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# Reducing the use of sleep-inducing drugs during hospitalisation by a multi-faceted intervention: a pilot study

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## ABSTRACT

**Objectives** Many patients receive benzodiazepines or Z-drugs during hospitalisation due to sleeping problems. In a pilot study, we aimed to find out whether, and to what degree, a multi-faceted intervention can reduce the use of these drugs, especially in older patients and those without a psychiatric or neurological disorder. The results of this pilot study should inform the design of a randomised controlled trial (RCT).

**Methods** In a quasi-experimental design, we implemented the intervention in a German hospital with the support of the hospital director, medical and nursing staff and employee representatives. We compared prescription data for sleep-inducing drugs before and after the intervention by Fisher's exact test and used odds ratios (ORs) with their 95% CIs as a measure of effect size.

**Results** The data from 960 patients aged  $\geq 65$  years before intervention and 1049 patients after intervention were analysed. Before intervention, 483 (50.3%) of the patients received sleep-inducing drugs at some time during their hospital stay. After the intervention, 381 (36.3%) patients received a sleep-inducing drug, resulting in an OR of 0.56 (95% CI 0.47 to 0.68) ( $p < 0.001$ ). The reduction was particularly pronounced in patients without a psychiatric or neurological disorder (from 45.0% to 28.8%). In particular, the consumption of benzodiazepines declined from 24.3% to 8.5% (OR 0.31; 95% CI 0.23 to 0.4) ( $p < 0.001$ ).

**Conclusions** A multi-faceted intervention to change the practice of the use of sleep-inducing drugs in one hospital was successful in terms of drug reduction, particularly for benzodiazepines. The intervention was effective especially for target persons—that is, those without a psychiatric or neurological disease. Awareness of the magnitude of the change and the role of important stakeholders could help researchers and hospital staff to design a large RCT, including control hospitals, to evaluate the success of a multi-faceted intervention on a scientifically sound basis.

## INTRODUCTION

Many patients have trouble sleeping in hospital due to environmental factors such as unfamiliar sounds, nursing interruptions, uncomfortable beds and bright lights and probably also due to worries and fears.<sup>1</sup> Although these sleep problems may not fulfil the clinical diagnosis of insomnia,<sup>2</sup> they may be treated with benzodiazepines and newer non-benzodiazepines, so-called Z-drugs.<sup>3</sup> While these drugs may help patients to sleep in the hospital

## WHAT IS ALREADY KNOWN ON THIS SUBJECT

- ⇒ Benzodiazepines and Z-drugs are still too often used for sleep problems in hospitals.
- ⇒ Simple interventions such as training seminars to reduce the use of benzodiazepines, Z-drugs and other drugs for insomnia treatment are limited in their effect.

## WHAT THIS STUDY ADDS

- ⇒ This multi-faceted intervention significantly reduced the rate of sleep-inducing drugs by 14 percentage points.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Hospitals should include non-drug alternatives such as sleeping masks, ear plugs and herbal tea in their inventory.
- ⇒ The results of this pilot study give a first impression of the possible impact of the intervention and provide essential information for the design of a randomised controlled study.

environment, they also have adverse effects such as confusion, falls, fractures and craving, especially in older patients.<sup>4</sup> Medications that are associated with a higher risk of adverse effects in elderly people have been defined as potentially inappropriate medication (PIM). Screening tools have been developed to help find PIM and suggest safer alternatives. In Germany, the PRISCUS list is a widely used screening tool for PIM in elderly people.<sup>5</sup> While sleep-inducing drugs can be a risk for many patients, in the group of patients with psychiatric and neurological diseases they might be indicated. A study found that patients with a psychiatric disease are at risk of being withheld the necessary medication.<sup>6</sup>

A recently published review showed that simple interventions (such as training seminars) to reduce the use of benzodiazepines, Z-drugs and other drugs for insomnia treatment are limited in their effect.<sup>7</sup> Some of the multi-faceted interventions studied in this review were effective, especially when healthcare professionals and patients were actively involved. The majority of these studies were based on small patient samples, selected hospital wards and short intervention periods. Consequently, we considered it important to expand our knowledge of what works by a larger intervention.

Together with all relevant stakeholders, we developed a tailored intervention called ‘The Sleep-friendly Hospital Initiative’,<sup>8</sup> with the ultimate goal of reducing the use of sleep-inducing drugs in hospitals or making their use more appropriate (for more details of this initiative, see the Methods section). As a first step, we needed to better understand this drug use in the hospital setting for two reasons:

- ▶ The use of drugs in hospitals only partly follows pharmacological criteria; their use is also a matter of non-medical or context factors, as Helman states in his early research,<sup>9</sup> or a matter of games with specific rules and strategies within the habitus of the social world of a hospital, as stated by Bourdieu and Nice.<sup>10</sup>
- ▶ Any attempts to interrupt this smooth-running game begin by showing all relevant stakeholders that we understand what is going on in the hospital and the reasons for their performance. Only then will it be possible to develop new and reliable rules of how to cope with transient sleep problems in hospital.

The project followed the Medical Research Council (MRC) framework for designing and evaluating complex interventions to improve healthcare.<sup>11 12</sup> One aim of this framework is to ensure that interventions are empirically and theoretically founded. We therefore explored the real extent of the use of sleep-inducing drugs in the hospital where the intervention should take place and the reasons for their use as well as the experience with these drugs, seen from the perspective of doctors, nurses and patients. We chose a mixed-methods approach to collect the data needed.

As a first step, we studied the use of sleep-inducing drugs in one hospital using mixed-methods and several different perspectives.<sup>8</sup> The goal of these studies, both individually and collectively, was to understand the current practice and to identify possible strategies that could improve this practice. A chart review of drugs given to older patients during normal hospital care (excluding intensive care or preoperative care) showed a high rate of sleep-inducing drugs, especially PIMs for older patients.<sup>13</sup> A survey of doctors and nurses showed differences in the perception of risks and benefits of sleep-inducing drugs between doctors and nurses,<sup>14</sup> as well as a lack of knowledge about unwanted drug effects.<sup>15</sup> An interview study with doctors and nurses underscored the professional stress and uncertainty in the night as well as the lack of non-drug alternatives to sleep-inducing drugs.<sup>16</sup> A standardised patient survey showed that many older patients who had never used sleep-inducing drugs before their hospital stay received them during their hospital stay.<sup>17</sup>

Based on our results, we identified several areas with a potential for improvement and worked together with the stakeholders of the hospital to create an intervention strategy and to implement a multi-faceted hospital intervention. The different facets of the intervention correspond to what Atkins *et al* have identified as domains which influence behaviour change, such as knowledge, skills, social/professional role, environmental context and resources.<sup>18</sup>

Reviews showed that formal didactic conferences and passive forms of medical education such as brochures or printed clinical guidelines are the least effective methods for changing physician behaviour.<sup>19</sup> Moreover, stakeholder engagement is essential for moving knowledge into action within healthcare.<sup>20</sup> This is the heart of the MRC framework and the guiding principle for the Sleep-friendly Hospital Initiative.



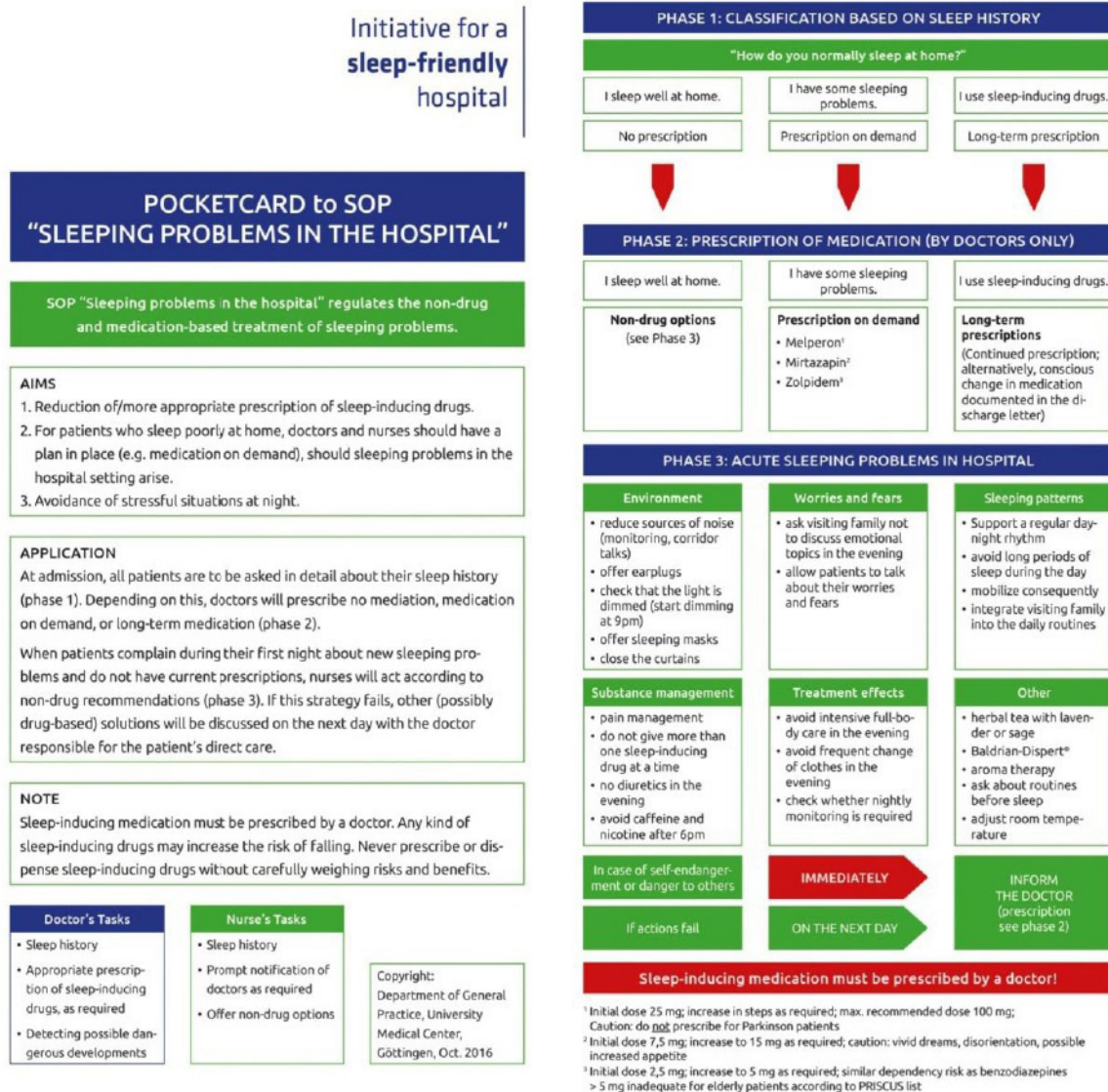
**Figure 1** Example of a poster highlighting alternatives to sleep-inducing drugs, which hung on every hospital ward (translation SH). The authors are the rights holders of the figure.

### The Sleep-friendly Hospital initiative

The initiative incorporates a strategy of making appropriate decisions about sleep-inducing drugs during the day in order to replace ad hoc prescriptions by the physician on duty during the night. The strategy consists of three main elements: (1) For patients who sleep well at home, the initiative encourages doctors and nurses to treat hospital-associated sleeping problems with non-drug options. (2) Only if these options fail should sleep-inducing drugs be ordered as a prn prescription (from the Latin ‘*pro re nata*’ meaning ‘as needed’ or ‘as the situation arises’), especially valerian, mirtazapine, melperone or zolpidem in low doses as recommended by the German PRISCU<sup>S</sup> list.<sup>5</sup> (3) For patients who regularly used sleep-inducing drugs before hospital admission, the initiative encourages hospital physicians to critically assess this prescription, making changes carefully to avoid withdrawal symptoms.

### Implementation of the Sleep-friendly Hospital initiative

The different recommendations of the Sleep-friendly Hospital Initiative were communicated over several avenues to doctors, nurses and patients. They were visible hospital-wide on two large posters with the message “Instead of pills, just use ear plugs” and “Instead of pills, just use a mask” (figure 1) displayed on all wards. For patients, the Sleep-friendly Hospital Initiative provided online information about sleep hygiene and tips for sleeping better in the hospital. For hospital doctors and nurses, the hospital administration published a hospital-wide



**Figure 2** Front and back side of the hospital Standard Operating Procedure (SOP) in pocket card format (translation SH). The authors are the rights holders of the figure.

interdisciplinary policy statement via the hospital computer system and distributed pocket-sized versions to each employee. This interdisciplinary action strategy underscored several main messages of the initiative, including the use of non-drug alternatives as a first-line treatment and a medication list of appropriate medicines for older patients (figure 2). These strategies were also highlighted in staff training courses for doctors, nurses and nursing students.

All stages of the implementation of the intervention were supported by the relevant stakeholders, such as hospital directors, administrators, medical and nursing staff and employee representatives.

The aim of this pilot study was to find out whether our multi-faceted Sleep-friendly Hospital Initiative (1) reduced the use of sleep-inducing drugs such as benzodiazepines and Z-drugs; (2) was especially effective in patients without a psychiatric or neurological disorder and avoided an increased prescription of sedative antidepressants or neuroleptics (which may be considered by hospital personnel as an alternative strategy); and (3) improved the adequacy of the medication, measured by the use

of PIM. The results of this pilot study should contribute to the design of a larger randomised controlled trial.

## METHODS

### Study design

In a quasi-experimental design, we implemented a multi-faceted tailored intervention<sup>21</sup> to reduce the use of sleep-inducing drugs for older patients in a German hospital over a period of 18 months (October 2016 to June 2017). To measure the success of the intervention, we compared prescription data before the beginning of the study period (July to August 2013) and after the intervention period (July to August 2017).

### Hospital

The intervention hospital is a mid-sized regional German hospital (485 beds) with departments of internal medicine, geriatrics and several surgical subspecialties.

### Data collection

Anonymous data from the hospital charts of all patients aged  $\geq 65$  years who spent at least one night in the hospital (and not in

intensive care) were extracted for analysis. Data were collected from two time points separated by exactly 4 years. The first time point was before the project began—that is, before any studies described in the study protocol<sup>8</sup> were carried out in the intervention hospital (July to August 2013). After an intervention phase lasting 18 months, which included several components described in detail in Chapter 5 of the 2020 publication by Heinemann,<sup>21</sup> the second time point was chosen (July to August 2017). Data collection for both time points was carried out retrospectively from June 2018 to March 2019.

Patients who died during their hospital stay were excluded. We assumed that an increased amount of care was necessary in these cases, which could go hand-in-hand with an increased use of sleep-inducing drugs. Another exclusion criterion was a stay that was spent entirely on the intensive care unit (ICU). Drugs that were administered on an ICU were not counted in the data collection.

### Drugs

Drug data included both the pharmacological class of drug and how often it was administered (number of days). We defined which drugs are sleep-inducing drugs, based on studies by several authors.<sup>22–25</sup> Our list included antidepressants, antipsychotics, benzodiazepines, Z-drugs and valerian. We divided the drugs into PIM and non-PIM according to the PRISCUS list to assess the adequacy of the medication.<sup>5</sup> The list of drugs and their classification as PIM or non-PIM is shown in the online supplemental appendix.

### Data extraction

Information on patients and their medication was not electronically available. We manually extracted the data from the patient charts into a databank. Patient charts varied in their order and length. Four advanced medical students and one nurse extracted the data and entered it into the study databank. To ensure data quality, we developed a standard operating procedure for data extraction and data entry.

Demographic data included sex, age and from where the patient was admitted to the hospital (home, nursing home, other hospital, other department within the same hospital).

Hospital data included length of hospital stay and department (internal medicine, surgery, geriatrics) where the patient was treated.

Medical data included whether or not the patient had specific psychiatric/neurological diagnoses (such as dementia, depression, panic, insomnia, etc) and if the patient reported a current prescription for sleep-inducing drugs at the time of admission.

Drug data included both the type of drug and how often it was administered (number of days).

### Outcomes

The primary outcome was the percentage of patients receiving any sleep-inducing drug at any time during their hospital stay. As a secondary outcome we analysed the use of sleep-inducing drugs in patients with and without a psychiatric diagnosis. The use of the specific classes of sleep-inducing drugs was analysed as another secondary outcome. Finally, we analysed the use of PIM before and after the intervention.

### Sample size calculation and statistical analysis

In a combined patient survey and chart review from the same hospital,<sup>17</sup> 21% of the older patients had received at least one benzodiazepine during their hospital stay. We intended to lower

this rate by at least 5 percentage points. To detect a significant reduction with an alpha of 5% and a power of 80%, we needed a sample of 982 patients in both time periods.<sup>26</sup> At the same time, it was the ultimate aim of the study to lower the use of all sleep-inducing drugs (and thus to avoid the simple replacement of benzodiazepines with other inadequate drugs). Therefore, we chose the reduction of all sleep-inducing drugs as the primary outcome of the study.

Differences between the characteristics of patients before and after the intervention were investigated by  $\chi^2$  tests and the t-test for independent samples, as appropriate, with p values >0.05 indicating non-significant differences. Fisher's exact test was used to investigate whether the change between these periods was significant. ORs with their 95% CIs were used as measures of effect size. All analyses were performed with SAS version 9.4.

### Re-analysis of a subsample of data

To assess how accurately we conducted our first data collection and how consistently we trained the data extractors, we drew a subsample of 220 patients and then compared the entries of the two datasets. The patient files for this confirmatory quality analysis were extracted and assessed by a person who had not been involved in the first data collection in this hospital and had no prior contact with that hospital and its patient files. Agreement between the first and second entry was assessed by the kappa statistic.<sup>27</sup>

There was no difference in the classification of the patients' gender between the first and second entries. Only in three cases (1.4%) did the two entries differ in the classification of whether a patient had received a sleep-inducing drug or not, yielding a kappa of 0.97. In seven cases (3.2%), the entries differed on whether a patient received a PIM or not (kappa 0.88). In 26 cases (11.8%), the patients' diagnoses were entered differently (kappa 0.71). Kappa values >0.61 are interpreted as substantial agreement and >0.81 as almost perfect agreement.<sup>27</sup>

## RESULTS

### Comparison of prescription data before and after the intervention

The data from 960 patients aged  $\geq 65$  years before intervention and 1049 patients after intervention were analysed. The percentage of female patients in 2013 and 2017 was nearly identical (58.1% vs 57.8%;  $p=0.87$ ; table 1), as was the mean age of the patients ( $79.4 \pm 7.5$  vs  $79.9 \pm 7.7$  years;  $p=0.15$ ). In both periods, most patients (41.2% vs 40.8%;  $p=0.88$ ) were treated on surgical wards. Slightly fewer patients entered the hospital without pre-existing sleep-inducing drug use in the pre-intervention period (67.1% vs 68.3%;  $p=0.48$ ). Somewhat more patients had at least one psychiatric or neurological disorder in the pre-intervention period (24.1% vs 22.3%;  $p=0.35$ ). The rate of individuals in the study with both a psychiatric or neurological disorder and pre-existing regular sleep-inducing drug use was slightly higher in 2013 (14.2% vs 12.0%;  $p=0.15$ ).

### Use of sleep-inducing drugs

Before the intervention, 483 (50.3%) of the patients received sleep-inducing drugs at some time during their hospital stay. After the intervention, 381 (36.3%) patients received a sleep-inducing drug, a significant reduction by 14 percentage points (OR 0.56 (95% CI 0.47 to 0.68);  $p<0.001$ ; table 2). The reduction was particularly pronounced in patients without a psychiatric or neurological disorder with a reduction of 16.2 percentage points from 45% (328/729) to 28.8% (235/815)

**Table 1** Characteristics of the hospital patients

Baseline characteristics*	2013 (n=960)	2017 (n=1049)
Sex		
Female (%)	58.1	57.8
Male (%)	41.9	42.2
Age group		
65–84 years (%)	71.8	70.7
≥85 years (%)	28.2	29.3
Type of ward		
Internal medicine (%)	39.9	37.1
Surgical departments (%)	41.2	40.8
Geriatrics (%)	19.0	22.1
Sleep-inducing medication at admission		
None (%)	67.1	68.3
Regular/daily use (%)	21.8	19.8
Use as needed (prn prescription) (%)	3.8	4.5
Regular and additional 'as needed' (%)	3.5	3.2
No documentation (%)	3.9	4.2
Psychiatric/neurological disorder		
Any diagnosis (%)	24.1	22.3
Dementia (%)	13.9	12.3
Depression (%)	9.7	8.2
Anxiety or panic disorder (%)	1.4	2.1
Sleeping disturbance (%)	0.6	0.6
Any diagnosis and any regular sleep-inducing medication at admission	14.2	12.0
Where the patient came from		
Home (%)	66.3	67.9
Nursing home (%)	14.7	12.6
Other hospital (%)	6.2	5.3
Other department of same hospital (%)	12.6	12.5
Unknown (%)	0.3	1.7
Length of stay		
Days, mean±SD	9.7±7.6	9.6±8.0

\*All differences between the two groups were non-significant ( $p>0.05$ ).

compared with a reduction of 4.7 percentage points in those patients with a psychiatric or neurological disorder (from 67.1% to 62.4%). The number of patients receiving a PIM at least once declined strongly from 21.5% to 8.7% ( $p<0.001$ ).

### Benzodiazepines

Prior to the intervention, one-quarter (24.3%) of all older hospital patients received benzodiazepines (table 2). After the intervention, this percentage was reduced by 15.8 percentage points to 8.5% ( $p<0.001$ ).

**Table 2** Change between pre- and post-intervention period

Patients with at least	2013*	2017*	OR (95% CI)	P value
One sleep-inducing drug	50.3	36.3	0.56 (0.47 to 0.68)	<0.001
One benzodiazepine	24.3	8.5	0.31 (0.23 to 0.4)	<0.001
One Z-drug	10.7	7.0	0.62 (0.45 to 0.86)	0.003
One antidepressant drug	17.1	14.7	0.84 (0.65 to 1.07)	0.143
One neuroleptic drug	14.1	12.8	0.90 (0.69 to 1.17)	0.431
Valerian	11.5	6.7	0.55 (0.4 to 0.76)	<0.001
One PIM **	21.5	8.7	0.35 (0.27 to 0.45)	<0.001

\*All data are percentage of patients receiving the respective drug

\*\*PIM, potentially inappropriate medication.

### Z-drugs

The percentage of patients treated with Z-drugs fell between the first and second measurement by 3.7 percentage points from 10.7% to 7.0% ( $p=0.003$ ).

### Other sleep-inducing drugs

The percentage of patients treated with sedative antidepressants was slightly reduced from 17.1% before the intervention to 14.7% after the intervention (2.4 percentage points). Antipsychotic treatment also declined slightly from 14.1% to 12.8%. Sleep-inducing drugs were not substituted by valerian on a large scale; on the contrary, the use of valerian itself was reduced from 11.5% to 6.7% ( $p<0.001$ ).

## DISCUSSION

### Summary of main findings

We observed a significant decline in sleep-inducing drugs in the intervention hospital. The prescription of benzodiazepines and Z-drugs was reduced without increasing the use of alternatives such as sedative antidepressants, neuroleptics or valerian.

### Strengths and limitations of the study

A strength of the study is that we introduced the intervention and analysed its effect in the entire hospital and not only on selected wards as in many other studies.<sup>28 29</sup> In these studies, the participating doctors and nurses may have gone the extra mile not mainly because of the intervention but because they felt they were pioneers and were being observed and singled out (Hawthorne effect).<sup>30</sup>

We chose the data collection time points, ensuring that the baseline data preceded any research activity (ie, chart reviews, employee surveys, interviews, patient surveys) in the intervention hospital. Such intensive research activity may have influenced employee or patient demands for sleep-inducing drugs. We were also careful to collect data from the same time of year so that seasonal differences (eg, number of daylight hours) would not play a role.

Further subanalyses helped determine whether the intervention reached the target drugs (benzodiazepines and Z-drugs) and the target population (patients without specific psychiatric/neurological diagnoses) without encouraging substitution with other sedative drugs.

The most important limitation of the study is the implementation of the intervention in only one hospital. Results of a single-hospital study can only be a starting point for future research and are generalisable for other settings only to a limited degree. Moreover, the study was embedded in a quasi-experimental design<sup>31</sup> where the intervention was not randomly assigned. So, in principle, we cannot exclude confounding.

### Comparison with the literature

#### Overall reduction of sleep-inducing drugs

We have witnessed an increasing sensitivity especially towards the use of benzodiazepines during the last decades, as can be seen by the German guidance for medical practice entitled “Medical drugs—harmful use and dependency” published in 2007.<sup>32</sup> This was also reported from 2010 onwards in annual prescription statistics from office-based physicians such as the German Arzneverordnungs-Reports.<sup>33</sup> However, the decline in the intervention hospital clearly outperformed the decline reported in these prescription statistics by a factor of around two.

Several research projects, mainly in English-speaking countries, have tried to reduce the use of sedatives and hypnotics in

hospitals,<sup>34</sup> with reduction rates between 3 and 19 percentage points. For example, a study in a UK hospital which improved the sleep environment, especially the noise level, reduced the percentage of as-needed sedatives from 37% to 16%.<sup>29</sup> A computer-based reminder in a Connecticut academic healthcare centre reduced the prescribing of sedative and hypnotic drugs from 18% to 12% of hospitalised older patients.<sup>35</sup> Our intervention is, to the best of our knowledge, the first one in German and its success is at the upper end of similar studies.

### Targeted reduction of benzodiazepines and Z-drugs

The relevant patient safety concerns when prescribing benzodiazepines and Z-drugs for older patients include confusion, falls, fractures and craving.<sup>4</sup> Previous work showed that benzodiazepines were being prescribed often—and in too high doses—to older patients in the intervention hospital.<sup>13</sup> Therefore, the intervention components of the Sleep-friendly Hospital Initiative were designed to change the habit of prescribing benzodiazepines to older patients with sleeping problems and to offer safer alternatives in line with the PRISCUS list, such as non-drug alternatives, valerian, melperone, mirtazapine and low-dose zolpidem.

As intended, the percentage of older patients receiving benzodiazepines was significantly reduced in the intervention hospital. In addition, the listing of zolpidem on the recommended list of drugs in the hospital-wide Standard Operating Procedure (SOP) did not increase the use of Z-drugs in the intervention hospital. Rather, the prescription rate of Z-drugs declined modestly over time. Moreover, we observed a very sharp decline in the number of patients who received a PIM (from 21.5% to 8.7%) so, when being prescribed a sleep-inducing drug, the chance of receiving a safer alternative almost tripled after the intervention. In contrast to many other studies,<sup>29 36</sup> our analysis controlled whether psychotropic drugs were not strongly reduced in patients who may benefit from them.<sup>6</sup> We could show that the reduction, indeed, addressed the target persons—that is, those without a psychiatric or neurological disease.

### Lessons learnt

In a single hospital setting over the course of several years, we were able to perform an in-depth investigation of the use of sleep-inducing drugs in the hospital, the reasons for their use and to incorporate the perspectives of the doctors, nurses and patients. Although it will not be possible to conduct such an in-depth study in all participating hospitals, an RCT based on this intervention will be able to make use of several aspects of these preliminary studies and the data collection strategy used in this paper. Posters, pocket cards and educational materials for staff training courses can be adapted to other settings with minimal changes, making the upscaling of the Sleep-friendly Hospital Initiative to other hospitals likely. One important aspect is the need for participating hospitals to expand their inventory to include non-drug alternatives such as sleeping masks, ear plugs and herbal tea.

The results of our pilot study could help to design future cluster RCTs where hospitals are randomised to either implement the intervention or act as controls. The effect of our intervention was bigger than expected for both the entire group of sleep-inducing drugs and for benzodiazepines. While we expected a reduction of at least 5%, the decrease was 14 percentage points or more. RCTs could be successful with smaller sample sizes than we calculated without being underpowered. However, a challenge for any RCT project is transferring the Sleep-friendly

Hospital Initiative into the hands of each local hospital staff and empowering these individuals to use the materials and the opportunity of the study to bring about long-lasting change. Similarly, a control group concept must be carefully created to include general input about the need for reduction of sleep-inducing drugs in older hospital patients, in order to minimise the Hawthorne effect.

### CONCLUSIONS

A multi-faceted intervention to change the practice of the use of sleep-inducing drugs in a German hospital proved to be successful in terms of reducing drug prescriptions. Before we recommend similar interventions and strategies for other hospitals, we should consider some prerequisites for being successful.

Since sleep problems are seldom at the top of the list of concerns in an average hospital, clear leadership by hospital directors is needed. These leaders must be committed and willing to champion this project by repeatedly emphasising the importance of first-line non-drug treatment. Our intervention may provide inspiration to those searching for a strategy to improve drug safety for older hospitalised patients. However, every institution must find its own way—that is, to adapt the intervention to the hospital and its staff. Such participatory development of an intervention seems to be vital for the success of the intervention. The results of this pilot study give an impression of the possible impact of the intervention and the role of important stakeholders. This could help researchers and the hospital staff to design a large RCT, including control hospitals, to evaluate the success of a multi-faceted intervention on a scientifically sound basis.

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#### REFERENCES

- Dobing S, Frolova N, McAlister F, et al. Sleep quality and factors influencing self-reported sleep duration and quality in the general internal medicine inpatient population. *PLoS One* 2016;11:e0156735.
- Sateia MJ, Buysse DJ, Krystal AD, et al. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med* 2017;13:307–49.
- Pek EA, Remfry A, Pendrith C, et al. High prevalence of inappropriate benzodiazepine and sedative hypnotic prescriptions among hospitalized older adults. *J Hosp Med* 2017;12:310–6.
- Petrovic M, Mariman A, Warie H, et al. Is there a rationale for prescription of benzodiazepines in the elderly? Review of the literature. *Acta Clin Belg* 2003;58:27–36.
- Holt S, Schmiedl S, Thürmann PA. Potentially inappropriate medications in the elderly: the PRISCUS list. *Dtsch Arztebl Int* 2010;107:543–51 <https://www.aerzteblatt.de/int/article.asp?id=77857>
- Lang PO, Hasso Y, Dramé M, et al. Potentially inappropriate prescribing including under-use amongst older patients with cognitive or psychiatric co-morbidities. *Age Ageing* 2010;39:373–81.
- Bourcier E, Korb-Savoldelli V, Hejblum G, et al. A systematic review of regulatory and educational interventions to reduce the burden associated with the prescriptions of sedative-hypnotics in adults treated for sleep disorders. *PLoS One* 2018;13:e0191211.
- Heinemann S, Weiß V, Straube K, et al. Understanding and reducing the prescription of hypnotics and sedatives at the interface of hospital care and general practice: a protocol for a mixed-methods study. *BMJ Open* 2016;6:e011908.
- Helman CG. The role of context in primary care. *J R Coll Gen Pract* 1984;34:547–50.
- Bourdieu P, Nice R. *The logic of practice*. Stanford, CA: Stanford University Press, 2014.
- Campbell NC, Murray E, Darbyshire J, et al. Designing and evaluating complex interventions to improve health care. *BMJ* 2007;334:455–9.
- Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Int J Nurs Stud* 2013;50:587–92.
- Arnold I, Straube K, Himmel W, et al. High prevalence of prescription of psychotropic drugs for older patients in a general hospital. *BMC Pharmacol Toxicol* 2017;18:76.
- Heinemann S, Himmel W. Searching for factors that may reduce the use of benzodiazepines in hospitals - a survey of hospital doctors and nurses. *Int J Clin Pharmacol Ther* 2017;55:905–10.
- Heinemann S, Brockmöller J, Hagmayer Y, et al. Why Z-drugs are used even if doctors and nurses feel unable to judge their benefits and risks – a hospital survey. *Eur J Clin Pharmacol* 2020;76:285–90.
- Kauffmann L, Heinemann S, Himmel W, et al. Nicht-medikamentöse Maßnahmen bei Ein- und Durchschlafproblemen von älteren Patienten Im Krankenhaus – qualitative Interviews mit Pflegenden. *Pflege* 2018;31:291–300.
- Heinemann S, Neukirchen F, Nau R, et al. Patient-reported factors associated with the desire to continue taking sleep-inducing drugs after hospital discharge: a survey of older adults. *Pharmacoepidemiol Drug Saf* 2019;28:1014–22.
- Atkins L, Francis J, Islam R, et al. A guide to using the theoretical domains framework of behaviour change to investigate implementation problems. *Implement Sci* 2017;12:77.
- Mostofian F, Ruban C, Simunovic N, et al. Changing physician behavior: what works? *Am J Manag Care* 2015;21:75–84.
- Greenhalgh T, Robert G, Bate P. How to spread good ideas: a systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery and organisation; 2004. <https://www.cs.kent.ac.uk/people/staff/saf/share/great-missenden/reference-papers/Overviews/NHS-lit-review.pdf>
- Heinemann S. Why are sleep-inducing drugs frequently used in hospitals? Applying mixed-methods to understand a common practice and develop a complex intervention to change it [Doctoral thesis]. Göttingen, Germany, 2020.
- Enzensperger C, Lehmann J. Neuroleptika und Antidepressiva als Hypnotika. *Pharm Unserer Zeit* 2007;36:196–200.
- Müller MJ. Antipsychotika. In: Benkert O, Hippus H, eds. *Kompendium der Psychiatrischen Pharmakotherapie*. Berlin, Heidelberg: Springer, 2019: 284–504.
- Regen F, Benkert O. Antidepressiva. In: Benkert O, Hippus H, eds. *Kompendium der Psychiatrischen Pharmakotherapie*. Berlin, Heidelberg: Springer, 2019: 1–208.
- Steiger A, Weber F, Benkert O. Medikamente zur Behandlung von Schlafstörungen. In: Benkert O, Hippus H, eds. *Kompendium der Psychiatrischen Pharmakotherapie*. Berlin, Heidelberg: Springer, 2019: 555–640.
- Faul F, Erdfelder E, Lang A-G, et al. G\*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39:175–91.
- McHugh ML. Interrater reliability: the kappa statistic. *Biochem Med* 2012;22:276–82.
- Fan-Lun C, Chung C, Lee EHG. Reducing unnecessary sedative-hypnotic use among hospitalised older adults. *BMJ Qual Saf* 2019;28:1039–45.
- Bartick MC, Thai X, Schmidt T, et al. Decrease in as-needed sedative use by limiting nighttime sleep disruptions from hospital staff. *J Hosp Med* 2010;5:E20–4.
- Franke RH, Kaul JD. The Hawthorne experiments: first statistical interpretation. *Am Sociol Rev* 1978;43:623.
- Döring N, Bortz J. *Forschungsmethoden und evaluation in den Sozial- und Humanwissenschaften*. 5th edn. Berlin, Heidelberg: Springer, 2016.
- Bundesärztekammer. *Medikamente – schädlicher Gebrauch und Abhängigkeit. Leitfaden für die ärztliche Praxis*. Köln: Deutscher Ärzte-Verlag, 2007.
- Schwabe U, Paffrath D, Ludwig W-D. *Arzneiverordnungsreport 2018*. Berlin, Heidelberg: Springer, 2018.
- Soong C, Burry L, Cho HJ, et al. An implementation guide to promote sleep and reduce sedative-hypnotic initiation for noncritically ill inpatients. *JAMA Intern Med* 2019;179:965–72.
- Agostini JV, Zhang Y, Inouye SK. Use of a computer-based reminder to improve sedative-hypnotic prescribing in older hospitalized patients. *J Am Geriatr Soc* 2007;55:43–8.
- Chung S, Youn S, Park B, et al. A sleep education and hypnotics reduction program for hospitalized patients at a general hospital. *Psychiatry Invest* 2018;15:78–83.