

## Core stabilization exercises impact on balance and foot pressure distribution in overweight children: A randomized controlled trial protocol

### Impacto dos exercícios de estabilização no equilíbrio e na distribuição da pressão plantar em crianças com excesso de peso: um protocolo de estudo randomizado controlado

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**ABSTRACT | INTRODUCTION:** Overweight children are associated with low neuromuscular function and postural imbalance. Core stabilization exercises have shown success in the cerebral palsy and Down syndrome children. However, its efficacy in overweight children is not known till date. **OBJECTIVES:** To measure the postural stability (static and dynamic) and foot pressure distribution in overweight children. To determine the efficacy of core stability training on postural stability (static and dynamic) in overweight children. To determine the efficacy of core stability training on foot pressure distribution in overweight children. **MATERIALS AND METHODS:** This is parallel design, non - blinded, two - group, pretest - posttest randomized controlled trial. The study will recruit 52 (26 in each group) aged 8-16 years old both boys and girls with BMI-for-age percentile growth between 85th to less than 95th percentile. The outcomes are foot pressure distribution, single limb stance, Y-Reach test and core strength respectively. The core stabilization exercises will be provided in the experimental group and no exercises will be given in the control group, 3 times a week for 6 weeks. **PREDICTED RESULTS:** The predicted results from this study will provide the first evidence of the effectiveness of core stabilization exercises in overweight children. A greater clinical understanding of core strength and balance in this age group may be helpful for incorporating activities in their daily life in order for the better overall development and growth. Kolmogorov Smirnov test will be used for checking the normal distribution of the data. Descriptive statistics will be expressed either as mean±standard deviation or median and inter- quartile range, based on the data distribution. Paired t-tests or Wilcoxon signed- rank test will be used to conduct within group analyses and Independent t- tests or Mann-Whitney U- test will be used for between group analyses. For all the analyses the level of significance will be set at 0.05.

**CLINICAL TRIAL REGISTRATION NUMBER:** NCT04315220 registered on 19th March, 2020. <https://clinicaltrials.gov/ct2/show/study/NCT04315220>

**KEYWORDS:** Paediatric: Non communicable disease. Balance. Posture balance. Childhood obesity. Overweight.

**RESUMO | INTRODUÇÃO:** O excesso de peso em crianças tem sido associado com perda na função neuromuscular e desequilíbrio postural. Exercícios de estabilização têm demonstrado sucesso no tratamento de crianças com paralisia cerebral e com síndrome de Down. No entanto, sua eficácia não foi testada com crianças com excesso de peso. **OBJETIVO:** Medir a eficácia de exercícios de estabilização postural no equilíbrio estático e dinâmico e na distribuição da pressão plantar em crianças com excesso de peso.

**MATERIAL E MÉTODOS:** Protocolo de um ensaio clínico randomizado paralelo não cego comparando pré e pós-teste. Serão recrutados 52 (26 em cada grupo) participantes com idade de 8 a 16 anos, meninos e meninas com índice de massa corporal (IMC) entre os percentis de crescimento de 85 e 95 de acordo com a idade. As variáveis serão a distribuição da pressão plantar com duplo apoio, apoio unipodal, teste de alcance e a projeção do centro de força. O protocolo de exercícios de estabilização será oferecido ao grupo experimental 3 vezes por semana durante 6 semanas. Estatística descritiva e inferencial serão aplicadas após a realização de testes de normalidade da distribuição (teste T ou Wilcoxon ou Mann-Whitney) considerando significância de 0,05. **RESULTADOS ESPERADOS:** Os resultados do presente estudo oferecerá a primeira evidência sobre a eficácia de exercícios de estabilização em crianças com excesso de peso. Espera-se uma maior compreensão clínica dos exercícios de estabilização em crianças com excesso de peso. Geração de dados para a incorporação de atividades da vida diária que favoreçam o desenvolvimento global e crescimento.

**NÚMERO DE REGISTO DO ENSAIO CLÍNICO:** NCT04315220 registrados em 19 de Março 2020. <https://clinicaltrials.gov/ct2/show/study/NCT04315220>

**PALAVRAS-CHAVE:** Pediátrico: doenças não-transmissíveis. Equilíbrio. Postura. Equilíbrio. Obesidade infantil. Excesso de peso.

## Introduction

Overweight and obesity in the 21st century, as per WHO have constituted as the most important health problem in the public sector. The prevalence of overweight and obesity has risen from 4% to 18% among children in the span of 41 years. The increase in the number about 70 million overweight and obese children can be expected by 2025 as per the current scenario of prevalence<sup>1</sup>. Impaired postural stability has been noticed in the overweight children aged 3-18 years, resulting in abnormal biomechanical development and poor postures<sup>1</sup>. Overweight children often do not like to participate in the physical activities because of social embarrassment and difficulty in performing high energy activities<sup>2</sup>. Overweight aggravates poor balance and have a negative impact on motor skills<sup>3</sup>.

The ability to maintain centre of gravity within the base of support is mandatory requisite to maintain postural stability<sup>4</sup>. The operational definition of postural stability includes the effort to maintain the balance in standing or sitting positions (static balance) and during the functional movements/tasks (dynamic balance)<sup>5</sup>. Researches have shown the connection between obesity and deficits in postural kinetics during static upright position<sup>6,7</sup> functional daily tasks<sup>8,9</sup> and walking<sup>10-12</sup>. The research has shown that there is an association between anthropometric indicators and postural stability in school children<sup>13</sup>.

Researchers have concluded that the obese children are at a risk of developing various musculoskeletal disorders of the lower extremity<sup>14,15</sup> gait variations<sup>16,17</sup> morphological foot variations<sup>18,19</sup> and improper foot pressure on loading<sup>20,21</sup>.

## Statement of the Problem

Overweight children are associated with low neuromuscular function and postural deformities<sup>22</sup>. Postural stability and neuromuscular control can be improved by the structured weight loss programme<sup>23</sup>. Researchers have confirmed reduced balance capabilities among overweight children, when compared to non-overweight children. Studies confirm the effectiveness of core stability exercises on children with Down syndrome and cerebral palsy<sup>24-26</sup>. To the best of knowledge, no study is available regarding core stability exercises in improving postural stability and foot pressure distribution among overweight children. Therefore, the objective of this study is to explore the effectiveness of core stability training in improving postural stability and foot pressure distribution in overweight children.

## Materials and methods

### Study Design

Parallel design, non – blinded, two – group, pretest - posttest randomized controlled trial

### Location

Department of Pediatric Physiotherapy in a tertiary care hospital.

### Target Population

Overweight children, both boys and girls.

## Sample Selection

Inclusion criteria	Variables
a. 8-16 years old both boys and girls b. BMI-for-age percentile growth between 85th to less than 95th percentile <sup>27</sup> .	Core stability training
Exclusion criteria	Independent variables
a. Uncooperative participants b. Upper or lower limb fracture or injury in recent 6 months c. Any musculoskeletal or neurological disorder affecting core strength and balance d. Refuse to participate because not able to understand the researcher instructions e. Unable to attend the whole sessions during the research period.	A) Conceptual: Postural stability (static balance and dynamic balance) Foot Pressure Distribution

## Statistical Hypothesis

Null Hypothesis (HO): There may be no difference of core stability training on postural stability improvement and foot pressure distribution in overweight children in both the genders.

Alternate Hypothesis (HA): There may be a difference of core stability training on postural stability improvement and foot pressure distribution in overweight children in both the genders.

## Variables

### Independent variables

Core stability training

### Dependent variables

A) Conceptual:

Postural stability (static balance and dynamic balance)  
Foot Pressure Distribution

B) Operational:

Pediatric balance scale; single limb stance; Y-reach test  
Podia scan (Diabetik Foot Care India Pvt Limited)

## Study design

Parallel design, non - blinded, two - group, pretest - posttest randomized controlled trial with setting at Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Department of Pediatric Physiotherapy and Maharishi Markandeshwar International School in Mullana, Ambala, Haryana, India.

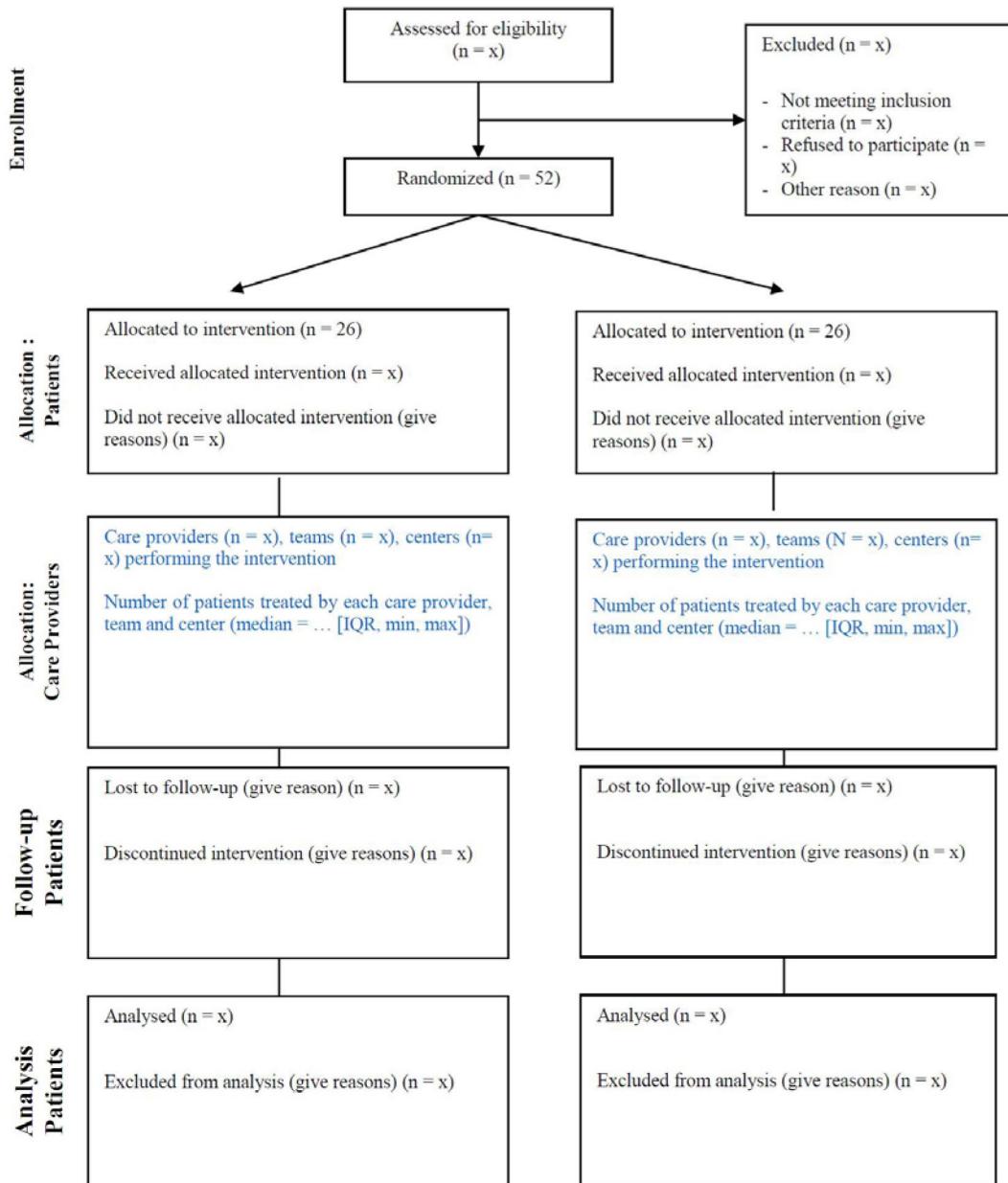
## Randomisation

All the subjects will sign the informed consent for participation in the study. Participants will be allocated randomly to either group A (Core stability training) or group B (Sham training) via block randomization following the allocation to concealment using the chit selected by the person other than the researcher. Blocks will have 4 x 13 (52) matrix design, suggesting a total of four blocks with thirteen rows. Block Randomization (4 x 13 matrix design) is displayed in Figure 2. The researcher therapist will supervise the procedure session and assess the outcome measures by herself. The flow chart of the study protocol following the Consolidated Standards of Reporting Trials is displayed in Figure 1.

**Figure 1.** Modified CONSORT flow diagram for individual randomized controlled trials of nonpharmacologic treatments

**Modified CONSORT flow diagram for individual randomized controlled trials of nonpharmacologic treatments.**

An extra box per intervention group relating to care providers and centers has been added.  
 IQR = interquartile range; max = maximum; min = minimum



**Figure 2.** Block Randomization (4 x 13 matrix design)

Blocks	1	2	3	4
Rows				
1	1E	2C	1C	2E
2	•	•	•	•
3	•	•	•	•
4	•	•	•	•
5	•	•	•	•
6	•	•	•	•
7	•	•	•	•
8	•	•	•	•
9	•	•	•	•
10	•	•	•	•
11	•	•	•	•
12	•	•	•	•
13	•	•	•	•

## Intervention

Each participant will be instructed to perform the core stabilization exercises in group A (Table 1) and no training in group B three times a week for 6 weeks period and each session lasted 30 minutes. There will be progressive increase in the difficulty of core training from Level 1 to Level 2.

The core stabilization exercises of the protocol titled "Pediatric Core Stabilization Exercises Protocol (P-CSE-P)" by Kanu Goyal, Manu Goyal and Asir John Samuel was copyrighted under the Copyright Office of the Government of India with unique registration no. L- 90430/2020 dated 16th March, 2020 (copyright filed with diary no. 231/2020-CO/L dated 5th January, 2020), is highlighted in Table 1.

Table 1. Pediatric Core Stabilization Exercises Protocol (P-CSE-P) (to be continued)

Exercise	Position	Description	Repetitions	Set	Hold time/set (seconds)	Purpose
<b>Level 1: Mat Exercise</b>						
<b>Abdominal muscle contraction</b>	Supine	Lie on the back with knees in flexion around 90 degrees and hip width apart.	15 times	03	10	12    15    Activation of core muscles (superficial & deep)
	4 Point Kneeling	<ul style="list-style-type: none"> <li>• Knees placed directly below the hip joint and hip width apart.</li> <li>• Ankles in plantar flexion</li> <li>• Hands placed directly below the shoulder joint</li> <li>• Head in neutral position</li> <li>• Shoulders and Scapula not hunched</li> <li>• Pelvis and spine in neutral position</li> <li>• Breathing (Inhale through nose and exhale through mouth)</li> </ul>	15 times	03	10	12    15    Improve scapular, lumbar & pelvic stability
	Side - Lying (R and L)	<ul style="list-style-type: none"> <li>• Pillow placed in between the knees to maintain neutral spine position.</li> <li>• Neutral head position by placing the pillow underneath.</li> <li>• Breathing (Inhale through nose and exhale through mouth)</li> </ul>	05 times each side	03	10	12    15    Activation of core muscles (superficial & deep)
	Supine	<b>Progression:</b> Posterior pelvic tilt with one leg straight and other in flexion at knee	10 times	03	10	12    15    • Pelvic and lumbar stability reinforcement

Table 1. Pediatric Core Stabilization Exercises Protocol (P-CSE-P) (continuation)

Exercise	Position	Description	Repetitions	Set	Hold time/set (seconds)	Purpose
<b>Level 1: Mat Exercise</b>						
<b>Bridging</b>	Supine	<ul style="list-style-type: none"> <li>Lie on the back with knees bent around 90 degrees and hip width apart.</li> <li>Raise the pelvis off the couch approximately 15 degree</li> <li>Breathing (Inhale through nose and exhale through mouth)</li> </ul>	10 times	03	10   12   15	<ul style="list-style-type: none"> <li>Activation of Deep core muscles</li> <li>Activation of Gluteus Maximus and Hamstrings muscles in producing hip extension</li> </ul>
Progression						
		<ul style="list-style-type: none"> <li>Lie on the back with knees in flexion around 90 degrees and hip width apart.</li> <li>Raise the pelvis off the couch approximately 15 degree</li> <li>Single leg, straight leg raise with other knee in flexion and vice - versa</li> </ul>	10 times	03	10   12   15	<ul style="list-style-type: none"> <li>Activation of Deep core muscles</li> <li>Activation of Gluteus Maximus and Hamstrings muscles in producing hip extension</li> <li>Challenging to maintain balance and coordination</li> </ul>
<b>Cat Stretch</b>	4 Point Kneeling	<ul style="list-style-type: none"> <li>Knees placed directly below the hip joint and hip width apart.</li> <li>Ankles in plantar flexion</li> <li>Hands placed directly below the shoulder joint</li> <li>Head in neutral position</li> <li>Pelvis and spine in neutral position</li> <li>Breathing (Inhale through nose and exhale through mouth)</li> <li>In- drawing (to make hump like camel) and outward movement of abdominal muscles (to arch spine like cat)</li> </ul>	10 times	03	10   12   15	<ul style="list-style-type: none"> <li>Facilitation of deep core stabilizers of pelvic and shoulder girdle respectively.</li> <li>Flexion and Extension mobilization throughout the spine.</li> </ul>

Table 1. Pediatric Core Stabilization Exercises Protocol (P-CSE-P) (continuation)

Exercise	Position	Description	Repetitions	Set	Hold time/set (seconds)	Purpose
<b>Level 1: Mat Exercise</b>						
<b>Single Leg Circles</b>	Supine	<ul style="list-style-type: none"> <li>Lie on the back with knees straight and arms by the side.</li> <li>Raising the leg at different degrees of hip flexion and doing circumduction (R and L).</li> </ul>	10 times	03	-	<ul style="list-style-type: none"> <li>Hip mobilization while maintaining pelvis and lumbar stability</li> <li>Alternate releasing and contraction of core muscles</li> </ul>
<b>Superman</b>	Prone	<ul style="list-style-type: none"> <li>Lie on the abdomen with legs straight and arms outstretched in the scaption plane.</li> <li>Raise the arms and legs alternate and then simultaneously.</li> </ul>	10 times	03	10    12    15	<ul style="list-style-type: none"> <li>Activation of superficial and deep core muscles.</li> <li>Activation of posterior oblique sling</li> </ul>

Table 1. Pediatric Core Stabilization Exercises Protocol (P-CSE-P) (conclusion)

Exercise	Position	Description	Repetitions	Set	Hold Time (seconds)	Purpose
<b>Level - 2 Swiss Ball (55 cm) Exercises</b>						
<b>Abdominal muscle contraction</b>	Seated	<ul style="list-style-type: none"> <li>Seated on the swiss ball and performing the in and out movement of abdomen</li> <li>Breathing (Inhale through nose and exhale through mouth)</li> </ul>	10 times	03	10	<ul style="list-style-type: none"> <li>Activation of core muscles (superficial &amp; deep)</li> <li>Challenging to maintain balance and coordination</li> </ul>
		<u>Progression</u>				
		<ul style="list-style-type: none"> <li>Seated on the swiss ball and contracting the abdominal muscles while raising the arms and legs alternate.</li> <li>Seated on the swiss ball and contracting the abdominal muscles while raising the contralateral arms and legs alternate.</li> </ul>				
	Half-Lying	<ul style="list-style-type: none"> <li>Lie on the back with knees in flexion around 90 degrees and hip width apart.</li> <li>Raise the upper back from the ball maintaining the abdominal contraction</li> <li>Diagonal curls (R and L)</li> </ul>	10 times	03	10	<ul style="list-style-type: none"> <li>Activation of core muscles (superficial &amp; deep)</li> <li>Challenging to maintain balance and coordination</li> </ul>
<b>Bridging</b>	Supine	Legs are placed on the swiss ball and raising the pelvis of the floor.	10 times	03	10	<ul style="list-style-type: none"> <li>Activation of core muscles (superficial &amp; deep)</li> <li>Challenging balance and coordination</li> </ul>
<b>Squats</b>	Standing	Place the swiss ball behind the lower back and stiffening the abdomen and doing squats.	10 times	03	-	<ul style="list-style-type: none"> <li>Activation of core muscles (superficial &amp; deep)</li> <li>Challenging to maintain balance and coordination</li> </ul>
	Lunge Standing	Place the swiss ball between the thighs and stiffening the abdomen and doing squats.	10 times	03	-	<ul style="list-style-type: none"> <li>Activation of core muscles (superficial &amp; deep)</li> <li>Challenging to maintain balance and coordination</li> </ul>

## Outcome measures

All outcomes will be assessed at baseline and 6 weeks after the intervention. The detailed time frame for enrollment, allocation and follow-up is displayed using Standard Protocol Items: Recommendations for Interventional Trials schedule for participation (SPIRIT) 2013 statement in Chart 1. The reliable and valid instruments have been used for assessment during the intervention. Here, the below mentioned outcomes will be measured as -

**Foot Pressure Distribution:** Each participant will be asked to walk barefoot along a 5-metre walkway with the Harris mat pressure distribution platform placed on a firm, level surface, in the centre of walkway. Familiarization sessions will be conducted to make the entire participants comfortable about the procedure. Participants will be encouraged to walk in their natural gait pattern at their self determined speed. Participants will be ensured to step on the Harris mat without pause, first with one foot and then repeat the same procedure with the other foot at constant speed<sup>28</sup>.

**Single limb stance:** The participants will be instructed to stand on the dominant leg with non dominant leg flexed to 90 degree, and maintain the position. The test will be performed first with eyes open and then with the eyes closed. The time for which participant will be able to maintain balance will be recorded.

**Y- Reach test:** The participants will stand on one foot in the center of the Y with the most distal aspect of the toes just behind the starting line. While maintaining single-leg stance, the participant will be instructed to touch the line with the reach foot as far as possible in the direction being tested and then return the reach limb to the starting position, resuming a bilateral stance. The balance will be tested in the anterior, posteromedial and posterolateral direction. The reach distance in all the three directions will be noted.

**Core Strength:** The core strength will be measured with the Chattanooga Pressure Biofeedback Unit. The device consists of three chamber pressure cells which will be placed under the lumbar spine in crook lying and inflated to a baseline of 40 mmHg. The participants will be instructed to perform drawing-in manoeuvre on the verbal instructions, maintain it for 10 sec. The change in pressure will be noted.

**Chart 1.** Standard Protocol Items: Recommendations for Interventional Trials schedule for participation

	Study period			
	Enrolment	Allocation	Post-allocation (treatment)	Follow-up
<b>Time point</b>	0 week	0 week	0 week	6 <sup>th</sup> week
<b>Enrolment</b>				
Eligibility screen	x			
Informed consent	x			
Selection criteria	x			
Allocation		x		
<b>Interventions</b>				
Core stability training			x	x
Sham training			x	x
<b>Assessments</b>				
Demographic data		x		x
Foot pressure distribution		x		x
Single limb stance		x		x
Y- reach test		x		x
Core strength		x		x

## **Statistical Analysis Plan**

The primary researcher will collect and analyze all data. Descriptive statistics will be used to present the baseline characteristics of all eligible participants. The normality distribution of the data will be checked using Kolmogorov Smirnov test. Descriptive statistics will be expressed either as mean±standard deviation or median and inter-quartile range, based on the data distribution. Paired t-tests or Wilcoxon signed-rank test will be used to conduct within group analyses and Independent t- tests or Mann- Whitney U- test will be used for between group analyses. For all the analyses the level of significance will be set at 0.05. The IBM SPSS statistical software ver. 22.0 (IBM Corp., Armonk, NY, USA) will be used for statistical analyses. Sample size estimated with G\*Power 3.1.9.4 software (Fig. 2) with anticipating the effect size of atleast 0.8 (ES =0.8), 5% LOS and 90% power, if the data is not normally distributed, the sample size will be 20 (n=20) in each group. By considering 30% dropouts, the final sample size will be, 26 (n=26) in each group.

## **Feasibility**

The Microsoft Office Excel 2019 (Microsoft Corp., Redmond, WA, USA) will be used to enter data and will be stored without internet connection in a desktop in order to avoid unauthorized access. Only the primary researcher and data analyst will be having the password to access the final data restored on a password-protected non-rewritable compact disc read only memory. The Data and Safety Monitoring Committee plays a role in monitoring the outcome of the intervention and is independent from the primary researcher. Any adverse events occurring during the study will prompt interim analysis.

## **Risk**

The treatment regime is considered safe. It has already been tested on adults. There has been nothing that has worried us at all. If anything unusual happen to you, however, we need to know and you should feel free to contact us anytime with your concerns or questions. This treatment program will not harm you or not show any side effects during treatment. Exercises performed during this program will definitely help you to improve your postural stability and foot pressure distribution.

## **Benefits**

The study will be published after completion and the evidence will be provided to the public health community - specifically in the school community about the importance of physical activity and school based exercise program including core stabilization in overweight and obese children. This will help to enhance the participation of overweight children in physical activities and prevent them to develop musculoskeletal complications later in the adulthood.

## **Ethical aspects**

The present study will be conducted in strict compliance to the conditions of the Institutional Research Ethics Committee of Maharishi Markandeshwar (Deemed to be University), Mullana- Ambala, and Haryana, India. The study has been registered prospectively in the World Health Organization International Clinical Trials Registry agency, ClinicalTrials.gov (NCT04315220) on 19 March, 2020 after procured its Universal Trial Number (U1111-1249-8305) on 16 March, 2020. The study will be performed on human participants in accordance with the Indian Council of Medical Research (2017) National Ethical Guidelines for biomedical and health research and the ethical principles stated in the Declaration of Helsinki (revised 2013) for medical research involving human subjects.

## **Expected results**

There is need of high quality evidence research of exercise program in order to improve the neuromuscular control, posture balance and foot pressure distribution in overweight children. The overall development viz. neuromotor, psychological, musculoskeletal and cardiovascular is affected in the overweight and obese children<sup>29,30</sup>. The core stabilization exercises might enhance the motor skills, strength, balance abilities both static and dynamic and gait pattern in the overweight children after the analysis of the data from the current study. The completed study will be published later in order to provide the first evidence of the effectiveness of core stabilization exercises in overweight children.

A greater clinical understanding of core strength and balance in this age group may be helpful for incorporating activities in their daily life in order for the better overall development and growth.

## Discussion

The efficacy of core stability training on postural stability (static and dynamic) and foot pressure distribution in overweight children will be determined at the end of the study. We anticipate that the core stabilization exercises will improve the motor planning and motor control, response to swaying and improvement in the sensitivity of the mechanoreceptors. In addition to the above, it may demonstrate the improvement in the postural kinetics during static and dynamic functional activities with the core stability exercises in overweight children. Foot loading patterns may be expected to be evenly distributed in the overweight children with an improvement of the core strength in these children, thereby will help in preventing the pain and ulceration as the preschool children put more weight on the medial side of the foot while walking<sup>31</sup>.

## Acknowledgements

This study forms the part of Post-Graduate dissertation titled, "Effectiveness of core stability training in improving postural stability and foot pressure distribution in overweight children: A randomized controlled trial" to be submitted by the first author, Dr. Kanu Goyal, BPT, DOMTP, Post-Graduate Student, Maharishi Markandeshwar Institute of physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), (NAAC accredited Grade 'A' University), Mullana- 133 207, Ambala District, Haryana, India, which forms a part of partial fulfilment of the requirements for the degree, Master of Physiotherapy (Pediatrics) to the University.

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## Author contributions

Goyal K and Goyal M participated in the conception, design, search, and statistical analysis plan of the research data, and writing of the scientific article. Samuel AJ participated in the conception, design, and plan for statistical analysis of research data and critical review of the scientific article .

## Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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