diabetology

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Protocol

Experiences, Needs, and Beliefs Regarding Footwear Among People with Diabetes Mellitus in Spain: A Qualitative Focus Group Study Protocol

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Abstract

Background/Objectives: Diabetes mellitus (DM) is a group of chronic metabolic disorders characterised by persistent hyperglycaemia and an increasing global prevalence, imposing a significant socioeconomic and healthcare burden. Among its associated complications, the diabetic foot is a critical condition that doubles the risk of mortality. Although therapeutic footwear is an essential preventive strategy, research on treatment adherence has predominantly focused on quantitative parameters. This protocol aims to explore the experiences, needs, and perceived barriers of people with DM regarding therapeutic footwear use from a qualitative perspective. **Methods:** A qualitative focus group study will be conducted in the province of Alicante, Spain. Participants will be adults with a confirmed diagnosis of DM recruited across IWGDF foot risk categories 1–3 through purposive sampling. A total of 8–10 focus groups of 10–12 participants will be conducted in separate in-person and online modalities. Data will be analysed using reflexive thematic analysis within a constructivist epistemological framework, following the six-phase approach proposed by Braun and Clarke. The study adheres to the Consolidated Criteria for Reporting Qualitative Research (COREQ). Ethical approval will be obtained from the relevant Ethics Committee prior to data collection. **Results/Expected Outcomes:** The findings are anticipated to generate patient-centred, evidence-based insights into the psychosocial and experiential dimensions of therapeutic footwear adherence, informing the development of novel educational strategies and improvements in footwear design to optimise treatment adherence and clinical outcomes. **Conclusions:** This protocol provides a rigorous and transparent methodological framework for qualitative investigation of therapeutic footwear adherence in people with DM, contributing to a more comprehensive and person-centred approach to diabetic foot prevention.

Keywords: diabetes mellitus; diabetic foot; therapeutic footwear; patient adherence; qualitative research; focus groups; health beliefs

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1. Introduction

Diabetes mellitus (DM) is a group of chronic metabolic disorders of carbohydrate metabolism characterised by the simultaneous underutilization of glucose as an energy source and its overproduction through inappropriate hepatic gluconeogenesis and

glycogenolysis, resulting in persistent hyperglycaemia. As a complex, chronic condition, DM requires continuous, multifaceted care that extends beyond glycaemic control alone [1]. It is estimated that 537 million adults aged 20–79 years are currently living with DM worldwide. Projections suggest that this figure will rise to 643 million by 2030 and reach 783 million by 2045 [2].

Delays in diagnosis, suboptimal management, and the development of complications associated with the disease impose a significant and growing socioeconomic burden. In 2007, global healthcare expenditure related to DM was estimated at USD 232 billion; by 2021, this figure had risen to USD 966 billion for adults in the 20–79 age group, representing a 316% increase over 15 years. Assuming current trends persist, direct costs derived from DM could reach USD 1.03 trillion by 2030 [2]. Due to the often asymptomatic nature of the disease, underdiagnosis rates remain high, with an estimated 44.7% of adults living with DM unaware of their condition. Consequently, early diagnosis is crucial to prevent or delay complications, reduce the risk of premature mortality, and improve the quality of life of those affected [3].

The most common complications of DM are chronic in nature, including retinopathy, nephropathy, cardiovascular disease, and diabetic foot (DF) [4]. DF is defined as the infection, ulceration, or destruction of foot tissues in a person with a previous diagnosis of DM, frequently accompanied by neuropathy and/or peripheral arterial disease (PAD) of the lower limbs [5]. This complication doubles the risk of mortality, and its global prevalence is estimated at 6.3% [6,7].

Current clinical guidelines for DF management emphasise preventive and therapeutic strategies aimed at reducing complications such as ulceration and lower-extremity amputation. Since elevated plantar pressure is a key pathophysiological mechanism in the formation of diabetic foot ulcers, therapeutic footwear constitutes a fundamental preventive strategy within clinical guidelines to offload at-risk areas. Several studies have reported statistically significant evidence supporting the use of therapeutic footwear in preventing ulcer recurrence in people with DM [5,8,9]. Furthermore, the effectiveness of this intervention in reducing lesions can be enhanced when combined with other preventive strategies, such as the use of custom-made orthoses [10–12].

Greater daily wearing time of prescribed therapeutic footwear has been associated with a significantly reduced risk of plantar ulceration, underscoring the clinical importance of sustained adherence to this intervention [13]. However, beyond biomechanical and clinical variables, adherence to therapeutic interventions in diabetic foot care is substantially shaped by psychosocial factors that quantitative metrics alone cannot capture. Research conducted in the broader context of diabetic foot disease has identified social stigma, reduced self-efficacy, impaired quality of life, and the psychological burden of chronic illness as significant determinants of patients' engagement with prescribed treatments [14–17]. Qualitative investigations have further demonstrated that living with diabetic foot complications involves complex experiential dimensions—including feelings of loss of autonomy, altered body image, and social withdrawal—that profoundly shape patients' daily health behaviours [18,19]. Despite this emerging evidence, the psychosocial dimensions of therapeutic footwear adherence specifically have received limited attention in the literature, with existing studies predominantly focusing on quantitative adherence metrics rather than on patients' subjective experiences, beliefs, and perceived barriers [13–16]. This gap constitutes the primary rationale for the present qualitative protocol, which aims to generate novel insights to inform innovative educational interventions and improvements in footwear design and functionality.

Consequently, the objective of this study is to identify, from a qualitative perspective, the needs, experiences, and perceived barriers of people with DM regarding the use of

therapeutic footwear, to inform educational strategies and design improvements that optimise treatment adherence.

2. Experimental Design

2.1. Research Design

This study will be conducted using a qualitative approach to identify the experiences, needs, and perceived barriers of people with diabetes mellitus regarding the use of therapeutic footwear to inform the development of educational strategies and improvements in footwear design that optimise treatment adherence and clinical outcomes. This design allows for the capture of both verbal and non-verbal channels, as well as spontaneous and unstructured responses characteristic of qualitative research [20,21].

The secondary objectives are: (i) to understand beliefs and perceptions regarding the importance of footwear in diabetes management and its role in preventing foot complications; (ii) to identify barriers (difficulties) and facilitators (needs) in the acquisition, fitting, and daily use of appropriate footwear; (iii) to explore the level of satisfaction with current footwear; and (iv) to propose improvements for the design and manufacturing of specialised footwear based on user needs and preferences.

Data will be collected through focus groups, a method well-suited to generating interactive, socially situated accounts of shared experiences [22]. The study will be conducted within a constructivist epistemological framework, which assumes that knowledge is co-constructed between participants and researchers and that meaning is context-dependent [20,21].

The focus group structure and sample size rationale are described in Section 3.1. Data will be analysed using reflexive thematic analysis as proposed by Braun and Clarke [22,23]. Full details of the analytical procedure, including the six-phase process and data saturation criteria, are provided in Section 3.4.

The study will adhere to the Consolidated Criteria for Reporting Qualitative Research (COREQ) as its methodological reporting framework [24].

2.2. Protocol Registration

This study protocol has been prospectively registered in the Open Science Framework (OSF) Registries, the appropriate platform for the registration of qualitative study protocols. The registration is publicly accessible at https://osf.io/c4n9h/overview accessed on 27 March 2026. OSF Registries provides a transparent and open-access repository for study protocols across all research designs, ensuring methodological accountability and reproducibility prior to data collection.

2.3. Recruitment

The study will be conducted in the province of Alicante, Spain. Patients over 18 years of age diagnosed with DM and belonging to the "Asociación de Diabéticos de Elche y Comarca" will be invited to participate voluntarily. The association will disseminate information to its members via email; interviews are scheduled between July and October 2026. Patients will also be informed about the study when attending consultations for other reasons. If they agree to participate, they will be provided with the study information sheet and the informed consent form.

The primary sampling strategy will be purposive sampling, selected because it allows for the intentional recruitment of participants who can provide information-rich accounts relevant to the research objectives. Convenience sampling refers to the practical modality of recruitment—through an existing patient association—and operates within the broader purposive framework rather than constituting an independent sampling strategy.

Both fall within a non-probability sampling approach, consistent with the epistemological foundations of qualitative inquiry [20,21].

To ensure diversity of experiences across the sample, participants will be purposively recruited to represent variation in key dimensions relevant to the study objectives, including: diabetes type (type 1, type 2, or other); disease duration; IWGDF foot risk category [1–3]; footwear experience (therapeutic and/or commercial); age group; and sex. This criterion-based diversity approach is consistent with maximum variation purposive sampling strategies recommended in qualitative health research [21,22]. The grouping logic within and across focus groups is described in detail in Section 3.1.

Inclusion criteria are: (a) confirmed diagnosis of DM, regardless of type; (b) age 18 years or older; (c) ability to communicate in Spanish; and (d) voluntary signature of informed consent. Participants will be recruited across IWGDF foot risk categories [1–3], as the study aims to capture footwear-related experiences across the full clinical spectrum of DM, from early prevention to established comorbidity.

Exclusion criteria are: (a) diagnosis of a non-diabetic systemic condition with primary foot involvement that could independently determine footwear needs (e.g., rheumatoid arthritis, Charcot–Marie–Tooth disease, or severe connective tissue disorders); (b) cognitive or communicative impairment that would preclude meaningful participation in a focus group discussion; (c) active diabetic foot ulcer or recent lower-extremity amputation (within the preceding six months), as acute clinical status may substantially distort the reporting of habitual footwear experience; and (d) inability to provide written informed consent.

A detailed record of the participation rate will be maintained, documenting the number of individuals who refuse the initial invitation and those who, having accepted, do not attend the sessions (dropouts). Whenever possible, reasons for refusal (e.g., lack of time, lack of interest, travel difficulties, or technical issues with the online modality) will be collected anonymously to analyse potential representation biases.

3. Materials and Methods

3.1. Focus Group Design and Procedure

The interview guide was designed ad hoc by the research team based on prior literature and clinical experience. Following COREQ recommendations [24], the guide includes open-ended questions and specific prompts to encourage in-depth discussion. The tool will undergo a two-phase validation process: first, a review by a panel of experts and users to ensure cultural appropriateness; and second, a pilot study with a small focus group (n = 6). This pilot will allow for the refinement of question clarity and the adjustment of online logistics before definitive recruitment.

Upon agreeing to participate and prior to the interviews, subjects will receive an information brochure detailing the discussion format, objectives, and justification. Participants will be informed of the researchers' personal characteristics and interests in the topic. Additionally, a questionnaire will be administered to determine diagnostic duration, sex, age, footwear use, and satisfaction. Explicit signed consent will be required for both study participation and audio recording of the sessions.

To accommodate work schedules and mobility constraints, two participation modalities will be offered: in-person and fully online via video call. Modalities will be kept separate, with each focus group conducted entirely in one format—either fully in-person or fully online. No hybrid or mixed-modality groups are planned, as combining both formats within a single session would introduce asymmetry in group dynamics and complicate moderation. Participants will be allocated to their preferred modality based on personal preference and practical availability.

The groups will be designed following Krueger's recommendations [22]. A total of 8–10 focus groups are proposed, each consisting of 10–12 participants and lasting approximately 60–70 min. This structure is justified on the following grounds: (i) focus group methodology literature recommends a minimum of three to five groups per homogeneous subgroup to achieve informational sufficiency in health research contexts [22,25]; (ii) given the anticipated heterogeneity of the target population—encompassing different diabetes types, disease duration, IWGDF risk categories, and footwear experiences—a larger number of groups is warranted to ensure adequate representativeness across participant profiles; and (iii) a group size of 10–12 participants follows Krueger's recommendations for generating diverse perspectives while maintaining manageable group dynamics [22]. Sample size will be guided by the principle of informational sufficiency rather than a priori power calculations, as described in Section 3.4.

Within each focus group, participants will share common characteristics relevant to the discussion topic—such as similar diabetes duration, IWGDF risk category, or footwear experience—to facilitate meaningful interaction and reduce social inhibition. Across the full set of groups, the sample will be designed to capture maximum variation across key dimensions, ensuring breadth of experiential coverage consistent with a maximum variation purposive sampling strategy.

To ensure meaningful individual contribution within groups of this size, the following measures will be implemented: (i) sessions will be co-facilitated by two experienced researchers [26,27], one acting as primary moderator and one as observer responsible for monitoring group dynamics and ensuring balanced participation; (ii) the moderator will employ structured turn-taking prompts to guarantee that all participants have the opportunity to contribute; and (iii) the interview guide includes specific prompts designed to elicit individual perspectives within the group setting, including direct questions addressed to participants who have not yet spoken during the discussion. Researchers will maintain a field diary to document personal impressions and potential biases, ensuring reflexivity.

Due to the study's nature, no follow-up sessions are required; data will be collected in a single session. Transcript return to participants as a member checking strategy will not be implemented in this study. Within a reflexive thematic analysis framework grounded in constructivist epistemology, member checking is not a mandatory validity criterion, as themes represent interpretive constructions co-produced between researchers and data rather than fixed, verifiable realities—an assumption more consistent with realist epistemological traditions. Nevertheless, to enhance the trustworthiness of the findings, a summary of emerging themes will be shared with a subset of participants and with members of the patient association at the dissemination stage, allowing for community-level feedback on the resonance and relevance of the findings without compromising the integrity of the analytical process. Rigour will be ensured through researcher triangulation and detailed field notes.

The dual role of the research team as both podiatrists and qualitative investigators warrants explicit reflexive attention. Participants may perceive the moderators as clinical evaluators of their footwear behaviour rather than as neutral facilitators of experiential inquiry, which could induce social desirability responses or inhibit the candid expression of non-adherent behaviours. To mitigate this authority bias, moderators will explicitly adopt a 'learning posture' at the outset of each session, framing their role as that of learners seeking to understand patients' lived experiences rather than assessors of clinical compliance. Reflexivity journals will be maintained throughout data collection and analysis to document and critically examine how the researchers' clinical background may shape their interpretive decisions.

Before recording, 5–10 min will be dedicated to establishing rapport through brief, informal questions. Subsequently, a detailed explanation of the procedure, objectives, and relevance of footwear research in DM will be provided. Verbal consent will be requested again immediately before starting the audio capture; this segment will be excluded from the transcription. Participants will be reminded that all identifying information will be removed, and audio recordings will be permanently deleted upon verification of transcript accuracy.

Moderators will maintain strict neutrality, refraining from expressing personal opinions. Their role is to encourage spontaneous accounts without directing the conversation. During each session, one moderator will take field notes to complement the transcript. Moderators will alternate roles across groups to ensure a consistent methodological approach [22,24].

3.2. Interview Content

Four fundamental areas of interest have been established: (i) beliefs and perceptions regarding the significance of footwear in DM management; (ii) difficulties and needs during acquisition, fitting, and daily use; (iii) satisfaction with current footwear; and (iv) proposals for design and manufacturing improvements. The interview guide is structured into four thematic blocks corresponding to these areas.

3.3. Data Management

Audio recordings will be stored on a password-protected, encrypted device accessible only to the principal investigators during the period between data collection and transcription. Upon verification of transcript accuracy, all audio recordings will be permanently deleted in accordance with data minimisation principles under Spanish Organic Law 3/2018 on Personal Data Protection. Anonymised transcripts and coded datasets will be handled in protected Microsoft Word (Mac V16.110) ocuments and managed through a coding matrix in Excel/NVivo® 15 (15.0.x) o ensure traceability. These anonymised analytical materials will be retained on a secure, password-protected institutional server for a period of five years following the conclusion of the study, after which they will be permanently deleted.

3.4. Data Analysis

Data will be analysed using reflexive thematic analysis within a constructivist epistemological framework, following the six-phase approach proposed by Braun and Clarke [22,23]. This method is epistemologically consistent with the qualitative, constructivist design described in Section 2.1 and is well-established for the analysis of focus group data in health research. The analytical process will be inductive in orientation, allowing themes to emerge from the data rather than being imposed by a predetermined coding framework.

The six phases will be implemented as follows:

(i) Familiarisation. Audio recordings will be transcribed verbatim. Transcription will be performed by team members who did not act as moderators during the sessions to minimise interpretive bias at this stage. Participants will be identified by alphanumeric codes throughout. Researchers will read and re-read the transcripts to develop an initial sense of the data as a whole.

(ii) Generating initial codes. Two researchers will independently generate initial codes from the transcripts. Coding will be hierarchical, progressing from descriptive observations to more abstract conceptual categories. In cases of ambiguity, multiple codings will be applied until consensus is reached through discussion.

(iii) Constructing themes. Initial codes will be grouped into candidate thematic units using conceptual maps and summary tables, identifying patterns of shared meaning across the dataset at both semantic and latent levels.

(iv) Reviewing themes. The research team will collectively review the candidate themes, assessing their internal coherence and their distinctiveness from one another. Themes will be merged, subdivided, or discarded as necessary until consensus is achieved.

(v) Defining and naming themes. Final theme definitions will be established, ensuring that each theme captures a meaningful and analytically distinct aspect of the data. Researcher triangulation will be employed throughout phases ii–v to enhance the credibility and trustworthiness of the analytical process.

(vi) Producing the report. The final report will integrate thematic findings with representative verbatim quotations, identified by alphanumeric codes indicating participant number, sex, and age group, in accordance with Spanish data protection legislation (Organic Law 3/2018).

Data collection will be guided by the principle of informational sufficiency—understood as the point at which additional data no longer substantially deepens or complicates the emerging analytical picture—rather than by saturation in its grounded theory sense, which carries epistemological assumptions not fully compatible with reflexive thematic analysis. This determination will be made iteratively and collectively by the research team and documented in reflexivity journals to ensure transparency. As a practical heuristic to guide this iterative assessment, data collection will continue until three consecutive group transcripts yield no substantial new analytical depth; should this threshold not be reached within the initially planned 8–10 groups, recruitment will be extended accordingly [22,28].

Microsoft Word 2021 and NVivo 14 (QSR International) will be used to support data management and organisation. The AI Auto Code feature available in NVivo 14 will be used exclusively as an organisational aid to generate an initial proposal of linguistic patterns and candidate categories. This automated output will not be treated as analytically definitive; two researchers will independently review all AI-generated code suggestions and either confirm, modify, or reject each one based on their own reading of the transcript data. Discrepancies between researchers will be resolved through discussion. All final coding, theme construction, and interpretive decisions will be performed manually by the research team to ensure full reflexivity and interpretive rigour, consistent with the principles of reflexive thematic analysis [22,23].

3.5. Study Chronology

Recruitment begins in June 2026. Interviews are scheduled for July–October 2026. Data analysis will conclude in December 2026 (see Table 1).

Table 1. Study Timeline (June–December 2026). *Note*: Phase 1 involves participant recruitment and pilot testing of the interview guide. Phase 2 covers the data collection through focus groups (in-person and online). Phase 3 includes simultaneous transcription and independent coding by two researchers to ensure reliability. Phase 4 concludes with the final thematic synthesis and dissemination of results. All procedures follow the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines for methodological rigour.

	June	**July**	**September**	**October**	**November**	**December**
Phase 1: Preparation & Recruitment						
Ethics Committee Approval & Association Contact	X					
Participant Recruitment & Informed Consent		X	X			

Table 1. *Cont.*

	June	July	September	October	November	December
Pilot Study and Guide Refinement		X				
Phase 2: Data Collection						
Focus Group Sessions		X	X	X		
Field Notes and Reflexivity Journals		X	X	X		
Phase 3: Data Processing & Analysis						
Transcription and Initial Coding			X	X	X	
Thematic Analysis (Braun & Clarke's Phases)				X	X	
Informational Sufficiency Assessment						X
Phase 4: Reporting & Dissemination						
Final Report and Manuscript Preparation					X	X
Synthesis Report for the Patient Association						X

3.6. Ethical Considerations

This study will be submitted for ethical review to the Ethics Committee prior to the commencement of any data collection. Recruitment and focus group sessions will not begin until formal approval has been obtained. Any subsequent methodological modifications will be communicated to the Committee.

Measures to ensure participant safety and data protection include voluntary informed consent, verbal confirmation during recordings, alphanumeric anonymisation, permanent deletion of audio recordings upon verification of transcript accuracy, and secure retention of anonymised analytical data for a maximum period of five years. The study will be conducted in full accordance with the Declaration of Helsinki, the European General Data Protection Regulation (EU) 2016/679, and Spanish Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights.

3.7. Dissemination of Results

Findings will be structured into a hierarchy of major and minor themes. A specific section will discuss divergent cases to enrich the understanding of the phenomenon. Each theme will be defined through an analytical narrative integrating participant voices with current literature. Findings will be supported by representative verbatim quotations identified by alphanumeric codes (participant number, sex, and age), ensuring anonymity according to Spanish Law 3/2018. Results will be published in high-impact journals and presented at podiatry and diabetes congresses. A non-technical synthesis report will be provided to the "Asociación de Diabéticos de Elche y Comarca" to return knowledge to the participating community.

4. Discussion

The present protocol addresses a critical gap between the biomechanical efficacy of therapeutic footwear and its real-world effectiveness in the daily lives of people with diabetes mellitus (DM). Although the existing literature has extensively examined quantitative adherence parameters—such as sensor-measured plantar pressure reduction and daily wearing time [29–32]—these data provide an incomplete picture. Quantitative metrics indicate how much prescribed footwear is used but do not explain the underlying reasons for non-adherence or rejection. By adopting a qualitative approach, this study aims to capture the lived experience of patients, allowing their needs, beliefs, and perceived barriers to

inform improvements in footwear design and clinical prescription. This perspective is consistent with recent socio-cultural approaches to diabetic foot care, which frame therapeutic adherence as a socially embedded phenomenon shaped not only by clinical variables but also by patient identity, stigma, embodiment, and social participation [19]. The ethnographic and integrated model is particularly relevant to the present protocol, as it situates diabetic foot management within the broader context of patients' lived realities and cultural practices, providing a valuable theoretical bridge between qualitative experiential research and translational clinical application. Incorporating this socio-cultural lens strengthens the conceptual rationale for our focus group design and reinforces the legitimacy of qualitative methodologies within a field still dominated by quantitative and biomechanical paradigms.

The selection of focus groups as the primary data collection method is strategically justified. Unlike individual interviews, group interaction fosters a social dynamic in which shared norms, stigmas, and tacit beliefs are more likely to emerge. Perceptions such as "orthopaedic footwear makes me look older" or feelings of social embarrassment are more likely to be expressed honestly among peers than in a one-to-one clinical encounter, where patients may be inclined toward social desirability—that is, responding in ways they perceive the researcher expects or prefers [22,33]. This social dimension of footwear behaviour is precisely what this study seeks to capture.

The methodological rigour of this protocol is further supported by its adherence to COREQ reporting standards, ensuring transparency and international comparability [24]. The use of reflexive thematic analysis within a constructivist framework provides a well-validated and epistemologically coherent analytical approach for focus group data [22,23]. The AI Auto Code feature in NVivo 14 will be employed exclusively as an organisational aid to identify initial linguistic patterns; all interpretive and thematic decisions will be made manually by the research team, ensuring full analytical rigour and reflexivity. Prior validation of the interview guide by an expert and user panel further reinforces the patient-centred orientation of the study from its earliest stages.

Consistent with the principles of qualitative rigour, this protocol acknowledges the dual role of the research team. The fact that the moderators are podiatrists with expertise in diabetic foot care constitutes a technical advantage for probing participants' accounts in depth; however, it also introduces a risk of authority bias and a potential tendency to prioritise clinical functionality over aesthetic preferences or emotional comfort. To mitigate this "clinical gaze", moderators will adopt a stance of analytical neutrality, and reflexivity journals will be maintained throughout data collection and analysis. The goal is for researchers to act as facilitators seeking to identify gaps between clinical practice guidelines and patients' lived reality, rather than as evaluators of patient behaviour. A further reflexivity consideration concerns the specific nature of the authority relationship between podiatrist-moderators and participants with DM. Unlike generic researcher–participant dynamics, the clinician–patient relationship carries an inherent asymmetry that may be particularly salient when discussing adherence to prescribed footwear—a behaviour directly evaluated in clinical consultations. Participants may consciously or unconsciously adjust their accounts to align with what they perceive the clinician-researcher expects or approves of, thereby introducing a social desirability bias that standard neutrality protocols may not fully eliminate. Acknowledging this limitation explicitly and maintaining detailed reflexivity journals that interrogate the influence of clinical assumptions on interpretive decisions constitutes a necessary—if not fully sufficient—strategy for managing this dual-role dynamic.

Several methodological limitations should be acknowledged. First, recruitment through a patient association may introduce a "proactive patient" bias, whereby participants' health literacy and motivation may be higher than average, potentially limiting

the transferability of findings to non-affiliated patients. Nevertheless, this group offers a richness of accumulated experience that is valuable for an initial in-depth exploratory phase. Second, the inclusion of an online participation modality, while facilitating access for participants with mobility or scheduling constraints, may create a digital divide that excludes older patients or those with limited technological resources. The inclusion of an in-person modality is therefore a methodological equity measure designed to ensure representativeness across age groups and socioeconomic profiles within the province of Alicante. Third, the use of purposive and convenience sampling, while appropriate for qualitative inquiry, may limit the transferability of findings to populations with different sociodemographic or clinical profiles. Fourth, as with all qualitative research, the findings will reflect the interpretive perspective of the research team; the reflexivity measures incorporated into the design aim to mitigate, though not eliminate, this inherent limitation.

The decision to recruit participants across IWGDF foot risk categories 1–3 reflects the prevention-oriented scope of the study. Current IWGDF guidelines recommend footwear-related education and appropriate footwear use across all risk categories [33]. By including participants at different stages of the clinical trajectory of DM, the study aims to identify how disease awareness, perceived risk, and footwear beliefs evolve over time—information that is essential for developing targeted, stage-appropriate educational strategies.

Future research should extend this line of inquiry to younger populations, including adolescents and young adults with type 1 diabetes or other early-onset forms of the condition, for whom psychosocial barriers to therapeutic footwear adherence—including body image concerns and peer-related stigma—may be particularly salient. Such studies would require age-adapted methodological designs and specific ethical provisions for research involving minors.

The potential impact of this study extends beyond the description of patient beliefs. By generating empirical data on user preferences and experiences, the findings may guide manufacturers towards the development of footwear that people genuinely want to wear—integrating biomechanical safety with aesthetic acceptability and cultural relevance. At the clinical level, understanding the "why" behind adherence will enable healthcare professionals to personalise their educational strategies, transforming the clinician–patient relationship from one based on the imposition of technical guidelines to one grounded in mutual understanding and shared decision-making. By returning knowledge to the participating community through a non-technical synthesis report, the study also aims to contribute to a more participatory model of diabetes care.

5. Conclusions

This protocol describes a rigorous and reproducible qualitative study designed to address a significant gap in the literature on therapeutic footwear adherence among people with DM. Through a focus group methodology grounded in reflexive thematic analysis and aligned with COREQ reporting standards, the study aims to generate patient-centred, evidence-based insights that can inform the development of educational interventions and improvements in footwear design. The heterogeneous sampling strategy, spanning IWGDF foot risk categories 1–3, will enable a comprehensive exploration of footwear-related experiences across the full clinical spectrum of DM, ultimately contributing to the prevention of diabetic foot complications and to a more participatory model of diabetes care.

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