Exploring the Effect of Nightly Infusion Pump Alarms on Sleep in the Hospital

Jojanneke AMC van Kooten (✉ j.a.m.vankooten-2@prinsesmaximacentrum.nl)

Princess Maxima Center for Pediatric Oncology: Prinses Maxima Centrum voor Kinderoncologie

<https://orcid.org/0000-0002-7740-3954>

Erik Koomen

Wilhelmina Children's Hospital University Medical Centre: Universitair Medisch Centrum Utrecht - Locatie Wilhelmina Kinderziekenhuis

Kees P. van de Ven

Princess Maxima Center for Pediatric Oncology: Prinses Maxima Centrum voor Kinderoncologie

Mit Patel

University of Toronto

Martine van Grotel

Princess Maxima Center for Pediatric Oncology: Prinses Maxima Centrum voor Kinderoncologie

Martha A. Grootenhuis

Princess Maxima Center for Pediatric Oncology: Prinses Maxima Centrum voor Kinderoncologie

Raphaële R.L. van Litsenburg

Princess Maxima Center for Pediatric Oncology: Prinses Maxima Centrum voor Kinderoncologie

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Abstract

Purpose

Optimal sleep helps parents and children cope with life-threatening disease. However, hospital-surroundings are noisy, negatively affecting sleep quality and quantity. We aimed to determine sleep quantity; sleep satisfaction; their relation to infusion pump alarms in pediatric cancer patients and parents; and sleep quality and daytime impairment in parents.

Methods

Patients (2–18 years), admitted for scheduled anti-cancer therapy were eligible, as were inrooming parents. Frequency and duration of nightly infusion pump alarms were recorded. Patients and parents wore an accelerometer to assess sleep quantity (sleep efficiency, wake after sleep onset, night awakenings), additionally daily sleep satisfaction was assessed. Parents filled out questionnaires on sleep quality (PROMIS Sleep Disturbance, Insomnia Severity Index) and daytime impairment (PROMIS Sleep-Related Impairment, PROMIS Fatigue). Sleep quality scores were compared to norms. In children and parents the relation between alarms and sleep was assessed using multilevel analyses.

Results

Nineteen children (age 8.8 ± 4.9 years, 40 nights) and 30 parents (age 41.1 ± 6.3 , 46 nights) participated (response 78%). Nightly alarms sounded median 3 times / 6 minutes in parents and 5 times / 10 minutes in children. Parents scored worse than the norm on sleep disturbances ($P .01$), but not on daytime impairment, 16% experienced clinical insomnia. There was no relation between alarms and sleep quantity or satisfaction for children and parents.

Conclusions

This explorative study showed that alarms sound frequently at night and parents sleep poorly during admissions. However, sleep of children and parents and alarms were not significantly related here. Future research should identify and improve (other) disrupting factors in the hospital.

Introduction

From the moment a child is diagnosed with cancer, families have to deal with the stress that accompanies this diagnosis and subsequent treatment[1, 2]. Stress and sleep are intertwined and influence each other: Distress can lead to hyperarousal and disrupted sleep, and is known as an important trigger and perpetuating factor for insomnia. Disrupted sleep also causes hyperarousal and distress[3, 4]. Nighttime rest of parents of children with cancer is often disturbed by care demands and

due to sleep problems of the child[5, 6]. During treatment, 30–50% of children experience sleep problems, significantly more than their healthy peers[7–9]. Parenting practices and strategies associated with the child's sleep often change and become more lax during this period[9]. Cancer and treatment effects such as pain and nausea can disturb sleep[10, 11]. Direct brain injury due to tumor location or treatment can also affect sleep regulatory systems[10, 11]. Moreover, the majority of families have to deal with frequent hospitalization, and the inevitable change in sleeping environment during these periods.

Sleep of both children and parents tends to be even more affected during admissions, influencing both sleep quality and quantity[12–16]. Care during the night, unfamiliar surroundings, loss of routine, and environmental stimuli such as bright light play an important role in sleep disruption during hospital admissions[10, 12]. The most disruptive to sleep, however, are environmental noises, especially when meant to be alerting[17]. The World Health Organization states that events generating sound levels of 45 decibel (dB) or greater are associated with disrupted sleep,[18] in hospitals mean nighttime sound levels exceed 45 dB, with abrupt increases over 80 dB[14, 16]. Infusion pump alarms are an important source of these sounds and are mandatory to be at least 45 dB at one meter distance of the pump (IEC 60601-2-24:2012).

Optimal sleep is important to help parents and children cope with a life-threatening disease. Disrupted sleep has many negative effects, including a lower quality of life[6–8]. More specifically, sleep problems in children are associated with worse mood, cognitive function and more problematic behavior[10, 19]. Parents who experience disrupted sleep, feel more exhausted, irritable, and forgetful,[5] and less equipped to make medical decisions about their child[6]. In contrast to children admitted for an acute illness, families facing cancer, face a long treatment trajectory and often do not get chance to recuperate once they are back home.

Sleep is often impaired in families dealing with childhood cancer and distress is high, even more so during hospitalisation. Both have many negative daytime consequences. The influence of the hospital environment, especially the generally high sound level, can be more easily adjusted than other factors influencing sleep and stress; cancer, treatment and personal factors. It is, however, unclear to what extent infusion pump alarms contribute to poor sleep in pediatric oncology patients and parents. Therefore, the aim of this explorative study was to determine sleep quality and daytime sleep-related impairment in parents; and to determine sleep quantity and sleep satisfaction, and the association with nightly infusion pump alarms in pediatric oncology patients admitted to the hospital for immunotherapy or chemotherapy, and in their parents.

Methods

1 Participants and procedure

In this prospective observational study, performed at the Princess Máxima Center for pediatric oncology in Utrecht, the Netherlands, families were eligible for inclusion if the child was aged 2–18 years and

admitted for a scheduled course of chemotherapy or immunotherapy, requiring at least one overnight stay. The study was also open to the inrooming caregiver. Since most caregivers are the parents, the term parents will be used hereafter. If parents alternated rooming-in during the child's hospital stay, both parents were given the opportunity to participate. Families were not eligible during the child's first course of therapy, to eliminate the additional stress accompanying a first admission. Another exclusion criterion was insufficient mastery of the Dutch language.

The Empatica E4 wristwatch was attached on the day of admission. The wristwatch and other measures are described in detail below. Study duration lasted until hospital discharge, unless admission exceeded seven nights, patients developed a fever/fell ill during admission, or elected to stop prior to that time.

Following regular hospital policy, patients were admitted to a private or a double room and one parent slept in a bed directly next to the child. Patients also occasionally moved between rooms, meaning they could sleep a part of their admission in a private room, and part in a double room. Infusion pumps were situated next to the patients' bed in a docking station and alarms were audible in the patients' room. The alarm sound levels could manually be regulated by the nurse, and could range from 59 to 74 dB, though pumps were mostly set at the lowest level. The infusion pumps were not automatically connected to the nurse call system (NCS), patients / parents needed to manually alert the nurse by activating the NCS.

2 Outcomes

2.1 Sociodemographic and medical information of children and parents

Parents filled out a general questionnaire about their child and themselves containing information on demographic variables, history of sleep problems, and use of medication. Information on cancer diagnosis and therapy was obtained from hospital records.

2.2 Infusion pump alarms of children and parents

Information on timing and duration of infusion pump alarms was collected by a cable-connection to the hospital server. If the infusion pumps were disconnected from the hospital server (e.g. bathroom visits), data was retrieved from the pump itself after the treatment course was completed. Both methods led to similar information on date, time, and duration of alarms. Bed and wake times from the sleep diary were used to determine the timeframe in which the participants attempted nighttime sleep. The number and duration of infusion pump alarms during these timeframes were extracted. When admitted in a double room, alarms of both the participants' pump and the other patients' pump were combined. In case bed and wake times were missing from the sleep diaries (five nights), sleep onset and offset were extracted from the Empatica data (described below).

2.3 Sleep quantity of children and parents

Sleep quantity was measured in children and parents using the *Empatica E4 wristwatch* (Empatica Inc., Cambridge, United States) referred to as E4[20]. The participants were asked to wear the E4 on their non-

dominant wrist day and night during the study period. The E4 uses a three axes accelerometer to measure wrist movement at a rate of 32 Hz. An accelerometer has the capability to measure sleep and wake minutes from the absence/presence of wrist movement, movement is captured by the device and subsequently translated to sleep and wake minutes through an algorithm on a computer: actigraphy. Actigraphy is generally accepted as a valid and reliable method to measure sleep in both children and adults[21, 22]. To support the accelerometer data, bedtime, waketime and non-wear time were reported in a sleep diary.

The raw data from the E4 was divided into epochs with one minute intervals. For each epoch, zero-crossings for all three axis were summed. The Cole-Kripke algorithm was then applied to label each epoch as 'sleep' or 'wake'. This algorithm is mostly used for adults,[23, 24] who are most represented in our study sample, but the algorithm has also successfully been used in children[25–27]. Since participant characteristics and type of device can influence the performance of the algorithm, we first analyzed the performance of the original Cole-Kripke algorithm in our study population. This original algorithm considers an epoch 'wake' when crossing a threshold of 1.0. The original algorithm significantly over-classified sleep in our population, therefore we altered the study threshold to 0.4. This value was determined by analyzing Cole-Kripke scores of a subset of participants during their wake and sleep periods and selecting the value that maximized the classification accuracy, as visualized in Fig. 1. Sleep onset and offset was determined by a partly automated algorithm used with the support of the sleep diary. First, the algorithm looked for 8 minutes of continuous sleep within 45 minutes of the sleep diary times. If the device was not worn during this time, sleep onset and offset were manually reviewed through the scored files, to prevent misclassification (since not wearing the device looks similar to sleep for the algorithm). Once each night and morning had sleep onset and offset times, epochs between the determined timings were spliced and the sleep outcomes were calculated: total sleep time (TST), defined as number of minutes scored as sleep between sleep onset and offset; wake after sleep onset (WASO), defined as number of minutes scored as wake between sleep onset and offset; sleep efficiency (SE), defined as percentage of sleep between sleep onset and offset; and night awakenings (NA), defined as number of wake blocks interrupting one or more minutes of continuous sleep.

2.4 Sleep satisfaction of children and parents

Participants were asked to rate daily how satisfied they were with their sleep in the sleep diary. A visual analogue scale (VAS) ranging from one to ten was used for parental sleep and for children below 8 years of age (proxy-report). A VAS with a range from one to five, illustrated with five faces was used for children 8 to 18 years (self-report). Both scales were then converted to a categorical variable ranging from one to five. A higher score indicated better sleep quality.

2.5 Sleep quality and daytime impairment of parents

Sleep and fatigue of parents was assessed by self-reported questionnaires on the last day of parents' study participation. Similar to previous studies on sleep during hospital admissions, recall time was the current hospital admission, instead of the original recall time of the questionnaires[28].

Insomnia severity index (ISI): A reliable and valid, 7-item self-report questionnaire assessing the nature, severity, and impact of insomnia. Questions were answered on a 5-point Likert scale (0 'no problem' to 4 'very severe problem'). The total score ranges from 0 to 28 and is interpreted as follows; absence of insomnia (0–7); sub-threshold insomnia (8–14); moderate insomnia (15–21); and severe insomnia (22–28). Questionnaires with $\geq$ one missing item could not be scored (n = 4)[29].

Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance item bank: A reliable and valid 27-item questionnaire, reflective of insomnia-like symptoms[30, 31]. PROMIS Sleep-Related Impairment item bank: A valid and reliable 16-item questionnaire, containing items related to sleepiness, fatigue, and cognitive difficulties during waking hours[30, 31]. PROMIS short form Fatigue: A valid and reliable 8-item questionnaire, containing items on the experience of fatigue and the impact of on daily activities[32, 33]. PROMIS' items were measured on a 5-point Likert scale (1 'not at all'/'never' to 5 'very much'/'always'). The official Health Measures scoring service tool was used to calculate T-scores using the US calibration parameters for all participants who filled out at least one item. T-scores are anchored on the US general population, with a mean of 50 and a standard deviation of 10. Higher scores indicate more sleep disturbances.

3 Statistical analyses

To describe sleep quantity and satisfaction during hospital admissions, mean sleep satisfaction and E4 outcomes (TST, SE, WASO, NA) were calculated for all participants. Norm scores are not available for comparison of these outcomes. Self-reported sleep and the daytime consequences parents experienced were described by comparing T-scores to norm scores by using one sample T-tests. A P-value of $< .05$ was considered significant. In addition, we reported the number of parents in each category of the ISI.

To determine the association between sleep satisfaction and quantity and nightly infusion pump alarms in children and parents, linear mixed models were performed using maximum likelihood estimation. As the models could include multiple nights per participant, and parents and children were combined in one model, two random intercepts were included to account for dependency; on individual subject level and on family level. Since it is plausible that children and adults react differently to alarming sounds,[34] secondary analyses were performed separately for children (random intercept on individual subject level) and parents (random intercept on individual subject level and on family level). Models were constructed for the outcomes sleep satisfaction, WASO, SE and NA, with number of alarms per night and total duration of alarms per night as independent variables. As a longer sleep duration would automatically infer a greater opportunity for alarms to sound, TST was not included as an outcome. All analyses were performed with SPSS Statistics 25.0.0.2.

Results

1 Population

In total 36 families were eligible for inclusion and were invited to participate in the study. Eight families declined due to focus on treatment, or due to refusal of the child, resulting in a response rate of 78%. In one participating family only the parents participated, in another family only the child participated. Due to technical problems, infusion pump data was not available in three children and four parents. Out of the families with infusion pump data, five children and two parents did not have any other data and were excluded from further analyses. This loss of data was mostly because a child refused to wear the watch, or a parent was distracted by the watch at night and removed it, and then also did not proceed to fill out the sleep diary and questionnaires. The final study population consisted of 19 children (40 nights) and 30 parents (46 nights). An overview of inclusions is shown in Fig. 2. Table 1 shows the demographic and medical characteristics. Distribution of diagnoses was similar in the study sample, compared to all admissions during the study period (58% solid, 36% hematological, 9% central nervous system). Of all parents 29/30 were mothers (57%) or fathers (40%), one grandmother participated. Most parents (89%) had more than one child to take care of. One parent had a history of sleep problems and was using sleep medication, none of the children did.

Table 1
Demographic and medical characteristics

	Children not participating (n = 11)	Participating children with data (n = 19)	Parent 1 with data (n = 22)	Parent 2 with data (n = 8)
Age (mean years $\pm$ SD; range)	7.4 $\pm$ 5.1; 2–16	8.8 $\pm$ 4.9; 2–17	40.8 $\pm$ 6.5; 27–51	42.0 $\pm$ 6.2; 33–50
Sex (n; % female)	5; 45%	8; 42%	14; 64%	4; 50%
Characteristics parents				
Marital status (n; % together with parent of their child)			15; 68%	6; 75%
Number of children (median; range)			2; 1–6	2; 1–3
Educational level (n; %)				
High school			3; 15%	3; 38%
Intermediate vocational training			6; 30%	3; 38%
Higher vocational training / university			11; 55%	2; 25%
Work (n; %)				
Paid job			13; 65%	4; 50%
Currently unemployed			5; 25%	1; 13%
Health insurance act (in part)			2; 10%	3; 38%
Medical characteristics children				
Diagnosis (n; %)				
Hematological	4; 33%	7; 37%		
Solid	7; 58%	11; 58%		
Central nervous system	1; 8%	1; 5%		
Time since diagnosis (median months; range)	4; 1–14	4; 1–21		
Duration of admission (mean nights $\pm$ SD; range)	6.2 $\pm$ 4.6; 2–7	3.1 $\pm$ 1.9; 1–7		

2 Description outcomes

All outcomes are described in Table 2. Alarms sounded median five times during nighttime sleep of children (median duration 10 minutes) and three times during sleep of parents (duration 6 minutes). On average children had a higher SE, less frequent NA and lower WASO than their parents. Twenty-eight percent of children did not get the required amount of sleep (TST) for their age group during admission, [35] although time spent napping during the day was not included. Only 8% of parents slept under the recommended 7h[36]. The mean VAS score was 3.2/5 in parents and 3.7/5 in children.

Table 2
Description of outcomes

	Children	Parents
Sleep quality and fatigue (self-reported)		
ISI (%)		
No insomnia		27%
Subthreshold insomnia		58%
Moderate clinical insomnia		12%
Severe clinical insomnia		4%
PROMIS Sleep Disturbance T-score (mean $\pm$ SD; range) ^a		54 $\pm$ 7; 34–71
PROMIS Sleep-Related Impairment T-score (mean $\pm$ SD; range) ^a		51 $\pm$ 8; 32–67
PROMIS Short Form Fatigue T-score (mean $\pm$ SD; range) ^a		50 $\pm$ 7; 33–63
Sleep satisfaction (self- and parent-reported)		
VAS (mean $\pm$ SD; range)	3.7 $\pm$ 0.7; 2.0–5.0	3.2 $\pm$ 0.6; 2.0–4.0
Sleep quantity		
TST (mean minutes $\pm$ SD; range)	585 $\pm$ 84; 377–792	490 $\pm$ 68; 363–647
SE (mean % $\pm$ SD; range)	93 $\pm$ 4; 84–99	91 $\pm$ 5; 79–100
WASO (mean minutes $\pm$ SD; range)	48 $\pm$ 28; 4–119	53 $\pm$ 30; 2–157
NA (mean $\pm$ SD; range)	11 $\pm$ 5; 3–22	14 $\pm$ 6; 2–30
Alarms		
Number of alarms (median minutes; range)	5; 1–20	3; 0–19
Duration of alarms (median minutes; range)	10; 0–61	6; 0–61
Abbreviations: ISI = Insomnia Severity Index; VAS = Visual Analogue Scale; TST = Total Sleep Time; SE = Sleep Efficiency; WASO = Wake After Sleep Onset; IQR = Interquartile Rang; NA = Night Awakenings		
^a Mean T-score norm population is 50 $\pm$ 10		

Parents reported significantly more sleep disturbances (mean difference 3.7, P.010), but not significantly more sleep-related impairment or fatigue than the norm. Eighty-five percent experienced subthreshold insomnia and 16% experienced clinical insomnia, more than the 7–8% in the general population[37].

3 Relation between sleep satisfaction, sleep quantity and infusion pump alarms in children and parents

Multilevel analyses showed no significant relation between alarms, sleep satisfaction (VAS-scores) and sleep quantity (WASO, SE and NA), shown in Table 3. Secondary analyses for children and parents separately similar results, shown in supplemental material.

Table 3
Relation between alarms and sleep satisfaction and quantity in children and parents

Independent variable	Dependent variable	B	Std. Error	P-value
Number of alarms per night	Sleep satisfaction	0.0	0.1	.193
	WASO	1.3	4.9	.088
	SE	-0.1	0.7	.445
	NA	-0.1	1.0	.541
Duration of alarms per night (in seconds)	Sleep satisfaction	0.0	0.1	.326
	WASO	0.0	4.6	.257
	SE	0.0	0.7	.775
	NA	0.0	0.9	.990
Abbreviations: SE = Sleep Efficiency; WASO = Wake After Sleep Onset; NA = Night Awakenings				

Discussion

The aim of this study was to determine sleep quality and sleep-related daytime consequences for parents during scheduled admissions of their child, and to determine the relation between sleep satisfaction, sleep quantity and nightly infusion pump alarms in children and parents dealing with childhood cancer. To achieve this, information on sleep quality of parents, and sleep satisfaction and quantity of children and parents was collected during admission, over a combined period of in total 86 nights.

Parents reported poor sleep during hospital admissions. The percentage of parents that reported clinical insomnia was twice as high as in the general population, and they reported significantly more sleep disturbances. There is a large amount of evidence to support the association between poor sleep at night and worse functioning on multiple domains during the day[10, 38]. However, in this study parents did not score significantly worse than the norm population on daytime impairment. Since acute insomnia is linked to cognitive and somatic hyperarousal, it is possible that hyperarousal masked daytime symptoms in our study population[4]. In addition to the short term negative daytime consequences of sleep problems, long term persistence of sleep problems is a risk when developing sleep problems during admission. From Rensen et al., we know that in a population of parents of children with cancer, even with

90% off-treatment, the prevalence of sleep problems remains high[1]: hyperarousal, together with maladaptive behaviors and a continuous stressor (e.g. having a child with cancer) can work as perpetuating factors for chronic insomnia[4]. Though no information on sleep quality of children is reported here, based on previous literature they are also at risk for persistence of sleep problems: In 33–42% of healthy children with sleep problems, these problems persisted from school age to adolescence and adolescence to young adulthood[39, 40]. In children admitted due to critical illness, sleep problems remained high until at least 6 months after admission, in-hospital sleep problems were a possible risk factor[41].

This study shows that infusion pump alarms sound frequently at night during a scheduled admission in the hospital to receive chemo-/immunotherapy. Vitoux et al., mapped infusion pump alarm frequency and found alarms to sound on average 0.18 times/hour, during 2.38 min/alarm. In a night of 8h, this extrapolates to 1.4 alarms, during 4 minutes[42]. Alarms tend to sound more frequently in pediatric (critical care) wards than in adult wards[42]. In addition, logistic aspects explain the high number of nightly alarms: Firstly, pumps are used less often to give intravenous fluids and medication in a general ward, then in oncology wards; no pumps equals no alarms. Secondly, before chemotherapy can be started, blood is drawn and tested; if results meet criteria for starting chemotherapy, an order is sent to the pharmacy. Thus in practice, chemotherapy runs from 2 pm to approximately 2 am.

We did not find a significant relation between sleep and infusion pump alarms in admitted children and their parents. Based on previous literature this relation would have been expected. Multiple studies in healthy adults,[43] hospitalized adult patients,[44] and children admitted for anti-cancer therapy,[12, 14, 45] found a significant relation between more sounds/higher noise levels, and worse sleep quality and quantity. These studies measured the general sound level during the night, as opposed to infusion pump alarms specifically. An experimental study in healthy participants by Buxton et al., tested the cortical arousal response to 14 different environmental hospital sounds through polysomnography. They found arousal to be greatest in reaction to alerting electronic sounds. The reason this current study did not find a relation could be found in the E4, since this accelerometer was not validated through comparison to polysomnography: The sensitivity and specificity of the E4 to measure sleep is therefore unknown and sleep minutes could have been overestimated as well as underestimated. Secondly, it is possible that 86 nights of data lacks the power to determine a significant relation. Another plausible reason however, is that other disrupting environmental influences clouded the relation between alarms and sleep. For instance, in five families the child's heart rate was also monitored, these alarms were not taken into account. Also, 14 out of 24 families slept at least part of the admission period in a double room. Other factors like staff conversations, light levels and staff interruptions for nighttime care and assessment, were also linked to worse sleep in previous studies[12, 14, 45].

Stremmer et al. performed focus groups with 30 pediatric nurses and bundled recommendations to improve sleep of patients: Decrease use and volume of alarms; decrease use of overhead lighting and instead use dimmers and soft lighting from machines; cluster nightly nursing assessments; and discuss the division of the child's care with the parents at the beginning of the night shift[46]. Decreasing alarms

and lighting needs to come with adequate safety monitoring and is accompanied by a higher financial cost. Simpler and less costly solutions, such as earplugs to block sound and eye masks to block light have also proven effective in improving sleep in the hospital and should be considered to improve overall well-being of patients and their families[47].

This study had a few limitations. Firstly, as mentioned, the reliability of the E4 in comparison to polysomnography is unknown. Secondly, no sleep questionnaires capturing subjective sleep in children were used. As there is a lack of psychometrically valid sleep questionnaires covering the whole pediatric age range, different instruments leading to different outcomes would have been needed. Considering the sample size, this study would have been underpowered for proper analyses, and sleep questionnaires for children were therefore not included as an outcome. Thirdly, norm values for comparison of sleep satisfaction and sleep quantity values of our study sample, were unavailable.

In conclusion, pediatric oncology patients and their parents have reduced sleep quantity and quality during hospital admissions. Short term sleep problems often persist throughout later childhood and adulthood. Daytime impairment for parents was comparable to the norm population, but is possibly masked by hyperarousal due to stress and poor sleep. Infusion pump alarms sound frequently at night, though they do not correlate with sleep in our study. Future research should therefore focus on mapping and improving broader disrupting aspects of the hospital environment on sleep.

Declarations

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Ethics approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Medical Ethical Research Committee of the University Medical Center Utrecht.

Consent to participate: Verbal informed consent was obtained from all participants, written informed consent was obtained from all legal guardians.

Availability of data and material: Data can be made available upon request.

Contribution statement: All authors contributed to the study conception and design, and material preparation. Data collection was performed by JvK, MG and EK. All authors contributed to data analysis. The first draft of the manuscript was written by JvK and RvL, all authors commented on previous versions of the manuscript and revisions were made. All authors read and approved the final manuscript.

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Figures

Figure 1

Visualization of rationale for lowering threshold Cole-Kripke algorithm

Figure 2

Flowdiagram inclusion

Supplementary Files

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