Effects of Single Manual Medicine Treatment for Infants with Postural and Movement Asymmetries and Positional Preference: A Multicentre Randomised Controlled Trial – SMMT for IPMA

Auswirkungen einer einmaligen manualmedizinischen Behandlung bei Säuglingen mit Haltungs- und Bewegungsasymmetrien und Positionspräferenz: eine multizentrische randomisierte kontrollierte Studie

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ABSTRACT

Objective The aim of the study was the evaluation of the effects of a single manual medicine treatment (SMMT) for infants with postural and motor asymmetries in upper cervical asymmetry disorder respectively kinematic imbalance due to suboccipital strain (KISS).

Methods Design: Multicentre double-blind randomised study Subjects/Setting: 202 infants at the age of 14–24 weeks with postural and movement findings were examined in four study centres using the standardized 4-item Symmetry-Score (points: 4 = symmetric to 17 = asymmetric). The inclusion criterion was a score of at least 10 points. The intervention group (IG) received a SMMT, whereas the control group (CG) did not receive any manual therapy. In addition, the infants of both groups were trained with a home exercise programme by their parents.

Statistical Methods The primary target parameter was the result of the Symmetry-Score, measured before the intervention and 4–6 weeks afterwards.

Results 171 children were randomised (IG = 83/CG = 88). All infants enrolled were measured to the second time-point (Intention-to-treat-analysis). The average improvement of IG compared to CG in Symmetry-Score was 2.3 points ($p < .001$). Following the score definition 80 % of IG and 49 % of CG fell

below the treatment threshold of 10 points. No side effects were observed.

Conclusions The SMMT significantly improves postural and motor asymmetries in infants with KISS.

ZUSAMMENFASSUNG

Studienziel Ziel der Studie war die Evaluation der Effekte einer einmaligen manualmedizinischen Behandlung bei Säuglingen mit posturalen und motorischen Asymmetrien bei Kopfgelenkinduzierter-Symmetriestörung (KISS).

Methoden Design: Multizentrische, doppelblinde, randomisierte Studie Probanden/Setting: 202 Säuglinge im Alter von 14–24 Wochen mit Haltungs- und Bewegungsauffälligkeiten wurden in vier Studienzentren mit dem standardisierten 4-Item Symmetrie-Score (Punkte: 4 = symmetrisch bis 17 = asymmetrische) untersucht. Einschlusskriterium war ein Score von mindestens 10 Punkten. Die Interventionsgruppe (IG) erhielt eine einmalige manualmedizinische Behandlung, während die Kontrollgruppe (KG) keine manuelle Therapie erhielt. Zusätzlich wurden die Kinder beider Gruppen von ihren Eltern zu Hause mit einem Übungsprogramm trainiert.

Statistische Methoden Der primäre Zielparameter war das Ergebnis des Symmetrie-Scores, der vor der Intervention und 4–6 Wochen danach gemessen wurde.

Ergebnisse 171 Kinder wurden randomisiert (IG = 83/KG = 88). Alle eingeschlossenen Kinder wurden zum zweiten Zeitpunkt gemessen (Intention-to-treat-Analyse). Die durchschnittliche Verbesserung der IG im Vergleich zur KG im Symmetrie-Score betrug 2,3 Punkte ($p < .001$). Nach der Score-Definition fielen 80 % der IG und 49 % der KG unter die Behandlungsschwelle von 10 Punkten. Es wurden keine Nebenwirkungen beobachtet.

Schlussfolgerungen Die einmalige manualmedizinische Behandlung verbessert signifikant die posturalen und motorischen Asymmetrien bei Säuglingen mit KISS-Problematik.

ABBREVATIONS

4-ISS	4-item Symmetry Score
FBS of the ÄMM	"Forschungsberatungsstelle (Research Consulting Office Manual Medicine) der Ärztevereinigung Manuelle Medizin, Berlin"
HEP	home exercise programme
IPMA	infantile postural and movement asymmetry (-ies)
KISS	kinematic imbalance due to suboccipital strain
SMMT	single manual medicine treatment

Introduction

The classic symptoms of infantile postural and movement asymmetries (IPMA) are variable combinations of torticollis, c-shaped scoliosis of the trunk, plagiocephaly, as well as asymmetries of muscle tension and movement of the body including the extremities [1]. The pattern of symptoms can be caused by underlying systemic diseases of the nervous system such as cerebral palsy, plexus paralysis, or even neuromuscular inflammation, as well as by diseases connected to the postural system e. g. malformations of the spine, tumors, muscular injuries, rarer as a result of congenital scoliosis [2–6]. However, in the majority of patients without underlying systemic diseases, other causes such as idiopathic and later than IPMA can be considered [1, 3, 7]. The explanation of the asymmetry lies presumably in the functional disturbance of the suboccipital or high cervical region.

According to studies in the Netherlands, the prevalence in young children for infantile postural asymmetries is estimated at 8–17 % [8, 9]. In addition, some infants present deviating asymmetry symptoms. They show fixed hyperextension with prone position intolerance, shoulder retraction and brachycephaly. There is often an increased developmental delay to observe for children with moderate or pronounced positional plagiocephaly and/or brachy-

cephaly. Dependent on age, different consequences concerning fine and gross motor skills, cognition or language development emerge [10–14].

Furthermore various physiotherapeutic [15], osteopathic [1, 16] and manual medicine treatment options [17, 18] are discussed. Restricted movements which affect the proprioceptively mediated posture patterns, can be restored to reversible musculoskeletal dysfunctions in key regions of the musculoskeletal system [19–22]. Therefore, treating reversible musculoskeletal dysfunctions with manual medicine treatment is a possibility to resolve articular and/or segmental movement disorders. Furthermore this leads to improvement of the infants' proprioceptive afferent pattern respectively postural activity [23].

In 1968, Gutmann described such connections as “cervical-diencephalic-static syndrome of the toddler” [24]. Later, Seifert found an increase in blockages of the upper cervical joint in symptomatic infants [25]. Buchmann confirmed the occurrence of functional disorders of the higher cervical region in young infants [26]. In the early 1990s, Biedermann introduced the term “kinematic imbalance due to suboccipital strain” (KISS) and pointed out the connection between dysfunctions of the cervical region and abnormal posture respectively movements [19, 27].

Manual medicine treatment approaches have been described as effective [18, 28, 29]. In contrast, Karch et al. [30] and Brurberg et al. [31] have referred to the current study situation, which has not yet sufficiently proven the positive effects of manual medicine treatment on posture and movement symmetry. Accordingly, there are no evidence-based studies of level II or I available at the current time to justify a recommendation of this therapeutic approach. The evaluation of a manual medicine therapy approach for infants of this age should close the gap.

Years of experience in the therapy of conspicuous infants aged three to six months suggest the sparing use of manual medicine treatment techniques. Thus, in the routine consultation, the treated infants are checked after six to eight weeks in order to record in particular delayed effects of the therapy [32]. Already in 2005, Biedermann reported comparable experiences of a one-time manual treatment of infants with IPMA [33]. Therefore, we decided to review this therapy scheme by application in the present study design.

By this point, the neurophysiological basis of this proprioceptive musculoskeletal coordination disorder has been analyzed and first evidence-based study results of a monocentre study have been published [34, 35]. In a second step, a larger multicentre study population has now been used to investigate the effectiveness of a single manual medicine treatment (SMMT). The results of this are reported in line with the recommendations of the updated Consolidated Standards of Reporting Trials (CONSORT) statement for randomised trials of nonpharmacologic treatments [36, 37].

To the authors’ knowledge, this is the first multicentre double-blinded randomised controlled study dealing with the manual medicine treatment for children affected by IPMA.

Objectives and hypotheses

A SMMT, combined with a daily home exercise programme (HEP) should be compared to the parent-regulated exercise programme for infants with IPMA. The difference between both groups should be illustrated and evaluated by the Symmetry-Score. Changes concerning the autonomic function and additionally the evaluation of postural development by the parents should be examined.

Methods

Design, setting and participants

This trial is a multicentre, double-blind, controlled, observational, parallel-group study carried out in Germany. The study groups were randomised within blocks with balanced randomisation [1:1]. The study protocol of the randomised controlled trail (RCT) was used without any deviations. Between January 2016 and July 2019, 202 children with constant posture and movement asymmetries were examined in a standardized video-based study using the reliable and valid 4-item Symmetry-Score (4-ISS, 4–17 points). The multicentre study was carried in outpatient practices with focus in manual medicine in Germany (Düsseldorf, Dortmund, Hannover and Cottbus). The last follow-up was performed in August 2019 and the infants were referred or recruited to participate by regional pediatrician practices or were recruited to participate while having a medical appointment in the respective practice.

All parents of the participating infants received written and verbal information regarding the study objectives, risks, study procedure and data protection. The written consent to participate in the study was obtained before enrollment. The study fulfilled the requirements of the Declaration of Helsinki.

All medical examiners are specialist in various fields. They have gained several years of experience in pediatric diagnosis and treatment of postural disorders in early childhood. All children have previously undergone examinations by their pediatrician. The therapists are certified experts in manual medicine and have more than ten years of experience in manual pediatric treatment. The choice of individual treatment techniques was not standardized. They are summarized in the appendix. The investigators have been intensively trained in the use of the 4-ISS [34].

Each examiner performed the initial examination in the presence of the parents and a medical assistant. In addition to a standardized anamnesis including autonomic symptoms, a clinical examination was performed concerning neurological, manual medical and, if necessary, differential diagnostic findings. The following assessment of movement asymmetry was performed by the examiner using the video-based standardized 4-ISS.

The inclusion criteria of the study refer to stereotypical IPMA (>9 points of the 4-ISS), a corrected age of 14 to 24 weeks as well as the finding of reversible functional articular and/or segmental disorders of the locomotor system.

Children with underlying systemic diseases (e. g. neurological or metabolic), malformation respectively genetic abnormalities, muscular torticollis, acute or chronic infection or preterm birth before the 37th week of pregnancy were excluded. Furthermore, manual medicine or osteopathic pre-treatment undergone within the previous four weeks, physiotherapy or vaccination in the previous two weeks and a substantial lack of German language skills on the part of the parents likewise led to exclusion.

The ethics committee of the University Hospital Jena approved the RCT. The study was registered in the German Register of Clinical Studies (DRKS00010105).

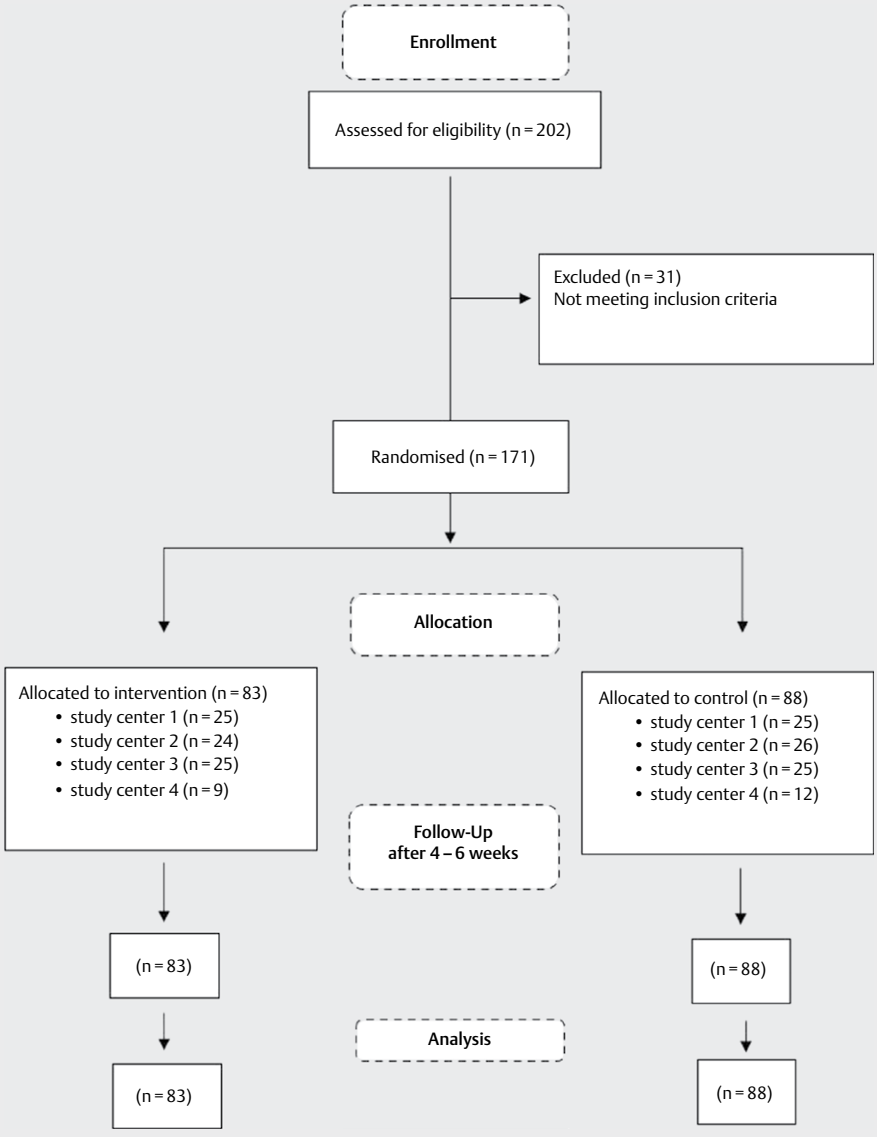
Intervention

In line with the respective blocked randomisation lists, the included children were divided into two groups. The infants in the intervention group (IG) received a SMMT of their individual articular or segmental dysfunction, whereas the control group (CG) did not receive such treatment. To maintain blindness, the infants were spatially separated from their parents and treated or looked after for about five minutes by the treating physician in the presence of a medical assistant. In the meantime, all parents received video-based training on how to conduct a HEP, which was to be performed three times a day at home.

The manual medicine diagnostics of all infants were based on movement tests and palpation. Depending on the individual findings, the IG was treated with mobilizing and infant-specific manipulative techniques. The techniques used largely corresponded to the curriculum of the "Ärztevereinigung Manuelle Medizin Berlin (ÄMM)" [38]. Three study centres treated the upper cervical region according to the method described by Gutmann and Biedermann [19], study centre 4 chose modified treatment regimens according to the ÄMM standard. A summary of the techniques used can be found in the appendix. All children received a HEP to promote development [39, 40].

Outcomes and measurement methods

The primary target parameter was the change of the Symmetry-Score. The assessment of the symmetry course was based on a standardized video-based overall score of the metric items head



▶ **Fig. 1** Flow-chart of trial course.

rotation in supine position, frontal labyrinth position reaction, head elevation in prone position (1–5 points each) and the muscular tone difference of the hip rotation (yes/no, 1–2 points) [34]. This resulted in a total score of four points (very symmetric) to 17 points (very asymmetric). Experts assumed the need for treatment from an overall score of more than 9 points i. e. at least 10 points. Video scoring was performed at the initial examination (Baseline, T0) and at the final examination after 4–6 weeks (T1).

The secondary target parameter was the parents' assessment of the course of vegetative aspects. For this purpose and following Philippi et al. [1] and Wurmser et al. [41], the children's' sleeping, crying, spitting and drinking behavior, mood, excitability and bowel movements were assessed in the categories very conspicuous, conspicuous, slightly conspicuous, inconspicuous, not knowing. The parents were interviewed at both time-points T0 and T1.

An additional parameter was the parents' assessment of the course of IPMA (marked improvement, little improvement, no improvement, deterioration). The information was recorded at time T1.

Implementation: Sample size, randomisation and blinding

For the comparison of the study populations in the four study centres, a sample of 50 children per centre was assumed. The sample size calculation was based on the statistical calculations of the pilot study [34]. The number of cases determined according to these calculations ($\alpha = 0.05$ and $1-\beta = 0.9$) is 21 per group. With a drop-out rate of 20 %, the required number of cases is 25 children per group in one study centre. To have the option of comparability of several study centres if needed at a later stage, we decided to reach the determined case number in every participating centre. Randomisation was carried out by means of 6-block randomisation. Each study centre obtained a randomisation list accordingly. Those were prepared by the Research Consulting Office of the ÄMM (Forschungsberatungsstelle, FBS) at the Institute for Physiotherapy, Jena University Hospital and administered by an independent medical assistant. The treating physician received appropriate instructions for each study participant included in the study. The medical examiner, his medical assistant and the parents were blinded until the end of the study. At the end of the study, blinding of the parents was removed. Depending on the indications and the parents' wishes, manual medical follow-up treatment was performed outside the study.

Statistical analysis

The verification of the hypothesis by means of the two-sided t-Test of the primary target parameter followed the results of the 4-ISS using the intention-to-treat analysis. To avoid baseline bias, both the 4-ISS results at time-point T1 and the dynamics of the 4-ISS results (difference between the time-points T0 and T1) were statistically evaluated using the t-Test for independent samples with a

▶ **Table 1** Demographic data of study patients.

		Intervention Group	Control Group
study centre	1	25	25
	2	24	26
	3	25	25
	4	9	12
	in total	**83**	**88**
		n = 171	
sex	♂	45	56
	♀	38	32
corrected age in weeks	(mean)	17.3 ± 2.5	17.6 ± 2.3
mode of birth (single answer option)	spontaneous	40	34
	Kristeller manoeuvre	12	9
	primary c-section	17	19
	secondary c-section	8	11
	vacuum extraction	5	12
	forceps extraction	1	0
	not specified	0	3
pretreatment (multiple answer option)	physiotherapy	3	2
	manual therapy	2	0
	osteopathy	9	12
	none	69	74

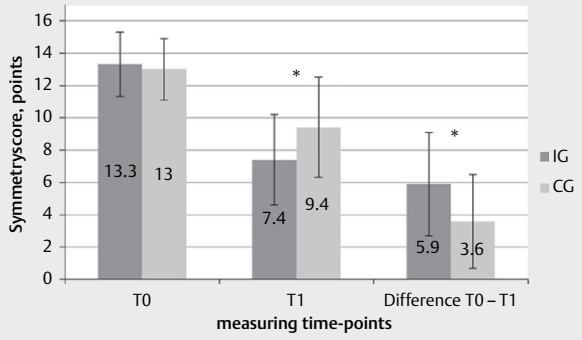
▶ **Table 2** Results of the 4-Item Symmetry-Score.

4-Item Symmetry Score (4–17 points)		Min	Max	mean	SD	CI 95-%
T0	IG	10	17	13.3	2.0	12.89–13.74
	CG	10	16	13.0	1.9	12.63–13.42
T1	IG	4	16	7.4	2.8	6.79–8.01
	CG	4	15	9.4	3.1	8.74–10.04
T0-T1	IG			5.9	3.2	5.22–6.61
	CG			3.6	2.9	3.02–4.25

(T = time-point, SD = standard deviation, CI = confidence interval).

significance level of α = 0.05. The t-Test requires a normal distribution of the data, which is met by the high sample seize.

The comparison of vegetative abnormalities was analyzed using the Mann-Whitney-U-Test. The parents' evaluation was assessed by descriptive statistics. The data collection and evaluation of the anamnesis and examination protocols was carried out by the FBS of the ÄMM at the Institute for Physiotherapy, Jena University Hospital. The statistical analysis was done by using IBM SPSS Statistics, Version 21. An interim analysis of effectiveness was to be carried out after receiving the required case number in at least three of four study centres. Termination criteria included the achievement of a highly significant group difference at T1 ($p < .001$) or the occurrence of severe side effects.



▶ **Fig. 2** Results of the Symmetry-Score (T = time-point, * = significant difference).

Results

Implementation: participant flow and recruitment

Between January 2016 and July 2019, 202 children were examined. 171 infants met the inclusion criteria and could participate in the study. 50 children were enrolled in centres 1–3 and 21 in centre 4. All children had a final examination at time-point T1 (▶ **Fig. 1**). The demographic parameters are summarized in ▶ **Table 1**. All children exhibited reversible dysfunctions of the upper cervical region.

One child from study centre 2 was inadvertently assigned to CG due to a transmission error. The blinding of the examiner and the parents remained unaffected. After consultation with the study coordinator, the study was conducted according to protocol. All parents confirmed the regular implementation of the HEP.

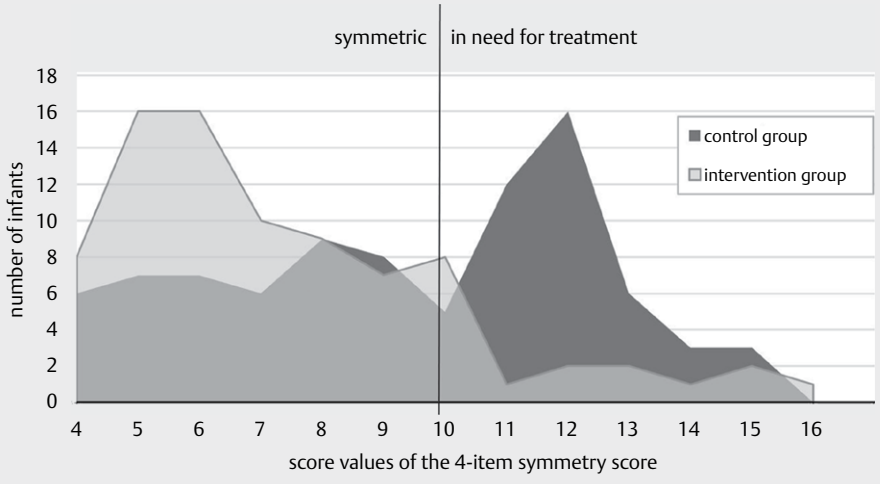
The total score results at time-points T0 and T1 and the difference between the score results T0-T1 are shown in ▶ **Table 2**. At T0, there was no significant difference between both groups regarding the Symmetry-Score, illustrated in ▶ **Fig. 2**. The CG improved on average by 3.6 points from 13.0 ± 1.9 points to 9.4 ± 3.1 points. The IG improved on average by 5.9 points from 13.3 ± 2.0 points to 7.4 ± 2.8 points. The average difference in symmetry (T0-T1) between the groups was 2.3 points ($p = .000$) and therefore significant.

According to the study protocol, asymmetry findings were assumed to require treatment if the Symmetry-Score exceeded nine points. Accordingly, 20 % of the infants in the IG (17 of 83) and 51 % of the CG (45 of 88) still had IPMA requiring treatment at T1. 4 % of the children of the IG (3 of 83) and 7 % of the infants in the CG (6 of 88) showed deteriorations regarding the Symmetry-Score (▶ **Fig. 3**).

The dynamics of the vegetative abnormalities are shown in ▶ **Table 3**.

The parents' estimations of the symmetry development compared to the score development can be seen in ▶ **Table 4**.

Harm was not observed in the initial phase after treatment by the practitioner or during the interview with the parents by the ex-



▶ **Fig. 3** 4-item Symmetry-Score results at time-point T1.

▶ Table 3 Vegetative conspicuousness.

	spitting		sleeping		drinking		crying		bowel movements		mood		excitability	
	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG
affected	44 of 83	52 of 88	40 of 83	32 of 88	30 of 83	35 of 88	36 of 83	38 of 88	25 of 83	15 of 88	24 of 83	30 of 88	42 of 83	44 of 88
better (%)	64	52	73	69	73	49	78	63	68	73	79	53	45	46
equal (%)	32	40	22	28	20	40	22	32	28	20	21	30	48	34
worse (%)	4	8	5	3	7	11	0	5	4	7	0	17	7	20
Mann-Whitney-U-Test (p-value)	.932		.108		.059		.354		.156		.168		.476	
	no significant difference between IG and CG													

aminer at time-point T1. No undesirable side effects have been reported.

Discussion

The aim of this multicentre study was to evaluate the effectiveness of a SMMT in infants with IPMA without systemic underlying diseases also known as KISS. A double-blind RCT design was chosen. All parents stated that they had completed the HEP with their children according to the protocol. It can be assumed that the high level of compliance results from the blinded study design. The parents had been ensured that their child would receive at least one form of treatment. The intervention period after the 12th week of child development was chosen in order to wait for effects of spontaneous motor development with the onset of increasing conscious motor activity [39, 42].

The study results show that the SMMT significantly improves the postural activity of the affected children. Accordingly, 80 % of the infants (66 of 83) in the IG fell below the predetermined treatment threshold of more than 9 points in the score and 4 % (3 of 83) deteriorated. In the CG, the ratio was 49 % (43 of 88) and 7 % (86 of 88), respectively. Score analysis between the study groups at time-point T1 and the score dynamics T0-T1 revealed significant differences in favor of the IG and thus in favor of SMMT. The 4-ISS used in this study had been tested as valid and reliable in a previous study [34].

Only 21 children could be recruited in study centre 4. Despite a significant extension of the planned study period from 12 to 42 months, not enough infants were enrolled in the study. In view of the significant study results of the other study centres, the RCT was terminated for ethical reasons in the respective centre during an interim analysis. The number of cases per study centre calculated by the authors serves to enable verification of the treatment results at a later time for at least three treatment centres. The incorrect assignment of one child to CG had no significant effect on the study population or results.

The items relating to autonomic symptoms did not show significant differences in the study groups. The previously observed significant improvements in autonomic functions in the previously performed not blinded pilot study could not be confirmed [34]. To what extent these enhancements could be valued as the results of improved interaction or placebo effects must be shown in subsequent studies. Furthermore, therapeutic side effects of manual medicine examination are conceivable and could result from the manual examination of infants' movements, which is comparable to the general movement examination as part of routine pediatric diagnosis [17].

The parents' assessment of the symmetry course was in line with the score results at time-point T1 in 87 % (72 of 83) of the IG and 63 % (55 of 88) of the CG. The majority of the parents were able to assess the postural symmetry development of their children well. The difference between the groups can be explained by the less clear improvement in symmetry in the CG, hence it is more complicated for parents to judge whether there has been an improvement or not.

A comparison of demographic and clinical values of both groups illustrates a well-balanced distribution of the sex, birth type, pre-treatment and autonomic symptoms. An overrepresentation

▶ **Table 4** Parents' evaluation to their childrens' symmetry (NR = not reported).

Parents Evaluation compared to Score	**Agreed with score**	**Parents yes, Score no**	**Parents no, Score yes**	
IG in %	87	6	7	(1x NR)
CG in %	63	11	26	
Parents evaluation to Symmetry	**Clear improvement**	**Minor improvement**	**No improvemnt**	**Deterioration**
IG in %	64	26	10	0
CG in %	30	36	34	0

of boys in the affected patient population has been mentioned before by other authors [1, 8, 18]. A genetic predisposition is assumed [43, 44].

At the initial examination (T0), all children in the study exhibited dysfunctions of the upper cervical joints in addition to variable articular and segmental dysfunctions of other regions. This supports the pathogenetic explanation model of IPMA. Accordingly, dysfunctions in the craniocervical transition lead to regional and supraregional imbalances in movement control in the sense of an upper cervical joint induced symmetry disorder [21, 22, 33]. The manual medicine treatment of reversible dysfunctions leads to an optimization of movement control. From a functional point of view, the combination with subsequent movement training appears to be sensible.

It is remarkable that the application of a targeted movement facilitation through the HEP also led to a significant improvement in the baseline score in the CG. The extent to which effects of spontaneous development are reflected in this process has not been investigated. It can be assumed that especially the uprighting of the head in the prone position can also be explained by spontaneous motor improvements due to the increasing developmental age of infants. No clinical evidence was found to indicate which infants with which specific abnormalities benefit sufficiently from the HEP alone. For reasons of clarity, a detailed analysis of the development of the individual items is not provided. This shall be reserved for a further publication, including also the comparison of different study centres.

Various authors emphasize the importance of early childhood IPMA for later child development. Boere-Boonekamp and van der Linden-Kuiper found asymmetry symptoms in 25 % of cases when following up infants with positional cranial asymmetries at the age of 2–3 years [8]. Recent studies have shown, that below the age of two years, motor skills are particularly affected. In toddlers and preschoolers, deficits in cognitive and language development are more frequent [10–14]. According to Collet et al. [13], the development of a positional plagiocephaly and/or brachycephaly is considered as a marker and not a cause for developmental delays. Early neuromotor deficits could have a cascade effect on other areas of child development.

The early facilitation of physical activity in the family home environment, beyond the recommendations on “tummy time”, is suitable as prophylaxis and early therapy of postural asymmetries in young infants [39].

The short intervention period is explained by the current recommendations for the therapy of infantile postural and motor asymmetries in Germany. Manual medicine treatment approaches are therein not considered [31]. A longer-term deviation from the established therapy scheme, such as physiotherapeutic interventions, was not justifiable for ethical reasons. We assume that the therapy recommendation will be revised based on the developing study situation.

None of the parents reported any harm. However, they were informed about possible adverse events before enrollment in the study. Diverse autonomic symptoms like short-term change in breathing pattern, short-term flushing, short-term hyperextension, short-term perspiration immediately after manual medicine are confirmed as physiological [45]. According to Saedt et al., those can be classified as vegetative responses [18]. The practitioner did not recognize similar reactions. Furthermore, the aforementioned autonomic symptoms can be more intense in infants, but last no longer than 24 hours. In the study by Philippi et al., those symptoms were reported in four children of the IG and six in the CG [1].

The findings (n = 62) of another study group also demonstrated the significant superiority of a combination of one-time manual medicine treatment and HEP over the sole facilitation of physical activity in this age group (14–24 weeks) [35].

Philippi et al. [1] demonstrated the effectiveness of osteopathic treatments versus sham osteopathic treatment in infants (n = 32) with postural asymmetries at 6–12 weeks of age. The children were treated once a week for 45–60 minutes over one month. In addition, all children received a HEP according to the Bobath therapy concept.

A prospective observational study reviewed the results of manual medicine treatment of children with upper cervical dysfunction (n = 259, mean age = 11.3 weeks) [18]. In the mean, 3.5 treatments were performed over an average of 18 weeks. Data analysis was performed using questionnaires before and after treatment. Both parents and manual therapists were interviewed in a standardized way. The manual therapists stated that in 90 % of the cases, manual treatment led to the elimination of functional limitations in head mobility. 63 % of the parents observed the cessation of their child's preferred postures, over 90 % noticed improvements in postural activity. No adverse side effects of therapy were observed.

In a controlled and blinded small study (n = 31), Haugen et al. compared the treatment results of both manual and physical therapy twice as compared to physical therapy alone [17]. The postur-ally conspicuous infants aged between three and six months received appropriate treatment for a period of eight weeks. There

were no significant differences in the group comparison. However, it should be noted that this was a pilot study to determine the number of cases in the main study.

The scientific situation in relation to the effectiveness of manual medical treatment in infancy could be a result from the different treatment concepts. The therapeutic approach of a one-time manual medicine treatment in combination with an easy-to-mediate HEP used in this study follows a minimal therapy strategy in terms of effort and treatment frequency and intensity.

Limitation

Further studies must show to what extent long-term effects can be achieved by manual medicine treatments, which has to be valued as limitation of this study. A particular problem is that the (spontaneous) course of the disease with its effects on the later sensomotoric development in children with conspicuous features has not been studied systematically nor in detail [11, 22, 46, 47]. According to current findings in infant and childhood developmental neurology [48, 49] and clinical experience, proprioceptive musculoskeletal coordination disorders can have complex effects on sensomotoric development [10, 12–14]. Early optimization of postural activity is therefore a central component of pediatric efforts.

Conclusion

The SMMT for reversible articular and segmental dysfunctions in combination with home exercises three times a day leads to a significant improvement in postural activity in infants aged 14–24 weeks. As the first multicentre, double-blinded, controlled and randomised trial with a higher case number, this study confirms that the manual medicine intervention is superior to the HEP alone in IPMA. Hence, the statement of the German neuropediatric society should be updated concerning the recommendation for therapeutic application of manual medicine for infants with IPMA.

Clinical Trial

Clinical Trial registration: German Clinical Trials Register (DRKS00010105)

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Conflict of Interest

The authors declare that they have no conflict of interest.

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Supplementary material

Appendix: Intervention group – Manual medicine treatment

- spinal manual therapy - techniques (SMT)
- manual therapy of the extremities (MTE)

SMT focuses on the biomechanical aspect of spinal dysfunction by eliciting neurological, physiological and/or muscular changes and reconfiguration of proprioceptive functions. All treatment techniques are applied at the moment of optimal muscular relaxation.

- **Mobilisation:** After segmental/regional adjustment of the reversible hypomobile dysfunction, either a sustained hold or repetitive (oscillating) mobilisation, suitable for infants, of the joint space with low-velocity and low-amplitude is performed.
- **Manipulation:** Alternatively or in addition, an infant-friendly manipulation technique with low force, short distance and high speed (HVLA) is used. Manipulations are carried out exclusively in a neutral position without locking and with minimal tension.

Diagnostics

Topical and functional diagnosis by means of palpation is performed with manual articular/segmental movement testing, taking into account segmental/regional irritation zones with analysis of the free and functionally disturbed motion direction.

Therapy

1) ***Upper Cervical Region***

Initial Traction:

- Child is lying in supine position or sitting in a reclined position.
- Traction relaxation of the cervical structures by means of a gentle, axial cranial traction via the pars lateralis occipitalis (or: via the occipito-mastoid connecting line).

Functional disorder- Inclination/ Reclination:

- Mobilisation: Child is lying in supine position; Inclination mobilisation of the occiput compared to atlas/axis
- Manipulation: Child is sitting in a reclined position; Sagittal impulse over arcus dorsalis under gentle traction

Functional disorder - Rotation/ Lateral flexion:

- Mobilisation: Child is lying in supine position; Lateral tilt mobilisation occiput against atlas/axis in the frontal plane
- Manipulation: Child is lying in supine position; lateral manipulation impulse on the region dorsal of the Processus transversus atlantis under consideration of possible relational asymmetries (usually on the side of the functional disorder or cervical convexity)

2) ***Cervicothoracic Junction***

- traction-lateroflexion-mobilisation while child is seated
- first rib in a sitting position - mobilisation/manipulation in a held ipsilateral inclination of the lower cervical spine

3) ***Thoracic Spine***

- Mobilisation/manipulation of the neutrally positioned, upright sitting infant from dorsally via the adjacent costo-transverse joints

4) ***Sacro-Iliacal-Joint***

- Manipulation treatment via the sacrum dorsally, medially of the connecting line of spina iliaca posterior superior and inferior in the infant positioned in ventral suspension while maintaining neutrality and kyphosis of the spine

5) ***MTE:*** The most frequent peripheral articular dysfunctions in the patient population concerned the **upper ankle joints**.
    - Manipulation
    - Child is lying in supine position
    - Ventral impulse of the talus towards tibia/fibula