Development and Validation of a Cloak-Shaped Device for Sham Pediatric Tuina: a Randomized Controlled Study

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Research

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Abstract

Background: To date, no well-recognized placebo device or procedure for pediatric Tuina (PT) has been reported. We developed a cloak-shaped device and designed an RCT to detect whether the device is effective as a placebo in PT research.

Methods: It was a two-arm, parallel-group RCT design. Children were randomly assigned to the genuine Tuina or sham Tuina group at a 1:1 ratio. The genuine and sham Tuina interventions were delivered using the same standardized procedure by adopting a cloak-shaped device. The primary outcomes were the judgement rates of the type of Tuina that participants received based on caregivers' and observers'evaluations. The analysis explored whether parents' attitude towards PT was related to their judgment rate.

Results: A total of 60 participants were enrolled (37 boys [61.7%]; 16.0[2.3] months). Thirty children received genuine PT, and 30 received sham PT. There was no significant difference in parents' judgment of the interventions received between the two groups ($\chi2=0.65$,$P=0.421$) or based on observers' judgments ($\chi2=0.07$, $P=0.795$). In terms of parents' attitude towards PT or compliance with PT, parents whose children were in the genuine Tuina group were not significantly different from those in the sham group($z=0.01$, $P=0.99$; $z=0.34$, $P=0.73$). Of the participants in the sham group, none of their parents recorded receiving the sham intervention.

Conclusions: The placebo device for sham PT was found to be a credible control for PT. This study supports its use in prospective, sham-controlled, randomized trials.

Trial registration: ClinicalTrials.gov, NCT03474172. Registered in March 2018.

Background

With the overwhelming acceptance of evidence-based medicine, valid placebo devices or placebo procedures have become key issues for randomization and placebo-controlled designed clinical trials on the validation of treatment modalities. Blinding is one of the important methodological elements in randomized clinical trials (RCTs)based on the principles of evidence-based medicine[1-2].A valid placebo device or procedure may successfully prevent stakeholders from detecting the group allocation situation[3-5]. Blinding can minimize the placebo effect as much as possible; therefore, the efficacy of the intervention can be evaluated to a large extent. In addition, in the trial design, a placebo or a sham control can not only provide a valid comparator but can also effectively control unknown variables to decrease the bias and show the contrasting efficacy of the intervention[6].

Placebos have frequently been used in pharmaceutical clinical trials. In recent decades, researchers have attempted to develop sham controls for nonpharmaceutical therapies in Chinese medicine (CM),including acupuncture[7-9], moxibustion[10] and cupping[11]. However, in nonpharmaceutical therapies, placebo or sham therapy has yet to be well recognized. Difficulties in the development of placebo devices or placebo procedures of nonpharmacological intervention occur when participants have had similar experiences[12-13]; additionally, when the placebo procedure is not rationally established, expectation bias may easily be introduced[14]. Therefore, the development of appropriate devices for sham massage or sham Tuina is warranted.

Pediatric Tuina (PT) is a form of traditional Chinese medicine (TCM) therapy in which trained practitioners manually stimulate specific acupoints of the body that are located primarily on the fingers, palms, arms, head, abdomen and back. This has been a valuable option for the promotion of children's health for more than one thousand years (652 AD) and is still widely used in the prevention or treatment of various kinds of pediatric diseases, such as diarrhea, dyspepsia, and pneumonia[15]. Some studies have shown that PT is effective and has few side effects[16-18]. More rigorously designed trials are needed to evaluate the efficacy of PT. The main obstacle in this field is to develop a valid placebo device or procedure to make sham Tuina comparisons possible. In this study, we evaluated the validity of a newly developed cloak-shaped device (CSD) for sham PT.

Methods

Trial design and setting

Eligible children were randomly assigned to the genuine PT or sham PT group at a 1:1 ratio. Trained practitioners manually performed 15-minute sessions of Tuina on each participant while the caregivers and observers were watching. The caregivers and observers were required to record their judgments of the type of Tuina, either genuine or sham PT, that the participant received. If the child was 3 years old or older, a questionnaire with 2 items was adopted to ask the child in terms of their feeling regarding the Tuina after the procedure was completed.

This study was designed by the Second Affiliated Hospital of Guangzhou University of Chinese Medicine and was conducted in Dongguan Kanghua Hospital in Guangdong Province. The ethics committees of both hospitals approved the study protocol (No. Z2017-212-01 and No. 2018003). Before each participant was randomized, a parent or guardian provided written informed consent. Computer-generated randomization lists were concealed in opaque envelopes and distributed by authorized experts from the Department of Medical Statistics of the Second Affiliated Hospital of Guangzhou University of Chinese Medicine who were not involved in the study. We followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

Participants and Trial Procedures

Participants were recruited from the outpatient department of pediatrics in Dongguan Kanghua Hospital in Dongguan, Guangdong Province, China. Eligible children were 6 years old or younger, diagnosed by pediatricians with either cough, dyspepsia or diarrhea, and had no simultaneous attendance in other studies. Their parents or guardians signed the informed consent form and agreed to be cooperative during the study period. Children were excluded for having one or more PT experiences on either arms, abdomen or back; having a previous history of convulsion; having any of the following conditions on the skin where the manipulation would be conducted, including phlebitis, open wound, fracture and tissue damage; or having any of the following conditions: disorders of consciousness, seizures or twitching, shock, varicella, hand-foot-mouth disease or encephalitis B. Recruitment occurred from May to August 2018; all children completed the study by August 15, 2018.

Baseline questionnaires included demographics, diagnosis, caregivers' educational background and occupation. After the intervention, caregivers were asked to guess their child's randomization assignment, and

they completed a five-item questionnaire (see Appendix 1) to assess their judgments of the intervention type and their degree of understanding of PT. Children who were older than 3 years old were asked to share their feelings after they received the therapy. Six observers independently responded through a four-item questionnaire (see Appendix 2) regarding their judgment of the therapy type and to gauge the parents' understanding of the intervention from the observers' point of view. Participants were compensated for their travel when they completed the trial.

All the researchers were trained before the trial was conducted, including communicationskills with caregivers and children, subject screening, randomization and evaluation procedures. Meanwhile, three experienced therapists received a well-designed session of a manipulation technical training course to reach a high level of standardization. Detailed information in terms of dropouts and adverse events was recorded.

Development of the CSD

The CSD was made of an opaque cotton cloth shaped like a cloak(see Figure 1). It was large enough to cover the upper body, including the upper limbs and trunk, of a child who was 6 years old or under. Two narrow holes were present for therapists to insert their hands through and perform Tuina(see Figure 2). The entire manipulation process was covered by the CSD. Blinding was maintained during the entire study process in both the genuine and sham Tuina groups.

Genuine PT and sham PT

All the techniques and acupoints were the same in both groups; the only difference was that the therapists performed the manipulation. For genuine PT, the manipulation was performed directly on the child’s skin. However, in the Sham PT group, the therapists placed one hand above the child's corresponding acupoint skin area and performed Tuina on their own hand instead of on the child's skin (see Figure 2)[19].Five acupoints located on the upper limbs and the trunk were involved, including *Neibagua* point, *Banmen* point and Large intestine meridian point on the hands, *Qijiegu* point on the sacroiliacregion and Abdomen. In order to minimize the possible treatment impact, we designed equal times of manipulation with nourishing techniques, i.e. clockwise and pushing up and those with clearing techniques, i.e. anti-clockwise and pushing down. There were250 times respectively for clockwise and anti-clockwise arc-push of *Neibagua* point, 300 times each for clockwise rubbing and anti-clockwise rubbing of Abdomen point, and150 times either for pushing up and for pushing down of *Qijiegu* point. For kneading Banmen point, the total number of times was 700.And the pushing endocentric and exocentric Large intestine meridian point was 300 times in all(see Appendix 3). The acupoints and manipulation times were the same for all subjects in the two groups. All manipulations were carried out with a light, fast, and soft touch, and coconut oil was used to protect the children’s skin in both groups.

Outcomes

The primary outcomes were the judgment rates of the type of Tuina that participants received based on caregivers' or observers' evaluations. Secondary outcome measures included parents’ attitudes towards PT and those from the observers’ perspectives, the perceptions of PT for children 3 years old or older, and

participants’ compliance with three continuous PT therapy sessions. We used the VRS-4, with a higher score representing a more positive attitude.

Statistical analysis

Sample size

The aim of this study was to evaluate whether the validity of CSD might have a balanced judgment rate (e.g., 50%) on the type of Tuina that the child received in the genuine or sham group when judged by caregivers or observers. Approximately 95% of the subjects could accurately distinguish genuine and sham PT without a placebo device in clinical practice. Based on the results from previous similar studies, an ideal blinding device was considered to have a good blinding effect, while the judgment rate of the subjects (the genuine PT group and the sham PT group) for guessing the Tuina type was 50%. Therefore, we adopted the single-sample test in PASS 11.0 software (NCSS LLC) to calculate the sample size and set judgment rate of subjects with 95% in non-blinding status, and 50% in blinding status, powered by 90%, and significance levelwith0.05. After calculations, 24 subjects of each group were needed of the 20% subject might drop out, the final sample size was 60 subjects in total, with 30 subjects in each group.

All the data in this study were recorded in a case report form (CRF). When the trial was completed, data were entered into the database by the double entry method. We used the Wilcox on rank-sum test for abnormally distributed data, the Mann-Whiney U test for ranked outcomes and the chi-squared test for binary outcomes.

In the primary outcome, we calculated the judgment of the type of Tuina the participants received according to the caregivers and observers. In the secondary outcomes, the Mann-Whiney U test was used for the comparison of the VRS in terms of parents’ attitudes towards PT, children's perceptions of PT, parents’ attitudes towards PT from the observers' perspective, and participants’ compliance with three continuous PT therapy sessions between groups. We used the chi-square test for the analysis of demographic sociological characteristics, including education level, age, children's perceptions, parents’ attitudes, and related factors.

Statistical Package for the Social Sciences (SPSS) for Windows version 18.0 (Chicago, IL) was adopted to conduct the analyses. For all tests, a two-tailed P value less than 0.05 was considered statistically significant.

Results

From May to August 2018, sixty children were approached in the Outpatient Pediatric Department of Dongguan Kanghua Hospital. All of them were recruited and completed their initial assessment and the entire trial procedure(see Figure 3,Table 1). Thirty participants were allocated to receive genuine Tuina, whereas the other thirty were allocated to receive sham Tuina. Six observers from The Second Affiliated Hospital of Guangzhou University of Chinese Medicine and Dongguan Kanghua Hospital completed the questionnaire; they did not take part in the Tuina manipulation therapy.

Table 1
General characteristics of the study subjects

	Genuine Tuina Group		Sham Tuina Group		χ^2	*P*
	n=30	%	n=30	%		
Age						
≥3	23	76.7	27	90.0	1.92	0.166§
3-6	7	23.3	3	10.0		
Sex						
Male	20	66.7	17	56.7	0.64	0.426§
Female	10	33.3	13	43.3		
Diagnosis						
Cough	16	53.3	15	50.0	-	0.522*
Indigestion	3	10.0	1	3.3		
Diarrhea	11	36.7	14	46.7		
Caregivers' age						
20~30	11	36.7	11	36.7	-	0.999*
30~40	16	53.3	17	56.7		
≥40	3	10	2	6.7		
Caregivers' gender						
Male	5	16.7	9	30.0	1.49	0.222§
Female	25	83.3	21	70.0		
Caregivers' education level						
Junior high school	2	6.7	5	16.7	-	0.553*
Senior high school/Junior College	20	66.7	18	60.0		
Bachelor degree	8	26.7	7	23.3		
Caregivers with medical education background						
Yes	0	0	1	3.3	-	-

Notes: * Fisher's exact test.§Chi-square test or continuity correction.

	Genuine Tuina Group		Sham Tuina Group		χ^2	*P*
	n=30	%	n=30	%		
No	30	100	29	96.7		
Caregivers' occupation						
Professionals	2	6.7	4	13.3	-	0.774*
Individually owned business/freelance career	10	33.3	7	23.3		
Worker/Service occupation/company employee	8	26.7	9	30.0		
Housewives	10	33.3	10	33.3		
Notes: * Fisher's exact test.§Chi-square test or continuity correction.						

In the genuine Tuina group, 28 out of 30 caregivers believed their child received true Tuina, while in the sham Tuina group, this number was 25 out of 30.No statistically significant difference between the groups was recorded based on either the caregivers' or the observers' judgments.

Furthermore, no statistically significant differences between groups were recorded in any of the secondary outcomes, i.e., VRS of caregivers' attitudes towards PT and those from the observers' perspectives, caregivers' and observers' attitudes towards PT and the compliance of three continuous PT therapists. Only ten participants were 3 years old or older, and they all reported no discomfort after Tuina (see Table 2). However, due to the limited sample size, the lack of significant differences is not equal to the proof of equivalence. None of the participants reported any adverse events.

Table 2
Questionnaire responses by caregivers, children and observers after Tuina

Respondent	Questions	Options	Genuine Tuina Group	Sham Tuina Group	Statistic of test	*P*
			n=30	n=30		
Caregivers	Which type of intervention do you think your child has received?	Real	28	25	0.65	0.421§
		Sham/uncertain	2	5		
	Do you familiar	Not familiar	10	13		0.544#
		A little familiar	20	16	0.61	
		Very/extremely familiar	0	1		
	with any related information of PT?					
	Have you ever seen other children do PT?	Never	19	19		0.991#
		Occasionally	10	10	0.01	
		Often/always	1	1		
	How confident do you have on PT in reducing your child's medical problems	No/somewhat	17	18		0.706#
		Very	10	11	0.38	
		Extremely	2	1		
	Do you think it is possible for you to let your child receive PT for three consecutive days	Improbable/somewhat improbable	1	1		0.730#
		Very probable	25	26	0.34	
		Extremely probable	4	3		

Notes:§Chi-square test or continuity correction. # Nonparametric test.

VAS: visual analogue scale, PT: pediatric Tuina.

Respondent	Questions	Options	Genuine Tuina Group	Sham Tuina Group	Statistic of test	*P*
Children who were 3 years or older	What do you feel after you received the PT?	No discomfort	7	3	-	-
		Some discomfort/uncomfortable/very uncomfortable/ uncertain	0	0		
Observers	Which type of therapy do you think the child has received?	Real	14	13	0.07	0.795§
		Sham/uncertain	16	17		
	Do you think the parents can guess which type of therapy their child has received?	Yes	4	5	<0.001	>0.999§
		No/not sure	26	25		
	How much trust do you think the parents have in PT?	No/somewhat	15	18		0.501#
		Very	12	9	0.67	
		Extremely	3	3		
	Do you think it is possible for the parents to let their child receive PT for three consecutive days?	Improbable/somewhat improbable	2	2		0.523#
		Very probable	24	26	0.64	
		Extremely probable	4	2		

Notes:§Chi-square test or continuity correction. # Nonparametric test.

VAS: visual analogue scale, PT: pediatric Tuina.

Discussion

To our knowledge, this trial is the first study that aims to assess the validity of a placebo device in regard to sham PT. On the basis of a rigorous randomized controlled design of our study, the credibility of sham Tuina

was found to be no different from that of genuine Tuina treatment. The results likely indicate successful subject blinding and could facilitate rigorous research in PT clinical trials adopting sham-controlled, subject- or assessor-blinded approaches. This device makes it possible to evaluate the effects of PT in placebo-controlled trials using a rigorous research methodology.

Studies have shown that the therapist-patient relationship is the most potent component of placebo effects[20],suggesting that the context or delivery of the sham PT device is important. To strengthen the evaluation reliability of the specific effects of PT, an intervention and placebo control should be delivered in the same way. Despite PT, other nonpharmaceutical therapies for Chinese medicine have developed sham or blinding methods, such as several types of sham acupuncture and sham cupping devices. The effects of these methods have been revealed by adopting a similar research design as employed in this study[821-23].Strengths of this study included the consistency of the interaction and all procedures used when delivering genuine or placebo interventions. Despite the treatment allocation, we aimed to produce an equivalent therapeutic experience for all the participants.

The small number of subjects involved in this study was the main limitation of this trial. Based on the purpose of our research, we were trying to evaluate the equivalence of the genuine and sham procedures, not their difference. In this situation, comparative statistical tests might carry the risk of a type II error, which risks producing a false negative result. In the responses to all the credibility questions, no trends in lower credibility were found regarding the sham intervention. Therefore, we have confidence that the CSD sham device for PT will not result in loss of blinding. In addition, the CSD is inexpensive and is simple to use.

PT has been found to be easily accepted by children based on a light and gentle technique and has a good safety record. To date, no severe adverse events due to PT have been reported, and some mild adverse events, such as skin abrasion, can be easily avoided with clear and correct operating instructions. Therefore, caregivers and children may have complied with completing the trial. Children less than 6 years old did not differ in their perceptions of genuine PT and sham PT when they lacked previous PT experience; consequently, the placebo effect for both groups was not generated systematically. In this case, caregivers' and observers' judgments were more important than children's own perspective in the placebo validation evaluation of the CSD.

Conclusions

Within the context of this study, the CSD sham PT intervention was credible as a placebo control. The findings of this study support its use in RCTs on children with similar interventions, such as PT. More rigorous RCTs for specific conditions will be needed to test the placebo effects of PT by adopting a subject-blind method with CSD.

Abbreviations

RCT
randomized controlled trial
PT

Pediatric Tuina
CM
Chinese Medicine
CRF
case report form.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethical Review Board at the Kanghua Hospital in Dongguan, Guangdong province,China (February 6, 2018) and Guangdong Provincial Hospital of Chinese Medical in Guangzhou, Guangdong province, China(January 12,2018). Signed informed consent will be needed for each participant by one of their guardians.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analyzed during the present study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Jianxiong Cai, Lin Dai and Darong Wu, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis; Jianxiong Cai, Lin Dai, Lingjia Yin and Darong Wu contributed to the concept and design; Lin Dai, Jianxiong Cai, Darong Wu drafted the manuscript; All authors had contributed to the interpretation of data, and the critical revision of the manuscript; Lin Dai, Huiyan Zhang, Lingjia Yin and Meiling Li carried out the trial; Taoying Lu, Li Wang, Yongping Zhang, Conghao

Zhu helped with the administrative, technical or material support of the trial. All authors reviewed the manuscript.

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References

1. Boutron I,Estellat C,Ravaud P.A review of blinding in randomized controlled trials found results inconsistent and questionable.J. Clin. Epidemiol.2005;58(12):1220-6.http://doi.org/10.1016/j.jclinepi.2005.04.006.
2. Bello S,Moustgaard H,Hrobjartsson A.Unreported formal assessment of unblinding occurred in 4 of 10 randomized clinical trials, unreported loss of blinding in 1 of 10 trials.J. Clin. Epidemiol.2017;81(42-50.http://doi.org/10.1016/j.jclinepi.2016.08.002.
3. Boutron I,Tubach F,Giraudeau B,Ravaud P.Blinding was judged more difficult to achieve and maintain in nonpharmacologic than pharmacologic trials.J. Clin. Epidemiol.2004;57(6):543-50.http://doi.org/10.1016/j.jclinepi.2003.12.010.
4. Boutron I,Guittet L,Estellat C,Moher D,Hrobjartsson A,Ravaud P.Reporting methods of blinding in randomized trials assessing nonpharmacological treatments.Plos Med.2007;4(2):e61.http://doi.org/10.1371/journal.pmed.0040061.
5. Farrar JT.The placebo response.J. Peripher. Nerv. Syst.2014;19 Suppl 2(S20-2.http://doi.org/10.1111/jns.12081_4.

6. Enck P,Bingel U,Schedlowski M,Rief W.The placebo response in medicine: minimize, maximize or personalize?Nat. Rev. Drug Discov.2013;12(3):191-204.http://doi.org/10.1038/nrd3923.
7. Wong EL,Leung PC,Zhang L.Placebo acupuncture in an acupuncture clinical trial. How good is the blinding effect?J Acupunct Meridian Stud.2015;8(1):40-3.http://doi.org/10.1016/j.jams.2014.10.010.
8. Chae Y.The dilemma of placebo needles in acupuncture research.Acupunct Med.2017;35(5):382-3.http://doi.org/10.1136/acupmed-2017-011394.
9. Dilli CR,Childs R,Berk J,Christian MK,Nguyen N,Brown RPet al.Does prior acupuncture exposure affect perception of blinded real or sham acupuncture?Acupunct Med.2014;32(2):155-9.http://doi.org/10.1136/acupmed-2013-010449.
10. Park JE,Lee MS,Choi SM.Letter to the editor - Re: Is it possible to blind subjects using sham moxibustion treatment?Am J Chin Med.2009;37(2):407-9.http://doi.org/10.1142/S0192415X09006928.
11. Lee MS,Kim JI,Kong JC,Lee DH,Shin BC.Developing and validating a sham cupping device.Acupunct Med.2010;28(4):200-4.http://doi.org/10.1136/aim.2010.002329.
12. Schulz KF,Grimes DA.Blinding in randomised trials: hiding who got what.Lancet.2002;359(9307):696-700.http://doi.org/10.1016/S0140-6736(02)07816-9.
13. Kaptchuk TJ,Goldman P,Stone DA,Stason WB.Do medical devices have enhanced placebo effects?J. Clin. Epidemiol.2000;53(8):786-92.http://doi.org/10.1016/s0895-4356(00)00206-7.
14. Linde K,Niemann K,Meissner K.Are sham acupuncture interventions more effective than (other) placebos? A re-analysis of data from the Cochrane review on placebo effects.Forsch. Komplementmed.2010;17(5):259-64.http://doi.org/10.1159/000320374.
15. Yan S,Xiong X,Wan Q,Liu F,Tang J,Jiang Zet al.Preventative effect of massage on gastric volvulus in infants with gastroesophageal reflux-induced pneumonia.J. Tradit Chin Med.2015;35(5):520-7.http://doi.org/10.1016/s0254-6272(15)30134-5.
16. Liu J, Ding X. The Randomized Parallel Controlled Study of Spleen-Deficiency Sub Health Children Treated with Classic Massage. Journal of Practical Traditional Chinese Internal Medicine 2017; 31(09):71-3.
17. Yaxin S, Boyu C and Rui S. Clinical observation on 42 cases of children with functional abdominal (syndrome of deficient cold of spleen and stomach) treated with Yuepei Tang and Tuina. J. Pediatrics of TCM 2017;13(05):75-8.
18. Yu L. Infantile TuinaCombined Therapy with Gold Dichotomous Secondary Lactose Intolerance Diarrhea Random Parallel Control Study. J of Practical Traditional Chinese Internal Medicine 2014;28(04):122-4.
19. Lu T,Yin L,Chen R,Zhang H,Cai J,Li Met al.Chinese pediatric Tuina on children with acute diarrhea: a randomized sham-controlled trial.Health Qual Life Outcomes.2021;19(1):4.http://doi.org/10.1186/s12955-020-01636-1.
20. Kaptchuk TJ,Kelley JM,Conboy LA,Davis RB,Kerr CE,Jacobson EEet al.Components of placebo effect: randomised controlled trial in patients with irritable bowel syndrome.BMJ.2008;336(7651):999-1003.http://doi.org/10.1136/bmj.39524.439618.25.
21. Irnich D,Salih N,Offenbacher M,Fleckenstein J.Is sham laser a valid control for acupuncture trials?Evid Based Complement Alternat Med.2011;2011(485945.http://doi.org/10.1093/ecam/neq009.

22. Wong YM.Evaluating blinding effectiveness of a novel Ryodoraku sham needle device.Acupunct Med.2018;36(1):56-7.http://doi.org/10.1136/acupmed-2016-011328.
23. Tough EA,White AR,Richards SH,Lord B,Campbell JL.Developing and validating a sham acupuncture needle.Acupunct Med.2009;27(3):118-22.http://doi.org/10.1136/aim.2009.000737.

Figures

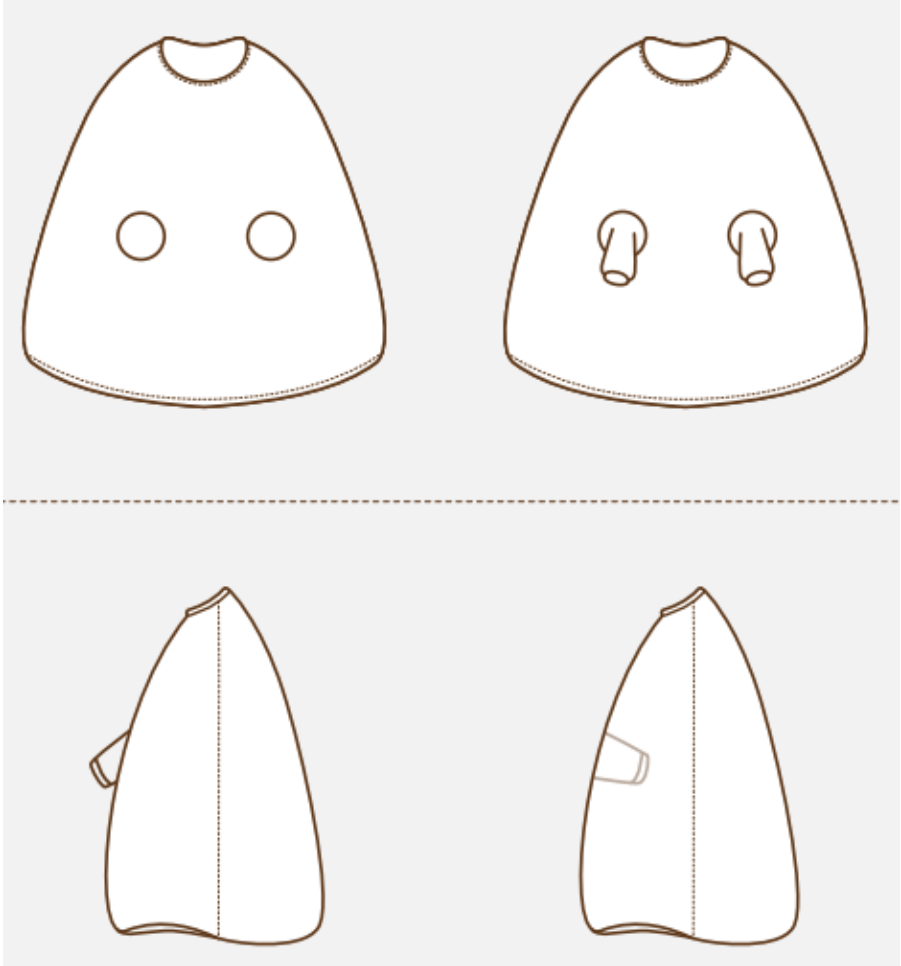

Figure 1

The outside and inside view of CSD

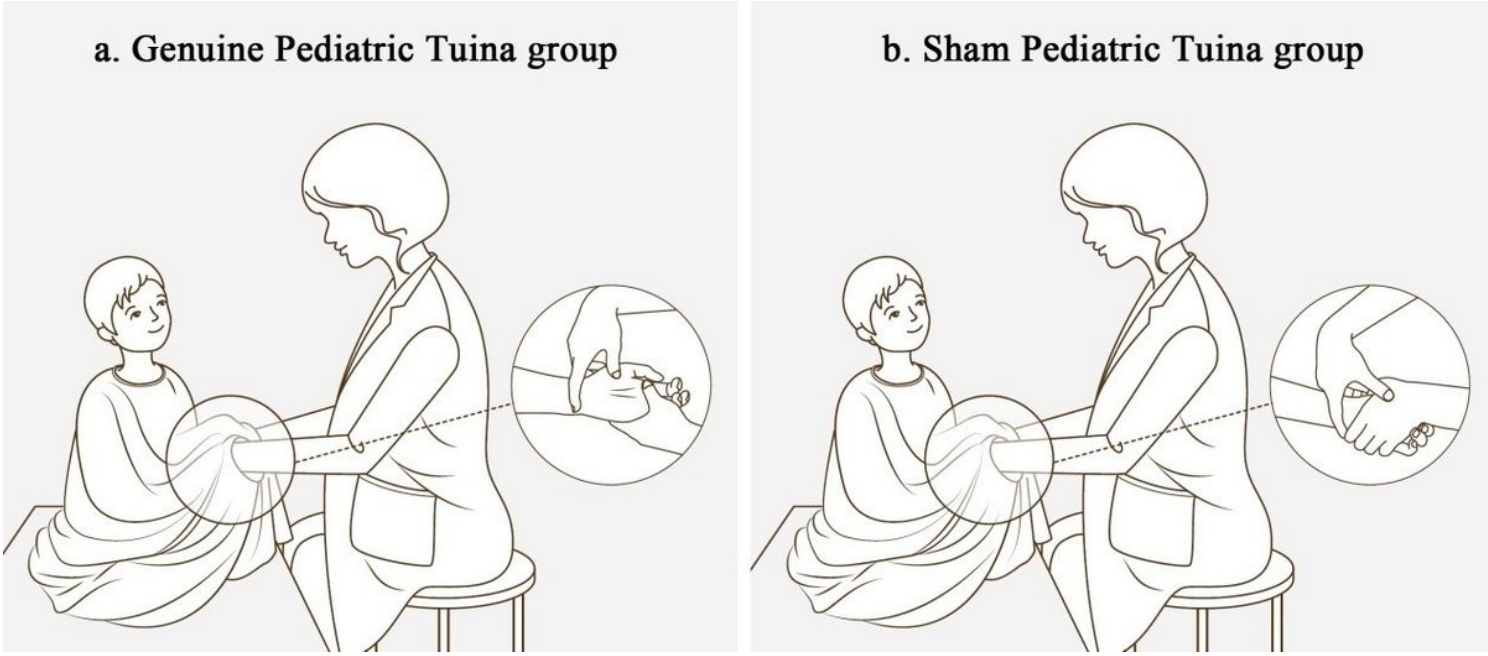

Figure 2

Genuine PT and sham PT view of CSD

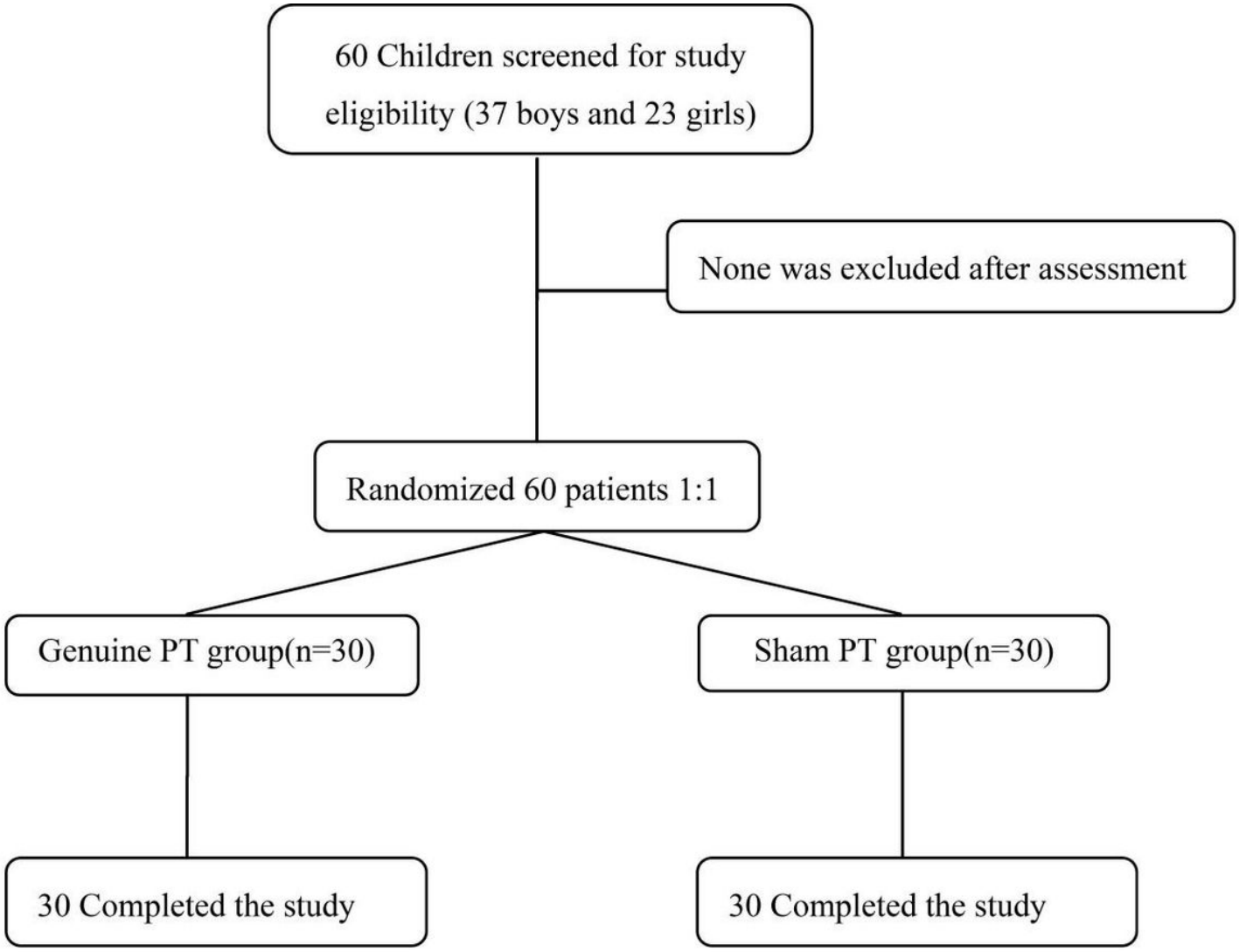

Figure 3. Study Process

Figure 3

Study Process

Supplementary Files

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