

# Online questionnaire, clinical and biomechanical measurements for outcome prediction of plantar heel pain: feasibility for a cohort study

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## Research

**Keywords:** Online Questionnaire, Graded Loading Challenge, Feasibility, Cohort.

**Posted Date:** May 19th, 2020

**DOI:** <https://doi.org/10.21203/rs.3.rs-28835/v1>

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**Version of Record:** A version of this preprint was published at Journal of Foot and Ankle Research on April 26th, 2021. See the published version at <https://doi.org/10.1186/s13047-021-00472-w>.

# Abstract

Background Plantar heel pain (PHP) accounts for 11-15% of foot symptoms requiring professional care in adults. Recovery is variable, with no robust prognostic guides for sufferers or clinicians. Therefore, we aimed to determine the validity, reliability and feasibility of questionnaire, clinical and biomechanical measures selected to generate a prognostic model in a subsequent cohort study. Methods Thirty-six people (19 females & 17 males; 20-63 years) were recruited with equal numbers in each of three groups: people with PHP (PwPHP), other foot pain and healthy controls. Eighteen people performed a questionnaire battery twice in a randomised order to determine online and face to face agreement. The remaining 18 completed the questionnaire battery once, plus clinical and biomechanical measurements. A progressive loading challenge was developed and assessed. Results There were no systematic differences between online and face to face administration of questionnaires (  $p$ -values all  $>.05$  ) nor an administration order effect (  $d = -0.31-0.25$  ). Questionnaire reliability was good or excellent (ICC 2,1\_absolute ) (ICC 0.86-0.99), except for two subscales. Full completion of the survey was only 77%, taking  $29 \pm 14$  minutes. Clinically, PwPHP had significantly less ankle dorsiflexion and hip internal rotation compared to healthy controls [mean ( $\pm$ SD) for PHP-OP-H =  $14^\circ(\pm 6)$ - $18^\circ(\pm 8)$ - $28^\circ(\pm 10)$ ;  $43^\circ(\pm 4)$ -  $45^\circ(\pm 9)$ - $57^\circ(\pm 12)$  respectively;  $p < .02$  for both]. Plantar fascia thickness was significantly higher in PwPHP (3.6(0.4) mm vs 2.9(0.4) mm,  $p = .01$  ) than the other groups. The graded loading challenge led to progressively increasing kinetic foot load. Conclusion Online questionnaire administration was valid therefore facilitating large cohort recruitment and being relevant to remote service evaluation and research. The graded loaded challenge increases load progressively and warrants future research. The physical and ultrasound examination revealed expected differences between groups. Clinician and researchers can be confident with these methodological approaches and the cohort study is feasible.

## Introduction

Plantar heel pain (PHP) is one of the most common foot and ankle problems, causing pain on the plantar aspect of the foot, particularly at the heel, and accounting for approximately 11–15% of all symptoms requiring professional care. People with PHP (PwPHP) often complain that the most severe pain occurs during the initial step, after a period of prolonged non weightbearing. The course of the disease has long been regarded as self-limiting but this is now known not to be the case.<sup>36</sup>

Various treatment strategies are proposed for PwPHP, but results are not satisfactory, with no accepted treatment of choice<sup>22</sup> and no clear prognostic indicators. Recovery rates from the many tested interventions vary between 50–80% at 6 months.<sup>9</sup> Footwear modification,<sup>51</sup> insoles and heel pads,<sup>3</sup> reduction in standing time, stretching<sup>16,43</sup> and shockwave therapy (ESWT)<sup>19</sup> have the best evidence for managing PHP. However, approximately 50% of individuals continue to have some symptoms after conservative treatment and at least 30% have recurrent symptoms.<sup>35</sup> The associated factors relevant to prognosis are thought to be a high body mass index (BMI) or sudden weight gain, excessive running, prolonged standing/walking, occupational environment, work-related weight bearing activities,<sup>29</sup> limited

ankle dorsiflexion, a cavus foot, excessive foot pronation<sup>50</sup> and psychological symptoms (e.g., depression, anxiety, and stress).<sup>12</sup> However, the prognostic evidence of these factors is neither complete nor causal.<sup>22</sup>

Prospective research for PwPHP has typically considered single or limited numbers of outcome predictors with analysis limited by relatively small sample sizes.<sup>22,23</sup> Although numerous studies using cross-sectional or matched case-control designs have been conducted,<sup>29,17</sup> at best single variable prediction models have been created.<sup>35</sup> In order to increase treatment success of more complex situations, enabling prognosis determination could be helpful by taking multi factors into consideration as in other pathologies.<sup>6,25</sup> Therefore, high-quality prospective cohort studies with a large sample size are needed to identify the relative importance of multiple outcome predictors. This would be useful to clinicians if the model performed better than single variables or overall clinician judgement of outcome.<sup>37</sup> In line with this purpose, a planned cohort study has been designed to build an accurate prognostic model for PHP outcome. Importantly, it may be that the model is specific to PHP but not other foot pain (OP), and so the investigation of people with other foot problems is needed to determine an outcome model that is specific to PHP.

In order to optimise the planned cohort study, it was essential to consider the validity and reliability of measures used and to evaluate their feasibility.<sup>40</sup> The planned cohort study will include online questionnaires, utilising normally completed in the presence of the clinician. Therefore, this feasibility study has three aims; firstly, to investigate the equality between online and paper version of questionnaires for remote use; secondly, to assess a novel graded loading challenge and thirdly we aimed to test validity, reliability and the feasibility of measures. The consort-PF<sup>18</sup> guidelines were consulted to guide study design.

## Methods

### Study population

A convenience sample of thirty-six participants with equal numbers of people with PHP, people with other foot pain (OP) and healthy controls were recruited from private clinics and local facilities in London, UK. The inclusion criteria were a diagnosis of PHP from a clinician for the PHP group and a diagnosed ankle or foot musculoskeletal condition for the OP group. Healthy controls were defined as not having any foot and ankle related problems. People under 18 years of age were the only exclusion.

The study procedures were ethically approved by QMERC ethics committee (approval No. QMREC2014/24/153). Written informed consent was sought from each recruited participant prior to study entry either via the online questionnaire or face to face.

### Measures

## Questionnaire battery

An online survey was constructed and administered using 'SurveyMonkey' ([www.surveymonkey.com](http://www.surveymonkey.com)). The standard patient reported outcome measures (PROMs) format was reproduced as closely as possible using the same wording of the items and instructions. The online survey consisted of eight PROMs and miscellaneous questions designed to collect outcome measures, consisting of pain severity, restriction level of some activities, kinesiophobia, and perception of pain, physical activity level, quality of life, age and BMI, which are all considered as relevant factors for prediction of PHP prognosis

The Foot and Ankle Outcome Score (FAOS) was used to assess foot and ankle problem severity, activity limitation, and participation restriction.<sup>34,44</sup> Psychosocial features were evaluated by the Pain Catastrophizing Scale (PCS) and Fear-Avoidance Belief Questionnaire (FABQ);<sup>49</sup> psychological variables are common in people with chronic musculoskeletal pain and are associated with pain and function<sup>13</sup>. Physical activity level was assessed with the Global Physical Activity Questionnaire (GPAQ)<sup>1</sup>; evidence suggests that a history of occupational/daily activities involving long periods of standing or inactivity may be associated with PHP.<sup>28,34</sup> Additionally, PHP has a significant negative impact on foot-specific and general health-related quality of life, itself assessed by using the EQ-5D-5L.<sup>24,30</sup>

## Clinical examination & Ultrasound assessment

A subset of eighteen participants underwent a lower-extremity physical examination, consisting of selected clinical measures based on clinical practice guideline<sup>34,36</sup> and clinical experience indicating relevance to prognosis. These measures included lower limb strength and range of motion measures,<sup>47</sup> mid-foot mobility<sup>8</sup> and palpation of the heel and calves.<sup>36</sup>

Ultrasound scanning (US) was used to examine the plantar fascia at its origin and mid-section, with long-axis sonograms using a 7.5 MHz probe (GE Logiq S8, Milwaukee, WI, USA). Heel pad thickness, echogenicity, bony erosions, heel spurs, ossification, and signs of fascia rupture or fibroma were sought as reduced fascia thickness and other US findings could also be a sign of PHP recovery.<sup>22</sup>

Neovascularization was graded using a modified Ohberg grading scale from 0-5.<sup>46</sup>

## Biomechanical assessment

Biomechanical assessment was performed twice (2–7 days between tests) with a subset of nine participants. A graded loading challenge (GLC) was developed to assess pain response and movement features in response to increasing step length and weight carried. The test consisted of four different difficulty levels: 1) normal walking with self-selected speed and step length, 2) walking with a 25% longer step length of participants' original step, 3) normal walking while carrying a load of 25% of body mass (BM), and 4) walking with the 25% longer step length plus the extra 25% load, which is a combination of tasks two and three. Participants performed each level 10 times, with each repetition consisting of six (level 1 and 3) or four (level 2 and 4) steps prior to the force plate and the same number of steps after; the total walking distance of walking was approximately 11 meters.

Kinetic and kinematic motion capture were performed during the GLC utilising in-floor force plates (500 Hz; 9281CA, Kistler) and an infrared motion analysis system (100 Hz; CX-1, Codamotion, Charnwood Dynamics Limited, Leicestershire, UK), respectively Thirty infrared markers were used, consisting of 14 individual markers on foot anatomical landmarks using Leardini protocol,<sup>32</sup> four rigid clusters of four markers were placed bilaterally on shank and thigh, and four markers were located on the anterior and posterior superior iliac spine.

## **Validity, Reliability and Feasibility of Procedures**

Thirty-six participants were divided into two groups based on willingness to participate in the clinical and biomechanical examinations (Fig. 1). Eighteen participants undertook all assessments (second aim). The remaining 18 participants undertook the questionnaire battery online and face to face (first aim).

### **Validity**

#### **a) Questionnaire Validity**

To assess the validity of delivering the questionnaires online, the delivery was conducted online and face-to-face in a randomised order.

#### **b) Clinical and Biomechanical Validity**

Validity of the clinical and biomechanical measurements was assessed utilising known-group validity (i.e. ability to detect differences between the three groups). This approach was considered to allow selection of useful measures for the proposed cohort study.

### **Reliability**

Survey reliability was evaluated by testing the consistency of measures regardless of administration type. Biomechanical measures were compared between the two testing sessions for consistency.

### **Feasibility**

Feasibility was assessed by completion time and feedback from participants/assessor.

### **Calculation of Sample Size**

The sample size was calculated separately for validity and reliability. Validity sample size was calculated using G\*Power (version 3.1), based on the FAOS foot function subscale. According to previous studies showing mean scores of  $57.8 \pm 24.4$ ,  $74.61 \pm 21.94$ ,  $96.1 \pm 12.4$  for PHP, OP and C, respectively,<sup>30,33</sup> a minimum of 18 participants was required for validity based on 90% power, and an  $\alpha$  level of 0.05. Sample size calculation for reliability was based on ICC values. A method that explicitly incorporates a prespecified probability of achieving the prespecified width or lower limit of a confidence interval was utilized.<sup>55</sup> This resulted in 14 participants being required based on ICC limits of 0.6 and 0.9. A final

sample size of 36 participants was determined, consisting of 18 for validity, reliability and for feasibility.<sup>47</sup>

## **Data analysis**

A list of all the measures (battery of questionnaires, and clinical and biomechanical assessments) is shown in Table 1 (results section).

Table 1

Values for all measures are reported with validity, reliability and feasibility outcomes.

MEASUREMENTS	DOMAIN	PURPOSE	RESULTS	OUTCOMES
Patient Reported Outcome Measures (n = 36)				
Pain Catastrophizing Scale (PCS)	Psychosocial factors	V	LoA = $0.1 \pm 4.4$ ; $d = 0.01$ ; $p = 0.79$	Online use valid Reliable measure
		R	Excellent (ICC = 0.97)	Redesign order of questionnaires
		F	Patients reported psychosocial questions duplication	
Global Physical Activity Questionnaire (GPAQ)	Activity level	V	LoA = $-837 \pm 3636$ $d = -0.31$ ; $p = 0.33$	Online use valid
		R	Good (ICC = 0.83)	Reliable measure
		F	Designed logic between relevant question to avoid time wasting and make appropriate GPAQ for online use	Time Saving
Fear-Avoidance Belief Questionnaire subscale (FABQ)	Psychosocial factors	V	<i>PA</i> : LoA = $1.6 \pm 15.9$ ; $d = -0.06$ ; $p = 0.55$	Online use valid
		V	<i>W</i> : LoA = $-0.5 \pm 8.5$ ; $d = 0.25$ ; $p = 0.77$	Reliable measure
		R	<i>PA</i> Excellent (ICC = 0.92)	Redesign order of questionnaires
		R	<i>W</i> : Poor (ICC = 0.39)	
		F	Patients reported psychosocial questions duplication	
Health-related Quality of Life (EQ5D-5L)	Quality of Life	V	<i>VAS</i> : LoA = $-0.3 \pm 13.6$ ; $d = -0.26$ ; $p = 0.07$	Online use valid
		RV	<i>VAS</i> : Excellent (ICC = 0.94)	Reliable measure
		R	<i>State</i> : LoA = $-1.1 \pm 8.5$ ; $0.16$ ; $p = 0.55$	Easy to use in online
		F	<i>State</i> : Moderate (ICC = 0.64)	
			Easy to report & understandable	

MEASUREMENTS	DOMAIN	PURPOSE	RESULTS	OUTCOMES
Foot and Ankle Outcome Score (FAOS)	Physical factors	V	LoA = $1.3 \pm 10 - 2.5 \pm 18.2$ ; d = 0.11-0.16 p = 0.49-.08	Online use valid
		R		Reliable measure
		F	Excellent to moderate (ICC = 0.99 - 0.73)	Redesign look
		F	Patient answers inconsistent for last subscale.  Patients reported many questions in terms of physical factors	Reduce repetition
Miscellaneous questions for populations characteristics	Age (y)	V	LoA = $2.2 \pm 18.5$ ; d = 0.25; p: 0.77	Online use valid
	Selected risk factors	R V		Reliable measure
		R V	Excellent (ICC = 0.92)	Feasible to use
	Morning pain duration (mins)	R	LoA = $0.00 \pm 1.38$ ; d = 0.00; p > 0.99	
	Morning pain severity (VAS)	V	Excellent (ICC = 0.99)	
		R	LoA = $2.2 \pm 18.7$ ; d = 0.10; p: 0.34	
		F	Excellent (ICC = 0.94)  LoA = $-2.1 \pm 19.0$ ; d = -0.10; p: 0.33  Excellent (ICC = 0.94)  Easy to report & understandable	
Pain map	Foot pain map	V	Pain-spreading region with 66% agreement.	Valid Use
		R		Reliable measure
		F	%98 matched; the medial aspect of RF  clumsy system	Navigate Pain
Clinic Examination (N = 18)				



MEASUREMENTS	DOMAIN	PURPOSE	RESULTS	OUTCOMES
Foot mobility	Navicular drift	V	PHP = $6 \pm 3$ ; OP = $8 \pm 1$ ; C = $7 \pm 3$ mm;	Require more sensible measure. It will be therefore
		F	difficult to control medial movement	
	Navicular drops	V		changed measures with arch height ratio device
	MLA angle	F	PHP = $10 \pm 4$ ; OP = $9 \pm 4$ ; C = $12 \pm 9$ mm;	
		V	Difficult to determine the change	
	F	PHP = $160^\circ \pm 7$ ; OP = $156^\circ \pm 11$ ; C = $155^\circ \pm 5$ difficult to position and maintain the arms of the goniometer along the feet		
ROM	Hip IR	V F	PHP = $43^\circ \pm 4$ ; OP = $45^\circ \pm 9$ ; C = $57^\circ \pm 12$	Valid measure Binary outcome is needed
		V	Difficult to estimate centre of rotation	
	Ankle active DF	F		Some modifications are applied for accurate measure
		V	PHP = $27^\circ \pm 6$ ; OP = $25^\circ \pm 3$ ; C = $27^\circ \pm 3$	
		F	Difficult to estimate true vertical and horizontal positions PHP = $36^\circ \pm 4$ ; OP = $38^\circ \pm 10$ ; C = $37^\circ \pm 7$ The test was affected by instrumentation, differences among joint actions.	
1MTPJ DF				

MEASUREMENTS	DOMAIN	PURPOSE	RESULTS	OUTCOMES
Strength (oxford scale)	H. ER	V	PHP = $4.7 \pm 4$ ; OP = $4.8 \pm 4$ ; C = 5	Valid use
	Ankle PF	F	Difficulty to detect	Binary outcome needed to easy and practical use. Ankle PF test is changed with functional test
	Inversion	V	difference between grades	
	Intrinsic muscle	F	PHP = $4.9 \pm 2$ ; OP = $4.9 \pm 2$ ; C = 5	
		V	assesses muscles when contracting concentrically	
		F	PHP = $\pm 3.5 \pm 5$ ; OP = 5; C = 5	
		F	No difficulty is detected	
		PHP = $4,8 \pm 4$ ; OP = 5; C = $4.8 \pm 6$		
		Difficulty to control participation of other muscle groups		
Modify knee to wall	ADROM before NP DFROM in full	V	PHP = $20^\circ \pm 8$ ; OP = $21^\circ \pm 9$ ; C = $21^\circ \pm 7$	Sensible values
		V	PHP = $\pm 14^\circ \pm 6$ ; OP = $18^\circ \pm 8$ ; C = $28^\circ \pm 10$	Test need to be modified
		F	Navicular drop not clear	
Ultrasound Assessment (N = 18)				
Thickness	PF origin	V	PHP = $\pm 3.7 \pm 0.4$ ; OP = 2.6 $\pm 0.8$ ; C = $2.9 \pm 0.4$ mm.	Sensible values
	Mid PF	V		Sensible values
	Heel pad	V	PHP = $\pm 3.7 \pm 0.4$ ; OP = 2.6 $\pm 0.7$ ; C = $2.8 \pm 0.4$ mm.	Sensible values
		F	PHP = $8.4 \pm 0.2$ ; OP = $7.8 \pm 0.2$ ; C = $9.3 \pm 1.9$ mm.	
		Difficult to control pressure		
Biomechanical Assessment (N = 9)				

MEASUREMENTS	DOMAIN	PURPOSE	RESULTS	OUTCOMES
Graded loading challenge (GLC)	First vGRF peak (N/BW)	V	NW = 7626 ± 1565; LS = 8866 ± 1822; NWW = 9445 ± 1564; LSW = 10825 ± 1320  Excellent (ICC = 0.92–0.95)  Easy to measure & high-quality data	Valid use
		V		Reliable method
		R		GLC have altered measure feasible
		F		
Second vGRF Peak (N/BW)	V	NW = 7826 ± 1656; LS = 8598 ± 1859; WW = 9569 ± 1541; LSW = 10919 ± 1805	Valid use	
	R		Reliable	
	F	Good to excellent (ICC = 0.81–0.92)  Easy to measure & high-quality data	measure feasible	
Rate of force development (N. s <sup>-1</sup> )	V	NW = 4741 ± 1307; LS = 5949 ± 1671; WW = 5235 ± 1518;  LSW = 7356 ± 1799	Valid use	
	V		Reliable method	
	R		Reliable	
	F		Excellent (ICC = 0.91–0.96)  Easy to measure & high-quality data	measure feasible
1.MTPJ DF on Toe off phase of gait cycle	V	NW = 14°±6; LS = 15°±7; WW = 15°±8; LSW = 14°±6	Sensible values mod reliability	
	R		discard	
	F		Moderate (ICC = 0.60–0.71)  Time consuming	
MLA during midstance	V	NW = 139°±15; LS = 139°±15; WW C = 140°±13; LSW = 143°±14	Sensible values mod reliability	
	R		discard	
	F		Poor to Good (ICC = 0.53–0.78)  Time consuming	

To allow for ease of comparison and presentation of findings across different PROMs, all scores were adjusted to a scale of 0-100 if necessary. Specifically, the GPAQ, FABQ and PCS scores were multiplied by a hundred, and then divided by the maximum score possible on the scale.

To assess reliability of the pain maps, participant-selected locations were marked with 1 if they matched, and 0 if they did not, with unselected locations also counted as matching; total percentage similarity was then used for reliability.

Biomechanical data was processed and analysed using custom-written scripts in MATLAB version R2018b (Mathworks, Natick, MA). Force plate data were low-pass filtered (Butterworth, 6th-order and cut-off frequency of 10 Hz). The peak vertical ground reaction force (vGRF) at loading response (first peak) and terminal stance (second peak) were selected based on previous research<sup>41</sup>. Kinematic marker data were low-pass filtered (Butterworth, 4th-order and cut-off frequency of 12 Hz). Medial longitudinal arch (MLA) and first metatarsophalangeal joint (MTPJ1) angles were analysed at 50% stance and toe off, respectively. Toe off was identified using the markers on the MTPJ1, hallux and navicular bones, verified with vertical GRF. Both kinematic variables were calculated in sagittal plane<sup>32</sup>.

## Statistical analysis

For validity of online delivery, differences between online and face to face questionnaires were tested using Limits of agreement with Bland & Altman plots<sup>5</sup> and paired t-test, considering order effect. Cohen d statistic was used to show the magnitudes of differences between two modes. Cohen's d was interpreted as,  $0.20 < d \leq 0.50$  indicated a "small effect",  $0.50 < d \leq 0.80$  a "medium effect", and  $d > 0.80$  a "large effect".<sup>10</sup> Mann-Whitney U test with Bonferroni correction were used to assess differences between groups for clinical and US examinations. Graded Loading Challenge values were analysed with Repeated Measures. Reliability was determined with Intraclass Correlation Coefficients (ICC, two-way random, absolute agreement), classified as  $< 0.5$ ,  $0.5$  to  $0.75$ ,  $0.75$  to  $0.9$ , and  $> 0.90$  being poor, moderate, good, and excellent reliability, respectively.<sup>31</sup> Outliers were removed if they were not within three standard deviations ( $\mu \pm 3\sigma$ ).<sup>2</sup> All data were analysed using Microsoft Excel Version 2013 (Microsoft, California, USA) and SPSS Version 24.0 (SPSS, Chicago, IL).

## Results

### Validity

#### Online survey

Mean values for all PROMs between online and face to face did not differ significantly, (all *p-values*  $> .05$ ; Table 1, Fig. 2, Fig. 3). There were no systematic differences between face to face and online methods in terms of order or administration modes (Fig. 3 and Table 1).

#### Clinical examination & ultrasound assessment validity

Clinical assessment showed PwPHP have less active ankle dorsiflexion ROM and hip internal rotation compared to healthy controls. In terms of ultrasound findings, both plantar fascia thickness insertion

from calcaneus and 0.5 cm away from calcaneal insertion were significantly higher in PwPHP compare to others. (Table 1).

## **Biomechanical validity**

Biomechanical assessment demonstrated the GLC shows increases in maximum and second peak of GRFs with no progressive change in kinematics. (Fig. 4 & Table 1).

## **Reliability**

### **Online survey**

Questionnaire reliability was good to excellent (ICC 0.86–0.99) except for two subscales. The quality of life subscale (QoL) of Foot & Ankle Survey (FAOS) had an ICC of 0.73 [−0.21–0.91] and Fear Avoidance Behaviour Questionnaire (FABQ) work subscale had an ICC of 0.39 [−0.03–0.77] (Table 1 and Fig. 3). Pain maps were 98% matched between first and second assessments, with eight PwPHP clearly indicating the usual inferior-medial area as painful.

### **Biomechanical reliability**

Biomechanical assessment reliability was typically moderate to excellent (ICC 0.60–0.92) except for the MLA within the walking-with-weight task (Table 1).

## **Feasibility**

### **Online survey**

Completion rate was 73% and completion time was  $26 \pm 14$  minutes. Participants reported the survey to be too long and have some repetition, particularly questions about psychosocial factors. It has been recognized that some terminological words such as “Plantar Heel Pain” need to be well-defined for participant understanding. Moreover, some participants had technical difficulties with the online survey system and were reluctant to share some personal details such as date of birth. Participant feedback details is presented in the supplement

### **Clinical examination & US assessment**

Clinical assessment took average of 1 hour and 25 minutes. The measures have been streamlined by further practice to improve efficiency.

## **Biomechanics**

The kinetic and kinematic motion capture system was found to be a feasible method for measuring of the foot and ankle during walking. No subjects reported any discomfort or undesirable effects associated with the use of the sensors.

## Discussion

This was a comprehensive validity, reliability and feasibility study designed in order to optimise a large planned prospective cohort study. Importantly, some of the questionnaires had not previously been tested for remote use, but we found the online approach was valid and suitable. A novel grade loading challenge test progressively increased kinetic load and may represent a potentially useful assessment tool for plantar heel pain severity. The validity of clinical, ultrasound and biomechanical measures was confirmed. Reliability of measures was also typically good or excellent. Overall, the measures included in this feasibility study, and the protocols developed, are feasible for the planned cohort study. Key lessons included improving explanation of technical words but otherwise feasibility was acceptable.

## Interpretation of outcomes

### Validity

Patient-reported outcome measures (PROMs) are becoming more commonly applied<sup>48</sup> for research health care evaluation purposes, with technology enabling easier access to more participants at lower cost. These advantages are central to maximising cohort study recruitment, but different administration modes require validation compared to the original.<sup>38</sup> In a recent meta-analysis concerning PROMs equivalence between computer and paper versions, the average correlation of 278 PROMs was excellent<sup>21</sup> similar to responses to a comparison across 16 health-related measures.<sup>42</sup> None of the current foot and ankle or more generic PROMS had been previously evaluated,<sup>21</sup> but the demonstrated limits of agreement<sup>4</sup> identified no systematic bias and compared well to previously reported questionnaire properties.<sup>20</sup> For example, our FAOS results (LoA = 9.13) compared favourably with published minimally important subscale differences ranging from 5.8 to 11.1,<sup>15</sup> giving confidence about online use. The consistent agreement between methods means that researchers and clinicians can be confident using these methods with similar populations although they may need to consider the particular population of interest and their e-Health literacy level in study or evaluation design.<sup>54</sup>

Clinical validity was important to consider, despite established procedures being used that have face validity.<sup>53</sup> We assessed whether between-group differences were of similar direction and magnitude to published work, accepting that we had powered the study primarily to assess questionnaire measure validity and the clinical aspects were relatively underpowered meaning differences, or their absence, would have to be interpreted with caution. As expected, PwPHP have less ankle dorsiflexion ROM and hip internal rotation compared to healthy controls (Table 1) which compares favourably with published data<sup>14</sup>. However, our measured differences in first metatarsophalangeal joint movement ( $36 \pm 4^\circ$  versus  $37 \pm 7^\circ$ ) were of the same direction but smaller than reported values ( $46.2 \pm 7.3^\circ$  versus  $68.5 \pm 13.0^\circ$ )<sup>14</sup> between PwPHP and control group. Similar to Wearing et al., our plantar fascia thickness measures agreed well. Control group insertion and 0.5 cm away from calcaneal insertion were higher in PwPHP.<sup>52</sup>

Overall, the clinical comparison of PwPHP and controls shows expected directions and magnitudes of differences supporting deployment of this protocol.

Considering that mechanical overload is thought to be a causal reason for PHP, and instrumented gait analysis the gold standard, we attempted to construct a graded loading challenge based on previous work to progressively challenge the load-bearing capacity of the plantar fascia by manipulating stride length and carried load.<sup>45</sup> If compressive or tensile load are aggravating factors for PHP, our results suggest the graded loaded challenge tasks may be a useful indicator of severity, particularly as the kinetic values show a graduated increase with task (Fig. 4).

## Reliability

The ICC calculated for the overall risk factor scores such as pain duration and severity were excellent (ICC 0.92–0.94), which again suggests equivalence.<sup>11</sup> Previously validated questionnaire reliability was typically good to excellent (ICC 0.86–0.99), except one subscale of the FABQ (work) and FAOS (QoL). However, FAOS comparisons have previously shown remote use suitability.<sup>39</sup> This may indicate that our online questionnaire order, design and burden led to problems and requires further consideration. Finally, the biomechanical measures were repeated and demonstrated similar (Table 1) reliability to published work for kinetics.<sup>27</sup> Kinematic re-test reliability was not as comparable necessitating particular care with marker placement.

## Limitations

The questionnaire design was kept as close to original as possible. However, some wording and layout had to be changed for the online mode; these 'faithful migrations'<sup>21</sup> are acceptable but required the comprehensive testing detailed here. The Patient specific function scale (PSFS) had to be removed as the technology does not yet allow the responses from one questionnaire to be carried forward to follow-ups.<sup>26</sup> An open-ended question will be utilized instead of PSFS in the cohort study. This feasibility study did not implement or evaluate the follow-up process.

## Feasibility lessons

In order to optimise questionnaire design, maximise data security, facilitate automated follow-up and enable eligibility screening we redesigned the survey to work on a different platform (SmartTrial 15005-ST-0021, MEDEI ApS, Aalborg, Denmark) and pain mapping was moved to a high-resolution and detailed digital-body chart using the NavigatePain application Version 1 (Aalborg University, Aalborg, Denmark). In doing so, the repetition from the original survey was removed, without compromising questionnaire validity, and the process streamlined to reduce time and inconvenience. A decision to add health literacy assessment was taken in order to ensure population characteristics and data credibility. The clinical, ultrasound and biomechanical examinations were streamlined to reduce contact time, and improve ease of collection.

## Conclusion

Questionnaire administration by online methods is valid and reliable, therefore it could be ideal for remote monitoring of patients for clinical and research purposes, including our planned cohort study. A graded loading challenge designed to progressively increase kinetic load was shown to be a potentially useful assessment tool for plantar heel pain severity and worthy of further research. Hence, the questionnaire and graded loading challenge results in particular could be utilized by clinicians and researchers for a wide range of purposes. The cohort study is feasible.

## Abbreviations

BMI → Body mass index

FABQ → Fear-Avoidance Belief Questionnaire

FAOS → Foot and Ankle Outcome Score

GLC → Graded loading challenge

GPAQ → Global Physical Activity Questionnaire

ICC → Intraclass Correlation Coefficients

MLA → Medial longitudinal arch

MTPJ1 → First metatarsophalangeal joint

OP → Other foot pain

PHP → Plantar heel pain

PwPHP → People with PHP

PROMs → Patient reported outcome measures

PCS → Pain Catastrophizing Scale

vGRF → Vertical ground reaction force

## Declarations

Ethics approval and consent to participate

Obtained.

Consent for publication

Not applicable



## Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request

## Competing interests

The authors declare that they have no competing interests

## Funding

This research was indirectly funded by PhD student's scholarship but approved by external ethical review. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Authors' contributions

DM designed the study and determine main outcomes. TP analysed and interpreted the patient data regarding clinical perspective. SM and ABJ analysed and interpreted the patient data of biomechanics. HG performed the examinations and was a major contributor in data collections and writing the manuscript. All authors read and approved the final manuscript.

## Acknowledgements

The authors would like to thank Mr. Ata Otaran for his contributions to the biomechanics data analysis. In addition, the authors also would like to specifically thank Mr. Abdulhamit Tayfur and Mr. Mehmet Delen for their help at various stages of the study.

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## Figures

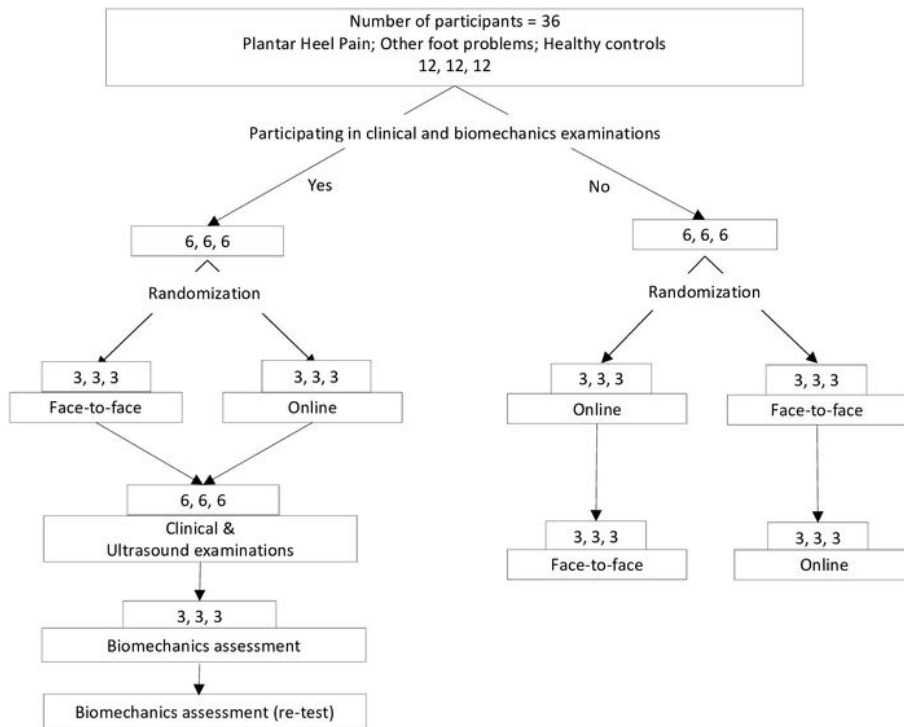


Figure 1: Feasibility study design with randomization.

## Figure 1

Feasibility study design with randomization.

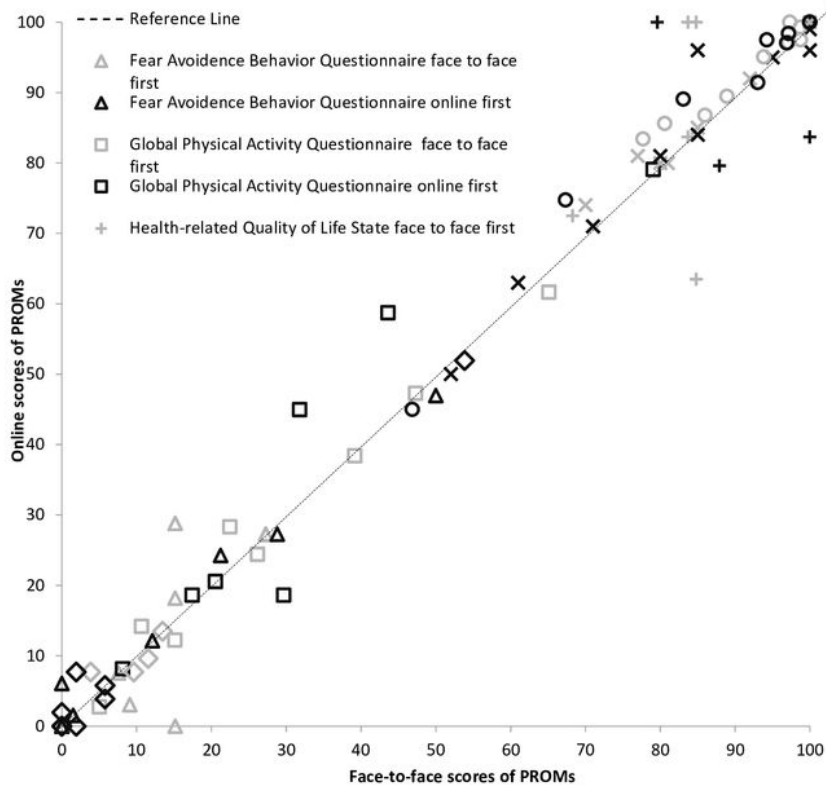


Figure 2: Systematic differences between face to face and online administrations. Two methods of data collections as face to face and online with a systematic difference from Table 1. All values are normalized with in a 100-total score. Broken dash line represent line of identity. Key= FAOS: The Foot and Ankle Outcome Score; PCS: Pain Catastrophizing Scale; FABQ: Fear-Avoidance Belief Questionnaire; GPAQ: Global Physical Activity Questionnaire; EQ-5D-5L: Health-related Quality of Life.

## Figure 2

Systematic differences between face to face and online administrations.

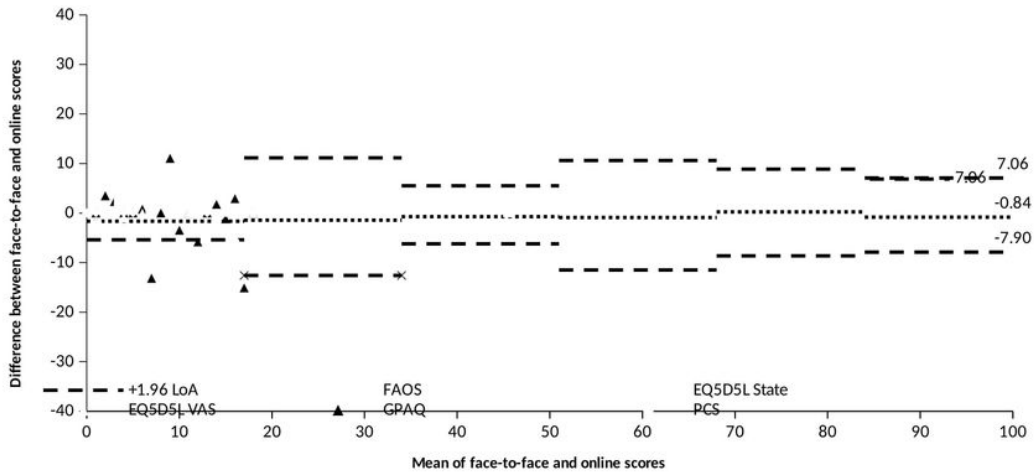


Figure 3: Bland–Altman plot of the relation between face to face and online scores of 5 PROMs and 2 subscales. The combined plots is based on the data presented in table 1. Dashed lines present 95% limits of agreement, where upper limits of agreement (LOA) is +1.96 SD and lower LOA is -1.96 SD from mean difference of methods. Here, the mean differences are between -1.1 and 1.6, whereas the highest limits of agreement are -12.58 and 11.13 out of 100 total score of EQ5D\_5L state, indicating that 95% of the differences between these two measurements are within this range. Key= FAOS: The Foot and Ankle Outcome Score; PCS: Pain Catastrophizing Scale; FABQ: Fear-Avoidance Belief Questionnaire; GPAQ: Global Physical Activity Questionnaire; EQ-5D-5L: Health-related Quality of Life.

### Figure 3

Bland–Altman plot of the relation between face to face and online scores of 5 PROMs and 2 subscales.

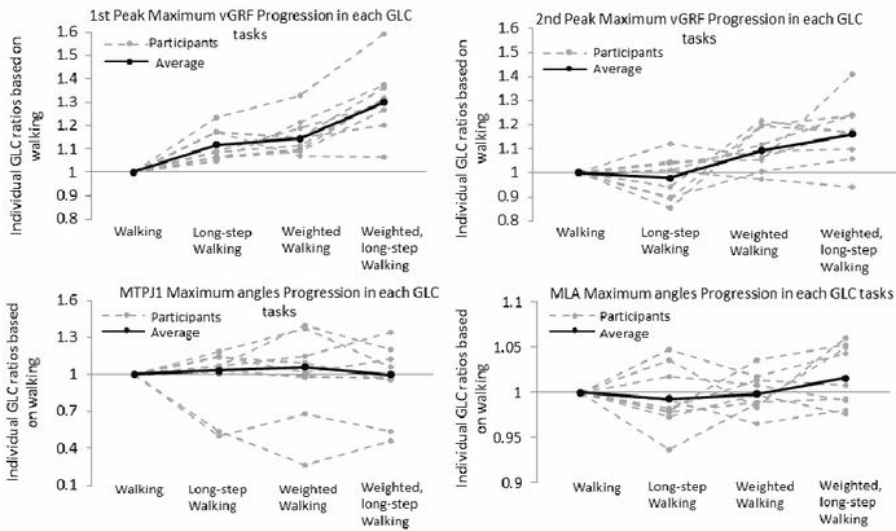


Figure 4: Individual ratio values of 9 participants for biomechanics measures progression in order of GLC tasks— the values in each tasks are divided results of walking by assuming walking values as baseline. Dashed grey lines are presented individual ratios of each participants; Thick black line is the ratio of mean values; Horizontal grey line at 1 is showing reference line. Key=vGRF: vertical Ground Reaction Forces; MLA: Medial Longitudinal Arch Angle; 1MTPJ: First metatarsal phalangeal joint; GLC: Graded Loading

## Figure 4

Individual ratio values of 9 participants for biomechanics measures progression in order of GLC tasks.