight, and wearing schedules. Weighted vests are typically used while in ambulatory and/or seated positions, whereas the weighted blanket is not meant for use while ambulating. Rather, the weighted blanket is used while in a lying down or seated position. Therefore, applying the same backpack safety guidelines to the use of the weighted blanket is unsubstantiated. Further, clinical experience of the authors suggests that for some consumers the use of a weighted blanket that is more than 10% of the person's body weight may be preferred. Hence, there is a need to explore whether the use of the 30 lb weighted blanket has a negative influence on physiological safety and whether there are patterns or preferences according to body weight. Vital signs provide information regarding a person's general health status and are used in this study to begin to assess whether the deep pressure provided from a 30 lb weighted blanket influences adverse changes in the vital signs of the test participants.

Measuring Effectiveness

Mixed research methodology, the use of a combination of quantitative and qualitative approaches, is considered a reliable way to measure the effectiveness of therapeutic interventions (Creswell, 2003). Edelson et al. (1999) used a mixed methods approach to explore the influence of DPS provided by Grandin's Hug Machine on the anxiety levels of children with autism using the Connors Parent Rating Scale and electrodermal activity (EDA). Skin conductance (SC), a measure of EDA, provides a

direct measure of sympathetic activity and has been one of the most widely used quantitative metrics in psychophysiology research (Boucsein, 1992; Cacioppo, Tassinary, & Bernston, 2000). Although only a marginal reduction in anxiety was revealed using SC, a significant decrease in tension (a behavioral measure of anxiety) occurred, and researchers concluded, "deep pressure appears beneficial for children with high levels of anxiety or arousal, and there may be a threshold of anxiety or arousal required for deep pressure to be beneficial" (Edelson et al., 1999, p. 151). Krauss (1987) examined the influence of DPS among college students using a self-controlled mechanical device to self-administer DPS with a pulley system, using qualitative surveys and body temperature to monitor anxiety. Temperature is also a measure of sympathetic arousal (Boucsein,1992). Although the results from Krauss' study were found to be inconclusive, these studies demonstrate the value of the use of mixed methodology, including psychophysiological metrics in addition to subjective self-report, when studying the influence of DPS.

Evidence demonstrates that sympathetic arousal is directly linked to emotional and other cognitive processes such as attention, decision-making, and memory (Damasio, Tranel, & Damasio, 1991; Damasio, 1994; Bechara, Tranel, Damasio, & Damasio, 1996; Bechera, Damasio, Tranel, & Damasio, 1997; Cahill, 1997). Further, chronic high levels of sympathetic arousal are hallmarks of anxiety disorders and stress, which are conditions associated with high levels of psychological and physical morbidity (Russek, King, Russek, & Russek, 1990; Steptoe, Cropley, & Joekes, 1999). It has also been demonstrated that treatments influencing the reduction of autonomic arousal often reduce anxiety and distress (Critchley, Melmed, Featherstone, Mathias, & Dolan, 2001). Thus, it is hypothesized that the weighted blanket assists in helping consumers decrease anxiety and levels of distress. Since SC is a direct measure of sympathetic nervous system activity, which is influenced by anxiety, SC is a quantitative measure used to explore effectiveness. The State Trait Anxiety Inventory-10 (STAI-10) and an exit survey are self-rating metrics, also used to explore effectiveness.

METHOD

Experimental Design

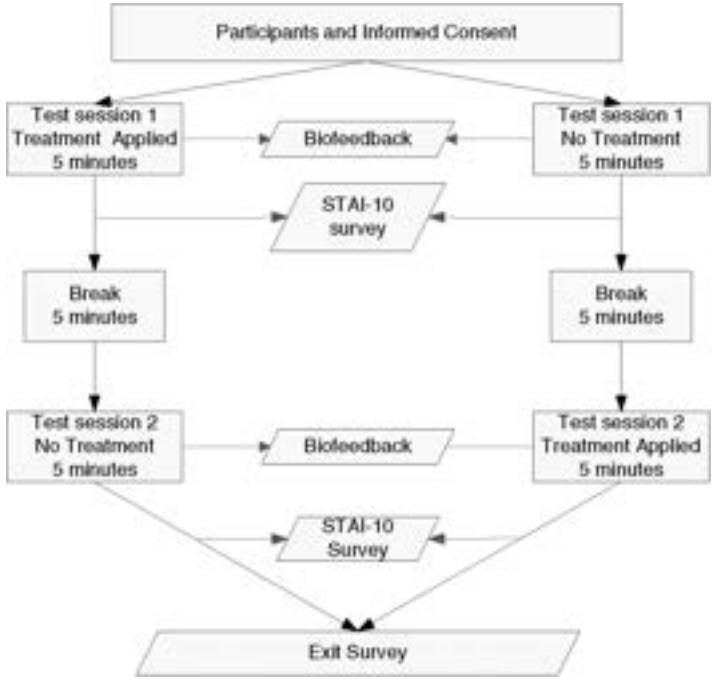
A concurrent, nested, mixed methods design was used to gather quantitative and qualitative data. The qualitative data gathering process was

embedded within the quantitative procedures. Figure 1 shows the experimental design.

Sample

A convenience sample of 34 people including 20 males and 14 females participated in the study. Testing was interrupted for two participants; therefore, the data for these two participants were not included in the statistical analysis or results. Consequently, the final sample size of the study was n = 32. The age range was 18-58, with a mean of 31 and a standard deviation of 11.7. The population was skewed toward younger people because a large number of the volunteers were undergraduate and graduate students. The lowest body weight of the participants was 112 lb and the maximum was 234 lb with a mean of 165 lb and a standard deviation of 27.8 lb. Inclusion criteria required consenting, non-hospitalized, volunteer adults with no apparent medical conditions or physical

FIGURE 1. Experimental design overview.



injuries between the ages of 18 and 64. Because this was an exploratory study, a diverse group of people participated. It is understood however, that age, sex, weight, and race may have varying influences on psychophysiological processes and responses.

Using random assignment and a cross over design the participants were divided into two groups, each person receiving an even or odd code and number designation. All persons participated in two-test sessions, one session with the treatment (the 30 lb weighted blanket) and one session without the treatment. The code the person was assigned determined whether the treatment was given during the first or second testing session. An even code required the use of the treatment (30 lb weighted blanket) during the first testing session, an odd code required use of the treatment during the second testing session. Before any testing or data collection occurred age, sex, and weight were recorded and all participants signed an informed consent document. The informed consent document explained potential risks or harm that could arise from being a participant in the experiment, provided a general summary of the instruments to be used, and also the procedures that would take place throughout the course of the experiment. Before starting the experiment, the participants were each individually introduced to the test environment, room, and equipment, and the procedures of the experiment were thoroughly explained. Questions were encouraged and answered before the volunteers were asked to sign the consent form. Being fully informed helps to reduce uncertainty regarding the testing procedures; otherwise, the novelty of the experience may influence the test responses.

Setting

The study was conducted at the nursing resource room at Skinner Hall at the University of Massachusetts-Amherst (UMASS). Two nursing resource rooms were set up to replicate a hospital-like setting, which was determined to best afford a relatively controlled environment, allowing for comparisons to be made in future studies conducted in an acute mental health care hospital setting. Hospital beds with pull curtains were used to seclude participants from the monitoring equipment and most of the stimulation of the rest of the room. During the experiment, the resource room door was locked, a sign was placed on the door to inform the public that an experiment was taking place, and only the participant and data collector were allowed in the room. Before the data collection phase of the test session, the curtain was closed around the bed; the data and all the equipment connected to the sensors were behind

the curtain and out of view of the participant. The room temperatures ranged between 72° and 75° Fahrenheit.

Procedures

Grandin (1992) reported the need to use 5 minutes of sustained DPS to produce a calming influence with children. Anecdotally, the authors have noticed that the influence is often observable within minutes of use with adolescent-, adult-, and geriatric-populations in acute care mental health settings. For the purposes of this initial exploratory study, 5-minute time frames with and without the treatment were used. The participants were given a 5-minute break between testing sessions where they were required to complete a STAI-10 survey and leave the testing area. The data collection equipment was set to have no alarms or noises and remained quiet throughout the monitoring phases. All participants were tested in the lying down position. Blood pressure was monitored on the right upper extremity and all pulse oximetry, pulse rate, and SC data were collected from the right hand. To ensure the consistency of procedures and data collection throughout the experiment for all participants, data collectors used a standardized data-recording protocol document and practice sessions.

Instruments

The Treatment: The Weighted Blanket

One 30 lb weighted blanket was located at each of the two experiment stations. The weighted blankets used in this study were 56 inches × 76 inches in size and each blanket weighed 5 lb in itself (with all of the weights removed). The blankets were each set up to contain five additional (removable) 5 lb sleeves of nylon material filled with popcorn seed, each running the length of the blanket and securely buttoned into place. Velcro secured each of the openings around the edge of the blanket. The additional five weighted sleeves served to provide an additional 25 lb of weight in an evenly distributed manner throughout the blanket. Thus, each blanket weighed a total of 30 lb. The blankets used in this study were purchased from *Weighted Wearables* and ordered specifically to be consistent in make/style, materials used, and weight. This was carefully specified and subsequently verified by the researchers.

Quantitative Measure of Safety: Vital Signs

For the purposes of this initial study exploring safety, the following vital sign metrics were used: pulse oximetry, pulse rate, and blood pressure. Each participant's vital signs, data with the blanket and without the blanket, were compared for each vital sign measured in order to determine if the blanket influenced a change in vital signs. Table 1 shows the safe ranges of the vital signs for adult populations, when in an upright position (Barkauskas, Baumann, & Darling-Fisher, 2002). There are no standardized vital sign parameters available for the lying down position; thus, the information in Table 1 was used as a general guideline. It is well established however that blood pressure and pulse rate decreases when someone is lying down (Barkauskas et al., 2002).

Vital signs were obtained using a GE 4000 vital signs machine (Model # DSH04490805GA). Pulse oximetry (SpO_2) is a measure of the amount of oxygen concentration in the blood. It is measured by placing a probe onto a person's finger. The SpO_2 reading is also known as the oxygen saturation level and is recorded as a percentage. The normal SpO_2 range is from 90 to 100% in adult populations (Barkauskas et al., 2002). Pulse rate indicates the number of times the heart beats per minute. The anatomy and physiology of the blood pressure "is the interaction of the cardiac output and peripheral resistance and is dependent on the velocity of the arterial blood, intravascular volume, and the elasticity of the arterial walls" (Barkauskas et al., 2002, p. 175). There are normal variations that can occur with a person's blood pressure. Typically the first reading is higher than others and at least one to three minutes should be left between readings for accuracy. An average of readings over time affords the best indication of an individual's baseline blood pressure (Barkauskas et al., 2002).

TABLE 1. Vital Signs Parameters

Age	Temperature	Pulse per/min	Respirations per/min	Oximetry Spo_2	BP Systolic (mm Hg)	BP Diastolic (mm Hg)
Adult	98.6 +/− 1	60 to 100 (Mean 75)	12 to 20	90 to 100%	100 to 130	60 to 85

Adapted from: Harkreader, H. and Hogan, M. A. (2004), and Barkauskas, Baumann, and Darling-Fisher (2002).

Quantitative Measure of Effectiveness: Electrodermal Activity (EDA)

The effectiveness of the 30 lb weighted blanket is measured using EDA, the STAI-10, and an exit survey. EDA continuously changes over time and influences the increased or decreased activity of the eccrine sweat glands, and is measured through the collection of SC (Stern, Ray, & Quigley, 2001). Hence, for the purposes of this study, SC is used as the quantitative indicator of anxiety. Skin Conductance (SC) is obtained using the ProComp+ SC sensor from *Thought Technology*, using a constant-voltage sampling of SC at a rate of 32 hz with an accuracy of ± 5%. Silver chloride cup electrodes were used to minimize the development of bias potentials and polarization. The electrodes were secured to the volar surfaces of the first and second distal phalanges of the right hand of each participant, using Velcro fasteners. Since the results will be compared, 10% accuracy is used as the significance level, because, when comparing the control group to the treatment group, it is possible that one of the readings may have an error of +5% and the other by −5%.

RESULTS

Vital Signs Analysis and Interpretation

For the purposes of this study, a negative influence in vital sign measures concludes that the use of the 30 lb weighted blanket is unsafe for the participant. When the vital sign measures remain within the participant's normal range it is concluded that the treatment is generally safe. Not taken into consideration during this initial exploration of the safety of the use of the 30 lb weighted blanket include additional safety factors related to medical conditions not experienced by the participants (e.g., fractured bones, open wounds, circulatory disorders, pregnancy).

The safety results, as evidenced by the three vital signs metrics used, are shown in the following sections. The ending values are analyzed closely because the end of the 5-minute test sessions shows the accumulated influence of the blanket use. The recorded values of the vital signs data during the sessions without the blanket were used as a baseline. The baseline data were compared to the data collected when the blanket was used to determine if the blanket is the cause of the participant being within an unsafe range. A baseline is necessary since some of the

participants may naturally be outside of the safe ranges at their baseline or because of some other unknown contributing variable.

Pulse Oximetry (SPO_2)

Only 20 of the 32 participants were included in the pulse oximetry analysis because of sensor attachment problems during data collection. Table 2 shows the initial and final SPO_2 measurements for 20 participants with complete sets of data collected, both with and without the blanket. None of the participants shown in Table 2 have a final oxygen level below 90%. Thus, there is no evidence to show that the weighted blanket causes any adverse affects to the amount of oxygen in the blood.

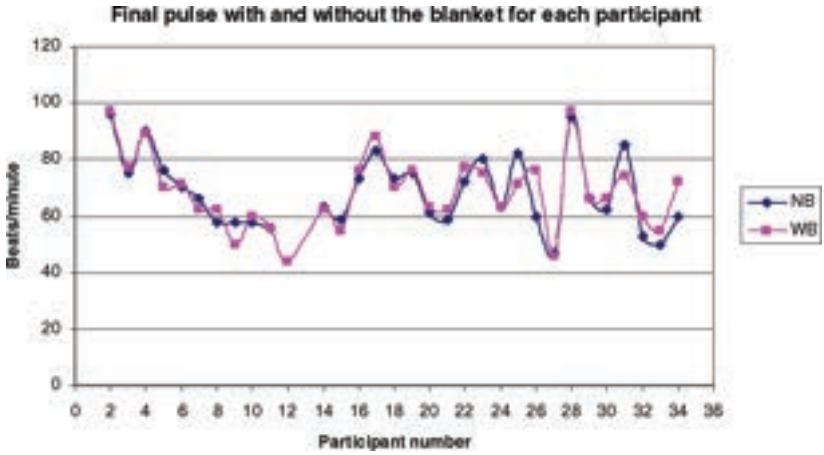
Pulse Rate

As shown in Figure 2, none of the participants have a final pulse rate greater than 100 beats per minute with or without the blanket. There are seven participants whose pulse rates are under 60 beats per minute, with and/or without the blanket. Of the participants with a pulse rate below

TABLE 2. Pulse Oximetry Results

	Without Blanket			With Blanket		
	%O2			%O2		
Participant #	Initial O2	min 5	Change Initial-Final	Initial O2	min 5	Change Initial-Final
3	96	95	1	96	95	1
4	98	97	1	97	97	0
7	96	98	0	98	99	-1
14	95	95	0	98	96	2
16	97	95	2	95	96	-1
18	95	91	4	90	91	-1
19	97	95	2	95	95	0
20	97	97	0	96	97	-1
21	97	99	-2	98	97	1
24	97	96	1	96	96	0
25	98	96	2	96	96	0
26	99	95	4	96	97	-1
27	100	97	3	99	99	0
28	99	99	0	99	99	0
29	96	98	0	96	97	-1
30	96	96	0	95	96	-1
31	96	96	0	95	96	-1
32	93	96	-3	95	96	-1
33	97	96	1	95	96	-1
34	96	97	-1	97	98	-1
Min	93	91	-3	90	91	-1
Max	100	99	4	99	99	2

FIGURE 2. Pulse rate results: Each participant's pulse rate after 5 minutes of testing with the weighted blanket (squares) and without the blanket (diamonds).



60 beats per minute, only one person's pulse rate with the blanket is below his/her control value without the blanket. This suggests that those participants may normally have a pulse rate outside the general safe range and that the weighted blanket was not the cause of the pulse rate being out of the safe range.

Blood Pressure (BP)

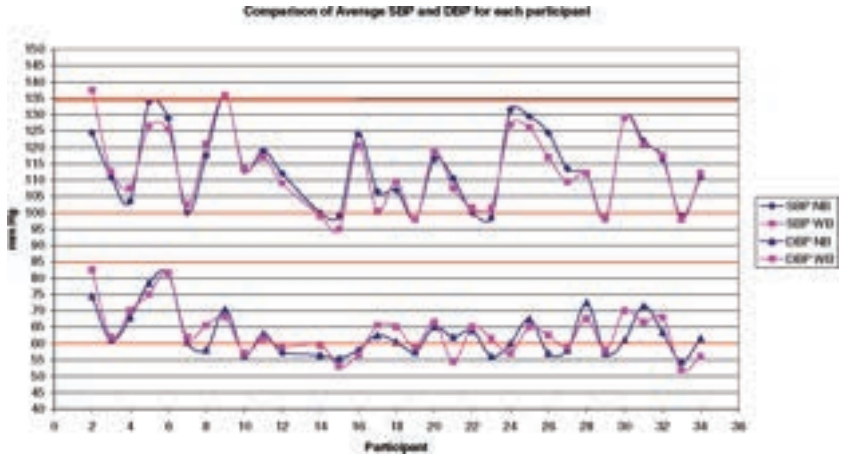
The volunteer's initial and final BP is averaged to account for the variation in BP as discussed in the introduction. On average, all participants are found to be at the low end of the safe range. Only one participant has an average BP, in either of the 5-minute test sessions, in the high end of the safe range. Participant #2 has a high BP average. Upon further examination of this participant's data, however, 3 of the 4 readings were on the low end of the safe range. Only the first BP reading was high and out of the safe range. Participant #2 had the blanket applied during the first test session; the BP right *before* the blanket application was 150/89. BP dropped to 121/76 by the end of the test session and was 124/77 and 125/72 for the beginning and end of the second test session, respectively. Since the blanket was applied during the first session and the BP was high *before* the blanket was applied, the high BP could have been a result of

anxiety caused by participating in the experiment. Thus, the conclusion should not be made that the blanket caused participant #2 to have an average BP out of the safe BP range over the test session.

Figure 3 shows the average systolic and diastolic BP for each person with and without the blanket. The bold horizontal lines denote the safe range over the course of the study. This figure shows that all but participant #2 were inside the safe range for the BP guidelines for systolic blood pressure. The majority of the participants were toward the lower end of the safe range for the average diastolic BP.

In sum, it can be concluded that the data from the three different vital sign measures collected show that the use of the 30 lb weighted blanket did not cause the participants to move into an unsafe physiological range. All 20 participants stayed above 90% for SPO_2, all 32 participant's pulse rates stayed below 100 beats per minute and only one participant's pulse rate with the blanket was below his/her control value without the blanket. Only one person was out of the safe range for systolic BP, which could be attributed to anxiety from participating in the experiment, and not to the blanket. No participant was outside of the safe range for diastolic BP. The data give no evidence to indicate that the use of the 30 lb weighted blanket is unsafe.

FIGURE 3. Average diastolic and systolic blood pressure for each participant with the blanket (squares) and without (diamonds) the blanket.



EDA Data Analysis and Interpretation

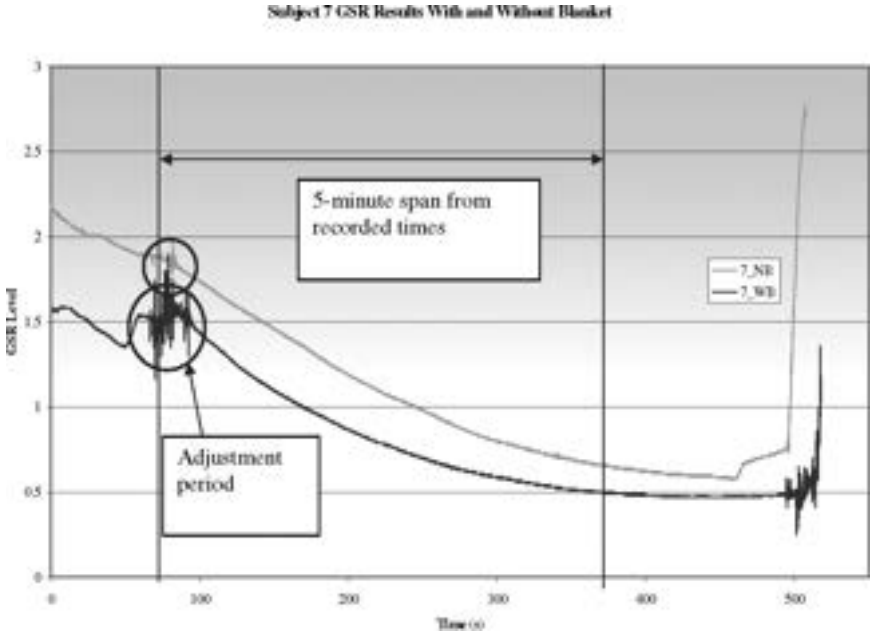
Data interpretation is a critical step in the scientific study of the time series data gathered using SC. It requires a standardization procedure that ensures the integrity of information contained in the raw data in a consistent and uniform manner. Accordingly, this study introduces one such procedure to address the lag time effects related to sensor amplification, the uncertainty associated with the response starting and ending times, and the influence of external factors such as the curtain is closing and opening affecting the responses. Specifically, to overcome the inherent drawbacks by using the raw data, the SC recordings were extended in this study to both before and after the actual test duration of 5 minutes. Additionally, the actual start time was identified as the time at which there was a noticeable drop in the SC reading caused by movement before the person was considered to be settled into the rest position, and the corresponding SC reading at this start time was taken as the average of the data up to that time. Figure 4 shows a sample time-series data and the identification of the resulting 5-minute actual test session for further data analysis.

Skin Conductance (SC) Results

Two of the 32 participants were dropped from the anxiety data analysis because of problems with the SC sensor during their test sessions. Table 3 shows the mean values for the whole sample, the blanket first sample, and the blanket second sample, as well as the standard deviation. The percent change in the SC data is examined to study if there is a difference between using the blanket and not using the blanket. This percent change acts as the indicator of how much change occurs over the 5 minute period, taking into account different starting values by normalizing the data. The average percent changes in Table 3 show that regardless of blanket order or test session, SC values decrease significantly over time indicating that the lying down position influences a reduction in anxiety. When examining each person's response, 27 of the 30 participants have a decrease in SC over both of the 5 minute test sessions.

Table 4 shows the comparison of percent change in SC between participants over a period of 5 minutes. To compare the participants' responses, the percent change with the blanket is subtracted from the percent change without the blanket for each person. If the resulting number is negative then the person had a larger percent change in SC without the blanket than with the blanket. Ten of the 30 participants

FIGURE 4. Example of the GSR level data with the landmarks of participants' adjustment period and curtain close time, and the 5-minute time span of testing window.



demonstrated a significantly larger drop in SC when using the blanket than when not using the blanket. Four of the 30 participants showed an increase in SC with the blanket compared to when not using the blanket and 16 participants had no significant difference between the two test sessions.

Table 5 shows the results from performing a Student's T-test assuming unequal variance comparing "with the blanket" to "without the blanket" sample populations. T-tests were also used to compare the blanket applied to the first group to the blanket being applied to the second group. The results from the statistical analysis show that there is no significant difference between using the blanket and not using the blanket, and therefore, no difference between the orders in which the blanket was applied, with an alpha of 0.05.

A z-test is also conducted for the entire sample because of the necessary assumption of having more than 30 participants to assume normality. The results shown in Table 6 reveal a statistically significant result

TABLE 3. Average and Standard Deviation of the SC Data for the Whole Population

With Blanket Treatment						
	All Participants		Blanket Applied 1st Sample		Blanket Applied 2nd Sample	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Initial	4.33	5.22	4.38	3.89	4.65	6.62
Final	2.65	4.21	2.47	2.46	3.07	5.70
Percent Change	38.73	20.00	43.59	18.90	33.94	21.65
No Blanket Treatment						
	All Participants		Blanket Applied 1st Sample		Blanket Applied 2nd Sample	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Initial	4.36	4.53	4.25	3.57	4.76	5.63
Final	2.79	3.53	2.54	1.95	3.31	3.28
Percent Change	35.88	22.20	41.45	23.70	30.86	21.24

when comparing "with the blanket" and "without the blanket," having an alpha of 0.05. This verifies that there is no difference due to ordering.

STAI-10 Analysis and Interpretation

The STAI-10, a subscale of the State Trait Anxiety Inventory, is a standardized quantitative (closed-ended) 10 question survey used to measure anxiety (Speilberger, Gorsuch, & Luchene, 1970). Data collected from the STAI-10 were analyzed to show each participant's self-rated perception of anxiety with and without the treatment. The results were also used in comparison with SC data for further SC validation. Since the STAI-10 data was to be directly compared to the SC data, the two participants who did not have SC results were not included in the analysis. Using the STAI-10 results and comparing the scores obtained, after using and not using the blanket, shows whether the use of the 30 lb weighted blanket influences a larger decrease in self-perceived anxiety ratings. STAI-10 scores and exit survey responses help to determine whether

TABLE 4. Each Participant's Percentage SC Change with and Without the Blanket

Participant #	WB Percentage Change	NB Percentage Change	Difference (WB-2NB)
3	36.67	28.71	7.96
5	20.68	23.02	−2.34
7	66.67	64.02	2.65
9	24.06	33.33	−9.28
11	55.33	46.70	8.63
15	48.35	44.19	4.17
17	44.32	−1.10	45.42
19	66.40	48.05	18.35
21	14.66	13.92	0.75
23	59.62	85.31	−25.68
25	49.22	25.02	24.21
27	64.33	33.72	30.61
29	30.77	25.00	5.77
31	29.65	45.31	−15.66
33	−7.89	17.24	−25.14
2	28.47	7.06	21.41
4	48.54	33.33	15.21
6	67.57	11.68	55.89
8	22.01	30.13	−8.12
10	50.00	42.07	7.93
12	12.31	44.99	−32.68
14	50.49	−25.17	75.66
16	27.71	22.92	4.79
18	6.67	5.26	1.40
20	42.52	39.06	3.46
22	56.17	45.46	10.63
24	59.17	43.43	15.74
28	66.05	61.85	4.20
30	43.37	47.98	−4.61
34	55.46	63.34	−7.88

TABLE 5. Statistical Results from the Student's T-test Comparison

	All Participants			Blanket 1st Sample Compared to Blanket 2nd Sample	
				With Blanket	No Blanket
t Stat	1.426	z Stat	1.401	0.302	−0.479
P(T ≤ t) one-tail	0.080	P(Z ≤ z) one-tail	0.081	0.383	0.318
t Critical one-tail	1.672	z Critical one-tail	1.645	1.701	1.701
P(T ≤ t) two-tail	0.159	P(Z ≤ z) two-tail	0.161	0.765	0.636
t Critical two-tail	2.002	z Critical two-tail	1.960	2.048	2.048

TABLE 6. Statistical Comparison of All Participants with the Blanket and Without the Blanket

	All Participants			Blanket 1st Sample Compared to Blanket 2nd Sample	
				With Blanket	No Blanket
t Stat	−3.102	z Stat	−2.721	−0.474	0.329
P(T ≤ t) one-tail	0.002	P(Z ≤ z) one-tail	0.003	0.320	0.372
t Critical one-tail	1.699	z Critical one-tail	1.645	1.725	1.701
P(T ≤ t) two-tail	0.004	P(Z ≤ z) two-tail	0.007	0.641	0.744
t Critical two-tail	2.045	z Critical two-tail	1.960	2.086	2.048

EDA alone is a metric that correlates with the subjective ratings of the blanket's influence. Table 7 shows the average STAI-10 scores for the participants. Higher scores correspond to higher anxiety ratings. On average the participants scored lower after using the blanket than without the blanket. For the participants having the blanket applied first, the mean STAI-10 score was 12.5 compared to a mean score of 15.7 without the blanket in the second session. For the sample population having the blanket applied second, the mean score was, 13.2 with the blanket and 15.3 without the blanket.

These results show that at least 33% of the sample using the blanket had a significantly greater drop in SC or anxiety than without using

TABLE 7. Average STAI-10 Data for All Participants with the Blanket and Without the Blanket

STAI-10	All Participants	Blanket 1st Sample	Blanket 2nd Sample
		Mean	
Blanket Applied	12.87	12.53	13.20
No Blanket Applied	15.50	15.73	15.27
NB-WB	2.63	3.20	2.07

the blanket, and 53% of the sample experienced no difference when comparing the blanket condition and the no-blanket condition. It was hypothesized that only a portion of the tested participants would respond to the blanket with a reduction in anxiety, particularly given that it was a low anxiety population as evidenced by the initial STAI-10 questionnaire results. Grandin (1992) specifically indicated that there might need to be a threshold anxiety before DPS will be effective. Also, given that the population is non-acute and, by lying down for 5 minutes anxiety levels dropped greatly, it may be possible that participants reached their steady (minimum anxiety) dynamic state or baseline SC so that the blanket could not reduce SC levels much further.

From the STAI-10 survey data collected, there were 19 participants whose anxiety decreased more with the blanket, 8 participants experienced no change, and 3 had higher anxiety with the blanket than without. Comparing the STAI-10 data to the SC data in Table 8, it seems that SC accurately indicated the participant's perceived change in anxiety when the use of the blanket resulted in higher anxiety than without the blanket. This raises the question as to why the SC data did not match the STAI-10 survey data. Since the SC measurements indicated when the anxiety of the participant was higher with the blanket and not for when the anxiety was lower with the blanket suggests that by lying down for 5 minutes the participants reach their baseline SC even though anxiety continues to decrease. For some participants using the blanket, the blanket influences an activating response and raises the SC above baseline so the effects could be seen.

Exit Survey Analysis and Interpretation

In addition to STAI-10 data, the exit survey questions were analyzed to explore each participant's responses regarding the use of the weighted

TABLE 8. Statistical Comparison of the Group with the Blanket and Without the Blanket

STAI-10	Skin Conductance			
	Greater Change With Blanket	Greater Change Without Blanket	No Change	Total
Greater change with blanket	7	3	9	19
Greater change w/o blanket	1	1	1	3
No change	2	–	6	8
Total	10	4	16	30

blanket, personal preferences, and whether the self-reports matched the STAI-10 and SC results. When asked, "when did you feel more relaxed, when using the blanket or when not using the blanket?" 25 of the 32 participants (78%) reported that they felt more relaxed with the blanket than without the blanket.

The exit survey included the question, "how did the amount of weight feel?" with three choices to choose from: too much, not enough (I would like it heavier), and good. Table 9 explores if there is a relationship between body weight and preference for a 30 lb weighted blanket. Only one person reported that the 30 lb weighted blanket was "too much," and, given the variability of body weight among the participants, body weight did not appear to significantly influence the person's preference regarding the 30 lb weighted blanket.

Additionally, the participants were asked to rank their preferences according to four of the qualities afforded by the weighted blanket using a Likert scale [ranking very effective (1) through very ineffective (5)]. These qualities include: the warmth of the blanket (temperature), the weight of the blanket (30 lb/deep pressure), the feel of the fabric (tactile), and that it was voluntarily used (not forced upon the participant). Table 10 shows the varied responses.

Finally, to the question "any other comments about the SC or weighted blanket?" Ten participants commented on the use of the blanket, and all were positive comments. When comparing the SC data for these ten particular participants, four had a larger percent change in SC with the blanket, four had a larger percent change in SC without the blanket, and two had no change.

TABLE 9. Deep Pressure Stimulation (DPS) Self-Report

DPS of the 30 lb. Weighted Blanket	Number of Responses	Body Weight Ranges
"Not enough"	5	112 -234 lbs.
"Good"	26	114 -206 lbs.
"Too much"	1	174 lbs.

TABLE 10. Weighted Blanket Qualities: Participant's Self-Ratings

Weighted Blanket Qualities Participant's Rankings	Very Effective (1)	(2)	(3)	(4)	Very Ineffective (5)
Warmth (Temperature)	12	15	3	1	1
Weight (Deep pressure)	13	15	2	2	0
Feeling of the fabric (Tactile)	11	11	7	2	1
Voluntarily used (Not forced upon you)	10	13	7	1	1

DISCUSSION

Limitations

There are several limitations in this study. One limitation is that only a 5-minute time frame was used in each of the test sessions; therefore, results cannot be generalized to the use of the 30 lb weighted blanket for longer time periods. Second, since one of the primary purposes of the study was to research safety, participants were all required to use the full 30 lb. When using the weighted blanket in clinical practice it is part of the protocol to individualize the amount of weight used and the preferred weight placement. Hence, different results may be obtained with the individualization of the amount of weight used. Third, the pulse oximetry and SC sensors did not stay in place for all of the participants; therefore, not all participants' pulse oximetry, pulse rate, and SC data were obtained. Fourth, there may be a difference in the results if the group without the blanket used a thin sheet rather than no sheet or blanket at all. Fifth, there is an absence of well-established mathematical models to characterize SC data without the use of other physiological measures such as respiration, though general guidelines have been put forward

using parameters such as number of SC peaks and their corresponding values (Boucsein, 1992). Thus, it is possible that the development and subsequent use of empirical models, through additional dynamic and statistical analysis of data, may provide more insight into the influence of the use of the weighted blanket. A final limitation includes the use of a low-to-no anxiety population, while according to Edelson et al. (1999), a threshold of arousal or anxiety may be necessary to influence SC changes when using modalities providing DPS. The low anxiety contributed to the physiological signal to seemingly reach a floor during the 5-minute test sessions.

Implications and Recommendations

This paper presents the results of a first exploratory study on the safety and effectiveness of the use of a 30 lb weighted blanket among a heterogeneous, non-hospitalized volunteer sample. A general protocol using quantitative and qualitative metrics was piloted to determine whether it would be useful in future studies on the safety and effectiveness of the weighted blanket. This research group will conduct these studies with both an adult population during an acute inpatient mental health hospitalization and a non-acute, volunteer adult population subjected to a high anxiety task.

The results of this study demonstrate that the use of a 30 lb weighted blanket did not adversely influence pulse oximetry, pulse rate, or blood pressure. Further, using SC as an anxiety metric, 33% of the participants were found to exhibit a greater reduction in anxiety with the weighted blanket than without the blanket. Observations however, reveal that there appear to be differences in the results. The corresponding STAI-10 survey responses showed that 63% of the participants rated their anxiety lower with the use of the weighted blanket. Furthermore, according to the exit survey, 78% reported a lower anxiety after using the blanket than when not using the blanket. Thus, the results indicate that the use of the 30 lb weighted blanket has a calming influence for some adults.

For many participants, the perceived sense of relaxation is greater than indicated by SC measures. This may be a result of some of the participants' reaching a SC floor as a sole result of lying down for 5 minutes. Further research comparing additional psychophysiological metrics more sensitive to changes in anxiety, in conjunction with SC, may enhance the ability to more accurately measure anxiety through the use of quantitative measures. Future studies looking at correlations among SC, DPS, age, sex, race, sensory tendencies, consumer preferences, and

diagnostic factors is recommended to continue exploring the safety and effectiveness of the therapeutic use of the weighted blanket. Research is needed to explore other aspects of safety, such as the use of the weighted blanket with people with different medical conditions. Additionally, future research may afford the ability to gain knowledge of how to engineer new technologies in the remote sensing of anxiety, and new DPS devices specific to people's unique needs and preferences.

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#5

A randomized controlled study of weighted chain blankets for insomnia in psychiatric disorders

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SCIENTIFIC INVESTIGATIONS

A randomized controlled study of weighted chain blankets for insomnia in psychiatric disorders

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Study Objectives: This study aimed to evaluate the effect of weighted chain blankets on insomnia and sleep-related daytime symptoms for patients with major depressive disorder, bipolar disorder, generalized anxiety disorder, and attention deficit hyperactivity disorder.

Methods: One hundred twenty patients were randomized (1:1) to either a weighted metal chain blanket or a light plastic chain blanket for 4 weeks. The outcome was evaluated using the Insomnia Severity Index as primary outcome measure and day and night diaries, Fatigue Symptom Inventory, and Hospital Anxiety and Depression Scale as secondary outcome measures. Sleep and daytime activity levels were evaluated by wrist actigraphy.

Results: At 4 weeks, there was a significant advantage in Insomnia Severity Index ratings of the weighted blanket intervention over the light blanket ($P < .001$) with a large effect size (Cohen's d 1.90). The intervention by the weighted blanket resulted in a significantly better sleep-maintenance, a higher daytime activity level, and reduced daytime symptoms of fatigue, depression, and anxiety. No serious adverse events occurred. During a 12-month open follow-up phase of the study, participants continuing to use weighted blankets maintained the effect on sleep, while patients switching from a light to a weighted blanket experienced an effect on Insomnia Severity Index ratings similar to that of participants using the weighted blanket from the beginning.

Conclusions: Weighted chain blankets are an effective and safe intervention for insomnia in patients with major depressive disorder, bipolar disorder, generalized anxiety disorder, or attention deficit hyperactivity disorder, also improving daytime symptoms and levels of activity.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Name: Controlled Study of Chain Blanket for Insomnia; URL: https://clinicaltrials.gov/ct2/show/NCT03546036; Identifier: NCT03546036.

Keywords: insomnia; major depressive disorder; bipolar disorder; ADHD; weighted blankets

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Insomnia is common in psychiatric disorders, contributing to the effect of disease. This study aims to evaluate the effect of weighted chain blankets as a treatment for insomnia in patients with psychiatric diagnoses.

Study Impact: In this randomized controlled study, we show that weighted chain blankets, a commonly used empirical treatment for insomnia, significantly reduce the severity of insomnia and improve daytime symptoms in a wide range of psychiatric disorders (major depressive disorder, bipolar disorder, attention deficit hyperactivity disorder, or generalized anxiety disorder). The clinical efficacy was supported by an objective assessment of sleep utilizing wrist actigraphy.

INTRODUCTION

Insomnia is a clinical condition characterized by difficulty of initiating or maintaining sleep, often accompanied by daytime symptoms such as fatigue, anxiety, and depression. Among adults, insomnia is one of the most prevalent psychiatric conditions. Depending on the criteria used, the prevalence in the population varies between 30% and 48% having insomnia symptoms to around 6% fulfilling criteria for the diagnosis.[1,2] In studies of patients with comorbid psychiatric diagnoses, the prevalence of insomnia tends to be higher, in average around 40% and reaching 80% in patients with depressive disorder.[1,3] Insomnia is often long-lasting. In a study by Mallon et al, 75% of participants with insomnia at baseline showed persistence of insomnia 12 years later.[4]

Insomnia causes considerable discomfort and decreases the working capacity of the individual. It increases the risk of accidents and mortality, leading to high societal costs.[5,6] Many psychiatric disorders are associated with high rates of severe insomnia, associated with substantial functional impairment.[7] Up to 70% of bipolar patients and 60% of adults with depression and anxiety suffer from insomnia.[8,9] Continued sleep disturbance after successful treatment of affective episodes is a risk factor for relapse in both major depressive and bipolar disorders.[9–11] Among patients with attention deficit hyperactivity disorder (ADHD), the prevalence of insomnia has been estimated at 6% to 80%, enhancing the burden of cognitive dysfunction, fatigue, and emotional symptoms.[12] Insomnia is a core feature of generalized anxiety disorder, affecting 60% to 70% of patients with this diagnosis.[13,14]

The primary therapeutic interventions for insomnia are cognitive behavioral therapy and pharmacological treatment. Although sufficient for a majority of patients, about 40% do not respond to those standard treatments.[15] There is a need for additional therapies for insomnia.

Two methods commonly used by occupational therapists for patients in psychiatric care is the therapeutic use of compression and weight.[16,17] A weighted chain blanket is a blanket in which metal chains have been sewn in. Chain blankets apply pressure to the whole body as a form of deep pressure stimulation and are used for sleeping problems and anxiety.

A suggested explanation for the calming and sleep-promoting effect is the pressure that the chain blanket applies on different points on the body, stimulating the sensation of touch and the sense of muscles and joints, similar to acupressure and massage.[18,19] This increases the sense of the body and its limits and provides confidence. There is evidence suggesting that deep pressure stimulation increases parasympathetic arousal of the autonomic nervous system at the same time reducing sympathetic arousal, which is considered to be the cause of the calming effect.[20,21] Also, the deep pressure on the body increases levels of oxytocin, which has a central role in relaxation and sleep. Oxytocin may produce anxiolytic-like or sedative effects and an increased pain threshold.[22,23] There have also been attempts to improve sleep by other sorts of manipulations of bed clothing. McCall et al randomized 29 healthy adults to either bedsheets impregnated with bioceramic far-infrared technology or standard bedsheets. They found that persons assigned to far-infrared sheets reported fewer insomnia symptoms and less napping.[24]

Evidence for the clinical effect of weighted blankets for insomnia is scant. In a controlled study of autistic children with sleeping problems, the use of a weighted blanket did not decrease the time to fall asleep or increase the total sleeping time. The weighted blanket was, however, appreciated by children and parents, and blankets were well tolerated.[25] In a study of children with ADHD, the authors concluded that the use of ball blankets is a suitable and effective method of treating insomnia.[26] In a study of 32 healthy students, the use of weighted blankets was considered safe and calming with a small impact on blood pressure and pulse rate.[17] An open study of 33 otherwise healthy participants complaining of chronic insomnia found that the weighted blanket had a positive impact on sleep, by both objective and self-reported measures.[27] Evaluations have shown that weighted blankets for adults are a safe method.[17,28] Controlled studies of weighted blankets as a treatment for insomnia in adults with co-occurring psychiatric disorders are nonexistent to our best knowledge, and a recent review of the clinical effects of weighted blankets found little evidence that they are helpful for insomnia.[29,30]

Despite the shortage of scientific evidence, treatment with weighted blankets is an increasingly recommended intervention for relaxation, insomnia, and other sleeping problems.[17,26,27] In Stockholm, around 2,700 chain blankets are prescribed to adults in psychiatric care every year.

This project started with an open clinical follow-up study of weighted blankets in 199 psychiatric patients with affective and ADHD diagnoses and co-occurring insomnia.[31] Due to the beneficial results, we decided to proceed with a controlled study.

Aims of the study

This study aimed to evaluate the effect of chain blankets on insomnia and sleep-related daytime symptoms for patients with major depressive, bipolar disorder, generalized anxiety disorder or attention deficit hyperactivity disorder in a controlled fashion.

METHODS

Study cohort

The study was performed in accordance with the World Medical Association Declaration of Helsinki after approval by the regional ethical review board in Stockholm (registration number 2015/102-31/2). All study procedures took place at the Affective Disorder Clinic at Psychiatry Southwest in Stockholm, Sweden, after oral information and the signing of a written consent form. Participants were free to withdraw from the study at any time without prejudice. Participants were recruited from affective disorder clinics in the Stockholm county through notification to doctors at the clinics that they could refer patients with psychiatric disorders and co-occurring insomnia to the occupational therapist at the Affective Disorder Outpatient Clinic for possible inclusion in a study of chain blankets. The referring doctors were not part of the study team and made their diagnoses of insomnia before patients consented to the study. The inclusion criteria for the study were clinical insomnia for more than 2 months with a score over 14 points at the Insomnia Severity Index (ISI) and a diagnosis of either major depressive disorder, bipolar disorder, generalized anxiety disorder, or ADHD. Exclusion criteria were active drug abuse, overuse of sleep medication, and illnesses affecting cognitive functions, such as dementia, schizophrenia, severe developmental disorders, Parkinson's disease and acquired brain injury.

Primary and secondary outcomes

The ISI is the primary outcome measure in this study. ISI is a 7-item, self-report measure for the evaluation of insomnia.[32] Items in the ISI concern difficulties falling asleep, problems staying asleep, daytime symptoms connected to the sleeping problem, and worrying about sleeping too little. Each item can be rated from 0 to 4, giving the rating scale a maximum summed score of 28 points. According to the guidelines for interpretation, 0–7 should be interpreted as no clinically significant insomnia, 8–14 as subthreshold insomnia, 15–21 as clinical insomnia of moderate severity, and 22–28 as severe clinical insomnia.[32]

The impact of sleep problems on quality of life and function during daytime was evaluated using the Fatigue Symptom Inventory, a self-report assessment to measure the intensity and duration of fatigue, and the Hospital Anxiety and Depression Scale (HAD) as a secondary outcome measure.[33–35] The HAD is divided into subscales for depressive symptoms (HAD-D) and anxiety symptoms (HAD-A), which are reported separately. Neither the depression nor the anxiety subscale of HAD includes an item related to sleep.

Patients' sleep symptoms were also evaluated from day and night diaries, a self-rating scale developed by Assistive Technology Stockholm (Stockholm, Sweden) for the evaluation of weighted

Table 1—Description of the sample and distribution between the randomized groups.

Variable		Total n = 120	Control Blanket n = 56	Weighted Blanket n = 64	*P*-Value
Sex	Female	82 (68.3%)	34 (60.7%)	48 (75.0%)	.093
	Male	38 (31.7%)	22 (39.3%)	16 (25.0%)	
Age (mean 39.6, range 18–77)	≤ 40	65 (54.2%)	30 (53.6%)	35 (54.7%)	.902
	>40	55 (45.8%)	26 (46.4%)	29 (45.3%)	
Diagnoses	Bipolar type 1	14 (11.2%)	8 (14,2%)	6 (9.4%)	.679
	Bipolar type 2	25 (20.1%)	13 (23.2%)	12 (18.8%)	
	Bipolar NOS	9 (7.5%)	3 (5.4%)	6 (9.4%)	
	Recurrent depression	46 (38.3%)	18 (32.1%)	28 (43.8%)	
	GAD	13 (10.8%)	7 (12.5%)	6 (9.4%)	
	ADHD	13 (10.8%)	7 (12.5%)	6 (9.4%)	
Use of hypnotics	Yes	44 (36.7%)	21 (37.5%)	23 (35.9%)	.859
Use of sedatives	Yes	39 (32.5%)	14 (25.0%)	25 (39.1%)	.101
Use of lithium	Yes	24 (20.0%)	9 (16.1%)	15 (23.4%)	.314
Use of anticonvulsants	Yes	17 (14.2%)	11 (19.6%)	6 (9.4%)	.108
Use of antipsychotics	Yes	27 (22.5%)	17 (30.4%)	10 (15.6%)	.054
Use of antidepressants	Yes	64 (53.3%)	26 (46.4%)	38 (59.4%)	.156
Use of stimulants	Yes	11 (9.2%)	6 (10.7%)	5 (7.8%)	.582
Sleep disturbance	Mean duration (years)	20.2 (SD 15.0)	19.7 (SD 14.0)	20.6 (SD 15.9)	.755

For the grouping of medications used by the participants of the study, see Table 2. ADHD = attention deficit hyperactivity disorder, Bipolar-NOS = bipolar disorder not otherwise specified, GAD = generalized anxiety disorder, SD = standard deviation.

blankets. In the day and night diaries, patients estimated the time it took to fall asleep (in minutes). They also rated 10 sleep-related symptoms on visual analog scales 65 mm in length, where 1 meant severe problems and 65 no problems. Five items concerned nighttime symptoms (awakenings, relaxed sleep, calm sleep, pain, and anxiety). The rating scale also contained 5 similar visual analog scales for daytime symptoms: alertness, concentration, worrying/relaxed, pain, and anxiety. We implemented objective analyses of nighttime sleep and daytime activity using wrist actigraphy. The study protocol did not include sleep diaries, which prevented us from calculating parameters using time in bed (such as sleep efficiency or latency to fall asleep). However, we could reliably estimate total sleep time, number of awakenings, and total time awake after sleep onset (wake after sleep onset, WASO) as objective measures of nighttime sleep and analyze them in relation with the main outcome measure. For daytime activity, we assessed the activity recorded during the most active 10 hours of the day (circadian peak of activity) by estimating the average hourly activity and the timing of peak of circadian activity.

Inclusion and randomization

From March 2015 to May 2017, 121 patients were referred for evaluation. One patient did not fulfill the criteria and was not included in the study. For a description of the study cohort, see Table 1. The patients were diagnosed clinically by psychiatrists who were not part of the study team or the evaluation of sleep disturbance with the ISI, and who had made the diagnoses before patients consented to be evaluated for the study. Participants were, with few exceptions, in a stable condition relative to their primary diagnoses but were experiencing problematic insomnia. Most of the patients used medication (Table 1). The patients and their doctor were told not to change doses during the study or stop or start using new drugs.

After inclusion, study participants were evaluated by ISI, the Fatigue Symptom Inventory (FSI), and HAD. During the first week after inclusion, participants were asked to wear an actigraph (GENEActiv, Activinsights Ltd., Cambridgeshire, UK) on the wrist of the nondominant arm in order to record activity. After completing the actigraphy recording, participants were randomly assigned either to a weighted chain blanket or a control blanket in a 1:1 proportion, using a concealed lottery method.

For the weighted chain blanket, a flexible weight protocol was used. Participants assigned to the weighted blanket tried an 8-kg chain blanket at the clinic. If they found it too heavy, a 6-kg weighted chain blanket was offered instead. As a control condition we used blankets into which plastic chains had been sewn of the same shape and size as the metal chains in the weighted blanket. The control blanket weighed 1535 g. When checking the weight of standard blankets for sale in one of the largest stores in Stockholm, we found their weights ranging from 550 to 2389 g (average 1332 g). Study participants were kept blind to treatment allocation by the information that they would be assigned to one of two types of chain blanket, without any information about the difference in weight. Blood pressure and heart rate were registered at randomization, and at the end of 4 weeks' use of the blankets.

The controlled phase of the study was evaluated with the ISI by a telephone interview at week 1–2 and by visits at 3 and

4 weeks' use of the blanket. Actigraphy recordings were acquired during the fourth week of the controlled phase of the study. FSI, HAD, and day and night diaries was also assessed at the fourth-week visit. ISI scores at 4 weeks after randomization was the primary endpoint. Response was defined as a decrease of 50% or more in the ISI from baseline to the endpoint. Remission was defined as a score of 7 or less on the ISI scale at the endpoint. All evaluations were performed by a rater blind to the randomization and allocation of blankets.

After completing the controlled phase of the study, participants were invited to enter a 12-month open continuation phase of the study. Participants who had been allocated to the weighted blanket were allowed to continue with weighted blankets, while participants assigned to the control blanket were switched to a weighted blanket. All patients, except 7, accepted the offer. Thus 112 participants continued using weighted blankets in the open part of the study. For the continuation phase, all participants tested 4 different weighted blankets: 2 chain blankets (6- and 8-kg) and two ball blankets (6.5- and 7-kg). After the test, the patients were freely allowed to choose the blanket which suited them best. Follow-up at 8 weeks after randomization with ISI consisted of a visit, and at 6 and 12 months after randomization, a telephone interview. The 7 participants who chose to stop using blankets were included in the follow-up study.

Objective evaluation of sleep

Actigraphic recordings were acquired using GENEActiv Original wrist-worn actigraphs (Activinsights). Briefly, the devices recorded wrist movement using 3-dimensional accelerometers capable of recording up to 8*g* with a resolution of 3.9mg in either direction at a 30-Hz sampling rate. The raw data was processed in MATLAB (The MathWorks, Natick, MD), using a modified version of the code (https://github.com/DavidRConnell/geneactivReader). The Euclidean norm of change in acceleration vector was first smoothed using a rolling Gauss window spanning 1 second (30 consecutive datapoints), then values below 20mg were set to 0 before computing the sum of changes in acceleration over 1-minute epochs. We defined 2 behavioral states, "sleep" and "wake" based on the recurrence rates calculated using recurrence quantification analysis (RQA), as described by Vanderlei Parro et al.[36] This method requires the optimization of 3 parameters: window size (for smoothing the actigraphy data before calculating the recurrence plot), epsilon (the size of the vicinity to define similarity between trajectories in the phase space to derive the binary recurrence plot for RQA), and threshold for binary state classification ("asleep" and "awake"). These parameters are typically optimized by comparing simultaneous recordings of wrist actigraphy and polysomnography, the gold standard for quantitative sleep analysis.[37] Polysomnography data were not available for this study, and the psychiatric pathology associated with insomnia in our population precluded the use of parameters optimized on populations of healthy controls available in the literature. Therefore, we used a combination of data-driven parameter optimization and heuristic selection of parameter values. We first smoothed the actigraphy data with a sliding Gauss window (width: 10 minutes). For the binary recurrence plot, we defined trajectories in the phase space to be "similar" if the distance between the points was smaller than the 10th percentile of all distances in the recurrence plot. Last, the threshold used for binary classification of states was determined using Otsu's method on the recurrence rate. The recurrence rate, calculated as the rate of occurrence of similar trajectories for each datapoint, typically assumes a bimodal distribution, where resting episodes (steady, low-level activity) are characterized by high recurrence rate, while active episodes (variable and relatively intense activity) are characterized by low recurrence rate. Otsu's method to set the threshold between the 2 states relies on optimization of intraclass variance. Individual thresholds estimated this way were used for binary classification of each datapoint as either "awake" or "asleep." The calculations for objective parameters of sleep were based on activity recorded between 20:00 and 12:00. The resting period

Table 2—Grouping of medications used by the participants of the study.

Hypnotics	Nitrazepam
	Zolpidem
	Zopiclone
	Propiomazine
Sedatives	Alprazolam
	Diazepam
	Hydroxyzine
	Oxazepam
	Promethazine
	Alimemazine
Lithium	Lithium citrate
	Lithium carbonate
Anticonvulsants	Lamotrigine
	Pregabalin
	Valproate
Antipsychotics	Aripiprazole
	Flupentixol
	Olanzapine
	Perphenazine
	Quetiapine
Antidepressants	Amitriptyline
	Bupropion
	Citalopram
	Duloxetine
	Escitalopram
	Fluoxetine
	Mirtazapine
	Nortriptyline
	Paroxetine
	Sertraline
	Venlafaxine
	Vortioxetine
Stimulants	Methylphenidate

was defined as the timespan between the beginning of the first episode of consolidated sleep longer than 5 minutes (ie, at least 5 consecutive "asleep" datapoints) and the end of the last episode of consolidated sleep longer than 5 minutes. By setting these criteria, we aimed to reduce the bias of including severely fragmented sleep at transitions between consolidated sleep and wake periods. Total sleep time and WASO were estimated as the total number of datapoints labeled as "asleep" or "awake," respectively, during the resting period.

To evaluate daytime activity, we focused on the circadian peak of activity defined as a continuous 10-hour-long recording segment containing the largest amount of activity. We divided the actigraphy recording into contiguous 24-hour segments (midnight to midnight) and smoothed the data with a 10-hour sliding Gaussian window before detecting the circadian peaks. We recorded the total amount of activity recorded during the circadian peak and the time of occurrence of the circadian peak of activity. All parameters were estimated separately for each 24-hour interval, then averaged per participant before statistical analyses. Participants with fewer than 3 consecutive days recorded were excluded because the within-participant variability is very high when intervals shorter than 4 days are analyzed (unpublished observation).

Statistical method

The analysis was done on an intention-to-treat basis. The randomization procedure was evaluated by a chi-square test for categorical variables (sex, age, diagnosis, and medication [yes/no]), and by *t* test for independent samples for the duration of sleep disturbance. We analyzed the change over time of the primary outcome variable ISI from preintervention to the end of the controlled phase of the study by the paired *t* test. Changes in ISI, FSI, and HAD scores during the study were also evaluated by repeated-measures analysis of variance. Response (yes/no) and remission (yes/no) were evaluated by logistic regression models with odds ratios and 95% confidence intervals. We also calculated the effect size by Cohen's *d*.

Eight- and 6-kg blankets were treated together as weighted blankets in the analysis. Changes in blood pressure and pulse frequency were tested by repeated-measures analysis of variance. Data for dropouts were treated by the last observation–carried forward method. For the analysis of secondary outcome

Table 3—Repeated measures analysis of variance.

Diagnosis	Blanket	PRE ISI	Week 1 ISI	Week 2 ISI	Week 3 ISI	Week 4 ISI	n	*P*-Value
All	Control	21.2	16.9	15.5	17.5	18.8	56	< .001
	Weighted	21.7	13.2	12.0	11.6	9.2	64	
Bipolar type 1	Control	20.6	15.9	14.0	16.4	16.5	8	.026
	Weighted	20.2	11.2	8.0	7.2	8.5	6	
Bipolar type 2	Control	21.1	16.8	12.9	15.1	18.4	13	.001
	Weighted	19.9	11.8	11.3	10.4	9.4	12	
Bipolar-NOS	Control	21.3	15.0	20.0	22.7	22.0	3	.001
	Weighted	22.2	14.0	12.0	13.2	10.5	6	
Recurrent depression	Control	21.7	17.7	17.0	17.8	18.7	18	< .001
	Weighted	22.7	13.5	13.2	13.0	9.6	28	
GAD	Control	21.6	16.9	15.7	18.6	20.0	7	< .001
	Weighted	22.0	16.3	10.2	8.5	6.2	6	
ADHD	Control	20.3	17.3	16.3	19.0	20.1	7	.003
	Weighted	21.0	13.5	13.8	14.0	9.5	6	
		FSI				**FSI**		
All	Control	84.0	—	—	—	74.5	56	< .001
	Weighted	85.1	—	—	—	52.9	64	
		HAD-D				**HAD-D**		
All	Control	9.5	—	—	—	8.9	56	< .001
	Weighted	10.5	—	—	—	6.1	64	
		HAD-A				**HAD-A**		
All	Control	13.6	—	—	—	12.9	56	< .001
	Weighted	13.8	—	—	—	10.3	64	

Repeated measures analysis of variance between control and weighted blanket on the Insomnia Severity Index (ISI), the primary outcome measure, and the secondary outcomes, FSI, HAD-D, and HAD-A, showing mean values, numbers, and test of significance between the interaction between time and the intervention. ADHD = attention deficit hyperactivity disorder, Bipolar-NOS = bipolar disorder not otherwise specified, FSI = Fatigue Symptom Inventory, GAD = generalized anxiety disorder, HAD-A = Hospital Anxiety and Depression Scale subscale for anxiety symptoms, HAD-D = Hospital Anxiety and Depression Scale subscale for depressive symptoms.

measures, we used repeated-measures analysis of variance models, followed by contrast analysis. All statistical analyses were performed in Statistica 13 (TIBCO, Palo Alto CA).

RESULTS

There were no significant differences between the randomized groups concerning sex, age, diagnostic composition, medication, or duration of sleep disturbance (**Table 1** and for the grouping of medications, see **Table 2**). Ten participants found the 8-kg chain blanket too heavy and chose to use a 6-kg chain blanket instead. One participant discontinued the study due to feelings of anxiety when using the blanket. Thus, 119 participants completed the controlled phase of the study. Only the participant mentioned above, experiencing anxiety by the blanket, discontinued the controlled phase of the study. Otherwise there were no reports of side-effects. Actigraphy was recorded in 113 patients before treatment (109 recordings included after quality control) and in 84 patients after treatment (79 included after quality control). In the longitudinal analyses we included 77 participants recorded both before and after treatment (35 controls and 42 using weighted blankets, out of which 16 were nonresponders and 36 were responders).

Primary outcome

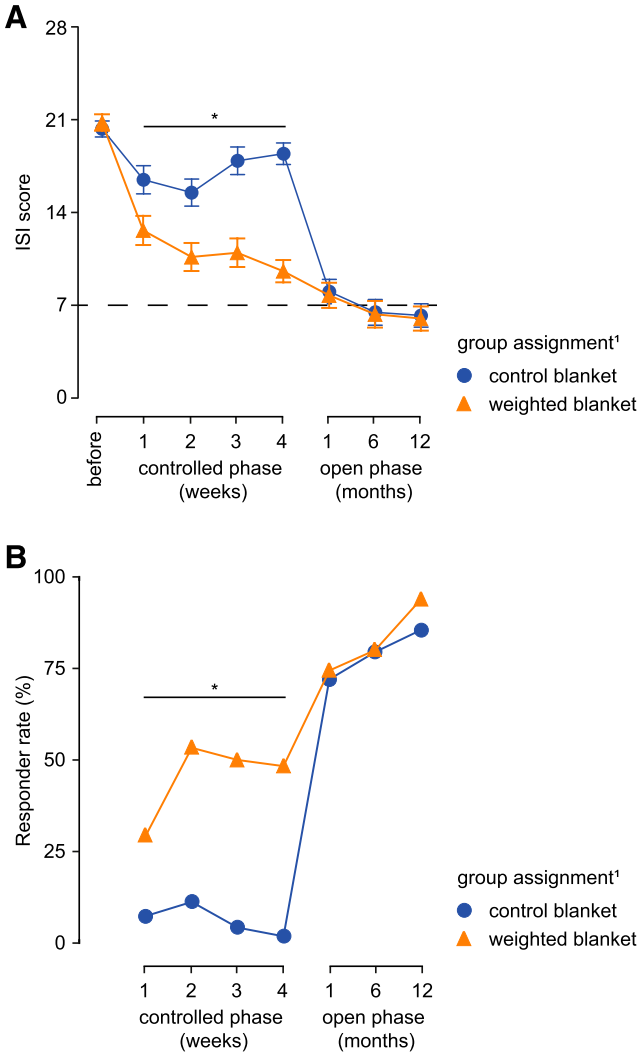
We found a significant effect of the weighted blanket on the primary outcome measure, ISI, compared to the control blanket for all study participants at endpoint ($P < .001$). In the analysis of all participants, the effect was significant after 1 week of blanket use (**Table 3**, **Figure 1**). We found no significant difference in the effect of the weighted blanket for sex or diagnostic subgroups.

The response rate was 59.4% (n = 38) for the weighted blanket group compared to 5.4% (n = 3) for the control blanket group (**Figure 1**). Remission rate was 42.2% (n = 27) compared to 3.6% (n = 2). The likelihood of responding was almost 26 times greater in the weighted blanket group than in the control blanket group (odds ratio 25.8, 95% CI 6.8–85.7) and the likelihood to remit was nearly 20 times greater (odds ratio 19.7, 95% CI 4.4–87.9). The effect-size was large, with a Cohen's *d* of 1.90. Participants who continued to the 12-month open phase of the study numbered 112. Participants who switched from the control blanket to a weighted blanket experienced an effect similar to patients who had used the weighted blanket from the beginning, and improvements increased during the 12-month follow-up period (**Figure 1**). At 12 months, 92% of all initial participants (n = 119), including those participants who chose not to continue with the blankets, were responders and 78% were in remission.

Analysis of nighttime sleep in relation to primary outcome

Next, we investigated the effects of weighted blankets on nighttime sleep using objective parameters of sleep derived from actigraphy recordings as well as self-reported scales. First, we validated WASO against the primary outcome measure and found that WASO was positively correlated with the total ISI score before treatment (**Figure 2A**), and that an increasing score on ISI item no. 2 (difficulty staying asleep) was associated with higher WASO (**Figure 2B**). Weighted blankets did not have a significant effect on total sleeping time (not shown) or WASO (**Figure 2C**). However, patients using weighted blankets reported an improvement in the ability to maintain sleep (**Figure 2D**).

Figure 1—Effects of weighted blankets on insomnia severity.

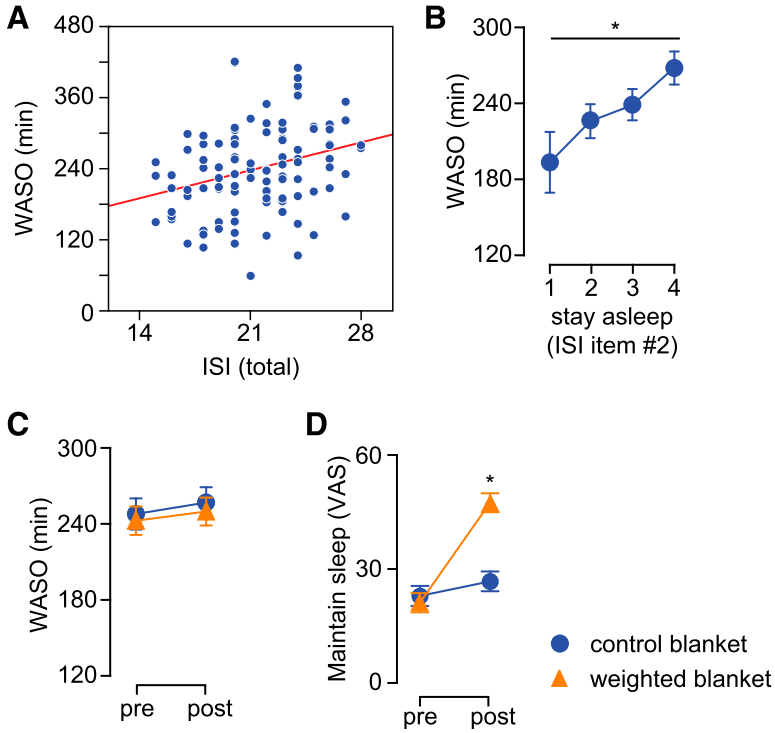


(A) In the controlled phase, total ISI score decreased significantly in patients using the weighted blankets already after 1 week. In the open phase, the average total ISI score decreased to 7 and lower, indicative of remission (dashed line indicates the ISI score defining remission). **(B)** The proportion of responders (ie, patients in whom ISI score decreased below 50% of initial value) is significantly higher in patients using weighted blankets compared to patients using control blankets in the controlled phase. In the open phase of the study, where all participants used a weighted blanket, the proportion of responders further increased and was not different between the patients assigned initially to control or weighted blankets. 1Group assignment applies only to the controlled phase (first 4 weeks of the study). *$P < .05$, interaction effect, repeated measures analysis of variance **(A)**; chi-square test for proportions **(B)**.

Effects on daytime activity

Poor sleep is associated with worse performance in daytime activity.[38] When we analyzed the daytime fatigue, as quantified

Figure 2—Assessment of nighttime sleep in relation to primary outcome measure.



(A) Total time awake after sleep onset correlated with total ISI score in all patients before treatment (Pearson $r = 0.29$, $P < .05$). **(B)** WASO increased with self-reported difficulty to maintain sleep (item no. 2 on ISI scale) before treatment. **(C)** Using weighted blankets did not have a significant effect on WASO. **(D)** Patients using weighted blankets reported improved ability to maintain sleep (assessed by means of visual analog scale, VAS). *$P < .05$, repeated measures analysis of variance, followed by contrast analysis. VAS = visual analog scale, WASO = wake after sleep onset.

by FSI, we found a significant reduction in FSI in patients using weighted blankets (**Table 3**, **Figure 3A**). Next, we asked whether the decrease in FSI was reflected in altered patterns of daytime activity. To this end we focused on the circadian peak of activity, which evaluates the participant's ability to output sustained activity during the day. We found that patients using weighted blankets displayed a significant increase in circadian peak of activity after treatment compared to controls (**Figure 3B**). In addition, the circadian peak was delayed in patients using weighted blankets (**Figure 3C**). This means that the level of activity was increased, and the patients were able to sustain activity for longer time, presumably also with lower number of resting periods required during daytime (illustrated in **Figure 3D**).

Effect on nighttime sleep and daytime activity in responders

We then analyzed in what way the changes in nighttime sleep may differ in relation to the response to treatment. To this end, we split the group of patients using weighted blankets into responders and nonresponders based on the relative change in ISI score using a threshold value of 50% (responder-relative decrease > 50%; nonresponder-relative decrease < 50%) before assessing the changes induced by the use of weighted blankets. We found that responders displayed a significant decrease in WASO (**Figure 4A**) and reported a larger improvement in sleep maintenance (**Figure 4B**) compared to nonresponders. In addition, the increase in the circadian peak of activity was similar in responders and nonresponders (**Figure 4C**). In contrast, the delay in the timing of the circadian peak of activity was significant only in responders (**Figure 4D**).

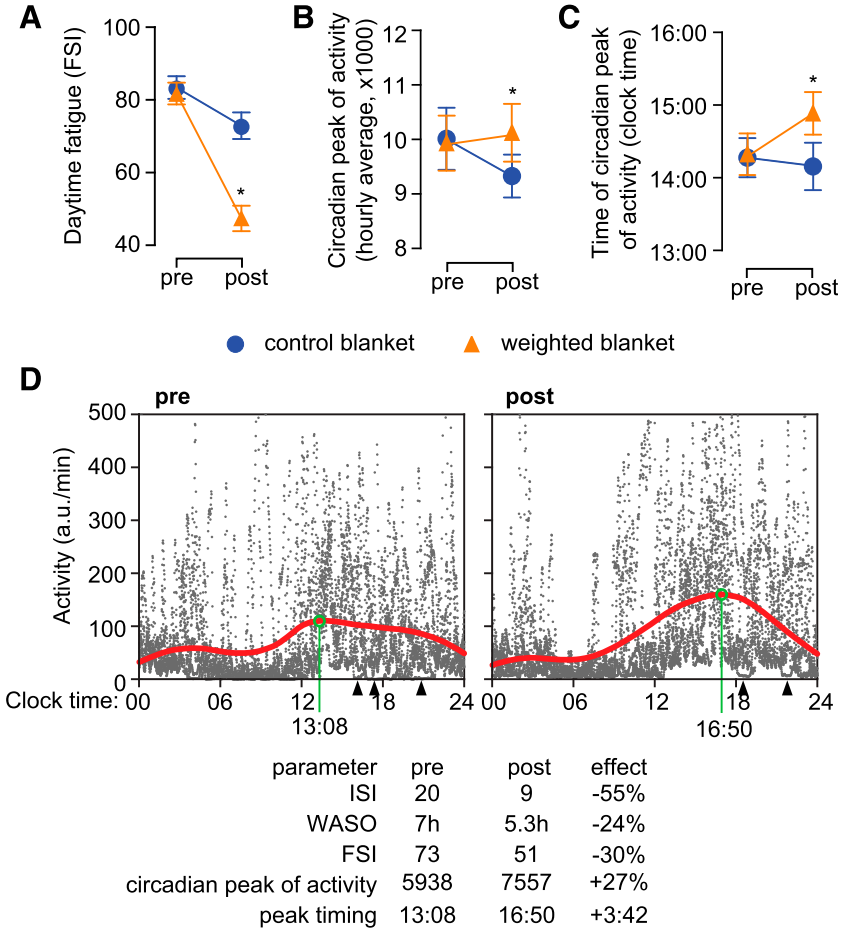
Effect on depression, anxiety, and blood pressure

Also, we found that depressive symptoms and anxiety symptoms decreased significantly for participants allocated to the weighted blanket, compared to participants assigned to the control blanket in the controlled phase (**Table 3**). The blood pressure decreased significantly from randomization to 4 weeks in both groups, with no significant differences between the weighted and control blanket (**Table 3**). A few patients with suspected hypertension were referred to primary care.

DISCUSSION

In this randomized study, weighted blankets showed a significant effect on insomnia in patients with major depressive disorder, bipolar disorder, generalized anxiety disorder, or ADHD. The impact on insomnia was clinically meaningful. The mean level of insomnia improved from almost reaching "severe," to a level of "subthreshold insomnia" on the primary outcome measure, ISI. The likelihood to remit was 26 times larger in the weighted blanket group than in the control blanket group. The 12-month follow-up study supports the long-term effect of weighted

Figure 3—Effects of weighted blankets on fatigue and daytime activity.



parameter	pre	post	effect
ISI	20	9	-55%
WASO	7h	5.3h	-24%
FSI	73	51	-30%
circadian peak of activity	5938	7557	+27%
peak timing	13:08	16:50	+3:42

(A) Daytime fatigue score decreased significantly after treatment in patients using weighted blankets. **(B)** Daytime activity increased only in patients using weighted blankets. **(C)** The time of occurrence of circadian peak of activity was delayed after treatment in patients using weighted blankets, but not in the control group. **(D)** Illustration of changes in patterns of activity in one patient after using weighted blanket for 4 weeks. Raw data (gray dots) is displayed as the amount of activity (integrated over 1-minute bins) plotted against the time of collection relative to the 24-hour cycle (6 consecutive days on both occasions). The circadian profile (red line) was obtained by smoothing the raw data with a sliding 10-hour-wide Gaussian window. Before treatment, the patient exhibited a rather flat circadian profile, with consistent activity during the night (consolidated sleep episodes between 4:00 and 13:00) and a very short period of consistent activity (between 13:00 and 16:00). In contrast, activity during nighttime was reduced after treatment, and the circadian peak of activity was more robust and occurred later (16:50 vs 13:08). Note that after treatment the patient had only 2 episodes of consolidated sleep (arrowheads) between 12:30 and 23:00 over 6 days, which illustrates the improved ability to sustain activity during daytime. *P < .05, repeated measures analysis of variance, followed by contrast analysis. FSI = Fatigue Symptom Inventory, ISI = Insomnia Severity Index, WASO = wake after sleep onset.

blankets. Participants who continued using the weighted blankets maintained the impact on sleep, while patients switching from a light to a weighted blanket got an effect on ISI ratings similar to participants using the weighted blanket from the beginning.

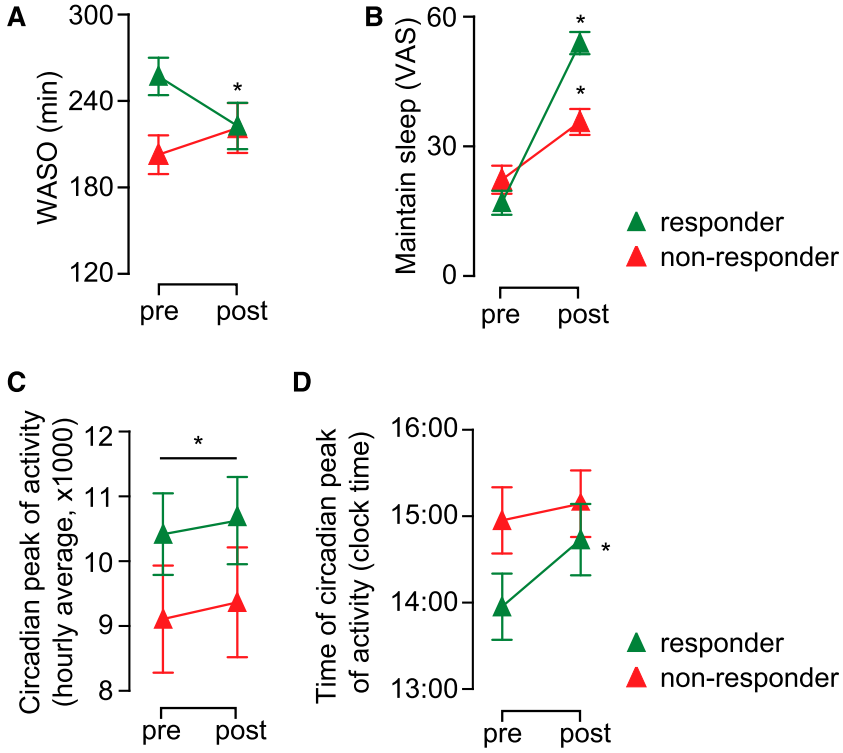
In the controlled phase of the study, 10 participants found the 8-kg chain blanket too heavy and used a 6-kg blanket instead. However, after 4 weeks of use, most of the participants in the open phase selected a heavier blanket. Only 1 participant discontinued the study due to feelings of anxiety when using the blanket. This is a rare occurrence in clinical practice, and patients with claustrophobia are usually able to continue treatment with a lighter blanket.

We found it interesting that there were more than twice as many women as men included in the study. This could be considered as sex bias, but it is consistent with earlier reports on the higher prevalence of insomnia among women.[39,40] There is a need for further research to understand why the prevalence of insomnia and other sleeping problems differ so much between women and men. However, no difference between sex in the effect of weighted blankets was found in this study.

In addition to decreasing the severity of insomnia, patients using weighted blankets reported positive effects on daytime fatigue. This was corroborated by objective measures of daytime activity: patients using weighted blankets appeared able to have more sustained active intervals, as demonstrated by the increase in activity level and the delay in the time of occurrence of circadian peak of activity.

The intervention by the weighted blanket also significantly improved symptoms of depression and anxiety compared to the control blanket group. These findings might seem surprising. However, previous studies described similar antidepressant

Figure 4—Differences between responders and nonresponders within the group of patients using weighted blankets.



(A) WASO decreased significantly only in responders. **(B)** Patients responding to treatment reported a more robust increase in sleep maintenance than nonresponders. **(C)** The increase in activity during the most active part of the day (circadian peak of activity) was similar in responders and nonresponders. **(D)** The circadian peak of activity was delayed in responders, but not in nonresponders. *$P < .05$, repeated measures analysis of variance, followed by contrast analysis. VAS = visual analog scale, WASO = wake after sleep onset.

effects of sleep therapy using cognitive behavioral therapy.[41,42] One suggested explanation for the antidepressant effect of improved sleep is that depression is more often caused or maintained by insomnia than vice versa.[43–45] In addition, reduced daytime fatigue may also facilitate behavioral activation, which is a cornerstone of cognitive behavioral therapy for depression. Other suggested mechanisms are the effect of decreased sleep on the production of brain-derived neurotrophic factor and changes in the cortisol hormonal and immune systems.[46,47]

We also investigated the differences in the effects of the intervention in patients who responded compared to patients who did not respond. Both self-ratings and objective measures of nighttime sleep indicated that responders experienced significantly better sleep maintenance. Similarly, the effect of weighted blankets on daytime activity point to a stronger effect in responders than in nonresponders.

A limitation of the study was the risk of disclosure of blanket-type to the rater, who was supposed to be blind to treatment allocation. Disclosure of blanket type, however, happened only once during the study when a participant unintentionally revealed the type by relating that the blanket had signaled in a metal detector at an airport security control station. In addition, the study protocol did not include sleep journals or polysomnographic recordings, which restricted the extent of the objective investigation of sleep.

Strengths of the study are the controlled design and the relatively large number of participants. The inclusion of patients with different psychiatric diagnoses improved the generalizability of the study since the reduction in the severity of insomnia was found in all diagnostic subgroups, implying that the effects of weighted blankets are independent of psychiatric diagnosis. The primary outcome measure ISI is an established rating scale for insomnia. In a comparative study of 6 rating scales for insomnia, ISI was found to be the most accurate measure to discriminate cases and non-cases of insomnia.[48] Also, the results are supported by objective sleep parameters derived from wrist actigraphy recordings. The long follow up period support the results of the controlled phase of the study. The study has a high ecological validity since the participants were real patients from psychiatric clinics.

In conclusion, we have shown that weighted blankets are an effective, safe, and clinically meaningful treatment for insomnia in patients with co-occurring major depressive disorder, bipolar disorder, ADHD, or generalized anxiety disorder. The intervention by the weighted blanket improved not only nighttime sleep but also daytime functioning, as illustrated by higher activity levels and reduced symptoms of fatigue, depression, and anxiety.

ABBREVIATIONS

ADHD, attention deficit hyperactivity disorder
FSI, Fatigue Symptom Inventory
HAD, Hospital Anxiety and Depression Scale

ISI, Insomnia Severity Index
WASO, wake after sleep onset

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#6

Weighted Blankets for Insomnia in Patients with Psychiatric Disorders

REMDESIVIR IN THE TREATMENT OF COVID-19

According to this study:
- The antiviral remdesivir is superior to placebo in the treatment of patients hospitalized with COVID-19.
- A variety of therapeutic approaches are needed to continue to improve outcomes in COVID-19 patients.

Since the emergence of COVID-19 in late 2019, researchers have evaluated several therapeutic agents, but no antiviral agent has been shown to be efficacious in the treatment of the virus. Researchers conducted a randomized, double-blind, placebo-controlled trial of the antiviral remdesivir for the treatment of patients hospitalized with COVID-19.

A total of 1,062 patients (mean age, 58.9 years; 64.4% were male) were randomly assigned to either intravenous remdesivir or placebo. The researchers assessed patients' clinical status daily using an eight-category ordinal scale and the National Early Warning Score, on which higher scores indicate greater clinical risk.

The median time to recovery was 10 days for patients assigned to remdesivir, compared with 15 days for those who received placebo. The benefit was greater when remdesivir was given earlier in the illness. The odds of clinical improvement on the ordinal scale were higher in the remdesivir group than in the placebo group, after adjustment for disease severity. Compared with the placebo group, the remdesivir group also had lower mortality estimates at day 15 (6.7% versus 11.9%) and day 29 (11.4% versus 15.2%). Patients who had a baseline ordinal score of 5 (receiving low-flow oxygen) showed the greatest benefit from remdesivir use. Serious adverse events occurred in 24.6% of patients receiving remdesivir compared with 31.6% of those receiving placebo.

The researchers note that high mortality rates in COVID-19 patients persist despite the use of remdesivir, pointing to the need for ongoing investigations into the use of combination therapies to improve outcomes in these patients.

Beigel JH, et al. *N Engl J Med* 2020;383(19):1813-26.

As we went to press: On November 20, after considering the results of several studies, the World Health Organization announced a conditional recommendation against remdesivir's use in hospitalized patients, saying that the medication has "no important effect on mortality, need for mechanical ventilation, time to clinical improvement, and other patient-important outcomes."

WEIGHTED BLANKETS FOR INSOMNIA IN PATIENTS WITH PSYCHIATRIC DISORDERS

According to this study:
- Weighted blankets have a clinically meaningful effect on insomnia and daytime functioning in patients with co-occurring major depressive disorder, bipolar disorder, generalized anxiety disorder, and attention deficit–hyperactivity disorder.

Insomnia is prevalent among adults, particularly in those who have comorbid psychiatric diagnoses. About 40% of people with insomnia do not respond to standard treatment, such as cognitive behavioral or pharmacological therapies. A controlled study was designed to evaluate the effect of weighted chain blankets, which provide a form of deep-pressure stimulation, on insomnia and daytime sleep-related symptoms in patients with major depressive disorder, bipolar disorder, generalized anxiety disorder, or attention deficit–hyperactivity disorder.

A total of 120 patients who had problematic insomnia were recruited from affective disorder clinics and randomly assigned a weighted chain blanket or a control blanket.

Compared with the control blanket, use of the weighted blanket had a significant effect on Insomnia Severity Index ratings, the primary outcome measure, in all participants. This became apparent after one week. In the weighted blanket group, the response rate was 59.4% compared with 5.4% in the control blanket group. The remission rate was 42.2% and 3.6%, respectively. The likelihood of responding was almost 26 times higher and the likelihood of remission nearly 20 times higher in the weighted blanket group compared with the control blanket group. Patients who switched from the control blanket to the weighted blanket had an effect similar to those who had used the weighted blanket from the beginning, and improvements increased during the 12 months of follow-up.

Patients who used weighted blankets also had less daytime fatigue, a higher daytime activity level, better sleep maintenance, and significantly decreased symptoms of depression and anxiety.

One limitation of the study was the risk that the type of blanket might be disclosed to the rater, who was supposed to be blind to treatment allocation. Another was that the objective evaluation of sleep was limited, because sleep journals and polysomnographic recordings weren't used.

Ekholm B, et al. *J Clin Sleep Med* 2020;16(9):1567-77.

#7

Weighted blanket and sleep medication use among adults with psychiatric diagnosis a population based register study

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Weighted blanket and sleep medication use among adults with psychiatric diagnosis – a population-based register study

Steinn Steingrímsson, Ellen Odéus, Mats Cederlund, Stefan Franzén, Carina Helgesson, Kristina Nyström, John Sondell & Arve Opheim

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ARTICLE

Weighted blanket and sleep medication use among adults with psychiatric diagnosis – a population-based register study

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ABSTRACT

Objective: To measure rate of subscription of common sleep medication and diagnoses of substance use disorder (SUD) before and after receiving a prescribed weighted blanket (WB) among patients with psychiatric diagnoses.

Materials and methods: Using register-based data of health-related factors in a Swedish region, a total of 1785 adult individuals with a psychiatric diagnosis, received a WB and resided in the region during the study period were identified. Using each individual as their own control, the rate of one-year prior prescription of WB or diagnosed SUD was compared to rate after a half year wash-out after prescription of WB for a full year.

Results: The number of patients without prescription of sleep medication increased by 3.3% (95% confidence interval (95%CI): 0.2–6.4, p=.04). Furthermore, the proportion without a prescription of benzodiazepine receptor agonist/antihistamines sleep medication increased by 5.5% (95%CI: 2.2–8.8, p=.001). Melatonin prescription increased after WB by 3.6% (95%CI: 1.1–6.2, p=.006). Younger age and unipolar-, anxiety-, attention-deficit/hyperactivity-, and post-traumatic stress disorder was associated with decreased use while psychotic-/bipolar- and personality disorder was not associated with a decrease in the use of sleep medication. The number of alcohol SUD diagnoses did not increase while sedative SUD rate increased statistically significantly by 0.7% (odds ratio = 1.63, p=.02). In a multivariate model, only younger age predicted discontinuation of sleep medication while psychotic-/bipolar- and personality disorder had statistically less decrease.

Conclusion: This observational register study found a statistically significant association between WB use and decreased use of common sleep medication except melatonin that increased slightly.

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Introduction

Sleep problems are ubiquitous among patients with psychiatric disorders [1]. There are several treatment methods used for insomnia including psychoeducation, pharmacological treatment and behavioral treatment [2], with pharmacologic treatment being frequently used. In 2019, almost one in 10 above the age of 15 years received at least one prescription of hypnotics and sedatives, classified in the group N05C in the Anatomical Therapeutic Chemical Classification System (ATC) in Sweden [3]. Since sleep problems are so common it is important to develop and utilize effective treatment modalities that have minimal risk of adverse events and are evidence-based.

Tactile stimulation, such as obtained through weighted blankets (WBs), is a non-invasive approach that has been gaining attention in recent years. The use of WB is mainly concerned with providing patients with external stimuli that may reduce anxiety and stress, most often included under the term deep pressure stimulation. The safety and effect of WB has been studied for adults and no risk for safety has been identified [4–6]. In healthy participants, WBs used for five minutes did not have negative effects on oxygen saturation, pulse rate, blood pressure or stress levels measured with either skin conduction or self-report [4]. Furthermore, a case series of 30 psychiatric in-patients using a similar experimental setup, showed comparable results with no adverse physiological responses and no increase in anxiety, albeit, when comparing WB to no blanket, both reduced anxiety to a similar degree [5]. A more acute stress response during tooth extraction may be ameliorated by WB as shown by

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more stable heart rate variability in a randomized-controlled trial [7].

Possible mechanisms that have been proposed for how tactile stimulation may alter well-being, is through pressure to the skin that modulates the automatic nervous system, ultimately affecting central parts, resulting in a calming effect [8,9]. Although the empirical basis for this theory is still mostly anecdotal, several studies have shown physiological responses to tactile stimulation. For example, by applying specific pressure stimulation of fingertips during day-time napping, no effect on the ability to perform a finger tap test was found; however, an altered pattern of recorded electroencephalogram was found where slow oscillations and sleep spindles differed between sham and active stimulation of fingers during sleep [10], indicating a physical effect of pressure stimulation.

Clinically, WBs seem to be generally accepted by adult patients with neurodevelopmental disorders [11]. A controlled trial in Stockholm, Sweden, showed a significant improvement in insomnia symptoms among patients with diverse psychiatric diagnoses [12] and another recent trial found positive effect of WB as an adjunct therapy for anxiety among oncological outpatients [13]. A recent systematic review concluded that WB may be effective for anxiety but that there was limited evidence for treatment of insomnia [14]; however, this review was published prior to the controlled trial from Stockholm. One associated field of interest is that WB can be to prescribed to those not responding to sleep medication or other treatments available but another indication might be to reduce the use of hypnotics that are generally not recommended for use longer than a few weeks which, however, is not followed in real life practice [15]. That is, WBs may be prescribed as a treatment for patients with sedative use disorder or other substance use disorder (SUD) since sleep medication can be substances of abuse [16] and sleep problems are common in SUDs [17].

A major knowledge gap that should be addressed is the pattern of regular use and the effect on adult patients with psychiatric diagnoses using WB for insomnia. For more than a decade, WB has been prescribed to patients with insomnia by physical- and occupational therapists in the West coast region of Sweden, free of charge for the patients. This provides the possibility for an administrative register database of the use of WB in clinical practice and, furthermore, to investigate whether WB use is associated with SUD diagnoses.

Aims of the study

The aim of this study was to investigate the intra-individual changes in the use of sleep medication by medication category, age, sex and diagnosis, as well as the changes in prevalence of SUD after prescription of a WB. Furthermore, an analysis of the rate of diagnosed SUDs was conducted to control whether patients were mainly prescribed WB due to overconsumption of substances.

Materials and methods

Study design

This is a register-based, observational study using administrative data on the use of WB prescribed in the region of Västra Götaland, Sweden during May 2015 through December 2017. A within-individual comparison was used where each individual served as their own control. Pre-prescription measures were collected from register-data from 365 days prior to receiving a WB and post-prescription measures were collected from register-data during a 365-day period after a wash-out period of 180 days.

Study population

The Region Västra Götaland is on the west coast of Sweden with a population of 1,713,907 as registered from January through March 2019 [18]. It contains both larger urban, as well as rural areas. All persons above 18 years of age who were registered with a psychiatric diagnosis (chapter F in ICD-10), and were prescribed and collected a WB were included in the study. Furthermore, they should be registered inhabitants in the region for at least one year after prescription to be included.

For the severe mental illnesses, a hierarchy was constructed, and an individual could only have one of these diagnoses in this order: psychotic-, bipolar- and unipolar disorder. Other diagnoses were non-exclusive of each other so any psychiatric diagnosis in the preceding year was considered a diagnosis in the analyses.

Measurements

Prescription of weighted blankets

WB is currently available as a prescribed medical-technical aid, free of charge for the patient, in the region of Västra Götaland, Sweden. It requires an assessment by a physical- or occupational therapist who then sends an application to the cost managers in the region. There are three different kinds of WB available: filled with balls, with chains or with fiber. The WB weight varies between 3 and 14 kg and is chosen by the prescribing therapist in agreement with the patient.

Sleep medication

Prescriptions of specific medications were registered in the national register of prescribed medication and the following commonly prescribed sleep medications were included under the following categories (ATC):

- Benzodiazepine receptor agonists (BZRA): flunitrazepam (N05CD03), zolpidem (N05CF02) and zopiclone (N05CF01).
- Antihistamines: alimemazine (R06AD01), levomepromazine (ATC code: N05AA02), promethazine (R06AD02) and propiomazine (N05CM06).
- Melatonin (N05CH01).
- Mirtazapine (N06AX11).

Prescriptions of BZRA and antihistamines were analyzed further for both discontinuation and new prescriptions since these were considered of special clinical importance. Furthermore, in the current paper, medication use and rate of prescription were used interchangeably but is by definition the registered prescription retrieval at a pharmacy. The selection of medications was decided in a consensus meeting by the research team in order to capture medication commonly used by clinicians to treat sleep problems. Other sedative medications such as antipsychotics were discussed but excluded since indication for use might be the primary disorder rather than for improvement of sleep.

Patient characteristics

Three patient variables were included:

- Age was calculated at time of retrieving the WB and divided into three age categories: 18–24, >24–64, and <64 years. These three age categories were chosen based on the main diagnostic groups to be expected, i.e. young adults with newly debuted major mental disorders and diagnosed neurodevelopmental disorders, adults with mood disorders and longer treatment history as well as older individuals where dementia would be more prevalent.
- Sex was defined by the unique personal identifier code issued to each individual at birth or at entrance into the Swedish administrative systems.
- Diagnosis was made at a registered visit with health care services according to Chapter V – 'Mental and behavioural disorders' in the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) [19]. Included categories were:
  - *Major mental disorders*. A hierarchy was constructed for these three categories so that schizophrenia excludes mood disorders and bipolar excludes unipolar and other:
    - Psychotic disorder including schizophrenia, schizotypal and delusional disorders = F20–F29.
    - Bipolar disorder = F30–F31.
    - Unipolar depressive disorder and other mood disorders = F32–F39.
  - *Neurodevelopmental disorders*
    - Autism spectrum disorder (ASD)=F84.
    - Attention deficit and hyperactivity disorder (ADHD)=F90.
    - Mental retardation = F70–F79.
    - Other developmental disorder = F80–F83 and F88–F89.
  - *Other*
    - Organic mental disorders (dementia)=F00–F09.
    - Anxiety disorders = F40–F41 and F44–F48.
    - Obsessive-compulsive disorder (OCD)=F42.
    - Post-traumatic stress disorder (PTSD) and other stress reaction = F43.
    - Eating disorders = F50.
    - Personality disorder = F60–F69.

Patients were included if they had received at least one of the above F diagnoses. The categories are based on clinical relevance and grouped together based on the exclusive criteria of major mental disorders within that category.

Substance use

An outcome measure of the rate of SUD, the year prior to WB and the year following inclusion period were defined per three substance categories: alcohol (ICD-10 diagnosis = F10), sedatives (F13) and other (F11–F12 and F14–F19).

Statistics

Pre-age and sex distribution as well as index diagnoses were described using counts and percentages. Pre and post index use of medication was compared using the difference in percentage together with a 95% confidence interval (95%CI) based on a normal approximation and a p value based from a Chi^2 test. Pre and post index substance abuse were compared using a mixed logistic regression model with a random effect for each individual accounting for repeated measures. The association between age, gender and pre index diagnoses as independent variables and continued medication was evaluated using a multiple logistic regression model. The doses of those who continued prescription were calculated as the number of prescribed tablets multiplied by the strength of the medication in mg and divided by number of days.

All tests used 5% as the significance level and due to the explorative nature of the study there was no adjustment for multiple comparisons. All analyses were done in SAS® 9.4 (SAS Inc., Cary, NC).

Ethical considerations

The study protocol was reviewed and approved by the regional ethical committee (1122-18/2019-00620). All data used in the study were administrative registered variables collected in databases which were not considered to be harmful or could reveal an individual identity, especially since all analyses were performed using pseudonymized codes.

Results

Demographics

In total, 1785 individuals were included in the study (Table 1). There were 72% females and most of the participants were between 25 and 64 years old (69%). The three most common psychiatric diagnoses were anxiety, unipolar depression and ADHD for both sexes and ages up to 65 years (Table 1). For the oldest age group, organic mental disorders were most common (67%).

Main outcomes of sleep medication use and diagnosis of substance use disorder before and after weighted blanket prescription

Out of the 1785 patients, 1186 (66%) received at least one prescription of the medications included in the study in the

Table 1. Demographics of patients receiving a prescription of weighted blanket in the Region Västa Götaland from April 2015 to January 2018.

				Age group		
Diagnosis	Total $n = 1785$	Males $n = 500$	Females $n = 1285$	18–24 $n = 404$	25–64 $n = 1223$	≥65 $n = 158$
Major mental disorders						
Psychotic and related	111 (6.2)	43 (8.6)	68 (5.3)	9 (2.2)	86 (7.0)	16 (10.1)
Bipolar disorder	214 (12.0)	37 (7.4)	177 (13.8)	23 (5.7)	180 (14.7)	11 (7.0)
Unipolar depression	664 (37.2)	173 (34.6)	491 (38.2)	149 (36.9)	480 (39.2)	35 (22.2)
Neurodevelopmental disorders						
ADHD	691 (38.7)	240 (48.0)	451 (35.1)	220 (54.5)	469 (38.3)	2 (1.3)
ASD	261 (14.6)	113 (22.6)	148 (11.5)	95 (23.5)	166 (13.6)	0 (0)
Mental retardation	153 (8.6)	70 (14.0)	83 (6.5)	32 (7.9)	117 (9.6)	4 (2.5)
Other developmental	55 (3.1)	27 (5.4)	28 (2.2)	24 (5.9)	31 (2.5)	0 (0)
Other						
Dementia	144 (8.1)	38 (7.6)	106 (8.2)	1 (0.2)	37 (3.0)	106 (67.1)
Anxiety	827 (46.3)	193 (38.6)	634 (49.3)	201 (49.8)	572 (46.8)	54 (34.2)
OCD	98 (5.5)	23 (4.6)	75 (5.8)	25 (6.2)	73 (6.0)	0 (0)
PTSD/stress reactions	359 (20.1)	60 (12.0)	299 (23.3)	54 (13.4)	304 (24.9)	1 (0.6)
Eating disorders	84 (4.7)	3 (0.6)	81 (6.3)	32 (7.9)	52 (4.3)	0 (0)
Personality disorder	268 (15.0)	27 (5.4)	241 (18.8)	55 (13.6)	211 (17.3)	2 (1.3)

ADHD: attention deficit/hyperactivity disorder; ASD: autism spectrum disorder; OCD: obsessive-compulsive disorder; PTSD: post-traumatic stress disorder. Diagnoses refer to diagnostic code given in the year preceding prescription. Numbers given as *n* (%).

Table 2. Main outcomes of sleep medication use and substance use disorder prior and following prescription of weighted blanket ($n = 1785$).

Prescription	Pre index *n* (%)	Post index *n* (%)	%-difference [95%CI; *p*]	Odds ratio [95%CI; *p*]
Sleep medication				
Melatonin	309 (17.3)	374 (21.0)	3.6 [1.1, 6.2; **0.006**]	1.27 [1.11, 1.44; **0.0003**]
Mirtazapine	272 (15.2)	243 (13.6)	−1.6 [−3.9, 0.7; 0.18]	0.88 [0.78, 0.99; **0.03**]
BZRA	719 (40.3)	650 (36.4)	−3.9 [−7.1, −0.7; **0.02**]	0.85 [0.79, 0.92; **<0.0001**]
Antihistamines	661 (37.0)	594 (33.3)	−3.8 [−6.9, −0.6, **0.02**]	0.85 [0.77, 0.93; **0.0005**]
No prescription	599 (33.6)	658 (36.9)	3.3 [0.2, 6.4; **0.04**]	1.16 [1.05, 1.27; **0.002**]
No BZRA/antihistamines	774 (43.4)	872 (48.9)	5.5 [2.2, 8.8; **0.001**]	1.25 [1.15, 1.35; **<0.0001**]
Substance use disorder				
Alcohol	69 (3.9)	64 (3.6)	−0.28 [−1.52, 0.96, 0.72]	0.92 [0.73, 1.17; 0.51]
Sedatives	21 (1.2)	34 (1.9)	0.73 [−0.08, 1.54, 0.10]	1.63 [1.06, 2.50; **0.02**]
Other	117 (6.6)	120 (6.7)	0.17 [−1.47, 1.80, 0.89]	1.03 [0.85, 1.24; 0.77]

BZRA: benzodiazepine receptor agonist; CI: confidence interval; *p*: *p* value. P-value of <0.05 is indicated in bold.

year preceding WB (Table 2). There was a significant reduction in the rate of prescription for BZRA and antihistamines (p=.02 for both), and also a significant increase in the rate of melatonin prescription (p=.006), as well as in the number of participants without a prescription of the analyzed sleep medications (p=.04). When analyzing odds ratio of continuation of prescriptions, the same rate was observed except for mirtazapine use which was less prevalent (Table 2).

The year before WB prescription 3.9% had a diagnosis of alcohol use disorder compared to 3.6% the year after, a non-significant difference (Table 2). However, there was a statistically significant increase in the proportion of patients with a diagnosis of sedative use disorder by 0.7% with an odds ratio of 1.6 (Table 2). Other SUDs were similar in proportion rate prior to and after WB.

Sleep medication use by sex, age and diagnostic category

Comparing between sexes, there was a reduction in the prescription of sleep medication for both women and men (Figure 1 and Supplementary table 1). However, melatonin increased for women and BZRA was decreased but for men this applied only to antihistamines.

In the youngest age category (18–24 year), the prescription of BZRA and antihistamines decreased. For the middle age group (24–64), the prescription of melatonin increased significantly and higher proportion were without BZRA/antihistamines. For the oldest age group, there was a statistical increase in prescription of melatonin and decrease in BZRA (Figure 1 and Appendix table 1).

Sleep medication use by diagnosis is presented in Figure 2 and Appendix Supplementary table 2. There was a significant increase in the proportion without a prescribed medication in the year following WB for the participants with unipolar depression, anxiety, ADHD and PTSD.

Multivariate analysis of discontinuation of sleep medication

When analyzing the rate of prescription of either BZRA or antihistamines, a total of 1011 patients received at least one prescription in the year prior to WB and of these 217 (21.5%) did not receive a prescription of these medications in the follow-up period. In a multivariate model, younger age was associated with lower medication use during follow-up, while the diagnoses psychotic disorder, bipolar disorder and personality syndrome were associated an increased risk for continuation of the medication (Table 3).

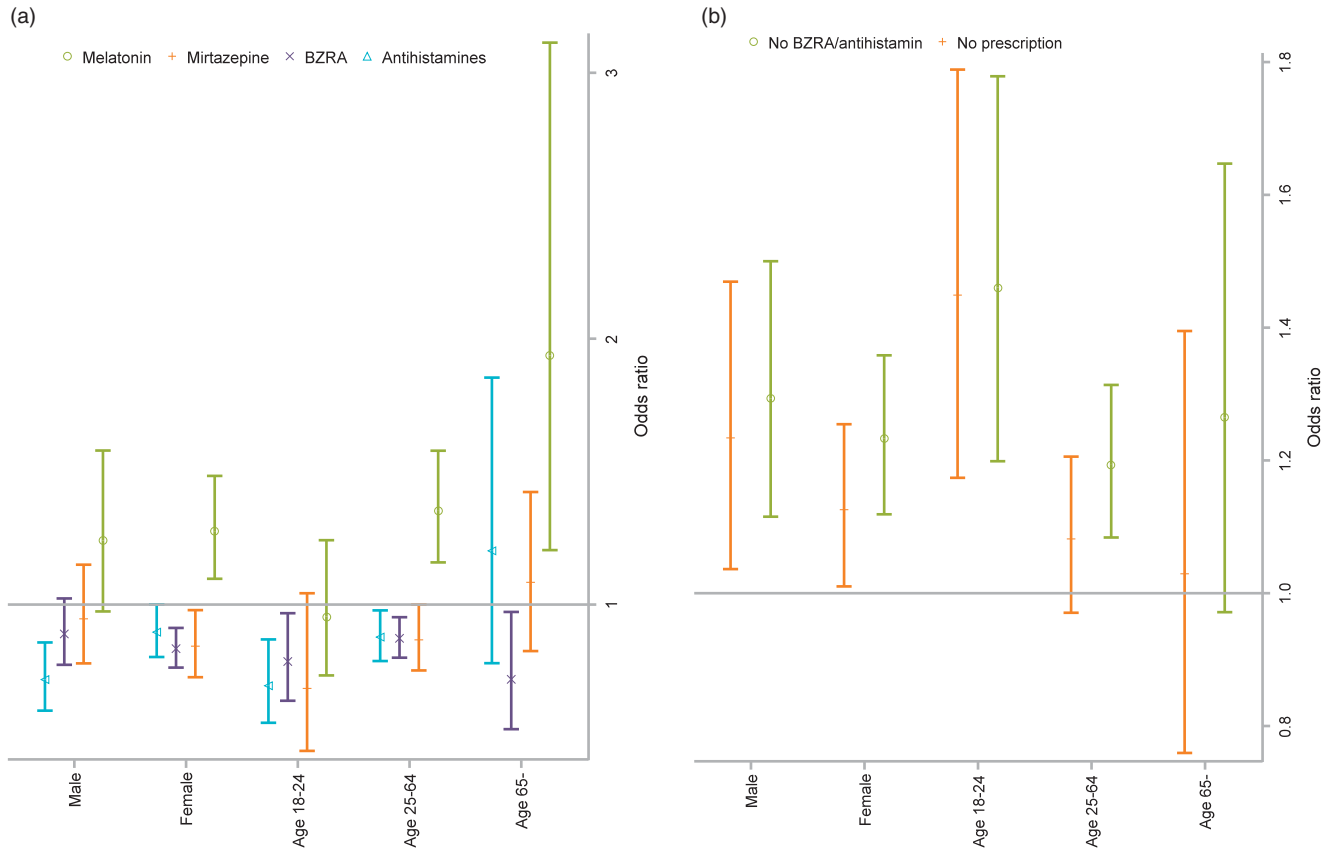

Figure 1. Forest plot of risk for continued prescription of sleep medication before and after weighted blanket by sex and age. (a) Prescribed medication after. (b) No prescription after.

Sleep medication doses for continued prescription

Comparing the doses as mg per day before and after the observation time is shown in Table 4. The patients who continued their sleep medication did not reduce their doses, rather for melatonin, propiomazine and zopiclone there was a statistically significant increase in dose.

Discussion

Main findings

This register study showed a modest reduction in the use of sleep medications following the prescription of WB, except for melatonin. The factors associated with lower prescription rate were younger age, unipolar depression, anxiety, ADHD and PTSD, while the diagnoses bipolar disorder, psychosis and personality syndrome were associated with a higher risk of continuing BZRA/antihistamines, albeit the rate did not increase in these groups.

Weighted blanket and sleep medication use

In the total population, the increase from 34% to 37% of persons without prescriptions of the studied substances was a significant reduction in the use of medication for sleep problems. This finding should be interpreted with care since the prescription of WB may have been started due to lack of effect or unwanted side-effects of the medication. However, this reduction supports the hypothesis that WB reduces the need for sleep medication. A recent randomized trial showed improved sleep in a population of psychiatric patients [12], where 120 patients received a WB or a non-WB. The primary outcome was the insomnia severity index (ISI, a self-rating scale), that showed a significant reduction in insomnia severity for those receiving a WB, regardless of diagnosis [12]. Furthermore, another recent study showed positive effects of WB on the general anxiety level in oncological patients receiving chemotherapy [13]. The present study may suggest that prescription of WB reduces sleep medication use especially among younger adults, as well as among those diagnosed with unipolar depression, ADHD, PTSD and anxiety.

The reduction in medication use was found to be numerically similar between the sexes. However, melatonin increased significantly for women, while BZRA were reduced. For the men, only antihistamines were significantly reduced. A further difference was that younger patients seem to have reduced sleep medication use albeit numerically this does not increase in the other age groups which might indicate an effect even there. A recent survey showed that younger age and women were at increased risk of road accidents in combination with insomnia and sleep medication [20], emphasizing how important it is to find methods that help these groups. Furthermore, the elderly group is of special importance since there is a lack of safe and effective interventions for insomnia [21] and there is a possibility that the present study lacks power with regards to this age group; however, BZRA were reduced during follow-up.

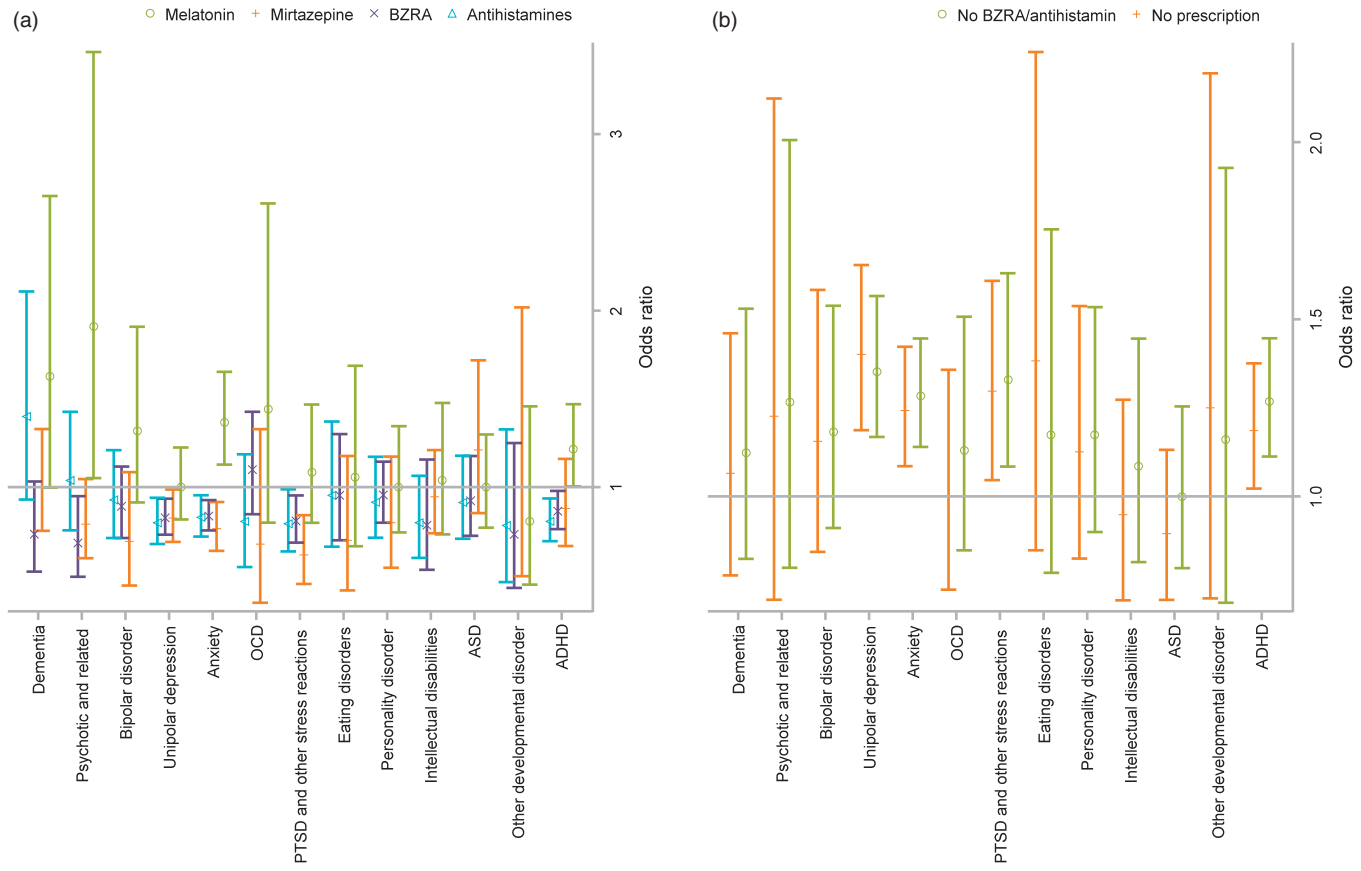

Figure 2. Forest plot of risk for continued prescription of sleep medication before and after weighted blanket by diagnosis group. (a) Prescribed medication after. (b) No prescription after.

Table 3. Multivariate risk factor analysis for continuing of prescription of sedatives/hypnotics the year after weighted blanket.

Variable	Odds ratio; 95%CI	*p* Value
Female	1.06; 0.88–1.28	.52
Age 18–24 years	0.55; 0.38–0.78	**.001**
Age 25–64 years	Reference	
Age >64 years	1.23; 0.71–2.13	.46
Major mental disorder		
Psychotic and related	2.56; 1.27–5.26	**.009**
Bipolar disorder	2.17; 1.27–3.70	**.005**
Unipolar depression	0.89; 0.64–1.25	.52
Neurodevelopmental disorders		
ADHD	0.88; 0.62–1.25	.46
ASD	1.12; 0.68–1.85	.66
Intellectual disabilities	0.92; 0.48–1.75	.80
Other developmental disorder	0.92; 0.35–2.44	.86
Other		
Dementia	0.72; 0.32–1.67	.44
Anxiety	1.37; 0.99–1.89	.06
Obsessive-compulsive disorder	1.47; 0.65–3.23	.35
PTSD and other stress reactions	0.88; 0.60–1.30	.53
Eating disorders	1.54; 0.70–3.33	.28
Personality disorder	2.04; 1.28–3.23	**.003**

ADHD: attention deficit/hyperactivity disorder; ASD: autism spectrum disorder; OCD: obsessive-compulsive disorder; PTSD: post-traumatic stress disorder. P-value of <0.05 is indicated in bold.

An important perspective to consider was that the use of melatonin in the general population of the region increased significantly during the study period. The proportion of inhabitants receiving a prescription of melatonin went from 4.2/1000 inhabitants in 2014 to 16.7/1000 inhabitants in 2019 [3]. At the same time, other sleep medications decreased, including BZRA and antihistamines. This might indicate that the reduction of sleep medication found in this study was a part of a general trend in the region, and probably in whole Sweden. Furthermore, one may speculate if WBs were associated with melatonin as a complement to chronotherapeutic way of thinking in clinical practice, that is circadian rhythm regulation. Our results of an increased use of melatonin might suggest such an association.

In the sub-analysis of risk for continued use of BZRA/antihistamines, it is important to note that patients with chronic disorders such as psychotic disorder, bipolar disorder and personality syndrome did not decrease their use, while younger patients did decrease the medication use. This might indicate that WB may be regarded as a possible add-on treatment in the case of patients with chronic disorders but may substitute medication for some patient groups such as anxiety disorders. That is, medication in the chronic disorders group can be part of a prophylactic treatment against severe worsening while for other disorders BZRA/antihistamines may be unnecessary over longer periods.

The outcome of the proportion of participants with SUD is perhaps not surprising. Alcohol SUD was numerically, but not statistically significantly, lower, while the rate of sedative SUD was significantly higher after the study period. The numbers were generally low, both before and after the introduction of a WB, and one can speculate that some patients were recommended WB in order to reduce overconsumption of BZRA, but that the diagnosis was only registered if the patient was unable to reduce the consumption. The

Table 4. Change in amount of sleep medication prior and after prescribed weighted blanket among patients receiving a medical prescription in both periods.

Prescription	*n*	Pre index mg [95%CI]	Post index mg [95%CI]	mg-difference [95%CI]	*p* Value
Benzodiazepine receptor agonists					
Flunitrazepam	14	0.5 [0.2, 0.9]	0.7 [0.4, 1.1]	0.2 [−0.3, 0.7]	.34
Zolpidem	192	8.4 [7.4, 9.5]	9.4 [8.3, 10.6]	1.0 [−0.6, 2.6]	.21
Zopiclone	496	5.5 [5.1, 6.0]	6.4 [5.9, 6.9]	0.9 [0.2, 1.5]	**.008**
Antihistamines					
Alimemazine	248	26.6 [23.2, 30.1]	29.8 [26.1, 33.5]	3.2 [−1.9, 8.2]	.22
Levomepromazine	62	29.3 [19.3, 39.2]	38.8 [27.7, 49.9]	9.5 [−5.4, 24.4]	.20
Propiomazine	326	26.2 [24.1, 28.3]	30.6 [28.3, 32.8]	4.4 [1.3, 7.4]	**.005**
Promethazine	175	34.5 [27.9, 41.1]	39.8 [33.1, 46.6]	5.3 [−4.1, 14.7]	.39
Melatonin	?	2.3 [2.0, 2.7]	3.4 [3.2, 3.7]	1.1 [0.7, 1.6]	**<.0001**
Mirtazapine	243	22.9 [20.7, 25.2]	26.1 [23.7, 28.5]	3.1 [−0.2, 6.4]	.06

CI: confidence interval. P-value of <0.05 is indicated in bold.

increased prevalence of sedative SUD may also suggest that the use of a WB did not influence the patients experienced need for sedatives. Furthermore, the finding that doses tended to increase for those continuing medication use may support that WB might sometimes be prescribed as a treatment method for individuals with overconsumption of BZRA/antihistamines.

Implications

This is the first large epidemiological register study of WB and shows a possible association to a reduced number of participants using sleep medications, and specifically BZRA and antihistamines. In combination with recent controlled trials, the use of WB could be considered as a possibly effective treatment modality for insomnia. However, there is a need for further randomized controlled trials that also measure long-term effects on sleep on a more detailed level.

There is generally a need for research and development of non-invasive physical treatments for sleep disorders that could be used outside the physical health-care environment by the patients themselves. Other examples of non-pharmacological treatments for behavioral changes include neurofeedback, chronotherapy and passive sensing digital data for feedback [22–25]. Perhaps the most established form of psychotherapy, delivered via digital means should even be included as a first-line treatment since it has been shown to have both short- and long-term effect [26]. In this line of thinking, WB may be more seen as part of a general sleep hygiene spectrum or lifestyle that may affect sleep [27].

In a larger sense, since sleep quality is a part of general well-being [28] and if environmental factors such as the weight of nighttime covers can improve well-being, WB might be a cost-effective means of achieving better public health.

Limitations

This is the first large scale epidemiological study investigating the use of WB in a population of patients diagnosed with psychiatric disorder. There is a strength in using objective measures such as prescribed WB, patient characteristics and prescriptions; however, this is also a limitation since there is no possibility to ensure that the administrative data reflect actual medication use or valid diagnoses. This limitation should be interpreted with caution since the registered data reflects how the clinicians make assessments and changes will likely represent an actual trend in real life.

A further limitation is that the design of epidemiological studies cannot define causality. That is, the reason for prescription of WB may be due to lack of response to medication or adverse events which would reduce the use in the follow-up period due to the individual's prior history.

Conclusion

In conclusion, in this register-based observational study, prescribed WB were associated with a reduced prescription rate of common sleep medications apart from an increase for melatonin. The reduction was especially prominent among younger patients and those diagnosed with unipolar depression, anxiety, PTSD or ADHD; however, younger age was the only factor that was significant in a multivariate model. Future research should focus on identifying which patient groups may gain from WB use and increase the level of evidence since this study and other recent studies are generally promising for this method of treating sleep problems.

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#8

Using weighted blankets in an inpatient mental health hospital to decrease anxiety

Using weighted blankets in an inpatient mental health hospital to decrease anxiety

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Abstract

Objective

Patients who are involuntarily committed to a psychiatric facility often experience anxiety or increased anxiety in response to being placed in the institutional environment. The weighted blanket introduced a proactive treatment option. The purpose of this study was to evaluate patients' anxiety symptoms before and after weighted blanket, compared to a group that did not use a weighted blanket to control anxiety.

Methods

This study was conducted in an inpatient mental health facility from June 10, 2019, through November 7, 2019, with psychiatric patients who were not actively psychotic. Participants were offered the choice of weighted or unweighted blankets for a 20-minute intervention. The treatment group was comprised of individuals who had opted to use a 14-pound weighted blanket, 20-pound weighted blanket or 5-pound weighted lap pad. Participants in the comparison group were active in a wider range of settings. Before application of the blankets, pulse rate was measured using a pulse oximeter, and anxiety was measured using the Spielberger State-Trait Anxiety Inventory shortened form (STAI: Y-6). Both measures were taken again after the intervention. A two-way mixed analysis of variance (ANOVA) was run to examine the interaction effects between time (pre/post) and group (comparison/weighted blanket). Simple main effects were then further examined for the comparison/weighted blanket groups using a repeated measures ANOVA. Within the weighted blanket group, additional two-way mixed ANOVA was run to determine if gender or blanket weight made a statistically significant difference.

Results

There was a statistically significant difference ($P < 0.05$) among those who used weighted blankets ($n = 61$) and those who did not ($n = 61$) based on the pre/post data for both the STAI: Y-6 inventory and the patients' pulse rates. The results of two-way ANOVA indicated a significant interaction effect between intervention time and group ($P < 0.001$). Repeated measures ANOVA indicated a change between pre/post for the weighted blanket group only, and showed significant reductions in both the STAI: Y-6 ($P < 0.001$) and pulse rates ($P = 0.040$). Within the weighted blanket group, additional two-way mixed ANOVA showed

that neither gender nor blanket weight had significant difference for either the STAI: Y-6 or the pulse measures.

Conclusion

The use of weighted blankets is a safe and potentially effective way to help individuals in a psychiatric facility manage anxiety. This study found a statistically significant drop in anxiety for adults at an inpatient facility, as shown by the STAI: Y-6 scores and drop in pulse rates among patients using weighted blankets. This study suggests a possible alternative to medications, seclusion and physical restraints, which are not patient-centered or trauma-supported.

Introduction

Anxiety is the most common mental health problem in the United States [1]. Although anxiety is not the primary admitting diagnosis for inpatient mental health facilities, patients often demonstrate anxiety symptoms and behaviors, including irritability, difficulty controlling worry, difficulty falling asleep or staying asleep, restlessness, difficulty concentrating and feeling edgy or wound up [2]. Exhibition of anxious behaviors often leads to the administration of medications meant to sedate a patient. Anxious behaviors can also lead to the use of restraints and seclusion, which can be traumatic experiences for patients [3].

A weighted blanket is a therapeutic blanket that includes weighted material designed to provide proprioceptive input to the body. Proprioception, sometimes referred to as the "sixth sense," is related to body position and movements [4]. Weighted blankets provide deep touch pressure stimulation, which has both physical and psychological advantages [5]. Deep pressure stimulation (DPS) affects the nervous system by increasing serotonin and melatonin concentrations while decreasing cortisol levels. This creates a calming effect, which may minimize stress, induce sleep and increase feelings of well-being [6].

The first exploratory study of weighted blankets by Mullen et al. [6] used a convenience sample of 32 non-hospitalized, heterogeneous individuals and the application of a 30-pound weighted blanket for 5 min. Participants were consenting, voluntary adults between the ages of 18 and 64, who were not hospitalized and had no apparent medical conditions or physical injuries. Participants were randomly assigned to one of two groups, which determined their assignment to either the control or treatment sessions. Sessions were 5 min in duration, with a 5-minute break between the two to complete the Spielberger State-Trait Anxiety Inventory (STAI-10) questionnaire [6]. The 5-minute timeframe for the sessions was selected based on Grandin's findings, which indicated that this was enough time to produce calming effects in children when using DPS [7]. It was also noted that results were often observable within minutes of a DPS intervention in adult populations in mental health settings.

The study took place in a nursing resource room where auditory interruptions in the testing environment were controlled, and a consistent temperature ranging between 72 and 75 degrees Fahrenheit was set. The room was designed to replicate a hospital setting and create a controlled environment that would allow for comparison to future studies conducted in various environments. Participants were introduced to the test environment, where the procedures were explained. They were provided the opportunity to ask questions before agreeing to participate in the study and signing the consent form. All participants were tested while lying down, and blood pressure, skin conductance, pulse rate and oximetry data were monitored throughout the sessions [6].

The study explored both safety and therapeutic effects in a relatively healthy population with low anxiety. Based on the population, it was hypothesized that the blanket effects would be minimal and that no safety concerns would be identified. The results indicated the weighted blanket was safe and that it did decrease anxiety, as average participants scored lower on their STAI-10 after using the blanket, even in a population that was generally characterized as "low anxiety" [6].

A pilot study conducted by Champagne et al. [8] consisted of a consecutive sample of 30 heterogeneous adults between the ages of 18 and 64 in an inpatient mental health facility. Exclusion criteria included impaired cognitive functioning, physical injuries, a positive pregnancy test and illiteracy. Participants were randomly assigned to one of two groups, which determined whether they would participate in the control or treatment sessions [8]. The study took place in the private rooms of participants staying in a 24-bed, locked, acute care mental health unit. The rooms had a standard temperature range of 65–79 degrees Fahrenheit with a privacy screen to reduce external stimulation. The STAI-10 survey and self-report anxiety rating were taken before participants lay down and after the 5 minutes was concluded. During the intervention, participants in the treatment group used a 30-pound weighted blanket for 5 min. Participants' blood pressure, pulse rate and oximetry data were monitored throughout the sessions [8].

Participants with blood pressure and pulse rates outside the normative range remained consistent during both treatment and control sessions. Additionally, the results indicated a positive effect of the weighted blanket use, with 60% of participants having a decrease in anxiety, as determined by the survey and analysis of physical measurements. This study indicated the need for future studies to explore client-centered methods that are effective and evidence-based and that would also encourage the reduction in use of restraints [8].

Studies of the use of weighted blankets have begun to show the blankets potential in reducing anxiety, providing a proactive treatment alternative to restraints, seclusion and medication that causes sedation and side effects. However, there have been very few studies to date, and both used the weighted blankets for very short intervals. The purpose of the current study was to identify if there was a significant difference in anxiety symptoms before and after weighted blanket use for adults in an inpatient mental health facility.

Section snippets

Study setting

The study was conducted in three units of a 66-bed inpatient mental health facility: (1) the critical care unit, where patients were involuntarily committed or voluntarily committed knowing they were a danger to themselves or others; (2) the drug/alcohol unit, where patients were being treated for drugs and/or alcohol addiction; (3) the older adult unit, where individuals were generally over the age of 60 and/or had a developmental disability or limited mobility. All three units were locked.

Baseline characteristics of participants

The mean ages of both the weighted blanket group and the comparison group were comparable. One hundred and twenty-two patients with the mean age of 39.5 years

participated in the study. The mean age of the comparison group was 39.2 years, and the mean age of the weighted blanket intervention group was 39.8. Males totaled 35.2% and females 64.8% of the weighted blanket intervention group, while the comparison group was comprised of 37.7% males and 62.3% females.

The primary diagnoses for patients

Discussion

This study found that use of a 14-pound or 20-pound weighted blanket or a 5-pound lap pad for approximately 20 min significantly decreased anxiety and pulse rate in adults experiencing anxiety in an inpatient mental health unit. The comparison group, who did not use a weighted blanket or lap pad, did not exhibit a statistically significant reduction in pulse rates or anxiety scores. In fact, their STAI: Y-6 scores increased between pre- and post-intervention assessments. The reduction in

Conclusion

Further research studies are needed to follow patients after discharge and measure anxiety, effects of medication use, and/or further use of the weighted blanket. Additional studies in care facilities should also control for medication usage before and after weighted blanket use, as well as any effects on the use of sedatives and/or physical restraints.

In addition, staff training is necessary to ensure safety and encourage the use of weighted blankets in lieu of typical methods. Staff should

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Author contributions

ALB designed the hypotheses and the experiments with the consultation and guidance of LRM. ALB and JN (supervised by ALB) used weighted blankets, facilitated the comparison group and collected anxiety measurements including measuring pulse and the STAI: Y-6 inventory as well as all data collection. LRM coordinated the data analysis via SPSS. All authors participated in data interpretation and manuscript review and writing. All authors were responsible for preparation of the tables and figures.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

#9

Intervention with weighted blankets for children with ADHD

BMJ Open

SLEEP: intervention with weighted blankets for children with attention deficit hyperactivity disorder (ADHD) and sleep problems: study protocol for a randomised control trial

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ABSTRACT

Introduction and objectives Children with attention deficit hyperactivity disorder (ADHD) have an increased risk of sleep problems. Weighted blankets are one possible non-pharmacological intervention for these problems in this group of children. However, the effectiveness of weighted blankets is insufficiently investigated. This study aims to investigate the effectiveness of weighted blankets in terms of sleep, health-related outcomes and cost-effectiveness as well as to explore children's and parents' experiences of a sleep intervention with weighted blankets.

Methods and analysis This study is a randomised placebo-controlled crossover trial comparing the effect of weighted fibre blankets (active) with fibre blankets without weight (control). Children aged 6–13 years, recently diagnosed with uncomplicated ADHD with verified sleep problems, were included in the study. The study period is 4 weeks for each condition, respectively, and then an 8-week follow-up. A total of 100 children diagnosed with ADHD and sleep problems will enter the study. The primary outcomes are sleep and cost per quality-adjusted life years. The secondary outcomes are health-related quality of life, ADHD symptoms, psychological distress and anxiety. Interviews with a subsample of the participating children and parents will be conducted for exploring the experiences of the intervention.

Ethics and dissemination Ethical approval of the trial has been obtained from the Swedish Ethical Review Authority (number 2019–-2158) and conforms to the principles outlined in the Declaration of Helsinki (WMA, 2013). Results will be reported as presentations at peer-review conferences, in articles in peer-review journals and meetings with healthcare providers.

Trial registration number NCT04180189.

Strength and limitations of this study

- The scientific evidence on the effectiveness of weighted blankets is insufficient.
- The results from this randomised controlled trial will provide new evidence of the efficacy, cost-effectiveness and experiences of the intervention.
- The design used to evaluate the intervention of weighted blankets in the trial may be applied to other healthcare settings and may lead to the development of systematic evaluations of the intervention in local contexts.
- Weighted blankets are prescribed to patients in healthcare as a non-pharmacological intervention for sleep problems, the results from this study make it also applicable to other categories of patients than children with attention deficit hyperactivity disorder.
- Potential limitations include loss to follow-up during the multiphase study and that the trial is only implemented at one Department of Child and Adolescent Psychiatry in the southern part of Sweden, which may limit generalisability of specific study findings to other populations and settings.

INTRODUCTION

Children with attention deficit hyperactivity disorder (ADHD) have an increased risk of poor health outcomes compared with healthy children.[1 2] The increased risk is especially apparent among girls.[3] Between 25% and 50% of children with ADHD have sleep problems,[1 2] commonly including bedtime resistance, night and early morning awakening and co-sleeping.[4] Sleep is important for everyday functioning and essential for health and well-being.[5–7] Sleep deprivation is associated with reduced quality of life,[8] an increased risk of various physical and mental health consequences[9 10] as well as increased risk-taking behaviour.[11–13] Furthermore, poor sleep negatively affects performance[10] and relationships in school,[14] which has consequences for school results and transition into adulthood and working life.[15 16] Sufficient sleep duration and quality is, on the other hand, associated with improved attention,

behaviour and cognitive functions as well as physical and mental health.[17 18]

The use of pharmacological treatment for sleep problems is common and has increased dramatically among children with ADHD in the last 10 years, although often with unfavourable side effects.[1 11 19] There is evidence supporting the commonly used melatonin compared with placebo, but the degree of benefit is uncertain.[20] There are various types of non-pharmacological interventions for children with ADHD to manage sleep problems, which are not associated with the side effects associated with pharmacological treatment. However, due to clinical heterogeneity, poor study quality and lack of randomised controlled trials (RCTs),[20–23] the evidence for the effectiveness of non-pharmacological interventions is inconclusive. Thus, there is a need for high-quality studies to evaluate the clinical effect and cost-effectiveness of non-pharmacological sleep interventions.

Weighted blankets were being prescribed in Sweden as a supplement to or replacement of pharmacological treatment for sleep problems among children with ADHD. However, the practice was recently stopped due to lack of evidence supporting the practice. The effectiveness of weighted blankets in this context has received little research attention and has generally had insufficient scientific quality,[21 24 25] with only one RCT.[26] This latter study had a randomised, placebo-controlled crossover design with a 4-week follow-up for each type of blanket. The population consisted of 67 children, aged 5–16 years, with autism spectrum disorders. Weighted blankets, compared with the control blanket, did not increase TST, sleep-onset latency or sleep efficiency (SE) as measured by actigraphy. However, parents and children preferred the weighted blanket, and the weighted blankets were well tolerated.[26] In a pilot study including only two children with an autism spectrum disorder, the use of weighted blankets improved the sleep quality, justifying the need for additional robust research.[27] A case–control study without randomisation included 21 children, aged 8–13 years, with ADHD and 21 matched healthy children as a control group showed some small positive effects of the weighted blankets on sleep onset latency (SOL).[28] In summary, these studies do not provide conclusive evidence of the effect,[25] economic effectivess[20 21] or children's and parents' experiences of weighted blankets for children with ADHD on sleep problems. Thus, an RCT evaluating weighted blankets for children with ADHD and sleep problems is timely. Given the societal cost and the quality of life implications of sleep interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be investigated.[20] The hypothesis of this RCT is that weighted blankets will improve objectively measured and self-reported sleep compared with control blankets in children with ADHD.

Objectives

This study targets children with newly diagnosed ADHD and sleep problems and aims to (1) evaluate the effect of an intervention with weighted blankets on sleep and other health-related outcomes, (2) evaluate the cost-effectiveness of weighted blankets and (3) explore children's and parents' experiences of the sleep intervention with weighted blankets.

METHODS

Study design

This is a randomised, placebo-controlled crossover trial investigating the effects of an intervention with fibre-weighted blankets in children with ADHD. The study period is 4 months, including 2×4 weeks of intervention with weighted blankets and control blankets, followed by an 8-week follow-up (figure 1). The study investigates the effect of the intervention in terms of (1) sleep and health; (2) cost-effectiveness and (3) experiences of sleep and health-related outcomes. The qualitative part will be performed using an explorative design based on interviews from a subsample of the included children and their parents. The interviews will be conducted at the end of the 4-month intervention in order to gain knowledge of the children's and parents' experiences of using these fibre-weighted blankets. The protocol is based on the Standard Protocol Items for Randomized Trials.[29]

Patient and public involvement

The design of the study and the preparation and formulation of this protocol have been coproduced with healthcare professionals at the child and adolescent mental health service (CAMHS). This includes being involved in; planning inclusion and exclusion criteria for the informants, preparing the arrangement for the intervention and selecting which questionnaires to be used to measure outcome variables for children and parents. The project manager has had regular meetings with the healthcare professionals at CAMHS throughout the preparation of the study. A pilot study, with seven children and their parents, has been performed to validate the design, interventions and questionnaires used. As part of this, we asked children and parents about their opinion of the intervention and also asked them for suggestions for improvements. This resulted in a few minor adjustments. The research project has been discussed with occupational therapists (who prescribe weighted blankets in Sweden) and representatives from the national occupational therapy association. The project and preliminary results have been and will be communicated through popular science reports, research conference contributions and research papers to the healthcare services, occupational therapists, patient groups and researchers during the research period.

Participants and recruitment

Children attending the ADHD unit at CAMHS in a county council in the southern part of Sweden during 2020–2021 will be asked to participate in the study. This ADHD unit is designed to assess and if indicated initiate treatment of

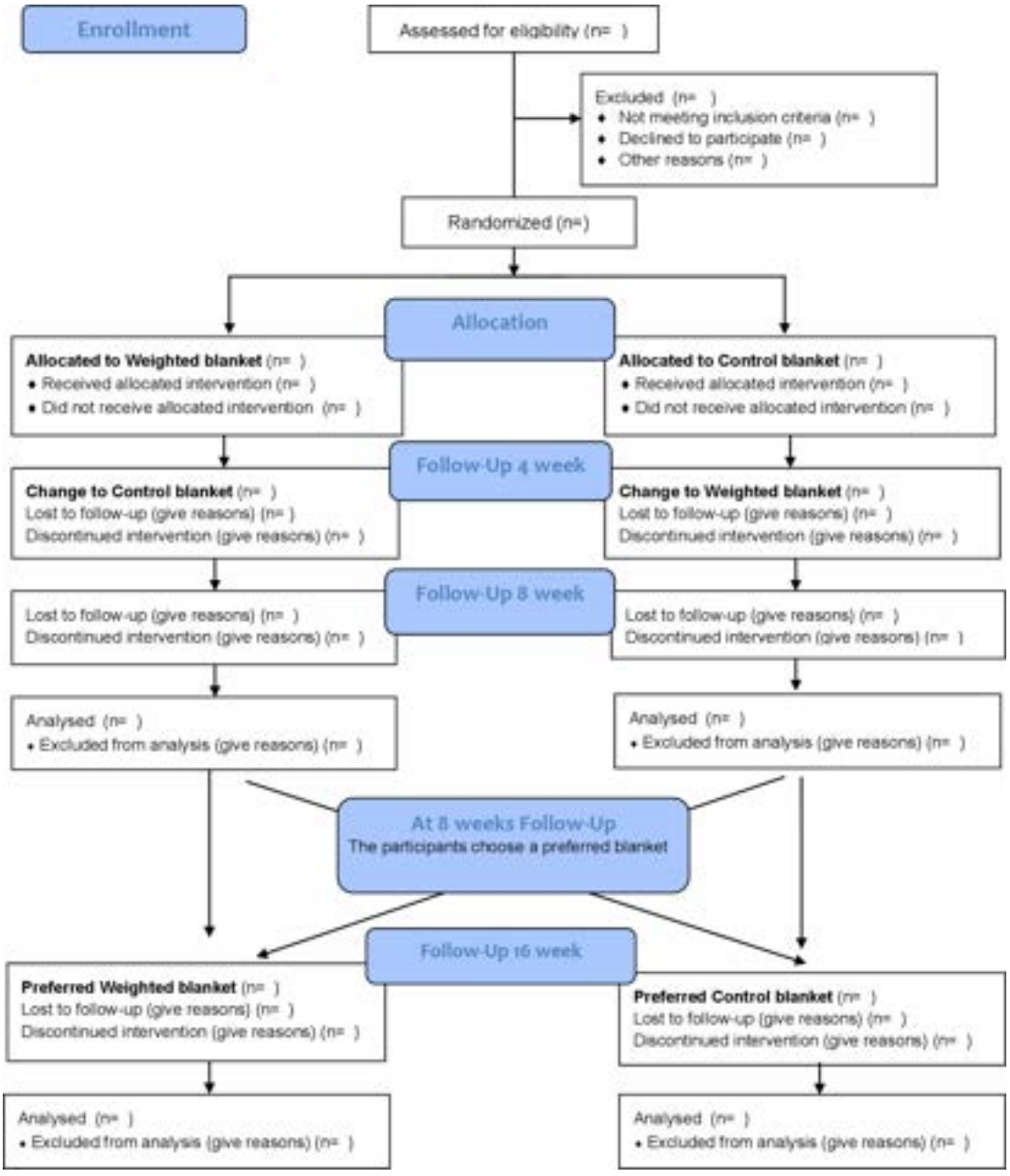

Figure 1 Flowchart RCT. The time between requirement, randomisation, intervention and follow-up. RCT, randomised controlled trial.

children with uncomplicated ADHD according to DSM-5[30] in order to increase effectiveness and reduce waiting lists. About one half of patients with newly diagnosed ADHD are seen in this unit. The triaging unit selected patients ages 6–12 when the structured Brief Child and Family Phone Interview (BCFPI) suggested a probable diagnosis of ADHD. Exclusion criteria for referral to this unit were significant comorbidity requiring immediate treatment, severe parental stress and intellectual impairment requiring more comprehensive interventions. The diagnostic assessment was based on written information from the present school (teacher report form and open questions about school functioning), the BCFPI, interview with parent and the child and observing the child during the 2-hour assessment. The diagnostic schedule was inspired by a short form of Kiddie Schedule for Affective Disorders and schizophrenia—Present and Lifetime version to cover ADHD, externalising and tic disorders as well as anxiety and affective disorders while infrequent diagnoses were not screened.[31] Patients in the ADHD unit received psychoeducation in groups and medication with fewer follow-ups than usual, and insufficient for the more complicated cases.[32] Recruitment of participants started in January 2020 and is estimated to be completed during autumn 2021. All children aged 6–13 years, recently diagnosed with uncomplicated ADHD with sleep problems verified by three selected questions from the Child's Sleep Habits Questionnaire (CSHQ),[33] will be

approached for participation in the study. Sleep problem is considered to be present if the child (1) seldom (0–1 times per week) or sometimes (2–4 times per week) fall asleep within 20 min after going to bed, (2) usually (5–7 times per week) or sometimes (2–4 times per week) sleep too little or (3) wake up several times per night. In addition to this, they need to report that the sleep difficulty in question is a problem. In addition, parents and children should understand (written and spoken) the Swedish language. Children will be excluded if they have already used weighted blankets as a sleep intervention, or if they were currently on and wished to stay on melatonin for sleep problems. Children diagnosed with ADHD and not started on a stimulant and with sleep difficulties above the threshold will be invited to get further information about the study at the 3-hour assessment visit. Children diagnosed with ADHD and started on a stimulant will again be reviewed for inclusion criteria at the medication follow-up after about 4 weeks.

First, eligible children and their parents will be informed verbally about the study by their doctor or nurse at the CAMHS. They will then receive written information about the study and be approached by healthcare professionals about participation. After the researchers have received written consent, the participants will be contacted by telephone and the research project leader will provide more detailed information about the study. The participants will be informed that they are about to try two different types of fibre blankets. The participants will be encouraged to contact the researchers if further questions arise.

Intervention

The participants (n=100) will be randomly assigned into two groups using simple randomisation with stratification.[34] A total of 100 sheets with the letter A (intervention) or the letter B (control) will be printed out and put into each envelope. The sealed envelopes will be mixed and one of the researchers will pick an envelope randomly for each child. The letter A or B indicates if the child will start with a fibre-weighted blanket (active) or with a fibre blanket without weight (control). After 4 weeks with either the active intervention (A) or control (B), the children will change blanket (if starting with active, the child will change into control, and vice versa). After this 8-week period, the child will decide which of the two blankets (active or control) that they want to retain.

Fibre-weighted blankets from Novista of Sweden (Novista.se) will be used in this study. The weight in the blankets is derived from longitudinal polyester fibres permitting flexibility. The blanket size is 150×210 cm, which is a standard size for children and adults in Sweden. The weight of each blanket will be individually tailored (weight between 6 kg and 10 kg) for the children, based on age, sex, height, weight, degree of sleep problems and subtypes of ADHD of two independent experienced occupational therapists. The fibre blankets without weight (controls) have been designed for the project, so that both active and control blankets have the same design. The weight is the only aspect that distinguishes them.

Data assessment

Data will be assessed at baseline (prior to the intervention) and during the 4th, 8th and 16th weeks of the study. The measurements are performed during the last of the 4 weeks to minimise the risk of bias due to carry over effects. A 7-day objective measurement of sleep will be conducted during these measurement periods. Self-reported data will also be gathered through the completion of a questionnaire by the parent and child, respectively (table 1).

Table 1 Overview of the questionnaires included in the study

	Assessed by children reports	Assessed by parents' reports
Socioeconomic variables		Children: age, gender, country of birth, Parents: age gender, country of birth, civil status, level of education, and work situation
Sleep habits	Insomnia Severity Index[39]	Child's Sleep Habits Questionnaire[33]
General well-being	Children Outcome Rating Scale[40]	Outcome Rating Scale[40 47]
Anxiety	State-Trait Anxiety Inventory[41 42]	
ADHD symptoms		Swanson, Peland and Nolan Scale[44 45]
Family situation and parental mood		The Brief Child and Family Phone Interview[49 50]
Health-related quality of life	EQ-5D-Y[51 53]	EQ-5D-3L[52 57]
Resource consumption		School absence (children), work productivity and absence (parents), and healthcare consumption according to Swedish adaptation[54 55] of the TIC-P instrument[56]

ADHD, attention deficit hyperactivity disorder; EQ-5D-3L, EuroQoL 5-Dimension 3-Level; EQ-5D-Y, EuroQol 5-Dimension Youth; TIC-P, Treatment Inventory of Costs in Patients with psychiatric disorders .

Interviews with an adequate sample of children (n=25) and parents (n=25) will be conducted after the intervention period in order to understand the experiences of the intervention's impact on sleep and health-related outcome.

Methods for investigating the health effects of weighted blankets

Primary outcome

The primary outcome is *objectively measured* and *self-reported sleep*. Variables of interest from the *objectively measured sleep* are: *Sleep onset latency* (*SOL*), which refers to the period of time between turning lights out to go to sleep (timing identified by marker from the event button or self-reported time in daily text messages) and falling asleep; *total sleep time* (*TST*), which is equal to the time of total sleep episode minus the awake time (the entire time spent sleeping); *sleep efficiency* (*SE*), which is the actual sleep time expressed as a percentage of the total time in bed (the time elapsed between "lights out" and "get up time)"; *wake after sleep onset (WASO)*, referring to periods of wakefulness occurring after sleep onset.

Objectively measured sleep will be assessed using actigraphy. This method for assessing sleep has been shown to be valid in several studies[35] and has shown to be strongly associated with polysomnographic measures with a correlation coefficient of at least 0.85 in healthy individuals.[36] Measurements from at least 4–7 nights have been recommended.[37] Motionwatch V.8 (Camntech), a triaxial accelerometer using Micro-electromechanical systems (MEMs) technology, capable of sensing motions in a resultant force range of 0.01–8 g[38] is used in this study. The actigraph registers total gross motor activity for analysis of sleep-wake patterns and has good validity for measuring sleep.[38] Recordings will be taken in 30 s epochs.

Participants will be instructed to wear the watch on their non-dominant wrist, for seven consecutive nights. If not worn during the day, the parent and child will be instructed to put on the watch in the early evening, or in good time prior to going to bed. The participant is instructed to push an event-button when they decide to go to sleep, for example, when they stop reading a book or turn off the lights. In addition to marking the event of going to sleep and waking up by pressing the button, the parents will answer questions daily (by text message): (1) What time did your child go to bed yesterday?; (2) How long time do you estimate the time for your child to fall asleep from the time your child went to bed? (hours, min); (3) What time did your child wake up today?; (4) Was your child restless and moved around a lot during sleep? (not at all restless, a little restless, moderately restless, very restless); (5) Was your child restless when falling asleep? (not at all restless, a little restless, moderately restless, very restless)

The variables of interest from the *self-reported sleep* will be assessed by CSHQ[33] and Insomnia Severity Index (ISI).[39]

The CSHQ assesses parental reported sleep and consists of 33 items related to eight subscales; (1) *Bedtime resistance*, (2) *Sleep onset delay*, (3) *Sleep duration*, (4) *Sleep anxiety*, (5) *Night wakings*, (6) *Parasomnias*, (7) *Sleep-disordered breathing* and (8) *Daytime sleepiness*. Each item is rated on a three-point scale: 'usually' if the sleep behaviour occurred five to seven times/week; 'sometimes' for two to four times/week and 'rarely' for zero to one time/week. A higher score indicates more sleep problems. The scale has good reliability and validity.[33]

Insomnia will be assessed by ISI, which comprises seven items for the children to respond to: (1) Severity of sleep onset, (2) Sleep maintenance, (3) Early morning awakening, (4) Satisfaction with current sleep pattern, (5) Interference with daily functioning, (6) Noticeability of impairment attributed to the sleep problem and (7) Level of distress caused by the sleep problem. Each item is rated on a 5-point Likert scale ranging from 'not at all' (scored at 0) to 'extremely' (scored at 4). Total score ranges from 0 to 28, with higher scores indicating greater severity. ISI is a reliable and valid instrument for quantifying the severity of perceived insomnia and measures insomnia in treatment research.[39] The ISI will be slightly modified in order to better correspond to a child's language.

Secondary outcomes

The children's general well-being will be assessed by the Child Outcome Rating Scale (CORS),[40] which is an overall measure of psychological distress. It was developed to give children a voice in the services they receive. CORS comprises four items where the child evaluates (1) Me (How am I doing?), (2) Family (How are things in my family?), (3) School (How am I doing at school?) and (4) Everything (How is everything going?). Each item is rated on a 100-millimeter Visual Analog Scale with smiling and sad faces as anchors. CORS has good reliability and moderate validity.[40]

The children's anxiety will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI).[41 42] Short-STAI includes six items.[43] Each item is rated on a 4-point Likert scale ranging with 1='not at all', 2='somewhat', 3='moderately' and 4='very much'. The total score range from 6 to 24 points, with six points indicating no anxiety and 24 points indicating the highest level of anxiety. Short-STAI has good reliability and validity for children.[41]

The children's ADHD symptoms—hyperactivity/impulsivity, inattention and oppositional—will be assessed by the parents filling in The Swanson, Peland and Nolan Scale (SNAP-IV).[44] The SNAP-IV consists of 30 items and is divided into three subscales: inattention (nine items), hyperactivity/impulsivity (nine items) and oppositionality (eight items) and four supplementary questions regarding oppositionality (two questions) and ADHD (two questions). Items are rated on a 4-point Likert scale range 0='not at all', 1='just a little', 2='quite a bit' and 3='very much'. Items for inattention and hyperactivity/impulsivity can be combined to create a 'combined ADHD' score.[45] Higher scores represent more symptoms.

The SNAP-IV is a robust and valid measure of outcome for research studies and is often used in RCTs.[46]

The parents' general well-being will be assessed by the Outcome Rating Scale (ORS),[47] which is a general mental health assessment of the past week in four items; (1) Personal well-being, (2) Interpersonal relationships, (3) Social relations and (4) Overall sense of well-being. Each item is rated on a 100-millimeter Visual Analog Scale with anchors from 0 (negative) to 100 (positive). ORS is a reliable and valid instrument.[40 48]

Family situation and parental mood will be assessed by the BCFPI,[49 50] BCFPI is a structured parent interview for triage at intake and follow-up evaluation of community care at CAMHS. It consists of 36 symptom items and another 36 items to assess function, adversity and family stress grouped into 12 subscales. The subscale 'family situation' contains three items rated on a 4-point Likert scale range 1=never, 2=sometimes, 3=often and 4=always. The subscale 'parental mood' contains six items based on the question 'How often during the past week has the parent experienced…?' rated on a 4-point scale; <1 day, 1–2 days, 3–4 days and >5 days. BCFPI has good reliability and validity.[49 50]

Health-related quality of life will be assessed for children with EuroQol 5-Dimension Youth (EQ-5D-Y)[51] and parents with EuroQoL 5-Dimension 3-Level (EQ-5D-3L).[52] EQ-5D-Y measures health-related quality of life 'today' for children and young people and is developed from the standard adult EQ-5D.[51] EQ-5D-Y comprises five items: (1) Walking about (mobility), (2) Looking after myself (self-care), (3) Doing usual activities (usual activities), (4) Having pain or discomfort (pain and discomfort) and (5) Feeling worried, sad or unhappy (anxiety and depression). Each item is divided into three levels: No problems, Some problems and A lot of problems. The EQ-5D-Y also includes an easily understandable modified vertical Visual Analogue Scale of EQ-5D, where the respondent rates the overall health status with the endpoints from 0 (the worst health state the child can imagine) to 100 (the best health state the child can imagine).[51] EQ-5D-Y has good reliability and validity.[53]

EQ-5D is a generic health-related quality of life instrument[52] measuring the parents' health comprising five dimensions: (1) Mobility, (2) Self-care, (3) Usual activities, (4) Pain/discomfort and (5) Anxiety/Depression. Each dimension is divided into three levels: no problems, some or moderate problems and extreme problems. In addition to the five dimensions, a 100-millimeter vertical Visual Analog Scale with endpoints of 100 means 'best imaginable health state' and 0 means 'worst imaginable health state is included'. The total score ranges from 0 to 1, where a higher score indicates a better health-related quality of life.

ADHD diagnosis and subtype as well as comorbidities will be extracted from the clinical records. In addition, symptom load from ADHD inattention or/and hyperactivity/impulsivity pharmacological treatment, sociodemographic data, resource consumption and will be collected via the survey at baseline and the 4th, 8th and 16th weeks of the study.

Methods for investigating the cost-effectiveness of weighted blankets

The health economic evaluation is a within-trial cost-utility analysis with a societal perspective based on the data collected at the 8-week follow-up, with the primary outcome costs per quality-adjusted life years (QALY). An incremental cost-effectiveness ratio (ICER) with a 4-week time horizon is calculated based on differences in societal costs (implementation costs and societal consequences) and quality of life when using either the fibre-weighted blankets or control blankets. No discounting of costs and health effects will be performed due to the short follow-up period. A number of sensitivity analyses are planned, including probabilistic analyses with bootstrapped differences of individual-level data on major societal consequences and quality of life as well as of the ICER.

The *societal cost consequences* combine parent-reported data on resource consumption with clinical register data to estimate the differences in societal costs between the two study arms at baseline and 8 weeks. The parent-reported resource consumption survey questions are based on a Swedish adaptation of the Treatment Inventory of Costs in Patients with psychiatric disorders (TIC-P) instrument[54–56] and consider the 4 weeks. The questions include school absence for the child (in numbers of full days, half days and 1–2 hours), work absence for one parent (in numbers of full days (8 hours), three-quarters of a day (6 hours), half a day (4 hours) and one-quarter of a day (2 hours)), work productivity of the parent (in 10 levels from no work accomplished to hardly no decreased work capacity) and healthcare appointments (nine types of healthcare including, eg, school healthcare, primary care and emergency care). The clinical register data include the number of appointments at the CAMHS and prescribed pharmacological therapy. The cost of the resource consumption items from the parent survey and the clinical register will be estimated according to Swedish published data on the average costs for healthcare appointments from the Swedish Association of Local Authorities and Regions (SALAR) and occupation-specific healthcare wages including wage taxes from Statistics Sweden. The cost of parents' work absence and decreased productivity will be estimated using average Swedish hourly wages including wage taxes from Statistics Sweden while the cost of child school absence is estimated according to estimated schooling costs from The Swedish National Agency for Education. The cost of prescribed pharmacological therapy will be estimated according to listed prices at the Dental and Pharmaceutical Benefits Agency.

The *implementation costs,* that is, the prescription of the weighted blankets, include the healthcare region's purchasing price for weighted blankets, administration and transportation from the assistive technology centre, child psychiatrist time for referral to an occupational

therapist, occupational therapist time for assessment, prescription and tailoring as well as parent and child time. The healthcare costs will be estimated based on data from SALAR and Statistics Sweden while the visiting and travelling time for the parent and child will be estimated according to data from Statistics Sweden and The Swedish National Agency for Education, as above.

Quality of life estimates for calculating *QALYs* over the 4 weeks period will be taken from the parent-reported EQ-5D instrument valued with a Swedish tariffs value set.[57] EQ-5D-3L is frequently used in Sweden and for economic evaluations and is considered a reliable and valid instrument.[57] There is currently no appropriate value set for the child version of EQ-5D (ie, EQ-5D-Y), so in a sensitivity analysis, the VAS ratings will be used and added to the parent-estimated QALYs. The QALYs during 4 weeks will be calculated based on the mean changes in quality of life of using weighted blankets versus control blankets, with an instant change assumed when initiating use of the weighted blankets.

Methods for investigating the experiences of weighted blankets

The qualitative data will consist of individual interviews with children and their parents in the intervention study. An open interview guide with initial questions will be used to ensure similar data from all participants. The initial questions refer to the experiences of sleep for children with ADHD, experiences of how the sleep intervention with weighted blankets influences the children's sleep and health-related outcomes as well as the family situation. *Questions to the children*: 'How do you usually sleep?', 'In what way can it be difficult to sleep?', 'How does sleep differ if you sleep well or badly?', 'What is important for you to be able to sleep?', 'How do you experience the two different blankets you have used?', 'How do you experience the weighted blanket?', 'Can you describe your sleep since you started using the weighted blankets?'. *Questions to the parents*: 'What does sleep mean for your child?', 'How does your child usually sleep?', 'What is important for your child to be able to sleep?', 'How is your child's life affected by sleep?', 'How do you experience the two different blankets your child has used?', 'How do you experience the weighted blanket?', 'Can you describe your child's sleep since he/she started using the weighted blankets?', 'How is your child's well-being since he/she started using the weighted blankets?', 'How has the situation for the family and you as a parent been affected since your child started using the weighted blanket?' *Follow-up probes* will be used to encourage children and parents to elaborate on the answers: 'Please tell me more' 'How do you mean?' or 'What do you have in mind when you say…?' The interviews will be digitally recorded and transcribed verbatim.

Statistical power

A power analysis was made based on estimated changes in the primary outcome variable SOL. Estimations of mean and SD were made based on previous studies of SOL in children. Mean SOL is expected to differ substantially with age among children. Gringras *et al* investigated children 5–16 years of age and found a mean value of 76,5 min of SOL with an SD of 46.1.[26] Hvolby and Bilenberg studied SOL in children 8–13 years of age and reported a mean value of 23.1 min of SOL with an SD of 9.4.[28]

Previous studies investigating the effect of similar interventions on SOL have found a 40% decrease in SOL after the intervention.[28] The power calculation of this study is based on the assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study, including children 6–13 years of age, estimating a mean of 35 min SOL and an SD of 15, the power analysis demonstrated that 58 children (29 in each group) will be a sufficient number if accepting a 30% difference between groups in SOL with 80% power. To allow for a 40% dropout, 100 children (50 in each group) will be enrolled in the study.

Data analysis

Statistical analyses will be performed using SPSS V.24 for Windows. The intervention will be evaluated in terms of effect and cost comparison. Differences will be evaluated with an intention to treat analysis. Objectively and subjectively measured sleep, anxiety and health-related quality of life will be evaluated with a paired t test or equivalent non-parametric tests and by independent sample t test for between-group analyses of carry over and period effect. Children included are stable on medication before inclusion and are encouraged not to initiate other sleep adjustments during the study period. ADHD symptoms and sleep problems are, thus, considered to be stable over the 4+4 cross over period minimising any period effects. The weighted blanket is only active under actual use, and the treatment effect is not likely to be carried over. Linear mixed-effect model will be used for evaluating the effect on sleep problems over time. Differences in societal costs will be analysed via non-parametric bootstrap analyses on individual-level data and reported as credibility intervals.[58] The qualitative data from interviews will be analysed with inductive qualitative content analysis.[59]

ETHICS AND DISSEMINATION

The study is approved by the Swedish Ethical Review Authority (number 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki.[60] The study will fulfil the requirements for research: information, consent, confidentiality and safety of the participants and is guided by the ethical principles: autonomy, beneficence, non-maleficence and justice.[61] All participation and data collection will be performed confidentially. Children and parents will receive written and oral information and parents give their informed consent in writing. The participants will be informed that they can withdraw from the project at any time without having to justify why. Data will be collected in anonymised form and keys that link data with personal information will

be stored separately and only accessible to the project leader. All personal data will be registered according to the General Data Protection Regulation (2016/679),[62] and the data will be stored in accordance with the Archive Act in Sweden (SFS1990:782).[63] This study is registered at http://clinicaltrials.gov. The results of this study will be communicated to the included participants, healthcare providers and companies, in manuscripts submitted to peer-reviewed journals as well as in presentations at national and international peer-review conferences.

DISCUSSION

Weighted blankets are prescribed to patients in healthcare in Sweden and are widely used as a non-pharmacological intervention for sleep problems, even though evidence for the effects of weighted blankets is lacking. The few previous studies investigating the effect of weighted blankets for children with ADHD have not shown conclusive results and, to date, there are too few high-quality studies to support the intervention.[25–28] The results from this RCT will, thus, be important for providing new evidence of the efficacy, cost-effectiveness and experiences of the use of weighted blankets to address sleep problems among children with ADHD.

Some methodological considerations can be highlighted. A strength is that this study will be the first randomised placebo-controlled crossover trial investigating the effects of fibre-weighted blankets in children with ADHD. Another strength is the use of both objective and subjective measures for sleep. Although subjectively measured sleep is highly relevant to assess and evaluate, objectively measured sleep has the advantages of being free from subjective expectations in relation to the intervention and less sensitive to recall bias. Furthermore, the evaluation of cost-effectiveness of weighted blankets is highly relevant though this has not previously been studied.[21] The costs and benefits of the intervention need to be taken into consideration when implementing the intervention in healthcare settings. Similarly, the inclusion of a qualitative approach in the design to increase the understanding of both children's and parents' experiences of effects is another strength. This latter aspect is of great relevance as children's perspectives are seldom taken into account in research.

There are, however, a few methodological challenges with this study. Assessing self-reported data from children is difficult for several reasons. Some of the questionnaires in this study are designed for the parent to respond on behalf of the child (eg, CSHQ). This may be a good approach for younger children, but depending on the habits around bedtime, the parents may only have (at best) a reasonably good perception of how the child's sleep was (eg, if sleeping in separate bedrooms). Under these circumstances, the parent and the child are instructed to fill in the questionnaire together to get a more reliable assessment. Another potential bias is the control blankets. The difference in weight will be obvious for parents and also for children. The participants are only informed that they are trying two different kinds of blankets. However, most have learnt about weighted blankets through media or their health providers, possibly affecting expectations in favour of the weighted blanket

We anticipate that the project will make several scientific contributions to the research on health-related outcomes, sleep and cost-effectiveness for non-pharmacological sleep interventions, such as weighted blankets. These findings will be essential for healthcare professionals in their practice though evidence today for the effects of weighted blankets is scarce. The results will also be relevant for children with ADHD, in particular, but will also be relevant for other target groups and other settings.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained from parent(s)/guardian(s)

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#10

Parents' Experiences of Weighted Blankets' Impact on Children

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Article

Parents' Experiences of Weighted Blankets' Impact on Children with Attention-Deficit/Hyperactivity Disorder (ADHD) and Sleep Problems—A Qualitative Study

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Abstract: Sleep disturbances are common among children with attention-deficit/hyperactivity disorder (ADHD). While pharmacological treatment has increased dramatically, parents often prefer non-pharmacological interventions. Research on experiences of weighted blankets and their effect in sleep improvement is scarce. The aim of this study was to explore parents' experiences of weighted blankets for children with ADHD and sleep problems, and the impact on their children's sleep. The explorative design was based on qualitative content analysis. Interviews were conducted with a purposeful sample of 24 parents of children with ADHD and sleep problems, after completing a sleep intervention with weighted blankets for 16 weeks. Parents reported that children sleeping with weighted blankets: (1) achieved satisfactory sleep, including improved sleep onset latency, sleep continuity, and sleep routines; (2) achieved overall well-being, including improved relaxation and reduced anxiety; and (3) mastered everyday life, including improved balance in life, family function, and participation in school and leisure activities. This study brings forward novel aspects of the effects of improved sleep among children with ADHD. The findings contribute to the understanding of potential positive effects of an intervention with weighted blankets critical for clinical practice to improve sleep, well-being, and everyday life of children with ADHD and their families.

Keywords: attention-deficit/hyperactivity disorder (ADHD); experiences; children; intervention; parents; qualitative content analysis; sleep problems; weighted blankets

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1. Introduction

Attention-deficit/hyperactivity disorder (ADHD) affects approximately 5% of school-age children worldwide [1] and is characterized by impulsivity, inattention, and/or hyperactivity [2]. Children with ADHD have an increased risk of poor health outcomes, compared to healthy peers. The negative behaviors associated with ADHD cause difficulties with interpersonal interactions and educational outcomes, and are likely to be exacerbated by sleep disturbances [3]. The prevalence of sleep disturbances among children with ADHD is high (up to 70%) [4,5], compared to healthy peers (20–30%) [6]. Children with ADHD have been found to have between 30 to 60 min shorter sleep duration and significantly more night awakenings, compared to healthy peers [7–9]. Sleep disturbance includes both initiation and maintenance of sleep. The most common sleep disturbances among children with ADHD are: bedtime refusal (e.g., resisting going to bed), difficulties in initiating sleep (e.g., insomnia), difficulties staying asleep (e.g., nighttime awakening), disproportionate daytime sleepiness, and fragmented sleep [3,5].

Sleep is essential for health and well-being and is important for everyday activities [10–12]. Among children, poor sleep negatively affects physical and mental health [13,14], quality of life, [15] along with performance [14] and relationships at school [16]. Sufficient duration and sleep quality are associated with better attention, behavior, and cognitive functions, and better physical and mental health among children [17,18]. Satisfactory sleep is thus important for school achievement and transition into adulthood and working life, especially for children with ADHD [19,20]. Further, children's sleep disturbances have a significant impact on parents' everyday lives and are associated with higher parental stress, poorer parental mental health, and increased parenting stress [21]. This emphasizes the importance of taking a whole-family perspective when managing sleep problems among children with ADHD [21,22].

The use of pharmacological treatment (e.g., melatonin) for sleep problems among children with ADHD is common and has increased dramatically in the past 10 years, although often with unfavorable side effects. Melatonin is the most common medication for sleep in various neurological conditions and is regarded as safe and effective [23] but might cause morning drowsiness, increased enuresis, headache, dizziness, diarrhea, rash, and hypothermia [24]. However, if there are alternatives, parents prefer non-pharmacological interventions to pharmacological treatment [25]. Interventions with weighted blankets are used as a replacement or supplement to pharmacological treatment for sleep problems [26–28]. The use of weighted blankets is based on the theory of sensory integration with assumptions of how the body reacts to different stimuli depending on the sensitivity to stimuli [29,30]. A weighted blanket is considered a sensory-stimulating, cognitive aid that provides a deep pressure on the body (deep pressure touch stimulation). The pressure created by the weight from the weighted blanket leads to a feeling of being enveloped and increasing body awareness [31]. The effectiveness of weighted blankets among children with ADHD is essentially unexplored [26–28]. Only two studies (one case-control study, and one intervention study without controls) investigating the effect of weighted blankets among children with ADHD have been found. The studies found positive effects of weighted blankets on sleep, ADHD symptoms, daily level of functioning, and quality of life [32,33]. Only one randomized controlled trial (RCT) investigating the effect of weighted blankets on sleep in children has been found; however, that study only included children with autism spectrum disorders. No positive effects on sleep were seen in the study, although both parents and children favored weighted blankets over their usual blanket [34]. In summary, there is no convincing evidence of the effect [28] or the economic impact [27,35], nor any qualitative studies from children's and parents' perspectives on using weighted blankets to improve sleep in children with ADHD [3]. In filling this gap [35], an RCT by our research group is underway to explore the effects of an intervention with weighted blankets on both sleep and everyday life for children with ADHD and sleep problems [36]. By way of this RCT, we will provide new evidence of the efficacy, cost-effectiveness, and experiences of the intervention from children's and parents' perspectives.

This qualitative study contributes to increased knowledge on the impact of an intervention with weighted blankets on sleep among children with ADHD from their parents' perspectives. This type of knowledge is important, both to provide understanding of the intervention as such, and in the development of sustainable interventions using weighted blankets for sleep improvement in clinical practice. The aim of this study was to explore parents' experiences of a non-pharmacological intervention with weighted blankets for children with ADHD and sleep problems and the impact on their children's sleep.

2. Materials and Methods

2.1. Design

The study had an explorative design based on inductive qualitative content analysis, which aims to explore variations by identifying differences and similarities in a text, formulated in categories and themes. Qualitative content analysis is useful for analyzing an individual's experiences, reflections, or attitudes [37,38]. To ensure trustworthiness, the

study is reported following the Consolidated Criteria for Reporting Qualitative Research 32-item checklist [39].

2.2. Intervention

This study focused on the parents' experiences of a sleep intervention with weighted blankets that included children aged 6–15 years old with newly diagnosed ADHD and sleep problems [36]. Diagnoses were based on a detailed written report from school including a SNAP-IV rating scale [40] and an interview with parents and the child performed by a registrar or locum junior doctor utilizing a structured protocol. The decision was always discussed and confirmed by a consultant child psychiatrist during the diagnostic session. The consultant could choose to interview the child and parents as needed but an oral report was mandatory and mostly sufficient. The sleep intervention was based on a comparison of fiber-weighted blankets and control blankets–i.e., fiber blankets without additional weight. The weighted blanket and the control blanket had the same design, so that the weight was the only aspect that distinguished them. The fibers used in the weighted blanket consisted of polyester filaments. The weight of each blanket was individually tailored (weight between 6 and 10 kg) for the children based on age, sex, height, weight, degree of sleep problems, and subtypes of ADHD, in accordance with the use in the clinical practice of two, independent, experienced occupational therapists. The children were randomized to start either with a weighted blanket or with a control blanket and used each blanket for four weeks and then changed to the other blanket (a crossover design). After eight weeks, the child was to choose one of the blankets and use this blanket for an additional eight weeks, thus the duration of the intervention was 16 weeks.

2.3. Participants

A purposeful sample was carried out among the parents in the sleep intervention. The inclusion criteria were: a parent of a child with ADHD and sleep problems, the child had completed the RCT, the child chose to continue with the weighted blanket for the 8-week follow-up. The participants were strategically selected to achieve variation in sex, age, civil status, educational level, employment, place of residence. Twenty-six parents of the children in the sleep intervention [36] were approached at the end of the intervention and asked to participate in an interview about their experiences of using weighted blankets. A total of 24 parents accepted the invitation and participated (Table 1).

Table 1. Sociodemographic data of parents to children preferring weighted blankets (n = 24).

Variable	Parents (n = 24)
Sex, female/male (n)	18/6
Age in years, median (range)	39 (32–55)
Civil status, co-habiting/living alone (n)	20/4
Educational level, primary school/secondary/university (n)	2/10/12
Employment, full-time/part-time/unemployed/sick leave (n)	15/7/1/1
Native-born/Foreign-born (n)	22/2
Place of residence, city/countryside (n)	8/16
Age of the child in years, median (range)	9 (6–15)
Sex of the child, female/male (n)	12/12
Perceived effect of the weighted blanket, fully/partially/no (n)	19/3/2

2.4. Data Collection

Data collection took place between March and September 2020. The interviews were performed by the first author (IL) in an undisturbed room at Halmstad University. Individual interviews were performed with 18 parents, and three parent couples (six parents) chose

to be interviewed in pairs. The interviews were conducted in Swedish. The interviews started with questions about the parents' experiences of the two different blankets and then in-depth questions about their experiences of the weighted blankets. The following questions were asked: "What are your experiences of the two blankets your child has tested?", "What are your experiences from your child's use of a weighted blanket?", "Has your child's sleep changed with the use of a weighted blanket? If yes, in which way?", "Has your child's everyday life changed with the use of a weighted blanket? If yes, can you describe how?", and "Has your family life changed with the use of a weighted blanket, and, if so, can you describe how?" To obtain comprehensive descriptions, follow-up questions were posed, such as: "What expectations did you have of each of the two blankets?", and "How have your expectations been met?" Probing questions were used, such as: "Please, tell me more about ... ", "What do you mean?" or "What do you have in mind, when you say ... ?" Two pilot interviews were conducted to test the questions and, because adjustments were not required, these interviews were included in the study. The interviews lasted between 35 and 64 min, with a median of 53 min and a total interview time of 17 h and 12 min. All interviews were digitally recorded and transcribed verbatim.

2.5. Data Analysis

Data were analyzed in a latent qualitative content analysis [37,41]. The interviews were listened to and transcribed. The transcriptions were read through repeatedly, to become familiar with the content and obtain a sense of the whole. Phrases containing content relevant to the aim were identified and extracted in meaning units. The meaning units were abstracted and coded. The codes were compared on the basis of similarities and differences and grouped into nine sub-categories and three categories that reflected the central and manifest content in the interviews. The analysis was conducted by the first (IL) and last authors (PS). There were continuous discussions and reflections between all the authors to achieve a consensus of the analysis.

2.6. Ethical Considerations

The study was approved by the Swedish Ethical Review Authority (no. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki [42]. The study fulfilled requirements on research: information, consent, confidentiality, and safety of the participants and was guided by the ethical principles of autonomy, beneficence, non-maleficence, and justice [43]. The parents received written and oral information from the first author (IL) and provided informed consent in writing. The information contained voluntary participation and the possibility of withdrawing at any time without having to give a reason.

3. Results

Parents experienced that, during the intervention, their children achieved satisfactory sleep, overall well-being, and mastered everyday life when they used the weighted blankets. Sleeping with weighted blankets resulted in satisfactory sleep, including improved sleep onset latency, sleep continuity, and sleep routines. The overall well-being of the children was improved, including improved relaxation, and reduced anxiety. Better sleep with weighted blankets contributed to an improved mastering of everyday life, including balance in life, family function, and participation in school and leisure activities for children with ADHD and sleep problems (Table 2).

3.1. Achieving Satisfactory Sleep

Satisfactory sleep was achieved through improved sleep onset latency, sleep continuity, and sleep routines when children used the weighted blanket.

Table 2. Overview of the categories and subcategories showing parents' experiences of the weighted blankets' impact on children with ADHD.

Categories	Subcategories
Achieving satisfactory sleep	Improved sleep onset latency
	Improved sleep continuity
	Improved sleep routines
Experiencing overall well-being	Improved relaxation
	Reduced anxiety
Mastering everyday life	Improved balance in life
	Improved family functioning
	Improved participation in school activities
	Improved participation in leisure activities

3.1.1. Improved Sleep Onset Latency

The parents described that the children had improved sleep onset latency with the weighted blanket. Before using weighted blankets, children had difficulties calming down, resting, and falling asleep when they lay in bed before nightfall. It was common that children felt worried or restless with difficulties lying still and coming to rest. The weighted blanket gave them a feeling of being embraced and a sense of security, making it easier for the child to fall asleep.

> *With the weighted blanket, he does not move as much when he goes to sleep. He becomes calmer and falls asleep faster. He said the weighted blanket is good to hold on to as it hugged him and that turning around and moving became harder and heavier. We think he sleeps better with the weighted blanket. He falls asleep faster and is less unsettled and also sleeps a little longer in the morning.* (Parent no. 21)

Many of the parents described that the children previously had wanted the parents to be there throughout the whole process of falling asleep, providing comfort by lying next to them, hugging them, and being very close, for example by placing a leg or arm over them, to make them feel safe. When the children instead used the weighted blanket, they acquired a similar embracing effect which allowed them to fall asleep by themselves. The parents further described that some children no longer showed resistance towards going to bed when using the weighted blanket.

> *She has just embedded herself (with the weighted blanket) and then it's just been good-night. It's been unbelievable. Before, she could lie in bed for several hours until 11 p.m.... So, at 11 p.m. you could hear, "Mom, Dad." But since she got the weighted blanket, it was just, "Go to bed". Before, I had to sit there and have the light turned on. Now she goes upstairs by herself and crawls under and turns off the light. We used to do that every night and we'd have to sit there. We could sometimes sit there for an hour, but it's completely over and also, it was quite important that both parents would come up and put her to bed. She wanted somehow to know that we were both at home. Now we don't have to be home. She goes to bed anyway. Yes, even if we're not at home.* (Parent no. 19)

Even when children still needed a parent by their side to fall asleep, they fell asleep faster with the weighted blanket. Their children's ability to stay asleep and not wake up when the parent left the room was further appreciated by parents.

> *He always has to sleep with an adult to relax and go to sleep, but he sleeps so lightly that you can't move and then it's often during the night that he sleeps so lightly. He has used me as a pacifier blanket. He fidgets and moves and stuff like that. With the weighted blanket, we've noticed that sleep initiation has shortened... Then you give him that pressure and put a heavy arm and sometimes I almost lean over him and then, when*

he has fallen asleep, I put on the weighted blanket and then we can walk out of his room almost without even sneaking. Before, I almost couldn't even sit up without him jerking on and off and saying, "Mom, mom" because he slept so super lightly and he has always been so easily awakened. (Parent no. 20)

There were parents who described that the child did not get the effect from the weighted blanket on the sleep onset latency as they expected, but that the child slept better during the night.

She might not fall asleep any faster, but she sleeps really, really well. (Parent no. 12)

3.1.2. Improved Sleep Continuity

The parents described that the children had improved sleep continuity. They slept more calmly, deeply, and continuously, and thus received more hours of night sleep than before using the weighted blanket. The weighted blanket contributed to a calmer and more restful sleep, in that the children were lying more still and not moving around in the bed as before. This, in turn, led to the children being more relaxed during the night. Previously, the children moved around a lot during sleep; for example, making rapid movements with the legs brushing the wall or moving so much that they could wake up with their head at the foot of the bed and without a blanket. This contributed to the children waking up more during the night, meaning that the parents and/or siblings also woke up. However, the parents described that the children's sleep was more persistent and continuous with the weighted blanket, resulting in increased sleep duration.

She seems to be calmer when she sleeps. You'll pretty much find her in the same position in the morning as when she fell asleep last night. It's not like this electric whisk. We've always called her the electric whisk, if she fell asleep with her head at one end, she was at the other end when she woke up. She has always been like that, but I feel like she is more at peace. But, as she says, she can't be bothered to move and it makes her lie still. She doesn't wake up needing to move... She said that with this (weighted blanket) she slept much, much better so she noticed a huge difference with it... She likes it very much and sleeps very well with the heavy blanket. (Parent no. 8)

The parents also expressed that the weighted blanket contributed to a more continuous and deeper sleep, without several awakenings during the night. Before using the weighted blanket, some children were easily disturbed during sleep and often went to the bathroom during the night or to the kitchen to drink water or woke up easily from any noise. Some parents described that their child seemed to get a deeper sleep than they had ever had before. Many children slept all night in their own bed with the weighted blanket, without going into their parents' bedroom.

He doesn't wake up. I think it happened once that he got up and then I reacted, but then he needed to wee or go to the bathroom. But it was completely different to the other weeks, so it was normal to get up if you needed to wee or something. But he sleeps all night now... he didn't before, absolutely not. His sleep was fragmented all the time. He woke up and fell asleep and he called for us many times. (Parent no. 5)

However, some parents described that the improved sleep disappeared or diminished during the intervention, when the child had to change to a fiber blanket without weight and that the effect was not fully restored when the child returned to a weighted blanket.

When she had the weighted blanket in the first period (of the intervention), she slept fantastically well. It was wonderful because she slept in her bed all night. I don't think she came in to us one single night during that period. The first day we switched to the lighter blanket, she came in to us right away and did so all the time with the lighter blanket. When we switched back to the heavy blanket, I thought, "Oh, good, let's see if she's asleep again." But now she's slept worse with that one. At some point she's probably slept in her bed, but she often comes in to us anyway now... Maybe she's slept a little better with the heavier than with the lighter blanket. Because then she came in as soon

as we went to bed. Now she sleeps a bit longer in her own bed... For the first four weeks (with the weighted blanket), she did not once come in to us but slept all the time in her own bed. It has never happened before. (Parent no. 14)

Some parents described that the children liked the weighted blanket in the beginning, especially the first few weeks, but then did not think that it had any special effect. Some children also experienced that the blanket was too hot or that it was too lumpy and uncomfortable (not the weight as such) and that, therefore, they did not like the weighted blanket. To prevent the weighted blanket from feeling lumpy and inconvenient, some children preferred to have a soft, thin blanket close to the body and the weighted blanket on top.

He liked it from the start, but then more and more he didn't want it. He thought it was lumpy, "rough" he called it. He didn't find it very comfortable. In the beginning, he liked it. I don't know what he said about it at the time, but then he still thought it was okay. Now he thinks it's rough and not nice. I don't think it's the weight itself, but more that it's uncomfortable and lumpy. (Parent no. 9)

3.1.3. Improved Sleep Routines

The parents described that the weighted blankets contributed to better sleep routines for their children. When the child felt the weight of the blanket, it was a sign that it was bedtime. The parents described that the routines around betimes were important for the children and the weighted blanket contributed to this process, by giving both more procedure to the routines and a feedback sensation that enforced the routine. Improved sleep routines for bedtime led to the children achieving a normal sleep–wake cycle.

It is becoming clearer that now we go to bed, to lie down under the blankets. Perhaps it is the clarity that is also beneficial. Now it's tucked in and we've gone to bed. We always pull on the weighted blanket, it's a natural part of it. He has his routine around this. He has to be on my arm, with his stuffed animal, and on with the blanket, then it's kind of done. Yes, it's dark and it's quiet, and that's it. Then it'll take five minutes. He falls asleep in his own bed every night. It's become more often that it's in his bed, his weighted blanket. I don't know, but I feel like the routine has got a little more settled. He likes it. He likes the bed and the blanket and how we arrange it, same procedure every evening. (Parent no. 4)

The parents described that the improved sleep routines resulted in the children preferring to stay in bed at bedtime. For some children, the weighted blanket contributed to a feeling of comfort and that the weight from the blanket was appreciated and made them want to stay in bed. For other children, the reason to stay in bed was more the result of convenience as it became more cumbersome to get out of bed due to the weight of the blanket. Before using weighted blankets, some children had a habit of getting out of bed after bedtime, repeatedly coming up with different reasons for not staying in bed and often wandering around the house for no particular reason. This behavior changed for the better with the weighted blankets.

NN likes this (weighted) blanket very much that she's had now because we don't hear her running around at all. She says herself that it just feels hard to get up and move. I don't even think she wakes up feeling like she needs to get up and go. (Parent no. 8)

Some children preferred to use the weighted blankets as an ordinary blanket, whereas others preferred to only use it to apply pressure to some parts of the body, for example, the back, or not to cover some part of the body, for example, the legs. The children who preferred to have their parents close to them experienced that when the blanket embraced them, it functioned as a substitute for the parent.

I put it behind his back like I was still there. So it's like he shouldn't feel much difference. There's still a pressure there, so I think it's a good thing it's going to be a little substitute

. . . that I could replace myself a little bit with this (weighted blanket) so he could still feel a little bit embraced and thus he is lying still and he likes it before. (Parent no. 4)

The change of routines supported by the weighted blankets required some patience on the part of the children before they got used to it and figured out individual adaptations. At first, some children found it uncomfortable and expressed a strange feeling. Some initially experienced side effects and that a period of habituation was needed. For example, some children experienced a feeling of confinement, resulting in nightmares about being trapped, but the children did not want to give up and when they got used to the weighted blankets after a few days, they felt secure and calm. They found a new routine and they did not want to change back to a regular blanket.

Initially, she had nightmares with the weighted blanket, she thought she was trapped... So it probably took three or four nights, I believe, before she felt she could settle down. (Parent no. 1)

3.2. Experiencing Overall Well-Being

Nights of good sleep with a weighted blanket had a positive effect on the child's well-being, through improved relaxation and reduced anxiety.

3.2.1. Improved Relaxation

The parents described that the weighted blanket provided a sensation of being touched and embraced and that this provided calm, comfort, and relaxation for the children. The feeling of pressure on the body provided comfort and calm. The calmness influenced the children, both mentally and physically.

He always wants the heavy blanket on top of him. He feels a bit calmer and somewhat more secure with the (weighted) blanket. He himself says that he feels more relaxed when he lies under it. He likes to be close and that's probably the feeling he gets... I think he feels closeness and security with the weighted blanket. (Parent no. 24)

The children expressed that the blanket hugged them and that it gave them a feeling of comfort. Some children described that they felt a big difference between the weighted and the ordinary blanket and that they loved the weighted one.

She says herself that it feels like, she calls it a cuddle blanket. It feels like the weighted blanket is hugging me. (Parent no. 10)

Some children even wanted to use the weighted blanket when they rested for a while after school. The parents described that the child wanted a relaxing and cozy moment when, for example, they would check their phone.

When she had that fiber blanket (the light blanket), she went in during the day on top of my bed to rest. Because she wanted to lie under my weighted blanket, because she thought it was nice to relax. Preferably after school and lie there and look into the phone... Just rest and feel a bit relaxed, I think. Yes, she did not sleep nearly as well (when the weighted blanket was removed and the child got the light blanket); then she was more unsettled. She needed to get some rest after school, as I said, then she wanted to lie in my bed and rest under my weighted blanket. It was the weight she wanted. (Parent no. 12)

3.2.2. Reduced Anxiety

The parents described an overall improved well-being in their children, with reduced anxiety due to the use of weighted blankets and the resulting improved sleep. The previous fear and anxiety of not being able to fall asleep or sleep through the night and the fatigue that they had experienced before had led to anxiety in some children. Reduced anxiety also allowed children to focus, reduced their hyperactivity and stress, and contributed to a more stable mood.

I see a difference in his anxiety, which has changed with the weighted blanket... It's gone. It's almost gone, I can tell you, all day. He is not as worried during the day. He has

always been a worrying child and it's like a rock is somehow lifted... There has been such a difference in his behavior, really in his anxiety. He was worried about or stressed about everything you would do, go to or do. This was concerning for him, but no more. He is basically much calmer. But, as I said, he still needs to know what we are to do and not to do. He is somehow more stable... He is a more secure child, I know. He is calm, as I said, he is not hyperactive, but he used to be much more stressed. So I sense like he is feeling better. No, he is not as worried as he used to be but somewhat more stable. (Parent no. 5)

Many of the children had previous experiences of severe anxiety, resulting in anxiety attacks, chest pain, palpitation, cramps, and migraines, for which the families had sought help from both primary and emergency care. The parents noticed that such symptoms decreased or disappeared when their child used the weighted blanket. One explanation for this, provided by the parents, was the improved sleep as the result of the weighted blanket.

She was kind of getting anxious . . . She suffered from pain that almost felt like stabbing and you get that in anxiety attacks. We went to the doctor and they pretty much agreed that it was from the anxiety. It's her head that haunts her, but it's been a long time since I've heard anything about it (since the child started with the weighted blanket). I think there are several different aspects to it. On the one hand, sleep is one aspect, which has made it much better on that front so that she doesn't have that anxiety in her body. Then the fact that she was diagnosed (with ADHD), and was told by a doctor why she is the way she is. Both things combined have kind of calmed her down to such a degree that she is like a normal person again... it feels like she is much calmer in every way. (Parent no. 13)

The parents expressed that their children, through a good sleep with the weighted blanket, got more energy in everyday life, became more positive and happier, and regained their zest for life. Some children had had previous experiences of losing their zest for life and some had suicidal thoughts or had even attempted suicide.

Lately, I think she has become more alert, I mean happy, she is generally happy but you noticed before when she had slept or been tired that she became more irritable and things like that. But I find it's positive. She is always happy and less tired. (Parent no. 6)

3.3. Mastering Everyday Life

Good sleep with a weighted blanket facilitated children's mastering of everyday life through improved balance in life, family function, and participation in school and leisure activities.

3.3.1. Improved Balance in Life

The parents described an improved balance in life when the children were sleeping with weighted blankets. They could wake up on their own without having to be woken by an alarm or the parents. Being well-rested and alert in the morning allowed the children to have a proper breakfast and to also manage other meals during the day, which had previously been a problem.

I can tell that she gets up at 6 a.m. every day. And even more rested and that's where we notice it. She's nice when she wakes up and has her breakfast. (Parent no. 1)

The parents described that the children were more stable in their mood and had greater patience in everyday life because they slept well during the night. The previous mood problems, such as anger, irritability, and rapid mood fluctuations, had a great impact on the parents' well-being and their relationship with their children. However, when the children had slept well, they were more able to cope in a better way with potential adversities during the day, resulting in fewer and less extensive mood problems. As an example, one mother described that her child was more satisfied with herself and able to deal with unplanned activities, not only those adapted to the child's interests. The

parents also described that better sleep influenced the children by letting them stay focused throughout the day without needing the attention of parents all the time.

> *He feels more satisfied with himself. It could be that he sleeps deeper with the blanket, which makes him sleep better. Sleep affects a lot, of course. That he feels more balanced. Before, he could say that he hated himself and he often got angry. I don't notice that as often anymore. It feels good to have a child who's feeling better. It's going in the right direction. It feels good. Just that he enjoys his weighted blanket. It feels good . . . Now it feels like we are more on track and he feels much more balanced as well and the days are moving on. It is not a battle all the time about what to do or an argument, but we complement each other more at home, even the children. NN can join in on something that I have suggested. It's not just that you focus and plan around him as it used to be. Everything was prepared so that he would not oppose it or get angry. Now he can take more adversities and when he feels better, it rubs off on everyone.* (Parent no. 24)

3.3.2. Improved Family Functioning

The parents described that the improvement in their children's sleep had a positive effect on their family situation. The improvement in sleep resulted in an improved family function for the family, with fewer conflicts, a sense of having more energy among all family members, and that the children were more inclined to do things together with other family members, such as eating together and participating in conversations.

> *So much less fuss about his behavior and ADHD symptoms, it's not at all the same... It's diminished. It's a big rock that's lifted somehow... That's the magic blanket, yes, it's magical. I never thought it would affect him so much, I didn't think it could give him the weight that makes... so it's really magical. It has made it much easier for us and for him.* (Parent no. 5)

When the children previously had problems sleeping or slept badly, it resulted in sleep for parents and siblings also being negatively affected. Parents had difficulties sleeping and relaxing in the evenings when they heard their children knocking on the walls, repeatedly getting up and wanting to urinate, have something to eat, or to get into their parents' bed during the night. This had the effect that the parents were not able to do what they wanted, such as watching movies or just spending time together.

> *She's really sensitive to any noise. I like to sit and watch a movie in the evening, then you have to wear headphones because otherwise she wakes up and gets really irritated. I can watch at any volume now, she lies there completely still, only when she's wearing the weighted blanket. Otherwise, when she has the normal blanket, she falls back and then it's like she's lying around spinning. There's a huge difference. She sleeps much deeper. Noise and stuff, it doesn't bother her then.* (Parent no. 13)

The parents described that a good sleep gave them more energy as parents and an improved ability to cope with problems in everyday life. Previously, the parents had to put a lot of their energy into dealing with the difficulties that came with their children's anger, or fights between the siblings, which felt manageable when the children slept well. Parents also described that this had previously been so challenging for them that they had been on sick leave to be able to handle everyday life at home.

> *I feel like I get more energy when she's slept well. A lot of my time went into taking on all the fuss with her if she had slept badly and was in a bad mood. Go between her and her siblings, all those squabbles have been a big problem for many years. We've been working on it a lot, just that she sleeps well. It makes it incredibly easy, I think... Yes, you start to feel like you can handle a little more yourself. I've even been on sick leave. A lot of this bother is one reason I've been so tired. It takes a lot of energy and so you have to cope with the rest as well, which takes a lot of energy. When this aspect has disappeared, you get a lot of energy back, so you can deal with other things instead.* (Parent no. 12)

When the children slept well with weighted blankets, parents described that they could spend time with their children without a lot of friction and manage to collaborate on daily routines. The children got energy to help with everyday things and to learn new things at home, such as cooking and cleaning. The children were more patient, and did not argue as much with their siblings, or get angry when asked to help their parents. Parents also described that siblings played and spent time together in a way that they were not able to before, socializing and having fun together, and talking to each other in a normal way.

> *She doesn't mess as much with her little sister and she can even hang out with her little sister all of a sudden because she's got better sleep. Otherwise, she is just bothered by everything her little sister does. But when she's been sleeping well, happy family sort of. I guess it's us (the family) that it affects the most. You lose energy when the child is affected so much. After all, it sucks all the energy out of you (when the child is not sleeping). Now, you get more help from her. Now, it's really nice for me at home. I live the super dream life.* (Parent no. 13)

3.3.3. Improved Participation in School Activities

The parents described that the children's participation in school had changed for the better. In the past, the children had difficulty coping with a full day at school and staying concentrated and sitting still. This had previously led to difficulties at school and that teachers often called the parents to talk about difficulties and to discuss solutions. When the children started to sleep well, the parents noticed that they received fewer calls from school about these problems. The children started to appreciate school more and even found it fun to go to school and to do homework.

> *I don't think I would have even thought of getting her a blanket like that, because I wouldn't have believed in it. But just giving her peace and thus can be at school and stuff, that does a lot . . . it is important for her to sleep her hours at night, in order to manage at school... There aren't that many days you get a call from school anymore. I think I've had one or two calls from school, since she started with this (weighted) blanket. Before, it was pretty often. We've even sat down with the school and talked about what we're going to do to make sure she can cope all day.* (Parent no. 8)

The parents described that sleeping with weighted blankets increased the children's participation in both structured and unstructured activities at school, resulting in increased school attendance.

> *But she seems more collected and concentrated (when the child has slept well) she doesn't get these outbursts of anger and leaves all the lessons or leaves school or jumps out of the window or things like that... Yes, given that she has not slept and so she was turning around the clock, she slept in the middle of the day when she should be going to school. We didn't even get her off to school and now (when she uses the weighted blanket) she's at school every day... It was terrible before, then we really had to keep going at least for an hour to get her out. Then she could just call from school and say "I'm going home now". Of course, if you haven't slept, you have no gusto or energy. You can't be bothered to eat or to do anything, that's the way it is. While I can't say 100 percent that it has to do with the weighted blanket, at least it's changed drastically.* (Parent no. 1)

3.3.4. Improved Participation in Leisure Activities

The parents described that the children started spending more time with their friends after school. They had got so much more energy that it allowed them to be active after school. They were out playing, hanging out with friends, and more active in their leisure time. This was a big change, as they previously did not have the energy to spend time with friends after school and mostly lay in bed or played on the computer.

> *She sleeps so much better now. That's why she gets so much energy for the rest of the day. Now you never see her, she is out playing. She is hanging out with friends all the time. A*

lot more active. It's awesome, that sleep can affect so much that all of a sudden you have the energy to do more things. (Parent no. 13)

The improved participation in leisure activities also included sleepovers with friends. When the children felt comfort in that they could fall asleep on their own, overnight stays with friends also improved.

From not wanting to sleep over at friends for maybe a year, he slept over for the first time and he brought his blanket. (Parent no. 7)

The parents also expressed that a better sleep with a weighted blanket contributed to the children having enough energy left over to do their homework, after having been at school for a full day. This meant that they achieved an inner calm, allowing them to sit still for longer periods and concentrate.

She can do homework. It barely happened before. That is, just this thing to stay seated. She can sit still. It's not a problem. She can sit in the same place for half an hour. It's not a problem. (Parent no. 19)

4. Discussion

This study explored parents' experiences of the impact of a non-pharmacological intervention with weighted blankets on sleep among children with ADHD and sleep problems. To the best of our knowledge, this is the first qualitative study investigating the parents' experiences of the impact of weighted blankets in this context. Overall, the results show that the parents described effects on sleep quality and reduced ADHD symptoms similar to those seen in the few previous intervention studies [32,33] investigating effects of weighted blankets among children with ADHD. However, the parents also expressed that weighted blankets had a positive impact on the children's overall well-being, as the children were able to relax more easily and their anxiety decreased, while their zest for life returned or increased. Another area where the weighted blankets had an impact was how the children mastered everyday life, resulting in an improved balance in life and family function, as well as in increased participation in school and leisure activities. The experiences expressed by the parents imply that weighted blankets may have positive, indirect effects from a wider perspective, rather than just on sleep problems. The study contributes to an in-depth understanding of the effects of the intervention on their children's sleep and the consequences this effect has had on their children's ADHD-related symptoms, their well-being, and their functioning in the family and in everyday life, including in the home environment, leisure time, and school.

4.1. The Impact on Sleep Problems

Achieving satisfactory sleep by using weighted blankets was experienced as an essential outcome for children with ADHD and sleep problems. Prolonged sleep onset latency was expressed by most parents as a significant reason why the children had sleep problems, and this was reduced when using the weighted blanket. There have been a few quantitative studies, which indicate that the use of weighted blankets significantly reduces sleep onset latency in a range from fewer than 20 min (measured by actigraph) [33], to 30 min (parent-reported), among children with ADHD [32,33]. The effect on sleep onset latency is of significant importance, given that problems with prolonged sleep onset latency are more common in children with ADHD than among healthy peers [32,33]. About one-third of children with ADHD have difficulties falling asleep [3,44], with up to one hour of sleep onset latency between children with ADHD and healthy peers [7].

The parents in our study also experienced an improvement in sleep continuity and depth, with fewer awakenings during the night. When the children slept more calmly, deeply, and continuously, they received more hours of night sleep than before. These improvements in sleep duration, sleep quality, and nightly awakenings described by the parents are, however, not confirmed by previous studies measuring the effect of weighted blankets among children with ADHD [32] and autism [32,34]. The discrepancy between

what the parents in our current study experienced and what has been seen in those small, controlled studies investigating measurable effects may be due to aspects related to, e.g., selection of study participants, or the size of the intervention and control groups. It could also be that the parents experienced improvements in sleep that were not captured by the instruments and objective measurements used in the previous quantitative studies. Further research is needed to better understand if and how weighted blankets could increase sleep continuity and sleep depth and how this contributes to health-related outcomes.

The parents in our study expressed how sleep routines are of importance for the children, and how the weighted blankets could serve as an aid in creating these routines around bedtime. Sleep routines are described as a set of behavioral, environmental, and cognitive modifications that need to be made to improve sleep, and it seems as if the use of the weighted blanket helped the children to make some of these modifications. One example of this was how placing the weighted blanket on the child served as a sign for bedtime. For the children, the weighted blanket contributed to a feeling of comfort and a desire to stay in bed or even acted as an obstacle to getting out of bed, thereby facilitating sleep. Another example was that the children fell asleep in their own bed, at a distance from the parents' bed. Thus, weighted blankets may serve as a part of a sleep intervention to improve sleep routines for these children. The benefits of improved sleep routines for this target group were confirmed in a systematic review [45] and are important because children with ADHD more often show bedtime resistance, compared to healthy peers [7,46]. Since children are closely tied to their parents in relation to sleep routines, modifications (behavioral, environmental, and cognitive) have to be designed together with both parents and children to meet their needs and preferences [21,22].

4.2. The Impact on Overall Well-Being

Experiences of effects related to overall well-being were another central finding in our study. The parents described that the children's well-being increased, both when they were going to sleep and lying in bed, but also during the day, in the form of decreased anxiety and increased feelings of happiness. The children had expressed that the weighted blankets gave them a feeling of calmness and that they felt embraced by the blanket. They expressed it as if they felt hugged and calm when they slept with it. Similar positive experiences have previously been presented, where children with autism "really liked" the weighted blanket and their parents felt that sleep was improved and that their child was calmer with it [34]. Overall well-being was also influenced when anxiety improved with the weighted blankets. Reduced anxiety is an important finding in our study, as anxiety is a significant and common problem for about half of all children with ADHD [47] and an important factor associated with sleep problems [9]. The consequence of reducing anxiety with weighted blankets has therefore dual advantages—both symptom relief and improved sleep. The parents in our study described how, after a good night's sleep with the weighted blanket, the children were more positive and happy, showing regained joy of life.

4.3. The Impact on Everyday Life

The findings from our study show that, when children woke up well-rested in the morning, they had an improved ability to cope with everyday life and the routines and challenges involved. This adds value to previous research that showed an improved level of functioning among children with ADHD sleeping with weighted blankets [33]. The parents in our study expressed that, when children's sleep was improved, it infused the family life with harmony; there were fewer conflicts and behavioral problems and improved family function. Results from an intervention study with weighted blankets among children with ADHD support this finding [33]. There is a great need to offer children sleep interventions, such as with a weighted blanket, since earlier research has shown that sleep problems are associated with a significant negative impact on children's functioning and quality of life, after controlling for ADHD symptoms [48]. The reduction of behavioral problems is, in itself, a positive outcome of our intervention, but has an additional effect on improving

sleep through diminishing the negative relationship between behavioral problems and sleep problems and the potential exacerbation of sleep problems in children with ADHD, as described in a systematic review by Bondopadhyay et al. (2021). This suggests that the reduction of behavioral problems is of great importance, both as an outcome to evaluate in clinical settings as well as in research studies, in conjunction with sleep interventions for this target group.

A further finding in our study was that the parents described how family functioning improved; children's improved sleep contributed to better sleep for the parents as well, which made them better equipped for the challenges of everyday life. Previous research demonstrated that families of children with autism spectrum disorder that have good sleep were also more resilient [49].

Another benefit of improved sleep was increased participation in both structured and unstructured school activities and improved coping with school work. Hvolby (2020) has previously reported fewer behavior problems, especially in relation to school, when children with ADHD use weighted blankets [33], which may be one reason for the increased participation at school seen in our study. Persistent sleep problems among children with ADHD are known to be associated with impaired academic performance [50–52], and impaired child–teacher relationships and greater conflicts between the child and the teacher [16]. Altogether, this highlights the importance of improving sleep among children with ADHD from the perspective of school participation and achievement and emphasizes the potential of providing interventions with weighted blankets for sleep problems at an early stage.

4.4. Methodological Considerations

In qualitative research, trustworthiness is defined according to the four criteria of credibility, dependability, confirmability, and transferability [37,53,54]. *Credibility* refers to confidence in the truth of the data and the analysis [37,54]. In this study, the credibility was strengthened by a purposeful sample of 24 parents of 12 girls and 12 boys with ADHD and sleep problems. There was variation in terms of sex, age, civil status, education, employment, and place of residence. However, the included parents represent to a great extent parents who have expressed positive effects of weighted blankets for their child's sleep at 8-week follow-up. Nevertheless, some of the parents interviewed had not seen a great effect from weighted blankets. A limitation is that parents of children who chose the control blanket for the 8-week follow-up had been excluded from this study. However, the selection of participants is considered appropriate since the purpose was to understand how parents experienced the long-term effects of weighted blankets and why they had chosen the weighted blanket for the 8-week-follow-up. To avoid memory decay over time, all interviews were conducted immediately when the intervention ended; despite this, some parents stated that they had forgotten the initial effect of the weighted blanket. Credibility was strengthened by the researchers' familiarity with the methodology, the careful descriptions of the data collection and analysis, and the continuous discussion between researchers during the analysis. *Dependability* refers to the stability of data over time and conditions [37,54]. Dependability was strengthened by the fact that the same researcher conducted all the interviews, and that all interviews began with the same opening question, follow-up questions were posed to avoid misunderstanding, and the participants were encouraged to talk openly. *Confirmability* refers to the neutrality of the data, which ensures that the data represent the information provided by the participants and accurately reflect their voices [54]. Confirmability was demonstrated through all steps of the analysis, which have been carefully reported and that the participants' experiences are described in as much detail as possible, with quotations that enhance and illuminate the content. The interviews were rich in content and contained a great variety of experiences. *Transferability* refers to the applicability of the results to other contexts [37,54]. A strength of this study is that it included parents of children who were recruited from a clinic in conjunction with recently diagnosed ADHD and sleep problems. The study was part of

a larger RCT study to recruit children requiring a sleep intervention in a clinical setting. The experiences expressed in this study are thus likely to be similar to those of parents in a clinical setting and the results are thus possibly transferable to children with other neurodevelopmental syndromes.

5. Conclusions

This study provides insights from the experiences of parents of children with ADHD and sleep problems who participated in an intervention with weighted blankets. When using weighted blankets, the children achieved satisfactory sleep, including improved sleep onset latency, sleep continuity, and sleep routines. The overall well-being among the children was also improved, with increased relaxation, reduced anxiety, and increased joy of life. The improved sleep improved their mastering of daily life, through better balance in life, family function, and participation in school and leisure activities, which is partially in line with previous intervention studies. However, this study brings forward new aspects of the effects of improved sleep among children with ADHD. These aspects should be included in the evaluation of weighted blankets, but also contribute to the overall understanding of the potential positive effects. Our findings reveal that using weighted blankets can improve the well-being and life of children with ADHD and their families.

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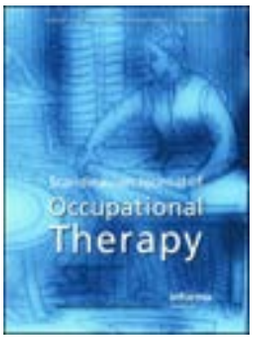
#11

The effectiveness of weighted blankets on sleep and everyday activities. A retrospective follow up study of children and adults with ADHD and Autism



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The effectiveness of weighted blankets on sleep and everyday activities – A retrospective follow-up study of children and adults with attention deficit hyperactivity disorder and/or autism spectrum disorder

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ABSTRACT

Background: Attention deficit hyperactivity disorder (ADHD) and Autism Spectrum Disorder (ASD) are often accompanied by sleep problems influencing social, emotional and cognitive functioning in everyday activities.

Aim: The aim of this study was to investigate whether the use of a weighted blanket has a positive impact on sleep and everyday activities in individuals with ADHD and/or ASD.

Material and methods: The study included 85 individuals diagnosed with ADHD and/or ASD, 48 children aged ≤17 (57%) and 37 adults ≥18 years (44%), who were prescribed with a weighted blanket. The participants responded *via* a telephone interview.

Results: Findings demonstrated that a weighted blanket improved abilities related to falling asleep, sleeping the whole night, and relaxing during the day. Using a weighted blanket improved morning/evening daily routine, including preparing/going to sleep and waking up in the morning.

Conclusions: Weighted blankets showed positive impact on falling asleep, sleeping the whole night, and relaxing during the day, and they were used frequently by children and adults with ADHD and/or ASD. Findings indicate that a weighted blanket improved morning/evening routine, however this research area needs further investigation using both subjective and objective parameters.

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Introduction

Attention-deficit hyperactivity disorder (ADHD) and Autism Spectrum Disorder (ASD) are among the most prevalent 'neurodevelopmental' disorders and share an early onset, often coexist and are associated with overlapping symptoms including difficulties with executive function, social relationships, communication and comorbid conditions [1–4]. In addition, both diagnoses are frequently associated with a variety of sleep problems. Sleep problems are prevalent in around 25–55% of children and adolescents [5], 43–80% of adults with ADHD [6] and tend to be even higher among individuals with ASD, occurring in up to 45–86% [7,8].

The broad term 'sleep problems' in this study was defined as incorporating both behavioural difficulties, such as bedtime resistance, as well as diagnosable sleep disorders (e.g. insomnia), diagnosed by e.g. the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) [9]; and the International Classification of Sleep Disorders (ICSD) [10]. Earlier studies reporting on sleep problems for both children, adolescents and adults with ADHD or ASD include a wide range of sleep problems including, longer sleep onset latency, night awakenings, poorer sleep efficiency, lower sleep quality, decreased total sleep time, bedtime resistance, night awakenings and significantly higher daytime sleepiness compared with their peers [11–15]. Studies have also reported on diagnosable sleep disorders common in children, adolescents and adults with ADHD or ASD classified into insomnias, parasomnias, sleep-related breathing disorders and sleep related movement disorders [11], including,

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obstructive sleep apnoea, restless legs syndrome, periodic limb movement disorder and sleep-disordered breathing [6,16–18]. Sleep problems have been consistently related to a variety of social, emotional and cognitive functioning, including cognitive difficulties (e.g. increased problems with attention, short-term and working memory) [19–22], emotional and behavioural problems [21,23–27] and quality of life (QoL) [28–30].

Among individuals with neurodevelopmental disorders, however, there is little knowledge of how sleep problems influence everyday activities in education, home, and work. To date, research focusing on sleep and everyday activities among individuals with ADHD or ASD have mostly focused on school aged children aged 5–14 years [31], relying either on parents' or teachers' reports of the relationship between sleep problems or daytime sleepiness and school/academic functioning. Together these findings show that sleep problems negatively impact multiple aspects of school/academic functioning among children with ADHD, including school grades, social and emotional functioning in the classroom, classwork completion in school and homework [23,32,33]. Less focus has been given to the academic performance of adolescents/young adults with ADHD or ASD (up to the age of 17–30 years) and adults [31]. Studies focusing on sleep and everyday activities in adolescents with ADHD or ASD report excessive daytime sleepiness which predicted the number of D and F grades (i.e. poor and failing) that students received [34,35]. Challenging behaviours in daytime functioning have been reported and include negative mood, irritability, self-injury, and aggression [36–38].

The occupational therapy literature has primarily focused on sleep in typically developing children [39,40], military veterans [41,42], adults with acquired brain injury [43], older adults [44–47] and children and adults with mental health disorders and neurological impairments [48,49]. Furthermore, although it is widely acknowledged within occupational therapy that sleep is essential to the performance of everyday activities and health, little attention has been paid to sleep and restorative activities within the literature, with current categories of activities and/or occupation excluding sleep [48–50]. Earlier studies on interventions targeting sleep problems among children and adults with neurodevelopmental disorders and individuals without disabilities show that a variety of non-pharmacological and behavioural interventions promote sleep quality. These include sensory integration–based measures such as music therapy, massage, tactile stimulation exercises, and weighted blankets [51,52]. Also, interventions aimed at modifying the sleep environment through selection of pillows that slow physiological and cognitive processes might improve sleep quality [53]. Furthermore, supporting individuals to create and maintain healthy sleep hygiene routines and nutrition routines might influence sleep positively [54,55].

Sensory-integration based interventions, such as the application of deep pressure simulation (DPS) using weighted blankets or vests, are commonly used interventions targeting sleep among individuals with neurodevelopmental disorders [51,52]. The underlying theory behind sensory-integration based interventions such as the use of weighted blankets is that deep pressure and consistent sensory input provided by weighted items reduces the body's physiologic level of arousal and stress, which might improve sleep [56,57]. The evidence to support the efficacy of using weighted items is scarce. Studies on the effectiveness on using weighted vests report limited evidence of improvement in school participation among children with ADHD or ASD [58] including on-task behaviour [59,60], attention [61] and a variety of behaviours such as in-seat behaviour [62], repetitive/stereotypic behaviour and aggression [63]. Most of the earlier studies on the effects of weighted blankets have focussed on measuring the overall quality of sleep among children with ADHD or ASD [51,52,64]. Weighted blankets have been reported to produce a calming and relaxing effect when lying down for children with ADHD or ASD [56,65]. These studies show limited evidence for the use of weighted blankets to improve sleep quality (sleeping for a longer period of time, falling asleep faster, and/or waking up less) [51,52,66]. Nevertheless, this intervention is favoured by children and parents with ASD [67], as well as adults [68], and is a safe intervention to use [64].

There are several weighted blankets available adding extra weight through the use of chain links built into the interior of the blanket together with padding for comfort [69]. Other weighted blankets use plastic balls to add weight [70]. There are also different weights available, ranging from 4 to 14 kilograms of excess weight. Despite the importance of sleep being highlighted in occupational therapy as a prerequisite for activity, participation, wellbeing and health [49], most of the above-mentioned studies focus on investigating the daytime functioning symptoms relating to behaviour and cognition, with very few studies investigating the effect of using weighed blankets on everyday activities at home, in school or work among

individuals with ADHD and/or ASD. Hence, the aim of the present study was to investigate whether the use of a weighted blanket may have a positive impact on sleep and everyday activities in children, adolescents, and adults with ADHD and/or ASD.

Method

Study design

A retrospective study was performed of 48 children ≤17 years of age and 37 adults ≥18 of age who were prescribed a weighted blanket *via* three child and adult Habilitation Centres (HCs) in Central Sweden between January 2012 and December 2015.

Participants

All participants were retrieved from the records of the local 'Hjälpmedelscentral' (i.e. the assistive technology centre). The list included personal security numbers and addresses of all individuals who were prescribed a weighted blanket between January 2012 and December 2015 by an occupational therapist. In Sweden, habilitation centres offer counselling, support and treatment to children, young people, and adults with disabilities throughout the country. Medical equipment and assistive technologies for people with disabilities are prescribed by publicly financed services and administered by local 'Hjälpmedelscentral'. Individuals were eligible for inclusion in this study if they were prescribed a weighted blanket due to sleep problems and diagnosed as having ADHD (ICD-10) and/or ASD (ICD-10). The participants were diagnosed in accordance with the ICD-10 by physicians [71].

Procedure

A total of 227 individuals were identified by the local 'Hjälpmedelscentral'. All 227 potential participants and their guardian(s) (if participant was younger than 18 years), received a cover letter explaining the purpose of the study, and which stated that data collection meant that they would be phoned and asked to take part in a semi-structured interview on their use of their weighted blanket, sleep and everyday activities. Potential participants and/or guardians were phoned and asked to participate. Of the potential participants, 89 individuals (39%) did not answer the phone, 38 individuals (17%) declined to participate in the study, nine individuals stated that they did not use a weighted blanket. Participants were contacted

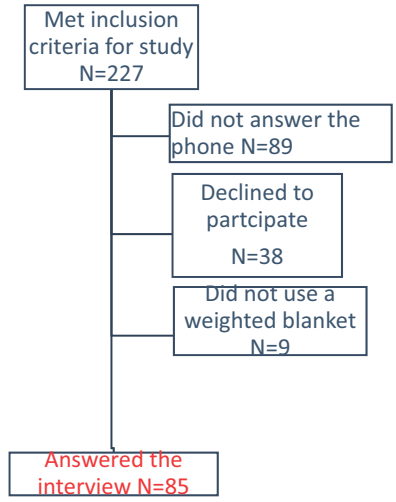

Figure 1. Study flow chart.

three times, on different days during the week, both during the day and evening before they were excluded from the study. Furthermore, six participants were excluded due to having Mild intellectual disabilities ($n = 2$), Major depressive disorder ($n = 3$) and Mixed receptive-expressive language disorder ($n = 1$) based on ICD-10 (71). Therefore, the final sample consisted of 85 individuals who responded to the telephone interview (see Figure 1), giving a response rate of 37%. Ethical approval for this study was granted by the regional ethics committee (Dnr 2014/197-37) and verbal consent of the participants and guardian (if participant was younger than 18 years) was obtained over the phone before starting the interview.

Semi-structured interview

A regional evaluation initiative with the aim of evaluating prescribed weighted blankets for children and adolescents up to 18 years [72] was further developed for the aim of the present study investigating effectiveness of weighted blankets, sleep and everyday activities in children and adults. The interview comprised of 15 questions of which eight were based on the structure and categories of the International Classification of Functioning, Disability and Health (ICF) domains [73]: body functions and activities and participation (Table 1). The questions were mostly *Yes/No* questions where participants were asked to explain their choice by using follow-up questions and probing questions. The first question asked for the name and age of the person being interviewed. The second question focused on body functions, especially (b134) sleep functions, with three sub-questions covering reason for use of the weighted blanket including prolonged onset of sleep (b1341), short amount of

Table 1. An overview of the questions in the semi-structured interview based on the ICF.

ICF domain		ICF category	ICF code	Example of sub questions
Question 2	Body functions	Sleep functions (b134)	Onset of sleep (b1341) Amount of sleep (b1340) Maintenance of sleep (b1342)	*'Why did you start using the weighted blanket?'* *a) Due to difficulties falling asleep/ prolonged onset of sleep* *b) Difficulties sleeping through the night* *c) Difficulties relaxing during the day*
Question 3 & 4	Activities and participation	General tasks and demands (d2)	Carrying out daily routines (d230)	*'Do you perceive that using the weighted blanket has influenced your morning/evening routines?' If yes, please give examples on how.*
Question 5	Activities and participation	Self-Care (d5)	Toileting (d530) Dressing (d540) Eating (d550)	*'How has the weighted blanket influenced your evening routines?' Please give examples.* *a) Preparing/eating dinner* *b) Going to sleep*
	Body functions	Sleep functions (b124)	Quality of sleep (b1343)	*c) Sleeping through the night*
Question 6 & 7	Activities and participation	Self-Care (d5)	Dressing (d540) Eating (d550) Education (d810–d830) Work and employment (d840–d850)	*'How has the weighted blanket influenced your morning routines?' Please give examples.* *a) Wakening/going up* *b) Eating breakfast* *c) Going to school/work*
Question 8	Activities and participation	Mobility (d4) Domestic life (d6) Community, Social and Civic life (d9)	Walking and moving (d450–d469) Moving around using transportation (d470) Household tasks (d630–d640) Recreation and leisure (d920)	*'How has the weighted blanket influenced your afternoon routines?' Please give examples.* *a) Going home from school/work* *b) Doing household chores (cooking, dishes, laundry)* *c) Engaging in leisure activities*

sleep (b1340), and difficulties in maintaining sleep (b1342). The third and fourth questions focused on activities and participation in the ICF [73], specifically how the use of the weighted blanket influenced carrying out daily routines (d230) in the morning and evening. The fifth question focused on self-care (d5) activities during evening activities and asked how the use of the weighted blanket influenced evening routines including preparing/eating dinner (d550) and activities related to preparing for going to sleep (b530–d550) as well sleeping through the night (b1343). The sixth and seventh questions focused on self-care activities during the morning including how the use of the weighted blanked influenced morning routines including eating breakfast (d550), dressing (d540) and getting to school (d810–830) or work and employment (d840–d850). The eighth question focused on activities after school/work and included four sub-questions covering how the use of the weighted blanket influenced getting from school or work (d810–d850) by either walking (d450) and/or using transportation (d470), such as driving (d475). Furthermore, the eight-question focused on how the use of the weighted blanked influenced domestic life (d6) such as performing household chores (cooking, dishes, laundry; d630–d640) and engaging in recreation and leisure activities (d920). The ninth to eleventh questions focused on frequency of use (every night/several times a week/once a week/once a month/never), as well as activities performed using the weighted blanket including watching tv, reading books, listening to music or relaxing. The 12th and 13th question focused on pharmacological treatment and if the use of the weighted blanket had influenced the amount of medicine taken or if medication had been stopped. Questions 14–15 focused on satisfaction with the prescription process including information received in connection to prescription as well as the follow up on use. Data from the questions 12–15 are not reported in the current study.

The interview was administered over the phone (ranging between 5 and 15 min). For adults some sub-questions were altered to cover work and employment (d840–d850). Participants' answers were noted by the interviewer (second and third authors) on printed score sheets. Information that appeared in addition to the questions asked was noted as comments.

Statistical methods

Differences between the participants were analysed using a chi-squared test with statistical significance set at $p < 0.05$. Where cell size was below five, Fisher's exact test was used [74]. Statistical analyses were carried out using IBM SPSS Statistics 25.

Table 2. Description of the participants' diagnosis at time of prescription of a weighted blanket, *n* (%).

	ASD	ASD + ADHD	ASD + behavioural/ Mental disorders[a]	ADHD	ADHD + behavioural/ Mental disorders[a]
Children (≤17 years of age) 48 (56.5)	2 (12.5)	11 (50.0)	1 (12.5)	29 (90.6)	5 (71.4)
Adults (≥18 years of age) 37 (43.5)	14 (37.8)	11 (50.0)	7 (87.5)	3 (9.4)	2 (28.6)
TOTAL 85 (100)	16 (87.5)	22 (25.9)	8 (9.4)	32 (37.6)	7 (8.3)

[a]Includes comorbid disorders such as Tics disorder, Obsessive-compulsive disorder, specific developmental disorders of speech and language, Phobic anxiety disorders, Mood affective disorders.

Results

Characteristics of the participants

The total sample consisted of 85 individuals, 43 males (50.6%) and 42 females (49.4%), aged 7-17 ($n = 48$, 56.5%), 18–30 ($n = 23$, 27.1%) and 31–59 years ($n = 14$, 15.4%). Significantly more children aged 7-17 years were male (66.7%) compared with adults (29.7%) aged 18–59 years, while more females were adults (70.3% vs. 33.3%; $p < 0.05$). Participants diagnose at time of prescription of weighted blanket are displayed in Table 2. When comparing children with adults aged >18 years, findings show that significantly more children were diagnosed with ADHD (90.6% vs. 9.4%), while more adults were diagnosed with ASD (37.8% vs. 12.5%; $p < 0.05$).

Analysis of response bias between participants in the present study and non-respondents regarding age, sex, type of blanket, weights used and number of years using the weighted blanket revealed that 42.4% of non-respondents were 18–30 years and 30.2% were 31–59 years of age, which is a significant difference between respondents ($p < 0.00$). No differences between gender, type of weighted blanket used or number of years using the blanket were evident between participants and non-respondents.

Type of blanket and reasons for use

The participants in this study either used a chain-weighted blanket (85.9%) or a ball- weighted blanket (12.9%). Participants used a 5-6 kg chain-weighted blanket (43.5%), or an 8 kg chain-weighted blanket (34.1%), or a 7 kg ball-weighted blanket (12.9%). Eighty percent of the participants had used the weighted blanket between 1 and 3 years and 20% between 4 and 6 years. No differences between children (≤17 years) and adults (>18 years) were evident concerning type of weighted blanket, weight used or number of years using the weighted blanket.

Participants started using their weighted blanket due to difficulties falling asleep (81.2%), difficulties sleeping the whole night (65.9%), and difficulties relaxing during the day (10.6%). Significantly more adults (18.9% vs. 4.2% of the children) used a weighted blanket due to difficulties relaxing during the day ($p < 0.05$). Eighty-nine percent of the total sample reported that using a weighted blanket improved the three stated reasons for starting to use a weighted blanket (difficulties falling asleep/sleeping the whole night /relaxing during the day). Significantly more children (68.8% vs. 45.7%) stated that using a weighted blanket improved their ability to fall asleep ($p < 0.05$).

Frequency of use

Seventy-eight percent of the total sample used the weighted blanket every night, and 24% used the weighted blanket during the day for activities such as watching TV (11.8%), reading/listening to music/books (3.6%), and relaxing during the day (12.9%).

Significantly more adults (37.8%) stated that they used the weighted blanket during the day compared with 12.5% of the children ($p < 0.05$). Of those participants that used a weighted blanket for watching TV, significantly more were children ($p < 0.05$), while significantly more adults (71.4% vs. 16.7%) used weighted blankets for relaxing during the day ($p < 0.05$).

Weighted blanket and daily activities

Almost half of the participants (45.8%) in the total sample said that using a weighted blanket improved their daily routines, especially during the evening and in the morning (see Table 3). Of the total sample 59% stated that using a weighted blanket improved preparing/going to sleep, with a significant difference between children and adults (68.8% vs. 45.7%; $p < 0.05$). Of the total sample 81 % stated improvements in sleeping through the night when using a weighted blanket. A quarter of the total sample (26.5%) said that using a weighted blanket improved waking up in the morning, and 16.5% stated that using a weighted blanket improved performance of activities at work or in school/education.

Table 3. Weighted blanket use and daily activities.

	Total sample ($n = 85$) N (%)	Children (≤ 17; $n = 48$) N (%)	Adults (≥ 18; $n = 37$) N (%)	*P (children vs adults)*
Overall improvement in daily routines	38 (45.8)	18 (37.5)	20 (57.1)	ns
Evening routines				
Preparing/eating dinner	1 (1.2)	1 (2.1)	0 (0)	ns
Preparing/Going to sleep	49 (59.0)	33 (68.8)	16 (45.7)	<0.05
Sleeping through the night	67 (80.7)	36 (75.0)	31 (88.6)	ns
Morning routines				
Wakening/going up	22 (25.9)	15 (31.3)	7 (20.0)	ns
Eating breakfast	6 (7.2)	5 (10.4)	1 (2.9)	ns
Going to school/work	6 (7.2)	4 (8.3)	2 (5.7)	ns
Going home from school/work	3 (3.6)	2 (4.2)	1 (2.9)	ns
Activities in school/work	14 (16.9)	5 (10.4)	9 (25.7)	ns
Doing homework/work related tasks at home	6 (7.1)	3 (6.3)	3 (8.6)	ns
Leisure activities	5 (6.0)	2 (4.2)	3 (8.1)	ns

Discussion

The overall findings demonstrated that 59% of children and adults with ADHD and/or ASD stated that using a weighted blanket improved their ability to fall asleep, confirming the results of other studies, which showed positive trends towards an increase in total amount of sleep per night, as well as a slight decrease in time to fall asleep [66]. This is particularly important as insufficient sleep has a crucial impact on performance in daily activities such as education, activities of daily living, work, play, leisure, and social participation [51,52]. However, it is possible that these findings are related to a perception of improved sleep brought about by improved sleep hygiene consisting of a set of behavioural, environmental, or cognitive modifications to improve sleep (i.e. modification of bedtime and bedtime routines, restriction of electronic media use, restriction of caffeine use, modifications to bedroom or sleeping environment), which are often the first-line treatment recommendations [75,76]. Nevertheless, it is reasonable to assume that the weighted blanket had a positive impact on participants' sleep in the current study as 80% of them had chosen to use the blanket for one to three years, and 81% of the participants described improvements in sleeping better throughout the night. Future research should compare weighted blanket interventions with other sleep hygiene interventions, to describe the inter-relatedness among these interventions. It is also of importance to investigate further the positive trend towards improved sleeping during the night and going to bed described by the participants in the current study, using objective measures of sleep (e.g. polysomnography, actigraphy), as the results in this study were based on subjective measures.

In the present study, the weighted blankets were frequently used by 78% of the participants every night for several years, indicating that weighted blankets were favoured by participants, in line with earlier studies reporting overall satisfaction with using weighted blankets [66–68]. Gringras et al. [67] reported that children with ASD really liked using the weighted blanket compared with a regular blanket, and Lindstedt and Umb-Carlsson [68] described that weighted blankets were highly valued by adults with ADHD. Despite being a frequent intervention to address sleep problems for individuals with ADHD or ASD favoured by the participants in this study as well as within earlier research [66–68], and the frequency of occupational therapists' recommendation for this intervention [57,66], there is a lack of evidence documenting the effectiveness of this intervention on daily activities among children, adolescents, and adults with ADHD and/or ASD. The current study adds to the body of knowledge on weighted blanket use related to the daily activities of children and adults with ADHD and/or ASD. Although subjective support for weighted blanket use exists from parents, caregivers, and children and adults with ADHD or ASD, it would be beneficial for occupational therapy research to strive to apply robust research designs to evaluate the effectiveness of this intervention on everyday activities, as highlighted by Green [48] and Tester and Foss [49], using more objective, and validated measures of sleep. This is especially important as current systematic reviews [52,57,75] report on narrow sampling methodology, small sample sizes, and low-level designs in the small number of studies on the effectiveness of weighted blankets. In addition, scrutinizing the routines concerning the process of prescribing weighted blankets among adults is urgent, as this study indicated that more children are prescribed weighted blankets compared with adults.

The current study shows that only 17% of the participants described improved performance of activities

at work or in school/education with the use of a weighted blanket. These results are in part similar and in part contrary to the results of Gringras et al. [67] and Gee et al. [66] which examined daytime behaviours of children with ASD. Gringras et al. [67] reported that parents of children with ASD described an improvement in next-day behaviours, especially that their child's behaviour was calmer when using the weighted blanket: a finding that the authors hypothesize might be due to improved bedtime behaviours or improved parent/child interactions. In contrast, Gee et al. [66] reported that the morning mood of children with ASD does not appear to improve with use of a weighted blanket. The inability to report on improved everyday behaviour was partly explained by the authors as being due to three factors: persistent patterns that represent learned behaviour for which sleep might be only a partial determinant, the need to examine behaviour throughout the day in school or work in order to find subsequent changes in functional behaviour, and the need to include objective measures of everyday behaviour. A possible explanation for our result showing a small improvement in performance of activities at work or in school/education among participants brought about by weighted blanket use might be related to the lack of use of reliable and validated measures of activities of daily living in relation to weighted blankets. Furthermore, using research designs incorporating observation in everyday settings such as school and/or home might provide relevant insights into daily morning/evening routines, as well as potential influence on school and work-related activities. Further studies need to explore the interrelation between weighted blanket use and aspects of improvement at work and/or school/education (e.g. on-task behaviour, attention-to-task, social, emotional, and communication skills and task completion) using reliable and validated measures of everyday activities. A quarter of the total sample, significantly more adults, used the weighted blanket during the day due to difficulties relaxing. This finding is supported by earlier studies on weighted vest use during school/education tasks, showing that weighted vests improve in-seat behaviour, attention-to-task, and task completion in children with ADHD in a classroom environment [57–63,77]. Further studies need to examine the use of weighted blankets during the day for relaxation, especially among adolescents and adults to establish their effectiveness in improving performance in work and/or school/education.

The findings indicate that morning and evening routines, such as preparing/going to sleep reported by 59% of the participants and waking up in the morning reported by 26% of the participants, may be improved with the use of a weighted blanket. These findings are in line with the results of Gee et al. [66] suggesting that children with ASD slept between 1 and 3 extra hours a night as a result of using a weighted blanket, as well as decreased duration needed to fall asleep, indicating that weighted blankets can assist in improving overall sleep quality for children with autism spectrum disorder. Furthermore, a recent review article on the use and effectiveness of weighted blankets suggests that weighted blankets can be effective in reducing or relieving anxiety and improving evening routines [57]. Improvements in preparing/going to sleep and waking up in the morning with the use of a weighted blanket reported in the current study are particularly significant considering the findings of van der Heijden et al. [25] which show that adults with ADHD more often have an extreme evening chronotype with 70% of adults reporting difficulties with getting to bed at night and getting up in the morning Boonstra et al. [78], suggesting a delayed phase in the circadian organization of sleep and wakefulness [25]. In addition, individuals with ADHD and ASD had later sleep onset during weekdays (around 30–45 min later in ADHD and ASD than in controls), and young people with ASD woke up earlier than controls despite a later sleep onset time [25]. Earlier studies on children with ADHD have also studied the importance of establishing morning and evening routines independently within set time, indicating a need for interventions targeting morning and evening routines [79]. Whether the improved evening and morning routine findings in the current study are due to differences in sleep patterns, reduced anxiety and/or improved sleep hygiene (e.g. behavioural, environmental, or cognitive modifications to improve sleep) remains unknown. Future studies using different measurements including subjective experiences, validated report scales, sleep logs, and objective measures (actigraphy or polysomnography) should shed further light on which evening and morning routines (e.g. anxiety, sleep onset latency, total amount of sleep time or bedtime routines) are improved in participants with ADHD and/or ASD.

There are methodological strengths of this study. Given the importance of sleep in daily activities, the consequence of disrupted sleep in individuals with ASD or ADHD is potentially serious for health and

wellbeing. To date, however, the knowledge about the relationship between sleep problems and everyday activities in individuals with ASD or ADHD is limited. This current study adds to the body of research on weighted blankets and children and adults with ADHD and/or ASD in three distinct ways. First, this study included a more heterogeneous sample, by including adults with ADHD and/or ASD, than early research which has largely focussed on examining sleep in children with ASD [75,80]. Second, the inclusion of adults with ADHD and/or ASD adds to the modest body of research on adults and weighted blanket interventions. As our data demonstrated, use of a weighted blanket varied between children and adults, with children using the weighted blanket consequently every night and adults using the weighted blanket during the day. Finally, only two earlier studies [64,66] have focussed on weighted blankets to improve daily activities or target everyday behaviour as an outcome measure. The current study sheds further light on the morning/evening routines (such as 'preparing for sleep' or 'getting up in the morning', as well as everyday functioning of children and adults with ADHD and/or ASD using weighted blankets, aspects of everyday routines which have not usually been measured [49,81].

However, this study also has limitations. First, assessments were based on subjective reports on the use of a weighted blanket and influence on sleep. Although the study derives from an interview based on the ICF [73] and is tested in an earlier study [72], using validated and reliable questionnaires of daily activities, such as the Weiss Functional Impairment Rating Scale (WFIRS-S-SWE) [82], would have strengthened our findings. The assessment of children's everyday activities took place through parents' reports, however it is not possible to establish if parents were fully aware of bedtime routines of their children once in their bedroom, such as evening media use, which could influence sleep. Second, this study used subjective reports of sleep difficulties, as opposed to an objective measure of sleep, such as actigraphy, which would allow for measurement of day-to-day variations in sleep problems, in contrast to a retrospective account of weighted blanket use, which introduces the possibility of fallible memories on the part of the participants. It is also possible that the findings are related to parents' desire to see improvement in their children's sleep or a desire to please the study team by reinforcing widely held beliefs about weighted blankets, as suggested by Gringras et al. [67]. Third, there was a drop-out rate in the study: a total of 136 individuals, dropped out partly due to 38 possible participants declining to participate, and partly because 89 individuals did not answer the phone. Therefore, caution should be employed in generalizing the results. Further studies are urged with preferably a randomized control study design. Analysis of response bias revealed that 40% of the non-respondents were adults (18–30 years and 31–59 years), which might indicate that adults stopped using the weighted blanket and were less satisfied with weighted blanket use. Although low response rates of 50% or lower might be considerable as acceptable [74], the 40% in the present study presents a considerable risk for biases. Efforts to achieve a higher response rate including establishing contact to set a time for the interview prior to conducting the telephone interviews, and sending or emailing the questions in advance, would have been beneficial in line with recommendations [74]. Face-to face interviews in which visual cues and flexible strategies, such as the participants' vocabulary could be used, represents an alternative to telephone interviews. However, this study is one of the few studies on the use of weight blankets among adults with ADHD and/or ASD who have sleep problems, adding to the documented need for further research in the field [76,80].

Disclosure statement

No potential conflict of interest was reported by the author(s).

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#12

Widespread Pressure Delivered by a Weighted Blanket Reduces Chronic Pain

Widespread Pressure Delivered by a Weighted Blanket Reduces Chronic Pain: A Renadomized Controlled Trial

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Highlights

- A 15-lb weighted blanket reduced aspects of chronic pain more than a 5-lb weighted blanket.
- The heavier weighted blanket was more pain relieving for highly anxious individuals.
- Weighted blanket-related pain reductions were not mediated by changes in state anxiety or sleep.
- Interoceptive or social-affective effects of deep pressure may mediate pain relief.
- 15-lb weighted blanket may be an accessible, low-cost tool to reduce aspects of chronic pain.

Abstract

Pleasant sensation is an underexplored avenue for modulation of chronic pain. Deeper pressure is perceived as pleasant and calming, and can improve sleep. Although pressure can reduce acute pain, its effect on chronic pain is poorly characterized. The current remote, double-blind, randomized controlled trial tested the hypothesis that wearing a heavy weighted blanket – providing widespread pressure to the body – relative to a light weighted blanket would reduce ratings of chronic pain, mediated by improvements in anxiety and sleep. Ninety-four adults with chronic pain were randomized to wear a 15-lb. (heavy) or 5-lb. (light) weighted blanket during a brief trial and overnight for one week. Measures of anxiety and chronic pain were collected pre- and post-intervention, and ratings of pain intensity, anxiety, and sleep were collected daily. After controlling for expectations and trait anxiety, the heavy weighted blanket produced significantly greater reductions in broad perceptions of chronic pain than the light weighted blanket (Cohen's $f = .19$, CI [-1.97, -.91]). This effect was stronger in individuals with high trait anxiety ($P = .02$). However, weighted blankets did not alter pain intensity ratings. Pain reductions were not mediated by anxiety or sleep. Given that the heavy weighted blanket was associated with greater modulation of affective versus sensory aspects of chronic pain, we propose that the observed reductions are due to interoceptive and social/affective effects of deeper pressure. Overall, we demonstrate that widespread pressure from a weighted blanket can reduce the severity of chronic pain, offering an accessible, home-based tool for chronic pain.

The study purpose, targeted condition, study design, and primary and secondary outcomes were pre-registered in ClinicalTrials.gov (NCT04447885: “Weighted Blankets and Chronic Pain”).

Perspective

This randomized-controlled trial showed that a 15-lb weighted blanket produced significantly greater reductions in broad perceptions of chronic pain relative to a 5-lb weighted blanket, particularly in

highly anxious individuals. These findings are relevant to patients and providers seeking home-based, nondrug therapies for chronic pain relief.

Introduction

Chronic pain is the leading cause of disability worldwide.[73] Efforts at treatment have spawned an ongoing opioid crisis, exposing the need for nondrug treatment options.[113] Chronic pain is amenable to modulation by cognitive interventions such as cognitive behavioral therapy and mindfulness meditation.[107,112,146,162] However, such therapies require resources and training, highlighting a need for more accessible complementary approaches.

Chronic pain has a strong affective component[17 10,11,32,138,148, 158] and is frequently accompanied by deficits in emotional regulation.[141] One underexplored therapeutic avenue for modulating chronic pain is pleasant sensation, which shares overlapping affective neural circuitry with pain.[129] By attending to pleasant sensations, individuals may break habitual loops of catastrophizing and negative bias towards incoming sensation that contribute to pain chronification.[60]

The "Social Touch Hypothesis",[108, 116] more recently referred to as the "Affective Touch Hypothesis",[98] proposes that the C-tactile (CT) afferent pathway is a specific sensory pathway that conveys the positively valenced social and/or affective components of touch. CT sensory afferents are unmyelinated, low-threshold mechanosensory afferents present predominantly in hairy skin[108,150,161] that respond maximally to gentle stroking at slow velocities (ie, strongest firing for 1-10 cm/s). CT-optimal touch induces positive affect, decreases anxiety,[20,91,92,116,119,120] and activates affective and interoceptive brain regions[20,63,82,97,117] critically involved in descending pain modulation[137] and pain relief by complementary therapies.[153,167,168]

We recently called for the expansion of the Social and/or Affective Touch Hypothesis to include deep pressure [20] – embedded in hugs, cuddling, and massage – as another bottom-up pathway for social and/or affective touch. Deep pressure is employed in therapeutic settings to induce calm[23,64,143] and may be especially beneficial in anxious individuals.[39,64] We recently demonstrated in healthy adults that deep pressure from a compression sleeve is perceived as pleasant and calming, and activates the mid-insula.[20]

Several studies demonstrate that pleasant social and/or affective touch can modulate pain. CT-optimal touch reduces experimental pain in healthy adults[45,67,89,94,111] beyond cognitive effects,[89] and can reduce ratings of chronic pain.[34] Pressure delivered through massage improves mood and pain,[46,49, 50, 51, 52, 53,71] with deeper pressure eliciting greater improvements and greater pleasantness.[36,47,58] Widespread mechanical compression also reduces experimental pain in healthy adults,[72] potentially via sensory gating effects.[99,149,160] However, the affective and sensory effects of deep pressure have not been tested in chronic pain.

One potential therapeutic tool to administer deep pressure is a weighted blanket – a blanket sewn with weighted materials that provide widespread pressure to the body. Weighted blankets elicit similar affective effects as deep pressure including feelings of calm[24,41,65] and reductions in anxiety[22,110]. In addition, weighted blankets improve insomnia in healthy adults [2] and psychiatric patients [41]. In addition to sensory gating and modulation of affect,[4,76,122,127,151] weighted blankets could plausibly reduce pain by decreasing anxiety[4,76,122,127,151] or improving sleep.[140,156] The present study tested the hypothesis that a heavy versus light weighted blanket would reduce perceptions of chronic pain, mediated by improvements in anxiety and sleep. Further, we explored whether trait anxiety would alter these effects.

Section snippets

Method

The current study was a double-blind, between-subjects randomized controlled trial conducted remotely during the COVID-19 pandemic (June to November 2020). A heterogeneous sample of

adults with chronic pain were randomly assigned to wear a heavy or light (placebo control) weighted blanket during a brief and weeklong trial, respectively, with self-report and ecological momentary assessment data collected pre-post blanket wearing.

Participant Flow Through the Study

A total of 211 individuals were assessed for eligibility, 118 were randomized to the intervention (53 to heavy blanket and 65 to light blanket), 16 were lost to follow-up (2 heavy blanket and 14 light blanket), and 8 were excluded after randomization but prior to analysis based on two criteria: 1) baseline PEG scores were less than 4 (n = 7), indicating a "mild" level of pain – a criterion employed in previous research,[100] and 2) weighted blanket was reported to be worn less than 30% of each

Discussion

The current study demonstrated a greater effect of a heavy versus light weighted blanket in reducing chronic pain intensity and interference ratings as measured by our secondary pain outcome (PEG)[86]. The effect of weighted blanket pressure on PEG ratings was significant after controlling for trait anxiety and for expectations of pain relief. In contrast, there was no overall effect of weighted blankets on purely sensory aspects of chronic pain as measured by our primary pain outcome (VAS pain

Acknowledgments

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REPORT

Weighted Blankets for Pain and Anxiety Relief in Acutely Injured Trauma Patients

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ABSTRACT

To determine the impact of a weighted blanket on acute pain and anxiety in trauma patients, a preliminary prospective/retrospective study at a level-one trauma center (n = 24 patients) was conducted. In this study, 12 patients using weighted blankets for five consecutive days were compared to a matched retrospective cohort of 12 patients not using a blanket. The change in morphine milligram equivalents (MME) and alprazolam milligram equivalents (AME) over five days were compared. There was a significant difference of MME per day between the intervention group (mean MME change = −22.9) and matched controls (mean MME change = 6.2; $p = 0.0072$) by blanket use. Total MMEs in the intervention group decreased by 275.5 and in the control group increased by 75 between day 1 and day 5. There was no significant difference in AME change between groups ($p = 0.3227$). The majority of patients who took a post-intervention questionnaire reported less pain and less anxiety with blanket use compared to those without blanket use (78% and 56% of patients, respectively). To summarize, trauma patients in acute pain had less opioid use and reported less pain and anxiety when using a weighted blanket for five consecutive days compared to a control group who did not use a blanket.

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Weighted blanket; deep-pressure therapy; opioids; pain management

Introduction

In trauma patients, pain management should provide adequate pain relief without overmedicating the patient. Trauma patients are at particularly high risk for large amounts of opioids and anxiolytics due to the nature of trauma-related pain and the ensuing acute pain and anxiety (1). Pain also can be exacerbated by anxiety (2), a common emotion among trauma patients. Using a trauma registry and personal interviews for follow-up information to study patient prognoses after polytrauma, Von Rüden et al. (3), found trauma patients who started early on pain management and psychological therapy had decreased chronic pain and decreased post-traumatic stress disorder (PTSD). These authors demonstrated that 62% of severely injured trauma patients progressed to chronic pain; 41% reported severe chronic pain and more than 40% showed signs of PTSD (3). Previous investigations regarding pain and anxiety relief relied mostly on self-reported improvements rather than objective data on pain. For instance, Wong et al. (4) using a quasi-experimental pre-and post-test design, looked at pre-operative educational programs targeting pain and anxiety management to aid patients during the postoperative period which were measured via self-reported surveys and found successful outcomes compared with participants who did not receive this education. Vinson et al. (5) used a randomized controlled trial on patients with newly diagnosed cancer who just started chemotherapy treatment and found significantly decreased self-reported anxiety with a visual analog scale during chemotherapy infusions when using a weighted blanket. Further, Ohene et al. (6) implemented a randomized controlled trial to determine anxiety reduction measured with the Beck Anxiety Inventory and demonstrated that the use of weighted blankets in patients with comorbid anxiety and eating disorders

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significantly decreased their reports of anxiety. The alleviation of *chronic* pain using a weighted blanket was studied by Baumgartner et al. (7) in a randomized controlled trial to show that heavier blankets were more effective at chronic pain control compared to lighter blankets, but this study also used self-reported measures and did not measure acute pain control.

Occupational therapists use deep pressure therapy to trigger the nervous system to relax by applying gentle pressure to the body (8). While this therapy has been studied and applied to treatment programs by occupational therapists (8), it is not currently a proven modality for patients with acute pain. Reynolds et al. (8) demonstrated that pressure on baroreceptors increases parasympathetic activity and decreases the activation of the sympathetic nervous system. Baroreceptors, modulated by the vagus nerve, play a large role in the pain pathway; stimulation of the vagus nerve helps to reduce the severity of pain perception and decrease pain in postoperative patients (8, 9). A weighted blanket is a form of deep-pressure therapy that stimulates vagal tone by activating baroreceptors in the skin and may cue a feeling of safety (5). The feeling of comfort also activates the ventral branch of the vagal nerve, which in turn, dampens the body's hyperactive state (5). Deep pressure therapy has been studied in relation to autism (10), patients with anxiety disorders (11), anesthetized patients undergoing dental procedures (12), and patients receiving chemotherapy (5).

As far as can be determined, no investigation has been performed on both self-reported and objective measures of *acute* pain relief in trauma patients by using weighted blankets. Although opioids are indicated for the management of acute pain in trauma and critically ill patients (12), there have been a number of efforts to reduce opioid use in this setting due to known side effects and potential for misuse. Such approaches often incorporate multimodal pain strategies with adjuvant medications such as acetaminophen, tramadol, gabapentin, and non-steroidal anti-inflammatories. The objective of this study is to assess the impact of a non-pharmaceutical approach using deep-pressure therapy with a weighted blanket on opioid and anxiolytic usage among patients with acute pain and anxiety after a traumatic injury.

Methods and materials

This was a single-center preliminary study using a retrospective and prospective analysis of data at a large public hospital in Florida. The hospital provides acute care, tertiary care, academic instruction, and is a level one trauma center. The hospital Institutional Review Board approved this study as minimal risk and informed consent was obtained from all prospective participants. The study contained two phases: retrospective and prospective data collection with 24 patients in the sample. For the retrospective phase, we extracted patient data from the trauma registry between January 2016 to January 2021 (n = 12). The patients were matched to the prospective cohort based on age, traumatic injury, previous comorbidities of alcohol or opioid dependence, and history of anxiety. For the prospective phase, a total of 14 trauma patients were consented between November 2021 and February 2022, of which 12 completed the study. One patient did not complete the study due to worsening respiratory status and the other patient developed hospital delirium after consenting but before receiving the blanket. The eligibility criteria for prospective patients included 18 years or older, admitted to the hospital following a trauma, an expected hospital length of stay of at least five days, and prescribed opioid pain medicine ± anxiolytics. Exclusion criteria included inability to give informed consent, practicing physician judgment of patient as unfit to use a weighted blanket due to injuries, and pregnant women.

Each eligible prospective patient who consented and enrolled in the study received a hospital-grade 25-pound weighted blanket. The instructions given to the patient were to use the blanket whenever they were resting in bed or in a chair. They were told to remove the weighted blanket during physical therapy, or if they were uncomfortable. At the end of day five, patients were asked four brief survey questions about their experience with the blanket. They were given the option to keep the blanket longer or to terminate the study at that time. Blankets were cleaned

based on the Guidelines for Environmental Infection Control in Health-Care Facilities, according to the Centers for Disease Control and Prevention (13), for use on subsequent patients.

Measures

The dependent variable was the intervention groups' use of morphine milligram equivalents (MMEs) and alprazolam milligram equivalents (AMEs) when using versus not using a weighted blanket, that is, as their own controls, and compared to a historical control group who did not use a blanket at any time. The other dependent variables were the intervention groups' self-reported anxiety and pain questionnaires. The independent variable or predictor of interest was the use of a weighted blanket. The total MME and AME were extracted from the electronic medical record (EMR). MMEs and AMEs were normalized by route of administration and drug type. Oral and intravenous medications were converted to the oral MME and oral AME using conversion tools validated for potency and dose equivalency: MME Calculator on MDCALC.com and Equivalent Benzodiazepine Calculator on ClinCalc.com. A five-day span that mimicked the timeframe of prospective patients was used to collect similar data points from matched retrospective patients. For retrospective patients the only exception was if a patient was intubated, day one MME and AME were calculated from the day after extubation, which was determined via chart review. All major diagnoses using ICD-10 codes were used to match retrospective patients to their equivalent prospective patients. The demographic data were measured as sex (male, female), length of hospital stay, and race/ethnicity (Black, White, and Hispanic). All data were pulled from the EMR or asked in person in a survey format.

For prospective patients, the MME and AME for day one and day five with the blanket were used to determine the change in medication usage over the five-day period of the study. The MME for each day with the blanket use was also recorded for intervention patients for at least three days prior to or following the study period. The mean MME for the days with and without blanket use served as paired data points for each patient in the intervention group. All opioid and anxiolytic medication information was extracted from the EMR. For the control group patients, the MME and AME for day one and day five were recorded based on a retrospective chart review of the five days that mimicked their matched intervention groups' blanket use timeframe and used to determine the change in MME and AME.

Four survey questions also were read to the participant and recorded at the end of day five. Survey questions are provided with the corresponding figure legend. The first three survey items used a Likert scale format ranging from 1–5. The first question asked about the patient's perception of the comfort of the blanket with the range being very uncomfortable to very comfortable. The second and third questions measured perceived anxiety with and without the blanket and were scored from very anxious to very calm. The fourth question asked participants if they believed they were in less overall pain while using the blanket (yes or no).

Statistical analyses

The demographic data are displayed as means and standard deviations for continuous data, while categorical data are displayed as frequencies and percentages. Chi-square tests were used to compare categorical demographic variables. The difference between mean MME and AME on day one and day five of each group (calculated as day five minus day one) was analyzed using independent student t-tests. A paired t-test was used to analyze the mean MME per day of individual prospective patients with and without the blanket. Absolute MME was calculated by summing day one and day five for both groups. Non-parametric tests, Wilcoxon signed-rank, and Mann Whitney U tests were performed on all non-normal data. Questions regarding comfort level, pain, and anxiety level were plotted and displayed in figures. Type 1 error rate was set at 5%. SPSS v. 28 was used for all statistical analyses. Power analysis was not performed as this is a pilot study, the aim of which is not to test the superiority of the intervention over the

control, although statistical significance was demonstrated in this study.

Results

The sample consisted of 24 patients, 12 in each group. The patients between groups were similar in characteristics including age, race/ethnicity, presence of long bone fractures, surgery, and BMI (Table 1). The intervention group had a non-significantly higher percentage of patients with a history of opioid and alcohol misuse (33%) as compared to the control group (17%); however, the control group had a higher percentage of patients with a history of anxiety (25%) compared to their counterparts in the intervention group (8%). The control arm of the study revealed a non-significantly higher percentage of patients who smoked (42%) compared to the intervention arm (17%). The median time between patient admission and day one of blanket use was 6.5 days with a range of 2–10 days and one outlier of 46 days due to prolonged intubation in the intensive care unit (ICU).

The patients were paired based on numerous characteristics including similar major injury and requirement for surgery. The exception was a patient with a perforated colon was matched with a patient with an arm fracture as both were similar in age, mechanism of injury by gunshot wound, and both required immediate surgery. The variety of injuries observed and matched among the sample is shown in Table 2. The mechanism of trauma injury was matched by blunt or penetrating trauma for all patients.

There was a significant difference in the change of MME requirements between the intervention group (MME change = −22.9) and matched controls (MME change = 6.2, $p = 0.0072$) between day one and day five of blanket use (Table 3). Figure 1A depicts day one total MME for both groups by their matched counterpart. Day five (Figure 1B) shows the overall decrease in total MME among the intervention group when compared to an increase in MME in the control group. There was a non-significantly higher mean MME of the intervention group prior to blanket use (MME = 43.7) than when the patients had the blanket (MME = 34.6; $p = 0.2506$) demonstrating that patients may have required fewer opioids while using the weighted blanket (results not displayed). The mean MME on day one was 46.2 in the intervention group and 46.3 in the control group but by day five decreased in the intervention group (mean MME = 23.3) when the patients had the blanket and increased in the control group (mean MME = 52.4) when the patients did not have blankets (Table 3). We suspect that a larger sample size would bring significance to this finding.

There was no significant difference in AME change as displayed in Table 3 between the

Table 1. Demographic characteristics and differences of weighted blanket usage between intervention and control group (N = 24).

Descriptive characteristics of sample							
Variable	Overall		Intervention group		Control group		*p*-value
	Mean	SD	Mean	SD	Mean	SD	
Age	42	17	42	16	42	18	0.96
BMI	27	8	28.4	9.8	26.2	6.2	0.52
Variable	Total n	%	Total n	%	Total n	%	*p*-value
Sex							>0.999
Female	4	17	2	17	2	17	
Male	20	83	10	83	10	83	
Race							>0.999
White	16	67	8	67	8	67	
Black	8	33	4	33	4	33	
Ethnicity							0.615
Hispanic	5	21	3	25	2	17	
Non-Hispanic	19	79	9	75	10	83	
Long Bone Fracture	4	16	2	17	2	17	>0.999
Surgery	19	79	10	83	9	75	0.615
Smoking	7	29	2	17	5	42	0.178
History of Anxiety Disorder	4	16	1	8	3	25	0.273
History of Opioid Use Disorder	6	25	4	33	2	17	0.346
History of Alcohol Abuse Disorder	6	25	4	33	2	17	0.346

p-values = difference between control and intervention groups.

Table 2. Matched diagnosis of major injuries in the intervention and control groups.

	Intervention group	Matched control group
a	C2 displaced, nasal fracture	C2 Fracture
b	Bladder injury	Bladder laceration, rectum laceration
c	Sigmoid perforation, tibia fibula, femur fracture	Small bowel perforation
d	Multiple facial fractures	Facial trauma
e	Rib fractures, pneumothorax, colon perforation	Rib fractures, hand degloving, facial Fractures
f	Rib fractures, pneumothorax, clavicle fracture	Rib fractures, pneumothorax
g	Pelvic fracture, mesenteric contusion	Pelvic ring fracture
h	Rib fractures, pneumothorax, shoulder dislocation	T2 spinal cord injury*
i	Perforated colon	Fractured arm**
j	Hangman fracture	Subdural hematoma and skull fracture
k	Pelvic fracture	Pelvic ring fracture, clavicle fracture
l	Rib fractures, pneumothorax	Rib fracture, liver laceration

*Patients with the same age and mechanism of trauma of motorcycle crash.
**Patients were both in their late 40's and injury of isolated gunshot wound.
Note: patients a through l are matched to those in Figures 1, 2, and 4.

Table 3. Outcomes of morphine milligram equivalents (MME) and alprazolam milligram equivalents (AME) (n = 12).

Outcome variable	Intervention	Control	*p*-value
Day 1 Mean MME	46.2	46.3	0.9980
Day 5 Mean MME	23.3	52.4+	0.1076
Day 1 Total MME	554.5	554.0	
Day 5 Total MME	279.0	629.0	
Mean change MME++	−22.9	6.2	**0.0072****
Mean change AME++	−0.2	0.2	0.3227

+Three patients had increased pain medication requirements while the majority of other patients remained about the same in the control group. See Figure 1.
++Mean change in MME/AME calculated by day five minus day one.
**$p < .05$ statistically significant difference.

intervention (mean AME change = −0.2) compared with control (mean AME change = 0.2) groups ($p = 0.3227$). Despite the differences in reported anxiety in the surveys (see Figure 2 which includes the questions asked and the Likert scale answers), both the control and intervention groups had relatively low use of anxiolytics with greater than 50% of the patients never using anxiolytics during their hospital stay (n = 9). The self-reported survey data from the intervention group suggested the blankets did provide some anxiety relief. Fifty-six percent of patients who took the post-intervention questionnaire reported much lower levels of anxiety when using the blanket compared to not using the blanket (Figure 2).

Less pain when using the blanket was reported by 78% of patients (n = 9) (see Figure 3 which includes the survey question). The majority (56%) reported the blanket as comfortable or very comfortable (see Figure 4 which includes the survey question and the Likert scale of answer choices). One participant felt the blanket was uncomfortable and three reported neutral feelings about the comfort level of the blanket. The most common complaint mentioned by some patients was that the blanket was too warm which was intensified by their already warm room. There were no adverse events reported during this study. Of note, three of the 12 surveys were not answered by participants. Two were discharged before the research team could reach them and the third patient started showing signs of early delirium, which would make this participant's responses of little value to the study.

Discussion

The purpose of this preliminary study was to see if a weighted blanket could decrease opioid and anxiolytic medication use in trauma patients who were experiencing acute pain and anxiety. This study was unique in that we were able to demonstrate through EMR and self-reported data, outcomes corresponding to significantly decreased opioid intake in trauma patients with deep-pressure therapy. Moreover, more than half reported decreased levels of anxiety and pain. This coincides with other studies that observed positive and beneficial effects of deep-pressure therapy (5, 11, 14).

We found in our cohort of trauma patients, the majority of whom underwent surgery, those who used the blanket consumed fewer opioids during the days measured than those who did not have a weighted blanket. We also found 78% of patients reported less pain while using the blanket. These are important findings as almost 20% of patients struggle with controlling severe pain during the first 24 hours after surgery and this statistic has remained constant for the past 30 years (15). One of the possible mechanisms for reduced pain and anxiety may be the result of better-quality sleep when using the weighted blanket (16). Although sleep quality/quantity was not measured in this study, poor sleep quality can aggravate the pain mechanism and increase anxiety in patients as well (17). In addition,

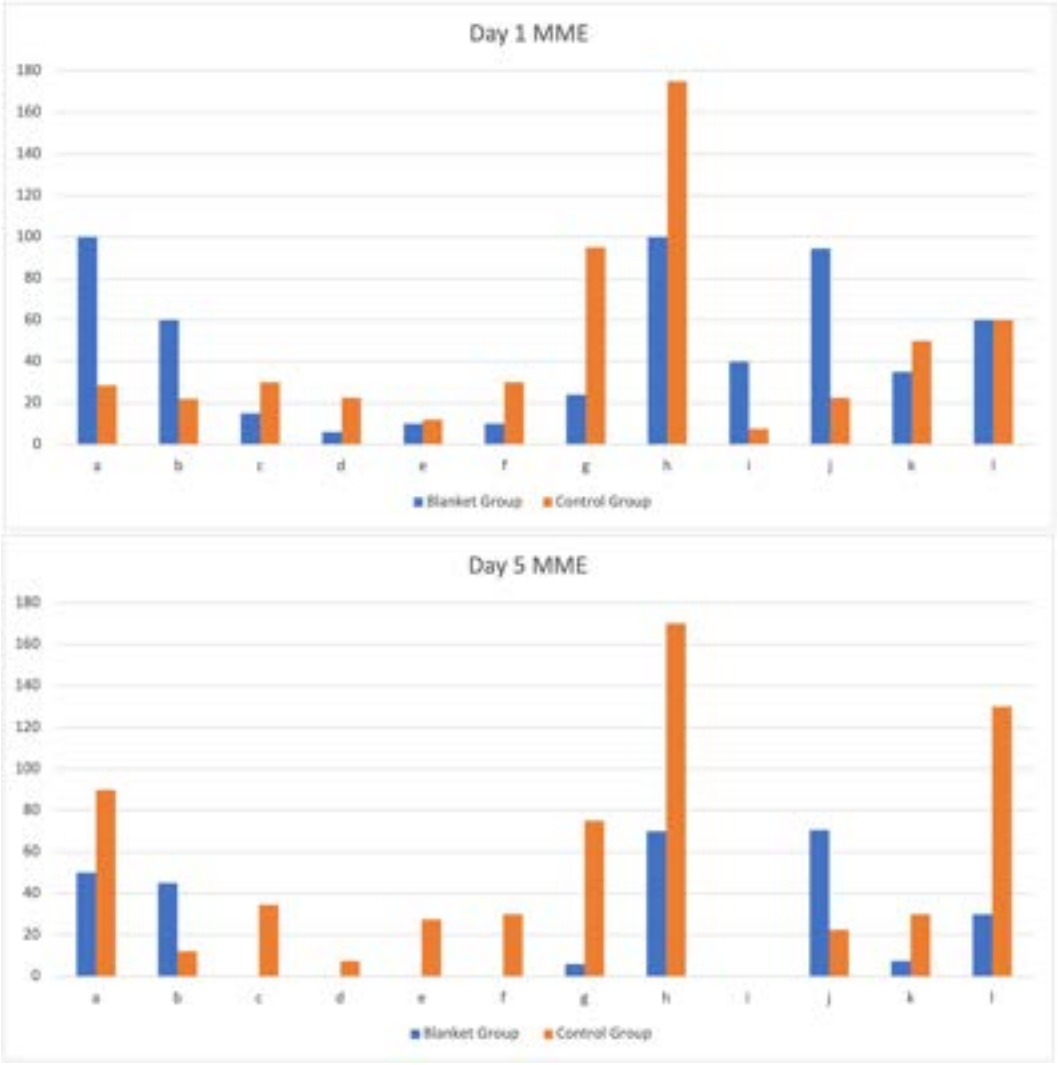

Figure 1. Change in morphine milligram equivalents (MME) on day 1 (A) and day 5 (B) for the intervention and control groups (n = 12).
Letters a through l on the x-axis represent the 12 intervention participants in the study.

postoperative sleep quality can suffer in the hospital setting (18), especially for patients who are put in a busy and noisy trauma intensive care unit. There is evidence in the literature that weighted blankets can improve sleep in institutional settings (19). Alternative treatments that can decrease discomfort and improve sleep quality, but do not share the deleterious side effects of opioid use, would be part of a welcomed approach to pain and anxiety management in these patients. Future studies should measure the attributes of sleep as a possible mediating factor in pain relief with blanket use.

We found no difference in anxiolytic medication intake between the intervention group and the control group or between day one and day five of blanket use. However, our survey revealed patients who experienced a traumatic injury and were given a weighted blanket self-reported being less anxious and more comfortable compared with before the blanket was used. Other studies looking at non-pharmaceutical ways to treat pain and anxiety only looked at self-reported data (4–6). Like these studies, we found lower stated anxiety in the majority of patients who used a weighted blanket, however, unlike these other studies we also measured consumption of anxiolytics and opioids using data from the medical record. In a systematic review, Eron et al. (11), assessed both physiologic and survey data to show a decrease in anxiety with weighted blanket use. Patients given weighted blankets to help

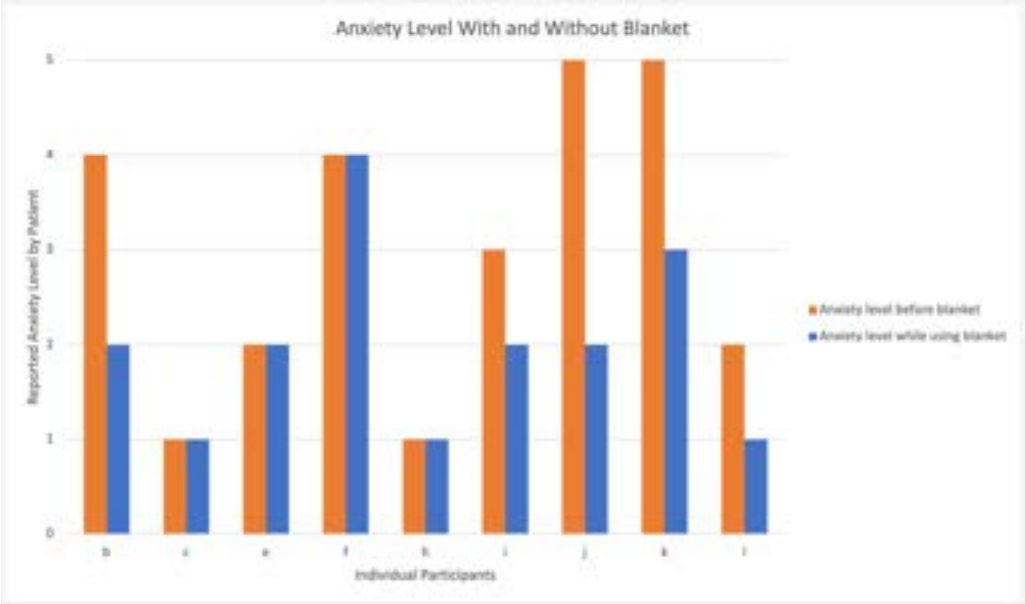

Figure 2. Patients' self-reported level of anxiety with and without the blanket in the intervention group for those who responded to the survey (n = 9).
Letters a through l on the x-axis represent the 12 intervention participants in the study.
*Note: patient a, d, and g did not respond to the post-intervention survey questions.
Survey questions:
How would you rate your level of anxiety before you started using the blanket?
How would you rate your level of anxiety after you started using the blanket?
Responses on the Likert scale included 1 = very anxious, 2 = anxious, 3 = neither anxious or calm, 4 = calm, or 5 = very calm.

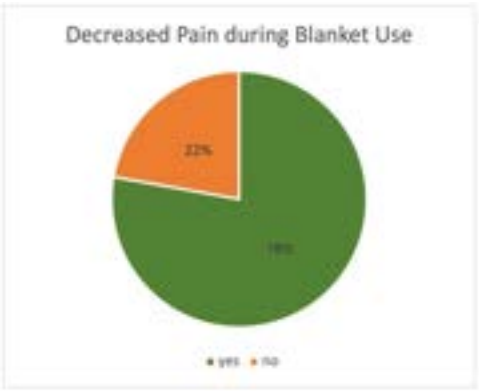

Figure 3. Patients' self-reports of decreased pain during blanket use for those responding to the survey (n = 9).
Survey Question:
When you were using the weighted blanket, did you feel like you were in less overall pain?
1 = yes 2 = no.

reduce anxiety when being committed to a psychiatric facility showed a lowered anxiety level compared to those who did not receive a blanket, based on self-reported data and objective pulse rates (20). While patients did consume similar amounts of anxiolytic medication with and without the blanket, our surveys did show a lowered anxiety level in those utilizing the blanket and our study demonstrated statistically significant objective data for decreased opioid use with the use of weighted blankets.

Postoperative pain is exacerbated by anxiety. Whereas there are numerous factors affecting pain and anxiety, repeated studies demonstrated their intertwined nature in relation to baroreceptors and vagal nerve stimulation (21, 22). Suarez-Roca et al. (9), discussed how baroreceptor activity regulates the physical and psychological response to external and internal stimuli. Acute and chronic pain reveal an increase in baroreceptor activity and meaningful changes in measurable blood pressure variability and heart rate (9). These investigators found vagal stimulation is a commonly researched area for modification of baroreceptor sensitivity (9). This aligns with how deep-pressure therapy in our study demonstrated positive results with a decrease in acute pain.

One of the patients in this study received the blanket at day 46 of hospital stay which was far longer than the median time of 6.5 days for the

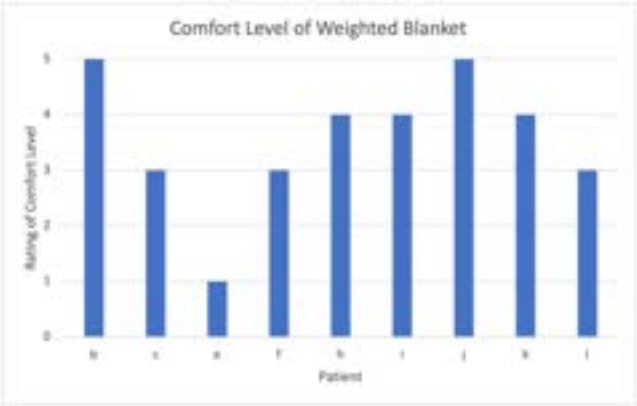

Figure 4. Self-reported level of comfort by patients while using the weighted blanket for those who responded to the survey (n = 9).
Letters a through l on the x-axis represent the 12 intervention participants in the study.
*Note: patient a, d, and g did not respond to the post-intervention survey questions.
Survey Question:
How would you rate your level of comfort when you used the weighted blanket? Rate it on a scale of 1–5.
where: 1 = very uncomfortable, 2 = uncomfortable, 3 = neither uncomfortable nor comfortable, 4 = comfortable, or 5 = very comfortable.

other patients. The reason for this delay was due to prolonged sedation in the ICU due to multiple surgeries and bedside wound care as a sequela of the patient's trauma. The patient was still in significant pain and anxiety when enrolled in the study and had a substantial decrease in MME during the intervention. Therefore, this patient did not appear to confound the results. Moreover, the timeline and hospital experience of this patient highlights a major topic of concern in ICU patients: Whether patients on prolonged mechanical ventilation would also benefit from a weighted blanket as these patients have high levels of pain and anxiety that inhibit the ability to extubate them safely. Further examination of this topic would be useful going forward.

This is the first study to collect EMR data and self-reported clinical outcomes by deep pressure therapy in the form of a weighted blanket in acutely injured trauma patients. Decreasing pain through deep-pressure therapy in acutely injured patients may reduce exposure to opioids thereby decreasing the risk of opioid use disorder while resulting in fewer negative side effects. This demonstrates promising results for weighted blankets being used as an effective adjuvant therapy to help decrease opioid intake amidst the ongoing opioid crisis within the United States.

Of note, there were several limitations to this study. Firstly, this was a small, first-of-its-kind preliminary study. Future studies using larger sample sizes may be able to confirm our results, show more outcomes of interest, and be able to generalize results to other trauma patients. Another limitation of this study was that we implemented a brief unvalidated survey to measure self-reported outcomes; despite the short four-question survey, we were able to obtain data demonstrating benefits from the blanket. However, future studies should ask questions about pain on a Likert scale to elicit more detailed information about the quantity or quality of pain, like those asked regarding anxiety in this study. Further validation of our survey in future larger studies may provide more statistically significant data. A potential confounding factor was differences in patients' hospital course including time of onset of blanket use, physical therapy sessions, bedside wound care, or procedures that may increase pain and anxiety. Additionally, there may be different prescribing patterns by attending surgeons and, although there is a standard pain control order set utilized for pain control in trauma patients, other trauma physicians may still have changed the quantity of pain and anxiety medicines received resulting in different amounts of opioid and anxiolytic usage among patient cohorts. Lastly,

we assumed a given weight of our participants when purchasing the blankets; therefore, patients were given a one-weight-fits-all blanket. For our smaller participants, the 25-pound weight may have been too heavy and decreased the potential benefits of the therapy. This study was unfunded so we could not tailor the weight of the blanket to be 10% of the participant weight as the manufacturer suggested because the price of the blankets would have been prohibitive.

There are several clinical practice messages that were learned during this pilot study to aid in future studies which include tailoring the weight of the blanket to the patient's body size, establishing a quick and easy process for sanitizing blankets, and finding a secure space to house the blankets when they are not in use. Moreover, having buy-in from other members of each patient's care team, such as floor nursing staff, physical therapists, and bedside family members can improve patient compliance thereby improving patient impact.

To summarize, weighted blankets show promising results in post-trauma patients for decreasing pain and opioid use and may help decrease anxiety levels. Future larger studies on post-trauma or post-surgical patients would be beneficial to evaluate weighted blankets' effectiveness in decreasing the use of opioids.

Declaration of interest

The authors report no conflict of interest. The authors alone are responsible for the content and writing of the article.

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#14

Weighted_Blankets_Anxiety reduction in adult patients receiving chemotherapy

Weighted Blankets

Anxiety reduction in adult patients receiving chemotherapy

Jaime Vinson, BSN, RN, HN-BC, RYT®, Jan Powers, PhD, RN, CCNS, CCRN, NE-BC, FCCM, and Kelly Mosesso, MA

BACKGROUND: Weighted blankets have been used as a deep touch pressure (DTP) tool to alleviate anxiety in many patient populations. Patients with cancer can experience anxiety related to diagnosis and treatments, such as chemotherapy infusions. Research on the effectiveness of weighted blankets as a DTP tool to alleviate anxiety in patients receiving chemotherapy is limited.

OBJECTIVES: This study assessed the effectiveness of a medical-grade therapeutic weighted blanket on anxiety in patients receiving their first and second chemotherapy infusions at an outpatient infusion center.

METHODS: A randomized controlled trial with a crossover design was performed with new patients in the outpatient chemotherapy infusion center. Patients were randomized to one of two study arms (given the weighted blanket during their first infusion or given the weighted blanket during their second infusion). Anxiety was measured using an anxiety inventory and a visual analog scale.

FINDINGS: Anxiety was reduced among patients receiving chemotherapy when the weighted blanket was used. Based on the results, a standard-weight, medical-grade therapeutic weighted blanket can be safely used to reduce anxiety in patients of various weights, and a visual analog scale can be a reliable indicator of patients' state anxiety.

KEYWORDS
weighted blanket; deep touch pressure; anxiety; infusion; chemotherapy; cancer

DIGITAL OBJECT IDENTIFIER
10.1188/20.CJON.360-368

PATIENTS WITH CANCER CAN EXPERIENCE HIGH ANXIETY related to their diagnosis and treatment (Grassi et al., 2017; Spiegel & Riba, 2015). Oncology nurses are often at the forefront of implementing complementary interventions for patients' levels of comfort, coping, and overall well-being. Complementary interventions for anxiety, such as massage, music therapy, and progressive muscle relaxation, have been shown to be effective in reducing anxiety among patients (Satija & Bhatnagar, 2017; Sheldon et al., 2014). Implementing similar interventions may also help oncology nurses to care for patients receiving chemotherapy who are experiencing anxiety.

Literature Review

The American Psychological Association (2019) defines anxiety as "an emotion characterized by feelings of tension, worried thoughts, and physical changes" (p. 1). Other symptoms of anxiety can include muscle tension, restlessness, sympathetic hyperactivity, gastrointestinal issues, increased heart rate, sweating, shaking, or fear of losing control. Anxiety is a common response to a cancer diagnosis and can continue throughout treatment, such as during chemotherapy infusions (Bates et al., 2017; Curran et al., 2017; Sheldon et al., 2014). According to Jadoon et al. (2010), adults with cancer have a high prevalence of depression and anxiety (66%) compared to patients with other diagnoses. In addition, anxiety levels are increased in patients receiving chemotherapy treatment compared to patients receiving other forms of cancer treatment (Lim et al., 2011).

Weighted blanket therapy has been identified as a method to decrease anxiety in autistic, psychiatric, dental, and nonmalignant patient populations (Champagne et al., 2015; Chen et al., 2012; Gee et al., 2017; Zimmerman et al., 2019). However, there is a lack of research on the effectiveness of weighted blankets as a method to alleviate anxiety in patients with cancer receiving chemotherapy infusions in an outpatient setting. Implementing a nonpharmacologic therapy option, such as a weighted blanket, can help to reduce anxiety in patients receiving chemotherapy, improve the patient experience during treatment, and decrease the use of medications to manage anxiety.

Deep Touch Pressure

Previous studies in different patient populations have found a reduction in anxiety with the use of weighted blankets (Champagne et al., 2015; Chen et al., 2012; Mullen et al., 2008; Zimmerman et al., 2019). A study by Mullen et al. (2008) discovered that 78% of nonhospitalized participants self-reported being more relaxed when using weighted blankets. This same study also

noted that, when participants were asked, body weight did not correlate with reports of the weighted blanket being too heavy. The authors did not expand on the possible correlation between body weight and anxiety reduction (Mullen et al., 2008).

Research on weighted blankets has typically focused on individuals who have autism spectrum disorder or attention-deficit/hyperactivity disorder (Blairs et al., 2007; Champagne et al., 2015; Losinski et al., 2016, 2017; Mullen et al., 2008; Sylvia et al., 2014; Zimmerman et al., 2019). The mechanism of action for weighted blanket therapy is deep touch pressure (DTP), which is a type of touch pressure that provides a mechanical deformation of the skin, underlying fascia, and periosteum (Mountcastle, 1968). Grandin (1992) described DTP as touch pressure applied to the body that provides some of the same sensations as a firm hug, holding, swaddling, or massage. DTP input can lead to improved arousal modulation consistent with a state of calmness (Chen et al., 2016; Olson & Moulton, 2004). DTP can also stimulate parasympathetic arousal (Chen et al., 2016; Reynolds et al., 2015). Parasympathetic nervous system engagement is inhibitory of stress and anxiety; it slows the heart rate and breathing and encourages digestion (Nazarewicz et al., 2015). In addition, when DTP is self-administered or gradually introduced, it has been shown to produce virtually no adverse effects (Sylvia et al., 2014).

When providing DTP, the following four components are necessary: conformation, consistency, compression, and constant contact with the nerve. This can be achieved through the use of swaddling; long, tight hugs; deep massage; compression sleeves; compression vests; and weighted blankets. This constant, consistent, and conformed compression stimulates proprioception—the subconscious sensation of body and limb movement and position—which is obtained from sensory input from the muscle spindles and joint capsules (Miller et al., 2003).

Weighted Blanket Guidelines

No previous research was found that supported an appropriate weight or pressure recommendation for weighted blanket therapy. However, many manufacturers have published guidelines for weighted blanket use, which recommend that a weighted blanket should be 10% of the individual's body weight and add one or two pounds (Drillinger, 2020; Mosaic Weighted Blankets, 2020; Price, 2019; Sensory Direct, 2020). Some studies have recommended using a weighted blanket weighing more than 10% of the individual's body weight, up to 30 pounds (Champagne et al., 2015; Mullen et al., 2008). Price (2019) suggested that weighted blankets should not be used by individuals who have diabetes, difficulty breathing, poor circulation, blood pressure issues, fragile skin, rash, or open wounds, or by those who are claustrophobic or cleithrophobic. Weighted blankets should not be used by children without adult supervision, used as a restraint, or used in conjunction with other weighted products (Sensory Direct, 2020).

Theoretical Framework

The theoretical framework for this study included sensory integration theory and polyvagal theory. Sensory integration theory is used by occupational therapists to explain why deep pressure causes a calming effect (Champagne et al., 2015; Mullen et al., 2008). Ayres and Robbins (2005) defined sensory integration as the central nervous system's translation of information into action. The theory is based on the belief that behavior is linked to neurologic processes, and brain stem–level sensory processing enables higher neural centers to develop and specialize (Roley et al., 2007).

DTP input influences the parasympathetic nervous system (Chen et al., 2012, 2016; Reynolds et al., 2015). Previous studies have suggested that stimulation of pressure receptors beneath the skin increases vagal tone and decreases cortisol and skin conductance levels (Field et al., 2010; Mullen et al., 2008; Reynolds et al., 2015). Polyvagal theory is a psychophysiologic theory that describes two vagal motor pathways and explains the body's phylogenetic neurophysiologic changes, adaptive reactions, and self-regulation, as well as the stress response in reaction to cues from the environment (Porges, 2014). This theory provides a biologic construct between sensory processing and psychophysiologic responses via the dorsal or ventral vagal motor pathways (Porges, 2014). Individuals may view a weighted blanket as a cue of safety, similar to swaddling in infants. When the body feels safe, the ventral vagus is activated, allowing the individual to access positive emotions (Dana, 2018). Not everyone perceives this subtle confinement as safe or comfortable depending on their individual neuroception molded from their life experiences (Dana, 2018; Porges, 2014).

Methods

Purpose

The purpose of this study was to assess the effects of a weighted blanket as an intervention to reduce anxiety in patients with cancer receiving chemotherapy infusions in the outpatient setting. The secondary aim of the study was to evaluate whether weighted blankets are safe for use and to examine whether anxiety reduction differed between weight classes. The third aim of the study was to determine the reliability of using a visual analog scale for anxiety (VAS-A) to measure state anxiety in this patient population.

Study Design

This randomized controlled trial with a repeated crossover design used a convenience sample to evaluate the effects of weighted blankets as an intervention to reduce anxiety in patients receiving chemotherapy in an outpatient infusion center. Data were collected during patients' first and second infusion visits. Rather than using a between-groups design, a crossover design was used to remove patient variation between the first and second visits.

A repeated crossover design has greater power than a between groups design and can reduce the chance of a type 2 error (Sibbald & Roberts, 1998).

The study took place at a large regional medical center in an outpatient infusion center located in the midwestern United States. The infusion clinic has 48 infusion bays and offers IV chemotherapy, IV hydration, phlebotomy, blood transfusions, and chemotherapy injections. The study was approved by the Parkview Health System Institutional Review Board in Fort Wayne, Indiana.

Sample

The study consisted of a convenience sample of 58 adult patients. Because there are no previous studies on the use of weighted blankets in patients receiving chemotherapy infusions, a power analysis was not completed. The goal was to recruit a small initial sample size to determine effect and feasibility for future studies. Patients were included if they were aged 18 years or older and were receiving their first and second chemotherapy infusions at the outpatient infusion center. Patients having specific cancers, cancer stages, or a mental health diagnosis were eligible but not targeted for this study. Based on the weighted blanket guidelines at the time that this study took place and to err on the side of safety, patients were excluded if they weighed 45 kg or less or were currently enrolled in another research study. Because of the possibility for altered sensory perception, patients who had a diagnosis of peripheral neuropathy or fibromyalgia were also excluded.

Instruments

Anxiety was measured using the State-Trait Anxiety Inventory for Adults Form Y-1 (STAI-AD) and the VAS-A. The STAI-AD is a 10-item self-rated questionnaire, with scores ranging from 1 (not at all) to 4 (very much so), was designed to evaluate the current state of anxiety of an individual in the moment. The STAI-AD was determined to be a valid and reliable measure of an individual's level of anxiety (Bergua et al., 2016; Metzger, 1976).

The VAS-A is a 100 mm horizontal line, with the left end representing no anxiety and the right end representing very anxious. Patients indicate their state anxiety by drawing one vertical slash on the line. The line is later measured in millimeters with a ruler from the left end of the line to the vertical slash mark to find the patient's VAS-A score. The VAS-A was determined to be reliable in measuring state anxiety in perioperative settings (Facco et al., 2013; Hernández-Palazón et al., 2018; Zemła et al., 2019).

Procedure

After obtaining informed consent, patients were randomized using blinded envelopes, which included a unique study identification number and identified which arm the patient was assigned to. Group A was given a weighted blanket to use during the first chemotherapy infusion and standard of care with no weighted blanket during the second infusion, and group B was given standard of care with no weighted blanket during the first chemotherapy infusion and a weighted blanket to use during the second infusion. Data were collected, including demographic information (e.g., gender, age), vital signs, weight, and STAI-AD and VAS-A scores. During the experimental visit (first infusion for group A and second infusion for group B), the weighted blanket was applied by the researcher to the patient from waist to feet, and the patient was instructed to keep the weighted blanket in place for at least 15 minutes. Patients were permitted to adjust the weighted blanket if desired. After the first 15 minutes of mandatory weighted blanket use, patients could don or doff the weighted blanket at their discretion throughout the remainder of the infusion. A digital clock was provided, and patients were instructed to record the times at which they donned or doffed the blanket during their infusion. At 30 minutes (plus or minus 5 minutes) after the weighted blanket was applied, the researcher returned to administer the STAI-AD and obtain the patient's VAS-A score and vital signs. These data were also collected following completion of the infusions at discharge, with the exception of STAI-AD because of the length of the measure. After the mandatory 15 minutes of blanket use and the 30-minute data collection, weighted blanket use and data collection times varied at discharge because of the varying lengths of infusion for each patient.

The standard-weight, medium-sized, medical-grade weighted blanket used in this study was obtained from CapeAble® Weighted Products. The weighted blanket was a one-piece design and measured 34 inches by 62 inches. The outer fabric was a Herculite's Sure-Chek® antimicrobial fabric, and the inner weight bladders were filled with clean recycled glass beads. These bladders were permanently internally fixed into the weighted blanket so that the weight did not shift when manipulated, which is important for providing consistent and accurate DTP. The weighted blankets

"Implementing a nonpharmacologic therapy option, such as a weighted blanket, can improve the patient experience during treatment."

were easily wiped clean after each patient's use with professional Sani-Cloth® AF3 germicidal disposable wipes.

Statistical Analyses

Linear mixed-effects models were paired with random patient-level intercepts to examine the association between weighted blanket use and each anxiety-related clinical outcome variable, accounting for the crossover design of this study and period effects. For each outcome, interactions with period were examined, and those that were statistically significant ($p < 0.05$) were retained in the model. To account for potential confounding, analyses were repeated with adjustment for patient age, weight, and gender. All patients were included in the analyses, even if they did not complete both visits. In a secondary exploratory analysis, the change in VAS-A and STAI-AD scores from admission were compared across weight classes by fitting linear mixed-effects models with random patient-level intercepts and restricting the data to include only observations during which the weighted blanket was used. To assess the correlation between STAI-AD and VAS-A scores, a repeated-measures correlation analysis was performed. All tests were performed using a Cronbach alpha of 0.05, and all analyses were conducted using R, version 3.6.0.

Results

The sample consisted of 58 patients, and most patients were female (n = 38). The mean age of patients was 63.2 years, and the mean weight of patients in the sample was 85.1 kg (median = 63 and 80.7, respectively). For those visits in which it was used, patients applied the weighted blanket for 156.6 minutes (median = 148) on average (see Table 1). Six patients attended only one appointment, and, of those, only four used the weighted blanket during their visit.

Missing observations and mean scores for the anxiety-related outcomes are presented in Table 2. All outcomes were collected at each of the three time points (at admission, after 30 minutes of weighted blanket use, and at discharge), with the exception of STAI-AD scores, which were only measured at admission and after 30 minutes of weighted blanket use.

The results from the unadjusted linear mixed-effects model are summarized in Table 3. Based on the STAI-AD and VAS-A scores, weighted blanket use resulted in a larger reduction in anxiety after 30 minutes compared to no blanket with standard of care. During visits where a weighted blanket was used, patient STAI-AD scores were reduced by an additional 2.15 points on average (95% confidence interval [CI] [4.05, 0.25]) as compared to visits where the weighted blanket was not applied. Similarly, weighted blanket use was associated with an additional reduction in VAS-A scores by a mean of 8.89 points (95% CI [16.59, 1.18]) at 30 minutes. Repeating the analyses while adjusting for patient age, gender, and weight did not substantially alter the results.

Patients were divided into five weight classes (70 kg or less, 70.1–85 kg, 85.1–100 kg, and 100.1–115 kg, and more than 115 kg). Differences in the reduction of STAI-AD and VAS-A scores at 30 minutes by weight class are presented in Table 4. Although patients in the highest weight class had smaller reductions in anxiety scores on the VAS-A on average than patients in the lower four weight classes, none of the differences reported were statistically significant. Because weighted blanket use was only required during the first 15 minutes of chemotherapy infusion, discharge anxiety data were not analyzed.

Additional analysis was completed to assess the validity of the VAS-A as compared to the STAI-AD. The correlation analysis of VAS-A and STAI-AD scores indicated a strong positive correlation between the two anxiety scores ($p = 0.7$, 95% CI [0.6, 0.78]).

Discussion

To the authors' knowledge, this is the first study to explore the use of weighted blankets as an intervention for reducing anxiety in patients receiving chemotherapy in the outpatient setting. A statistically significant reduction in anxiety was found with weighted blanket use compared to standard of care with no weighted blanket. For some patients, chemotherapy infusions can be a time of increased anxiety (Bates et al., 2017; Curran et al., 2017; Lim et al., 2011; Sheldon et al., 2014). Having a therapeutic weighted blanket available for patients undergoing infusion provides nurses with a complementary anxiety reduction strategy that they can implement immediately. In addition,

TABLE 1.
SAMPLE CHARACTERISTICS (N = 58)

CHARACTERISTIC	$\bar{X}$	SD
Age (years)	63.2	10.8
Weight at first visit (kg)	85.1	24.9
Blanket usage (minutes)	156.6	108.9
CHARACTERISTIC		**n**
Gender		
Female		38
Male		20
Weight class (kg)		
70 or less		16
70.1–85		20
85.1–100		11
100.1–115		3
More than 115		8

TABLE 2.
OUTCOME VARIABLE RESULTS WITH AND WITHOUT WEIGHTED BLANKET APPLICATION

	AT ADMISSION				AFTER 30 MINUTES				AT DISCHARGE			
VARIABLE	$\bar{X}$	SD	MEDIAN	MISSING	$\bar{X}$	SD	MEDIAN	MISSING	$\bar{X}$	SD	MEDIAN	MISSING
With weighted blanket (N = 54)												
Temperature (°F)	97.7	0.5	97.8	–	97.9	0.4	97.9	–	97.9	0.5	97.9	1
SBP (mmHg)	136.2	22.4	135	1	126.1	18.9	124.5	–	130.6	20.1	126	1
DBP (mmHg)	73.9	13.7	74	1	69.3	12.5	69.5	–	69.8	12.1	69	1
Heart rate (bpm)	78	14.6	75.5	–	73.6	12.6	72.5	–	79.5	11	78	1
Respirations (breaths per minute)	17.8	1.4	18	1	17.8	0.7	18	2	17.3	1.2	18	2
O_2 saturation (%)	98.2	2	98	–	97.9	2.3	98	–	97.3	2.4	98	1
Anxiety (VAS-A)	29.2	24.9	24	–	26	23.1	19.5	–	15.9	17.6	10.5	–
Anxiety (STAI-AD)	19.3	7	19	–	18.3	6.5	18	–	–	–	–	54
Without weighted blanket (N = 56)												
Temperature (°F)	97.8	0.5	97.8	1	97.9	0.4	97.9	–	98	0.5	98	3
SBP (mmHg)	133.8	22.9	128	–	125.7	20	123	–	130	20	127.5	2
DBP (mmHg)	71.4	13.2	69	–	66.8	12	65	–	69.3	13.4	67	2
Heart rate (bpm)	78.5	16.4	74	–	74.9	13.1	75	–	78.9	10.2	80	2
Respirations (breaths per minute)	18	1.7	18	3	17.3	1.1	18	–	16.9	1.3	16	3
O_2 saturation (%)	98.1	1.9	99	–	98.1	2.1	99	–	98.8	2	98	2
Anxiety (VAS-A)	34	26.5	25	–	21.9	19.2	14	–	15.4	16.9	6.5	–
Anxiety (STAI-AD)	20	6.4	20	–	16.9	5.6	17	1	–	–	–	56

bpm—beats per minute; DBP—diastolic blood pressure; SBP—systolic blood pressure; STAI-AD—State-Trait Anxiety Inventory for Adults Form Y-1; VAS-A—visual analog scale for anxiety
Note. 6 patients only attended 1 visit. Anxiety was measured using the STAI-AD and the VAS-A. Total scores on the STAI-AD range from 10–40, with higher scores indicating greater anxiety. Total scores on the VAS-A range from 0–100, with higher scores indicating greater anxiety.

patients in this study were able to remove the weighted blanket if they did not like the sensation it provided, unlike pharmaceutical anxiety interventions, whose effects can only decrease with time.

Based on the results of this study, weighted blankets are a safe therapy option for adult patients receiving chemotherapy in the outpatient infusion setting who weigh at least 45 kg. The use of weighted blankets was not tested in patients diagnosed with fibromyalgia or peripheral neuropathy. No statistical differences were found among vital signs among patients in the two study arms. No adverse events were reported following the use of weighted blankets in this study, which is consistent with the findings of previous studies that used a weighted blanket weighing up to 30 pounds (Ackerley et al., 2015; Champagne et al., 2015; Chen et al., 2012; Mullen et al., 2008).

Although most weighted blanket manufacturer guidelines suggest that weighted blankets should ideally weigh 10% of the individual's body weight (Drillinger, 2020; Mosaic Weighted Blankets, 2020; Price, 2019; Sensory Direct, 2020), the total weight of a weighted blanket does not indicate the exact amount of pressure that the weighted blanket provides. A more effective method for finding an appropriate weighted blanket would be to use one that provides the desired coverage for the patient (i.e., area of body covered receiving DTP) based on individual diagnosis or needs. Some patients, such as those diagnosed with restless leg syndrome, traumatic brain injuries, chronic pain, or

Parkinson's disease, may require more or less DTP (CapeAble Weighted Products, 2020; Price, 2019). The weighted blanket chosen for this study was the size of a standard throw blanket, which did not cover as much body area on larger-sized patients compared to smaller-sized patients. For larger-sized patients, a larger blanket could have provided more coverage and produced a better DTP response. According to the results of this study, patients of various weights reported reduced anxiety using the weighted blanket, but statistical significance was not demonstrated. This may be because of the limited number of patients in each weight class.

Another aim of this study was to compare the STAI-AD to the VAS-A to ensure reliability of using the VAS-A as a measure of state anxiety in patients in the outpatient infusion setting. In this study, the STAI-AD and VAS-A produced similar results, confirming reliability. During data collection, it was noted that patients seemed to prefer the VAS-A instead of the STAI-AD because of the length of time it took to complete the STAI-AD. This may be because one-item assessment tools are less of a burden to patients than assessment tools consisting of many items (Butts & Rich, 2018). In addition, one-item assessment tools do not pose the burden of calculation to find the assessment score (Butts & Rich, 2018). For anxiety, the STAI-AD is more likely to be skewed by the test-retest effect than the VAS-A. When marking the VAS-A at 30 minutes, it was not likely that patients remembered exactly where they had previously placed a mark. This study established significant correlation between the VAS-A and the STAI-AD, indicating that the VAS-A may be an option for measuring self-reported anxiety in future studies.

IMPLICATIONS FOR PRACTICE

- Offer weighted blanket therapy as an alternative nonpharmacologic strategy for reducing anxiety in patients receiving chemotherapy.
- Standardize the use of a reliable indicator to measure state anxiety among patients receiving chemotherapy in an outpatient setting, such as a visual analog scale.
- Use a standard-weight, medical-grade weighted blanket to effectively reduce anxiety for patients in any weight class who are receiving treatment in the outpatient infusion setting.

Limitations

The primary limitation for this study was its small sample size. Although nurses ensured that weighted blankets were used during the required 15 minutes, patients were not monitored by study investigators continuously during that time. Patients also self-reported blanket use on a time log. Because patients were only required to use the blanket for the first 15 minutes of their visit, variations in treatment and infusion lengths may have affected the results in the discharge data. Patient attrition was also a limitation. Data were collected during both visits; however, data from the first visit were added to the aggregate data for statistical analysis, regardless of which study arm patients were assigned to.

TABLE 3.
UNADJUSTED LINEAR MIXED-EFFECTS MODEL RESULTS (N = 58)

	WITHOUT WEIGHTED BLANKET			WITH WEIGHTED BLANKET			DIFFERENCE		
MEASURE	EST	95% CI	p	EST	95% CI	p	EST	95% CI	p
Change after 30 minutes									
VAS-A (visit 1)	−4.14	[−10.7, 2.41]	0.215	−13.03	[−19.56, −6.5]	< 0.001	−8.89	[−16.59, −1.18]	0.024
VAS-A (visit 2)	−2.19	[−9.05, 4.66]	0.53	−11.08	[−17.77, −4.39]	0.001	−8.89	[−16.59, −1.18]	0.024
VAS-A[a]	−3.24	[−8.78, 2.3]	0.251	−12.09	[−17.51, −6.67]	< 0.001	−8.85	[−16.62, −1.08]	0.026
STAI-AD[a]	−1.04	[−2.39, 0.31]	0.131	−3.18	[−4.51, −1.86]	< 0.001	−2.15	[−4.05, −0.25]	0.027
Change at discharge									
VAS-A (visit 1)	−17.6	[−24.16, −11.04]	< 0.001	−23.09	[−29.62, −16.56]	< 0.001	−5.49	[−13.2, 2.22]	0.162
VAS-A (visit 2)	−8.3	[−15.16, −1.45]	0.018	−13.79	[−20.48, −7.11]	< 0.001	−5.49	[−13.2, 2.22]	0.162
VAS-A[a]	−13.3	[−18.84, −7.75]	< 0.001	−18.61	[−24.02, −13.19]	< 0.001	−5.31	[−13.08, 2.46]	0.179
STAI-AD[a]	–	–	–	–	–	–	–	–	–

[a]Model was not associated with a visit.
CI—confidence interval; est—estimated mean change in score; STAI-AD—State-Trait Anxiety Inventory for Adults Form Y-1; VAS-A—visual analog scale for anxiety
Note. Anxiety was measured using the STAI-AD and the VAS-A. Total scores on the STAI-AD range from 10–40, with higher scores indicating greater anxiety. Total scores on the VAS-A range from 0–100, with higher scores indicating greater anxiety.
Note. Because of the time it took to administer, STAI-AD scores were not collected at discharge.

TABLE 4.
DIFFERENCE IN 30-MINUTE CHANGE SCORES WITH WEIGHTED BLANKET THERAPY BY WEIGHT CLASS (N = 58)

	VAS-A		STAI-AD	
WEIGHT CLASS (kg)	EST	p	EST	p
85.1–100 versus 70 or less	−0.333	0.967	0.9	0.605
85.1–100 versus 70.1–85	−2.516	0.747	0.784	0.638
100.1–115 versus 70 or less	3.267	0.751	2.115	0.373
100.1–115 versus 70.1–85	1.084	0.914	1.999	0.389
100.1–115 versus 85.1–100	3.6	0.742	1.215	0.627
More than 115 versus 70 or less	14.438	0.114	1.943	0.319
More than 115 versus 70.1–85	12.256	0.164	1.827	0.332
More than 115 versus 85.1–100	14.771	0.133	1.043	0.62
More than 115 versus 100.1–115	11.171	0.339	−0.172	0.948

est—estimated mean change in score; STAI-AD—State-Trait Anxiety Inventory for Adults Form Y-1; VAS-A—visual analog scale for anxiety
Note. Anxiety was measured using the STAI-AD and the VAS-A. Total scores on the STAI-AD range from 10–40, with higher scores indicating greater anxiety. Total scores on the VAS-A range from 0–100, with higher scores indicating greater anxiety.

Nurses in the outpatient infusion center do not administer anxiety or pain medications. Therefore, patients may have taken their own medications prior to receiving treatment, which may have affected their levels of anxiety, making the lack of investigation into self-administered medication a limitation.

Future Research

Additional research with a larger sample size is needed to validate the results of the current study. A replication of this study should include a more rigorous time schedule and ensure blanket use fidelity. More research is also needed to determine whether differences in anxiety reduction are based on a patient's weight when using a weighted blanket that delivers the same consistent DTP.

An optimal time frame for weighted blanket use is yet to be determined. Future studies are needed to identify the time needed to elicit the effects of weighted blankets or DTP. Laboratory tests done before, during, and after blanket use that measure oxytocin, melatonin, and cortisol levels could also help determine any lingering effects from weighted blanket therapy. Measurements, such as heart rate variability, can be used to evaluate relaxation response as well (Chen et al., 2012, 2016). Research establishing whether different amounts of pressure are required for individuals with varying diagnoses is also needed to determine better guidelines for varying blanket weights.

Implications for Nursing

Nonpharmacologic interventions are often underused by nurses in treating anxiety. The somatosensory self-stimulation of DTP provided by a weighted blanket can reduce anxiety in patients with cancer receiving treatment in outpatient infusion centers. Weighted blankets may be an alternative strategy for reducing anxiety in patients receiving chemotherapy that can help to decrease the use of pharmacologic medications. A standard-weight, medical-grade weighted blanket can be safely used; no adverse events were reported during this study. If patients do not like using the weighted blanket, they are able to remove it, unlike medications whose effects can only be eliminated from the body over time.

Based on this study's results, the VAS-A is a valid and reliable instrument to measure state anxiety compared to the STAI-AD. Because the VAS-A is an easy instrument to use and takes less time to administer, it may be preferred by patients. By administering one-item instruments as compared to instruments with many items like the STAI-AD, nurses can also decrease the burden on patients.

Conclusion

This study explored the use of weighted blankets for anxiety reduction in patients receiving chemotherapy. Using a standard-weight, medium-sized, medical-grade therapeutic weighted blanket as a complementary modality can reduce anxiety in patients with cancer of various weights in the outpatient infusion setting. No clinically significant changes in vital signs or adverse events were noted, demonstrating that weighted blankets are safe to use in this adult population. A weighted blanket offers nurses the option to provide a nonpharmacologic intervention that can reduce anxiety in patients. Future studies can reliably use the VAS-A to measure state anxiety instead of the STAI-AD for patient convenience.

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#15

Weighted Blankets' Effect on the Health of Older People Living in Nursing Homes

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Weighted Blankets' Effect on the Health of Older People Living in Nursing Homes

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Abstract: Background: An increasingly aging population is a global phenomenon. While considered a positive step forward, vulnerability to age-related health problems increases along with the ageing population. The aim of the study was to investigate weighted blankets' effect on health regarding quality of life (QoL), sleep, nutrition, cognition, activities of daily living ADL and medication in older people living in nursing homes. Methods: In total, 110 older people were involved in an intervention with weighted blankets, and 68 older people completed the intervention. Measures before and after were performed regarding quality of life; QoL-AD, EQ-VAS, sleep; MISS, nutrition; MNA, cognition; S -MMSE (ADL) and medication. Comparative statistical analyses were applied. Results: After intervention with weighted blankets, health in general, such as QoL, improved. Sleep also improved significantly, especially with respect to waking up during the night. Nutrition was enhanced, health as a cognitive ability improved, and medication in the psychoanaleptic group decreased. The effect size varied between small and large. Conclusions: A weighted blanket seems to be an effective and safe intervention for older people in nursing homes, as several improvements were made regarding the health of older people.

Keywords: health; nursing home; older people; weighted blanket

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1. Introduction

An increasingly aging population is a global phenomenon. While considered a positive step forward, vulnerability to age-related health problems increases along with the ageing population [1]. The meaning of healthy ageing is defined by [2] as "the process of developing and maintaining the functional capacity that enables well-being in old age." Optimising "functional ability" is this decade's goal for healthy ageing [2]. Older people's health and quality of life (QoL) are affected by several factors. An overall fragility increases the risk of mortality, reduces the ability to participate in daily activities and provides limitations on sensory functions and physical strength, which heightens the risk of falls [3,4]. In addition, an overall fragility also results in health-related changes that negatively affect mental health, decrease independence, cause difficulty maintaining personal relationships, decrease sense of meaning and context in life, and reduce opportunities for social support [5,6]. Multiple illnesses, often combined with polypharmacy, also affect the health of older people. These different conditions lead to a greater risk of adverse health effects for older people [7].

The experience of QoL is essential for maintaining the health of older people. Depression, loss of function, physical limitations and pain are associated with reduced QoL. When using a QoL measurement for people with dementia, self and proxy reports can complement each other to address all aspects [8–10]. Moving to a nursing home affects older people. They report critical events that negatively affect their health and QoL, for instance, falls, hospital stays, cognitive impairment and loss of loved ones, and this presents a risk of ending up in nursing homes, further reducing QoL [11].

One of the age-related health problems is trouble sleeping [12]. Many of the changes that occur with ageing are related to cognitive functions and abilities where questions have

arisen as to whether they are partly a response to sleep deprivation [13]. Older people's sleep in nursing homes is generally poor [14]. Sleep parameters such as sleep quality, daytime sleepiness and insomnia are associated with cognitive impairment [15]. Short or disturbed sleep and the combination of both also increase the risk of future depressive symptoms and falls in older people [16,17].

Nutritional status is associated with the overall functional ability of older people, and it is a complex aetiology of interacting factors such as sleep problems [12,18]. A good nutritional status is vital to older people's ability to perform (ADL) [18,19]. Malnutrition is a relevant pathological condition and not entirely uncommon in older people, which causes loss of autonomy, lower QoL, higher frequency of hospitalisations and early death. Older people with impaired nutritional status have risk factors for other serious health problems such as multiple physical disabilities, decreased cognition, and impairment compared to healthy older people living in their own homes [19,20]. Older people in hospitals or nursing homes have an increased risk of malnutrition (50.2%) and measured malnutrition (46.4%) compared to more independent older people [5,6]. Malnutrition is a multifactorial condition often caused by comorbidity, which affects activity functions [21]. Malnutrition leads to reduced health, is associated with poor physical function and can cause an increased risk of falls, anemia, impaired immune system and impaired cognitive status, as well as a greater need for health care [18,22].

When the cognitive ability of older people declines, regardless of the cause, health is also negatively affected. Older people with cognitive impairment have a higher risk of various adverse outcomes such as higher mortality, higher incidence of delirium and dehydration, decreased nutritional status, pain, and impaired physical and cognitive function than more independent older people [5,6,23]. The incidence of behavioural and psychological symptoms of cognitive impairment increases when older people are cared for in hospitals or nursing homes, manifested as increased stress or agitated behaviour. They stay up to six times longer in hospital than other older people and have a greater risk of dying in connection with medical care than more healthy, independent older people [23,24]. Alternative health improvements have tried to affect the cognitive ability of older people using non-pharmacological light therapy, which showed significant beneficial effects on the cognitive decline [25,26].

Even normal ageing can mean a reduction in the functional status of older people. The decline can place the older adult in a negative spiral that leads to additional health problems, affecting their ability to perform (ADL). The ability to perform ADL refers to fundamental activities that are focused on taking care of one's own body to enable basic needs for health and well-being, such as the ability to act independently regarding baths, toilets, clothing and food. The older people's health experience is closely related to their ability to perform ADL [27], which plays an essential role in older people's ability to feel autonomy and thus age healthily [28].

As health problems arise among older people, they lead to increased use of medication. With the high use of medication in older people, the risk of side effects and drug interactions also increases compared to older people who do not utilise as much medication [29]. The negative impact of medication on the body with increasing age is related to changes in body composition and organ function. These physiological age changes cause further changes in medication pharmacokinetics and pharmacodynamic characteristics, giving the opposite effect on older people [30]. Fragile older people in nursing homes are particularly vulnerable to polypharmacy, and polypharmacy is more common in older people in nursing homes than in older people who live in their own homes [31,32]. There is thus a need for alternative medical treatments given the prevalence of multimorbidity, which affects the health of older people, especially when considering that multimorbidity can result in polypharmacy among the older population and consequently increased side effects [33].

One of the alternative non-medical treatments available are weighted blankets. The effect of the weighted blanket is based on theories of deep pressure therapy that originated in the theory of sensory integration. Sensory integration describes how sensory stimuli af-

fect how the brain processes sensory information and can reduce anxiety and stress [10,34]. The effect of deep pressure, as with a weighted blanket, is described as calming, providing better sleep, reducing anxiety and generally increasing well-being. However, few studies have been performed on older people among populations with psychiatric and neuropsychiatric diagnoses [35,36]. This requires research on non-pharmacological methods such as weighted blankets to measure the effect on older people in a nursing home in order to gain increased knowledge and understanding of its impact on the health of older people.

Aim

The aim of the study was to investigate weighted blankets' effect on health regarding QoL, sleep, nutrition, cognition, ADL and medication in older people living in nursing homes.

2. Materials and Methods

2.1. Design

A quasi-experimental design was adopted [37].

2.2. Participant/Sample

The study included 110 older people > 65 years old who lived in nine comparable nursing homes in municipalities in southwest Sweden. The average age of the participants was 87 years (range 67–99); the proportion of women was 77%. Purposeful sampling was done with the older people. The inclusion criteria were based on sleep problems from the Swedish version of ICD-10, G47.0, which means difficulty falling asleep, sleeping at night or getting enough sleep [38]. Older people with severe lung or heart disease and/or palliative care were excluded from the study. The older people were identified and recruited by the leader of the nursing home and nursing staff. The leaders of the nursing homes made a preliminary request to older people who met the criteria or proxy (relative) for the older people regarding participation in the study, who passed the information to the researcher. The number of older people who discontinued participation in the study was (n = 42); this was due to death (n = 2), hospital stay (n = 2), or the weighted blanket feeling uncomfortable, which was expressed verbally and/or with facial expressions and gestures (n = 38). There were 68 remaining older people who participated fully. Mean age in the dropout group was 83 years, while the mean age for those who completed the study was 88 years, indicating a significant difference (p = 0.002). The distribution of gender in the dropout group was 57% women. Those who completed the study were 76% women and 24% men (p = 0.005). The number of days with a weighted blanket before the withdrawal was, on average, 1.5 days, with intervals of 0–6 days. Those who dropped out came from comparable nursing homes.

2.3. Intervention

The weighted blanket used in the study was filled with chains and weighed between 4 and 8 kg, about 10% of participant's body weight, as this weight percentage has been shown to have a calming effect [39]. Most of the older people used the 6 kg weighted blanket. The chains in the weighted blankets were sewn in channels, and the fabric was durable and fireproof. Hygiene covers were not used due to the risk of suffocation. The intervention period was conducted over 28 days, which was based on previous studies where the effect of the weighted blanket was shown after 2–4 weeks [40,41]. If the older people were cold, an ordinary blanket was placed over the older people and then the weighted blanket. The weighted blanket was first tested when the older people were in a normal sleeping position, with the soft side against the older person's body, starting at the feet. The nursing staff were urged to stay and follow their reaction to observe whether older people could remove the weighted blanket independently. The chains in the weighted blanket were not designed to prevent the older people from moving. If there were no side effects, the weighted blanket was raised farther up the body. The nursing staff was instructed not to place the weighted

blanket twice over the chest and not to place the blanket too tightly around the older people's bodies. The nursing staff was also encouraged to remove the weighted blanket if the older people showed signs of discomfort.

2.4. Measurement

To estimate the residents' QoL, the Quality of Life-Alzheimer's Disease Measure (QoL-AD) was used (Logsdon et al., 2002). This instrument measures the QoL, including people with Alzheimer's disease, but can also be used by people without Alzheimer's disease. The scale has 13 items covering the domains of physical health, energy, mood, living situation, memory, family, marriage, friends, chores, fun, money, self and life. It is also possible to answer open-ended questions. Each item is scored on a four-point Likert scale, ranging from 1 (poor) to 4 (excellent), with a possible score range from 13 to 52 [42]. QoL-AD has good validity and reliability, with a Cronbach's alpha of 0.80 [43].

In addition to estimating QoL, EQ-VAS was used. EQ-VAS is a part of EQ-5D, a standardised instrument for measuring and describing the health-related quality of life [44]. EQ-5D contains a vertical visual analogue scale (EQ-VAS) where the older people mark on a scale from 0 to 100. EQ-VAS shows the self-rated health state where 0 is the worst possible health and 100 is the best [44]. EQ-VAS shows high correlations with the MOS SF-20 health perceptions scale (r $\frac{1}{4}$ 0.70 and 0.72). The test–retest reliability of the EQ-VAS proved to be very high; the intra-class correlation for the VAS was 0.87 [45].

The Minimal Insomnia Symptom Scale (MISS) was used to examine sleep. MISS is an instrument for insomnia that consists of three items: difficulty falling asleep at night, the ability to fall asleep again and the experience of feeling rested when waking up. This is in line with criteria from the International Classification of Diseases, ICD-10, which describes the cardinal symptoms of insomnia as difficulty falling asleep or maintaining sleep or insomnia [46]. Each item is scored on a 4-point Likert scale, ranging from 1 (poor) to 4 (excellent), with a possible score ranging from 13 to 52. MISS shows good sensitivity and specificity in sleep problems and relates to a diagnosis of poor sleep quality based on ICD-10. An ROC analysis identified the optimal cut-off score as $\geq$7 with a sensitivity of 0.93, specificity of 0.84 and the positive/negative predictive values 0.256/0.995. MISS possessed satisfactory reliability and validity, identified with a Cronbach's alfa of 0.73 [46,47].

Nutritional status was measured with the Mini Nutritional Assessment-Short Form (MNA-SF). MNA-SF is adapted for older people over the age of 65 and is used to screen the risk of malnutrition [48,49]. MNA-SF consists of six parameters concerning reduced food intake during the last 3 months due to impaired appetite, digestive problems, chewing or swallowing problems, weight loss, physical mobility, mental stress or acute illness, neuropsychological problems and BMI. A score of 12 or greater indicates normal nutritional status, whereas a score of 8–11 indicates 'at risk of malnutrition' and a score of 7 or less malnutrition. All parameters scored from 0 to 2 or 3 with a total score of 0–14 [48,49]. MNA-SF is a validated instrument with high sensitivity and specificity [48]. Correlation between MNA-SF and full MNA is high (Pearson's r = 0.969) [50].

A Standardised Mini-Mental State Examination (S-MMSE) instrument consists of 20 questions divided into 11 areas, with a maximum score of 30. The questions cover orientation to time and space, memory, language, and visuospatial functions that relate to visual and spatial interpretive ability, time orientation, and immediate reproduction. A score of >20 indicates an indication of normal cognitive function. Scores of <20 indicate the presence of cognitive impairment [51–53]. S-MMSE is used as a clinical screening test for cognitive impairment, with good reliability [51,54]. The internal consistency obtained by Cronbach's alpha shows 0.826 [55].

Katz ADL index is a standardised measure for evaluating treatment, prognosis and functional changes in older people and people with chronic illnesses in institutionalised settings [56]. The instrument describes dependence on personal activities of daily living (PADL) [57] (pp. 171–178). The Katz ADL index is specially developed to measure activity in older people based on six activities in daily life. Each activity is graded with

dependence, independence, and partial dependence on activities regarding food intake, continents, movement, toilet visits, dressing and undressing, showering and bathing. A dichotomisation of independent or dependent can be carried out by considering shower/bath, dressing/undressing and food intake as independent and activity's toilet visits, movement and continence as dependent. Six points indicate full independence and two points or less dependence [58,59]. Katz ADL index shows a high internal consistency with a Cronbach's alpha of 0.838 [52].

Mapping of the resident's medication use was carried out based on the Anatomical Therapeutic Chemical Classification ATC-Kode. Adopted by the WHO, this allows pharmacology to be divided into different groups according to the indication area. The drug doses collected were based on the name of the generic pharmacy drug power per mg [60].

2.5. Procedure

The data collection took place from 2019 to the summer of 2021 in nursing homes during the daytime. A preliminary request for participation was sent to older people or a proxy together with written information about the aim of the study and the consequences of being included. Nursing home leaders informed the researcher which older people had agreed the researchers could contact them to inform them about the study and acquire their consent to participate. The researcher then sent informed consent forms to the older people or their proxy to acquire a signature. In connection with the start of the study, oral information was given again, and oral consent was obtained. A baseline assessment of the older people was conducted using the instruments. The questions in the instruments were assessed by the older people themselves and the researcher in cases where the older people had the cognitive ability to answer independently. In cases where older people had an S-MMSE rating of four or lower, it was assessed on the basis of what the older people would do according to the nursing staff who knew the older people as well as a representative (a person-proxy perspective), together with the researcher. If older people had S-MMSE between 4 and 10, collection for the instrument was performed with the proxy and the older people. After 28 days, the weighted blanket was removed. The same day the weighted blanket was removed, data were collected with the instrument for a post-measurement to assess the outcome of the weighted blanket.

2.6. Analysis

To determine the sample size required to obtain adequate power, a priori sample size calculation was performed using Power Calculation [61]. In this calculation, the specified alpha was 0.05 and Beta 0.80, resulting in a required sample size of 34 older people. Due to the high risk of dropout within this population, a total of 110 persons were enrolled in the study, and 68 older people completed the study. Descriptive statistics [62] were used to describe the study group. Comparative statistical analyses were used to examine health differences at the individual level and between groups regarding QoL, sleep, nutrition, cognitive ability, ADL ability and medication concerning the intervention with a weighted blanket. The medication use was summarised 28 days before the intervention and 28 days during the intervention on the last day of weighted blanket use. The variables of the QoL scale were divided into four domains: behavioural competence meant physical health; psychological well-being was about mental health; the third domain, perceived QoL, involved evaluating family and friends; and the environmental domain included housing quality and the ability to perform housing duties [63]. Due to the lack of a control group, comparisons were made between measurements before and after the intervention, and the older people were their own control group. To compare the mean value of customarily distributed variables from baseline to post-measurement, a paired-sample student t-test was used, where the sample was normally distributed. For all analyses, a p-value < 0.05 was considered statistically significant [62]. Cohen's d was used as an effect size to indicate the magnitude of the effects for the comparative analyses. To interpret the effect sizes, the suggested cut-offs were small = 0.2, medium = 0.5 and large > 0.8 [62] (pp. 114–116).

3. Results

Baseline measurement on the summary of older people's QoL was 26.4 points, with a possible total range from 13 to 52 [42]. Compared to baseline, QoL as summary improved after using a weighted blanket for 28 days ($p < 0.001$, d = 0.78). The results also showed a statistically significant increase in behavioural competence ($p = 0.003$, d = 0.37) and environmental quality ($p < 0.001$, d = 0.76). In addition, self-rated health-related quality of life increased significantly ($p < 0.001$, d = 0.61); see Table 1.

Table 1. QoL before and after utilisation of weighted blanket for 28 days, $n = 68$.

QOL-AD, Mean (sd)	Before Weighted Blanket	After Weighted Blanket	*p*-Value [1]	Effect Size [2]
Behaviour	8.6 (2.3)	9.5 (1.9)	0.003	0.37
Environment	6.3 (1.4)	7.5 (1.2)	<0.001	0.76
Anticipation	9.1 (10.7)	8.4 (1.9)	0.586	0.35
Psychological	3.9 (0.9)	4.2 (0.9)	0.043	0.25
Sum	26.4 (4.5)	30.1 (3.9)	<0.001	0.78
EQ VAS, Mean (sd)	52.3 (15.4)	59.4 (12.8)	<0.001	0.61

[1] Student's *t*-test; [2] Cohen's.

The limit value for sleep problems in older people is considered to be ≥7 points [48], the baseline measurement for the group of older people was 6.9 points. In summary, sleep quality increased ($p < 0.001$, d = 0.68), waking up ($p < 0.001$, d = 1.10) and sleep latency ($p < 0.001$, d = 0.43) all improved after using a weighted blanket for 28 days compared to baseline. The group at baseline measurement showed 7.1 points, which indicated a risk of malnutrition. The nutritional status improved significantly in summary ($p < 0.001$, d = 0.44). The results also showed a statistically significant increase in food intake ($p < 0.001$, d = 0.42); see Table 2.

Table 2. MNA before and after utilisation of weighted blanket for 28 days, $n = 68$.

	Before Weighted Blanket	After Weighted Blanket	*p*-Value [1]	Effect Size [2]
MISS, Mean (sd)				
Sleep latency	2.2 (1.2)	1.7 (0.9)	<0.001	0.43
Waking up	2.8 (1.0)	1.6 (0.8)	<0.001	1.10
Well rested	1.9 (1.0)	1.9 (0.8)	0.909	0.01
Sum	6.9 (2.8)	5.4 (2.2)	<0.001	0.68
MNA, Mean (sd)				
Reduced food intake	1.5 (0.7)	1.8 (0.5)	<0.001	0.42
Weight loss	1.9 (0.9)	2.0 (1.0)	0.387	0.11
Mobility	0.2 (0.8)	1.1 (0.8)	0.106	0.20
Mental stress	0.3 (0.4)	0.6 (0.5)	<0.001	0.47
Neuropsychological problem	0.6 (0.6)	0.6 (0.6)	0.698	0.05
BMI	1.8 (0.6)	1.9 (0.6)	0.382	0.26
Sum	7.1 (2.0)	8.1 (1.6)	<0.001	0.44

[1] Student's *t*-test; [2] Cohen's d.

Baseline measurement regarding the cognitive ability of the older people was 8.6 points, which indicated severe cognitive impairment, as severe dementia is considered between 0 and 9 points [51]. In the group, 22 (32%) older people had moderate dementia, and 39 (57%) severe dementia. The cognitive ability improved in summary ($p < 0.001$, d = 0.51), and regarding orientation ($p = 0.002$, d = 0.46), it increased significantly after weighted blanket use for 28 days compared to baseline; see Table 3.

Table 3. S-MMSE before and after utilisation of weighted blanket for 28 days, *n* = 68.

	Before Weighted Blanket	After Weighted Blanket	*p*-Value [1]	Effect Size [2]
S-MMSE, Mean (sd)				
Orientation	1.0 (1.5)	1.4 (1.6)	0.001	0.46
Registration	1.6 (1.3)	1.9 (1.2)	0.002	0.38
Attention/calculation	2.3 (2.1)	2.8 (2.0)	0.006	0.34
Recall	0.6 (1.0)	0.9 (1.1)	0.002	0.38
Langue	3.0 (2.3)	3.4 (2.4)	0.146	0.30
Sum	8.6 (7.4)	10 (7.5)	<0.001	0.51

[1] Student's *t*-test; [2] Cohen's d.

Dependency in ADL was most common regarding continence, toileting and transfer, but there were no significant differences between baseline and after weighted blanket. Compared with the baseline, medication use in the psychoanaleptic group decreased significantly ($p = 0.014$, d = 0.29); see Tables 4 and 5.

Table 4. Percentage movement in ADL dependent before and after utilisation of weighted blanket for 28 days, *n* = 68.

	Before Weighted Blanket	After Weighted Blanket	*p*-Value [1]
Dependent, %			
Bathing	47	43	0.375
Dressing	48	44	0.250
Toileting	72	72	1.000
Transfer	60	56	0.453
Continence	75	69	0.219
Eating	12	12	1.000

[1] Wilcoxon signed rank test.

Table 5. Medication, before and after utilisation of weighted blanket for 28 days, *n* = 68.

	Before Weighted Blanket	After Weighted Blanket	*p*-Value [1]	Effect Size [2]
Medication, Mg, Mean (sd)				
Analgetica	31,600 (38,597)	31,268 (37,955)	0.849	0.01
Neuroleptica	967 (4338)	445 (1308)	0.256	0.14
Hypnotics	43 (82)	42 (81)	0.321	0.12
Psykoanaleptica	975 (1275)	938 (1273)	0.014	0.29

[1] Student's *t*-test; [2] Cohen's d.

4. Discussion

The use of weighted blankets provides various improvements in older people's QoL. In this study, the weighted blanket improved the health in QoL regarding behaviour, anticipation, and psychological and mainly environmental aspects. The domain environment includes increased participation in tasks and daily activities at the nursing home, primarily concerning housing activities. Older people who experience a high QoL have shown participation and activity to be crucial in maintaining health [9,10]. There are limited previous studies on the age group of older people who have examined the effect of weight blankets on QoL. The previous studies have mainly studied children with ADHD and/or ASD and participants with psychiatric disorders [61–64]. However, in those groups, the weighted blanket showed an improvement in the activities around the morning and evening routines that facilitated the ability to master everyday life, which led to a higher level of well-being and health [64–66]. The term QoL is comprehensive and describes several parameters in life, where physical ability is included as a prerequisite for a possible high QoL [67]. In

addition, low QoL is associated with a higher mortality rate, even among initially healthy elderly [68]. There is an advantage in improving QoL in older people. The environment around older people can create conditions for better health where changes are made by creating interventions that can provide conditions for a better quality of life [69]. It is possible to predict that interventions with weighted blankets can increase the QoL in many domains for older people living in nursing homes. More studies on this age group are needed to clarify the relationship between the weighted blanket and improved QoL.

Weighted blankets can be a valuable aid in improving sleep. The results of this study showed that the number of awakenings during the night decreased, and less awakening resulted in a more cohesive night's sleep. It also became more manageable for older people to fall asleep in the evening. Previous studies have also described this overall improved effect on sleep using the weighted blanket [40,70,71] Insomnia in older people is associated with cognitive impairment [15]. A weighted blanket can also affect depressive symptoms, which are alleviated in connection with sleep problems and vice versa [17]. The weighted blanket is considered to dampen the nervous system's stress system via its deep pressure, which may be the reason for the calming effect that improves sleep for older people [35,72,73]. However, some studies do not support this finding regarding improved sleep. Regardless, they describe the anti-anxiety effects of weighted blankets [74]. The deep pressure that the weighted blanket causes create effects and anxiety suppression that are considered to predict improved sleep. The heart rate is also lowered, which creates the conditions for improved sleep [75]. The weighted blankets' prerequisites to improve sleep are essential in clinical practice in nursing homes, where sleep problems are common among older people. Despite the high proportion of discontinuations in the study, the beneficial effects of the weighted blanket still outweigh the discomfort that the weighted blanket caused some older people. Those older people who experienced discomfort with the weighted blanket showed it clearly and directly in the intervention, which reduced the risk of someone using the weighted blanket against their will. The weighted blanket seems to be a relatively simple way, with minimal risks, to help older people with sleep problems.

A weighted blanket may decrease the utilisation of inappropriate medication with a high level of side effects for older people. The current study showed that mainly psychohanaleptics decreased with the weighted blanket. The reduction in psychoanaleptics is significant given that psychoanaleptics are not recommended for older people due to an increased risk of serious side effects [76–80]. Alternative interventions that reduce the use of medication in older people are essential, given that the combination of multimorbidity and polypharmacy is common and leads to a greater risk of adverse health effects [7,31]. One study even highlighted the weighted blanket as a possible alternative to medication [75], and it has been shown that nursing staff stated that older people's medication use decreased in connection with using weighted blankets [71]. There is a link between increased health problems in older people and increased medication use. With the high use of medication in older people, side effects and medication interactions also increase [29]. Weighted blankets could contribute to being a non-pharmacologically safe and clinically meaningful alternative for older people in nursing homes. However, more studies in this age group need to be conducted to understand the effect of weighted blankets on older people.

Methodological Considerations

There is a weakness in the internal validity given that the older people who had cognitive decline did not respond independently and had to rely on proxy assessment. However, the strength increased, considering that the proxy knew the older people well. There was also a risk that used instruments were misinterpreted by cognitively healthy older people and proxies. However, the instruments used were validated and previously tested on older people, strengthening the reliability. Conducting studies in which people with cognitive weakness participate is a strength, as many older people in nursing homes have a cognitive weakness. The researcher was involved in filling in the instruments together with older people during the study period despite remaining neutral. In cases

where the questions in the instruments were clarified, the researcher left time for older people to answer the questions without interference or disturbance.

There is a weakness related to how well the nursing staff followed the instructions for using and handling the weighted blanket. Oral and written guidelines were given about how the weighted blanket should be implemented, which was a strength. The researcher also made regular visits to nursing homes to follow up on the implementation of the intervention. In connection with the COVID-19 pandemic, it was impossible to carry out on-site visits to the same extent as before, which was a weakness. However, the researcher conducted a telephone follow-up instead, which added strength.

The study included nine separate nursing homes in different places in southwest Sweden. Nevertheless, a weakness for objectivity is that the study only included 68 older people. The power analysis indicated a sample of 34 older people for significant results, but the larger sample in the study provided more strength in conclusion, which also reinforced the objectivity [37].

The proportion of older people who dropped out of the study may have affected the results. The proportion of men was higher, and the average age was lower in the dropout group than in the participant group. The study was conducted with a comparative analysis, baseline measurement and post-measurement, which was considered useful as older people were their own control group; in that way, differences at the group level were examined [62] (pp. 521–570).

5. Conclusions

A weighted blanket seems to be an effective and safe intervention for older people in nursing homes, as several improvements were made regarding the health of older people, especially regarding the improved quality of life and sleep. The weighted blanket could be a beneficial non-pharmacological intervention for older people, as this study showed a reduction in the utilisation of medication for the group, significantly so for psychoanaleptics. Thus, the study results can, in clinical work, help older people maintain health. Furthermore, the intervention with a weighted blanket is safe to use and influences many parts of older people's lives. Therefore, the weighted blanket can be an intervention to improve the health of older people. This study showed that the use of weighted blankets had an effect on health regarding the quality of life, sleep, nutrition, cognition, ADL and medication in older people in nursing homes. To further clarify the impact of the weighted blanket on health, more and larger studies are needed to clarify the effects of the weighted blanket on older people in a longitudinal view.

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Institutional Review Board Statement: The study was ethically approved by the Swedish Ethical Review Authority, Dnr. 2019-03817.

Informed Consent Statement: The data collection took place from 2019 to the summer of 2021 in nursing homes during daytime. A preliminary request for participation was sent to older people or a proxy together with written information about the aim of the study and the consequences of being included. Nursing home leaders informed the researcher which older people had agreed the researchers could contact them to inform them about the study and acquire their consent to participate. The researcher then sent informed consent forms to the older people or their proxy to acquire a signature. In connection with the start of the study, oral information was given again, and oral consent was obtained. A baseline assessment of the older people was conducted using the instruments. The questions in the instruments were assessed by the older people themselves and

the researcher in cases where the older people had the cognitive ability to answer independently. In cases where older people had an S-MMSE rating of four or lower, it was assessed on the basis of what the older people would do according to the nursing staff who knew the older people as well as a representative (a person-proxy perspective), together with the researcher. If older people had S-MMSE between 4 and 10, collection for the instrument was performed with the proxy and the older people. After 28 days, the weighted blanket was removed. The same day the weighted blanket was removed, data were collected with the instrument for a post-measurement to assess the outcome of the weighted blanket.

Data Availability Statement: Data are available on request due to restrictions, e.g., privacy or ethical. The data presented in this study are available on request from the corresponding author. The data are not publicly available due to sensitive personal data regarding the health of study participants.

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Conflicts of Interest: The authors declare no potential conflict of interest.

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Nursing staff's experiences of how weighted blankets influence resident's in nursing homes expressions of health

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Nursing staff's experiences of how weighted blankets influence resident's in nursing homes expressions of health

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ABSTRACT

Purpose: The most common treatment for resident's health problems is pharmacological. Little research has been done on how an intervention with a non-pharmacological method, such as a weighted blanket, Through the nursing staff view, we can learn how weighted blankets influence resident's health in nursing homes. The aim of this study was to explore nursing staff's experiences of how an intervention with weighted blankets influenced resident's expressions of health.

Methods: The study had a descriptive qualitative design with semi-structured interviews with 20 nursing staff working in nursing homes, and an inductive content analysis was applied.

Results: The nursing staff expressed that the weighted blanket positively influenced resident's health in the areas of sleep, physical activity, and psychological behaviour. The weighted blanket made them fall asleep faster, sleep was uninterrupted andthey felt more rested in the morning. The nursing staff observed an increased level of activity as the resident became more energetic . The nursing staff also experienced reduced negative psychological behaviours like anxiety and worrying.

Conclusion: This study indicated that the weighted blanket changed the health expression of resident in several crucial areas. Deep pressure treatment indicates an alternative health-improved treatment for resident in nursing homes.

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Introduction

Older people's health is influenced by several factors, not just diseases. As the proportion of older people in the world increases, the various health problems are also increasing. Although the increased number of older people is a very positive development, it means challenges. Older people's health problems are both challenging and resource intensive, which leads to pressure on care providers' services for older people (He et al., 2016). In previous studies, older people expressed that health experiences did not automatically have to do with diseases. On the contrary, many older people were aware that a certain degree of morbidity was a natural part of ageing. It was only when the diseases influenced the ability to experience independence that the perceived health of older people declined (Glasberg et al., 2014; Karppinen et al., 2016). Other important factors for the health of older people are to maintain mental and cognitive ability. Older people who have maintained cognitive ability with preserved personality and role function in life experience a higher degree of health (Glasberg et al., 2014; Karppinen et al., 2016). Social relationships and participating in physical and mental activities also positively influence health in older people (Glasberg et al., 2014; Hörder et al., 2013; Malderen et al., 2016; Sini et al., 2015; Sundsli et al., 2013). Supporting older people 's activity, independence, and cognitive capacity can positively influence their health regardless of their underlying physical or mental illness.

Health problems in older people with physical and mental illness can lead to problems such as sleep problems and loss of appetite. In addition, these aggregate dilemmas often strengthen each other negatively, which worsens the health problems (Gulia & Kumar, 2018). It also makes the health problems of older people complex because the circumstances of the health problems influence and reinforce each other. These health problems become apparent when older people move in as residents of nursing homes, leading to increased challenges in maintaining health and independence. (Overbeek et al., 2018). In addition to physical illnesses that many resident experiences in the nursing home, it is also usual to have health problems such as depressive symptoms and anxiety problems. One in three women and almost one in five men in the oldest age group (85 years or older) suffer from anxiety and depressive symptoms (Gonçalves et al., 2011;

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Lennartsson & Heimerson, 2012). Both anxiety and depressive health problems are correlated with sleep disturbances to varying degrees, indicating the complexity of the health of resident as they often have numerous ill-health factors influencing each other (Gulia & Kumar, 2018; Overbeek et al., 2018). Chronic stress has also been identified as an essential factor in many older people's sleep problems. The complexity increases because older people who experience anxiety and stress have an increased risk of experiencing mental illness (Braam et al., 2014; Segel-Karpas et al., 2017). Sleep problems can occur as a result of anxiety, depression, and stress, but sleep problems can also lead to anxiety, depression, and stress. These health problems are also affected by social factors (such as loneliness or hospitalization), which become more common in the older population (MacLeod et al., 2018; Sagayadevan et al., 2017). The opportunity for older people to experience health is a multifaceted experience, and health in older people involves more than just treating diseases. Numerous circumstances reinforce each other, and sleep problems are one of these factors that negatively influence health.

Inadequate sleep affects the health of older people regardless of the underlying circumstances behind the lack of sleep. Insufficient sleep also means a higher risk of falls and other accidents. Poor sleep also intensifies and contributes to the progression of dementia (Brewster et al., 2015; Phelan et al., 2010; Sagayadevan et al., 2017; Shi et al., 2018; Wennberg et al., 2013). The health problems connected with inadequate sleep, whether they are secondary or primary, also influence older people's psychosocial and social capabilities with more limited enthusiasm for social interaction. Sleep problems can also be associated with increased agitation (Ryden et al., 2019; Suzuki et al., 2017; Webster et al., 2020). In nursing homes, it is common for the resident's health problems to be treated pharmacologically. Pharmacological treatment (e.g., hypnotics, sedatives, antidepressants) is today a first-line treatment strategy in nursing homes as a sleep-promoting and anxiety-suppressing treatment, although these drugs are not recommended for resident due to an increased risk of severe side effects (Bloom et al., 2009; Hill et al., 2007; O`Neill et al., 2020; Pitkala et al., 2015; Salzmann-Erikson et al., 2016; Zuidema et al., 2015). These unwelcome side effects of pharmacological treatments may lead to other interventions in the care of resident (Bloom et al., 2009; Hellström et al., 2014).

Alternative non-pharmacological interventions can attenuate expressions associated with unhealthy conditions, which can occur with increasing age. The unhealthy conditions can mean mild or severe cognitive impairment, insomnia and mental illness, most often pharmacologically treated (Voyer et al., 2005). There are side effects of pharmacological treatment that can influence resident's health in many ways. The nursing staff works close to the resident and are important because they experience changes in the resident' s health.

When older people end up in some form of care as residents, they must adapt to a considerable extent to the new situation. They become dependent on nursing staff and therefore lose a large part of their control over their lives. The nursing staff's responsibility becomes essential in everyday life for residents. Much of the daily routines is governed by the nursing staff's routines and their ability to understand the needs and expressions of residents (Jarling et al., 2018). When there is a reduction in resident's self-determined ability, nursing staff need to make sense of everyday life and assess the resident's needs. When residents and the nursing staff understand each other, it is experienced as satisfying. The nursing staff who work narrowly with the residents can also experience the consequences of health-related problems and view variations. Therefore, the experiences of nursing staff are essential in assessing and understanding the influence on health expression that the non-pharmacological implementation as a weighted blanket may have on residents (Ancoli-Israel, 2009; MacLeod et al., 2018; Slettebø et al., 2017; Webster et al., 2020). The non-pharmacological intervention of a weighted blanket creates deep pressure on the body and dampens the sympathetic response associated with, for example, anxiety and sleep problems (Mullen et al., 2008; Reynolds et al., 2015).

Theories behind deep pressure therapy have their origins in the theory of sensory integration, which describes how different sensory stimuli affect how the brain processes sensory information. Deep pressure is a part of the sensory integration theory and leads to reduced anxiety and worry (Kimball et al., 2007; Reynolds et al., 2015). Methods that provide deep pressure, such as weighted blankets, have been reported to have valuable influences by reducing several conditions that unfavourably influence health. The effect of deep pressure is described as calming, providing improved sleep, reducing anxiety, and generally increasing well-being. However, most studies performed with this form of intervention have been performed among populations with psychiatric and neuropsychiatric diagnoses and not among older people (Morrison, 2007; Sylvia et al., 2014). Thus, there is a lack of research on non-pharmacological methods such as a weighted blanket to improve sleep and health in resident living in a nursing home. As the population of older people increase, the incidence of health problems will increase, making assessing and treating this problem essential. Due to systematic use of weighted blankets for resident in nursing homes with sleep problems, we could understand through the nursing staff's experiences the influence that a

weighted blanket has on health expression as an alternative solution to the resident's health problems in nursing homes, especially the high incidence of sleep disorders.

2 Aim

The aim was to explore nursing staff's experiences in how an intervention with weighted blanket influenced resident's in nursing homes expression of health.

3 Methods

3.1 Design

The study had a descriptive qualitative design with semi structured interviews with nursing staff in nursing homes and followed an inductive content analysis (Graneheim & Lundman, 2004).

3.2 Intervention

Written and oral information was given to the nursing staff at the introduction of the weighted blanket. The weighted blanket was first tested when the residents were in a normal sleeping position, with the soft side against the person's body, starting at the feet. The nursing staff were urged not to leave the residents alone but to stay and follow their reaction, to observe that residents could remove the weighted blanket independently. The chains in the weighted blanket were not designed to prevent residents from moving. If there were no side effects, the weighted blanket was raised farther up the body. The nursing staff was instructed not to place the weighted blanket twice over the chest and not to place the blanket too tightly around the resident's bodies. The nursing staff was encouraged to remove the weighted blanket if the residents showed signs of discomfort. If they expressed that the weighted blanket felt too heavy, but they still wanted to try it, the nursing staff was told to contact the researchers to get a weighted blanket of lighter weight. In the absence of effect, the nursing staff was encouraged to contact the researchers to change to a heavier weighted blanket. Information on how the weighted blanket test was to be performed was also provided in writing to all nursing staff. The weighted blanket used in the study was made of chains and weighed about 10% of each participant's body weight A weighted blanket with about 10% of a person's weight has been shown to have a calming effect (Mullen et al., 2008). In this study, the weighted blanket varied between 4 and 8 kg, depending on the weight of the resident. The chains in the weighted blankets were sewn in channels, and the fabric was durable and fireproof. Hygiene covers were not used due to the risk of suffocation. Most of the resident used the 6 kg weighted blanket, and those who slept with the weighted blanket were 65 years or older with sleep problems and were living at a nursing home. Sleep problems for these residents was defined based on Diagnosis of Insomnia (ICD 10- SE) (The National Board of Health and Welfare, 2010). The study period of 28 days was based on previous studies where the influence on sleep by the weighted blanket was shown after 2–4 weeks (Ackerley et al., 2015; Hvolby & Bilenberg, 2011). If the older person was cold with the weighted blanket, an ordinary blanket was also placed over the older person and then the weighted blanket. Resident in palliative care or who had severe muscle loss, severe lung disease, or heart failure were excluded.

3.3 Sample

The study included 23 participants who worked as nursing staff in seven comparable nursing homes in municipalities in the southwest of Sweden. Three of the participants rejected the interview the day before the interview—two stated that their high workload was the reason, and the third stated illness as the reason. Those who dropped out of the study came from different nursing homes. Twenty participants were included in an individual interview, and 90% had an (nursing) education at the secondary school level. The term nursing staff used in this study refers to nursing staff who provide care in nursing homes for resident. They had the main responsibility for the everyday care of the residents in the nursing homes, for example, helping with meals, dressing, washing, and toileting. The participants ranged in age from 25 to 70 years, and professional experience as nursing staff varied between 4 months and 45 years. A purposive sampling was done among participants who had the best knowledge concerning the research topic of how an intervention with a weighted blanket might influence resident's expression of health. The participants were identified and recruited by the manager of each nursing home. The nursing home managers selected the participants who worked night shifts or were contact persons for an older person who had used a weighted blanket for 28 days. A preliminary request for participation was distributed together with written information about the aim of the study and the consequences of being included. Interested participants left their name and email address with the nursing home manager, who in turn provided the information to the researcher. All participants who received information via email from the researcher agreed to participate in the interview.

3.4 Data collection

Data collection with interviews was provided between February 2020 and December 2020. The ten-month time delay occurred due to a ban on visiting nursing homes in connection with Covid-19. The researcher and the participants planned a meeting for an interview during the participants' working hours. Before the interview, the researcher made sure that the participant had received written information about the study and understood what it meant to participate, that the study was voluntary, and that they could drop out at any time without consequences. At the physical meeting prior the interview, a written informed consent was obtained from the participant. An interview guide with semi-structured open-ended questions was used. The main questions in the interviews were: *Can you describe what older person's sleep was like before the introduction of the weight blanket, Tell me if you have experienced any health changes in resident who used weight blankets at your nursing homes*, and *Describe the older person's activity during the day after using the weighted blanket*. Two interviews were conducted as pilot interviews. After the pilot interviews, four more questions were added to the interview guide. The pilot interviews were included in the study. The interviews lasted 25–60 minutes. All interviews were conducted in premises near the workplace and were recorded digitally and then transcribed.

3.5 Data analysis

The interviews were analysed with qualitative content analysis (Graneheim & Lundman, 2004). The transcribed text was read several times, and the transcribed interviews were discussed in the research group. The text was then divided into meaning units and abbreviated into condensed meaning units. The condensed meaning units were abstracted and labelled with a code. The different codes were sorted based on similarities and differences and sorted into subcategories. A process of reflection and discussion resulted in an agreement on how the codes should be sorted. The codes were revised, reviewed, and discussed in the research group and then condensed into categories (Graneheim & Lundman, 2004). Examples of meaning units, condensed meaning units, codes, subcategories, and categories are shown in Table I.

4 Results

Three categories were derived from the nursing staff's interviews regarding their experiences of resident's health expressions after using a weighted blanket. The categories were *Influenced sleep*, which meant that the nursing staff experienced that the resident improved their sleep by falling asleep more quickly and were sleeping more undisturbed at night, *Influenced activity*, which meant that the older person had more energy to participate in physical activities, more energy to have conversations, and more energy to eat independently, and *Influenced psychological behaviour*, which meant that the residents showed calmer expressions and behaviours where they could express their desires in a more nuanced way with less anxious outbursts. The residents who did not like the weighted blanket expressed it clearly and early during the intervention.

5 Influenced sleep

The nursing staff experienced that the weighted blanket influenced the sleep of the residents in many ways. This influenced sleep meant that nursing staff experienced that the residents fell asleep faster in the evening, got an uninterrupted night's sleep, and slept longer in the morning. The residents who were usually awake were already sleeping with the weighted blanket in the evening when the nursing staff began their night shift. The residents who were awake when the nursing staff started to work often fell asleep immediately when they got the weighted blanket. The nursing staff described that they could observe how the resident's body relaxed and sank into a state of calmness with the weighted blankets. The relaxation became most evident in the residents who were mobile in bed before the weighted blanket was introduced. The mobility of the residents in the bed meant that they got up and down from the bed and twisted and turned incessantly without sleeping.

> *We got her ready, put on the weighted blanket, and we could see over her whole body that she had relaxed and was in a cosy atmosphere* (Interview 8).

The nursing staff also experienced that many residents began to express the desire to go to bed and that this desire came in connection with introducing the weighted blanket. The change to more consistently improved sleep also became apparent when the room alarm decreased at night. It was not

Table I. Example of the analysis process.

Meaning units	Condensed meaning units	Codes	Subcategories	Category
She was already asleep when we arrived. However, before that, the alarms came immediately (7)	Asleep when we arrived. Before, the alarm came immediately	Falls asleep early Fewer alarms	Falls asleep faster Undisturbed night's sleep	Sleep quality

uncommon for the residents to use the room alarm long after going to bed at night and then repeatedly at night. In some cases, the residents completely stopped triggering the alarm in the room during the night when using the weighted blanket, and in other cases partially.

> *She rang the alarm pretty much all the time, and we were coming and then she did not know what she wanted once we were there, and she was very confused during these periods before the weighted blanket* (Interview 14).

Before the weighted blanket was introduced, it was common for the residents to wake up several times during the night and express the need to go to the toilet. Several of the nightly toilet visits yielded no results. The nursing staff experienced that it was as if the residents did not know what they wanted when they woke up at night but interpreted it as a need to go to the toilet. When the residents started sleeping with the weighted blanket, the proportion of toilet visits decreased.

> *There is a man here who sleeps much better with his weighted blanket. He thinks it is cosy when you put it on him. He is not up that much anymore. He woke up more in the past, it was like a toilet fixation, really. It is not certain that there is a need for the toilet, and it is more of just "I have woken up, then I have to go to the toilet"* (Interview 19).

The residents who slept with the weighted blanket were not as tired and did not wake up as early as before the weighted blanket was implemented. The nursing staff described that the number of sleeping pills was reduced as the sleep improved. Giving the residents a smaller number of sleeping pills was something that the nursing staff experienced as very positive. The nursing staff experienced that sleeping pills increase the risk of falls and that sleeping pills do not always lead to the residents falling asleep or sleeping all night and could lead to more wakefulness during the night.

> *This, with the sleep of the residents, has gotten so much better with the weighted blanket[…]With medicines there is a risk of falling, and other injuries are possible. I do not know if the medicines do any good. A lot of the medicines have probably been left standing, I think, since a long time ago* (Interview 12).

The nursing staff also experienced that the weighted blanket had been a link to better sleep. Several residents continued to maintain good sleep after the study period with the weighted blanket. When it came to resident with dementia, the nursing staff had different experiences. Some nursing staff claimed that the weighted blanket did not help with sleep problems in the residents with advanced dementia. Other nursing staff experienced that the weighted blanket worked very well and improved resident's sleep even if they had a dementia disease.

> *Of course, they have dementia, but I still think I have imagined that the blanket had a good effect on them* (Interview 12).

The weighted blanket did not work for all residents, and those who did not like the weighted blanket showed it clearly and early in the introduction of the weighted blanket, mainly connected to bedtime. They expressed dissatisfaction by throwing the weighted blanket on the floor or by telling or showing discomfort with a facial expression. Although the resident did not express discomfort from the weighted blanket, the nursing staff described that the same sleep problems could persist despite the weighted blanket. The nursing staff felt that the residents who did not like closeness and hugs had a greater challenge in accepting the weighted blanket. The nursing staff also described how their own behaviour could have an impact on whether the residents liked the weighted blanket or not. If the nursing staff was stressed at bedtime, the residents had a more challenging time accepting the weighted blanket. The nursing staff experienced that a calm approach from the nursing staff at bedtime led to increased peace and higher acceptance by the residents for the weighted blanket. The nursing staff experienced that there may be other reasons for sleep problems that must be understood when the weighted blanket did not improve sleep. The discomfort was mainly seen in the residents who usually did not sleep with a regular blanket. The nursing staff expressed that those who did not usually sleep with a regular blanket mainly expressed their dissatisfaction with the weighed blanket, and this was something that the nursing staff said and to be considered in the implementation.

> *He got agitated immediately when he got the weighted blanket on. It turned out that he did not usually sleep with a regular blanket, so of course he did not want a weighted blanket, and he wondered what we were doing to him* (Interview 3).

5.1 Influenced activity

The nursing staff experienced that the resident's activity was influenced when they started with the weighted blanket, and the change occurred about 3 weeks after implementation. The nursing staff experienced that the residents turned back the clock, which meant that they were more awake during the day and could participate in daily activities. They also became more active in social contexts, showed more independence, and were more active in meal situations.

> *She was tired all the time before, so there we see a difference, she has got a different routine […] More*

order in everything that is good for the body (Interview 5).

The nursing staff described that the morning routine became more manageable after the implementation with the weighted blanket. It was easier to get the residents motivated to start the day, less persuasion was needed, and the residents expressed energy for the activities. The nursing staff experienced that the increased energy level was especially noticeable during the morning when the residents got up, and it became easier to get the residents out of bed. Before the weighted blanket, many residents sat and slept during the day without participating in any activities. The residents who previously only sat and slept during the day partially reduced their sleep daytime when they started using the weighted blanket, while others stopped sleeping entirely during the daytime. The residents who got better naps during the day became more active during the day. This change was related to using a weighted blanket. Before the weighted blanket, the residents lay in bed almost all day, slept in a chair or could sit and snooze all day without any distinction between activity and rest. The experience of the nursing staff was that more balance was created between rest and activity. The changed activity level also led to the residents sitting up longer and being more active in the evening.

She became more involved in activities. Yes, she sat more in the wheelchair before. After about a month or three weeks, we could get her up more and then she could sit and listen to music […] and then we could take away the wheelchair […] then she could just walk, and we just thought, 'Oh my god' (Interview 8).

The nursing staff experienced that many residents who previously did not want to be alone changed after using the weighted blanket, and they performed several activities more independently. Before the weighted blanket, many residents just wanted to sit in their wheelchair during the day with no energy for independent activities. As their energy increased, activities became more independent. Independence was shown by the residents walking and moving around by themselves without any wheelchair or other aids on more occasions than before. The nursing staff also experienced that the residents independently wanted to make their beds themselves. However, they described the weighted blanket as heavy and challenging to handle, something that the nursing staff found frustrating for the residents.

He makes the bed himself, and it may happen that the weighted blanket fell off. It is pretty heavy for him. He tried to fix it himself and so on, but at the same time, he slept much better. So it's a bit like that (laughs) (Interview 1).

Activity also increased in terms of the energy to participate in conversations. The increased energy for participating in conversations was shown by the residents giving increased feedback and by being more active in asking follow-up questions. Previously, they had not shown the same activity in the conversations, and for the most part they just sat quietly without interest in the conversation. The increased communication was directed to the nursing staff and other residents in the nursing homes.

When you talked to her, she answered, and it was in the right context, and maybe even a question came back so you could sit and have a conversation. She managed to have a conversation, quite simply (Interview 2).

The residents who used the weighted blanket also became more socially active with other residents in the nursing homes. The increased social activity made the residents more interested in their surroundings and increased their involvement in more activities. Before implementing the weighted blanket, many residents avoided social contexts and activities. The interest in participating in the social community and physical activities gradually increased during the intervention. The activity around mealtimes changed, where the ability to feed oneself increased. Some residents needed continued support in meal situations, while others could handle their meal situation more independently. The nursing staff also described how many residents before the weighted blanket could not chew their food or use utensils. Previously the residents might fall asleep in the middle of the meal. The meal-time activity changed when the residents could chew their food, use utensils, and drink from a glass. The nursing staff experienced that the proportion of residents who could eat on their own increased as the level of activity increased.

Before we had to feed her in the morning because she was so tired, but now she can eat her sandwich by herself (Interview 2).

5.2 Influenced psychological behaviour

The nursing staff experienced that the consequence of implementing the weighted blanket influenced the resident's ability to formulate their feelings more clearly. As a result of this change with more peaceful emotional and psychological expression, less pharmacological treatment was needed during the day. The more relaxed psychological-emotional expressions that residents showed meant less anxiety and worry and less aggressive behaviour. Behaviours such as anxiety, worry, and aggression were psychological expressions for which the residents previously received pharmacological treatment. In some cases, pharmacological treatment was required, mainly with benzodiazepines, but not to the same extent when the weighted blanket was used. The decreased

pharmacological treatment was applied to both on-demand drugs and standing prescriptions.

> *When she got the weighted blanket, we removed some medicines because she was not as worried anymore, and she began taking fewer on-demand drugs because she was not just as worried anymore, so it was very good. I experienced that her whole demeanour had changed* (Interview 8).

The nursing staff expressed that before the weighted blanket, it was not uncommon for the residents to express disorderly and anxious behaviours, which made it challenging for nursing staff to understand what the residents wanted. This confusing behaviour gradually changed, and the nursing staff experienced an increased understanding between the residents and the nursing staff when the residents manifested calmer psychological behaviour.

> *Before the weighted blanket, they became messy, and they became aggressive as well, so they did not understand things, so it did not connect, it was almost like a psychosis […] now they are very kind and happier as well, so they have completely different personalities (*Interview 9).

The nursing staff experienced changes in the resident's cognitive abilities in connection with the introduction of the weighted blanket, and the residents showed an increased degree of psychological and cognitive understanding of the nursing staff's communication. The nursing staff felt that it was previously a challenge to understand the residents when emotional expressions manifested through different psychological behaviours. The behaviour could be expressed by the residents biting on nearby things such as furniture, making inexplicable picking movements, or screaming. Psychological behaviour of this kind calmed down after the implementation of the weighted blanket. The nursing staff described how they experienced that some of the residents had undergone a personality change since the weighted blanket was used.

> *It was very upsetting behaviour, and before the weighted blanket he wanted to tear things and was very verbally unpleasant. So, it is clear that we are noticing a big personality change with the weighted blanket* (Interview 7).

With the weighted blanket, the resident's psychological expressions became easier to handle, and the emotional expressions became easier to understand, according to the nursing staff. The residents also complained less when they became psychologically calmer, and the previously anxious, stressed, aggressive, irritated, and frustrated emotional expressions were replaced by more psychologically cooperative behaviours and a higher degree of patience.

> *She is no longer as angry and annoyed. She is actually in a better mood. Before the weighted blanket, she complained about everything, and nothing was good, and she felt so bad, and it was such a shame for her. Now there is not as much of it anymore. She is much calmer* (Interview 19).

The nursing staff experienced that the residents had a change in psychological and emotional behaviour by becoming more active in the conversations by showing a higher ability to express different psychological dimensions. The residents showed emotions such as joy through more laughter than before, and they became more aware of their surroundings. The residents gained a greater understanding of the discussions through changed psychological behaviour in social contexts. With the changing psychological behaviour, the residents became more inclined to communicate and became more socially close to others in the nursing homes. The residents consistently showed their emotions through calmer and clearer psychological behaviours as their cognitive ability increased.

> *You can even get such an excellent comment like, "I want to sit with you and eat". It is so good with fellowship thinking when you are alert and happy, and it gives you self-confidence instead of hiding in your room. That is nice* (Interview 5).

The weighted blanket was also used when the residents were sitting in a wheelchair or another chair during the daytime. The weighted blanket could then be placed over the resident's legs and arms. Using the weighted blanket during the day influenced the residents to become less contact-seeking. The contact-seeking behaviour was previously manifested by the residents constantly yelling at the nursing staff without formulating what they needed.

> *We have an old man, he asks for the weighted blanket during the day and then he calms down, he does not scream as much […] I know I asked him about the weighted blanket, and he has experienced it very, very positively in that it hugged him. He says it held him!* (Interview 20).

The nursing staff expressed how the resident's behaviour was influenced by more psychologically positive expressions than negative expressions. The nursing staff also described that the longing for food was expressed more than before the weighted blanket, where the interest in food was previously nonexistent. Even expressions such as that the food tasted better increased when the residents were longing for the food.

> *So before she got the weighted blanket, she could lie down all day and did not want to get up and so on. We wanted to see if a weighted blanket helps, and after three weeks we got her up, and she could be social and laugh and talk and thought the food tasted good, and just, 'Oh this was good, I have never eaten this', we just, how good* (Interview 8).

6 Discussion

The use of weighted blankets provides various improvements in sleep among the residents in nursing homes. The nursing staff experienced that healthy sleep was attained because the weighted blanket helped the residents fall asleep faster and to sleep more undisturbed through the night. Similar influences of the weighted blanket have been reported from previous studies (Ackerley et al., 2015; Bundy & Lane, 2020; Ekholm et al., 2020; Reynolds et al., 2015). Previous studies were not performed on the older population per se, but on more mixed target groups. Adjusting sleep with weighted blankets has been described as a tactile non-pharmacological complement to improve sleep quality (Ackerley et al., 2015). In this study, the nursing staff experienced a reduction in pharmacological treatment and that this reduction was related to implementing the weighted blanket. The weighted blanket as a complementary health-promoting treatment can be considered as an innovation that can improve sleep or supplement the pharmacological practice in nursing homes. In addition to the point that pharmacological treatment increases the risk of side effects in the residents, they also have other interacting health-influencing factors such as multi-morbidity and ageing itself that affect opportunities for good sleep (Gulia & Kumar, 2018). This phenomenon of possible reduced pharmacological treatment in connection with the implementation of weighted blankets is interesting in clinical practice but needs to be studied more. In this study the improvement in sleep occurred relatively quickly. This rapid influence from weighted blankets was also observed in a previous study by measuring the vital parameters related to the use of a weighted blanket. The reaction occurred after only five minutes, with notable changes in decreased blood pressure and heart rate and increased calm (Reynolds et al., 2015). There are advantages to the fact that the weighted blanket's influence shows up quickly during implementation. This facilitates measuring the effect of the weighted blanket because it is possible to experience the result of the intervention quickly. This study is unique because it was performed on the residents in nursing homes. Studies with a weighted blanket are normally conducted on a more mixed target group, usually young people.

The consequences of the weighted blankets are often described as a result of the deep pressure the weighted blanket exerts. This influence with a focus on deep pressure treatment has often been described in young people with different sensory integration dysfunction conditions (SPD). The dysfunction includes disorders with an inability to interpret sensory signals leading to anxiety, motor control problems, behavioural problems, and depression (SPD Foundation, 2016). Attention has been drawn to the point that deep pressure also shows sleep improvements in individuals other than those with SPD (Ackerley et al., 2015) The improvement in sleep in the residents may be illustrated by the influence of deep pressure on the central nervous system (CNS) (Bundy & Lane, 2020; Reynolds et al., 2015). Sensory responses in the nervous system are often interpreted as a reflection of the autonomic nervous system, and when someone acts defensively or stressfully there is an overreaction in the sympathetic component of the autonomic nervous system (Bundy & Lane, 2020). Interestingly, this attenuation in the sympathetic part of the CNS might also can explain why the residents utilized the weighted blanket in the current study even if they did not have known SPD problems. However, more studies are needed to understand the relationship between deep pressure treatment with weighted blankets on fragile residents. To our knowledge, only one study has been performed on the target group of residents, and the weighted blanket was used on older persons with dementia for five months. The results from their study were similar to the results from our study, where the consequences of using the weighted blanket were, among other things, generally improved sleep (Nakamura & Yamauchi, 2021). More clinical trials on the target group of residents in nursing homes and more participants are needed to support these results. Previous studies highlight the prevalence of sleep problems in resident and the importance of maintaining and improving healthy sleep in old age (Brewster et al., 2015: Siddarth et al., 2020). Morrison (2007) highlighted that studies performed with deep pressure treatment using weighted vests on children with inattention and hyperactivity problems exposed methodological weaknesses in ensuring that the treatment with weighted vests worked adequately (Morrison, 2007). Indeed, they used deep pressure treatment with weighted vests, while our study used weighted blankets, which can have different influences on sleep. Regardless of this, our results are compatible with previous research suggesting that sleep is improved using the weighted blanket (Ackerley et al., 2015; Ekholm et al., 2020: Nakamura & Yamauchi, 2021). It is essential to emphasize that the residents in this study who did not like the weighted blanket showed it early in the implementation.

Interventions with weighted blankets may lead to increased activity in the daytime in the residents in nursing homes. The observations of the changed activity level came gradually after the residents slept with the weighted blanket. One explanation for this could be that when the residents get better sleep, their ability and strength to perform activities increase. Previous research has found a link between reduced sleep time and reduced ability to engage in

physical activity. Previous studies show that decreased sleep time with several awakenings during the night is associated with low physical activity during the day (Medic et al., 2017; Song et al., 2015). In our study, the nursing staff experienced that the improved activity level influenced the residents in several activity areas, and this was accompanied by increased independence in everyday activities. Thus, many indications are that the improved level of activity has positive consequences for resident's quality of life and health experience. Improved activity and independence are prerequisites for healthy ageing regardless of illness, as highlighted in previous studies. Higher activity levels give the vitality that increases the opportunity to experience health (Karppinen et al., 2016; Medic et al., 2017; Ryden et al., 2019; Suzuki et al., 2017) Previous studies emphasize that insomnia in older persons can contribute to the lack of energy that prevents coping with daily activities (Ryden et al., 2019; Suzuki et al., 2017). The link between sleep deprivation and reduced activity could be understood as circumstances that negatively influence the health (Medic et al., 2017) The results of previous studies are entirely in line with the experiences that nursing staff presented in our study. The changes in the health of residents give the weighted blanket a vital position for health improvement, which cannot be ignored. Further study is needed to determine whether interventions to improve sleep will delay the decline in functional activity in the residents living in a nursing home.

Weighted blankets have a positive influence on the psychological behaviours of the residents living in a nursing home. Observations from the nursing staff were that the residents showed calmer expressions and behaviours and could express their wishes in a more nuanced way. A generally calmer behaviour with less anxious outbursts could be attributed to the deep pressure effect of the weighted blanket and the known outcomes of deep pressure treatment (Bundy & Lane, 2020). Stimulation of deep pressure induces changes in autonomic arousal and suppresses outward behaviour and expression (Reynolds et al., 2015). The current study showed that resident had a greater ability to understand their surroundings, which indicates that fewer misunderstandings arose between the nursing staff and the residents. This result is meaningful and indicates that improved cognitive ability in the residents can lead them to be more able to make themselves understood. Previous studies showed that maintaining cognitive ability is vital for the health of the residents because they associate high cognitive ability with the experience of feeling healthy (Karppinen et al., 2016; Medic et al., 2017). The current study showed that when the residents have a mentally calmer behaviour, they create conditions to participate in social contexts and express themselves in a more nuanced manner. Essential components for the health of the residents can be the possibility for autonomy and meaning in social contexts. This is highlighted in previous studies where meaningfulness and experiences of autonomy are essential for the experience of healthy ageing (Karpinnen et al., 201 2016). Cognitive impairment and accelerated brain ageing are effects of long-term sleep deprivation (Brewster et al., 2015; Carvalho et al., 2017; Shi et al., 2018) In addition, accelerated brain ageing associated with sleep deprivation can lead to the development of Alzheimer's disease and vascular dementia (Carvalho et al., 2017; Shi et al., 2018). The improvements that occurred in the residents in the present study are easier to understand based on long-term sleep deprivation on cognitive ability. The expressions of psychologically calmer behaviour and increased ability to express their desires in a more nuanced way became easier to follow. The negative psychological behaviours during the day that occur in connection with sleep deprivation are significantly associated with increasing memory problems, a frequent but underestimated symptom (Siddarth et al., 202 2020) It is apparent that adequate and high-quality sleep promotes cognitive psychological health expression and memory problems (Dzierzewski et al., 2018). Moreover, these negative psychological expressions and behaviours can be easy to miss in fragile residents with comorbidities. To our knowledge, this is the first study investigating whether a weighted blanket can influence resident's health expressions in nursing homes. By using nursing staff to describe the influence of the weighted blanket on the resident's health, we had the opportunity to gain access to several different health results. Several of the health expressions can be partly understood based on the theory of deep pressure and sensory integration because the weighted blanket reduces autonomous arousal. This connection is not completely clear in the previous study and needs to be studied further (Bundy & Lane, 2020). Just measuring the nursing staff's observations says nothing about how the residents experienced the weighted blanket. Objectively measuring the sleep influence confirmed the outcome of the result on sleep, although more studies with larger sample sizes are needed in these cases. In summary, our results suggest that the weighted blanket has a good influence on resident's expressions of health in nursing homes.

7 Strengths and limitations

To maintain confirmability, the researchers strived to be neutral and objective throughout the research process (Malterud, 2014). The researchers' pre-understanding could affect the research process at all levels. However, pre-understanding can also be

advantageous in this study by creating the research question, which facilitated the researchers understanding of the nursing homes' problems and conditions. Nevertheless, the pre-understanding has also contributed to and justified the research that was carried out. It was important for the researchers to raise awareness of pre-understanding through discussions between the researchers in all phases of the study. By conducting discussions about pre-understanding, it became easier for researchers to keep the pre-understanding in the background through all the research process steps, which made it easier at all stages of the research to reproduce the participants' words (Malterud,) 2014. When the results were presented, the participants' own words were reflections of what they experienced happened to the residents, not in their own experiences, but their described experiences. Therefore, the study was performed with manifest content analysis with an inductive method. To further confirm the participants' own words, several quotes from the various interviews were presented. In this way, neutrality can be maintained, and the distance between the researchers and those participating in the study were clarified (Elo et al., 2014; Polit & Beck, 2018). The interviews were semi-structured, which meant that the standardized questions allowed follow-up questions, which gave more in-depth answers as the participants had the opportunity to develop their answers. The interview guide was created in advance and tested through two pilot interviews. After the pilot interviews, questions were added to clarify and receive a more accurate description of the investigated phenomenon. When nothing new emerged in the interviews, a few more interviews were conducted to ensure that data saturation had occurred (Elo et al., 2014; Polit & Beck, 2018) It is common for residents of nursing homes to have cognitive disabilities in the form of dementia. Nevertheless, despite the cognitive barriers, residents' health must be preserved (Chua et al., 2016). In this study, the nursing staff as proxy observed health differences even if residents were not able to respond for themselves. In previous studies, the nursing staff has acted as a proxy for the residents. Proxy ratings can provide a unique insight into residents' health and can be a contributing factor in improving the health in cognitively impaired residents (Robertson. et al., 2019)

Credibility was strengthened by conducting the data collection with 20 interviews at seven different nursing homes in the county. The selection was made strategically with the nursing staff who worked close to the residents who used weighted blankets. The interview included six nursing staff who worked at night caring for at least one older person who used the weighted blanket. The 14 nursing staff who worked during the day were asked when they were the contact persons for the residents who used weighted blankets. The advantage of using nursing staff who were contact persons was that they knew the habits and behaviours of the residents well. The nursing staff who worked at night met several residents who used the weighted blanket, which meant that they could see the resident's changes. The prerequisite for the credibility of the study increased because the nursing staff knew the residents well (Malterud, 2011; Polit & Beck, 2018). The nursing staff were of different ages and with varying work experiences. A weakness in the study was that fewer men were included, which might mean that the results might have been different if more men participated. However, the gender distribution reflects what it looks like in nursing homes, making it difficult to influence the study's selection method to obtain an equal gender distribution in the sample. The results were also presented with quotes from many different interviews, which increased the credibility of the results (Polit & Beck, 2018).

When it comes to the transferability of the results, this is contextual. The similarities in the interviews mean that it is possible to transfer the results in similar contexts. However, it is a weakness that it is difficult to know whether the results from this study can be transferred to other contexts outside nursing homes (Polit & Beck, 2018). Throughout the research process, the researchers have compared their thoughts based on individual assessments of everything from raw data in the interviews to the coding process and the creation of categories.

During the compilation of meaning units, condensed meaning units, codes, subcategories, and categories, the researchers regularly analysed the material independently of each other (Graneheim & Lundman, 2004). The results were discussed, and similarities and differences between the researchers were compared. Adjustments to the material were made after several discussions until an agreement was reached between the researchers. Discussions, comparisons of suggestions, and adjustments in the material were made during all the parts of the study. Categories were abstracted in discussions between the researchers until consensus was reached. Throughout the analysis process, the researchers regularly returned to the raw data material to see that they had stayed close to the interviews (Polit & Beck, 2018). This study's presentation of the results increases the authenticity as the study also reports a lack of influence on some of the residents' health concerning the weighted blanket. By reporting the participants' different experiences, the researchers reported a representative and varied picture in order to increase the opportunities to relate to the different perspective's authenticity. Data stability over time involved the authors conducting interviews over a long time and at several different nursing homes, with questions constructed through agreement

among the authors. The interviews took place in an environment under conditions in which the participants felt comfortable in speaking openly about their opinion as confidently as possible (Polit & Beck, 2018).

8 Conclusion

This study indicated that the use of weighted blankets changed the health expression of the residents in several crucial areas. It is challenging to determine which health changes occurred initially, but it can be assumed that they influenced each other. The nursing staff viewed that sleep improved, anxiety was reduced, anxious outbursts decreased, and energy and the ability to participate in activities during the daytime increased among the residents. All in all, the weighted blanket created health-promoting expressions, which could partly be explained by the theory of sensory integration in which deep pressure calms the overactivity of the sympathetic nervous system. Deep pressure treatment with weighted blankets might be an alternative health-promoting treatment for the residents. However, more studies are needed to explore the influence of weighted blankets on the residents in nursing homes.

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9 Disclosure statement

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10 Ethical consideration

The study was approved by the Swedish Ethical Review Authority, Dnr. 2019-03817.

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#17

The use of weighted blankets as a novel approach for treatment of persistent vocalizations in late stage dementia

The use of weighted blankets as a novel approach for treatment of persistent vocalizations in late stage dementia

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Abstract

This study explored the use of weighted blankets as a non-pharmacological treatment for persistent vocalizations in late stage dementia. A weighted blanket was applied to three individuals with a diagnosis of dementia who had frequent and intense persistent vocalizations which were not responsive to other treatment modalities and necessitated in-patient hospitalization within a specialized behavioural unit. The evaluation found a non-statistically significant reduction in the duration of persistent vocalizations during the ten-minute application of the weighted blanket and a statistically significant reduction in the duration of persistent vocalizations during the ten minutes following the application of the weighted blanket. The use of weighted blankets may therefore be a promising non-pharmacological intervention for the treatment of persistent vocalizations in late stage dementia.

Introduction

Persistent vocalizations are a common and disturbing responsive behaviour for people with late stage dementia. According to Sefcik, Ersek, Hartnett, and Cacchione,1 persistent vocalizations are “vocal sounds or inappropriate use of words that are repetitive and persistent and upsetting to persons exhibiting them or to others in the same environment, including other residents, care providers, and family members”. Persistent vocalizations can result in negative consequences for the individual, including increased risk of abuse, social isolation, and neglect1 as well as overmedication.2 Furthermore, exposure to noise levels above 85 decibels over an eight-hour period may cause hearing loss over time.3 Intense and frequent persistent vocalizations may therefore put the person with dementia and others in their environment at risk for hearing loss.

The aetiology of persistent vocalizations is often complex, multifactorial, and may vary greatly between individuals. It is often difficult to understand the meaning behind responsive behaviours in dementia, particularly when individuals are unable to communicate. Cohen-Mansfield's unmet needs model hypothesizes that needs are central to the dynamic behind behavioural expressions in dementia, including persistent vocalizations.4 While the unmet needs model provides a useful way of explaining and analyzing persistent vocalizations, the problem remains that people in late stage dementia and their caregivers are often unable to identify which needs are unmet. Several factors have been identified in the literature as potential causes of persistent vocalizations such as sensory deprivation or unmet emotional needs, such as social isolation.5 Given the unknown and likely heterogeneous cause of persistent vocalizations, it is not surprising that there has also been limited empirical evidence

to support specific non-pharmaceutical interventions to ameliorate persistent vocalizations6 and that pharmaceutical interventions have had limited efficacy.7 Recently, weighted blankets have garnered media attention for use with a number of different populations. Previous studies have indicated weighted blankets are effective in reducing anxiety among adults residing in an inpatient psychiatric setting8 and individuals undergoing dental procedures9 using both objective (electrodermal activity) and subjective (self-reported anxiety) measures. Given the need for interventions to treat persistent vocalizations in dementia care, the potential for weighted blankets to reduce persistent vocalizations in individuals with late stage dementia was explored in this study. It was hypothesized that the application of a weighted blanket would result in fewer vocalizations during the period that the blanket was applied and that the effect would last for at least 10-min after the blanket was removed.

Section snippets

Material and Methods

Sample. The interdisciplinary healthcare team identified eight patients who were within the late stages of dementia (7a through 7d as defined by the FAST scale10) and had persistent vocalizations as the primary responsive behaviour. Two patients were excluded due to the presence of antibiotic resistant organisms, one patient died, and two had potential medical contraindications, leaving three patients in the study. The three patients selected were female with a mean age of 79 who were unable to

Results

We employed generalized estimating equations (GEE) for the inferential statistical analysis to account for the correlated data structure. We used the identity link function with a normal distribution for the response variable to assess effects across the three time points (baseline, blanket-on, post-blanket). We considered a number of structures for the working correlation matrix, including exchangeable, independent, auto-regressive, and unstructured.11 The working correlation structure

Discussion

The results of this evaluation suggest that weighted blankets are a promising non-pharmacological treatment for adults in late stage dementia who exhibit frequent and intense persistent vocalizations that are not responsive to other treatment modalities. While not statistically significant, the duration of persistent vocalizations was reduced when the weighted blanket was applied. The statistically significant reduction in persistent vocalizations occurred within the “post-blanket” period,

Conclusions

The results of this small scale evaluation indicate that weighted blankets may be a promising non-pharmacological treatment for persistent vocalizations in late stage dementia. The mechanism by which weighted blankets appear to ameliorate persistent vocalizations in the late stages of dementia remains unknown; however, insights can be drawn from theoretical

approaches to understanding persistent vocalizations including the unmet needs model and sensory integration theory. These theories not

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

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