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A randomized crossover trial with weighted blankets shows improvement in behavior and sleep outcomes in adults with Prader–Willi syndrome

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Abstract

Prader–Willi syndrome (PWS) is a rare neurodevelopmental disorder characterized by hypotonia, hyperphagia, challenging behaviors, sleep abnormalities, and altered body composition. Non-pharmacological interventions targeting sensory modulation may represent a safe therapeutic strategy. Deep proprioceptive stimulation (DPS), delivered via weighted blankets, has shown anxiolytic and sleep-modulating effects in other neurogenetic and psychiatric populations; however, its efficacy has not been systematically evaluated in PWS. To evaluate the effects of DPS using weighted blankets on sleep, behavior, hyperphagia, and body composition in adults with PWS. In this randomized, crossover trial, 40 adults with genetically confirmed PWS underwent two 14-day intervention periods using either a weighted proprioceptive blanket or a visually identical placebo blanket, separated by a 4-week washout period. Behavioral outcomes (including anxiety, skin-picking, and hyperphagia scales), actigraphy-derived sleep and activity metrics, and body composition measured via bioelectrical impedance analysis were assessed. Use of the weighted blanket was associated with significant improvements in anxiety, hyperphagia and self-injurious skin-picking behaviors ($p<0.05$). Objective sleep efficiency improved, accompanied by reductions in nocturnal awakenings and daytime somnolence. Actigraphy showed reduced percentage of sedentary time and increased percentage of moderate physical activity, with concomitant increases in fat-free and skeletal muscle mass following weighted blanket use. No adverse events were reported. DPS via weighted blankets is a safe, well-tolerated, and effective non-pharmacological intervention for behavioral regulation, sleep efficiency, and body composition in adults with PWS. These findings support the integration of DPS as a complementary therapeutic tool in the multidisciplinary management of PWS.

Keywords Prader–Willi syndrome · Deep proprioceptive stimulation · Weighted blanket · Hypotonia · Hyperphagia · Sleep disorders · Challenge behavior

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Introduction

Prader–Willi syndrome (PWS) is a rare, complex neurodevelopmental disorder caused by the loss of expression of paternally inherited genes in the chromosome 15q11–q13 region. The underlying genetic mechanisms include paternal deletions (~ 70%), maternal uniparental disomy (~ 25–30%), and imprinting center defects (rare)[1,2].

Clinically, PWS follows a characteristic developmental trajectory. The neonatal and early infancy stages are dominated by severe hypotonia, poor sucking, feeding difficulties, delayed motor development and growth retardation. During early childhood, hyperphagia emerges—typically between 2 and 4 years of age—leading to rapid weight gain and severe obesity if not strictly controlled. Adolescence and adulthood are marked by persistent hyperphagia, endocrine abnormalities (such as hypogonadism), mild to moderate intellectual disability, and prominent behavioral disturbances such as rigidity, emotional lability, compulsivity, and self-injurious behaviors, particularly skin picking[3–5].

Body composition in PWS is distinct from that observed in individuals with primary obesity. Patients exhibit a disproportionately high fat mass and markedly reduced lean and skeletal muscle mass, even when matched for age, sex, and body mass index. This unfavorable composition contributes to reduced basal energy expenditure, physical inactivity, and further metabolic vulnerability[6]. While growth hormone (GH) treatment improves body composition, function and cognition[7,8], additional non-pharmacological strategies are warranted to address persistent metabolic challenges.

Sleep disturbances are highly prevalent in PWS and include excessive daytime sleepiness, obstructive and central sleep apnea, altered sleep architecture, and circadian rhythm dysregulation. These disturbances further exacerbate behavioral dysregulation, cognitive impairment, and caregiver burden[9,10].

Deep proprioceptive stimulation (DPS) is a sensory-based intervention that delivers sustained deep pressure input, modulating autonomic nervous system activity and arousal levels. Weighted blankets are a commonly used DPS modality, grounded in Ayres' sensory integration theory and supported by early experimental work by Grandin in autism spectrum conditions. DPS is hypothesized to enhance parasympathetic activity, regulate serotonergic neurotransmission, and exert anxiolytic effects analogous to pharmacological agents, but without systemic adverse effects[11,12].

Although DPS has demonstrated benefits for sleep and anxiety in other psychiatric and neurodevelopmental populations, no studies to date have systematically examined its effects in individuals with PWS.

We hypothesized that DPS delivered through weighted blankets would improve sleep quality, reduce anxiety and maladaptive behaviors, attenuate hyperphagia and self-injurious behaviors, and positively influence physical activity and body composition in adults with PWS[13].

Methods

Participants

A total of forty adults with genetically confirmed PWS were recruited from the Department of Endocrinology and Nutrition of Hospital Universitari Parc Taulí (Sabadell, Spain), a national reference center for PWS. All descriptive data of the cohort can be seen in Table 1.

Inclusion criteria

- Molecularly confirmed diagnosis of PWS (deletion, UPD, or ID).
- Adults aged ≥ 18 years.

Table 1 Participants' characteristics.

Age; mean ± SD [min-max] (years)	28.80 ± 10.06 [18–53]
Sex; male/female (n)	11/29
Body Mass Index; mean ± SD [min-max] (kg/m^2)	36.28 ± 10.56 [19.33–59.30]
Genetic subtype; n (%)	
Deletion	26 (65%)
Maternal Uniparental Disomy (UPD)	9 (22.5%)
Imprinting Defect (ID)	3 (7.5%)
UPD or ID	2 (5%)
Comorbidities; n (%)	
Hypogonadism	40 (100%)
Hypothyroidism	4 (10%)
Type 2 Diabetes Mellitus	10 (25%)
Arterial Hypertension	3 (7.5%)
Dyslipidemia	8 (20%)
Obstructive Sleep Apnea	30 (75%)
Concomitant Medications; n (%)	
GH Replacement Therapy	24 (60%)
Sex Hormone Replacement Therapy	27 (67.5%)
Thyroxine	3 (7.5%)
Anti-Diabetics	10 (25%)
Antidepressives	2 (5%)
Antipsychotics	18 (45%)
Mood Stabilizers	15 (37.5%)
Psychostimulants	1 (2.5%)
Benzodiazepines	6 (15%)
Impulse Modulators	16 (40%)
Living characteristics; n (%)	
At home, with family	30 (75%)
At residencies (or similar facilities)	10 (25%)

- Obtainment of written informed consent from legal guardians and, where applicable, assent from the participants.
- Stable pharmacological treatment (including GH replacement therapy) for at least 3 months prior to enrollment.

Exclusion criteria

- Severe untreated or uncontrolled obstructive sleep apnea defined as a residual apnea hypoapnea index (AHI) ≥ 30 despite use of continuous positive airway pressure (CPAP) device.
- Narcolepsy or other non-respiratory sleep disorders associated with daytime sleepiness.
- Inability to tolerate weighted blankets after a structured desensitization protocol.
- Active psychiatric disorder (e.g., acute psychosis) that could interfere with the reliability of sleep and behavioral outcomes.
- Initiation of or significant changes in hypnotic or sleep-modulating medications during the study period.

No participants withdrew or were excluded after randomization. Compliance, registered in a sleep diary, for the weighted blanket (WB) and placebo blanket (PB) was 13.175 ± 2.49 days and 14 ± 0 days, respectively. Compliance for the actigraph was 14 ± 0 days.

As this was a single-site trial conducted entirely at Hospital Universitari Parc Taulí, no additional eligibility criteria were applied to sites or to the personnel delivering the intervention.

Study design

This was a randomized, longitudinal crossover clinical trial with repeated measures. Participants were randomized in a 1:1 ratio to one of two sequences: weighted blanket followed by placebo (sequence 1, WB/PB) or placebo followed by weighted blanket (sequence 2, PB/WB). Each sequence consisted of two 14-day intervention periods separated by a 4-week washout period to minimize carryover effects (Fig. 1).

All participants completed the following assessments:

- Screening and training visit (V-1) to ensure protocol familiarity and tolerance.
- Baseline assessments at the start of each phase (V0 and V3).
- End-of-intervention visits after each treatment period (V2 and V5).
- Interim safety telephone follow-ups (V1 and V4) to monitor adherence and potential adverse events. Adverse events were defined as any untoward physical or behavioural change temporally associated with blanket use (e.g., skin irritation, respiratory discomfort, worsening of sleep or behavioural symptoms) and were ascertained non-systematically through caregiver report during interim telephone follow-ups (V1, V4) and at each in-person visit.

No changes were made to the trial protocol, eligibility criteria, interventions, or prespecified outcomes after the trial commenced.

Ethical considerations and trial registration

The study protocol was approved by the local Institutional Review Board (Comitè d'Ètica d'Investigació amb Medicaments, CEIM) of Hospital Universitari Parc Taulí (ref. 2021/3016). The trial was prospectively registered at ClinicalTrials.gov (TRN: NCT05044000, Registration date: 14 September 2021). The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (ICH-GCP) guidelines. The full trial protocol and statistical analysis plan are available from the corresponding authors upon reasonable request.

Written informed consent was obtained from all legal guardians. Additionally, all participants provided written or verbal assent after being informed alongside their parents or caregivers, with the study procedures adapted to their cognitive level to ensure voluntary participation.

Recruitment took place between 10 February 2022 and 14 October 2024; the last participant completed follow-up on 10 December 2024.

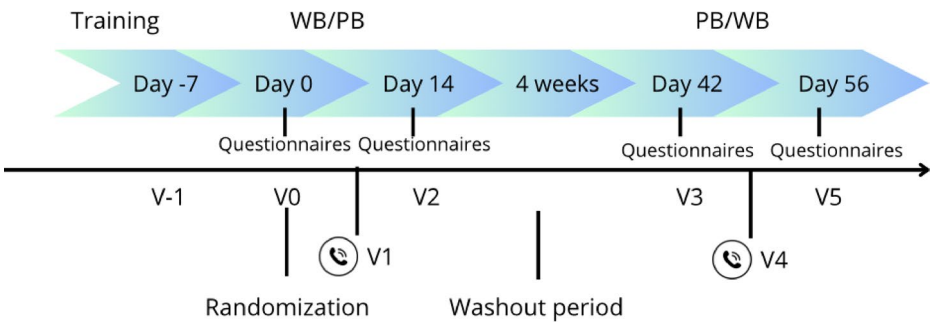


Fig. 1 Study design and timeline. Schematic representation of the randomized crossover study design. Participants were allocated to one of two sequences: weighted blanket (WB) followed by placebo blanket (PB) or PB followed by WB, with a 4-week washout period between intervention phases. Assessment visits included screening (V−1), baseline (V0, V3), post-intervention (V2, V5), and interim safety evaluations (V1, V4).

Intervention

Weighted blankets (Protac Ball Blanket®; Protac, Denmark) weighing either 7–10 kg were selected to approximate 10% of the participant's body weight. The placebo consisted of a visually identical duvet weighing approximately 1 kg. To maintain visual similarity between conditions, both the active and placebo blankets were fitted with identical covers, maintaining a consistent external appearance throughout the trial.

The study followed a randomized crossover design where all participants received both the WB intervention and the PB condition or vice versa. The randomisation sequence was generated by a statistician independent of outcome assessment using R software and was stratified by body weight (≤70 kg and >70 kg) using permuted block randomization to ensure balance between sequences within each stratum. Allocation concealment was achieved using sequentially numbered, opaque, sealed envelopes prepared in advance by personnel independent of recruitment and enrolment. Participants were enrolled and assessed for eligibility by the clinical study team at Hospital Universitari Parc Taulí. Sequence assignment was performed by an independent statician, who released allocation only after enrolment, ensuring that clinical staff had no access to the sequence in advance.

During the WB condition, the blanket weight was adjusted according to participants' body weight: participants weighing≤70 kg received a 7-kg blanket, and those weighing>70 kg received a 10-kg blanket. Conversely, the PB condition consisted of an approximately 1-kg blanket for all participants. A 4-week washout period was included between intervention periods to minimize potential carryover effects. Both interventions were used during full sleep time.

One week prior to the start of the intervention, participants completed a graded tolerance protocol (1–2 nights) to familiarize them with the WB proprioceptive materials and ensure sensory comfort. This protocol consisted in gradually increasing the area of the body covered by the WB, according to the participant tolerance, until achieving full sleep time tolerance of WB covering from feet to shoulders.

Outcome measures

Primary outcome: behavioral and psychological assessment

To evaluate the multi-faceted behavioral phenotype of PWS, primary outcomes were assessed using validated scales. Hyperphagia-related behaviors were quantified using the Hyperphagia Questionnaire for Clinical Trials (HQ-CT)[14,15]. The frequency and severity of skin-picking and other self-injurious behaviors were measured via the Scale for the Assessment of Self-Injurious Behaviors (SRCA)[16]. Broader behavioral disturbances were captured through the Aberrant Behavior Checklist – Community (ABC-C)[17], while anxiety symptomatology was screened using the Beck Anxiety Inventory (BAI)[18]. All psychological instruments were administered by a psychiatrist and a psychologist to the participants' primary caregivers to ensure data reliability and minimize reporting bias. Both professionals were PWS experts and blinded with regard to the intervention sequence.

Primary outcome: sleep and circadian metrics

Subjective sleep assessments were conducted using a comprehensive battery of questionnaires: the Pittsburgh Sleep Quality Index (PSQI)[19], the Epworth Sleepiness Scale (ESS)[20], adapted for populations with intellectual disabilities, the Composite Sleep Score (CSS)[21], and the Insomnia Severity Index (ISI)[22].

Objective sleep architecture and activity patterns were monitored via wrist-worn actigraphy (wGT3X-BT; ActiGraph LLC, Pensacola, FL, USA). Participants were instructed to wear the device on their non-dominant wrist continuously for each 14-day intervention period. Key metrics extracted from the actigraphic data included total sleep time (TST), sleep onset latency (SOL), sleep efficiency (SE), and frequency of nocturnal awakenings. Prior to the intervention, a single-night home polysomnography (WatchPAT® 300; Itamar Medical, Caesarea, Israel) was performed to establish a respiratory baseline and screen for sleep-disordered breathing.

Secondary outcome: physical activity

Physical activity was also measured via wrist-worn actigraphy (wGT3X-BT; ActiGraph LLC, Pensacola, FL, USA), following the same wear protocol as for sleep assessment. Measurements obtained included total metabolic rate, total sedentary time, and total moderate activity time.

Secondary outcome: anthropometry and body composition

Changes in physical parameters were assessed using multi-frequency bioelectrical impedance analysis (BIA) with the Inbody 770 S system (Microcaya, Bilbao, Spain). To maintain high measurement precision, assessments were performed under standardized conditions (fasting, empty bladder, and consistent time of day). The variables of interest included total body weight, Body Mass Index (BMI), fat mass (FM), fat-free mass (FFM), and skeletal muscle mass (SMM).

Statistical analysis

No formal a priori sample size calculation was performed. The sample of 40 participants corresponds to the full cohort of adults with genetically confirmed PWS followed at this national reference centre who met eligibility criteria during the recruitment period, an approach commonly adopted in rare-disease trials where the target population is inherently limited. No formal interim efficacy analyses or statistical stopping guidelines were prespecified. Safety was monitored on an ongoing basis through interim telephone follow-ups (V1, V4), with no prespecified stopping rule linked to these checks.

Data were analyzed using SAS v9.4. The normality of the distribution for all variables was assessed using the Shapiro-Wilk test. Continuous variables are presented as mean ± standard deviation (SD) or as median and interquartile range (IQR), as appropriate.

For behavioral variables, subjective sleep questionnaires, and body composition variables, all measured only before and after each intervention, treatment response was defined as change from the corresponding baseline, calculated as post-intervention minus pre-intervention. Changes were first assessed within each intervention condition, and differences between WB and PB effects were then tested by comparing paired intervention change scores. For actigraphy data, full intervention period means were compared directly between WB and PB treatment conditions.

Parametric paired-samples t-tests or Wilcoxon signed-rank tests were used, as appropriate, depending on the distribution of the corresponding change scores or paired differences. To test period, sequence and carryover effects, repeated-measures models were used with intervention as the within-subject factor and order (WB first or PB first) as the between-subject factor. Baseline values were additionally compared between periods within each allocation group and between allocation groups, using paired and two-sample t-tests, respectively. Intervention effects were also compared between sequences within the first period alone.

As an exploratory analysis, participants were classified according to the presence or absence of an anxiety disorder diagnosis, and the difference between WB and PB effects on the BAI scores was compared between subgroups. Participants were also classified according to genetic subtype (deletion versus non-deletion), and the treatment effect was compared between subtypes for all outcomes.

Analyses were performed using available paired data for each comparison. Statistical significance was set at a two-tailed $p < 0.05$. P values for all the between-condition contrasts were adjusted for multiple comparisons with the Benjamini-Hochberg false discovery rate procedure (FDR < 0.05).

Patient and public involvement

Patients and caregivers were not involved in the design, conduct, or reporting of this trial. However, two patient advocacy organisations (Associació Catalana de Síndrome de Prader-Willi and Associació Valenciana de Síndrome de Prader-Willi) contributed to participant recruitment support and dissemination of results to the PWS community."

Results

Behavioral outcomes

WB use resulted in a significant reduction in anxiety scores (BAI), whereas no significant changes were observed during the PB phase. When participants were classified according to the presence ($n=21$) or absence ($n=19$) of an anxiety disorder diagnosis, this reduction was significant only in the former; however, the effect of the intervention did not differ significantly between subgroups (Supplementary Table S1). Hyperphagia scores (HQ-CT) decreased significantly following WB use and differed significantly between interventions. Self-injurious skin-picking behaviors (SRCA) improved significantly in terms of frequency and intensity, predominantly during the WB phase (Table 2).

Significant improvements were also observed in multiple ABC-C domains, including agitation, lethargy, stereotypies, hyperactivity, and inappropriate speech; during WB use. In contrast, PB exposure did not yield comparable improvements and was associated with a slight increase in hyperactivity (Table 2).

Sleep outcomes

Subjective sleep quality scores did not significantly change across interventions, except for daytime sleepiness that decreased significantly following WB use, with no change during PB exposure (Table 3).

Objective sleep outcomes also improved, with higher sleep efficiency, reduced wake after sleep onset, and fewer nocturnal awakenings during the WB condition compared to PB (Table 4).

Physical activity and body composition

WB use was associated with significant improvements in physical activity distribution and body composition. Total metabolic equivalent rate was higher during the WB condition compared to PB. While absolute sedentary time did not differ significantly between conditions, sedentary time expressed as a percentage was significantly lower during the WB intervention prior to correction for multiple comparisons ($p=0.033$), although this did not survive correction ($p=0.058$). Similarly, moderate activity did not show significant differences in absolute minutes but was significantly higher during WB intervention when expressed as a percentage (Table 4).

Physical activity changes reported by actigraphy were accompanied by significant increases in fat-free mass and skeletal muscle mass, without significant changes in body weight, BMI, waist perimeter or fat mass percentage (Table 5).

PWS genetic subtype comparisons

Across the behavioral, sleep, physical activity, and body composition outcomes, exploratory analyses by genetic subtype (deletion, $n=26$; non-deletion, $n=14$) showed no significant between-group difference in the treatment effect; where the effect was significant, it was in the same direction in both subtypes (Supplementary Tables S2-S5).

Table 2 Behavioral and psychiatric outcomes. Changes in anxiety, hyperphagia, self-injurious behaviors, and ABC-C domains following weighted blanket (WB) and placebo (PB) interventions. Data are presented as mean ± SD or median (IQR), as appropriate. Within- and between-intervention comparisons are reported, with parametric or non-parametric tests selected according to the distribution of change scores. Adjusted p values are corrected for multiple comparisons (Benjamini-Hochberg, FDR 5%) across all between-condition contrasts of Tables 2–5.

	Intervention	Time	Mean ± SD or Median (IQR)	p (within)	p (Δ WB vs. Δ PB)	Adjusted p (Δ WB vs. Δ PB)
BAI	WB	Pre	6.00 (3.00–11.00)	0.006	0.218	0.265
		Post	3.00 (1.00–5.00)			
	PB	Pre	4.00 (3.00–8.00)	0.288		
		Post	4.00 (2.00–6.00)			
HQ-CT	WB	Pre	12.68 ± 8.13	< 0.0001	0.006	0.017
		Post	8.09 ± 6.10			
	PB	Pre	12.08 ± 9.75	0.749		
		Post	11.29 ± 9.33			
SRCA Affected areas	WB	Pre	4.00 (2.00–6.00)	0.001	0.077	0.113
		Post	2.00 (1.00–4.50)			
	PB	Pre	4.00 (3.00–7.00)	0.364		
		Post	3.00 (2.00–5.00)			
SRCA Frequency	WB	Pre	18.15 ± 16.89	< 0.0001	0.024	< 0.001
		Post	9.15 ± 9.48			
	PB	Pre	16.84 ± 12.62	0.016		
		Post	13.68 ± 12.12			
SRCA Intensity	WB	Pre	9.00 (4.00–16.00)	< 0.0001	0.012	0.028
		Post	3.00 (1.00–9.50)			
	PB	Pre	9.00 (5.00–18.00)	0.201		
		Post	6.00 (4.00–12.00)			
ABC-C Agitation	WB	Pre	13.00 ± 7.97	< 0.0001	< 0.0001	< 0.001
		Post	7.13 ± 6.44			
	PB	Pre	11.45 ± 7.61	0.361		
		Post	11.26 ± 8.15			
ABC-C Lethargy	WB	Pre	4.00 (1.00–9.00)	< 0.0001	0.0005	0.003
		Post	1.50 (0.00–6.00)			
	PB	Pre	4.50 (1.00–7.00)	0.566		
		Post	4.00 (1.00–6.00)			
ABC-C Stereotypies	WB	Pre	1.00 (0.00–4.00)	0.0004	0.0004	0.003
		Post	0.00 (0.00–1.00)			
	PB	Pre	1.00 (0.00–4.00)	0.062		
		Post	1.00 (0.00–5.00)			
ABC-C Hyperactivity	WB	Pre	8.50 (4.50–11.00)	< 0.0001	< 0.0001	< 0.001
		Post	4.00 (2.00–6.00)			
	PB	Pre	6.00 (3.00–10.00)	0.0006		
		Post	7.00 (3.00–10.00)			
ABC-C Inappropriate Speech	WB	Pre	5.78 ± 3.30	< 0.0001	< 0.0001	< 0.001
		Post	3.71 ± 2.31			
	PB	Pre	5.34 ± 3.51	0.150		
		Post	5.35 ± 3.37			

BAI beck anxiety inventory, *HQ-CT* hyperphagia questionnaire for clinical trials, *SRCA* scale for the assessment of self-injurious behaviors, *ABC-C* aberrant behavior checklist – community, *WB* weighted blanket, *PB* placebo blanket, *SD* standard deviation, *IQR* interquartile range, *p* p-value, *Δ* difference between pre and post intervention.

Period, sequence and carryover effects

No significant period effects were identified across the analyzed outcomes (all $p \geq 0.059$). That is, the difference between WB and PB responses did not differ according to whether the intervention was administered in the first or in the second period. Significant sequence effects were identified in 4 out of 28 analyzed outcomes: SRCA

Table 3 Subjective sleep parameters. Questionnaire-based sleep outcomes including Epworth Sleepiness Scale, Composite Sleep Score, and Insomnia Severity Index. Data are expressed as mean ± SD or median (IQR), as appropriate. Within- and between-intervention comparisons are reported, with parametric or non-parametric tests selected according to the distribution of change scores. Adjusted p values are corrected for multiple comparisons (Benjamini-Hochberg, FDR 5%) across all between-condition contrasts of Tables 2–5.

	Intervention	Time	Mean ± SD or Median (IQR)	p (within)	p (Δ WB vs. Δ PB)	Adjusted p (Δ WB vs. Δ PB)
PSQI	WB	Pre	13.76 ± 9.40	0.764	0.268	0.312
		Post	13.08 ± 9.21			
	PB	Pre	11.50 ± 7.58	0.413		
		Post	12.91 ± 9.05			
ESS	WB	Pre	13.76 ± 5.09	0.003	0.039	0.061
		Post	10.92 ± 5.81			
	PB	Pre	11.70 ± 5.45	0.676		
		Post	11.51 ± 4.69			
CSS	WB	Pre	8.68 ± 2.36	0.308	0.731	0.758
		Post	8.92 ± 2.48			
	PB	Pre	9.00 ± 2.12	0.339		
		Post	9.11 ± 2.32			
ISI	WB	Pre	6.87 ± 6.77	0.432	1.000	1.000
		Post	6.39 ± 7.41			
	PB	Pre	5.92 ± 4.95	0.186		
		Post	5.21 ± 4.92			

PSQI pittsburgh sleep quality index, *ESS* epworth sleepiness scale, *CSS* composite sleep score, *ISI* insomnia severity index, *WB* weighted blanket, *PB* placebo blanket, *SD* standard deviation, *IQR* interquartile range, *p* p-value, *Δ* difference between pre and post intervention.

Table 4 Actigraphy-derived sleep and activity variables. Objective measurements of sleep efficiency, sleep fragmentation, and physical activity levels obtained through actigraphy during weighted blanket (WB) and placebo (PB) conditions. Data are expressed as mean ± SD or median (IQR), as appropriate. Between-intervention comparisons are reported, with parametric or non-parametric tests selected according to the distribution of scores. Adjusted p values are corrected for multiple comparisons (Benjamini-Hochberg, FDR 5%) across all between-condition contrasts of Tables 2–5.

	Intervention	Mean ± SD or Median (IQR)	p (WB vs PB)	Adjusted p (WB vs PB)
Total Metabolic Rate (MET)	WB	1414.24 ± 139.78	0.017	0.036
	PB	1369.98 ± 161.55		
Total Sedentary Time (min)	WB	9096.50 (7612.00-9874.00)	0.131	0.166
	PB	9295.00 (8096.00-10263.00)		
Total Sedentary Time (%)	WB	55.61 (47.86-60.01)	0.033	0.058
	PB	56.60 (51.63-62.33)		
Total Moderate Activity Time (min)	WB	1460.42 ± 722.85	0.096	0.128
	PB	1303.83 ± 719.62		
Total Moderate Activity Time (%)	WB	9.19 ± 3.60	0.018	0.036
	PB	8.00 ± 3.67		
Sleep Algorithm Efficiency (%)	WB	93.64 ± 2.99	0.002	0.007
	PB	92.07 ± 3.45		
Wake After Sleep Onset (min)	WB	20.49 ± 9.09	0.002	0.007
	PB	25.06 ± 10.64		
Awakenings (n)	WB	7.88 ± 3.58	0.0007	0.003
	PB	9.75 ± 3.97		

MET metabolic equivalent of Task, *min* minutes, *%* percentage, *n* number of events, *WB* weighted blanket, *PB* placebo blanket, *SD* standard deviation, *IQR* interquartile range, *p* p-value.

Table 5 Body composition outcomes. Changes in anthropometric and body composition parameters measured by bioimpedance, including body weight, BMI, fat mass, fat-free mass, and skeletal muscle mass. Data are presented as mean ± SD or median (IQR), as appropriate. Within- and between-intervention comparisons are reported, with parametric or non-parametric tests selected according to the distribution of change scores. Adjusted p values are corrected for multiple comparisons (Benjamini-Hochberg, FDR 5%) across all between-condition contrasts of Tables 2–5.

	Intervention	Time	Mean ± SD or Median (IQR)	p (within)	p (Δ WB vs. Δ PB)	Adjusted p (Δ WB vs. Δ PB)
Body Weight (kg)	WB	Pre	89.95 (73.60–102.30)	0.302	0.094	0.128
		Post	89.90 (73.30–103.30)			
	PB	Pre	89.90 (72.50–104.50)	0.271		
		Post	87.70 (72.60–104.60)			
BMI (kg/m ^{2})	WB	Pre	36.28 ± 10.57	0.096	0.039	0.061
		Post	36.50 ± 10.28			
	PB	Pre	36.58 ± 10.64	0.270		
		Post	36.56 ± 10.29			
Waist Perimeter (cm)	WB	Pre	109.25 (102.00–121.50)	0.597	0.687	0.739
		Post	107.00 (101.00–120.00)			
	PB	Pre	109.00 (102.00–120.00)	0.911		
		Post	109.50 (100.50–122.00)			
Fat Percentage (%)	WB	Pre	49.50 (43.70–55.00)	0.128	0.297	0.332
		Post	49.70 (43.90–53.70)			
	PB	Pre	50.20 (44.80–54.90)	0.542		
		Post	51.10 (44.90–54.90)			
Fat Free Mass (kg)	WB	Pre	44.60 ± 9.19	0.004	0.005	0.016
		Post	45.03 ± 9.42			
	PB	Pre	45.22 ± 9.15	0.298		
		Post	44.78 ± 9.12			
Skeletal Muscle Mass (kg)	WB	Pre	24.12 ± 5.41	0.010	0.010	0.025
		Post	24.32 ± 5.50			
	PB	Pre	24.48 ± 5.45	0.319		
		Post	24.22 ± 5.39			

BMI Body Mass Index expressed in kg/m^2; *kg* kilogram; %, percentage; WB weighted blanket; *PB* placebo blanket; *SD* standard deviation; *IQR* interquartile range; *p* p-value; *Δ* difference between pre and post intervention.

affected areas ($p = 0.041$), SRCA frequency ($p = 0.023$), SRCA intensity ($p = 0.031$), and awakenings ($p = 0.030$). That is, for these outcomes, overall response levels, averaged across both intervention periods, differed between allocation groups.

A carryover phenomenon was identified for the five ABC-C domains, whose baseline values had not returned to study entry levels in the "WB first" group. For instance, ABC-C agitation at V0 showed a mean ± SD of 13.75 ± 6.92 and at V3 a mean ± SD of 9.45 ± 5.80 ($n = 20$; difference = 4.30; t = 4.3 and $p = 0.0004$). By contrast, the corresponding difference was not significant in the "PB first" group ($n = 18$; 13.67 ± 8.87 versus 13.11 ± 9.08; difference = 0.56; t = 0.6 and $p = 0.571$). The same pattern was observed in the remaining four domains ($p = 0.001$ to 0.036 versus $p \geq 0.364$). The between-group comparison was significant for agitation ($p = 0.011$) and hyperactivity ($p = 0.007$). For the SRCA subscales, baseline values declined comparably in both groups (between-group $p \geq 0.375$).

When the first period alone was considered, WB remained superior to PB for the five ABC-C domains ($p = 0.0007$ to 0.020), the three SRCA subscales ($p = 0.025$ to 0.029), hyperphagia ($p = 0.004$), and the Epworth Sleepiness Scale ($p = 0.020$), but not for awakenings ($p = 0.527$).

Safety and tolerability

The intervention was well-tolerated across the cohort. No adverse events, sensory intolerance, or dropouts were reported during either the WB or the PB intervention periods.

Discussion

This study provides the first systematic evidence that deep proprioceptive stimulation delivered via weighted blankets may confer clinically meaningful benefits in adults with PWS in terms of behavior, sleep efficiency, physical activity, and body composition.

Deep proprioception is the sense that informs the organism about the position of its muscles and joints and can be defined as the ability to perceive the relative position of adjacent body parts[23]. It plays a fundamental role in the individual's relationship with space by regulating movement direction and enabling automatic responses such as balance control, bilateral coordination, and postural stability[24]. Deep proprioception also contributes to maintaining an appropriate level of central nervous system alertness and influences emotional development and behavior[24].

The design of proprioceptive stimulation blankets, also known as weighted blankets, is based on A. Jean Ayres' sensory integration theory and her work with children with learning disabilities[25–27]. This theory describes a neurological process through which sensory information from the body and the environment is organized, allowing the individual to use the body effectively within the surrounding environment[13,28].

In children with autism spectrum disorder (ASD), Olson et al.[29] reported that 92.2% of therapists from the American Occupational Therapy Association recommended weighted vests, and 70% observed improvements in attention during tasks performed while wearing them. Since the underlying mechanism of action, modulating autonomic arousal, is comparable between weighted vests and weighted blankets, these findings support the rationale for extending deep proprioceptive stimulation approaches to other neurodevelopmental conditions. Likewise, evidence from psychiatric and psychosocial settings suggests that weighted blankets may reduce the need for caregiver assistance and healthcare services, while also alleviating depressive and anxiety symptoms, thereby representing a potentially useful non-pharmacological intervention for individuals with specific sensory regulation needs[30].

As the behavioral phenotype of PWS shares several neurobehavioral features with ASD, including anxiety-related self-injurious behaviors[31,32], the reductions observed in the present study in anxiety and maladaptive behaviors are consistent with DPS-mediated modulation of autonomic arousal and align with previous findings in ASD and psychiatric populations[12,33]. This evidence supports the biological plausibility of DPS efficacy in the PWS population. In this sense, our results showed a significant improvement in anxiety after the intervention with WB, with a mean reduction in BAI of 2.19 points, whereas virtually no change was observed after PB exposure. Anxiety is a central driver of hyperphagia, compulsivity, and self-injurious behaviors in PWS[34]; therefore, its attenuation likely underlies the broad behavioral improvements observed in our cohort, despite the lack of statistically significant treatment effect. This potential anxiety reduction was reflected not only in food-related behaviors, reflected by a mean reduction of 4.59 points in the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) after WB, but also in the reduced frequency and intensity of skin-picking and other characteristic maladaptive behaviors (Table 2).

Sleeping disorders in PWS have traditionally focused on the well-established association with central sleep apnea and obstructive sleep apnea (OSA). Concerns regarding OSA arise early, often from the time of diagnosis, because profound hypotonia, progressive weight gain, and tonsillar hypertrophy may exacerbate airway obstruction, particularly after initiation of growth hormone therapy[10]. However, clinical experience and growing evidence indicate that additional sleep disturbances are highly prevalent in PWS, including excessive daytime sleepiness, narcolepsy-like and cataplexy-like phenotypes, and insomnia, all of which may significantly impact behavioral functioning[35]. In the present study, these conditions were either excluded or adequately controlled before participant enrollment.

In this context, the sleep-related improvements observed after DPS are also biologically plausible. Objective actigraphy demonstrated a significant improvement in sleep efficiency during WB use, despite this effect not being fully reflected in questionnaire-based assessments. Moreover, sleep fragmentation and arousals were

significantly reduced during the WB period. The discrepancy between subjective and objective sleep measures may reflect caregiver-reported bias and the limited sensitivity of questionnaires when applied to intellectually disabled populations, particularly when subtle physiological improvements occur without obvious perceived behavioral change[36].

Nevertheless, although not statistically significant, sleep quality also showed a favorable trend following DPS, as indicated by a 0.68-point reduction in Pittsburgh Sleep Quality Index score, whereas PB exposure was associated with worsening sleep quality, reflected by a 1.41-point increase. By contrast, negligible changes were observed in overall sleep health as measured by CSS, and insomnia severity assessed through ISI remained largely unchanged after both interventions. Nonetheless, basal ISI scores for both intervention periods were low, hindering the finding of significant differences for this parameter.

Interestingly, the only subjective sleep parameter that clearly improved after DPS was daytime sleepiness, with an almost 3-point reduction in Epworth Sleepiness Scale scores and no relevant difference after PB exposure. This finding is consistent with the objective increase in sleep efficiency and suggests that improved nocturnal sleep may have translated into better daytime functioning.

Our findings partially differ from those reported by Gringras et al.[37], who conducted a randomized controlled trial in children with ASD and found no significant objective effect of WB on sleep disturbances, although both parents and children subjectively favored their use. In contrast, in our cohort of adults with PWS, objective improvements were evident while subjective measures remained less sensitive. This difference may be related to disorder-specific sensory processing patterns, age differences, or the distinct mechanisms underlying sleep dysregulation in PWS. This discrepancy underscores the importance of objective metrics.

The sleep improvement observed in the present work is also in line with previous studies conducted in other clinical populations. Children with Attention Deficit Hyperactivity Disorder experienced improved sleep patterns while using weighted blankets, including shorter sleep-onset latency, fewer nocturnal awakenings, and less sensitivity to environmental disturbances[38]. Similar benefits have also been reported in individuals with sensory hypersensitivity[39], as well as in people with intellectual disability, in whom DPS improved sleep efficiency and reduced the need for hypnotic medication[40]. Improved sleep quality is known to have relevant downstream effects on daily functioning and physical activity[41,42]. Adequate sleep is associated with higher levels of movement and reduced sedentary behavior[43], a pattern that was also observed in our cohort. In the present study, improved sleep efficiency was accompanied by increased physical activity and metabolic expenditure. Importantly, this increase occurred in a regulated manner, since hyperactivity frequency, a common behavioral feature in PWS, was reduced after DPS, suggesting better behavioral regulation rather than simple motor overactivation.

Furthermore, the increase in physical activity and metabolic rate ultimately translated into favorable changes in body composition, including increased fat-free mass and skeletal muscle mass, but without significant changes in fat mass percentage nor in body weight. These findings are particularly relevant given the profound sarcopenic obesity phenotype that characterizes PWS and the limited availability of effective non-pharmacological interventions targeting body composition[44–46]. Nevertheless, these findings need to be cautiously interpreted due to the short-term duration of the intervention.

Limitations

This study has several strengths, including its randomized crossover design, which allows each participant to serve as their own control, thereby increasing statistical power despite the challenges of rare disease research. Furthermore, the use of both objective (actigraphy, bioelectrical impedance) and validated clinical scales provides a comprehensive overview of the intervention's impact.

However, some limitations must be acknowledged. First, the relatively small sample size, while typical for rare disease research, may have limited the statistical power of our exploratory analyses to detect differences between genetic subtypes, and precluded any comparison by GH treatment status. Second, the short duration of the intervention (14 days) precludes conclusions about the long-term sustainability of the observed effects. Future

longitudinal studies are warranted to determine if these benefits persist and are enhanced over extended periods. Additionally, environmental factors such as potential blanket intolerance during warmer seasons could influence adherence in different climates. Finally, while the blankets were visually identical, the nature of the intervention makes a perfect double-blind design challenging, as participants may perceive the weight difference.

A further limitation concerns carryover effects. Although a complete counterbalancing prevents inflation of either intervention option, ABC-C baseline values in the "WB first" group had not returned to study entry levels before the second period. Nonetheless, intervention effects estimated within the first period alone, not subject to carryover, confirmed the behavioral findings. Although this persistence would interestingly suggest that the behavioral effect of DPS is long-lasting, washout time should be better adjusted in future studies.

Nevertheless, as stated in the inclusion criteria, participants remained clinically stable throughout the study in terms of psychopathological status and psychotropic medication. This reduces the likelihood that medication changes or acute psychopathological instability accounted for the observed improvements and further reinforces the interpretation that deep proprioceptive stimulation (DPS) exerts a genuine therapeutic effect in adults with PWS.

Conclusions

In conclusion, DPS via weighted blankets represents a safe, well-tolerated, non-pharmacological, and easily implementable intervention for improving behavioral regulation, sleep efficiency, and body composition in adults with Prader–Willi syndrome. Our results highlight a significant reduction in anxiety and hyperphagia, suggesting that DPS targets the core neurobehavioral challenges of the PWS phenotype. These findings support the incorporation of WBs into multidisciplinary care guidelines for the management of PWS, although further research with larger, longer-term studies is needed to confirm the durability of these clinical benefits.

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Author contributions S. E-C, A. C and R. P. conceived and designed the study. A. C secured funding for the project. The three of them supervised all phases of the trial — participant recruitment, randomization, intervention delivery, and data acquisition — contributed to the formal analysis and interpretation of the behavioral, sleep, and body composition data, and led the drafting and critical revision of the manuscript (Conceptualization, Methodology, Funding Acquisition, Supervision, Investigation, Formal Analysis, Project Administration, Writing – Original Draft, Writing – Review & Editing).A. M-A performed the statistical analysis of the behavioral, sleep, and body composition outcomes and drafted the manuscript, including preparation of the tables (Formal Analysis, Writing – Original Draft).L. V contributed to the design of the study, conducted participant visits, and critically reviewed the manuscript for important intellectual content (Methodology, Investigation, Writing – Review & Editing).L. B-H performed statistical analyses and contributed to drafting the manuscript (Formal Analysis, Writing – Original Draft).R. Coronas. conducted participant visits and critically reviewed the manuscript for important intellectual content (Investigation, Writing – Review & Editing).O. G-P. conducted participant visits and critically reviewed the manuscript for important intellectual content (Investigation, Writing – Review & Editing).J. D. contributed to the design of the study and critically reviewed the manuscript for important intellectual content (Methodology, Writing – Review & Editing).R. Corripio. critically reviewed the manuscript for important intellectual content (Writing – Review & Editing).All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.A. C. and S. E-C. are designated as corresponding authors and all authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Data availability The datasets used and/or analysed during the current study are available from the corresponding authors on reasonable request.

Declarations

Competing interests The authors declare no competing interests.

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