Effect of Osteopathic Treatment on Premature Infants with Regulation Problems

Master Thesis zur Erlangung des Grades
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Preface

Mein herzlicher Dank gilt,……..

….zuallerst meinem lieben Mann und meinen Kindern, die mich immer ermuntert haben und viel Geduld mit mir hatten.

….meinen Freunden, die mit aufmunternder Unterstützung vieles dazu beitrugen, dass ich die These abschließen konnte.

….der Nachsorgeambulanz der Univ. Klinik für Kinder und Jugendliche, die mir großzügigerweise viele Frühgeborene schickte und das Projekt unterstütze.

….Dr. Gebhard Woisetschläger, der mich tatkräftig unterstütze und aufmunterte, die Arbeit doch zu beenden.

ABSTRACT

BACKGROUND: Regulation disorders of young infants are a common and often serious problem for parents. My intention was to evaluate the effect of osteopathic treatment on excessive crying and sleeping disorders among preterm infants delivered by caesarean section.

METHODS: Data about the crying and sleeping behaviour of ten preterm infants were collected by means of a questionnaire and journals filled by the parents during two five-day observation periods. The first observation period started immediately after the first osteopathic treatment, the second four weeks later. Osteopathic treatment was individually adjusted to the infants.
Variables used for the evaluation were the daily duration of crying, whining and uneasiness as well as the daily sleeping time, the number and duration of individual periods and the intervals between two succeeding periods. Additionally, time needed to fall asleep and the number of wake periods during night were considered. A general comparison of the data of the initial state and the two observation periods was performed by means of paired samples-t-tests and for each infant individually by independent samples t-tests.

RESULTS: Crying behaviour is significantly improved by osteopathic treatment. On average, the infants cry more than two hours less per day compared to the initial state before osteopathic treatment ($p= 0.006$) and in most cases, an additional reduction of whining can be observed. Individually, improvements in crying behaviour, that means less and shorter periods of crying, can be observed among 90% of the infants.
In contrary, sleeping behaviour of the infants does not improve significantly.

CONCLUSIONS: Crying behaviour is significantly improved by osteopathic therapy, but no significant changes of the sleeping behaviour could be observed. Either osteopathic treatment affects the reasons for sleeping disorders and excessive crying in different ways or the reorganisation of the sleep-wake rhythm takes a longer time.

KEY WORDS: preterm infant, caesarean section, regulation problem, excessive crying, sleeping disorder, osteopathy, osteopathic treatment

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Never before,
we have longed for a moment with more desire

Never before,
we have witnessed a moment with more relieve

Never before
we have loved a moment more deeply.

Never before
we have spent a moment in deeper gratitude.

In this moment you have been born
and enriched our lives.

Poem on a birth announcement (n.n.)

1. Introduction and Purpose of the Study

For me, the poem above expressively verbalizes the sentiments of many parents at the birth of their child. Nevertheless, some aspects can be perceived differently, for example, at the birth of a premature infant.

I have been working as physiotherapist and osteopath at the University Department of Pediatrics and Adolescent Medicine at the Vienna General Hospital (AKH) for many years and have gained some experience with these little characters.

In this study I want to focus on a special problem, I am confronted with, by parents and doctors: Excessive crying and sleep problems of preterms.

Many questions came in my mind about this theme, and with this work, I want to establish more clarity about the definitions of crying and crying behaviour. Then, I will lead you through the history of a preterm infant, so you can understand the crying, not only as a symptom, but as an expression of an entired personality.
In my practitional work I also use the biodynamical approach, so I treat the babies as an entity and try not to narrow down treatment on one field.

The aim of my research is to find out, whether osteopathic treatment influences the regulation problems (excessive crying and sleep problems) of preterm infants.
In the next chapter I will lead you through the various definitions and show you some vertices these preterms have to go through, until they are able leave hospital.

2. Basicals

2.1. Preterms and Preterm Delivery

"The salvaging cavern of the womb is abandoned early…"(Schenk-Danzinger, 1974: 31, translated by Rajchl, 2007).

Yet regular delivery requires high adaptation capacities of the parents, but these requirements are disproportionally higher in case of preterm delivery, since other strains are associated with, in addition to the normal adaptation processes.

This challenge may result in crises and turbulences (Affleck et al., 1991), taking a heavy toll on the accomplishing potential of the parents (see Tab.1).

inner adaptation to the "preterm parentship"
concern about the survival of the baby and about the future
grief about the imagined healthy baby
upset by the separation of the baby
feelings of helplessness and plight
feelings of guilt due to possible failures
depressiveness
anger and blames
denial of threats
overloading by manifold requirements

Table 1: Emotional challenges for "Preterm Parents" according to Sarimski (Sarimski, 2000: 59, translated by Rajchl)

Affleck et al. (1991) report, that in most cases preterm babies are delivered by Caesarean section and the premature infant is isolated immediately, in order to ensure an adequate medical sustenance. This traumatic event generates feelings of deep disappointment about the shortened pregnancy, the lack of the experience of regular delivery and the early isolation of their child (Hantsche et al., 1992).

So, the individual coping resources can be momentarily overstrained. Papousek et al. (2004) describe, that this increased requirement for the intuitive co-regulatory competences of the parents may lead to the development of regulatory disorders.

In this connection, Rautava et al. (1993) describe a distinct correlation between the experience of a traumatic delivery and excessive crying during the first trimenon.

In the following chapters, firstly I will summarize the basicals (definitions, epidemiology, reasons and syndromes) of preterm deliveries, regulation problems in general, and excessive crying and sleeping disorders in special. Afterwards, I will concentrate on the medical issues of Caesarean section and endangerments for development of preterm infants.

2.1.1 Definition of Preterms

Children are referred to as *preterms*, if they are delivered before the completion of the 37th week post menstruationem (p.m.), or if gestation period lasts for shorter than 259 days p.m. Formerly, birth weight was a diagnostic criterion, too, but nowadays the duration of gestation period is the only crucial one (Berg, 1988).

2.1.2 Conceptuality of Preterm Delivery

According to WHO recommendations, preterm infants can be classified into different subgroups by gestation period or weight at birth.

Grouping into three categories by weight at birth:

- LBW ("low birth weight") infants: weight at birth <2500 g
- VLBW ("very low birth weight") infants: birth weight <1500 g
- ELBW ("extremely low birth weight") infants: weight at birth <1000 g.

Grouping by gestation period:

Delivery…

- … before the 28th week: extremely short gestation period.
- … between the 28th and 31st week: very short gestation period.
- … between the 32nd and 36th week: shortened gestation period.

In the Medical Encyclopedia (Medical Encyclopedia, 2007) a system for classification, taking in account birth weight as well as gestational age, both, is presented, that can be used for ascertaining the maturity level and the intrauterine growth of the fetus or infant:

- Appropriate for gestational age, or AGA, describes a fetus or newborn infant whose size is within the normal range for his gestational age.
- Small for gestational age (SGA) is a term used to describe a baby who is smaller than the usual amount for the number of weeks of pregnancy. SGA babies usually have

birth weights below the 10th percentile for babies of the same gestational age. This means that they are smaller than 90 percent of all other babies of the same gestational age (Lucile Packard Children's Hospital, 2007).

- Large for gestational age (LGA) is a term used to describe babies who are born weighing more than the usual amount for the number of weeks of pregnancy. LGA babies have birth weights greater than the 90th percentile for their gestational age, meaning that they weigh more than 90 percent of all babies of the same gestational age Lucile Packard Children's Hospital (2007).

Generally speaking, there is no coherent classification for preterm infants. Attention must be directed on weight, gestational age, growth and the perinatal as well as postnatal state of health (Kopp, 1983).

The preterms (ten infants), which I worked on osteopathically for this theses, were all born between the 27 and 32 week of gestation. Their weight at birth was between 700 and 1650g. Nine of ten cases can be classified into VLBW and one into LBW. Three cases were born after an extremely short gestation period, six in a very short and one case in a shortened gestation period.

2.1.3 Epidemiological Aspects of Preterm Delivery

Approximately, one percent of all children are born before the 32nd gestational week and 6 - 8% between the 32nd and 36th week with upward tendency in the developed industrialized countries (AKH Consilium, 2007).

Statistical data, released on the occasion of the 42nd anniversary of the Austrian Society of Pediatrics and Adolescent Medicine, show, that incidence of preterm deliveries increased by 13% and incidence of preterm deliveries of infants with less than 1000g birth weight by 87% since 1990. (Austrian Society of Pediatrics and Adolescent Medicine, 2004).

According to a study published in Vermont Oxford Network (2006), 0.99% of the infants born at the Vienna General Hospital (AKH) between January and December 2005, had a birth weight lower than 501 grams, 12.84% a birth weight between 501-1000 grams, 14.36% a birth weight between 1001 and 1500 grams, 29.05% a birth weight between 1501 and 2500 grams and 42.74% a birth weight over 2500 grams.

According to Statistic Austria (1996), the percentage of infants born with a birth weight lower than 1500 grams is 0.9%. These Austrian proportions are comparable to the numbers of the Central European neighbour countries (Rauh, 1984).

2.1.4 Conditions and Mechanisms which May Lead to Preterm Delivery

Reasons for preterm deliveries are various and individual. Nevertheless, according to Rauh (1984), each kind of strain of the mother or foetus caused by medical factors as well as psychosocial ones, may lead to a preterm delivery (cf. Fig. 1).

Mercer et al. (1996) developed a risk assessment system for the prediction of spontaneous preterm delivery (cf. Fig. 1). They could not find significant causalities, but some risk factors, leading to preterm delivery. These are socioeconomic status (poor social environment, work during pregnancy, single parents,…), current pregnancy symptoms (including vaginal bleeding, hypertension, acute or chronic lung disease, placental presentation, …), diseases of the mother (diabetes mellitus, infections of the urogenital tract,…), medical history (preterm delivery, aborts, tubal pregnancy, …) and psychical strains (ego disturbance, negative attitude towards pregnancy, stress, …).

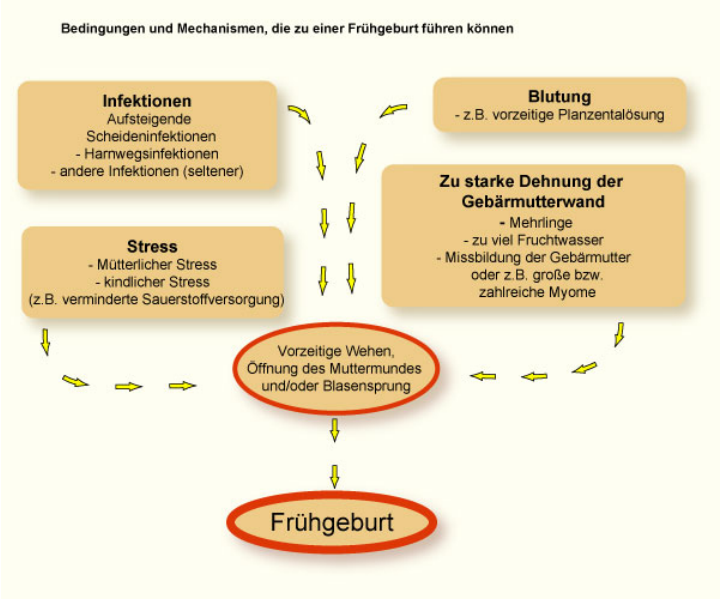

Fig. 1: Conditions and mechanisms which might lead to preterm delivery (Erich Saling-Institut für Perinatale Medizin e.V., 2005).

2.2. General Information about Regulatory Problems

2.2.1 Conceptuality of Regulatory Problems

There is no adequate diagnosis for early childhood regulatory disorders in the international classification systems. In form and content, it may be integrated into the system of adaptation disorders in early childhood.

The German Society for Child and Adolescent Psychiatry and Psychotherapy (Arbeitsgemeinschaften der wissenschaftlichen medizinischen Fachgesellschaften, 2003) describes regulatory disorders as *"an extraordinary difficulty* [of an infant]*, to control behaviour in a single, and often in several, interaction- and regulative contexts (self-soothing, crying, sleeping, feeding, attention) with regard to physical and mental age of the infant. […] Regulatory disorders express themselves in childlike symptoms, which are typical for age and development stage. In particular, these are excessive crying as well as perturbations in sleep and feeding in the first year of age."*

This passage covers the complex clinical presentations, which can become evident at the infantine, parental as well as interaction level with different conspicuousness.

Papousek (2000: 118, translated by Rajchl, 2007) writes: *"The trias of regulation problems during early childhood implies the infantine party with unappeasable crying and problems of sleep-wake regulation as well as the parental with exhaustion and psychosocial strain and the frequent malfunction and escalation of interaction."* The individual components of this system can be observed in Table 2.

Child
- excessive crying
- motoric restlessness with disaffection/whining
- irritability, sensoric hyperirritability
- disposition to overstretching and tactile defence
- urge in vertical, refusal of horizontal body positions
- urge to be carried around (vestibular stimulation and visual distraction)
- pseudostability by distraction and new stimuli
- paradox "hunger for stimuli" "eye babies"
- oversensitive overanxiousness, anxious retreat
- inability of "switching off", self-soothing and to fall asleep
- cumulated sleep deficiency with extremely short sleeping periods during daytime
- overfatigue and overexcitement with crying peaks in the evening
- lack of calm and vigilant wake phases

Table 2: Syndrome of regulation problems during early childhood with excessive crying according to Papousek et al. (Papousek et al., 2004: 116, translated by Rajchl, 2007).

Parent- Child - Interaction - complicated handling with motoric restlessness and uncertainty of the parents - interruptibility of the phases with restlessness by carrying and varying stimuli - inefficacy of normal soothing aids during crying periods - dysfunctional interactions during soothing and laying the baby to sleep with frequent variation of intensive and sometimes bizarre soothing aids - abatement of a stimulation initiates further crying, which is responded to by intensified stimulation - "fight against falling asleep" on the arm, with motoric unrest and tactile defence, opisthotonus - vicious circles of mutual escalating tension and excitement - in contrary, only rare intuitively modulated dialogues after successful soothing or during calm and vigilant phases **Parental Loads** - profound exhaustion, exertion and mental overload - depressiveness, helplessness, feelings of failure - vulnerability, insensate fury, feeling of being rejected - inhibition of the intuitive parental competences - negligence of own needs - tense relationship

Table 2-cont: Syndrome of regulation problems during early childhood with excessive crying according to Papousek et al. (Papousek et al., 2004: 116, translated by Rajchl, 2007).

Papousek et al. (2004) recommends to use the neutral expression "regulation problem", because it does not stigmatize the infants or their parents. Concretely, the dysfunction is present in interactional everyday life. They read this expression as a diagnosis of a complex disorder with different syndromes, that can not be delimited in terms of their genesis, risks, progression and prognosis.

2.2.2 Manifestations at Different Touchpoints during Development

Multiple phase-characteristic syndromes are:

- Excessive, persistent crying with problems of the sleep-wake regulation
- Unrest, disinclination, dysphoria, attention deficits
- Feeding and thriving disorders
- Sleep disorders
- Excessive, persistent clasping, anxiety, social retreat
- Excessive, persistent defying
- Aggressive oppositional behaviour

Wolke et al. (1995) describe a possible contemporaneous occurrence of several disorders (crying, sleeping and feeding problems), too, and conclude that 14.6% of the infants at the age of five months show at least two of these symptoms.

Most of the behaviour problems cumulatively arise during certain development stages of the infants. There are periods (mental leaps, touch points, crises), characterized by broad reorganisation processes with respect to physiological, affective, motoric, cognitive and social components and observable across cultures. (Brazelton, 1999)

Brazelton, 1999 describes *"touchpoints as periods of disorganized behavior in an infant that are associated with imminent developmental change. They are predictable, as they arise out of well-known changes in any area of development. For example, language skills may seem lost as an infant begins to walk. Each change in behavior reflects the infant's increasing organization, self-regulation of internal physiological states, perceptual skill, and cognitive understanding."*

"It is assumed, that the probability of the development of disorders in these behavioural domains is increased, which have priority in the development period at these times." (Brazelton, 1999: 6, translated by Rajchl, 2007).
Developmental phases in early childhood are presented in Fig. 2.

Therefore, according to Papousek et al. (2004), the syndrome of excessive crying mostly occurs during the first trimenon, the period, when maturation of the physiological regulation processes are the central development tasks.

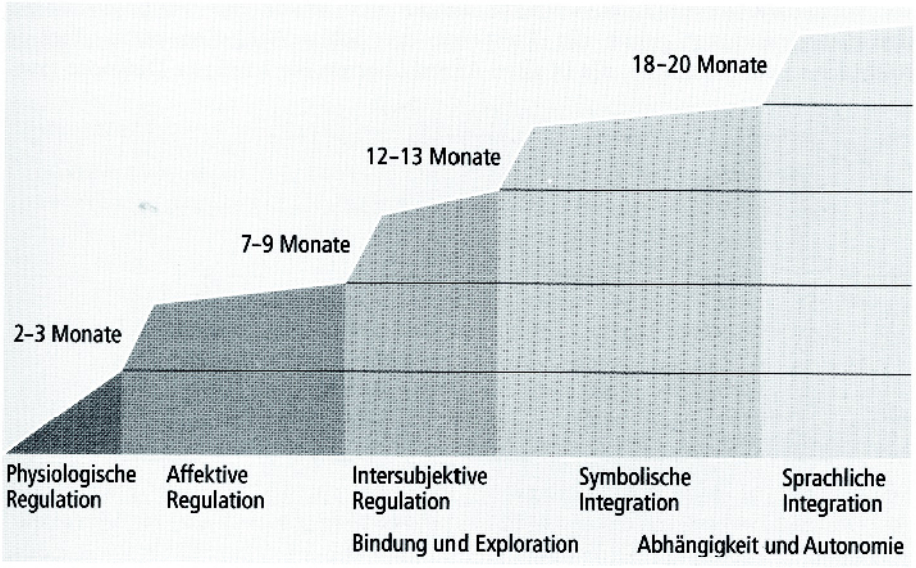

Fig. 2: Developmental phases in early childhood (Papousek et al., 2004: 57)

As depicted in Fig. 2., physiological adjustment processes are priority tasks during the first trimenon: Ingestion, digestion, energy budget, thermoregulation and immunizing as well as the activities of sleeping and being awake.

In this trimenon, excessive crying and problems with the regulation of sleeping and being awake is one of the most frequent complaint brought to the physicians (Barr, 2007).

After the first three months, some new advances in the development are set to start. Flehmig (1990) describes a new integration of affects and experiences, the awakening of social communication. There are new adaptations in sleeping and ingestion behaviour and a progress in motoric output, as gaining symmetry. Babies establish eye contact and gain the ability of social smiling and phonation.
Around the sixth month, according to Papousek et al. (2004) problems of sleeping and waking regulation change to nocturnal sleep disorders.
From the sixth month on, the infant starts to move on its own. During this time regulation between nearness and distance, weaning and reorganisation of the nocturnal sleep takes place. During this time, excessive clining is the main syndrome.

From the first year of age on, with free running, the child has limitless potential for exploration. It has control of 1-3 meaningful words and independent ingestion. The first oneirophobia start. Important landmarks of development are the recognising of it's own mirror image and the dealing with social rules and limits.

With progression of the development of the prefrontal neuronal inhibition systems tasks of emotional regulation (frustration tolerance) have to be managed.
In this period, with a climax around the second year of age, the syndrome of excessive defying and aggressive/oppositional behaviour becomes more peculiar.

If the mental stability is upset and if normal crises are persisting, this is referred to regulation problems of this particular phase.

2.2.3 Circumstances Promoting the Development of Regulation Problems

There are indications, that pre- peri- and postnatal strains, on organic as well as psychosocial level are cross-linked to a large extent.

Relative frequencies of risk factors for regulation problems in two samples are summarized in Table 3 (organic) and Table 4 (psychological and psychosocial risk factors). Data sources are a sample of the Special Ambulance of the Institute for Social Pediatrics and Adolescent Medicine at the University of Munich ("Sample") and the Bavarian perinatal survey 2001 performed by the Kinderzentrum München and the Bavarian Permanent Working Party for Quality Assurance (Perinatal inquiry).

	Sample	**Perinatal inquiry**
Prenatal (risk factor ≥1)	68.9%	-
condition after ≥ 2 miscarriages	9.0%	3.7%
condition after infertility treatment	7.4%	2.5%
multigravity	6.3%	1.7%
age of mother ≥ 40 years	2.0%	2.9%
severe hyperemesis	17.3%	0.4%
preterm labour with tocolysis	20.3%	5.6%
nicotine use	11.9%	9.6%
cerclage	1.9%	0.5%
gestosis	5.6%	2.1%
Perinatal (risk factor ≥1)	38.8%	-
caesarean section	22.3%	23.3%
forceps/vacuum extraction	12.0%	6.5%
amniotic infection syndrome	5.2%	0.7%
preterm delivery (<37th week of gestation	10.6%	4.8%
birthweight < 10. percentile	15.6%	~ 10.1%
severe birth complications child	5.0%	
severe birth complications mother	2.1%	
Postnatal (risk factor ≥1)	85.4%	
family atopy history	54.7%	
manifest atopy (child)	18.2%	
recidive infections	28.6%	
hospitalisation	16.0%	
neurological conspicuities	33.9%	
development disorders	3.1%	

Table 3: Percentage of organic risk factors for regulation problems according to Papousek et al. (Papousek et al., 2004: 64, translated by Rajchl, 2007).

The most frequent prenatal risk factors in the sample of the Munich Special Ambulance described are early labour treated with drugs and severe hyperemesis.

Psychosocial risk factors described in the sample of the Special Ambulance of the Institute for Social Pediatrics and Adolescent Medicine at the University of Munich are summarized in the next table.

	Sample
Prenatal (risk factor ≥1)	56.1%
abnormal distress load	23.2%
extraordinary fears	25.7%
depression during pregnancy	6.3%
tense relationship	18.1%
primary undesired pregnancy	10.2%
Perinatal (risk factor ≥1)	23.2%
traumatically experienced delivery	8.9%
early separation of mother and newborn	14.6%
Postnatal (risk factor ≥1)	80.7%
continuos tense relationship	49.4%
psychic disorders of the mother	47.4%
actual conflicts with birth family	33.7%
burdened relational experiences during the childhood of the mother	37.3%
social isolation	30.1%
unresolved trauma of the mother (loss, abuse)	16.1%
socio-economic burden	6.0%
migrational culture specific strains	5.6%
role conflict of the mother	9.3%
other chronic strains	9.8%
chronic physical diseases of the mother	6.7%

Table 4: Percentage of psychosocial risk factors for regulation problems according to Papousek et al. (Papousek et al., 2004: 66, translated by Rajchl, 2007).

A remarkable high number of mothers (56, 1%) describe distinctive prenatal psychical and psychosocial risc factors. According to Papousek et al. (2004), distress, fear or depression are exceeding former estimations. The impact of pre and perinatal risc factors for excessive crying can be significantly related with the development of this disorder, on the basis of this sample.

According to Rautava et al. (1993) there is a distinct correlation between traumatic experiences during delivery and excessive crying of the children.

Additionally, Thomson (1968) found a higher prevalence of regulation problems among preterm infants (infants with a birth weight lower than the 10^{th} percentile). In this connection, psychosocial stress factors are more frequent.

Preterm infants most commonly are delivered by Caesarean sections, the preterm normally is separated from the parents and transferred to a Neonatological Intensive Care Unit. In contrary to regular deliveries, a preterm delivery has to be classified as traumatic crisis, without restrictions (Affleck et al., 1991).

This traumatic event generates feelings of deep disappointment about the shortened pregnancy, the lack of the experience of regular delivery and the early isolation of their child (Hantsche et al., 1992). In addition, Hantsche et al. (1992) describe, that women blame the

committed misconduct of early delivery on themselves. In connection with these feelings of guilt, it is often referred to the widespread depressive alienation of the mother (Als, 1992).

The first encounter with the baby is characterized by new, sometimes alarming, experiences. The sight of the little, often "wired" baby, triggers fear and shock reactions (Als, 1992). Additionally, the parents are confronted with burdening information about the health status of their child and the medical treatment. Affleck et al. (1991) reports, that parents of preterm infants are more fraught and concentrated in dealing with their child and feel worried easily.

According to Papousek et al. (2004), these particular demands on the intuitive co-regulatory competence of the parents can add to regulation problems.

Esser et al. (1994) confirms the context between constituted pregnancy risks and the generation of psychosomatic load factors. That means, that psychosocial loads during pregnancy can be interpreted as signifier for regulation problems. Nevertheless, aetiology of these problems can not be traced back to organic reasons or primarily parental failures without any doubts.

2.2.4 Prognosis

Shaver (1974), St. James-Roberts et al (1998), Wolke et al (1995) found an explicit correlation between regulation problems during early childhood and behavioural problems later on.

According to Papousek et al (2004) this needs to be seen in a more differentiated way. They think that this problematic remains transient, if parents and/or the child have sufficient resources. Only with multiple risk strains and low resources of parents and/or the child with long-term endangerment of the parent-child relationship, these syndromes may persist.

2.3. Excessive Crying and Sleep Disorders

Main problems of the test persons, I treated for this study, are regulation problems within the scope of excessive crying and sleep disorders. These syndromes belong to the most prevailing disorders during babyhood. (Barr, 2007).

2.3.1 Excessive Crying

The syndrome of "excessive crying" is a collection of signs and symptoms without a homogenous cause. (Herman et al., 2006).

During crying due to infantile colic, babies pull up their legs, their extremities are hypertone, their stomach is distended, their face is red and their crying is shrill and dysphone (Lester et al, 1990).

Prevalence turned out not to be gender dependent (James and Halil, 1991), but there is a accumulation among siblings and twins.

2.3.1.1 Normal Crying Behaviour

When we speak about crying infants, it is necessary to talk about the normal crying behaviour of an infant, first.

So, what is normality?

Brazelton (1962) says that there is an average of 2 ¼ hours crying in the first seven weeks, with less each week thereafter. The crying duration peaks at six weeks and abates by 12 – 16 weeks. (Hiscock and Jordan, 2004).

Healthy infants show also increased crying in the evening during the second month (Barr et al. 1996). According to Barr et al (1991) there is even no difference in the early peak pattern of Western and Eastern infants, it seems to be " *a behaviour universal to the human species:"*

To determine whether the crying of preterm infants manifests similar features, the pattern of crying from 40 weeks gestational age through 24 weeks corrected age was described by Barr for 35 relatively healthy preterm infants born between 28 and 34 weeks gestational age. It is interesting to recognize that preterms born between 28 and 34 weeks gestational age still have a peak and evening clustering at 6 weeks corrected age (Barr et al 1996).

2.3.1.2 Abnormal Crying Behaviour

As already mentioned in chapter 2.2.2, the first trimenon is a phase of intense physiological adjustment processes (ingestion, digestion, energy budget, thermoregulation and immunizing as well as the activities of sleeping and being awake). For some infants, a lack of maturity in their ability to modulate their reactions to internal physical symptoms (e.g., bowel spasm) and

external stimuli (e.g., loud noise) may result in problem crying, hyperreagibility, lack of consolability, self-soothing and the ability to fall asleep (Lester et al, 1992).
This "excessive crying" is a complex presentation with "conspicuities on infantine, parental as well as interaction level" (Papousek et al., 2004) and should be differentiated from the term "infantile colic". For most irritable infants, there is no underlying medical cause of their crying syndromes, but some exclusion criteria facilitate diagnosis.

2.3.1.3 Diagnosis and Definition of Excessive Crying

Due to the reasons described above, it is often hard to differentiate the normal crier from the one with pathologic crying for the practitioners. The authors (Herman et al., 2006) propose the mnemonic, "IT CRIES" (cf. Fig. 3) for exclusion diagnosis.

Reijneveld (2001) recommends in an article called “The Impact of Varying Definitions” the use of clearly described definitions. This may improve the comparability of studies on the cause and treatment of excessive infant crying. Relatively small differences between definitions seem to cause large changes in prevalence rates.

The common definitions mostly concern the duration of infant crying or its effect on the parents. A standardized case definition increases the ability to compare similar trials.
In studies of infant colic, the ideal case definition has generally been considered the Wessel definition, which specifies not only symptoms but frequency and duration as well. Wessel et al. (1954) describe a rule of “*three*”, unexplained paroxysmal bouts of whining and crying that lasted more than *three* hours a day, for more than *three* days a week for more than *three* weeks of duration.
These criteria are widely accepted and are used to determine, whether the amount of crying is normal or excessive (Wessel et al., 1954).

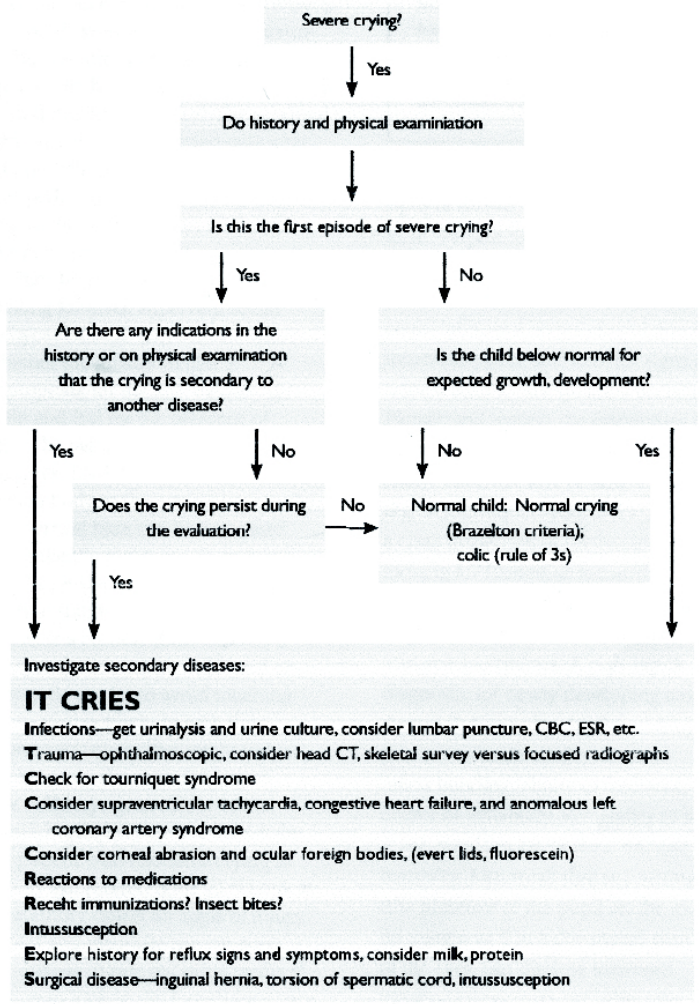

Fig. 3: Decision tree for infant crying (Herman et al., 2006:)

2.3.2 Sleeping Disorders

In contrary to excessive crying, there is no general definition for sleep problems (Dilling et al, 1993). Basler et al. propose, that high individual variability and age dependent changes of sleep and sleeping behaviour make it difficult to find a general definition (Basler et al., 1980).

The main syndromes of sleeping problems are:

- Problems in falling asleep with prolonged time for falling asleep.
- Falling asleep in the evening/night only with parental assistance and regulation facilities.
- Repeated waking up during night time with crying and whining periods.
- Sleeping in parental bed, which is conceived as nuisance by the parents.
- Shift of the circadiane distribution of sleep and wake phases.

2.3.2.1 Normal Sleeping Behaviour

Normal sleep requirements of infants, for example, are described by Hiscock and Jordan (2004). They write that the babies sleep in average for 16 of every 24 hours at birth, falling to 14 hours by 2–3 months of age.

If babies are awake during the day and happy, they are unlikely to need more sleep. Generally, a 6-week-old baby becomes tired after being awake for 1.5 hours, while a 3-month-old baby becomes tired after being awake for 2 hours.

Reports often tell that sleeping problems are a frequent complaint from parents of preterm infants. Wolke (1995) illustrates in a prospective epidemiological study the incidence and stability of sleeping problems of very preterm (< 32 weeks gestation at birth), preterm (32-36 weeks gestation) and fullterm infants. They figure out that preterm infants have fewer and shorter night-wakings at five months but there were no differences in sleeping behaviour compared with healthy term children at 20 and 56 months of age.

2.3.2.2 Diagnosis of Sleeping Problems

A possible way to differentiate the severity of a sleep disorder is described by Minde et al. (1993). He uses a so-called sleep score, taking into account the duration for going to bed, the time needed to fall asleep, mean sleeping time per night, number of wake periods during night per week and per night, their duration and the time per week spent in parent's bed.

According to the German Society for Child and Adolescent Psychiatry and Psychotherapy (2003) for diagnoses of exclusion for sleep problems additionally has to be considered:

- Limited airflow due to obstructed airways (adenoids, asthma, bronchitis)
- sleep apnoea syndrome
- Undine's syndrome
- Cerebral organic disorders with missing or disorganized sleep-wake rhythm
- Cerebral organic seizure disorders

As irritability in most infants has no underlying medical cause, the task of healthcare practitioners, after eliminating medical causes, is to explain babies' normal crying and sleep

patterns, to assist parents to help their baby deal with discomfort and distress, and to assess the mother's emotional state and the mother–baby relationship. (Hiscock and Jordan, 2004).

2.3.3 Therapeutical Concepts for Excessive Crying and Sleep Problems

This should be a short cut of evidence-based practice, to bring a little more clarity in the almost snowballing offers of therapies.

2.3.3.1 Pharmaceutical Interventions

Simethicone (Infacol Wind Drops, Pfizer; and Degas Infant Drops, Wyeth) has no effect on infant crying when compared with placebo. Anticholinergic medications (e.g., dicyclomine) have been shown in three randomized controlled trials to effectively reduce infant crying. (Garrison and Christakis, 2000).

However, the risk of adverse effects, including apnoea and seizures, precludes the use of these medications.

2.3.3.2 Dietary Interventions

In some irritable infants, food allergy may play a causal role, cow's milk protein and soy protein, these allergens can cause reactions of vomiting, erythema and diarrhoea. In practice, a trial of eliminating cow's milk by modifying the mother's diet or changing the formula may be the best.

It has been hypothesized that some babies have a transient underlying lactase deficiency, leading to a build-up of lactose derived from breast milk or formula. In a double-blind, placebo-controlled, crossover study of 46 infants with excessive crying and diarrhoea, treating breast milk or formula with lactase drops resulted in significantly less crying.(American Academy of Pediatrics, 2000). Lactose-free formula is readily available,

for breastfed babies, expressed breast milk needs to be pretreated with lactase drops.

2.3.3.3 Naturopathic Interventions

Garrison and Christakis (2000) investigated the efficacy of herbal teas in reducing the symptoms of infant´s crying. There were no significant differences seen in the average numbers of night wakings and no adverse effects were reported.

2.3.3.4 Behavioural Interventions

The duration of crying bouts has been shown to be shorter when parenting practices include more carrying of babies with colic symptoms (Hunziker and Barr, 1986). Carrying excessive crying babies, it seemed, was not effective (Barr et al., 1991).

Sound and movement stimulation, like car riding, do not have any effectiveness in daily hours of crying or in measurements of maternal anxiety. (Garrison and Christakis, 2000)
It is useful to assist parents to help their baby deal with discomfort and distress, and to assess the mother's emotional state and the mother–baby relationship. (Taubmann, 1984).

Parents can use a simple diary to record their baby's crying, feeding, and sleeping patterns on a daily basis. A diary can show the baby's usual crying patterns, the total amount of sleep the baby is having per 24 hours, and can help parents and doctors monitor the response to settling techniques (Wolke et al., 1994).

A number of different settling techniques are presented in books and videos, and recommended by parenting centres, which are useful to aggravate a background of security and confidence of the parents.
E.g., *"Reading an infant's behaviour: Help parents to "read" their infant's behaviour as an indicator of the infant's emotional state and ways of self-regulating distress."* (Hiscock and Jordan, 2004: 508).

2.4. Physiological Aspects of Preterm Delivery

2.4.1 Caesarean Section

Preterm infants are delivered by Caesarean section in most cases. This applies for the University Department of Pediatrics and Adolescent Medicine at the Vienna General Hospital (AKH), too (Vermont Oxford network 2006).
Additional to the multiple burden for the mother (Circumstances Promoting the Development of Regulation Problems) it means an increased demand for the baby (Carreiro, 2004), too.
Children, who were delivered by Caesarean section, were not able to experience the labour contractions. Möckel (2006) describes having labour contractions, means stimulation and stress for the newcomer. Because the mother produces hormones, which support physiological the adaptation process after birth.

De Jong (2003) even speaks of a shock syndrome due to Caesarean section or respiratory distress syndrome of the newborn, respectively.

According to Brüggemann (1993), it comes to the so-called "wet lung" or transient tachypnea. This is caused by residual amniotic fluid in the lung, since the baby does not pass the narrow birth channel as during a spontaneous delivery.

Weiss (1994) describes the pressure during caesarean is unilateral, discontinuous, intermittent and even higher than the normal pressure during labour.

According to Möckel and Mitha (2006), in an osteopathic session, newborn after caesarean section often show compression patterns on the cranial base and the whole body, which can be seen as a restriction of the whole spine or be often noticed as disturbance of the neck symmetry.

Emerson (1997) found hyperreagibility among children delivered by caesarean section, expressing itself at noise and tactile stimulations. He speaks of a psychical shock at caesareans. English (1997) registers typical characteristics of children delivered by caesarean sections, as there is a different space perception and perception of borders.

The early separation of the preterm infant in many cases, when the baby is transferred to the Neonatological Care Unit, hinders the sensible phase of "bonding". Instead of being near to the mother, the baby has to undergo many medical interventions, like aspiration, artificial respiration or infusions. This sensible phase is considered as a central trigger of parent identification (Strobel, 1998). Studies show, that the missing mother-child bonding may lead to interaction problems (Kennell et al., 1983).

At the Neonatological Care Unit the baby has to undergo an unpleasant procedure, dependent on medical condition, weight and maturity.

For osteopaths and especially for pediatric osteopaths, it is important to have a comprehensive knowledge about functional disorders and medical problems of preterm infants, in order to be able to focus on these during treatment.

The preterm infant has functional deficits, which may cause complications and require different medical interventions. The immaturity of the infant has top priority among the reasons of functional disorders.

2.4.2 Endangerments for Development of Preterm Infants.

2.4.2.1 Respiratory Organs

Since all organ systems, that have to guarantee the viability after delivery are physiologically immature, preterm infants are extraordinarily endangered (Strobl, 1998).

Of paramount importance for the reasons of functional disorders is the disturbed breathing, caused by central immaturity but also organic immaturity of the lungs (Dick et al., 1999).

According to Brüggemann (1993), the lung is an organ, developing latest during gestation. Respiratory function of many preterm infants born before the 36th week of gestation is insufficient.

1) The anatomical immaturity of this organ is characterized by the fact, that only few small alveoli have contact with just as few sprouted capillaries (cf. Fig. 4). Thus, oxygen exchange is hindered, the infants have to be supplied with additional oxygen.

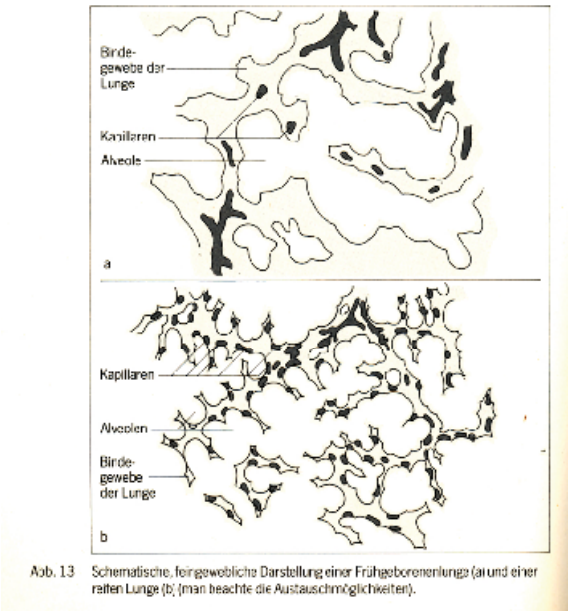

Abb. 13 Schematische, feingewebliche Darstellung einer Frühgeborenenlunge (a) und einer reifen Lunge (b) (man beachte die Austauschmöglichkeiten).

Fig. 4: Schematic histological image of a preterm lung (a) and a mature lung (b) (Brüggemann, 1993: 70)

2) The biochemical immaturity can be observed in the lack of pulmonary surfactant (anti-collapse factor). The generation of this proteinous substance (phospholipids) starts around the 24th gestational week and is available in sufficient quantity in the 35th week. The pulmonary surfactant reduces the surface tension at the air-fluid barrier and thus prevents alveolar collapse during expiration (Obladen and Wille, 1984).

Typical medical problems are the Respiratory Distress Syndrome (RDS) or Hyaline Membrane Disease (HMD). In this case, the inadequate amount of surfactant causes the alveoli to collapse at the end of expiration. As the alveoli collapse, damaged cells collect inside the alveoli (hyaline membranes) and further lead to insufficient lung function (Brüggemann, 1993).

The blood can not be oxygenised, resulting in an intrapulmonary right-to-left shunt and further on to hypoxia. According to Obladen and Wille (1984), RDS can be observed at up to 14% of all preterm infants with a birth weight lower than 1500 g and born before the 32nd gestational week.

Standard prophylaxis for RDS is the administration of surfactant preparation (glucocorticoids), causing the maturation of the fetal surfactant factor system (Dick et al., 1999).

One of the first symptoms of hypoxia caused by RDS, is the expiratory moaning, sternal and intercostal indrawing, nostril movements and tachypnoea (>60 per minute). Tachypnoea can raise until absolute exhaustion.

If blood gas analysis attests a non-tolerable acidosis or if the need of oxygen raises within a short time, special respiration methods have to be applied:

- Slight respiratory distress syndrome: Spontaneous respiration with increased oxygen concentration
- Fairly serious respiratory distress syndrome: Continuous positive airway pressure (CPAP) test. During a nasal CPAP or pharyngeal CPAP a nasotracheal tube is applied as respiration support (cf. Fig. 5). The tube is inserted into the nasal cavity or laryngeal cavity. A positive air pressure is produced by a respiration apparatus (at the University Department of Pediatrics and Adolescent Medicine a 'Babylog 8000 plus' is used). By this, a collapse of the alveoli is prevented. This ventilation facilitates autonomous respiration of the baby (Obladen and Wille, 1984).

Fig. 5: Preterm infant with CPAP system (n.n.).

- Artificial ventilation (e.g., positive endexspiratory pressure (PEEP) has to be used for babies with aperiodic or even missing ventilation. In this case an endotracheal tube is the linkage between respiration apparatus and lung (Fig. 6).

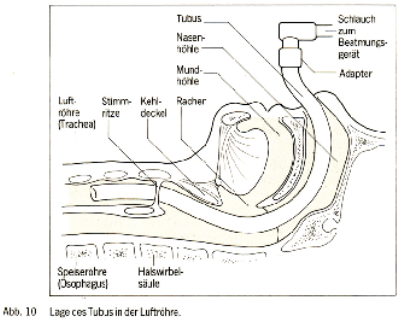

Abb. 10 Lage des Tubus in der Luftröhre.

Fig. 6: Placement of the endotracheal tube in the trachea (Brüggemann, 1993: 62)

Although artificial ventilation of newborn often is inevitable and life-saving, it carries risks and secondary complications. In the long term, risk of a bronchopulmonal dysplacy (BPD), the most frequent chronic lung disease among newborn after artificial ventilation, is increased. According to Obladen and Wille (1984), prevalence is 20% among all preterm infants with a birth weight lower than 1000g.

Pathologic alterations are thickened alveolar walls, interstitial fibrosis and narrowed air passages (Cotran et al., 1989). Thus, right heart hypertrophy may arise.

Further long-term secondary damage may be retinopathy (ROP), intraventricular haemorrhages and brain damage (Carreiro, 2004).

3) The central immaturity of the respiration centre (medulla): A regulation disorder of the brain, caused by immaturity, may lead to apnoea (Strobel, 1998). Apnoea are respiratory arrests lasting longer than 20 seconds. They can primarily be observed among preterm infants during sleep and are caused by the inhibition of sensible inlets and motoric outlets of the central nervous system.
   Various stress factors, like infections, cerebral haemorrhages, heat and cold, taking of blood samples, but also simple handling may lead to lapses in respiration or apnoea of the babies (Gleason et al., 1993). According to Obladen and Wille (1984), apnoea can be observed among 25- 50% of preterm infants, predominantly, if they were delivered after a gestations period less than 30 weeks.

Additionally, it has to be mentioned, that spontaneous breathing frequency of preterm infants is higher than among older infants:

preterm (< 30^{th} - 34^{th} week of gestation)	50-60 breaths per minute
newborn	40 breaths per minute
adults	12 breaths per minute

Respiration intensity can be read off the pulse of the baby, too. A pulse with less than 80 beats per minutes is called "brachycardy", a pulse with more than 180 beats per minute "tachycardy" (Hertl, 1989). Regular pulse is 120 - 160 beats per minute.

Seven of the infants, taking part in this study, had a Respiratory Distress Syndrome (RDS) and were ventilated by means of a Continuous Positive Airway Pressure System (CPAP, Infant flow), one infant had to be ventilated artificially and the two of the infants did not need respiratory support.
All of the ten infants were diagnosed with apnoes and brachycardias and received coffein citrate treatment.

2.4.2.2 Central Nervous System

The second highest risk for the development of preterm infants are disorders of the central nervous system.

Disorders of the nervous systems are the most dreaded complications among preterm infants, because they may be accompanied by life-long handicaps. The brain is the central regulatory organ. As previously reported, respiration, but also the cardiovascular system, body temperature, muscle tensions, and metabolism are controlled by the brain.

During embryogenesis, vascularisation of the brain develops from caudal to cranial. The blood vessels are thin and vulnerable, they sprout from the brain surface and the deeper brain regions and conflue towards each other (cf. Fig. 7). This process is not completed in preterm infants. Thus, one region is highly endangered, the periventricular region, which is characterized by a fragile capillary structure and the cells of the germinal matrix (ventricle septum) are rich in mitochondria (Obladen and Wille, 1984).

Obladen and Wille add, that cerebral ventricular autoregulation is limited among preterm infants. That means, the ability to regulate the cerebral blood flow is not yet functioning. Brüggemann (1993) considers this fact as the biggest functional problem of blood circulation in brain: Too high blood pressure might result in haemorrhaging, and too low pressure in insufficient supply of the brain tissue. The ability of ventricular autoregulation is not gained before the 31st - 32nd week of gestation.

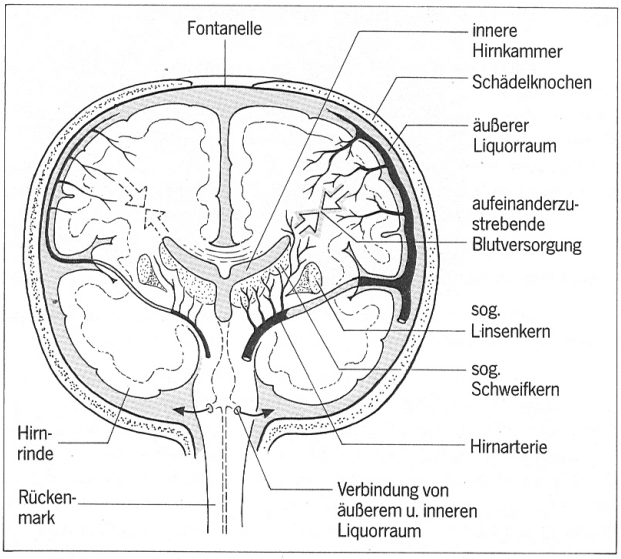

Abb. 36 Entwicklung der Hirndurchblutung.

Fig. 7: Development of the cerebral perfusion (Brüggemann, 1993: 201).

During constant exposure risks of cerebral haemorrhage is low, but trigger events, like birth traumata, transportation, infections, taking of blood samples, hypoxia and intubations may cause haemorrhages (Als, 1992).

Intraventricaulary haemorrhaging (IVH) is graded from 1 to 4 according to the severity of the bleeding (Obladen and Wille, 1984):

- Grade 1 - bleeding occurs just in a small area of the ventricles, the subependyma
- Grade 2 - bleeding also occurs inside the ventricles. They are partly filled or one ventricle is more than half filled.
- Grade 3 - ventricles are completely filled and enlarged by the blood.
- Grade 4 - bleeding into the brain tissues around the ventricles.

Prognosis of the most common grades 1 and 2 is good, and often there are no further complications. Grades 3 and 4 may result in long-term brain injury to the baby (posthaemorrhagic hydrocephalus, seizures, cerebral palsy, retarded development).

Two of the ten preterm babies of my study have had an IVH 1-2, without further complications.

For the prevention of cerebral haemorrhages, research is done about the "principle of minimal handling" or "environmental stress-reducing interventions". The idea behind is to reduce care intervention to an extent as little as possible, in order to decrease risks by strain (Hantsche et al., 1992).

Medical intervention methods are administered depending on medical condition, weight and maturity of the infant, but often preterm infants need only an extrauterine adaptation phase, during which respiratory regulation, working of the heart, thermo regulation and are digestion develops.

2.4.2.3 Adaptation Problems

Sometimes, a preterm infant needs support for the gastrointestinal and renal system, in terms of extrauterine food supply (McQuaid Cox et al., 1993).

The actual task of the gastrointestinal tract is transportation of food, the segregation of digestive juices and the assimilation of food (Brüggemann, 1993).

A mature newborn is born with well-functioning sucking and deglutition reflexes. In contrary, coordination of the oral, pharyngeal and oesophageal deglutition phases is missing until the 34th week of gestation. Swallowing as well as sucking are reflex movements, depending on the neurological maturity of the infant (Carreiro, 2004).

Sucking, breathing and swallowing involve a complex and coordinated process. According to Conrath-Pelotte (2004), preterm infants delivered between the 24th and 32nd gestational week need 6-8 weeks, for gaining this coordination. As long as coordination is not working properly, they have to be nourished by means of a duodenal or feeding tube (cf. Fig. 8).

Fig. 8: Preterm with feeding tube (n.n.)

If preterm infants do not get along with enteral feeding, they are feeded parenternally. That means, nutrients are administered intravenously by infusions (Steidinger and Uthicke, 1989).

Although breast milk is desired, the VLBW infant is often fed a commercial special premature formula (derived from bovine milk). The importance of breast milk is described in a study, which indicated that infants fed human milk had significantly higher cognitive scores when evaluated at 8 years than infants who did not receive human milk. (Newman, 1986).

Chatoor et al. (2001) observed, that traumatic early childhood experiences, as e.g., aspiration, artificial respiration or feeding tubes are experienced as threatening, because they are associated with displeasing stimuli. "Posttraumatic feeding disorders" can early lead to feeding problems.

An equally important and typical adaptation problem of the newborn is the physical thermoregulation and energy balance.

Thermoregulation and energy balance: Newborn acquire energy by sugar metabolism. Preterm infants have only little adipose tissue in relation to their large body surface. Thus, heat loss by radiation is high and hypothermia may occur, leading early to exhaustion.
Disregarding hypothermia may lead to acidosis, hypoglycaemia, apnoea, bradycardias as far as brain seizures (Brüggemann, 1993).

These endangerments can be prevented by common measures, like continual transcutane measurements of pulse, respiratory frequency and temperature (see Fig. 9), as well as taking blood gas analyses (Astrup).

Fig. 9: Preterm with transcutane measurements (n.n).

Additionally, preterm infants are placed into an incubator (cf. Fig. 10), where temperature is kept stable at 34-36°C (Stern, 1965).

Fig. 10: Incubator (n.n).

Apart from the support of the regulation of vital functions, the neurobehavioral organisation (sensorial development, reflexes, ...) should be stabilized, in order to let this development proceed without constrains.

The proprioceptive system

The embryo, with its covered fasciae is exposed to stimuli. As described in chapter behavioural interventions preterm infants do not adequately react on stimuli. Proprioreception (Latin: proprius= own and recipere= to percept) is affected by a lack of maturation of the functionality of the sensory organs, of the physiological system, of the motor function, the autonomous mobility as well as self regulation (Als, 1992).
Proprioreception is that component of perception of beings, providing information not via the environment but via the own body.

Proprioreceptions in the fasciae is a collection of sensations in the course of a lifetime since conception (Gibson, 1973). As Gibbson describes, energy and emotion have a physical component. If we suppress our emotions, we consciously or inconsciously suppress our body perception, too.

For example, Möckel (2006) and Upledger (1999) describe the lung to be a reservoir of grief and fear, while the liver stores anger and depression. Thus, a valuable starting point of an osteopathic treatment is to re-establish a fascial balance on physical but also emotional level.

Neurobehavioral development of the preterms

Although, all sensory organs are developed, the preterm does not react adequately to environmental stimuli, as mature newborn do. This can be explained by the low degree of maturity of the sensory organs, the physiological system, the motoric and autonomous system as well as by self-regulation (Als, 1992).

Tactile perception is developed first during the fetal period. From the 16th week of gestation, the fetus can distinguish between touch and pain reception (Rauh, 1995).

Tactile perception

Sensory experience of preterm infants is characterized by two extremes: Over- and understimulation. On one hand, the baby is overstrained by the highly technologised

environment and indispensable medical measures connected with noise and bright light, on the other hand, they receive only few social stimuli.

Admission for parents is restricted to the visiting hours and even then, contact is short with their baby laying in the incubator. That means, manifold forms of expression of tactile communication (holding, kissing, petting, …) are possible after a view days or weeks for the first time. Greenough et al. (1987) report, that tactile stimulation influences the maturation of the nervous system and supports physical growth and prosperousness.

In different studies performed under separation conditions, it was observed, that tactile stimulation does not only influence biochemical mechanisms of growth, but also the level of activity and sleep-wake rhythms of babies (Hofer, 1987).

The ongoing believe, that premature infants do not have the neurological capability to experience pain, turns out to be not correct. It was only observed, that premature infants react differently to medical interventions than babies, who were born in time, but still with definite physiological changes. (Mc Vey, 1998).

Also the interaction via the vestibular system is functioning early.

Auditive perception

The human cochlea and peripheral sensory end organs complete normal development by 24 weeks of gestation. A busy Neonatal Intensive Care is by default a noisy environment. Disruptive noise may occur even in the confines of an incubator. The Social and Sensory Environment Studies of very low birthweight infants have described the sound environment in an incubator and described that loud noise (approximately 80dB) has been associated with hypoxemia and altered behavioral and psychological responses. (Newman, 1986).

Visual perception

Development of the visual system is strongly connected with stability of the physiological and motoric status. From the 31st week on babies can fix their eyes on an object and from the 34th week they can distinguish faces from objects.

Many hospitalized premature infants are exposed to continuous dim lighting rather than to cycled lighting. Recent evidence shows, that the circadian system of primate infants is responsive to light at very premature stages and that low intensity can regulate the developing clock.(Rivkees S., 2003).

The preterm is overstimulated by the permanent noise and light level and by the numerous nursing and medical measures. Negative responses, like a change in sleep pattern (Hansen and Okken, 1980), segregation of catecholamines, a decline in blood pressure, brachycardia, apnoea, crying, enhanced muscle tone and other symptoms …(Sarimski, 1995) could be observed.

Interventions at the Neonatological Unit

In order to prevent harm by overstimulation, several intervention programmes have been developed. They are primarily concerned with

- overstimulation on neonatological units (measures to reduce the light and noise level and "minimal handling"),
- stimulation programmes (stimulations, like heart beat of the mother are imitated, in order to compensate sensorial deprivation , "kangarooing method" (cf. Fig. 11) and
- the development of an individualised nursing care.

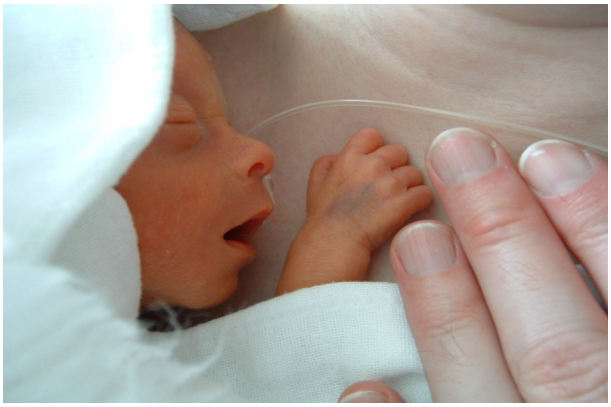

Fig. 11: Preterm during "kangarooing"(n.n.)

This relationship-orientated nursing care focussing on promoting development, *"NIDCAP (Neonatal Individualized Developmental Care Program) have been demonstrated to improve clinical outcome for premature. Individualized developmentally appropriate care, care designed for the level of tolerance of each individual infant results in improved behavioral organisation with consequent medical outcome*." (Ariagno et al., 1997).

Hypersensibility to environmental stimuli characterizes the behaviour of the preterms not only in the postnatal period, but also several months after birth (Dudley et al., 1993). That implies, that it takes a longer time, before these children find a rhythm in their behavioural organisation (Field et al., 1983).

3. Osteopathic Considerations

3.1. Osteopathic Studies

Carruthers (1999) describes in his study about the effectiveness of cranial osteopathy in common infantile disorders, such as sleep problems, constant crying, colic, wind problems, feeding difficulties, irritability and reflux. The effectiveness in treatment was evaluated with visual analog scales included in questionnaires sent to 56 mothers of infants who were treated from May, 1997 to September, 1998. The first part of this clinical audit was conducted in early 1997 and involved 30 infants with common infantile disorders. In this audit, slightly more than 50% of the mothers of these infants felt that cranial osteopathy helped their child "a great deal." This second clinical audit was conducted to determine the effectiveness of Cranial Osteopathy for each of the child's disorders. Fifty-three percent of the infantile disorders were helped by 50% or more, 14% were symptom free, and 86% were helped at least to some extent by the cranial treatment.

Cutler et al (2005) showed statistically significant effects on the application of the CV4 in sleep latency (the length of time that it takes to go from full wakefulness to falling asleep) and the reduction of sympathetic nerve activity. He made out, that in a controlled environment, healthy subjects went to sleep faster if the CV4 was applied compared to subjects who received only a light touch control protocol or no touch at all.

Hayden and Patel (1999) did a study about cranial osteopathic manipulation in the treatment of infantile colic and come to the following results: In the treated group there is a statistically highly significant effect of treatment over a 4 week period on the crying ($p= 0.001$) and sleep patterns ($p=0.002$), and significant improvement of the awake and being held patterns ($p= 0.015$). In comparison, the control group results for these same variables showed only statistically insignificant improvements over the same time span.

Hayden and Mullinger (2006), write about a preliminary assessment of the impact of cranial osteopathy for the relief of infantile colic. The purpose of this randomised, controlled prospective study was to evaluate the efficacy of cranial osteopathy on the treatment of colicky infants under the age of 12 weeks. They wanted to calculate the significance of changes in crying and sleep patterns. This pilot study showed a beneficial effect of cranial osteopathic manipulation for infants suffering from infantile colic.

Gludovatz (2004) did a controlled study about the frequency and intensity of crying periods and the length of periods of sleep. In the treated group there a distinct reduction of the frequency, length and intensity of crying periods and longer intervals between feeding times could be observed.

3.2. Osteopathic Treatment

I put emphasis on establishing contact with the *"organism as an entity, as a designed and integratedly becoming being, as a material substantiality, as a growing essence, as mental-animal nature and intellectually acting character"* (Blechschmidt, 1982: 11) along with his lesions.

During treatment, I came to a release of the craniosacral system, the harmonisation of the membranes and fasciae, the stimulation of the fluctuation of the body fluids and to the integration of the midline.

The key zones were similar in the preterms, but I could not fix therapy on a single cause. Nevertheless, anatomical, physiological and embryological background knowledge were very helpful and served as a guide during therapy. The different treatments were adapted individually for each infant and were evolved in a processual way. That means, I did not always use the same techniques during therapy, but drew on the pool of the techniques, I have internalised during my training in osteopathy, pediatric osteopathy and biodynamic osteopathy.

There are two important reasons, why I do not want to give preference to any standardised procedure for treatment of crying and sleeping disorders. Firstly, the boundary between normality and pathology can not be exactly defined. A crying and sleeping disorders aspect is the parents' ability to endure the behaviour of the infant (ressources). Secondly, crying and sleeping disorders are symptoms of a very complex and individual medical history. The individual traumata even need not to be in causal context and different symptoms might arise due to different medical reasons.

It was my first priority that every baby was coping with their ability of health. There was also an attention on the socioeconomic organisation within the family.

4. Methodology

4.1. The Test Persons

Preterm infants were allotted to me by medical practitioners of the aftercare unit of the University Department of Pediatrics and Adolescent Medicine at the Vienna AKH. The babies had to meet the following inclusion criteria:

- Delivery earlier than the 32nd week of gestation
- delivered by caesarean section
- younger than one year
- crying more than three hours a day, at least three days a week for a period of at least three weeks according to Wessel et al. (1954)
- and/or sleeping problems

The exclusion criteria were:

- hereditary diseases
- severe cerebral disorders (cerebral haemorrhages of degree 3-4)

Additional medical or physiotherapeutic treatments were no exclusion criteria.

According to their parents all of the infants were cry babies, all babies except Julia H. (case 2) and Leonard H. (case 6) additionally had problems to fall asleep at night. Anna Lea S. (case 9) and Marcel H. (case 10) had problems with feeding.

4.2. Procedure

In the beginning the parents were introduced in the procedure.
Additional to the standard anamnesis, they were asked to fill a questionnaire (Panagl and Leiss, 2002; cf. appendix 2) concerning their baby's sleeping- crying- and feeding behaviour.
The babies were treated osteopathically at least 3-5 times in weekly interval (additionally to medical or physiotherapeutic treatment).

During this period, the parents were asked to fill a journal concerning their baby's sleeping- crying- and feeding behaviour (Papousek et al., 2004; cf. appendix 3) for ten days, according the time table shown in Fig. 12.

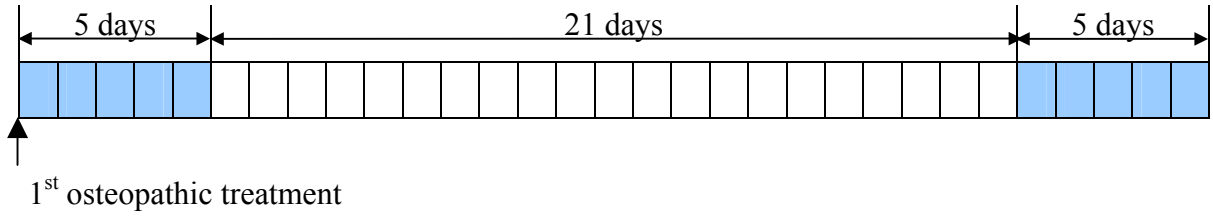

Fig. 12: Time table for filling the journal according to Papousek et al. (2004).

4.3. Collected Data and Definition of Variables

Since two different methods were used to evaluate regulatory disturbances before and after osteopathic treatment, several data can not be used for evaluation.

In the following two subchapters all collected data will be introduced. Data which can be used for evaluation on principle are marked with **bold letters**.

4.3.1 The Questionnaire according to Panagl and Leiss

The questionnaire according to Panagl and Leiss (Panagl and Leiss, 2002) comprises the following items:

Crying:

Time of day, when the baby cries predominantly

Duration of crying periods

Number of days per week, periods of crying occur

Beginning of crying periods

Moderating strategies of the parents and their efficacy

Reasons for crying, considered by the parents

Behaviour of the baby during a period of crying

Intensity of stress caused by crying periods of the baby

Sleeping:

Time when the baby is put to bed at night

Average duration of sleep at night

Number of sleeping periods in the day time

Sleeping locations of the baby and the parents

Problems with falling asleep

Number and duration of periods the child is awake at night

Strategies of the parents to lull their baby and their efficacy

Beginning of sleeping problems

4.3.2 The Journal according to Papousek et al. (2004)

On the days marked blue in Fig. 12, the parents journalised periods of different actions and circumstances in their babies' lives. A section of this journal (normally from 06:00 a.m. to 06:00 a.m the next day) is shown in Fig.13.

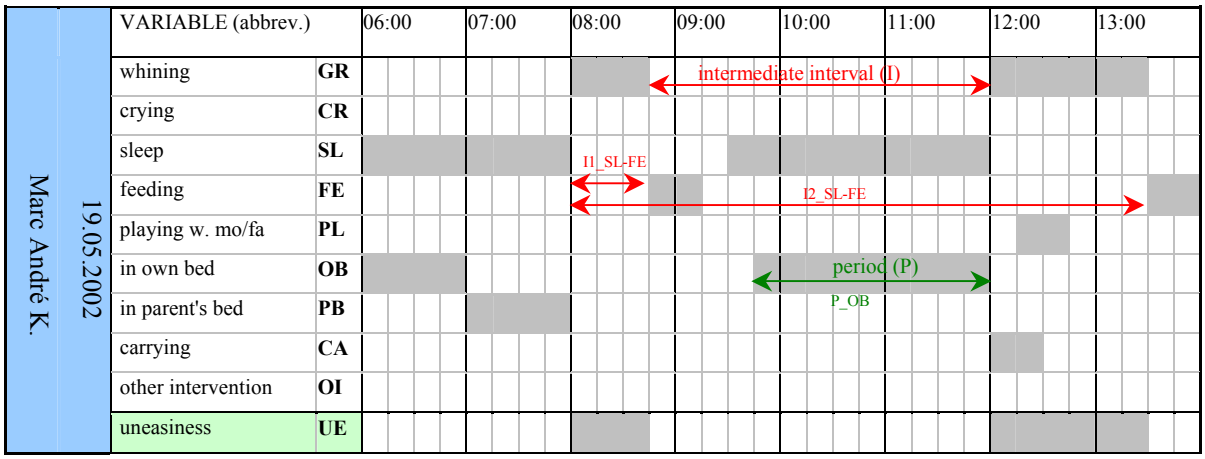

Fig.13: Dependent variables used for the evaluation.

Additionally, one new dependent variables was introduced (marked light green):

Periods when the baby either whines or squalls I call "**uneasiness (UE)**". This variable is used, because parents might interpret crying periods differently.

Parents were asked about their **general mood**, their **energy level**, their **stress level** and about the time when the infant is brought to bed, the **time it needs to fall asleep** and **wake periods during the night**, additionally.

4.4. Evaluation of the Data

First of all, the questionnaire- and journal data were collected in a databank. By means of databank queries output files, identical with the original journals, were created for an easier check of the numerous data (raw data cf. appendix 4).

Synchronicities of crying and whining in the journal were corrected in that way, that the worse - i.e. crying - was chosen. By the introduction of the variable "uneasiness" these synchronicities are considered additionally.

Computation of the variables was performed by databank queries and macros, too.
Software used for the data input was MS Access 97® and for evaluation SPSS 12.0.0®.

The aim of the evaluation is to find out possible influences of the osteopathic treatment on the behaviour of the babies, with special emphasis on whining and crying, but also sleep.
Thus, for the statistical evaluation the null hypothesis "Osteopathic treatment has no influence on crying and sleeping of preterm infants" is used.
My (alternative) hypothesis is, that osteopathic treatment of preterm infants with crying and sleeping problems results in a reduction or complete solution of these symptoms.

Variables used for the statistical evaluation are:

Independent Variables:

- Observation week after first osteopathic treatment (**Week**)

Dependent Variables (cf. Fig.13)

- Intermediate intervals (**I**) (without splitting by date)
- Periods (**P**)
- Duration per 24 hours (**D24**; i.e. the sum of the duration of periods between 06:00 a.m. and 06:00 a.m. the next day)
- Number of periods per 24 hours (between 06:00 a.m. and 06:00 a.m. the next day; **n**)
- Time needed for falling asleep at night (**D_FASL**)
- Number of wake periods at night (**n_WAKEN**)

Statistical Methods used:

1. Tests for assumptions of normality and homogeneity
The normality assumption was checked by Kolmogorov-Smirnov tests, the homogeneity assumption by Levene's tests. Both assumptions are met by all variables. Thus, parametric tests can be used.

2. Paired samples t-tests
For a general overview, the mean values of each variable were computed for each child and each observation week individually. Afterwards, paired samples t-tests were computed, in

order to calculate the mean differences of these data between the two observation periods and their significance (level of significance $\alpha = 0.05$). Thus, the variability of different infants is considered and by these tests it is possible to distinguish between systematic and random differences of crying and sleeping behaviour between the two weeks for all children.

2. Independent samples t-tests

Differences between all values of the variables listed above collected during the first and second observation period were evaluated by independent samples t-tests for each test person individually (1- tailed, level of significance $\alpha = 0.05$). By these tests, intraindividual variance of the data is considered and it is possible to distinguish between systematic and random differences of crying and sleeping behaviour during the two weeks for each individual infant.

3. One sample t-tests

One sample t-tests were used to compare the average duration of crying per day before the first osteopathic treatment with the values during the first and second observation week, respectively for each individual infant. The initial value is an estimation by the parents and was used as comparative value, interpreted as population mean. In the case of ranges, the arithmetic mean was used, instead. Deviations of this value can be classified into systematic (significant) or random effects by this test.

4. Calculation of the percent changes

Finally, in order to normalise changes between two observation periods, to be able to compare them easier, they were expressed by the percentage difference relative to the earlier value.

5. Results

Since characteristics as well as osteopathic treatments are different for each infant, results will be summarized individually for each case. Afterwards, a general summary will be given.

5.1. Individual Results

After a description of the conditions before treatment, changes of the relevant characteristics will be summarized.

5.1.1 Case 1: Marc André K.

5.1.1.1 Initial Situation

Delivery: Marc André K. was delivered by caesarean section 10.5 weeks before due date.

Crying: Without known reason he started daily crying approximately three months after birth. During these periods, lasting between three and five hours, he stiffens, but the colour of his skin remains normal. Predominantly, he cries between 5 p.m. and 11 p.m.

The parents state that they are massively stressed by his crying.

Sleeping: Marc André K. sleeps in his own bed situated in the sleeping room of his parents. According to them he needs more than 30 minutes for falling asleep, but does not wake up in the night. These problems arose the same time, when his crying periods started.

Eating: There are no reported problems with eating.

5.1.1.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Mark André cries most often between 5 p.m. and 8 p.m. and 2 p.m. and 5 p.m. In the second week there is a shift of the crying periods towards morning hours (08:00 - 11:00).

Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 5. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.14).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	before treatment	**180- 300**		
		W1	153	29 - 277	100
		W2	15	0*-38	18
Duration of individual periods	P_CR	W1	128	35-220	88
		W2	25	0*-68	17
Number of periods	n_CR	W1	1.2	1-2	0
		W2	0.6	0*-1	1
Intervals between periods	I1_CR-CR	W1	30	-	-
		W2	-	-	-

Table 5: Characteristics of crying periods of Mark André. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks. *Negative values are set zero.

After a reduction in the first observation week from 180-300 minutes before treatment to 153 minutes on average, there is a distinct reduction of crying in the second observation week (mean value: 15 minutes). While the reduction is not significant in the first observation week

(one sample t-test: t= 1.951 and p= 0.123), in the second observation week, on average, the infant cries 225 minutes less than before the first treatment (mean value 240 minutes). The one sample t-test results in t= 27.39 and p< 0.001.

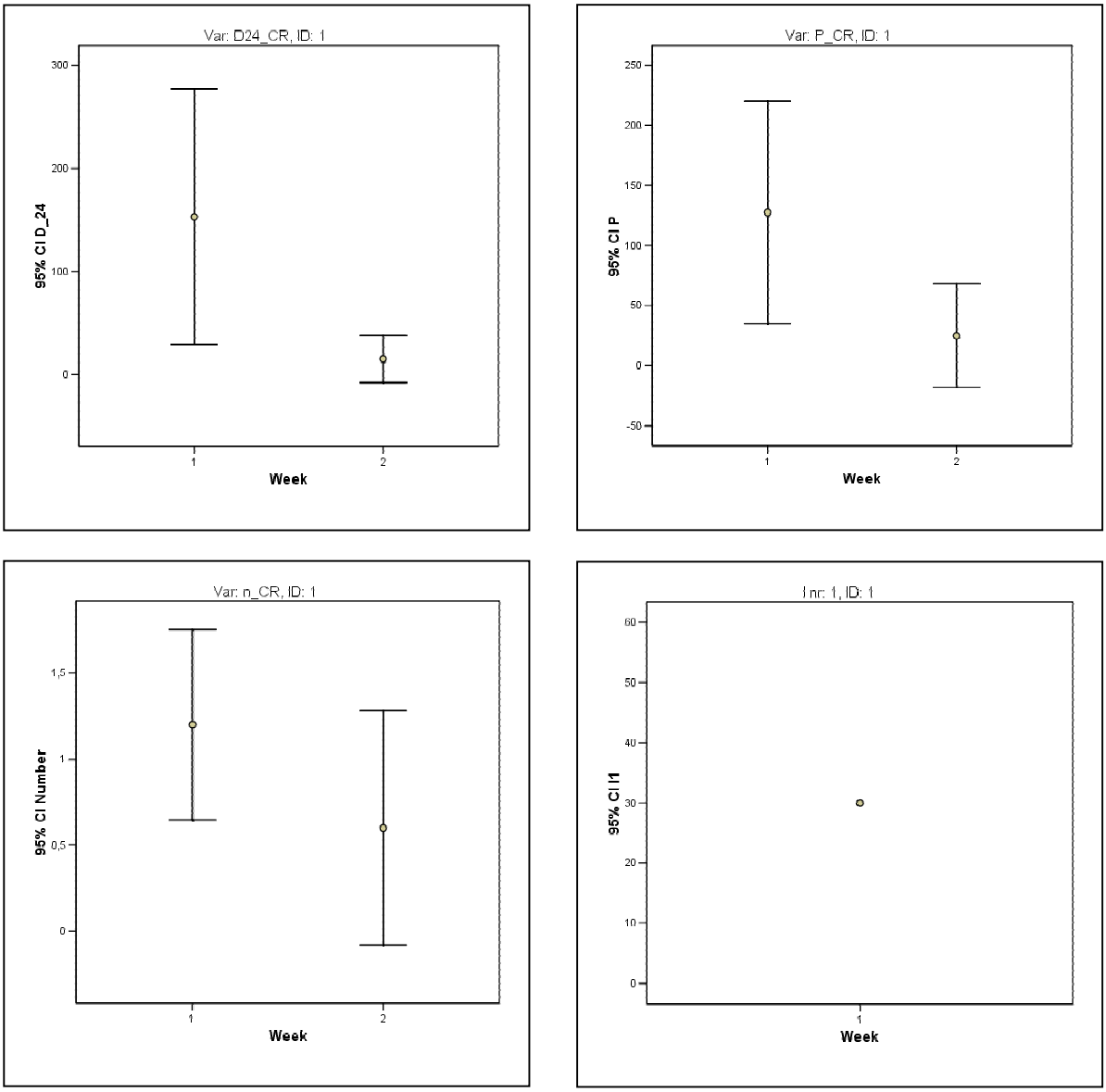

Fig.14: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

During the observation time crying periods are significantly reduced in number (t=1.90, p= 0.05) and individual duration (t=2.74, p=0.02). Thus, total duration decreases (t= 3.04,

p= 0.02). There is only maximum one crying period per day in the second observation week and only one day in the first observation week, when Mark André cried twice. Therefore, the lower right chart only shows one single interval lasting 30 minutes.

Uneasiness: The mean duration of uneasiness in the first observation week after osteopathic treatment is approximately the same as the reported maximum value of the daily crying duration (300 vs. 309 min).

Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 6. In order to visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.15).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	309	203-415	85
		W2	48	20-76	22
Duration of individual periods	P_UE	W1	74	47-100	58
		W2	24	16-32	10
Number of periods	n_UE	W1	4.2	3-5	1
		W2	2	1-3	1
Intervals between periods	I1_UE-UE	W1	177	92-261	140
		W2	203	0*-492	182

Table 6: Characteristics of periods of uneasiness of Mark André. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks. *Negative values are set zero.

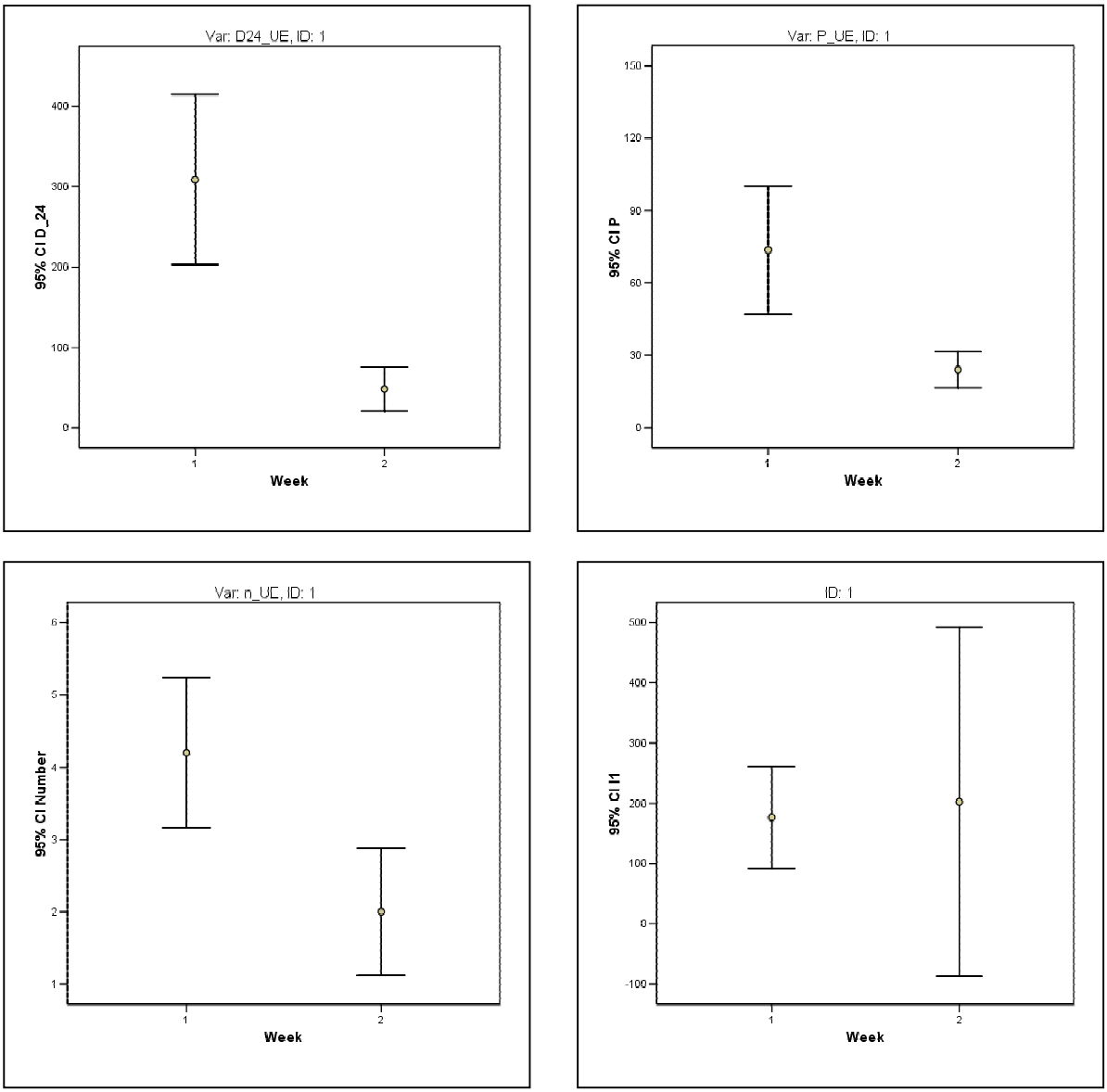

Fig.15: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

In the second week, compared to the first week after osteopathic treatment total duration of uneasiness as well as number and individual duration are significantly reduced (P: $t= 3.76$, $p<0.001$, D24: $t= 6.62$, $p<0.001$, n24: $t= 4.49$, $p=0.001$). The intervals between the individual periods of uneasiness on average remain quite similar, but the variability of the intervals increases (no significant difference).

Sleeping: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of sleeping characteristics are summarized in Table 7. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.18 and Fig.19).

Sleeping	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_SL	W1	504	226-782	388
		W2	612	236-988	526
Duration of individual periods	P_SL	W1	215	146-285	148
		W2	278	188-367	192
Number of periods	n_SL	W1	4	2-6	2
		W2	4	3-5	1
Intervals between periods	I1_SL-SL	W1	151	62-239	189
		W2	88	53-123	70
Time to fall asleep at night	D_FASL	W1	8.0	4.6-11.4	2.7
		W2	1.0	0*-2.2	1
Wake periods at night	n_WAKEN	W1	0	-	-
		W2	0	-	-

Table 7: Characteristics of sleeping periods of Mark André. Duration of all these periods in 24 hours (D24_SL), Duration of single periods (P_SL), number of periods of uneasiness in 24 hours (n_ SL) and intervals between individual periods (I1_ SL - SL), time to fall asleep at night (D_FASL) and wake periods at night (n_WAKEN) grouped by observation weeks.

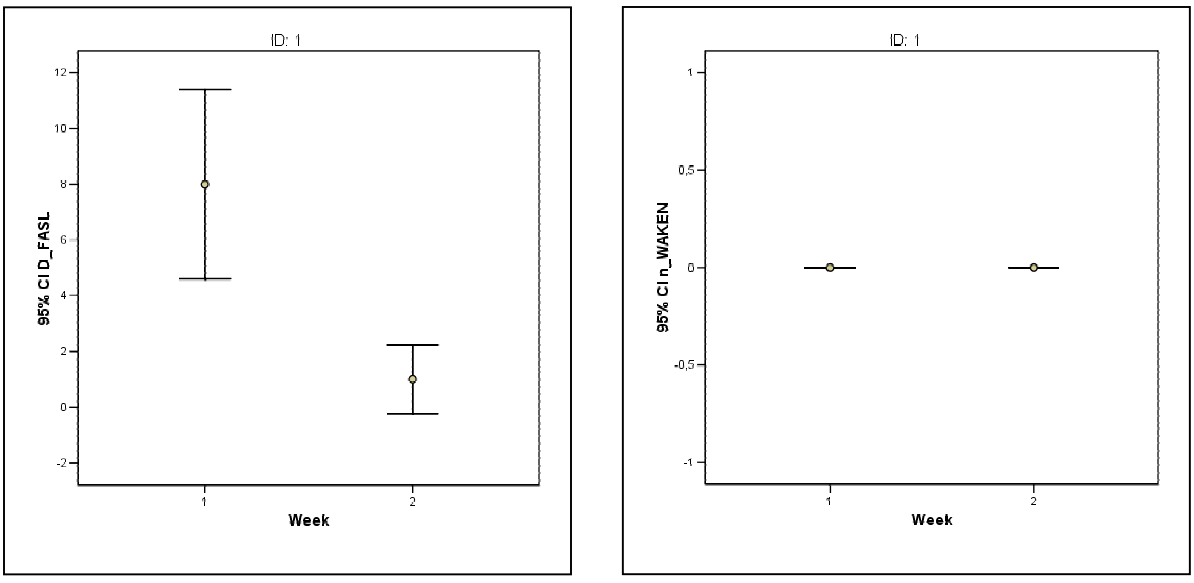

Fig.18: Left chart: Average duration of time needed to fall asleep at night (D_FASL, [min]) grouped by observation weeks (± 95%CI).

Right chart: Average number of wake times at night (n_WAKEN) grouped by observation weeks (± 95%CI).

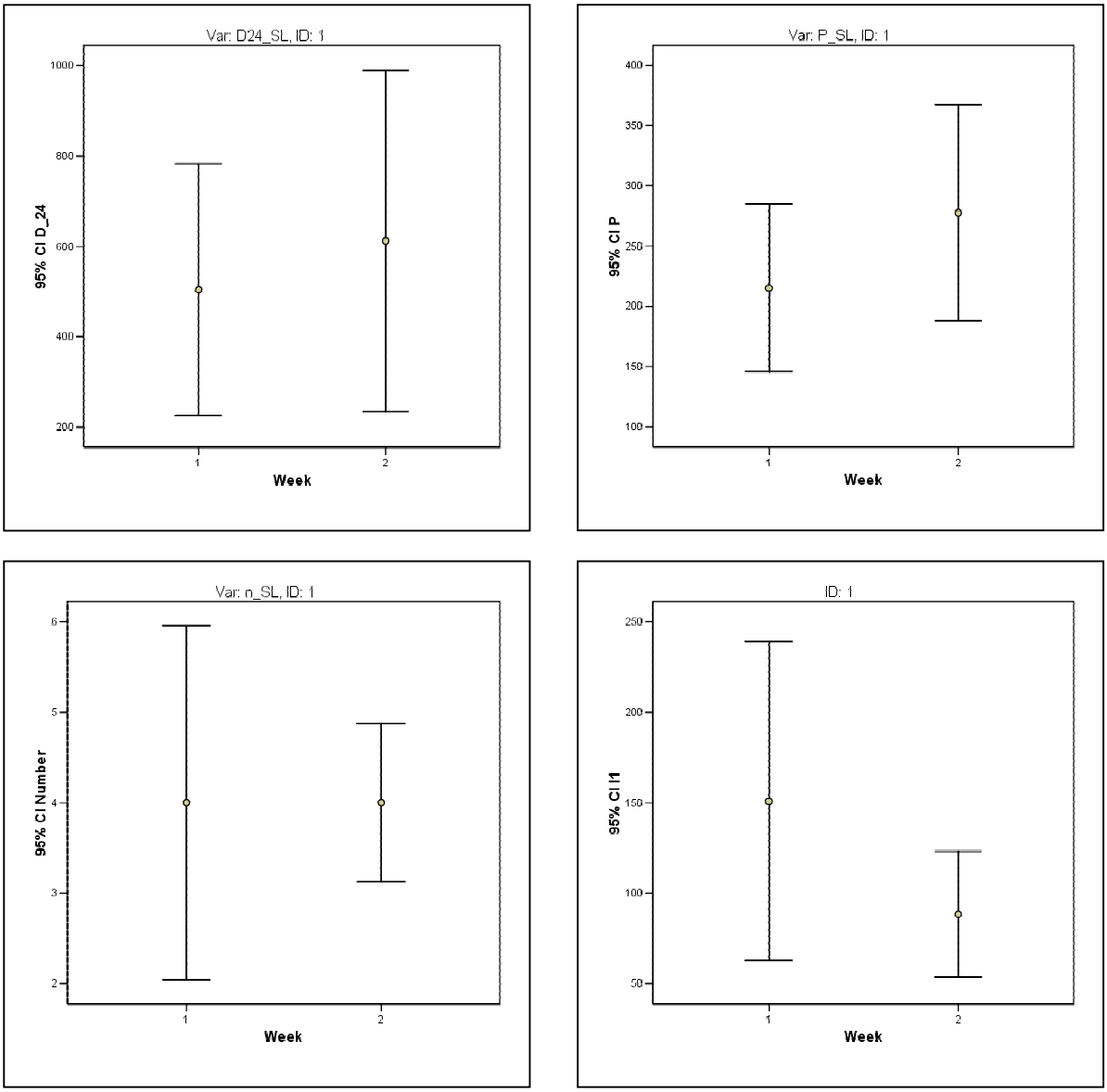

Fig.19: Upper left chart: Average duration of all periods of sleep in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single sleeping periods (P_SL, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of sleeping periods in 24 hours (06:00 - 06:00, n_SL) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between sleeping periods (I1_SL-UE, [min]) grouped by observation weeks (± 95%CI).

Time needed for falling asleep is significantly reduced (t=5.37, p=0.001).

An average increase of 21% in total sleeping time as well as of 29% in the individual periods can be observed in the second observation week compared to the first one. These changes are statistically not significant (D24: t=0.52, p=0.30, P: 1.15, p=0.13).

Sleeping periods are more regular with regard to the number and intervals. Differences in these concerns are not statistically significant.

Thus, significant improvements in crying and sleeping behaviour can be deduced.

5.1.2 Case 2: Julia H.

5.1.2.1 Initial Situation

Delivery: Julia H. was delivered by caesarean section 13 weeks before due date.
Crying: Crying periods four times a week started approximately three months after birth. Julia's parents did not answer the duration of these periods. According to them crying periods result from bad digestion and flatulence. During these periods her abdomen is distended and she presses until her face gets red. Predominantly, she cries between 11:00 a.m. and 2:00 p.m. and 5:00 to 8:00 p.m.
The parents state that they are stressed only a little by her crying.
Sleeping: There are no reported problems with sleeping.
Eating: There are no reported problems with eating.

5.1.2.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Julia cries most often between 11 a.m. and 2 p.m. and 5 a.m. and 11 p.m. In the second week no crying periods are reported. Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 8. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.20).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**missing**		
		W1	15	0*-41	21
		W2	-	-	-
Duration of individual periods	P_CR	W1	25.0	3.5-46.5	8.7
		W2	-	-	-
Number of periods	n_CR	W1	0.6	0*-1.7	0.9
		W2	0	-	-
Intervals between periods	I1_CR-CR	W1	-	-	-
		W2	-	-	-

Table 8: Characteristics of crying periods of Julia. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks. *Negative values are set zero.

Data for the time before treatment are missing. In the first observation week Julia on average cries 15 minutes, in the second observation week no crying periods are reported.

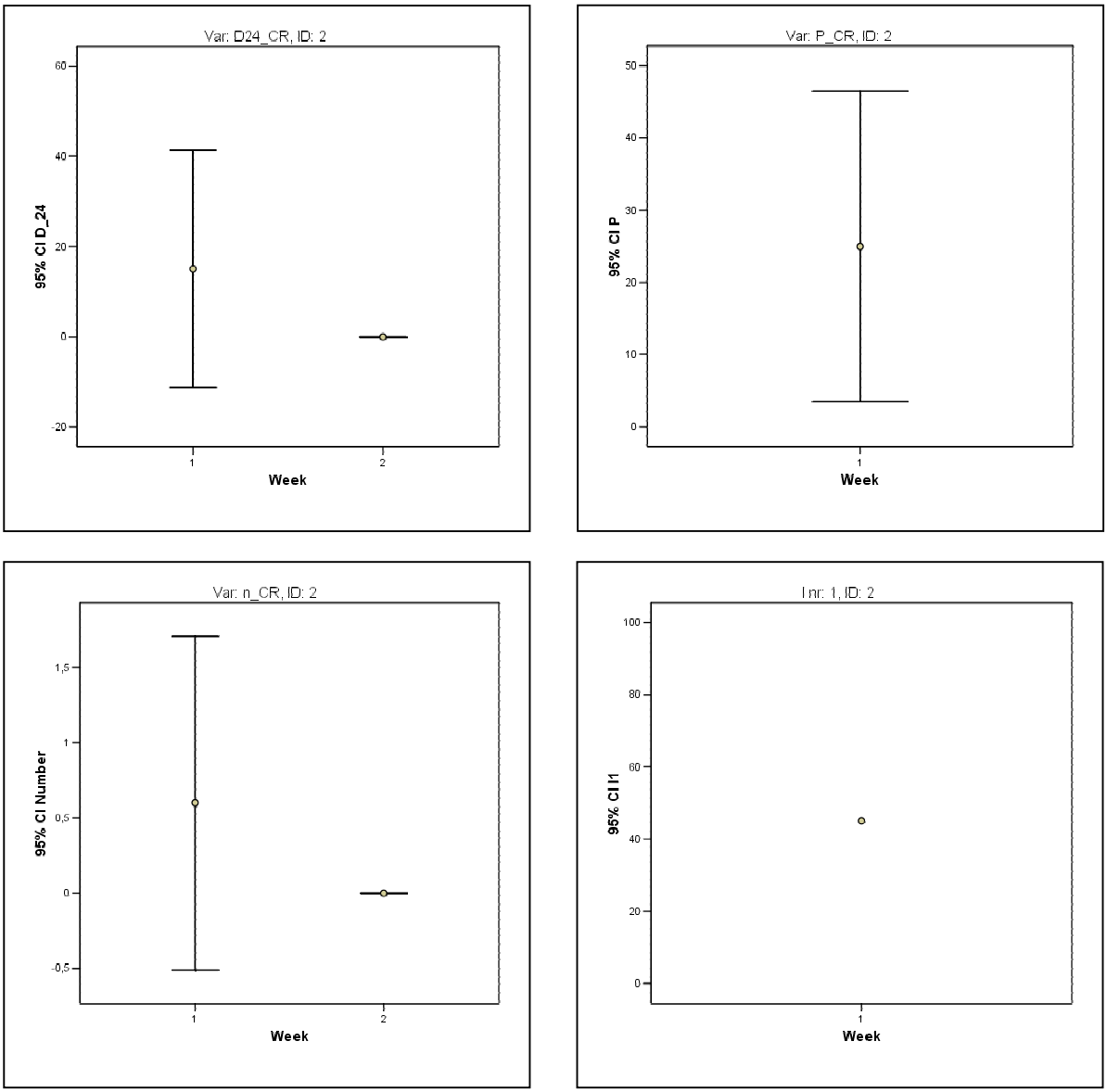

Fig.20: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

There are no reported crying periods in the second observation week. Additionally, due to missing data, changes in relation to the time before treatment can not be evaluated.

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or

whining, are summarized in Table 9. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.21).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	273	145-401	103
		W2	-	-	-
Duration of individual periods	P_UE	W1	59.3	38.3-80.4	48.6
		W2	-	-	-
Number of periods	n_UE	W1	4.6	1.2-8	2.7
		W2	-	-	-
Intervals between periods	I1_UE-UE	W1	108	52-164	109
		W2	-	-	-

Table 9: Characteristics of periods of uneasiness of Julia. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

In the first observation week, the periods of uneasiness are similar to the other cases (mean value: 246 min uneasiness per day). In the second week no such phases are reported.

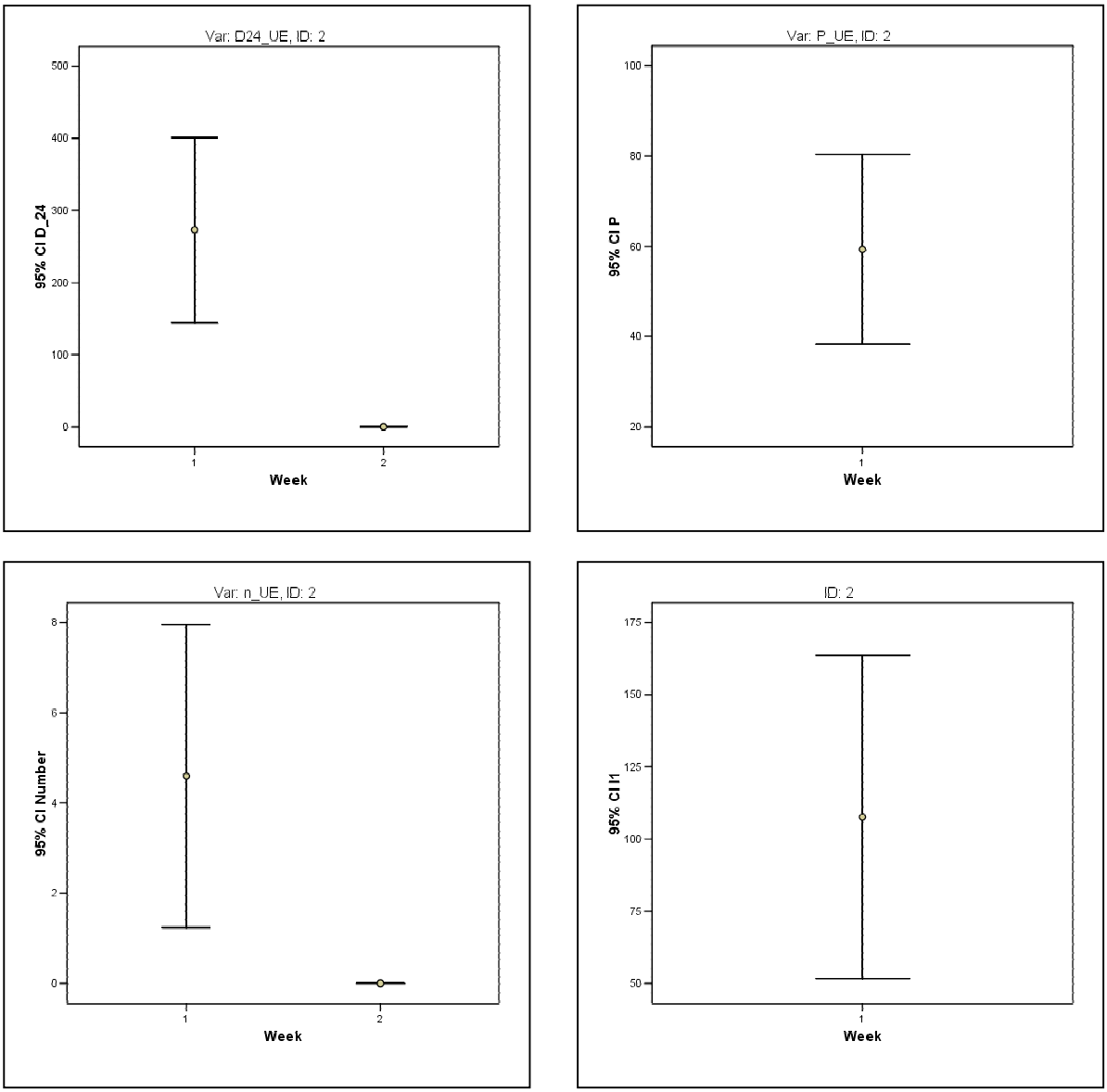

Fig.21: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

No statistics could be computed since no crying periods occurred in the second observation week.

Julias parents described the periods to happen four times a week. Thus, the observation period should have been long enough to encounter at least one day when Julia had these troubles. **Thus, a significant improvement of the initial problems can be deduced.**

5.1.3 Case 3: Matthias B.

5.1.3.1 Initial Situation

Delivery: Matthias B., the fraternal twin of Lukas B., was delivered by caesarean section nine weeks before due date.
Crying: Already since birth, Matthias B. has had crying periods lasting between two and three hours a day and occurring three or four days a week. The parents do not know any reason for his discomfort. During his extremely loud crying he has a high muscle tonicity. Predominantly, he cries between 5 a.m. and 8 a.m. and 5 p.m. and 8 p.m..
The parents state that they are heavily stressed by his crying.
Sleeping: Matthias B. normally sleeps in the bed of his parents. The parents are troubled only a little by this fact. According to them he needs more than 30 minutes for falling asleep, and sometimes he is awake in the night (less than three times) for more than 20 minutes. These problems arose some weeks before and occur more often than four times a week.
Eating: There are no reported problems with eating.

5.1.3.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Matthias cries most often between 11 a.m. and 2 p.m.. In the second week there are also some periods between 2:00 and 5:00 in the night. Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 10. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.22).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**120-180**		
		W1	120	0*-1073	106
		W2	6	0*-23	13
Duration of individual periods	P_CR	W1	26.7	12-42	19.5
		W2	30	-	-
Number of periods	n_CR	W1	4.5	0*-36.3	3.5
		W2	0.2	0*-0.8	0.4
Intervals between periods	I1_CR-CR	W1	201	105-297	104
		W2	-	-	-

Table 10: Characteristics of crying periods of Matthias. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks. *Negative values are set zero.

After a reduction in the first observation week of 120-180 minutes before treatment to 120 minutes on average, there is a distinct reduction of crying in the second observation week to 6 minutes on average. While the reduction is not significant in the first observation week (one sample t-test: t= 0.4 and p= 0.76), in the second observation week, on average, the infant cries 144 minutes less than before the first treatment (mean value 150 minutes). The one sample t-test results in t= 24.0 and p< 0.001.

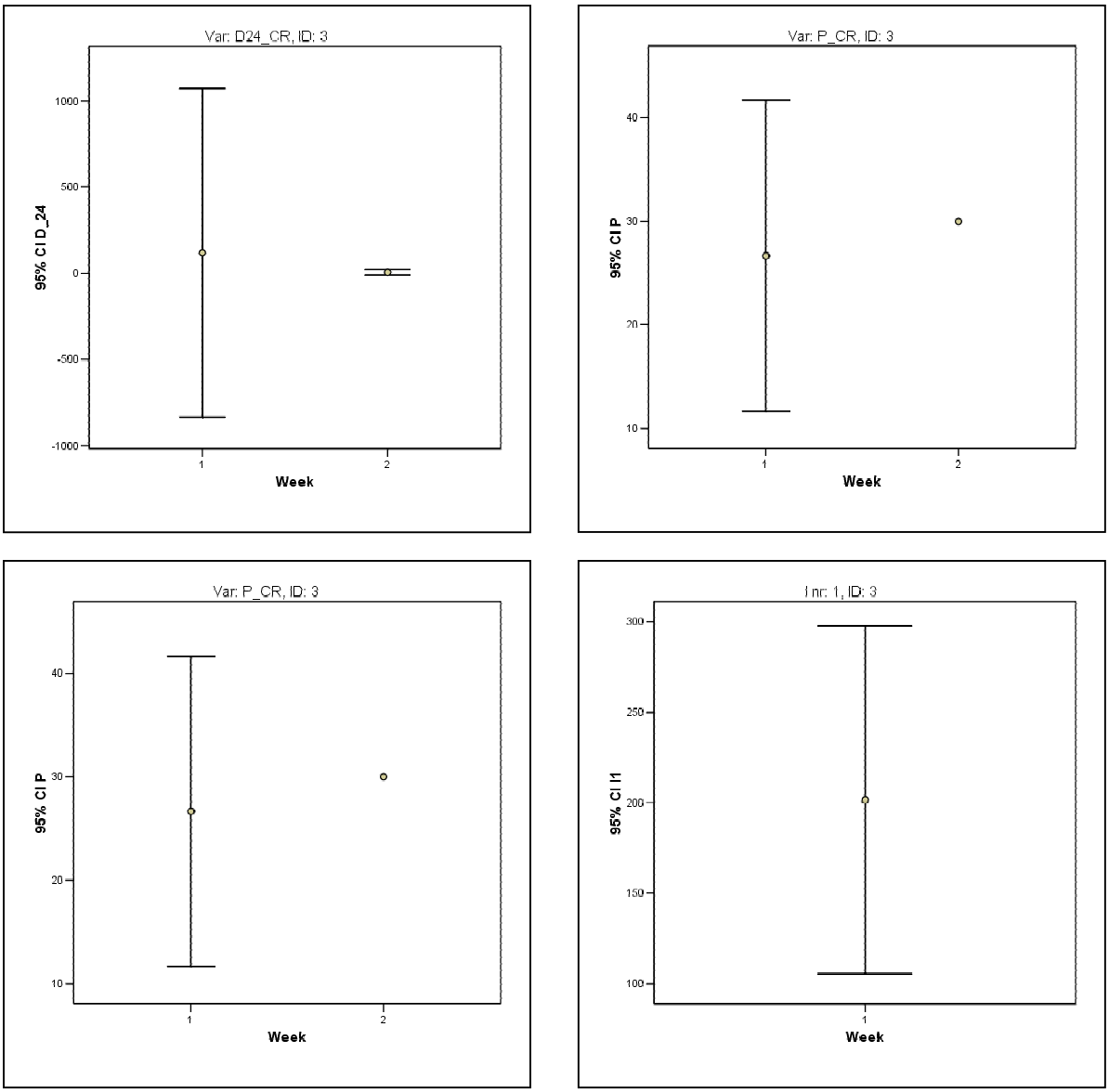

Fig.22: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

During the observation time crying periods are reduced in number and individual duration. Thus, total duration decreases. There is only maximum one crying period per day in the second observation week and only one day in the first observation week, when Matthias cried twice. Therefore, the lower right chart only shows one single interval.
Due to the high variability of data in the first observation week, t-tests result in no statistical significant differences of means (D24: t= 1.52, p= 0.18, P: t= 0.16, p= 0.44, n24: t= 1.71, p= 0.17, I1: not computed due to lack of data).

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 11. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.23).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	458	0*-1506	117
		W2	261	122-400	112
Duration of individual periods	P_UE	W1	61.0	30-93	56.8
		W2	46.6	33-61	36.4
Number of periods	n_UE	W1	7.5	0*-39	3.5
		W2	5.6	4-8	1.7
Intervals between periods	I1_UE-UE	W1	158	76-240	135
		W2	167	89-245	171

Table 11: Characteristics of periods of uneasiness of Matthias. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks. *Negative values are set zero.

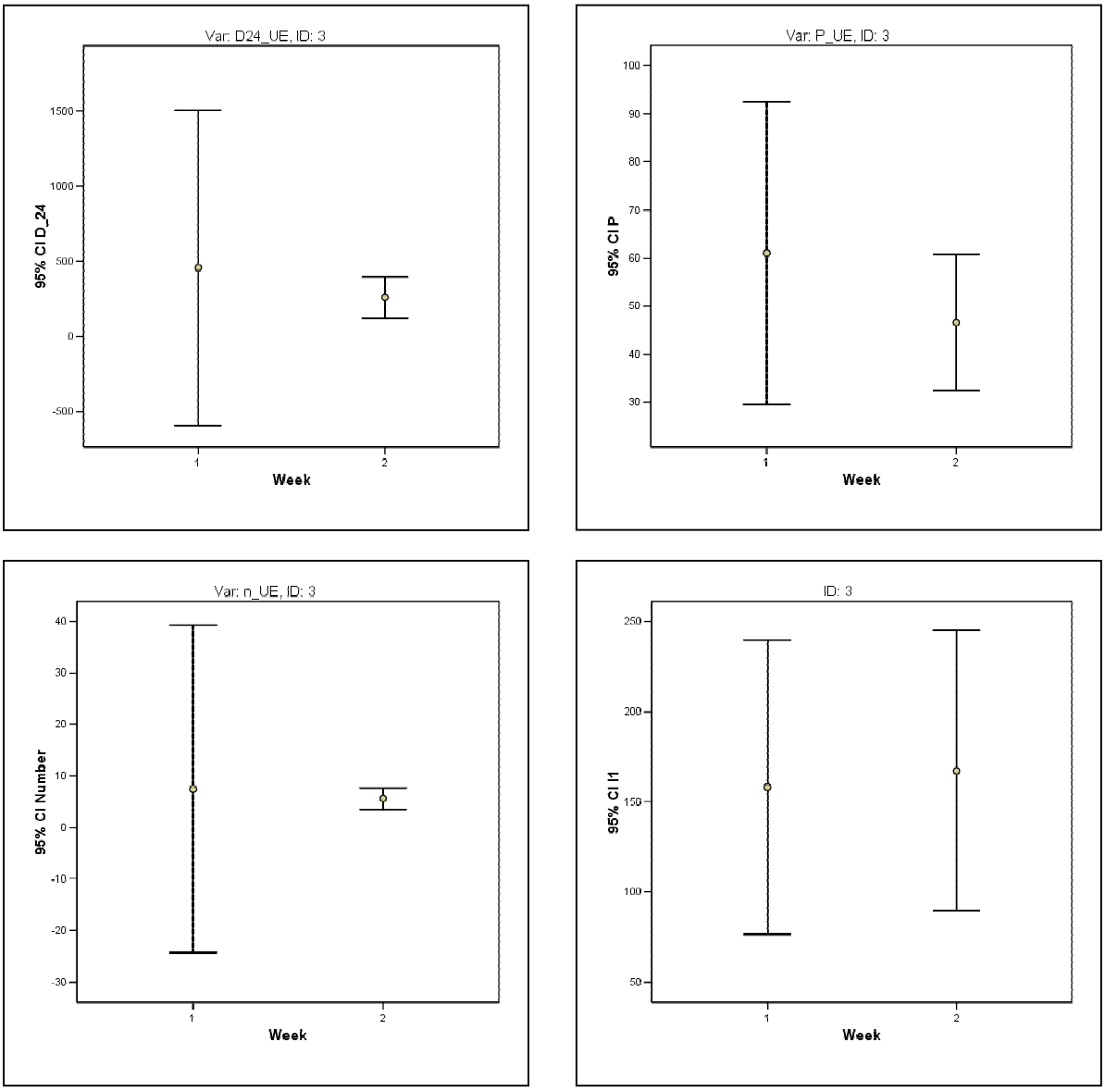

Fig.23: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

In the second week, compared to the first week after osteopathic treatment total duration of uneasiness is significantly reduced (t= 2.07, p= 0.046). The duration of the individual periods is not changed significantly (t=0.89, p= 0.19), neither is the number of daily periods of uneasiness (t=1.04, p= 0.17) and the interval between two individual crying periods (t= 0.16, p= 0.44).

Sleeping: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 12. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.26 and Fig.31).

Sleeping	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_SL	W1	435	0*-1050	387
		W2	475.5	199-752	387
Duration of individual periods	P_SL	W1	116.5	68-165	80.1
		W2	140.0	105-175	93.2
Number of periods	n_SL	W1	6.5	0.1-12.9	0.7
		W2	6	4.5-7.5	1.2
Intervals between periods	I1_SL-SL	W1	145	54-236	143
		W2	149	82-216	169
Time to fall asleep at night	D_FASL	W1	no data		
		W2	0	-	-
Wake periods at night	n_WAKEN	W1	no data		
		W2	2.3	1.5-3	0.5

Table 12: Characteristics of sleeping periods of Matthias. Duration of all these periods in 24 hours (D24_SL), Duration of single periods (P_SL), number of periods of uneasiness in 24 hours (n_ SL) and intervals between individual periods (I1_ SL - SL) grouped by observation weeks.

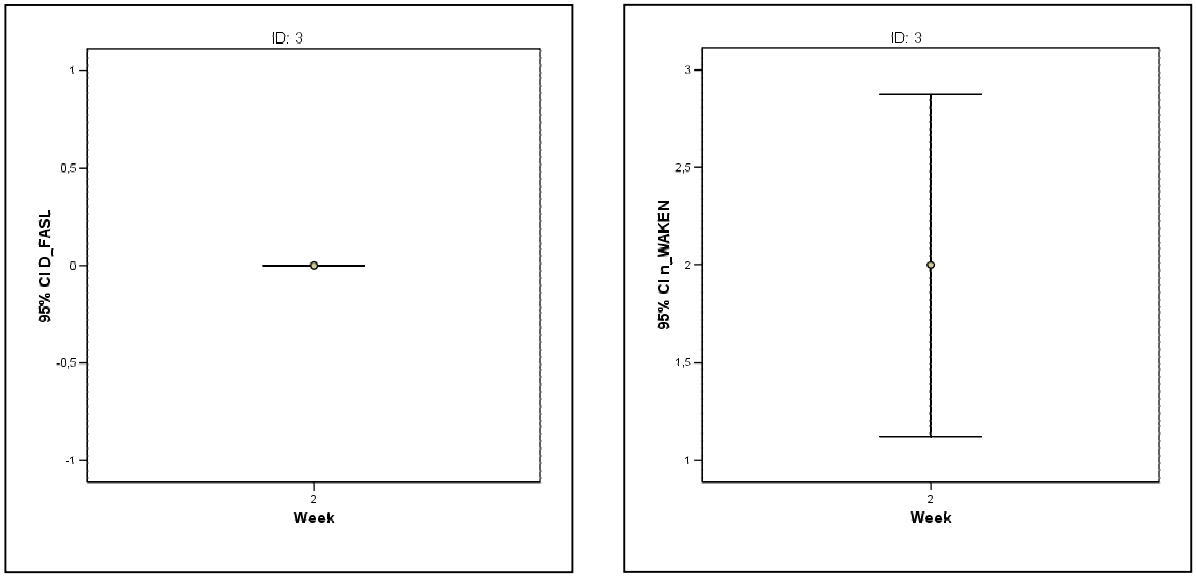

Fig.26: Left chart: Average duration of time needed to fall asleep at night (D_FASL, [min]) grouped by observation weeks (± 95%CI).

Right chart: Average number of wake times at night (n_WAKEN) grouped by observation weeks (± 95%CI).

There are no data for the first observation week. In the second observation week, Matthias falls asleep immediately. The problem with wake periods at night is unchanged.

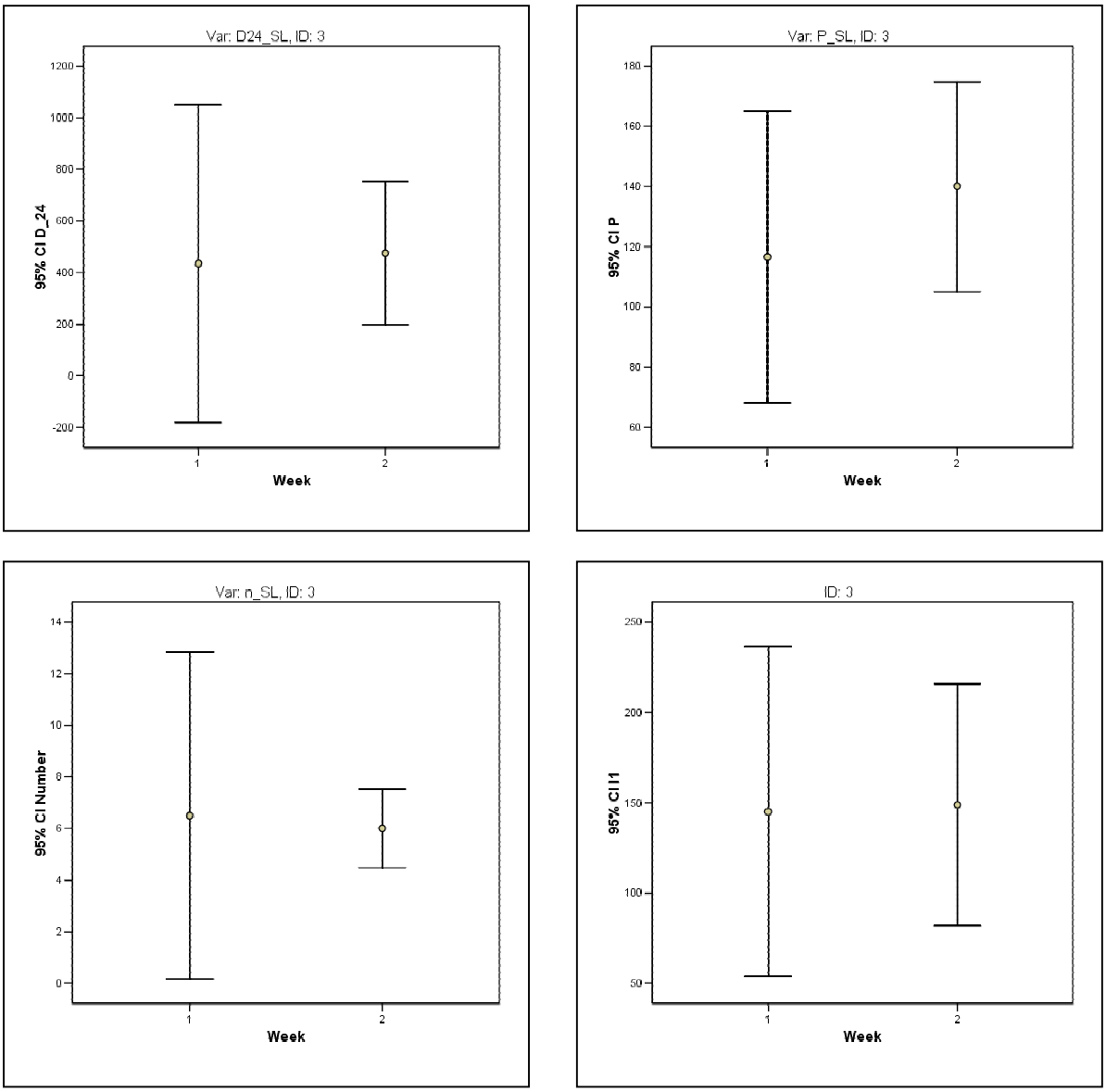

Fig.31: Upper left chart: Average duration of all periods of sleep in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single sleeping periods (P_SL, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of sleeping periods in 24 hours (06:00 - 06:00, n_SL) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between sleeping periods (I1_SL-UE, [min]) grouped by observation weeks (± 95%CI).

Variability of duration, number of and intervals between sleeping periods is reduced in the second observation period. Obviously, a more stable rhythm is established.

Intervals between sleeping periods are slightly shorter, and the individual sleeping periods as well as total sleeping time are longer. The differences are not statistically significant (D24: t= 0.18, p= 0.43, P: t= 0.79, p= 0.22, n24: t= 0.52, p=0.31, I1: 0.07, p= 0.47).

With regard to the initial situation, significant improvements concerning the duration of crying periods can be observed. Additionally, significant changes between the first and second observation week can be observed in the reduction of the total duration of uneasiness. The problem with wake periods at night is not solved at all.

5.1.4 Case 4: Lukas B.

5.1.4.1 Initial Situation

Delivery: Lukas B., the fraternal twin of Matthias B., was delivered by caesarean section nine weeks before due date.
Crying: Already since birth, Lukas B. has had crying periods lasting between two and three hours a day and occurring five days a week. The parents do not know any reason for his discomfort. During crying his face gets red. More complaints are not described. Predominantly, he cries between 11 a.m. and 2 p.m. and 5 p.m. and 8 p.m..
The parents state that they are heavily stressed by his crying.
Sleeping: There are no reported problems with sleeping.
Eating: There are no reported problems with eating.

5.1.4.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Lukas cries most often between 11 a.m. and 2 p.m (n=4). In the second week only one crying period could be observed. Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 13. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.32).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**90 - 180**		
		W1	75	0*-266	21
		W2	39	0*-88	39
Duration of individual periods	P_CR	W1	37.5	6.7-68.3	19.4
		W2	39.0	22.3-55.7	13.4
Number of periods	n_CR	W1	2	-	-
		W2	1	0.1-1.9	0.7
Intervals between periods	I1_CR-CR	W1	113	0*-589	53
		W2	150	-	-

Table 13: Characteristics of crying periods of Lukas. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks. *Negative values are set zero.

After a reduction in the first observation week of 90 - 180 minutes before treatment to 75 minutes on average, another reduction of crying takes place in the second observation week (mean value: 39 min). While the reduction is not significant in the first observation week (one

sample t-test: t= 4 and p= 0.156), in the second observation week, on average, the infant cries 96 minutes less than before the first treatment (mean value 135 minutes). The one sample t-test results in t= 5.488 and p= 0.005.

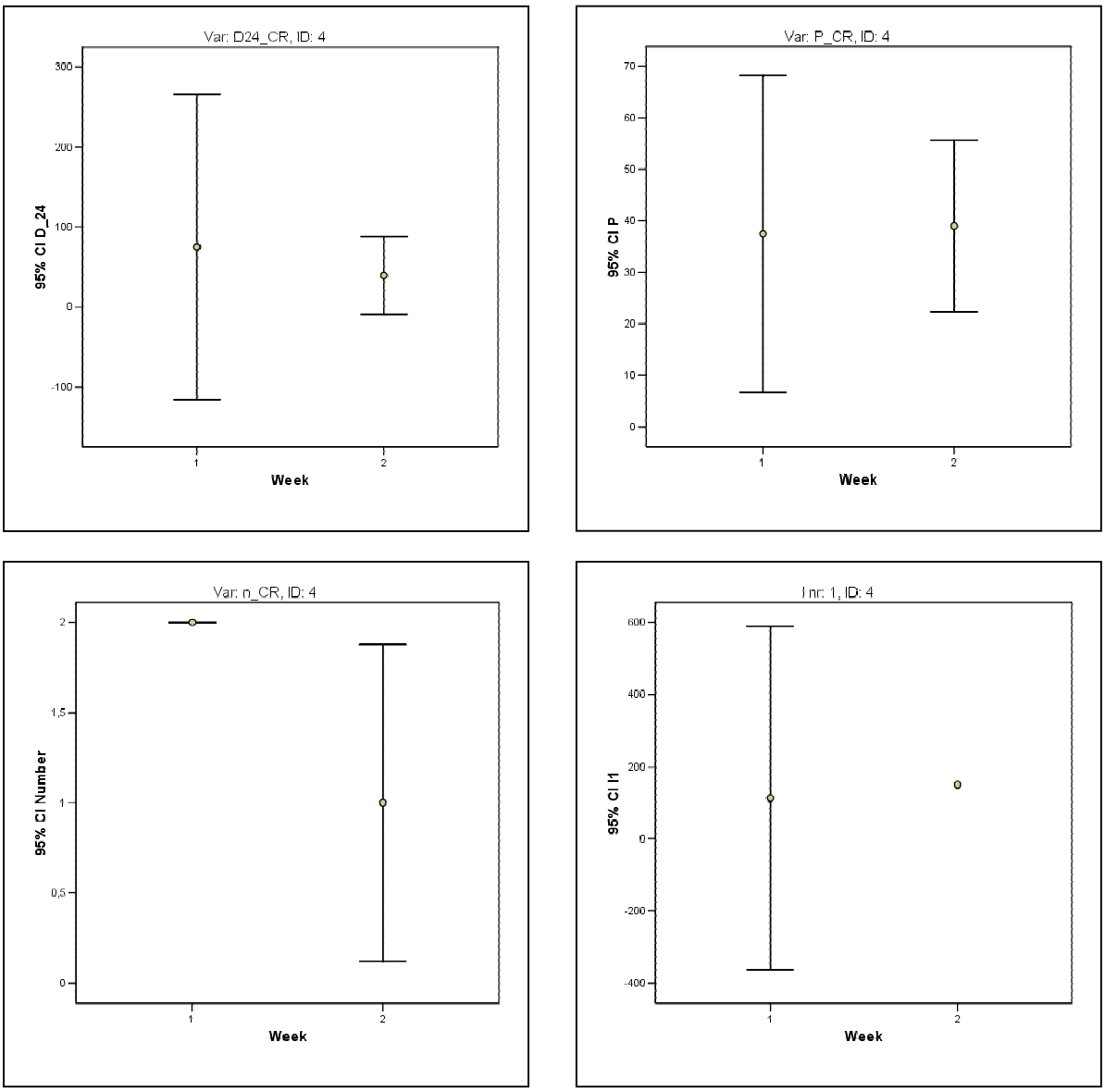

Fig.32: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

Beforehand, it has to be mentioned, that the journals were filled completely on only two days during the first observation week, and hence only the data of these days could be considered. During the observation time total duration of crying gets shorter. Every day of the first week Lukas cries twice. In the second week on average a decrease of the number of crying periods can be observed.

Total duration is reduced from 75 minutes to 39 minutes per day (t=1.18, p=0.14), but the individual phases are slightly longer (t= 0.14, p= 0.45). Neither significant is the reduction of the number and the increase of the interval between two crying periods.

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 14. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.33)

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	435	244-626	21
		W2	336	188-484	119
Duration of individual periods	P_UE	W1	62	36-88	45.1
		W2	44	32-56	35.9
Number of periods	n_UE	W1	7	-	-
		W2	7.6	6.2-9	1.1
Intervals between periods	I1_UE-UE	W1	132	9-256	184
		W2	128	94-162	91

Table 14: Characteristics of periods of uneasiness of Lukas. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

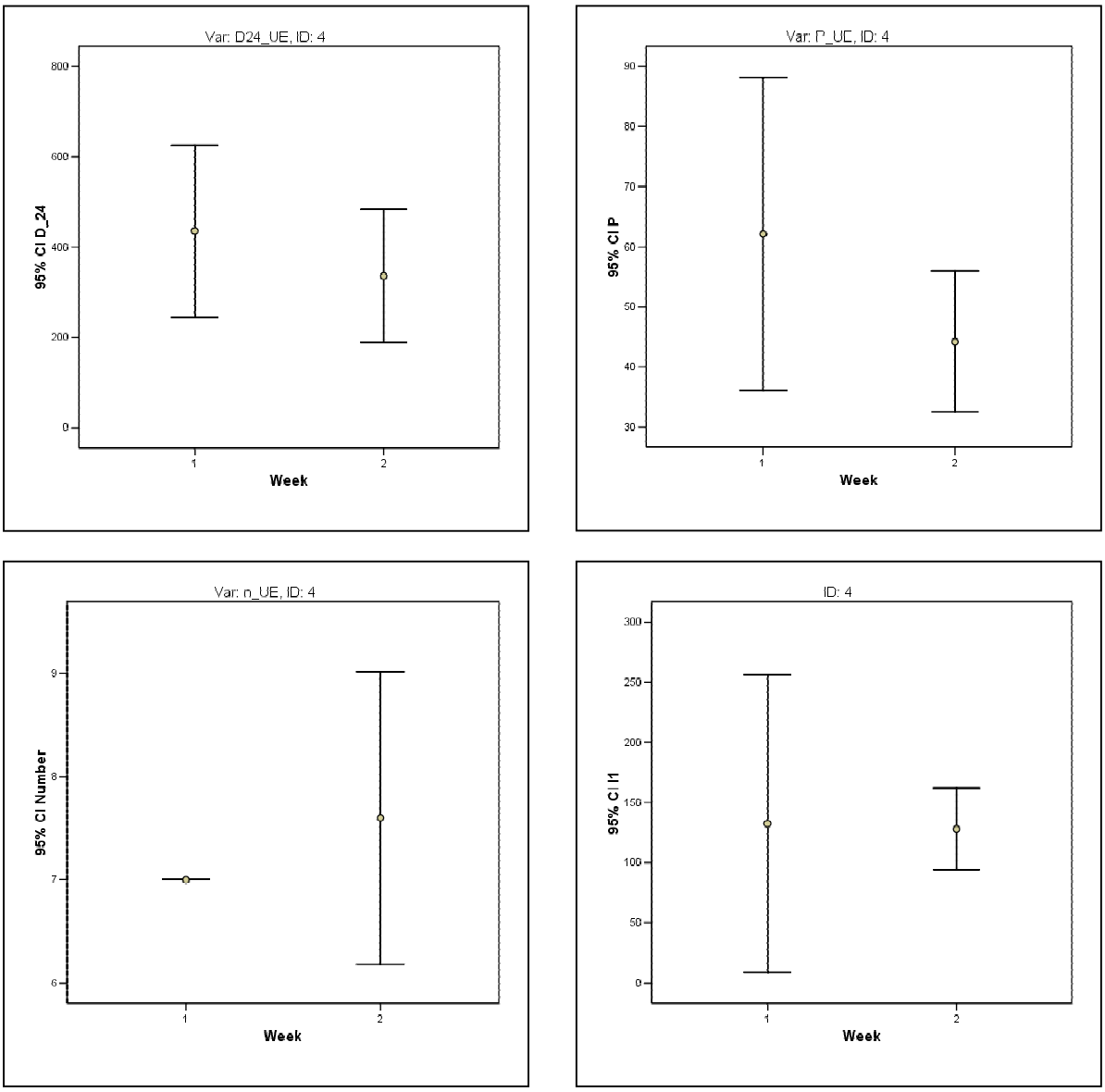

Fig.33: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

Periods of uneasiness occur more often in the second observation week, but are shorter in individual and total duration. Again, it has to be considered, that only data of two days of the first week could be used for evaluation, and again neither of the results is statistically significant (D24: t=1.79, p=0.07, P: t= 1.49, p= 0.07, n24: t=1.04, p=0.17 and I1: t= 0.07, p= 0.47).

There are no significant changes during the two observation periods, but crying is significantly reduced compared to the initial situation.

5.1.5 Case 5: Thomas U.

5.1.5.1 Initial Situation

Delivery: Thomas U. was delivered by caesarean section 11 weeks before due date.
Crying: Since his 6th week, Thomas U. has had crying periods lasting three hours a day and occurring five days a week. The parents think they are caused by tiredness because he has problems in falling asleep. During crying his face gets deep red, he sweats and his eyes are swollen. Predominantly, he cries between 11 a.m. and 8 p.m..
The parents state that they are heavily stressed by his crying.
Sleeping: Thomas U. normally sleeps in his own bed located in the sleeping room of his parents. According to them he needs help for falling asleep and he sometimes is awake in the night (less than three times and less than 20 minutes).
Eating: There are no reported problems with eating.

5.1.5.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Thomas cries most often between 11 a.m. and 2 p.m.. In the second week most crying periods are between 2 p.m. and 5 p.m.
Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 15. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.34).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**180**		
		W1	30	0*-70	32
		W2	105	32-178	59
Duration of individual periods	P_CR	W1	16.7	12.8-20.5	5
		W2	21.9	16.9-26.8	11.7
Number of periods	n_CR	W1	1.8	0*-4	1.8
		W2	4.8	1.5-8.1	2.7
Intervals between periods	I1_CR-CR	W1	133	0*-279	140
		W2	158	65-251	194

Table 15: Characteristics of crying periods of Thomas. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks. *Negative values are set zero.

After a reduction in the first observation week of 180 minutes before treatment to 30 minutes on average, crying periods are longer in the second observation week (mean value: 105 min). In the first observation week, the infant cries 150 minutes less than before the first treatment

(mean value: 180 minutes), on average. The one sample t-test results in t= 10.54 and p<0.001. In the second observation week, on average, the infant cries 75 minutes less than before the first treatment. The one sample t-test results in t= -2.84 and p= 0.047. That means, that crying behaviour is still significantly better than before treatment.

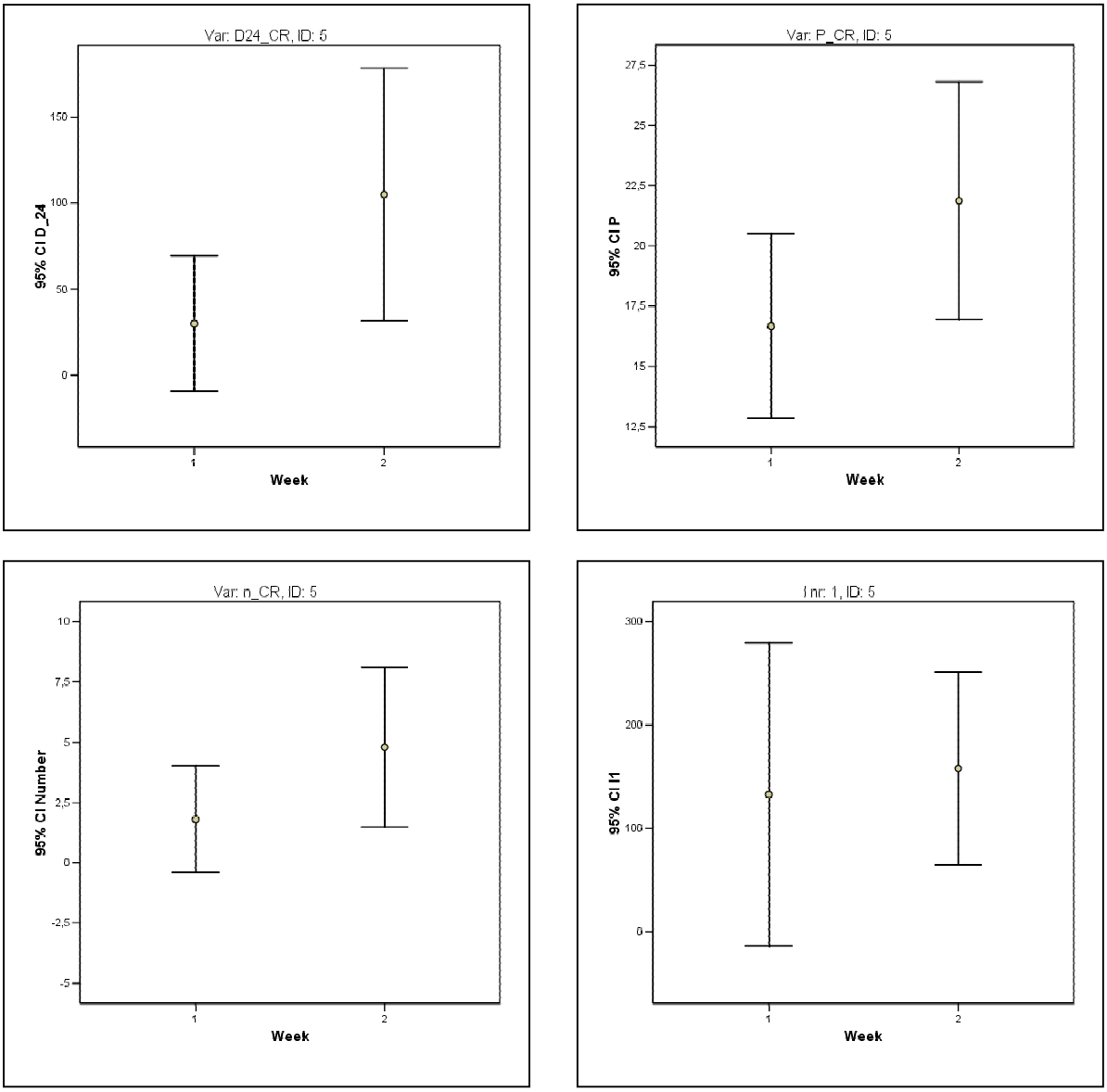

Fig.34: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

During the observation time a significant increase of the duration and number crying periods can be observed (D24: t= 2.5, p= 0.02, P: t= 1.79, p= 0.04, n24: t= 2.08, p=0.04). Additionally, the intervals between the crying phases increase, too (statistically not significant, t= 0.52, p= 0.39).

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 16. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.35).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	144	70-218	60
		W2	219	127-311	74
Duration of individual periods	P_UE	W1	21.8	17.6-26	11.9
		W2	21.5	18.6-24.3	10.1
Number of periods	n_UE	W1	6.6	2.2-11	3.5
		W2	10.2	6.3-14.1	3.1
Intervals between periods	I1_UE-UE	W1	99	60-137	100
		W2	80	50-109	99

Table 16: Characteristics of periods of uneasiness of Thomas. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

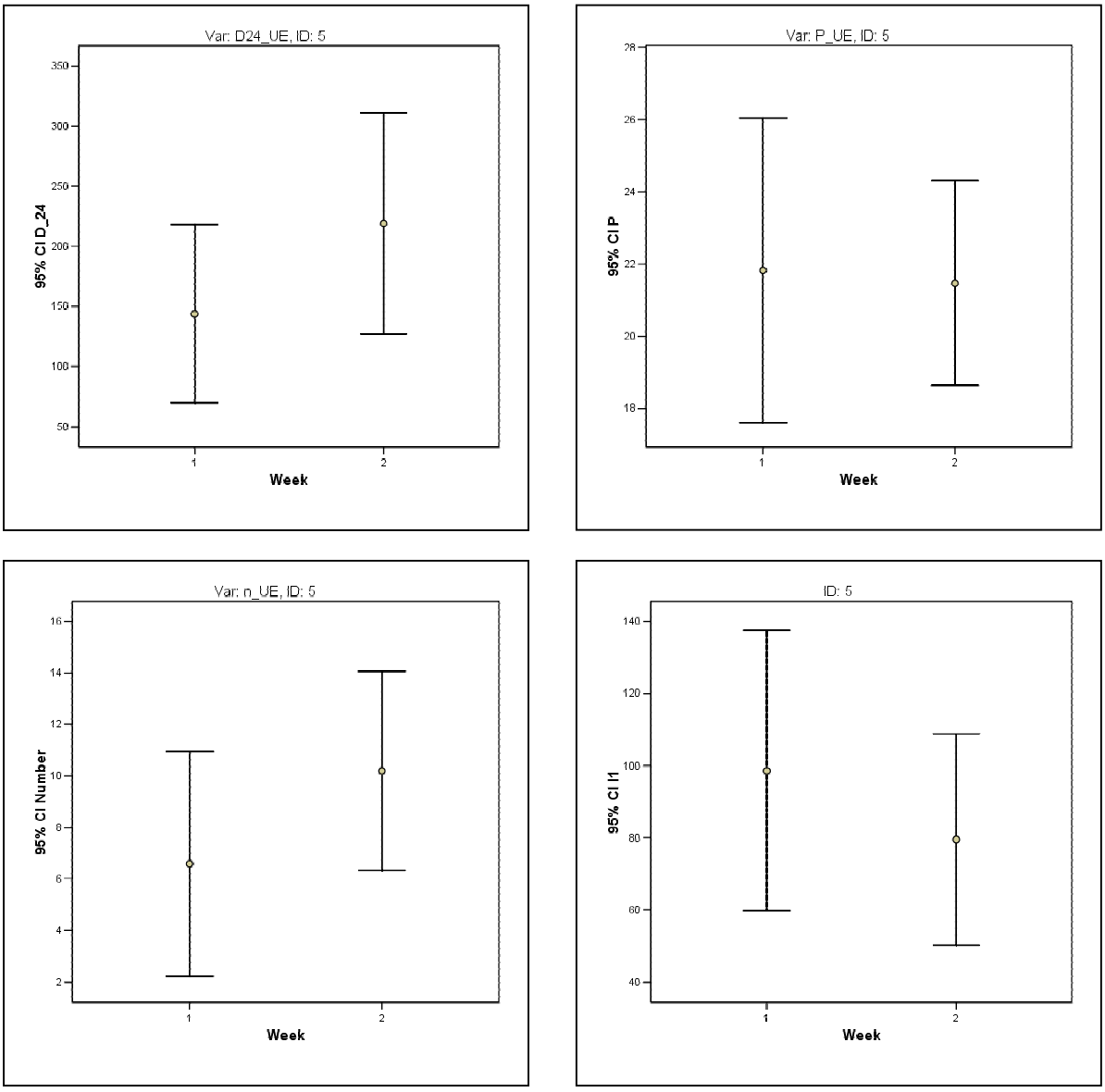

Fig.35: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

Increases of the durations of periods of uneasiness can be observed in Fig.35. Nevertheless, these differences are statistically not significant on the level of significance α=0.05 (D24: t= 0.80 , p= 0.21, P: t= 0.14 , p= 0.44, n24: t= 1.72 , p= 0.06, I1: t= 0.80 , p= 0.21).

Sleeping: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of sleeping periods are summarized in Table 17. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.36 and Fig.37).

Sleeping	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_SL	W1	466.5	215-718	351
		W2	439.5	216-663	313
Duration of individual periods	P_SL	W1	93	60-125	105.2
		W2	92	65-118	81.7
Number of periods	n_SL	W1	8.6	7.5-9.7	0.9
		W2	8	6.5-9.5	1.2
Intervals between periods	I1_SL-SL	W1	106	87-125	59
		W2	149	107-190	116
Time to fall asleep at night	D_FASL	W1	1.0	0*-3.8	2.2
		W2	0	-	-
Wake periods at night	n_WAKEN	W1	2.0	1.1-2.9	0.7
		W2	2.5	0.4-4.6	1.3

Table 17: Characteristics of sleeping periods of Thomas. Duration of all these periods in 24 hours (D24_SL), Duration of single periods (P_SL), number of periods of uneasiness in 24 hours (n_ SL) and intervals between individual periods (I1_ SL - SL) grouped by observation weeks.

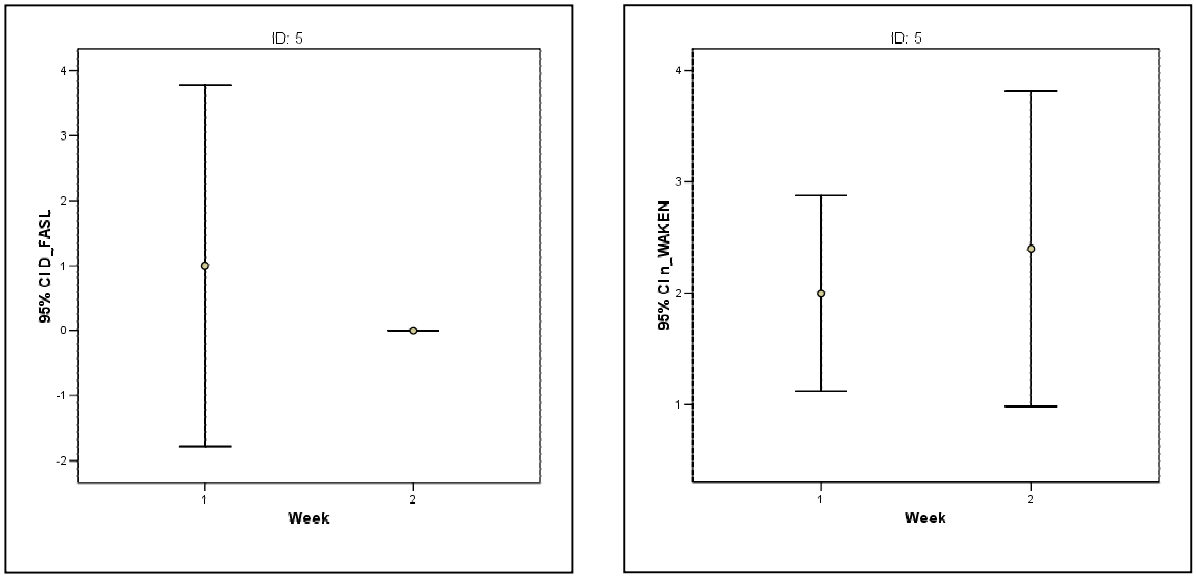

Fig.36: Left chart: Average duration of time needed to fall asleep at night (D_FASL, [min]) grouped by observation weeks (± 95%CI).

Right chart: Average number of wake times at night (n_WAKEN) grouped by observation weeks (± 95%CI).

Thomas falls asleep easier, but wakes up more often during the night.

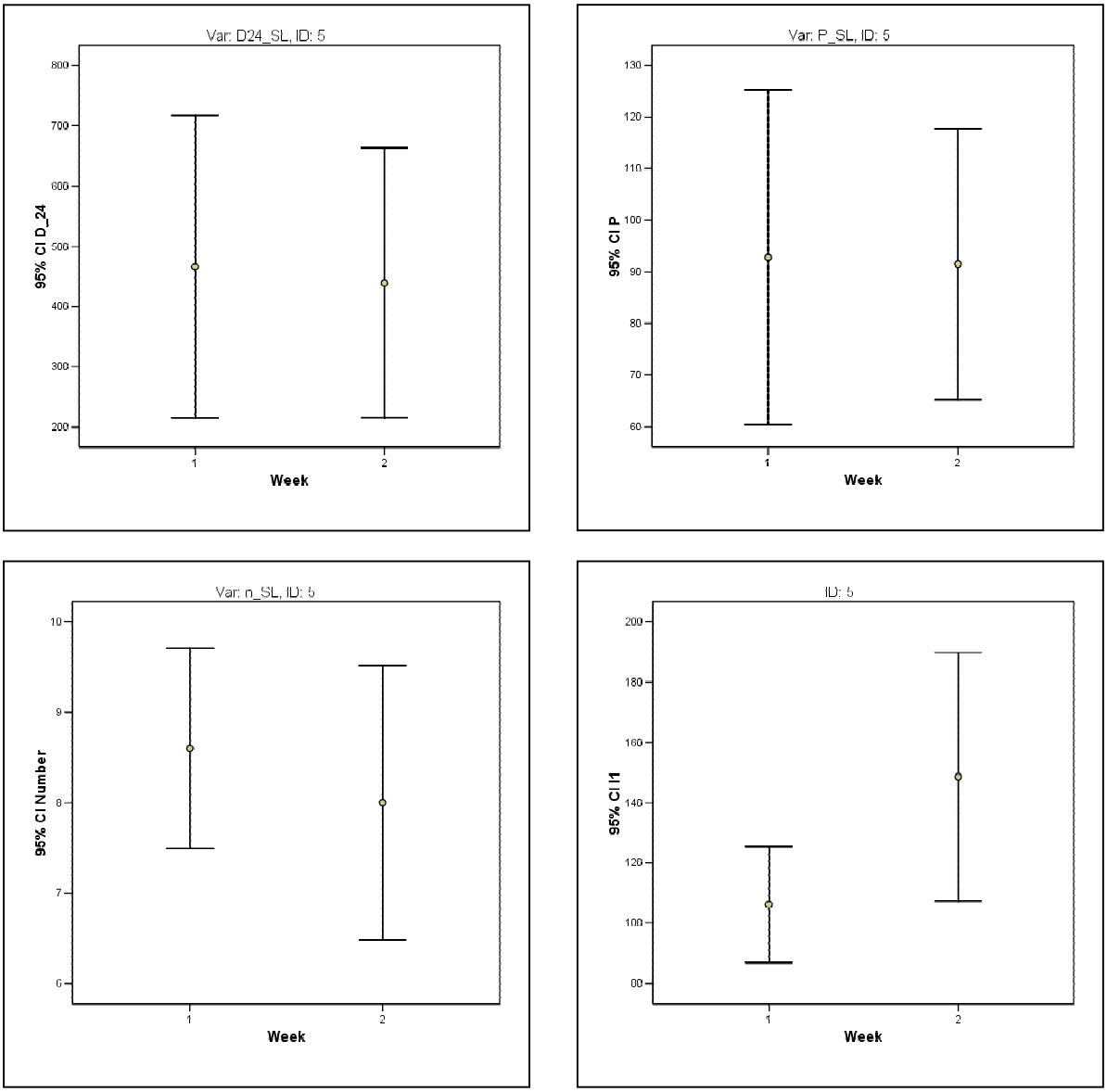

Fig.37: Upper left chart: Average duration of all periods of sleep in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single sleeping periods (P_SL, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of sleeping periods in 24 hours (06:00 - 06:00, n_SL) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between sleeping periods (I1_SL-UE, [min]) grouped by observation weeks (± 95%CI).

Daily total duration of sleep on average is reduced by 27 minutes per day (t= 0.18, p= 0.43, not significant), the individual periods by 1.3 minutes (t= 0.06, p= 0.48, not significant), the number of sleeping periods per day increases (t= 0.88, p= 0.20, not significant), and in contrary, intervals between sleeping phases increase significantly. (t= 1.90, p= 0.03)

After an initial improvement in the first observation week, both problems with crying and wake phases at night become more severe again in the second observation week. Nevertheless, Thomas still cries significantly less than before treatment.

5.1.6 Case 6: Leonard H.

5.1.6.1 Initial Situation

Delivery: Leonard H. was delivered by caesarean section eight weeks before due date.
Crying: Since his 6th week, Leonard H. has had crying periods lasting between three and four hours a day and occurring three to four days a week. The parents think they are caused by bad digestion and flatulence, but also boredom. During crying he stiffens, his face gets deep magenta and he loses voice. Predominantly, he cries between 11 a.m. and 2 p.m. and 5 p.m. and 8 p.m..
The parents state that they are massively stressed by his crying.
Sleeping: There are no reported problems with sleeping
Eating: There are no reported problems with eating.

5.1.6.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Leonard cries most often between 11 a.m. and 2 p.m. (n=6) and 5 a.m. and 8 p.m (n=6). In the second week no predominant periods can be observed.
Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 18. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.38).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**180-240**		
		W1	282	75-489	167
		W2	-	-	-
Duration of individual periods	P_CR	W1	64.1	40-88	54.8
		W2	-	-	-
Number of periods	n_CR	W1	4.4	3-5.8	1.1
		W2	-	-	-
Intervals between periods	I1_CR-CR	W1	125	65-185	117
		W2	-	-	-

Table 18: Characteristics of crying periods of Leonard. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks.

In the first week after osteopathic treatment, average duration of crying periods is even 72 minutes longer than the duration reported before treatment (mean value: 210 minutes, one sample t-test: t= 1.367 and p= 0.243). In the second observation week Leonard did not cry remarkably long. The one sample t-test could not be computed because the standard deviation is 0.

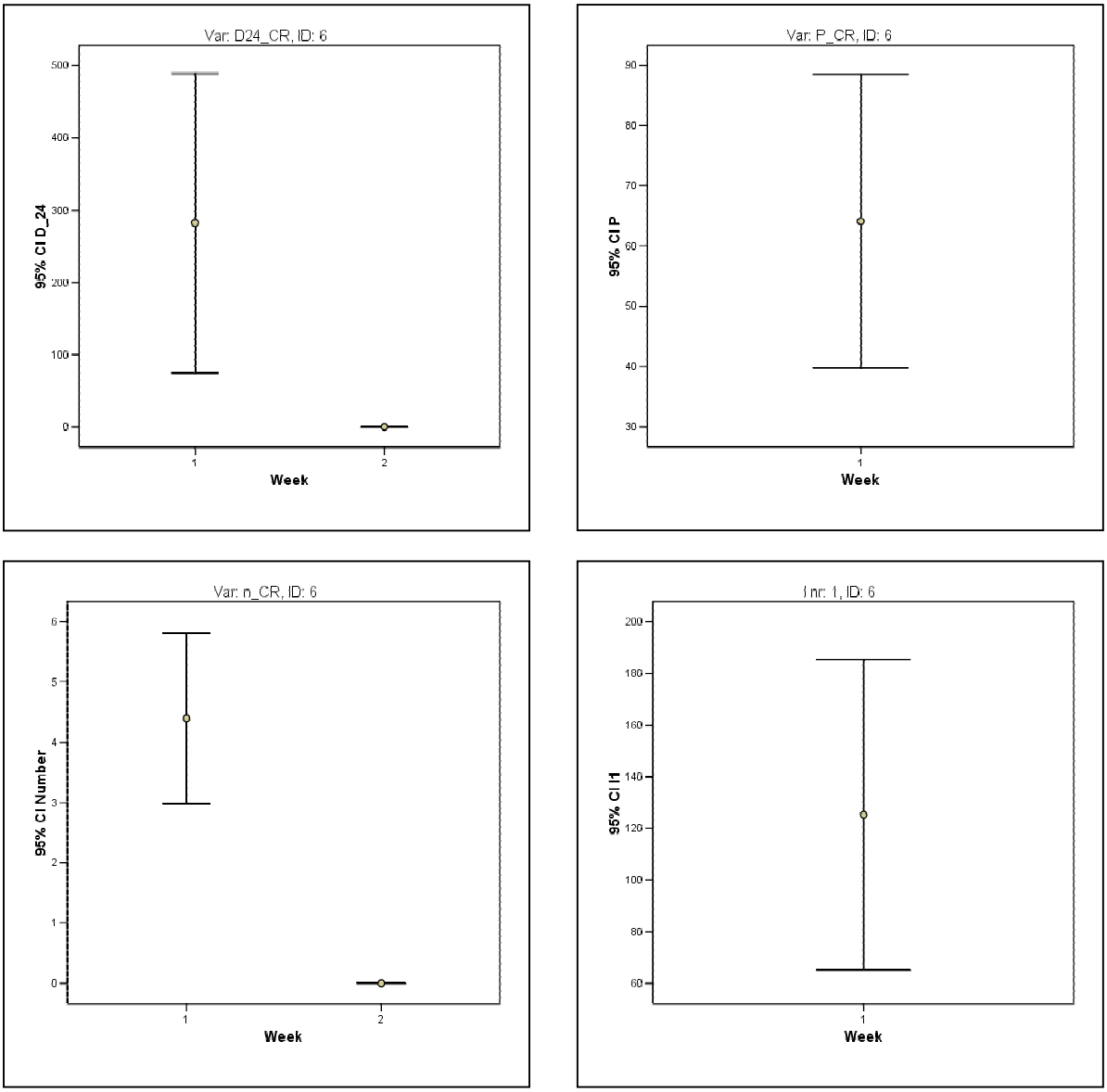

Fig.38: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

Leonard did not cry during the second observation week. Thus statistics for intervals and individual crying periods could not be computed. Significant changes could be calculated for D24 ($t= 3.78$, $p= 0.009$) and n24 ($t= 8.63$, $p<0.001$).

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 19. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.39).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	360	202-518	127
		W2	36	19-53	13
Duration of individual periods	P_UE	W1	43.9	29.4-58.4	45.9
		W2	15	-	-
Number of periods	n_UE	W1	8.2	5-11.4	2.6
		W2	2.4	1.3-3.5	0.9
Intervals between periods	I1_UE-UE	W1	97	67-126	84
		W2	300	242-358	63

Table 19: Characteristics of periods of uneasiness of Leonard. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

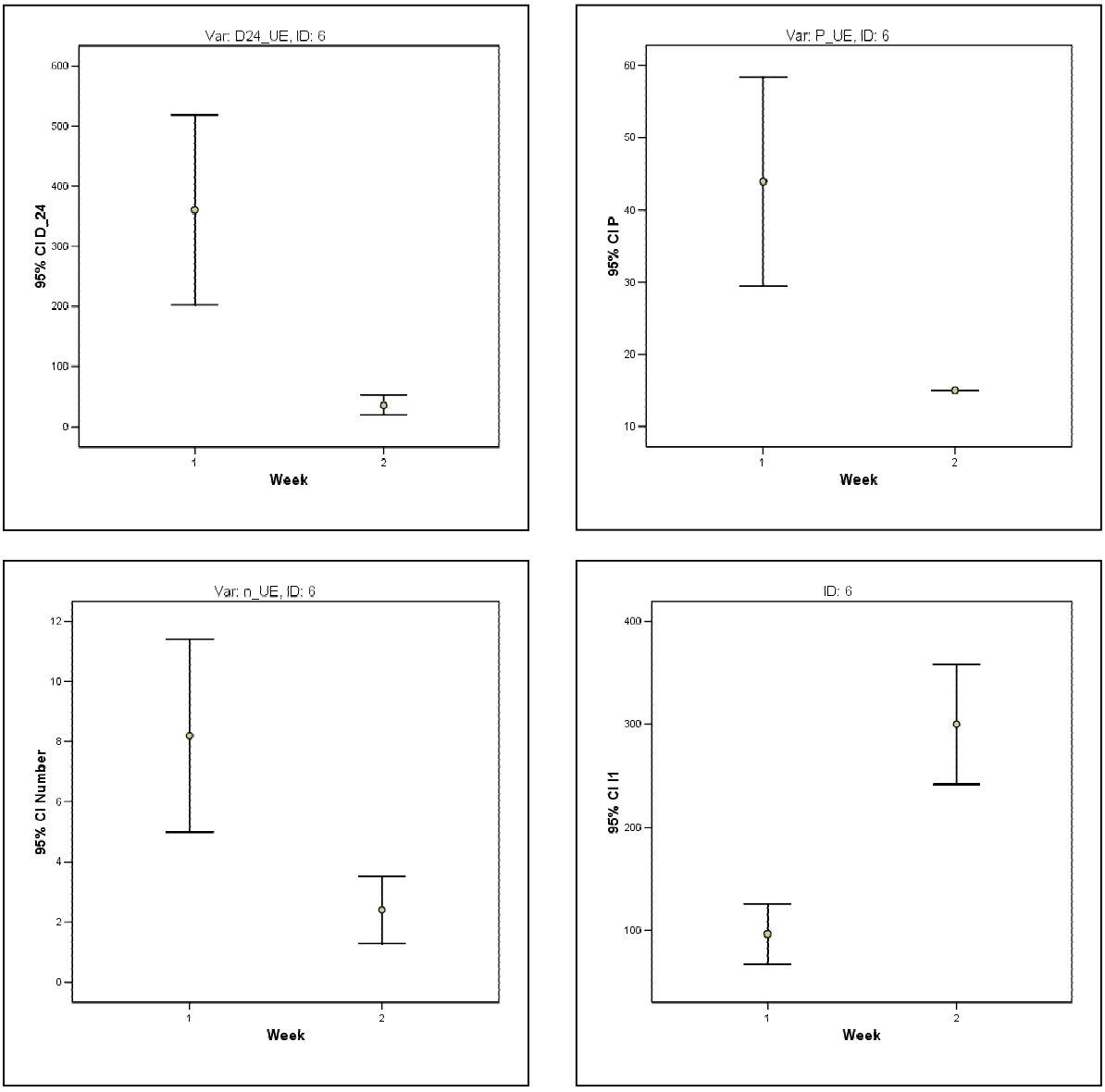

Fig.39: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

In the second observation period, total duration of uneasiness as well as number and individual duration are significantly reduced compared to the first week after osteopathic treatment (D24: t= 5.66, p= 0.002, n24: t= 4.74, p= 0.003, P: t= 4.03, p<0.001). Additionally variability decreases. Intervals between the individual periods of uneasiness are longer in the second observation week compared to the first one (t= 6.02, p<0.001).

Significant improvements could be gained in the crying behavior of Leonard H.

5.1.7 Case 7: Anna H.

5.1.7.1 Initial Situation

Delivery: Anna H. was delivered by caesarean section 13 weeks before due date.
Crying: Anna H. cries between three to four days a week without known reason. The parents did not answer the question concerning the average duration of crying periods per day. Predominantly, she cries between 11 a.m. and 2 p.m. and 5 p.m. and 8 p.m.. The parents state that they are heavily stressed by her crying.
Sleeping: Anna H. sleeps in her own bed located in the sleeping room of her parents but also in their bed. In these cases they feel disturbed only to a little extent. According to them less than four times a week she has sleeping problems. Then she either needs longer than 30 minutes to fall asleep and/or she sometimes is awake in the night (less than three times and less than 20 minutes).
Eating: There are no reported problems with eating, but compared to other children at a similar age, intervals between feeding times are longer (five hours).

5.1.7.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Anna cries most often between 5 a.m. and 8 a.m. In the second week she cries most often between 5 and 8 p.m..
Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 20. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.40).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**missing**		
		W1	63	39-87	20
		W2	42	0*-84	34
Duration of individual periods	P_CR	W1	26.3	14.7-37.8	18.2
		W2	23.3	17.3-29.4	7.9
Number of periods	n_CR	W1	2.4	1.3-3.5	0.9
		W2	1.8	0.2-3.4	1.3
Intervals between periods	I1_CR-CR	W1	302	74-531	247
		W2	195	0*-450	206

Table 20: Characteristics of crying periods of Anna. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks.

On average, crying periods are approximately one third shorter in the second week.

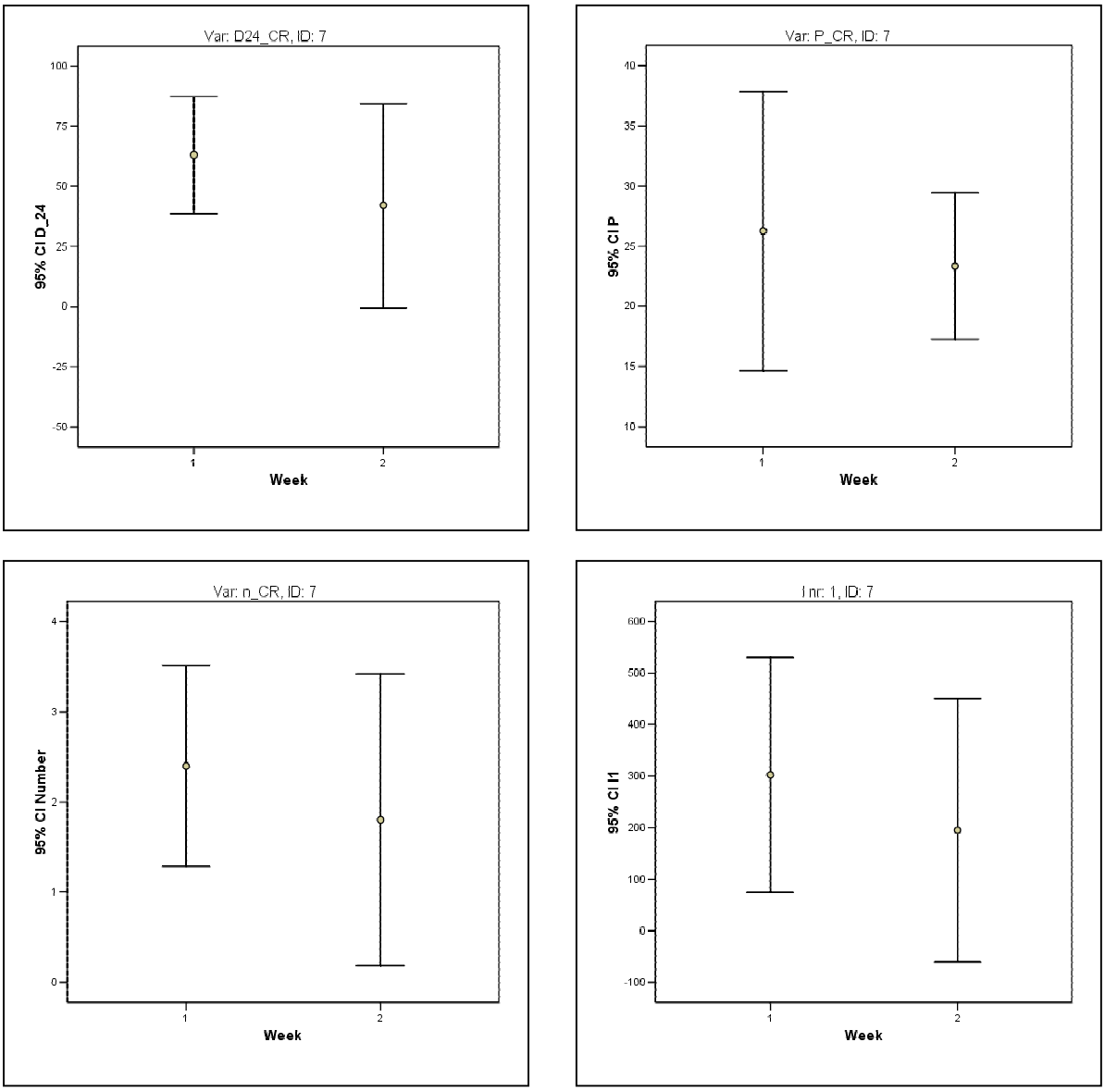

Fig.40: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

During the observation time crying periods are reduced in number and individual duration. Thus, total duration decreases. The intervals between crying periods get shorter, too. Nevertheless, differences are not statistically significant (D24: t= 1.19, p= 0.13, n24: t= 0.85, p=0.21, P: t= 0.45, p= 0.33, I1: 0.66, p= 0.22).

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 21. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.41).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	120	66-174	44
		W2	174	64-284	88
Duration of individual periods	P_UE	W1	30.0	17.7-42.3	26.2
		W2	27.2	18.8-35.6	23.3
Number of periods	n_UE	W1	4	1.8-6.2	1.7
		W2	6.4	3-9.8	2.7
Intervals between periods	I1_UE-UE	W1	198	54-341	225
		W2	80	39-120	101

Table 21: Characteristics of periods of uneasiness of Anna. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

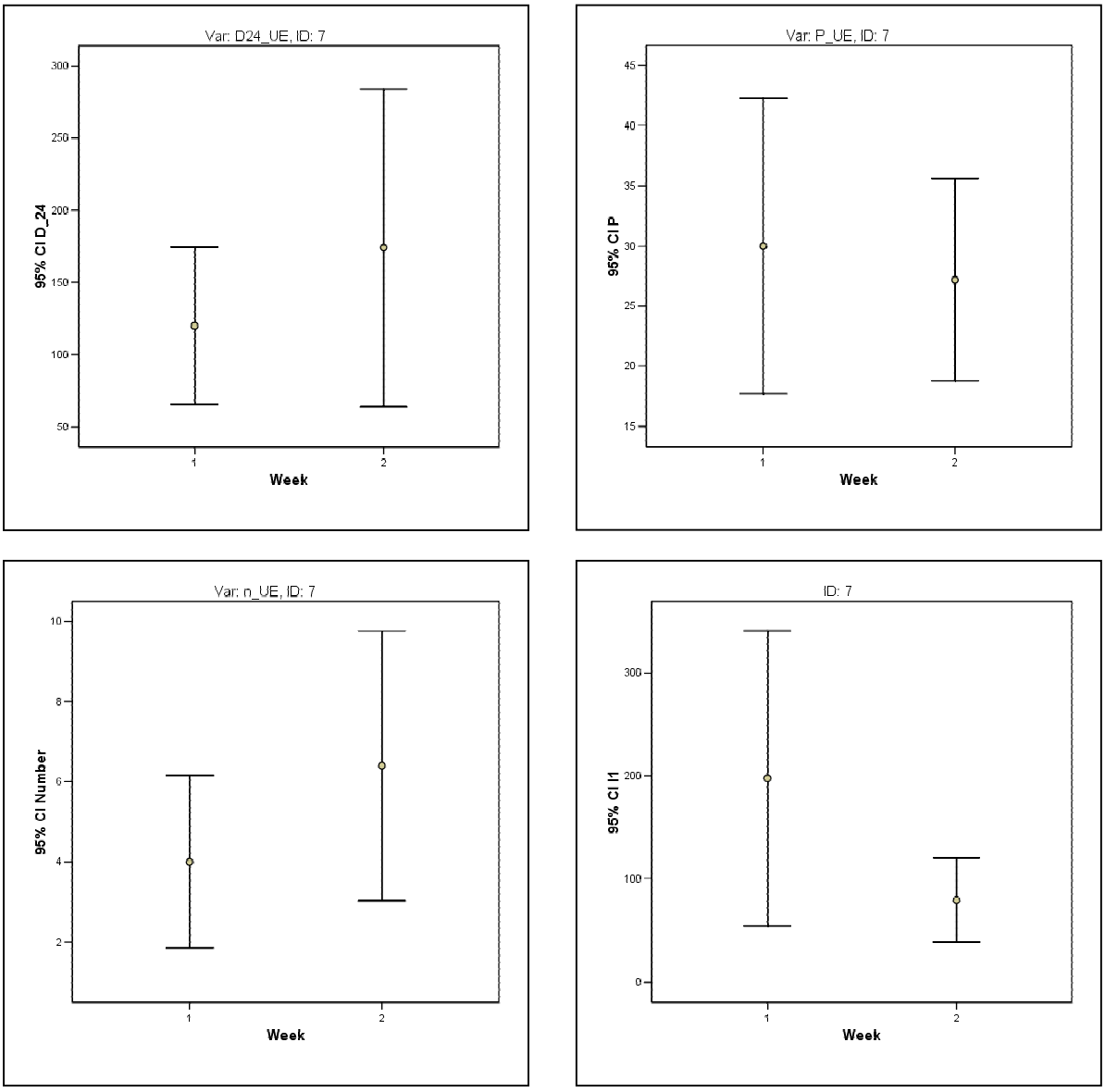

Fig.41: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

Contrary to crying, periods of uneasiness are more frequent in the second observation week. The duration of the individual periods decreases slightly, but in total Anna spends more time with whining and crying per day and the intervals are shorter in the second week. The results of the t-tests show no significant but distinct differences: D24: t= 1.22, p= 0.13, n24: t= 1.67, p=0.07, P: t= 0.4, p= 0.34, I1: 1.74, p= 0.053).

Sleeping: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of sleeping periods are summarized in Table 22. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.42 and Fig.43).

Sleeping	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_SL	W1	481.5	204-759	388
		W2	463.5	218-709	344
Duration of individual periods	P_SL	W1	126	5-158	90
		W2	123	84-162	108
Number of periods	n_SL	W1	6.6	5.2-8	1.1
		W2	6.4	5.3-7.5	0.9
Intervals between periods	I1_SL-SL	W1	128	83-174	120
		W2	149	102-196	124

Table 22: Characteristics of sleeping periods of Anna. Duration of all these periods in 24 hours (D24_SL), Duration of single periods (P_SL), number of periods of uneasiness in 24 hours (n_ SL) and intervals between individual periods (I1_ SL - SL) grouped by observation weeks.

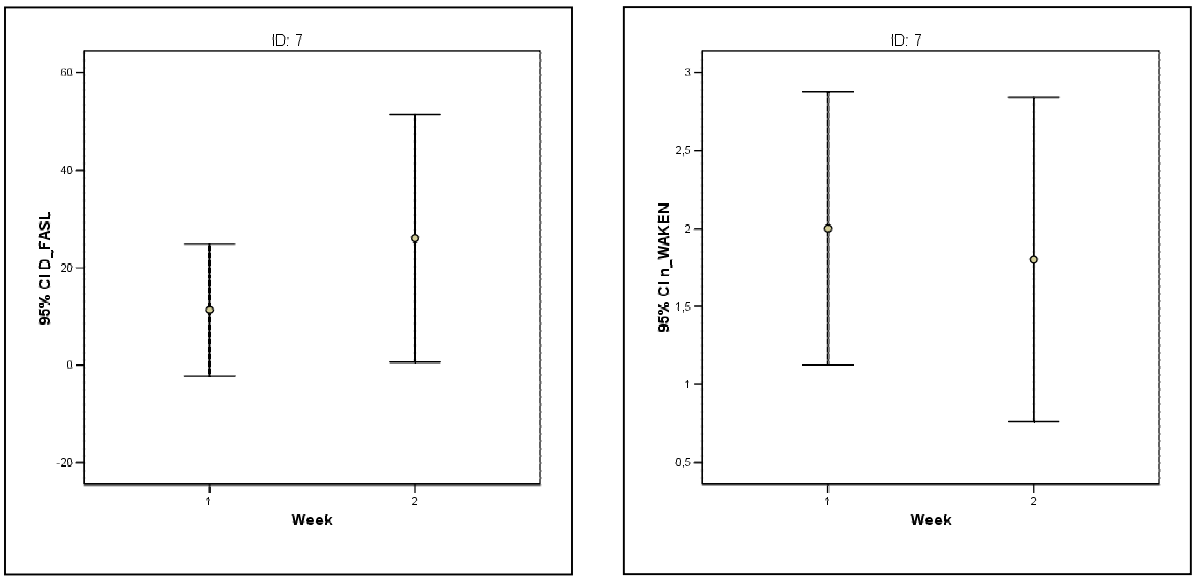

Fig.42: Left chart: Average duration of time needed to fall asleep at night (D_FASL, [min]) grouped by observation weeks (± 95%CI).

Right chart: Average number of wake times at night (n_WAKEN) grouped by observation weeks (± 95%CI).

On average, time needed to fall asleep is shorter in the first week after treatment than before treatment, but again gets longer in the second week. The number of wake periods during night decreases in the second week.

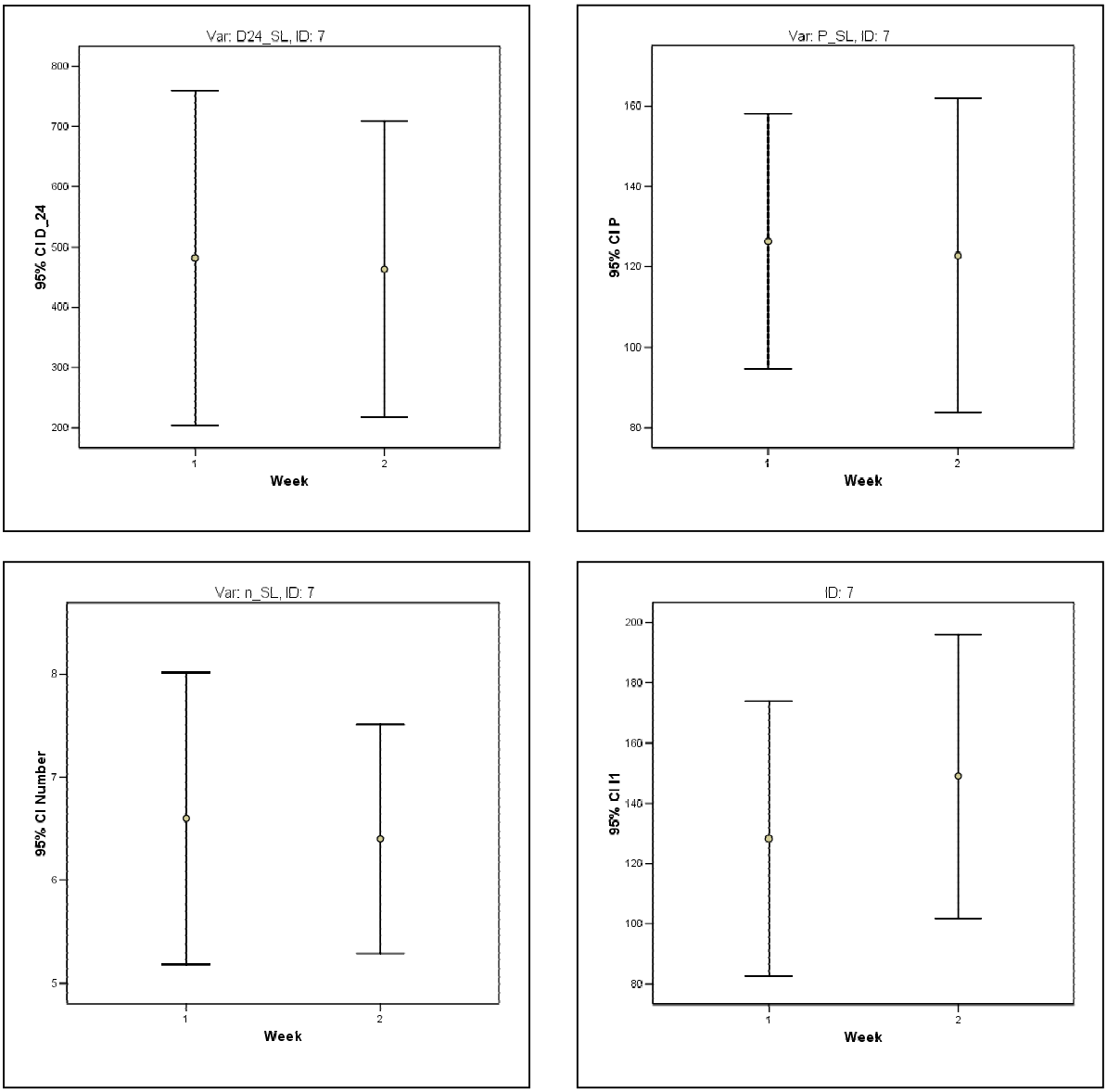

Fig.43: Upper left chart: Average duration of all periods of sleep in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single sleeping periods (P_SL, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of sleeping periods in 24 hours (06:00 - 06:00, n_SL) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between sleeping periods (I1_SL-UE, [min]) grouped by observation weeks (± 95%CI).

No significant changes can be observed in the sleeping behaviour of Anna H.. On average, she sleeps 18 minutes shorter per day (t= 0.11, p= 0.46). Statistics for the individual periods are t= 0.14, p= 0.44, for n24: t= 0.31, p= 0.38 and for I1: t= 0.65, p= 0.26).

Crying time is distinctly but not significantly shorter in the second observation week compared to the first one (-33%), but Anna is uneasy for a distinctly longer time per day. No significant changes can be observed in her sleeping behaviour.

5.1.8 Case 8: Martin L.

5.1.8.1 Initial Situation

Delivery: Martin L. was delivered by caesarean section ten weeks before due date.
Crying: Daily, Martin L. cries between two and three hour per day. The parents do not know any reason. Predominantly, he cries between 11 a.m. and 2 p.m. and 5 p.m. and 8 p.m.. The parents state that they are stressed only a little by his crying.
Sleeping: Martin L. normally sleeps in his own bed located in the sleeping room of his parents but also in their bed. In these cases they feel very disturbed. According to them he has sleeping problems more often than four times a week. Then he wakes up and is awake in the night (less than three times and less than 20 minutes).
Eating: There are no reported problems with eating.

5.1.8.2 Changes during Observation Phases after Osteopathic Treatment

Crying: No crying periods are reported during the both observation periods.
Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 23.

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**120-180**		
		W1	0	-	-
		W2	0	-	-
Duration of individual periods	P_CR	W1	-	-	-
		W2	-	-	-
Number of periods	n_CR	W1	0	-	-
		W2	0	-	-
Intervals between periods	I1_CR-CR	W1	-	-	-
		W2	-	-	-

Table 23: Characteristics of crying periods of Martin. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks.

No crying periods during the two observation weeks are reported. According to his parents, before treatment he has cried two to three hours per day. This is a similar duration as Martin has periods of uneasiness. Errors due to different interpretation of the term crying can not be precluded.

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 24. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.44).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	123	45-201	63
		W2	144	79-209	53
Duration of individual periods	P_UE	W1	30.8	25.9-35.6	10.3
		W2	24.8	19.3-30.4	14.6
Number of periods	n_UE	W1	4	1.7-6.3	1.9
		W2	5.8	3.8-7.8	1.6
Intervals between periods	I1_UE-UE	W1	132	55-209	139
		W2	166	91-242	174

Table 24: Characteristics of periods of uneasiness of Martin. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

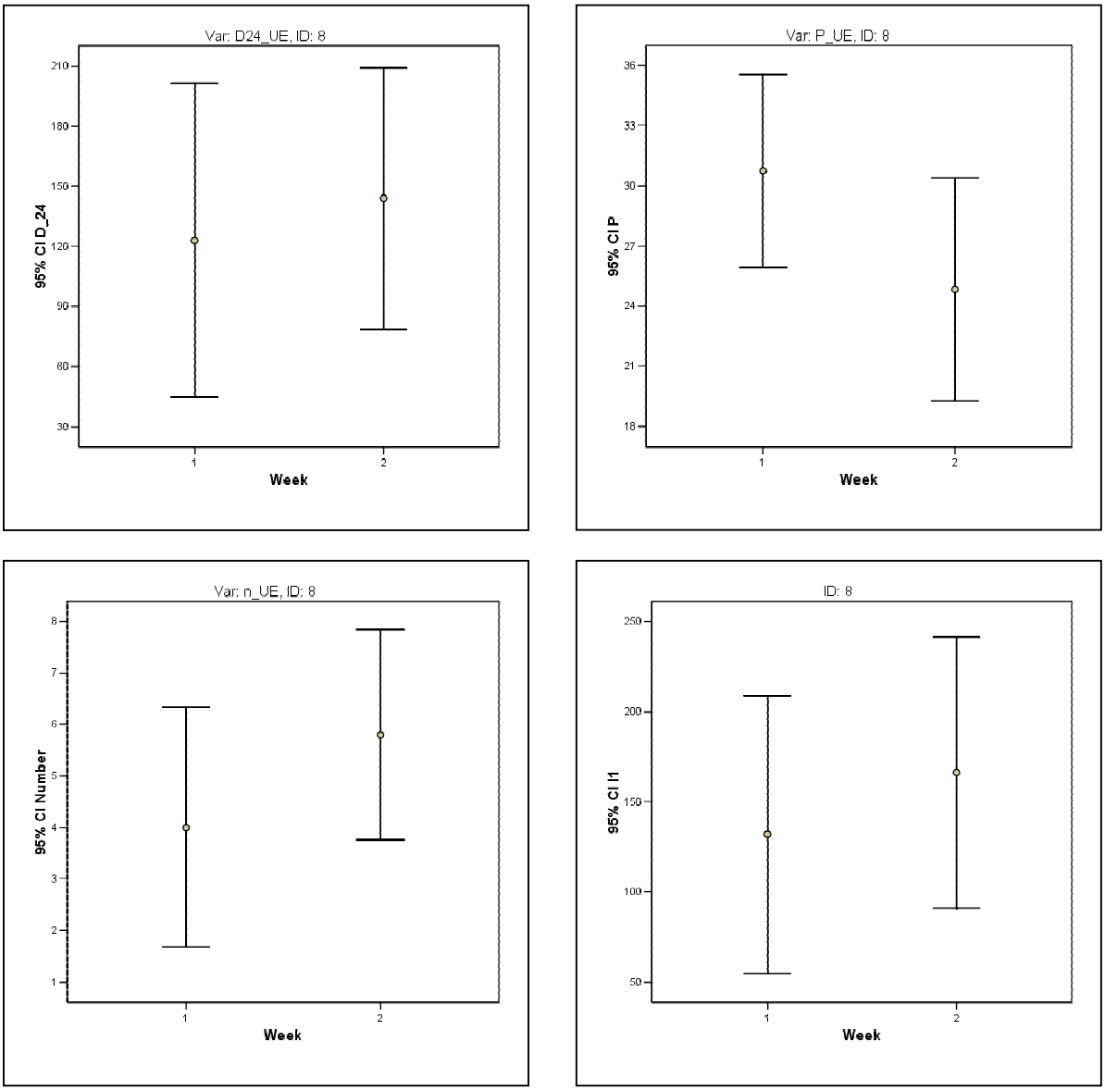

Fig.44: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

On average, periods of uneasiness are shorter during the second observation week than in the first one (t=1.56, p=0.05), but on average Martin is uneasy more often per day (t= 1.6, p=0.07). Both results can be interpreted as distinct tendencies.

Total daily average duration of uneasiness is 21 minutes higher (t= 0.57, p=0.29, not significant). Nevertheless, intervals between two subsequent periods are longer, too (t=0.64, p= 0.26).

Sleeping: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of sleeping periods are summarized in Table 25. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.45 and Fig.46).

Sleeping	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_SL	W1	450	236-664	299
		W2	418.5	217-620	282
Duration of individual periods	P_SL	W1	85	60-110	80.4
		W2	76.7	60.8-92.5	52.7
Number of periods	n_SL	W1	8.6	7.5-9.7	0.9
		W2	9	7.5-10.5	1.2
Intervals between periods	I1_SL-SL	W1	131	102-160	87
		W2	108	81-136	82
Time to fall asleep at night	D_FASL	W1	19.0	3.5-34.5	12.4
		W2	27.0	14.9-39.1	9.7
Wake periods at night	n_WAKEN	W1	2.2	1.6-2.8	0.4
		W2	2.8	1.8-3.8	0.8

Table 25: Characteristics of sleeping periods of Martin. Duration of all these periods in 24 hours (D24_SL), Duration of single periods (P_SL), number of periods of uneasiness in 24 hours (n_ SL) and intervals between individual periods (I1_ SL - SL), time to fall asleep at night (D_FASL) and wake periods at night (n_WAKEN) grouped by observation weeks.

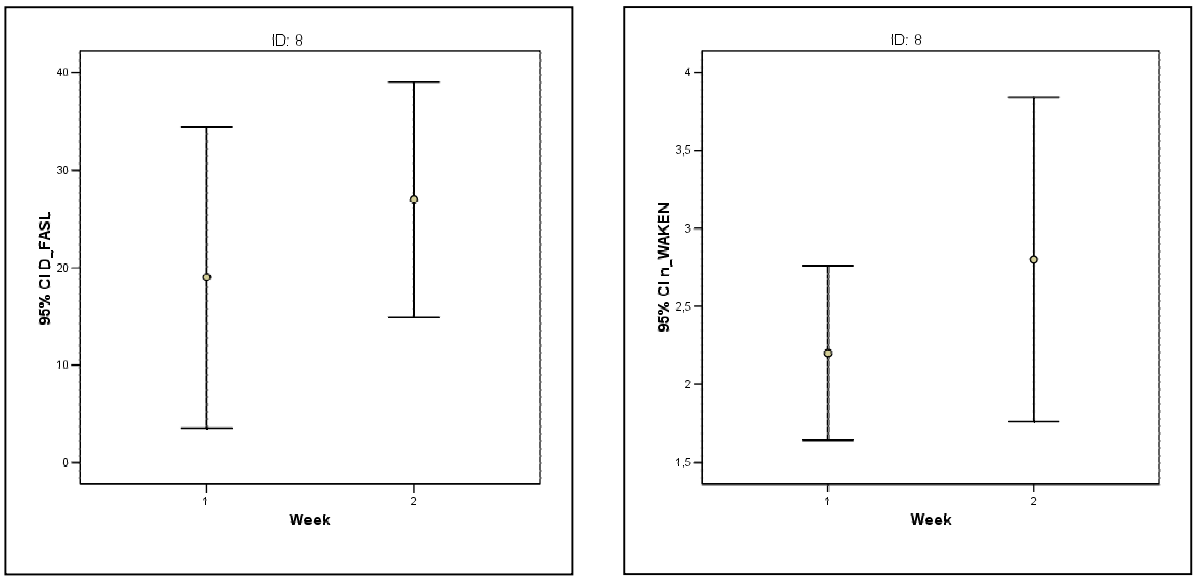

Fig.45: Left chart: Average duration of time needed to fall asleep at night (D_FASL, [min]) grouped by observation weeks (± 95%CI).

Right chart: Average number of wake times at night (n_WAKEN) grouped by observation weeks (± 95%CI).

Time needed for sleeping is longer in the second observation week (t= 1.13, p=0.15, not significant), and Martin wakes up more often in the night (t= 1.41, p=0.10, not significant).

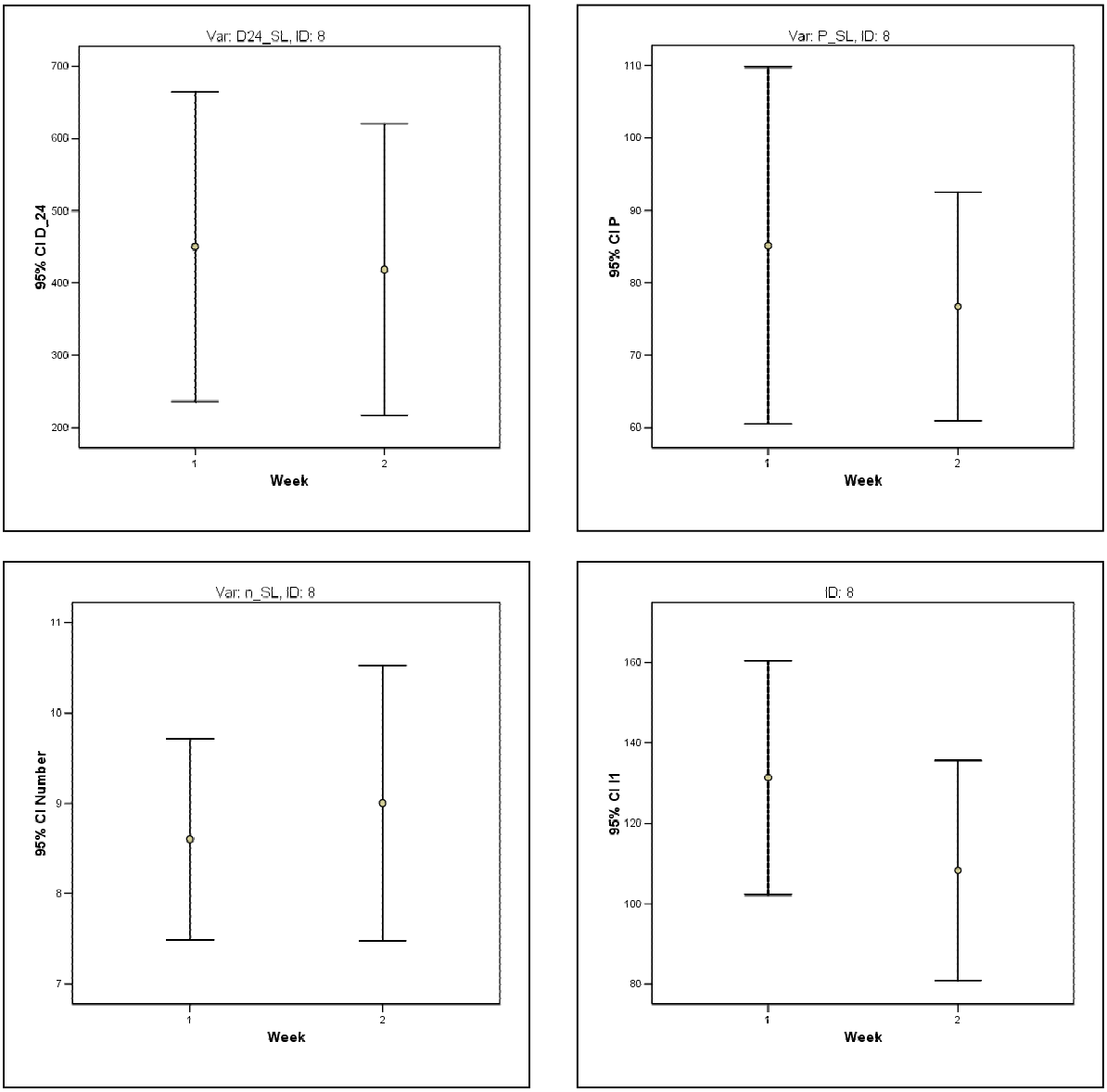

Fig.46: Upper left chart: Average duration of all periods of sleep in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single sleeping periods (P_SL, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of sleeping periods in 24 hours (06:00 - 06:00, n_SL) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between sleeping periods (I1_SL-UE, [min]) grouped by observation weeks (± 95%CI).

On average, periods of sleep are shorter in the second observation week (t= 0.59, p= 0.41). The shorter intervals between them (t= 1.17, p=0.12) and the higher number of sleeping periods (t= 0.59, p=0.29) can not equalize this effect and thus total daily sleeping duration is lower (t= 0.24, p= 0.41). All differences are not statistical significant.

There are probable improvements in crying (misinterpretations of "crying" by the parents can not be precluded), but deteriorations in the duration of uneasiness are distinct and sleeping problems are not solved at all.

5.1.9 Case 9: Anna-Lea S.

5.1.9.1 Initial Situation

Delivery: Anna-Lea S. was delivered by caesarean section ten weeks before due date.
Crying: Since she is eight months, crying periods occur. Her parents did not answer frequency and duration, but they think it they are caused by "inner unrest". She is angrily resisting sleep. Predominantly, she cries between 2 p.m. and 5 p.m. and 8 p.m. and 5 a.m. the next day. The parents state that they are massively stressed by her crying.
Sleeping: Anna-Lea S. sleeps in her own bed located in the sleeping room of her parents. According to them she has sleeping problems more often than four times a week. Then she is awake in the night more often than three times and longer than 20 minutes. The onset of her troubled sleep was at the same time when her crying periods started.
Eating: Anna-Lea's parents state that for the last month she has had feeding problems, too. She has had a weight loss or stagnation between the eighth and ninth month. She refuses food and plays with it. Nevertheless, time needed for feeding is normal. Seemingly, this is a normal condition for her age.

5.1.9.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In the first week after the first osteopathic treatment Anna-Lea cries most often between 2 p.m. and 8 p.m and 8 a.m and 11 a.m.. In the second week crying periods are most frequent between 11 a.m. and 2 p.m., but probably this is no distinct peak value. Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 26. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.47).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**missing**		
		W1	66	0*-133	54
		W2	33	0*-75	34
Duration of individual periods	P_CR	W1	19.4	14.9-23.9	8.8
		W2	18.3	13.2-23.4	6.6

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Number of periods	n_CR	W1	3.4	0-6.8	2.7
		W2	1.8	0*-4	1.8
Intervals between periods	I1_CR-CR	W1	61	36-86	39
		W2	195	81-309	92

Table 26: Characteristics of crying periods of Anna-Lea. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks. *Negative values are set zero.

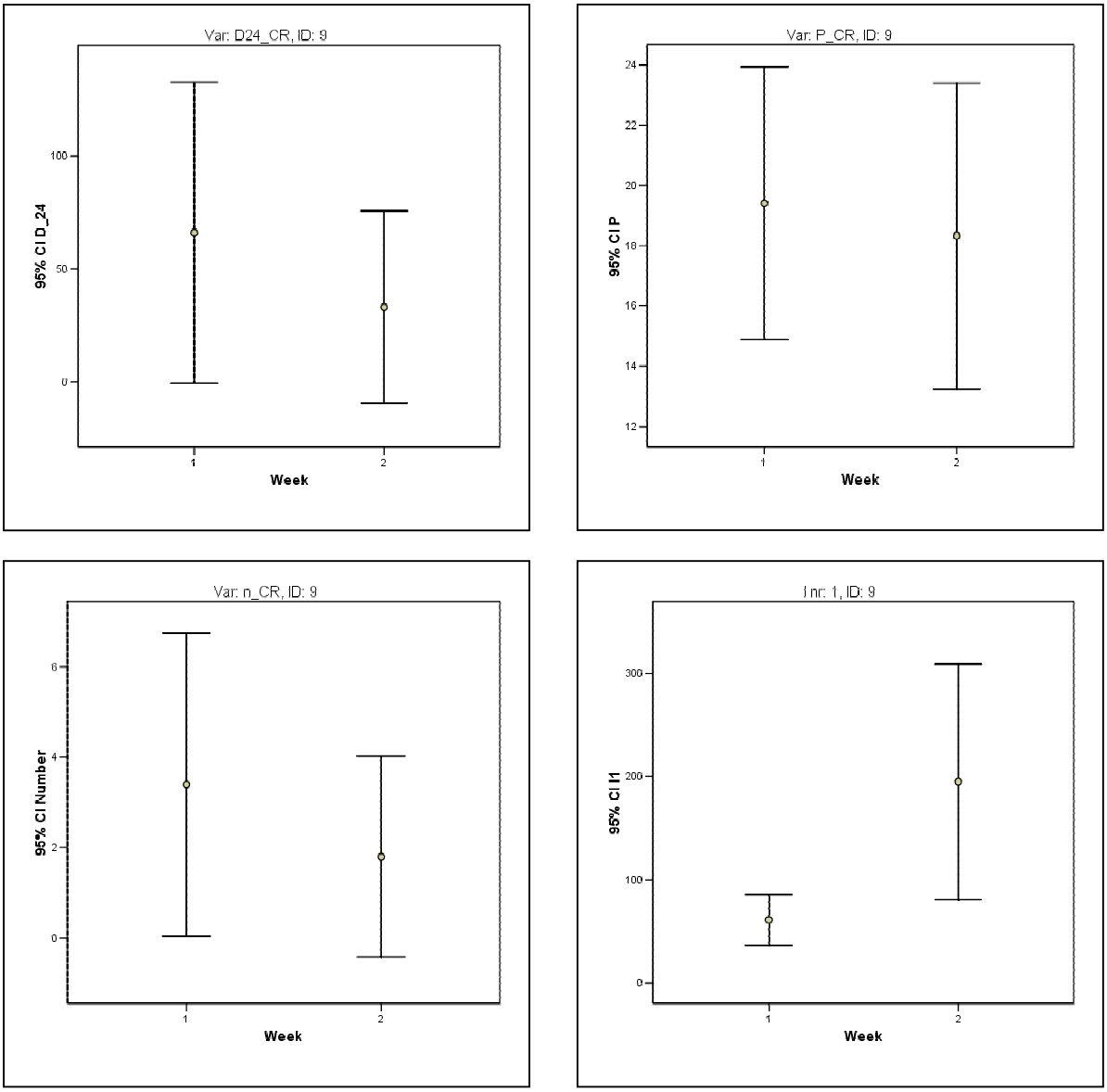

Fig.47: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

During the observation time crying periods on average are reduced in number (t= 1.10, p=0.15) and individual duration (t=0.32, p= 0.38). Thus, total duration decreases (t=1.16, p= 0.14) and intervals are longer (t=3.14, p= 0.014). Only the latter differences are significant in spite of the higher variability.

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 6. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.15).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	231	75-387	126
		W2	183	109-257	59
Duration of individual periods	P_UE	W1	21.8	18.4-25.2	12.5
		W2	22.9	18.5-27.2	13.6
Number of periods	n_UE	W1	11	4-18	5.6
		W2	8	4.4-11.6	2.9
Intervals between periods	I1_UE-UE	W1	103	64-142	130
		W2	135	88-181	128

Table 27: Characteristics of periods of uneasiness of Anna-Lea. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

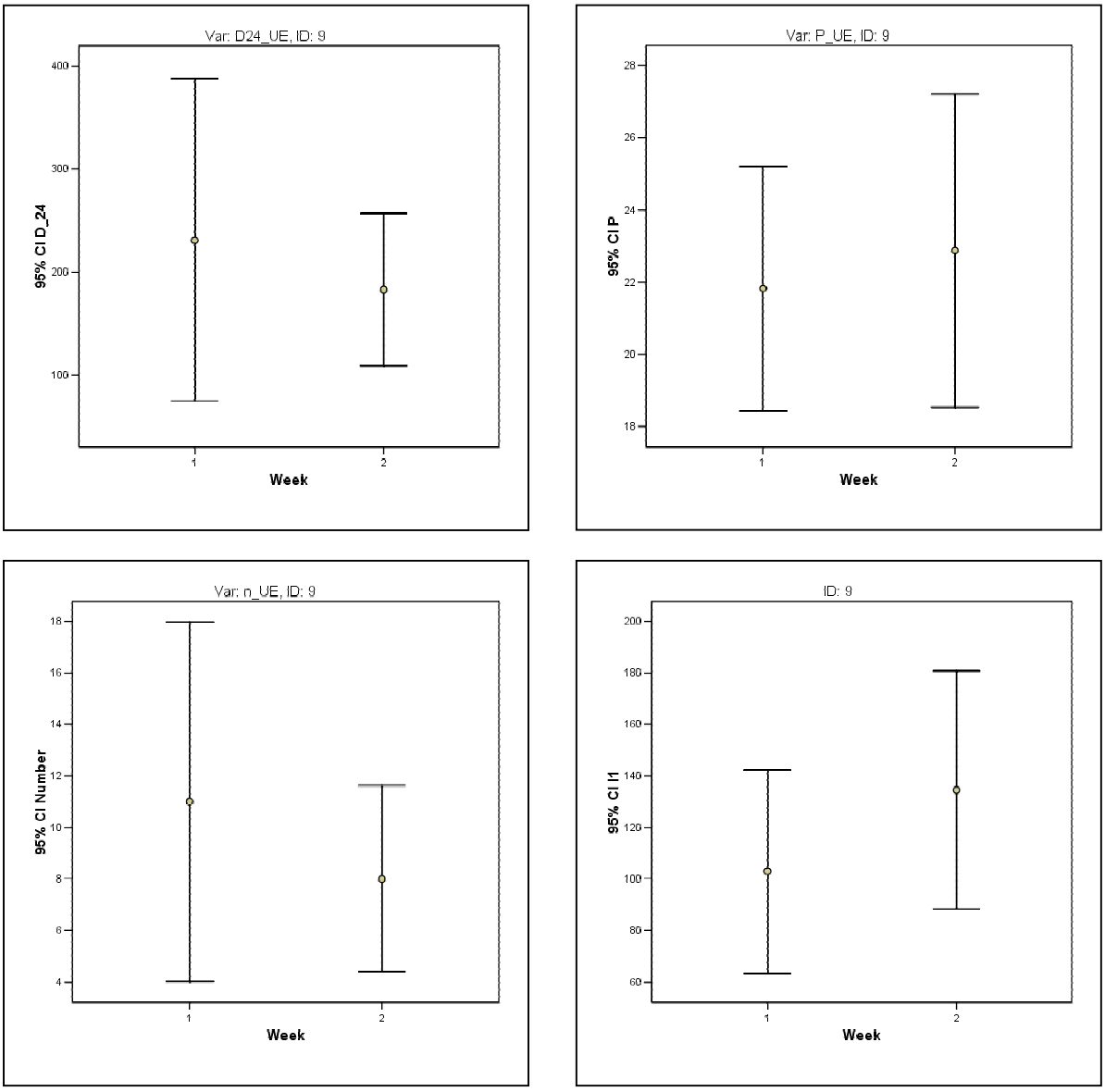

Fig.48: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

Number and total daily duration of periods of uneasiness decrease, individual lengths and intervals between such phases increase between the first and second observation week. Neither of these differences is statistically firm (D24: t=1.05, p= 0.15, P: t= 0.39, p= 0.35, n24: t= 0.32, p= 0.16, I1: t= 1.05, p= 0.15).

Sleeping: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of sleeping periods are summarized in Table 28. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.49 and Fig.50).

Sleeping	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_SL	W1	411	168-654	340
		W2	400.5	176-625	314
Duration of individual periods	P_SL	W1	138.5	70-207	169.6
		W2	96.7	56.5-136.9	118.8
Number of periods	n_SL	W1	5.2	3.8-6.6	1.1
		W2	7.2	6.2-8.2	0.8
Intervals between periods	I1_SL-SL	W1	181	125-237	116
		W2	122	103-141	54
Time to fall asleep at night	D_FASL	W1	4.4	0*-9	3.7
		W2	0	0	0
Wake periods at night	n_WAKEN	W1	1.0	0.1-1.9	0.7
		W2	3.2	0.1-6.3	2.5

Table 28: Characteristics of sleeping periods of Anna-Lea. Duration of all these periods in 24 hours (D24_SL), Duration of single periods (P_SL), number of periods of uneasiness in 24 hours (n_ SL) and intervals between individual periods (I1_ SL - SL), time to fall asleep at night (D_FASL) and wake periods at night (n_WAKEN) grouped by observation weeks.

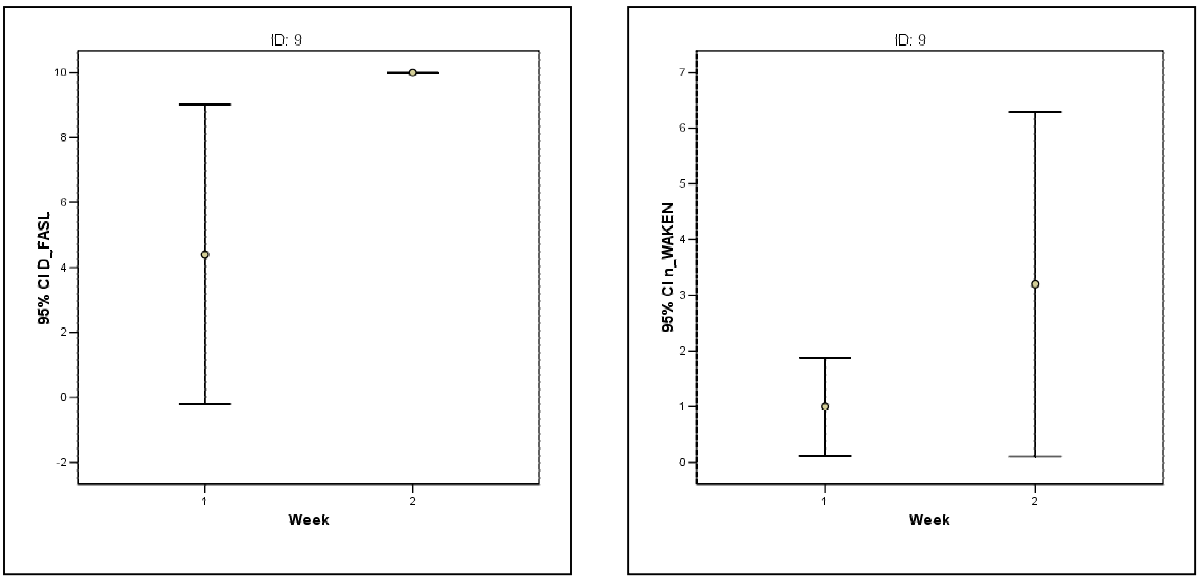

Fig.49: Left chart: Average duration of time needed to fall asleep at night (D_FASL, [min]) grouped by observation weeks (± 95%CI).

Right chart: Average number of wake times at night (n_WAKEN) grouped by observation weeks (± 95%CI).

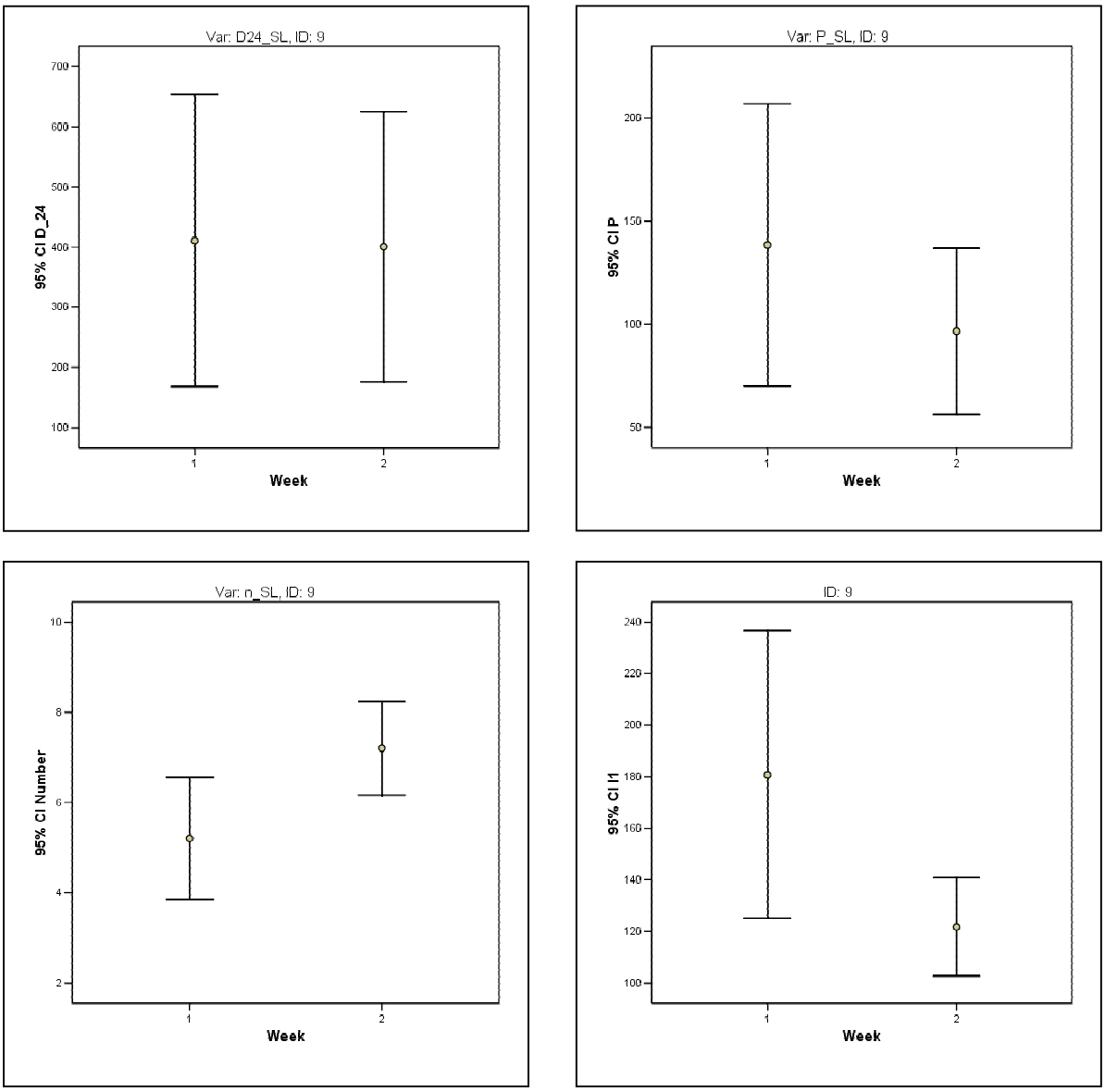

Fig.50: Upper left chart: Average duration of all periods of sleep in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single sleeping periods (P_SL, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of sleeping periods in 24 hours (06:00 - 06:00, n_SL) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between sleeping periods (I1_SL-UE, [min]) grouped by observation weeks (± 95%CI).

In the first observation week, Anna-Lea did not wake up more than three times during night sleep, but in the second week she did again (t=3.37, p= 0.014, significant differences). Similar, time needed for falling asleep, became longer in the second week (t=1.90, p= 0.06, not significant). Intervals decreased with the reduced duration of the individual sleeping periods and with increase of the number of these periods. Total daily sleeping time remains quite the same in the two observation weeks. Differences in durations are not statistically firm

(D24: t=0.07, p= 0.47, P: t= 1.14, p= 0.13) the differences in number and intervals are (n24: t= 3.24, p= 0.006, I1: t= 2.09, p= 0.02).

Anna Lea's average crying time is reduced by 50% between the first and second observation period (the difference is not significant). Due to a lack of comparative data before the first osteopathic treatment, it is not possible to compare the final with the initial state.

5.1.10 Case 10: Marcel H.

5.1.10.1 Initial Situation

Delivery: Marcel H. was delivered by caesarean section 12 weeks before due date.

Crying: Marcel H. cries at least one hour per day since he was 14 weeks old. The parents think he likes to draw their attention. Predominantly, he cries between 8 a.m. and 11 a.m. and 5 p.m. and 8 p.m.. His parents state to be only a little stressed by his crying.

Sleeping: Marcel H. sleeps in his own bed located in the sleeping room of his parents According to them he needs support in falling asleep. Sometimes he is awake in the night (less than three times and less than 20 minutes).

Eating: There are problems with eating, but they are not specified.

5.1.10.2 Changes during Observation Phases after Osteopathic Treatment

Crying: In both observation weeks after osteopathic treatment Marcel cries most often between 11 a.m. and 2 p.m..

Descriptive characteristics of crying periods (mean values, 95% confidence intervals (95% CI) and standard deviations (SD) are summarized in Table 29. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.51).

Crying	Var	Observation period	Mean value [min]	95% CI [min]	SD
Duration per day	D24_CR	**before treatment**	**> 60**		
		W1	156	88-224	55
		W2	99	71-127	23
Duration of individual periods	P_CR	W1	20.0	17-23	9.3
		W2	18.3	14.9-21.8	8.7
Number of periods	n_CR	W1	7.8	5.1-10.5	2.2
		W2	5.4	4.3-6.5	0.9
Intervals between periods	I1_CR-CR	W1	128	91-166	105
		W2	236	164-307	152

Table 29: Characteristics of crying periods of Marcel. Duration of crying periods in 24 hours (D24_CR), duration of single crying periods (P_CR), number of crying periods in 24 hours (n_CR) and intervals between crying periods (I1_CR-CR) grouped by observation weeks.

During both observation periods durations of daily crying are longer than the 60 minutes minimum crying time per day stated by the parents before osteopathic treatment. It is impossible to perform statistical tests, since the estimation of the parents is too coarse.

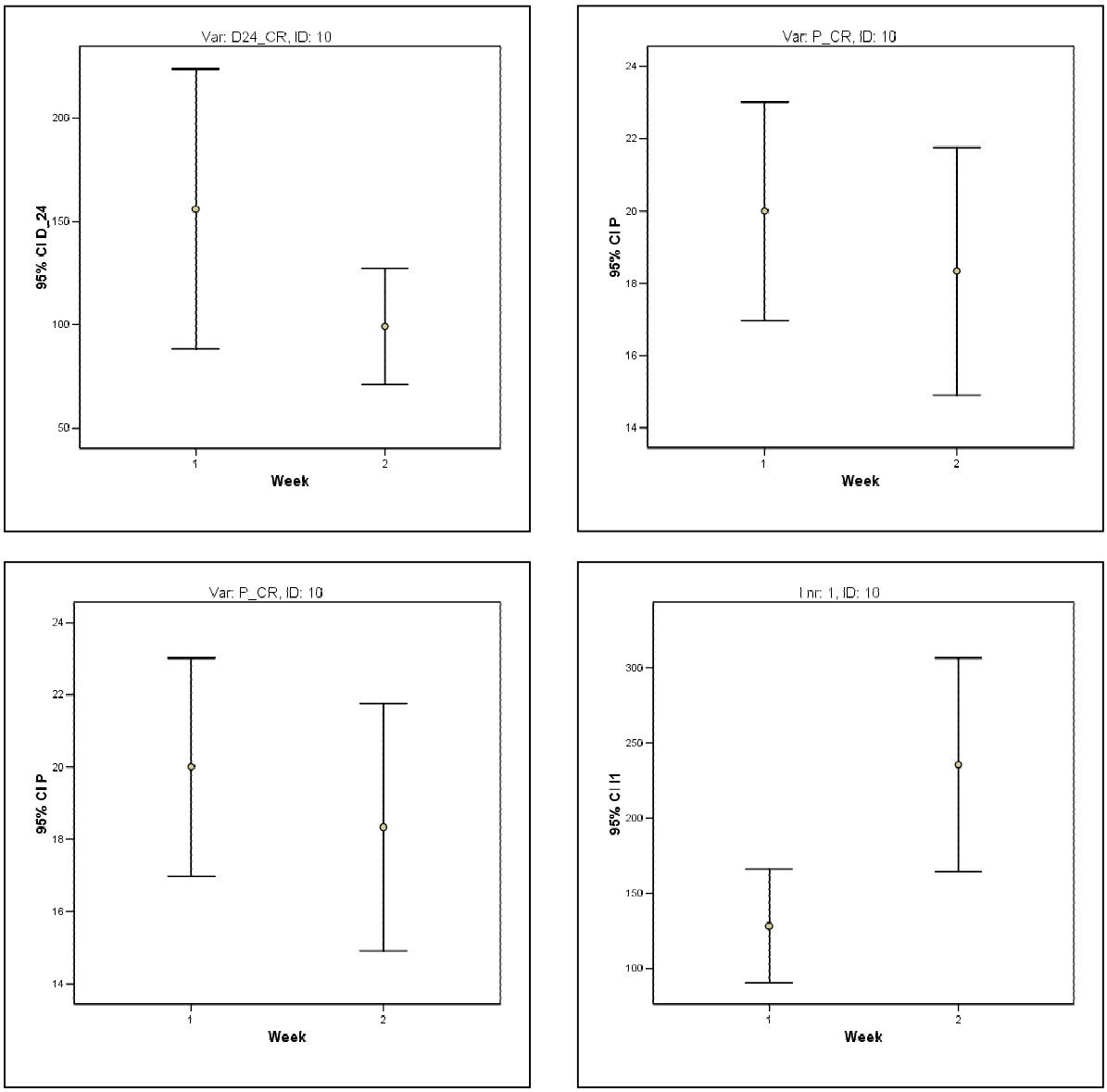

Fig.51: Upper left chart: Average duration of all crying periods in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single crying periods (P_CR, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of crying periods in 24 hours (06:00 - 06:00, n_CR) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between crying periods (I1_CR-CR, [min]) grouped by observation weeks (± 95%CI).

During the observation time crying periods are reduced in number and individual duration. Thus, also total duration decreases and intervals become longer. Differences are statistically significant (D24: t=2.15, p= 0.03, n24: t=2.29, p=0.03, I1: t= 3.01, p= 0.002) except the duration of individual crying periods (P: t= 0.74, p=0.23).

Uneasiness: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of periods of uneasiness, i.e. periods when the infant is crying or whining, are summarized in Table 30. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.52).

Uneasiness	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_UE	W1	249	166-332	67
		W2	207	171-243	29
Duration of individual periods	P_UE	W1	20.8	18.4-23.1	9.2
		W2	22.5	19-26	11.7
Number of periods	n_UE	W1	12	8.4-15.6	2.9
		W2	9.2	7.4-11	1.5
Intervals between periods	I1_UE-UE	W1	107	81-132	91
		W2	129	104-154	77

Table 30: Characteristics of periods of uneasiness of Marcel. Duration of all these periods in 24 hours (D24_UE), Duration of single periods (P_ UE), number of periods of uneasiness in 24 hours (n_ UE) and intervals between individual periods (I1_ UE - UE) grouped by observation weeks.

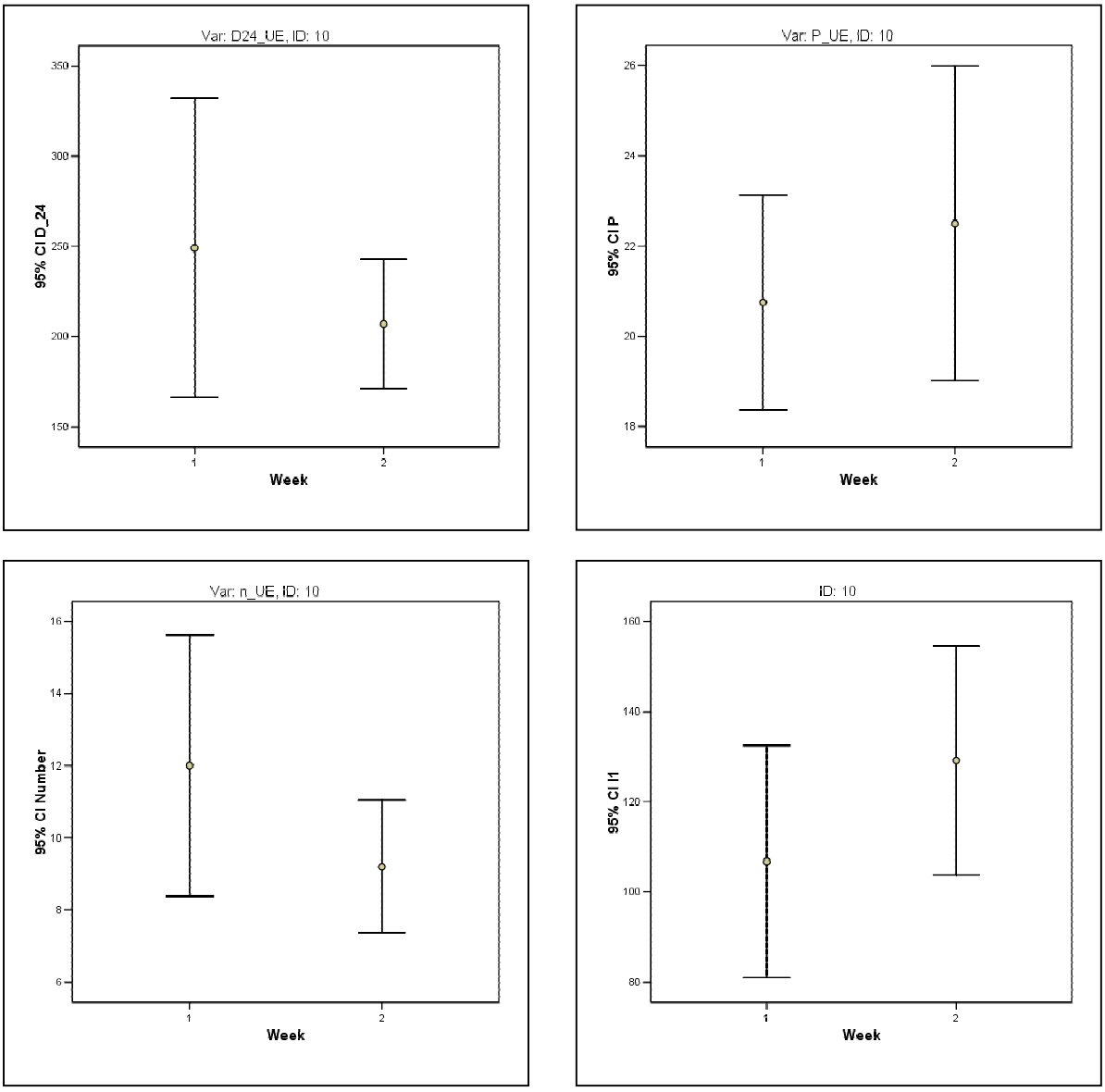

Fig.52: Upper left chart: Average duration of all periods of uneasiness in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single periods of uneasiness (P_UE, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of periods of uneasiness in 24 hours (06:00 - 06:00, n_UE) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between periods of uneasiness (I1_UE-UE, [min]) grouped by observation weeks (± 95%CI).

On average, Marcel cried or whined approximately three times less per day during the second observation time (t=1.91, p=0.05). The durations of the individual periods of uneasiness are slightly higher (t=0.86, p=0.20, not significant). Total daily duration of uneasiness is lower in the second observation week (t=1.29, p=0.12) and intervals between two phases of uneasiness are significantly longer (t=3.01, p= 0.002).

Sleeping: Descriptive characteristics (mean values, 95% confidence intervals (95% CI) and standard deviations (SD)) of sleeping periods are summarized in Table 31. To visualize possible changes, mean values and 95% confidence intervals are also summarized in error bar plots (cf. Fig.53 and Fig.54).

Sleeping	Var	Observation period	Mean value	95% CI [min]	SD
Duration per day	D24_SL	W1	480	191-769	404
		W2	477	194-760	396
Duration of individual periods	P_SL	W1	120	86.4-153	98
		W2	133	105-161	77
Number of periods	n_SL	W1	7.2	5.4-9	1.5
		W2	6.4	5.7-7.1	0.5
Intervals between periods	I1_SL-SL	W1	151	114-188	98
		W2	173	117-228	138
Time to fall asleep at night	D_FASL	W1	30.0	10.9-49.1	15.4
		W2	15.0	1.8-28.2	10.6
Wake periods at night	n_WAKEN	W1	1.6	0.5-2.7	0.9
		W2	2.4	1.7-3.1	0.5

Table 31: Characteristics of sleeping periods of Marcel. Duration of all these periods in 24 hours (D24_SL), Duration of single periods (P_SL), number of periods of uneasiness in 24 hours (n_ SL) and intervals between individual periods (I1_ SL - SL), time to fall asleep at night (D_FASL) and wake periods at night (n_WAKEN) grouped by observation weeks.

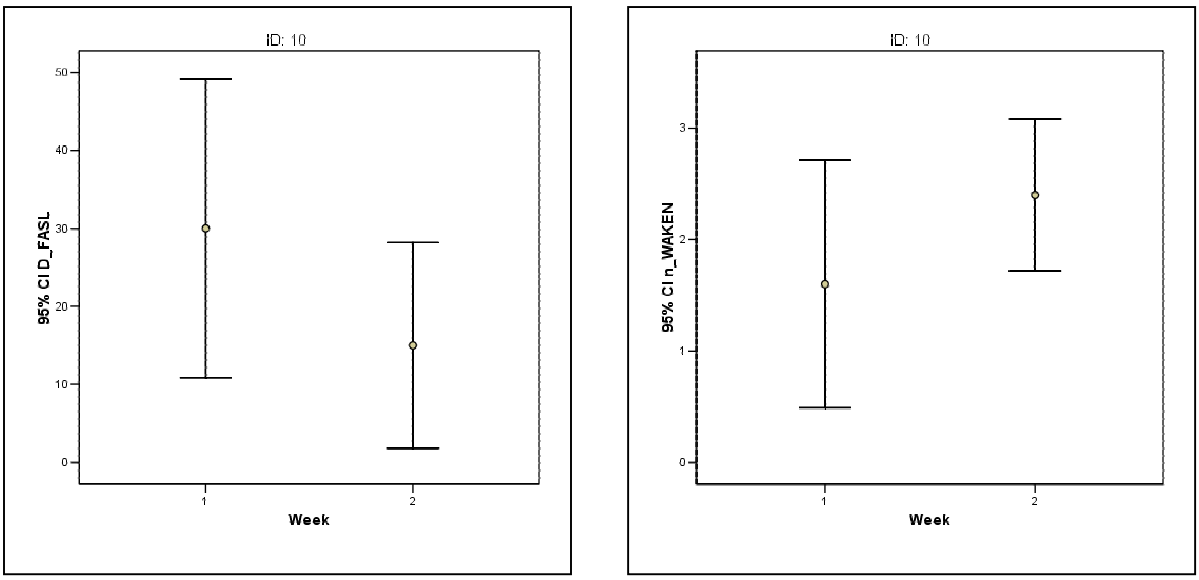

Fig.53: Left chart: Average duration of time needed to fall asleep at night (D_FASL, [min]) grouped by observation weeks (± 95%CI).

Right chart: Average number of wake times at night (n_WAKEN) grouped by observation weeks (± 95%CI).

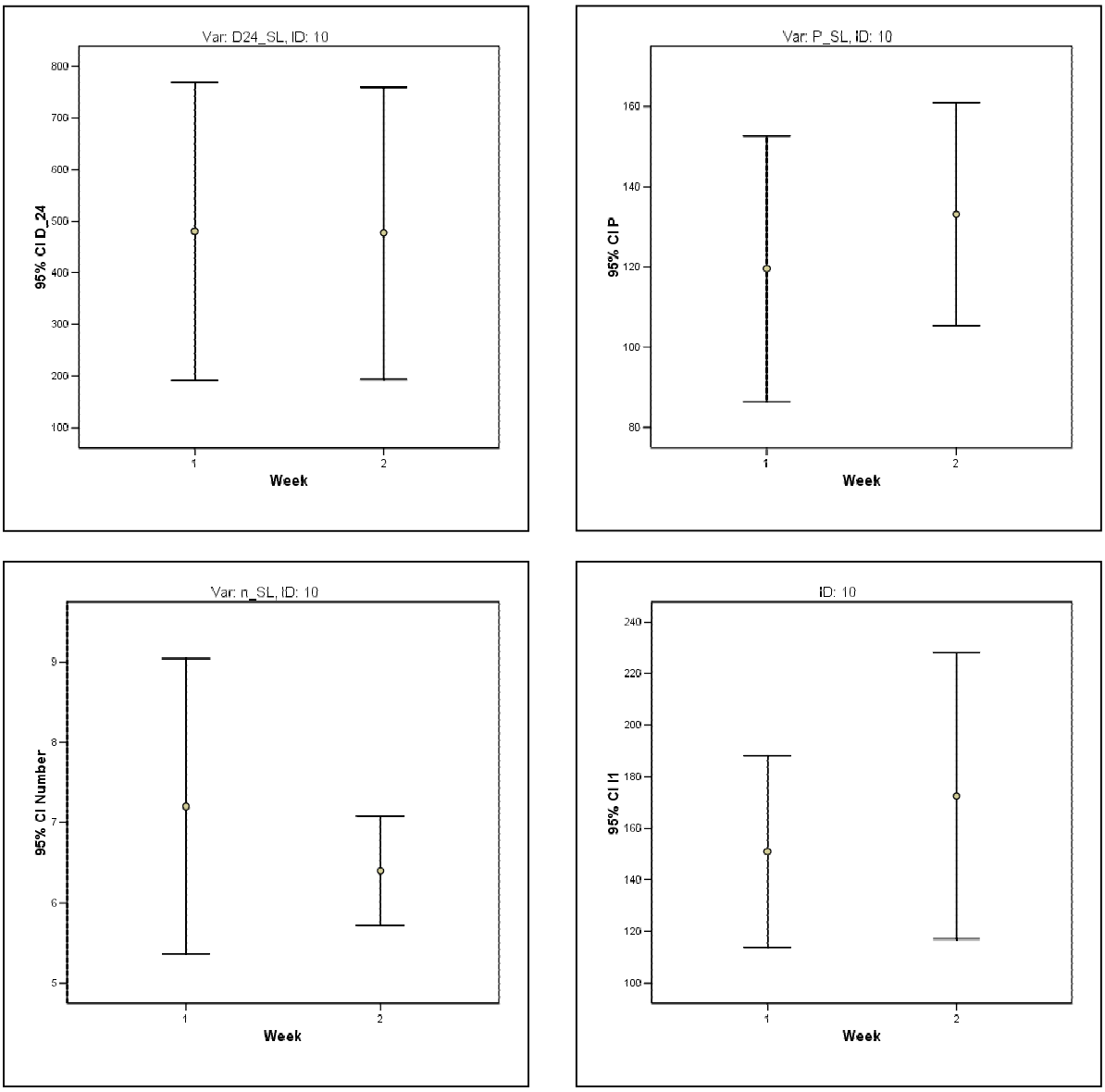

Fig.54: Upper left chart: Average duration of all periods of sleep in 24 hours (06:00 -06:00, D_24, [min]) grouped by observation weeks (± 95%CI).

Upper right chart: Average duration of single sleeping periods (P_SL, [min]) grouped by observation weeks (± 95%CI).

Lower left chart: Number of sleeping periods in 24 hours (06:00 - 06:00, n_SL) grouped by observation weeks (± 95%CI).

Lower right chart: Average length of the intervals between sleeping periods (I1_SL-UE, [min]) grouped by observation weeks (± 95%CI).

There are tendencies, that time for falling asleep is reduced in the second observation week (t= 1.79, p= 0.06), but also that Marcel wakes up more often during night time (t=1.71, p= 0.06).

Total sleeping time is almost unchanged (t= 0.02, p= 0.5). Sleeping periods are longer, but the number is lower in the second observation week (P: t= 0.63, p= 0.27, n24: t=1.13, p= 0.15). Intervals are shorter in the second observation week (t= 0.67, p= 0.25).

Since comparative data of the time before the first observation week are too coarse (according to his parents, Marcel cries longer than one hour), a comparison between the first and the second observation period is the only possibility to assess possible improvements. Between these periods, crying behaviour is significantly improved. Again, sleeping behaviour is not positively influenced.

5.2. Summary of the Individual Results

5.2.1 Whining, Crying and Uneasiness

5.2.1.1 Daily Duration

Data of the first and second observation week compared to the initial state

Since data were collected by two different methods before and after osteopathic treatment, the only variable which can be compared is the daily duration of crying (D24_CR). Its initial values, the results during the first and second observation week, and the changes compared to the initial state (in minutes and percent) as well as the results of the one sample t-tests are summarized in Table 32. Three infants could not be considered due to a lack of initial data (cases 2, 7, 9). Significant changes are demarked light green, improvements with bold letters.

ID	Before treatment	Observation week 1					Observation week 2				
	Mean value	D24_CR	Change		t	p	D24_CR	Change		t	p
	[min]	[min]	[min]	%			[min]	[min]	%		
1*	240	153	-87	**-36**	1.95	0.12	15	-225	**-94**	-27.4	<0.001
2*	missing	15					0				
3*	150	120	-30	**-20**	0.40	0.76	6	-144	**-96**	24.0	<0.001
4*	135	75	-60	**-44**	4.00	0.16	39	-96	**-71**	5.50	0.005
5*	180	30	-150	**-83**	10.54	<0.001	105	-75	**-42**	2.84	0.047
6*	210	282	72	+34	0.97	0.39	0	-210	**-100**	*	*
7*	missing	63					42				
8*	150	0	-150	**-100**	*	*	0	-150	**-100**	*	*
9*	missing	66					33				
10*	90	156	66	+73	2.70	0.054	99	9	+10	0.89	0.43

Table 32: Duration of crying per 24 hours before osteopathic therapy and during the first and second observation week, and changes in relation to the initial state as well as results (p-values) of the t-tests (*… t could not be computed, because the standard deviation is 0).

Duration of daily crying of five of the seven infants (71.4%) is shorter during the first observation week compared to the initial state. In one case this difference is statistically significant (case 5), in another case, no (remarkably long) crying periods are reported (case 8: D24_CR=0) during the first observation week.

In two cases the infants cry longer during the first observation week than before the first osteopathic treatment and in three cases there is no data about the daily duration of crying (cases 2, 7 and 9) before osteopathic therapy.

Six of the seven infants cry shorter during the second observation week compared to the initial state. In four cases this difference is statistically significant (cases 1.3, 4 and 5), in two cases, no long crying periods are reported (cases 6 and 8: D24_CR=0). One infant cries longer than before osteopathic treatment (case 10) and again, in three cases comparative data are missing.

That means, that additional improvements could be gained during the further treatment period.

Data of the first observation week compared to the second one

In all cases, where there is no information about the initial state (cases 2.7.9), crying is distinctly reduced during the second observation week compared to the first one (at least 33%, cf. Table 33). Nevertheless, these differences are not significant.

A single worsening between the first and second observation period can be observed in case 5: After a reduction of the daily crying time in the first observation week, this time becomes longer again. Nevertheless, the initial duration of 180 minutes per day is not reached anymore, and this difference is still statistically significant (p= 0.047).

Changes of the daily duration of crying, whining and uneasiness are summarized in Table 33 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements with bold letters.

		Crying				Whining				Uneasiness			
		D24_CR				D24_GR				D24_UE			
ID	Name	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	153	15	**-90%**	0.02	462	63	**-79%**	<0.001	309	48	**-84%**	0.001
2*	Julia H.	15	0	**-100%**	0.1	288	0	**-100%**	0.003	273	0	**-100%**	0.002
3*	Mathias B.	120	6	**-95%**	0.19	578	267	**-24%**	0.173	458	261	**-43%**	0.046
4*	Lukas B.	75	39	**-48%**	0.14	510	375	**-18%**	0.2	435	336	**-23%**	0.069
5*	Thomas U.	30	105	250%	0.02	174	324	0%	0.5	144	219	52%	0.058
6*	Leonard H.	282	0	**-100%**	0.01	642	36	**-54%**	0.117	360	36	**-90%**	0.002
7*	Anna H.	63	42	**-33%**	0.13	183	216	132%	0.041	120	174	45%	0.128
8*	Martin L.	0	0	-	*	123	144	17%	0.292	123	144	17%	0.292
9*	Anna-Lea S.	66	33	**-50%**	0.14	297	216	**-14%**	0.316	231	183	**-21%**	0.236
10*	Marcel H.	156	99	**-37%**	0.03	405	306	16%	0.192	249	207	**-17%**	0.116

Table 33: Changes of the daily duration of crying, whining and uneasiness. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. *According to the Wessel criteria (Wessel et al., 1954) and the answers of the parents all infants were cry babies.

As described above, there are improvements of the crying behavior between the first and second observation week: Eight of the infants cry shorter in the second week compared to the first one. In four cases this difference is significant. One infant (case 8) did not cry anymore during the first observation week, neither did he in the second one.

That means, that only one infant (case 5) cried longer than during the first observation period. Nevertheless, as mentioned above, the duration of crying is still significantly lower compared to the initial state.

Analogous to crying, also duration of whining in 24 hours is reduced. Six of the ten infants whine shorter per day during the second observation week. Three infants whine longer per day (cases 7, 8 and 10) and in one case duration of whining does not change.

Combining the two variables discussed above, that means considering the duration of uneasiness in 24 hours, it can be observed, that the duration of uneasiness is reduced in seven cases (70%), in four cases statistically significant.

In three cases, the duration of uneasiness increases (30%). In case 8 the duration of uneasiness is subaverage (144 min compared to the mean value of all cases: 161 min). In case 5 the duration is 219 minutes and in case 7 174 minutes.

5.2.1.2 Duration of Individual Periods

Changes of the duration of individual crying-, whining- and uneasiness periods are summarized in Table 34 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements with bold letters.

		Crying				Whining				Uneasiness			
		P_CR				P_GR				P_UE			
ID	Name	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	128.0	25.0	**-80%**	0.018	52.0	23.6	**-55%**	<0.001	74.0	24.0	**-67%**	0.001
2*	Julia H.	25.0	0.0	**-100%**	-	64.5	0.0	**-100%**	-	59.3	0.0	**-100%**	-
3*	Mathias B.	26.7	30.0	13%	0.438	112.5	47.2	**-58%**	0.001	61.0	46.6	**-24%**	0.192
4*	Lukas B.	37.5	39.0	4%	0.447	72.0	45.0	**-38%**	0.038	62.0	44.0	**-29%**	0.071
5*	Thomas U.	16.7	21.9	31%	0.042	23.8	21.1	**-11%**	0.205	21.8	21.5	**-2%**	0.443
6*	Leonard H.	64.1	0.0	**-100%**	-	20.5	15.0	**-27%**	0.015	43.9	15.0	**-66%**	<0.001
7*	Anna H.	26.3	23.3	**-11%**	0.33	35.6	28.7	**-19%**	0.285	30.0	27.2	**-9%**	0.344
8*	Martin L.	0.0	0.0	-	-	30.8	24.8	**-19%**	0.051	30.8	24.8	**-19%**	0.051
9*	Anna-Lea S.	19.4	18.3	**-6%**	0.375	22.9	24.2	6%	0.354	21.8	22.9	5%	0.348
10*	Marcel H.	20.0	18.3	**-8%**	0.233	22.1	28.4	28%	0.042	20.8	22.5	8%	0.203

Table 34: Changes of the lengths of periods of crying, whining and uneasiness. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. *According to the Wessel criteria (Wessel et al., 1954) and the answers of the parents all infants were cry babies.

In six of ten cases (60%) individual crying periods are shorter in the second observation week than in the first one, in two cases this difference is statistically significant. No computations could be done in two cases, when no crying periods in the second observation week were recorded. No crying period at all was reported of Martin L. (case 8).
Worsening can be observed in three cases (cases 3, 4 and 5). In case 3 only a single period of 30 minutes is responsible for the increase, in case 4 periods are only 1.5 minutes (4%) longer, on average, but are above average. The highest increase can be observed in case 5 (5.2 min, on average). This result is statistically firm ($p=0.04$). Nevertheless, the 21.9 minutes per crying period is almost identical with the mean value of all infants during the second observation period (21.7 minutes).

The individual whining periods are shorter in eight of the ten cases (80%). Only in the cases 9 and 10 longer whining periods can be observed during the second observation period. In case 10 this statistically significant average difference is six minutes (28%, 22 minutes in the first week and 28 minutes in the second week). In case 9, the difference is only one minute (6%).
Considering the individual periods of uneasiness, it can be observed, that eight of the ten infants (80%) have shorter periods of uneasiness during the second observation week than in the first one. In two cases this difference is statistically significant and in one case no periods of uneasiness were observed during the second week at all. Thus, no statistical test could be performed.
The two cases where periods of uneasiness became longer, are the same as discussed under consideration of whining (cases 9 and 10). Neither of the differences (5% and 8%, respectively) are statistically significant.

5.2.1.3 Number of Individual Periods

Changes of the number of crying-, whining- and uneasiness periods per day are summarized in Table 35 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements with bold letters.

		Crying				Whining				Uneasiness			
		n24 CR				n24 GR				n24 UE			
ID	Name	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	1.2	0.6	**-50%**	0.047	3	1.4	**-53%**	0.007	4.2	2	**-52%**	0.001
2*	Julia H.	0.6	0	**-100%**	0.104	4	0	**-100%**	0.006	4.6	0	**-100%**	0.009
3*	Mathias B.	4.5	0.2	**-96%**	0.167	3	5.4	80%	0.021	7.5	5.6	**-25%**	0.172
4*	Lukas B.	2	1	**-50%**	0.059	5	6.6	32%	0.008	7	7.6	9%	0.152
5*	Thomas U.	1.8	4.8	167%	0.036	4.8	5.4	13%	0.261	6.6	10.2	55%	0.062
6*	Leonard H.	4.4	0	**-100%**	<0.001	3.8	2.4	**-37%**	0.185	8.2	2.4	**-71%**	0.003
7*	Anna H.	2.4	1.8	**-25%**	0.21	1.6	4.6	188%	0.014	4	6.4	60%	0.067
8*	Martin L.	-	-	-	-	4	5.8	45%	0.072	4	5.8	45%	0.072
9*	Anna-Lea S.	3.4	1.8	**-47%**	0.151	7.6	6.2	**-18%**	0.225	11	8	**-27%**	0.16
10*	Marcel H.	7.8	5.4	**-31%**	0.034	4.2	3.8	**-10%**	0.307	12	9.2	**-23%**	0.052

Table 35: Changes of the number of crying-, whining- and uneasiness periods per day. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. *According to the Wessel criteria (Wessel et al., 1954) and the answers of the parents all infants were cry babies.

Five infants whined less often during the second week than in the first one (50%). In two cases differences are statistically firm. Due to the reduction of crying periods in eight cases (80%, half of them statistically significant), a reduction of the number of periods of uneasiness is gained in six cases (60%), in total.

Among them three cases differ significantly in number. The increase of the number of crying periods only once is responsible for the increase of the number of periods of uneasiness (case 5).

5.2.1.4 Intervals between Individual Periods

Changes of the intervals between subsequent crying-, whining- and uneasiness periods are summarized in Table 36 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements with bold letters.

		Crying				Whining				Uneasiness			
		I1_CR-CR				I1_GR-GR				I1_UE-UE			
ID	Name	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	30	0	**	**	212	390	**84%**	0.329	177	203	**15%**	0.383
2*	Julia H.	-	-	**	**	98		**	**	108	-	**	**
3*	Mathias B.	201	-	**	**	165	173	**5%**	0.467	158	167	**6%**	0.436
4*	Lukas B.	113	150	**33%**	0.333	131	133	**2%**	0.485	132	128	-3%	0.471
5*	Thomas U.	133	158	**19%**	0.385	136	126	-7%	0.413	99	80	-19%	0.214
6*	Leonard H.	125	-	**	**	135	300	**122%**	<0.001	97	300	**210%**	<0.001
7*	Anna H.	302	195	-35%	0.224	350	98	-72%	0.159	198	80	-60%	0.053
8*	Martin L.	-	-	**	**	132	166	**26%**	0.263	132	166	**26%**	0.263
9*	Anna-Lea S.	61	195	**218%**	0.014	137	141	**3%**	0.455	103	135	**31%**	0.148
10*	Marcel H.	128	236	**83%**	0.002	170	159	-7%	0.391	107	129	**21%**	0.114

Table 36: Changes of the intervals between subsequent crying, whining and uneasiness periods. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. *According to the Wessel criteria (Wessel et al., 1954) and the answers of the parents all infants were cry babies. ** no or only one period in 48 hours in at least one week.

Intervals between crying periods get longer in four of five valid cases (80%, half of them statistically significant). Only Anna H. (case 7) is crying in shorter intervals during the second observation week (statistically not significant). The other data can not be computed because intervals between periods are only considered, if they are shorter than 48 hours. In the cases demarked with two asterisks, this condition is never fulfilled in at least one of the two observation periods.

Intervals between periods of uneasiness are longer in six of nine valid cases (66.7%), but only in one case, the difference is statistically firm.

5.2.2 Sleep and Related Data

5.2.2.1 Daily Duration

Changes of the daily duration of sleeping and time spent in own and parent's bed are summarized in Table 37 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements with bold letters. Only infants, whom sleeping problems are reported of are considered.

		Sleeping				Own bed				Parent's bed			
		D24_SL				D24_OB				D24_PB			
ID	Name	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	504	612	21%	0.304	864	1068	**24%**	0.021	0	51	°	-
3*	Mathias B.	435	476	9%	0.431	203	756	**273%**	0.103	98	189	94%	0.198
5*	Thomas U.	467	440	-6%	0.429	813	732	-10%	0.04	9	0	**-100%**	0.187
7*	Anna H.	482	464	-4%	0.457	399	765	**92%**	0.048	423	6	**-99%**	0.021
8*	Martin L.	450	419	-7%	0.406	714	444	-38%	<0.001	18	249	1283%	<0.001
9**	Anna-Lea S.	411	401	-3%	0.472	723	681	-6%	0.282	0	12	°	-
10*	Marcel H.	480	477	-1%	0.493	867	834	-4%	0.207	0	18	°	-

Table 37: Change of the duration of sleeping periods per 24 hours and time spent in the own or parent's bed. "p" demarks the significance of the 1-tailed t-test and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. Children demarked with an asterisk have sleeping problems, ** demarks children with more than three wake periods during the night. ° sleep in parent's bed only in the second observation week.

Two of the seven children slept longer per day during the second observation period after the osteopathic treatment, five shorter. All differences are not statistically significant.

Three children stay longer in their own bed and two shorter in parent's bed.

Three of the seven children stay in parent's bed only during the second observation week, but only for a short while.

Special cases are Anna H. who spends significantly more time in own bed and significantly less in parent's bed.

Mathias B. (case 3) spends more time in own as well as parent's bed without being asleep and Martin L. (case 8) is the only infant who spends significantly more time in parent's bed during the second observation period.

These changed conditions do not affect daily sleeping time significantly.

5.2.2.2 Duration of Individual Periods

Changes of the duration of individual sleeping periods and phases in own and parent's bed are summarized in Table 38 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements with bold letters.

		Sleeping				Own bed				Parent's bed			
		P_SL				P_OB				P_PB			
ID	Name	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	215	278	29%	0.129	227	267	**17%**	0.242	0	85	°	-
3*	Mathias B.	117	140	20%	0.217	135	164	**22%**	0.315	65	118	82%	0.105
5*	Thomas U.	93	92	-1%	0.475	99	92	-8%	0.36	45	0	**-100%**	-
7*	Anna H.	126	123	-2%	0.443	125	128	**2%**	0.456	151	30	**-80%**	0.122
8*	Martin L.	85	77	-10%	0.282	87	79	-9%	0.318	30	91	204%	0.001
9**	Anna-Lea S.	138	97	-30%	0.129	145	100	-31%	0.125	0	60	°	-
10*	Marcel H.	120	133	11%	0.266	120	135	**12%**	0.26	0	90	°	-

Table 38: Changes of the duration of individual sleeping periods and phases in own and parent's bed. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. Children demarked with an asterisk have sleeping problems, ** demarks children with more than three wake periods during the night. ° sleep in parent's bed only in the second observation week.

No significant changes can be observed in the duration of the individual sleeping phases either. Three children sleep in longer and four in shorter periods in the second observation week. Again, there is no remarkable influence whether the children sleep in their own or their parents' beds.

5.2.2.3 Number of Individual Periods

Changes of the number of sleeping periods and phases in own and parent's bed per day are summarized in Table 39 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements with bold letters.

ID	Name	Sleeping				Own bed				Parent's bed			
		n24_SL				n24_OB				n24_PB			
		W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	4.0	4.0	0%	0.5	3.8	4.0	**5%**	0.371	0.0	0.6	°	-
3*	Mathias B.	6.5	6.0	-8%	0.311	1.5	4.6	**207%**	0.022	1.5	1.6	7%	0.447
5*	Thomas U.	8.6	8.0	-7%	0.201	8.2	8.0	-2%	0.396	0.2	0.0	**-100%**	0.187
7*	Anna H.	6.6	6.4	-3%	0.383	3.2	6.0	**88%**	0.027	2.8	0.2	**-93%**	0.019
8*	Martin L.	8.6	9.0	5%	0.286	8.2	5.6	-32%	0.002	0.6	2.8	367%	0.001
9**	Anna-Lea S.	5.2	7.2	**38%**	0.006	5.0	6.8	**36%**	0.027	0.0	0.2	°	-
10*	Marcel H.	7.2	6.4	-11%	0.145	7.2	6.2	-14%	0.113	0.0	0.2	°	-

Table 39: Changes of the number of sleeping periods and phases in own and parent's bed per day. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. Children demarked with an asterisk have sleeping problems, ** demarks children with more than three wake periods during the night.

In total, two infants sleep more often a day, and four in fewer periods. Only in one case a significant change can be observed in the daily number of sleeping periods. Anna-Lea S. (case 9) has more sleeping phases in the second week.

Four children are more often in their own bed, but again no remarkable influence can be observed on the number of sleeping periods by the fact, if the infants spend more or less time in parents' or own bed,.

5.2.2.4 Intervals between Individual Periods

Changes of the intervals between subsequent sleeping periods are summarized in Table 40 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green.

ID	Name	Sleeping			
		I_SL-SL			
		W1	W2	rel. ch.	p
1*	Marc André K.	151	88	-41%	0.09
3*	Mathias B.	145	149	3%	0.473
5*	Thomas U.	106	149	40%	0.032
7*	Anna H.	128	149	16%	0.26
8*	Martin L.	131	108	-18%	0.123
9**	Anna-Lea S.	181	122	-33%	0.024
10*	Marcel H.	151	173	14%	0.252

Table 40: Changes of the intervals between sleeping periods. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. Children demarked with an asterisk have sleeping problems, ** demarks children with more than three wake periods during the night.

The intervals between subsequent sleeping periods are shorter in three of the seven cases, in one case (case 9) significantly. In one case (case 5) the intervals are significantly longer.

5.2.2.5 Time needed for Falling Asleep and Wake Times at Night

Changes of time needed for falling asleep and of the number of wake times at night are summarized in Table 41 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green.

		Time needed for falling asleep				Wake times at night			
		D_FASL				n_WAKEN			
ID	Name	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1*	Marc André K.	8	1	**-88%**	0.001	0.0	0.0	0%	-
3*	Mathias B.	missing	0			missing	2.3		
5*	Thomas U.	1	0	**-100%**	0.187	2.1	2.5	19%	0.262
7*	Anna H.	11	26	128%	0.098	2.0	1.8	**-10%**	0.347
8*	Martin L.	19	27	42%	0.145	2.2	2.8	27%	0.098
9**	Anna-Lea S.	4	0	127%	0.014	1.0	3.2	220%	0.06
10*	Marcel H.	30	15	**-50%**	0.055	1.6	2.4	50%	0.063

Table 41: Changes of time needed for falling asleep and of the number of wake times at night. "p" demarks the significance of 1-tailed t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. Children demarked with an asterisk have sleeping problems, ** demarks children with more than three wake periods during the night. +... sleeps immediately in first observation week and takes longer in second week.

In three of six valid cases, infants need less time for falling asleep (one significant result), in three cases wake times at night are reduced (one significant result).

Anna-Lea S. (case 9), who woke up more than three times at night before treatment, even has more wake periods during the second observation week than in the first one, when wake periods during the night were reduced to a single one, on average. In the second observation week, she wakes up three times on average.

5.2.3 Side Effects on the Parents

Changes of the parent's general mood, their energy level and their stress level are summarized in Table 42 by the mean values, the relative change of the mean values of these variables in the two observation weeks (rel. ch.) and the significance of the mean differences between the two observation weeks (p). Significant changes are demarked light green, improvements (negative values) with bold letters.

ID	Name	Energy				Mood				Stress			
		VAS_Eng				VAS_Mood				VAS_Relax			
		W1	W2	rel. ch.	p	W1	W2	rel. ch.	p	W1	W2	rel. ch.	p
1	Marc André K.	0.65	0.27	**-58%**	0.039	0.54	0.17	**-69%**	0.015	0.56	0.21	**-63%**	0.015
2	Julia H.	0.54	0.28	**-47%**	0.058	0.41	0.34	**-17%**	0.231	0.62	0.39	**-36%**	0.061
3	Mathias B.	0.53	0.48	**-9%**	0.283	0.23	0.22	**-3%**	0.476	0.53	0.49	**-7%**	0.367
4	Lukas B.	0.52	0.51	**-1%**	0.465	0.27	0.22	**-19%**	0.213	0.52	0.51	**-1%**	0.469
5	Thomas U.	0.38	0.41	8%	0.331	0.39	0.47	20%	0.248	0.51	0.38	**-25%**	0.19
6	Leonard H.	missing	missing	-	-	missing	missing	-	--	missing	missing	-	--
7	Anna H.	0.54	0.45	**-16%**	0.209	0.26	0.15	**-41%**	0.055	0.54	0.47	**-13%**	0.263
8	Martin L.	0.20	0.31	54%	0.117	0.25	0.25	0%	0.5	0.34	0.31	**-8%**	0.381
9	Anna-Lea S.	0.72	0.83	15%	0.198	0.81	0.79	**-3%**	0.446	0.81	0.85	4%	0.414
10	Marcel H.	0.30	0.54	80%	0.016	0.30	0.38	25%	0.244	0.34	0.56	63%	0.044

Table 42: Change of the parent's general mood, their energy level and their stress level. "p" demarks the significance of the t-tests and "rel. ch." the relative change between the first and the second five-day period after onset of the osteopathic treatment. The parents of Leonard H. did not answer these questions.

Five of nine parents (55.5%) feel a higher energy level in the second observation week, but this difference is statistically significant only in one case (case 1). The parents of Marcel H. (case 10) are significantly more exhausted.

Six of nine parents (66.7%) have a better mood in the second observation week. Again, the parents of Mark André K. with statistical significance.

Seven of the nine (77.8%) parents are less stressed during the second observation period, but again, the parents of Marcel H. (case 10) significantly more.

5.3. Summary of Average Data

The mean value of the daily total duration of crying, whining, uneasiness and sleeping of all ten infants can be observed in Table 43. Mean values of individual durations of these periods are summarized in Table 44, mean daily frequencies in Table 45 and mean intervals between the periods in Table 46.

Duration per day	Var	Observation period	Mean value [min]	95% CI [min]	SD
Crying	D24_CR	initial state (**7 infants**)	**165**	**119-211**	**50**
		W1 (**7 infants**/10 infants)	**117**/96	**30-204**/35-157	**94**/85
		W2 (**7 infants**/10 infants)	**38**/34	**0-80**/6-62	**46**/39
Whining	D24_GR	W1	175	98-252	107
		W2	127	56-194	94
Uneasiness	D24_UE	W1	270	183-357	122
		W2	161	85-237	106
Sleeping	D24_SL	W1	457	438-477	27
		W2	462	420-505	59

Table 43: Daily duration of crying, whining, uneasiness and sleeping grouped by observation weeks.

Data of the first and second observation week vs. initial state

For a comparison of the average data of the daily duration of crying (D24_CR), only seven infants can be considered, since in three cases data of the initial state are missing. For these seven children 48 minutes average reduction of crying per 24 hours could be calculated for the first observation period (SD: 91 min). This reduction is not significant (paired samples t-test: t= 1.4, p= 0.21). During the second observation period, on average, the seven infants cry 127 minutes shorter, compared to the initial state. This reduction of D24_CR is significant (paired samples t-test: t= 4.15, p= 0.006).

That means, that the major reduction of crying time takes place after the first observation week.

Data of the first vs. data of the second observation week

The results of the paired samples t-tests with the data of the first and second observation week show a significant decrease of the duration of uneasiness in the second observation week (mean reduction: 109 minutes/24 hours, t= 2.383, p= 0.041) and distinct differences in the duration of crying (mean reduction: 62 minutes/24 hours, t= 2.022, p= 0.074) and whining (mean reduction: 48 minutes/24 hours, t= 1.636, p= 0.14).

No significant changes can be observed in the daily duration of sleep (D24_SL: mean difference: 5 minutes/24 hours, t= 0.348, p=0.74).

Duration of periods	Var	Observation period	Mean value [min]	95% CI [min]	SD
Crying	P_CR	W1	36.3	10.6-62.1	36.0
		W2	17.6	7.9-27.3	13.5
Whining	P_GR	W1	45.7	24.3-67.1	29.9
		W2	25.8	16.1-35.5	13.6
Uneasiness	P_UE	W1	42.5	28.2-56.8	20.0
		W2	24.9	15.4-34.4	13.3
Sleeping	P_SL	W1	133.4	106.3-160.5	37.9
		W2	148.3	102.7-193.9	63.8

Table 44: Duration of crying-, whining-, uneasiness- and sleeping periods grouped by observation weeks.

The results of the paired samples t-tests show a significant decrease of the duration of individual periods of whining (mean reduction: 20 minutes/period, t= 2.398, p= 0.040) and uneasiness (mean reduction: 18 minutes/period, t= 2.559, p= 0.031) in the second observation week and distinct differences in the duration of crying (mean reduction: 19 minutes/period, t= 1.636, p= 0.14).

No significant changes can be observed in the duration of the sleeping periods (D24_SL: mean difference: 15 minutes longer sleep/period, t= 1.204, p=0.26).

Number per day	Var	Observation period	Mean value (n)	95% CI (n)	SD
Crying	n24_CR	W1	2.8	1.2-4.5	2.3
		W2	1.6	0.1-3.0	2.0
Whining	n24_GR	W1	4.1	3.0-5.2	1.6
		W2	4.2	2.6-5.7	2.2
Uneasiness	n24_UE	W1	6.9	4.9-9.0	2.9
		W2	5.7	3.3-8.1	3.3
Sleeping	n24_SL	W1	6.3	5.2-7.4	1.6
		W2	6.0	4.7-7.3	1.8

Table 45: Number of crying-, whining-, uneasiness- and sleeping periods grouped by observation weeks.

The results of the paired samples t-test shows a distinct decrease of the number of crying periods (on average, 1.3 periods less per day, t= 1.838, p= 0.099).
No significant changes can be observed in the number of whining periods (on average 0.06 periods more, t= 0.86, p= 0.93), periods of uneasiness (on average, 1.2 periods less per day, t= 1.202, p= 0.26) and sleeping periods (D24_SL: 0.3 periods less/day, t= 0.846, p=0.42).

Intervals	Var	Observation period	Mean value [min]	95% CI [min]	SD
Crying	I1_CR-CR	W1	127	62-191	84
		W2	187	144-229	34
Whining	I1_GR-GR	W1	166	115-217	71
		W2	187	115-260	95
Uneasiness	I1_UE-UE	W1	131	105-156	36
		W2	154	102-206	68
Sleeping	I1_SL-SL	W1	156	133-178	32
		W2	149	123-175	37

Table 46: Intervals between crying-, uneasiness- and sleeping periods grouped by observation weeks.

No significant changes can be observed in the intervals between crying periods (on average 39 minutes longer intervals, t= 0.938, p= 0.40), whining periods (on average 13 minutes longer intervals, t= 0.325, p= 0.75), periods of uneasiness (on average, 21 minutes longer intervals, t= 0.744, p= 0.48) and sleeping periods (on average, 7 minutes shorter intervals, t= 0.548, p=0.60).
Since several infants are uneasy less than twice a day during the second observation period, no intervals were calculated. Thus, five infants could not be considered in the paired samples t-test for crying and one each for the tests for whining and uneasiness.
Generally said, crying behaviour is improved in the second observation week (after osteopathic treatments).

There is a significant decrease of the **duration** of uneasiness **per day** and a distinct reduction of crying time.
Predominantly, this is caused by a significant decrease of the duration of **individual periods** of whining and uneasiness and a distinct decrease of the duration of crying periods.
Additionally, a distinctly lower **number** of crying periods can be observed.
Intervals between the individual crying- and whining periods as well as periods of uneasiness did not change to a statistically relevant extent.
No significant changes of the sleeping behaviour could be observed.

6. Discussion

6.1. Discussion of the Method

6.1.1 Limitations Arising from the Therapist

Number of Therapists

The infants were treated by only one single therapist. Thus the results cannot be considered as having a general application i.e. one applying to other therapists. The reproducibility and consistency and consequently the reliability of the treatment cannot be concluded from this study. According to my experience, osteopaths have preferences in their diagnosis and therapy. The application of other techniques by different therapists would possibly have resulted in other outcomes.

6.1.2 Limitations in the Design of the Study

6.1.2.1 General Restrictions

Lack of comparative data

The patients were directly allotted to me by medical practitioners of the aftercare unit of the University Department of Pediatrics and Adolescent Medicine at the Vienna AKH, where I am working in an employed position. That means, the doctors as well as the parents expect immediate treatment. Thus, the parents had no time to fill the journal according to Papousek et al. (2004) and subsequently there are only few comparative data of the time before the initial osteopathic treatment. That means, that the first complete data sets are available of the week after the first osteopathic treatment. Nevertheless, these deviations from the within-subjects design are not of methodological relevance because:

- it is possible to compare relevant data before treatment (mean daily duration of crying),

- this comparison results in (statistically not significant) improvements during the first observation period, and thus
- improvements after the complete treatment period have to be more distinct for resulting in significant reductions of regulation problems.

Lack of control group

Due to the lack of a control group temporal changes which might occur due to the natural maturation of the infants are not considered.

The best option for my investigation would have been to make use of a matched control group. Due to the manifold exterior peri- pre and postnatal influences it would be almost impossible to form an adequate matching control group. At least the premature infants should be matching by gestation period, weight at birth and medical interventions. Due to the considerable organization necessary to get in contact with parents of such infants, I chose the within subject design.

Interpretation of the term "crying"

Errors due to different interpretation of the term "crying" can not be precluded.

For example, no crying periods are reported for Martin L. (case 8) during the two observation periods. In this time, daily duration of uneasiness is similar the duration of crying before osteopathic therapy. Thus, it can not be taken for granted, that crying behavior really improved.

Reijneveld (2001) applied studies should use both a definition regarding the duration of crying and whining per day and one regarding the resulting parental distress. It would lead to the inclusion of different groups of infants.

The second Wessel (1954) definition may be less interesting, as parents and clinicians are not be willing to wait for 3 weeks. The inclusion of a definition of parental distress will be important, as this could be a main impulse for seeking professional care.

Data collection

Two different methods were used for data collection. Therefore, it is impossible to compare some data. A third observation phase, in advance of the first osteopathic treatment, during which a journal according to Papousek et al. (2004) should be filled, would be the best option.

Sustainability of Treatments

A further issue would be to examine the lasting effect of the treatments, which would require further data from another journal after a period of time.

Sample size

Sample size is low (10 infants all of them with excessive crying behaviour and seven of them with sleep problems) and the sample might not represent the population. Generally, statistical tests are dependent on a sufficient sample size, in order to be able to distinguish between systematic and random effects and to yield reliable results.

6.1.2.2 The Variables used

By the variables used, duration of crying, whining, uneasiness, sleep per 24 hours, as well as the duration and the number of individual periods, it is possible to characterize the crying behaviour quite well. The intervals between the periods were used to visualize possible changes in crying behaviour and are of minor interest. The time the infant spends in parent's or in its own bed is also used to show possible changes in parent's behaviour. Nevertheless, it is impossible to distinguish between cause and effect: Is there an improvement of excessive crying, because the child lies longer in its own bed, or are the parents able to lay down their child, because it cries less?

Under consideration of the duration of different periods, the 15-minute scale of the questionnaire is accurate enough for the variables listed above.

Nevertheless, this scale is too coarse for time needed for falling asleep and the characterization of the time, when the child is awake in the night.

In the questionnaire according to Panagl and Leiss (2002), the parents had to fill before osteopathic treatment, they had to estimate the time how long per day their infant cried. In one case parents did not use an exact value, and generally they used ranges. Therefore, the mean value was used for statistical evaluation.

Generally, the journal according to Papousek et al. (2004) provides more reliable data than the questionnaire.

6.1.2.3 Missing Data

Key assumption underlying paired samples t-tests is an equal number of comparative data.

Due to three missing answers, there are no data about the mean daily duration of crying before osteopathic treatment. Thus, only seven comparisons with data of the two observation weeks could be performed.

6.1.3 Osteopathic Treatment

There are two important reasons, why I did not want to give preference to any standardised procedure for treatment of crying and sleeping disorders. Firstly, the boundary between normality and pathology can not be exactly defined. A crying and sleeping disorders aspect is the parents' ability to endure the behaviour of the infant (resources). Secondly, crying and sleeping disorders are symptoms of a very complex and individual medical history. The individual traumata even need not to be in causal context and different symptoms might arise due to different medical reasons. Therefore different treatments were adapted individually for each infant and were evolved in a processual way. That means, I did not always use the same techniques during therapy, but drew on the pool of the techniques I have internalised during my training in osteopathy, pediatric osteopathy and biodynamic osteopathy.

6.2. Discussion of the Results

6.2.1 Crying Behaviour

On average, daily crying time (initial mean value: 165 minutes/24 hours) is 48 minutes shorter during the first observation week after the first osteopathic treatment and further 109 minutes shorter during the second observation week three weeks later. That means, the infants cry only 38 minutes per day during the second observation week, on average.
The difference between the initial situation and the data of the second observation week is statistically significant ($t=4.15$, $p= 0.006$).
The reduction between the initial state and the first observation period is not significant (paired samples t-test: $t= 1.4$, $p= 0.21$).

Responsible for the improvement during the second observation period is, that six of the seven infants (85.7 %) cry shorter during the second observation week than before the osteopathic treatments. In four cases (57.1%) this difference is statistically significant (cases 1.3, 4 and 5), in two cases (28.6%), no (remarkable long) crying periods are reported (cases 6 and 8). These two cases could not be evaluated by significance tests, since the standard deviation is zero. Of course, these improvements are most advantageous.

Only one infant (14.3%) cries longer than before osteopathic treatment (case 10: 90 minutes before treatment, 99 minutes during the second observation period). This difference is not significant.

Additionally, in the three cases, where there is no information about the initial state (cases 2, 7 and 9), crying is distinctly reduced during the second observation week compared to the first one (at least by 33%). Nevertheless, these differences are not significant.

Thus, generally said, crying behavior is improved in the second observation week after the osteopathic treatments.

Total daily crying time is reduced by distinct reductions of the time as well as number of individual crying periods. The duration of crying periods during the first observation period is 36.3 minutes, on average, the corresponding result during the second period is 17.6 minutes, that means approx. 19 minutes less ($p= 0.14$). The number of crying periods decreases from 2.8 to 1.6 per day between the two observation periods ($p= 0.10$).

This improvement among almost all infants is remarkable, because many various influences (of organic or psychosocial kind) sometimes interconnected in vicious circles are considered as reasons for regulatory disorders.

For example, regulatory disorders may arise from prenatal reasons (e.g., abnormal distress of the mother, fear and depression or early labour, severe hyperemesis, smoking, etc…), perinatal reasons (early separation of the newborn, and traumatic delivery or medical interventions during delivery and severe complications, …) and postnatal reasons (like family conflicts and psychic disorders or atopies, hospitalisation and recidive infections).

Already in 1968, Thomson found a higher prevalence of regulation problems among preterm infants and more frequent psychosocial stress factors in this connection (Thomson, 1968).
Preterm infants most commonly are delivered by Caesarean sections. The preterm normally is separated from the parents and transferred to a Neonatological Intensive Care Unit. In contrary to regular deliveries, a preterm delivery has to be classified as traumatic crisis (Affleck et al., 1991).

Examples for symptoms described after Caesarean sections are shock syndromes (De Jong, 2003), physical reactions, like compression patterns, disturbtion of the symmetry (Möckel and Mitha, 2006), a higher pressure level on the cranium (Weiss, 1994), wet lungs (Brüggemann, 1993), an increased sympathicus activity, but also reactions like psychic shock (Emerson, 1997) or different sensoric sensibility (English, 1997)

But also the parents are affected by preterm deliveries, what can add to regulation problems of the infants, too: Birth is encountered as traumatically, feelings of deep disappointment may arise and the early isolation of their child puts a strain on the parents (Hantsche et al., 1992). Additionally, the parents are confronted with burdening information about the health status of their child and the medical treatment. Affleck et al. (1991) reports, that parents of preterm infants are more fraught and concentrated in dealing with their child and feel worried easily.

According to Papousek et al. (2004), these particular demands on the intuitive co-regulatory competence of the parents can add to regulation problems.

By the adaptation of osteopathic treatment to the individual needs of each infant instead of using a standardised procedure the complex syndrome of excessive crying could be improved even without knowledge of the effective reason.

Additionally, not only crying, but also time of whining - and thus uneasiness - is reduced in the second observation period compared to the first one (whining: -48 min/24 hours, p= 0.14, not significant; uneasiness: - 109 minutes/24 hours, p= 0.04, significant), That means, that the infants do not express their regulatory problems by whining instead of crying and excessive crying is really improved.

These changes are predominantly caused by a significant decrease of the duration of **individual periods** of whining and uneasiness (whining: -20 minutes/period, p= 0.040, significant; uneasiness: 18 minutes/period, p= 0.031, significant) and the distinct decrease of the duration of crying periods (19 minutes/period, p= 0.14).
Intervals between the individual crying- and whining periods as well as periods of uneasiness did not change to a statistically relevant extent.

6.2.2 Sleeping Behaviour

In spite of 15 minutes more sleep per period on average, the seven children with according problems sleep only five minutes longer, during the second observation period compared to the first one, on average, since the number of such periods becomes lower and variability increases.
Only three infants need less time for falling asleep and only one wakes up less often during night.

That means, no significant changes of the sleeping behavior could be observed.

There are two possible reasons for the contrasting results of crying and sleeping behaviour: Either osteopathic treatment affects the reasons for sleeping disorders and excessive crying in different ways or the reorganisation of the sleep-wake rhythm takes a longer time. Normally, a reorganisation of the nocturnal sleep takes place takes place, when the infants start to move on their own.

6.2.3 Side Effects on the Parents

55.5% of the parents feel a higher energy level in the second observation week, but only in one case, this difference is statistically significant. On contrary, in another case the parents are significantly more exhausted.
66.7% of the parents have a better mood during the second observation week. Again, only one difference is statistical significant.
77.8% of the parents are less stressed during the second observation period (one significant difference), but again, in another case significantly more.
These data can be differently interpreted. On one hand they might mirror the improvements of the regulation disorders, on the other hand they may describe reasons for the presence of these disorders, since they might be caused by psychosocial reasons, too.

Under consideration of these data, in general, neither significant influences due to better mood or energy level of the parents on the regulation problems nor a significant improvement of the parents' condition by the improvements can be deduced.

As discussed in chapter 6.1.2.1 (Lack of control group), another possible exterior reason which can not be precluded due to the study design, is the natural development of the infants. Since changes can be observed during the observation period directly after the first osteopathic treatment, osteopathic treatment is very likely to be at least the "initial spark" for the infants' self healing mechanisms.
Thus, osteopathic treatment should be responsible for the results, singly.

7. Summary and Conclusions

Excessive crying of young infants is a common and often serious problem for parents. It may affect parental feelings negatively and may cause the infant to be regarded as vulnerable or difficult (Barr, 1998).

My study is an attempt to show up the manifold range of traumata among preterm infants, which may lead to the syndromes of crying and sleeping disorders and the ability of osteopathy to improve these problems.
The knowledge about the multiple reasons behind these syndromes enables the therapist to proceed in a differentiated way during therapy.
Ten preterm infants, all of them delivered by caesarean section and cry babies and seven of them with sleeping disorders, were treated osteopathically for four weeks. During two observation periods of five days each (the first immediately after the first osteopathic treatment, the other four weeks later), data concerning their crying and sleeping behaviour were collected by the parents. Osteopathic treatment was applied by myself only. It was crucial to adapt therapy individually for each child and an intuitive approach has proved itself as essential.

The main outcomes of this study are:
Crying behaviour is significantly improved by osteopathic treatment ($p= 0.006$).
On average, the infants cry more than two hours less per day compared to the initial state before osteopathic treatment and in most cases, an additional reduction of whining can be observed. Improvements in crying behaviour, that means less and shorter periods of crying, can be observed among 90% of the infants.

In contrary, sleeping behaviour of the infants does not improve significantly.

There are two possible reasons for the contrasting results of crying and sleeping behaviour: Either osteopathic treatment affects the reasons for sleeping disorders and excessive crying in different ways or the reorganisation of the sleep-wake rhythm takes a longer time.

Main limitations for a generalisation of the results are:

- The infants were treated by only one single therapist.
- The lack of a control group.
- Possibly, different interpretations of the term "crying" by the parents.
- The use of two different methods for data collection.

Therefore, for further investigations, the following procedure can be recommended:
Since prospective studies with large random sample sizes are almost impossible to perform without the support and infrastructure of a neonatological department of a hospital, a matched control design will be the best choice. Members of the study group and the control group at least shall be matched in terms of medical interventions and diagnoses as well as gestational weeks and birth weight (A matching in terms of psychological and sociopsychological aspects will be difficult).
Treatment by several osteopaths will enable the assessment of the reliability of osteopathic treatments as well as the treatment of a larger sample.
Data will have to be collected in a standardized form before and after treatment as well as after some more time for testing sustainability (e.g., one month after the end of therapy might be a compromise between a sufficiently long interval after the treatments and avoidance of exterior influences, like regular development of the infants).
Terms like "crying" or "time, when the child is laid down to sleep" have to be defined as accurate as possible and the parents have to be introduced into these definitions in order to prevent own interpretations.

Nevertheless, the "within subject" design is sufficient for a first assessment of my basic questions. Exterior influences, like changes in parents' mood, energy and distress, changes in the infants' environments (time spent in own or parent's bed) and regular development can be precluded by the additional variables considered and the results of the first observation period, respectively.

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9. Table of Illustrations

Fig. 10: Incubator.
(n.n.)

Fig. 11: Preterm infant during "kangarooing".
(n.n.)

10. List of Tables

Appendix 1:
Concept

Concept

by Elisabeth Rajchl
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Effect of osteopathic treatment on premature infants with regulation problems

Objective:

Crying and sleeping disorders are symptoms of a very complex and long medical history. There are indications, that pre- peri- and postnatal strains, on organic as well as psychosocial level are cross-linked to a large extent. There was also an attention on the socioeconomic organisation within the family

My study is an attempt to show up the manifold range of traumata among preterm infants, which may lead to the syndromes of crying and sleeping disorders and the ability of osteopathy to improve these problems.

Research question:

Is there a positive influence in the symptoms of crying and sleeping problems of preterms with osteopathic treatments?

Relevance for the patient/generality:

In my job at the children`s hospital in Vienna, I become acquainted with a lot of preterms with regulation problems and their parents. I realized their extremely psychosocial and organic stress, they are confronted with. In the improvement of their symptoms, there could be a positive feedback indicated for both of them.

Relevance for the Osteopathy:
Besides the conventional therapeutical concepts for excessive crying and sleep problems (pharmaceutical, dietary, naturopathic, behavioural interventions), there could be created a new advantage of treatment for these kids. This will be have a positive influence in the osteopathic existence in Austria. Statistical data, released on the occasion of the 42nd anniversary of the Austrian Society of Pediatrics and Adolescent Medicine, show, that incidence of preterm deliveries increased by 13% and incidence of preterm deliveries of infants with less than 1000g birth weight by 87% since 1990. (Austrian Society of Pediatrics and Adolescent Medicine, 2004).

Hypothesis:
Osteopathic treatments have a positive influence on preterm infants with regulation problems.

Design of the study: experimental, clinical, within subject

Method:

Inclusion criteria:

- Delivery earlier than the 32nd week of gestation
- delivered by caesarean section
- younger than one year
- crying more than three hours a day, at least three days a week for a period of at least three weeks according to Wessel (1954)
- and/or sleeping problems

Exclusion criteria:

- hereditary diseases
- severe cerebral disorders (cerebral haemorrhages of degree 3-4)

Additional medical or physiotherapeutic treatment are no exclusion criteria.

Procedere:

Test persons: 10-14 preterm infants who are allotted to me by medical practitioners of the aftercare unit of the department of paediatric surgery of the medical university of Vienna.
Additional to the standard anamnesis, they will be asked to fill a questionnaire (Panagl and Leiss, 2002) concerning their baby's sleeping- crying- and feeding behaviour.
The babies will be treated osteopathically at least 3-5 times in weekly interval (additionally to medical or physiotherapeutic treatment).
During this period, the parents will be asked to fill a journal concerning their baby's sleeping- crying behaviour (Papousek et al., 2004: 112) for ten days.

Additional information: This masterthesis will be a experimental, clinical, within subject study. I am not able to select a control group, in the knowledge, that osteopathy can really help to allay the distress of these infants and their stressed parents.

Variables

Dependent variables:

The parents will be asked to fill a questionnaire (Panagl and Leiss, 2002) concerning their baby's sleeping- crying- and feeding behaviour.

- Intermediate intervals
- Central intervals
- Periods Duration per 24 hours (i.e. the sum of the duration of periods between 06:00 a.m. and 06:00 a.m. the next day)
- Number of periods per 24 hours (between 06:00 a.m. and 06:00 a.m. the next day; n)
- Time needed for falling asleep at night
- Number of wake periods at night

Independent variables:

Experimental group: medical or optionally physiotherapeutic treatment, osteopathic treatment (Observation week after first osteopathic treatment)

Validity and reliability of the variables:

The parents will be asked to fill a journal concerning their baby's sleeping- crying behaviour (Papousek et al., 2004: 112) for ten days.

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Appendix 2:
Questionnaire according to Panagl and Leiss (2002)

Sleeping Behaviour

When is your infant put to bed at night? ……
How many hours sleeps your baby at night, on average? ……
How often sleeps your infant during in the day time? ……
Where do you sleep?

Mother/female caregiver: ……
Father/male caregiver: ……

Where sleeps the child?

in its own bed ☐
in the bed of the parents ☐
elsewhere: ☐ ……

When the infant sleeps in the bed of the parents? How much are you disturbed?

not at all ☐
a little ☐
very much ☐
massively ☐

Has your infant problems with falling asleep in the evening?

no ☐
yes ☐

- if yes what kind of problems?

needs help for falling asleep ☐
needs more than 30 minutes ☐
wakes up several times in the night ☐

Has your infants problems to sleep without interruptions during the night?
(that means wakes your child up several times per night?)

no ☐
yes ☐

- if yes, how often per night?

up to three times per night ☐
more often than three times? ☐

How long is your child awake during these periods, on average:

- less than 20 minutes ☐
- more than 20 minutes ☐

How do you try to lull your baby?

- body contact ☐
- vestibular stimulation (dandling) ☐
- soother ☐
- feeding ☐
- distraction ☐
- else ☐ ……

How falls the child asleep again?

- body contact ☐
- vestibular stimulation (dandling) ☐
- soother ☐
- feeding ☐
- on its own ☐
- exhaustion ☐
- in parents' bed ☐
- distraction ☐
- else ☐

For how long is your infant having these sleeping problems?

……

During how many nights per week has your child sleeping problems?

- less than 4 nights per week ☐
- more than 4 nights per week ☐

Crying Behaviour

Are there acutely appearing episodes of excessive crying or unrest without obvious reason?

no	☐
yes	☐

- if yes: When do they start predominately?

05-08	☐	17-20	☐
08-11	☐	20-23	☐
11-14	☐	23-02	☐
14-17	☐	02-05	☐

How long do these episodes last per day on average?
……

How many days per week do these crying periods occur?
……

What do you think, why your infant cries?
……

How do you try to moderate your baby?

body contact	☐	
vestibular stimulation (dandling)	☐	
soother	☐	
feeding	☐	
distraction	☐	
else	☐	……

How relaxes your child mostly, then?

body contact	☐
vestibular stimulation (dandling)	☐
soother	☐
feeding	☐
on its own	☐
exhaustion	☐
distraction	☐
else	☐

Please describe these episodes (colour of the skin, muscle tone, …)

……

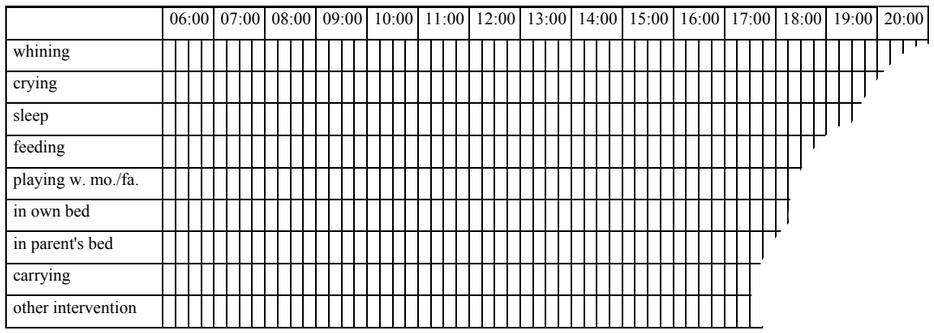
Do you feel stressed by these crying episodes ?

not at all	☐
a little bit	☐
very much	☐
massively	☐

Appendix 3:
Journal according to Papousek et al. (2004)

Note: In the original journal, the timetable ranges from 06:00 to 06:00

Name of the infant: …… Date: .....



.....06:00

When did you lay down your baby for sleeping at night? ……..

How long did it need to fall asleep? ……

How often did it wake up in the night? ……..…….

How did you feel today?

very happy _____ very unhappy

very energetic _____ very exhausted

very relaxed _____ very stressed

Appendix 4:
Raw Data

		1	2	3	4	5	6	7	8	9	10
		Marc André K.	Julia H.	Mathias B.	Lukas B.	Thomas U.	Leonard H.	Anna H.	Martin L.	Anna-Lea S.	Marcel H.
	date of birth	30.01.2002	02.05.2002	15.03.2002	15.03.2002	19.03.2003	23.07.2002	01.12.2002	12.08.2002	11.10.2001	06.09.2003
	birth weight	1535	958	1065	850			648		1648	1193
	gestational age (weeks)	29,6	27,4	31,3	31,3	29,0	32,3	27,0	30,0	29,7	28,0
Are there acutely appearing episodes of excessive crying or unrest											
	no										
	yes	x	x	x	x	x	x	x	x	x	x
if yes: When do they start predominately?											
	05:00-08:00			x							
	08:00-11:00										x
	11:00-14:00		x		x	x	x	x	x		
	14:00-17:00					x				x	
	17:00-20:00	x	x	x	x	x	x	x	x		x
	20:00-23:00	x								x	
	23:00-02:00									x	
	02:00-05:00									x	
How long do these episodes last per day on average? (h)		3-5		2-3	1,5-3	3	3-4		2-3		1
How many days per week do these crying periods occur?		7	4	3-4	5	5	3-4	3-4	7		7
For how long is your infant having these crying episodes?		05.05.2002	21.07.2002	15.03.2002	15.03.2002	6.LW	01.09.2002			16.06.2002	14.12.2003
What do you think, why your infant cries?			bad digestion and flatulence			tiredness, sleeping problems	bad digestion and flatulence/ boredom			"inner unrest"	likes to draw attention
How do you try to moderate your baby?											
	body contact	x	x	x	x	x	x		x	x	x
	vestibular stimulation (dandling)	x		x	x		x	x			x
	soother	x		x	x		x	x	x	x	x
	feeding	x		x	x	x		x			x
	distraction	x	x	x	x		x		x		
	else	x					x			x	
How relaxes your child mostly, then?											
	body contact			x	x	x			x	x	x
	vestibular stimulation (dandling)	x		x				x			x
	soother				x			x	x	x	x
	feeding				x	x		x			
	on its own		x								
	exhaustion	x	x	x	x	x				x	
	distraction								x		
	else										
Please describe these episodes (colour of the skin, muscle tone, …)		stiffens, colour of his skin remains normal	distended abdomen, face gets red	extremely loud, high muscle tonicity	red face	deep red face, he sweats, eyes are swollen	stiffens, face gets deep magenta, loses voice			angrily resisting sleep	red face
Do you feel stressed by these crying episodes ?											
	not at all										
	a little bit		x						x		x
	very much			x	x	x		x			
	massively	x					x			x	

ID		1	2	3	4	5	6	7	8	9	10
Patient		Marc André K.	Julia H.	Mathias B.	Lukas B.	Thomas U.	Leonard H.	Anna H.	Martin L.	Anna-Lea S.	Marcel H.
When is your infant put to bed at night?			20:30	20:00-21:00		20:00-21:00		20:00-21:30	21:00	19:30-20:00	19:00-21:00
How many hours sleeps your baby at night, on average?			8,5	9		10	7,5	9	6,5	10	11
How often sleeps your infant during in the day time?				2-3		3-5	1	1-2	3	2-4	2-3
Where do you sleep?											
	Mother/female caregiver	sleeping room	sleeping room	sleeping room		sleeping room	sleeping room	sleeping room	sleeping room	same room	sleeping room
	Father/male caregiver:	sleeping room		sleeping room		sleeping room		sleeping room	sleeping room	same room	sleeping room
Where sleeps the child?											
	in its own bed	x	x			x	x	x	x	x	x
	in the bed of the parents			x				x	x		
	elsewhere:							x			
When the infant sleeps in the bed of the parents? How much are you disturbed?											
	not at all		x								
	a little bit			x				x		x	
	very much						x		x		
	massively										
Has your infant problems with falling asleep in the evening?											
	no		x				x				
	yes	x		x		x		x	x	x	x
if yes what kind of problems?											
	needs help for falling asleep					x					x
	needs more than 30 minutes	x		x				x			
	wakes up several times in the night					x		x	x	x	
Has your infants problems to sleep without interruptions during the night?											
	no	x	x				x				
	yes			x		x		x	x	x	x
if yes, how often per night?											
	up to three times per night			x		x		x	x		x
	more often than three times?									x	
How long is your child awake during these periods, on average?											
	less than 20 minutes		x			x		x	x		x
	more than 20 minutes			x						x	
How do you try to lull your baby?											
	body contact	x		x		x	x	x			
	vestibular stimulation (dandling)	x						x			
	soother	x						x		x	
	feeding			x		x		x	x	x	x
	distraction										
	else						x			x	

ID		1	2	3	4	5	6	7	8	9	10
Patient		Marc André K.	Julia H.	Mathias B.	Lukas B.	Thomas U.	Leonard H.	Anna H.	Martin L.	Anna-Lea S.	Marcel H.
How falls the child asleep again?											
	body contact	x							x		
	vestibular stimulation (dandling)	x									
	soother			x				x		x	
	feeding		x	x		x		x			
	on its own									x	x
	exhaustion	x							x	x	
	in parents' bed										
	distraction										
	else										
For how long is your infant having these sleeping problems?		05.05.2002		some weeks					since birth	7 weeks	
During how many nights per week has your child sleeping problems?											
	less than 4 nights per week							x			
	more than 4 nights per week			x					x	x	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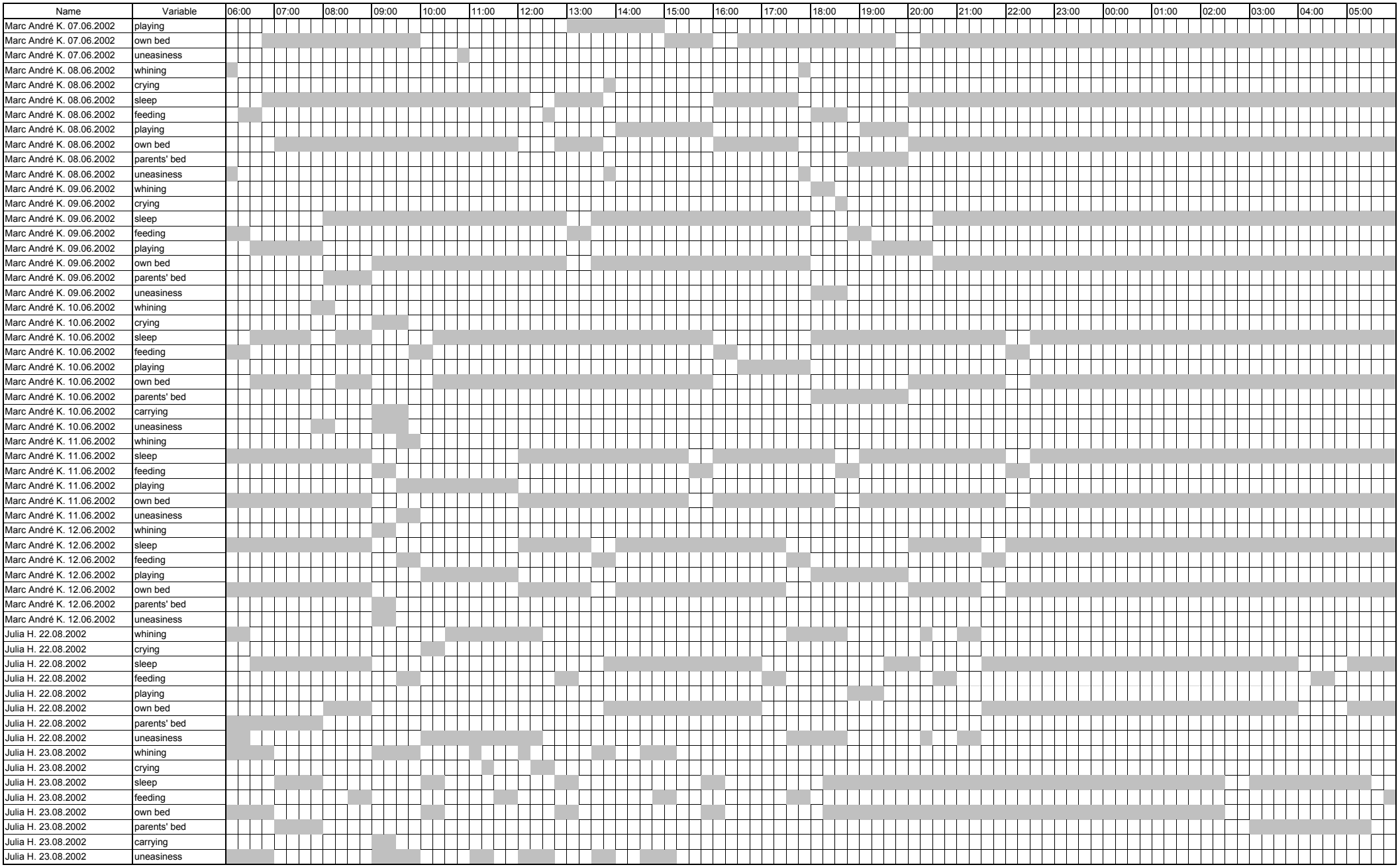
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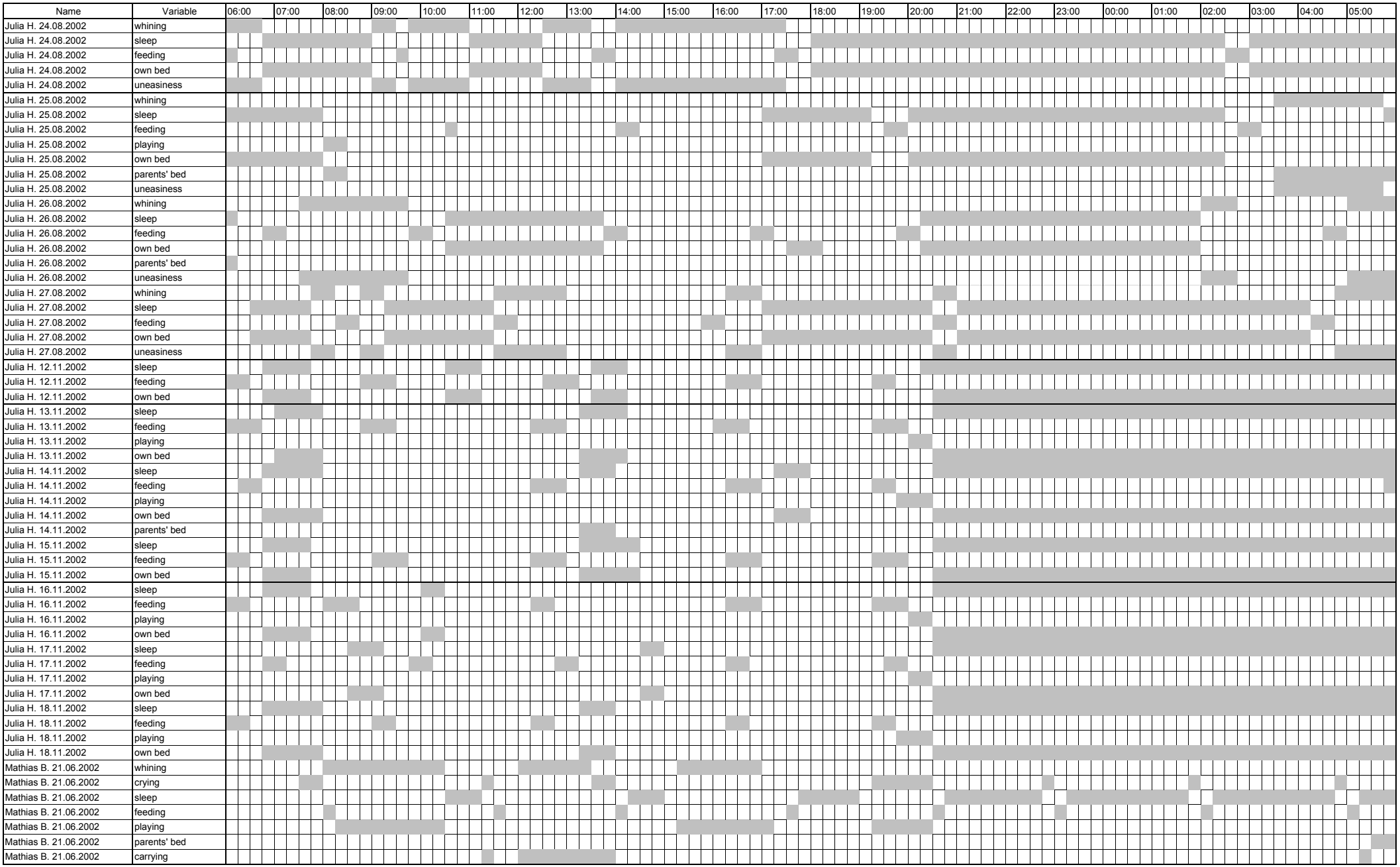
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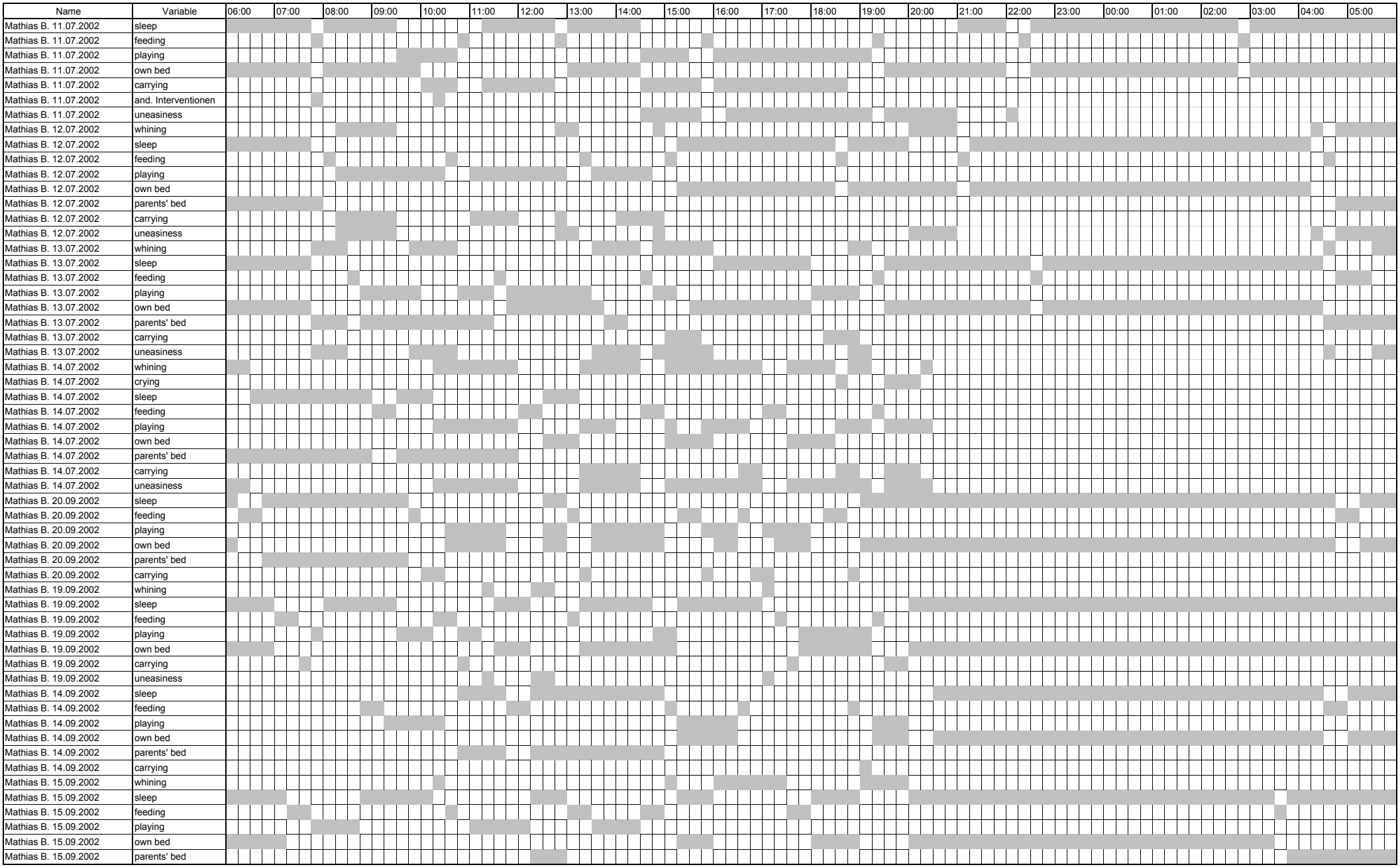
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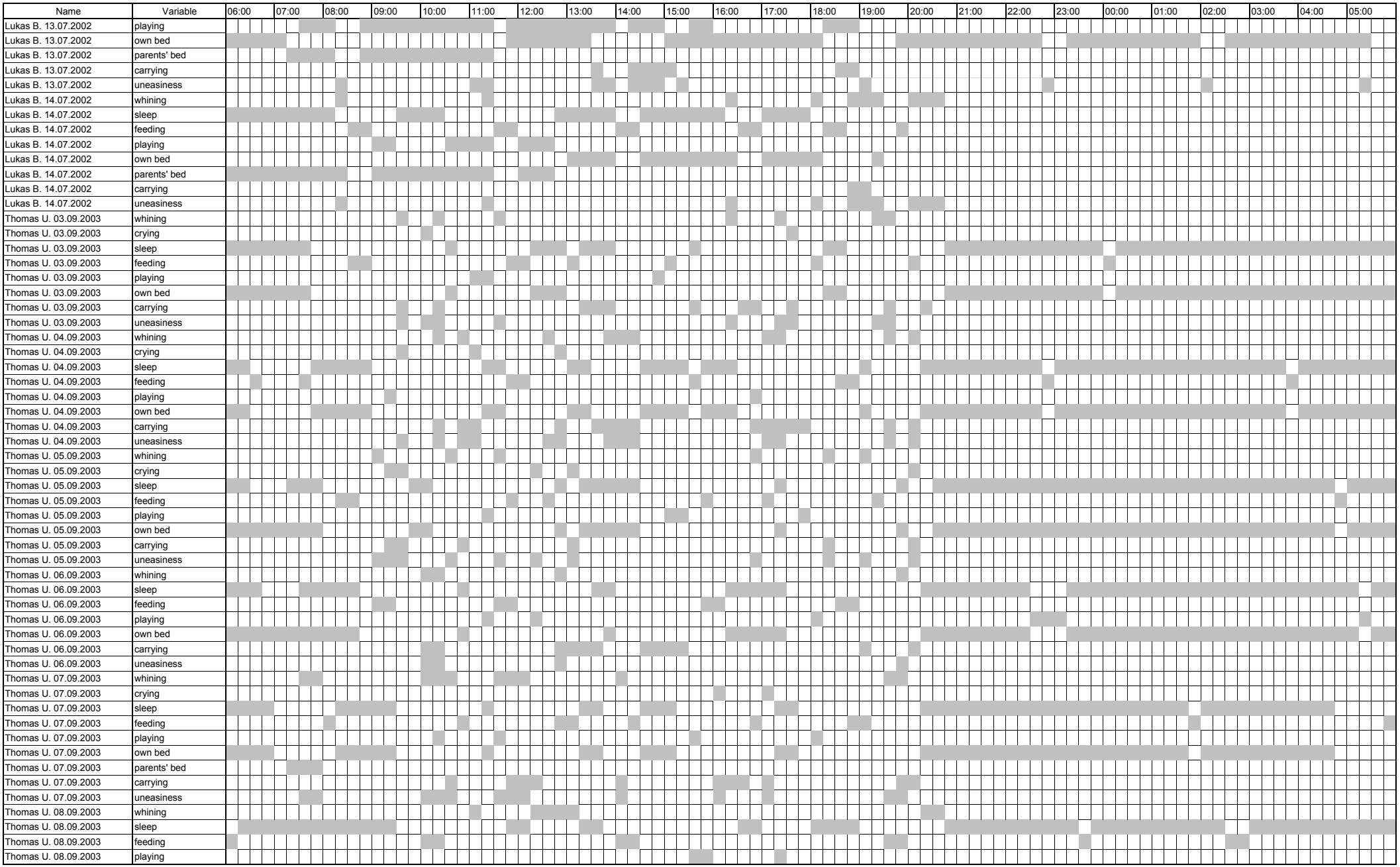
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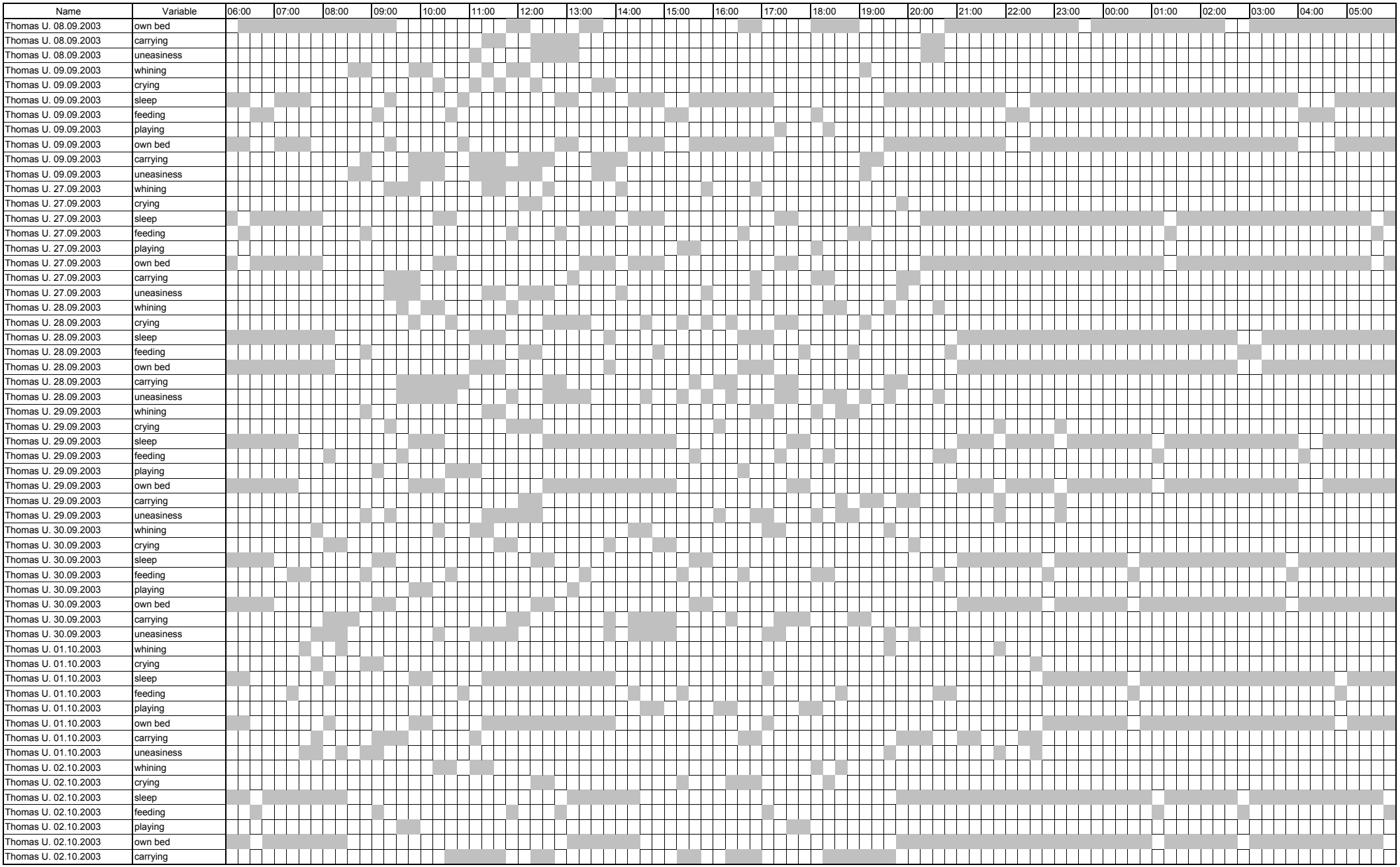
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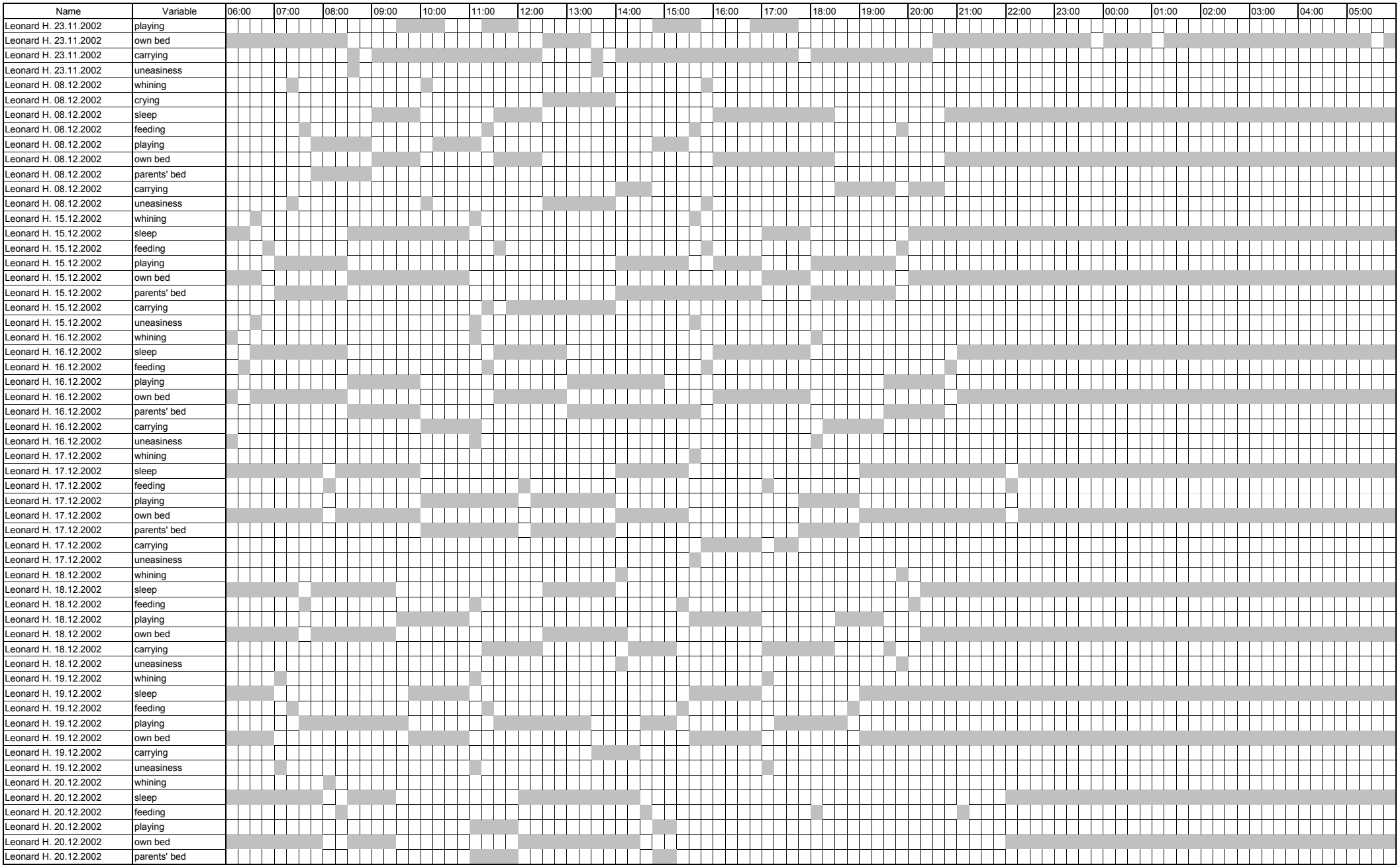
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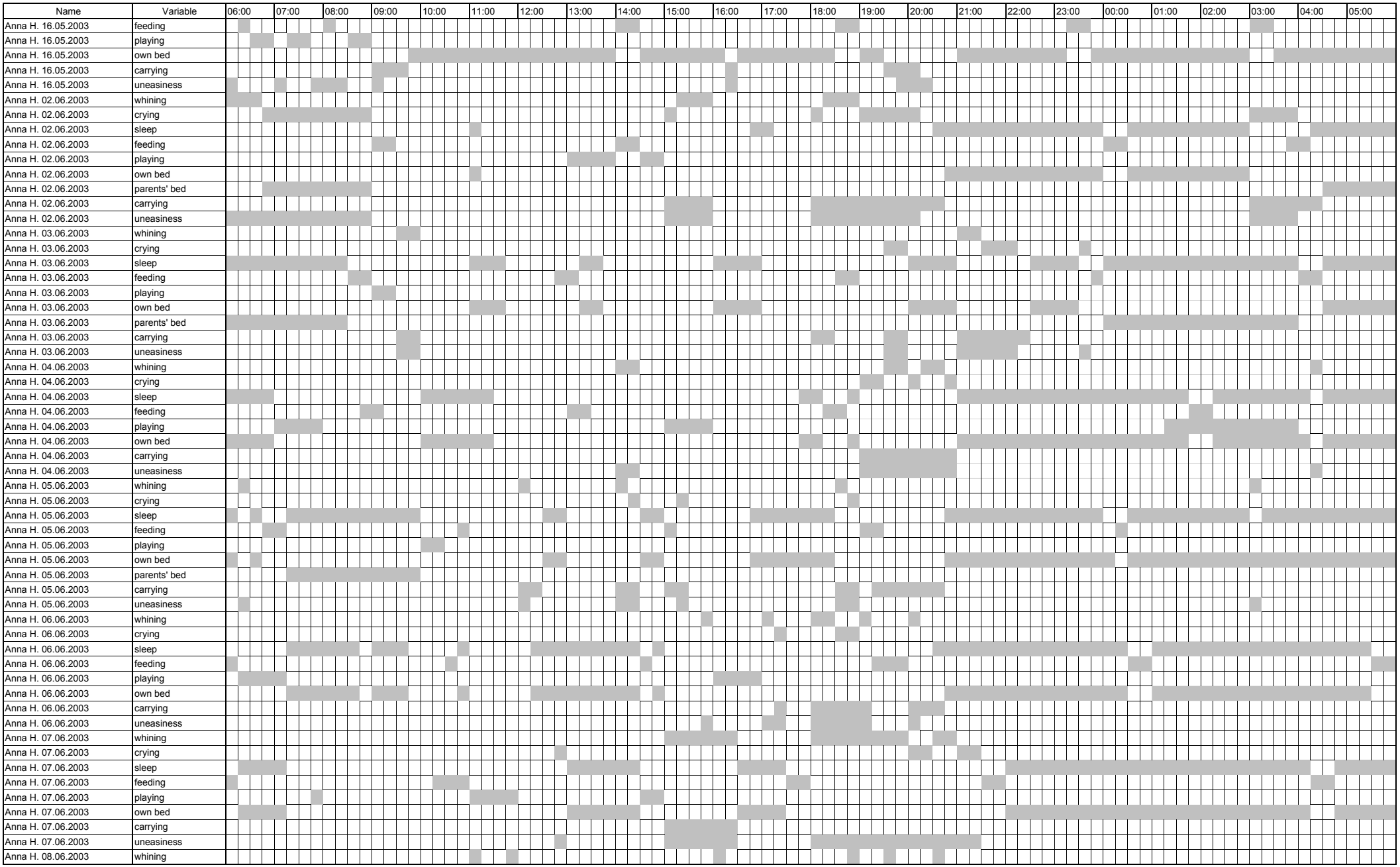
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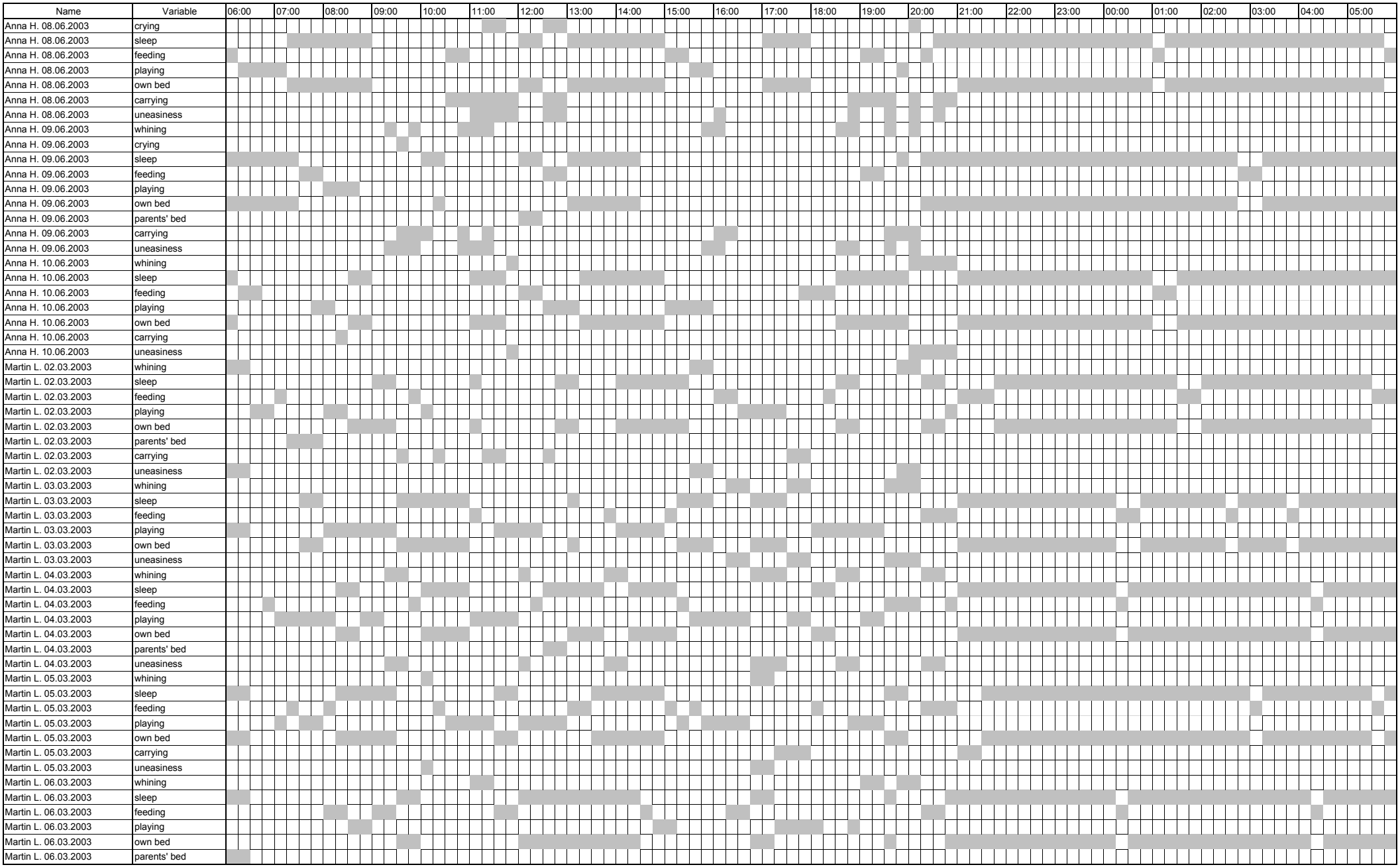
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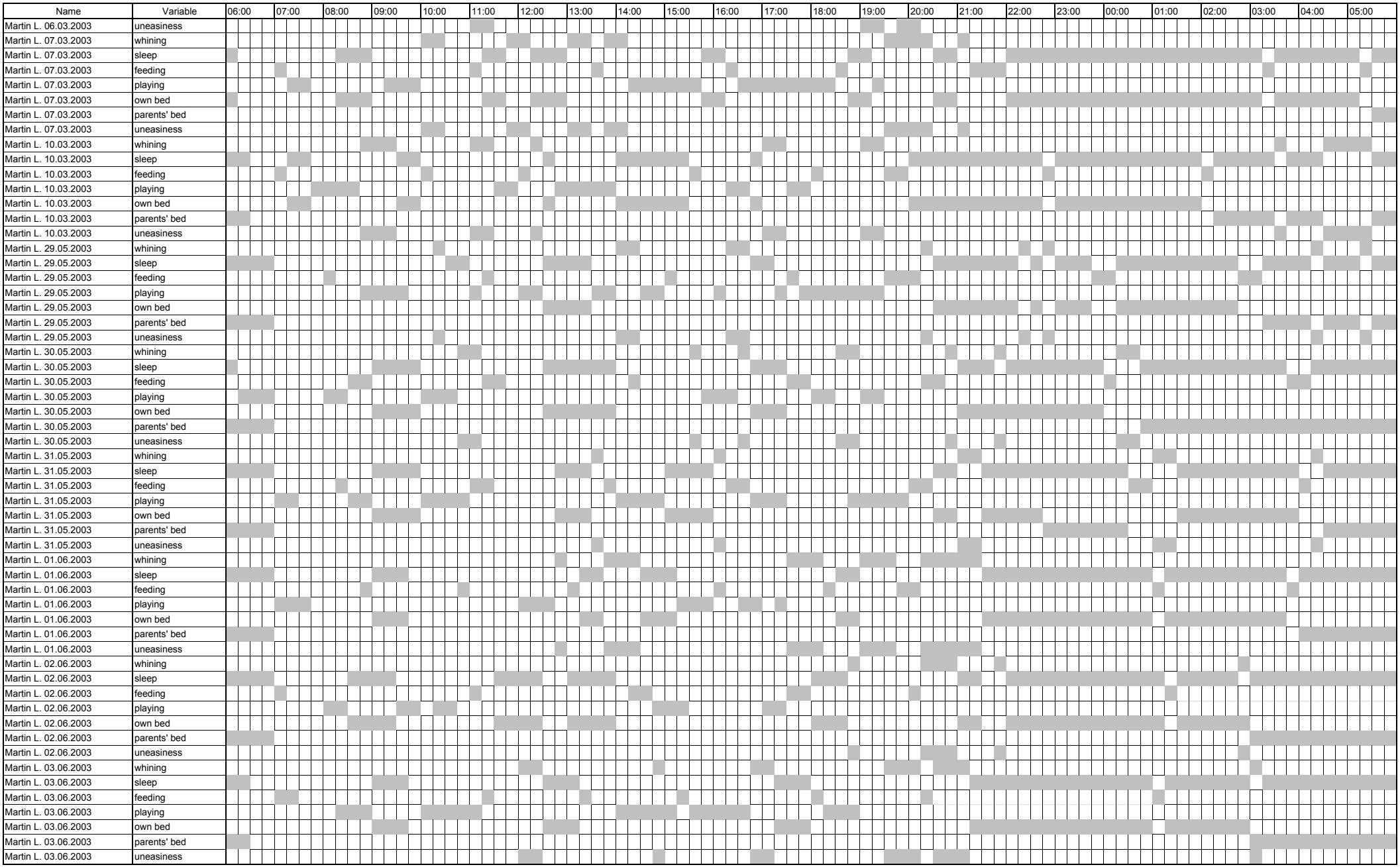
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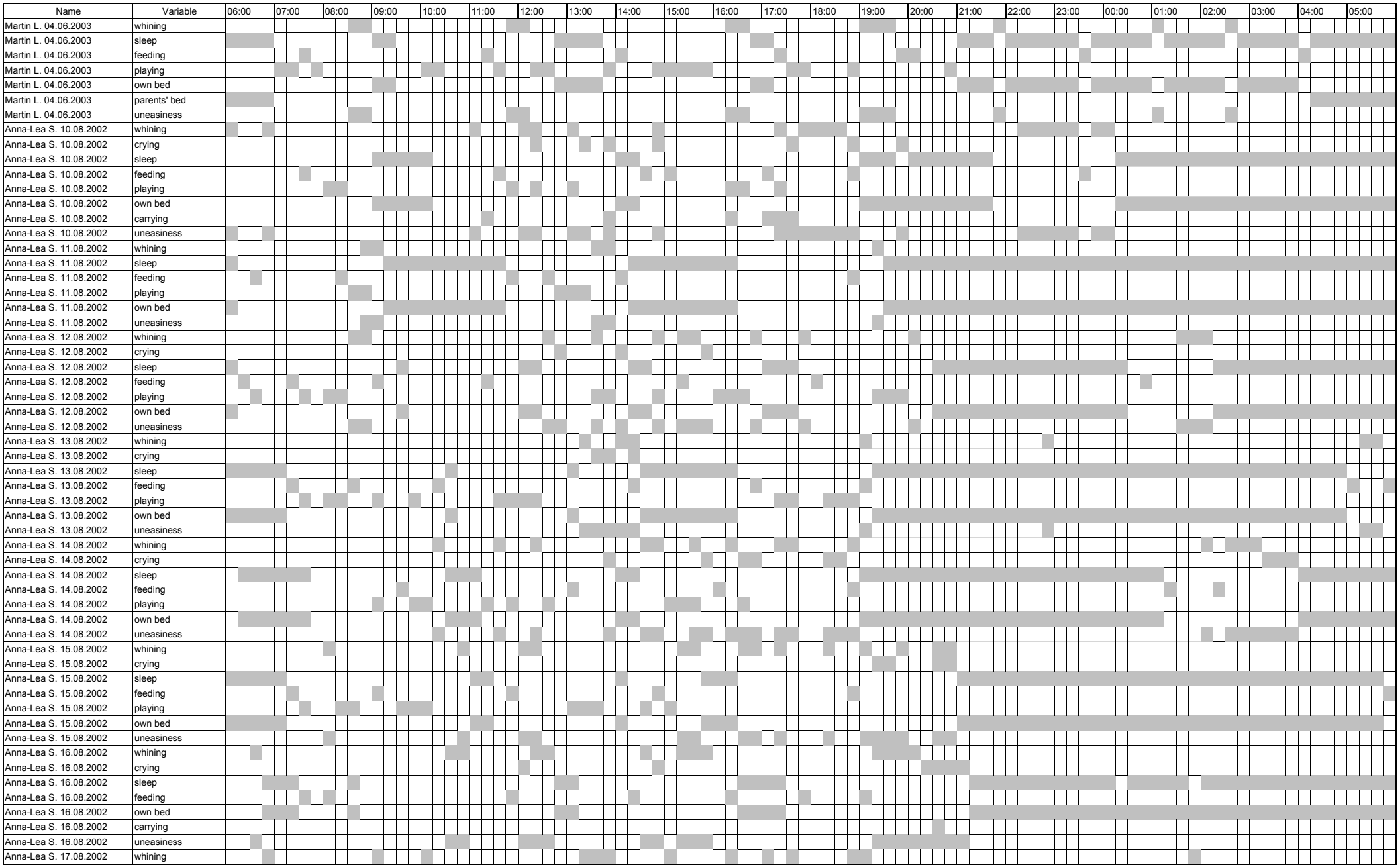
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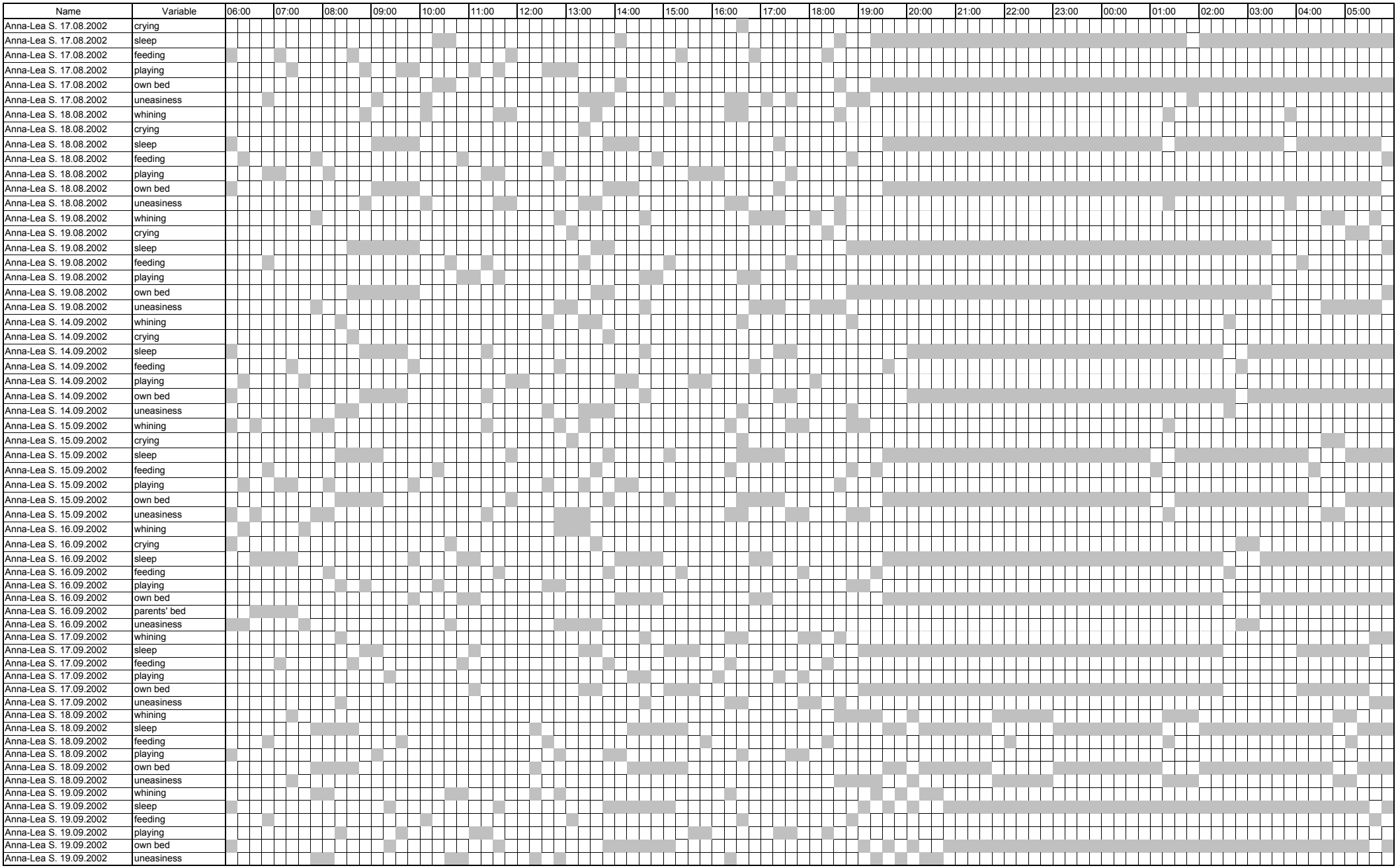
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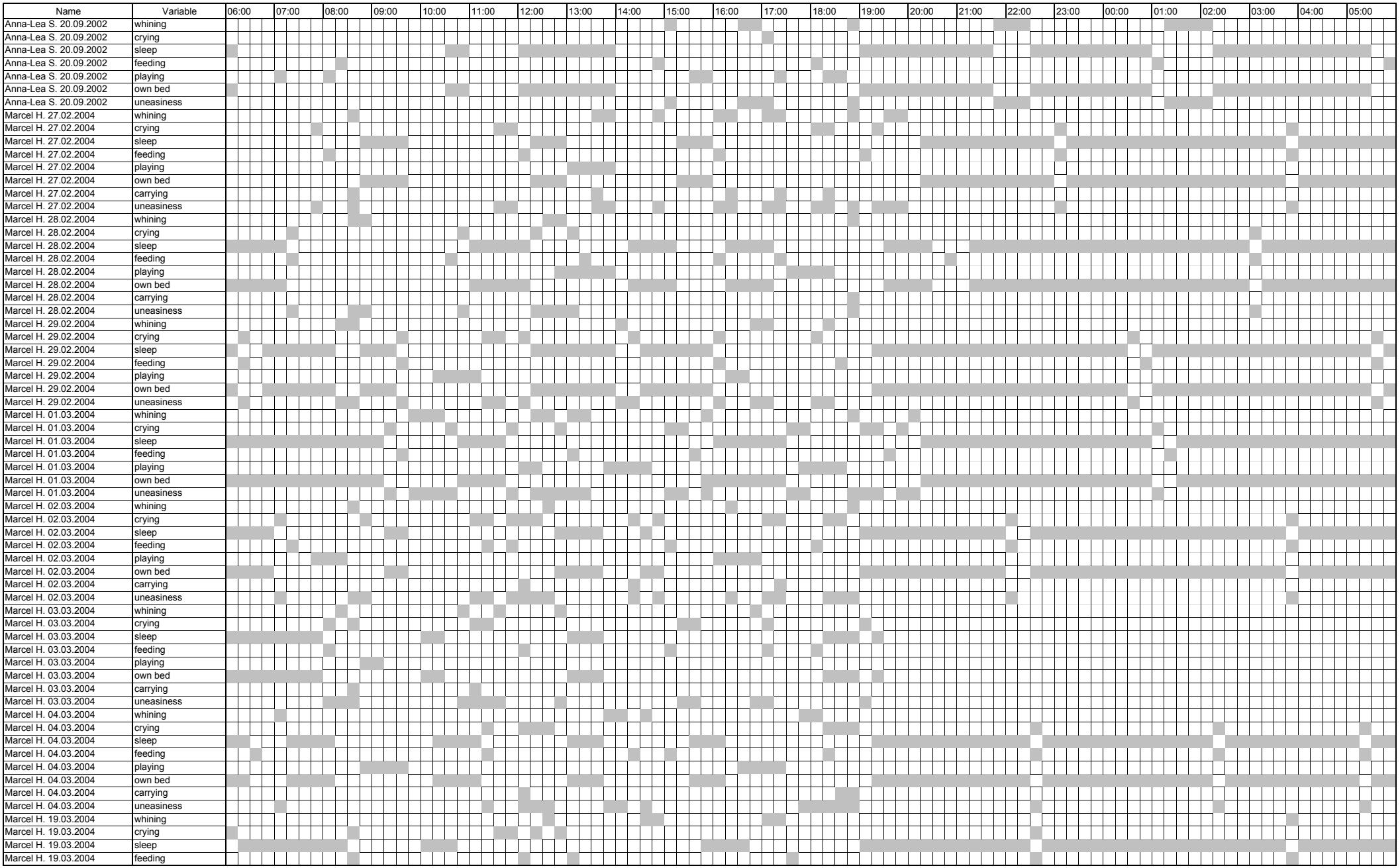
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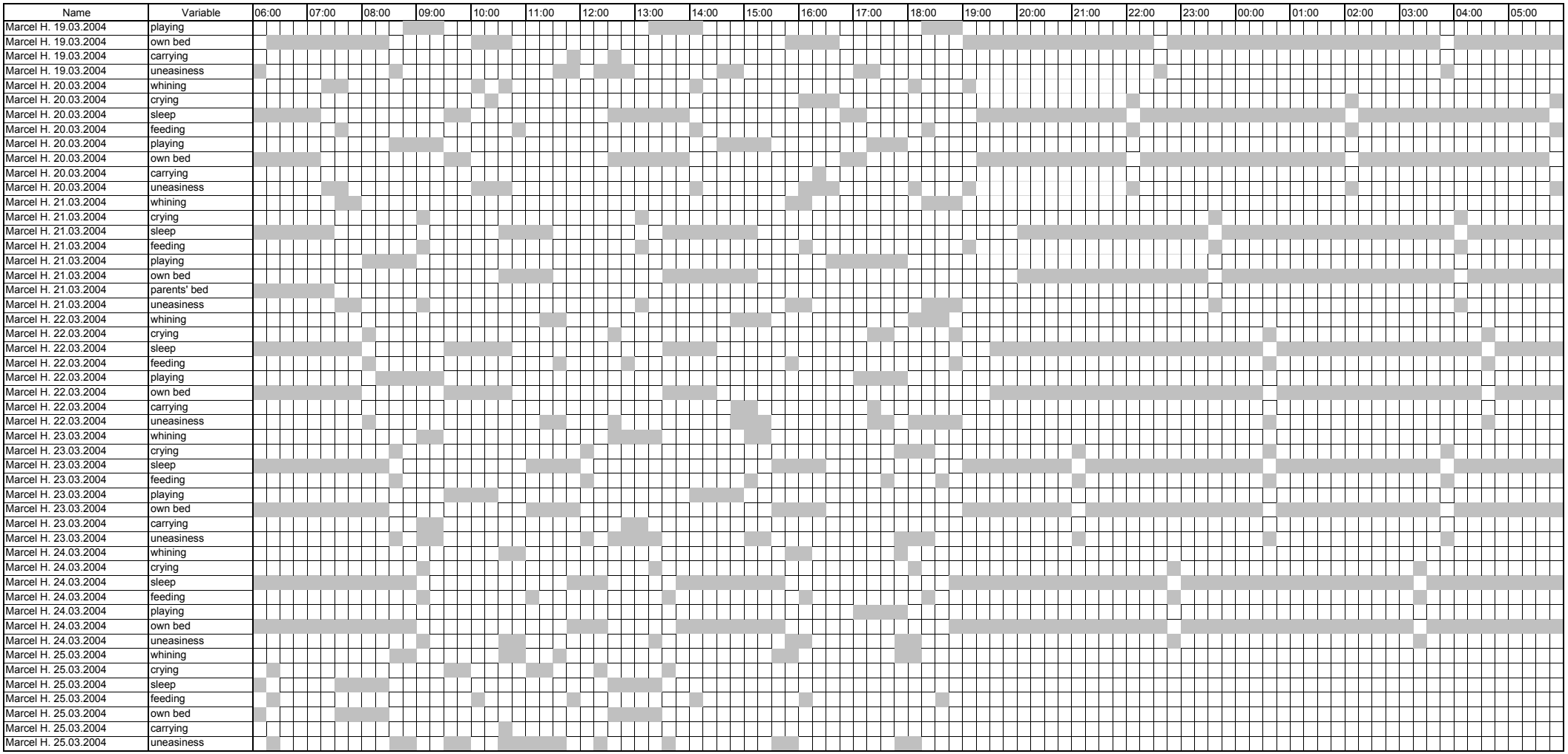
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