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Linköping University Post Print

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This is the authors' version of the following article:

Pia Yngman Uhlin, Anders Fernström, Sussanne Börjeson and Ulla Edéll-Gustafsson, Evaluation of an individual sleep intervention programme in people undergoing peritoneal dialysis treatment, 2012, Journal of Clinical Nursing, (21), 23-24, 3402-3417.

which has been published in final form at:

<http://dx.doi.org/10.1111/j.1365-2702.2012.04282.x>

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Postprint available at: Linköping University Electronic Press

<http://urn.kb.se/resolve?urn=urn:nbn:se:liu:diva-68040>

Title: Evaluation of an individual sleep intervention programme in people undergoing peritoneal dialysis treatment

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Acknowledgement: We thank the PD-nurses: Berith Boo, Karin Berggren, Birgitta Lundberg, Annelie Ljungdal-Jonsson, Anette Strömberg and physician Mattias Alvunger at the participating clinics for assistance with patient recruitment. Tanks, also to physician Martin Ulander, Department of Neurophysiology at Linköping University Hospital, for support in sleep medicine matters.

Contributions

Study design: PY-U, UE-D, AF. Data collections and analysis: PY-U. Manuscript preparation: PY-U, AF, SB, UE-G.

Funding of support: Research Council of South-East of Sweden (FORSS) No; 37121, 87301

Disclosures: We hereby declare that no financial conflict of interest exists.

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Running title: Sleep hygiene in people on peritoneal dialysis

ABSTRACT

Aims and objectives: This study aimed to evaluate effects of a non-pharmacological intervention on sleep, activity and fatigue in patients receiving peritoneal dialysis by the use of both actigraphy registration and self-assessed questionnaires.

Background: Insomnia is estimated to affect up to 60% of hemo- and peritoneal dialysis patients. It is associated with two common uremic symptoms, pruritus and restless legs syndrome. To our knowledge no interventions have been evaluated by actigraphy.

Design: A prospective multiple baseline single-case experimental design.

Methods: Two women and seven men with sleep problems, 48-77 years, treated with PD participated in a 17-week study from January 2009 to February 2011. Two interventions were separately implemented. First, a pressure relieving mattress and second, a four week individual sleep hygiene and sleep scheduling intervention. The two interventions were evaluated both objectively by actigraphy and subjectively by questionnaires.

Results: A total of 315 sleep-wake cycles from nine individuals were evaluated. Three patients improved clinically significantly in five or more of the nine outcomes sleep onset latency, nocturnal sleep duration, numbers and duration of napping, movement and fragmentation index, number of steps, metabolic equivalent unit, sleep efficiency and fatigue. The other six patients also showed improvements but to a lesser degree. Physical activity advice was the intervention that yielded most sleep improvements.

Conclusions: This study illuminates the need for regular assessment of sleep and tiredness. It also demonstrates how a non-pharmacological treatment and self-management can be applied within renal supportive care to improve sleep quality.

Relevance to clinical practice: This study is a clinical example of a non-pharmacological intervention with supportive care and self-management. This model can improve health and

reduce the pharmacological burden since hypnotics can be replaced by sleep hygiene self-care activities.

Keywords: Peritoneal dialysis, renal supportive care, sleep hygiene, non-pharmacological treatment, insomnia, fatigue, self-care

INTRODUCTION

Sleep problems are estimated to affect up to 60% of people undergoing hemo- and peritoneal dialysis (PD) treatment (Al-Jahdali *et al.* 2010, Novak *et al.* 2006, Yngman-Uhlin & Edell-Gustafsson 2006). Insomnia is one of the dominating sleep problems varying from persistent trouble falling asleep, difficulties in maintaining sleep and too early morning awakening combined with daytime symptoms (WHO 1993). Insomnia is also associated with two prevalent and often persistent uremic symptoms in people with PD; restless legs syndrome (RLS) 21.5-47% (Araujo *et al.* 2010, Pisoni *et al.* 2006, Sabry *et al.* 2010) and pruritus 39-42% (Pisoni *et al.* 2006, Yngman-Uhlin & Edell-Gustafsson 2006). Furthermore a previous study by our research group revealed that difficulties finding a good sleeping position explained sleep quality in 56% of the patients (Yngman-Uhlin & Edell-Gustafsson 2006). People receiving PD treatment at home require self-care management abilities. ~~A complex series of behaviours take place in the self care management (Riegel & Weaver 2009) which can be altered by decreased sleep quality.~~ The complex series of behaviours which take place in self-care management (Riegel & Weaver 2009) may be adversely affected by a decreased sleep quality. Patients need to evaluate their fluid balance, perform treatment in an aseptic manner and be ready to act if complications occur. Decreased sleep quality results in sleepiness, tiredness as well as impairments of attention and concentration abilities (Drummond *et al.* 2004) which can reduce self-care skills. Further, decreased sleep quality

has been reported to have a negative effect on health-related quality of life (HRQoL) in patients with PD (Bilgic *et al.* 2008, Yang *et al.* 2007).

Background

~~Many people on dialysis treatment are physically deconditioned from the chronicity of their disease and co-morbidities (Davison & Jhangri 2010, Murtagh *et al.* 2007), making them vulnerable to sleep problems, as dialysis alters both metabolic (Knutson 2007) and immunological (Chiu *et al.* 2009, Redwine *et al.* 2000) functions. This is serious since the two most common causes of death in people with dialysis are cardiovascular diseases and infections (Kendrick & Teitelbaum 2010).~~ Many people on dialysis treatment are physically deconditioned from the chronicity of their disease and co-morbidities (Davison & Jhangri 2010, Murtagh *et al.* 2007), making them vulnerable to sleep problems. Loss of deep sleep i.e. fragmented sleep, alters both metabolic (Knutson 2007) and immunological (Chiu *et al.* 2009, Redwine *et al.* 2000) functions. This is serious since cardiovascular diseases and infections are the two most common causes of death in patients undergoing dialysis (Kendrick & Teitelbaum 2010).

In general hypnotics is the most frequently used treatment for insomniacs in general (Lieberman 2007, Neutel & Patten 2009) but there are side-effects such as daytime sleepiness, dependency and drug-drug interactions (Barbera & Shapiro 2005). Non-pharmacological treatment such as sleep hygiene interventions (Morin *et al.* 1999), daytime sleep restrictions and bright-light therapy (Fetveit & Bjorvatn 2004) has been evaluated in a nursing home population with successful improvements of sleep onset. This might be the treatment of choice for people with self-care management abilities and with alterations in drug absorption, drug metabolism and, in many cases, polypharmacy. Renal supportive care can be used for

complex self-care management (Noble *et al.* 2007) in PD patients with sleep problems. Sleep quality has shown to be improved by increased activity in people undergoing haemodialysis (Tentori *et al.* 2010) and long term effects of sleep behavioural therapy has shown to be more effective than medication in older people (Morin *et al.* 1999).

There is a knowledge gap concerning sleep problems among PD patients and sleep intervention studies have been requested. To our knowledge only one research group has performed a non-pharmacological intervention study, i.e. cognitive behavioural therapy in combination with a sleep hygiene intervention, with a positive effect on insomnia in PD patients (Chen *et al.* 2008). This said, the intervention effects on sleep parameters were solely assessed by subjective measurement i.e. questionnaires. Further, there is only one study that has used one-week actigraphy registration in a small group of PD patients (n=6) (Koch *et al.* 2010). This is the best way of evaluating the sleep-wake cycle for an extended period of time in the home environment. In addition physical activity ~~was~~ can concurrently be registered.

Aim

The aim of this study was to evaluate the effects of a nurse-led non-pharmacological intervention on sleep, activity and symptoms of fatigue in PD patients by the use of both actigraphy registration and self-assessed questionnaires.

THE STUDY

Design

This study had a prospective multiple baseline single-case, AABBC experimental design with five repeated measure phases in which each participant served as his/her own control (table 1). The A phases were two multiple baseline data collections, the B phases were intervention

phases and the C phase was a non-treatment phase with a follow-up. This design was chosen because of the patient-centered focus and the near-clinical situation. It is suitable for research in behavioural interventions that directly measure therapeutic and individual outcomes (Kazdin 1982). It was used since a behavioural treatment intervention effect i.e. education, is irreversible (Morgan & Morgan 2009).

-Insert table 1 here-

Participants

Twenty eight eligible patients from two university hospitals and two general hospitals in the southeast of Sweden were invited to participate in the study from January 2009 to September 2010. Data collection ended in February 2011. The patients were invited one by one due to the logistical availability of the study equipment. Inclusion criteria were: over 18 years of age, self-managed peritoneal dialysis treatment at home for more than two months, medically stable at the time of inclusion, listed for transplantation < 6 months and having indications of sleep problems with daytime symptoms. Nineteen patients accepted participation, although four did not actually have persistent sleep problems and were not included. During the baseline phase two patients dropped out due to disease-related complications, two underwent transplantation and two died. Finally, two women and seven men (Table 2) fulfilled the 17-week study plan. Patients who were on hypnotics treatment before study inclusion maintained the same dose during the study.

-Insert table 2 here-

Interventions

The interventions were performed in two phases. First, a mattress (Tempur®) made of polyurethane foam was offered to all participants for two consecutive weeks. This intervention aimed to evaluate if the difficulties finding a good sleeping position could be reduced, a previously detected problem by our research group (Yngman-Uhlin & Edell-

Gustafsson 2006). Second, an individual sleep hygiene advice program, which was designed after careful review of the collected baseline data, was put into practice. Sleep hygiene advice, sleep scheduling and bright light therapy were recommended depending on the type of sleep problem (Morin & Espie 2004) (Table 3).

In *sleep hygiene advice*, sleep-related lifestyle and sleep context can together form a set of sleep-related behaviours that may be suitable for sleep (Morin & Espie 2004), for instance reducing disturbing noise at bedtime or increase daytime activity. Activity could be any physical activity such as walking, gardening, and light exercise. Stretching or light exercise can be used to reduce RLS (Aukerman *et al.* 2006). Further, avoiding caffeine intake since this can delay sleep onset or cause RLS, was recommended. *Sleep scheduling* was recommended to establish regular sleep habits. This aimed to build up the sleep drive and increase sleep efficiency by spending less time in bed and increase sleep-wake specificity by avoiding sleep in the daytime (Morin & Espie 2004). For misaligned sleep-wake phases, *bright light therapy* (Sunrise system 320® Bright LED portable light box, 10.000 Lux) was recommended in the morning for 30-45 minutes, applied at 30-50 centimeters distance to inhibit the internal secretion of melatonin (Gooley 2008). Numbers of sleep promoting recommendations were limited to no more than three for each patient.

-Insert table 3 here-

Data collection

The interventions were evaluated by nine outcome variables; 1) sleep onset latency, 2) nocturnal sleep duration, 3) numbers of and 4) duration of napping, 5) movement and fragmentation index (MFI), 6) number of steps, 7) Metabolic Equivalent Unit (METs), 8) sleep efficiency and 9) fatigue. Data were collected both for assessment of sleep problems at baseline and for evaluation of the interventions (Table 1). This was done objectively by

actigraphy registration and subjectively by four questionnaires and a sleep diary. Medical data were collected from the patients' records.

The objective assessment consisted of a wireless wearable body monitor, SenseWear® pro actigraph (Bodymedia, Pittsburgh, PA). The device is designed to be worn comfortably at the upper arm under clothing in a normal everyday environment. One-week registrations were recorded and ended each of the five study phases of four weeks (Table 1). Four sensors registered physiological body signals every minute: skin temperature, galvanic skin response, heat flux and a 2-axis accelerometer. Data were thereafter processed by the software program SensWear® 6.1 (Bodymedia Inc.) where the sensors' information combined with the algorithms calculated and reported: METs (Kcal/Kg/hour), total number of steps, sleep duration, time lying down and sleep efficiency index (%), i.e. the amount of time in bed actually spent sleeping. A sleep efficiency index above 85% is generally considered to be good. For each night a movement index (MI) and fragmentation index (FI) were calculated. MI was obtained by dividing every minute of movement with total time in bed multiplied by 100. FI was the ratio of one-minute immobility to the total number of immobility phases multiplied by 100. By adding MI and FI, a global index for disrupted sleep was obtained; movement and fragmentation index (MFI) (Aubert-Tulkens *et al.* 1987). An index of more than 50 represents serious fragmentation whereas below 20 represents well consolidated sleep (Camtech 2007). In addition, visual graphs of the sleep wake-cycles were provided by the program. These were used to motivate and educate the patients when providing them with sleep hygiene advice. Validations between actigraphy and polysomnography have shown high sensitivity (89%) and specificity (95%) for diagnosing sleep apnoea (Aubert-Tulkens *et al.* 1987, Stepanski 2002) as well as accuracy in number of nocturnal awakenings, awakenings after sleep onset, total sleep time and sleep efficiency in insomnia patients (Lichstein *et al.* 2006)

The Functional Assessment of Chronic Illness Therapy (FACIT)- fatigue scale was used to measure the degree of fatigue (Yellen *et al.* 1997). The 13 items were answered in a five-point scale from “not at all (0) to “very much” (4). The scale ranges from zero to 52, where a lower score indicates a higher degree of fatigue. The cut-off score is set to 43 in a general population (Yellen *et al.* 1997). Examples of the questions are: “I feel too weak” and “I am able to do my usual activities”. The items in the scale essentially assess activity i.e. functional fatigue. The scale has been tested for internal consistency where Cronbach’s alpha was 0.94 (Yellen *et al.* 1997).

To evaluate sleep problems at baseline, a study-specific sleep diary was completed during the five weeks of actigraphy registration. This was used as a complement for interpreting the actigraphy data during the study. Habitual sleep information referring to the last four weeks was assessed by a modified version of the Uppsala Sleep Inventory (USI) (Hetta *et al.* 1985) (Yngman-Uhlin & Edell-Gustafsson 2006). The health profile was assessed by SF-36 (Sullivan *et al.* 1995, Ware & Sherbourne 1992), which is the most frequently used questionnaire for evaluation of health outcome (Garratt *et al.* 2002). It assesses eight health domains where a higher score indicates better health (0-100). The severity of restless legs was assessed by a validated scale; The International Restless Legs Scale (IRLS) which has previously shown a good internal consistency (Cronbach’s alpha 0.76-0.81) (Abetz *et al.* 2006, Walters *et al.* 2003).

Procedure

Eligible patients matching the inclusion criteria were identified by the PD nurses at the participating clinics. and They were then sent an invitation letter which also contained a few

questions about sleep quality and daytime symptoms. If the patients experienced persistent sleep problems and agreed to participate they were scheduled for a 17-weeks registration-, and intervention program. The study is divided into five phases and each phase ends with an actigraphy registration (Table 1). During an initial home visit, made by the first author, a sleep history was obtained by a study-specific standardised outline plan for sleep history assessment inspired by Morin and Espie (Morin & Espie 2004). At this first home visit the actigraph and the questionnaires were delivered by the first author but were thereafter sent by post. At the second home visit, in study phase three, the mattress which was the first intervention was delivered. The individual sleep hygiene intervention plans, based on baseline data, were discussed with a neurophysiologist before being presented and implemented in concordance with the patients at the third home visit. During the second intervention phase the first author had a supporting and coaching function by telephone twice weekly. A final follow-up registration was performed four weeks after the completion of the sleep hygiene intervention.

Ethical considerations

The study was performed in accordance with the Declaration of Helsinki (WMA 2008) after approval by the Regional Ethical Review Board at the faculty of Health Sciences, Linköping University. Written informed consent were obtained from all participants.

Data analysis

Data are presented in accordance with single-case studies (Morgan & Morgan 2009) in tables and as graphs with each patient represented over a timeline. Changes of the outcome variables of half a standard deviation ($\frac{1}{2}$ SD) or more compared to the mean value of the two baselines, were applied as an indicator for an individual clinically significant change (Frost *et*

al. 2007). This was used to avoid reflections of normal fluctuations. To evaluate the effect of the intervention at group level non-parametric statistics, Friedman's test followed by Wilcoxon signed rank test were used (Field 2009). Bonferroni was performed as a post hoc test where a significant level was set to 0.016, otherwise 0.05 was accepted. Microsoft Office Excel 2007 and PASW statistical software, version 18.0 were used for graphs and statistical analyses.

RESULTS

Three of nine patients (*B*, *G* and *I*) improved clinically significantly in five or more of the nine outcome variables when comparing baseline and the final week of the second intervention i.e. individual sleep hygiene advice (table 4). For three of the patients unexpected events not related to the study occurred during the intervention period (Table 3). Two of the participants (*F*, *H*) did not want to take part in the first intervention i.e. sleep on the mattress and two took the mattress away after only two nights (*I*, *G*) due to discomfort.

-Insert table 4 here-

Sleep duration

All patients except patient *D* had a sleep duration shorter than 6 hours (Figure 1) at baseline. Patients *G*, *C* and *I* increased their sleep duration ~~clinically~~ significantly during the second intervention compared to baseline (Figure 1), but none of them improved their sleep duration to 6 hours or more during the intervention. Patient *D* did decrease nocturnal sleep duration but this was also an improvement since the sleep duration at baseline two was high, 13 hours and 6 minutes.

-Insert figure 1 and 2 here-

Three patients, patients *F*, *G* and *I*, ~~clinically~~ significantly reduced their napping time during the second intervention. Patient *G* and *I* reduced their daytime sleep to less than 30 minutes.

In total, six patients slept less than 30 minutes during the day at the follow-up phase *D-I* (Figure 1).

Activity

Seven patients were advised to increase physical activity and of these, *B*, *G* and *I* improved the number of steps ~~clinically~~ significantly compared to baseline. METs were ~~clinically~~ significantly increased for the same patients (Figure 2).

-Insert figure 3 here-

Sleep efficiency and sleep fragmentation

Sleep efficiency was significantly ~~clinically~~ improved for patients *A*, *G*, *H* and *I* compared to baseline, only two of the patients were above the recommended 85%; *B* and *D* (Fig 3). Three patients *A*, *D* and *I* improved ~~clinically~~ significantly in MFI and finished below index 20.

Fatigue

All patients except one (*H*) were classified as having fatigue at baseline. After the sleep hygiene intervention, two patients were above the cut off score 43. ~~Clinically~~ Significant improvement in four of the patients *B*, *D*, *E* and *H* was shown between baseline and study phase 4 (Figure 3).

Health profiles were assessed at baseline 1 and at follow-up. Of the three patients *B*, *G* and *I* who improved in five or more of the outcome variables, only *G* had visual improvements in one of eight dimensions in SF-36, vitality, but decreased in social function, role emotional and mental health (Figure 4).

-Insert figure 4 here –

Of the five patients who fulfilled the mattress intervention, improvements were found in three of the variables for patients *A* and *D*. Patient *C* and *E* improved in one variable (Table 4). At the follow-up, patient *I* had maintained the improvements in five of the outcome variables four weeks after the intervention period (Table 4).

Analysis at group level showed no statistical significances in any variables between any of the study phases. The sleep efficiency index improved in study phase 4 compared to 3 ($p=0.028$), but this was not statistically significant after correction with Bonferroni.

DISCUSSION

The present study demonstrates that individual, nurse-led, non-pharmacological, sleep interventions improved sleep and daytime activities in patients on PD treatment in a near-clinical situation. By supporting the patients to make simple, inexpensive lifestyle changes three out of nine, patients *B*, *G* and *I*, stopped or reversed the progression of a negative sleep behaviour and improved in five or more of the nine outcome variables. In addition, the other six patients showed improvements which are notable in this multi-disease and frail patient group. Although the patients did not reach the recommended sleep duration of six hours they may have obtained benefits from their improved sleep.

This study also shows the importance of systematic assessment in daily clinical practice. Based on this data, sleep advice i.e. behavioural interventions can be provided, thus possibly resulting in an improved daily life for these frail patients. Behavioural treatment has been described as being sustainable over time in people with insomnia in late-life, compared to hypnotics which was more effective in the short term (Morin *et al.* 1999). PD nurses are a group of healthcare providers with a unique position for supporting self-care management. A

Carefully conducted sleep history can provide important information that is frequently overlooked in the standard anamnesis. This is especially important in patients on PD since they have a high prevalence of sleep problems (Al-Jahdali *et al.* 2010, Novak *et al.* 2006, Yngman-Uhlin & Edell-Gustafsson 2006). For patients with indications of sleep problems we suggest that an individual sleep assessment followed up with targeted interventions should be prescribed as a regular part of their medical care.

All patients in the study had disturbed sleep and fulfilled the criteria for insomnia (WHO 1993). At baseline, eight of the nine patients had shorter nocturnal sleep duration than the recommended six hours (WHO 1993). Two of the patients decreased their napping time significantly; both of them had naps of less than 30 minutes in study phases 4 and 5. For insomniacs, daytime restrictions often limit naps to no more than 30 minutes and not later than 3.00 pm (Morin *et al.* 1999). From our results we identified one patient (*G*) who succeeded significantly both in reducing napping time and increasing nocturnal sleep duration. Although reduced napping time is mostly beneficial for nocturnal sleep, one study has suggested that napping time contributes to significant increase of the 24-hour quota (Campbell *et al.* 2005). This must be considered when deciding if restrictions should be prescribed in PD patients with such decreased nocturnal sleep duration.

Sleep efficiency was improved for as many as five of nine patients. Sleep efficiency is an important variable measuring the amount of time in bed actually spent sleeping. Three patients improved in MFI and reached values below 20. This is important since fragmented sleep is a serious problem. It reduces restorative deep sleep i.e. sleep quality with metabolic (Knutson 2007) and immunologic (Chiu *et al.* 2009, Redwine *et al.* 2000) alterations.

All three patients who succeeded in improving five or more of the nine outcome variables were prescribed increased physical activity, i.e. number of steps and METs, which was also the most successful intervention in the whole group. Regarding the activity, two of the nine patients had a stationary exercise bike at home. The actigraph applied at the upper arm does not measure such activity and therefore energy expenditure was an important additional outcome variable. Nevertheless, those who had clinically significantly increased METs also had an increased number of steps.

During the last intervention week self-reported fatigue was low in all patients except *F* and *H*. We have previously reported a high prevalence of fatigue 88% in the PD population from the same geographic area as the patients in this study. (Yngman-Uhlin & Edell-Gustafsson 2006), This is also supported by another study (Ossareh 2003). Fatigue was improved in four patients, but only one who improved in five or more variables also improved in fatigue. One explanation could be that the experience of decreased fatigue could be delayed or in need of an extended intervention period. Fatigue could also be the result of other disease-related factors than sleep disturbances.

The three patients with the lowest numbers of improved outcome variables were patients *D*, *F* and *H*. They were the youngest and they also scored the highest on the SF-36 (widest areas). They did not have the most deteriorated sleep at baseline and might have had other expectations of their sleep. This may suggest that they needed another kind of intervention or support.

It is difficult to evaluate the mattress interventions in this study since four of the patients had not used the mattress at the time of the first intervention assessment. For those who fulfilled

the two-week mattress intervention few variables were changed. We assumed that the mattresses might facilitate a better anatomic position since they mould themselves to the exact shape of the body. Another study demonstrated fewer twists from side to side with a polyurethane mattress (Bergholdt *et al.* 2008) which might indicate less fragmented sleep. However, this was not detected in the present study.

The variables which started to improve during study phase 3 (mattress), even for patients who declined to use or removed the mattress, might be explained by other effects e.g. the Hawthorne effect, which is defined as the additional response from increased attention provided from the study situation (Wolfe & Michaud 2010). Likewise, in clinical situations improvements have been explained by the nurse-dose effect which refers to the amount of nurse time and number of contacts (Brooten & Youngblut 2006). The coaching function by the first author might have been an important intervention since telephone follow-ups have been demonstrated to improve adherence to self-care in heart failure patients (Riegel *et al.* 2002, Wong *et al.* 2010). Nevertheless this is analogous to a clinical situation and may be an important intervention in itself.

Two of the patients in this study suffered severe joint pain during the night. It can only be presumed that an optimized treatment for the pain in combination with sleep hygiene interventions might have resulted in a better sleep outcome. For more intensive interventions other symptom management strategies have to be considered in parallel. In the assumptions behind the theory of unpleasant symptoms, Lenz and co-workers state that multiple symptoms may be experienced to have a multiplicative effect and consequently, interventions of different kinds may be effective for more than one symptom (Lenz *et al.* 1997). This requires

an awareness of symptoms related to poor sleep and sleep disturbing factors which makes the healthcare providers better prepared to intervene in these conditions.

Study limitations

Nine patients fulfilled the 17-week study plan. In traditional experimental studies this seems a small number of participants. However, in single-case studies, three or more subjects is considered a good number because the second, the third and so on are replications of the first subject which is a primary mechanism for establishing generality of empirical findings (Morgan & Morgan 2009). We have objectively collected data from totally 315 sleep-wake cycles, i.e. 35 per patient, which is a strength in the study. Since there is no consensus on how to measure clinical significances, $\frac{1}{2}$ SD of change was used (Frost *et al.* 2007) and applied to define clinical significance in HRQoL measurements. However, estimations of that kind must be seen as a guidance to interpret the effect of the interventions rather than a rule (Sloan *et al.* 2005). In addition, some authors suggest that differences of less than $\frac{1}{2}$ SD may be considered as clinically significant (Cella *et al.* 2003).

Despite the fact that the inclusion criteria were strictly followed, the participants in this study were a very heterogeneous group with regard to lifestyle, habits, morbidity and life situation. Some of the participants were stressed due to social issues and progressing morbidity, which were not possible to control in the study. This may have affected the results, but not for all as patient *G* improved in six of the nine outcome variables despite a serious family incident during the intervention. The individual intervention approaches also strengthen the study since they can be compared to a clinical situation.

The interventions were limited to primarily sleep hygiene and sleep scheduling interventions which are two components in the concept of cognitive-behavioural therapy (CBT) for primary insomnia (Pinto *et al.* 2010). A broader approach i.e. a full CBT intervention might have been more beneficial. Adaptation to new routines, i.e. behavioural or lifestyles changes, might need more time than the 4-week program used. However, the patients in our study improved in a number of variables, but the effect could perhaps have been more profound and maintained for longer with an extended program.

This study demonstrates many clinically significant individual improvements despite no statistical significances on group level having appeared. Positive outcomes for separate individuals are not always visible in studies conducted at group level. Therefore, studies with different designs are meaningful. Further studies are needed to discover how Patients responsive to non-pharmacological interventions can be identified. Moreover, studies combining both non-pharmacological and pharmacological interventions are required in this population.

CONCLUSION

This study illuminates the need for regular assessment of sleep and tiredness and demonstrates how non-pharmacological treatment and self-management can be applied with renal supportive care to improve sleep quality.

Conflict of interest

The authors declare no conflict of interest.

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Table 1. The study design shows the flow in the five study phases and the time points for intervention and data collection

^{a)}Outcome variables evaluating the intervention, ^{b)}anamnesis and assessment of sleep behavior, **O**=objective measurement, **S**=self-reported

Table 2. Patient characteristics and biochemical parameters at the inclusion

Patient	Diagnosis	Sex Male (M) Female (F)	Age	Body Mass Index (BMI)	Marital status	Working	Dialysis modality/month of treatment	Hemo- globin g/L	Creatinine μmol/L	Urea mmol/L	Albumin g/L	Hypnotics
A	Hypertensive nephropathy, Nephrectomy due to nephrolithiasis Ischemic heart disease Knee prosthesis	M	75	26	Single	Retired	CAPD/48	120	683	22.2	41	Zopiclone
B	Unspecified renal disease Diabetes mellitus type II Multiple myeloma Coxarthrosis Heart failure	M	76	29	Married	Retired	CAPD/11	121	480	19.8	30	-
C	Diabetes mellitus type I with renal complications Nephrosclerosis Atrial fibrillation	M	74	26	Married	Retired	CAPD and APD/16	96	672	22	29	-
D	Polycystic kidney disease Hypertension Hyperlipidemia Epigastralgia	F	47	26	Married	Sick leave fulltime	CAPD+HD once a week/30 Waiting list for renal graft	119	907	14.7	34	Propiomazin
E	Glomerulonephritis MGUS+light-chain deposition disease	M	77	25	Married	Retired	APD+2 daytime exchanges /84	118	860	11.7	Missing data	-
F	Polycystic kidney disease	M	48	24	Married	Working fulltime	CAPD and APD/9 Waiting list for renal graft	136	595	22.3	37	-
G	Unspecified renal disease	F	73	28	Married	Retired	CAPD/15	120	693	24	36	-
H	Diabetes mellitus type I with renal complications	M	55	31	Married	Working half time	CAPD/4 Waiting list for renal graft	124	730	23.8	32	-
I	Hypertensive nephropathy Polycystic kidney disease Asthma Heart failure	M	64	25	Single	Retired	CAPD/4	92	840	17.8	32	-

CAPD=manual dialysis daytime, APD=Nocturnal automatic dialysis with a machine

Table 3. Treatment plan with identified sleep problem, treatment goals, sleep hygiene applied, unexpected incidences and other symptoms of relevance for each patient A-I.

<i>Patient /Sleep problems</i>	<i>Sleep intervention goals</i>	<i>Outdoor activity for minimum 30 minutes per day</i>	<i>Daytime sleep restriction: max. 30 minutes and before 3 pm.</i>	<i>Go to bed earlier, when sleepy</i>	<i>Go to bed later</i>	<i>Bright light therapy in the morning</i>	<i>Ear plugs</i>	<i>No coffee after 6 pm</i>	<i>Unexpected incidences during the study</i> <i>e Other symptoms</i>
A Fragmented sleep with several naps	Consolidate nocturnal sleep Reduced freq. and time napping. Increased activity (steps, Metabolic Equivalent Unit (METs))	X	X						^a Joint pain in lower extremity and esophageal dysfunction
B Too early morning awakenings, daytime sequelae and frequent napping	Consolidate nocturnal sleep Reduced freq. and time napping. Increased activity (steps, METs)	X	X		X				
C Delayed sleep phase, short sleep duration, fragmented sleep and daytime sequelae	Replaced sleep phases, Reduced freq. and time napping		X			X			^d Severe infection and surgery at the lower extremity after the first intervention
D Sleep onset difficulties, Delayed sleep phase, RLS	Reduce nocturnal sleep duration Replaced sleep phases, Reduced freq. and time napping.	X (sedentary activities before bedtime reducing RLS)	X						^d Serious social incident after first intervention
E Sleep onset difficulties, nocturnal awakenings	Improve sleep onset Consolidate nocturnal sleep Increased activity (steps, METs)	X	X						^e Joint pain in lower extremity
F^b Sleep onset difficulties due to noise from PD-machine and daytime sequelae and work in a reduced light environment	Improve sleep onset Consolidate nocturnal sleep					X	X		
G^c Nocturnal awakenings and daytime sequelae	Consolidate nocturnal sleep Reduced freq. and time napping. Increased activity (steps, METs)	X	X						^d Family incident after first intervention
H^b Sleep onset difficulties, nocturnal awakenings related to RLS	Improve sleep onset Consolidate nocturnal sleep	X (sedentary activities before bedtime reducing RLS)						X	
I^c Difficulties, with daytime sequelae, napping and sleep onset	Improve sleep onset Consolidate nocturnal sleep Reduced freq. and time napping. Increased activity (steps, METs)	X	X	X					

^a=Sunrise system 320@ Bright LED portable light box – up to 10.000 Lux. Applied 30-45 min at 30-50 cm distance.

^b=Refused mattress

^c= Took the mattress away after two nights

Table 4. Changes in the outcome variables between the two baselines and study phase 3: mattress, 4: sleep hygiene interventions and 5, follow-up in patient A-I. A change of half a standard deviation or more was applied as a clinically significant individual change, improved (+), impaired (-) or unchanged (0) outcomes are presented, for examples a shortened napping time is marked (+). Shadowed squares show specific individual intervention goals.

Patients	A					B					C					D					E					F ^a					G ^b					H ^a					I ^b					Group improvements (n=9)				
	3	4	5			3	4	5			3	4	5			3	4	5			3	4	5			3	4	5			3	4	5			3	4	5												
<i>Outcome variables</i>																																																		
Sleep latency onset	-	0	0			+	+	+			+	+	+			0	-	+			0	-	0			-	0	-			-	0	0			0	-	+			-	+	+			2	3	5		
Nocturnal sleep duration	+	0	+			0	+	+			0	+	+			0	0	0			-	-	-			-	0	0	0			0	0	0			0	0	+	+			1	3	2					
Napping time	+	0	0			-	-	0	0		-	-	-			+	-	-			-	0	-			-	0	-			0	+	0			-	-	0	+	0			3	3	1					
Number of naps	+	-	+			0	+	0			0	-	-			0	+	0			0	0	0			0	0	0			0	0	0			+	-	0	0	-		4	3	2						
Sleep efficiency	0	+	+			0	0	0			0	+	0			0	0	0			-	-	-			-	-	-			-	0	+	0			0	+	0			0	5	1						
Number of steps	-	0	0			0	+	+			-	-	-			0	0	0			0	0	0			-	0	0			-	0	+	+			0	0	+	+			2	3	4					
Metabolic Equivalent Unit (Kcal/kg/hour)	0	0	0			0	0	+			0	0	0			0	0	0			0	0	0			0	0	+			-	0	0			+	0	-			3	3	4							
Movement and Fragmentation Index	0	+	+			0	0	0			0	0	0			0	0	-			-	-	-			-	-	-			0	0	-		0	-	0	0	+	0			1	3	2					
Fatigue	-	-	-			0	+	0			0	-	-			+	+	+			+	+	+			-	-	-			-	+	+			-	+	-			3	4	4							
Individual improvements	3	2	4			2	5	3			1	3	2			3	3	3			1	1	2			0	1	2			5	6	4		2	2	1			2	7	5								

^a=Declined use of the mattress, ^b=Removed the mattress after two nights due to discomfort.

Figure 1. Illustrations of nocturnal sleep duration (top) and napping time (bottom) for patient A-I during the study phase 1-5. Nocturnal sleep duration 6 hours or more and daytime napping less than 30 minutes is recommended if Insomnia is persisting. Note that this is not a continuous assessment, the lines between the dots is just to visualize the changes for each patient.

Figure 2. Illustrations of changes in Metabolic Equivalent Unit (METs)(top) and number of steps (bottom) for patient A-I, during the five study phases. Four patients had clinical significantly improvements, marked out with bold lines. Note that this is not a continuous assessment, the lines between the dots is just to visualize the changes for each patient.

Figure 3. Illustrations of changes in sleep efficiency (above), movement and fragmentation index (MFI) (middle) and fatigue score (below) in patient A-I during the five study phases. Sleep efficiency more than 85% and MFI below 20 are well consolidated sleep. MFI above 50 are indicating seriously

Figure 4. Health profiles (SF-36) from baseline 1 (dotted line) to follow-up (continuous line) in patient A-I. A narrow area indicates poor health and a wide area indicates good health. PF=physical functioning, RP=role limitations due to physical health problems, BP=bodily pain, GH=general health, VT=vitality, SF=social function, RE=role limitations due to emotional problems and MH=mental health. Scale: 0 (centre)-100.