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Lycra splinting garments for adults with intellectual disabilities who fall due to gait or balance issues: a feasibility study

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Abstract

Background Adults with intellectual disabilities (IDs) experience high rates of falls and have high rates of gait or balance issues which contribute to falls. Lycra splinting garments (LSGs) have potential to improve gait or balance, but they have never before been tested with adults with IDs who fall due to gait or balance issues. The aim of this study was to test in adults with IDs, the feasibility of using LSGs to improve movement and function and reduce falls, whilst also exploring usability and likely compliance.

Method A convenience sample of nine adults with IDs wore tailored LSGs over a 6-week assessment period. Laboratory-based foot clearance, balance, and gait measures were collected pre- and post-LSG-wear. Falls charts and questionnaires on usability and likely compliance were also completed.

Results Seven participants experienced a reduction in falls during their six weeks of LSG wear; most notably in the group of five participants who wore lycra splinting socks, compared with only two in the group of four who wore lycra splinting shorts or leggings only.

Conclusion Lycra splinting socks are likely to bring about positive outcomes for adults with IDs who fall due to gait/balance issues on an individual case by case basis over time, but further research is required to test this hypothesis under randomised controlled trial conditions. Potential benefits of more intrusive LSGs are outweighed by reported problems with usability and compliance.

Introduction

Falls and fall injuries are a serious problem for people with intellectual disabilities (IDs) across all ages. Between 25% and 40% of people with IDs experience at least one fall in a 12-month period (Sherrard *et al.*, 2001; Finlayson *et al.*, 2010; Cox *et al.*, 2010; Hsieh *et al.*, 2012), and falls are the commonest cause of injury reported for this group/population (Sherrard *et al.*, 2001; Finlayson *et al.*, 2010). Indeed, people with IDs experience falls at similar rates reported for older adults in the wider population but at a younger age (Ambrose *et al.*, 2013).

A previous review of the literature on balance and gait issues in people with IDs found preliminary evidence, to suggest a relationship between falls and balance and gait issues (Enkelaar *et al.*, 2012). To further demonstrate this point, Oppewal *et al.*

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(2013) conducted balance tests with 1050 adults with IDs (aged 50 years and over) and found that their balance capabilities were similar to those of adults in the wider population who were 20 years older.

A Lycra splinting garment (LSG) is a made-to-measure Dynamic Elastomeric Functional Orthosis, which when worn, allows a wide range of function and movement for the individual wearer (e.g. a person with cerebral palsy), whilst providing additional support to the area covered by the splint (Health Improvement Scotland, 2013). LSGs can be used with people with neurological and musculoskeletal conditions because the mechanisms by which they are presumed to work are a combination of both physiological and biomechanical effects, whereby the areas of high pressure provided the tight fit of the LSG increases sensory and proprioceptive awareness, and produce a mechanical compressive effect (Michael *et al.*, 2014; Woo *et al.*, 2014; Attard and Rithalia, 2004). Wearing LSGs to cover the centre of the body (bodysuits) and/or lower limbs (shorts, leggings, and/or socks) has been shown to enhance postural stability and improve gait when walking for children with cerebral palsy (Blair *et al.*, 1995; Edmonson *et al.*, 1999; Rennie, 2000; Nicholson *et al.*, 2001; Mathews *et al.*, 2009), and neuro-motor deficits (Hylton and Allen, 1997). The use of LSGs in lower limb studies, however, has also determined that the wearer should be an active participant in daily activities to achieve the greatest benefits, and that, in terms of usability and compliance, they are likely to gain greater benefits using less intrusive splints (socks rather than bodysuits) (Blair *et al.*, 1995). The latter point refers to previously reported issues with usability and compliance with wearing whole body LSGs, which are intended to be snug for maximum support and benefit, namely decreased respiratory function (Blair *et al.*, 1995), difficulty putting on and taking off the garment (e.g. to use the toilet) (Blair *et al.*, 1995; Nicholson *et al.*, 2001), and problems with body temperature control, particularly in hot weather (Edmonson *et al.*, 1999). These issues have caused parents and children to refuse to wear LSGs despite their potential benefits to movement and function (Rennie, 2000; Nicholson *et al.*, 2001). Hon and Armento (2014) for example, conducted a single case study of a child with ataxia and

hypotonia (low muscle tone) and reported that the LSG led to a reduction in falls and near falls, and promoted a near normal gait.

The number of LSG studies conducted with adults is extremely limited, and no previous study has investigated the use of LSGs to prevent or reduce falls in adults with gait or balance issues.

Occupational Therapist, Scott-Tatum (2003) conducted a 2-year study of LSG wear with 17 children and 23 adults, covering a wide range of disabilities and movement disorders. Overall, she concluded that both children and adults achieved functional gains wearing LSGs, and that individuals with spasticity in particular benefit from Lycra-based splinting. LSGs are also recommended in the management of spasticity in adults by Nair and Marsden (2014), as, unlike more traditional splints, they are dynamic (flexible) and apply support over long periods without holding the joint in a fixed position. One previous case series study of six adults with chronic stroke has shown LSGs increase the range of movement and function at the wrist and fingers (Doucet and Mettler, 2013), whilst clinical trials of LSGs in the same patient group have shown benefits for upper limbs (Gracies *et al.*, 2000) but not lower limbs (Ibuki *et al.*, 2010). This perhaps reiterates an earlier point from previous lower limb studies with children, in that the LSG wearer should be an active participant in daily activities to gain the greatest benefits (Blair *et al.*, 1995).

Not only is there a paucity of evidence on the use of LSGs with adults who fall due to gait or balance issues, but no study at all has investigated the use of LSGs with adults with IDs, despite adults with IDs being an obvious group/population of concern (Cuesta-Vargas & Gine-Garriga, 2014). Adults with IDs are much more likely, when compared to the wider population, to experience physical impairments which can lead to gait and balance issues; such as cerebral palsy and spasticity, as well as mobility problems attributable to specific conditions (e.g. Down's syndrome, which can cause low muscle tone in the body resulting in joint laxity or instability) (Emerson & Baines, 2011).

The aim of this feasibility study, therefore, is to investigate the use of LSGs with adults with IDs who fall due to gait or balance issues, to answer the following research questions:

- 1 What is the feasibility of LSG wear for adults with IDs with gait or balance issues to prevent or reduce further falls?
 - 2 What is the feasibility of using laboratory based measures of movement and function (foot clearance, balance, and gait) to characterise outcomes associated with LSG wear in adults with IDs with gait or balance issues?
 - 3 What are the views and experiences of adults with IDs and their supportive carers (relative or support worker), and their clinicians, on the usability and acceptability of LSGs?
- Person has, following Physiotherapy assessment, been identified as having a gait or balance problem which has contributed to their fall/s; and
 - Person has mild to moderate IDs and capacity to consent.

Method

Study design

This study was designed in accordance with a feasibility test framework (Campbell *et al.*, 2000) and Medical Research Council (MRC) guidelines in the United Kingdom (Craig *et al.*, 2008), which emphasise the need to consider tailoring the intervention to individual and local circumstances and evaluating the effectiveness in everyday practice. The method of a series of single case experiments was chosen, as there is such a wide variation of presentations of people with IDs (e.g. with cerebral palsy or hemiplegia). The consistent presentation was that they experienced falls due to gait or balance issues.

Participants

A convenience sample of nine adults with IDs was recruited into the study via Falls Pathway Services (Crockett *et al.*, 2014) within NHS (National Health Service) Greater Glasgow and Clyde and NHS Lanarkshire Community Intellectual Disability Physiotherapy Services. Final sample size was determined by the time frame of the study. Participants were recruited on a first-come-first-serve basis from the current caseloads of community-based physiotherapists, based on the following inclusion criteria:

- Person has experienced at least one fall injury (requiring medical attention or treatment) or frequent falls (three or more) with or without injury in the previous 12 months;

This study was limited to adults with capacity to consent to allow for the feasibility of the LSG to be tested, and to ensure no unnecessary burden was being placed on adults with severe or profound IDs, who do not have capacity, at this initial stage of testing. Participants were recruited via project information sheets given to them and their supportive carers (relatives or support workers) by their physiotherapists, who identified them as suitable potential participants for the study. A request was made for each participant's physiotherapy and general exercise routines to be as consistent as possible during the study period, and this was checked via a follow-up questionnaire (described in the 'Materials' section to follow). Only one participant (participant 1) had a change to his physiotherapy routine during the 6-week assessment period of the study, in that he joined an exercise group.

Ethical approval

Ethical approval for this study was obtained from the National Health Service (NHS) Scotland Research Ethics Committee, and subsequent permissions were granted from NHS Greater Glasgow and Clyde and NHS Boards. The clinicaltrials.gov identifier for this study is NCT02345512.

Funding

This study was funded by a Scottish Government Development Fund, which is aimed at developing initiatives to reduce health inequalities experienced by people with intellectual disabilities.

Conflict of interest

None of the authors have any conflicts of interest to declare. Co-author, (JC) works within NHS Greater Glasgow and Clyde Community Intellectual Disabilities Physiotherapy Services. No clients with intellectual disabilities were recruited into this study from her own caseload.

Procedure

Each participant was visited at home by a researcher, who obtained their written consent to participate in the study, and provided further information about LSGs using easy language and pictures. Each participant was then visited by a physiotherapist from *DM Orthotics*, who assessed their requirements and measurements for their LSG/s, according to pre-determined orthotic criteria (DM Orthotics, Unit 2, Cardrew Way, Redruth TR15 1SS, United Kingdom). Individual requirements and measurements were based on clinical presentation (e.g. ataxia) and physical measurements (e.g. foot shape and size).

Each participant completed laboratory walking tests at [insert name of university] on two separate occasions: a first visit before wearing their LSG/s; and a second visit after wearing their LSG/s for six weeks. There is no consensus on the duration of a balance intervention, but current evidence (Zech *et al.*, 2010) suggests, that for significant sensorimotor adaptations, a minimum of six weeks is required for balance training, thus sufficient for this feasibility study. At the end of their second visit, all participants—with their supportive carers—were asked to complete a questionnaire about the usability of their LSG/s.

Materials

Lycra splinting garment/s

Individually tailored LSGs were purchased from UK-based *DM Orthotics Limited*.

Laboratory-based pre- and post-test outcome measures were recorded at two different time periods: time 1, before wearing the LSG/s; and time 2, six weeks after wearing the LSG/s.

Gait and balance assessment

Three-dimensional (3D) motion analysis was used to track the movements of the feet during gait. 3D motion analysis is a valid and reliable method of measuring body movement, in relation to evaluating trips, slips and stair/step negotiation to help in the reduction of the incidence of falls (Menz *et al.*, 2004). Three-dimensional body movement analysis was carried out in this study using a 10-camera *Qualisys* motion analysis system (version 2.10), encircling an

entire 10-m walkway, to record the 3D location of retro-reflective markers placed on the participant's foot/shoe.

Force plate measurements were used to determine the movement of the centre of pressure during standing balance trials. A *Kisler* force plate was used, recording ground reaction forces, and therefore allowing calculation of the centre of pressure location.

Temporal spatial characteristics of gait were assessed using a 6-m *GAITrite* walk mat which recorded the location of each foot placement.

A copy of the laboratory protocol for this study, which includes details of marker placement and calibration, is available directly from the authors.

Each of the following tests was repeated three times in succession. Participants' walking speeds during these tests were self-selected, and physical support (minimal loading) from a laboratory assistant (either co-author, SS or BS) was allowed for those participants who required support/assistance.

Foot clearance

The distance between the base of the participant's shoe at the toe and the floor or stair was used to assess foot clearance. Foot clearance was measured during the following three tasks/activities:

- Stair ascent (using a portable staircase of 6 steps)
- Flat straight walking over 10 m
- Timed-Up-And-Go (TUG) (insert reference).

TUG is a timed test used to assess a person's mobility and requires both static and dynamic balance (Podsiadlo & Richardson, 1991). Enkelaar *et al.* (2012) conducted a review of gait and balance tests completed with people with IDs and found TUG to have good reliability for this group/population. The test requires the participant to rise from a chair, walk a distance of 3 m, turn around, and then sit down again in the chair. The time taken to complete the test indicates the following: normal mobility (less than 10 seconds); normal mobility for frail older adults and disabled persons (11 to 20 seconds); person requires assistance outdoors and further examination and intervention (greater than 20 seconds); and person may be prone to falls (greater than 30 seconds).

Balance

Balance was assessed using the characterisation of the movement of the centre of pressure (COP) during a standing test. Initially, the participant was asked to stand alongside a force plate, and then asked to step forward and stand on the plate for 45 s with their feet a comfortable width apart facing in one direction. The following tests were completed:

- 1 Standing on a hard surface (force plate) with eyes open.
- 2 Standing on a hard surface with eyes closed.
- 3 Standing on a soft surface (which was introduced) with eyes open.
- 4 Standing on a soft surface with eyes closed.

The progression from test 1 to 4 was dependent on the individual's comfort and ability. Balance assessment results are presented as absolute values of movement of the centre of pressure, whereby the times spent in 'hold' position were averaged over the whole time period of each test. Particularly, the standard deviation of the centre of pressure is presented along with the mean velocity of the centre of pressure location movement. These measures were recorded for the whole test period and so represent measures of how controlled the participant's movements were during each balance test.

Gait

Stepping characteristics (gait) were recorded using a 6-m *GAITrite* walk mat, which allowed individual step data to be collected over a continuous number of steps during walking. Mean outcome measures were used to report on the following gait characteristics:

- Velocity of walking (walking speed)
- Step length (one foot contact to opposite foot contact)
- Base of support (width between heel strikes perpendicular to direction of travel)
- Step symmetry score (shortest of left or right mean step length/opposite side step length)
- Double support time (when both feet are on the ground together) as percentage of the gait cycle.

Falls chart

Each participant was asked to complete a daily falls chart, which was completed by their supportive carer (relative or support worker), for 6 weeks prior to wearing their lycra splinting garment/s, and for the 6-week assessment period wearing their garment/s. The pre-intervention data serves as a control.

Usability and likely compliance

At the end of their second visit to the laboratory, participants were asked to complete a questionnaire with their supportive carers, on their compliance with wearing their LSGs, and their views and experiences of wearing their LSG/s over the 6-week test period. Participants were deemed to be compliant if they wore their LSG/s for at least 5 h per day at least 5 days per week. This questionnaire, which was informed by current literature (Blair *et al.*, 1995; Edmonson *et al.*, 1999; Rennie, 2000; Nicholson *et al.*, 2001; Attard & Rithalia, 2004) and developed by the research team for the purpose of this study, was used to collect data on the usability and likely compliance with wearing LSGs. The questionnaire comprised open-ended questions, and six-point Likert scales using smiley/sad faces. A copy is available directly from the authors. The questionnaire was piloted with family carers of children with intellectual disabilities who currently wear LSGs, to check face validity and ensure the questions were relevant and easy to understand and report on. The questionnaire was specifically tested with people with intellectual disabilities and their families known to be in current use of LSGs, but no adults with intellectual disabilities in current use of LSGs could be identified during piloting. In addition, each participant's physiotherapist was contacted at the end of the 6-week assessment period and asked to complete a questionnaire to give their clinical opinion on the functional, physical, usability and compliance outcomes of LSG use with their client. The questionnaire comprised yes/no questions and open-ended questions. A copy of this questionnaire is also available directly from the authors. All nine physiotherapists provided questionnaire feedback on the clinical use of LSGs with their individual clients with intellectual disabilities.

Analysis

Foot clearance measures were calculated using custom implementations of Visual3D software to determine the minimum distance between the base of the toe of the shoe and the floor during the swing through phase of gait. The location of the COP of the foot on the force plate was determined within Visual3D and over a 30-s period the SD of the location in the anterior-posterior and medio-lateral directions was determined. Also, the mean velocity of the movement of the COP in these two directions was calculated. Proprietary computer software was used to analyse the *GAITrite* laboratory tests. Outcomes are presented as the mean of the three repeats of each assessment.

For foot clearance, a reduction in SD and/or a change in mean value to better fall within the range 10–20 mm (Barrett *et al.*, 2010) was considered a positive outcome, as was a reduction in TUG time. Reductions in SD and velocity of the COP were considered positive. Increased velocity of gait, step length and step symmetry were considered positive as was a reduction in percentage of double support time. For base of support, a positive outcome was defined as a more normal gait pattern as concluded from both the quantitative outcome and visual observation. If the mean change from pre- to after 6 weeks of LSG wear was greater than 1 SD of the outcome, then a meaningful change in that particular foot clearance, balance or gait function was considered to have occurred. This threshold was set pragmatically to try and protect against too many false positive identifications of meaningful outcomes. This was a feasibility study looking to explore within multiple aspects of physical performance. To highlight only substantial changes, 1 SD was used. Data collected via falls charts and usability and likely compliance questionnaires were reported directly, as totally scores and verbatim, respectively.

Results

Participants

The individual characteristics and presentations of all nine participants are reported in Table 1. Five participants were female, six lived with their families and the average age was 36 years (ranging from 20 to 59 years).

Foot clearance, balance and gait outcome measures and falls

The pre- and post-LSG wear outcome measures are reported separately for comparison, between those who wore socks or socks with shorts (5 people), and those who wore only shorts or leggings (4 people), in Tables 2 and 3, respectively. Categorisation of participants into these two groups was justified by the evidence that participants benefited most from sock/s-wear, regardless of whether or not they were also wearing shorts. Categorisation of participants into these two groups is appropriate for this feasibility study, according to MRC guidelines (Craig *et al.*, 2008). Participant 9 was unable to complete the series of foot clearance and balance tests during both assessments, due to epileptic seizures. Changes in outcomes between pre and post LSG wear were judged as either, negative, the same or positive. Overall positive results for each outcome have been highlighted in the tables. For foot clearance, the outcomes were variable, as within participants were both positive and negative for different tests. For balance participants, 3 and 4 had generally poorer performance post, whereas 2 and 5 showed generally positive outcomes. For gait parameters, participants 1, 2, 3, 6, 7, and 9 were overall positive. The number of falls experienced pre- and during-wear are also reported in these tables. All those wearing Lycra socks demonstrated reduced falls as did two of those without (participants 5 and 8).

Usability and likely compliance

All participants complied with wearing their LSG/s throughout the day during the six-week assessment period. Five participants and their supportive carers gave feedback on the usability and likely future compliance with wearing their lycra socks (participants 2, 4, 6, 7 and 9). All five reported that the lycra socks were very/easy to put on and very/comfortable to wear. No issues with wearing the lycra socks were reported. The reported benefits of wearing the lycra socks were as follows: increased confidence (4 participants); improvements in walking posture or style (4 participants) (*walks more in a straight line*, 3 participants; *better foot clearance*, 1 participant; *improved heel strike*, 1 participant; *walking faster*, 1 participant; and *walks better*, 1 participant); more stable/steady on feet (4 participants);

Table 1 Case series characteristics, presentation, and lycra splinting garment prescription

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6	Participant 7	Participant 8	Participant 9
Sex	Male	Male	Female	Female	Female	Male	Female	Male	Female
Age	49 years	25 years	20 years	41 years	32 years	38 years	59 years	25 years	35 years
Lives with	Family	Family	Family	Supported living – individual home	Family	Supported living – group home	Family	Family	Supported living – individual home
Case presentation	Participant was born with meningocele and hydrocephalus. Participant has a left hemiparesis and epilepsy. Left-sided weakness, ataxia with a spastic gait and scissor gait style.	Participant has Dravet's syndrome, autism and cortical dysplasia.	Participant has Pyruvate Dehydrogenase Deficiency syndrome.	Participant has cerebellar ataxia.	Participant has Down's syndrome.	Participant has intellectual disabilities from an unknown cause and epilepsy.	Participant has intellectual disabilities from an unknown cause and epilepsy.	Participant had hydrocephalus with a shunt fitted at birth and has epilepsy.	Participant has intellectual disabilities from an unknown cause, autism, cerebral palsy and epilepsy. Right hemiparesis.
Walking, balance and gait presentation	Wears a left ankle foot orthosis.	Walking on toes with a scissor gait style (internal rotation and abduction at the hips), and poor heel strike during gait style with minimal base of support.	Poor coordination with overall reduced muscle tone resulting in poor core stability with low crouched wide-based gait.	General coordination difficulties.	Hypotonia (low muscle tone) throughout the body, and joint hypermobility with arthritis in hips, knees and ankles.	Left hemiparesis.	Right hemiparesis.	Left-sided weakness and high muscle tone.	Right hemiparesis.
Mobility level	Walking stick (outdoors only).	Walks with support from another person (outdoors only).	Walks with support from another person (outdoors only). None.	Walks with a walking frame (outdoors only).	Walks with a wheeled walker (outdoors only).	Walks independently.	Walks with support from another person (outdoors only).	Wheelchair user (outdoors only).	Walks with support from another person (outdoors only). None.

Table 1. (Continued)

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6	Participant 7	Participant 8	Participant 9
Sensory, body temperature or pain issues	Circulatory issues in feet and reduced sensation in left hand.	Can be cold and clammy on occasion.		Can feel cold on occasion, and limbs can be cold. Has right knee pain due to arthritic changes.	Can become too hot easily. Experiences pins and needles sensation in feet and hands occasionally, and occasional pain in back, legs, feet and arms.	Can become too hot easily.	Occasional chest pain underneath breasts.	Reduced sensation on left side.	
Visual issues	Tunnel vision.	None.	Registered partially sighted (poor lower vision).	Short-sighted.	Wears spectacles.	None.	Wears spectacles due to reduced peripheral vision and reduced depth perception.	Partially sighted with reduced peripheral vision and reduced depth perception.	Wears spectacles.
Hearing issues	Deaf in one ear.	None.	None.	Partially deaf and wears hearing aids.	None.	None.	None.	None.	Wears hearing aids.
Lykra splinting garment prescription	Shorts and glove.	Shorts and socks.	Shorts.	Shorts and socks.	Leggings.	Left Sock.	Right Sock.	Leggings and long-sleeve glove.	Socks.

Table 2 Pre- and post-measures for participants wearing lycra socks/s with/without lycra shorts (SD = standard deviation). (See text for meaning of positive + or negative - change in outcome). Changes judged to be overall positive for each outcome are highlighted in grey

Measures (mean of 3 tests per measure)	Participant 2			Participant 4			Participant 6			Participant 7			Participant 9†		
	Pre (SD)	Post (SD)	+ or - change	Pre (SD)	Post (SD)	+ or - change	Pre (SD)	Post (SD)	+ or - change	Pre (SD)	Post (SD)	+ or - change	Pre (SD)	Post (SD)	+ or - change
Foot clearance (mm) and timed up and go (TUG) (s): (R = right foot, L = left foot)															
Walk R	15.2 (8.5)	22.0 (13.3)	Same	19.5 (8.7)	8.6 (5.5)	-	25.0 (4.3)	14.6 (5.8)	+	14.6 (4.9)	2.1 (1.9)	-	Void	Void	NA
Walk L	20.9 (16.8)	16.2 (9.1)	+	10.8 (8.7)	5.7 (11.0)	-	10.9 (7.0)	-0.2 (2.7)	-	15.2 (9.2)	19.8 (10.1)	Same	Void	Void	NA
TUG R	13.7 (8.6)	13.3 (9.0)	Same	12.0 (10.4)	19.0 (8.1)	+	28.5 (6.3)	18.8 (6.8)	+	26.8 (10.2)	15.0 (8.8)	-	Void	Void	NA
TUG L	-1.0 (5.9)	16.7 (10.2)	+	20.2 (13.7)	24.3 (13.5)	Same	16.0 (10.7)	-1.0 (7.1)	-	11.0 (7.5)	12.8 (4.8)	Same	Void	Void	NA
TUG time	26 (3.4)	21.7 (void)	+	14.5 (1.5)	13.0 (0.4)	+	13.6 (1.2)	14.8 (0.1)	-	30.5 (1.8)	27.1 (0.7)	+	Void	Void	NA
Stairs R	8.5 (11.3)	19.3 (11.3)	+	26.3 (7.6)	17.2 (12.9)	+	94.0 (15.0)	13.5 (3.5)	+	18.8 (8.9)	19.8 (9.6)	Same	Void	Void	NA
Stairs L	11.7 (7.6)	29.2 (18.4)	-	31.0 (17.1)	16.8 (8.2)	+	29.3 (21.4)	25.5 (14.5)	Same	26.7 (9.4)	10.8 (5.8)	+	Void	Void	NA
Balance (HS = hard surface, SS = soft surface, EO = eyes open, EC = eyes closed)															
Centre of pressure (COP) standard deviation (SD) (mm/s ²):															
AP HS EO	5.5	7.4	-	15.0	20.7	-	5.3	6.2	-	24.0	8.5	+	Void	Void	NA
ML HS EO	9.4	11.5	-	4.8	6.3	-	5.3	5.4	Same	16.5	12.7	+	Void	Void	NA
AP HS EC	10.1	10.7	Same	11.1	20.3	-	Void	9.4	NA	8.0	9.9	-	Void	Void	NA
ML HS EC	11.3	10.1	+	4.0	8.7	-	Void	6.0	NA	8.0	13.0	-	Void	Void	NA
AP SS EO	35.8	7.4	+	15.5	21.1	-	7.6	5.9	+	7.7	9.6	-	Void	Void	NA
ML SS EO	58.0	12.1	+	5.8	10.6	-	5.7	4.6	+	12.8	12.3	+	Void	Void	NA
AP SS EC	9.7	6.6	+	18.2	23.2	-	Void	7.1	NA	7.5	9.2	-	Void	Void	NA
ML SS EC	11.0	7.3	+	6.1	16.3	-	Void	4.6	NA	10.2	13.0	-	Void	Void	NA
COP velocity (mms ⁻¹)															
AP HS EO	15.9	16.9	-	19.5	25.0	-	17.7	13.7	+	63.4	40.7	+	Void	Void	NA
ML HS EO	10.5	12.7	-	12.3	13.3	-	11.5	9.3	+	60.6	32.4	+	Void	Void	NA
AP HS EC	28.2	16.4	+	18.6	37.9	-	Void	33.2	NA	30.2	49.4	-	Void	Void	NA
ML HS EC	13.7	13.1	+	9.7	18.0	-	Void	26.4	NA	19.4	26.8	-	Void	Void	NA
AP SS EO	Void b	19.2	NA	17.4	30.0	-	13.2	13.0	Same	34.4	40.4	-	Void	Void	NA

Table 2. (Continued)

Measures (mean of 3 tests per measure)	Participant 2			Participant 4			Participant 6			Participant 7			Participant 9 [†]		
	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change
ML SS EO	Void	13.6	NA	8.9	23.9	–	10.8	9.1	17.5	24.2	–	Void	Void	0.796	NA
AP SS EC	35.2	14.6	+	20.4	42.0	–	Void	22.4	30.4	45.7	–	Void	Void	0.494	NA
ML SS EC	19.2	9.9	+	10.9	45.3	–	Void	18.7	25.5	26.7	–	Void	Void	0.036	NA
Gait (GAITrite): SL = step length, BS = base of support, SLSym = step length symmetry, DS% = Double support % of time															
Velocity (ms ⁻¹)	0.511 (0.062)	0.505 (0.006)	Same	0.836 (0.048)	0.599 (0.147)	–	0.578 (0.083)	0.629 (0.054)	0.361 (0.039)	0.364 (0.05)	Same	0.657 (0.084)	0.796 (0.047)	0.796 (0.047)	+
SL (m)	0.406 (0.045)	0.427 (0.056)	+	0.588 (0.036)	0.441 (0.106)	–	0.359 (0.064)	0.362 (0.049)	0.268 (0.059)	0.282 (0.066)	+	0.428 (0.092)	0.494 (0.036)	0.494 (0.036)	+
BS (m) [§]	0.034 (0.028)	0.066 (0.045)	+	0.155 (0.049)	0.201 (0.053)	–	0.191 (0.031)	0.193 (0.042)	0.220 (0.024)	0.205 (0.021)	+	0.167 (0.019)	0.172 (0.019)	0.172 (0.019)	+
SLSym	0.95	0.98	+	0.96	0.96	Same	0.84	0.86	0.77	0.75	–	0.80	0.91	0.91	+
DS%	21.9	21.2	+	14.1	18.8	–	17.6	16.7	22.7	22.8	Same	17.5	15.6	15.6	+
Number of non-epilepsy falls experienced (pre = prior to 6 week assessment period & post = during 6 week assessment period, not post-intervention):															
	18	12	+	12	8	+	1	0	6	0	+	3	0	0	+

[†]Participant 9 was unable to complete most tests due to epileptic seizures during laboratory visits.

[‡]Void and N/A = test not completed.

[§]BS change rating based on a combination of the quantitative outcome variables and visual observation of change in base of support.

Table 3 Pre- and post-measures for participants wearing lycra shorts or leggings only (SD = standard deviation). (see text for meaning of positive + or negative – change in outcome). Changes judged to be overall positive for each outcome are highlighted in grey

Measures (mean of 3 tests per measure)	Participant 1			Participant 3			Participant 5			Participant 8 (10)		
	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change
Foot clearance (mm) and timed up and go (TUG) (s): (R = right foot, L = left foot)												
Walk R	25.1 (20.6)	26.7 (8.8)	Same	39.1 (9.0)	33.0 (16.1)	+	2.8 (4.8)	-0.2 (6.2)	-	42.4 (9.4)	34.6 (10.6)	+
Walk L	30.8 (25.7)	23.7 (7.9)	+	26.0 (7.7)	19.7 (4.1)	+	0.0 (5.8)	-4.3 (13.6)	-	39.1 (7.4)	26.5 (8.1)	+
TUG R	18.3 (14.7)	25.8 (16.2)	-	30.0 (3.3)	23.2 (22.7)	+	13.3 (13.4)	4.5 (4.3)	-	30.0 (5.4)	32.5 (4.4)	-
TUG L	11.3 (5.4)	20.3 (8.2)	+	31.8 (29.8)	46.2 (36.6)	-	25.3 (30.7)	10.7 (14.0)	+	32.3 (9.0)	12.8 (10.0)	+
TUG time	17.3 (1.2)	14.3 (1.0)	+	9.7 (1.2)	10.5 (0.7)	-	13.4 (0.3)	14.3 (0.4)	-	40.5 (3.8)	42.1 (3.8)	-
Stairs R	57.3 (12.5)	49.8 (18.3)	+	72.7 (28.8)	68.8 (26.4)	+	9.5 (3.5)	17.8 (5.4)	+	52.8 (23.9)	30.5 (7.6)	+
Stairs L	37.6 (24.0)	25.8 (21.0)	+	71.3 (15.8)	46.0 (23.5)	+	9.7 (15.3)	50.8 (46.3)	-	15.8 (4.5)	14.0 (7.1)	-
Balance (HS = hard surface, SS = soft surface, EO = eyes open, EC = eyes closed)												
Centre of pressure (COP) standard deviation (SD) (mm/s ²):												
AP HS EO	11.4	10.7	+	10.9	12.9	-	5.3	4.6	+	6.0	7.3	-
ML HS EO	3.1	3.1	Same	6.3	8.1	-	1.6	1.3	+	6.9	5.5	+
AP HS EC	10.4	9.1	+	8.7	12.5	-	5.1	5.0	Same	5.3	7.2	-
ML HS EC	3.9	3.4	+	5.1	12.2	-	1.4	0.9	+	5.3	6.3	-
AP SS EO	6.5	16.1	-	8.3	13.4	-	5.5	7.5	-	5.5	Void	NA
ML SS EO	2.3	18.9	-	6.7	14.4	-	1.9	1.7	+	3.0	Void	NA
AP SS EC	14.1	11.7	+	9.8	12.9	-	5.9	6.5	-	Void	Void	NA
ML SS EC	3.6	4.9	-	7.9	11.6	-	1.4	1.5	Same	Void	Void	NA
COP velocity (mms ⁻¹)												
AP HS EO	36.8	35.4	Same	42.9	27.9	+	15.0	13.3	+	23.1	30.2	-
ML HS EO	14.0	15.4	-	19.6	23.4	-	6.4	6.7	Same	14.4	21.0	-
AP HS EC	36.1	35.4	Same	31.0	32.7	Same	19.9	17.2	+	17.0	24.3	-
ML HS EC	17.7	16.3	+	22.4	36.1	-	7.0	5.3	+	11.7	16.8	-

Table 3. (Continued)

Measures (mean of 3 tests per measure)	Participant 1		Participant 3		Participant 5		Participant 8 (10)				
	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change	Pre (SD)	Post (SD)	+ or – change		
AP SS EO	27.0	57.2	–	20.1	29.5	–	17.4	18.1	17.1	Void	NA
ML SS EO	12.2	98.0	–	17.0	22.6	–	8.6	7.3	11.0	16.0	–
AP SS EC	39.5	39.0	Same	25.0	35.8	–	20.6	21.3	Void	Void	NA
ML SS EC	15.5	19.5	–	17.3	30.8	–	5.8	8.2	Void	24.6	NA
Gait (GAITRite): SL = step length, BS = base of support, SLSym = step length symmetry, DS% = double support % of time											
Velocity (ms ⁻¹)	0.741 (0.062)	0.819 (0.083)	+	0.752 (0.13)	0.842 (0.13)	+	0.579 (0.039)	0.478 (0.029)	0.325 (0.071)	0.318 (0.068)	–
SL (m)	0.436 (0.038)	0.457 (0.058)	+	0.506 (0.094)	0.533 (0.063)	+	0.385 (0.056)	0.354 (0.041)	0.243 (0.089)	0.230 (0.077)	–
BS (m) [†]	0.216 (0.025)	0.241 (0.025)	–	0.123 (0.03)	0.083 (0.047)	+	0.266 (0.013)	0.278 (0.011)	0.310 (0.027)	0.322 (0.023)	–
SLSym	1.0	0.89	–	0.94	0.89	–	0.86	0.9	0.59	0.62	+
DS%	19.8	18.9	+	14.0	13.1	+	23.5	23.2	26.3	24.9	+
Number of non-epilepsy falls experienced (pre = prior to 6 week assessment period and post = during 6-week assessment period, not post-intervention):											
	1	2 ^b	–	0	0	Same (+)	10	4	2	0	+

[†]BS change rating based on a combination of the quantitative outcome variables and visual observation of change in base of support.

^bVoid and N/A = test not completed.

improvements in walking distance and range (3 participants) (*more able to walk longer distances, 2 participants; and walking more outdoors, 1 participant*); more able to participate in hobbies (2 participants) (*able to play badminton, 1 participant; and more able to participate in hobbies, 1 participant*); feels safer walking or less afraid of falling (2 participants) (*feels safer walking, 1 participant; less afraid of falling, 1 participant*); and two carers reported that their participants required less support from them when they were wearing their lycra socks. All five participants intended to continue wearing their lycra socks. Participant 2 had been wearing his lycra socks in place of his traditional ankle foot orthosis, with his clinician's agreement. Clinician's agreement with the positive functional and movement benefits of wearing lycra socks was 100% for these five participants.

Four participants and their supportive carers gave their feedback on wearing lycra shorts (participants 1 to 4). Only two of these participants reported benefits of wearing lycra shorts: participant 1 and his carer reported the shorts gave him better position at the legs, which led to an initial reduction in scissoring; and participant 3 and her carer reported that the shorts improved her posture when sitting, which led to a reduction in back ache she had been experiencing. All four participants, however, reported multiple issues with wearing the shorts, which were as follows: poor fit (4 participants, e.g. sliding down often, 2 participants); toileting issues (3 participants); reduced independence due to requiring extra support to put them on, use the toilet, etc. (2 participants); difficult to put on (2 participants); too warm to wear (2 participants); and issues with washing and drying them overnight to wear the next day (1 participant). All four participants did not intend to continue wearing their lycra shorts. Clinician's agreement with these negative usability outcomes was 100% for all four participants.

Two participants wore lycra leggings (participants 5 and 8). Both participants and their supportive carers reported the main benefit of wearing them as being improved posture; whereby, participant 5 felt more supported at the hip and stomach areas during wear, which led to improved body shape/posture when standing, and participant 8 reported a better walking pattern, due to his knees not being so close together, and a better sitting posture. Both participants experienced poor fit issues with their lycra leggings, in

that they often slid down during wear and had to be readjusted/repositioned. Participant 5 found this issue too distracting during walking, and also found the leggings to be too hot to wear at times. Participant 5 did not intend to continue wearing her lycra leggings, and participant 8 was unsure whether he would continue wearing them. In both instances, the participant's clinician was more positive about the outcome of wearing leggings; due to the reduction in falls for participant 5, and an improvement knee position for participant 8.

Discussion

Overall, there were both positive and negative effects of lycra wear on outcomes. For foot clearance, there were several positive changes; however, in general these were not consistent within participants suggesting that outcomes should be considered on an individual basis in relation to the particular activity being undertaken. We expressed a positive outcome as either a reduction in over stepping, to move towards the normal range of 10–20 mm (Barrett *et al.*, 2010), or an increase from very small foot clearance (i.e. <10 mm).

There are important considerations when interpreting foot clearance, balance and gait patterns of participants with intellectual/disabilities (Enkelaar *et al.*, 2012; Skvortsov, 1997), and participants who are known to fall (Schulz *et al.*, 2010). People with intellectual disabilities are a heterogeneous population, especially with regards to physical presentation, but many can have high levels of stiffness during gait execution due to co-contraction and contraction of antagonist muscle groups (Enkelaar *et al.*, 2012), as well as musculoskeletal changes which occur to compensate for injury and disease, e.g. the normal leg making greater adjustments and deviations to compensate for the affected leg (Skvortsov, 1997). This could account for some of the higher minimum foot clearance values in this study, which demonstrate over-stepping.

Variability in foot clearance has also been shown to be important in predicting falls. Older people without intellectual disabilities in the wider population who are known to fall demonstrate great variation in minimum foot clearance, and this appears to be the same for people with intellectual disabilities who fall (Schulz *et al.*, 2010). In light of this, minimum foot

clearance consistency may be a better predictor of falls in adults with intellectual disabilities who fall, rather than actual foot clearance values. Similar to foot clearance, mean values the variability (SD of foot clearance) did improve for several participants for particular activity, but again this was not consistent.

Certain participants tended to demonstrate enhanced balance (COP SD and velocity) following LSG wear (e.g. 1, 2, 5, 6); however, these were not consistent across all conditions, and for some participants balance was worse following the intervention (e.g. 3, 4). Of all eight participants who completed pre- and post-wear balance tests, six were not comfortable completing the harder tests (soft surface and/or eyes closed), one was unable to complete most of the tests pre-wear for the same reason, and conversely one other demonstrated improvements in balance post-wear during the harder, more demanding tests (participant 2). Increased familiarity with these tests through more practice may have improved findings. In order to avoid potential issues around being easily fatigued or distracted, all tests in this study were completed three times only with each participant. It is recommended in the literature that tests are completed up to five times for more reliable results (Le Clair and Riach, 1996; Ruhe *et al.*, 2010).

Of all the laboratory tests conducted in this study, the *GAITrite* walking mat (and similar products on the market) appeared to be the most successful in providing data per participant, and potentially the most relevant to everyday functional mobility (Cuesta-Vargas & Gine-Garriga, 2014). All except participant 4 of those with LSG socks demonstrated generally improved gait characteristics, suggesting enhanced walking confidence. For those in the study without socks, there were mixed results with some positive and some negative changes in gait characteristics. The use of this pressure mat allowed each participant to walk unencumbered by markers and replicated as far as possible a normal walking pattern, and the task was easier than the others to complete (as it did not involve walking up and down steps or standing with eyes closed). Chiba *et al.* (2009) previously reported that people with intellectual disabilities who fall show greater stance width, shorter step length and lower walking speed than non-fallers. The results within the current study do not support these observations at the individual level, although

generally positive changes in gait parameters appeared to be associated with lower number of falls.

Seven of the nine participants with intellectual disabilities experienced a reduction in falls during their six weeks of LSG wear; most notably in the group of five participants who had been wearing lycra splinting socks, compared with only two in the group of four who had been wearing lycra splinting shorts or leggings (one experienced an increase in falls, and one experienced no falls in the six weeks prior to and during LSG wear). However, of the eight participants tested, only four improved their Timed Up and Go score at the end of the 6-week period, and six remained in the high falls risk category, which is greater than 13.5 seconds for older adults in the wider population (Shumway Cook *et al.*, 2000).

In terms of usability and likely compliance with LSG wear, all five participants who wore socks benefited most and found them to be both usable and comfortable to wear. Six participants who wore shorts or leggings reported a number of important issues with wearing them, from poor fit (6 participants) to being too warm to wear (3 participants). These issues led to five of the six participants no longer intending to wear their shorts or leggings (with one further participant being undecided). The findings from our study, therefore, reiterate what has already been written in the literature; that usability and compliance are only likely for less-intrusive lycra splinting socks.

Strengths and limitations

This is the first study of its kind to feasibility test the use of LSGs with participants with intellectual disabilities who fall due to balance and gait issues. Inconsistency of measurable foot clearance, balance and gait outcomes across and within participants does make it difficult to summarise findings for the group as a whole, hence the importance of presenting our results by case series across Tables 1–3. It is important to present individual results for transparency, and to illustrate individual variation between participants, and at the same time, summarise data within the article. The main limitation of this study is that sample size was small. This limitation was mitigated by the in-depth nature of the case descriptions, which additionally illustrate the wide presentation of intellectual disabilities and individual variation in outcomes. Another important limitation is the short

duration of the 6-week observational period. In addition, one participant joined an exercise group during the 6-week assessment period, which may have influenced their results. Future research should ideally be conducted over a 12-month observational period, as this is the recommended observation period for falls research (Chang *et al.*, 2004) and would tell us more about the integrity of LSG wear over a longer period of time.

Conclusion

Prescribing tailored lycra splinting socks on a case by case basis, to individuals with intellectual disabilities who fall due to balance/gait issues, is likely to bring about positive outcomes to prevent/reduce falls over time, but further research is required first, to test this hypothesis with a randomised controlled trial over a longer time period. LSGs which are more intrusive (shorts or leggings) are unlikely to result in lasting benefits, due to issues with usability thus non-compliance; at least until designers and manufacturers find solutions to these well-documented issues. Not all participants were able to complete balance and motion analysis tests, suggesting that walking mat gait characterisation may be the most feasible option within this population. Balance and gait tests which are familiar and easy to understand and complete are important for developing clinical measures to use with participants with intellectual disabilities.

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