

Jun 18, 2024

Toe separators - a systematic review protocol.

DOI

<https://dx.doi.org/10.17504/protocols.io.eq2lyjqkwlx9/v1>

Hanna Krześniak¹, aleksandra.truszczyńska¹

¹Józef Piłsudski University of Physical Education in Warsaw



Hanna Krześniak

Józef Piłsudski University of Physical Education in Warsaw

Create & collaborate more with a free account

Edit and publish protocols, collaborate in communities, share insights through comments, and track progress with run records.

Create free account

OPEN  ACCESS



DOI: <https://dx.doi.org/10.17504/protocols.io.eq2lyjqkwlx9/v1>

Protocol Citation: Hanna Krześniak, aleksandra.truszczyńska 2024. Toe separators - a systematic review protocol.. protocols.io <https://dx.doi.org/10.17504/protocols.io.eq2lyjqkwlx9/v1>

Manuscript citation:

[Author(s)]. [Year]. [Title of the systematic review]. [Journal Name]. [Volume Number](Issue Number): [Page Range]. DOI: [Digital Object Identifier].

Example:

Smith, J., Johnson, A., Brown, L. (2022). Efficacy and Clinical Applications of Toe Separators: A Systematic Review. Journal of Foot and Ankle Research. 9(2): 123-135. DOI: 10.1186/s13047-022-0456-7.

License: This is an open access protocol distributed under the terms of the **Creative Commons Attribution License**, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited

Protocol status: Working

We use this protocol and it's working

Created: December 11, 2023

Last Modified: June 18, 2024

Protocol Integer ID: 92095

Keywords: systematic review, toe separators, foot, forefoot, toe spacer, halluxvalgus, toe spreaders, toe separators hallux valgus, foot deformities, clinical applications of toe separator, effectiveness of toe separator, toe separators in clinical practice, potential benefits of toe separator, comprehensive overview of toe separator, use of toe separator, limitations of toe separator, toe separator, different types of toe separator, potential therapeutic benefits in various foot condition, incorrect usage of toe separator, importance of proper toe alignment, proper toe alignment, toe alignment, enhancing overall foot health, overlapping toe, toe spreader, management of common foot condition, improving toe alignment, foot health, term effects on foot health, overall foot health, common foot condition, anatomical structure of the foot, various foot condition, optimal foot function, including podiatrist, comprehensive analysis of the efficacy, such as bunion, based separator, bunion

Abstract

Toe separators, also known as toe spacers or toe spreaders, have gained significant attention in recent years for their potential therapeutic benefits in various foot conditions. This scientific article aims to provide a comprehensive analysis of the efficacy and clinical applications of toe separators.

The study begins by reviewing the anatomical structure of the foot and the importance of proper toe alignment for optimal foot function. It then delves into the different types of toe separators available in the market, including gel, foam, and silicone-based separators, highlighting their unique features and potential advantages.

Furthermore, article explores the potential benefits of toe separators in the management of common foot conditions such as bunions, hammertoes, and overlapping toes. It examines existing research studies and clinical trials that have investigated the effectiveness of toe separators in relieving pain, improving toe alignment, and enhancing overall foot health.

The article also discusses the potential limitations and contraindications associated with the use of toe separators, emphasizing the importance of proper fitting and individualized treatment plans. Additionally, it addresses the potential risks of prolonged or incorrect usage of toe separators, including skin irritation and pressure-related complications.

Moreover, this analysis highlights the role of healthcare professionals, including podiatrists and orthopedic specialists, in prescribing and guiding the use of toe separators as part of a comprehensive treatment approach. It emphasizes the need for evidence-based recommendations and further research to establish standardized protocols for the use of toe separators in clinical practice.

In conclusion, this scientific article provides a comprehensive overview of toe separators, their efficacy, and clinical applications. It serves as a valuable resource for healthcare professionals and researchers interested in understanding the potential benefits and limitations of toe separators in various foot conditions. Further research is warranted to establish clear guidelines for their optimal usage and to explore their long-term effects on foot health.

Guidelines

The systematic review will be proceed. The first selection will be based on titles and abstracts, followed by subsequent selections based on full texts. Two authors will independently analyse and select articles, then their results will be compared before the final analysis. In the event of disagreements between those doing the selection or data collection, a

consensus is reached through discussion. The next step is the selection of studies based on the inclusion and exclusion criteria defined in the protocol,

first on the basis of titles and abstracts and then on the full texts of the publications.

Once the data have been collected, it will be analysed and the results presented in tabular form.

The systematic review will take a descriptive form, i.e. a narrative presentation of the scientific data found, due to the wide variation in the results of the papers, as well as the small number of eligible papers

Materials

1. Title of the systematic review: Toe separators as a therapeutic tool in physiotherapy - a systematic review.

2. Authors: Hanna Krześniak, Aleksandra Truszczyńska-Baszak, Józef Piłsudski University of Physical Education in Warsaw.

3. Objective: evaluate the efficacy and clinical applications of toe separators in various foot conditions.

4. Methods: used for conducting the systematic review:

a. Search Strategy: A systematic search will be performed across multiple electronic databases, including PubMed, Science Direct, and Web of Science. Key words to be used in search: toe separators, toe spreaders, toe spacers, toe separators hallux valgus. A search through research databases will be carried out, searching for all key words one by one, and then selecting articles that concerned the topic of toe separators. Additionally, reference lists of identified articles will be screened to ensure a comprehensive inclusion of relevant studies.

b. Study Selection:

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines are used. These guidelines provide a structured framework for the transparent and comprehensive reporting of systematic review protocols, ensuring the reproducibility and quality of the review process. The detailed process of study selection, including the screening of titles and abstracts, full-text assessment, and any criteria used for inclusion or exclusion, will be conducted.

c. Data Extraction:

The PICO strategy (Population, Intervention, Comparison, Outcome) framework to guide our research question and study selection is used. This framework helps to define the key elements of review, including the target population (patients with foot and lower limb conditions), the intervention of interest (toe separators), the comparison groups (if applicable), and the desired outcomes (e.g., pain reduction, functional improvement).

By incorporating the PRISMA-P guidelines and utilizing the PICO framework, we aim to enhance the rigor and transparency of our systematic review, enabling readers to better understand the methodology employed and the implications of our findings.

d. Inclusion criteria: encompassed randomized controlled trials, quasi-experimental studies and observational studies that investigated the use of toe separators in interventions. Studies focusing on various foot and lower limb conditions, such as hallux valgus, plantar fasciitis, and metatarsalgia, were considered.

e. Exclusion criteria: articles written in a language other than English, lack of accessible article content or even abstracts alone, topics not related to toe separators, use of other types of orthoses (e.g. orthoses to abduct the hallux valgus, not acting as toe separators), descriptions of surgical procedures, articles describing other topics not related to toe separators.

f. Quality Assessment: the quality and risk of bias of the included studies will be conducted using the PEDro scale.

g. Data Synthesis: in order to present the results of a systematic review, a narrative synthesis will be carried out.

5. Results: Summary of the main findings of the systematic review, including:

a. Study Characteristics: the characteristics of the included studies, such as study design, sample size and intervention details.

b. Outcomes: the outcomes measured in the included studies and their findings related to the efficacy and clinical applications of toe separators.

c. Quality Assessment: Summarizing the quality assessment results, highlighting any potential biases or limitations identified.

6. Conclusion:

State the overall conclusion of the systematic review based on the findings, highlighting the implications for clinical practice and future research.

7. Funding: no funding, no conflicts of interest related to the systematic review.

Safety warnings

- ❗ 1. Consult a healthcare professional: The information provided in this systematic review is intended for informational purposes only and should not replace professional medical advice. Individuals with foot conditions or concerns should consult a healthcare professional before using toe separators.
2. Proper fitting and usage: It is crucial to ensure that toe separators are properly fitted and used according to manufacturer instructions or under the guidance of a healthcare professional. Incorrect usage or ill-fitting toe separators may lead to discomfort, skin irritation, or other complications.
3. Individualized treatment approach: The findings of this systematic review should not be considered as a one-size-fits-all solution. Each individual's foot condition may vary, and treatment plans should be tailored to their specific needs. Healthcare professionals should consider factors such as foot anatomy, existing conditions, and patient preferences when recommending or prescribing toe separators.
4. Monitoring for adverse effects: Users of toe separators should monitor their feet regularly for any adverse effects such as increased pain, numbness, tingling, or skin discoloration. If any concerning symptoms arise, it is important to discontinue use and seek medical attention.
5. Contraindications: Certain individuals may have specific contraindications for using toe separators. These may include individuals with open wounds, infections, circulatory disorders, or neuropathy. It is essential to consult a healthcare professional to determine if toe separators are appropriate for your specific condition.
6. Gradual adaptation: When starting to use toe separators, it is recommended to gradually increase the duration and frequency of use. This allows the feet to adapt to the new alignment and reduces the risk of discomfort or strain.
7. Regular cleaning and maintenance: To maintain hygiene and prevent the risk of infection, toe separators should be regularly cleaned according to the manufacturer's instructions. Replace worn-out or damaged toe separators promptly.
8. Long-term effects: The long-term effects of using toe separators are still being studied. While this systematic review provides insights into their efficacy, it is important to consider potential long-term effects and consult with healthcare professionals for ongoing monitoring and guidance.

Ethics statement

no conflict of interest

Before start

Methods of randomisation, treatment allocation, blinding will be assessed. There will be 2 reviewers that will be involved in the quality assessment. In the event of disagreements between those doing the selection or data collection, a consensus is reached through discussion.

Toe separators - a systematic review protocol

1. **1. Define the Research Question:** Clearly articulate the research question or objective of the systematic review on toe separators. This should include the specific population, intervention (toe separators), comparison (if applicable), outcomes of interest, and study design.
2. **2. Select a Suitable Registry:** Identify a reputable and recognized registry for systematic review protocols. Examples include PROSPERO (International Prospective Register of Systematic Reviews) and the Cochrane Database of Systematic Reviews. Ensure that the chosen registry aligns with the scope and requirements of the review.
3. **3. Familiarize with Registry Guidelines:** Thoroughly review the guidelines provided by the selected registry. Understand the specific information and documentation required for protocol registration. This may include details on study eligibility criteria, search strategy, data extraction methods, and analysis plan.
4. **4. Prepare the Protocol:** Develop a comprehensive protocol for the systematic review on toe separators. This should include a detailed description of the research question, study objectives, inclusion and exclusion criteria, search strategy, data extraction methods, quality assessment criteria, and statistical analysis plan.
5. **5. Complete the Registration Form:** Access the registration form provided by the chosen registry and complete all the required fields. Provide accurate and concise information based on the protocol developed in the previous step. Ensure that all sections of the form are filled out correctly and completely.
6. **6. Submit the Protocol for Registration:** Follow the instructions provided by the registry to submit the completed registration form. Pay attention to any additional documentation or supplementary materials that may be required, such as the full protocol document or any supporting references.
7. **7. Review and Approval Process:** The registry will review the submitted protocol for completeness and adherence to their guidelines. They may provide feedback or request revisions if necessary. Once the protocol is deemed satisfactory, it will be assigned a unique registration number and made publicly available on the registry's website.
8. **8. Update the Protocol:** If any changes or amendments are made to the protocol during the course of the systematic review, it is important to update the registered protocol accordingly. This ensures transparency and helps avoid any potential bias or selective reporting.



By following these methods, researchers can effectively register their protocol for a systematic review on toe separators, promoting transparency, reducing duplication, and enhancing the credibility of the review process.

2

Protocol references

Park CH, Chang MC. Forefoot disorders and

conservative treatment. *Yeungnam Univ J Med.* 2019 May;36(2):92-98. doi: 10.12701/yujm.2019.00185. Epub 2019 May 14. PMID: 31620619; PMCID: PMC6784640.

Waizy H, Stukenborg-Colsman C,

Abbara-Czardybon M, Emmerich J, Windhagen H, Frank D. Eine spezielle Weichteilplastik am Großzehengrundgelenk bei Hallux-valgus-Operationen [A special soft tissue procedure for treatment of hallux valgus]. *Oper Orthop Traumatol.* 2011 Feb;23(1):46-51. German. doi: 10.1007/s00064-010-0005-7. PMID: 21359628.

Leucht AK, Younger A, Veljkovic A, Perera

A. The Windswept Foot: Dealing with Metatarsus Adductus and Toe Valgus. *Foot Ankle Clin.* 2020 Sep;25(3):413-424. doi: 10.1016/j.fcl.2020.05.005. Epub 2020 Jul 11. PMID: 32736739.

Bała

MM, Leśniak W, Jaeschke R. Proces przygotowywania przeglądów systematycznych, z uwzględnieniem przeglądów Cochrane. *Pol Arch Med Wewn.* 2015 Dec 22;125 Spec No.:16-25. Polish. PMID: 26794237.

Dissaneewate T, Na

Rungsri T, Cheunchokasan P, Leelasamran W. Comparison between the plantar pressure effects of toe separators and insoles in patients with hallux valgus at a one-month follow-up. *Foot Ankle Surg.* 2022 Jan;28(1):93-99. doi: 10.1016/j.fas.2021.02.005. Epub 2021 Feb 12. PMID: 33612377.

Tang SF, Chen CP, Pan

J-L, Chen J-L, Leong C-P, Chu N-K. The effects of a new foot-toe orthosis in treating painful hallux valgus. *Arch Phys Med Rehabil* 2002;83:1792-5.

Chiong

Y, Tay SS, Lim PA, Tan DM. The effects of toe spreader in people with overactive toe flexors post stroke: a randomized controlled pilot study. *Clin*

Rehabil. 2013 Jan;27(1):90-5. doi: 10.1177/0269215512446157. Epub 2012 May 29. PMID: 22643727.

Lee, KS, Ko, E, & Lee, S. (2013). Immediate Effect of the Toe Spreader on Tibialis Anterior and Peroneus Longus Muscle Activities: a Pilot Study. *Journal of Physical Therapy Science*, 25, 293-295.

Cashin AG, McAuley JH. Clinimetrics: Physiotherapy Evidence Database (PEDro) Scale. *J Physiother*. 2020 Jan;66(1):59. doi: 10.1016/j.jphys.2019.08.005. Epub 2019 Sep 11. PMID: 31521549.

Alkhalifah KM, Almotiri MM, Alharbi AE, Alrashidi A, Aldhali IK, Alsaqry OS, Alharbi KH, Almogbil I. A Systematic Review and Meta-Analysis of the Prevalence of Hallux Valgus in the General Population. *Cureus*. 2023 Jul 31;15(7):e42739. doi: 10.7759/cureus.42739. PMID: 37654927; PMCID: PMC10467527.

Ying J, Xu Y, István B, Ren F. Adjusted Indirect and Mixed Comparisons of Conservative Treatments for Hallux Valgus: A Systematic Review and Network Meta-Analysis. *Int J Environ Res Public Health*. 2021 Apr 6;18(7):3841. doi: 10.3390/ijerph18073841. PMID: 33917568; PMCID: PMC8038851.

Deschamps K, Birch I, Desloovere K, Matricali GA. The impact of hallux valgus on foot kinematics: a cross-sectional, comparative study. *Gait Posture*. 2010 May;32(1):102-6. doi: 10.1016/j.gaitpost.2010.03.017. Epub 2010 May 6. PMID: 20451392.