The impact of a cognitive behavioural pain management program on sleep in patients with chronic pain: Results of a pilot study

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Abstract

Objective:

To determine the impact of a cognitive behavioural pain management programme on sleep in patients with chronic pain.

Design

Prospective non-randomised controlled pilot study with evaluations at baseline and 12 weeks

Setting

Out-patient multidisciplinary cognitive behavioural pain management programme in a university teaching hospital

Subjects

Patients with chronic pain who fulfilled the criteria for participation in a cognitive behavioural pain management programme.

Methods

Patients assigned to the intervention group (n=24) completed a four week cognitive behavioural pain management programme, and were compared with a waiting list control group (n=22). Assessments for both groups occurred at baseline and two months post cognitive behavioural pain management programme. Outcome measures included self-report (Pittsburgh Sleep Quality Index) and objective (actigraphy) sleep measures, pain and quality of life measures.

Results

Both groups were comparable at baseline, and all had sleep disturbance. The Pittsburgh Sleep Quality Index correlated with only two of the seven objective sleep measures (fragmentation index r=0.34, p=0.02, and sleep efficiency percentage r=-0.31, p=0.04). There was a large treatment effect for cognitive behavioural pain management programme group in mean number of wake bouts (d=0.76), where a significant group*time interaction was also found (p=0.016), showing that the CBT-PMP group improved significantly more than controls in this sleep variable

Conclusions

Patients attending a cognitive behavioural pain management programme have high prevalence of sleep disturbance, and actigraphy technology was well tolerated by the patients. Preliminary analysis of the impact of a cognitive behavioural pain management programme on sleep is promising, and warrants further investigation.

Key words:

Sleep, cognitive behavioural therapy, pain management programme

INTRODUCTION

Reduced quality of life (QOL) and sleep quality are common complaints in patients suffering from chronic pain [1,2]. It is estimated that between 50-59% of people with chronic low back pain have sleep disturbance [3,4], leading to poor daytime function and greater sleep dissatisfaction and distress [5]. Increasing evidence suggests a deteriorating cycle of pain and sleep. Pain can lead to poor sleep which in turn may result in increased next day pain, leading to further problems with next night sleep, as reported in other pain conditions such as burns and fibromyalgia [6-8].

Cognitive behavioural therapy pain management programmes (CBT-PMP) are widely used in the non-pharmacological treatment of chronic non-malignant pain [9-11]. The efficacy of this model of care in terms of improving QOL, reducing the pain experience, improving pain behaviours and general daily functioning has been established [10-12]. There is, however, limited objective evidence for it's effect on sleep quality in this patient cohort. Currie et al [13] investigated the effect of a CBT-PMP on objective sleep quality however this study only used two nights of objective data which may not be enough to provide a reliable sleep quality pattern [14].

Whether cause or consequence, sleep disorder must be taken into account in the overall management of the patient in the same way as pain [15], as it has been hypothesised that better daytime pain control may lead to improved sleep quality [16]. Poor sleep quality has been associated with lower pain thresholds, an increase in pro-inflammatory cytokines and a reduction in physical function. Psychologically people's mental capacity to manage pain is lowered with increased risk of anxiety disorders and alcohol abuse. Depression is also strongly associated with disturbed sleep patterns in patients with chronic pain [17,18].

This pilot study was undertaken to determine the impact of a CBT-PMP on sleep quality compared with a waiting list control (WLC) group. The aim of this pilot is to (i) to determine the relationship between subjective and objective sleep variables and other outcome measures

(physical and psychological) measures, (ii) to explore between group differences in changes to objective and self-report sleep measures in patients two months after completion of a CBT-PMP, (iii) to evaluate the feasibility of using equipment to measure sleep in an RCT.

METHODS

This prospective non-randomized between-groups pilot study with two time points (baseline, two month follow-up) involved patients who fulfilled the inclusion criteria for the CBT-PMP and were on the waiting list. Full ethical approval was granted from the Ethics Committee, Adelaide and Meath Hospital, Tallaght, Dublin 24. Whilst formal power calculations are not required for a pilot study we aimed to recruit 24 patients for each study arm.

Potential participants were given written and verbal information regarding the study and invited back to the pain clinic one week later where, after all questions had been answered, written consent was obtained. Participants then completed the Pittsburgh Sleep Quality Index (PSQI). Those patients with a sleep disturbance (PSQI >5) were assigned to either the intervention group (immediate CBT-PMP treatment), or WLC group (deferred treatment). Assignment was managed based on where the patients appeared on the CBT-PMP waiting list i.e. patients in the WLC group were listed for a CBT-PMP that was more than six months away. Group membership was concealed from the principal investigator who completed all the assessments.

All participants completed self-report questionnaires and underwent the timed functional outcome measures to obtain a baseline measure of pain, function, mood and sleep. Subjects were also given the Actiwatch to wear for seven days (24 hours a day). Twelve weeks later all participants repeated the battery of tests.

Control group:

Patients in the WLC group underwent the same recruitment process as the study participants in terms of giving consent, completing the outcome measures and wearing the Actiwatch. After 12 weeks of usual care the WLC group repeated the battery of tests.

The Cognitive Behavioural Therapy Pain Management Programme

The multi-disciplinary CBT-PMP provides the patient with multiple therapies involving comprehensive rehabilitation in each of the specialized areas [19]. The core multi-disciplinary team includes a pain management physician, a senior occupational therapist, a senior physiotherapist and a senior clinical psychologist. All have specialist training in the management of patients with chronic pain.

The programme runs three days a week (six hours per day) for four weeks (six to eight patients per group) with review sessions held two and six months post-programme completion. Outside of the three days of the programme patients are expected to practice cognitive behavioural therapy (CBT) skills e.g. pacing, goal setting, and undertake daily relaxation and exercise sessions, and note these in a weekly diary. The programme is based on principles of Fordyce [19] and Turk [20], and incorporates operant and cognitive behavioural principles across all specialties. The programme aims to identify and change unhelpful thoughts and beliefs; promote relaxation, and help to change habits that contribute to disability [21, 22].

The CBT-PMP comprises daily physiotherapy sessions (one and a half hours): two sessions are gym-based (patient-driven quota-based programme), and one session in the hydrotherapy pool (progressive strengthening programme). Occupational therapy sessions (one and a half hours daily) focuses on promoting energy conservation techniques and developing pacing strategies for activities of daily living. Daily group psychology sessions focus on CBT principles, and identifying and changing maladaptive behaviours. A number of sleep hygiene and behavioural strategies are also recommended: (i) sleep environment (a quite dark room and comfortable bed using pillows to support back and legs if necessary, (ii) foods and substances (avoid nicotine,

caffeine, alcohol and a large meal before bedtime), (iii) sleep schedule (get up and go to bed at the same time, if sleep does not come get up and practice relaxation techniques, avoid daytime napping), and (iv) exercise (avoid exercising physically or mentally e.g. reading or working close to bed time).

Pain medicine consultants give weekly one hour lectures on a range of topics including explanations of the pain gate control theory; they reinforce CBT-PMP principles and discuss medication reduction strategies.

A programme manual supports all components of the programme and the patients systematically work through the multidisciplinary information during the programme.

Outcome Measures

In line with best practice recommendations a broad range of categories were measured. Pain [numerical rating scale, (NRS)] [23], physical function (Simmond's functional tests) [24], emotional function [Hospital Anxiety and Depression Scale (HAD-A and HAD-D) [25], Tampa scale of Kinesophobia, (TSK)] [2], QOL [Short Form 36 (SF-36)] [27], participant global impression of change and satisfaction [28, 29], and adverse events and compliance (attendance at follow-ups).

Sleep

Both subjective and objective sleep assessments methods were included due to the only modest correlation scores between them and the need to capture both dimensions of sleep disturbance [30, 31].

The Pittsburgh Sleep Quality Index

The Pittsburgh sleep quality index (PSQI) assesses sleep quality [32]. It comprises seven subscales: sleep quality, sleep onset latency, sleep duration, sleep efficiency, sleep

disturbances, use of sleep medications and daytime dysfunction. It is scored between zero and 21, with a global score of greater than five indicative of a sleep disorder. The tool has a sensitivity of 98.7 and specificity of 84.4 [33].

Actigraphy

Sleep quality was measured objectively using the Actiwatch AW7a. This compact and lightweight 'watch-like' electronic device worn on the non-dominant hand records physical motion in all directions which is then analysed for activity and sleep data. Activity is measured in counts; the number of counts is proportional to the intensity of the movement. The peak intensity of the movement in each second is summed into a user selectable epoch. Recorded epoch length range between two seconds-15 minutes with shorter the epoch lengths providing more accurate data. In line with recommendations data were recorded for seven days using a 30 second epoch length [34].

The Actiwatch software calculates seven sleep variables: sleep efficiency % (actual sleep time / time in bed), wake after sleep onset % (% of the amount of wake time as determined by an algorithm after actual sleep onset), sleep onset latency (latency before sleep onset following bed time), actual sleep % (% of the amount of sleep as determined by an algorithm equivalent to assumed sleep minus wake time), mean night-time activity (mean activity count per epoch), fragmentation index (The addition of % minutes moving' and 'percentage immobility'- an indicator of restlessness), number of wake bouts (number of episodes of wakefulness).

Data Analysis

All data were coded, entered into SPSS v20 [35], and subsequently cleaned. Raw data from the Actiwatch were screened prior to analysis for missing values and/or malfunction of the device.

The sleep variables were automatically calculated using the Actiwatch software (Sleep V7.27 analysis software b), using the 30 second epoch length sensitivity.

Continuous data were screened for normality and no significant deviations from the normal distribution were noted except for sleep latency (Kolmorogov Smirnov test). Pearson's correlation coefficients assessed baseline associations between the subjective and objective sleep measures (actiwatch and PSQI) and between the sleep measures and other constructs. The correlation matrix was reported, with statistical significance set at $p \leq 0.05$. Stepwise backwards regression models were then constructed to identify combinations of variables associated with the PSQI and fragmentation index with R2 values representing the proportion of variance of the dependent variable explained by the predictors. Models were selected on the basis of fit (F test; variable excluded if $p > 0.1$) and parsimony.

To assess differences in sleep variables two months after completion of the PMP, between the CBT-PMP and WLC control groups, Cohen's d effect sizes were calculated for change between groups and a MANOVA model assessed the overall difference between the groups in the multivariate sleep construct comprised of subjective and objective measure, following which differences in individual measures were explored with two factor ANOVA models. The pre to follow up measures represented a repeated time factor and treatment the group factor. A significant group*time interaction was taken to demonstrate difference in response between the intervention and WLC groups. Correlation (Spearman's Rank Order) was also performed to assess relationship between change in sleep outcomes and patient satisfaction.

RESULTS

Participants

Participant flow and retention are summarised in Figure 1. Twenty-four patients were included in the CBT-PMP group: male (n=11), females (n=13). The mean age was 47.7 (±11.5)

years, with a history of chronic pain for 6.9 (±6.6) years. More than three quarters (79%, n=19) of patients reported having pain in two or more locations, with low back pain frequently involved (n=19, 79%). Only a minority reported taking any pain medication. Fidelity to the programme was high with all CBT-PMP patients completing the intervention, and all bar one attended the 12 week follow-up session.

Twenty-two WLC patients were included in this study: male (n=6), female (n=16). The mean age was 46.8 (±13.2) years, with a history of chronic pain for 7.9(±5.4) years. More than three quarters of patients (77%, n=17) had pain in two or more locations, with low back pain frequently involved (n=13, 59%). Again, only a minority reporting taking any pain medication. One WLC group patient was unable to wear the activity watch at follow-up but all other outcome measures were completed.

Participant's baseline demographics according to group allocation are summarised in Table 1.

Baseline Data

No significant difference was found between the CBT-PMP and the WLC group in terms of demographics (age, gender, number of years with pain, smoking and employment status), except that patients in the trial group took more daily non-steroidal medication than those in the control group (trial n=8, control n= 0, p=0.001). Similarily, no significant differences were found between groups regarding baseline physical, psychological and sleep quality scores except that patients in the CBT-PMP group had higher levels of depression (HADS-D, $p<0.05$).

(i) Relationship between sleep quality and physical and psychological outcome measures

Table 2 illustrates the correlation coefficients describing the baseline relationships between sleep quality, pain, physical and psychological measures.

The PSQI correlated with only two of the seven objective sleep measures (fragmentation index r=0.34, p=0.02, and sleep efficiency percentage r=-0.31, p=0.04).

Poor subjective sleep quality (PSQI) was associated with low mood HADS-A (r=.41, p=0.005), HADS-D (r=0.40, p=0.005), and fear of re-injury -TSK (r=0.40, p=0.002). It was also associated with lower measures of QOL: [SF36MCS r=-0.37, p=0.006, SF36PCS r=-.33, p=.035) and increased pain (NRS r=0.43, p=.005)].

Objective sleep measures (actigraphy) however were not generally associated with mood except for HADS-A which correlated with fragmentation index (r=.37, p=0.01), and HADS-D which correlated with actual sleep percentage (r=-.30, p=0.001), fragmentation index (r=.39, p=0.007) and wake after sleep onset (r=.29, p=0.05).

Similarly lower QOL scores (SF36MCS) were only associated with one of the actigraph measures: FI (r=-0.34, p=0.023).

No significant association was found between the PSQI or Actigraph measures and physical function (Simmonds's functional tests).

On the basis of results of bivariate correlation, the subjective PSQI and objective Fragmentation Index were the sleep variables most associated with the clinical measures of pain, physical and psychological function, so further analysis focused on identification of predictors of these two sleep indices using backwards stepwise linear regression. The physical and psychological predictor variables were entered in step one and then eliminated if they did not contribute significantly to model fit, using a criterion of p ≥0.1 until the best fitting and most parsimonious model was achieved. Pain intensity (NRS), anxiety (HADS-A), and TSK explained 35.4% of the variance in the global PSQI score. Depression (HADS-D) and TSK explained 21% of the variance in the sleep fragmentation index (Table 3).

(ii) Impact on Sleep Quality two months post completion of CBT-PMP

At baseline no differences were found between the CBT-PMP group and WLC for self-report (PSQI) and objective (actigraphy) measures ($p>0.05$). At the two month follow up MANOVA showed that there was no overall significant difference in the sleep outcome between the groups (Wilks lambda =0.772, F=1.293, p=0.279), but, the CBT-PMP group improved significantly more than WLCs in terms of the number of wake bouts recorded (p=0.016) with a large treatment effect (d=0.76) (Table 4).

Impact of CBT-PMP on Function and Mood

While not the main focus of this investigation, changes in secondary outcome measures from baseline to two month follow up were compared between CBT-PMP and WLC groups to provide context for exploration of sleep measures (Table 4). The CBT-PMP group had significant improvements in the HADS-A, HADS-D and TSK ($p<0.05$) compared with the WLC.

Satisfaction with CBT-PMP

Improved sleep quality (PSQI) was associated with increased patient satisfaction with the CBT-PMP in that satisfaction rating were correlated with changes in patient's PSQI scores (Spearman's rho=0.42, p=0.04).

(iii) Feasibility of equipment

The actigraphy as a measure of sleep was successful in measuring sleep. The patients found it easy to apply and use, and had access to the researcher via mobile phone if they had issues with the equipment, so almost no issues arose. Only one patient in the WLC group reported a difficulty at follow-up leading to a loss of valid Actiwatch data. The protocol of sending and receiving the actiwatches by registered post worked well and no watches were lost / broken throughout the study. The patients did not find the actiwatch intrusive.

DISCUSSION

Principle Findings

This pilot study found that sleep disturbance is a common problem for people with chronic pain attending a CBT-PMP. With regards to sleep measurement only two of the seven objective sleep measures (actigraphy) correlated with the self-report measure of sleep (PSQI). Participants who completed the CBT-PMP had significantly fewer number of wake bouts than the WLC. We also report on the feasibility of using actigraphy as a means of measuring sleep in patients with chronic pain.

All patients screened were classified as having sleep disturbance (PSQI>5), demonstrating that sleep is a significant issue for patients with chronic pain and reflect rates reported elsewhere [13,36,37]. This would suggest that recruitment of patients with sleep disturbance for a future RCT would not be a significant issue.

Sleep disturbance in chronic disease has been reported in patients with chronic abdominal pain,[38] chronic low back pain [39], and musculoskeletal pain [40]. However, a limitation of these studies is that sleep disturbance was investigated using either just using self-report or objective measures of sleep for a maximum of three nights only rather than the seven night period recommended by the American Academy of Sleep Medicine [41]. The current study has addressed this limitation by monitoring sleep over a seven night period.

The low pattern of correlations between baseline self-report (PSQI) and objective sleep measures (actigraphy) found in our study is clinically important, and suggests the need to measure both aspects when investigating sleep disturbance, as one quantifies sleep, while the other assesses a person's perception of their sleep pattern which has been shown to correlates with their pain scores i.e. if a person feels sleep deprived their pain is worse. Other authors have reported similar low correlations between both aspects of sleep measurement in patients with primary insomnia and in recovering alcoholics [42-44]. Of interest is that this pattern is similar to that reported in other core outcome measures used in research of chronic pain e.g. physical

function and mood where self-report and objective measures correlate moderately at best [25,45].

The current study is based on the assumption that pain experienced in a chronic pain population is the primary cause for their poor sleep quality. The development of co-existing behavioural habits surrounding their beliefs about pain, and their coping strategies for pain may result in exacerbation and/or maintenance of their sleep disturbance and a reduction in their QOL. The aim of a CBT-PMP is not to focus on a patient's pain, but on these co-morbid factors, and interestingly, the relationship between sleep and physical and psychological measures established in the current study provides further validation that treatment of these co-existing co-morbidities may have a positive effect on sleep quality in this patient population. Similar findings have been reported in CBT-PMPs for recovering alcoholics [43].

We found evidence of a positive treatment effect in favour of CBT-PMP in a range of sleep variables including subjective PSQI, and objective measures (sleep efficiency, mean activity and fragmentation index). The greatest statistically significant effect for CBT-PMP over WLC was in mean number of wake bouts (d=0.76). In fact, these improvements on self-report sleep and reduced number of sleep bouts through the treatment of behavioural problems demonstrates the benefits of such a programme for patients with sleep disturbance, and justify the need for a fully-powered RCT. Little previous research into the effect of CBT-PMPs on sleep quality in patients with chronic pain has been undertaken. To our knowledge the only other study is by Currie et al [13] whose results are limited as they only described the treatment effects on one of the seven main actigraphy measures (mean activity which significantly improved for the CBT-PMP group) over a two night period, rather than the recommended seven nights (including weekends) in order to obtain reliable patterns of sleep quality.

The use of actigraphy over seven nights proved successful in monitoring patients sleep. This technology has gained popularity in the past decade and is now quite often substituted as a less expensive, less intrusive alternative to the gold standard polysomnography for the assessment of sleep in a range of diagnoses e.g. insomnia patients [46], children and adolescents [47], and

the elderly [48]. The high level of compliance with the actigraphy in our study supports it use as a suitable, cheap and user-friendly apparatus for monitoring sleep.

Limitations of this study include the small sample size and the low statistical power which limits the results. However, they are justified in that this was a pilot study. In addition the participants were not randomized but managed based on where they appeared on the waiting list for participation in the CBT-PMP.

Conclusion

Sleep disturbance is high in people with chronic pain. Improvements on self-report sleep and reduced number of sleep bouts through the treatment of behavioural problems demonstrates the benefits of a CBT-PMP, and thus, sleep should be routinely included as an outcome measure. Patients high level of compliance with the programme, and of monitoring of their sleep and other QOL measures suggests that the methodologies utilised in this pilot study are appropriate for this patient cohort.

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Conflict of interest / disclosure summary: The authors declare that they have no conflict of interests

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Suppliers

a Actiwatch AW7 (Cambridge Neurotechnology). CamNtech Ltd. Upper Pendrill Court, Ermine Street North, Papworth Everard, Cambridge, CB23 3UY, United Kingdom

Table 1 Participant Demographics

Demographics	**Trial Group**	**WLC Group**	**P-value**
Male n, (%)	11 (46)	6 (27)	0.32 *
Female n, (%)	13 (54)	16 (73)	
Age- years [(mean (sd)]	47.7(11.5)	46.8(13.2)	0.56 **
Pain duration [years, mean (sd)]	6.9 (6.6)	7.9 (5.4)	0.80**
Pain- NRS, mean (sd)	5.8 (2.1)	5.4 (2.1)	0.54 **
Smoker n, (%)			
Yes	6 (25)	7 (32)	
No	18 (75)	15 (68)	0.85 *
Employment Status n, (%)			
Employed	8 (33)	7 (32)	0.91 *
Disability	10 (42)	7 (32)	
Student	-	1 (4)	
Retired	1 (4)	3 (14)	
Pain Locations, n (%)			
One location	5 (21)	5 (23)	0.94*
Two locations	8 (33)	8 (36)	
Three or more locations	11 (46)	9 (41)	
Lower Back n (%)			
Involved	19 (79)	13 (59)	
Not-involved	5 (21)	9 (41)	0.25*
Pain Medications n (%)			
Opioids	5 (21)	4 (18)	0.82*
Anti-depressants			
Daily	4 (17)	4(18)	0.62*
As needed	1 (4)		
Anti-convulsants	8 (33)	6 (27)	0.65*
NSAIDs			0.01* (a)
Daily	8 (33)	0	
As needed	0	3 (14)	
Paracetemol			0.19*
Daily	4 (17)	1 (4)	
As needed	4 (17)	8 (36)	
Co-codamol			0.38*
Daily	2 (8)	0	
As needed	1 (4)	1 (4)	
Benzodiazepines	2 (8)	1 (4)	0.60*

NRS- Numerical Rating Score, WLC- Waiting list control, P-value- for difference between trial and control group, * Chi^2 test, ** Independent Samples T-test (a)-significant difference between Trial group and WLC

Table 2. Baseline correlations between sleep quality measures and physical and psychological scores

LEGEND

N=46	Actual sleep %	Sleep Efficiency	Sleep Latency	Wk bouts	Mean act	FI	WASO	PSQI	HADA	HADD	NRS	TSK	STS	RO	SF36 MCS	SF3 PCS
Sleep %	-															
Sleep Eff	.84**	-														
Sleep Lat	-.43**	-.83**	-													
Wk bout	-.65**	-.46**	-	-												
Mean act	-.89**	-.74**	-.36*	.40**	-											
FI	-.81**	-.75**	.48**	.58**	.65**	-										
WASO	-.99**	-.83**	.43**	.65**	.90**	.81**	-									
PSQI	-	-.31*	-	-	-	.34*	-	-								
HADA	-	-	-	-	-	.37*	-	.41**	-							
HADD	-.30*	-	-	-	-	.39**	.29*	.40*	.55**	-						
NRS	-	-	-	-	-	-	-	.23**	-	.36*	-					
TSK	-	-	-	-	-	.30*	-	.40**	-	-	-	-				
STS	-	-	-	-	-	-	-	-	-	-	-	.39**	-			
RO	-	-	-	-	-	-	-	-	-		-		.68**	-		
SF36MCS	-	-	-	-		-.34*	-	-.37**	-.62**	-.55**	-	-	-	-	-	
SF36PCS	-	-	-	-	-	-	-	-.33*	-	-.40**	-	-	-.32*	-	-	-
											.39**					

%=Percentage, Eff.=Efficiency, LAT=Latency, Wk Bouts=Wake bouts, act=Activity, FI=Fragmentation Index, WASO=Wake after sleep onset, PSQI=Pittsburgh sleep quality index, HADA=Hospital anxiety and depression scale – Anxiety, HADD=Hospital anxiety and depression scale – Depression, NRS=Numerical rating scale, TSK=Tampa scale of kinesophobia, STS=Sit to stand, RO=Rollover, SF36MCS=Short form 36 mental component score, SF36PCS=Short form 36 physical component score

Table 3. Relationship between Sleep, Physical and Psychological Outcome Measures

	Regression coefficient	**Standard error of coefficient**	**t statistic**	**P value**	**R^2**
Global PSQI					
Constant	1.394	2.902	0.480		
HADSA	0.267	0.109	2.370	0.022	
NRS	0.525	0.240	2.190	0.034	
TSK	0.142	0.068	2.098	0.042	0.354
Fragmentation Index					
Constant	10.844	10.801	1.004	0.321	
HADSD	0.988	0.390	2.535	0.015	
TSK	0.435	0.250	1.737	0.090	0.210

LEGEND

HADA=Hospital anxiety and depression scale – Anxiety, NRS=Numerical rating scale, TSK=Tampa scale of kinesophobia, PSQI=Pittsburgh sleep quality index

Table 4 Baseline and Two-Month Follow-Up Data for Trial and Control Group

Variable	**Group**	**Pre**	**Follow-up**	N	**Effect size***	**Significance group* time interaction**
		Mean (SD)	**Mean (SD)**		**Cohen's d**	
HADS Anxiety	Trial	11.1 (3.9)	8.9 (3.4)	24	0.61	$F_{1,44}$=4.254
	WLC	8.7 (3.8	8.7 (4.8)	22		p=0.045
HADS Depression	Trial	11.9 (3.7)	9.8 (3.7)	24	0.67	$F_{1,44}$=4.947
	WLC	8.1 (4.9)	7.9 (4.5)	22		p=0.031
TSK	Trial	42 (6.9)	36.1 (5.8)	24	1.06	$F_{1,44}$=12.676
	WLC	43.2 (7.7)	43.0 (7.9)	22		p=0.001
SF-36 PCS	Trial	31.3 (6.9)	31.8 (7.4)	24	0.27	$F_{1,44}$=0.783
	WLC	35.7 (8.2)	34.1 (8.6)	22		p=0.381
SF-36 MCS	Trial	33.6 (9.5)	39.9 (10)	24	0.31	$F_{1,44}$=1.083
	WLC	33.8 (16.4)	37.1 (13.9)	22		p=0.304
STS (seconds)	Trial	23.2 (12.4)	21.2 (11.5)	24	0.44	$F_{1,44}$=2.196
	WLC	20.6(17.4)	20.5 (18.8)	22		p=0.145
360° Rollover (secs)	Trial	14.7 (9.5)	13.0 (8.5)	24	0.46	$F_{1,44}$=2.238
	WLC	13.6 (5.8)	13.8 (6.5)			p=0.137
NRS	Trial	5.8 (2.1)	6.1 (2.1)	22	-0.12	$F_{1,44}$=0.172
	WLC	5.4 (2.1)	5.1 (1.5)	24		p=0.681
Sleep PSQI	Trial	13.0 (3.5)	11.9 (4.1)	22	0.18	$F_{1,44}$=0.997
	WLC	12.9 (4.1)	12.4 (3.6)	23		p=0.557
Sleep efficiency %	Trial	83.9 (8.2)	83.4 (6.9)	22	0.21	$F_{1,44}$=0.498
	WLC	86.5 (5.1)	84.3 (7.3)	23		p=0.484

WASO%	Trial WLC	10.9 (4.4) 10.0 (3.0)	11.3 (4.7) 11.1 (4.2)	21 23	-0.08	$F_{1,44}$=0.067 p=0.798
Sleep Latency (mins)	Trial WLC	29.9 (30.5) 16.4(14.3)	28.6 (28.0) 25.1 (32.1)	21 23	-0.40	$F_{1,44}$=1.201 § p=0.278
Actual Sleep%	Trial WLC	89.1 (4.4) 90.0 (4.3)	88.7 (4.8) 88.9 (4.2)	21 23	-0.06	$F_{1,44}$=0.036 p=0.850
Mean Activity (epoch counts)	Trial WLC	8.0 (3.3) 8.1 (4.0)	10.2 (6.8) 9.1 (4.8)	21 23	0.34	$F_{1,44}$=1.264 p=0.271
Mean N. Wake Bouts	Trial WLC	42.4(15.3) 35.3(11.3)	35.5(9.3) 38.7(10.6)	21 23	0.76	$F_{1,44}$=6.251 p=0.016
Fragmentation Index %	Trial WLC	41.5 (15.0) 36.9 (10.7)	37.5 (11.9) 37.6 (9.2)	21 23	0.30	$F_{1,44}$=0.997 p=0.324

§ test performed on log transformed data, since variable not normally distributed, * Difference between group change, HADS-Hospital anxiety and depression scale, TSK=Tamps scale of kinesophobia, sf-36-short-form 36, STS-Sit to stand, NRS=Numerical rating scale, PSQI=Pittsburgh sleep quality index, %=Percentage, N=Num