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Acceptance-based behavioural treatment for insomnia in chronic pain: A clinical pilot study

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ABSTRACT

Background: For patients with chronic pain the prevalence of insomnia is 5–8 times higher as compared to the general population. Acceptance and Commitment Therapy (ACT) has gained strong empirical support in the treatment of chronic pain and is today increasingly used in pain clinics. However, no ACT-consistent treatment for insomnia in chronic pain has yet been empirically evaluated, although preliminary data show a relation between acceptance and aspects of insomnia. The aim of this clinical pilot study was to develop and evaluate the feasibility and preliminary outcome of an acceptance-based behavioural group treatment protocol for insomnia in patients with chronic pain.

Methods: Patients with chronic pain who had completed an ACT program to improve behavioural flexibility and functioning, and continued to have poor sleep to an extent that met the diagnostic criteria for insomnia, were considered eligible for participation in an acceptance-based behavioural group treatment for insomnia. Sixteen patients were enrolled in the study. Feasibility and treatment effects (primary outcome measure: Insomnia Severity Index, ISI) were assessed pre- and post treatment, as well as three months post-treatment.

Results: There was a satisfying degree of retention and treatment compliance. On average patients participated in 5.31 (SD = 0.70) out of six group sessions and completed 4.63 (SD = 0.62) of the five homework assignments. Overall, the completion rate of planned assessments was acceptable. However, assessment of sleep diary data at follow-up had 37.5% missing data and the recruitment rate averaged one patient per month. Significant improvements were seen in most outcomes, and results were maintained at follow-up, with large effects on primary outcome (ISI) at post-treatment $g' = 2.02$, 95% CI [0.90–3.14], and at follow-up $g' = 1.69$, 95% CI [.59, 2.78]. At follow-up twelve (75.0%) of the patients were classified as responders, of which five (31.2%) were remitters.

Conclusion: Results overall showed a satisfying degree of feasibility with regards to retention, treatment compliance and completion of planned assessments. Changes in procedure are required in order to optimise recruitment rate. The treatment is potentially promising in terms of improved sleep for patients with longstanding pain. Larger, randomised controlled studies are needed to evaluate the treatment.

1. Introduction

Longstanding pain affects 12–30% of the population and often has a substantial impact on an individuals' life, leading to sleep disturbance, depression, decreased functioning and lowered quality of life (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). In chronic cases, pharmacological and surgical treatments are many times not sufficiently effective in reducing the pain, thus signifying the need for

treatments aiming at reducing pain impact (McCracken & Turk, 2002).

One of the most common complaints related to pain is sleep disruption (Smith & Haythornthwaite, 2004). For patients with chronic pain the prevalence of insomnia is 50–70%, which is 5–8 times that of the general population (Breivik et al., 2006). Experimental studies show that sleep disruption is related to increased pain sensitivity and lowered pain thresholds. In cross-sectional studies sleep disruption is consistently positively related to pain severity (Smith & Haythornthwaite,

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2004). Longitudinal studies however show mixed results. When investigated in time-series analyses poor sleep seems to predict next day pain (Affleck, Urrows, Tennen, Higgins, & Abeles, 1996; Raymond, Nielsen, Lavigne, Manzini, & Choinière, 2001; Stone, Broderick, Porter, & Kaell, 1997). When investigating prediction over longer time some studies show that sleep disruption does not predict pain severity (Nicassio & Wallston, 1992), whereas other studies show that sleep related variables predict pain related outcomes such as disability, daily uptime and physical symptoms independent of pain or depression (e.g. McCracken, Iverson et al., 2002).

Insomnia is a condition of difficulty falling or staying asleep, causing daytime impairment (Roth et al., 2011). Cognitive Behaviour Therapy (CBT) is considered “treatment of choice” for insomnia (CBT-I), with moderate empirical support regarding improvements in sleep that are maintained over time (Okajima, Komada, & Inoue, 2011). There are also a handful of studies on CBT for insomnia in chronic pain patients, demonstrating moderate to large effects on sleep-related outcomes, moderate effects on pain severity and moderate to large effects on pain related functioning (Finan, Buenaver, Runko, & Smith, 2014).

During the last decades new forms of CBT have emerged, that emphasise the concept of *acceptance*, that is a willingness to experience private events in the moment without unnecessary attempts at altering their frequency or form (Hayes, Luoma, Bond, Masuda, & Lillis, 2006) and *values*, that is personally chosen adaptable patterns of action which serve to give behaviour purpose over time (Plumb, Stewart, Dahl, & Lundgren, 2009). Acceptance has been shown to be an important therapeutic process in for example the treatment of chronic pain (Wicksell, Olsson, & Hayes, 2010). Acceptance and Commitment Therapy (ACT), is one example of a therapeutic model that utilise acceptance strategies to manage treatment resistant symptoms such as chronic pain (Wicksell et al., 2010). Empirical support for ACT as a treatment for longstanding pain has grown substantially (Veehof, Trompetter, Bohlmeijer, & Schreurs, 2016) and is now considered a treatment with strong empirical support by the American Psychological Association's Division of Clinical Psychology (Division 12, 2010). ACT is increasingly implemented in regular clinics worldwide, but there is not yet empirical support for an ACT-consistent treatment for insomnia or other sleep disruptions in chronic pain, incorporating the behavioural components of CBT-I that are found to be the most efficacious, e.g. sleep restriction and stimulus control (Epstein, Sidani, Bootzin, & Belyea, 2012).

One of the major goals in existing protocols for acceptance-based interventions used for insomnia is to increase willingness to experience the short-term physiological and psychological discomfort commonly associated with not falling asleep in the evening, being awake at night, or being tired in the daytime (Lundh, 2005). Another treatment target is to increase engagement in value driven behaviours. This may prevent unhelpful efforts to cope with sleep disturbances, such as staying in bed to gain more sleep and daytime napping, which unintentionally perpetuate the problem (Dalrymple, Fiorentino, Politi, & Posner, 2010; Hall et al., 2007).

The potential importance of acceptance-based treatment approaches related to sleep problems in chronic pain has gained preliminary empirical support, e.g. sleep-related acceptance and values-based action are found to correlate strongly with subjective (but not the objective) aspects of insomnia (Bothelius, Jernelöv, Fredrikson, McCracken, & Kaldo, 2015). Notably, in an intervention study using traditional CBT-I, increases in acceptance and values-based action during treatment was related to reduction in perceived insomnia and anxiety (Bothelius et al., 2013). In a preliminary retrospective study of chronic pain patients with insomnia (McCracken, Williams, & Tang, 2011) acceptance was found to be a significant predictor of insomnia severity, problems with sleep and rest, low sleep efficiency, and fatigue. Thus, acceptance appears to be an important factor in psychological treatment of sleep disruptions that warrants further studies.

The aim of this study was to evaluate aspects of feasibility, and

preliminary outcome of an acceptance-based behavioural group treatment protocol for insomnia in patients with chronic pain, delivered subsequent to participation in an ACT program for chronic pain at a tertiary pain treatment service.

2. Methods

2.1. Participants

Participants were recruited from the Behavioural Medicine Pain Treatment Services at Karolinska University Hospital, during the course of 24 months. This unit is a specialist service, assessing and treating patients with longstanding pain. The standard treatment program offered is based on ACT, and is delivered individually or in a group format, in a multidisciplinary setting. Patients were considered eligible for participation if they had received the regular treatment program offered at the unit, and presented with persistent sleeping difficulties (i.e. fulfilled the diagnostic criteria for insomnia according to the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013)*). For inclusion in the study it was also required that participants 1) had insomnia on a clinically relevant level, defined as > 10 points on the Insomnia Severity Index (Morin, 1993), 2) were at least 18 years old, 3) had a pain duration of at least six months, 4) had been medically evaluated by a pain physician, who had ascertained that there were no on-going pain conditions that required other medical treatment, or were expected to deteriorate considerably during the next six months, 5) were able to understand and communicate in Swedish, 6) were not using, or committed to fading out, the use of sleep medications before or during treatment, 7) were not working night-shifts, 8) did not have an alcohol or drug dependence, 9) did not have a psychiatric comorbidity which made the treatment contraindicated (high risk of suicide, on-going psychosis, bipolar disorder). A preliminary power calculation was performed using GLIMM-PSE, a free internet-based program for power calculation recommended by Guo, Logan, Gluek, and Muller (2013). In our calculation we specified a power of 0.80 and a type I error rate of 0.05, entered the actual correlations for the main outcome measured at different measurement points, the estimated mean values and standard deviations at different measurement points, as well as the number of and spacing between measurement points. The power calculation was based on the smallest effect size of CBT for insomnia in longstanding pain, found in a meta-analysis (Hedges $g' = 0.87$; Wu, Appleman, Salazar, & Ong, 2015) and on the standard deviation for Insomnia Severity Index found in a validation study of the instrument ($SD = 4.1$; Bastien, Vallières, & Morin, 2001). Results indicated that inclusion of a maximum of 16 participants would be enough to detect a Hedges $g' = 0.87$ within-group effect on the main outcome. Also, since an acceptance-based behavioural treatment for insomnia has not been evaluated before, the results from the current study can be used as a basis for power calculation when planning for a larger controlled trial.

2.2. Design and procedure

The project was an open pilot study with three intakes. Eligible participants attending scheduled follow-up appointments posterior to the standard treatment, were provided with verbal information about the study by their regular therapist. Those who showed an interest of partaking were booked for an intake interview. Prior to the interview, eligible participants were provided an information sheet and consent form, and those consenting to participate were asked to fill out the self-report measures used in the study. The intake interviews were carried out by two experienced clinical psychologist, specialised in pain. The interviews contained diagnostic assessment of the insomnia diagnosis (as outlined by Edinger & Carney, 2014), as well as assessment of the other inclusion criteria. If insomnia diagnoses or other criteria were ambiguous, they were discussed in the multi-professional team. Study

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