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The use and benefits of Craniosacral Therapy in primary health care: A prospective cohort study

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ABSTRACT

Background: Patients frequently use treatments complementary to standard primary care. This prospective cohort-study examined the use, benefits, and safety of Craniosacral Therapy (CST).

Methods: Consecutive out-patients utilizing CST from 2015 to 2019 were asked to provide anonymized data on symptom intensity, functional disability, and quality of life before and after treatment using an adapted 11-point numerical rating scale (NRS) version of the Measure Yourself Medical Outcome Profile (MYMOP). Treatment expectations were assessed as were concurrent therapies/medication and safety. Mean differences were analyzed using paired sample t-tests with 95 % confidence intervals (CI), predictors of treatment response using linear regression modelling.

Results: CST therapists submitted 220 patient records (71.4 % female) including 15.5 % infants and toddlers, 7.7 % children, and 76.8 % adolescents and adults. Patients received on average 7.0 ± 7.3 CST sessions to treat 114 different, acute and chronic conditions. Symptom intensity significantly decreased by -4.38 NRS (95 %CI=-4.69/-4.07), disability by -4.41 NRS (95 %CI=-4.78/-4.05), and quality of life improved by 2.94 NRS (95 %CI = 2.62/3.27). Furthermore, CST enhanced personal resources by 3.10 NRS (95 %CI = 1.99/4.21). Independent positive predictors of change in the adapted total MYMOP score included patients' expectations ($p = .001$) and therapists' CST experience ($p = .013$), negative predictors were symptom duration ($p < .002$) and patient age ($p = .021$); a final categorical predictor was CST type ($p = .023$). Minor but no serious adverse events occurred.

Conclusions: In primary care, patients and parents of underage children use CST for preventive and therapeutic purposes. Considering the design limitations, CST appears to be overall effective and safe in infants, children, and adults.

1. Introduction

Primary care patients suffering from acute and chronic diseases frequently use complementary treatments approaches in addition to standard medical care. This not only applies to adults [1–3] but also to parents of young children and adolescents.[4–6]

Craniosacral Therapy (CST) is derived from osteopathic manipulative treatment and uses mindful, very gentle fascial palpation techniques to reduce sympathetic arousal by modifying body rhythms [7,8] and to support the body's function and capability of self-regulation by relaxing physical and mental structures.[9–11] Treated areas not only include those between cranium and sacrum (as osteopathy does not exclusively treat bones) but also joints, muscles, fasciae, cardiovascular structures, and organs. While physical mechanisms of CST are still understudied, initial randomized controlled trials have shown specific treatment effects of CST on patient-reported outcomes.[12] Clinical trials have also revealed significant effects of CST in addition to treatment and effectiveness compared to standard therapies in e.g. patients suffering from chronic pain conditions,[13] infantile colic,[14] attention deficit hyperactivity disorder,[15] and asthma.[16]

Beyond that, patients report using CST as a complementary treatment strategy for headaches and migraine, dizziness and tinnitus, gastrointestinal disorders as well as stress-related and mental problems like depression and anxiety.[17,18] In children, CST is used to support symptom alleviation of respiratory, oncological, allergic, autism spectrum, and gastroenterological diseases.[19–21] In the UK and Switzerland, NHS cancer centers [22] and psychiatric university hospitals [23] have established treatment concepts integrating CST into conventional in-

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and out-patient care.

This study aims to prospectively investigate individual experiences and expectations, effects and side effects on symptoms and disorders, where CST is used in primary care. Predictors of treatment response are studied as well.

2. Methods

2.1. Design and participants

The project was designed as a prospective cohort study of consecutive patients requesting CST in primary care. Data were acquired anonymously by CST therapists from January 2015 to December 2019. Therapists were considered eligible, if they were members of local craniosacral associations organized in the European Craniosacral Association Network.[24] Patients had to be consecutive adults or parents of underage children who accessed CST through either self-referral or physician referral gave their written informed consent and were physically and psychically able to fill out two short questionnaires. The baseline assessment was scheduled either prior to the first CST session of a new patient or prior to the first CST session of a familiar patient presenting with a new symptom. The point of post-intervention assessment was chosen individually, after the patient noticed a sufficient symptom alleviation or in case the therapist did not expect further changes in symptom severity.

2.2. Data assessment

Data were collected from patients and therapists in different countries using hard copy questionnaires in German, English, Dutch and Czech. Patient questionnaires included sociodemographic data on age, gender, education, and employment status. Patients were further questioned, whether they had had prior experiences with CST, and to what extent they expected CST to be effective in treating their symptoms using a numeric rating scale (NRS) ranging from 0 not effective to 10 very much effective.

Health-related variables were assessed using the Measure Yourself Medical Outcome Profile (MYMOP) that demonstrated high construct validity in both English and German and good sensitivity to change across a variety of conditions.[25,26] For the requirements of this study, the original MYMOP items were adapted now consisting of three instead of two symptom severity items, two instead of one disability in daily activity item, and three instead of one quality of life item. While patients were asked to complement the symptom and disability items according to their individual load,[24,25] predefined quality of life items requested the patients' estimations of their general wellbeing and, in addition, of their mental health and sleep quality. Symptom duration was assessed as well. Instead of a symptom they would like to alleviate, patients could also choose to specify a personal resource they would like to strengthen through the therapy. A further adaption of the MYMOP consisted of using an 11-point instead of a 7-point NRS ranging from 0 to 10 with higher scores indicating higher symptom intensity/burden as well as higher quality of life. The adapted total MYMOP score was calculated by the mean of all eight MYMOP items using reversed quality of life items. Two items assessing the patient' global impression of change and medication intake on 6-point Likert scale as well as one free text item completed the follow-up questionnaire.

Therapists were also asked to provide sociodemographic data on their age, gender, country, basic profession, type and years of practice of CST as well as the main complaints of the patient, detailed content and number/duration (in weeks) of the treatments provided, side effects, and concurrent therapies/medication. Both patient and therapist data on symptoms reported were taken into consideration and classified according to standard International Classification of Diseases (ICD) codes.

2.3. Statistical analyses

Sociodemographic and health-related data were analyzed descriptively and expressed as mean and standard deviations or frequencies and percentages as appropriate. Differences in treatment expectations between different age groups and between patients with and without prior experiences with CST were analyzed using univariate analysis of variances. Effects of CST were displayed by mean differences (MD) and 95 % confidence intervals (CI) and analyzed using paired sample t-tests, if sufficient normally distributed data of symptoms of the same ICD category within a predefined age group were available. Predictors of treatment response (change in the adapted total MYMOP score) were analyzed using forward stepwise linear regression modelling. All analyses were carried out exploratory considering all p-values below 0.05 as significant. Free text items were analyzed by qualitative content analysis. Statistical analyses were performed using IBM SPSS® software (release 27.0. Armonk, NY: IBM Corp.), the qualitative ones using MAXQDA® software (release 20.0. Verbi).

3. Results

3.1. Participants

A total of 69 therapists (mean age: 50.9 ± 6.9, female: 81.4 %) contributed to the survey. They reported 11.1 ± 6.5 years of experience in clinical CST practice. The majority (51.6 %) used a combination of structural and biodynamic CST techniques, while some of them exclusively applied biodynamic techniques (37.1 %), structural in combination with somato-emotional techniques (6.5 %), or other (4.8 %). The basic profession of the therapists consisted of 52.5 % non-medical practitioners/naturopaths, 31.1 % physical therapists, 6.6 % nurses, and 9,6% other health professionals such as psychotherapists, speech therapists, pediatricians, dental assistants, occupational therapists, and sport scientists.

The therapists provided 222 patient questionnaires of which 220 could be included in the final analysis. Two of the questionnaires had to be excluded as the patients completed baseline data but no data at follow-up. Sociodemographic characteristics of the final patient sample are presented in Table 1.

The patients' mean age was 37.9 ± 22.7 with a range of 0.02–79 years including 11.4 % infants, 4.1 % toddlers, 7.7 % older children, 1.4 % adolescents, and 75.4 % adults. Among the sample, 71.4 % were female, 95.0 % were from Germany, and 54.1 % had an A-level diploma or a university degree. In sum, 34.1 % of the total sample reported prior experiences with CST, while in adults, this number raised to 42.6 %. The expectations that CST would be effective in individual symptom alleviation ranged from 2 to 10 NRS points with a mean score of 7.8 ± 1.8. Throughout all age groups, the expectations were comparably high and did not significantly differ between adults and parents of underage children ($p = .633$). In contrast, patients with prior experiences in CST reported slightly but significantly higher expectations than those without CST experience ($p = .033$).

3.2. Conditions being treated

Patients reported 114 different ICD conditions (Table 2) with a mean symptom duration of 6.7 ± 9.0 years. Among them, 73.9 % can be classified as recurrent or chronic complaints lasting longer than 3 months, 15.6 % were subacute ones, and 10.5 % acute conditions.

Parents of infants and toddlers up to 3 years requested CST for alleviating unspecific symptoms of the ICD-R category in 40.2 % of the cases. Congenital deformations (Q) were the second most common ICD category with 36.8 %. Symptoms associated with ICD-F mental/behavioral disorders were reported by 10.3 %. Further symptom clusters were conditions originated in the perinatal period (P), diseases of the ear (H), the respiratory system (J), and the skin (L) (Table 2). On average, young

Table 1
Sociodemographic characteristics of the patients (N = 220).

	N	Mean ± SD
Age (in years)	–	37.94 ± 22.72
Infants (<1 year) (N = 25)	–	0.29 ± 0.23
Toddlers (1–3 years) (N = 9)	–	1.81 ± 0.81
Children (4–12 years) (N = 17)	–	9.00 ± 2.74
Adolescents (13–17 years) (N = 3)	–	14.33 ± 0.58
Adults (≥18 years) (N = 166)	–	48.98 ± 13.37
Gender		
Female	157 (71.4 %)	–
Male	63 (29.6 %)	–
Diverse	0	–
Country		
Germany	209 (95.0 %)	–
Netherlands	4 (1.8 %)	–
Switzerland	2 (0.9 %)	–
Czech Republic	1 (0.5 %)	–
United States	1 (0.5 %)	–
Education		
Below kindergarten	33 (15.0 %)	–
Kindergarten & primary school	18 (8.2 %)	–
Secondary & high school	44 (20.0 %)	–
A-Level diploma	45 (20.5 %)	–
University degree	74 (33.6 %)	–
Employment		
Below working age	55 (25.0 %)	–
Not working	12 (5.5 %)	–
Currently working	112 (50.9 %)	–
Retired	23 (10.5 %)	–
Parental time	2 (0.9 %)	–
Prior experience with CST		
Infants and toddlers	0	–
Children	3 (1.4 %)	–
Adolescents and adults	72 (32.7 %)	–
All age groups	75 (34.1 %)	–
Expectation of CST effectiveness (NRS)		
Infants and toddlers	–	7.85 ± 2.12
Children	–	8.00 ± 1.37
Adolescents and adults	–	7.76 ± 1.77
All age groups	–	7.79 ± 1.79

Abbreviations: CST = Craniosacral Therapy, N = Number of patients, NRS = 11-point Numeric Rating Scale, SD = Standard Deviation. Note: Percentages of missing values are not reported.

children were treated 5.4 ± 3.0 times within 12.3 ± 10.7 weeks. Concurrent treatments including (either individually or in combination) physical therapy, osteopathy, herbs, and homeopathic remedies were used by 36.4 % of the parents.

In older children aged 4–12 years, symptoms associated with ICD-F mental/behavioral disorders were the most frequently treated complaints (54.8 %). Unspecific symptoms (R) as well as diseases of the nervous system (G) together with those of the ear (H) were reported by 11.9 % of the parents. Less frequent symptoms were related to diseases of the respiratory system (J), the musculoskeletal system (M), and congenital deformations (Q) (Table 2). Parents of those children used CST on average 6.9 ± 3.4 times within a duration of 18.5 ± 9.4 weeks. Concurrent treatments were used by 52.9 % of the parents and again included physical therapy, osteopathy, herbs, and homeopathic remedies as well as occupational therapy.

Adolescents and adults used CST to treat 84 individual symptoms of 13 ICD categories (Table 2), with47.1 % of the most commonly reported symptoms classified as those of the musculoskeletal system (M). Further 17.5 % reported unspecific symptoms (R), while 14.6 % had symptoms of mental/behavioral disorders (F). Further symptoms were associated with diseases of the nervous system (G), the ear (H), or the digestive system (K) in 8.9 %, 3.1 % and 3.1 % of the participants, respectively. Symptoms resulting from injury, poisoning and other external causes (S) were reported by 1.7 % of this subsample. A total of 4% used CST for treating symptoms associated with conditions of the skin (L), the respiratory system (J), the circulatory system (I), the genitourinary system

Table 2
Cumulative frequency of the conditions being treated.

ICD-10 code		Cumulative Frequency
Infants and toddlers (0–3 years): N = 34		
R	Excessive crying (R68.1), Restlessness and agitation (R45.1), Unspecified abdominal pain due to colic (R10.4), Dysphagia (R13.9), Snoring (R06.5)	40.2 %
Q	Plagiocephaly (Q67.3), Congenital deformity of spine (Q67.5), Ectopic testis (Q53.0), Congenital malformation of middle ear NOS (Q16.4)	36.8 %
F	Developmental disorder of gross motor function (F82.0), Nonorganic sleep disorder (F51.9), Speech articulation disorder (F80.0), Separation anxiety disorder of childhood (F93.0)	10.3 %
P	Slow feeding of new-born (P92.2), Vomiting in new-born (P92.0), Hyperbilirubinemia (P59.0), Convulsions of new-born (P90)	8.0 %
J	Chronic rhinitis (J31.0), Chronic bronchitis (J41.0)	2.3 %
H	Sudden idiopathic hearing loss (H91.2)	1.2 %
L	Eczema infantile (L20.8)	1.2 %
Children (4–12 years): N = 17		
F	Developmental disorder of gross motor function (F82.0), Social anxiety disorder of childhood (F93.2), Separation anxiety disorder of childhood (F93.0), Auditory processing and perception disorder (F80.20), Nonorganic insomnia (F51.0), Dissociative sensory loss (F44.6), Mild depressive episode (F32.0), Mild mental retardation (F70.1), Speech articulation disorder (F80.0), Childhood autism (F84.0), Attention deficit disorder with hyperactivity (F90.0), Oppositional defiant disorder (F91.3), Nonorganic enuresis (F98.0)	54.8 %
R	Loss of appetite (R63.0), Apnea NOS (R06.88), Nausea and vomiting (R11), Anger (R45.4)	11.9 %
G	Migraine with aura (G43.0), Tension-type headache (G44.2)	9.5 %
J	Chronic rhinitis (J31.0), Chronic bronchitis (J41.0), Nonallergic asthma (J45.1)	7.1 %
M	Scoliosis NOS (M41.9), Cervicalgia (M54.2), Low back pain (M54.5)	7.1 %
K	Functional dyspepsia (K30)	4.8 %
H	Vertiginous syndrome in migraine (H82)	2.4 %
Q	Trigonocephaly (Q75.0)	2.4 %
Adolescents and adults (13–79 years): N = 169		
M	Cervicalgia (M54.2), Low back pain (M54.5), Pain in knee joint (M25.56), Pain in shoulder joint (M25.51), Radiculopathy (M54.1), Pain in hip joint (M25.55), Pain in ankle joint (M25.57), Pain in jaw joint (M25.58), Sciatica (M54.3), Specific low back pain (M51.1), Pain in thoracic spine (M54.6), Lateral epicondylitis (M77.1), Scoliosis NOS (M41.9), Fibromyalgia (M79.7), Pain in wrist joint (M25.54), Polyarthritis NOS (M13.0), Primary gonarthrosis (M17.0), Pain in jaw joint (M25.58), Cervical disc disorder with radiculopathy (M50.1), Myositis in sarcoidosis (M63.30), Idiopathic gout (M10.07), Bone spur NOS (M77.9)	47.1 %
R	Restlessness and agitation (R45.1), Fatigue (R53), Dizziness (R42), Paresthesia of skin (R20.2), Difficulty in walking NOS (R26.2), Tendency to fall NOS (R29.6), Nausea and vomiting (R11), Dyspnea (R06.0), Disturbances of smell and taste NOS (R43.8), Hoarseness (R49.0), Cramp of the lower limbs (R25.2), Abnormal posture (R29.3), Nocturia (R35), Drowsiness (R40.0), Jaundice NOS (R17)	17.5 %
F	Nonorganic insomnia (F51.0), Teeth-grinding (F45.8), Anxiety disorder NOS (F41.9), Neurasthenia (F48.0), Mild depressive episode (F32.0), Persistent somatoform pain disorder (F45.4), Acute stress reaction (F43.0), Posttraumatic stress reaction (F43.1), Moderate depressive episode (F32.1), Body dysmorphic disorder (F45.2), Somatoform autonomic dysfunction (F45.30), Dissociative sensory loss (F44.6)	14.6 %
G	Tension-type headache (G44.2), Migraine with aura (G43.0), Trigeminal neuralgia (G50.0), Spasticity (G95.83), Restless legs syndrome (G25.81), Facial palsy (G51.0), Spastic hemiplegia (G81.1)	8.9 %
H		3.1 %

(continued on next page)

Table 2 (*continued*)

ICD-10 code		Cumulative Frequency
	Tinnitus (H93.1), Other abnormal auditory perceptions (H93.2), Dry eye syndrome (H04.1), Cataract NOS (H26.9), Photophobia (H53.1), Diplopia (H53.2), Sudden idiopathic hearing loss (H91.2)	
K	Functional dyspepsia (K30), Ulcerative colitis (K51.0), Acute anal fissure (K60.0)	3.1 %
S	Whiplash injury (S13.4), Fracture of tarsal bones (S92.2), Fracture of carpal bones (S62.1), Fracture of shaft of femur (S72.3), Rupture of ligaments at ankle (S93.2)	1.7 %
L	Pruritus NOS (L29.9), Painful scar (L90.5)	1.2 %
J	Nonallergic asthma (J45.1), Allergic rhinitis due to pollen (J30.1), Chronic rhinitis (J31.0)	1.0 %
I	Hemiplegia (I69.1), Lymphedema of the lower limbs (I89.0), Idiopathic hypotension (I95.0)	0.7 %
N	Chronic cystitis (N30.1), Endometriosis NOS (N80.9), Primary dysmenorrhea (N94.4)	0.7 %
D	Immunocompromising after cancer therapy (D90)	0.2 %
O	Hyperemesis gravidarum (O21.0)	0.2 %

Note: Singe ICD-10 diagnoses are listed in descending order of frequency.

(N), the immune system (D) as well as those associated with pregnancy (O) (Table 2). Adolescents and adults visited CST therapists on average 7.3 ± 8.1 times during a period of 17.3 ± 21.3 weeks. In 47.1 %, they used concurrent treatments including various drugs such as non-steroidal anti-inflammatory analgesics, opiates, cortisone, anticonvulsants, antihistamines, antidepressants, and beta-blockers as well as herbs, vitamins, homeopathic remedies, physical therapy, psychotherapy, osteopathy, speech therapy, and occupational therapy.

In addition, 13.4 % of the adolescents and adults used CST not only to reduce symptoms but to improve health and personal resources. Those included the objective for an enhanced body perception and awareness, fostering the inherent healing abilities of the body, and the search for inner peace, appreciation, self-love and self-awareness.

3.3. Effectiveness of CST

3.3.1. Effects on symptom severity and functional disability

Symptoms that were significantly improved in infants and toddlers belong to ICD-F diagnoses (MD = -6.19, 95 %CI = -7.79 / -4.58, p < .001), ICD-P diagnoses (MD = -6.40, 95 %CI = -8.69 / -4.10, p = .002), ICD-Q diagnoses (MD = -5.50, 95 %CI = -6.64 / -4.35, p < .001), and ICD-R diagnoses (MD = -6.50, 95 %CI = -7.40 / -5.61, p < .001). Symptom severity of the ICD categories H, J, and L decreased likewise but could not be tested statistically because of insufficient number of cases for analyses.

In older children, symptoms of ICD-F diagnoses (MD = -4.05 95 %CI = -5.58 / -2.51, p < .001), ICD-M diagnoses (MD = -4.50, 95 %CI = -6.55 / -2.45, p = .006), and ICD-R diagnoses (MD = -6.20, 95 %CI = -9.82 / -2.54, p = .009) could be reduced significantly. In contrast, symptoms of the ICD-G category did not reach the level of statistical significance (MD = -5.25, 95 %CI = -10.51 / 0.01, p = .050). For the symptoms of the ICD-categories H, J, K and Q, whose intensity was also reduced, no statistical test could be performed, the reason, again, being the insufficient number of cases.

Adolescents and adults reported significantly reduced symptom severity for complaints of the ICD-F category (MD = -3.98, 95 %CI = -4.74 / -3.21, p < .001), the ICD-G category (MD = -3.57, 95 %CI = -4.46 / -2.89, p < .001), the ICD-H category (MD = -3.36, 95 %CI = -5.18 / -1.54, p = .002), the ICD-J category (MD = -3.80, 95 %CI = -6.34 / -1.26, p = .014), the ICD-K category (MD = -2.73, 95 %CI = -4.46 / -0.99, p = .006), the ICD-M category (MD = -4.11, 95 %CI = -4.51/ -3.70, p < .001), the ICD-R category (MD = -4.67, 95 %CI = -5.30 / -4.04, p < .001), and the ICD-S category (MD = -3.67, 95 %CI = -5.62 / -1.71, p = .005). The reduction in symptom severity of the ICD-I and ICD-L category did not reach the level of statistical significance, while those of the ICD-D, N, and O category contained insufficient data for statistical analyses.

Adding up all symptoms across all age groups, the mean symptom reduction observed was MD = -4.38 (95 %CI = -4.69 / -4.07, p < .001), while functional disability was reduced by MD = -4.41 (95 %CI = -4.78 / -4.05, p < .001).

3.3.2. Effects on personal resources

Personal resources were significantly improved as well. After CST, adults reported an increase of MD = 3.10 NRS (95 %CI = 1.99 / 4.21, p = .001).

3.3.3. Effects on quality of life

All subscales of quality of life improved. Patients reported that general wellbeing was enhanced by MD = 3.17 (95 %CI = 2.83 / 3.52, p < .001), mental health by MD = 2.80 (95 %CI = 2.42 / 3.18, p < .001), and sleep quality by MD = 2.87 (95 %CI = 2.51 / 3.24, p < .001).

3.3.4. Global change and change in medication

Analyzing the adapted total MYMOP score, the mean reduction reported was MD = -3.75 (95 %CI = -4.03/ -3.47, p < .001). When answering about the perceived global change, none of the patients reported overall worsening, 1.4 % experienced no global change in their complaints, 9.5 % reported a minimal reduction, 32.3 % a reduction of value, 46.4 % a major reduction, and 10.5 % a complete remission. Concurrent medication use was reported by 47.3 % of the sample. Of these, no patient reported an increase of medication intake, 23.1 % reported no change, 8.7 % a minimal reduction, 16.3 % a reduction of value, 17.3 % a major reduction, and 34.6 % that medication intake was no longer necessary.

3.3.5. Predictors of CST effectiveness

Patient variables that independently predicted the change of the adapted total MYMOP score included: the duration of the respective symptom (p < .002), with patients suffering from acute and subacute symptoms reporting higher response than those presenting with chronic symptoms, the patients' expectation of CST effectiveness (p = .001,) with higher expectations leading to higher responses, and the patients' age (p = .021), with lower age leading to higher responses. Significant therapist characteristics were the years of clinical CST practice (p = .013,) with longer practice predicting higher responses, and the type of CST (p = .023), with the highest response descriptively observed in patients treated with structural in combination with somato-emotional CST techniques, while biodynamic techniques alone or together with structural ones led to slightly lower, and other CST techniques to considerably lower reductions of the adapted total MYMOP score. Excluded predictors that did not systematically influence treatment response were: the age, gender, and basic profession of the therapist as well as the gender and prior experiences of the patient. Equally, the number of provided CST sessions and the use of concurrent treatments did not systematically predict treatment response. More detailed information is displayed in Table 3.

3.3.6. Free text

Of the 220 patients, 128 contributed further individual experiences in form of free text. Qualitative content analysis revealed five major topics that describe CST to enable patients: 1. getting in touch with their body, 2. becoming aware of symptom correlations, 3. perceiving motion, release and reorganizing processes, 4. experiencing integration, and 5. gaining empowerment.

Getting in touch with their own body during treatment enabled patients to intensify their body awareness, to view their symptoms, emotions and themselves in a different light, and to better recognize physical signals.

Table 3
Predictors associated independently with treatment response.

Dependent variable	Predictor variable		B ± SE	β	P-value	R^2
Change in adapted total MYMOP score	Included	Symptom duration	−0.68 ± 0.22	−0.22	.002	0.24
		Patient expectation	0.27 ± 0.08	0.23	.001	
		Patient age	−0.02 ± 0.01	−0.18	.009	
		Therapist experience	0.06 ± 0.02	0.17	.013	
		Type of CST	−0.36 ± 0.16	−0.15	.023	
	Excluded	Therapist age	–	−0.04	.585	
		Therapist gender	–	−0.09	.227	
		Therapist basic profession	–	−0.04	.612	
		Patient gender	–	−0.08	.277	
		Patient prior CST experience	–	−0.11	.118	
		Number of CST sessions	–	0.09	.153	
		Concurrent treatments	–	0.09	.171	

Abbreviations: B = Unstandardized regression coefficient, β = Standardized regression coefficient, CST = Craniosacral Therapy, MYMOP = Measure Yourself Medical Outcome Profile, R^2 = Proportion of the variance of the dependent variable that is explained by the predictor variables, SE = Standard error.

"Thanks to the treatment, I realized that I didn't feel my body before. […] Now I notice when my body feels stressed in contrast to relaxed." (119)
"I view me and my body in a different light." (220)
"I obtain access to painful areas and to emotions such as grief." (111)
"My sensibility is strengthened. I recognize signals coming from my body." (201)

Beyond that, several patients reported new insights in correlation with and explanations for their symptoms.

"I have gained more understanding about my illness, my emotional barriers, and my patterns of action." (198)
"I now recognize the interaction of physical and mental imbalances." (187)

As a result, many patients reported internal processes of motion, turmoil, release, and reorganization leading to less general tension and more flexibility, the sense of relaxation and deceleration, and enhanced energy and inner power. Improvements ranged from no change to complete freedom from symptoms.

"Stagnations have been resolved. Old themes have become apparent." (83)
"After the first treatment, it got worse first before it got better." (128)
"I am totally relaxed. Slowed down. My body feels lightened and […] more flexible." (174)
"I have experienced a great boost of energy and more inner strength." (9)
"My symptoms have remained almost the same." (184)
"The treatment resulted in complete and long-lasting recovery." (11)

Subsequently, patients experienced states of integration and physical/mental balance, which they described in words of harmony, calmness, happiness, being in the center, being normal, being connected to the ground/universe, and being safe.

"The two halves of my body reunited. And my scar feels light and soft, integrated." (215)
"Already after the first treatment, my daughter was much calmer and more pleased." (127)
"I am confident. I am aware of my fears and they are given their place." (215)
"My son is so happy today. After the second treatment, I had a completely different child." (128)
"I am more grounded, I feel connected and I now notice, if I'm not centered" (202)

Finally, numerous patients reported gaining empowerment due to CST. This included a higher acceptance of themselves and their fellows, the discovery of new resources and development of new visions, an improved communication of needs, as well as a more relaxed dealing with stress and more responsible self-care.

"That means to accept myself and to let my fellows be as they are." (43)
"I now stand up for myself and express my needs." (214)
"I am more relaxed when dealing with stress and allow my body to take breaks." (21)
"I care better for me and my body. I recognized that this is my responsibility." (123)
"I do these craniosacral relaxation and perception exercises at home. They […] take away my fears and improve my physical condition." (169)

3.4. Safety

Of the 220 patients analyzed, 75.8 % reported no side effects during or after CST treatment. Parents of infants and toddlers reported transient symptom worsening in 5 of 34 cases (14.7 %), parents of older children in 4 of 17 cases (23.5 %). The need to rest, emotional turmoil and dizziness were also detected in older children in 3 of 17 (17.6 %), 1 of 17 (5.9 %), and 1 of 17 (5.9 %) of the cases, respectively. In adolescents and adults, transient symptom worsening occurred in 19 of 169 cases (11.2 %), the need to rest and emotional turmoil in 6 of 169 cases (3.6 %) each, muscle ache in 2 of 169 cases (1.2 %), and diarrhea, swelling of the nasal mucous membranes, and eczema in 1 of 169 cases (0.6 %) each. All side effects occurred can be classified as minor ones. No serious adverse events were reported.

4. Discussion

Primary care patients participating in this study mainly used CST to treat physical and mental, acute and chronic complaints, which can be attributed to 114 different ICD diagnoses. Frequent symptoms included ICD-M musculoskeletal diagnoses and ICD-R unspecific complaints, while ICD-F mental disorders were common as well, both in children and adults. Satisfactory symptom reduction across all age groups was achieved after on average 7 CST sessions and resulted in a mean alleviation of 4.4 points NRS. This indicates a substantial clinical benefit that is usually associated with 50 % of symptom reduction.[27] Further statistically and clinically significant effects with small confidence intervals were observed on functional disability, general wellbeing, mental health, and sleep quality. Additionally, CST is used for preventive purposes to enhance personal resources such as body awareness, coping and self-help strategies, inner peace, and self-love.

Studies on CST efficacy indicate that non-specific treatment effects explain up to 1.6 points NRS [12] suggesting higher placebo mechanisms than in pharmacological interventions.[28] This observation is also supported by the predictive value of the patients' expectations about the effectiveness of CST. Prior meta-regression revealed patient-reported outcomes as being associated with larger placebo effects as well, while blinding of patients was shown to have no significant impact on the

extent of placebo-responses.[28] And although it is unlikely that the overall variance and size of the effects observed can be explained by placebo effects, further randomized efficacy trials are required to confirm this conclusion. In contrast to uncontrolled studies, randomized trials must be controlled for statistical effects, like regression to the mean,[29] and for the natural course of the disease.[30]

Further limitations, which impact the replicability and the generalizability of the results, include the use of a non-validated assessment tool. Overall, the adaptions of the MYMOP were minor in wording and content and were required to assess the variance and often high comorbidity of symptoms in primary care. The used 11-point NRS (in contrast to the original 7-point NRS) even may enhance the comparability with other studies, which often use an 11-point NRS to assess particularly symptom intensity.[27,31] However, future clinical trials focusing on CST efficacy/effectiveness should include validated instruments and monitor the development of symptoms without treatment using longer-term follow-up assessments and strict methodological designs.[32] Another limitation of the used study design is the method of classifying symptoms post hoc by a study physician. Thus, it remains unclear, whether the treated symptoms reach full ICD criteria in any case or were rather sub-clinical symptoms, likewise prevalent in primary care.[33–36] Future cohort studies may request information about preexisting clinical diagnoses directly, which would allow a more precise estimation of the clinical relevance of the effects occurred. Finally, although consecutive sampling was intended, the results may not be representative for the entire population of primary care patients but rather for the subpopulation of users of complementary and integrative medicine, who are more likely to be female and well-educated [37,38] and to have musculoskeletal complaints [39] or mental problems.[5]

A strength of the study is the systematic assessment of safety data in a bigger cohort of CST patients. Results suggested no serious adverse events of CST. Three out of four patients did not report any adverse event. Mild, transient side effects of CST are correspond l to those reported by other trials and reviews.[13,40,41] In patients with preexisting severe pathologies of the spine, the literature reported one serious adverse event.[42] Thus, CST can be considered as safe as other conventional or commentary manual therapies.[42]

5. Conclusions

CST is used for preventive and therapeutic purposes to improve personal resources and to treat a wide range of physical and mental symptoms in all age groups from infants to older adults. The utilization of CST may provide a promising additional treatment option for primary care patients who are interested in complementary therapies. As for the health-care providers and insurances, supporting the use of CST might not only improve patient health but also reduce costs.[43] Further trials using randomized controlled designs are needed to confirm the exploratory study results in different patient populations.

Ethics approval and consent to participate

The study protocol was developed in accordance with the Declaration of Helsinki. An ethical approval was not required as the study exclusively deals with anonymous patient data. All patients received written study information about the publication of their anonymized data.

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CRediT authorship contribution statement

Heidemarie Haller: Conceptualization, Methodology, Formal analysis, Data curation, Writing - original draft, Visualization, Project administration. **Gustav Dobos:** Resources, Writing - review & editing. **Holger Cramer:** Writing - review & editing, Supervision.

Declaration of Competing Interest

The authors report no declarations of interest.

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