‘Do Valerian tea-bags improve subjective sleep quality for male remand prisoners with a dual diagnosis?’

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Background: Insomnia is a common problem identified by remand prisoners who also have a concurrent dual diagnosis of substance misuse and mental health problems. Historically sleep problems have been treated within the prison with either hypnotics or benzodiazepines. These medications caused adverse side effects and were often misused themselves. As an alternative treatment Valerian tea bags were introduced in 2004, but their efficacy was untested within the prison setting.

Aim: To establish if Valerian Teabags improve subjective sleep quality for men with sleep disturbance and dual diagnosis in a remand prison setting within a 14-day period.

Method: This was a randomised double blind between-subjects clinical trial, with pre-test and post-test outcome measures. The research was a pilot study of an experimental design, the key characteristic being that it involved the manipulation of variables under the control of the researcher.

Results:

- An improvement in both subjective sleep quality and sleep duration as measured by the PQSI between the baseline measures at time 1 and fourteen days later at time 3, for both groups.

- Statistically significant improvement for both the GHQ-28 and the FAMHA between time 1 and 3 for the Valerian group, which was not found for the control group.

- It is also possible that the Valerian extract may have had a positive affect on factors other than sleep, such as mood and anxiety levels which could have improved ratings of psychological well-being and levels of functioning.

Conclusion: Insomnia is a commonly reported problem for those with a dual diagnosis in prisons, often treated with potentially addictive medication. This study showed that herbal
alternatives can improve sleep quality, for prisoners with complex needs and that as sleep quality improved there were also improvements in both levels of psychological well-being and level of functioning

Key Words: Dual Diagnosis, prisoners, insomnia, Valerian

Introduction:
Insomnia is a frequently reported health problem within the prison setting although rates of severity and duration are unknown (Turnball and Stimson 1994, Vasseur 2001). Sleep disturbance can be an early indicator of an impending psychiatric disorder (Stores 2003). A review by Gillin (1998), demonstrated that in both those with and without serious psychiatric history, insomnia is a risk factor for later development or recurrence of depression, anxiety states and or substance misuse. It is possible that the detection and treatment of a sleep disturbance might have an important preventative value against developing mental health or substance misuse problems (Ford and Kammerow 1989)

At a male remand prison based in southern England, anecdotal evidence from the Healthcare team had reported that prisoners commonly complained during the reception screening that they were experiencing sleep difficulties. Historically, sleep disturbance had been treated with a range of hypnotics and benzodiazepines. The effect of hypnotics, however, is not stable: epidemiological investigations have shown that sleep disturbances persist in 40 –50 % of the treated patients (Holzrichter et al 1994). Benzodiazepines, often produce a hangover effect, drug intolerance, rebound insomnia after withdrawal and the risk of addiction (Laux 1995). A natural alternative to medication was required to help aid sleep. This could help reduce the use and potential abuse of expensive and addictive medication in a population, who are vulnerable both to abusing substances and to bullying by other prisoners to gain medication.

Valerian is one of the most useful relaxing remedies that are available. It may be safely used to reduce tension, anxiety, over-excitability and hysterical states. It is an effective aid in insomnia, producing a natural healing sleep (Hoffman 1991), and positive effect on both sleep structure and sleep perception of insomnia patients (Donath et al 2000). Rasmussen (1997) and Donath et al (2000), found evidence from their clinical trials that valerian can improve the quality of sleep without ‘hangover effect’ the next day. Donath et al (2000), reported an extremely low number of adverse effects of valerian use over
a 14 day period in their trial and Rasmussen (1997), argues that no adverse effects have emerged
despite its wide consumption. The valerian root tea bags were first introduced in September 2004, as
an alternative to the use of medication to treat sleep problems, but their effectiveness in improving the
sleep quality of male prisoners with a dual diagnosis was unknown.

The pilot study concentrated on establishing the effectiveness of valerian root teabags in improving
sleep quality, for a small group of prisoners who had been identified by the Mental Health In reach
team as having co-morbid mental health, substance misuse and sleep problems. The pilot, randomised,
double blind, control study aimed to build upon previous clinical research, which had found that
valerian preparation was extremely effective in improving sleep quality (Lindahl and Lindwall 1988,
Rasmussen 1997, Donath et al 2000). The overall aim of the study was to establish if Valerian Teabags
improved subjective sleep quality for men with sleep disturbance and dual diagnosis within a remand
prison setting within a 14-day period.

Method
This was a randomised double blind between-subjects clinical trial, with pre-test and post-test outcome
measures. The research was a pilot study of an experimental design.

Double blind was achieved by contacting the company who manufactured the tea bags who agreed to
supply valerian tea bags in unmarked bags in an unmarked box. For the purpose of this trial they also
agreed to manufacture tea bags with just the Valerian omitted, so that otherwise both types of tea bag
looked, tasted and smelt the same. One box was marked ‘A’ and the other ‘B’. The envelope containing
which box contained the Valerian was kept sealed in the pharmacy department until after the trial was
completed. Therefore, prisoners, staff nor the researcher were unable to detect which prisoner was
assigned to what group until after the trial.

Following a screening by the Mental Health In-reach Team, prisoners who had reported experiencing
a sleep problem and had agreed to participate in the pilot study, were referred to the pharmacy
department. The pharmacy department who selected a card with A or B written on it from a box then
randomly allocated them. Prisoners were interviewed on a one to one basis within the Outpatient department in the Healthcare wing of the prison or in their own cell if they preferred.

Fifteen participants were recruited from all new prisoners screened by the Mental Health In-Reach team who were identified as having a dual diagnosis and a problem sleeping during the month of February 2006. This also included prisoners located within the inpatient unit of the prison as well as those on normal house block location. Those with a limited grasp of the English language, and those already on a prescription of benzodiazepines were excluded from the trial.

All participants were given time to read the information detailing the study and to ask the researcher for any clarifications. For those who could not read, the researcher read through the information sheet for them and also gave them the opportunity to ask others to read it for them as well if they wished. All were asked to give written consent and it was made clear that they could leave the study at any time during the trial if they wished. This was repeated to them again at each interview session. A copy of the signed consent was given to participants and another copy kept in their medical record. Prisoners did not receive any material reward for participation, but they did get extra time out of their cell in order to complete the assessments and this is a reward in itself, and may have been a factor in them agreeing to take part.

Before the teabags were dispensed questionnaires to assess quality of sleep, psychological well-being and daily functioning were completed. Principles of sleep hygiene were explained and given out in written form, (Kupfer and Reynolds 1997, Folks and Burke 1998, Vincent and Lindberg 2001, Schenck et al 2003, Elgar 2003).

Baseline measures using all data collection tools were taken on the same day as the prisoner agreed to participate in the study (Time 1), prior to Valerian teabags being dispensed so that any changes following use could be directly attributed to the use of the Valerian tea bag. Participants were then assessed after seven days (Time 2) using the PSQI, and after fourteen days (Time 3), using all three data collection tools. The study was only conducted for a short period of time due the high turnover within the remand setting, which has up to fifty discharges and 50 new admissions daily.
The three data collection methods used were the Pittsburgh Sleep Quality Index (PQSI), General Health Questionnaire (GHQ-28) and the Functional Analysis of Mental Health and Addiction (FAMHA). Permission from the authors was not required to use these data collection tools for the purpose of this study.

The PQSI (see appendix) is a self-rating questionnaire resulting in a global score between 0-21, which consists of seven sub-scores, (21 being poor sleep quality). The questionnaire is easy to handle and can be completed in five minutes (Backhaus et al 2002). The PQSI has been shown to provide a reliable, valid and standardised measure of sleep quality, to distinguish between ‘good’ and ‘bad’ sleepers and to provide a clinically useful assessment of a variety of sleep disturbances that might affect sleep quality (Elgar 2003). Although originally developed to measure sleep quality and disturbances over long periods of time with measurements completed on a monthly basis, pre-test and post-test reliability and validity using shorter periods of time is high (Backhaus et al 2002). For the purpose of this study questions regarding sleep patterns in the previous month were altered to read ‘in the previous week’.

The second questionnaire administered was the GHQ-28, which is one of the most widely administered questionnaires to screen for psychiatric morbidity (Anderson et al 2002). The GHQ-28 was used as a measure of psychiatric morbidity at two points in time (time 1 and Time 3). This was completed by the participant in the presence of the researcher due to high levels of security, which dictated that paper and pens should not be given to prisoners. All prisoners, at their request, had the questionnaire read to them as they had difficulty in reading and writing.

The GHQ-28 (Goldberg and Hillier 1979) is a scaled 28-item version of the original GHQ-60 and has been used and validated previously with prisoners (Harding and Zimmerman 1989, Anderson et al 2002, Elgar 2003). Besides the original screening purpose of the GHQ there is evidence that the questionnaire is capable of measuring change in symptomology over time in quantitative aspects (Kitamura et al 1994, Ormel et al 1989).
The final measurement to be used was the FAMHA. Functional assessments are key not only to measuring the outcomes of treatments on a broad scale, but crucial to the clinician’s full understanding of patient’s individual needs.

The FAMHA is a clinician’s rating scale specifically designed to accurately assess dually diagnosed clients across a wide range of symptom and functional domains. The 46 items of the scale document functional deficits across all bio-psychosocial functional domains in such a way as to capture the current state of functioning. Thus, it can be used as both an indicator of current functioning and as a repeated measure to demonstrate the changes that occur over time (Anderson and Bellman 1999).

The FAMHA documents the outcomes of treatment by quantifying the substantial and enduring changes in client behaviours, cognitions, moods and day to day client functioning. It also notes reductions in distress due to the effects of treatment (Anderson and Bellman 1999).

A major advantage of the scale is that it can be quickly administered to provide diagnostic indicators and the effect of treatment over time. The FAMHA documents the outcomes of treatment by quantifying the substantial and enduring changes in client behaviours, cognitions, moods and day-to-day client functioning. It also notes reductions in distress due to the effects of treatment (Anderson and Bellman 1999).

**Data Analysis**

Descriptive statistics, for age, status, average night’s sleep, substance use and mental state were carried out to illustrate any similarities or differences of the two groups. All statistical analysis was performed using SPSS. Sleep quality was measured at time 1, time 2 and time 3 as collated using the PQSI for both the control and experimental group. Psychological well-being (GHQ-28), and level of functioning (FAMHA), were both measured only at time 1 and time 3 for both groups as there needed be at least a two week period between the application of the measurement tools used. This data was then compared between the two groups to detect any statistically significant differences.
A repeated measures t-test was used to analyse the parametric data. As some of the data was not ratio or interval and due to the very small sample size it was not possible to use a parametric test, therefore Wilcoxon Signed Ranks tests was used for the repeated measures of individual scores on subjective sleep quality and global scores of the questionnaires. To compare the scores between the two groups, Mann-Whitney U tests were used.

**Results**

All 15 of the prisoners who participated in the research, completed the two-week study period, with no known problems with compliance. There were also no reported side effects of either of the tea bags. Following completion 12 prisoners opted to stay on whichever tea bag they had been taking, one asked to change to Valerian and two felt that their sleep had improved so much as to not need any further interventions.

**Table 1** Personal Characteristics at Baseline of Participants (Time 1).

<table>
<thead>
<tr>
<th>% In stable housing</th>
<th>14%</th>
<th>13%</th>
</tr>
</thead>
<tbody>
<tr>
<td>% With consistent and reliable income</td>
<td>29%</td>
<td>2</td>
</tr>
<tr>
<td>% With important intimate relationship</td>
<td>43%</td>
<td>4</td>
</tr>
<tr>
<td>% On remand</td>
<td>71%</td>
<td>62%</td>
</tr>
<tr>
<td>% Serving sentence</td>
<td>28%</td>
<td>37%</td>
</tr>
<tr>
<td>% With own cell</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
This shows clearly that despite random allocation, personal characteristics of both groups did not differ significantly and were representative of the prison population as a whole.

**Sleep**

Table 2 Baseline Measures of Sleep Characteristics of Participants (Time 1)

<table>
<thead>
<tr>
<th>Sleep characteristics at the beginning of the study</th>
<th>Valerian group N=7</th>
<th>Control group N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total length of sleep in hours</td>
<td>3.57 (1.81)</td>
<td>3.71 (1.50)</td>
</tr>
<tr>
<td>Range</td>
<td>0-4</td>
<td>2-6</td>
</tr>
<tr>
<td>Rating for subjective sleep quality</td>
<td>4 (1.0)</td>
<td>3.5 (1.07)</td>
</tr>
<tr>
<td>Median</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>% Take more than 30 mins to get to sleep at least 4 times a week</td>
<td>86%</td>
<td>75%</td>
</tr>
<tr>
<td>% Getting up to go to the toilet at least 4 times during the night</td>
<td>86%</td>
<td>88%</td>
</tr>
</tbody>
</table>

The result show that all subjective sleep characteristics were similar across both the valerian and control group prior to use of either teabag at time 1.

Table 3 Sleep Characteristics of Participants at Study end (Time 3)

<table>
<thead>
<tr>
<th>Sleep characteristics at time 3</th>
<th>Valerian group N=7</th>
<th>Control group N=8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total length of sleep in hours</td>
<td>6.14 (.77)</td>
<td>6 (.31)</td>
</tr>
<tr>
<td>Range</td>
<td>3-8</td>
<td>5-7</td>
</tr>
<tr>
<td>Rating for subjective sleep quality</td>
<td>6.71 (0.60)</td>
<td>6.71 (0.60)</td>
</tr>
<tr>
<td>Median</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>% Take more than 30 mins to get to sleep at least 4 times a week</td>
<td>29%</td>
<td>25%</td>
</tr>
<tr>
<td>% Getting up to go to the toilet at least 4 times during the night</td>
<td>43%</td>
<td>63%</td>
</tr>
</tbody>
</table>

Mean scores for total length of sleep for both groups did not differ greatly at time 3. However, there was a difference in range, in that there was a greater difference between the lowest and highest total hours sleep within the valerian group, compared to the control. There were also 20% fewer participants who needed to get up to use the bathroom at least 4 times a night in the valerian group.
Table 4 Mean Scores of Questionnaires for Participants at all time points

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th>Time 2</th>
<th>Time 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Valerian</td>
<td>Control</td>
<td>Valerian</td>
</tr>
<tr>
<td></td>
<td>N=7</td>
<td>N=8</td>
<td>N=7</td>
</tr>
<tr>
<td>PSQI Mean (Std.D.)</td>
<td>14 (1.0)</td>
<td>14.13 (1.55)</td>
<td>8.3857 (3.59)</td>
</tr>
<tr>
<td>Median</td>
<td>14</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>GHQ Mean (Std.D.)</td>
<td>67.57 (17.96)</td>
<td>71.38 (16.08)</td>
<td>50.42 (12.99)</td>
</tr>
<tr>
<td>Median</td>
<td>69</td>
<td>69.50</td>
<td>49</td>
</tr>
<tr>
<td>FAMHA Mean (Std.D.)</td>
<td>59.44 (4.70)</td>
<td>64.88 (8.73)</td>
<td>70.55 (9.21)</td>
</tr>
<tr>
<td>Median</td>
<td>58.10</td>
<td>66.60</td>
<td>70.2</td>
</tr>
</tbody>
</table>

The global scores reflect a similar trend of both the Valerian group and Control group. Both groups had increased sleep quality, and an increased level of functioning over the two-week study period. The mean PQSI scores decreased at time 2 and again decreased at time 3 (end of study), however, both groups were very similar. Of interest are the GHQ-28 scores, which were reduced for both groups at time 3, but especially for those in the Valerian group.

Table 5 Comparison of Global Scores of both Groups at Different Time Points

<table>
<thead>
<tr>
<th></th>
<th>Valerian group (N=7)</th>
<th>Control group (N=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test statistic Z value</td>
<td>Significance level</td>
</tr>
<tr>
<td>PSQI scores for time 1 and 2</td>
<td>-2.38</td>
<td>.018*</td>
</tr>
<tr>
<td>PSQI scores for time 2 and 3</td>
<td>-.96</td>
<td>.34 ns</td>
</tr>
<tr>
<td>GHQ scores for time 1 and 3</td>
<td>-2.36</td>
<td>.018*</td>
</tr>
<tr>
<td>FAMHA scores for time 1 and 3</td>
<td>-2.21</td>
<td>.027*</td>
</tr>
</tbody>
</table>

ns = not significant
* = p,<05

The data was further analysed to establish if there were differences in individual participant scores between the three time points in the pilot study. Wilcoxon Signed Ranks test compared the global
There was statistically significant improvement in PSQI scores for both sample groups between time 1 and time 2, and although there was an improvement in mean scores for both groups between time 2 and time 3 this was not statistically significant.

Also whilst there was an improvement in GHQ-28 and FAMHA scores for individuals in both groups, this was much more pronounced in for the Valerian group and showed a statistically significant difference between the baseline measures at time 1 and the end of the study at time 3.

Finally, the data was analysed to test whether there are any differences in scores of the PSQI, GHQ-28 and FAMHA between the two sample groups at each time point in the study.

<table>
<thead>
<tr>
<th>Test statistic Z value</th>
<th>Significance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSI time 1 -0.12</td>
<td>0.90</td>
</tr>
<tr>
<td>PSI time 2 -0.06</td>
<td>0.95</td>
</tr>
<tr>
<td>PSI time 3 -0.35</td>
<td>0.73</td>
</tr>
<tr>
<td>GHQ time 1 -0.70</td>
<td>0.49</td>
</tr>
<tr>
<td>GHQ time 3 -1.51</td>
<td>0.13</td>
</tr>
<tr>
<td>FAMHA time 1 -1.22</td>
<td>0.22</td>
</tr>
<tr>
<td>FAMHA time 3 -0.23</td>
<td>0.82</td>
</tr>
</tbody>
</table>

The Mann-Whitney U test carried out to compare the global rating scores between the Valerian and Control group, showed that there were no statistically significant differences for any of the scores at any of the time points between the two groups.

**Discussion**

The baseline measures provided a rich tapestry of data, which emphasised the vulnerability of the remand prison population at High Down and clearly demonstrated their need for effective interventions to help support them. The participant’s characteristics were remarkably similar despite random allocation. The mean age of the Valerian group was 30.57 years compared to 29.25 years for the
control group. As found in previous studies (Edens et al 1997, Brooke et al 2000), low levels of functioning were recorded. The Valerian cohort had only 14% with stable housing, 29% had a consistent and reliable income prior to incarceration and 43% had an important intimate relationship. The control group reported 13% in stable housing, 25% with a consistent and reliable income and 50% with an important intimate relationship.

As With Donath et al’s study (2000), the primary finding of the study is that there was an absence in differentiation between the two groups. This contrasted sharply with Leathwood and Chaufford (1982 and 1984), and Zeigler (2002), who had found a significant improvement in sleep quality and duration in their small sample groups. However, both trials had used a valerian preparation in tablet or solution form, which contained a far greater concentrate of Valerian plant extract than is present within the Valerian teabags used in this trial (450mg and 900mg of aqueous valerian extract in Leathwood and Chaufford’s trial 1982 and 1984, 600mg tablet in Zeigler et al’s trial compared to 350mg of Valerian root extract in the tea bags).

There was little difference in PQSI scores for both groups throughout the pilot study; despite baseline measures showing they’re to be heterogeneity between the two groups. There was an improvement in both subjective sleep quality and sleep duration as measured by the PQSI between the baseline measures at time 1 and fourteen days later at time 3, for both groups. The Valerian group scored a mean of 14 at time 1 and 8 at time 3. Similarly, the control group also scored a mean of 14 at time 1 which had greatly reduced to a mean of just 6.5 by time 3. Due to the very small sample used there was an increased vulnerability to more extreme scores/ratings, there was a greater range of improvement in sleep for the Valerian group, so perhaps one individual score affected the means.

There was a statistically significant improvement for both groups between baseline measures (time 1) and time 2 (seven days later), but this was not repeated for either group between time 2 (7 days) and time 3 (after 14 days). This initial increase in subjective sleep quality for both groups between baseline and time 2, possibly could be attributed to a natural improvement over time as participants adjusted to the prison environment and social situation, rather than as a direct result of the tea bags. This theory could also explain why on comparison of PQSI scores for all time points between the two groups there
was no statistically significant difference. Elgar (2003), also found that significant improvement in PQSI scores took place in the first week, but similarly that despite further treatment, PSQI scores did not improve significantly again between week 1 and on follow up two months later.

Sleep duration increased for both groups throughout the study period with those in the Valerian group reporting a mean length of sleep at time 1 of 3.57 hours, compared to a mean of 3.71 hours for the control group. By time 3, length of sleep was a mean of 6.14 hours for those using Valerian teabags and a mean of 6 hours for those in the control group, however, this was not statistically significant.

However, there was a statistically significant improvement for both the GHQ-28 and the FAMHA between time 1 and 3 for the Valerian group, which was not found for the control group. The Valerian group presented mean GHQ –28 score of 67.57 at time 1, decreasing to a mean of 50.4 at time 3, compared to the control group’s mean GHQ –28 score of 71.38 at time 1 and mean score of 66.5 at time 3. This was accompanied by an increase in level of functioning over the 14-day period measured by the FAMHA, again both groups’ scores having little differentiation

This improvement in GHQ-28 and FAMHA scores between time 1 and 3 for the Valerian group, may in part have been due to those participants in the Valerian group (43%) reporting a marked decrease, in needing to get up to use the bathroom more than 4 times a night compared to the control group (63%). Consequently, although the duration of sleep was similar for all participants across both groups, those on Valerian were more likely to experience uninterrupted sleep.

It is possible that the Valerian extract may have had a positive affect on factors other than sleep, such as mood and anxiety levels which could have improved ratings of psychological well-being and levels of functioning. Valerian is widely used for its anxiolytic properties, although as yet its efficacy and side effects are not fully established (Miyasaka et al 2005). Furthermore, previous studies by Donath et al (2000) and Wheatley (2005), have commented that Valerian did seem to positively reduce other non-specific problems such as headache and gastrointestinal problems, for those participants within their trials. It was hypothesised that an increase in sleep quality would have a positive impact on both psychological well being as measured by the GHQ-28, and level of daily functioning as measured by the FAMHA. Both pre and post Valerian/Placebo measures were taken at three timed
intervals to increase the possibility that any change occurring in sleep quality, psychological well being and level of functioning could be directly attributable to the use of the Valerian tea bag, and also showed there to be heterogeneity in personal characteristics between the two groups at the trial start.

The constraint of a rapidly changing population within a remand prison and the specific needs of prisoners required to participate, meant that the sample was smaller than had previously been anticipated. The duration of the study was restricted to just 14 days, this ensured that all those recruited did complete the full duration of the trial, increasing the validity results and quality of the overall study (Jaded et al 1996). A further limitation of this study was the reliance on self reported facts, which may not have been a true reflection of reality, however, there is no reason to believe the prisoners would have given biased responses as it is in their interest to find a suitable treatment for sleep problems and validated questionnaires (PQSI, GHQ-28), were used.

Finally, it was not possible for this study to eliminate the presence of other variables which may have had an effect on sleep, such as use of relaxation techniques, other herbal remedies like lavender oil, the intake of caffeine and levels of activity. In conclusion, this was a well-designed and executed pilot study, which showed that randomised double blind control studies are possible within a difficult environment. The study was successful in that sleep quality did improve for all participants as did ratings for level of functioning and psychological well being between baselines and time 3 measurements. However, the results between the two groups were not statistically significant.

This study showed that herbal alternatives can improve sleep quality, for prisoners with complex needs and that as sleep quality improved there were also improvements in both levels of psychological well-being and level of functioning. This supports the continued use of Valerian tea bags with this population as an alternative and effective treatment to anxiolytic and hypnotic medication. However, this study was a pilot, using a very small sample and was of short duration, future research should consider using the same methodology but with a much larger sample and a longer follow up period to ascertain if sleep quality persists or improves/diminishes over time and whether there is a significant difference between Valerian and Control groups.
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