Volumen 25, número 2, 2025

THERAPY

PSYCHOLOGICAL

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OF

JOURNAL

INTERNATIONAL

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Volume 25, number 2 Volumen 25. número 2

June 2025 Junio 2025

ISSN: 1577-7057

IJP&PT

INTERNATIONAL JOURNAL OF PSYCHOLOGY & PSYCHOLOGICAL

THERAPY



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ISSN 1577-7057

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Feasibility and Preliminary Efficacy of Online-Delivered Paradoxical Intention Therapy among Adults with Insomnia Symptoms and High Sleep Effort

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Abstract

The aim of this study was to determine the feasibility and preliminary efficacy of online-delivered paradoxical intention therapy (PI) among adults with insomnia symptoms and high sleep effort. A two-arm randomised controlled trial was conducted. Twenty-six adults (18-54 years) were randomly allocated to receive either PI (n=13) or sleep hygiene instructions (n=13). PI sessions were delivered via the Internet across two hour-long sessions over two weeks whereas sleep hygiene instructions sessions were one-off. Participants completed 5 consecutive days of wrist actigraphy and sleep diary, the Glasgow Sleep Effort Scale (GSES), Pittsburgh Sleep Quality Index (PSQI) and Patient Health Questionnaire (PHQ-9) at baseline, post-intervention (2 weeks) and follow-up (1 month). Thirtyfive adults of the 46 recruited (76%) presented with insomnia symptoms and high sleep effort. The randomised participants who persisted with the study (n=24) showed good adherence (85%-100%) throughout the intervention and follow-up periods. Significant reductions were observed on the GSES indicating the role of PI in reducing sleep effort. Findings also show that PI significantly improved self-reported sleep parameters (sleep onset latency, wake after sleep onset, sleep efficiency), and sleep quality measured by PSQI, yielding moderate to large effect sizes. Preliminary findings indicate that PI is a feasible, standalone psychological intervention for insomnia symptoms that can be administered successfully via the Internet. Future trials are needed to address the sustained efficacy of online PI on both objective and self-reported sleep quality, sleep effort and depression outcomes.

Key words: paradoxical intention, feasibility, preliminary efficacy, insomnia, sleep effort, depression.

How to cite this paper: Ong GSC, Lazar AS, & Broomfield NM (2025). Feasibility and Preliminary Efficacy of Online-Delivered Paradoxical Intention Therapy among Adults with Insomnia Symptoms and High Sleep Effort. *International Journal of Psychology & Psychological Therapy*, 25, 1, 151-166.

Novelty and Significance

What is already known about the topic?

- Sleep effort is a proactive cognitive and behavioural attempt to initiate sleep which disrupts the natural process of falling asleep, resulting in symptoms of insomnia.
- Paradoxical intention is typically delivered as part of the multicomponent cognitive behavioural therapy for insomnia.

What this paper adds?

- This study includes the use of a validated screening measure of sleep effort.
- This study showed promising findings of internet-delivered paradoxical intention on reducing insomnia symptoms and high sleep effort among adults.
- The results indicated that paradoxical intention can be used as an alternative standalone psychological intervention.

Paradoxical Intention therapy (PI) is a cognitive behavioural sleep intervention used to treat insomnia in adults (Espie & Lindsay, 1985). Since its inception, the theoretical basis of PI was grounded on the idea that individuals with insomnia were trying too hard to fall asleep. The understanding was that those who put effort into falling asleep experienced higher levels of sleep performance anxiety, which was suggested to stimulate the autonomic nervous system, thus interfering with the physiological ability to initiate sleep onset (Ascher & Efran, 1978). This phenomenon is referred to as 'sleep effort' (Broomfield & Espie, 2005).

Sleep effort is a proactive cognitive and behavioural state of attempting to control sleep engagement (Broomfield & Espie, 2005; Espie, Broomfield, MacMahon, Macphee,

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& Taylor, 2006). As sleep is an involuntary behaviour that cannot be initiated intentionally (Espie *et alii*, 2006), the active control of sleep disrupts the natural process of falling asleep by preventing relaxation and inducing performance anxiety, thereby extending sleep latency (Broomfield & Espie, 2003, 2005). Clinically, the notion of sleep as an involuntary process is often confirmed by asking what good sleepers 'do' to fall asleep. Typically, good sleepers report doing nothing to fall asleep, suggesting good sleep is effortless. In a recent exploratory study, heightened sleep effort was strongly associated with severe self-reported insomnia, demonstrating the possible putative role of sleep effort in the aetiology and treatment of insomnia (Herteinstein, Nissen, Riemann, Feige, Baglioni, & Spiegelhalder, 2015), and suggesting the significance of targeting sleep effort in interventions for insomnia.

The rationale of PI is that rather than voluntarily controlling sleep, the act of trying to stay awake in bed is more likely to induce the natural process of sleep because pre-sleep cognitive activities that arouse wakefulness are eliminated (Turner & Ascher, 1979; Espie, 2002). To date, several studies have shown the effectiveness of PI in managing sleep-onset insomnia in single cases (Ascher & Efran, 1978; Espie, Lindsay, Brooks, Hood, & Turvey, 1989) and randomised-controlled trials (Turner & Ascher, 1979; Jansson-Fröjmark, Alfonsson, Bohman, Rozental, & Norell-Clarke, 2022) with significant reductions to sleep onset latency and sleep complaints among people with insomnia symptoms following PI. Recently, Jansson-Fröjmark *et alii* (2022) conducted a systematic review and meta-analysis to explore the effectiveness of PI on insomnia. Of ten randomised controlled trials (RCT) included in the review, PI yielded moderate to large improvements in insomnia symptoms compared to passive and active comparators, particularly with reductions observed in sleep-related performance anxiety (Jansson-Fröjmark *et alii*, 2022).

PI is however more typically delivered as part of the multicomponent cognitive behavioural therapy for insomnia (CBT-I) rather than as a single-component therapy. Thus whilst it is included as part of the American Association of Sleep Medicine (AASM) clinical practice guideline as a single-component treatment (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008), it remains under-recognised and unspecified in most other clinical practice guidelines including the European Sleep Research Society (ESRS) and National Institute for Health and Care Excellence (NICE). PI may thus remain under-researched despite some indications of promise as a single-component therapeutic (Jansson-Fröjmark *et alii*, 2022). And interestingly, none of the studies included in the Jansson-Fröjmark *et alii* (2022) review involved online delivered PI nor formally evaluated the acceptability of PI, and whilst only two included a measure of sleep performance anxiety (Broomfield & Espie, 2003; Buchanan, 1988), neither used a validated pre-screen.

Moreover, sleep disturbances including insomnia are commonly associated with mental health difficulties. The meta-analysis by Hertenstein *et alii* (2019) indicated that insomnia is a significant predictor of the onset of various mental health disorders including depression, anxiety, alcohol abuse and psychosis. Freeman *et alii* (2020) further highlighted the role of insomnia in perpetuating existing mental health disorders such as depression, anxiety, schizophrenia, and post-traumatic stress disorder. It was suggested that in the context of treatment, improving insomnia symptoms could reduce the severity of these mental health difficulties (Freeman *et alii*, 2020). As such, there appears to be potential for implementing sleep-focused interventions not only to alleviate sleep disturbances but also to potentially improve mental health.

In summary, the objective of the present study was to determine the feasibility and acceptability of delivering online PI among adults with insomnia symptoms and high sleep effort, with the aim to inform future large-scale RCTs. Additionally, the present study also assessed the impact of PI on mental health, focusing particularly on depressive symptoms, among adults experiencing these sleep difficulties.

Method

Participants

Participants were recruited between March and July 2021 via electronic and printed advertisements distributed at the host university and word of mouth referrals. Individuals who expressed interest in participating were screened according to the eligibility criteria, which included those who 1) were aged 18 years and older, 2) met criteria for insomnia symptoms by scoring ≤ 16 on the Sleep Condition Indicator (Espie, Kyle, Hames, Gardani, Fleming, & Cape, 2014), and 3) reported high sleep effort during night-time sleep with scores of >2 on the Glasgow Sleep Effort Scale (Broomfield & Espie, 2005). We excluded individuals who 1) were diagnosed with sleep disorders other than insomnia (e.g. sleep-related breathing disorders), 2) had sensorial impairments (e.g. deafness, blindness), 3) used medications that had an effect on sleep, and 4) were receiving any ongoing psychological interventions for insomnia or any other psychological disorders. No compensation for participating was offered. Given that this was a feasibility study, no formal power calculation was conducted. Nevertheless, considerations to achieve an adequate sample size were made. As the recommended range of sample size for feasibility and pilot studies were reported to be at least between 24 and 50 (Browne, 1995; Julious, 2005; Sim & Lewis, 2012), this study recruited 46 participants at screening.

Ethical approval for this study was obtained from the Faculty of Medicine and Health Sciences Research Ethics Committee at the University of East Anglia (ref: 2020/21-062).

Design

Feasibility is defined by Eldridge *et alii* (2016) as the overarching concept for research studies that are conducted prior to the main trial and assesses whether a future RCT can be done. Following this framework, this study adopted the randomised pilot study approach in which the main features of acceptability such as eligibility, recruitment and retention rates are explored along with the evaluation of preliminary efficacy of the intervention within a small-scale randomised trial. The acceptability of PI was assessed based on 1) the number of individuals who met inclusion criteria at screening (eligibility), 2) the number of participants enrolled to interventions (recruitment), 3) session attendance and completion of interventions (adherence), and 4) the number of participants at follow-up (retention).

Moreover, this study assessed the preliminary efficacy of PI on reducing sleep effort (primary outcome), as well as improving objective and sleep diary sleep parameters, perceived sleep quality and depressive symptoms (secondary outcomes). This part of the study was designed as a two-arm RCT with two phases: screening and intervention. Eligible participants identified from screening were randomly assigned to receive either PI or sleep hygiene (SH) instructions. Randomisation was conducted using an online computer-generated randomisation platform (*https://www.sealedenvelope.com*), with random permuted blocks to ensure groups were balanced and concealment for future allocations were maintained. SH instructions were chosen as the active control condition because they have strong face validity given that they are commonly used in clinical settings for individuals with sleep complaints (Irish, Kline, Gunn, Buysse, & Hall, 2015). Moreover, the use of SH as an intervention can entail a similar delivery format, session engagement and level of effort as the sleep intervention, as described by Hauri (1993).

Instruments and Measures

- Sleep Condition Indicator (SCI; Espie et alii, 2014). The SCI is an 8-item screening tool of insomnia disorder based on DSM-5 criteria. All SCI items are scored on a 5-point scale of 0 to 4, with scores ≤ 2 for each item representing threshold score for insomnia. Thus, a cut-off score of ≤ 16 reflects putative insomnia disorder. The SCI has strong construct and concurrent validity in distinguishing individuals with insomnia disorder and normal sleepers (Espie et alii, 2014; Palagini et alii, 2015), as well as good internal consistency (Cronbach's $\alpha = .83$; Hellstrom et alii, 2019).
- Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005). The GSES is a 7-item self-report scale that measures persistent efforts to sleep. The scale addresses core behavioural and cognitive components of sleep effort such as having the need to control sleep, making voluntary attempts of controlling sleep and experiencing performance anxiety around sleep. GSES items are assessed on a 3-point Likert scale (0= not at all, 1= to some extent, 2= very much), with scores above 2 indicating high sleep effort. The GSES has high internal consistency (Cronbach's α = .77) and there is evidence to support the convergent and criterion validity of the scale, suggesting GSES is effective in quantifying sleep effort and can adequately distinguish good sleepers from individuals with insomnia (Broomfield & Espie, 2005; Meia-Via, Marques, Espie, da Silva, & Allen Gomes, 2016).
- Consensus Sleep Diary (CSD; Carney et alii, 2012). The CSD is an expert consensus, patient-informed and standardised measurement tool for assessing self-reported night-time sleep. The 9-item measure includes subjective questions and a 5-point Likert scale (e.g. very poor to very good) covering critical sleep parameters. Past research supported the validity and sensitivity of CSD in subjectively assessing sleep between good and poor sleepers (Carney et alii, 2012; Maich, Lachowski, & Carney, 2018). Furthermore, sleep diaries are "gold-standard" subjective sleep measures (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006).
- Pittsburgh Sleep Quality Index (PSQI; Buysse et alii, 1989). The PSQI is a 24-item questionnaire that assessed seven components of sleep: sleep quality, sleep disturbances, sleep latency, sleep duration, habitual sleep efficiency, use of sleep medications and daytime dysfunction. The questionnaire consists of open-ended and close-ended questions, and item scores are combined to form the seven component scores, each ranging between 0-3. Total scores are added to yield a global score, with scores >5 indicating severe sleep disturbance. The PSQI is sensitive to clinically meaningful changes across time following intervention to improve sleep. Moreover, the PSQI has a high degree of internal consistency (Cronbach's α = 0.83; Zhong, Gelaye, Sánchez, & Williams, 2015).
- Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a 9-item self-report tool used to measure depression severity. Each item reflects the nine diagnostic criteria of depression listed in DSM-IV. Item scores range from 0 (not at all) to 3 (nearly every day) with higher overall scores indicating more severe depression. The cut-off score is set at ≥ 10 , indicating moderate depression. Studies evaluating the psychometric properties of PHQ-9 found that the tool demonstrated good validity as well as high sensitivity and specificity (88% respectively) in detecting symptoms of major depressive disorder (MDD). The PHQ-9 also obtained good internal consistency (Cronbach's α =.85; Rancans, Trapencieris, Ivanovs, & Vrublevska, 2018; Maroufizadeh, Omani-Samani, Almasi-Hashiani, Amini, & Sepidarkish, 2019). In this study, participants who scored ≥ 1 on item 9 indicating suicide/self-harm risks were

signposted to mental health support services and crisis helplines.

Wrist actigraphy. The wrist-worn actigraphic recording device, MotionWatch 8 (Cambridge Neurotechnology Ltd; Cambridge, UK) estimates sleep quality by sensing and recording motions during sleep and provides an objective proxy measurement of sleep-wake timing, sleep duration and sleep efficiency, as computed by the MotionWare Sleep Analysis software (Aili, Åström-Paulsson, Stoetzer, Svartengren, & Hillert, 2017). Actigraphy is useful in assessing overall sleep quality in the natural sleep setting (Martin & Hakim, 2011), with actigraphy-measured sleep latency, sleep duration and total wake time being correlated with polysomnography (PSG), the "gold-standard" for objective measurements of sleep (Ancoli-Israel, Cole, Alessi, Chambers, Moorcroft, & Pollak, 2003; McCall & McCall, 2013).

Procedure

At screening, individuals who expressed interest were given a participant information sheet and were required to complete a consent form. Demographic information, along with self-reported sleep quality (SCI, GSES, PSQI) and depressive symptoms (PHQ-9) were then collected using an online questionnaire. Individuals who did not meet inclusion criteria were informed and signposted to relevant support services. Individuals who met inclusion criteria were invited to take part in the intervention, in which those who consented to participate were given a personal reference code, and they were randomised to either the PI or control group. Given the limited availability of actigraphic equipment at the host university, interventions took place between August and November 2021.

As the intervention phase was conducted during the COVID-19 pandemic, all sessions were delivered remotely via Microsoft Teams. Eligible participants who were randomised into intervention groups were contacted by email to arrange intervention appointments. A follow-up email consisting of an invitation link to a Microsoft teams meeting was then sent to each participant. Furthermore, in-built platform functions (e.g., share screen, whiteboard) were used during sessions to aid engagement and collaboration between researcher and participant.

Intervention

All intervention sessions were delivered remotely by the first author (GO) under the supervision of the primary research supervisor (NB), who is an expert in the field of PI.

Paradoxical Intention: Two sessions of online-delivered PI lasting 1-hour were administered individually across two weeks. The sessions introduced the rationale of PI and instructed participants to stay awake without making effort to sleep (Broomfield & Espie, 2003; Espie, 2006). PI was delivered following the steps by Espie (2011). In session 1, participants were asked about their nighttime sleep difficulties and their daytime routine. We then considered sleep normalcy and developed a formulation of insomnia symptoms as a sleep effort syndrome (see Appendix A). Participants were then encouraged to give up any effort to fall asleep for the next 14 nights. In session 2, participants were asked to reflect on their experiences with implementing the PI instructions. We collaborated in the discussion to differentiate between motivation/ commitment to sleep, in comparison to unproductive effort/preoccupation around sleep. We also considered helpful parallels (e.g., 'the white bear experiment') in understanding the concept of paradoxical processes.

Sleep Hygiene (Control): Participants received a one-off 1-hour session to understand sleep hygiene, again delivered via the Internet. The session followed the guide by Hauri (1993). The session outlined the impacts of lifestyle on night-time sleep, and between two to four well-understood sleep hygiene recommendations were made

for each participant. An instruction sheet (see Appendix B) was developed to include environment and behavioural recommendations (Irish *et alii*, 2015).

The following measures were taken:

Measures of acceptability outcomes: Acceptability outcomes were assessed by participant eligibility, recruitment and adherence to interventions, and participant retention at follow-up.

Measures of preliminary efficacy outcomes:

- *Primary outcome*. The GSES was measured at three timepoints: before the intervention (baseline), after the 2-week intervention (post-intervention) and at 1-month follow-up.
- Secondary outcomes. Like the primary outcome, perceived sleep (PSQI) and depressive symptoms (PHQ-9) were measured at baseline, post-intervention and follow-up.

Participants wore a wrist actigraphy and completed the CSD for 5 consecutive nights at baseline and post-intervention. Both measures recorded sleep parameters including time in bed (TIB), sleep onset latency (SOL), wake after sleep onset (WASO), sleep duration (SD), sleep period time (SPT), sleep efficiency (SE). Actigraphy was worn on non-dominant wrists and participants were instructed to press the event marker on the face of the actiwatch at 'lights out' (night) and 'final awakening' (morning). Participants completed the CSD upon awakening each morning.

Actiwatch data were downloaded and analysed using the MotionWare Sleep Analysis software. Sleep diary responses were used to confirm the 'lights out' and 'final awakening' times as identified using the timestamped event markers. In cases of disagreements between start and end times of a sleep window on both measures, the light sensor data was used to determine the 'lights out' and 'final awakening' times (Landry, Best, & Liu-Ambrose, 2015). Moreover, objective composite sleep quality was calculated by averaging standardised sleep duration, sleep efficiency and sleep fragmentation scores. The fragmentation score was multiplied by -1 prior to averaging. Higher composite scores represented better sleep quality (Landry *et alii*, 2015).

Data Analysis

IBM SPSS Statistics version 27 was used for all analyses. Descriptive statistics was used to report the demographic data of the sample and acceptability outcomes of the intervention. To assess preliminary efficacy, independent t-tests (continuous data) and Mann-Whitney U tests (categorical data) were used to explore group differences on all outcomes, following the use of Kolmogorov-Smirnov test to check for data normality. Moreover, a general linear model (GLM) evaluated the interaction effects across time for all outcomes. Controlling for age, mean values of all outcomes were analysed. Residuals were inspected for normality, and effect sizes (η^2) for each variable were computed. Additional exploratory analysis on the impacts of PI on self-reported questionnaires from baseline to follow-up were conducted using chi-square analysis and GLM. Statistical significance was set at .05 ($p \le .05$).

RESULTS

Table 1 shows the characteristics of the overall sample and the intervention conditions. Twenty-four participants (22 females) were included for analysis. The mean age of the sample was 28.88 years, with participants ranging from 18 to 54 years old.

Figure 1 outlines the participant flowchart throughout the study. At screening, a total of 46 adults were recruited. Excluding 11 adults who did not complete the

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1	Variables	Total sample $(n=24)$ M(SD)	PI (n=13)	SH Control (n=11)	р
Age		28.88 (13.61)	25.85 (12.27)	32.45 (14.81)	.18
Range		18 - 54	18-54	18-54	
Saw	Male	2 (8.3)	0	2 (18.2)	.20
Sex, n (%)	Female	22 (91.7)	13 (100)	9 (81.8)	.20
SCI scores (s	screening) M (SD)	10.21 (2.62)	9.39 (2.53)	11.18 (2.48)	.13
GSES scores	(screening)M(SD)	8 67 (2.48)	9 39 (1 90)	7 82 (2 89)	32

Table 1. Demographic information for the study sample.

Notes: M= mean; SD= Standard Deviation; SCI= Sleep Condition Indicator; GSES= Glasgow Sleep Effort Scale; PI= Paradoxical Intention; SH= Sleep Hygiene.

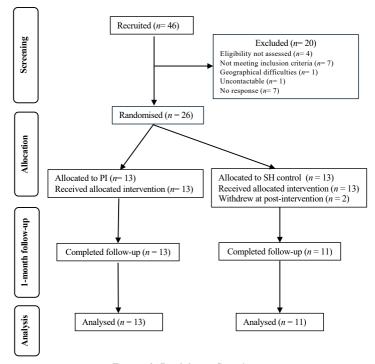


Figure 1. Participant flowchart.

screening questionnaire and/or did not meet the inclusion criteria of the intervention phase, a total of 35 adults (76%) obtained scores on the SCI and GSES indicating the presence of insomnia disorder and high sleep effort. Twenty-six adults who met the inclusion criteria consented to participate in the intervention phase and were randomised, resulting in a recruitment rate of 56.5%. Twenty-four participants of the 26 recruited (92%) completed the study. There were 100% adherence and retention rates within the PI group as participants attended all intervention sessions and were retained at follow-up. Whilst all participants attended scheduled SH sessions, the retention rate was at 85% as two participants were lost at post-intervention. One participant withdrew due to medical reasons unrelated to the study, and another dropped out with no further reply to communication attempts.

PI showed promising effects in reducing sleep effort. The PI group (M=3.77, SD=2.42, U=32.50, z=-2.05, p=.04) reported significantly reduced sleep effort compared to the control group (M=5.60, SD=1.96) at post-intervention (see Table 2). The positive

		Baseline		Pos		
	Variables	PI	SH Control	PI	SH Control	
		M(SD)	M(SD)	M(SD)	M(SD)	р
	Lights Out Time (hh:mm)	23:19 (1:01)	23:25 (1:14)	23:53 (1:12)	23:16 (1:23)	.79
	Final Awakening Time (hh:mm)	8:27 (1:32)	8:14 (1:50)	8:19 (1:18)	8:05 (5:49)	.12
	Time in Bed (h)	9.27 (1.18)	9.03 (0.85)	8.65 (0.93)	9.07 (1.00)	.92
	Sleep Onset Latency (min)	31.00 (28.00)	14.00 (13.00)	22.00 (19.00)	29.00 (49.00)	.64
Astiguanhy	Sleep Period Time (h)	8.62 (0.90)	8.55 (0.78)	8.05 (0.78)	8.55 (0.93)	.70
Actigraphy	Wake After Sleep Onset (min)	66.00 (35.00)	65.00 (29.00)	55.00 (19.00)	67.00 (30.00)	.32
	Sleep Duration (h)	7.50 (0.75)	7.45 (0.80)	6.58 (1.87)	7.40 (0.88)	.15
	Sleep Efficiency (%)	81.59 (8.67)	82.59 (6.84)	76.77 (21.15)	82.07 (5.52)	.66
	Fragmentation Index	31.54 (17.27)	31.80 (11.65)	29.68 (5.89)	32.67 (13.14)	.93
	Composite Score	-10.14 (5.79)	-10.22 (3.91)	-9.54 (2.00)	-10.51 (4.40)	.93
	Lights Out Time (hh:mm)	23:35 (1:04)	23:06 (1:06)	23:56 (1:14)	23:40 (1:31)	.91
	Final Awakening Time (hh:mm)	8:01 (1:32)	7:59 (2:04)	7:57 (1:39)	7:59 (5:42)	.44
	Time in Bed (h)	8.45 (1.1)	8.87 (1.82)	8.38 (2.05)	8.75 (1.42)	.60
	Sleep Onset Latency (min)	56.00 (44.00)	29.00 (13.00)	31.00 (27.00)	23.00 (13.00)	.91
	Sleep Period Time (h)	7.48 (0.95)	9.20 (4.45)	7.47 (1.08)	8.37 (1.27)	.79
Sleep diary	Wake After Sleep Onset (min)	37.00 (34.00)	37.00 (30.00)	15.00 (15.00)	32.00 (25.00)	.049*
	Sleep Duration (h)	6.88 (1.17)	8.98 (4.50)	7.15 (1.17)	7.82 (1.50)	.36
	Sleep Efficiency (%)	82.09 (10.54)	86.40 (6.98)	89.11 (7.77)	88.88 (6.26)	.43
	GSES	8.15 (1.63)	7.55 (2.51)	3.77 (2.42)	5.60 (1.96)	.04*
	PSQI	11.92 (2.57)	9.00 (2.28)	5.23 (2.83)	6.50 (2.56)	.17
	PHQ-9	9.69 (4.54)	9.20 (3.89)	4.69 (0.79)	5.89 (3.98)	.49

Table 2. Between group differences in actigraphy data, sleep diary data and self-reported sleep and mental health questionnaires.

Notes: hh:mm= hours and minutes; h= hours; min= minutes; GSES= Glasgow Sleep Effort Scale; PSQI= Pittsburgh Sleep Quality Index; PHQ-9= Patient Health Questionnaire; PI= Paradoxical Intention; SH= Sleep Hygiene; M= mean; SD= standard deviation; *= $p \le 0.5$.

effects of PI in reducing GSES scores were also sustained at post-intervention ($F_{1,20}$ = 9.30, p= .006, η^2 = .32; see below Table 4) and 1-month follow-up (see below Tables 5 and 6).

No significant effects were found on actigraphy-recorded sleep parameters in most analyses. The GLM revealed that actigraphy SOL was the only objective outcome that yielded large effect, approaching significance (p=.06, $\eta^2=.16$; see below Table 4). Conversely, sleep diary parameters yielded some significant improvements. The PI group (M=15.00, SD=15.00, U=37.50, z=-1.97, p=.049) reported significantly reduced WASO compared to the control group (M=32.00, SD=25.00; see Table 2). Sleep efficiency as measured from the sleep diary was also significantly better in the PI group ($\eta^2=.22$, p=.03, see Table 3).

Table 3. Between group differences following the normalisation and calculation of relative differences (%) on all sleep and mental health outcomes.

	Variables	Between gro	Between group differences			
	variables	M (SD)	$ES(\eta^2)$	р		
	Lights Out Time	110.32 (46.83)	0.07 ^M	.19		
	Final Awakening Time	100.42 (13.41)	0.004s	.75		
	Time in Bed	97.37 (13.18)	0.06 ^M	.24		
	Sleep Onset Latency RD	-0.10 (0.48)	0.04 ^s	.32		
A	Sleep Period Time	97.67 (12.93)	0.12 ^M	.10		
Actigraphy	Wake After Sleep Onset	107.21 (59.23)	0.01 ^s	.66		
	Sleep Duration	96.95 (11.40)	0.11 ^M	.11		
	Sleep Efficiency	101.03 (7.11)	0.001s	.89		
	Fragmentation Index	114.35 (47.27)	0.01 ^s	.66		
	Composite Score	114.93 (51.43)	0.002s	.84		
	Lights Out Time	104.27 (23.63)	0.04 ^s	.35		
	Final Awakening Time	100.20 (18.73)	0.07 ^M	.21		
	Time in Bed	98.76 (11.68)	0.07 ^M	.20		
	Sleep Onset Latency RD	-0.13 (0.42)	0.08 ^M	.17		
	Sleep Period Time	103.75 (17.50)	0.09 ^M	.16		
Sleep diary	Wake After Sleep Onset RD	-0.25 (0.46)	0.14 ^L	.07		
	Sleep Duration	107.94 (19.73)	0.04 ^s	.37		
	Sleep Efficiency	107.69 (11.81)	0.22^{L}	.03*		
	GSES	64.42 (36.39)	0.30 ^L	.05*		
	PSQI	57.11 (33.18)	0.20 ^L	.03*		
	PHQ-9	61.20 (67.97)	0.06 ^M	.27		

Notes: ES= effect size; GSES= Glasgow Sleep Effort Scale; L = large; M = moderate; M= mean; PHQ-9= Patient Health Questionnaire; PSQI= Pittsburgh Sleep Quality Index; RD = relative difference; S = small; SD= standard deviation; * = $p \le 0.5$.

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No significant group differences in self-reported sleep quality (PSQI) were found at post-intervention. However, the GLM revealed a significant interaction favouring the PI group, with large effect size ($F_{1,20}$ = 8.33, p < .001, η^2 = .49; see Table 4). Moreover,

'able 4. Interaction effects of interventions on actigraphy data, sleep diary	
data and self-reported sleep and mental health questionnaires.	

	Variables	Group-by-time interacti		
	variables	р	$ES(\eta^2)$	
	Lights Out Time	.15	0.09 ^M	
	Final Awakening Time	.52	0.02 ^s	
	Time in Bed	ables p ts Out Time .15 ts Out Time .15 I Awakening Time .52 in Bed .26 p Onset Latency RD .06 p Period Time .23 e After Sleep Onset .45 p Duration .36 p Efficiency .53 mentation Index .91 posite Score .92 ts Out Time .93 I Awakening Time .87 e in Bed .12 p Onset Latency RD .13 p Period Time .28 e After Sleep Onset RD .12 p Duration .11 p Efficiency .27 S .04* I .01* -9 .54	0.06 ^M	
	Sleep Onset Latency RD		0.16 ^L	
tigraphy	Sleep Period Time	.23	0.07 ^M	
tigraphy	Wake After Sleep Onset	.45	0.03s	
	Sleep Duration	.36	0.04 ^s	
	Sleep Efficiency	.53	0.02s	
	Fragmentation Index	.91	0.01 ^s	
	Composite Score	.92	0.00s	
	Lights Out Time	.93	0.00 ^s	
	Final Awakening Time	.87	0.00 ^s	
	Time in Bed	.12	0.12 ^M	
	Sleep Onset Latency RD	pables p tables p the out Time .15 al Awakening Time .52 e in Bed .26 up Onset Latency RD .06 up Period Time .23 tex After Sleep Onset .45 up Duration .36 up Efficiency .53 gmentation Index .91 uposite Score .92 ts Out Time .93 al Awakening Time .87 e in Bed .12 up Onset Latency RD .13 up Period Time .28 tex After Sleep Onset RD .12 up Duration .11 up Efficiency .27 is .04*	0.11 ^M	
	Variables P Lights Out Time .15 Final Awakening Time .52 Time in Bed .26 Sleep Onset Latency RD .06 Sleep Period Time .23 Wake After Sleep Onset .45 Sleep Duration .36 Sleep Efficiency .53 Fragmentation Index .91 Composite Score .92 Lights Out Time .93 Sleep Period Time .87 Time in Bed .12 Sleep Period Time .28 Wake After Sleep Onset .13 Sleep Period Time .28 Wake After Sleep Onset .12 Sleep Duration .11 Sleep Efficiency .27 GSES .04* PSQI .01* PHQ-9 .54	.28	0.06 ^M	
eep diary	Wake After Sleep Onset RD	.12	0.11 ^M	
	Sleep Duration	.11	0.12 ^M	
	Sleep Efficiency	.27	0.06 ^M	
	GSES	.04*	0.19 ^L	
	PSQI	.01*	0.49 ^L	
	PHQ-9	.54	0.24 ^L	

es: ES= effect size; GSES= Glasgow Sleep Effort Scale; ^L= large; ^M= moderate; PHQ-9= ient Health Questionnaire; PSQI= Pittsburgh Sleep Quality Index; ^S= small; *= $p \le 0.5$.

sustained improvements were notable as significant reductions were found in PSQI in the PI group at post-intervention and follow-up (see Tables 5 and 6).

Between group analysis and GLM revealed no significant differences in PHQ-9 scores. However, there were sustained reductions in depressive symptoms from baseline to follow-up noted reported among the PI group (see Table 5).

	follow-up.									
			PI				Coi	ntrol		
Variables	Baseline	Post-I	F-U	γ^2		Baseline	Post-I	F-U	χ^2	
	Md	Md	Md	χ-	P	Md	Md	Md	χ-	р
GSES	8.00	4.00	3.00	15.17	<.001*	7.50	6.00	5.50	0.89	.64
PSOI	12.00	8.00	4.00	20.67	<.001*	9.00	7.00	6.00	4.90	.09

Table 5. Self-reported measures of sleep and mental health outcomes at baseline, post-intervention, and

Notes: F-U= Follow-Up; GSES= Glasgow Sleep Effort Scale; PHQ-9= Patient Health Questionnaire; PI= Paradoxical Intention; Post-I: Post Intervention; PSQI= Pittsburgh Sleep Quality Index; SH= Sleep Hygiene; Md= Median; χ^2 = Chi-square; $*=p \le 0.5$.

.003*

9.00

8.50

6.00 2.26 .32

11.39

Table 6. Main effects and interaction of interventions on the GSES, PSQI and PHQ-9.

Variables	Main effect by groups		Main effect of time		Group-by-time interaction			
	р	ES (η^2)	р	ES (η^2)	р	ES (η^2)		
GSES	.32	0.05s	.01*	0.21 ^L	.08	0.12 ^M		
PSQI	.09	0.14 ^L	.001*	0.33 ^L	.02*	0.18 ^L		
PHQ-9	.13	0.11 ^M	0.21	0.07 ^M	.19	0.08 ^M		

Notes: ES= effect size; GSES= Glasgow Sleep Effort Scale; ^L= large; ^M= moderate; PHQ-9= Patient Health Questionnaire; PSQI= Pittsburgh Sleep Quality Index; ⁸= small; *= $p \le .05$.

DISCUSSION

The aim of this study was to assess the feasibility and preliminary efficacy of internet-delivered PI among adults with insomnia symptoms and high sleep effort, pre-

PHQ-9

10.00

5.00

4.00

selected for elevated sleep effort (sleep performance anxiety) using a validated scale (GSES). The present findings indicated that two sessions of PI focusing on the intention to reduce sleep effort along with two weeks of using PI instructions were feasible. There were 100% adherence and retention rates among the PI group throughout the study period. Moreover, findings of the preliminary analysis suggest that PI sessions had positive effects on sleep effort, self-reported sleep parameters including WASO and SE, perceived sleep outcomes and depressive symptoms.

To the authors' knowledge, this study is the first to demonstrate the effectiveness of online-delivered PI on improving sleep effort using a validated measure, GSES. Findings showed that there was a significant GSES score reduction among the PI group compared to the SH group at post-intervention, suggesting that participants allocated to PI reported lesser attempts of initiating night-time sleep, thus having reduced sleep effort. This remained statistically significant across time and when baseline differences were accounted for, yielding large effect sizes. The improvement in sleep effort is further reflected by the decrease in self-reported WASO and SOL. This finding supports the notion that PI alleviates insomnia symptoms severity by reducing voluntary attempts at initiating sleep (Broomfield & Espie, 2003; Ascher & Turner, 1979).

Moreover, our findings demonstrated an improvement in both objective and selfreported sleep parameters. At post-intervention, the PI group presented with reduced WASO and SOL as well as increased SE compared to the SH group. Despite this, only the sleep diary WASO obtained statistical significance. After normalisation to baseline, similar trends were found in which sleep diary WASO and SOL were reduced and SE increased. Although moderate to large effect sizes were found, only the sleep diary SE reached statistical significance. Notably, however, sleep diary WASO and SOL approached near significance. These findings are in line with previous evidence supporting the effectiveness of PI in improving self-reported sleep initiation and sleep maintenance (Broomfield & Espie, 2003; Ascher & Turner, 1979, 1980). Nevertheless, our findings warrant for further studies to be conducted in a larger sample size given that preliminary analyses of the effects of PI demonstrated improvement in both objective and self-reported sleep parameters, with near significance and at least moderate effect sizes obtained for sleep diary outcomes.

Improvements in PSQI scores were observed among the PI group at postintervention. Although the between group analysis yielded near-significant values for the change in PSQI scores, further exploratory analyses indicated that the changes were significant and yielded large effects. The direction of score changes demonstrates that individuals who received PI reported a positive change in self-reported sleep quality, and this finding is in line with past evidence indicating the effectiveness of cognitivebehavioural interventions for insomnia on perceived sleep quality (Espie, MacMahon, Kelly, Broomfield, Douglas, & Engleman, 2007; Buysse *et alii*, 2011; Taylor *et alii*, 2014).

Similar trends were observed in the PHQ-9 scores, whereby the severity of depressive symptoms in the PI group reduced, as indicated by the average scores decreased from mild severity (M= 9.69) to non/minimal severity (M= 4.69). Like the PSQI scores, significant findings were only observed in the exploratory analysis. Nevertheless, the results indicate that PI may improve depressive symptoms alongside perceived sleep quality. This finding supports the results of previous research demonstrating the effectiveness of sleep-focused interventions, such as CBT-I, in treating depression (Cunninghan & Shapiro, 2018; van der Zweerde, Straten, Effting, Kyle, & Lancee, 2018).

This study has both clinical and research implications. Firstly, the acceptability and preliminary efficacy outcomes of the study support the original approach by Ascher and Efran (1978) in which PI can be administered as a brief cognitive-behavioural intervention with the rationale of "trying to stay awake by gently resisting sleep

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onset" to reduce high sleep effort. Whilst CBT-I remains as the first-line intervention for insomnia, our findings suggest that PI could be used as an alternative standalone approach, particularly for adults with insomnia symptoms who also present with high sleep effort and depression (Jansson-Fröjmark *et alii*, 2021). The preliminary efficacy of PI is further strengthened by the positive, moderate to large effect sizes yielded when outcomes were compared to an active control condition, consistent with a recent review finding (Jansson-Fröjmark *et alii*, 2021). Our suggestion that PI be used as a standalone therapy would be contingent on clarifying the extent of the insomnia population who show high sleep effort. This is not yet known.

Furthermore, these promising findings resulted from the delivery of internet-based PI, which, to the authors' knowledge, is also the first of its kind. Although this delivery format was adopted to adhere to the COVID-19 pandemic restrictions, it had several benefits. For one, our findings support the notion that internet-based interventions including therapist contact and individualised guidance can ensure adherence and therapeutic efficiency (Andersson & Titov, 2014). Session engagements and participant collaboration were also further enhanced by the incorporation of in-built platform functions (e.g., share screen, whiteboard) during sessions. Notably, the use of digital sleep interventions are not uncommon. More recently, CBT-I has also been delivered via the internet. Not only has this improved the accessibility of sleep interventions, internet-based CBT-I is also cost-effective with high treatment efficiency (Soh, Ho, Ho, & Tam, 2020). A recent meta-analysis of 15 RCTs reported that internet-based CBT-I had significantly positive and sustained effects in reducing insomnia severity and improving sleep parameters including sleep onset latency, total sleep time, wake after sleep onset, sleep efficiency and number of nocturnal awakenings (Ye et alii, 2016). Hence, further research should investigate the effectiveness of PI in larger RCTs, adopting both conventional face-toface and online approaches.

Finally, the lack of agreement between actigraphy and sleep diary data adds to evidence that there may be discrepancies between sleep-wake misperceptions (Lund, Rybarczyk, Perrin, Leszczyszyn, & Stepanski, 2013; Te Lindert *et alii*, 2020), in which may be independently associated with age factors (Valko, Hunziker, Graf, Werth, & Baumann, 2021). Both types of measures may reflect varying aspects of sleep quality, and whilst this highlights the importance of utilising both objective and self-reported measures of sleep quality, this also calls for future studies to identify possible factors that may explain the inconsistencies of association between both measures.

This study has several limitations. First, all phases of the study were conducted by the primary researcher. As this included intervention delivery and data analysis, double blinding was not achieved. With all intervention sessions being led by the same researcher, there may have been an increased risk of researcher bias favouring the intervention group. Nevertheless, the inclusion of a control which involved similar delivery format and engagement as the sleep intervention may have minimised this risk. Moreover, given that full blinding is difficult in psychological intervention studies, personal reference codes were given to all participants and used throughout the study. The control condition was a single session of sleep hygiene mismatched to PI on duration thus it could be argued it was a passive rather than active treatment comparator. Our study was not pre-registered. For pragmatic purposes, we used a self-report inventory (SCI) rather than a clinical interview to determine inclusion. Consistent with most previous PI studies, insomnia symptoms were measured using sleep diary and wrist actigraphy, not SCI. Furthermore, we used GSES as the primary outcome, raising the possibility of response bias whereby given the PI intervention, the participants may have felt compelled to report a reduction in sleep effort. Confirmation bias may also have been present as statistical analyses were conducted by the same researcher. However, the primary

researcher received regular supervision from the secondary research supervisor (ASL) to ensure that all analyses were conducted and interpreted appropriately. Excluding hypnotic users and individuals receiving psychological treatment may limit generalisability of the findings. Future studies should consider involving a larger research group with allocation of tasks between randomisation, delivery of intervention and data analyses.

Another potential limitation is that the feasibility and acceptability rates were not set *a priori* (Teresi, Yu, Stewart, & Hays, 2022). Nevertheless, the small sample size (n= 24) yielded moderate to large effect size in both primary and secondary outcomes, indicating a reasonable degree of practice significance.

Multiple comparisons/family-wise errors were also not corrected. However, given that this study was designed as a feasibility pilot study, only the outcomes of effects sizes were interpreted. Moreover, the lack of corrections may improve the sensitivity of the study (e.g., avoiding false negatives or type 2 statistical error) as well as detect potential effects that could be trialled in future studies with powered sample sizes.

Overall, findings of the present study provide support for the feasibility and preliminary efficacy of using PI as a single component sleep intervention to reduce sleep effort among adults with insomnia symptoms. Moreover, this study demonstrated the potential use of internet-based PI in delivering sleep intervention for insomnia symptoms remotely. Future studies with a larger RCT are needed to establish the sustained efficacy of PI on both objective and self-reported sleep quality as well as depression outcomes.

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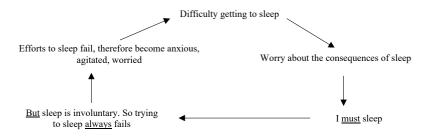
Received, September 10, 2024 Final Acceptance, December 10, 2024

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APPENDIX A

Instructions for Paradoxical Intention

Sleep is a natural process which happens involuntarily. This means that you cannot make yourself fall asleep, rather, sleep must occur naturally. And if you try to switch sleep on, you could switch it off. People who actively try to control their sleep often find it difficult to fall asleep because their aroused state of mind disrupts the natural sleep process. Not being able to sleep, people may start feeling worried about losing sleep, which in turn urges them to try even harder to fall asleep. This can put them in a cycle of struggling to sleep and eventually worsen their sleep problem.



The more you try to control your sleep, the less likely you are able to fall asleep. By giving up trying to sleep, your sleep pattern should improve. This is what we would like you to do in this study.

For the next 14 nights, test giving up trying to sleep when you go to bed at night. Instead, we want you to try staying awake. Paradoxically, staying awake should help you get to sleep more quickly because it stops you from trying hard to fall asleep and worrying about losing sleep. Here's how you can try to stay awake:

- 1. As you go to bed tonight, lie down comfortably in your bed with the lights off, but keep your eyes open.
- 2. Give up any effort to fall asleep and any concerns about still being awake.
- 3. When your eyelids feel like they want to close, say to yourself gently "Just stay awake for another couple of minutes, I'll fall asleep naturally when I'm ready."
- 4. If at any stage you feel worried or irritable at not sleeping, remind yourself "Staying awake will help me get to sleep quicker" and "The plan is to remain awake so I'm doing fine."
- 5. Try to stay awake for as long as you can.
- <u>Do not</u> purposefully make yourself stay awake, but if you can shift the focus off attempting to fall asleep, you will find that sleep comes naturally.

The above instructions may take time to have an effect on your sleep. Continue to have patience and perseverance as you follow the instructions to stay awake for the next 14 nights. Good luck!

APPENDIX B

Sleep Hygiene Instructions

"Sleep hygiene" refers to healthy sleep habits. Good sleep hygiene helps you fall asleep at night and improve your sleep quality. Here's how to develop good sleep hygiene:

1. Avoid caffeine.

• Caffeinated beverages and food (e.g. coffee, tea, soft drinks, chocolate) can cause difficulty falling asleep, night awakenings and poor sleep. Try to cut down on all caffeine products as even caffeine in the day can disrupt night-time sleep.

2. Avoid nicotine.

• Nicotine is a stimulant which can disrupt sleep. Try to avoid smoking, especially during the night, if you have trouble with your night-time sleep.

3. Avoid alcohol.

Try to refrain from drinking alcohol, especially during the night. Although alcohol can help people fall
asleep more easily, it increases arousal during the second half of the night which induces overnight
awakenings.

4. Exercise regularly.

- Exercises makes it easier to initiate sleep and deepen sleep. However, schedule exercise times so that
- they do not occur within 2 hours of going to bed which may make it more difficult to fall asleep.
- 5. Manage stress.
 - Worrying can keep you up at night, which makes it difficult for you to fall asleep and achieve deep sleep. Avoid taking your worries to bed. You may find it useful to assign a "worry time" earlier in the evening to address any problems or create a "worry diary" to write down your problems.

6. Have a comfortable sleeping environment.

 A comfortable, noise-free sleep environment will reduce the likelihood that you will wake up during the nights. Although it is possible to get used to background noises, it may disturb the quality of your sleep.

7. Maintain a regular sleep timing.

- Only sleep as much as you need to feel refreshed the next day. Excessively long periods in bed can result in fragmented sleep.
- Have a regular morning wake time, no matter how little you slept the night before, seven days a week. This helps you have a regular sleep timing at night.

8. Avoid daytime naps.

Sleeping a lot during the day will affect your ability to fall asleep at night. If you do need a nap, try to
limit it to 15 minutes. This should prevent you from going into deep sleep which would usually make it
more difficult for you to wake up.

For the next 14 nights, try incorporating these healthy sleep habits to improve your sleep. It may be difficult to do all changes immediately and at the same time. They may also take time to have an effect on your sleep. Continue to have patience and perseverance as you follow the instructions (as relevant to you). Good luck!