Effect of individualized social activity on sleep in nursing home residents with dementia

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined an individualised social activity intervention (ISAI) for the management of sleep disturbances in nursing home residents suffering from dementia. The ISAI consisted of several activities suitable for participants with various interests and cognitive and functional abilities, a tool for tailoring the activities, a method for prescribing the activities, a training programme for the project nursing assistants to deliver the intervention, and a method to evaluate the efficacy of the individual activities. The list of activities was divided into activities appropriate for everyone, such as listening to music, and different activities were undertaken by individuals with severe, moderate and mild dementia. The intervention was individualised using four primary participant characteristics. Specifically, interests (work and leisure history), cognition, functional status (mobility, hearing, vision, and fine motor skills), and napping patterns (time of unscheduled naps). Project nursing assistants delivered the ISAI.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised nursing home residents with dementia. The inclusion criteria were:

- age 55 and older;
- baseline actigraph data showing less than 85% sleep efficiency and at least 30 minutes of daytime sleep;
- at least 1 month's residency; and
- a Mini Mental State Examination (MMSE) score of 24 or less indicating dementia.

Sleep/wake pattern disturbance was defined as less than 85% sleep efficiency (percentage of night-time in bed asleep) and daytime sleep of more than 30 minutes at baseline.

Setting
The setting was a nursing home. The economic study was carried out in the USA.

Dates to which data relate
The period during which the effectiveness and resource use data were gathered was not reported. The price year was not stated.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

**Link between effectiveness and cost data**
The costing was carried out prospectively on the same sample of patients as that used in the clinical study.

**Study sample**
Power calculations showed that a sample size of 70 per group would have a power of 80% to detect a decrease in minutes of daytime sleep of one third from baseline. Eligible individuals were selected from participating resident nursing homes. Of the 172 participants who agreed to participate, 25 did not meet the inclusion criteria because their sleep efficiency was greater than 85% or daytime napping was less than 30 minutes. Of the 147 remaining participants, 7 were hospitalised and 1 returned home. Thus, the final study sample comprised 139 participants (51.8% men). Age and MMSE scores were missing for one person. The mean age was 79 (+/- 8.4) years. The mean MMSE score was 8.7 (+/- 7.1), suggesting moderate to severe dementia. There were 71 participants in the ISAI group and 68 participants in the control group.

**Study design**
This was an open, randomised clinical trial that was carried out in one Department of Veterans Affairs nursing home and six for-profit community nursing homes in central southeastern USA. Sleep/wake patterns were measured using the Actigraph, a motion-sensing device that uses an algorithm to differentiate sleep from wake based on motor activity. Patients wore their Actigraph during days 1 to 5 of baseline and days 17 to 21 of the treatment or control condition. To determine time in bed, the nursing home nursing assistants recorded daily bedtime (time participant went to bed for night) and rise time (time participant awakened spontaneously or was awakened to begin day) on data collection sheets. Since almost 30% of the data were missing, the coordinator substituted the less accurate Actigraph software's determination of sleep onset and offset times, which excluded time awake in bed before falling asleep and time awake in bed before rising. No patient was lost to follow-up.

**Analysis of effectiveness**
The analysis of the clinical study appears to have been conducted on an intention to treat basis, as all the patients initially included in the study sample were considered in the analysis of effectiveness. The outcome measures used were:

- daytime minutes slept;
- night-time variables such as minutes to sleep onset, minutes slept, minutes awake, sleep efficiency (defined as percentage of time in bed asleep); and
- day-to-night sleep ratio.

Baseline data were collected for the first 5 days. Following this, the ISAI group received 1 to 2 hours of social activities in 15- to 30-minute sessions on 21 consecutive days between 9:00 am and 5:00 pm. Between days 17 and 21, the actigraph measured sleep/wake data again for both groups. No statistically significant differences emerged between completers and non-completers on gender, age or MMSE score. However, the baseline comparability of the two study groups was not discussed.

**Effectiveness results**
Daytime minutes slept changed from 110.24 (+/- 68.70) to 71.64 (+/- 69.04) in the ISAI group, and from 113.64 (+/- 63.02) to 110.80 (+/- 68.70) in the control group, (p=0.001).

No statistically significant differences were observed between the groups in night-time outcomes. However, the day-to-night sleep ratio changed from 0.66 (+/- 0.81) to 0.48 (+/- 0.58) in the ISAI group, and from 0.59 (+/- 0.46) to 0.64 (+/-...
0.80) in the control group, (p=0.03).

A sub-group analysis was carried out in 50 patients with sleep efficiency less than 50%, which clearly indicated inadequate baseline night-time sleep. There were 20 patients in the ISAI group and 30 patients in the control group.

Daytime minutes slept changed from 101.95 (+/- 61.86) to 60.29 (+/- 45.83) in the ISAI group, and from 103.48 (+/- 43.88) to 105.41 (+/- 51.81) in the control group, (p=0.005).

Night-time minutes to sleep onset changed from 88.22 (+/- 71.51) to 50.45 (+/- 57.16) in the ISAI group, and from 49.74 (+/- 58.92) to 40.58 (+/- 35.91) in the control group, (p=0.03).

Night-time minutes awake changed from 460.09 (+/- 95.37) to 396.48 (+/- 133.58) in the ISAI group, and from 422.82 (+/- 95.76) to 418.33 (+/- 119.18) in the control group, (p=0.04).

The day-to-night sleep ratio changed from 1.37 (+/- 1.24) to 0.81 (+/- 0.91) in the ISAI group, and from 0.84 (+/- 0.57) to 0.98 (+/- 1.08) in the control group, (p=0.02).

**Clinical conclusions**
The effectiveness analysis showed that the ISAI reduced daytime sleep and was associated with a lower day-to-night sleep ratio in comparison with standard care.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was carried out.

**Direct costs**
The perspective adopted in the study was unclear. The analysis of the costs included training, activity and administration costs. The unit costs were presented separately from the quantities of resources used for most items. Resource use was estimated using data collected prospectively alongside the effectiveness study. Training and administration costs were estimated using the average wages of certified nursing assistants, registered nurses, and certified recreation therapists in the Little Rock metropolitan area, which were obtained from the US Bureau of Labor Statistics. Fringe benefits (25%) were added. Activity costs were based on the mean cost for each activity. Discounting was not relevant since the costs were incurred during a short timeframe. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.

**Estimated benefits used in the economic analysis**
Cost results
The weekly cost of the daily administration of ISAI was approximately $70 per participant.

Initial training costs were $1,179.

Supply costs were $765.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was carried out.

Authors’ conclusions
The individualised social activity intervention (ISAI) improved sleep/wake pattern disturbances in nursing home residents with dementia. However, higher costs were observed in comparison with standard care.

CRD COMMENTARY - Selection of comparators
The selection of the comparator was appropriate as it reflected standard care in nursing homes. You should decide whether this is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. Information on the approach used to randomise the patients to the study groups was not reported. Despite the limited number of patients participating, power calculations were performed to determine the appropriateness of the sample size. Some demographics and other characteristics of the patients included in the study were reported, but it was unclear whether the study groups were well matched at baseline. However, the randomisation approach should ensure comparability among groups, and the final results were adjusted for baseline daytime sleep. Statistical analyses were carried out to test the significance of differences between the groups. The length of follow-up might not have been appropriate to detect statistically significant differences in some outcome measures. A sub-group analysis was also carried out. The evidence came from several centres, which enhances the representativeness of the patients enrolled in the trial. No blinding was performed because of the nature of the intervention.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective adopted in the study was unclear. The analysis of the costs was restricted to the extra costs associated with the intervention. Thus, it was implicitly assumed that the other categories of costs were comparable between groups. The unit costs were reported separately from the quantities of resources used, and the source of the data was provided. This enhances the possibility of replicating the results of the analysis in other settings. Statistical analyses were not carried out and the cost estimates were specific to the study setting. The price year was not reported, which will make reflation exercises in other time periods difficult.

Other issues
The authors reported the results from other studies, but did not explicitly address the issue of the generalisability of the study results to other setting. Sensitivity analyses were not carried out, which limits the external validity of the study.
The authors provided some possible explanations for the lack of statistically significant differences in night-time outcomes. The study referred to nursing home residents with dementia and this was reflected in the authors’ conclusions.

**Implications of the study**
The study results suggested that the ISAI provides an alternative to medications, without side effects. Future studies should investigate the impact of cost reductions on clinical outcomes.

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**Other publications of related interest**


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