Survey on the Effectiveness of the MiS Micro-Stimulation®-System Thevo-Adapt “Sleeping Star“

MiS Internationale Fördergemeinschaft Micro-Stimulation® e.V.

(MiS International Registered Development Association Micro Stimulation®)

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… sometimes the story about the sandman is quite difficult

In our part of the world parents and adults have quite different ideas about the sleep behaviour of children. Some think that children should go happily to bed after watching sandman's good night wish on TV and sleep through for 12 hours after another quick bedtime story. The next morning, filled with verve they should jump out of bed, be in a good temper, fit, and relaxed and start the new day full of beans. Other adults share the opinion that children don't like to go to bed and do it rather late. Their favoured sleeping berth is the parents' bed and they like to sleep long. These people find it absolutely comprehensible, if also children are grumpy in the morning and need a longer warm-up time to get going for the day. Beside these two rather oppositional beliefs many other variations exist. Just look at our neighbours in Southern Europe. There it is absolutely normal, that children, even toddlers, take part in social life until late in the evening together with their parents. For most German parents this would be completely unimaginable. The European comparison alone shows us, how different the sleeping behaviour of children can be.

If children don't sleep according to their parents' wishes, stress inside the family can develop. By all means, children can bring their parents to exasperation by grouching, screaming, crying, waking up often, or needing a long time to go to sleep. Frequently the result means stress in the parents' relationship. Ongoing sleep problems of children can lead to a parents' state of exhaustion. These exhaustion states can even go as far as affecting the job or bringing health problems. At the latest, the family needs external help and support from this point on.

But unfortunately, it isn't easy to quickly find the correct contact person for children's sleep problems. Usually, the first contact person is the paediatrician. If the family is lucky, its attending physician has dealt with children's sleep problems or disorders before and can therefore help or can refer the family to a specialist. Paediatricians who can give the best support are those that have acquired additional knowledge in the medical field of sleep science.

Beside the direct effects of children's sleep problems on parents, they certainly have direct influence on the children's existential orientation. Here, various effects have been observed. The children are trapped in a tense family situation which builds up discomfort. Often, going to bed is negatively occupied for children, as they notice parental disharmonies quite clearly. For children, the own bed often is a place which increases their indisposition. They are separated from the rest of the family. For small children this implies separation anxiety, as they haven't learned yet that the parents are in the house and will come back. Older children, who know that the parents are there, develop different fears and anxieties. They have a lot of imagination, something we adults often envy them for. But also this imagination has the side effect that children's experiences made during the day become real at night. All of a sudden, monsters crawl out of the cupboard, the Wicked Witch of the West passes the window on a broom, or a crocodile lies under the bed. For us adults, this obviously is complete nonsense, but in a child's imagination these things are very real. But real is especially the fear that children develop due to their imagination.

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Sleep problems also have many more consequences on children than just fears or anxieties. For example children are tired, lethargic, restless, nervous, or short-tempered. Therefore they turn into unenjoyable contemporaries, which again results in stress for parents. Also, and this is very significant, tired children are unmotivated and not very attentive. So it will be hard for the children to explore new things, to develop their kinetic abilities, or to sensibly deal with their environment. Consequently, long-lasting sleep problems or disorders will have a negative impact on a child's development and learning behaviour.

On the basis of the short description it becomes apparent which massive consequences infantile sleep problems can have on parents as well as on children. Strangely, this difficulty is seldom picked out as a central public theme, though many families are affected.

Even more dramatic is the situation for parents with disabled children. A survey with over 200 affected parents shows, that often sleep of disabled children is a massive problem which lets whole families suffer. Parents have to bring up a lot of time and creativity to get their children to sleep. But even if the children fell asleep, they often wake up again during the night. This is more a rule than an exception. Thereupon, with a lot of patience the children have to be brought back to sleep again. As a consequence, not only the children are permanently stressed, but also the parents, brothers, and sisters are disturbed during their sleep. The sleep problems' effects on the existential orientation of family members often is more drastic than the effects of sleep problems of non-disabled children and their families. They are more drastic because on the one hand this situation often lasts for a long period of time and on the other hand parents of disabled children are also more stressed during the day compared to other parents. Most of the time, these parents are beyond their personal load limit.

Reasons for sleep problems are as manifold as the affected children themselves. Health-related organic disorders can be the reason for such sleep problems. But also pain is often responsible for the circumstance that children cannot find rest. Sometimes children are utterly missing a feeling of security. For example, some rooms of disabled children look more like a sickroom than a children's bedroom. Often, toddlers and young children are supplied with hospital beds that are far too big. These huge beds take the feeling of safety off the children, as they don't provide the little ones with security-giving borders. But also ortheses, bed wedges, and other rest aids increase the children's feeling of discomfort in many ways. A lot of circumstances that lead to sleep problems can easily be eliminated, provided that they were identified as such.

This kind of identification often needs the consultation and assistance of sleep experts. Unfortunately, there aren't many. They are as rare as scientific studies on the subject of disabled children's sleep problems. This problem area isn't a focus of research – internationally as well as nationally. So this shows that on the one hand we have the massive sleep problems of disabled kids with their whole problem area, but on the other hand we don't have enough experts who deal with this subject. That's why the following assignment, which deals with the sleep behaviour of multi-disabled children, is highly welcome.

The MiS Micro-Stimulation®-System Thevo-Adapt “Sleeping Star“

According to the company Thomashilfen, a bedding and therapy system has been developed with Thevo-Adapt “Sleeping Star” which is suitable for children and eases the children’s care at night very much. This bedding and therapy system belongs to the MiS Micro Stimulation® Systems that, according to Thomashilfen, will support the cognition and development of a child. As per producer, it can be used for increasing cognition, reducing pain, developing a physiological sleep pattern, as well as pressure ulcer prevention and treatment.

Aim and Problem of the Survey

The survey’s aim was to analyse the effects of the MiS Micro-Stimulation®-System Thevo-Adapt “Sleeping Star“ on children’s sleep disorders. Especially the changes regarding the sleep disorder insomnia, which means going to sleep problems as well as problems with sleeping through of children with chronic neurological detractions of the musculoskeletal system, were to be examined. Also it was to be analysed whether the usage of the Thevo-Adapt „Sleeping Star“ had changed the extent of the child’s pain and how the system affected the children’s motor function as well as their tonicity.

Design of the Survey and Development

The survey was made in an experimental pre-post design. The questionnaire which had to be answered included open as well as closed questions. All allocated subjects, who according to random sample could be integrated, joined the survey over a 12 months period. The particular test took place over a period of a maximum of 31 days. All subjects (test persons) were bedded on their usual mattress during the first part of the survey. During the second part they were bedded on the Thevo-Adapt “Sleeping Star“ system.

1. Gender of the child

The overall 94 participants were comprised of 54 boys (57 %) and 40 girls (43 %). The average age was 7.3 years with a standard deviation of 4.3 years.

2. Children's age (in years)

Age and gender

The following verified whether boys and girls differed in age.

Parametrically: t-test for independent samples

Sex	n	Average value	s	t	df	Sig. (2-sided)
Male	54	7.6	4.5	.667	92	.507
Female	40	6.9	4.2			

The boys were slightly older on average. However, this difference is insignificant for independent samples according to the t-test, that is, the age difference must be regarded as coincidental.

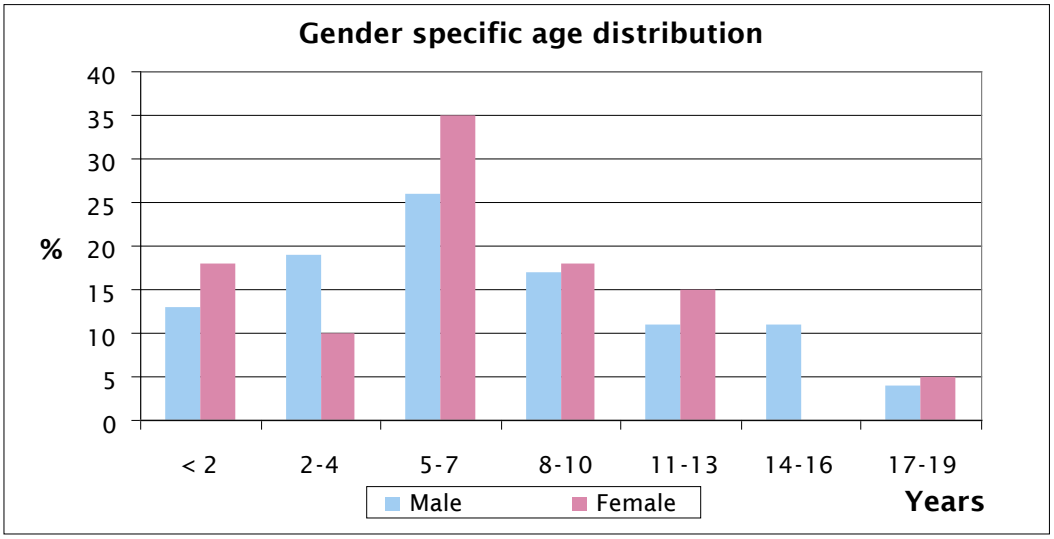
The age was further subdivided into age groups as follows.

Non-parametrically: Chi square test / non-parametrically: Chi square test

Years	Male		Female		Total	
	n	%	n	%	n	%
< 2	7	13	7	18	14	15
2-4	10	19	4	10	14	15
5-7	14	26	14	35	28	30
8-10	9	17	7	18	16	17
11-13	6	11	6	15	12	13
14-16	6	11	0	0	6	6
17-19	2	4	2	5	4	4
Total	54	100	40	100	94	100

(4 cells, 28.6 have an expected frequency less than 5)

The verification of the gender differences in the various age classes was also insignificant (Chi square: 6.889; df= 6; p=.331).

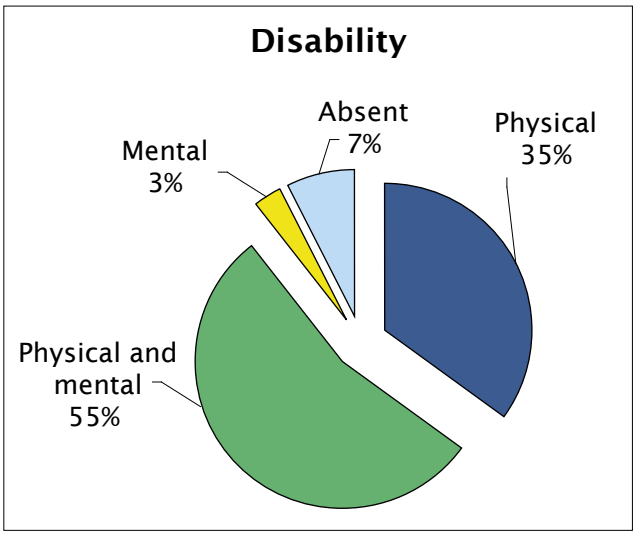


Here, it becomes clear that girls were more frequently represented in all age categories except in the category 2 – 4 years and the category 14 – 16 years, in which they were not represented at all.

4. and 5. disability

More than half of the children (55 %) are physically and mentally disabled. Only 3 % have a mental disability.

Disability	Frequency	
	n	%
Physical	33	35
Physical and mental	51	55
Mental	3	3
Total	87	93
Absent	7	7
Total	94	100



Gender and disability

Here as well, it was shown that the genders scarcely differed in the type of disability.

Non-parametrically: Chi square test

Disability	Male		Female		Total	
	n	%	n	%	n	%
Physical	20	38	13	37	33	38
Physical and mental	30	58	21	60	51	59
Mental	2	4	1	3	3	3
Total	52	100	35	100	87	100

(2 cells (33.3 %) have an expected frequency less than 5)

The Chi square test therefore shows no significant results (Chi square = 0.088, df = 2; p = .957).

6. Seizure problems

Overall, 43 parents (47 %) stated that their children suffered from seizures.

Gender and seizure disorders

Here as well, there are only slight and therefore insignificant gender differences (Chi square = 0.508, df = 1; p = .476).

Non-parametrically: Chi square test

Seizure disorders	Male		Female		Total	
	n	%	n	%	n	%
No	31	57	20	50	51	54
Yes	23	43	20	50	43	46
Total	54	100	40	100	94	100

7. Medications

The question regarding use of medications was answered positively by a total of 51 parents (57 %).

Gender and medications

At 63 %, girls took medication slightly more often than boys. However, this difference was also insignificant with the Chi square test
(Chi square = 1.129, df = 1; p = .288).

Non-parametrically: Chi square test

Medications	Male		Female		Total	
	n	%	n	%	n	%
No	25	48	14	37	39	43
Yes	27	52	24	63	51	57
Total	52	100	38	100	90	100

Absent: n= 4 (4%)

8. Aids

Most of the children (88 %) were dependent on various aids.

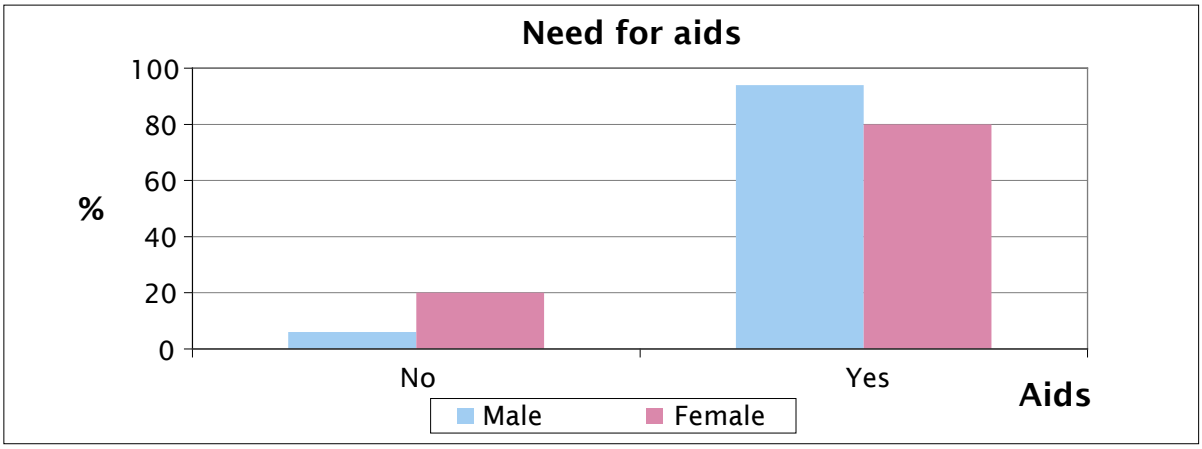
Gender and aids

94 % of boys used aids, while only 80 % of girls used aids. This gender difference was significant on the 5 % level
(Chi square = 4.640; df = 1, p = .031).

Non-parametrically: Chi square test

Aids	Male		Female		Total	
	n	%	n	%	n	%
No	3	6	8	20	11	12
Yes	51	94	32	80	83	88
Total	54	100	40	100	94	100

One cell (25.0 %) has an expected frequency less than 5. The minimal expected frequency is 4.68. Since the prerequisites of the Chi square test are violated, the precise test as per Fisher was additionally utilised, also producing significance with p (two sided) = .049.

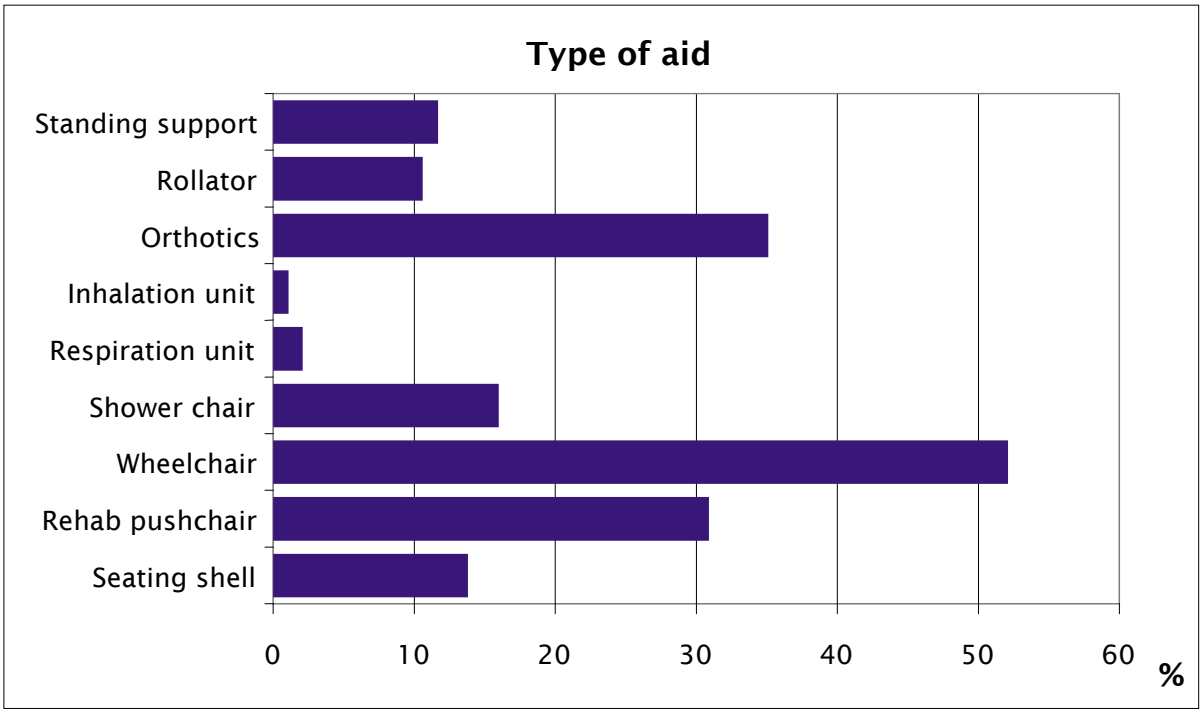


Types of aids

Approximately half of the children needed wheelchairs. Orthotics and rehab carriages were also used by approx. one third.

Type if aid	Frequency	
	n	%
Seating shell, car / child seat	13	14
Rehab pushchair	29	31
Wheelchair	49	52
Shower chair	15	16
Respiration unit (VPAAP)	2	2
Inhalation unit (IPPB)	1	1
Orthotics	33	35
Rollator	10	11
Standing support	11	12

Missing information: n = 1 (1 %), (not applicable: n = 11 (12 %)



1.1 Sleeping behaviour

Sleeping behaviour prior to using the Thevo-Adapt „Sleeping Star“ was evaluated from 1= very good to 4= unsatisfactory. The following frequency distribution resulted:

Sleeping behaviour prior to using the Thevo-Adapt „Sleeping Star“

Evulation	Frequency	
	n	%
Good	11	12
Satisfactory	32	34
Insufficient	47	50
Total	90	96
Absent	4	4
Total	94	100

The average sleeping behaviour was 3.4 (s = 0.7). Therefore, the evaluation of the sleeping behaviour was satisfactory to unsatisfactory.

Gender differences:
It was first examined whether the boys and girls differed in sleeping behaviour prior to use of the Thevo-Adapt „Sleeping Star“. The t-test for independent samples was done for this purpose. It showed the following results:

Parametrically: t-test for independent samples

Gender	n	Average value	s	t	df	Sig. (2-sided)
Male	52	3.3	.7	1.790	88	.077
Female	38	3.6	.6			

Girls slept less well than boys on average. This difference is insignificant, but a tendency can be recognised.

Since the grades of 1 = very good to 4 = unsatisfactory are not metric, the u-test was additionally used as a non-parametric method, showing corresponding results. It also barely misses the 5 % level with z = - 1.810 and p = .070.

Age differences:
As the following table shows, the group of children with satisfactory sleeping behaviour at 6.8 years showed the lowest age difference, while the children who showed good sleeping behaviour were 9.5 years old on average.

Evulation	n	AM	s
Good	11	9.5	5.2
Satisfactory	32	6.8	3.6
Unsatisfactory	47	7.1	4.6
Total	90	7.3	4.4

These differences were verified with the single factor variance analysis, which did not turn out significant (F = 1.689, df = 2; p = 191); that is, the age differences must be regarded as coincidental.

1.2 Number of sleeping hours

The average nighttime sleep duration was 8.1 hours. The minimum was 3 hours and the maximum was 14 hours. Most children slept 10 hours at night. Most children did not sleep during the day. Here, the average sleep duration was only 1.2 hours, with a maximum of 8 hours.

Sleep hours	Nighttime	Daytime
Average	8.1	1.2
Mode	10.0	0.0
Standard deviation	2.5	1.3
Minimum	3.0	0.0
Maximum	14.0	8.0
Absent	7.0	21.0

Gender differences:

As shown in the following table, boys and girls did not differ in sleep duration either at night or in the day.

The t-test for independent samples was done for this purpose. It showed that on average, girls slept slightly more at nighttime than boys. The daytime sleep duration for girls and boys was equal at 1.2 hours.

Parametrically: t-test for independent samples

Sleep hours	Gender	n	Average value	s	t	df	Sig. (2-sided)
Nighttime	Male	37	7.8	2.9	-.764	85	.447
	Female	50	8.2	2.3			
Daytime	Male	32	1.2	1.1	.094	71	.925
	Female	41	1.2	1.5			

Missing information: n= 7 (7 %) nighttime, n= 21 (22 %) daytime

Age differences:

In order to determine connections between the sleep duration and the age of the child, the product moment correlation was calculated:

The correlation between age and nighttime sleep duration was r = - .18, p = .101. The correlation between age and daytime sleep levels was slightly higher with r = .24, p = 0.38, but it was still low. It was significant at the 5 % level.

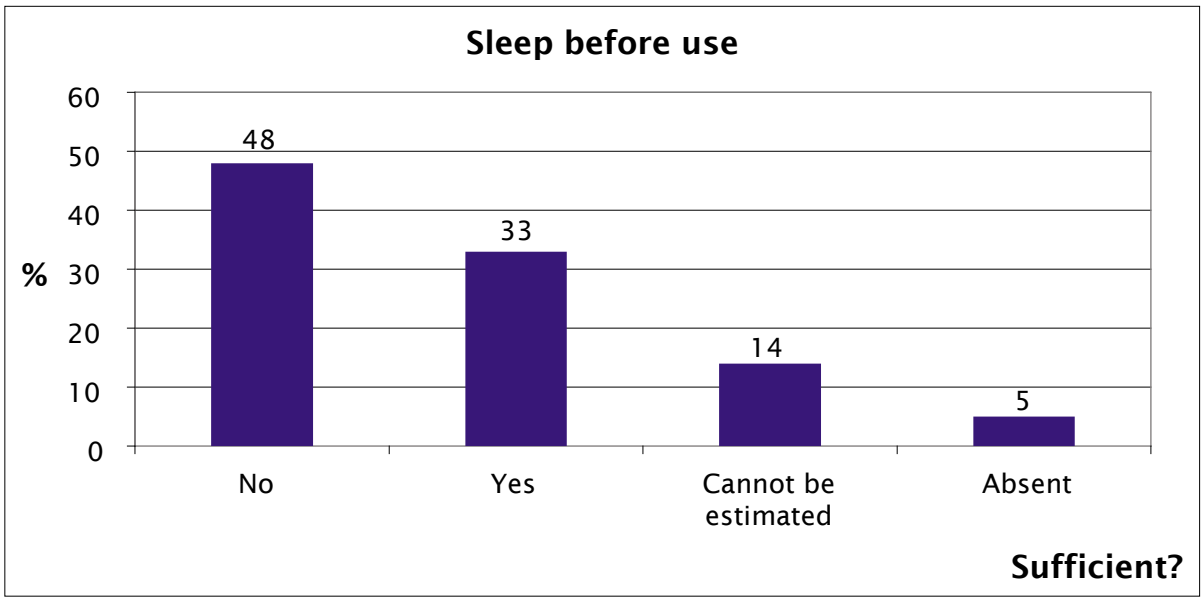
1.3 Sufficient sleep?

Only 31 parents stated that their child slept sufficiently, while 13 parents were unable to assess this. Nearly half of all children was not getting the sleep they needed, in their parents' opinion.

Information about sufficient sleep

Sufficient sleep?	Frequency	
	n	%
No	45	48
Yes	31	33
Total	76	81
Cannot be estimated	13	14
Absent	5	5
Total	94	100

This information is shown again in the following diagram.



Gender differences:
Here as well, it was verified whether boys or girls were more likely to have sufficient sleep. This produced the following distribution:

Non-parametrically: Chi square test

Sufficient sleep?	Male		Female		Total	
	n	%	n	%	n	%
No	21	51	24	69	45	59
Yes	20	49	11	31	31	41
Total	41	100	35	100	76	100

Parents stated that 49 % of the boys but only 31 % of the girls slept sufficiently. This gender difference was verified with the Chi square test, which turned out insignificant (Chi square: 2.54; df= 1; p (two sided) = .125)

Age differences

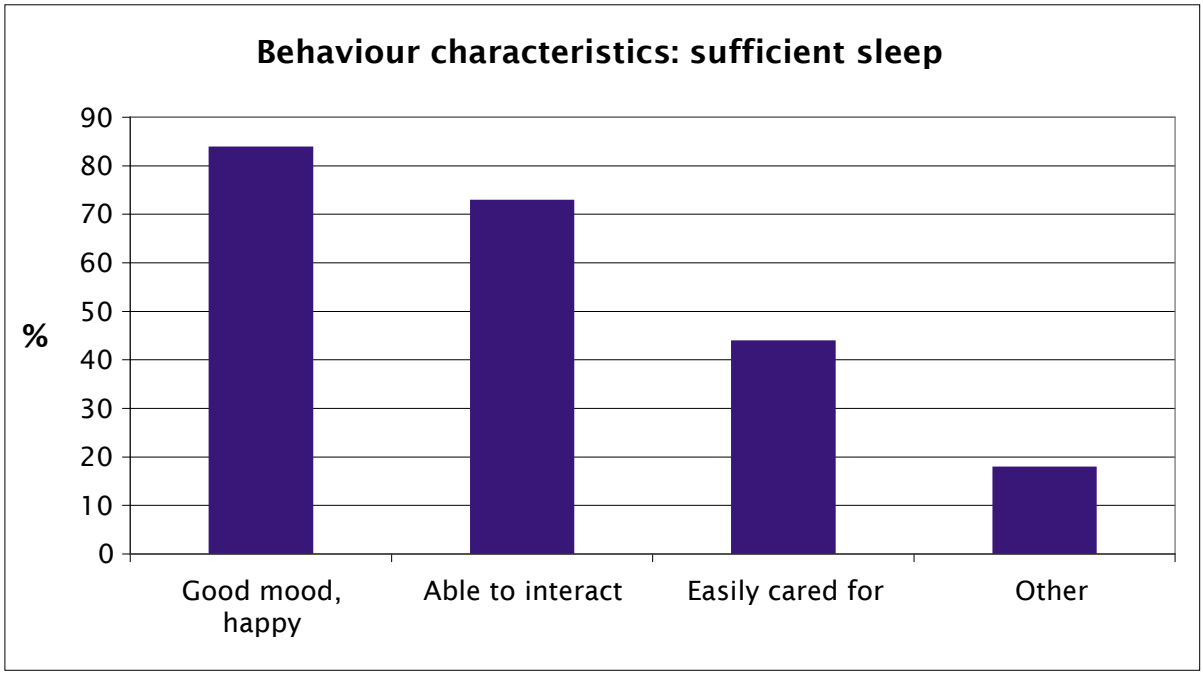
Sufficient sleep?	n	Average value	s	t	df	sig. (2-sided)
Yes	31	7.5	4.8	.311	57.5	.757
no	45	7.2	4.1			

Since the children with sufficient sleep scarcely differed from the children with insufficient sleep in terms of age, the t-test for independent samples was negative.

1.4 Behaviour characteristics with sufficient / good sleep

84 % of parents stated that mood and happiness of their child was an indicator for sufficient sleep.
73 % were of the opinion that their child found it easier to learn when it had slept well / sufficiently.
44 % of parents stated that their child was easier to care for when it had slept well.

Behaviour characteristics	Frequency	
	n	%
Good mood, happy	79	84
Able to interact	69	73
Easily cared for	41	44
Other	17	18



Description of the other typical behaviour characteristics with sufficient sleep

The following characteristics were each named once (that is, n = 1 [1 %]):
- good body control
- no sweating, tension, vomiting
- better able to concentrate
- participates well in therapy
- muscle tone not too hypotonic
- active participation in life after waking phase
- not as aggressive
- less excitable
- calm
- quickly awake and alert
- low spasticity
- speaks more
- fewer seizures
- always wants to be occupied

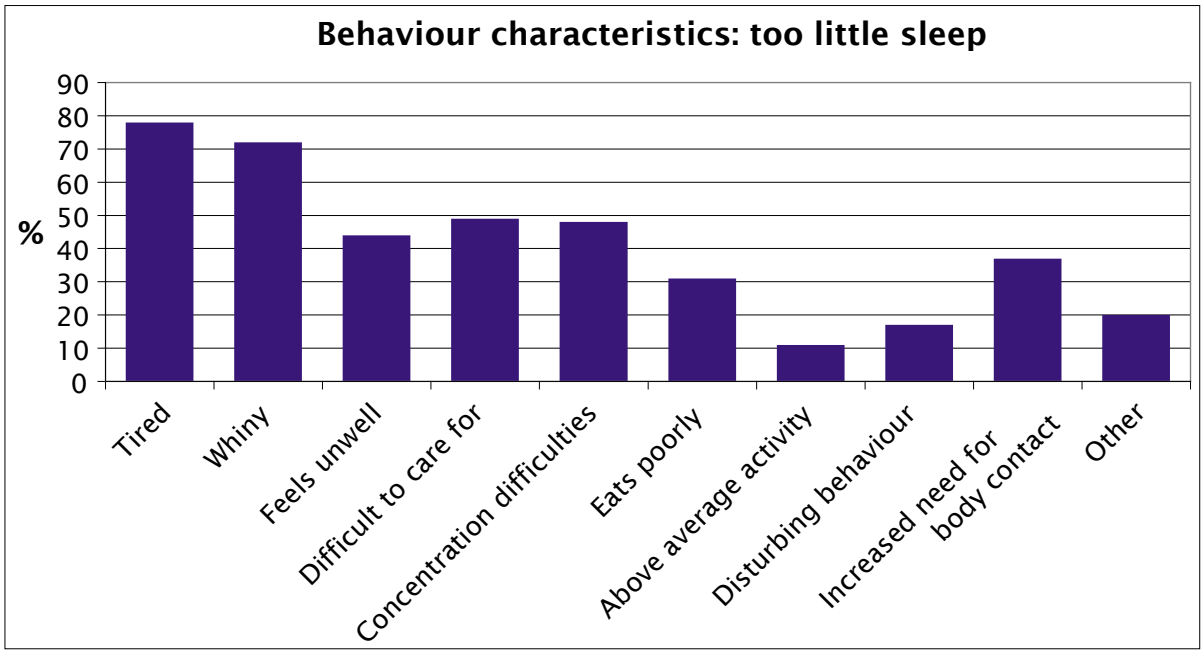
1.5 Behaviour characteristics for poor / insufficient sleep

The following behaviour characteristics were shown by children with poor or insufficient sleep.

Behaviour characteristics	Frequency	
	n	%
Tired	73	78
Whiny	68	72
Feels unwell	41	44
Difficult to care for	46	49
Concentration difficulties	45	48
Eats poorly	29	31
Above average activity	10	11
Disturbing behaviour	16	17
Increased nedd for body contact	35	37
Other	19	20

Tired and whiny were named by more than 70 % as behaviour with insufficient sleep. Over 40 % of parents named the following behaviour characteristics: feeling unwell, difficult to care for and difficult to concentrate. 37 % named the increased need for body contact. 31 % of parents observed that their child tended to eat poorly with insufficient sleep. Disturbing behaviour and above average behaviour tended to be observed less.

These statements are shown in the diagram.



Description of other typical behaviour characteristics with insufficient sleep

The following information was provided here:
- daytime tendency to fall asleep
- reduced muscle tone
- exhaustion
- yawns constantly, less able to handle stress in the afternoons
- sensitive to noise
- physically aggressive actions
- noisy, more dissatisfied
- sleeps a lot in the daytime
- bad mood, complains about pain
- bad mood, slowed reactions
- spasticity very severe and uncontrolled
- quiet, little activity
- restless, difficult to calm
- tense, vomiting, pale, motor disturbances
- increased seizures
- increased spasticity
- avoids body contact with parents and other children
- cries a lot – anything which is usually fun unnerves them
- temper tantrums

1.6 Sleeping through the night

Only 10 children (11 %) were able to sleep through the night.

Gender and sleeping through the night

Only 7 % of boys and 15 % of girls were able to sleep at night.

Non-parametrically: Chi square test

Sleeping through the night	Male		Female		Total	
	n	%	n	%	n	%
No	50	93	34	85	84	89
Yes	4	7	6	15	10	11
Total	54	100	40	100	94	100

1 cell, 25.0 % have an expected frequency less than 5. The minimum expected frequency is 4.26.

This difference was shown as insignificant in the Chi square test (Chi square = 1.393, df = 1; p (two sided) = .238). Since too many expected frequencies are less than 5, the prerequisites of the Chi square test are violated. The precise test as per Fisher, which is therefore additionally utilised, also shows insignificant results (Fisher: p (two sided) = .315).

The frequency of nighttime awakening in the 84 children (89 %) with problems sleeping through the night is shown in the following table.

Frequency of nighttime awakening	Frequency	
	n	%
1 - 2 times	18	19
3 - 4 times	37	39
5 - 6 times	19	20
7 - 8 times	4	4
More often	6	6
Total	84	89
Absent	10	11
Total	94	100

Children most frequently woke up at night 3 – 4 times. 20 % of children woke up 5 – 6 times, and 19 % woke up 1 – 2 times.

Gender and frequency of nighttime awakening

Since boys and girls did not differ significantly in the frequency of awakening, the Chi square test did not show significant results (Chi square = 6.291; df = 4; p (two sided) = .178).

Non-parametrically: Chi square test

Frequency of nighttime awakening	Male		Female		Total	
	n	%	n	%	n	%
1-2 times	11	22	7	21	18	21
3-4 times	26	52	11	32	37	44
5-6 times	8	16	11	32	19	23
7-8 times	1	2	3	9	4	5
More often	4	8	2	6	6	7
Total	50	100	34	100	84	100

4 cells (40.0 %) have an expected frequency less than 5. The minimum expected frequency is 1.62.

1.7 Child's bedtime behaviour

60 % of children went to bed in the evening without problems.
21 % of parents stated that bedtime was difficult, and 17 % felt that bedtime was extremely difficult for the child.

Frequency of problems with going to bed in the evening

Going to bed in the evening	Frequency	
	n	%
Unproblematic	56	60
Problematic	20	21
Extremely difficult	16	17
Total	92	98
Absent	2	2
Total	94	100

Gender and going to bed in the evening

The comparison between boys and girls showed that they were not very different. The Chi square test therefore shows no significant results (Chi square = .479, df = 2; p = .787).

Non-parametrically: Chi square test

Going to bed in the evening	Male		Female		Total	
	n	%	n	%	n	%
Unproblematic	33	63	23	58	56	61
Problematic	10	19	10	25	20	22
Extremely difficult	9	17	7	18	16	17
Total	52	100	40	100	92	100

1.8 Time required by the child to go to sleep

The children required an average time of 1.1 hours to fall asleep. The longest time required was 4 hours. 1 hour was the most frequent time required to fall asleep.

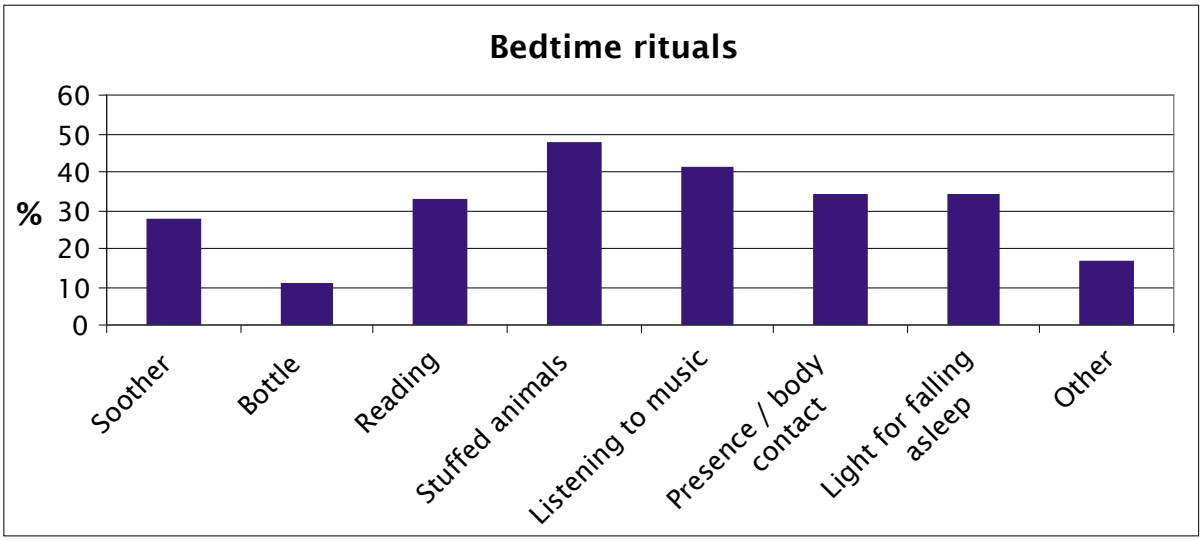
Time needed to fall asleep, in hours:

	Time required to fall asleep
Average	1.10
Median	1.00
Mode	1.00
Standard deviation	0.80
Minimum	0.03
Maximum	4.00
Absent	10.00

1.9 Bedtime rituals

The most used bedtime rituals were stuffed toys at 48 % and listening to music with 41 %, while 34 % needed light to fall asleep. 33 % of parents stated that they read to their children at night. 28 % of children used a soother.

Bedtime rituals	Frequency	
	n	%
Soother	26	28
Bottle	10	11
Reading	31	33
Stuffed animals	45	48
Listening to music	39	41
Presence / body contact	32	34
Light for falling asleep	32	34
Other	17	18



Description of other bedtime rituals
For three children, it was important to have the door open. The other listed rituals were named once, respectively.

- cradling in the arm
- from dusk to darkness, approx. 15 °C room temperature
- Darkness and soft noises
- holding hands
- chatting (telling stories, babbling)
- cuddly cloth, water
- light mobiles
- one always has to pray with her
- checking on him from time to time, possibly repositioning him
- toys and brief attention
- door open
- we are as quiet as possible
- twin in the bed

1.10 Special care due to care and/or medical needs at night

Overall, 56 children (60 %) needed special nighttime care.

Gender and special nighttime care
A comparison of genders showed that at 70 %, boys clearly need special care due to care and/or medical needs at night more often than girls (45 %).

Non-parametrically: Chi square test

Special care	Male		Female		Total	
	n	%	n	%	n	%
No	16	30	22	55	38	40
Yes	38	70	18	45	56	60
Total	54	100	40	100	94	100

A significant result was shown. Chi square = 6.141; df = 1; p (two sided) = .013 – that is, boys needed special care at night more often than girls.

Care type

Type of special care	Frequency	
	n	%
Repositioning	42	45
Diaper change	27	29
Feeding / tube feeding	12	13

Nearly half of all children had to be repositioned at night. Nearly 30 % had to be changed, and only 13 % needed a nighttime feeding or tube feeding.

1.11 Special positioning due to care and/or medical needs at night

35 children (37 %) needed special positioning at night. (1 missing statement)
The following problem zones occurred with positioning.

Problem zones with positioning	Frequency	
	n	%
Legs	4	2
Heels	1	1
Free extremities	1	1
Hip	1	1
Head	3	1
Tailbone	1	1
Total	11	8

1.12 Special pillows or positioning aids

A special positioning devices or special pillow for the positioning was required by 22 children.

Positioning devices	Frequency	
	n	%
No	71	76
Yes	22	23
Total	93	99
Absent	1	1
Total	94	100

As shown in the following tables, pillows were primarily used for positioning.

Type of positioning aid	Frequency	
	n	%
Pillows	9	10
Positioning pillows	4	4
Wedge pillows	1	1
Side sleeper pillows	2	2
Grain pillows	2	2
Head pillows	1	1
Breastfeeding pillows	4	4
Positioning snake	2	2
Buckwheat snake	1	1
Neck horns around knees and head	2	2
Bed horn, decubitus sheepskin	1	1
Cloth	1	1
Wool blankets	1	1
Corpo med, sand bags	1	1
Towel roll	1	1

1.13 Medications which could disturb nighttime sleep

Only two parents (2 %) stated that their child took medications which, due to their activating effect, could disturb nighttime sleep. 10 parents (11 %) stated that they were unable to assess this, while 82 parents (87 %) stated that their child did not take sleep disturbing medications.

1.14 Preferred sleeping position of the child

More than two thirds of children preferred the side lying position as a sleeping position, and approx. one third preferred the belly-down or prone positions.

Sleeping position	Frequency	
	n	%
Supine	27	29
Prone	35	37
Side lying	66	70

1.15 Independent change of sleeping positions

50 children were independently able to change their sleeping positions, while the other 45 % needed help to change their sleeping position.

Independent change	Frequency	
	n	%
No	42	45
Yes	50	53
Total	92	98
Absent	2	2
Total	94	100

1.16 Pain due to lying

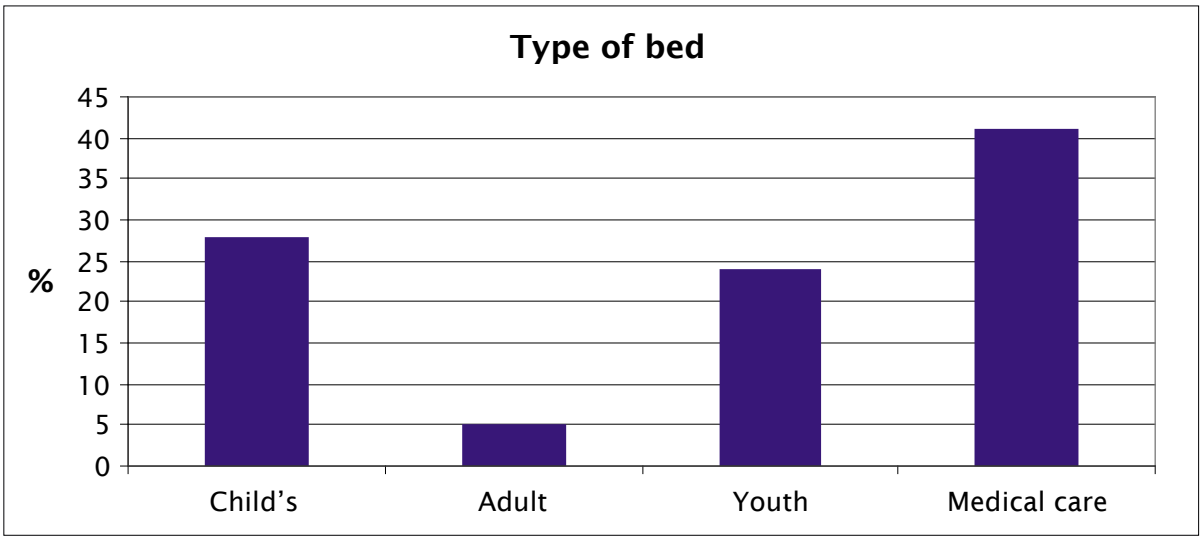
20 children had pain due to lying.

Pain	Frequency	
	n	%
No	34	36
Yes	20	21
Total	54	57
Cannot assess	37	39
Absent	3	3
Total	94	100

1.17 Bed

A medical care bed was most frequently used. 28 % or 24 % of children used a children's or youth bed.

Bed	Frequency	
	n	%
Child's bed	26	28
Adult bed	5	5
Medical care bed	23	24
Youth bed	39	41
Total	93	99
Absent	1	1
Total	94	100



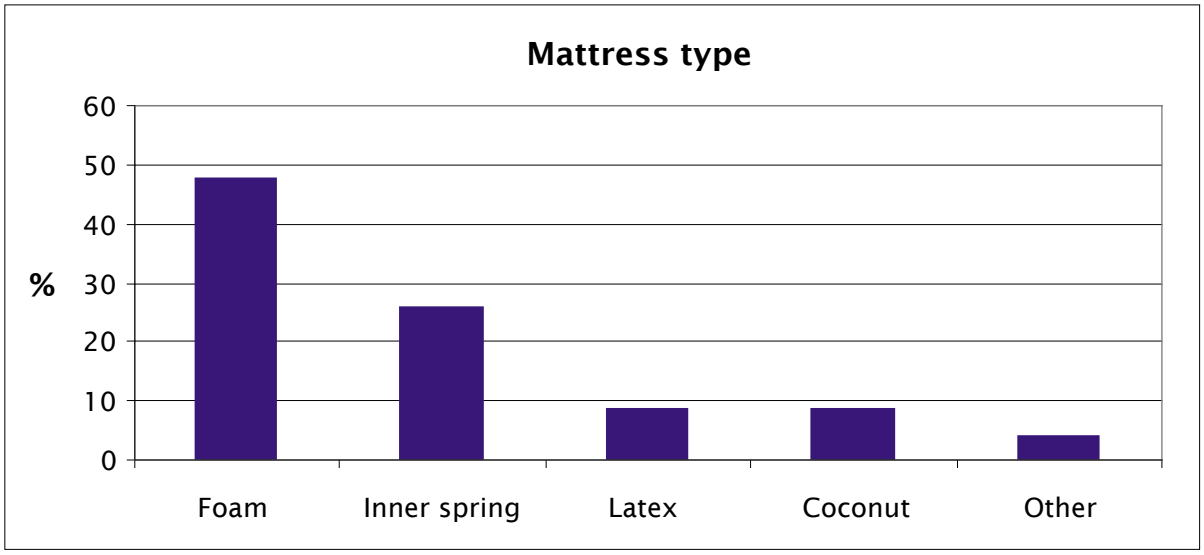
1.18 Mattress type

Nearly half of the children slept on a foam mattress. The inner spring mattress was also relatively frequent with 26 %.

Mattress	Frequency	
	n	%
Foam	46	49
Inner spring	24	26
Latex	8	9
Coconut	8	9
Other	3	3
Total	89	95
Absent	5	5
Total	94	100

Description Mattress Other

Other	Frequency	
	n	%
Coconut and sheepskin	1	1
Inner spring and soft covers	1	1
Cold foam	3	3
Foam and magnet field mattress from Nikken	1	1
Semi-permeable cover "Care-Sorb"	1	1



1.19 Need for a special mattress in order to prevent skin reddening (development of sores from lying) or pain

Only 9 children needed a special mattress, as shown in the following table.

Special mattress	Frequency	
	n	%
No	81	86
Yes	9	10
Total	90	96
Absent	4	4
Total	94	100

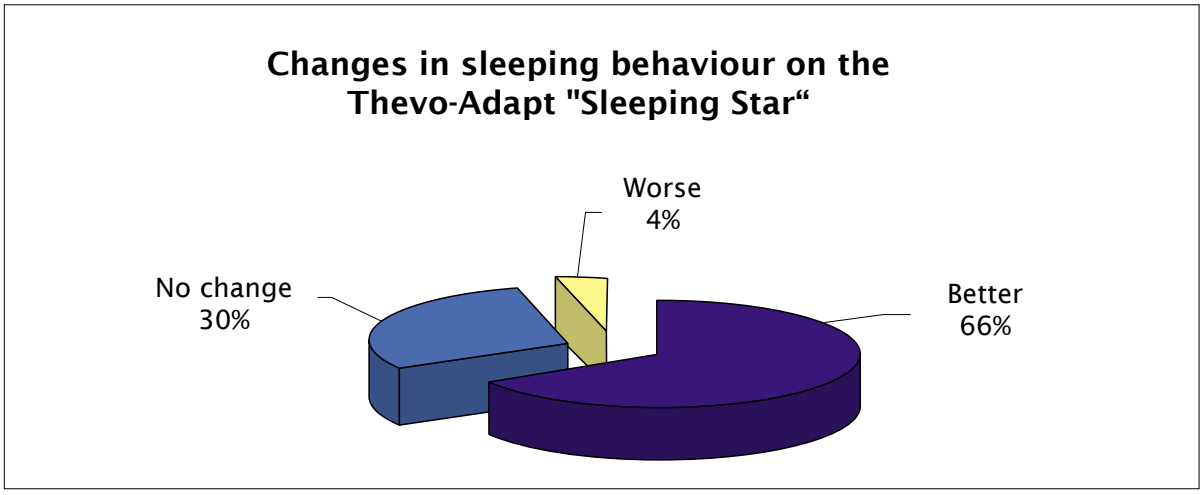
Type of special mattress

Two parents named a decubitus mattress, and one person stated that their child sleeps on a very soft mattress. 6 parents provided no information about the type of mattress.

1.1 Changes in sleeping behaviour

Approx. two thirds (66 %) of parents saw a change in their child’s sleeping behaviour.

Change	Frequency	
	n	%
Very clear	11	12
Clear	22	23
A little	29	31
No change	28	30
Total	90	96
Absent	4	4
Total	94	100



1.2 Sleeping behaviour after using the Thevo-Adapt „Sleeping Star“

Comparison of sleeping behaviour (grades)

Sleeping behaviour before and after using the Thevo-Adapt „Sleeping Star“

The sleeping behaviour prior to use correlates to r= .43 with p = .000 highly significant – with sleeping behaviour after use of the Thevo-Adapt „Sleeping Star“. The non-parametric correlation as per Spearman is also Rho= .43*** (p= .000).

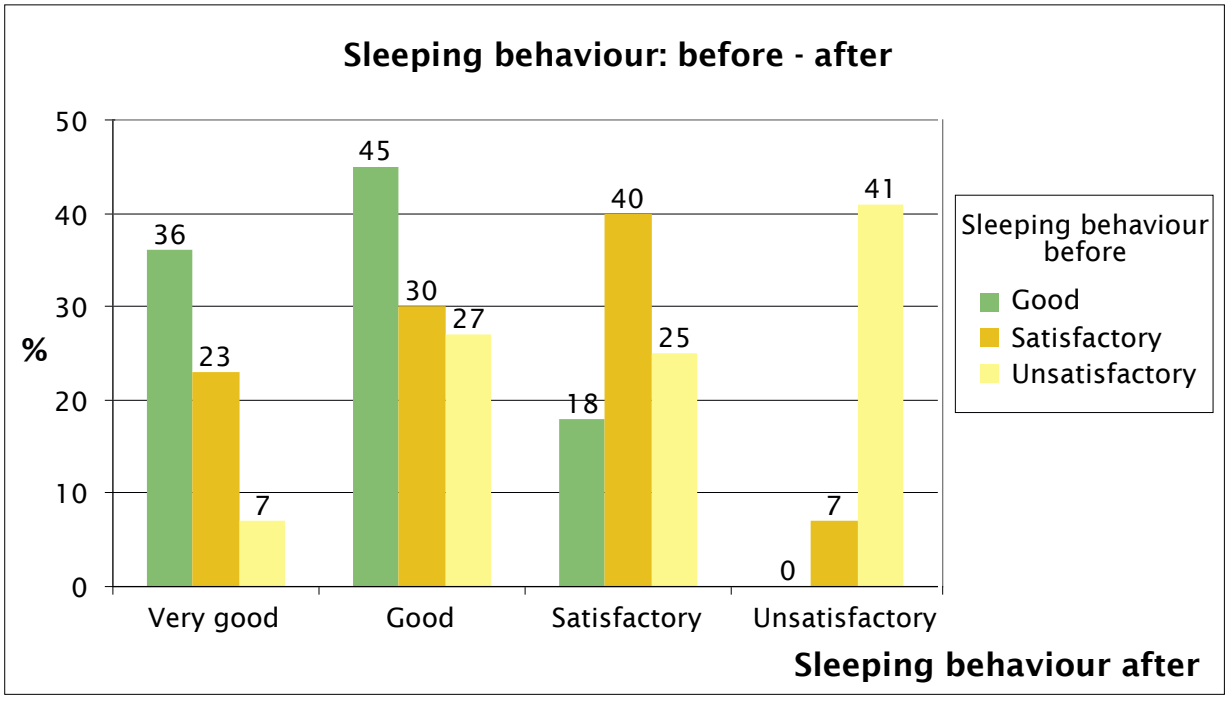
The comparison of sleeping behaviour before and after use is documented in the following table:

	Sleeping behaviour prior to use							
	Good		Satisfactory		Unsatisfactory		Total	
Sleeping behaviour after use	n	%	n	%	n	%	n	%
Very good	4	36	7	23	3	7	14	16
Good	5	45	9	30	12	27	26	31
Satisfactory	2	18	12	40	11	25	25	29
Unsatisfactory	0	0	2	7	18	41	20	24
Total	11	100	30	100	44	100	85	100

There were data about sleeping behaviour before and after use for a total of 85 children.
Of these, an improvement in sleeping behaviour was found for a total of 46 children:

- 4 (36 %) of the 11 children which had good sleeping behaviour before use had very good sleeping behaviour after use.
- improvement in the 30 children in the category with satisfactory sleeping behaviour: 9 showed good sleeping behaviour after use, while 7 showed very good sleeping behaviour.
- improvement in the group of 44 children which showed unsatisfactory sleeping behaviour before use: 11 changed to satisfactory sleeping behaviour, while 12 changed to good and 3 to very good sleeping behaviour.

Overall, only 4 children showed worse sleeping behaviour. In two children, the sleeping behaviour changed from good to satisfactory, and in another two children, it changed from satisfactory to unsatisfactory. The number of children in whom there was no change in sleeping behaviour was approx. 40 % in each category.



In order to be able to verify this change with interference statistics, a summary is necessary due to the low case numbers. Two categories were formed (sleeping behaviour unsatisfactory versus very good to satisfactory, that is, not unsatisfactory). This produced the following distribution:

Non-parametrically: McNemar test (binomial distribution)

	Sleeping behaviour prior to use					
	Very good to satisfactory		Unsatisfactory		Total	
Sleeping behaviour after use	n	%	n	%	n	%
Very good to satisfactory	39	95	26	59	65	76
Unsatisfactory	2	5	18	41	20	24
Total	41	100	44	100	85	100

As shown above, there are clearly more positive changes at 59 % than negative changes (at 5 %). The changes were verified with the McNemar test. With p = .000, this test showed significant results at the 0.1 % level. This test only takes the changes into account. A likelihood of p = 0.5 is assumed for both changes.

In addition, the average values were included for the verification of the changes in sleeping behaviour before and after use of the Thevo-Adapt „Sleeping Star“. As shown in the following, the sleeping behaviour before use was clearly assessed as worse – with an average of 3.4 – than after use of the Thevo-Adapt „Sleeping Star“ (AM = 2.6).

Parametrically: t-test for dependent samples

Sleep behaviour	**Average value**	**n**	**s**
Before use	3.4	85	.7
After use	2.6	85	1.0

For interference statistical confirmation of this difference, a t-test for dependent samples was utilised. This also showed highly significant results (t = 7.532; df = 84; p = .000).

Effect intensity:

The effect intensity as per Kazis (Leonhart, 2004) was selected here. That is, in order to reduce the influence of the homogeneity of the differential values, the standard deviation of sleeping behaviour before use was utilised in the determination of the effect intensity. This represents a good estimation of the population scatter rate as per Leonhart, since the intervention group was not yet influenced at this time.

$$d = \frac{\bar{x}_1 - \bar{x}_2}{s_{prä}} = \underline{\underline{1.14}}$$

If one uses the division of effect intensity for independent samples as per Cohen as a basis, a significant effect results as per Leonhart.

Additionally, the difference in sleeping behaviour before and after use of the Thevo-Adapt „Sleeping Star“ was non-parametrically verified with the Wilcoxon test. This also showed a highly significant improvement (z = - 5.757; p (two sided) = .000).

Inclusion of gender

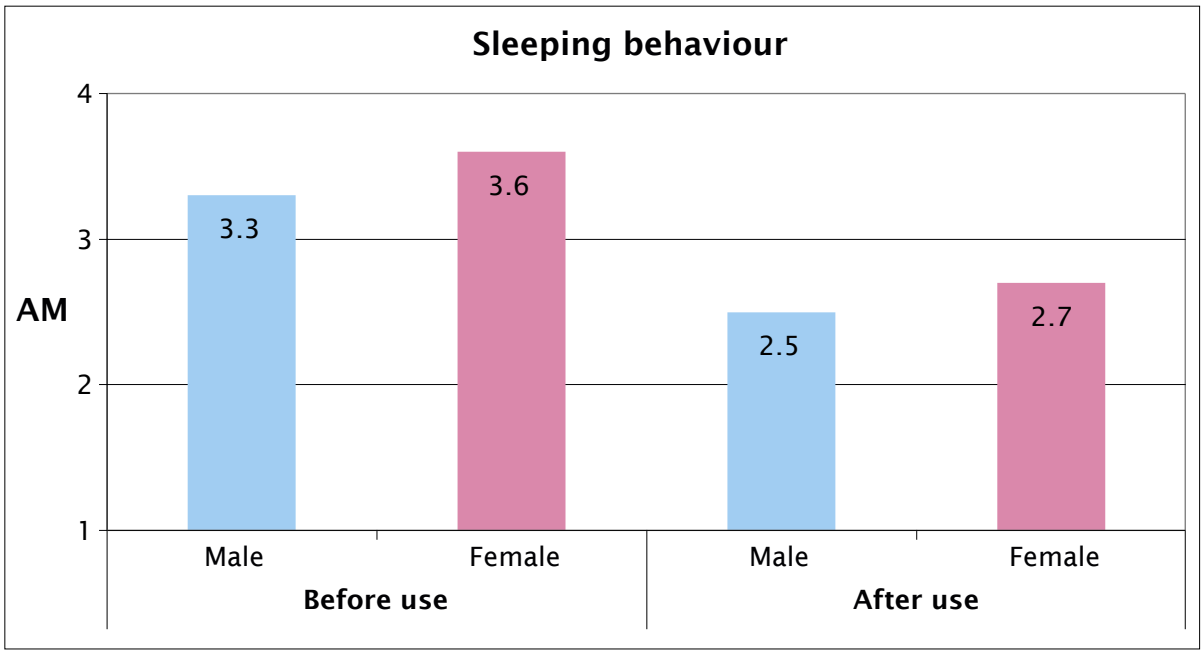
Furthermore, a two factor variance analysis was done for a gender specific verification of the change.

Parametrically: Two factor variance analysis

Sleeping behaviour	Gender	Average value	s	n
Before use	Male	3.3	.7	49
	Female	3.6	.7	36
	Total	3.4	.7	85
After use	Male	2.5	1.0	49
	Female	2.7	1.1	36
	Total	2.6	1.0	85

Source	F	df	Significance	Partial Eta Square
Measurement repetition	56.341	1	.000	.404
Measurement repetition / gender	.354	1	.554	.004
Gender	1.987	1	.162	.023

As shown, the change was similarly positive in both boys and girls. Therefore, even the change in itself was highly significant here.



1.3 Change in sleep duration

Only 26 % of persons (n = 24) stated that there were changes in the sleep duration. The number of nighttime sleep hours changed most frequently.

Increased sleep at night

73 persons (78 %) were unable to notice a change in sleep duration at night. Therefore, a total of 21 statements were made about increased sleep as shown in the following table.

Hours	Frequency	
	n	%
1.00	7	33
1.50	5	24
2.00	3	14
2.50	2	9
3.00	1	5
4.50	1	5
6.00	1	5
7.00	1	5
Total	21	100

Increased daytime sleep

The larger part of the sample, that is, 93 % (n = 87), noticed no change in daytime sleep duration. Only 7 parents stated a change in sleep duration. Of these, 3 stated that their children slept one half hour more in the daytime. 3 parents stated 1 hour and one person stated 2 hours more daytime sleep.

Less sleep at night

Only 3 statements were made here. They were: 1 hour, 1.5 hours and 2.5 hours.

Less sleep in the daytime

Only one test subject stated that the sleep duration of his child had lessened by 1.5 hours in the daytime.

1.4 Change in daytime behaviour

In nearly one third, that is, 30 % (n = 28) of children, a change was noticed in the daytime, so that 57 children (61 %) showed no changes in daytime behaviour. No information was provided here for 9 children (10 %).

Of the 28 parents who noticed a change in the child’s behaviour, 25 described the behaviour change more precisely.

Behaviour change	Frequency n	Evaluation of the change
More alert and lively	2	+
More attentive, concentrated	4	+
Better mood	5	+
More balanced	4	+
Better rested	2	+
More relaxed sleep	2	+
More relaxed	1	+
Lessened spasticity	3	+
More friendly in the morning	1	+
Less stiff in the morning	1	+
Upper body more relaxed in the morning	1	+
Greater noise tolerance	1	+
Free of pain	1	+
Less sweating	1	+
Fewer bed changes required	2	+
Less sleep, more whining, dissatisfaction	1	-
Tired, but does not want to sleep	1	-
Sleeps more often in the daytime	1	-

As shown in the following table, 88 % positive changes were shown, while only 3 parents (12 %) noted negative behaviour changes.

Change in daytime behaviour	Category	n	Observed share	Test share	Exact significance (two sided)
Group 1	Positive	22	.88	.50	.000
Group 2	Negative	3	.12		
Total		25	1.00		

In order to verify this difference, the warning sign test was done. Only the 25 parents who had described the change more precisely were included here. The warning sign test, which assumes a likelihood p = 0.5 for both changes, was highly significant. Therefore, a clear overhang of the positive changes was shown here.

1.5 Change in frequency of nighttime awakening

Precisely half of all persons (n = 47) stated that the frequency with which their child woke up had changed. 42 persons found no change, and 5 persons (5 %) made no statement here.

1.6 Average nighttime awakening

71 parents (76 %) stated the average frequency of nighttime awakening of their child. 1 – 2 waking phases per night were stated by almost half of all persons.

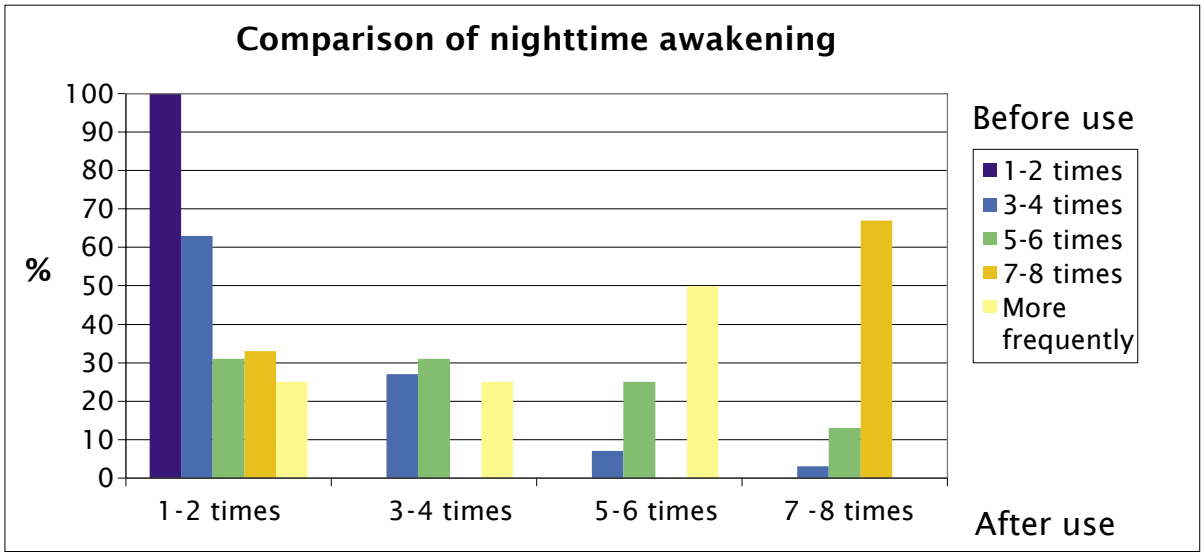
Frequency of awakening	Frequency	
	n	%
1-2	43	46
3-4	15	16
5-6	8	9
7-8	5	5
Total	71	76
Absent	23	24
Total	94	100

Comparison of average awakening at night before and after use of the Thevo-Adapt „Sleeping Star"

Since a total of 67 persons made statements about the frequency of awakening before and after use, the sample decreased correspondingly in this comparison.

Nighttime awakening after use	Nighttime awakening before use											
	1-2 times		3-4 times		5-6 times		7-8 times		More frequently		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
1-2 times	14	100	19	63	5	31	1	33	1	25	40	60
3-4 times	0	0	8	27	5	31	0	0	1	25	14	21
5-6 times	0	0	2	7	4	25	0	0	2	50	8	12
7-8 times	0	0	1	3	2	13	2	67	0	0	5	7
Total	14	100	30	100	16	100	3	100	4	100	67	100

28 children showed no change in the frequency of nighttime awakening. Out of the 39 changes, 34 were positive – that is, the child woke up less frequently – and only 5 were negative, that is, the child woke up more frequently. All children who woke up 1 – 2 times per night before use of the Thevo-Adapt „Sleeping Star" remained in the same category after use. The category of more than 8 times was no longer named after use.



These differences were tested for significance with the Wilcoxon test. It showed the following results:

Average awakening per night, afterwards – average awakening per night, before

	n	Middle rank	Rank sum
Negative ranks	34(a)	20.3	689.5
Positive ranks	5(b)	18.1	90.5
Bondings	28(c)		
Total	67		

a. Average awakening per night, afterwards – average awakening per night, before
b. Average awakening per night, afterwards – average awakening per night, before
c. Average awakening per night, afterwards – average awakening per night, before

As shown in the table, the middle rank of the negative ranks, which show a reduction in the frequency of nighttime awakening, is higher than in the positive ranks. The Wilcoxon test, with z = - 4.384 and p= .000, shows significant results at the 0.1 % level.

A further comparison of frequencies before and after use was made in that only the dichotomies of 1 – 2 times per night versus more than twice per night were compared. This categorisation produced the following distribution:

Awakening after using the Thevo-Adapt „Sleeping Star“	**Awakening prior to using the Thevo-Adapt “Sleeping Star“**					
	1-2 times		> 2 times		Total	
	n	%	n	%	n	%
1-2 times	14	100	26	49	40	60
> 2 times	0	0	27	51	27	40
Total	14	100	53	100	67	100

In the category ‘waking more than twice per night’ before use, nearly half (49 %) changed to the category ‘ 1 – 2 times per night’, while 51 % remained in the same category afterwards. In the group of children which woke up 1 - 2 times per night, there was no change.
The McNemar test which was used for the interference statistical confirmation of these differences was highly significant with p (two sided) = .000.

1.7 Changes in going to bed at night

28 % of parents (n = 26) stated that the child’s evening process of going to bed had changed, while 68 % (n = 64) noticed no changes. 4 parents made no statement here.

Type of change in going to bed in the evening:
Of the 23 descriptions, 21 were regarded as positive, and only 2 as negative.

Change in going to bed	**Frequency** n	**Evaluation of the change**
Looks forward to going to bed	3	+
Willingly goes to bed	1	+
Seldom goes to bed alone	1	+
Absence is better tolerated	1	+
Calmer, falls asleep better	2	+
Falls asleep more rapidly	6	+
Falls asleep alone	2	+
Does not get back up	1	+
Positioning easier	1	+
Position change to the other side possible	2	+
Change from indoor carriage to child’s bed	1	+
No longer cries	1	+
Plays around more	1	–
Seems to take longer	1	–

1 description could not be assessed

1.8 Change in the time needed to fall asleep

23 parents (24 %) noticed a change in the time their child needed to fall asleep. 3 parents (3 %) made no statement here, while 68 parents, that is, 73 %, noticed no change in the time required to fall asleep.

Type of change in the time required to fall asleep:

Change in the time required to fall asleep:	**Frequency** n	**Evaluation of the change**
Shorter	14	+
Slightly shorter	1	+
About half	1	+
Half	1	+
Calmer	2	+
Lies in bed until she falls asleep	1	+
Falls asleep directly	1	+
Takes still longer	2	–

Here as well, only two statements were evaluated as negative.

1.9 Changes in the bedtime ritual

Only 8 parents (9 %) stated that the child’s bedtime ritual had changed. 78 parents (83 %) noticed no change in the bedtime ritual, while 4 parents made no statement.

Type of change in the bedtime ritual:

Change in the bedtime ritual	Frequency n	Evaluation of the change
Slightly easier	1	+
Body contact no longer needed, falls asleep alone very well	1	+
After going to bed: falls asleep with music	1	+
Falls asleep on back, better for child, worse for parents	1	+
Falls asleep in the bed within 10 – 20 minutes	1	+
Cries less often	1	+
Asks less	1	+
Moves around more	1	-

1.10 Changes in repositioning the child

18 parents stated changes in repositioning the child. 7 parents made no statement here, while 69 do not reposition their child differently since use.

Type of change in repositioning:

Change in repositioning	Frequency n	Evaluation of the change
Easier	5	+
Lies on side softer and better	1	+
More relaxed	1	+
Rarer	3	+
Absent	1	+
Able to slightly change position him/herself	1	+
Side change possible	1	+
No redness	1	+
Less sweating	3	+
Falls asleep on back	1	+
Falls back asleep more quickly	1	+
Sleeps more calmly	1	+

1.11 Changes in the possibilities of changing the sleeping position

71 parents stated no change, 9 made no statement, and 14 (15 %) stated a change.

Type of change in the possibilities of changing the sleeping position:

Changes in the possibilities for changing the sleeping position	Frequency n	Evaluation of the change
Better able to turn alone	1	+
Better sleeping position	1	+
Moves more, turns back and forth	1	+
Able to turn almost without help since 2 nights	1	+
Simpler	1	+
Freer	1	+
Child is now able to turn to both sides	1	+
Longer on one side and longer in one position	1	+
Only turns once now	1	+
Fewer changes	1	+
Child is repositioning themselves from time to time	1	+
Only back lying position	1	-
No longer turns alone	1	-

Below is a summarising verification of the changes:

Results of the warning test:

Change	Categories	n	Observed share	Test share	Exact significance (two sided)
1.7 Going to bed in the evening	Positive	21	.90	.50	.000
	Negative	2	.10		
		23	1.00		
1.8 Time required to fall asleep	Positive	20	.91	.50	.000
	Negative	2	.09		
		22	1.00		
1.9 Bedtime rituals	Positive	7	.88	.50	.070
	Negative	1	.13		
		8	1.00		
1.10 Repositioning	Positive	16			
1.11 Possibilities of changing the sleeping position	Positive	11	.85	.50	.022
	Negative	2	.15		
		13	1.00		

The slightest changes took place in the bedtime rituals. Here, only 8 parents said that there were changes. The most frequent changes were in going to bed in the evening and in the time taken to fall asleep.
The share of positive changes ranged from 85 % to 100 %, as in repositioning. This difference was significant in everything except the change in the bedtime ritual, wherein the low range of samples must be taken into account.

⇨ **That is, when there were changes, they were largely positive!**

1.12 Pain due to lying

Only 5 parents stated that their child suffered from pain due to lying. Approx. 15 stated that they could not assess this.

Change	Frequency	
	n	%
No	60	64
Yes	5	5
Total	65	69
Cannot assess	23	24
Absent	6	6
Total	94	100

1.13 Change in sleeping behaviour depending on…

In order to verify the average value differences, a two factor variance analysis was done in each case.

…taking medications:

	Medications	Average value	s	n
Sleeping behaviour prior to use	No	3.5	.7	35
	Yes	3.4	.7	46
	Total	3.4	.7	81
Sleeping behaviour after use	No	2.7	1.0	35
	Yes	2.6	1.1	46
	Total	2.6	1.0	81

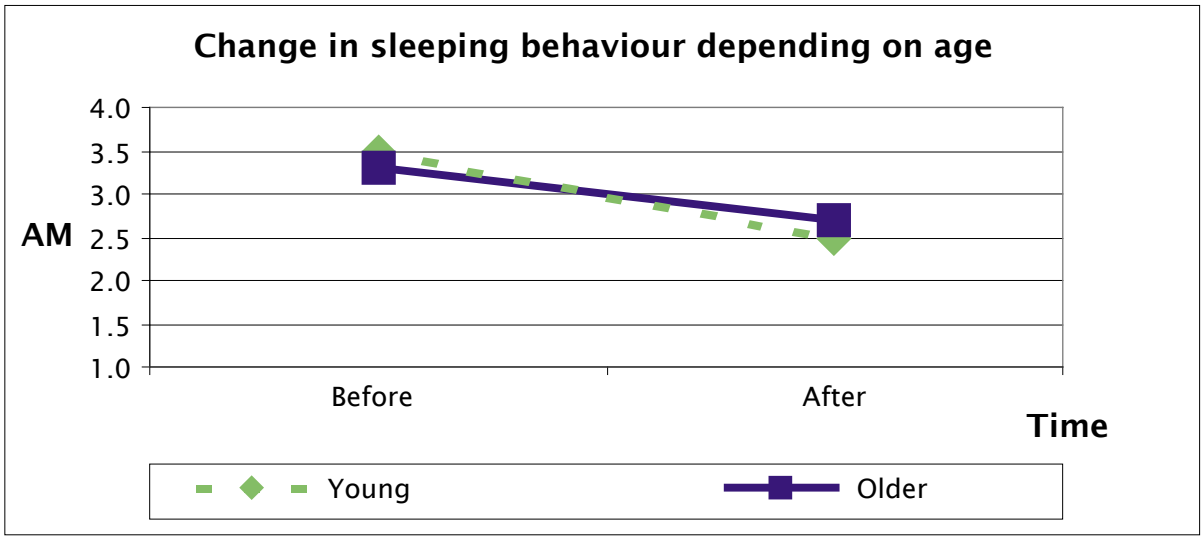
Here as well, the change was highly significant overall at the 0.1 % level (F = 49.508; df = 1; p = .000). Since the change in both groups (medications: yes/no) is similarly positive, the interaction between sleeping behaviour and medication use is not shown as significant here (F = .078; dl = 1; p = .780). The factor of medication use also showed no significant influence on sleeping behaviour (F = 0.349; dl = 1; p = .556).

…age

In order to test whether the change in sleeping behaviour is different in younger children than in older children, the sample was subdivided into younger and older children. 6.5 years was used as a separating value in order to obtain nearly equal samples. The overall change was again significant (F = 56.969; df = 1; p = .000).

	Age	Average value	s	n
Sleeping behaviour prior to use	Young	3.5	.7	44
	Older	3.3	.7	41
	Total	3.4	.7	85
Sleeping behaviour after use	Young	2.5	1.1	44
	Older	2.7	.9	41
	Total	2.6	1.0	85

As shown in the table, younger children have a clearer improvement in sleep than older children. This interaction, which is shown again in the following graphic, misses the 5 % level with p = .100 (F= 2.768; df= 1).



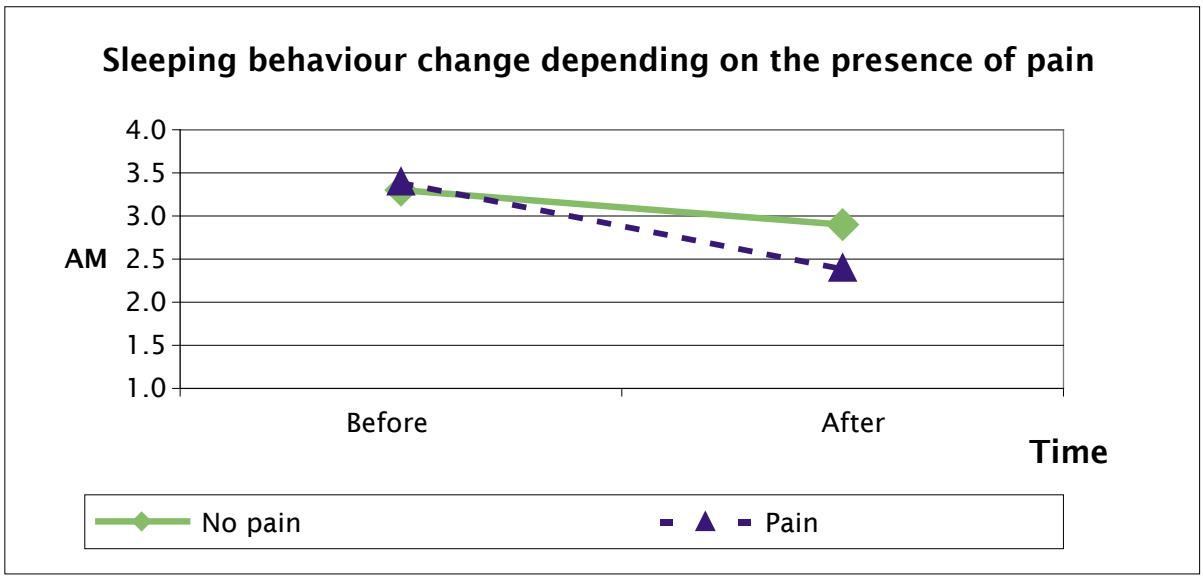
Overall, younger children do not differ from older children in sleeping behaviour (F = .136; df = 1; p = .714).

…pain due to lying

	Pain	Average value	s	n
Sleeping behaviour prior to use	No	3.3	.7	33
	Yes	3.4	.8	18
	Total	3.4	.7	51
Sleeping behaviour after use	No	2.9	1.0	33
	Yes	2.4	1.2	18
	Total	2.7	1.1	51

Here, the factor of sleeping behaviour (before and after) again showed highly significant results with (F = 26.073; df = 1).

The following diagram shows the difference in changes in both groups. Prior to use of the Thevo-Adapt „Sleeping Star“, the sleeping behaviour of children who suffered from pain due to lying was assessed similarly to the sleeping behaviour of children who did not show pain. In the group of children with pain, the positive change is, however, stronger than in the children without pain. This interaction between the two factors only narrowly misses the 5 % level with p = .058 (F= 3.766; df= 1).



The verification of the difference between the two groups overall was not significant with F= .767; df= 1; p= .385.

…chronic pain

	Chronic pain	Average value	s	n
Sleeping behaviour prior to use	No	3.3	.7	66
	Yes	3.6	.7	10
	Total	3.4	.7	76
Sleeping behaviour after use	No	2.6	1.0	66
	Yes	2.8	.9	10
	Total	2.6	1.0	76

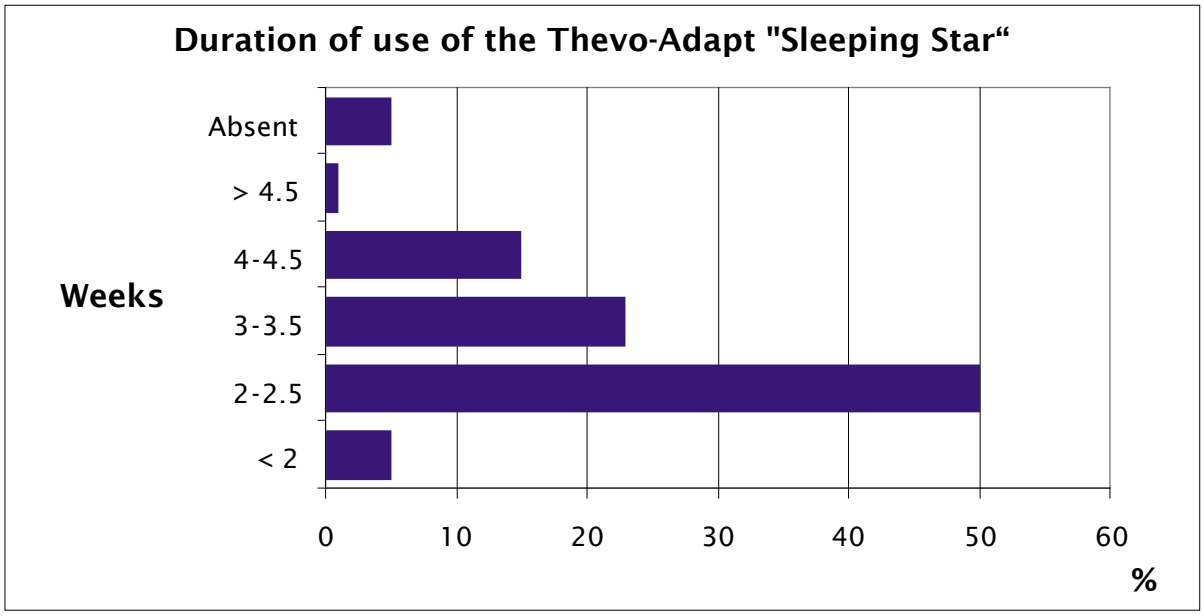
Sleeping behaviour was again highly significant in its difference with p = .000 (F= 23.022; df= 1). Children who suffered from chronic pain showed poorer sleeping behaviour before and after. However, this difference was insignificant (F= .981; df = 1; p= .325). Since the change in both groups turns out similarly well, there is no interaction (F= .017; df= 1; p= .896).

1. Duration of sleeping on the Thevo-Adapt „Sleeping Star“

The duration of use of the Thevo-Adapt „Sleeping Star“ is shown in the following table.

Weeks	Frequency	
	n	%
< 2 Weeks	5	5
2 - 2.5 Weeks	47	50
3 - 3.5 Weeks	22	23
4 - 4.5 Weeks	14	15
> 4.5 Weeks	1	1
Total	89	95
Absent	5	5
Total	94	100

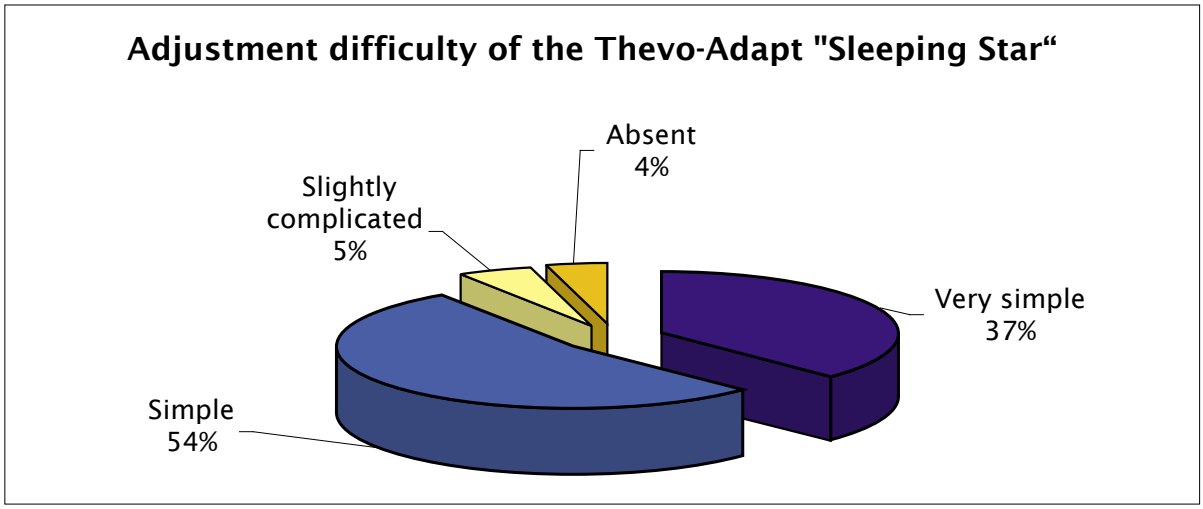
The greatest share of children used the Thevo-Adapt „Sleeping Star“ for 2 to 4.5 weeks. 50 % of children slept on the Thevo-Adapt „Sleeping Star“ for 2 to 2.5 weeks, 23 % of children slept on it for 3 to 3.5 weeks, and 15 % of children slept on it for 4 to 4.5 weeks.



2. Adjusting the Thevo-Adapt “Sleeping Star“

Adjustment	Frequency	
	n	%
Very simple	35	37
Simple	50	53
Slightly complicated	5	5
Total	90	96
Absent	4	4
Total	94	100

More than half of parents (53 %) regarded the Thevo-Adapt “Sleeping Star“ as easy to adjust.
37 % stated that they found adjustment very simple, and 5 % thought that it was slightly complicated.



3. Adjustment of the Thevo-Adapt “Sleeping Star“

Only 24 parents (26 %) had adjusted the Thevo-Adapt “Sleeping Star“, as shown in the following table.

Adjustment	Frequency	
	n	%
No	66	70
Yes	24	26
Total	90	96
Absent	4	4
Total	94	100

Does the adjustment of the Thevo-Adapt "Sleeping Star" depend on ...

... perception of the body and all body areas?

	Perception and feeling of body areas					
	No		Yes		Total	
Readjustment	n	%	n	%	n	%
No	18	82	42	72	60	75
Yes	4	18	16	28	20	25
Total	22	100	58	100	80	100

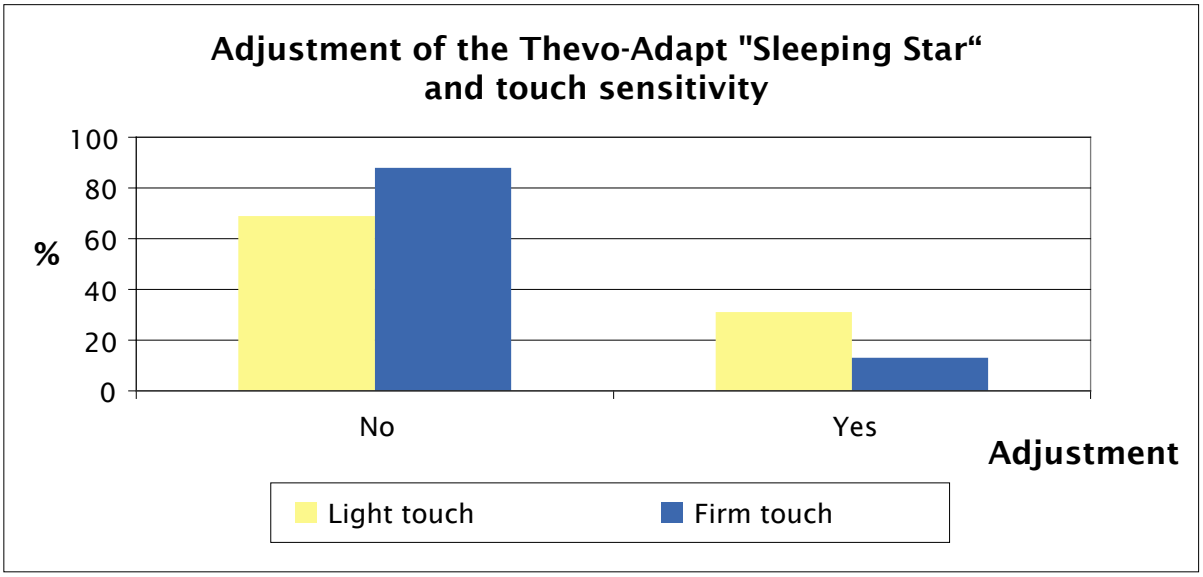
The Thevo-Adapt "Sleeping Star" was readjusted 28 % more frequently for children who were able to sense their body areas than in children who could not sense and feel their body areas. This difference is shown as insignificant in the Chi square test (χ^2= .752; df= 1; p= .386).

... touch sensitivity?

Since only one child could only barely feel touch, it was not included in the following calculation. A differentiation was made solely between the ability to feel firm and light touch.

	Touch sensitivity					
	Light touch		Form touch		Total	
Readjustment	n	%	n	%	n	%
No	40	69	21	88	61	74
Yes	18	31	3	13	21	26
Total	58	100	24	100	82	100

The Thevo-Adapt "Sleeping Star" was adjusted more frequently in children who were able to sense light touch (31 %) than in children who were only able to sense more firm touch (13 %). The Chi square test with which these differences were verified showed insignificant results (χ^2= 3.061; df= 1; p= .080). However, since the likelihood is still below 10 %, One can speak of a tendency here. That is, the Thevo-Adapt "Sleeping Star" was tendentially adjusted more frequently in children with higher touch sensitivity than in children with lower touch sensitivity.



The frequency of adjustment is shown in the following table.

Frequency of adjustment	Frequency	
	n	%
1 time	14	15
2 times	4	4
3 times	3	3
4 times	1	1
6 times	1	1
Total	23	24
Not applicable	66	70
Absent	5	5
Total	94	100

Out of the 24 persons who adjusted the Thevo-Adapt “Sleeping Star“, 14 had only adjusted it once. Only 9 persons had adjusted the Thevo-Adapt “Sleeping Star“ twice or more often.

4. Increased sweating

More than 2/3 of the test subjects (77 %) had no increased sweating.

Increased sweating	Frequency	
	n	%
No	72	77
Yes	11	12
Sometimes	7	7
Total	90	96
Absent	4	4
Total	94	100

11 persons stated that increased sweating was noticed on the Thevo-Adapt “Sleeping Star“. 7 persons only noted this occasionally.

The survey's results show that the way of implementation has been reasonable and professionally applicable to deal with and answer the survey's questions and aim. The aim was to analyse the effectiveness of the MiS Micro Stimulation® System Thevo-Adapt "Sleeping Star" on children with going to sleep and sleep through problems.

Among other things, the estimated sleep behaviour of 94 children all together (54 boys and 40 girls) aged 11 months to 18 years before using the Thevo-Adapt „Sleeping Star" was recorded. This was done with the help of a questionnaire.

The children's sleep behaviour was estimated via a four-stage scale (1 = very good, 2 = good, 3 = satisfactory, 4 = inadequate) in each case before and after the usage of the Thevo-Adapt „Sleeping Star". This assessment included 85 statements in total (49 boys and 36 girls).

This provided evidence, that Thevo-Adapt "Sleeping Star" improved the sleep behaviour of 54 % of the children. Through this, a positive change in the behaviour during the day, such as higher receptiveness, concentration, and mental balance, has been developed. In addition, a couple of children even experienced a reduction of spasticity.

Over and above, it was analysed whether the changes had the same intensity in all groups. This lead to the following results:

- **Sex:**
  The positive changes were almost similar with boys and girls.
- **Age:**
  As a tendency, the sleep behaviour of younger children improved more than that of older ones (group classification: until including 6.5 years vs. over 6.5 years).
- **Pains that occur from lying in bed:**
  A more intense increase is noted with children that suffer from pains that occur from lying in bed.
- **Chronic pains:**
  Children with and without chronic pains showed an almost as intense positive change.

Conclusion

The children's quality of sleep visibly increased thanks to the usage of Sleeping Star.

The usage of Sleeping Star is highly recommendable with children, who suffer from pains that occur from lying in bed.

The usage of Sleeping Star already seems appropriate in early life.

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Medications

51 children (54 %) take medications (4 absent statements [4 %]).

Medications	Frequency n	Frequency %	Category
Orfiril	11	11.7	Anti-epileptic
Ospolot	3	3.2	Anti-epileptic
L-Thyroxin	1	1.1	Hormone
Trileptal	5	5.3	Anti-epileptic
Sabril	2	2.1	Anti-epileptic
Topamax	2	2.1	Anti-epileptic
Primidon	2	2.1	Anti-epileptic
Keppra	2	2.1	Anti-epileptic
Melatonin	5	5.3	Hormone
Lamictal	6	6.4	Anti-epileptic
Timonil	3	3.2	Anti-epileptic
Luminal	5	5.3	Anti-epileptic
Ergenyl	4	4.3	Anti-epileptic
Botox	3	3.2	Muscle relaxant
Dipiperon	2	2.1	Psychopharmaceutical drug
Cortison	2	2.1	Corticoid

Primarily:

Psychopharmaceutical drug

Anti-epileptic

Muscle relaxant

Further medications

Further medications	Category
Aconitum D6	Homeopathic substance
Amphetamin	Psychopharmaceutical drugs
ASS	Analgesics / antirheumatic drugs
Clopidrogel	Thrombocyte aggregation inhibitor ⇨ reduces atherosclerotic events
Baclofen	muscle relaxant
Diamox	Ophthalmic drugs “against epilepsy etc.”
Biocarn	Enzyme inhibitor (preparation for enzyme deficiency and transport protein)
Cloraldurat blue	Sleeping medication
Convuler intravenous solution	Anti-epileptic
Diazepam	Psychopharmaceutical drug
Myoson	Muscle relaxant
Musaril	Muscle relaxant
Dibro Be mono	Anti-epileptic
Growth hormone subcutaneous	Growth hormone
Euthyrox	Thyroid therapy drug
Bifiteral	Laxative
Ferro-Sanol	Anti-anaemia drug
Lioresal	Muscle relaxant
Mesuximid	Anti-epileptic
Frisium	Psychopharmaceutical drug

⇨

Further medications	Category
Mylepsinum	Anti-epileptic
Phenhydan	Anti-epileptic
Nifuretten	Chologic drug (against urinary tract infections)
Mictonetten	Chologic
Phenobarbital	Anti-epileptic / hypnotic drug
Risperdal	Psychopharmaceutical drug
Ritalin	Psychopharmaceutical drug
Suxilep	Anti-epileptic
Timox	Anti-epileptic
Truxal	Psychopharmaceutical drug
Valiquid	Psychopharmaceutical drug
Valproinic acid	Anti-epileptic
Zentropil	Anti-epileptic
Zymafluor D	Vitamin

Diagnoses

	Frequency	
Diagnosis	**n**	**%**
Paralysis or paresis	53	56.0
Epilepsy	30	31.9
Speech disturbance	10	10.6
Visual disturbance	9	9.6
Chromosomal aberration	8	8.5
Brain damage	27	28.7
Hydrocephalus	8	8.5
Developmental disturbance	38	40.4
Heart defect	4	4.3
Muscular dystrophy	4	4.3
Muscle atrophy	6	6.4
Muscle hypotony	4	4.3
Other	34	36.2

Other diagnoses

Other diagnoses	Frequency
Adeno-pituitary aphasia	1
ADHS	1
Alloimmune thrombocytopenia	1
Angelmann syndrome	2
Autism	1
Bipolar affective disturbance	1
Autoaggressiveness	1
Hypothalamus insufficiency	1
Premature birth	1

⇨

Other diagnoses	
Walking disability, left arm restricted	1
Multiple very severe mental and physical disabilities	1
Hallervorden-Spatz syndrome	1
Hip dysplasia	1
Hip luxation, reflux, spinal surgery after scoliosis	1
Isolated non-ketonic hyperglycaemia	1
Joubert syndrome	1
Caudal regression syndrome	1
KISS syndrome	1
Congenital muscle weakness	1
Leukodystrophia	1
Lissencephaly	1
Microcephalus, Lissencephaly	1
Mps3a metabolic disturbance	1
Inability to sit, walk	1
Constipation	1
Rhett's syndrome	2
Crookneck	1
Shunt, PEG treated	1
Smith-Magenis syndrome	1
Spastic cerebral paresis with scoliosis and hip luxation	1
Spina bifida	1
Severe problems sleeping through	1
Stickler's syndrome	1
Trichothiodystrophy	1
Perception disturbance	1
Wolf-Hirschhorn syndrome (multiple disability)	1
Central coordination disturbance	1