Final report

October 2016

Innovating for Improvement

Stabilising sleep for patients admitted at acute crisis to psychiatric hospital: a pilot randomised controlled trial.

Oxford Health NHS Foundation Trust & University of Oxford

The Health Foundation

About the project

Project title:

Stabilising sleep for patients admitted at acute crisis to psychiatric hospital: a pilot randomised controlled trial.

Lead organisation:

Oxford Health NHS Foundation Trust

Partner organisation:

University of Oxford

Project lead/s:

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Part 1: Abstract

Background: Empirical evidence shows that sleep disturbance is a contributory cause of poor mental health and low psychological wellbeing. Eight out of 10 patients admitted to psychiatric wards report clinically significant insomnia. To address this clinical need, Oxford Health NHS Foundation Trust and the University of Oxford have collaborated to trial an innovative sleep treatment, tailored for people admitted to an acute psychiatric ward.

Method: The project involved treating sleep problems using the latest evidence-based techniques and technologies, with three key elements: targeting unhelpful cognitions and behaviours that disrupt sleep using cognitive behavioural techniques; using state-of-the-art sleep monitoring devices to promote patient discussion about their sleep; and regulation of the body clock through the timing of light and darkness. This intervention was delivered intensively over a two week period by clinical psychologists.

The intervention was tested via a pilot randomised controlled trial set on one male acute psychiatric inpatient ward. Patients were assessed at baseline and then again at weeks 2 (the end of the therapy window), 4 and 12. Patients admitted to Vaughan Thomas Ward, Oxford Health NHS Foundation Trust were screened for participation, 40 participants were recruited to take part in the study. Half of the participants (n=20) were randomly allocated to receive the novel intervention (in addition to standard care) and half (n=20) continued with standard care alone.

Results: The therapy was highly popular: all 20 participants (100%) who were offered the therapy completed the full course. Therapy satisfaction was high; the majority of participants who completed a satisfaction questionnaire rated their satisfaction with the therapy as mostly satisfied (7/16) or very satisfied (9/16). Assessment data for the therapy group and the standard care alone group were compared. Results revealed that symptoms of insomnia were lower in the group who received the sleep therapy, compared with those who continued with standard care alone, after two weeks. The difference between the two groups was large (cohen's d effect size = 0.9). At 4 weeks (d= 0.7) and 12 weeks (d=0.5), there was a medium effect size improvement in insomnia symptoms in the sleep therapy group compared with standard care alone. With regards to psychological wellbeing, the group that received the therapy reported a small effect size (d = 0.3) improvement in psychological wellbeing, compared with standard care alone at weeks 2, 4 and 12. On average, the group who received the intervention were discharged over a week earlier (8.5 days) than those who received standard care alone. Overall the results show that it is feasible and acceptable to deliver sleep therapy to patients in an acute psychiatric inpatient ward setting and the sleep therapy may be highly efficacious for improving symptoms of insomnia in this group.

Learning points: We invested time consulting with patients, which taught us the best time and place to approach patients for the study and how to adapt the

intervention for the ward setting. Close liaison with staff throughout the duration of the study was helpful for developing study specific processes on the ward (e.g. risk assessment procedures and ensuring room availability) and ensuring trial specific procedures (e.g. blind assessments) were supported. We learnt that a variety of communication strategies ensured the large staff pool was kept up to date. This included leaflets, posters, and attendance at ward round and business meetings. The time invested in liaising with staff and patients was valuable both for continual learning fostering an environment that was open to feedback and committed to the developing a successful innovation.

Sustaining the intervention: The plan for sustaining and spreading the intervention has begun. On Vaughan Thomas ward, all staff members have been invited to a brief training session on the importance of sleep. A patient resource ('10 top tips for better sleep') has been developed (see appendix). In addition, four sleep champions and the ward clinical psychologist have attended a day long skills workshop to embed the intervention into routine clinical practice. In October, the sleep champions opened a weekly sleep clinic, which has received five referrals to date, all of whom are receiving individual CBT for sleep improvement, delivered by the sleep champions and supervised by the study therapists. Beyond Vaughan Thomas ward there are plans for a series of workshops to train clinicians in using the sleep treatment techniques. In addition, we will submit the findings from the study to a peer reviewed journal with an international readership. We will approach a health economist for a full health economic evaluation of the intervention and apply for funding for a suitably powered phase 3 randomised controlled trial to complete a more rigorous test of the efficacy of the intervention.

Part 2: Progress and outcomes

Methods:

Design of the trial: All patients admitted to Vaughan Thomas ward, Oxford Health NHS Foundation Trust were considered for participation in the trial. They were each initially approach by a member of the NHS care team and if suitable, invited for a full screening meeting with the research team. Inclusion criteria were: i) self-reported symptoms of insomnia ii) would like help to improve sleep iii) willing and able to give informed consent iv) willing to allow his community team to be notified of participation. Exclusion criteria were: i) planned discharge date within 14 days of screening ii) patient lives outside of the area covered by the Oxford Health NHS Foundation Trust iii) command of English language inadequate for engaging in psychological therapy or assessments iv) diagnosis of learning disability or organic syndrome (e.g. head injury).

Those who screened positive to take part, and were interested, completed informed consent. Following this, study assessments took place at weeks 0, 2, 4 and 12.

After the week 0 assessment participants were randomly allocated to one of two groups: to receive the sleep intervention in addition to standard care, or to receive standard care alone (but offered a one off session to improve sleep at the end of the trial). Participants were allocated with a ratio of 1:1. Participants were informed of the outcome of the randomisation procedure by one of the trial clinical psychologists.

The primary objective for the trial was to assess trial procedures (recruitment and retention rates and uptake of therapy). A secondary objective was to collect preliminary efficacy data for primary (Insomnia Severity Index and Warwick Edinburgh Mental Wellbeing scale) and secondary (Positive and Negative Syndrome Scale, Young Mania Rating Scale, CORE-10, Beck Suicide Scale, duration of admission and satisfaction with therapy) outcomes. Each of the self-report questionnaires and clinical interviews are validated outcome measures. The pre-specified primary end point was the week 2 assessment (the end of the sleep therapy window).

Analyses: To assess the effect of the intervention, linear mixed effects models were carried out. Adjusted mean difference and confidence intervals were extracted from the model and effect sizes were calculated. Analysis controlled for baseline (week 0) score on that variable, diagnosis, insomnia and psychological wellbeing. Dr Bryony Sheaves completed the analysis and results were validated by a trial statistician from the University of Oxford.

The intervention: The sleep intervention comprised of three elements. The first element was cognitive behavioural therapy for insomnia. We adapted the delivery for the inpatient ward setting by providing the complete course intensively over a two week period. The second element was light therapy for stabilising circadian rhythms. Our preference for light input was natural daylight (given that this is also accessible when the participant is discharged home) however where outside light was not possible (for example if the individual was too depressed or paranoid to leave the ward) we used Lumie Brazil Light therapy boxes which emit 10,000 lux of light at a distance of 35 cm from the device. The third element was the use of sleep monitoring watches: the Basis Peak. These were used to provide additional information regarding sleep to inform a collaborative ‘pro-sleep plan’. They were also used as a motivational tool to boost daytime activity (via the step count function), which is known to aid better sleep the subsequent night.

The intervention was offered alongside all standard care. It was compared with a control group who received standard care alone. Standard care was delivered according to national and local protocols and guidelines. This typically included medication and contact with full time psychiatry, nursing, occupational therapy, social work and health care assistant staff. A clinical psychologist offered staff support and patient sessions one day per week. Patients were invited to weekly multi-disciplinary ward round meetings.

Assessing trial procedures

Recruitment took place over 9.5 months, with a 4 week break to account for therapist leave. During the recruitment period 109 patients were admitted to the ward, all were considered for participation. From these, 40 participants were recruited (37% of those admitted). The key reason for exclusion are as follows:

24 had a planned discharge within two weeks.
21 did not want to participate in research / declined to be screened.
7 had no self-reported symptoms of insomnia.
6 lacked capacity to consent to research.
4 had dementia or an organic syndrome (E.g. head injury) with associated cognitive decline.
2 were admissions from outside of Oxford Health NHS Foundation Trust.
2 did not want help with their sleep problem.
1 had high forensic risk.
1 had a command of English inadequate for engaging in psychological therapy & assessments.

From the 40 participants recruited, thirty four participants completed all assessments (85%), whilst 6 were lost to follow up (15%). Appendix 1a is a consort diagram showing patient flow through the study.

Uptake of therapy

Of the 20 participants offered the therapy, all 20 (100%) took up the therapy, and all patients (n=20) completed therapy. The mean number of sessions received was 8.6 (SD 1.5). On the basis of at least five CBT sessions constituting a minimum therapeutic dose. The actual number of treatment sessions attended was five (n=1), six (n=1), seven (n=1), eight (n=6), nine (n=8), ten (n=1), eleven (n=1), and twelve (n=1). The mean session duration was 44.8 minutes (SD 15.6).

Efficacy

On each of the primary and secondary outcome measures, the standard care alone group exhibited an improving trajectory of symptoms (with the exception of negative symptoms of psychosis; PANSS negative). The CBT for sleep group was therefore compared to a standard care group exhibiting (as expected) a degree of recovery in their symptoms over time.

Table 1. Scores for primary outcome measures

	CBT for sleep (n=20)	Standard care (n=20)	Adjusted mean difference (95% CI)	Effect size (d)
Primary outcome measures				
Insomnia (ISI)				
Week 0	17.1 (6.0)	16.1 (4.9)		
Week 2	8.5 (5.4)	12.5 (5.5)	-4.6 (-7.7;-1.4)	-0.9
Week 4	6.8 (5.2)	10.1 (5.6)	-3.6 (-7.0;-0.3)	-0.7
Week 12	5.8 (4.9)	8.6 (4.4)	-2.8 (-6.3.0;.7)	-0.5
Wellbeing (WEMWBS)				
Week 0	39.8 (15.4)	42.3 (13.1)		
Week 2	47.4 (10.5)	44.8 (13.4)	3.7 (-2.8; 10.1)	0.3
Week 4	48.3 (11.7)	45.6 (10.3)	3.6 (-2.8; 9.9)	0.3
Week 12	48.3 (12.3)	44.4 (12.9)	4.3 (-4.1; 12.7)	0.3

Data are mean (SD). ISI = Insomnia Severity Index (higher scores indicate poorer sleep). WEMWBS = Warwick-Edinburgh

Mental Wellbeing Scale (higher scores indicate better psychological wellbeing). All analyses controlled for stratification factors (insomnia severity, wellbeing and diagnosis).

The primary outcome of insomnia revealed a large effect size improvement (cohen's d = -0.9) in the CBT for sleep group, compared with the standard care alone group. Improved sleep in the intervention group was also found at weeks 4 (d= -0.7) and 12 (d= -0.5), with a medium effect size improvement in the CBT for sleep group, compared with standard care alone. As expected, the standard care alone group exhibited recovery of their sleep over time: their insomnia severity index score halved over the duration of the trial. The CBT for sleep group therefore evidenced a faster and perhaps fuller recovery in sleep disturbance than standard care alone.

The primary outcome of wellbeing revealed a small effect size (d= 0.3) improvement in psychological wellbeing in the CBT for sleep group, compared to standard care alone at weeks 2, 4 and 12. It is of note that the measure of psychological wellbeing was likely impacted upon by symptoms of mania at each of the time points (i.e. very high psychological wellbeing was reported by those experiencing an acute manic episode). This is supported by the following planned sub-group analysis, split by baseline manic symptoms:

Table 2. Psychological wellbeing split by baseline mania symptoms.

	CBT for sleep	Standard care
Wellbeing (WEMWBS)		
Mania (n=7)		
Week 0	54.8 (12.4)	52.7 (13.1)
Week 2	52.0 (14.5)	57.7 (6.8)
Week 4	56.3 (5.9)	49.7 (5.5)
Week 12	58.3 (10.2)	53.0 (17.0)
No mania (n=33)		
Week 0	36.1 (14.0)	40.5 (12.6)
Week 2	46.3 (9.6)	42.5 (13.1)
Week 4	46.2 (12.1)	44.9 (10.8)
Week 12	46.0 (11.9)	43.4 (12.6)

Data are mean (SD). Definition of mania = score of ≥20 on baseline YMRS.

Table 3 shows secondary outcome data. The CBT for sleep group had no clear effect on positive symptoms of psychosis (PANSS positive symptoms). There was a small effect (d= -0.3) on negative symptoms of psychosis (for example blunted affect, emotional withdrawal; PANSS negative), which improved to a large effect size by week 12 (d= -0.8). There was a small effect size improvement (d= 0.4) in general psychopathology (e.g. depression, anxiety, somatic symptoms; PANSS general) at week 2 for the CBT for sleep group, compared with the standard care alone group. However by week 4 and 12 the standard care alone group had an improvement that was similar to that of the intervention group at week 2. There was a small effect size improvement (d= -0.2) in manic symptoms by the 12 week assessment point as a result of the intervention, but effect before this time. There was a medium effect size improvement in global distress (d= -0.5) in the CBT for sleep group, when compared to standard care at the 2 week assessment point. However there was no further

improvement in distress in the treatment group by weeks 4 and only a small effect size (d=-0.2) improvement over standard care by week 12. Lastly, there was a small effect size improvement in suicidal ideation at week 2 for the treatment group, but no effect of the intervention on suicidal ideation beyond this time.

Table 3. Scores for secondary outcome measures

	CBT for sleep (n=20)	Standard care (n=20)	Adjusted mean difference (95% CI)	Effect size (d)
Secondary outcome measures				
Positive symptoms (PANSS)				
Week 0	15.3(6.6)	15.4 (5.2)		
Week 2	12.2 (4.8)	12.5(4.6)	0.2 (-2.1;2.4)	0.0
Week 4	11.2 (3.9)	11.2 (4.3)	0.1 (-2.1;2.4)	0.0
Week 12	9.4 (2.9)	10.4 (3.5)	-0.4 (-3.0;2.3)	-0.1
Negative symptoms (PANSS)				
Week 0	14.7 (6.0)	13.9 (4.3)		
Week 2	12.8 (4.1)	13.8 (5.7)	-1.4 (-4.3;1.4)	-0.3
Week 4	11.9 (4.6)	13.6 (5.1)	-2.0 (-5.3;1.2)	-0.4
Week 12	11.9 (3.5)	15.1 (7.3)	-3.9 (-7.8;0.1)	-0.8
General psychopathology (PANSS)				
Week 0	38.4 (9.2)	39.2 (8.3)		
Week 2	31.4 (6.6)	34.7 (8.5)	-3.1 (-7.2;1.1)	-0.4
Week 4	30.8 (8.8)	30.2 (8.0)	0.8 (-3.8;5.5)	0.1
Week 12	29.1 (8.4)	30.4 (11.9)	-0.3 (-7.2; 6.7)	-0.0
Manic symptoms (YMRS)				
Week 0	14.6 (9.8)	13.9 (6.2)		
Week 2	9.4 (6.8)	11.2 (6.6)	-1.1 (-5.0; 2.7)	-0.1
Week 4	8.1 (8.3)	7.8 (6.4)	0.0 (-4.4; 4.4)	0.0
Week 12	5.4 (6.4)	7.8 (6.7)	-1.8 (-6.2; 2.6)	-0.2
Global distress (CORE-10)				
Week 0	19.5 (5.8)	19.3 (8.7)		
Week 2	11.9 (4.9)	15.6 (7.1)	-3.3 (-5.8;-0.7)	-0.5
Week 4	13.1 (5.2)	12.7(6.1)	0.9 (-1.7;3.4)	0.1
Week 12	13.1 (6.5)	13.4 (5.4)	1.4 (-1.6;4.4)	0.2
Suicidal ideation (BSS)				
Week 0	4.6 (8.3)	6.7 (10.1)		
Week 2	0.8 (3.3)	3.6 (8.7)	-1.8 (-5.0;1.5)	-0.2
Week 4	1.1 (4.6)	3.0 (6.9)	-0.7 (-3.6; 2.3)	-0.1
Week 12	1.3 (3.5)	2.0 (5.9)	0.4 (-3.3;4.2)	0.0
Duration of admission in days (baseline to 12 week)	32.5 (22.9)	37.9 (25.1)	-5.8 (-21.6;10.0)	-0.2
Duration of admission (baseline to discharge)	33.5 (25.6)	41.0 (33.7)	-8.5 (-28.0;11.1)	-0.3

Data are mean (SD). PANSS = Positive and Negative Syndromes Scale. YMRS = Young Mania Rating Scale. CORE-10 = Clinical Outcomes in Routine Evaluation, 10 item scale. BSS = Beck Suicide Scale. All analyses controlled for baseline score for that variable and stratification factors (insomnia severity, diagnosis and wellbeing). On all scales higher scores indicate a poorer outcome.

We measured the duration of hospital admission from medical records, as a marker of speed of recovery. Given that we couldn't guarantee that all patients would have been discharged by the 12 week assessment point, we capped the duration of admission at 12 weeks (84 days). This indicated that those who received the CBT for sleep intervention spent on average 5.8 days less in hospital than standard care

alone. This analysis controlled for baseline measures of: duration of admission, insomnia severity, diagnosis and wellbeing. In fact all patients had been discharged by the end of the study allowing analysis of the true length of admission. This revealed that the sleep intervention group spent 8.5 fewer days in hospital than the group who received standard care alone.

Client satisfaction

80% (16 out of 20) of participants returned a client satisfaction questionnaire. Scores are shown in table 1. Scores indicate a high level of satisfaction by the majority of participants.

Table 4. Client satisfaction questionnaire score (n=16)

Questionnaire item	Scale rating				
How would you rate the quality of the therapy that you have received?	Very poor *n = 0*	Poor *n = 0*	Fair *n = 0*	Good *n = 6*	Excellent *n = 10*
Did you get the kind of therapy that you wanted?	No, definitely not *n = 0*	No, not really *n = 0*	Somewhat *n = 1*	Yes, generally *n = 5*	Yes, definitely *n = 10*
If a friend were in need of similar help, would you recommend the programme?	No, definitely not *n = 0*	No, probably not *n = 0*	Unsure *n = 0*	Yes, probably *n = 3*	Yes, definitely *n = 13*
How satisfied are you with the amount of therapy that you have received?	Quite dissatisfied *n = 0*	Mildly dissatisfied *n = 0*	Somewhat satisfied *n = 1*	Mostly satisfied *n = 7*	Very satisfied *n = 8*
Has the therapy helped you to deal more effectively with your problems?	No, it hasn't helped at all *n = 0*	No, it didn't really help *n = 0*	Unsure if it has helped *n = 1*	Yes, it has helped *n = 6*	Yes, it's helped a great deal *n = 9*
In an overall, general sense, how satisfied are you with the therapy you have received?	Quite dissatisfied *n = 0*	Mildly dissatisfied *n = 0*	Somewhat satisfied *n = 0*	Mostly satisfied *n = 7*	Very satisfied *n = 9*

Safety

Adverse events are sadly common in people experiencing severe mental illness. For example, when asked in the first study assessment (week 0), the study participants had on average one previous suicide attempt and one previous hospital admission. This emphasises the importance of assessing safety in this group. The trial protocol (approved by Leicester NHS Research Ethics Committee, ref: 15/EM/0341) specified that a safety assessment would be completed for each participant, via reporting serious adverse events (SAE). SAEs were defined as i) deaths ii) suicide attempts iii) serious violent incidents iv) admissions to secure units and v) formal complaints about the therapy.

When the research team became aware of an adverse event this was reviewed and a report written. In addition we actively searched every participant's medical record to check for SAEs. Each SAE report was sent to the Oxford Health NHS Foundation Trust Trial Safety Review Group (TSRG). This group is independent from the research team and their role was to determine whether or not the SAE was related to

participation in the trial. There were two SAEs throughout the duration of the study, one suicide attempt following discharge from hospital (CBT for sleep group) and one hospitalisation (standard care alone group). Both were deemed by the TSRG to be unrelated to participation in the study.

Qualitative interviews with patients

Each patient who received the intervention was invited to complete a qualitative interview with a research assistant who was independent of the research group. We have written informed consent to use quotes from these interviews. Below are three example quotes from patients:

"I found it useful. If I didn't have that [the sleep study] I think I would have been far more worried about sleep. When I thought there was something I could do to address it; that really helped. And I didn't like the idea of taking sleep pills at all. I took one and felt horrible the next day so I vowed never to take them again.

It was very useful. And if I have trouble sleeping again there are measures I can take to address it, not just one tool, but several tools. I'd give it [the sleep study] 10 out of 10."

"During therapy they gave me some coping mechanisms, like radio, wind down at night time before bed, not watching too much TV or stimulate the brain too much, which helped. Do something like reading instead of watch TV – stuff like

"At the moment I'm not sleeping too much, or not enough, it's not like before, it's definitely improved. I'm not relying on other stuff, like sleeping tablets or other stuff too…

Part 3: Cost impact

The highest cost associated with this study group is the cost per day of an inpatient admission. The 2015-2016 figure for one day on Vaughan Thomas ward is: £352.

The adjusted mean difference of duration of admission indicated that the sleep treatment group spent 8.5 fewer days in hospital. This equates to £2992 per person per admission. Given this, we will approach a health economist to conduct a full economic evaluation of the intervention from data collected within the study.

The sleep intervention is now imbedded into routine clinical practice on Vaughan Thomas ward. It is run as a weekly clinic by staff already employed by Oxford Health NHS Foundation Trust (an occupational therapist, a psychiatric nurse and 2 health care assistants) and hence at no extra cost. Supervision is offered via the study therapists (for a 6 month period) and the ward clinical psychologist (in the longer term), at no extra cost to Oxford Health NHS Foundation Trust.

Below is an estimation of the costs for therapy tools for the study participants who received the intervention. Note, for sustaining the intervention in routine clinical practice, this is a highly conservative estimate of costs per patient, given that the majority of therapy tools (e.g. iPad, bean bags) can treat many more than 20 patients before requiring replacement.

Table 5. Estimate of costs for therapy tools

	Unit cost	Number of units required (for 20 participants treated)	Cost per participant treated (unit cost*number of units required for 20 patients / 20)
Black out blinds (optimising sleep environment)	£22.99	3	£3.45
Eye mask & ear plugs (optimising sleep environment)	£4.99	10	£2.50
Bean bag (for winding down outside of bed)	£32.95	5	£8.24
Radio & USB (for relaxation audios)	£10.00	5	£2.50
Fitbit sleep monitoring watches (to replace Basis Peak watches)	£74.99	10	£37.50
Lumie light therapy box	£149	1	£7.45
Resources for risk approved wind down (e.g. Mindful colouring book)	£30	1	£1.50
Cost of iPad mini for uploading sleep watch data	£219	1	£10.95
TOTAL PER THERAPY PARTICIPANT			**£74.08**

The above calculations have been costed per patient. In real terms the cost saving from a reduction in admission length will only translate into a cost saving for Oxford Health NHS Foundation Trust if the reduction in admission length leaves a free bed for a new patient who would otherwise be sent to an alternative NHS Trust (an 'out of area' admission). Out of area admissions are common psychiatric practice in the UK (for example at least 2 patients from other NHS Trusts were admitted to Vaughan Thomas ward during the study period). Unfortunately we were not able to locate accurate data for out of area bed days avoided for Vaughan Thomas ward patients. However we can provide the below estimate.

The cost of an out of area bed is currently up to £795 per patient per day (£346 more than a Vaughan Thomas ward bed). This does not include transport costs.

Based on admission and length of stay data collected as part of the study, we consider it likely that an out of area admission was avoided, based on a reduction in occupancy rates, illustrated in the below calculations:

- On average 12.82 patients are admitted per month to Vaughan Thomas ward, which equates to 153.84 admissions per year.
- Their average stay is 41.00 days (without sleep therapy).
- This means over a year there are 6307 bed days *used* on VT.
- In terms of bed days *available*, there are 18 beds on the ward which is therefore a total of 18 beds x 365 days = 6570 bed days per year available on the ward.
- Therefore the standard occupancy rate is 6307/6570 x 100 = 96.0%

- On average 12.82 patients are admitted per month to Vaughan Thomas ward, which equates to 153.84 admissions per year.
- If they receive the intervention, their average stay is 35.50 days.
This means over a year there are 5153.64 bed days *used* on VT.
As before, given that there are 18 beds on the ward the number of bed

Part 4: Learning from your project

This section is intended to summarise your learning from implementing your project.

We have achieved our key objectives: i) to test whether the sleep therapy is feasible and acceptable ii) to gain preliminary efficacy data iii) to embed the intervention in routine clinical practice, based on learning from the year.

Contributors to success:

Consulting with patients taught us the best time and place to approach patients for the study and how to adapt the intervention for the ward setting. Close liaison with ward staff throughout the duration of the study was helpful for developing study specific processes on the ward (e.g. risk assessment procedures and ensuring room availability) and ensuring trial specific procedures (e.g. blind assessments) were supported. We learnt that a variety of communication strategies ensured that the large staff pool was kept up to date. This included leaflets, posters, and attendance at ward round and business meetings. Outside of the ward environment we sought to keep senior management contacts up to date with study progress. This has included research and development contacts and head of nursing for inpatient wards and the chief executive of Oxford Health NHS Foundation Trust. The time invested in liaising with staff and patients has been valuable for continual learning, fostering an environment that was open to feedback, supported a solution focused approach to implementation, and a commitment to sustaining the innovation in the long term.

One contributor to successful implementation of psychological therapy on an inpatient ward is the choice of sleep as the target for treatment. Patients were able to engage in the therapy. This is evidenced by the mean number of sessions completed (8.6, SD 1.5). The mean session duration was 45 minutes (SD 15.6),

which is very similar to typical outpatient psychology work. This result is perhaps counter to a traditional perception that inpatients would be "too unwell" to engage in therapy. We believe that engagement in therapy was facilitated by the following factors:

- Firstly, the topic of focus was relevant to the participants. The majority experiences sleep difficulties, many were distressed by it, or saw it as an important benchmark for health, which is likely to have increased motivation to engage.

- Secondly, the topic was normalising. Almost everyone can identify with having sleep difficulties, it is a very common and normal problem to experience on occasion. Working on sleep may have been particularly engaging for a patient group who often report feeling stigmatised and set apart from society, particularly whilst in hospital.

- Thirdly the session content was not overly emotionally demanding, and, indeed, was often enjoyable. There was a focus on practical strategies and patients weren't typically discussing things that would be particularly distressing as might occur with a different focus (e.g. reviewing evidence for and against a delusional belief; making links between traumatic history and current difficulties). When patients are acutely unwell, sleep therapy may be a particularly good fit.

As part of the process for sustaining the innovation we recruited a group of sleep champions and offered training in using the intervention. We quickly saw that the team were highly enthusiastic about innovating to improve patient care. We set up a training workshop in which we provided resources and learning for delivering the intervention, but encouraged discussion and decision making from the sleep champions regarding how this would best work within routine clinical practice. The sleep champions decided that setting up a sleep clinic would be the best model for implementation. With their ownership of this development in care and key decisions in its design, we think that the implementation is more sustainable in the very long term.

Challenges:

Working in an acute care setting is a challenging and at times stressful environment. The following are challenges specific to this setting, and the innovation we designed:

i) Treatment delivery needs to happen very rapidly (to complete prior to discharge). This meant that our therapy window was intentionally short, set at two weeks and session attendance was important. A timely handover from the research assistant to the study therapist was necessary. We also set up a shared sleep team diary to ensure that the sleep therapist was

available for therapy the following day after a baseline assessment. Communication within the sleep study team and with the ward was imperative to ensure this process happened successfully.

ii) Use of technology (e.g. watches) meant devices needed to be charged very regularly and hence staff needed to be able to contact us easily to let us know when this was required. In addition, the team needed to be adept at problem solving technical issues, which will naturally occur with any technology. Online user forums were particularly helpful.

iii) Everything that is taken on to a psychiatric inpatient ward requires risk assessing in principle and risk assessing for each individual patient. We set up a standard operating procedure for risk assessing therapy tools. This was agreed with the management team and created an understanding of what needed to happen, that was shared between the sleep study team and the ward team.

The ward staff (lead by the ward manager and Dr Barerra) and the research team shared an enthusiasm about trying to improve inpatient care and it was this enthusiasm, coupled with good working relationships that meant the above challenges were met and managed efficiently.

Part 5: Sustainability and spread

This section is intended for you to communicate your plans for sustainability and spread.

We have plans to sustain the intervention within Vaughan Thomas ward, Oxford Health NHS Foundation Trust. There are also plans to spread the intervention to clinicians outside of the setting within which the intervention has been tested and also to continue gathering evidence for the efficacy of the intervention.

Sustainability of the intervention within Vaughan Thomas ward

We have liaised with staff and patients to build a model of sustainable change on Vaughan Thomas ward. This has included two levels of training on sleep:

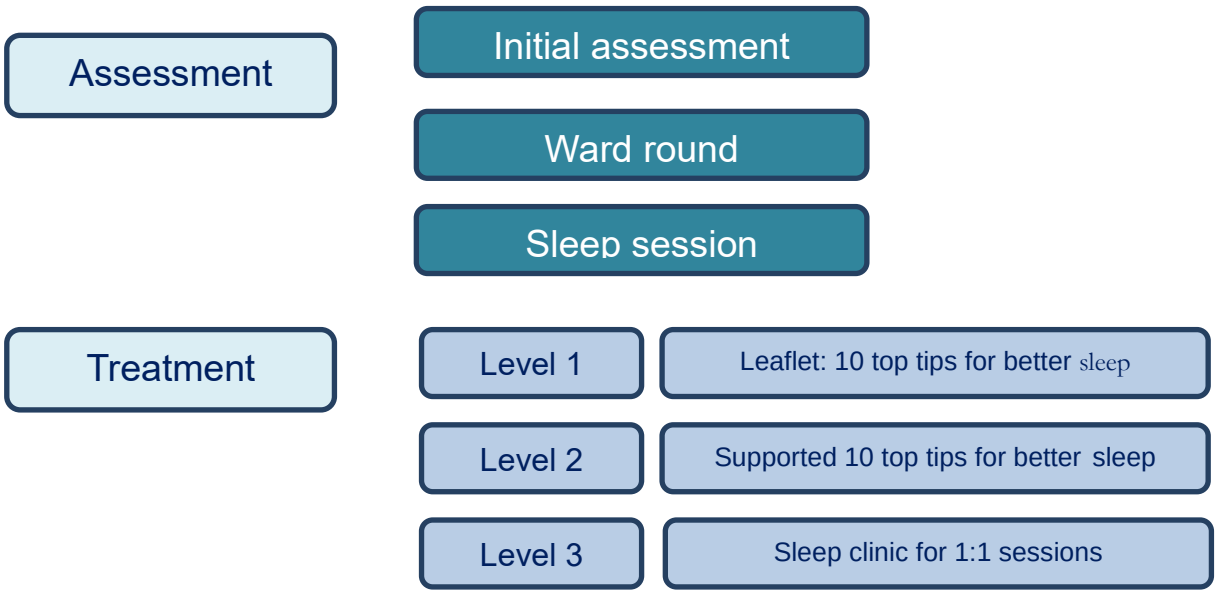
LEVEL 1: Training for all ward staff on the importance of sleep. Within this we introduced the concept of 10 top tips for improving sleep on inpatient wards (see poster in appendices).

LEVEL 2: We advertised for sleep champions to embed the sleep intervention into routine clinical practice. We held a one day skills workshop with the sleep champions where we shared the sleep study intervention manuals:

The sleep champion team developed a shared vision for taking the work forwards:

> ***"Vaughan Thomas ward considers good sleep as crucial for mental and physical wellbeing. Therefore, we aim to provide everyone with the opportunity and environment to improve their sleep, whilst also maintaining high standards of patient safety."***

The following treatment pathway was developed for the ward which includes a range of sleep assessment opportunities. The team felt a stepped care approach would be most appropriate to offer timely help to all, whilst offering more intensive help to those that require it.



A poster has been developed which outlines our 10 top tips for better sleep on Vaughan Thomas ward (see appendices). We have also developed a patient leaflet version. This will be offered to all patients who report a sleep problem. Some patients may require a one off session to discuss a plan for implementing one of the 10 top tips. For patients who require more intensive support, they will be referred to the ward's sleep clinic, which runs on a weekly basis and is run by 1-2 of the sleep champions. The sleep champions deliver the sleep intervention techniques on a one to one basis with patients.

The clinic has received 5 referrals to date, each of whom has been assigned a sleep champion for 1:1 work. The clinic has the support of the ward management team and the head of inpatient nursing. The biggest challenge to sustaining the innovation is staff time. Staff shortages and high turnover of staff is common in acute care settings. The sleep study therapists will supervise the clinic for 6 months to monitor

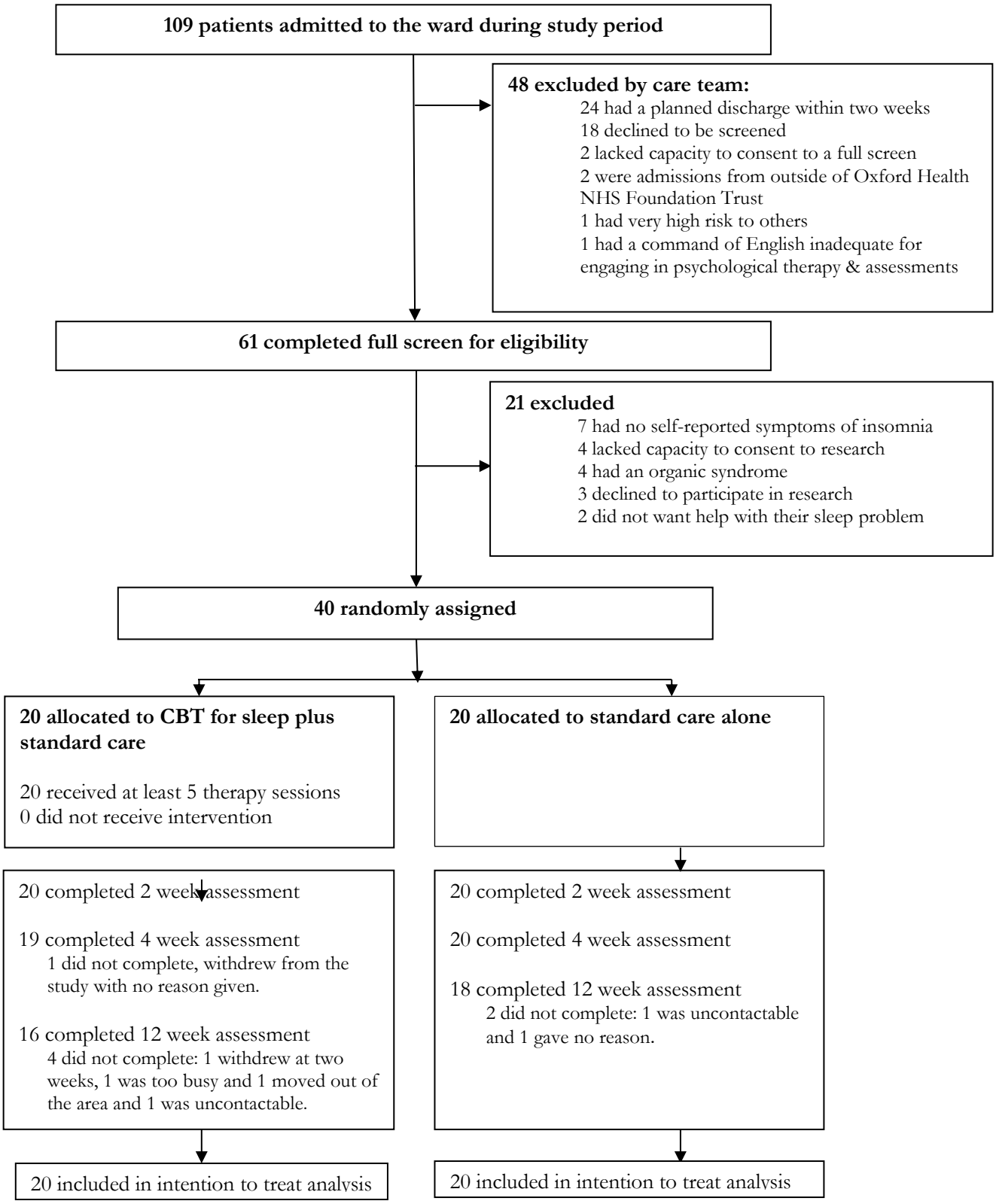
referral rates, therapy provision and barriers to provision and problem solve when needed.

Sustainability of the intervention beyond Vaughan Thomas:

The results of the study will be submitted for publication in a peer reviewed journal with an international readership. Once the study has been published in a journal, the publication will be further advertised via social media, conferences and workshops. We have two workshops planned for the 2017-2018 calendar year to train clinicians in using CBT for insomnia techniques on inpatient wards. These workshops are typically attended by clinicians across the UK and Europe.

Given that there is an indication of a shorter admission length associated with receiving the intervention, we will approach a health economist for a full health economic evaluation of the intervention. We also plan to apply for funding for a suitably powered phase 3 randomised controlled trial to complete a larger test of the efficacy of the intervention. This will take forward the invaluable learning from this study.

Appendix 1a: CONSORT diagram showing flow of participants through the study



Appendix 1b: Poster: 10 top tips for better sleep

Having trouble with your sleep?

Try out these 10 tips for better sleep.

Lying at wake at night can feel like a lonely experience, but evidence shows that you are not alone. In fact around a third of the general population experience symptoms of insomnia and when people are admitted to hospital, sleep problems are even more common. For some these sleep difficulties might be short lasting, but for others they are more persistent and require some extra help. We hope that the following tips will help to get your sleep back on track.

1. THE 15 MINUTE RULE

If you have difficulties sleeping you've probably noticed that you spend lots of time in bed awake. This means that bed might become connected with being awake, frustrated or anxious. To promote your bed – sleep connection, follow the 15 minute rule: if you notice that you aren't asleep within around 15 minutes of going to bed, try getting out of bed, doing something to wind down until you are feeling sleepy-tired and ready to return to bed for sleep.

2. BED IS JUST FOR SLEEP

Our minds are clever and create lots of links without us necessarily being aware. This is why it's important to create a strong link between bed and sleep by avoiding using your bed for other activities that aren't sleep, for example chilling out in the daytime, or worrying. See if you can find another spot to do these. You can also ask the staff about a bean bag so you have somewhere comfy to sit in your room outside of your bed.

3. NATURAL LIGHT

Natural light suppresses the production of melatonin (a hormone associated with sleep). Try to avoid bright light before bedtime to promote melatonin production. Conversely, try to expose yourself to lots of natural daylight when it's time to be awake (particularly early morning). This will help you wake yourself up and get going for the day.

4. BE SMART WITH YOUR NAPS

The longer we are awake, the more likely we are to sleep, because our 'sleep pressure' has had time to build up. To increase your chances of drifting off at night try to avoid naps throughout the day. Of course, if you feel dangerously tired, do take a short nap (of around 20 minutes) but try to plan this earlier in the day to allow your sleep pressure to build again afterwards.

5. RISE TIME

If you aren't getting enough sleep at the moment, it can be tempting to try and catch up on lost hours by having a lie in. In fact, this is likely to decrease the likelihood of a good night of sleep the following night, because you won't have built up enough 'sleep pressure' throughout the day. Set a regular rise time and see if you can stick to it 7 nights a week. It might be hard work in the short term but will improve your chances of falling asleep each night. To help with getting out of bed at your rise time, plan some things to help get you going. Perhaps a shower or a chat with another patient or staff.

6. WIND DOWN ROUTINE

Take time to prepare your mind and body for winding down before sleep. Set time aside, ideally around 90 minutes, for doing something relaxing. Some ideas might include reading a book, listening to calming music or practicing relaxation exercises. If you find that your mind is racing when you head to bed, you could use part of this time to find a way to close off the day. Perhaps write a diary to take the power out of your thoughts, or make a plan of the things that you would like to do the following day to stop these thoughts popping up when you are in bed.

7. CREATE A SLEEP FRIENDLY BEDROOM

Is there anything obvious in the bedroom that is getting in the way of a good night's sleep? Do you need to speak to the staff about getting an extra pillow? Are your blinds closed before you get into bed? Create a bedroom space that is as dark and comfortable as possible to increase the chances of sleep.

Written by Dr Bryony Sheaves,
Clinical Psychologist Sleep
& Circadian Neuroscience institute
in collaboration with the
Vaughan Thomas Ward's
sleep clinic

8. CONSIDER WHAT YOU PUT INTO YOUR BODY

You want to give your body the message that the later part of the evening is for switching off. So try to avoid stimulants such as caffeine and nicotine in the hours before bed. Lastly, consider the timing of meals – the purpose of food is to supply energy, so eat at regular times through the day and avoid eating a big meal within four hours of bedtime.

9. KEEP ACTIVE!

Keeping active can set us up for a good night's sleep, both physically and emotionally. Physical exercise can help give us energy during the day, but also leave us feeling sleepy enough to sleep later that night. You could speak to the activity co-ordinator about activities on offer, or use your leave for this (e.g. walking or running). But try to make sure that you don't exercise too close to bedtime (ie. within 2 hours of bedtime) otherwise this may leave you feeling too awake to sleep.

10. HELP THE MEDICS TO HELP YOU

Some medications can increase the chances of sleep. This may mean that it is helpful to talk to the medical team about whether they are timed to match your bed time. The team also want to ensure that you are able to get up the following morning so if medications are making this difficult let the team know so that they can consider all the options.

If you would like further help with your sleep,
you can ask to be referred to the
Vaughan Thomas Ward's sleep clinic.

Appendix 1c: Three case examples

Case example 1: Kian

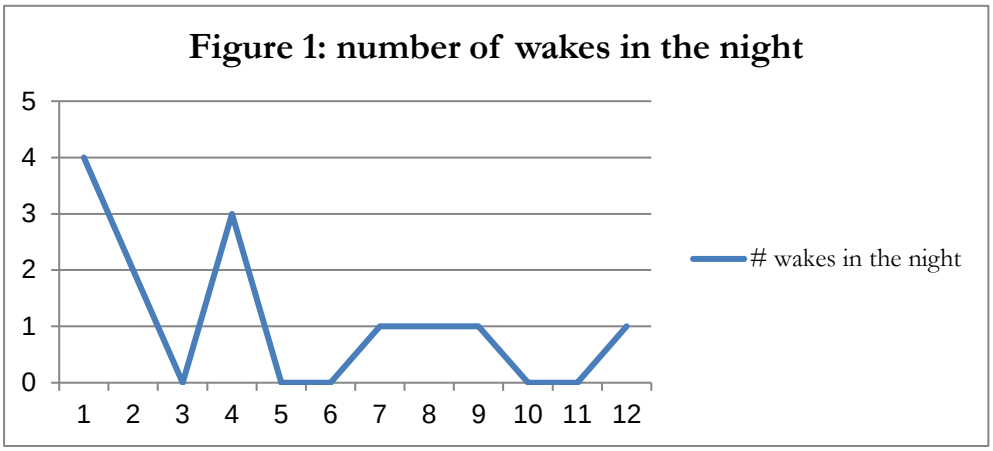
Kian* is an unemployed divorced gentleman in his 40s. He has a diagnosis of recurrent depression. He was admitted informally due to a depressive episode with suicidal intent.

At the start of therapy Kian reported that he was spending a lot of time in bed but finding it difficult to sleep at night. He was napping during the day, and waking frequently at night (sleeping for less than 5 hours in total). Kian scored 16 out of 28 on the Insomnia Severity Index, indicative of moderate insomnia. His goal for therapy was to be able to sleep solidly between midnight and 6am without waking.

A collaborative sleep plan was developed. This included the following key techniques:

- Anchoring sleep and wake times (midnight and 7am).
- Avoiding naps in the day.
- Planning “wind down” and “rise up” routines (to help get ready for sleep at night, and to get up in the morning). The “wind down” involved doing relaxing activities for the 1.5 hours before sleep (such as dimming the lighting, listening to relaxing music or a relaxation CD, doing a puzzle, chatting with others, or drawing). The “rise up” routine included opening the curtains, getting outside for some fresh air, having a shower, and eating breakfast.
- Stimulus discrimination (learning to associate bed with sleep). The use of one of the study’s beanbags was crucial for this, as it gave Kian an alternative option to lying in bed if he wanted to stay in his room during the day.
- Increasing activity during the day (to help boost sleep at night, avoid naps, increase energy, and improve mood).
- Developing a relapse management plan to help maintain progress once discharged home. This included planning to purchase a bed which he had not got before admission to hospital.

Kian had 8 sessions over a two week period. By the end of therapy his score on the insomnia severity index had dropped from 16 out of 28 to 2 out of 28 (indicating a shift from moderate insomnia to no insomnia). He had reduced the number of times he was waking in the night from 4 times to 0-1 times, and had reduced the amount of time he was lying awake at night from 270 minutes to only a few minutes at a time. He had also achieved his goal of being able to consistently sleep solidly between midnight and 6am. These achievements are shown in Figures 1 to 3 below. Kian was pleased with the outcome and reported a high level of satisfaction with the therapy (reflected by his score of 35 out of 35 on the Client Satisfaction Questionnaire).



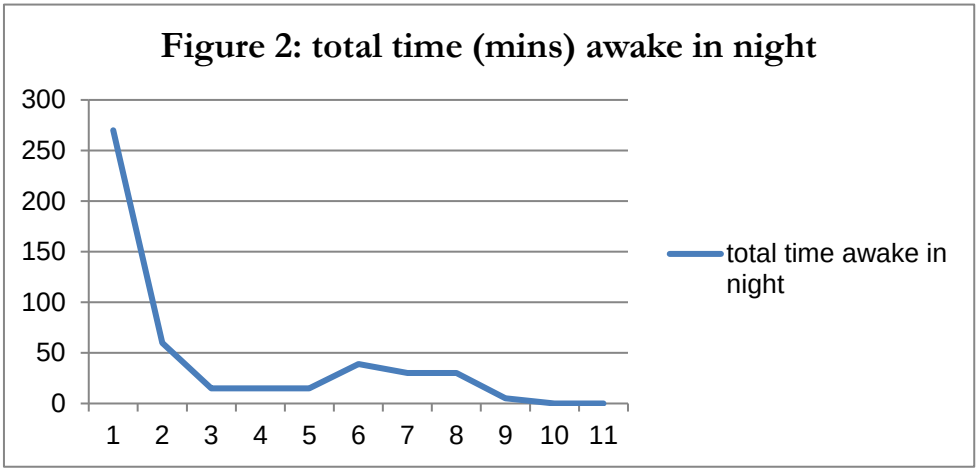


Figure 3: Excerpt from therapy report showing Kian's success in reaching his goal of sleeping between midnight and 6am without waking.

Day	1	2	3	4	5	6	7	8	9	10	11	12
Slept 00:00-06:00 without waking?	**No**	**No**	**Yes**	**No**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

Case example 2: David

David* is an unemployed married man in his 50s who is a father and grandfather. He has a diagnosis of bipolar affective disorder and was admitted to hospital informally due to a relapse (depressive episode).

At the start of therapy he reported that it took him several hours to get to sleep and that he woke frequently (up to 10 times each night). He scored 28 out of 28 on the Insomnia Severity Index indicative of severe insomnia. He also reported symptoms of severe low mood, guilt and suicidal ideation.

David's therapy goals were to be able to get to sleep within 15-20 minutes, and to get up fewer than 10 times in the night.

Key strategies used in therapy are outlined below:

- Psychoeducation about the processes that influence sleep.
- Setting the window for sleep (11pm and 6am).
- Developing a wind down routine to use in the 1.5 hours before sleep (key aspects of this were listening to a bespoke relaxation audio made for David, and use of a handheld radio that was given to him as part of the study).
- Stimulus discrimination (to make a bed=sleep association). David was loaned one of the study's beanbags so that he had somewhere to sit when he couldn't sleep rather than staying in his bed.
- Understanding the importance of activity. This was a key aspect of the treatment as we identified that David had initially become stuck in a vicious cycle of inactivity, low mood, and poor sleep (see Figure 4). We identified how, by increasing activity, David could improve his mood and sleep (see Figure 5). David successfully implemented this idea by adding walks of increasing distance and pace, and exercise sessions at the nearby outdoor gym, to his daily routine. This effort is reflected in Figure 6 which shows heart rate data captured using the Basis Peak study watch during therapy.
- Relapse managament planning of how to maintain progress once returning home.

Figure 4: Diagram developed in therapy showing David's "vicious" cycle of poor sleep, inactivity and low mood.

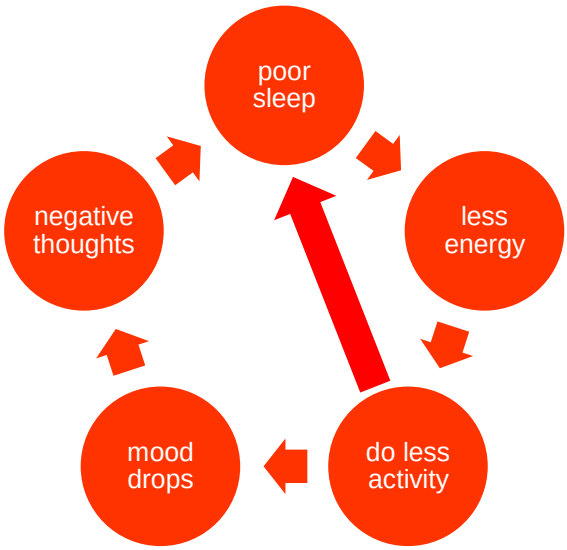


Figure 5: Diagram developed in therapy showing a virtuous cycle of increased activity, improved mood, and better sleep.

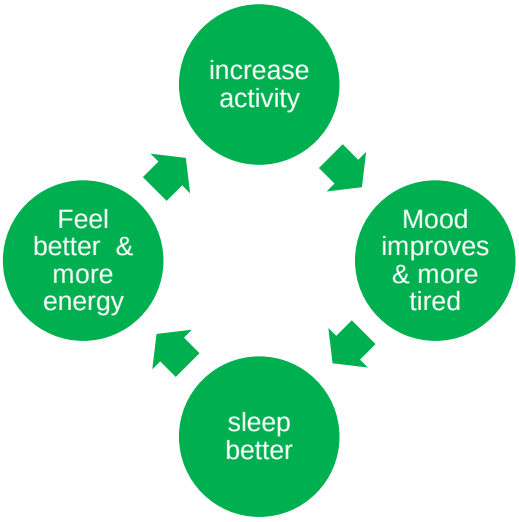
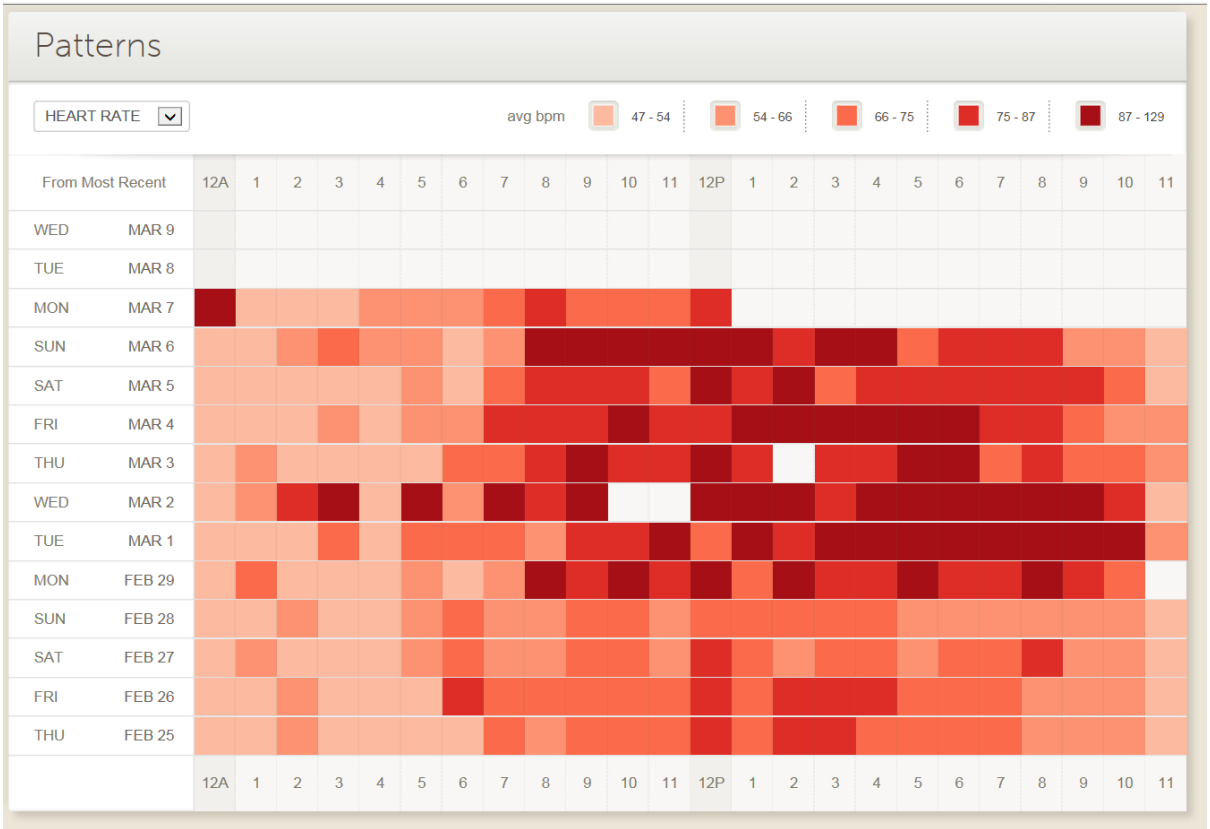


Figure 6: Graph showing David's heart rate across the therapy period. David enjoyed seeing this output as a mark of his efforts to increase his daytime activity.



At the end of therapy David reported that he was getting off to sleep much more quickly (mostly within 20 minutes), and was typically only waking 1 or 2 times in the night rather than up to 10 times. His scores on the Insomnia Severity index dropped from 28 out of 28 to 2 out of 28 (from severe insomnia to no insomnia), and he also reported a significant improvement in his mood. David said he was very pleased with the therapy reported a high level of satisfaction with the input offered to him via the Sleep Study(reflected by his score of 35 out of 35 on the Client Satisfaction Questionnaire).

Case example 3: Robert

Robert* is a professional man in his 50s with a diagnosis of Bipolar disorder. He was admitted to hospital under Section of the Mental Health Act due to experiencing a relapse (manic episode).

The Basis Peak watch was invaluable in monitoring his sleep across the course of therapy.

Figure 7 below shows a screenshot of the sleep data recorded by the watch during Robert's first night in the study. It shows that he got only 1 hour and 59 minutes sleep on this night, and this was split up into three short episodes. The watch

revealed similar problems on nights 2 (when he got 2 hours and 7 minutes sleep) and 3 (when he did not sleep at all).

Figure 7: Data from the Basis Peak Sleep monitoring watch showing Robert's sleep on his first night in the Sleep Study.

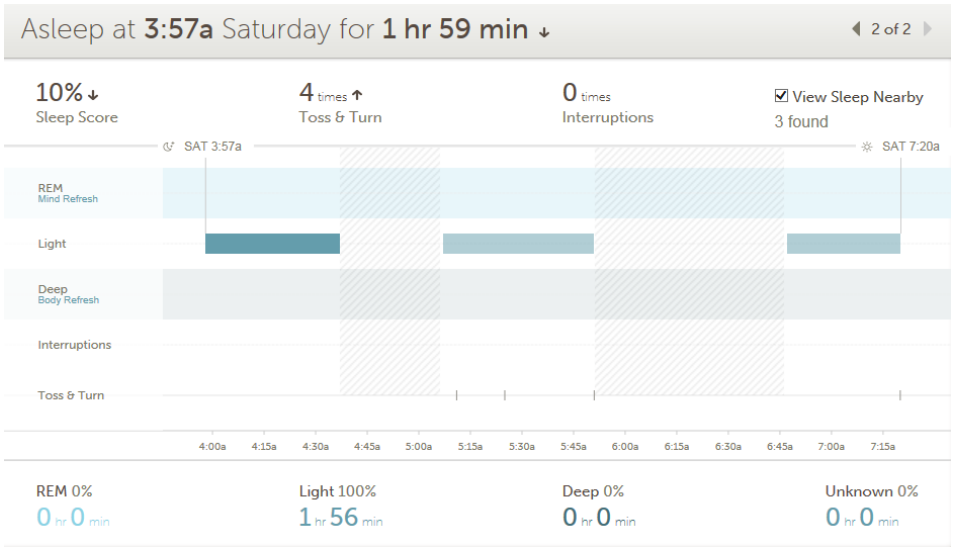


Figure 8 shows a screenshot of the sleep data 10 days later (towards the end of the therapy window). This shows Robert now getting in excess of 6 hours sleep which is an exciting achievement given his manic presentation at the start of therapy. The objective data provided by the watch was very useful both as a tool for congratulating the participant and motivating them to continue with the sleep work, and also as a method for sharing improvements with ward staff.

Figure 8: Data from the Basis Peak Sleep monitoring watch showing Robert's sleep on night ten of the Sleep Study.