**The effect of a running intervention for children with symptomatic joint hypermobility**

**Background**

**Brief project background & objectives** Running is an important skill that enables children to participate in physical activity1.Children with symptomatic joint hypermobility often have difficulty with running due to various factors including difficulty generating lower limb power, fear of movement (kinesiophobia), pain or fatigue2.This impacts participation in physical activity and everyday life2. A running intervention conducted by this research group has been demonstrated to assist children with cerebral palsy to achieve running goals3, but it in unknown whether such an intervention would be effective in children with hypermobility.

**Objectives**: This pilot study will investigate if a running intervention is a feasible intervention to improve running performance and participation and reduce kinesiophobia for children with symptomatic joint hypermobility.

**Significance of the project** There is currently no evidence with regards running or running interventions for children with hypermobility. Running is important for children’s participation in physical and social activities. Children with hypermobility can find it difficult to participate in physical activity, yet physical activity is critical for the health of children.

**Methods**

Study design

This is a mixed-methods study, employing a single subject research design and qualitative description to assess the feasibility of the intervention4. Participants will be randomized to start the intervention after four, five or six weeks of baseline measures. Participants will undertake baseline, intervention (10 weeks), and withdrawal (6 weeks) phases, and follow-up at 6 months.

Participants

Children 9 to 18 years old with symptomatic joint hypermobility or hypermobile Ehlers-Danlos syndrome (hEDS) will be recruited through Western Kids Health (WKH), a paediatric allied health provider. To be included in the study participants must have a Beighton Score ≥6/9, have a goal to improve their running, and be able to attend one training session each week for 10 weeks. Children will be excluded if they are unable to undertake strenuous exercise for medical reasons, have cognitive or behavioural problems that hinder working in a group, have coexisting neurological or orthopaedic conditions or have had an injury in the past 6 months that impacts their ability to run.

Running in hypermobility Intervention protocol

The intervention is adapted from: Gibson N, Chappell A, Blackmore AM, Morris S, Williams G, Bear N, Allison G. The effect of a running intervention on running ability and participation in children with cerebral palsy: a randomized controlled trial. Disabil Rehabil. 2018 Dec;40(25):3041-3049. doi: 10.1080/09638288.2017.1367426. Epub 2017 Aug 21. PMID: 28826274.

**Table 1: Intervention protocol according to Consensus on Exercise Reporting Template guidelines**

|  |  |
| --- | --- |
| **Item** | **Details** |
| 1. Exercise Equipment | Trampette, stairs, resistance bands, single step, cones, agility ladder, dumbbells, leg curl machine, leg press machine |
| 2. Qualifications and training | Two or three senior physiotherapists (PTs) with experience in working with school-aged children with hypermobility spectrum disorder (HSD) will deliver the program. The lead physiotherapist has delivered this intervention for the past 8 years, undertook 15 hours training in rehabilitation of running for people with neurological conditions and undertook eight hours training in motivational interviewing which was delivered by a clinical psychologist. |
| 3. Individual/group | Individualized programs will be established and progressed at individual rates. The individualized program will be delivered and performed in a group setting once per week and a home program provided tobe performed three times per week. |
| 4. Supervision | Participants will be supervised in a ratio of 1PT:3participants. The participants will be taught the exercises individually and once performing the exercise correctly, allowed to practice independently. |
| 5. Adherence to exercise | Progress notes will be completed at the end of each session, including the level of difficulty of each exercise and number of repetitions, or time spent doing the exercise. Attendance will be recorded for eachparticipant and reported as a number of sessions out of 10 possible sessions. Home program exercises will be prescribed weekly and home exercise diary sheets will be collected at the end of each week. |
| 6. Motivation strategies | Participants will be encouraged with verbal feedback about their technique, both what was done well and what changes need to be made. Participants will be given a time or number of repetitions toaim for. Exercises will sometimes be incorporated into games. Participants will also be encouraged to “buddy up” with another group participant to encourage each other. Each participant will have a home program, with diary sheets issued and collected weekly to encourage adherence. Participants who do not attend a session without informing PTs of the reason will be called by one of the PTs the next day to encourageattendance. The PTs will use motivational interviewing techniques to encourage participants to explore options for adhering to home prescribed exercises and for exploring and promoting physical activity in the community. |
| 7a. Decision rule(s) for determining progression | Once the participant is consistently able to perform the exercise with good technique they will be progressed to the next level. Speed and quality of movement will be prioritized over load as the focus on ballistic movement is necessary for running. |
| 7b. How program was progressed | The program incorporates a series of hierarchically challenging activities. [See Williams & Schache 20105 and Schache et al. (2014)6 for more detail on the activities].Participants will be prescribed relevant activities to address the running gait impairments demonstrated for that individual. The individually tailored exercises will be derived by the therapist viewing slow motion observational sagittal and frontal video footage of the participant’s running gait and determining the abnormalities affecting the acquisition of typical running skill. The exercises/activities will target the three main muscle groups responsible for forward progression when walking and running, i.e. the ankle plantar flexors, hip flexors and hip extensors. Exercises will be progressed once good form/technique is demonstrated on the starting activity. The exercises may be performed on the trampette until the participant is able to perform the exercises overground. For simulation of leg turnover and appropriate foot contact alignment an activity termed the “claw” exercise will be utilized [See Williams& Schache 20105 and Schache et al., 20146 for more detail]. For participants whose motor control does not enable good technique, activities such as the “claw” will either be broken down into components, or facilitated with therapist handling until the participant is able to perform a cycle withgood technique. This will be progressed by decreasing therapist facilitation and eventually adding resistance (for e.g., with resistance bands). Once the participant can run with good technique overground, slopes may be added, and the distance or speed increased depending on the individual goal. From slopes, participants progress to agilityexercises. These began with simple cutting/side stepping exercises and progress in complexity. Once a reasonable level of agility is attained, sport specific skills relevant to the individual participant’s interest may be introduced. |
| 8. Exercises | Please refer to Williams & Schache 20105 and Schache et al. (2014)6 for the types of exercises utilized to address different running impairments. Each session will utilise the following structure:1 Warm-up: 5 min2 Individualized exercises/activities: 45 min3 Cool down: 5 min4. Provision of home program: 5 min |
| 9. Home program | All participants will receive a home program to be performed three times per week, which contains individually tailored exercises that have been learnt with the PTs and which they can perform independentlywith good technique.  |
| 10. Non-exercise components | N/A |
| 11. Type and number of adverse events | Adverse events will be recorded and followed up as per the protocol. |
| 12. Setting | A community paediatric allied health clinic with an outdoor grassed area and access to exercise equipment.  |
| 13. Exercise intervention | Participants are asked to attend one one-hour session per week with the home program performed another three times per week, for a total of 10 weeks. |
| 14a. Generic/tailored | Each participant will receive an individually tailored program based on a core group of hierarchical exercises |
| 14b. How the exercises are tailored | The exercises will be tailored for each participant according to the identified impairments impacting their running skill and by level of difficulty. The PTs will progress the exercises according to the participant’sresponse. Adjunct exercises will be added by the PTs if necessary, for example hip abductor strengthening exercises may be added if the participant cannot stabilize the pelvis while performing the exercises. |
| 15. Decision rule for starting level | Participants will be started at the most challenging level they can perform with good technique. |
| 16a. Adherence/fidelity | PTs will meet for 10 min following each session to discuss issues experienced by individuals in the group and find solutions.  |
| 16b. Intervention delivered as planned? | N/A |

Outcomes

*Participant characteristics*

Children will be characterised at the start of the study by their age, height, weight, Beighton score and Lower Limb Assessment Score.

*Primary outcome*

At the start of the study, the goals of each child will be identified using Goal Attainment Scaling (GAS)7. Each child will identify: 1) a running-related physical performance goal, 2) a physical activity attendance goal, and 3) a physical activity involvement goal8. A proxy measure of each child’s goal will be determined e.g., if the child’s goal is “I want to run faster in my running races” then a proxy goal could be the child’s running speed over an appropriate distance to reflect a race. Achievement of the GAS goals will be scored every week.

*Secondary outcomes*

Quantitative outcomes

These will be assessed every two weeks by a blinded assessor:

1. The Muscle Power Sprint Test is a measure of anaerobic capacity and involves six 15m sprints with a 10 second rest between sprints9.
2. Submaximal hopping on a portable force plate is a measure of stretch-shortening cycle function10. This will be assessed every two weeks by a blinded assessor.

These will be assessed in weeks 1, 17, 22, 27, and 42

1. The Lower Extremity Grading System (LEGS) is a measure of neuromuscular function which combines scores from the Y-balance test, drop vertical jump test, and triple crossover hop for distance test into a single composite score11.
2. Sprinting kinematics will be assessed using 2-dimensional visual gait analysis (2DGA). Each participant will be videoed while running in both frontal and sagittal planes. The following kinematic variables will be assessed:
	1. Foot strike pattern
	2. Forward trunk lean
	3. Cadence
	4. Position of the centre of mass relative to the posterior point of the shoe at initial contact
	5. Rearfoot angle at initial contact
	6. Knee flexion at initial contact
	7. Knee flexion at midstance
	8. Pelvic obliquity at midstance
	9. Lateral trunk lean at midstance
	10. Arm position at midstance
	11. Rearfoot angle at midstance
	12. Hip extension at toe-off
	13. Knee flexion at mid-swing
	14. Hip flexion at mid-swing
	15. Peak hip internal rotation in swing

The visual assessment of these kinematic variables has been shown to be reliable in adult and adolescent runners, with the exception of hip internal rotation in swing21,22. Sprinting kinematics will be analysed by an experienced, blinded assessor.

1. Kinesiophobia will be assessed using the Tampa Scale of Kinesiophobia (TSK), which will be administered to both parents and children. This is a 17-item questionnaire which has been reported to have acceptable validity and good internal reliability in adolescents19.
2. Health related quality of life will be assessed using the KIDSCREEN-10, which will be administered to both parents and children. The KIDSCREEN-10 is a short questionnaire which has been reported to be valid and reliable20.

These will be assessed in weeks 1, and 22:

1. Physical activity levels will be assessed using the APARQ, which is a self and parent report retrospective questionnaire that assesses the type, intensity, frequency, and duration of activity across the seasons of a year13. The APARQ has been documented as having acceptable to good reliability and acceptable validity and is the preferred tool for assessing PA among adolescents in Australia14,15. The tool has been validated in 13–15-year-old children13.
2. Physical activity levels will also be assessed using wrist mounted Actigraph GT9X accelerometers, collected over a 7-day period. Accelerometry has been reported to be a valid16, reliable17 and accurate18 measure of physical activity in school-aged children.

These will be assessed weekly during the intervention phase:

1. Pain, Fatigue and rating of perceived exertion will be measured at the start and end of each intervention session by an interventionist using a visual analogue scale (VAS)12.

Feasibility outcomes23-25

**Table 2: Feasibility areas of focus25**

|  |  |
| --- | --- |
| **Area of focus** | **Measure** |
| Acceptability | Patient and staff satisfaction with the intervention, as measured on a 10-point Likert scale and qualitative interview |
| Demand | Recruitment to the studySurvey of WKH patientsAttendance at the intervention program |
| Implementation | Fidelity to the intervention protocol |
| Practicality | Cost to run the intervention program Attendance at the intervention programAdherence to home exercise programmeNumber and type of adverse eventsEvaluation of resources |
| Adaptation | N/A |
| Integration | Cost to run the intervention programQualitative interviews with WKH staff and management at 17 weeks |
| Expansion | N/A |
| Limited efficacy testing | Quantitative measures |

Qualitative outcomes

Parents and children will undertake semi-structured interviews. The overarching question is “What could children with symptomatic hypermobility tell us about the value of participation in a targeted running intervention programme for their physical performance, attendance, involvement and kinesiophobia?”

Questions for children (for parents “you” will be replaced by “name of child”):

At end of the intervention (week 17):

*For physical activity performance*

* Can you tell me what you thought of the running program we have been doing? (probes re things that helped/didn’t help)
* What were you hoping to get better at?
* During the programme, what was the most important goal for you?  Why?
* Can you tell me how that is going?
* What did you have to do to get better at xxxx?  (of if it isn’t any better – what do you think you might need to do to get better at that? What would help?)
* How did the running program help (if at all)?

*For participation attendance and involvement*

* Apart from the running program, what other physical activities have you been

doing? What is new or different? How is that going? What works well for you, what makes it harder to do?

* What do you think of when you hear the word involvement?
* What might ‘being involved’ look like for you?
* How involved are you when doing xxxx – tell me about that… is it going how you want? Would you like to be more involved – how would that look? What might be needed to help you be more involved? What happens when you are not involved – how does that feel? What do you do to try to change it if it isn’t going well? What might help?
* What is needed to keep you being active?
* Is there anything else you would like to say or tell me?

*For kinesiophobia*

* Can you tell me if the programme had an influence on how you feel about being active

(specifically with your flexible joints)?

* Has the program influenced how you feel about attending, and being involved in, your physical activities (specifically with your flexible joints)? (probes about confidence)
* Can you tell me if there is anything that you will be able to apply beyond the programme in

terms of your joints and how you feel about moving?

At follow-up (week 42)

*For physical activity performance*

* Can you tell me if the program led to any changes in your physical activity performance? i.e., from the start of the study to now?
* If we were to offer the running programme to other kids, is there anything we should do differently? Would you recommend it to other kids? What would you tell them?
* Is there anything else you would like to say/tell me?

*For participation attendance and involvement*

* Apart from the running program, what other physical activities have you been

doing? What is new or different? How is that going? What works well for you, what makes it harder to do?

* How involved are you when doing xxxx – tell me about that… is it going how you want? Would you like to be more involved – how would that look? What might be needed to help you be more involved? What happens when you are not involved – how does that feel? What do you do to try to change it if it isn’t going well? What might help?
* Do you have plans for how to stay physically active? Can you tell me about them?
	1. What will you need to help you do this?
	2. What might you need to keep sustaining physical activity moving forwards?
* Is there anything else you would like to say or tell me?

*For kinesiophobia*

* Can you tell me if the programme had an influence on how you feel about being active

(specifically with your flexible joints)?

* Has the program influenced how you feel about attending, and being involved in, your physical activities (specifically with your flexible joints)? (ask about confidence)
* Can you tell me if there is anything that you have applied beyond the programme in

terms of your joints and how you feel about moving?

Questions for WKH physiotherapy and management personnel at week 17:

* Can you tell me what you thought of the running program we have been doing? (probes re things that helped/didn’t help)
* What did you need to do differently for WKH to run the program? (Probes re fit within infrastructure)
* Do you think WKH would offer this program in the future? Why / Why not? (Probes re sustainability, costs and benefits)

Assessment Protocol

The study will have four phases. Phase one is the pre-intervention period where baseline assessments will be undertaken weekly for four to six weeks. Phase two is the intervention period of 10 weeks duration. Phase three is the follow-up or withdrawal phase, in which assessments will be undertaken weekly for six weeks. Phase four involves two further follow-ups at six months and 12 months. All assessments will be undertaken by a blinded assessor, except for the in-training session Pain VAS, Fatigue VAS and Borg RPE measures.

**Table 3: Assessment Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Measure** | **Baseline** | **Intervention** | **Withdrawal** | **Follow-up** |
| **Week** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **42** |
| APAR-Q | 🗸 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 🗸 |  |
| Accelerometry | 🗸 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 🗸 |  |
| LEGS | 🗸 |  |  |  |  |  | 🗸 |  |  |  |  |  |  |  |  |  | 🗸 |  |  |  |  | 🗸 | 🗸 |
| KIDSCREEN-10 | 🗸 |  |  |  |  |  | 🗸 |  |  |  |  |  |  |  |  |  | 🗸 |  |  |  |  | 🗸 | 🗸 |
| TSK | 🗸 |  |  |  |  |  | 🗸 |  |  |  |  |  |  |  |  |  | 🗸 |  |  |  |  | 🗸 | 🗸 |
| Sprint kinematics | 🗸 |  |  |  |  |  | 🗸 |  |  |  |  |  |  |  |  |  | 🗸 |  |  |  |  | 🗸 | 🗸 |
| GAS – performance | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |  |
| GAS – attendance | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |  |
| GAS - involvement | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |  |
| Hopping | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 | 🗸 |
| MPST | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 |  |  | 🗸 | 🗸 |
| Pain VAS |  |  |  |  |  |  | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |  |  |  |  |  |  |  |
| Fatigue VAS |  |  |  |  |  |  | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |  |  |  |  |  |  |  |
| Borg RPE |  |  |  |  |  |  | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |  |  |  |  |  |  |  |
| Staff survey |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 🗸 |  |  |  |  |  |  |
| Semi-structured interviews | 🗸 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 🗸 |  |  |  |  |  | 🗸 |
| Demand survey | 🗸 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Analysis

Quantitative data will be represented graphically and analysed visually using published minimal clinically important differences where available. Kendell’s Tau will be used to test for trend in mean for each phase and the HPS d-statistic will be used to calculate the effect size26,27, if appropriate. Gait and feasibility data will be reported descriptively. Qualitative description approach will be employed. Qualitative interview data will be transcribed verbatim. Two researchers will immerse themselves in the data, undertaking repeated reading and analysis using sorting and coding to develop meaning statements, sub themes and themes. Methodological quality and trustworthiness will be developed by employing recommended methods of maintaining an audit trial and reflective journal, member checking and peer discussions.

Reporting

Results of the study will be reported according to SCRIBE guidelines28.

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