From Evidence to Data Framework: Decision Factors and Structured Data for AI-Driven Clinical Decision Support Systems in Offloading Footwear

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Abstract

Background

Diabetes-related foot ulcers (DFUs) are a serious complication of diabetes, often resulting in infection, amputation, or even mortality. Offloading footwear is a key intervention that promotes ulcer prevention and healing by reducing pressure on affected areas of the foot. However, patient adherence to prescribed footwear remains low. Current clinical guidelines, such as those from the International Working Group on the Diabetic Foot

(IWGDF), offer general recommendations but lack a standardized and structured framework. Furthermore, they do not support personalized footwear prescription or integration into clinical decision support systems (CDSSs) and artificial intelligence (AI) applications.

Objective

The primary objective of this study was to identify and systematically categorise the key factors influencing footwear prescription and design for patients with DFUs. A secondary objective was to integrate these factors into a structured framework aligned with HL7 Fast Healthcare Interoperability Resources (FHIR) standards, with the goal of informing the development of AI-powered CDSSs.

Methods

A systematic scoping review was conducted in accordance with the PRISMA-ScR guidelines. Seventeen academic databases and Google Scholar were searched for relevant studies published between 2014 and 2025. Eligible studies included original research involving adults with diabetes or diabetic foot ulcers (DFUs) and focused on offloading footwear or orthotic interventions. Data were extracted and categorized using the WHO Dimensions of Adherence to Long-Term Therapies framework and mapped to FHIR resources using standardized terminologies such as SNOMED CT, and LOINC. Where existing standards were insufficient, custom FHIR extensions were proposed.

Results

A total of 81 studies met the inclusion criteria, encompassing data from 5,001 participants. Key outcome measures across the studies included plantar pressure reduction (n = 55), adherence (n = 27), gait and balance (n = 20), and ulcer recurrence (n

= 13). The review identified 90 unique decision factors influencing footwear prescription, classified according to the five WHO dimensions of adherence to long-term therapies: patient-related, condition-related, therapy-related, socioeconomic, and healthcare system–related factors. Of the 90 factors identified, 48 were categorized as input variables and 42 as output variables. The review found that only 16/90 of the decision factors could be mapped directly to existing FHIR standards, while the remaining 74/90 required custom extensions—particularly those related to detailed footwear attributes and socioeconomic patient data. This is because of the unique nature of the domain as the result of lack of standardized definition related to the domain.

Conclusions

This study introduces the first structured and interoperable framework for prescribing offloading footwear in the management of diabetic foot ulcers (DFUs). By aligning key decision factors with HL7 FHIR standards and the WHO Dimensions of Adherence, the framework enables seamless integration into electronic health records and supports the development of AI-driven clinical decision support systems (CDSSs). Future work should prioritize expert validation of the identified factors, implementation studies, and real-world testing to evaluate the framework's usability, clinical relevance, and impact on patient outcomes.

Keywords: Diabetic foot ulcer, clinical decision support systems, offloading footwear, orthotics, ulcer healing, plantar pressure, footwear adherence

Introduction

Diabetes-related foot ulcers (DFUs) are a serious complication of diabetes, affecting approximately 15% of diabetes patients in their lifetime [1]. While repetitive mechanical stress on the foot is the primary cause of DFUs, other conditions such as diabetic peripheral neuropathy (DPN) and peripheral arterial disease (PAD) further impair healing and increase the risk of infections [2]. If left untreated, DFUs can lead to severe complications, including amputations, and higher mortality rates[3]. Despite developments in DFU care, significant gaps persist in optimizing clinical interventions such as offloading footwear [4, 5].

Appropriate offloading footwear is a key intervention for reducing excessive plantar pressure (PP) and redistributing mechanical stress, subsequently preventing DFU formation and allowing ulcers to heal [6]. The efficacy of offloading footwear is well-documented, with studies demonstrating significant reductions in PP and slower DFU progression [7-9]. Additionally, research evidence suggests that around 75% of DFUs can be prevented with offloading footwear [10]. Despite these benefits, the effectiveness of footwear is impaired due to lack of adherence by patients. As a result, approximately 40% of DFU patients with low adherence experience a recurrence within one year of healing, and 65% within five years [11]. Various studies have found different reasons behind the lack of adherence. For instance, some studies have indicated that patients often underutilize offloading footwear due to aesthetic concerns, discomfort, or a lack of perceived benefits [12-14]. Another study found that patients often struggle to integrate prescribed footwear into their daily routines [15]. Furthermore, factors such as fit, lifestyle constraints, and cultural beliefs are also been shown to influence adherence [16]. While specific findings behind low adherence vary among studies, non-clinical factors play a major role in this. As a result, research suggests a patient-centric approach that accounts for both pathological and non-pathological factors to improve adherence [4].

Current guidelines, including those from the International Working Group on the Diabetic Foot (IWGDF) [17], and Australian guidelines [18] provide evidence-based recommendations for DFU prevention. While these guidelines outline key features of DFU offloading footwear, such as appropriate fit, cushioning, and rigidity to offload high-pressure regions of the foot, they do not account for specific non-clinical factors. A systematic review of DFU guidelines has highlighted a lack of standardized and structured frameworks for footwear prescription [19]. Current approaches often emphasizing general recommendations rather than defining a comprehensive set of attributes necessary for effective prescription [19]. Footwear prescription for DFU patients is a complex process involving various clinical and non-clinical factors, as well as personalization based on patient needs. In addition to clinical factors, effective footwear prescription requires consideration of non-clinical factors such as patient expectations, living environments, and footwear aesthetics to enhance adherence [4]. This added complexity underscores the need for standardization to improve clinical efficiency and ensure optimal patient outcomes.

Despite the well-established role of footwear in DFU prevention, a significant gap exists in the literature regarding the standardization of factors needed for making footwear decisions. Existing studies primarily focus on specific footwear components, such as insole materials or rocker profiles, but lack a comprehensive framework defining the essential decision factors for prescription. This absence of standardization leads to variability in footwear recommendations and affects the development of optimal prescriptions for individual patients. This scoping review aims to address this gap by systematically identifying key decision factors and developing a standardized framework to guide data collection in practice. By synthesizing existing literature, this study will establish a foundation for improved data collection and the development of artificial intelligence (AI)-driven clinical decision support systems (CDSS) for footwear prescription. These CDSSs can assist healthcare providers in making evidence-based decisions and potentially improve patient outcomes such as reducing ulcer incidence, promoting efficient healing, and improving adherence.

Study Objectives

- To identify and categorize key factors used in DFU footwear prescription decisions across clinical studies.
- To establish a structured framework of data elements for DFU footwear prescription, providing a foundation for AI-driven clinical decision support systems.

Methods

Study Design

This study conducts a systematic scoping review to explore quantitative and qualitative studies that identify factors influencing the prescription of offloading footwear for diabetic foot ulcers (DFUs), and to summarize these factors along with appropriate data types and sample values. A scoping review is the most feasible study design to address the broad objectives of the study and map diverse empirical evidence. This review was guided by the methodologies of Arksey and O'Malley [20], Munn et al [21], and Pollock et al [22], and follows the Preferred Reporting Items for Systematic Review and Meta-analysis extension for Scoping Reviews (PRISMA-ScR) guidance [23]. The study does not assess methodical quality of the included studies because it does not align with the research objectives. The review was registered prospectively on the open science framework for systematic reviews [24].

Search Strategy

Search was facilitated through Primo Library Search tool. Primo contains the following list of databases: DOAJ Directory of Open Access Journals, EBSCOhost, ScienceDirect, Food Science Source, IngentaConnect, Ovid, Open Access Digital Library, ProQuest, PubMed, ROAD: Directory of Open Access Scholarly Resources, SAGE, Web of Science, SciTech, Scopus, Single Journals, Springer, and Wiley. Additionally, Google Scholar was searched to identify studies not included in Primo. The initial search strategy consisted of broad terms synonymous with "foot ulcer", "orthotics", "adherence" and "offloading footwear”. Further analysis of keywords from extracted articles was used to develop the final search strategy, as displayed in Table 1.

Table 1: Search keywords

Field	Search Terms	Boolean
1	“diabetes” OR “diabetic” OR ”diabetic foot ulcer*” OR ”diabetes-related foot ulcer” OR ”foot ulcer” OR ”ulcer”, OR ”adherence”, OR ”compliance”	AND
2	”ulcer prevention” OR ”offloading”, OR ”offload*” OR ”plantar pressure*” OR ”treatment” OR ”therapy”	AND
3	”footwear” OR , ”shoe*” OR ”insole” OR ”orthotics” OR ”ortho*” OR ”pedorthic”	

Eligibility Criteria

The reviews eligibility criteria is guided by the PICO framework [25], which is commonly used to guide research questions in the medical field. Studies were selected based on the following inclusion criteria: (1) population: adults aged 18 years and over, and a diagnosis of diabetes or DFU; (2) intervention: conventional offloading footwear or orthotics; (3) comparator: another treatment option or no treatment or no comparator; (4) outcome: Ulcer prevention (plantar pressure reductions, gait or balance, temperature changes, ulcer incidences, ulcer recurrence, or patient adherence, or other outcomes identified during data extraction) ; (5) type of study: the review included both epidemiological and experimental study designs including randomized controlled trials, non-randomized control trials, before and after studies, quasi-experimental, cross-sectional studies, prospective and retrospective studies, case study, and observational studies. Additionally, the study placed specific focus on recent research articles that were published between 2014 and 2025.

Excluded studies included those that were: (1) not accessible in full text, (2) review articles, (3) not original research including case series, case reports, and expert commentaries, (4) grey literature and thesis databases (5) did not focus on DFU population in isolation, (6) did not focus on offloading footwear in isolation, (7) did not focus on offloading footwear and orthotics in isolation, or (8) focused on removable cast walker(RCWs), (9) focused on specialized, smart, or intelligent footwear and insoles, or (10) did not sufficiently discuss the study outcomes.

Data Extraction and Charting

Study screening and data extraction was conducted by a team of researchers (KK, AK, LD, MN, SA). Potential studies were imported to Covidence for screening where two reviewers (KK and MN) independently screened each articles title and abstract. Articles marked for inclusion by both reviewers were moved to full-text screening, which was subsequently completed by the two reviewers (KK and MN). Any conflicts during the screening process were resolved by discussion among the research team. After screening, one reviewer (KK) extracted study characteristics including purpose of the study, year of publication, country of publication, study design, and population demographics using NVivo software. Additionally, the reviewer conducted a framework based thematic analysis with NVivo software. The thematic was used the WHO Dimensions of Adherence to Long-Term Therapies, systematically identifying and categorizing all data elements of footwear prescription into patient-related, condition-related, socioeconomic, therapy-related, and health-system-related factors. Subcategories and associated values will be thematically coded in NVivo under one of these categories. Furthermore, the study performed concept alignment with Fast Healthcare Interoperability Resources (FHIR) resources, where each data element was mapped to concepts in standardized terminology systems such as SNOMED, ICD-10, UCUM, and LOINC. Custom extensions were created for data elements that do not match existing concepts. The data extracted by KK was independently reviewed by two team members (LD, SA), where conflicts and disagreements will be resolved by a third reviewer (AK).

Data Extraction Frameworks

Data extraction was guided by two frameworks, "WHO Dimensions of Adherence to Long-Term Therapies" and "Fast Healthcare Interoperability Resources (FHIR)". The WHO Dimensions guided the thematic analysis while the FHIR resources was used for mapping the data elements to FHIR code systems.

WHO Dimensions of Adherence to Long-Term Therapies

The findings of the 2003 WHO report "Dimensions of Adherence to Long-Term therapies" was used to structure each studies data [26]. The report categorizes data elements into five key categories, namely, patient-related, condition-related, socioeconomic, therapy-related, and health-system related. The WHO report did not provide explicit definitions for the five domains, rather it lists factors that it believed to fall in that category.

Fast Healthcare Interoperability Resources (FHIR)

FHIR is the latest standard developed by Health Level 7 (HL7) to enhance information exchange among healthcare systems. These standards are essential for the adoption of electronic health record systems (EHRs) and their integration with CDSSs. FHIR resources can be mapped to real-world data elements, enabling structured and standardized data representation. This study categorized each identified data element into appropriate FHIR categories by mapping them to FHIR terminologies. The mappings were determined using standardized terminology databases supported by FHIR, such as SNOMED CT, RxNorm, and LOINC.

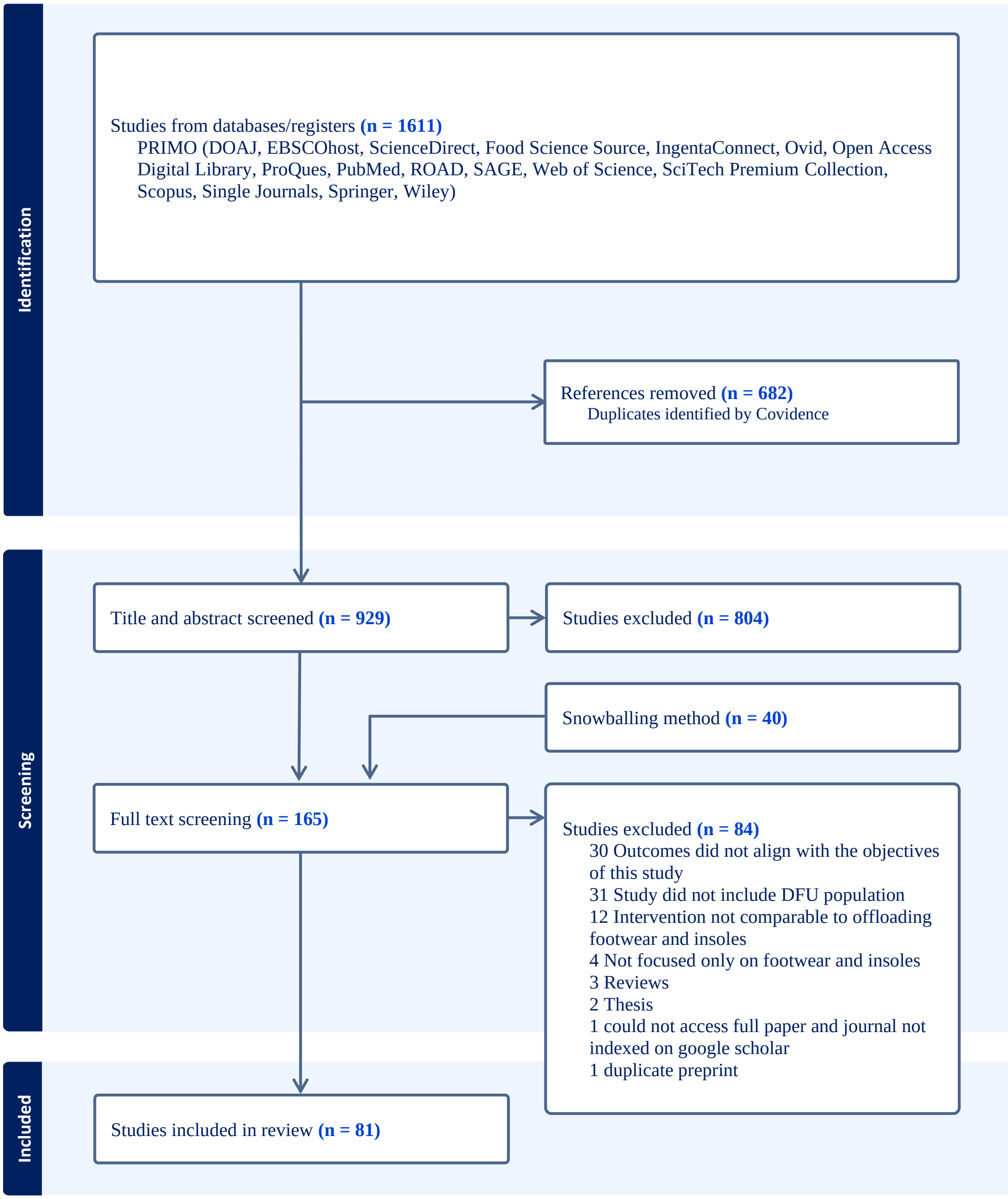
Ethical Considerations

Since this research was solely based on literature and did not engage any research participants or subjects, no formal ethics approval was required from the Charles Sturt University Human Research Ethics Committee.

Results

Study Selection

A total of 1,611 studies were identified across various academic journals. After removing duplicates using the Covidence tool, 929 unique records remained eligible for screening. Following the title and abstract screening, 125 articles were deemed eligible for full-text review. An additional 40 papers were identified at this stage through the snowballing technique, resulting in 165 articles eligible for full-text screening. After full-text assessment, 84 studies were excluded for reasons such as inaccurate outcomes, population mismatch, and inappropriate interventions. The PRISMA flowchart is shown in Figure 1.



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234 Figure 1: PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-

235 Analyses) diagram.

Study Characteristics

A total of 5,001 participants were included across the studies. The mean age was 46.01 years (SD 10.56), ranging from 18 to 84 years, indicating a predominance of middle-aged adults. Gender was inconsistently reported, with 1,813 participants (36.2%) identified as male and 1,007 (20.1%) as female. Diabetes type was not consistently described; among those with available data, 298 participants (6.0%) had type 1 diabetes and 1,729 (34.6%) had type 2 diabetes. Glycemic control was reported in a subset of studies, with a mean value of 56.91 mmol/mol (SD 14.93). Mean BMI was 30.0 kg/m² (SD 5.33), suggesting most participants were in the obese range. Mean weight was 80.76 kg (SD 15.37), and mean height was 166.38 cm (SD 8.46). This demographics information is presented in Table 2. Demographic variables such as gender and diabetes classification were frequently underreported, limiting subgroup analyses and the ability to assess representativeness across study populations.

Table 2: Participant Demographics

Category	**Participants (N = 5001)**
Age	46.01 ± 10.56
Age Range	18 - 84
Gender:	
Male	1813
Female	1007
Diabetes:	
Type 1	298
Type 2	1729
HbA1c (mmol/mol)	56.91 ± 14.93

BMI	30 ± 5.33
Weight (kg)	80.76 ± 15.37
Height (cm)	166.38 ± 8.46

Assessment of study origin by country indicated that the Netherlands is identified as the leading contributor, with 20 studies conducted in this setting [15, 27-45]. The United Kingdom [12, 46-53] and Australia [13, 54-60], each contributed 8 studies respectively. The United States contributed with 7 studies [12, 53, 61-65], while Spain has 5 studies [66-70]. Iran [52, 65, 71, 72], China [73-76], and Thailand [77-80] contributed 4 studies each. Germany [38, 81, 82], Malta [83-85], and Sweden [14, 86, 87] each contributed 3 studies. Several countries had 2 studies each, including India [88, 89], Italy [90, 91], Portugal [92, 93], and Egypt [94, 95]. The following countries contributed one study each: Jordan [96], Canada [97], Indonesia [98], Colombia [99], Singapore [100], Israel [101], and Fiji [102].

Four studies were conducted across multiple countries. One study was conducted between the Netherlands and Germany [38], another study was jointly conducted by the United States and the United Kingdom [12], two studies were conducted in collaboration between Iran and the United Kingdom [52, 65], and one study was conducted in United Kingdom and Germany [82]. These overlaps highlight a small but important trend toward international collaboration in technology-enabled diabetes and mental health care research.

Figure 2 presents the geographic distribution of study origins, revealing a clear imbalance between developed and developing countries. Western nations such as the Netherlands, the United Kingdom, and Australia dominate research contributions. In contrast, only a few developing countries are represented, and their contributions remain limited. This underscores the need for greater support and inclusion of developing nations in research within this field.

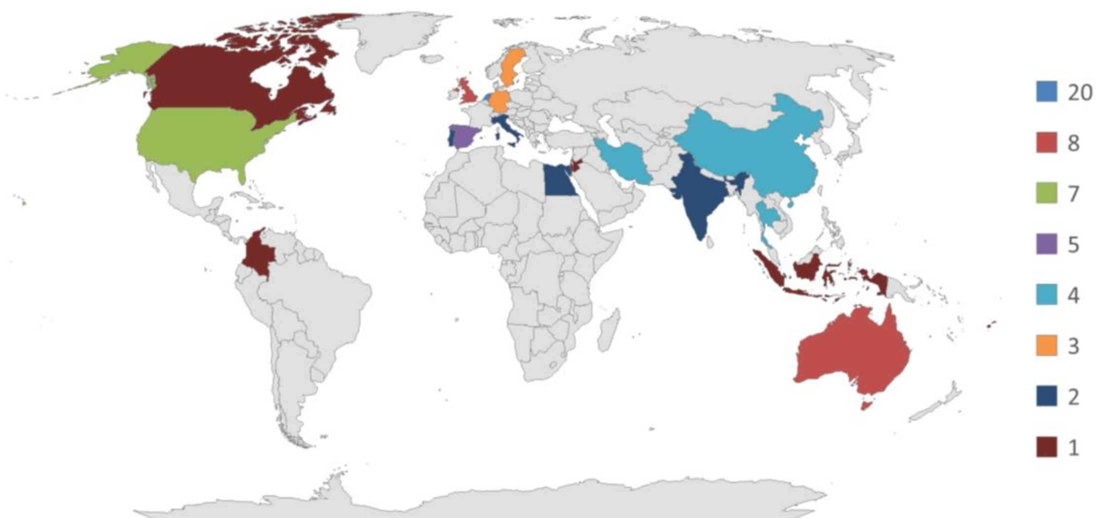

Figure 2: Countries by number of studies

Figure 3 summarizes studies based on the study designs. The most common design was the cross-sectional study (n=20), capturing data on exposure and outcome at a single time point. This design was used predominantly for prevalence estimates and behavior assessments [14, 15, 31, 37, 39, 41, 43-45, 58, 61, 68, 69, 76, 80, 84, 87, 90, 96, 103]. Randomized controlled trials (RCTs) were used by 12 studies, offering randomization and control groups to test intervention efficacy [27, 38, 46, 47, 49, 56, 62, 66, 86, 93-95]. A total of 14 studies were observational, where outcomes were tracked without intervention, often in real-world or longitudinal settings [12, 28, 29, 32, 40, 42, 55, 59, 67, 70, 73, 81, 85, 89].

Quasi-experimental study designs were utilized by nine studies, providing controlled conditions without randomization and were typically used to assess device or footwear effects across time or conditions [48, 51, 60, 65, 72, 74, 77, 79, 98]. Seven studies utilized qualitative assessments methodologies such as interpretative phenomenological analysis and thematic coding to explore patient perspectives on footwear adherence, usability, and self-management [13, 36, 50, 75, 97, 100, 102].

A group of randomized crossover experimental studies (n=7) used within-subject designs with randomized order of conditions, allowing participants to serve as their own control. This study design was a common approach in biomechanics and gait research [33, 35, 53, 78, 82, 99, 101]. Smaller and preliminary investigations included pilot studies (n=5), which focused on early-stage feasibility and effect trends [34, 52, 71, 88, 91], and feasibility studies (n=2), which tested practical implementation without assessing outcomes [63, 64].

Two studies used a pre-clinical mixed-methods design, combining qualitative and quantitative methodologies data across iterative phases involving usability, validation, and device refinement [57, 92]. One exploratory qualitative study [83] focused on user experience in context, and one retrospective clinical audit [54] reviewed historical clinical data to assess practice patterns across expected standards.

The included studies represent a methodologically diverse body of evidence, spanning from exploratory, hypothesis-generating research to confirmatory randomized controlled trials. This diversity reflects the evolution of a maturing research field that increasingly integrates clinical effectiveness with user-centered design, implementation science, and contextually informed evaluation approaches.

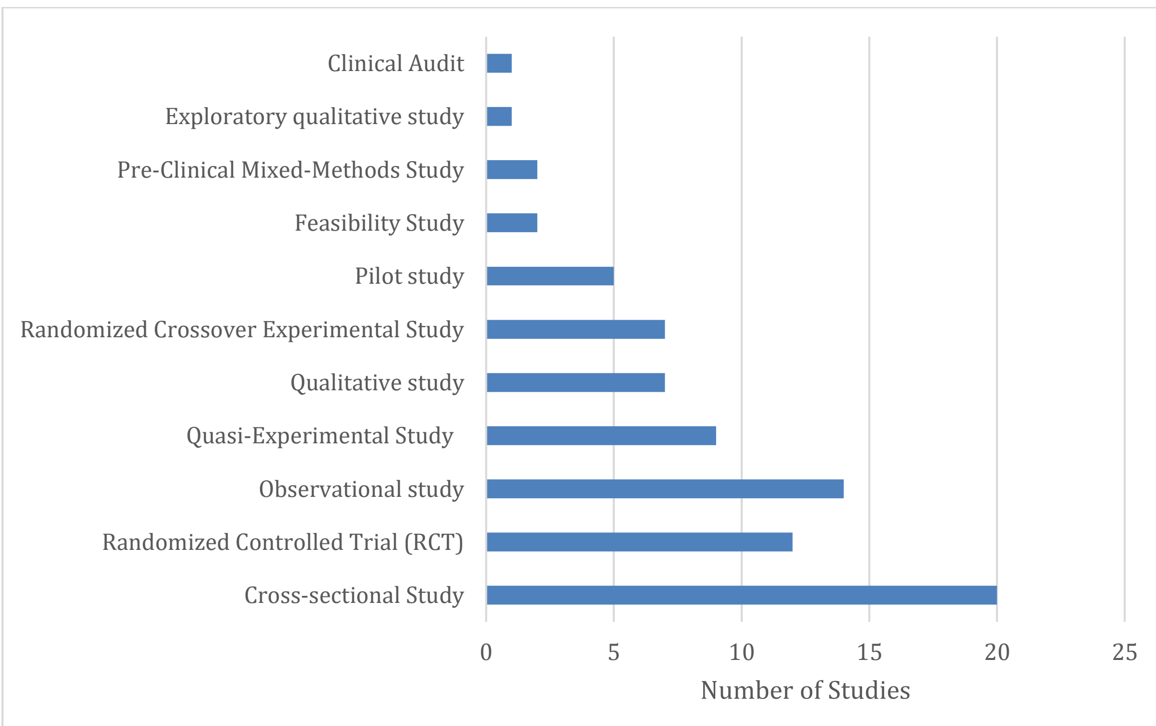

Figure 3: Number of studies by study design

The studies utilized a diverse set of outcomes to examine the effectiveness of the footwear interventions, as shown in Table 3. Among the studies investigating therapeutic footwear and insoles for people with diabetes, plantar pressure was the most common outcome, reported in 55 studies. Plantar pressure was assessed using peak plantar pressure (PPP) in 40 studies [29, 31, 33, 35, 37-39, 41-45, 47-49, 53, 55, 57, 58, 60, 63, 64, 69, 74, 77-79, 82, 84-86, 88, 90-92, 95, 96, 98, 99, 104], and pressure time integral (PTI) in 13 studies [37, 58, 60, 64, 69, 74, 77-79, 84, 85, 95, 104]. PPP evaluates the maximum pressure in the affected region while PTI quantifies the cumulative pressure applied over time to a specific area. Only one study reported more advanced plantar pressure metrics such as peak pressure gradient (PGrad), peak pressure time curve (PTC), peak pressure map (PMap), and peak pressure time map (PTM) [44], highlighting the limited adoption of these multidimensional approaches in routine clinical or research evaluation.

Adherence was the second most common outcome reported across the studies (n=27). Self-reported adherence was used in 18 studies [13-15, 30, 38, 45, 50, 55, 67, 75, 83, 86, 87, 93, 94, 96, 102, 105] through interviews, questionnaires, or visual analog scale (VAS) ratings. Objective monitoring techniques were applied in eight studies [15, 27, 28, 40, 42, 49, 81, 96], where temperature sensors were used to assess mean daily wear time and step count. In addition, one study [12] employed an activity monitor to capture physical activity data. Together, these measures reflect increasing efforts to quantify real-world device usage accurately.

Gait and balance were evaluated in 20 studies, with 15 studies analyzing gait and postural parameters such as double support time, stride length, sway velocity, and stability indices

[32, 36, 39, 52, 61, 65, 69, 71, 72, 76, 89, 92, 93, 101, 105]. Additionally, center of pressure (COP) metrics was reported in five studies [39, 51, 78, 90, 101], assessing foot trajectory, velocity, and foot-off signals as markers of dynamic and static balance.

Patient satisfaction and preferences were reported in 19 studies using a combination of questionnaires like QUEST 2.0, structured interviews, and subjective assessments of fit, comfort, aesthetics, and ease of use [30, 31, 33, 36, 41, 43, 55, 57, 58, 68, 69, 75, 86-88, 92, 100, 101, 105]. Ulcer incidence or recurrence was reported in 13 studies [28, 49, 58, 62, 64, 66, 67, 70, 73, 81, 94, 95, 105] , using clinical data to track reulceration frequency, time to recurrence, and number of affected patients.

Other outcomes were reported less frequently. Quality of life and capability were assessed in five studies [47, 92, 93, 97, 101] via validated tools such as EQ-5D-5L and SF-36. Contact area was measured in five studies [76-79, 90], and ambulatory activity was assessed in four studies [15, 32, 38, 91] through stair navigation time, Timed Up and Go (TUG), stride count and using an activity monitor [15, 32, 38, 91]. Ground reaction force [39, 89, 90], plantar temperature [61, 63, 99], and healing rates [38, 59, 94] were each reported in three studies. A small number of studies examined insole compression [31, 96], functional tests [93, 101], adverse events such as amputation or mortality [73, 87], foot measurements [76], and insole aging [86], each appearing in only 1–2 studies.

The use of diverse outcome measures suggests a prevailing research focus on biomechanical parameters, particularly PPP, while also demonstrating increasing attention to adherence monitoring, patient satisfaction, and clinical outcomes such as ulcer recurrence and healing. Notably, recent studies have incorporated adherence as a secondary outcome to evaluate the effectiveness of therapeutic footwear and insoles. The integration of both quantitative and subjective measures reflects a maturing research field with a growing emphasis on real-world effectiveness and user-centered care.

Footwear Prescription Decision Factors

The footwear prescription decision factors are mapped using the World Health Organization's (WHO) five dimensions of adherence: (1) patient-related, (2) condition-related, (3) therapy-related, (4) socioeconomic, and (5) healthcare system–related factors. The decision-making factors are summarized in Table 4, which consolidates variables cited in the eligibility criteria and those discussed in the results across the included studies.

Patient-Related Factors

Seventy-one (72) studies reported patient-related inclusion criteria. The most common factor was age, with all studies requiring participants aged >18 years [12, 14, 15, 27-29, 31-38, 40-45, 47-58, 60, 62-72, 74-80, 82, 84-100, 102, 103]. Gender-specific studies were rare, with only three studies focused on females [35, 52, 71] and one on males [101]. Clinical thresholds included HbA1c values between 7% and 12% (n=2) [38, 95], BMI between 25 and 30.1 kg/m^2 (n=3) [52, 95, 101], and systolic/diastolic blood pressure

≤140/90 mmHg (n=3) [78-80]. Four studies [52, 65, 68, 95] required diabetes duration ≥5 years, and one study used BMI to tailor insole cushioning density [85].

Condition-Related Factors

Included participants were diagnosed with either type 1 (n=49) [14, 15, 27-29, 31-33, 36-51, 54, 55, 57, 61, 62, 66, 67, 69, 70, 72, 74, 76, 77, 81, 82, 84, 86, 87, 89, 92, 94, 96, 97, 100, 103] or type 2 diabetes (n=64) [12, 14, 15, 27-29, 31-33, 36-51, 53-57, 61, 62, 66, 67, 69-72, 74-76, 78, 80-87, 89-100, 102, 103], with many studies involving both populations. DPN was reported across 50 studies [12, 15, 29, 31-33, 37-41, 44, 46-57, 61-63, 66, 67, 69-73, 75-80, 84-86, 91, 93-95, 97, 98, 103], while peripheral arterial disease (PAD) was reported across 5 studies [40, 46, 60, 73, 86]. One study specifically excluded participants with PAD [99].

Foot risk status and ulcer history were important inclusion markers. Six studies recruited participants with current ulcers [12, 38, 59, 60, 62, 94]; 25 studies included those with recent or healed ulcers within the previous 18 months [15, 27, 29, 32, 37, 39, 49, 53-55, 57, 59, 61, 62, 66, 69, 70, 73, 81, 83, 86, 95, 97, 99, 103]. Conversely, six studies [46, 52, 76, 82, 89, 90] required no recent ulceration. Presence of pre-ulcerative callus was used as inclusion criteria in five studies [61, 73, 77, 78, 80], and 14 studies [28, 31, 33, 37, 39-41, 43, 45, 59, 67, 73, 75, 96] included patients with stratified risk using the IWGDF ulcer risk categories 1 to 3.

Footwear usage history was another common factor for inclusion. Prefabricated footwear use (>3–6 months) was used in 12 studies [14, 27, 31, 33, 44, 47, 50, 54, 57, 73, 83, 87], while 18 studies included participants already using custom-made footwear and insoles [14, 27, 28, 31, 40, 41, 44, 45, 47, 50, 54, 57, 59, 73, 83, 87, 96, 103]. Five studies included patients who used custom insole use alone [41, 50, 54, 81, 83]. While most of the studies only included patients who were existing users of footwear or insole, only two studies enrolled participants receiving footwear for the first time [67, 93]. Additionally, one study included existing users of footwear with documented low adherence [27].

Comorbidities such as cardiovascular disease, controlled hypertension, Charcot neuroarthropathy, and hyperkeratosis were used to select participants in four studies[54, 78, 79, 97]. Functional mobility was emphasized in 29 studies, which required unaided walking across distances ranging from five meters to greater than 500 meters [15, 31, 32, 34, 41, 46, 47, 49, 56, 60, 62, 64, 65, 68, 72, 76-80, 84-86, 89-91, 98, 100, 103]. Standing unaided (10–30 seconds) was an inclusion criterion in three studies[49, 51, 72]. Some studies also required participants to be free from gait-affecting injuries or diseases (n=2) [34, 35], major neurological disorders (n=3) [52, 76, 89], and limb-length discrepancies (n=1) [60]. Additional criteria included smartphone ownership (n=1) [62], recent hospital admission (n=1) [58], and shoe size within predefined ranges (n=2) [34, 35].

Foot structure and motor capacity were used for inclusion. Four studies excluded individuals with deformities [47, 54, 82, 99], while ten studies included patients with mild deformities [31, 39, 54, 55, 73, 77, 78, 80, 83, 86]. Joint range of motion was assessed in two studies, toe-in/out angle in one [71], and peak plantar pressure thresholds above 450 kPa in another [62]. Cognitive and visual competence were included in two studies to ensure informed participation [65, 98]. Amputation status was variably used to include participants across studies, as two studies included patients with a history of amputation [73, 86] and two excluded them [39, 68].

Therapy-Related Factors

Therapy-related factors were reported in 72 studies. A variety of footwear types were described, including custom-made, prefabricated, modular, wedge, retail, sports, and indoor shoes. Some of these studies examined open footwear styles such as mules or thongs were described in a subset of studies. Several footwear configurations were considered across studies, with rocker soles being the most common feature considered before prescription. Rocker profiles were considered in 12 studies with variations in forefoot, heel, and double rocker configurations [28, 34, 36, 39, 41, 45, 55, 66, 67, 79, 82, 86]. Common features of rockers considered included adjustments to rocker angles by eight studies [33, 43, 52, 65, 67, 69, 79, 82], apex positions (n=3), and apex angles in four studies [34, 35, 52, 82], outsole materials [33, 35, 36, 41, 43, 65, 69], rocker radii by two studies [34, 35], density by 11 studies [28, 35, 55, 57, 58, 66, 67, 69, 82, 86, 93].

Other footwear attributes included rigid heel counters (n=4) [58, 66, 67, 86], wide toe boxes, soft uppers, fastenings options, lightweight or water-resistant design options discussed by 17 studies [28, 39, 52, 55, 58, 65-71, 76, 77, 80, 86, 103], anti-slip outsoles, and spacer inlays in two studies [36, 55]. One study specifically highlighted comfort and usability features of the footwear [28].

While footwear modifications are a common aspect of footwear prescription, few studies reported the type of modifications. Fittings adjustments are common, where footwear is adjusted at initial fitting [28, 54, 55, 73]. Rocker profile medication was also seen across studies, with four studies modifying rocker outsoles [29, 55, 67, 82], three studies on rocker angles [67, 79, 82], two studies adding rocker reinforcement [43, 52] and one study modifying rocker apex angle and apex position [82]. Other footwear modifications included stretching or widening of shoes [62, 79], modifying tongue pads and performing shoe repairs [62], medial arc support [76], and reinforcing toe cap and collar [45].

Fifty-four studies reported insole characteristics as part of the results. This included type of insole such as custom-made, prefabricated, semi-custom, modular, and textured insoles. Insole density was reported by 14 studies [28, 38, 39, 41, 46, 61, 66, 71, 72, 74, 81, 84, 85, 95], and hardness in 17 studies [34, 35, 41, 47, 48, 66, 67, 70-72, 74, 78, 86, 88, 89, 93, 101]. Materials were reported in 33 studies [29, 31, 33-35, 41, 46-49, 51, 56, 61, 62, 64, 66, 67, 70-72, 77-79, 82, 85, 86, 88, 89, 91, 93, 95, 99, 101], and insole thickness in 17 studies [31, 38, 39, 46, 48, 49, 51, 64, 71, 74, 79, 84, 85, 89, 93, 95, 96]. Less common insole features reported included weight in two studies [45, 89], inserts in two studies [35, 82], and depth in one study [46].

Insole modifications were more common across studies in comparison to footwear modifications. Thirteen studies described localized material removal [29, 47-49, 54, 57, 66, 67, 70, 90, 93, 95, 101], and five reported softening or cushioning strategies [29, 47, 51, 57, 84]. Addition of metatarsal bars and pads were a common modification utilized across ten studies [29, 41, 47, 48, 57, 62, 70, 71, 86, 95]. Another common modification was addition of arch support reported in nine studies [29, 41, 51, 71, 73, 74, 90, 93, 98]. Additional modifications included heel lifts [49, 90], addition of wedges [47, 90], repair or replacement of top cover [29, 47], and providing replacement insoles [47, 86]. A few studies focused modifications on additional support and heel padding [86], offloading bony prominence [54, 86], addition of heel pad [71], heel lift or reinforcements [49, 90], fitting adjustments [49], and trimming of orthosis [62]. Few studies reported use of extra top covers with deflections [57] and medial arch supports [76]. One study conducted structured modifications guided by Human-Centered Design (HCD) methodology and ISO standards for medical device ergonomics [92].

Socioeconomic Factors

Socioeconomic factors were commonly discussed among footwear adherence studies, highlighting factors behind low adherence. Based on patient feedback, adherence is affected by footwear size [83, 103], weight [36, 59, 73, 83, 103], appearance [36, 50, 67, 73, 83, 87, 103], seasonal discomfort and inefficient replacements [83], usability [36, 59, 67, 103], comfort [73, 86], and additional features such as water resistance [100].

Other studies reported that patient education is associated with better adherence [27, 58, 62, 68, 83, 93, 97, 102, 103]. Gender [58, 81, 87], age [103], and social context [50, 87, 100] affect adherence behavior, with lower adherence observed among women. Context-dependent use [27, 28, 32, 36, 57, 103] has an impact on adherence with studies demonstrating that adherence is generally lower at home or at night. Cultural and psychosocial factors such as embarrassment, fashion preferences, and work routines also contribute to nonadherence [73, 96, 102].

Clinical factors such as disease severity affect adherence, with greater adherence linked to prior ulceration, pain, neuropathy, and amputations [12, 36, 50, 58, 100]. Comfort and fit [36], and the functional effectiveness of footwear [46, 50] over time are also essential, while environmental conditions [36, 75] and financial constraints [62, 97] further affect consistent use of footwear.

Monitoring and behavioral strategies such as continuous monitoring [81] and evaluation [47] , habitual preferences such as storing shoes visibly [14], patients with paid employment self-efficacy, and routine behavior have shown potential in improving adherence. Social support from family, caregivers, and clinicians [62, 97] is also critical, and involving patients in co-designing acceptable footwear solutions may enhance uptake and long-term use [100].

Healthcare System–Related Factors

Two studies reported barriers related to access and cost. Participants identified limited availability of appropriate therapeutic footwear [102] and footwear costs [45] as barriers to access of care.

Mapping to FHIR

Table 5 presents a structured framework for creating a dataset suitable for training AI and machine learning models. It categorizes key decision-making factors into input and output variables, aligning each with FHIR resources, coding systems, data types, units, and sample values. Input variables include patient-related data, condition-specific indicators, socioeconomic factors, and healthcare-related elements. These variables are primarily Boolean, integer, decimal, or coded, facilitating straightforward integration into binary and categorical models.

Therapy-related factors constitute the output group, encompassing footwear and insole specifications. These output variables are mostly discrete or Boolean, making them well-suited for multi-class classification and recommendation systems. Therapy related factors constitute the output group, encompassing footwear and insole specifications. These output variables are primarily discrete or Boolean, which makes them suitable for multi class classification and recommendation systems. Most modification variables are represented using Boolean values rather than detailed specifications or measurements. This approach reflects the framework's focus on identifying the presence or absence of specific modifications to uncover patterns that support the decision-making process.

Including full configurations and exact measurements for each modification or footwear element would significantly increase the complexity of the dataset and create challenges for consistent data collection. For instance, footwear measurements are often captured using three-dimensional foot scanners. While these are important for the manufacturing process, the goal of this framework is to understand the type of footwear prescribed for specific patient conditions, rather than to capture precise measurements. Additionally, integrating devices like foot scanners into existing CDSSs may be impractical in many healthcare environments.

The integration of FHIR resources and standardized coding systems such as SNOMED CT and LOINC enhances interoperability. However, several variables rely on custom codes, reflecting the current lack of standardization in footwear prescription terminology—an area that presents opportunities for future development. Each variable's datatype, unit, and sample values are clearly specified, offering practical guidance for data collection and preprocessing. It is important to note that while the sample values serve as a reference point, real-world data distributions may differ significantly.

In summary, Table 5 outlines a well-structured and comprehensive dataset schema that balances clinical detail with behavioral and contextual relevance. Further validation from clinical and industry experts is recommended to refine custom-coded fields and ensure applicability across diverse real-world scenarios.

Discussion

Principal Findings

This study presents a structured and interoperable framework for prescribing offloading footwear in the management of diabetic foot ulcers, designed to integrate into electronic health records and clinical decision support systems using FHIR standards. The schema captures a wide range of clinical, behavioural, environmental, and therapeutic factors, organized within a consistent structure informed by the WHO Dimensions of Adherence framework.

A central feature of the framework is its emphasis on semantic clarity. Redundant or overlapping factors are intentionally assigned to the most relevant domain by the WHO dimensions. For example, although footwear type may influence both clinical assessment and therapeutic planning, it is mapped solely within the therapy-related domain. This design choice improves clarity, prevents duplication, and ensures that the data can be applied consistently across longitudinal tracking systems and digital infrastructures.

In addition to enabling clinical documentation and decision support, the framework provides a foundation for AI and machine learning (ML) applications. Its structured categorization supports the development of high-quality datasets that can be used to develop CDSSs and train AI and ML models.

Comparison With Prior Work

To the best of our knowledge, no previous study has systematically standardized or structured the decision factors involved in footwear prescription. Existing research has primarily focused on evaluating the effectiveness of offloading interventions, with limited attention to the underlying decision-making processes or their representation in digital systems. While clinical guidelines, such as those from the IWGDF on the Diabetic Foot, offer valuable principles, they lack the structure necessary for integration into electronic health records (EHRs) or computational tools such as CDSSs.

Recent work has begun to explore the application of artificial intelligence in this space. So far, only one study has conceptually proposed the idea of applying AI-powered clinical decision support system for personalized offloading device prescriptions, integrating patient-specific factors such as preferences, ulcer risk, and usage context to recommend tailored footwear and orthotics [4]. This study is among the first to conceptualize AI-driven personalization in DFU offloading footwear and presents an initial set of decision factors. However, the study focuses solely on forefoot ulceration and does not provide a structured approach to integrating in CDSSs or utilizing with AI and ML techniques.

The concept of AI and ML has been explored with smart and sensor-based footwear interventions. For example, a study presented the design and implementation of a real-time smart insole system that monitors plantar pressure and temperature using cost-effective, wearable sensors [106]. The study emphasizes home-based monitoring and the potential for integration with intelligent alert systems. While smart footwear has the potential to collect data and support the application of AI and ML models, its use in practice remains limited. This is largely due to the high cost of embedded sensors [107], which makes these interventions prohibitively expensive for many patients. This is one of the main reasons we excluded smart footwear interventions from the review, as their practical application remains limited.

Some studies have explored the ML techniques in orthotics. For example, a review highlighted the growing use of algorithms such as support vector machines, decision trees, and deep learning to optimize orthotic design and performance [108]. However, this review did not focus solely on orthotic interventions but also included prosthetic interventions. Another study conducted a case study that applied machine learning models to predict adherence to medical footwear based on behavioural and contextual variables, highlighting the importance of non-biomechanical factors [109]. Other empirical studies have applied ML model such as decision trees to prescribe orthotics for patients with Pes Planus [110] and deep learning models to prescribe orthotics that can improve patients' gait [111].

While existing studies only discuss the feasibility of applying AI in footwear and orthotic contexts, they lack a standardized framework for organizing input and output factors. In contrast, this study offers a formal structure aligned with FHIR resources, designed to support both digital documentation and ML workflows. The therapy-related factors can serve as output for CDSSs or class labels for a dataset needed to train AL and ML modes. While patient-related, condition-related, socioeconomic, and health system-related can form the inputs of CDSSs or act as dependent variables in a dataset for AI and ML models. This dual-use model positions the schema for integration into real-world clinical decision support systems and intelligent predictive platforms.

Limitations

The main objective of this scoping review was to identify and organize relevant decision factors, rather than to evaluate outcome effectiveness. As a result, the methodological quality of the included studies was not assessed. However, the relevance of the identified factors should be further evaluated through expert engagement, such as surveys and focus group discussions.

In addition, mapping these factors to FHIR resources should be guided by expert review and the use of standardized terminology systems. The proposed custom FHIR extensions will also require validation in real-world settings. It is important to note that some variables naturally span multiple domains, and rigid classification may not fully reflect their multidimensional relevance.

The proposed schema has not yet been tested in clinical workflows. Future work should include implementation studies to assess the usability of the framework, its integration into CDSSs, and its effectiveness in supporting real-time decision-making and predictive analytics.

Conclusions

This scoping review systematically identified and organized clinical, behavioural, and contextual factors influencing the prescription of offloading footwear in the management of DFUs. By synthesizing evidence from a diverse body of literature, it developed a structured data schema aligned with the WHO Dimensions of Adherence and HL7 FHIR standards. This schema supports standardized data representation, facilitates integration into electronic health records, and provides a foundation for developing CDSSs and AI-driven tools.

While the review did not assess the methodological quality of the included studies, it prioritized breadth and comprehensiveness. Notably, it mapped 117 unique decision factors, 54% of which required custom FHIR extensions, offering a novel contribution to the field. The inclusion of socioeconomic and behavioural determinants underscores the importance of patient-centred approaches, particularly for enhancing adherence to prescribed footwear.

Future research should focus on validating the proposed schema through expert consensus, surveys, and focus group discussions. Implementation studies are also needed to evaluate its usability, effectiveness, and integration within CDSSs, with the goal of improving DFU management, reducing ulcer recurrence, and enabling personalized care at scale.

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Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

KK conceptualized and designed the study, conducted the scoping review, performed data extraction and analysis, and led the manuscript drafting. MAK contributed to the study design, conceptual development, methodology, and visualization; supervised and administered the project; secured funding; and substantively revised the manuscript. LD contributed to the interpretation of findings and critically reviewed the manuscript with a focus on clinical implications. SA provided input on industry applications and offered insights into real-world implementation. MN participated in the review process and supported data extraction and analysis. All authors have read and approved the final manuscript and agree to be personally accountable for their own contributions and to ensure the accuracy and integrity of the work, even in areas where they were not directly involved.

Ethics approval

NA

Patient and public involvement

N/A

Abbreviations

AI: Artificial intelligence

CDSS: Clinical decision support system

COP: Centre of pressure

DFU: Diabetes-related foot ulcer

DPN: Diabetic peripheral neuropathy

EHR: Electronic health records

FHIR: Fast Healthcare Interoperability Resources

HCP: Human centered design

HL7: Health Level Seven International

HRQoL : Health-related quality of life

IWGDF: International Working Group on the Diabetic Foot

ML: Machine Learning

PAD: Peripheral arterial disease

PGrad: Peak pressure gradient

PICO: Population intervention comparison outcome

PMap : Peak pressure map

PP: Plantar pressure

PPP: Peak plantar pressure

PTC: Peak pressure time curve

PTI: pressure time integral

PTM: Peak pressure time map

RCT: randomized controlled trial

SNOMED: Systematized nomenclature of medicine

LOINC: Logical Observation Identifiers Names and Codes

ICD-10: International Classification of Diseases, 10th Revision

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Large Tables

Table 3: Studies by offloading Outcomes

Outcome	**Evaluation Methods**	**Reference**	**Count**
Plantar Pressure ***(55)***	Peak plantar pressure (PPP)	[29, 31, 33, 35, 37-39, 41-45, 47-49, 53, 55, 57, 58, 60, 63, 64, 69, 74, 77-79, 82, 84-86, 88, 90-92, 95, 96, 98, 99, 104]	40
	Pressure time integral (PTI)	[37, 58, 60, 64, 69, 74, 77-79, 84, 85, 95, 104]	13
	Peak Pressure Gradient (PGrad)	[44]	1
	Peak Pressure Time Curve (PTC)	[44]	1
	Peak Pressure Map (PMap)	[44]	1
	Peak Pressure Time Map (PTM)	[44]	1
Adherence (27)	*Self-reported insole wear:* interviews; Questionnaires; Visual Analog Scale (VAS) scores to assess usage hours per day/per week or Mean wear time.	[13-15, 30, 38, 45, 50, 55, 67, 75, 83, 86, 87, 93, 94, 96, 102, 105]	18

	Temperature sensor: Evaluate mean daily wearing time (hours/day), daily step count.	[15, 27, 28, 40, 42, 49, 81, 96]	8
	Activity monitor to assess usage	[12]	1
Gait and balance (20)	Reduction in gait initiation double support time (10.4%); static and dynamic balance; Overall Stability Index (OSI); Anterior–Posterior Stability Index (APSI); Medial–Lateral Stability Index (MLSI); foot rotation; anterior–posterior and mediolateral sway; sway velocity and area; step length change; stance phase duration (including immediate post-intervention); stride length; step velocity; cadence; Foot-Off Signal (FOS); plantar flexion angle and moment; ankle joint power; gait symmetry; response to forward and backward perturbations measured by Response Strength Scale and Response Latency; Margin of Stability in anteroposterior (MOSap) and mediolateral (MOSml) directions.	[32, 36, 39, 52, 61, 65, 69, 71, 72, 76, 89, 92, 93, 101, 105]	15
	Centre of pressure (COP) metrics: trajectory, velocity, path length, proximal-to-distal trajectory, heel/midfoot location (% of stance time), Foot-Off Signal (FOS), and maximum COP speed.	[39, 51, 78, 90, 101]	5
Patient satisfaction and preferences	Questionnaires (QUEST 2.0); Interviews; Walking comfort and fit; Usability; Footwear type selection (e.g., walking shoes, running shoes, oxfords, moccasins,	[30, 31, 33, 36, 41, 43, 55, 57, 58, 68, 69, 75, 86-88, 92, 100, 101, 105]	19

	boots, Ugg boots, high heels, flip flops, slippers, backless slippers, court shoes, mules, sandals, bespoke footwear, socks only) classified as adequate or inadequate; Appearance; Weight; Ease of donning/doffing; Comfort (VAS score).		
Ulcer incidences or recurrence, lesions	No reulcerations during the monitoring period; Percentage of patients with reulcerations; Clinical assessments; Number of recurrences; Time to recurrence.	[28, 49, 58, 62, 64, 66, 67, 70, 73, 81, 94, 95, 105]	13
Quality of life and capability	Health-related quality of life (HRQoL) and capability were assessed using EQ-5D-5L; interviews; questionnaire (SF-36 questionnaire).	[47, 92, 93, 97, 101]	5
Contact area	Cm^2	[76-79, 90]	5
Ambulatory activity	Time to ascend and descend stairs; Proportion of weight-bearing activity time footwear was worn; Timed Up and Go (TUG) components: sit-to-stand, walking with turning, stand-to-sit; Stride count.	[15, 32, 38, 91]	4
Ground reaction force	Newtons (N)	[39, 89, 90]	3
Temperature	Reduced temperature in region of interest (°C).	[61, 63, 99]	3
Healing rates	Healing rate (%); Healing time; Ulcer size reduction.	[38, 59, 94]	3
Insole compression	Insole thickness; top cover thickness	[31, 96]	2
Functional tests	Lower Extremity Functional Scale (LEFS); Functional Reach Test (FRT);	[93, 101]	2

	Unipedal Stance Test (UST); Tandem Stance Test (TST); Tandem Walk Test (TWT); Timed Up and Go Test (TUGT); Six-Minute Walk Test (6MWT).		
Adverse events	Amputation rates; mortality rates	[73, 87]	2
Foot measurements	Width and height of foot during weight bearing activities	[76]	1
Insole aging	Duration of use	[86]	1

Table 4: Footwear prescription decision factors

Category (WHO Dimensions)	**Factors (inclusion factors)**	**Study**	**Count**
Patient-related	Age (> 18)	[12, 14, 15, 27-29, 31-38, 40-45, 47-58, 60, 62-72, 74-80, 82, 84-100, 102, 103]	71
	Gender:		
	Female	[35, 52, 71]	3
	Male	[101]	1
	Glycated hemoglobin (HbA1c - 7% - 12%)	[38, 95]	2
	BMI (normal range, 25 – 30.1 kg/m²)	[52, 95, 101]	3
	.BMI is a clinically accessible indicator for determining the required cushioning stiffness.	[85]	1
	Diabetes duration (>= 5 years)	[52, 65, 68, 95]	4
	Blood pressure (≤140/90 mmHg)	[78-80]	3
Condition-related	**Diabetes Type:**		

	Type 1	[14, 15, 27-29, 31-33, 36-51, 54, 55, 57, 61, 62, 66, 67, 69, 70, 72, 74, 76, 77, 81, 82, 84, 86, 87, 89, 92, 94, 96, 97, 100, 103]	49
	Type 2	[12, 14, 15, 27-29, 31-33, 36-51, 53-57, 61, 62, 66, 67, 69-72, 74-76, 78, 80-87, 89-100, 102, 103]	64
	DPN (loss of protective sensation)	[12, 15, 29, 31-33, 37-41, 44, 46-57, 61-63, 66, 67, 69-73, 75-80, 84-86, 91, 93-95, 97, 98, 103]	50
	PAD (angiopathy, palpable or biphasic pulses)	[40, 46, 60, 73, 86]	5
	No PAD	[99]	1
	Presence of Ulcers:		
	Presence of foot ulcer (full-thickness ulcer below the malleoli, non-healing ulcer, Unilateral ulcer)	[12, 38, 59, 60, 62, 94]	6
	History of Ulcers:		
	No history (< 6 months)	[46, 52, 76, 82, 89, 90]	6
	Existing History (recently healed ulcer [under MTHs]/ pre-ulcerative callus < 18 months, forefoot ulceration, > 2 months DFU, high barefoot peak plantar pressure [>600 kPa])	[15, 27, 29, 32, 37, 39, 49, 53-55, 57, 59, 61, 62, 66, 69, 70, 73, 81, 83, 86, 95, 97, 99, 103]	25
	Presence of pre-ulcerative callus	[61, 73, 77, 78, 80]	5
	Ulcer risk (IWGDF category 1-3)	[28, 31, 33, 37, 39-41, 43, 45, 59, 67, 73, 75, 96]	14
	Low adherence (< 80% steps taken in prescribed footwear)	[27]	1

	Existing users of:		
	Prefabricated Footwear (> 3 - 6 months)	[14, 27, 31, 33, 44, 47, 50, 54, 57, 73, 83, 87]	12
	Custom Footwear & Insole (> 3 - 6 months)	[14, 27, 28, 31, 40, 41, 44, 45, 47, 50, 54, 57, 59, 73, 83, 87, 96, 103]	18
	Custom Insoles only (> 6 months)	[41, 50, 54, 81, 83]	5
	First footwear prescription	[67, 93]	2
	Comorbidities (hyperkeratosis, cardiovascular disease, high blood pressure [≤140/90 mmHg], Charcot neuroarthropathy (stages 1–3))	[54, 78, 79, 97]	4
	Foot Structure and Mobility:		
	Walk unaided (> 5m, > 10m, > 20m >100m, >500m, Community ambulators, up to 3 hrs with breaks)	[15, 31, 32, 34, 41, 46, 47, 49, 56, 60, 62, 64, 65, 68, 72, 76-80, 84-86, 89-91, 98, 100, 103]	29
	Stand (10 - 30 seconds)	[49, 51, 72]	3
	No intrinsic limb-length discrepancy >1 mm	[60]	1
	No foot deformity (neuro-osteoarthropathy, Charcot foot, equinus deformity**)**	[47, 54, 82, 99]	4
	Existing foot deformities (hallux valgus, hammer toes, bunions)	[31, 39, 54, 55, 73, 77, 78, 80, 83, 86]	10
	Normal toe-in/out angle during walking	[71]	1
	No biomechanical disorders	[99]	1
	Normal range of motion at wrist, knee, and hip joints	[65, 72]	2
	No history neurological disorders	[52, 76, 89]	3
	Normal cognitive function and vision	[65, 98]	2
	Peak plantar pressure (PPP) > 450 kPa	[62]	1

	Ownership of a smartphone (for broader study integration)	[62]	1
	No history of gait-affecting injuries or diseases	[34, 35]	2
	History of amputation	[73, 86]	2
	No history of amputation (major lower-extremity amputation)	[39, 68]	2
	Admitted for at least one night for any medical reason.	[58]	1
	Shoe size (EU 38 – 41, French 43 – 44)	[34, 35]	2
Socioeconomic	**Feedback from participants:**		
	Size (Bulky)	[83, 103]	2
	Weight (Heavy)	[36, 59, 73, 83, 103]	5
	Unaesthetic (mostly women, color)	[36, 50, 67, 73, 83, 87, 103]	7
	Seasonal discomfort	[83]	1
	Inefficient replacements	[83]	1
	Usability is important (comfort, easy doning/ doffing, easy to clean)	[36, 59, 67, 103]	4
	Patient satisfaction scores for footwear (comfort)	[73, 86]	2
	Water resistant features on shoes will be helpful	[100]	1
	Other findings:		
	Patient education improves adherence (motivational interviewing, should emphasize perceived benefits of footwear, Poor understanding of offloading and wound care is common among patients, awareness and motivation is needed, influence behavior change)	[27, 58, 62, 68, 83, 93, 97, 102, 103]	9

	Gender influences adherence (women less adherent)	[58, 81, 87]	3
	Need for continuous monitoring	[81]	1
	Need for re-evaluation (> 6 months)	[47]	1
	Functional effectiveness affects adherence (deteriorates after 12 months)	[46, 50]	2
	Cultural and psychosocial influences (embarrassment, working barefoot, need for fashionable footwear) affect adherence	[73, 96, 102]	3
	Age influences adherence	[103]	1
	Social implications affect adherence (esp. women, navigating between appearing "normal" and protecting one's fee)	[50, 87, 100]	3
	Financial constraints lead to use of standard or ill-fitting footwear	[62, 97]	2
	Self-management can improve patient lived experience and adherence	[62, 97]	2
	Family, caregivers, and clinicians support essential to access proper footwear and improve adherence	[62, 97]	2
	Adherence is affected by patients perceived wellbeing (Greater adherence associated with more severe ulcers, history of amputations, higher neuropathy scores, severe PAD, and greater foot pain) and their environment	[12, 36, 50, 58, 100]	5
	Values regulating use were shaped by life experience, self-image, function, and risk perception	[50]	1

	Participants also valued their footwear and aimed to preserve it by limiting use in certain conditions	[50]	1
	Patients' adherence to footwear varies by context (home vs away, day vs night, indoor [indoor adherence is generally lower] vs outdoor)	[27, 28, 32, 36, 57, 103]	6
	Separate indoor footwear improved adherence	[45, 59]	2
	High adherence factors (Patients with paid employment, ulcer experience, self-efficacy, and routine behavior)	[14]	1
	Storing therapeutic footwear in visible locations and putting conventional shoes out of sight increased use (behavioral cues and habit formation may be critical for long-term adherence)	[14]	1
	Clinicians should engage patients in co-designing acceptable solutions	[100]	1
	Environmental challenges (hot climate, fieldwork) affect adherence	[36, 75]	2
	Comfort and fit are critical for adherence	[36]	1
Therapy Related	**Footwear:**		
	Footwear type (Custom-made [high, ankle-high, low height, 3D foot scanning, foot box impression], Prefabricated/ medical grade [extra depth and width, ankle high], Double rocker-modified prefabricated shoes, Relasting shoes [widened midfoot by cutting shoe and inserting polyurethane] Semi-customizable, standard/regular/ retail shoes, sports/ athletic shoes, wedge style[women], indoor shoes,	[12, 14, 15, 28, 29, 31-41, 43-46, 48-85, 87, 89-93, 95-97, 99-103]	72

	walking shoes, running shoes, oxford shoes, Darco APB, inadequate footwear [moccasins, boots, ugg boots, high heels, thongs/flip flops, slippers, backless slippers, court shoes, mules, sandals)		
	Heel counters (rigid)	[58, 66, 67, 86]	4
	Rocker profiles (heel rocker, ankle rocker, forefoot rocker, double rocker, toe-only rocker outsole)	[28, 34, 36, 39, 41, 45, 55, 66, 67, 79, 82, 86]	12
	Rocker apex position (Distal, mid, and proximal heel apex positions, 50% and 60% of shoe length)	[34, 35, 39]	3
	Rocker radius (small and large)	[34, 35]	2
	Rocker outsole material (rubber, EVA, Poron, carbon-reinforced outsole replacing part of the rubber layer, Flexible rocker shoes [allow toe dorsiflexion], Composite fiber, 330 kg/m², Shore A)	[33, 35, 36, 41, 43, 65, 69]	7
	Rocker soles (stiff, rigid, semi-rigid)	[28, 35, 55, 57, 58, 66, 67, 69, 82, 86, 93]	11
	Rocker angle (10 - 20º)	[33, 43, 52, 65, 67, 69, 79, 82]	8
	Rocker apex angle (80 - 100º)	[34, 35, 52, 82]	4
	Apex position (52%, 57%, 62%, 67%)	[52, 65, 82]	3
	Anti-slip (microcellular rubber outsole added [70 Shore A])		
	Spacer inlays	[36, 55]	2
	Standard configurations (height/size of toe box, wide heel, heel height, fasteners [laces [laces, straps, velcro, buckles, or adjustable fasteners],	[28, 39, 52, 55, 58, 65-71, 76, 77, 80, 86, 103]	17

	soft upper material, leather, stretchable materials)		
	Comfort and usability features (lightweight soles, microfiber or felt vamps, and zipper or Velcro fasteners to improve donning and doffing)	[28]	1
	Insole:		
	Type (Custom-made [3D foot scanning, foot box impression to create plantar contouring, suspension plaster casts], custom-made indoor footwear, Prefabricated, Semi-customizable, modular, dimple insole, textured insole)	[12, 28, 31-35, 38-41, 43, 45-51, 53-57, 60, 62-64, 67, 70, 71, 73, 74, 76-79, 82, 83, 85-91, 93-96, 98, 99, 101, 103]	54
	Density (medium, firm, 270 mg/cm³, dual density cushioning)	[28, 38, 39, 41, 46, 61, 66, 71, 72, 74, 81, 84, 85, 95]	14
	Hardness (10-95 ShoreA, soft, hard)	[34, 35, 41, 47, 48, 66, 67, 70-72, 74, 78, 86, 88, 89, 93, 101]	17
	Material (Poron, EVA, Silicon, ballistic nylon lining, Rubbatex neoprene, plastazote, PPT, laminated PPT, bi-lam, cork, leather, silicone rubber, multifoam, Microcellular rubber, P-cell, Nora, DiaPod, Vibram, Biomech mt197, POD 50, Orthoshock, Duroform, Lunasoft, polyamide base, Thermoplastic Polyurethane, Filaflex TPU A72, multi-density internal honeycomb structure, closed cell structure, flexible material, shock-absorbent)	[29, 31, 33-35, 41, 46-49, 51, 56, 61, 62, 64, 66, 67, 70-72, 77-79, 82, 85, 86, 88, 89, 91, 93, 95, 99, 101]	33
	Thickness (2 - 13mm, > ¼ inch)	[31, 38, 39, 46, 48, 49, 51, 64, 71, 74, 79, 84, 85, 89, 93, 95, 96]	17
	Insole depth (1st metatarsal head and heel seat)	[46]	1

	Inserts (folex, flexible [carbon], rigid [cardboard] inserts, wool felt)	[35, 82]	2
	Insole weight (lightweight)	[45, 89]	2
	Insole Modifications:		
	Local removal of material (metatarsal cutout, toe unloading, 3mm under high pressure region)	[29, 47-49, 54, 57, 66, 67, 70, 90, 93, 95, 101]	13
	Local softening/ cushioning of material (soft to stiff material)	[29, 47, 51, 57, 84]	5
	Addition/ adjustment of metatarsal pad or bar (lower/higher)	[29, 41, 47, 48, 57, 62, 70, 71, 86, 95]	10
	Addition of Wedge or Skive (medial)	[47, 90]	2
	Repair or glue top cover	[47]	1
	Replacement of top cover	[29, 47]	2
	Insole damaged/ replaced	[47, 86]	2
	Additional lateral/medial support	[86]	1
	Heel padding	[86]	1
	Offloading bony prominence	[54, 86]	2
	Arch support	[29, 41, 51, 71, 73, 74, 90, 93, 98]	9
	Addition of heel pad	[71]	1
	Heel lift/ reinforcements	[49, 90]	2
	Fitting adjustment	[49]	1
	Trimming of orthosis	[62]	1
	Modifications guided by Human-Centered Design (HCD) methodology and ISO standards for medical device ergonomics. **Phase I**: User requirements, functional needs, ergonomic limitations defined	[92]	1

	Phase II: Ergonomic/functional features assessed; satisfaction and intention to use measured **Phase III**: Safety, efficacy (reduction of plantar pressures), and usability of final functional prototype evaluated		
	Extra top covers or base layers with deflections targeting high-pressure zones	[57]	1
	Footwear Modifications:		
	Fitting adjustments (protection, gait correction, foot deformities, forefoot amputations, spacer inlays)	[28, 54, 55, 73]	4
	Rocker outsoles (rigid vs. semi-rigid)	[29, 55, 67, 82]	4
	Polyethylene reinforcement	[29]	1
	Footwear structure and material	[55]	1
	Rocker angle (10 - 20º)	[67, 79, 82]	3
	Rocker apex angle (95º)	[82]	1
	Apex position (52%, 57%, 62%, 67%)	[82]	1
	Rocker reinforcement (steel shank inserted, carbon)	[43, 52]	2
	Stretching/ widening of shoes	[62, 79]	2
	Addition of tongue pad	[62]	1
	Shoe repairs	[62]	1
	Medial arch support to accommodate midfoot height loss	[76]	1
	Strengthened toe cap and collar	[45]	1
	Others:		
	Socks	[56, 61, 73]	3

Healthcare system related	Lack of access to proper footwear, financial barriers	[102]	1
	Footwear costs	[45]	1

Table 5: FHIR mappings of footwear prescription decision factors

	Factor	FHIR Resource	Code System	Datatype	Unit	Sample Values
Input						
Patient-related	Age	Patient	LONIC	Integer	Years	18 - 200
	Gender	Patient	LONIC	string	-	0 – male, 1 – female, 2 – other, 3 - unknown
	Glycated hemoglobin	Observation	LONIC	decimal	%	4.0 – 9.0
	BMI	Observation	LOINC	decimal	kg/m^2	0 – 50.0
	Diabetes duration (>= 5 years)	Condition	FHIR data element (onsetDateTime)	dateTime	years	onsetdatetime – currentdatetime
	Blood pressure (Systolic)	Observation	LONIC	Integer	mmHg	0 – 250
	Blood pressure (Diastolic)		LONIC	Integer	mmHg	0 – 250
Condition -	Diabetes Type	Condition	SNOMED CT	Code		0 - type 1, 1 - type 2, 2 - gestational, 3 - unspecified

	DPN	Condition	SNOMED CT	Boolean		0 - true, 1 - false
	PAD	Condition	SNOMED CT	Boolean		0 -true, 1 -false
	Presence of foot ulcer	Condition	SNOMED CT	Boolean		0 - true, 1 - false
	History of ulcers	Condition	Custom	Boolean		0 - true, 1 - false
	Presence of preulcerative callus	Condition	SNOMED CT	Boolean		0 - true, 1 - false
	Ulcer risk	RiskAssessment	Custom	Integer		0 - very low risk, 1 - low risk, 2 - moderate risk, 3 - high risk
	Adherence	Observation	Custom	Code		0 - low - < 20%, 1 - medium - 20 – 80%, 2 - high - > 80%
	Footwear prescription history	Observation	SNOMED CT	Boolean		0 - true, 1 - false
	Comorbidities	Condition	SNOMED CT	Code		0 – hypertension, 1- heart disease, 3 – charcot foot
	Walking ability	Observation	Custom	Decimal	Meters	0 - 50
	Standing ability	Observation	Custom	Boolean	Minutes	0 - 60
	Leg-length discrepancy	Condition	Custom	decimal	mm	|right leg length – left leg length |

	Foot deformity		SNOMED CT			0- hallux valgus, 1 - hammer toe, 2 - claw toe, 3 - pes planus, 4 - pes cavus, 5 - clubfoot, 6 - metatarsus adductus
	Normal toe-in/out angle	Condition	Custom	Boolean		0 - true, 1 - false
	Biomechanical disorders	Condition	Custom	Boolean		0 - true, 1 - false
	Normal joint motion	Condition	Custom	Boolean		0 - true, 1 - false
	Neurological disorders	Condition	Custom	Boolean		0 - true, 1 - false
	Cognitive function and	Condition	Custom	Boolean		0 - true, 1 - false
	Vision	Condition	Custom	Boolean		0 - true, 1 - false
	Peak plantar pressure (affected region)	Condition	Custom	decimal	kPa	0 - 1500
	Smartphone ownership	Condition	Custom	Boolean		0 - true, 1 - false
	Gait-affecting injuries	Condition	Custom	Boolean		0 - true, 1 - false
	History of amputation	Observation	SNOMED CT	Boolean		0 - true, 1 - false

	Admitted for any medical reason	Observation	Custom	Boolean		0 - true, 1 - false
	Shoe size	Device	Custom	Integer	EU	16 – 55
Socioeconomic	Footwear feedback (size, weight, aesthetics, usability)	Observation	Custom	Code		size → 1 – 5 likert scale weight → 1 – 5 likert scale asthetics → 1 – 5 likert scale usability → 1 – 5 likert scale comfort → 1 – 5 likert scale fit → 1 – 5 likert scale overall satisfaction → 1 – 5 likert scale
	Patient education	Observation	Custom	Code		0 - needed, 1 - in progress, 2 - completed
	Need for continuous monitoring	Observation	Custom	Boolean		0 - true, 1 - false
	Need for re-evaluation (>6 months)	Observation	Custom	Boolean		0 - true, 1 - false
	Cultural and psychosocial influences	Observation	Custom	Code		0 - low effect on footwear,

						1- moderate effect on footwear, 2 -high effect on footwear,
	Financial constraints	Observation	Custom	Code		0 – no support, 1 – partial support, 2 –full support
	Self-management support	Observation	Custom	Code		0 – low effort, 1 – moderate effort, 2 – high effort
	Support from caregivers/clinicians	Observation	Custom	Code		0 – low, 1 – moderate, 2 – high
	Footwear mostly worn	Observation	Custom	Code		0 – home 1 – work, 2 – home and work, 3 – day, 4 – night, 5 – day and night, 6 – other [specify]
	Separate indoor footwear improves adherence	Observation	Custom	String		0 → indoor footwear, 1 → outdoor footwear, 3 → other
	Employment status	Observation	Custom	Code		0 – employed, 1 – unemployed

	Place of shoe storage	Observation	Custom	Code		0 – easily accessible/ visible, 1 – not easily accessible/ visible
	Patients engagement on co-design	Observation	Custom			0 – low engagement, 1 – high engagement
	Regular environment	Observation	Custom			0 – less active, 1 – moderate activity level, 2 – high activity level
Health system	Lack of access to proper footwear	Observation	Custom	Boolean		0 - true, 1 - false
Output						
Therapy-related	Footwear type (custom, prefabricated, etc.)	Device	Custom	Code		0 – prefabricated, 1 – semi-custom, 2 - custom
	Rocker profile	Device	Custom	Code		0 – heel rocker, 1 – ankle rocker, 2 – forefoot rocker 3 – double rocker
	Rocker soles	Device	Custom	Code		0 – stiff, 1 – semi - rigid,

						2 – rigid
	Rocker apex position	Device	Custom	Code		0 – distal, 1 – mid, 2 – proximal
	Rocker radius	Device	Custom	Code		0 – small, 1 – large
	Rocker outsole material	Device	Custom	Code		0 – poron, 1 – reinforced carbon, 2 – flexible 3 – anti - slip
	Rocker angle	Device	Custom	Integer	degrees	0 – 100
	Rocker apex angle	Device	Custom	Integer	degrees	0 – 100
	Apex position	Device	Custom	Integer	percent	0 – 100
	Spacer inlays	Device	Custom	Boolean		0 - true, 1 - false
	Toe box	Device	Custom	Code		0 – normal, 1 – wide
	Heel height	Device	Custom	Code		0 – normal, 1 – wide
	Heel width	Device	Custom	Code		0 – normal, 1 – wide
	Laces/ fasteners	Device	Custom	Code		0 – lace, 1 – velcro , 2 – buckles, 3 – adjustable fasteners

	Upper materials	Device	Custom	Code		0 – soft, 1 – hard, 2 – fabric, 3 – leather, 4 - flexible
	Insole type	Device	Custom	Code		0 – prefabricated, 1 – semi-custom , 2 – custom
	Insole density	Device	Custom	Code		0 – medium, 1 – hard, 2 – dual density
	Insole hardness	Device	Custom	Integer	ShoreA	0 – 100
	Insole Material	Device	Custom	Code		0 – poron, 1 – rubber, 2 – cork, 3 - other
	Insole thickness	Device	Custom	Integer	mm	0 – 20
	Insole inserts	Device	Custom	Code		0 – soft, 1 – medium, 2 – hard, 3 - none
	Modifications					
	Local cutout	Device	Custom	Boolean		0 - true, 1 - false

	Local softening/ cushioning	Device	Custom	Boolean		0 - true, 1 - false
	Addition of metatarsal bar	Device	Custom	Boolean		0 - true, 1 - false
	Addition of metatarsal pad	Device	Custom	Boolean		0 - true, 1 - false
	Repair/ replace top cover	Device	Custom	Boolean		0 - true, 1 - false
	Insole replacement	Device	Custom	Boolean		0 - true, 1 - false
	Addition of lateral/ medial support	Device	Custom	Boolean		0 - true, 1 - false
	Heel padding	Device	Custom	Boolean		0 - true, 1 - false
	Arch support	Device	Custom	Boolean		0 - true, 1 - false
	Heel lift/ reinforcements	Device	Custom	Boolean		0 - true, 1 - false
	Trimming of orthosis	Device	Custom	Boolean		0 - true, 1 - false
	Addition of extra layers	Device	Custom	Boolean		0 - true, 1 - false
	Medial arch support to accommodate midfoot height loss	Device	Custom	Boolean		0 - true, 1 - false
	Fitting adjustment	Device	Custom	Boolean		0 - true, 1 - false

	Outsole reinforcement	Device	Custom	Boolean		0 - true, 1 - false
	Rocker reinforcement	Device	Custom	Boolean		0 - true, 1 - false
	Stretching/ widening of shoes	Device	Custom	Boolean		0 - true, 1 - false
	Addition of tongue pad	Device	Custom	Boolean		0 - true, 1 - false
	Shoe repairs	Device	Custom	Boolean		0 - true, 1 - false
	Strengthened toe cap and collar	Device	Custom	Boolean		0 - true, 1 - false
	Require socks	Device	Custom	Boolean		0 - true, 1 - false