The long-term clinical effectiveness of a community, one day, self-referral CBT workshop to improve insomnia: a 4 year follow-up

Background

Insomnia is the most common mental health symptom in the UK and its prevalence is increasing[1]. Symptoms of insomnia affect at least one third of the population, with 5 -10% within the clinical range[2]. The economic impact of insomnia is considerable[3], with 76% of costs due to insomnia-related absenteeism and reduced workplace productivity. It is strongly associated with increased risk of later development of depression and among those with insomnia, significantly increases the risk of depressive disorder[4].

CBT for insomnia (or CBT-I) has been specifically designed to reduce insomnia, focussing on improving sleep quality. There is substantial evidence for the effectiveness of CBT-I, with 70-80% of treated participants experiencing both short and long term improvement[2]. Additionally, CBT-I shows longer term benefits than pharmacotherapy, it does not have physical side effects and is preferred by patients[5]. CBT-I is also effective in improving insomnia secondary to other physical and mental disorders[2]. There is also promising evidence that CBT-I improves depression outcome[6] but the pilot study was small.

Despite the high prevalence and impact of insomnia, and strong evidence for the effectiveness of CBT-I, the majority of individuals with insomnia remain untreated, with only a third of individuals with insomnia seeking professional help[7]. Reasons for this reluctance include a tendency to trivialise sleep problems as well as a perceived lack of effective treatment options[8]. Even for those individuals who do consult, assessment and treatment of persistent insomnia are frequently inadequate in primary care[9]. Finally, even if professionals are aware of CBT-I, there are few available services[10].

Given the size of the problem and the limited services, Espie[11] has proposed a five-tier stepped-care model for delivering CBT-I which aims to make best use of resources. The first step would involve self-help methods, with the resource requirement gradually increasing in terms of time, cost and expertise.

There is a small but growing body of evidence for the effectiveness of less intensive CBT-I based interventions. Group CBT-I has been shown to be reasonably effective[12] although the evidence base is smaller than that for individual CBT-I. Self-help with telephone consultations has also been found to lead to significant sleep improvements[13]. Additionally, a brief two-session intervention has also been found to be effective[14]. Finally, an internet based adaptation of CBT-I achieved significant improvements in insomnia symptoms[15].

A new and accessible group approach to addressing treatment barriers is to deliver CBT-I in a day-long psycho-educational workshop format, with each workshop accommodating up to 30 people. This CBT format, aiming to reach large numbers of the general public at once, was originally developed by Brown and colleagues[16] for stress problems. To maximise accessibility, the workshops were run at the weekend in non-mental health settings, such as leisure centres, and members of the public could directly refer themselves to these workshops rather than relying on GP referral.

In a randomised controlled trial[17] conducted in 2008/9 of 151 participants with a waiting list control, scores of the experimental group and the control group were compared three months after baseline. The workshops proved to be accessible, with 50% of the participants never having previously sought help from their GP for their sleep problems before. All participants had chronic insomnia. Over 67%

scoring within the clinical insomnia range on the Insomnia Symptom Inventory (ISI) and 65.6% reported sleep efficiency of below 85%. The workshops were clinically effective at 3 months' follow-up with significant group differences between the experimental and control groups in symptoms measured by the Insomnia Severity Index (ISI) at three months' follow-up. The controlled effect size was 1.0, indicating a large effect size. Sleep diary data indicated that participants also reported benefits in their patterns of sleep, particularly reducing their waking in the middle of the night.

These findings were replicated in a secondary sub-group analysis of participants with case-level insomnia at baseline. Participant satisfaction with the workshops was very high. Overall, the results indicate that the CBT-I workshops appear to be an accessible, clinically effective intervention for insomnia, as well as being an acceptable service to members of the public.

A follow-up of the trial is now necessary to show the efficacy and clinical effectiveness of this intervention over a 4 year period. There are several reasons.

(1) To assess if a day-long CBT intervention can maintain its effects after 4 years.

(2) To examine if a longer term follow-up shows if CBT-I may have a preventative effect on the development of depression.

(3) To assess if some groups may benefit more than others. For example, baseline insomnia score and/or gender may affect outcome.

(4) To qualitatively explore the aspects of the intervention that were helpful and less helpful so that this can be fed back to the workshop leaders who presently run the workshops.

Method

Design

This will be a mixed methods design. A pre-post design will be used to assess the clinical changes that have occurred in the 4 years since the workshop. A qualitative design will be used to explore the experiences of the participants in the 4 years since they attended the workshops.

Intervention: Day-long CBT-I workshop programme

The workshops were designed for up to 30 people. The day long workshop incorporated psycho-educational and cognitive behavioural techniques based on Morin and Espie[19] and is adapted to fit into a one day format. The workshops were led by two psychologists with CBT expertise and group facilitation experience. The workshops lasted from 9.30am until 4.30pm with regular refreshment breaks, to reduce possible fatigue. Brightly coloured slides were used, with the workshop material corresponding to manuals given to participants.

The seven workshop sessions included: 1. Basic sleep information and education; 2. Explanation of the CBT-I model; 3. Sleep habits and hygiene; 4. Sleep restriction and stimulus control; 5. Sleep cognitions; 6. Relaxation techniques and preparing for sleep; and 7. Overview and action planning. Techniques were practised either in large groups (e.g. relaxation) or individually (e.g. goal-setting).

Participants were expected to practise the various methods described during the period between workshop and 3 month follow-up.

Quantitative Measures

The following self-report assessments will be completed at follow-up. This is a subset of the measures used in the previous trial.

Insomnia Severity Index (ISI) This will be the primary diagnostic and outcome measure. It has been found to have robust psychometric properties[20], is brief and is easy to complete. It consists of seven

items measuring different aspects of impaired sleep on a five point scale. Total scores can be categorised into 'no clinically significant insomnia' (0-7), 'sub threshold insomnia' (8-14), 'moderate clinical insomnia' (15-21) and 'severe clinical insomnia' (22-28).

Beck Depression Inventory (BDI)[22] The BDI is a well-validated and commonly used measure of depressive symptoms. The 21 items generate total scores which can be categorised as 'mild depression' (10-18), 'moderate/severe depression' (19-29) and 'severe depression' (30-63).

Statistical analyses

Power analysis:
We calculated the statistical power of the proposed study needed to detect a change in ISI score over time that corresponds to an effect size d=0.8, which is a more conservative effect than that found in our previous study. Taking account of the within subject correlation due to repeated measures (assuming intraclass correlation =10%) a sample of size 55 should be sufficient to detect the anticipated effect with 80% power at 5% (one sided) significance level.

Analysis:

Baseline and follow-up data from both experimental and control (who received the same intervention 3 months after the experimental subjects) groups will be combined to investigate any changes in the mean primary and secondary outcome measures between baseline and at 3-month and 4-year follow-up. A linear mixed model including a random intercept for subjects to take account for any correlations between repeated measures will be considered. The fixed part of the model will include dummy coded time factor to compare the mean scores between baseline and at each follow-up. A group indicator (control vs. experimental) and any other relevant confounding factors may also need to be tested in the fixed part of the model. We do not expect the experimental group to differ from the control group as both received the same intervention, but this factor will be investigated to see if there is any effect of time lag as the control group waited for three months to receive the intervention. All analyses will be performed using maximum likelihood assuming missingness to be driven by the variables included in the analysis, i.e, missing at random (MAR) assumption which was justified in our previous study.

A second linear mixed model analysis considering BDI depression scores as the outcome and longitudinal ISI scores as a predictor will be considered to test the secondary hypothesis that CBT-I may have a preventative effect on the development of depression. This model will also include time and any other relevant confounding factors.

Qualitative study
Design and topic guide Qualitative interviews will be conducted to explore participants' experience since their participation in the workshop 4 years previously, including (1) current experience of insomnia and change since workshop 4 years ago, (2) memories of workshop and impact of this on current status of insomnia, (3) what helped/did not help or suggestions for improvements to workshop. A semi-structured Interview Topic Guide will be developed to incorporate these issues, along with relevant prompts to engage participants. An experienced researcher will conduct the interviews, following relevant training in qualitative interview techniques.

Sampling A sub-sample of total participants in the quantitative sample will be selected purposively for the qualitative study, based on sampling for a range of demographic variation, such as age, gender, and severity of insomnia at the time of intervention workshop. Iterative analysis will guide

our total sample size, but we will roughly aim for a sub-sample of around 12-15 participants. All participants will be assured of confidentiality and anonymity when reporting findings.

Analysis We will use the principles of Framework Analysis[23] which incorporates 5 stages of analysis: (1) familiarising yourself with the research, (2) identifying a thematic framework mostly based on *a priori* questions such as those on the Interview Topic Guide, (3) indexing or coding and annotating all transcripts by applying the thematic framework to them, (4) charting or iteratively rearranging the emerging themes to make it a cohesive whole, and (5) interpreting the existent typologies or patterns in the data.

Procedure

Follow-up

Ethical approval will first be sought to enable us to contact the 95 participants who attended the workshops (49 from experimental group and 46 from control group). Following this, participants will be contacted and informed of the study. They will then be invited to a follow-up session the workshop, during which they will be asked to complete another set of assessment measures as well as discuss how they have progressed in the 4 years since they attended the workshops. All follow-up sessions will be held in the community venues where the original workshops were held.

All participants with missing assessments will be sent the assessment forms in the post and given phonecall reminders and offered the opportunity to talk through the assessments if required.

A smaller sub-group of 12-15 participants will be recruited by letter and interviewed using a semi-structured interview.

Feasibility

In the RCT[15], workshops proved very popular with 158 recruited after a 2 month recruitment period using a self-referral route. In order to maximise our completion rate, we are planning to organise a follow-up meeting which will be preceded by telephone contact with the participants to encourage attendance at the follow-up meeting or else willingness to complete the forms. As a 74% follow-up rate was achieved at follow-up, we hope to obtain a follow-up rate of 55-60% of the participants.

In previous studies, we have achieved good rates of follow-up with members of the public. For instance, we conducted a 2 year follow-up study from a different workshop and achieved a 55% completion rate using a postal follow-up after a 66% follow-up rate at 3 month follow-up.

Addendum

Background

Insomnia is strongly associated with increased risk of later development of depression. This was found in a review of the eight longitudinal epidemiological studies by Rieman and Voderholzer (2003) who found this to be a very consistent pattern with depression likely to occur 1-3 years after an initial episode of insomnia. In one study, Ford and Kamerov (1989) found that the risk of developing new major depression was much higher in those who had insomnia at both baseline and follow-up compared to those without insomnia (odds ratio =39.8). The risk of developing new major depression was much less (odds ratio=1.6) for those who had insomnia that had resolved by the follow-up. Eaton et al (1995) estimated that the attributable (one year) risk of major depression due to insomnia is 47%. Breslau et al (1996) found that at 3 year follow-up, the odds of major depression was nearly fourfold (odds ratio =3.95) in persons with a prior history of insomnia compared with no prior history of Insomnia .

There is promising evidence that individual CBT-I improves depression outcome among participants with insomnia and depression (Manber et al 2008) although the pilot RCT study was small (n=30). Specifically, at 3 month follow-up, depression remission occurred in 83% of those whose insomnia had remitted compared to 39% of those whose insomnia had not remitted.

As our CBT-I workshop aimed to attract those with insomnia, and most of our participants did have insomnia, we cannot test if CBT-I actually prevents depression among those with no insomnia at baseline. However, we can study the group with both insomnia and depression at baseline, similar to the group studied by Manber et al (2008) and examine if a longer term follow-up shows if a CBT-I workshop significantly reduces depression levels in this co-morbid group.

Method

Hypothesis

We hypothesise that the proportion of people with depression among the first group (insomnia remitters) will be significantly lower than the 2nd group (insomnia non-remitters).

Sample

We will only include those whose depression scores on the BDI are 14 and above (indicating depression), and whose insomnia scores on the ISI are above 7(indicating at least sub-threshold insomnia) at baseline (n=52).

Analysis

We will then compare the remission of depression (BDI < or equal to 14) between the following two groups:

a) Participants whose insomnia has remitted (ISI < or equal to 7 indicating no clinically significant insomnia) (remitter group)
b) Participants whose insomnia has not remitted (ISI >7) (non-remitter group)

The figures from Manber et al (2008) indicate that at follow-up, remission of depression was experienced by 83% and 39% respectively in the insomnia remitting and non-remitting groups respectively. This is equivalent to an effect size of OR=7.64. The required minimum sample size needed to detect such an effect at 5% level with 80% power is 38 (19 per group).

We will first compare the 'remitter' and 'non-remitter' groups using a Chi square test.

Then, we will use a linear mixed model analysis, using BDI depression scores as the outcome and longitudinal ISI scores and dummy coded time as predictors. A time by ISI score interaction effect in the model will enable us to test if BDI scores improve over time and also how this improvement depends on the level of ISI scores. We expect the improvement in BDI scores to be better for reduced ISI scores (i.e. within remitter group).