

INPLASY PROTOCOL

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Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: The research question was defined according to the PICOS criteria: P - participants of any age with a scar / keloid / hypertrophic scar. I -

Dry needling for physical therapy of scar. A protocol for a systematic review

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Review question / Objective: The research question was defined according to the PICOS criteria: P - participants of any age with a scar / keloid / hypertrophic scar. I - interventions: local management with needling, dry needling, acupuncture or combination of local needling / dry needling / acupuncture with distal acupuncture. C - comparator: local intervention (physical therapy) aimed at scar, keloid or hypertrophic scar treatment or no treatment. O - objectives: changes in pain associated with scar, keloid or hypertrophic scar. Pigmentation, vascularity, height / thickness, pliability / plasticity, itchiness of the scar area. S - study design: The articles were included based on the following inclusion criteria: full text articles in English, randomized controlled trials, clinical trials, case reports, case-series, case control studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 January 2023 and was last updated on 18 January 2023 (registration number INPLASY202310058).

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scar, keloid or hypertrophic scar treatment or no treatment. O - objectives: changes in pain associated with scar, keloid or hypertrophic scar. Pigmentation, vascularity, height / thickness, pliability / plasticity, itchiness of the scar area. S - study design: The articles were included based on the following inclusion criteria: full text articles in English, randomized controlled trials, clinical trials, case reports, case-series, case control studies.

Rationale: Acupuncture has been adopted to modern physiotherapy practice based on anatomy, neuroscience, pathology and evidence-based medicine and has been integrated into the Western Medical Model (White, 2009). Administered using this model, acupuncture is now quite commonly used in the treatment of soft tissue injuries (Godley, 2020). The American Alliance for Professional Acupuncture Safety (AAPAS) concluded dry needling was a simplified version of acupuncture and describe dry needling systematically. Consequently, dry needling can be considered an equivalent of acupuncture and traditional acupoints are equivalent with trigger points (dry needling points) (Fan et al., 2017). In a literature review, Dunning et al. (2014) noted the terms acupuncture and dry needling were used interchangeably. However, acupuncture originates from Traditional Chinese Medicine (TCM) and aims at treating disease by inserting needles into specific points along meridians emphasizing local, distal and whole body responses. Dry needling practitioners, on the other hand, focus on acupuncture's local response (Fan et al., 2017). Dry needling is based upon Western Medical Concepts (Kalichman & Vulfsons, 2010). It does not include the stimulation of auricular or distal points or injection of some substance (Legge, 2014). Dry needling is used to treat muscles, ligaments, tendons, subcutaneous fascia and scar tissue. When inserted in the area of peripheral nerves / neurovascular bundles, dry needles may help relieve neuromusculoskeletal pain syndromes (Dunning et al., 2014). Dry needling improves the elasticity of scar tissue; the technique loosens tissues which enables

various layers to slide over each other (Zanier & Bordoni, 2015).

Dry needling can be classified in various ways. Based on the depth of needle insertion, needling can be termed as superficial and deep needling. Based on the structure that is being needled, it can be classified as trigger point dry needling, fascial needling or scar tissue needling (Das & Kulkarni, 2022). The mechanisms of action of dry needling are differently accounted for. Dunning et al. (2014) mention the biomechanical, chemical and vascular effects of needling into either superficial subcutaneous tissue (non-muscular) or deep (intramuscular tissue) at trigger point and non-trigger point locations. The potential effects include pain relief, wound healing acceleration, and changes in myofascial system. Das and Kulkarni (2022) believe the mechanisms of action of dry needling include increased blood supply, biomechanical changes and inhibitory regulation of the pain gate. Peter Baldry, a proponent of superficial dry needling, points out pain can be modulated by A delta stimulation through insertion of the needle only a few millimeters into the skin (Baldry, 2002). Needle insertion may also stimulate the release of opioids or serotonin into the central nervous system and hence the analgetic effect (Chou et al., 2012). Superficial dry needling (SDN) involves insertion of the needle into the subcutaneous, but not muscle tissues and seems to adequately address scar tissue. In our search process we used the terms 'acupuncture' or 'needling' or 'dry needling' so that no important publications would be missed.

Condition being studied: Scar formation results from wound healing processes that occur following physical injury to body tissues. Prolonged and abnormal wound healing may cause the development of hypertrophic scars which can be itchy and painful, resulting in serious functional and cosmetic disability. Scars can produce different symptoms, which can have an impact on the neurological sphere as well as the fascial and visceral areas (Bordoni & Zanier, 2013). Scar tissue may produce adhesions between skin layers and fascia

causing impaired blood supply to the scar and adjacent tissues (Stecco et al., 2016). Therefore scars can negatively impact the quality of life of patients (Bock et al., 2006). A systematic review and meta-analysis of Deflorin et al. (2020) indicate a whole range of physical therapies can be employed for scar treatment. Physical scar management options can be grouped into mechanotherapy, occlusive and hydrogenatic therapies, light therapy or a combination of the above. Scar pain in burn patients may be effectively reduced using extracorporeal shockwaves therapy (EWST), soft tissue techniques and high-intensity light therapy. Regarding the treatment of scar thickness and pliability, positive effects of pulsed dye laser (PDL) were seen in postsurgical scars while silicone gel and silicone gel sheets effectively improved hypertrophic scars pliability. Scar thickness was positively affected when hypertrophic and burn scars were treated with soft tissue techniques, scar surface area was positively influenced by laser therapy modalities (PDL and CO2 laser) (Deflorin et al., 2020).

Other suggestions for scar treatment are also offered including naturopathic and herbal approach to scars, connective tissue massage, deep transverse friction massage, siatsu, crochitage and diacutaneous fibrolysis. However, no peer reviewed literature is currently available to confirm the efficacy of these techniques (Zanier & Bordoni, 2015).

We have focused on the efficacy of dry needling/local acupuncture for different types of scars.

METHODS

Search strategy: As mentioned above, the terms needling, dry needling and acupuncture have been used interchangeably. Therefore the search strategy included different combinations of the following keywords: 'scar', 'keloid', 'dry needling', 'needling', 'acupuncture', 'treatment', 'physical therapy'

A detailed search strategy for PubMed:
 ((dry needling*[tiab]) OR (needling*[tiab]) OR (dry needling[tw]) OR (intradermal[tiab]) OR (intradermal[tw]) OR (needling[tw]) OR

(acupuncture*[tiab])) AND ((scar[tiab]) OR (scar[tw] OR (scar[mh]) OR scars[tw])) AND ((therapy[tw]) OR (physical therapy[tw]) OR (treatment[tiab])).

Participant or population: Participants of any age with a scar / keloid / hypertrophic scar were included. Post acne scarring, animal and in vitro studies were excluded.

Intervention: Local management with needling, dry needling, acupuncture or combination of local needling/dry needling/acupuncture with distal acupuncture. We excluded only Traditional Chinese Medicine (TCM), wet needling, microneedling, radiofrequency microneedling, trigger point (TrPs) / myofascial trigger point (MTrPs) dry needling beyond scar area, non-therapeutic dry needling, electrical needling, electroacupuncture.

Comparator: Control physical therapy intervention for scar / keloid / hypertrophic scar or no treatment. Trials assessing intervention costs, adverse effects only, surgical treatment were excluded.

Study designs to be included: This review included full-text, peer-reviewed research including randomized controlled trials, clinical trials, case reports, case-series, case control studies. All written in English language. Abstracts, posters, conference proceedings, letters, protocols, reviews (also meta-analyses) and non-clinical trials were excluded.

Eligibility criteria: Eligibility criteria are based on the PICOS framework. Inclusion criteria: Population: participants of any age with a scar / keloid/hypertrophic scar Intervention: local management with needling, dry needling, acupuncture or combination of local needling/dry needling/acupuncture with distal acupuncture. Comparator: control physical therapy intervention for scar / keloid / hypertrophic scar or no treatment. Objectives: Changes in pain associated with scar, keloid or hypertrophic scar. Pigmentation, vascularization pattern, shape/thickness, pliability/plasticity, itchiness of the scar area. S - study design:

The articles were included based on the following inclusion criteria: full text articles in English, randomized controlled trials, clinical trials, case reports, case-series, case control studies Exclusion criteria: Population: Post acne scarring, children, animal and in vitro studies were excluded. Intervention: We excluded only Traditional Chinese Medicine (TCM), wet needling, microneedling, radiofrequency microneedling, trigger point (TrPs) / myofascial trigger point (MTrPs) dry needling beyond scar area, non-therapeutic dry needling, electrical needling, electroacupuncture. Comparator: Trials assessing intervention costs, adverse effects only, surgical treatment were excluded. Objectives: studies on pain / symptoms unrelated to scar / keloid were excluded and so were studies which did not use any scar assessment prior to and after dry needling Study design: Abstracts, posters, conference proceedings, letters, protocols, reviews (also meta-analyses) and non-clinical trials were excluded.

Information sources: MEDLINE (PubMed, EBSCOHost and Ovid), EMBASE (Elsevier) Databases were searched for relevant publications from their inception to 27 July, 2022, by two lead reviewers (D.C. and M.N.). The reviewers gained knowledge on search strategy through video tutorials and close cooperation with an experienced librarian from the Medical University Library. To minimize the risk of omitting relevant sources, the strategies to explore grey literature (Google Scholar) was implemented (M.K.).

All literature search results were compared; duplicate publications were removed manually by two independent researchers (D.C and M.N.), who then compared the outcomes of their selection.

The reference lists of studies meeting the inclusion criteria were searched to identify additional relevant studies. Two researchers (J.M. and P.D.) performed screening independently.

Main outcome(s): Main outcomes measures will be:

- The Numeric Rating Scale (NRS), Visual Analog Scale (VAS) or Likert Scale for

assessment of the intensity of pain or other symptoms (e.g. itch)

- The Vancouver Scar Scale (VSS): vascularity, pigmentation, pliability, height
- The Patient and Observer Scar Assessment Scale (POSAS): vascularity, pigmentation, thickness, relief, pliability, surface area.

Additional outcome(s): - quality of life
- other.

Data management: The two reviewers (D.C. and M.N.) will independently collect data from all included studies using a customized data extraction table in Microsoft Excel. They will independently copy appropriate extracts from the full text of the publications and paste them into the table. In the final version of the table, the data extracted by both reviewers will be compared. Data to be entered into text tables will be jointly agreed on. A third author (J.M.) will checked all extracted data for accuracy. In case of disagreement, three reviewers debated until a consensus was reached.

The following data items will be sought: basic publication characteristics (first author, publication year, country/countries of the research center) and study-specific parameters (study type, aim of the study, inclusion criteria, sample size, group/s), characteristics of the intervention (e.g. technique, kind of needle, number of sessions), outcomes and results.

PRISMA flow diagram will be presented.

Quality assessment / Risk of bias analysis:

Assessment of the methodological quality of a study will be performed depending on study design. For RCT we will use the Physiotherapy Evidence Database (PEDro) scale consisting of 10 questions pertaining to the internal validity and statistical information provided (Moseley et al., 2002). Based on the PEDro score, the methodological quality of trials will be rated as high (PEDro scores ≥ 7), medium (4 to 6), or low (≤ 3). Two reviewers (D.C and J.M.) will independently assess the methodological quality of the articles included in this systematic review. In cases of disagreement, consensus will be sought

by involving a third researcher (M.S.) (Ma et al., 2020).

The JBI Critical appraisal tools developed by the JBI and collaborators and approved by the JBI Scientific Committee will be used for case reports, case series or case control studies [<https://jbi.global/critical-appraisal-tools>].

Strategy of data synthesis: Data will be summarized using descriptive statistics, with means and standard deviations for continuous variables and frequencies and percentages for dichotomous variables.

Subgroup analysis: Not planned.

Sensitivity analysis: Sensitivity analysis will be conducted to exclude studies of low-quality (PEDro scale and JBI Critical appraisal tools) and high risk of bias.

Language restriction: Articles published in English will be considered for inclusion.

Country(ies) involved: Poland: Academy of Physical Education in Katowice, Poland; Medical University of Silesia, Poland; Czech Republic: Charles University, Prague, Czech Republic, Charles University and University Hospital Motol, Prague, Czech Republic.

Keywords: scar; keloid; hypertrophic scar; dry needling; needling; acupuncture; treatment; physical therapy.

Dissemination plans: We are planning to submit the article with the systematic review synthesis to an international peer-reviewed journal with impact factor.

Contributions of each author:

Author 1 - Daria Chmielewska: conceptualization; designing the review; data collection; data management; analysis of data; interpretation data; writing the protocol, writing the manuscript.

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