Effectiveness of an educational intervention for general practice teams to deliver problem focused therapy for insomnia: pilot cluster randomised trial

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Introduction

Sleep problems are common, leading to physical and psychosocial morbidity and impaired quality of life. Sufferers often seek help from primary care and receive advice or hypnotic drugs which are ineffective long term. Cognitive behavioural therapy for insomnia (CBTi) is effective but is not widely used in general practice. We conducted a pilot study to test procedures and collect information in preparation for a larger definitive trial to measure effectiveness and cost-effectiveness of an educational intervention for general practitioners and primary care nurses a to deliver problem focused therapy to adults.

Method

Four general practices were randomised: two to an educational intervention (2 x 2 hours) providing problem focused therapy which comprised assessment (of secondary causes, severity and use of sleep diaries) and modified CBTi compared with two practices providing usual care (sleep hygiene advice and/or hypnotic drugs).

We recruited patients with insomnia (Pittsburg Sleep Quality Index [PSQI≥4]) due to lifestyle causes, pain, mild to moderate depression and anxiety.

The primary outcome was PSQI and secondary Outcomes including Insomnia Severity Index (ISI), Epworth Sleepiness Scale, Beck Depression Inventory and PSYCHLOPS were measured at 0, 4, 8 and 13 weeks.

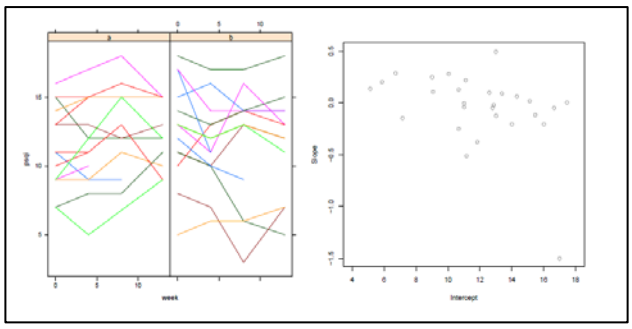
Intervention fidelity was evaluated using telephone Interviews of participating practitioners and patients.

Results

Out of 64 participants recruited, 37 completed the trial. The dropout rate was mainly due to delays in recruitment of patients to the trial and a delay in delivery of the intervention until all patients were recruited prior to randomisation. The statistical analysis was conducted masked to treatment allocation. We used a mixed effects model to test for overall change and whether the intervention affected the rate of change over time.

We detected neither an overall change over time PSQI score increase per week 0.06 (95%CI -0.03 to 0.16) nor differential change between intervention and control groups 0.10 (-0.03 to 0.23) although the study was not powered to detect such a change.

Figure 1. PSQI over time (left graphic) and results of fitting a model to each person (right graphic)



The gradients on the left hand graphic of figure 1. represent the change in PSQI outcome over the 13 week trial period. The intercept reflects the baseline PSQI score.

"One thing that the trial has done is that it's made me less likely to give them Z drugs" [GP intervention arm]

"I think the biggest problem was the kind of the lack of momentum…if we'd got cracking when we'd all had the training at the start I think that would have made a hell of a difference" [GP intervention arm]

Sample size calculation for a definitive trial

A power calculation based on detecting a 2-point difference in ISI would be more efficient than using PSQI for numbers of participants.

Table 1. Number of clusters per arm for power 0.9 for cluster sizes 5-15 and ρ = 0,…0.2.

Clusters	Intracluster correlation coefficient			
	0	**0.02**	**0.1**	**0.2**
5	16	17	22	28
10	8	9	15	22
15	6	7	13	20

Conclusion

This study confirmed that it was feasible to conduct a trial of education for primary care clinicians to deliver problem focused therapy for insomnia in general practice. However, it also exposed problems with study recruitment, dropout, and intervention fidelity which should be addressed in the design of a full trial.

For a full trial the number of data collection points could be reduced (e.g. to baseline, midpoint and end of trial) which would reduce the burden of measurement and should result in a lower rate of attrition and missing data. The education may need to be reinforced, e.g. using e-learning.

Reference: Siriwardena AN, Apekey T, Tilling M, Harrison A, Dyas JV, Middleton H, Ørner R, Sach TS, Dewey M, Qureshi MZ. Effectiveness and cost-effectiveness of an educational intervention for practice teams to deliver problem focused therapy for insomnia: rationale and design of a pilot cluster randomised trial. *BMC Family Practice* 2009; 10:9.