Research Square

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Efficacy of Pediatric Integrative Manual Therapy in Positional Plagiocephaly: A Randomized Controlled Trial.

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Research

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Abstract

Background: positional plagiocephaly frequently affects healthy babies. It is hypothesized that manual therapy tailored to pediatrics is more effective in improving plagiocephalic cranial asymmetry than just repositioning and sensory and motor stimulation.

Methods: 34 neurologically healthy subjects aged less than 28 weeks old with a difference of at least 5 mm between cranial diagonal diameters were randomly distributed into 2 groups. For 10 weeks, the pediatric integrative manual therapy (PIMT) group received manual therapy plus a caregiver education program, while the controls received the same education program exclusively. Cranial shape was evaluated using anthropometry; cranial index (CI) and cranial vault asymmetry index (CVAI) were calculated. Parental perception of change was assessed using a visual analogue scale (-10 cm to +10 cm).

Results: CVAI presented a greater decrease in PIMT group: 3.72 ± 1.40 % compared with 0.34 ± 1.72% in the controls (p=0.000). CI changes did not present any significant differences between the 2 groups. Manual therapy increased positive parental perception of cranial changes (manual therapy: 6.66 ± 2.07 cm; control: 4.25 ± 2.31 cm; p= 0.004).

Conclusion: manual therapy plus caregiver education program improved cranial symmetry and parents' satisfaction more effectively than solely caregiver education program.

Trial registration: trial registration number: NCT03659032; registration date: September 1, 2018. Retrospectively registered.

https://clinicaltrials.gov/ct2/show/NCT03659032?term=NCT03659032&cond=Plagiocephaly&draw=2&rank=1

Background

Head and neck asymmetries are very common in typical healthy newborns [1]. Within these asymmetries, positional plagiocephaly (PP) is a general term describing cranial distortion from pre- or postnatal forces on the infant head [2, 3]. PP features asymmetrical occipital flattening, accompanied by anterior displacement of the ear on the same side, parietal protuberance on the opposite side, and often ipsilateral frontal protuberance, with fellow frontal flattening. These characteristics make the head look like a parallelogram when viewed from above [4]. Facial findings can be associated with the condition, but the term does not imply or connote this [5].

Prevalence data are limited and depend on the geographic location. However, prevalence seems to be high as the best estimations of the presence of PP in infants range from 20 to 40% [6–8].

Many intrinsic and extrinsic factors can play a role before, during and after childbirth. Besides being associated with supine position, development of plagiocephaly is linked to gestational diabetes [9], male

sex [10, 11], maternal age [12], skull circumference [12], prematurity [13], primiparity [10, 11], brachiocephaly [9, 10], intra-uterine constraints [14], prolonged labor [14], multiple births [14], improper fetal position during birth [14], the use of obstetrical forceps or a suction cup [15], lengthy hospital stay [16], congenital torticollis [6, 17], head orientation preference [10–12, 18], infant being awake in a prone position less than 3 times a day [10] and delayed motor milestone acquisition [10].

Although many cases of PP improve over time, the scientific evidence suggests that conservative management strategies can safely and effectively minimize the degree of cranial asymmetry [19]. The controlled clinical trial carried out by Van Vlimmeren et al (2008) constituted one of the highest quality studies. Those researchers compared an intervention group receiving standardized repositioning and physiotherapy treatment and a control group that received the usual care (parents received a leaflet describing basic preventive measures with no further education or instructions to intervene). After the intervention, the ratio of babies with severe PP was significantly lower in the treatment group than in the control group. Their findings suggest that, without intervention, some babies with PP and positional preference could develop severe PP [20]. The results also imply an optimal time framework for the treatment, in which the earlier the intervention, the better the outcomes are [19].

The main conservative treatment options for PP are parent education [21–27], repositioning [23–25, 28–30], physiotherapy [20, 28, 31–33] and orthotic helmet therapy [26, 29, 34–36].

There are very few studies on how manual therapy affects non-synostosis plagiocephaly [37–39]. Most of these studies have been unable to establish a sufficient level of evidence because of the general lack of proper samples sizes, control groups, or randomization.

The objective of this study was to analyze the effectiveness of adding an integrative pediatric manual therapy approach to a caregiver education program in anthropometric cranial measurements and the subjective parental perception of the cranial shape change in infants with PP.

Methods

Subjects

The Ethics Committee at the Aragon Health Sciences Institute approved recruiting a cohort for this study. Pediatricians in Section III of the Aragon Health Services referred 34 subjects aged less than 28 weeks having signs of positional plagiocephaly. The inclusion criterion was a difference of at least 5 mm between cranial diagonal diameters [40], that is infants with moderate or severe PP [41]. We excluded infants that had received other orthotic treatment or physiotherapy or that presented genetic, communicable, metabolic or neurological illness or craniosynostosis.

For the calculation of the sample size, we used non-published data from a previous pilot study with 41 subjects with similar characteristics and receiving a manual therapy intervention similar to the one used in the present study. A decrease of 4,52 ± 2,91% in the cranial vault asymmetry index was obtained in this

pilot study. The sample size was calculated using the GRANMO calculator (https://www.imim.cat/ofertadeserveis/software-public/granmo/), with the selection of two independent population means, bilateral contrast, with a α risk of 0.05, a ß risk of 0.20 and a ratio of 1 of the number of subjects between the groups. A minimal number of 7 subjects per group was obtained.

The subjects were randomized into 2 groups with a final number of 17 subjects per group. The subjects were randomized following a design generated with the on-line computer application at www.random.org/sequences. The evaluators were not told about this design.

An informative document about the study was provided to the parents and an informed consent was signed after they had read the document and their questions about the study had been answered. Regulations and guidelines regarding freedom, absence of coercion, disclosure of economic interests, understandable and complete information, confidentiality and acceptance were followed [42].

The Ethics Committee at the Aragon Health Sciences Institute approved the study (Registry No. C.P. - C.I. PI16/0275. Date: October 25, 2017). The study is registered at clinicaltrials.gov, with identification number NCT03659032. Registration date: September 1, 2018

Measured Parameters

Clinical and demographic data were extracted from the medical history and the testimony of the parents: age (weeks), birth weight (gr), sex, prematurity, instrumental delivery, firstborn, multiple birth, head positional preference, pediatrician diagnosis of congenital torticollis, plagiocephaly side, transport type and time that the infant spent in prone position awake and watched with 1 month (min) and with 2 months (min).

The following anthropometric parameters, constituting the dependent study variables, were measured: maximum cranial circumference (MCC) [43], maximal cranial length, maximal cranial width and diagonal cranial diameter taken from the frontozygomatic suture (fz) to the fellow lambdoid suture (lb) [44]. From these data, we calculated the cranial vault asymmetry (CVA) (the difference between the diagonal diameters) [45], cranial index (CI) and cranial vault asymmetry index (CVAI). CI was calculated by dividing the cranial width by cranial length "Cranial Width ÷ Cranial Length × 100", while CVAI was calculated using the formula "difference between diagonal cranial diameters ÷ short diagonal cranial diameter × 100" [24].

Normal range described for CI is between 75 and 85% [44]. According to Mortenson & Steinbok, CVA can be classified into the following categories: normal CVA < 3 mm, mild / moderate CVA ≤ 12 mm, moderate / severe CVA > 12 mm [41]. Plagiocephaly severity scale, according to the CVAI, pursuant to the Children's Healthcare of Atlanta, 2015 [46] is: level 1: <3.5%; level 2: 3.5 to 6.25%; level 3: 6.25 to 8.75%; level 4: 8.75 to 11.0%; level 5:> 11.0%.

At the end of the study, the parents were given a visual analogue scale (VAS) to evaluate their perception of head shape change [47]. The parents made a vertical mark on a line graduated from − 10 (much

worse) to + 10 (much better); there was an intermediate Item 0 (no change).

Intervention.

17 subjects received 10 sessions of manual therapy and a caregiver education program, an integrative concept of treatment that will be identified in the manuscript as pediatric integrative manual therapy (PIMT). Each PIMT treatment for remodeling the cranial deformation consisted of:

- one maneuver to mobilize the neuromeningeal tissue at the lumbosacral level, based on the technique of John E. Upledger [48] but adapted to the pediatric field. Very light traction is induced through the pelvis to stimulate a tissue response. The physiotherapist follows the movements of the baby's pelvis according to the active movements, trying to move towards increasingly flexed positions in order to act on the general dural tension.
- one technique for the cervical spine based on the works of Giammatteo [49]. Very slight traction is applied through the head and the active movement of the head is accompanied to different positions of flexion and extension, lateralization and rotation, stabilizing the atlas gently in a dorsal direction.
- one technique applying manual pressure to mold the skull base in the opposite direction from the PP torsion on the skull base, based on the work of Arbuckle [50]. The manual pressure was applied to the occipital bone to displace it dorsally, insisting on the flattest area, representing attempted cranial torsion (Fig. 1).
- two techniques; one to balance intracranial membranous tension and one molding technique for decompressing coronal suture based on the work of Carreiro [51].

This PIMT protocol was applied by several pediatric physical therapists with specialized training and 4 years of experience. The results obtained with PIMT treatment in cervical spine mobility are described in another manuscript pending publication.

Each manual therapy session lasted 20 minutes, once a week.

The caregiver education program consisted of a series of literature-based recommendations [52, 53] that encompassed repositioning, sensory and motor stimulation of the opposite side to the prefered one and prone positions. Parents were instructed with the help of a trained pediatric physiotherapist and an informative booklet about basic recommendations.

The 17 subjects from the control group received solely the same caregiver education program. The control group was convened once during the 10 weeks to control their evolution, listen to their difficulties, solve their questions and insist on the importance of the program of stimulation and positional advice.

Statistical analyses

The Kolmogorov-Smirnov test with the Lilliefors correction was used to test the normality of the distribution of the quantitative variables; the Shapiro-Wilk test was used for this purpose if n < 30. A

descriptive analysis of the qualitative variables was carried out, offering the absolute and relative frequencies; as well as a descriptive analysis of the quantitative variables, offering the mean ± standard deviation or the median (Q1; Q3) values, depending on whether the distribution of the variables was normal or not, respectively.

If distribution was normal, the Student t-test for independent samples was used for the intergroup comparisons of the dependent pre-intervention variables. The Mann-Whitney U test was used for these comparisons if the distribution was not normal. To compare intervention effectiveness between the groups, we calculated the improvement indexes of the dependent variables using the difference of the final measurement values minus the baseline measurement values. If the distribution was normal, the improvement indexes were compared using the Student t-test for independent samples; if not, the Mann-Whitney U test was used. The effect size of the interventions evaluated was calculated using Cohen's d.

We analyzed the correlations between the improvement index of the CVAI and of the VAS reflecting the parental perception of head shape change in the entire sample. To do so, the Pearson correlation coefficient was calculated when the variables followed a normal distribution. If the distribution of a variable was not normal, the Spearman Rho coefficient was used.

A confidence interval of 95% was established for the analyses. Statistical significance was set at $p < 0.05$. The statistical study was performed following the principles of intention-to-treat analysis, without attributing values in the second assessment to the subjects lost to study throughout the intervention.

Results

Study population. A total of 34 subjects were included in the study. 17 were assigned to the PIMT intervention group and 17, to the control group (solely caregiver education program). Two subjects were lost in the intervention group, so the final measurement covered 15 subjects in the intervention group and 17 in the control group (Fig. 2). Demographic characteristics were comparable in the 2 groups (Table 1). Anthropometric measurements and head shape were comparable in both groups (Table 2). There were no adverse events with the treatments performed in the study.

Table 1
A comparative descriptive analysis of the qualitative variables in the baseline examination. PIMT: (Pediatric Integrative Manual Therapy) [a]Statistical analysis using the Chi Square test; [b]Statistical analysis performed with the Fisher exact test.

Features at baseline examination				
Qualitative variables		PIMT Group (n = 17)	Control Group (n = 17)	p value
Sex [a]	Women	52.9%	41.2%	0.492
	Men	47.1%	58.8%	
Prematurity [a]		29.4%	5.9%	0.175
Instrumental delivery [b]		17.6%	23.5%	1.000
Firstborn [a]		70.6%	70.6%	1.000
Multiple birth [b]		23.5%	17.6%	1.000
Head position preference [b]		100%	88.2%	0.485
Pediatrician diagnosis of congenital torticollis [b]		5,9%	11,8%	1,000
Plagiocephaly side [a]	Right	52.9%	76.5%	0.151
	Left	47.1%	23.5%	
Transport type [b]	Trolley	100%	94.1%	1.000
	Babies backpack	0%	5.9%	

Table 2

Table describing the homogeneity of the quantitative variables in the baseline examination. PIMT (Pediatric Integrative Manual Therapy). MCC (Maximum Cranial Circumference). CVA: (Cranial Vault Asymmetry). CI: (Cranial Index). CVAI: (Cranial Vault Asymmetry Index). [a] Statistical analysis using the Student t-test. [b] Statistical analysis using the Mann-Whitney U test.

Features at baseline examination			
Quantitative variables	PIMT Group (n = 17)	Control Group (n = 17)	p value
Age [a] (weeks)	17.29 ± 4.27	17.18 ± 4.55	0.938
Birth weight [a] (gr)	3040 ± 605.3	3188 ± 483.7	0.437
Time in prone position with 1 month [b] (min)	1 (0 ; 5)	5 (5 ; 16)	0.520
Time in prone position with 2 months [b] (min)	2 (0.5 ; 10)	10 (5 ; 11)	0.228
MCC [a] (cm)	40.76 ± 2.01	41.08 ± 2.14	0.610
Cranial Length [b] (mm)	131 (129.9 ; 136.8)	134.8 ± 8.06	0.480
Cranial Width [a] (mm)	116.8 ± 8.02	117.1 ± 8.66	0.846
Long diagonal cranial diameter [a] (mm)	134.52 ± 7.41	135.39 ± 7.11	0.835
Short diagonal cranial diameter [a] (mm)	126.01 ± 7.11	127.35 ± 7.76	0.479
CVA [b] (mm)	8.20 (6.50 ; 11.75)	7 (5.83 ; 9.33)	0.196
CI [a] (%)	88.35 ± 6.39	87.04 ± 7.14	0.522
CVAI [b] (%)	6.59 (5.20 ; 9.30)	5.37 (4.51 ; 7.86)	0.153

Outcome. In the improvement indexes of the anthropometric measurements between the 2 groups (Table 3), the intervention group showed a statistically significant increase in MCC: 2.16 ± 0.69 cm against 1.35 ± 0.75 cm (p = 0.004). Likewise, there was a significant increase in cranial length in the intervention group: 7.57 ± 2.33 cm against 4.25 ± 2.47 cm in the control group (p = 0.001). The improvement index for the CVA presented a significantly greater reduction in the intervention group: 4.39 ± 1.51 mm compared with 0.11 ± 2,14 mm in the control (p = 0.000). The CVAI improvement index presented a significantly greater decrease in the intervention group: 3.72 ± 1.40% compared with 0.34 ± 1.72% in the control group (p = 0.000). The CI improvement index did not present any statistically significant differences between the 2 groups.

Table 3
Table summarizing the variables with descriptive and comparative data on their Improvement Indices. PIMT: (Pediatric Integrative Manual Therapy). MCC: (Maximum Cranial Circumference). CVA: (Cranial Vault Asymmetry). CI: (Cranial Index). CVAI: (Cranial Vault Asymmetry Index). [a] Statistical analysis using the Student t-test; [b] Statistical analysis using the Mann-Whitney U test; * Significant p value.

Descriptive and comparative of the Improvement Indices				
Variables	PIMT Group n = 15	Control Group n = 17	Sig.	Cohen's d effect size
MCC [a] (cm)	2.16 ± 0.69	1.35 ± 0.75	0.004*	1.12
Cranial Length [a] (mm)	7.57 ± 2.33	4.25 ± 2.47	0.001*	1.39
Cranial Width [a] (mm)	5.42 ± 4.24	3.97 ± 3.11	0.277	0.39
Long diagonal cranial diameter (mm) [b]	5.33 (2.33 ; 6.50) [b]	4.93 ± 2.58 [a]	0.610	0.23
Short diagonal cranial diameter [a] (mm)	8.88 ± 3.27	5.04 ± 2.71	0.001*	1.28
CVA [a] (mm)	4.39 ± 1.51	0.11 ± 2.14	0.000*	2.32
CI [a] (%)	0.85 ± 3.63	0.16 ± 2.00	0.516	0.24
CVAI [a] (%)	3.72 ± 1.40	0.34 ± 1.72	0.000*	2.16

In the VAS reflecting the perception of head shape change, the parents of the intervention group subjects evaluated the change perceived as 6.66 ± 2.07 cm (between − 10 cm and + 10 cm). However, the parents of the control group evaluated the change perceived as 4.25 ± 2.31 cm (p = 0.004).

In the correlation study, the outcomes show a statistically significant association (Pearson correlation coefficient = -0.365; p = 0.04) in the entire sample. This association was present between the CVAI improvement index (-1.92% ± 2.31) and the VAS of head shape change perception (5.38 cm ± 2.49) in the entire sample.

Discussion

In our study, the use of PIMT has been shown to be more effective than applying solely a caregiver education program. The addition of PIMT to a caregiver education program have produced better outcomes in cranial anthropometric values (improved vault asymmetry index, increased maximum circumference and length, and decreased vault asymmetry) and in parental perception of head shape changes.

The mean gain in MCC, in the 10-week study period, was 2.16 ± 0.69 cm in the PIMT group and 1.35 ± 0.75 cm in the control group. The growth rates observed by Martini et al (2018) in healthy babies from

4 months to 12 months was an increase of 43.4 ± 9 cm to 46.9 ± 7 cm [29]. For Meyer-Marcoti et al (2018), the total increase of cranial circumference during the first year was 11–13 cm [43]. In their study on a sample of 40 subjects without cranial asymmetry, a mean MCC of 41.38 cm is observed at 4 months, evolving to 43.23 cm at 6 months (1.85 cm of increase). In this 8-week period, the natural skull growth is close to the values of evolution of our PIMT group but are higher than the control group values. Consequently, it might be declared that the MCC skull growth data in the PIMT group are closer to the physiological evolution of the skull of a healthy baby in the same time period [54]. The increase in cranial length was also greater in the PIMT group.

The CVA is one of the main cranial indicators for analyzing the possible effectiveness of the PIMT protocol used in this population. Kim et al (2013) found a significant improvement in this parameter using an orthotic treatment. The variable changed from a mean of 13.28 mm ± 3.57 to 6.48 mm ± 1.92. The control group in this study changed its values to a lesser degree, going from 11.38 mm ± 3.30 to 10.05 mm ± 1.43 [55]. In our study, the PIMT treatment (with an improvement of 4.39 ± 1.51 mm) is significantly better than that obtained by the control group ($p = 0.000$). The PIMT treatment shows quite similar effectiveness than orthotic treatments, which are evaluated as the most effective in the literature [29, 56]. Lessard et al (2011), in a pilot study without a control group on 12 subjects, using a manual intervention, found a significant improvement of 4.1 mm in the diameter difference [38]. This is close to the outcome in our study.

The cranial index improved in both groups of our study, with no significant differences between them. The predominantly brachiocephalic skull (mainly wide and short) changed towards normal values, without dropping below the limit of 85% that marks the upper limit of the range of normality [24]. In the PIMT group, CI increased from 88.35–87.73%. This was a slightly better improvement than that of the controls, who changed from 87.04–86.89%. The somewhat positive data in the PIMT group may be related to the significant improvement in cranial length, a factor needed to balance the CI downwards.

CVAI improvement was significantly greater in the PIMT group (3.72% ± 1.40) than in the control group (0.34% ± 1.72) ($p < 0.05$), with a high size effect ($d = 2.16$). This variable is one of the main cranial indicators for analyzing the possible effectiveness of the PIMT protocol used in this population. Kim et al (2013), with a sample of 27 subjects, found a comparable (although somewhat higher) improvement using an orthotic helmet treatment. The intervention group improved a mean of 5.5%, which was a significant improvement compared with the control, with a mean of 1.53% [29]. Kluba et al (2014), with an orthotic helmet intervention, obtained a CVAI reduction of 4.1%, very close to what we obtained in our study, that was significantly better than the control group’s decrease (2.7%), on 128 subjects [56]. The studies by di Chiara et al. (2019) [39], Cabrera-Martos et al. (2016) [37] and Lessard et al. (2011) [38], can be considered more similar to our study due to the similarities of the intervention protocol. The CVAI outcomes in these studies are not comparable with ours because either the parameter is not measured, or it does not appear with specific figures for before and after results but with the outcome given in a classification by CVAI severity.

Parental perception of head shape change has been one of the variables seen in the literature to assess user satisfaction about the intervention. Naidoo et al (2015) found that parents whose babies had received helmet treatment were more satisfied than parents whose babies were only indicated repositioning [57]. In our study, PIMT treatment has demonstrated that it boosts parental perception of improvements in head shape changes more than applying just caregiver education program does. In addition, the parents' perception of such head shape improvement is related to the CVAI changes in the entire sample. This shows that this subjective perception is coherent with objective cranial asymmetry assessment.

Our study findings are subject to limitations. The lack of assessments of the skull base asymmetry and of the face constitutes one of them. Including an evaluation of ear position, using a tragus-subnasal measurement with the methodology of Lessard et al (2011) [38] or that of Kim et al (2010) [29], would have made possible to analyze the change in skull base asymmetry and not just the vault change. Measuring jaw asymmetry would have increased the evidence available on facial morphology changes obtained using the treatment. Fenton et al (2018) found jaw asymmetry in 10% of their sample of subjects with congenital torticollis and PP; they described a significant change after 4 months of treatment with physiotherapy [58]. Widening assessment to include facial and skull base measurements is a possible future line of research. It would increase the evidence on the effect of treatments with pediatric manual therapy on cranial base symmetry and on face morphology. The current lack of follow-up data on our subjects for analysis of outcome evolution is another limitation. The authors plan to remedy this in future, by obtaining follow-up data linked to continuing this line of research.

Conclusions

Manual therapy plus caregiver education program improved cranial symmetry and parents' satisfaction more effectively than solely caregiver education program.

Abbreviations

CI
Cranial Index
CVA
Cranial Vault Asymmetry
CVAI
Cranial Vault Asymmetry Index
MCC
Maximum Cranial Circumference
PIMT
Pediatric Integrative Manual Therapy
PP
Positional Plagiocephaly

VAS
Visual Analogue Scale

Declarations

Ethics approval and consent to participate

An informed consent document with information about the study and in accordance with the requirements established by the "Ethics Committee at the Aragon Health Sciences Institute" was offered to the parents.

The Ethics Committee at the Aragon Health Sciences Institute approved the study (Registry No. C.P. - C.I. PI16/0275).

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

All data generated or analysed during this study are included in this published article.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Conceptualization: IPP; Methodology: IPP; Investigation: MBL, IRP; Resources: MBL; Data Curation: IRP; Writing – Original Draft: IPP; Writing – Review – review & editing: OLL, CHG; Formal Analysis: OLL; Visualization: ALRF, JMTM; Supervision: ALRF, JMTM. All authors read and approved the final manuscript.

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Figures

Figure 1

Cranial Base Molding Technique applied in the intervention group.

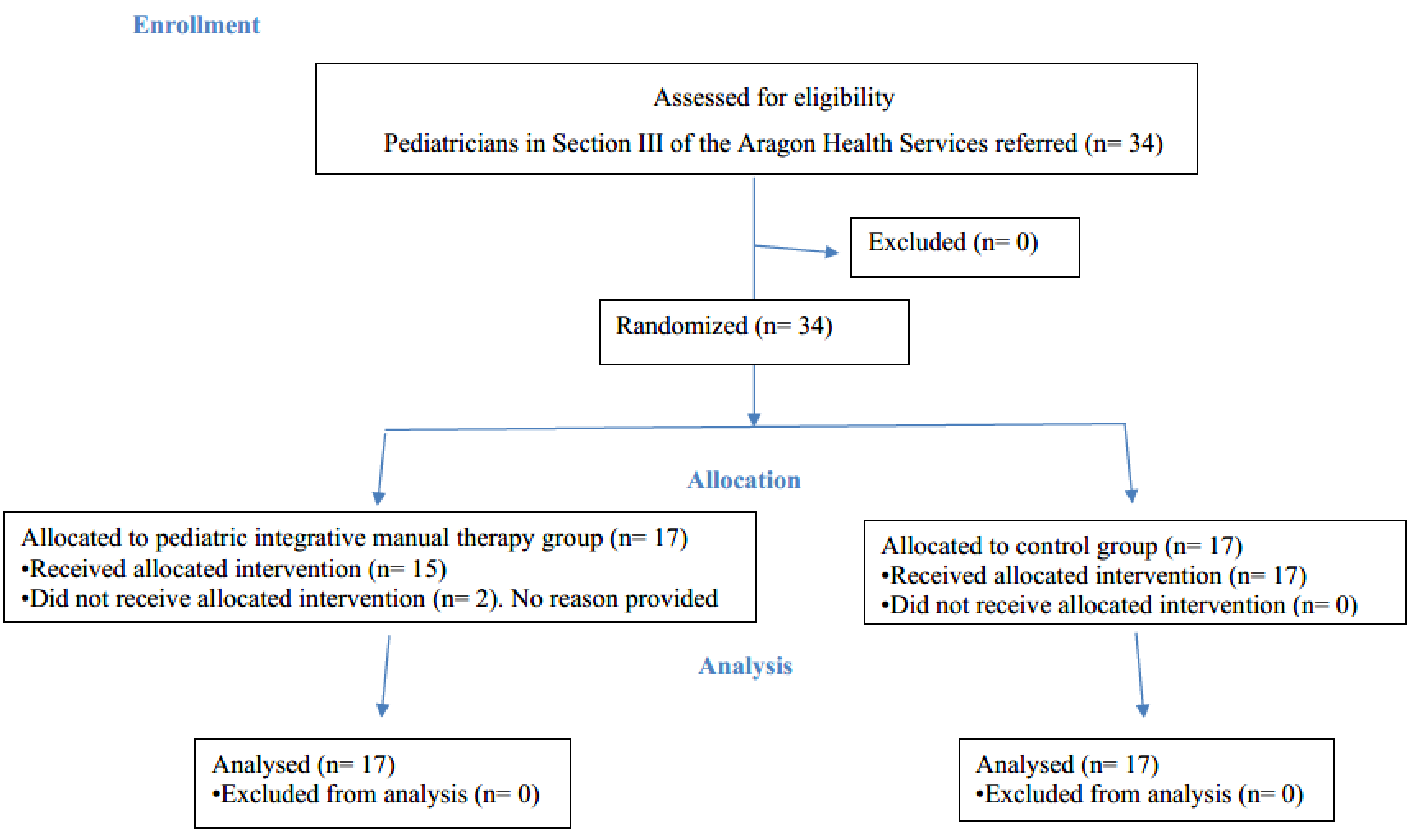

Figure 2

Consolidated Standards of Reporting Trial (CONSORT) flow diagram.