Calf muscle stretching is ineffective in increasing ankle range of motion or reducing plantar pressures in people with diabetes and ankle equinus: a randomised controlled trial

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Abstract

Background: Limited ankle dorsiflexion, or equinus, is associated with elevated plantar pressures, which have been implicated in the development and non-healing of foot ulcer. A stretching intervention may increase ankle dorsiflexion and reduce plantar pressures in people with diabetes.

Methods: Two arm parallel randomised controlled trial from September 2016 to October 2017. Adults with diabetes and ankle equinus (≤ 5 degrees dorsiflexion) were randomly allocated to receive an 8 week static calf stretching intervention or continue with their normal activities. Primary outcome measures were change in weight bearing and non-weight bearing ankle dorsiflexion and forefoot peak plantar pressure. Secondary outcome measures were forefoot pressure time integrals and adherence to the stretching intervention.

Findings: 68 adults (mean (standard deviation) age and diabetes duration 67.4 (10.9) years and 14.0 (10.8) years, 64.7% male) were randomised to stretch (n=34) or usual activity (n=34). At follow up, no significant differences were seen between groups (adjusted mean difference) for non-weight (+1.3 degrees, 95% CI:-0.3 to 2.9, p=0.101) and weight bearing ankle dorsiflexion (+0.5 degrees, 95% CI:-2.6 to 3.6, p=0.743) or forefoot in-shoe (+1.5kPa, 95% CI:-10.0 to 12.9, p=0.803) or barefoot peak pressures (-19.1kPa, 95% CI:-96.4 to 58.1, p=0.628). Seven of the intervention group and two of the control group were lost to follow up.

Interpretation: Our data failed to show a statistically significant or clinically meaningful effect of static calf muscle stretching on ankle range of motion, or plantar pressures, in people with diabetes and ankle equinus.

Keywords: Ankle, Diabetes Mellitus, Pressure, Dorsiflexion, Equinus, Stretching

Introduction

Foot ulcers are a common complication of diabetes and are a major risk factor for lower extremity amputation.(1) Neuropathy, foot deformity, minor foot trauma and high plantar pressures have been identified as critical risk factors in the development and recurrence of diabetic foot ulcers.(1) In people with diabetes limited ankle dorsiflexion, an equinus, is associated with high plantar pressures, and may act independently of neuropathy to alter gait patterns.(2) A major contributor to the higher rates of equinus seen in this group is believed to be the accumulation of advanced glycation end products (AGEs) in tissues such as ligaments and muscle-tendon units, which alters their structure and contributes to increased stiffness.(3)

While surgery and other treatment options, such as night splints, have been used to correct an equinus, these methods can involve significant risks and costs.(4, 5) There is currently no validated, low cost conservative treatment option to correct limited ankle dorsiflexion, and reduce ulcer risk, that could be easily implemented in clinical practice. Current guidelines for people with diabetes, including those from the American Diabetes Association, recommend stretching to maintain and increase joint range of motion, and stretching is widely prescribed in clinical practice to increase ankle joint dorsiflexion.(6, 7) However, while calf muscle stretching has been demonstrated to improve ankle range of motion across both young and older adult populations without diabetes, it has not yet been investigated in a population with diabetes.(6)

Therefore, the primary aims of this study were 1) to determine if an eight-week static stretching intervention is effective in increasing ankle joint range of motion in people

with diabetes and ankle equinus, and 2) to determine if an increased ankle joint range of motion in people with diabetes and ankle equinus results in an associated reduction in forefoot plantar pressures.

Methods

The study was a two-arm parallel group randomised controlled trial with an eight-week follow up period. The trial was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12616000230459). Ethics approval was granted by the University of Newcastle Human Research Ethics Committee (H-2015-0354) and written informed consent was obtained from all participants prior to their participation.

Potential participants were recruited from the University of Newcastle Podiatry Clinic at Wyong Hospital, NSW, Australia and from newspaper advertisements in local newspapers. Inclusion criteria were adults, 18 years of age and over, able to speak and read basic English, and a diagnosis of either type 1 or type 2 diabetes. Exclusion criteria were existing foot ulcer, any previous lower limb amputation, any surgery to the foot or lower limb involving fixation of a joint, any neurological condition that may affect the lower limb other than loss of sensation due to diabetes, inability to walk 8 metres unaided, or current pregnancy.

After enrolment and baseline data collection participants were randomised to an intervention group that received the stretching intervention or a control group that received advice to continue with their normal activities. A researcher not involved in the trial prepared sequentially numbered, opaque sealed envelopes containing a computer generated random allocation schedule with mixed block lengths of four and six participants. The investigators administering the intervention (VC and MS)

assigned participants to groups by selection of the next sequential envelope. Statistical analysis was performed independently by statisticians not involved in the trial (CO, SC). One person (AS) conducted all assessments at both baseline and follow-up and was blinded to group allocation.

Procedures

All data were collected at the University of Newcastle Podiatry Clinic, Wyong Hospital between September 2016 and October 2017. Testing was conducted on the participants' dominant leg only, determined by asking the participant which foot they would kick a football with, to maintain independence of data.(8) Details of chronic medical conditions and medications, glycated haemoglobin, and duration of diabetes were obtained by self-report and from medical history supplied by the participant's general practitioner. Health related quality of life was assessed using the Medical Outcomes Study Short Form 36 questionnaire, with higher scores (1-100) indicating better health.(9) Physical activity levels were assessed using the International Physical Activity Questionnaire (IPAQ) - Short Form.(10)

Ankle joint range of motion was measured both non-weight bearing and weight bearing using a modified Lidcombe template and a Lunge test respectively.(11) An equinus was defined as less than or equal to 5 degrees of non-weight bearing dorsiflexion as there is evidence that this degree of restriction may contribute to increased plantar pressures.(12) Neuropathy was assessed with a monofilament and a neurothesiometer and participants were assessed as neuropathic if they recorded one or more abnormal test results.(13) Four points on the plantar surface of the dominant foot were tested with a 10 gram Semmes-Weinsten monofilament, and an

abnormal test was noted if the participant failed to identify the monofilament at one or more test sites.(13) A neurothesiometer (Horwell ,Bailey Instruments, Manchester,UK) was used to detect the vibration perception threshold (VPT) at the pulp of the hallux. Three readings were taken and the average used in analysis. A VPT value of >25V was regarded as abnormal.(13)

The Novel Pedar-X® system, (Novel GmbH, Munich, Germany) was used to measure in-shoe plantar pressures.(14) Participants walked along a flat twelve metre walkway at their normal walking speed wearing a standardised shoe (New Balance® 624, Boston, MA, USA), with the insole placed between the sock and the shoe. A minimum of two walking trials was required to capture twelve midgait dominant foot footsteps.(14) Barefoot plantar pressures were collected using the Tekscan HR Mat™ Pressure Measurement System (Tekscan Inc., South Boston, USA) using a 2-step protocol with the average of four successful trials used for data analysis.(15)

Percentage masks were applied to each Pedar footprint, with the rearfoot and midfoot masks occupying 50% of the total foot length, the forefoot 30%, and the hallux and lateral toes the remaining 20% (Fig.1). To evaluate HR MAT™ pressures, a mask similar to that used in previous studies was used,(16) with the only change being a consolidation of three metatarsophalangeal joint regions into one forefoot region (Fig.1). Forefoot pressure time integrals (PTI) and peak pressure variables are included in this statistical analysis.

Intervention

Participants in the intervention group were first shown and then practised a stretching program consisting of a standing static calf stretch with the knee

extended. The participant assumed the same position for both the stretch and measurement of weight bearing ankle dorsiflexion (Fig.2). The stretch was held for 30 seconds and repeated four times on each leg during each session (2 minutes of stretching per leg per session). Participants were required to perform one stretching session a day, five days a week, for the eight-week trial period for a total stretch time of 80 minutes for each leg. A similar stretch routine increased non-weight bearing ankle range of motion in older women with restricted ankle range of motion,(17) and a systematic review also found increased ankle dorsiflexion in adults without diabetes using this method.(6) A stretch diary, which included a diagram and instructions for the stretch, were provided to the participants and they were asked to complete the diary to record how often they performed the stretches. Adherence was defined as successful completion of at least 85% of the stretching sessions, which is based on a previous stretching trial in older people where there was a significant change in ankle dorsiflexion range of motion.(18)

Primary outcome measures were change in ankle dorsiflexion range of motion in weight bearing and non-weight bearing and forefoot peak plantar pressure. Secondary outcome measures were forefoot pressure time integrals and adherence to the stretching intervention.

Statistical analysis

We based the a priori sample size calculations on a difference of 5 degrees, and a standard deviation of 6.5 degrees, for non-weight bearing ankle dorsiflexion, between the control group and the experimental group being clinically meaningful.(19) Assuming a power of 0.80 and alpha of 0.05 and allowing for 20%

attrition rate, 34 participants per group were required making a total sample size of 68 participants.

Physical activity status (inactive, minimally active, HEPA (health-enhancing physical active)) was calculated following IPAQ guidelines.(10) Quality Metric Health Outcomes ™ Scoring Software 4.5 © was used to transform SF-36v2 data. Differences in participant characteristics between intervention and control groups were evaluated by independent samples t-test for continuous variables and Chi-square test for categorical variables.(20) All other statistical tests were conducted using SAS® Version 9.2 (Cary, USA) by a statistician blinded to group allocation. Statistical significance was delimited at $P < 0.05$. Data were assessed for normality of distribution, internal consistency, homogeneity of variance and linearity. The difference between groups at follow-up for the primary and secondary outcome measures was analysed with analysis of covariance (ANCOVA) using a linear regression approach. We pre-specified that the baseline measure was the only covariate in each analysis. Cohen's d was used to calculate effect sizes for the primary and secondary outcomes. An effect size of greater than or equal to 0.8 was considered to represent a large clinical effect, 0.5 a moderate effect and 0.2 a small effect.(21)

Data were analysed by intention to treat. Missing outcome measures for the eight-week follow-up were estimated in SAS using multiple imputation with a regression model for all continuous variables.(22) Age, baseline scores and group allocation were used as the only predictors. Eighty imputed data sets were found to provide stable means and standard deviations, and the results of each imputed data set

were pooled to provide model estimates. The data contained only monotone missing patterns with nine participants lost to follow up (seven from the intervention group, two from the control group) representing 13.2% of the data.

Results

Sixty-eight participants were recruited and their progression through the trial is shown in Fig.3. Participant baseline characteristics are included in Table 1. Only seventeen (25%) of the group reported levels of physical activity meeting health-enhancing physical active (HEPA) guidelines at the initial assessment, with the remainder classed as minimally active or inactive. Physical activity levels did not change substantially over the period of the trial with sixteen (27.1%) of the group meeting guidelines for HEPA at the eight-week follow-up. The SF-36v2 questionnaire was completed by 67 of the 68 participants and their results were comparable to an Australian population with diabetes for the domains of general health, vitality, social functioning and mental health(23). However, compared to the Australian population with diabetes the trial group exhibited low scores for the physical functioning (62.1 vs 71.4), role physical (65.3 vs 70.0) and bodily pain (53.5 vs 67.4) domains.(23)

Seven of the participants in the intervention group dropped out and another person did not return their stretch diary, resulting in 26 (76.5%) stretch diaries submitted at the completion of the trial. On average, participants completed 71% of the 40 stretching sessions they were scheduled to undertake. However, eleven participants (32.4%) reported completing all or greater than the required number of stretching sessions, which increased the average figure. When the completed sessions are analysed on an individual level, only 18 (53%) of the participants reported completing

85% or more of the total stretching sessions. Three of the participants reported transient pain or discomfort following the stretching sessions, and one of these participants subsequently withdrew from the trial.

When compared to the control group, participants in the stretch intervention group demonstrated no statistically significant increase in the primary outcome measures of non-weight bearing ankle dorsiflexion range of motion (adjusted mean difference +1.31°, 95% CI:-0.3 to 2.9, p=0.101), weight bearing ankle dorsiflexion (adjusted mean difference +0.5°, 95% CI:-2.6 to 3.6, p=0.743) or forefoot in-shoe (adjusted mean difference 1.5kPa, 95% CI -10.0 to 12.9,p=0.803) or barefoot peak pressures (adjusted mean difference -19.1kPa, 95% CI:-96.4 to 58.1, p=0.628) (Table 2). Similarly, when compared to the control group, participants in the stretch intervention group demonstrated no statistically significant reduction in secondary outcome measures of barefoot or in-shoe forefoot pressure time integrals at eight weeks (Table 2). The 95% confidence interval for these effects were also sufficiently narrow that they excluded likely clinically meaningful differences; for example, for non-weight bearing ankle range of motion, the upper limit of the difference was 2.9 degrees, which is less than the pre-specified minimal difference of 5 degrees.

Discussion

This study sought to determine if an eight-week stretching intervention would increase ankle dorsiflexion range of motion and reduce forefoot plantar pressures in people with diabetes and ankle equinus. The results showed the stretching intervention did not produce a statically significant difference between groups, implying the intervention was ineffective in this population. The study was adequately powered, allowing for dropouts, to detect a minimal difference of a 5 degree change

in non-weight bearing ankle dorsiflexion range of motion, which has indicated a statistically significant difference between groups in previous stretching trials in people without diabetes.(17, 19) Non-weight bearing ankle dorsiflexion range of motion had the largest mean difference between groups at follow up (adjusted mean difference +1.31°, 95% CI:-0.3 to 2.9, p=0.101). As the upper limit of the mean difference in our present study is almost half that of statistically significant differences in previous trials, it is likely that this change is not clinically significant. Finally, no clinically relevant reduction in forefoot plantar pressures was recorded following the stretching intervention, which is consistent with the lack of significant increase in ankle dorsiflexion.

While current physical activity guidelines for people with diabetes recommend incorporating stretching to maintain and improve joint range of motion,(7) the evidence to support stretching in this population is not strong. Trials reporting increased range of motion in people with diabetes used stretching in combination with other interventions such as range of motion or strength exercises, massage, joint mobilisation and physical therapy.(24-27) As such, the increased range of motion reported in these trials may have resulted from the other modalities used in the intervention, or the combination of stretching with the other modalities, from the stretching itself, or from a false positive error resulting from low powered studies.

Accumulation of advanced glycation end products (AGEs) and increased collagen cross links in articular capsule, ligaments and the muscle-tendon unit occurs with both aging and diabetes, and is believed to contribute to reduced joint range of motion.(28) Previous studies have shown that calf stretching can increase ankle

range of motion in older people without diabetes. Gajdosik et al.(17) reported a mean increase of 5.1 degrees of passive dorsiflexion in a group of 19 women (aged 65-89 years) with limited dorsiflexion range of motion following a stretch routine three times a week for eight weeks with a total stretch time of 60 minutes. With the total stretch time doubled to 120 minutes, a study of 20 older women (aged 76 to 91 years) with limited ankle dorsiflexion undertaking a supervised stretching intervention occurring five days a week for six weeks reported a much larger increase of 12.3 degrees increase in passive ankle dorsiflexion range.(29) However, the effect of increased stretching time is unclear as another study reported a smaller but significant 3.5 degrees increase in ankle dorsiflexion in a group of 40 older adults (mean age (SD): 72.1 years (4.7 years)) following a twice daily eight-week stretch program with a total stretch time of 252 minutes.(18) As calf stretching has been shown to be effective in older people, it was plausible that our comparable calf stretching intervention in people with diabetes, which required a total of 80 minutes of stretching over an eight week period, would also be effective.

Diabetes related musculoskeletal changes may have made the stretching intervention less effective. It has been proposed that stretching increases joint range of motion through adaptations in mechanical properties in the muscle-tendon unit, resulting in reduced passive stiffness.(30) Long standing hyperglycaemia, as seen with diabetes, may have resulted in much higher levels of AGE deposition in the muscle-tendon, compared to that occurring with aging. These alterations in the muscle-tendon may make it more resistant to stretch. In this cohort, where 50% presented with neuropathy, high AGE deposition could be expected as

hyperglycaemia and AGE formation have been implicated in the development of diabetic peripheral neuropathy.(28)

Diabetes related neurological factors may also render stretching less effective. An alternate sensory stretch theory suggests that increased joint range of motion results from an increased stretch tolerance, possibly due to adaptations of nociceptive nerve endings, rather than mechanical changes to the muscle-tendon unit.(31) It is suggested that a stretching intervention allows a participant to tolerate a greater amount of force applied to a muscle, which results in greater joint range of motion, while not experiencing higher levels of discomfort.(31) However, people with diabetes related neuropathy display a decreased number of mechano-responsive nociceptors, and degenerative fibres which have lost mechanical and heat responsiveness.(32) Half of the stretching intervention group had neuropathy, and this could result in reduced detection of the force applied during the stretch, and may impair their ability to develop a stretch tolerance.

Low adherence to the intervention is a commonly reported problem in many exercise trials and may also have affected the results.(33) Just over half of the intervention group completed 85% or more of the allocated stretching sessions. An exercise type intervention may not have been well tolerated by this cohort as 75% were classified as minimally active or inactive according to their self-reported physical activity levels. In addition, the low health-related quality of life scores indicated that the participants had limitations in performing physical activities, and experienced levels of pain that impact activities. These factors may have affected the participant's ability to perform the stretch as well as their adherence to the stretch intervention.(9, 33) Nonetheless,

this cohort is representative of a community dwelling population with diabetes who are likely to be prescribed a similar home based calf stretch by many primary care practitioners. Therefore, despite current guidelines recommending stretching for people with diabetes, these results demonstrate that a calf stretching intervention is unlikely to increase ankle dorsiflexion in this cohort.

Our results should be viewed in light of several limitations. Firstly, the stretching sessions were undertaken at home and unsupervised, so it is not possible to know if the stretch was performed correctly (for both number of repetitions and duration). Secondly, the participants self-reported their adherence to the intervention by completing a stretch diary, and while this is a simple and commonly used method to track home based exercise compliance, it is not possible to know if the correct number of completed sessions were recorded. Additionally, while a static stretch was chosen as a safe option for an unsupervised home based intervention, other forms of stretching, such as eccentric stretching, may have resulted in different outcomes.

Conclusion

An eight-week static calf stretching intervention did not significantly increase ankle dorsiflexion range of motion, or reduce plantar pressures, in people with diabetes and an ankle equinus. Similar stretching programs have been effective in older people with restricted ankle range of motion and no diabetes. Musculoskeletal or neural changes related to diabetes may have reduced the efficacy of stretching in this cohort. Static stretching is widely used in physical therapy, and while recommended for people with diabetes, is ineffective when used as a stand-alone modality to increase ankle joint range of motion in this population. As no increase in

ankle dorsiflexion was seen in this trial, it was not possible to determine if an increase would result in an associated reduction in plantar pressures.

Declarations of interest

None.

359 Table 1: Characteristics of the study population. Values are number (%) unless

360 stated otherwise

	All (n=68)	**Intervention (n=34)**	**Control (n=34)**	**p value**
Age (mean years(SD))	67.4 (10.9)	65.6 (12.1)	69.1 (9.5)	0.188
Men	44 (64.7%)	18 (52.9%)	26 (76.5%)	0.042*
BMI (mean kg/m^2(SD))	32.8 (6.8)	32.5 (6.5)	33.1 (7.2)	0.698
Type 1: Type 2 diabetes	60 (88.2%)	31 (91.2%)	29 (85.3%)	0.452
Duration of diabetes (mean years(SD))	14.0 (10.8)	11.7 (8.4)	16.4 (12.5)	0.075
HbA1c (n=53)				
mmol/mol	55 (14)	54 (13)	56 (15)	0.610
% NGSP units	7.2 (1.3)	7.1 (1.2)	7.3 (1.4)	
Insulin therapy alone	10 (14.7%)	6 (17.6%)	4 (11.8%)	0.732
Oral hypoglycaemics alone	37 (54.4%)	19 (55.9%)	18 (52.9%)	1.0
Combination insulin and oral hypoglycaemics	11 (16.2%)	4 (11.8%)	7 (20.6%)	0.510
Diet-controlled diabetes	10 (14.7%)	5 (14.7%)	5 (14.7%)	1.0
Cardiovascular disease	24 (35.3%)	11 (32.3%)	13 (38.2%)	0.612
Hypertension	48 (70.6%)	23 (67.6%)	25 (73.5%)	0.595
Neuropathy	37 (54.4%)	17 (50%)	20 (58.8%)	0.465

361 * significant difference between groups

362

Table 2: Primary and secondary outcome measures of ankle dorsiflexion range of motion and forefoot plantar pressure variables at baseline and 8 week follow up. Values are means (standard deviations) unless otherwise stated.

Measure	**Intervention**		**Control**		**Adjusted mean† difference (95% CI)**	**p value**
	Baseline	**Follow-up**	**Baseline**	**Follow-up**		
Ankle DF non-WB (%)	-0.4 (3)	0.8 (4.7)	-0.4 (2.5)	-0.5 (2.9)	1.3 (-0.3, 2.9)	0.101
Ankle DF WB (%)	33.1 (7.5)	35.2 (7.9)	32.9 (6.5)	34.5 (6.9)	0.5 (-2.6, 3.6)	0.734
In-shoe						
Peak Pressure (kPa)	234.8 (46.3)	234.3 (49.5)	245.2 (58.8)	241.9 (56.3)	1.5 (-10.0, 12.9)	0.803
PTI (kPa*s)	82.7 (22.1)	78.9 (18.0)	84.6 (27.2)	83.3 (27.1)	-2.9 (-7.5, 1.8)	0.225
Barefoot						
Peak Pressure (kPa)	682.0 (298.7)	633.2 (288.4)	693.3 (240.9)	661.1 (244.9)	-19.1 (-96.2, 58.1)	0.628
PTI (kPa*s)	82.1 (23.4)	71.3 (20.4)	84.3 (20.3)	78.9 (25.3)	-6.1 (-14.5, 2.3)	0.155

DF: dorsiflexion, WB: weight-bearing, PTI: pressure time integral, † adjusted for baseline effect

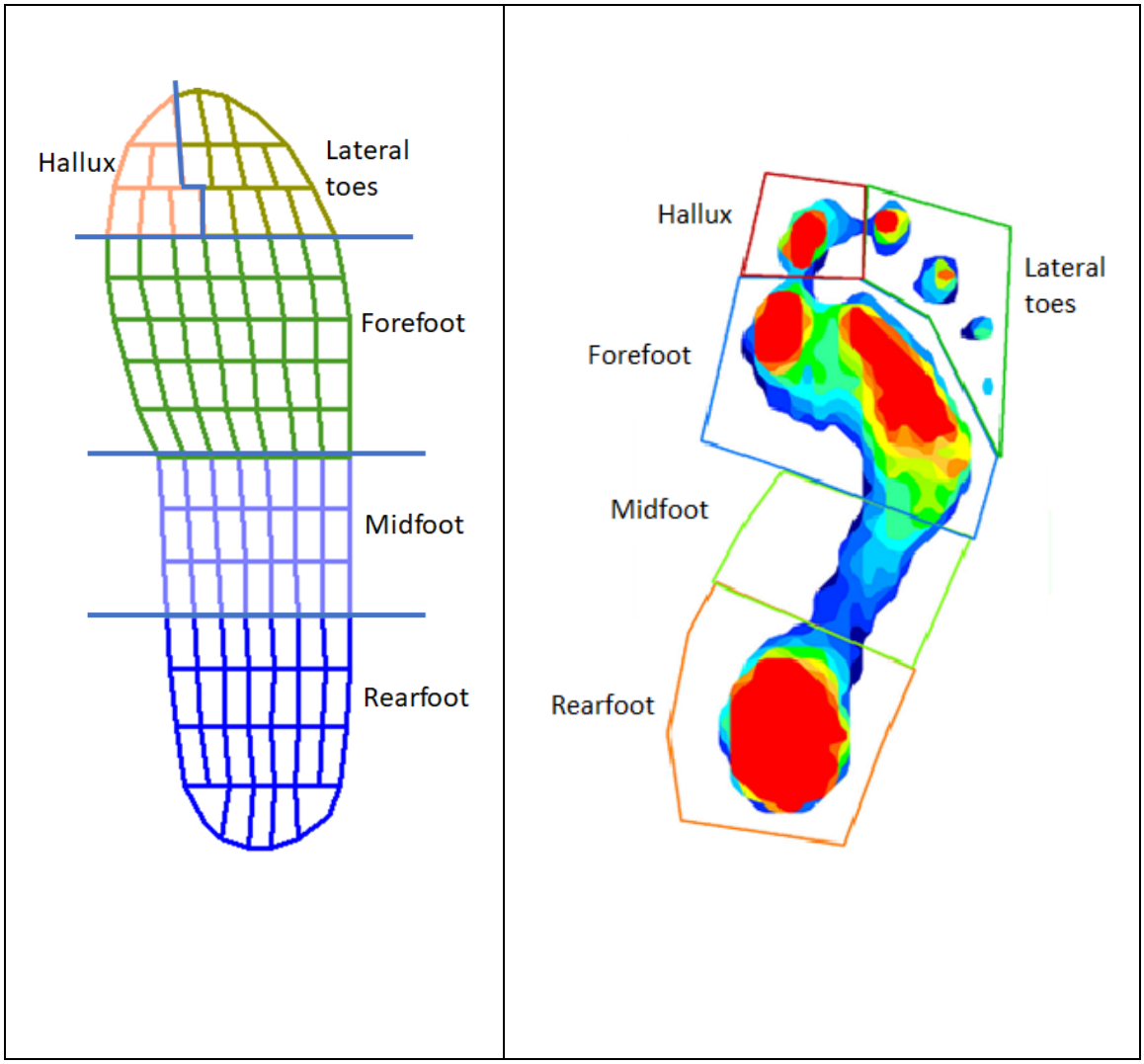

Fig. 1: The five footprint masks (forefoot, midfoot, rearfoot, hallux and lateral toes) displayed for the Novel Pedar-X ® footprint at the left, and over a typical Tekscan HR Mat™ footprint on the right.

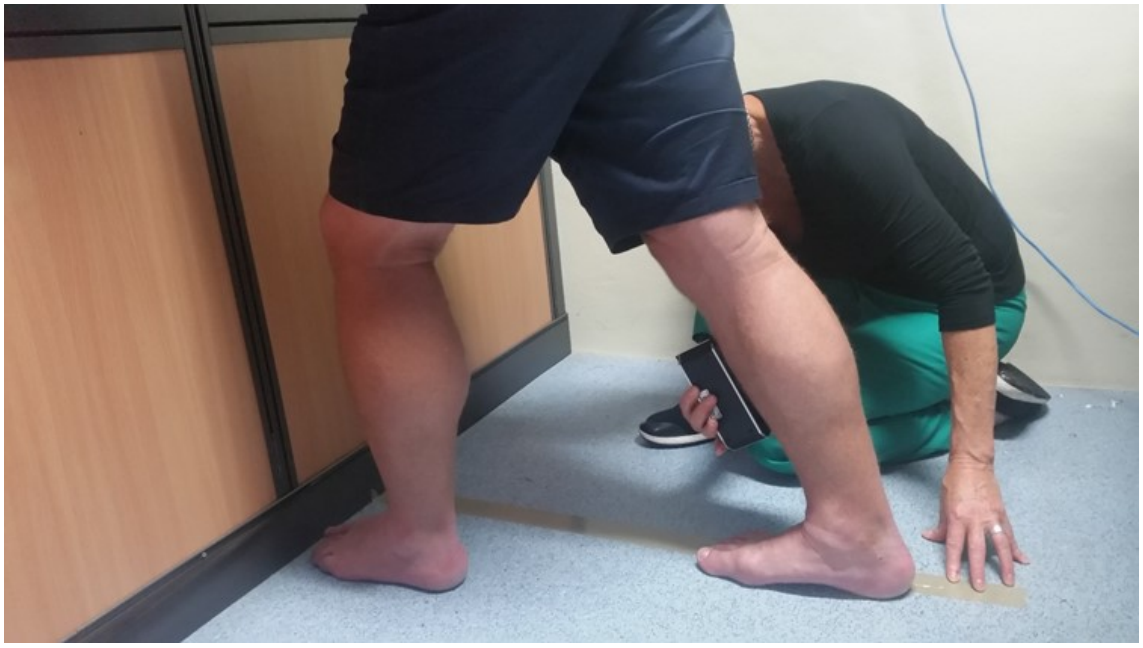

Fig. 2: Measurement of ankle joint dorsiflexion using a Lunge test with knee extended.

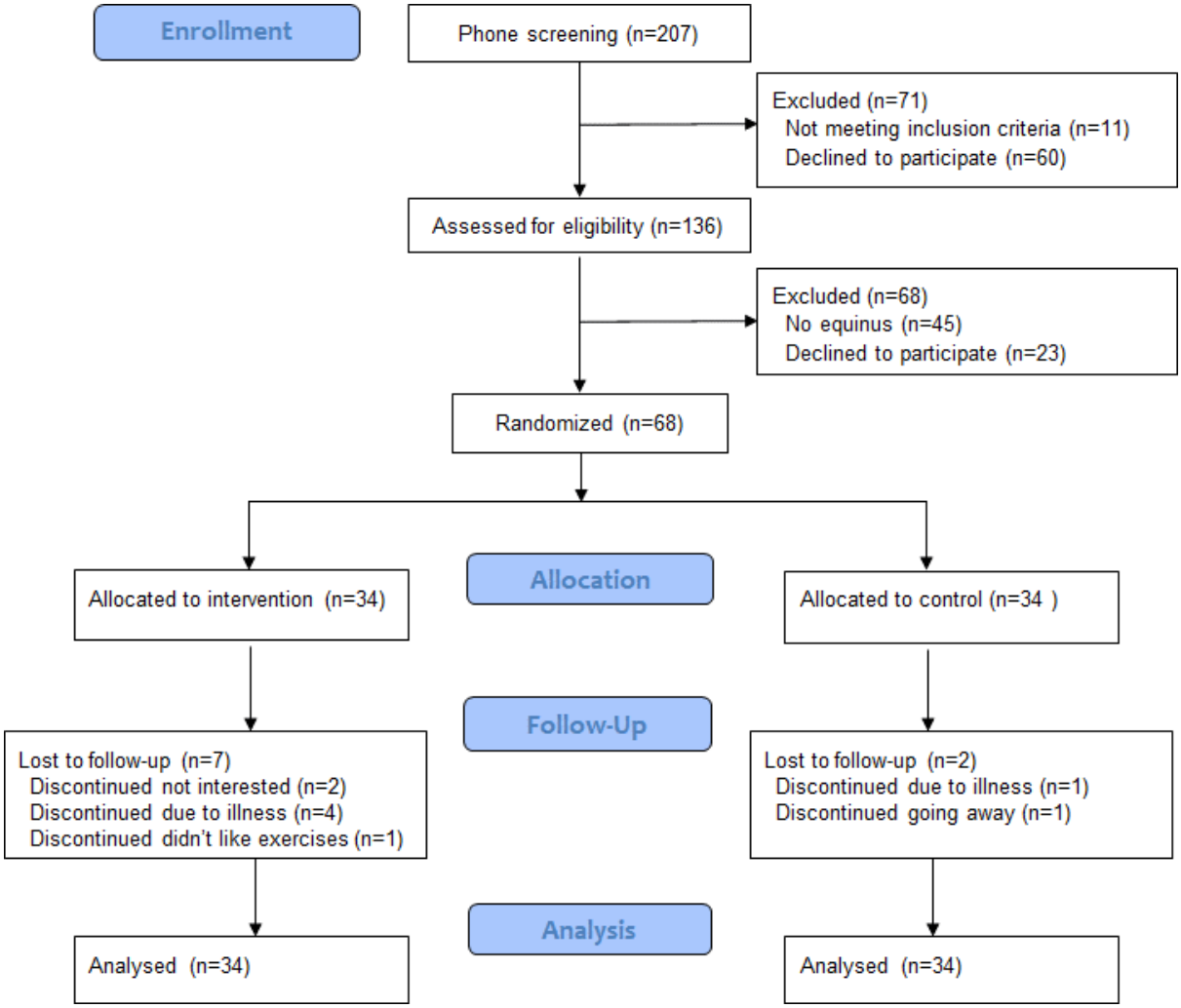

Fig. 3: Trial flow chart.

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