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Original article

The effect of white noise on sucking success and infant comfort in premature babies: a paired randomized controlled trial

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Abstract

Purpose: This study was conducted in a paired randomized controlled trial manner to determine the effect of white noise on sucking success and infant comfort in premature babies.

Methods: Sixty-six preterm babies were randomized into two groups (33 newborns in the white noise group and 33 newborns in the control group). In the white noise group, preterm babies were exposed to white noise during breastfeeding. Patient identification form, application registration form, Premature Infant Comfort Scale (PICS), and LATCH Breastfeeding Assessment Tool were used in the study.

Results: There was no significant difference between the pre- and post-procedure LATCH scores of the babies in the white noise and control groups ($p > 0.05$). However, in the comparison within the groups, a statistical difference was found between the pre- and post-procedure scores of the newborns in the white noise and control groups ($p < 0.05$). The breastfeeding success scores of the newborns in the white noise group were found to be higher than that of the control group (white noise group Cohen d value = 0.45, control group Cohen d value = 0.17). While there was no significant difference between the groups in terms of pre-procedure PICS scores ($p = 0.114$), a significant difference was found in the post-procedure PICS

scores (p = 0.031). The increase in the comfort levels of newborns in the white noise group was found to be significant.

Conclusion: The white noise played to premature babies during breastfeeding was effective on the sucking success and the comfort level.

Keywords

Premature baby, sucking success, white noise, comfort.

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Introduction

The basis of a healthy life begins with a healthy pregnancy and birth. However, many babies in the world are born before the normal period. A baby born before the 37th week is considered as a premature baby [1]. It is estimated that approximately 11% of births in the world are premature births, and almost 15 million babies are born prematurely each year [2, 3].

Premature babies have an increased risk of short- and long-term morbidity and mortality. Infant deaths in the neonatal period are mostly due to prematurity and its complications [4, 5]. The majority of premature babies need special care in the Neonatal Intensive Care Unit (NICU) until they can maintain their nutritional and respiratory needs without assistance [6].

Feeding is one of the basic requirements for growth and development and for survival itself, to survive and to protect their health [7]. The American Academy of Pediatrics (AAP) states that breastfeeding should be preferred as the source of nutrients for premature babies [8]. Studies have shown that breast milk is the first "vaccine" for infants [9] and, thanks to its uniqueness of composition and characteristics, it is the first crucial nutrient for the right growth and development of the different body systems and of their immune functions [10, 11].

Breast milk prevents intestinal disorders such as diarrhea and constipation in infants, especially protects premature infants from necrotizing enterocolitis, and is associated with a lower rate of infectious and allergic diseases and a minor risk of sudden infant deaths [12-14]. The sucking behavior allows newborns to relax. The newborns desire to suckle when they need physical and emotional relief, and when they are exposed to environmental stimuli such as light, color, sound, noise and touch as they are overstimulated [15].

Sense of hearing is one of the earliest abilities to develop in the fetal era [16]. The fetus hears the sounds created by the amniotic fluid and the sounds caused by shaking in the intrauterine environment, the sound of the blood flow through the arteries of the mother and the heartbeat, and the sounds of the gastrointestinal system, and gets used to these sounds [17]. It is known that the sounds that the baby hears in the mother's womb have a relaxing effect on the baby after birth. In the literature, it has been stated that such sounds have soothing effects on the fetus and newborn, reduce pain, stress, anxiety, and positively affect the sucking success of newborns [18-20]. The white noise, which is similar to the sounds in the mother's womb, has a relaxing and soothing effect, suppresses the disturbing sounds from the environment, and is a continuous and monotonous sound in the form of humming [21].

This study was carried out to determine the effect of white noise on sucking success and comfort in 34-37-week newborns who were hospitalized in the NICU and fed orally. In this study, two hypotheses were suggested: (i) white noise has a positive effect on sucking success in premature babies; (ii) white noise has a positive effect on comfort in premature infants.

Materials and methods

The aim and type of the study

This study was conducted in a paired randomized controlled trial manner on preterm infants who were hospitalized in the NICU of a University Hospital from September 2020 to March 2021.

The study has been submitted to Clinical Trials and Clinical Trials ID No. has been taken (Protocol ID 12102020100153, Clinical Trials ID No. NCT04807647).

The universe and sample of the study

The inclusion criteria of the study are as follows:

- gestational age of 34-37 weeks and birth weight of 1,800-3,500 g;
- absence of congenital anomaly;
- being treated at the NICU;
- stable condition;
- absence of congenital malformation of hearing;
- the mother should not have a condition that prevents breastfeeding.

G-Power 3.1 analysis program was used to calculate the sample size. The minimum sample size of the study was calculated as 66 according to the power analysis (in 0.62 effect size, 0.05 margin of error, 0.95 confidence interval, 80% population representation power). At the beginning of the study, 176 preterm newborns were included; however, 106 newborns were excluded from the sample as they did not meet the sampling criteria. Considering that there could be case losses and cases that could disrupt the homogeneity of the groups in terms of variables affecting pain, 70 newborns were included in the sample.

The newborns were randomly divided into two groups, each with 35 infants. Numbers from 1 to 70 were assigned to two groups using a program on computer without recurrence of the numbers at randomization. 2 newborns from the white noise group and 2 from the control group were lost to follow-up. The final number of newborns in each group became 33, and thus, 66 newborns in total were included in the analysis. **Fig. 1** describes the study flow. The design, conduct and reporting of this study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [22].

Since the same researcher has performed the intervention and assessment, the design of the study is not appropriate for a double-blind study. Only the statistician did not know which group was the white noise group or the control group.

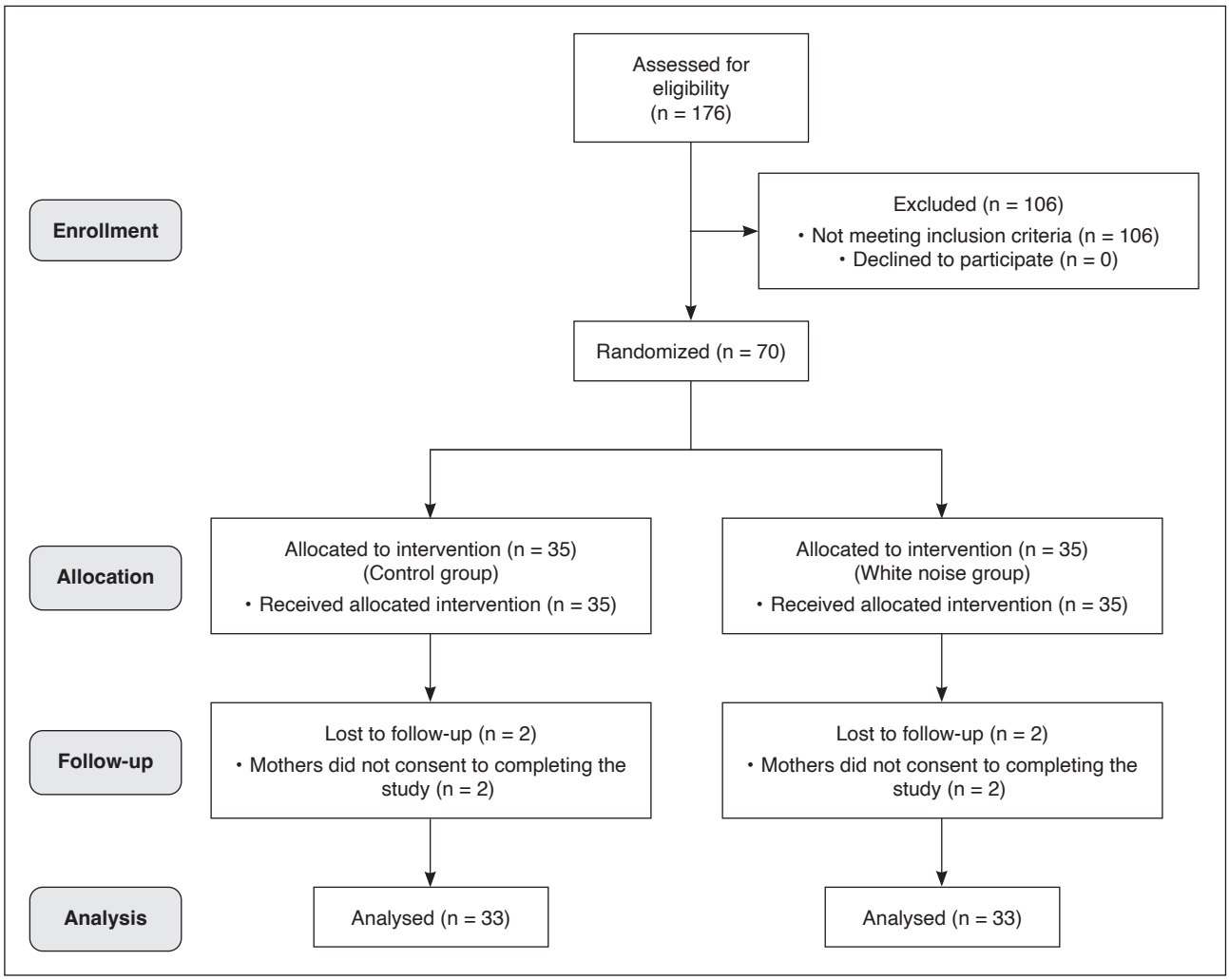

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram of this study.

Instruments

Mother-infant identification form

This form, prepared by the researchers, consists of 15 questions and includes open-ended and multiple-choice introductory questions about the mother (age, education, employment status, number of children, etc.) and the infant (delivery type, Apgar score, gestational age, gender, weight and height, and head circumference).

LATCH Breastfeeding Assessment Tool

The LATCH Breastfeeding Assessment Tool is a method visually developed in 1986 in the same form as the Apgar scoring grid. It was prepared to assess breastfeeding objectively, reveal breastfeeding problems and make training plans. It consists of 5 assessment items, and each item is scored between 0 and 2. A high score on the scale indicates good breastfeeding success. The reliability of the LATCH Breastfeeding Assessment Tool was re-performed in the USA by Adams and Hewell, in 1997 [23]. Its reliability in Turkey was performed by Yenal and Okumus, in 2003, and Cronbach's alpha value was found to be 0.95 [24]. In this study, Cronbach's alpha value was calculated as 0.83.

Premature Infant Comfort Scale

The Premature Infant Comfort Scale (PICS) was developed by Ambuel et al., in 1992 [25], to measure the pain and stress levels of children aged 0-18 in the Pediatric Intensive Care Unit and adapted by Caljouw et al., in 2007, for premature babies ≥ 28 and ≤ 37 weeks of age. PICS is a multidimensional scale tool used to evaluate comfort and pain behaviorally and psychologically. PICS consists of 7 assessment items, and each item is scored between 0 and 5. A high score on the scale indicates that the infant's comfort is low [26]. Its reliability in Turkey was performed by Kücük Alemdar and Güdücü Tüfekci, in 2015, and Cronbach's alpha value was found to be 0.88 [27]. In this study, Cronbach's alpha value was calculated as 0.78.

Sound meter and telephone tool

The UNI-T® UT353 sound meter device was used to measure the sound level of the music that the baby was made to listen to. The volume of the music was set at 55 decibels. The baby was made to listen to it via iPhone® 11.

Orhan Osman's "*Colic*" album – "*Do not Let Your Baby Cry – 2*"

In this study, the song "*Do not Let Your Baby Cry – 2*" from the album of Orhan Osman called "*Colic*" was used in the white noise group. Orhan Osman, in 2007, was inspired by Harvey Karp's album "*The Happiest Baby*", which reflected the sounds inside the uterus and was specially designed for newborn babies to relax, sleep and feed [21].

Implementation of the study

A mother-infant identification form was filled out with mothers who agreed to participate in the study. The babies who were completely fed in an oral way in the NICU were preparing for discharge. The mothers of these babies were called to the hospital and were made to stay in the mother-baby room with their babies. It was a room in the NICU but with a different entrance. Each of the mothers was given training about breastfeeding when she was with her baby in this room. The nurses evaluated how the mothers cared for and fed their babies. If the mother could feed her baby well, measure her baby's temperature, perform her baby's cares such as eye care, and if the baby's vital signs were stable, the baby was discharged by the nurse and doctor.

White noise group

Before breastfeeding, it was ensured that the baby and mother were alone in the room. The mother and baby were positioned appropriately, and the baby was breastfed by the mother. During the breastfeeding procedure, the LATCH Breastfeeding Assessment Tool and PICS were filled out. 12 hours after the first breastfeeding, the mother and baby were repositioned in an appropriate way for breastfeeding. Orhan Osman's song "*Do not Let Your Baby Cry – 2*" was played for a minute before breastfeeding. No other interventions that would support breastfeeding were performed. Breastfeeding lasted 15-20 minutes. At the end of breastfeeding, the LATCH Breastfeeding Assessment Tool and PICS were filled out.

Control group

No intervention that would support breastfeeding was performed on the infants and the mothers in the control group. Only the sucking behavior of the infant was observed by the researcher. For breastfeeding, the mother and the baby took a suitable position. It was ensured that no one was in the room except the mother, baby and researcher. During the first breastfeeding session, the LATCH Breastfeeding Assessment Tool and PICS were filled out. 12 hours after the first breastfeeding, the mother and baby repositioned in an appropriate way. At the end of breastfeeding, the LATCH Breastfeeding Assessment Tool and PICS were filled out.

Ethics of research

An informed consent form from the parents, Institution permission (2020-11-05/47607) and Ethics Committee approval (2020-24-06/2020/13) were obtained.

Data analysis

In data analysis, SPSS® 22.0 program was used for statistical analysis. Results were evaluated in the confidence interval of 95%, and $p < 0.05$ was considered as statistically significant. While frequency and percentage were used in data analysis of categorical variables, arithmetic mean, standard deviation, median, minimum and maximum scores were used for continuous variables. Differences between the groups in categorical variables were examined with Chi-square test and Fisher exact test. The normality distribution ($n > 30$) of LATCH and PICS scores was analyzed with Kolmogorov-Smirnov test, skewness and kurtosis coefficients. In the analysis of continuous variables, independent samples t-test was used for the variance between independent groups and paired samples t-test was used for the variance between repeated measurements. The Cohen d index was used to calculate the effect size of the variance between the groups. 0.2, 0.5 and 0.8 on the Cohen d index were considered as small, medium and large effects, respectively.

Results

Mother-infant identification

In this study, the mothers of the newborns in both groups were found to be similar in terms of age, status of employment, education and planned pregnancy. No statistically significant difference was found between the groups ($p < 0.05$). The observed newborns in both groups were determined to be similar in terms of gender, mode of delivery, gestational week, birth weight, length, head circumference, and Apgar score distribution, and no statistically significant difference was found between them ($p < 0.05$). This situation showed that the experimental and control groups were homogenous.

LATCH Breastfeeding Assessment Tool scores

In terms of LATCH scores before ($p = 0.650$) and after the procedure ($p = 0.247$), no significant difference was found between the breastfeeding success scores of the newborns in the white noise and control groups (**Tab. 1**).

However, a statistically significant difference was found between the pre- and post-procedure LATCH scores of both groups (white noise group $p = 0.000$ and control group $p = 0.014$). The effect size index for the effectiveness of this increase in newborns in the white noise group was found to be Cohen d value = 0.45. It was considered as a medium effect size. The effect size index for the effectiveness of the increase in the control group was found to be Cohen d value = 0.17. This value was considered as a small effect size (**Tab. 1**, **Fig. 2**).

Table 1. Pre- and post-procedure LATCH score means by groups.

	Pre-procedure		Post-procedure		Test, p and Cohen d value
	Mean ± SD	Min-max (median)	Mean ± SD	Min-max (median)	
White noise group (n = 33)	7.06 ± 1.95	3-10 (7)	8.18 ± 1.74	4-10 (8)	t = -5.178, p = 0.000 [b], d = 0.45
Control group (n = 33)	7.27 ± 1.82	4-10 (7)	7.69 ± 1.62	4-10 (8)	t = 2.603, p = 0.014 [b], d = 0.17
Test and p value	t = -0.456, p = 0.650 [a]		t = 1.168, p = 0.247 [a]		-

[a] t-test for independent groups, [b] t-test for repeated measurements.

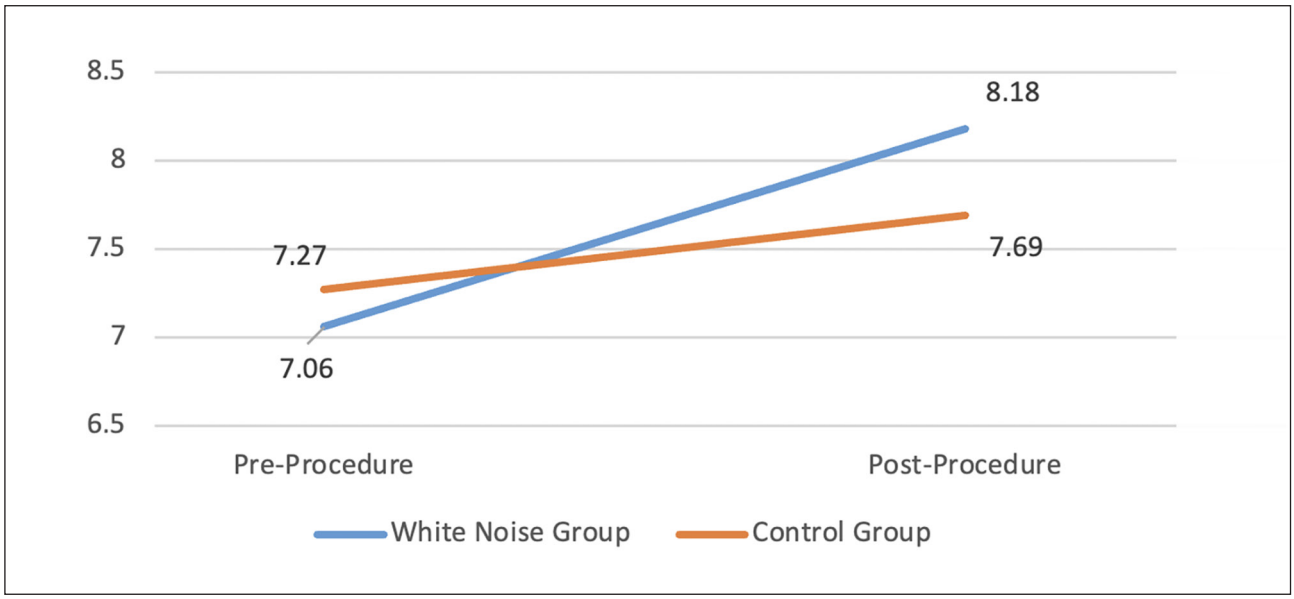

Figure 2. Pre- and post-procedure LATCH score variance.

Premature Infant Comfort Scale scores

While no significant difference between the groups in terms of PICS scores was found before the procedure (p = 0.114), a significant difference was found after the procedure (p = 0.031). The increase in the comfort level of newborns in the white noise group was significant; the effect size of variance was determined as Cohen d value = 0.54. This value was considered as a medium effect size (**Tab. 2**).

A statistically significant difference was determined between the pre- and post-procedure scores of the newborns in the white noise group (p = 0.023), while there was no significant difference between the pre- and post-procedure scores of the newborns in the control group (p = 1.000) (**Tab. 2**, **Fig. 3**).

Table 2. Pre- and post-procedure Premature Infant Comfort Scale (PICS) score means by groups.

	Pre-procedure		Post-procedure		Test, p and Cohen d value
	Mean ± SD	Min-max (median)	Mean ± SD	Min-max (median)	
White noise group (n = 33)	12.30 ± 1.33	10-14 (12)	12.15 ± 1.25	10-14 (12)	t = 2.390, p = 0.023 [b], d = 0.42
Control group (n = 33)	12.78 ± 1.11	11-15 (13)	12.78 ± 1.08	11-15 (13)	t = 0.000, p = 1.000 [b]
Test and p value	t = -1.604, p = 0.114 [a]		t = -2.207, p = 0.031 [a], d = 0.54		-

[a] t-test for independent groups, [b] t-test for repeated measurements.

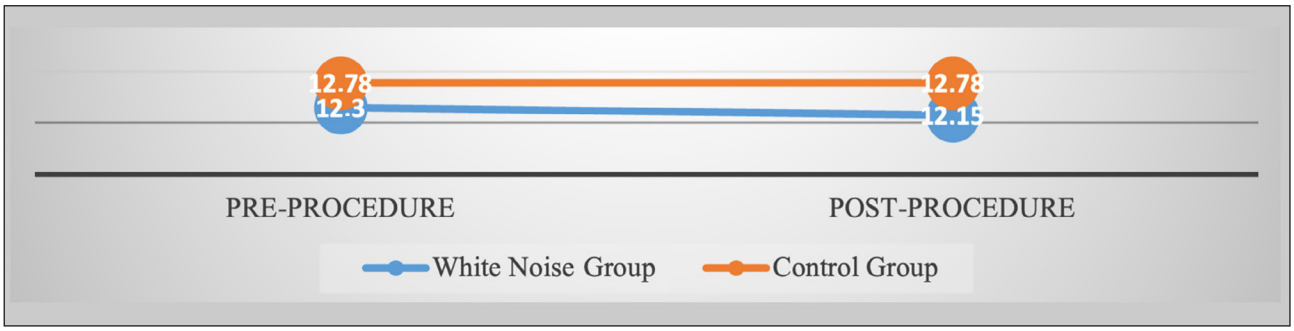

Figure 3. Pre- and post-procedure Premature Infant Comfort Scale (PICS) score means by groups.

Discussion

It was found in the study that there was no significant difference between the pre- and post-procedure LATCH scores of the newborns in the white noise and control groups; however, a statistical difference was found within the group comparisons. The increase in the white noise group was considered as a medium effect size, and the increase in the control group was considered as a small effect size. This shows that the sucking success score of newborns in the white noise group increased more than that of the control group. This result confirms the first hypothesis of the study that "White noise has a positive effect on sucking success in premature babies". In the studies conducted, it has been determined that white noise increases the sucking success of babies, which supports the results of this study [28-30]. Soyer, in 2019, and Akca and Aytekin, in 2014, reported that white noise increased sucking success in newborns. Similarly, another study stated that listening to lullabies and giving pacifiers fastened the transition of infants to oral feeding and increased their sucking success [31].

While there was no significant difference between the groups in terms of pre-procedure PICS scores, a significant difference was found after the procedure: newborns in the white noise group were more comfortable after the procedure; this value represented a medium effect size. A statistically significant difference was detected between the pre- and post-procedure scores of the newborns in the white noise group, while no significant difference was detected between the pre- and post-procedure scores of the newborns in the control group. These results confirm the hypothesis that "White noise has a positive effect on comfort in premature infants".

As a result of the detailed literature review, no study was found to evaluate the effect of white noise on the comfort of infants in newborns. When the results of other studies in the literature were examined, it was seen that white noise had a positive effect on pain and vital signs in newborns [19-21, 32]. Sezici and Yiğit, in 2018, reported that white noise was more effective in reducing the crying time of babies and increased their sleep time compared to swinging in babies with colic [19]. Döra and Büyük, in 2021, and Çetinkaya et al., in 2022, stated in their studies that white noise is effective in reducing pain during invasive procedures [20, 32].

In the study conducted by Alay and Esenay, in 2019, it was stated that classical music reduced stress symptoms in infants [33]. Van Dokkum et al., in 2020, found in their study that music therapy in premature infants improved the respiratory rates of infants [34]. Lubetzky et al., in 2010, stated in their study that the energy waste of healthy preterm newborns who listened to Mozart music during resting was less [35]. Lordier et al., in 2019, stated in their study that music exposure in NICU's environment can induce brain functional connectivity changes that are associated with music processing [36].

Conclusions

In this study, it was determined that the sucking success of the premature newborns who were made to listen to white noise was higher and their comfort was better.

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Declaration of interest

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