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Do external stimuli impact the gait of children with idiopathic toe walking? A study protocol for a within-subject randomised control trial

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ABSTRACT

Introduction: Frequently, toe walking gait is the result of disease processes, trauma or neurogenic influences. Idiopathic toe walking (ITW) is, by definition, the diagnosis of a toe walking gait adopted in the absence of one of these medical conditions. Long-term ITW has been associated with reduced ankle range of motion. Reported treatments have included serial casting, Botulinum toxin type A or surgery to improve the ankle range of motion. Investigating the impact of simple and non-invasive treatment options for ITW is important for future research and clinical outcomes. This study investigates the immediate impact of footwear, footwear with orthotics and whole body vibration on ITW to determine if any one intervention improves heel contact and spatial-temporal gait measures. This determination is important for future clinical trials into treatment effectiveness.

Methods and analysis: *Design*: this protocol describes a within-subject randomised controlled trial that measures changes in gait following changes in external stimuli. *Participants*: 15 children diagnosed with an ITW gait will be recruited from the Victorian Paediatric Rehabilitation Service at Monash Children's Hospital Toe Walking Clinic provided they have ITW and meet the inclusion criteria. *Procedure*: participants will have their gait recorded walking barefoot, in usual footwear, a custom-made, full-length carbon fibre orthotic in usual footwear and following whole body vibration. Outcome measures will include the presence of bilateral heel contact preintervention and postintervention, stride length (cm), stride width (cm), left and right stride time (s), left and right stance and swing percentage of the gait cycle, gait velocity (m/s), left and right foot toe in/toe out angle (°) and weight-bearing lunge pre and post each condition.

Ethics and dissemination: The results of this study will be published at the conclusion and have been approved by Southern Health HREC:12102B.

Clinical trial registry number: ACTRN1261200097 5897.

INTRODUCTION

It is generally understood that toe walking is the observation of an absence or limitation of heel strike at initial contact of the gait cycle.[1] Toe walking has been acknowledged as a symptom of disease processes, trauma and/or neurogenic influences, and when there is no identifiable medical cause of the gait pattern, it is labelled idiopathic toe walking (ITW).

In publications of paediatric gait development, children's ability to walk on their toes during the development of gait has been described as a natural and non-compulsory part of gait development.[2] There is no report of why toe walking has been observed, and nor are there subsequent studies conclusively proving a reason for its continuation in the absence of a medical diagnosis.

The incidence of ITW has been reported to be present in up to 7% of the general paediatric population in some small studies.[3 4] However, owing to a small sample and variance in cultural influences, it may be presumed that there is no agreement on the true prevalence of ITW. There is strong agreement within the literature of a positive family history and no single sex dominance for children who have an ITW gait.[4 5]

ITW and its relationship to equinus have been discussed in the literature. The suggestion that equinus is secondary to the development of this gait abnormality is common, yet unproven.[6] The effectiveness of equinus treatment has been the focus of several studies in children with an ITW gait. The presence of ITW into adolescence and beyond has now been highlighted both in long-term case-controlled studies and within case reports leading to conflicting opinions on the necessity of treatment.[7 8] The long-term effect ITW has on the foot and ankle has not been definitively established; however, there is prolific research of equinus and its negative impact on the foot and its function as well as changes in gait in adults and the elderly.[9–12] There is limited research

on many of the conservative treatment options for ITW including orthotics[8 13 14] and footwear.[13 14] These treatment options have only been reported within case studies or author opinion pieces and it is not fully understood how these treatment options are thought to minimise the toe walking gait. Studies in normal gait and the paediatric foot have found that footwear provides a tactile input that may change the neurological input, which may in turn change the gait pattern. Footwear also has a mechanical influence at the foot which affects stride length[15] and motion of the subtala, midtarsal and ankle joint[16] and may also change the toe walking pattern. The full-length carbon fibre orthotic may have a mechanical and inhibitory action on the gait pattern, but this is yet to be established. Currently, serial casting,[4 17] Botulinum toxin type A (BoNT-A)[18 19] and surgical Achilles tendon lengthening[7] have the best evidence for improved outcomes.

There is no research on the impact of whole body vibration on gait in children with ITW. Recent research into whole body vibration has found that short bursts of vibration have a positive effect on muscle length and strength.[20] As many children who have an ITW gait also have equinus, it is unknown if the whole body vibration will provide a short-term muscle change, thus impacting the gait style. Children with ITW have also been reported to have sensory processing challenges, particularly with vibration as a tactile stimulus.[21] It is unknown if whole body vibration will have a neuro-modulation effect on the gait style and heel strike.

The primary objective of this research was to measure the spatial (or distance) and temporal (or timing) parameters of gait in children who have been diagnosed with ITW and examine if any changes in gait are the result of three different external stimuli. The interventions chosen, footwear, orthotic and vibration, are thought to provide external stimuli by means of tactile stimuli, a mechanical inhibitor or vibration stimuli. Any gait changes observed by these measures are important for clinicians working with children with this gait pattern and for further research into long-term interventions. The evidence for conservative treatment for ITW is in deficit; therefore, without this base knowledge of the short-term impacts of different external stimuli, future clinical trials are unable to be explored and designed.

METHOD

Study protocol

This study protocol was finalised on 21 January 2013 and is V.1.2. The revision chronology is displayed in table 1 and on the Australian and New Zealand Clinical Trials Registry website.

Table 1 Protocol revision chronology

Date	Action
1 September 2012	Original protocol
11 September 2012	Amendment 1: Addition of weight bearing lunge test as a measure due to the potential impact of whole body vibration on muscle length
21 January 2013	Amendment 2: Modification of cognitive task from reciting colours to thumb finger apposition to be inclusive of all abilities of all ages

Study design

Within subject randomised controlled trial with Latin-square allocation for the first three and a quasi-experimental fourth external stimulus condition conducted following completion of the first three external stimuli conditions.

Participants and setting

Fifteen children diagnosed with an ITW gait will be recruited from the Victorian Paediatric Rehabilitation Service Toe Walking Clinic located at Monash Children's Hospital, Clayton, Australia.

Inclusion criteria:

- Children diagnosed with ITW by multidisciplinary assessment within the Toe Walking Clinic of Monash Children's Hospital;
- Children between the ages of 4 and 10 years;
- Children who are able to heel toe walk on request and have a minimum of 15° of ankle range of motion as measure on the weight-bearing lunge.[22]

Exclusionary criteria:

- Children who toe walk from a neuromuscular medical condition;
- Children with an ITW gait who have had treatment with the use of full-length orthotics or serial casting within the past 12 month;
- Children who have a toe walking gait and have autism or global developmental delay;
- Children who have had BoNT-A as part of their treatment for ITW.

Sample size

A sample size of 14 participants is required to achieve 82% power, to detect an effect size of 0.833 as a result of the intervention using an α criterion of 0.05. This effect size was calculated based on pretreatment data for children with an ITW gait.[23] It is based on increasing the proportion of steps with heel strike from 0.5 to 0.7, assuming a common SD of 0.24 and a correlation between preintervention and postintervention assessment of 0.5. Recruiting 15 participants will provide marginally greater power than recruiting 14 participants, while allowing the Latin-square randomisation approach to be balanced so that order effects of the different treatment conditions can be eliminated.

Measurements

All testing will be at the Kingston Gait Laboratory, Cheltenham, Australia. Following recruitment and introduction to the study, informed consent for participation in this study will be obtained from the child's parent or carer and assent for participation from the children. Demographic data, including participant age, gender, height and weight, will be collected for all participants.

Participants will have their gait recorded on an 8.3 m long electronic walkway system, GaitRite (CIR Systems Inc, Havertown, Pennsylvania, USA), which has excellent reliability in children.[24]

Children will be familiarised to the GaitRite system by allowing them to walk the length of the GaitRite mat a number of times in their normal athletic footwear they have been asked to wear to the appointment. In a similar manner to the normative population study with this age group,[25] the protocol for the recording of gait changes will involve the children walking twice (two trials) along the GaitRite mat for each condition at their own preferred speed. During the recording, if the initial or final contact is a partial foot fall, due to the potential for the foot to strike the mat in a partial sensor area, these data will be excluded. All other contacts within the recording, including subsequent partial foot falls from each trial, will be recorded for analysis. A 1 m space will be provided at each end of the mat to allow the children to accelerate and decelerate as required. Data from each of the external stimuli conditions will be compared with published normative data for this age group.[25] During gait testing, the participants will be required to complete a finger-thumb motor apposition task in order to minimise the self-correction of the gait pattern. As the ITW gait pattern is modulated within the environment and often decreased when the child is aware of the gait, this task has been shown to challenge neurotypical children who have an autism spectrum disorder.[26] It is anticipated that the finger-thumb motor apposition task will sufficiently challenge the child's attention, minimising self-correction of their gait pattern.

The following gait parameters will be collected and analysed:

1. Primary measure: bilateral heel contact preintervention and postintervention.
2. Secondary measures:
   - A. Stride length (cm);
   - B. Stride width (cm);
   - C. Left and right stride time (s);
   - D. Left and right stance percentage;
   - E. Left and right swing percentage;
   - F. Gait velocity (m/s);
   - G. Left and right foot toe in/toe out angle (degrees).

The weight bearing lunge test[22] will be conducted pre and post each condition. This test is a clinical measure of available ankle dorsiflexion and has been used as a measure for this participant group in other research.[27] The intra-rater reliability of experienced raters conducting this test has been shown to be high when using a digital inclinometer (average intraclass correlation coefficient (ICC)=0.88, average 95% limits of agreement=–6.6° to 4.8°). The intrarater reliability of an inexperienced rater has also been demonstrated to be good to high when using a inclinometer (ICC=0.77, 95% limits of agreement=–9.1° to 8.3°).[28] Inter-rater reliability for inexperienced raters has also been found to be high when using the inclinometer (ICC=0.95, 95% limits of agreement=–5.7° to 5.7°).[28]

A randomisation procedure by use of a Latin-square design will be employed for the first three gait/external stimuli conditions (table 2). Condition 4 will be conducted at the end of the randomised conditions as it involves whole body vibration and there is potential for overflow effects. Given the short-term nature of this trial, it could not be reasonably accepted that these potential effects are to be washed out during this period. Therefore, Condition 4 was removed from the randomised component of the study, and instead, all participants are to be subjected to this condition once they have completed all other conditions.

Conditions

Each condition consists of two trials.

Condition 1

After familiarisation, the child will be asked to remove their footwear and walk along the GaitRite mat at their preferred pace. As children can control their ITW with concentration, the child will be asked to do the finger-thumb motor apposition task at the same time.

Condition 2

The child will be placed in socks and their usual footwear worn for everyday athletic activities. The shoe will be laced securely by the researcher and the child will be asked to complete the finger-thumb motor apposition task while walking along the GaitRite mat.

Condition 3

A custom made, full-length carbon fibre orthotic (figure 1) will be placed in the same shoes as those used in condition 2. The orthotic will have rear and midfoot control and the carbon fibre material extended and fitted to the full length of the shoe. The device will be manufactured to the length of the child's current footwear to ensure correct fit and the midfoot and rear foot control will be generic to each device. The child will then be asked to complete the finger-thumb motor apposition task while walking along the GaitRite mat.

Table 2 Randomisation

Condition 1	Condition 2	Condition 3	Condition 4
Condition 2	Condition 3	Condition 1	Condition 4
Condition 3	Condition 1	Condition 2	Condition 4

Figure 1 Full-length carbon fibre orthotic.

Condition 4

The immediate gait effect of whole body vibration will be measured after the administration of five sets of 1 min vibration followed by 1 min of rest with the Galileo Basic (Novotec Medical GmbH, Germany). The set frequency of 15 Hz will be used for each child while the child stands in a semisquat position on the machine. This frequency has been reported within whole body vibration studies as the minimal level to elicit muscular response while minimising a negative systemic response[20 29] as the use of vibration has the potential to cause dizziness or nausea when the level of vibration is too high. The child will then be asked to walk along the GaitRite mat at 1, 5, 10 and 20 min after the completion of the final set of vibration. The child will be asked to complete the finger-thumb motor apposition task while walking along the GaitRite mat.

Data analysis

Primary and secondary outputs will be analysed by Stata (V.11) data analysis software. Comparisons between conditions will be undertaken using linear mixed model analysis with conditions treated as a fixed effect and subject, and trial number within a condition as a random effect. Trials will be nested within-subject. A balanced Latin-square design will not require adjustment for order effects; the comparison between outcomes from the different intervention conditions will not require adjustment for order effects, given the balance Latin-square design.

Adverse events

Adverse events will be measured and recorded during the study. The adverse events may include incidents such as skin reactions (eg, blisters or skin irritation) from the orthoses or vibration platform.

Ethics and dissemination

The Southern Health Human Research Ethics Committee HREC Ref has given approval for this study: HREC12102B. The participant information and consent form and the participant assent form can be found in additional files 1 and 2, which give the information on privacy, storage of results and dissemination. Registration of this randomised control trial has been completed with the Australian New Zealand Clinical Trial Registry: ACTRN12612000975897. This study protocol has been prepared according to the SPIRIT checklist.[30]

DISCUSSION

Within the literature, the highest related evidence for treatment of equinus related to ITW gait is the use of serial casting,[4] with or without BoNT-A.[18 19] Surgical lengthening of the Achilles tendon has also had positive results in the short-term and long-term.[7] Complications for surgical Achilles tendon lengthening procedures are not limited to, but can include, postoperative infection, tendon necrosis, deep vein thrombosis or sensory loss.[31] While serial casting runs the risk of skin irritation, pressure wounds and permanent tissue damage,[32] this is less likely to occur in healthy and normally sensate children. In recommended doses, BoNT-A is very safe with a very low complication rate. There have been reports of local complications, including pain at the injection site and local muscle weakness, which is a direct effect of the BoNT-A, and when it occurs, it is always temporary, lasting up to a few weeks. Systemic complications may also include a short-lived 'flu-like illness which may last 2–3 days. In larger doses, regional complications may occur such as bladder incontinence when upper leg injections are performed and swallowing difficulties when proximal upper limb or neck injections are performed. In children with severe cerebral palsy GMFCS V, there have been a small number of deaths worldwide associated with injections of large doses of BoNT-A given under general anaesthetic. The cause of these deaths is not clear.[33–35] Each of these treatments has a greater potential for complications that may impact the child's function in the short-term or long-term compared with conservative measures such as a change in footwear and/or orthotic therapy.

There is limited evidence of conservative measures having a positive impact on ITW gait and no evidence to support the use of whole body vibration. Authors reporting the use of orthotics with or without specific footwear are anecdotal reports of author opinion[13] or have limited participant numbers within a case study[8] of which has also not been published in peer reviewed media. Despite this, many clinicians report the use of full-length flat carbon devices or advise parents to purchase heavy shoes for their children.

The use of whole body vibration has been determined to have an immediate positive effect on gait in individuals with cerebral palsy.[20] It is unknown what, if any, gait effect will be observed by the introduction of these external stimuli.

This trial is limited in its ability to test the long-term effect of these external stimuli. The treatment (footwear and orthoses) approaches were selected as they are in current use with the Victorian Paediatric Rehabilitation Service Toe Walking Clinic (Melbourne, Australia) at

Monash Children's Hospital. The use of whole body vibration was chosen as a novel and non-invasive treatment option, and its impact is unknown in children who have equinus and may also have sensory processing challenges. It is also understood that a long-term study investigating the impacts of these different stimuli would provide more definitive answers. However, no short-term impacts have been investigated with the use of gait analysis equipment; therefore, it is prudent to proceed with short-term investigations before progressing to future randomised control trials into treatment options.

CONCLUSION

The treatment of ITW is complex due to the unknown aetiology; therefore, it is necessary to have well-designed research investigating possible and feasible interventions.

There is no single treatment option proven to have a positive, long-term effect on ITW. The use of simple, relatively inexpensive and conservative measures is important for clinicians, and it is hoped that this trial will enable a better understanding of the effectiveness of these options. The results of this study will be published following full recruitment and completion.

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