PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Appraising the safety and reporting quality of Tread Embedding Acupuncture: a protocol for systematic review and meta-analysis
Update	1b	Not applicable
Registration	2	PROSPERO(CRD42022297123)
Authors:		
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Contributions	3b	Study administration: J H Kim, Research theme selection: J H Kim, Data investigation: D H Lee, J W Suh Research method design: Y Woo, Y Kim, Systematic review registration: J H Kim Protocol draft writing: Y Woo, B I Kwon, Protocol review & editing: J H Kim, B Koo, Validation: S S Nam
Amendments	4	Important protocol amendments will be implemented to PROSPERO registration
Support:		
Sources	5a	Traditional Korean medicine R&D programme fund
Sponsor	5b	Ministry of Health and Welfare(MOHW), Korea Health Industry Development Institute (KHIDI)
Role of sponsor or funder	5c	Sponsor only provided the financial support
INTRODUCTION		

Rationale	6	Acupuncture is an effective and safe treatment and thread embedding acupuncture (TEA) is a special type of acupuncture that involves inserting medical threads into subcutaneous tissues or muscles at therapeutic points. TEA is a subtype of acupuncture treatment method, but there are differences between TEA and traditional acupuncture treatment. As such, it is necessary to evaluate the safety of TEA.
Objectives	7	This study aimed to assess the safety of TEA and reporting quality of the available studies regarding TEA.
METHODS		
Eligibility criteria	8	The participants will include all patients treated with TEA at least once and the intervention will be TEA. The comparator groups will include patients who did not undergo TEA. Placebo, sham control, waiting list, and any other active controls, including conventional treatments will be included. The primary outcomes will be the incidence (or frequency) and the types of AEs associated with TEA. The secondary outcomes will be severity, causality, and follow-up information. The types of studies included will be all clinical trials, observational studies or case studies in which TEA represented at least one of the independent variables.
Information sources	9	The following databases will be systemically searched from their inception date to August 2022: MEDLINE(via PubMed), Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure(CNKI), CiNii, J-STAGE, Korean Medical Database, Korean Studies Information Service System (KISS), ScienceON, and Oriental Medicine Advanced Searching Integrated System (OASIS).
Search strategy	10	Search strategy for the MEDLINE ((thread embedding acupuncture) or (thread embedding) or (catgut embedding)) and ((safety) or (safe) or (adverse event) or (adverse reaction) or (adverse effect) or (side effect) or (complication) or (risk) or (harm))
Study records:		
Data management	11a	Records will be managed through Review Manager (REVMAN) software for Windows.
Selection process	11b	Two reviewers will independently perform the screening procedure. Duplicate studies will be excluded first. Subsequently, studies will be excluded based on the screening of titles and abstracts. The two reviewers will independently review the full texts of the remaining articles to confirm inclusion or exclusion using predetermined criteria. Reasons for exclusion will be documented. Any disagreement between the two reviewers will be resolved through discussions. If the two reviewers fail to reach a consensus, a third reviewer will make the final decision.
Data collection process	11c	Using a standardised form, two reviewers will extract the data independently. The third reviewer will independently check the data for consistency and clarity.
Data items	12	Data extracted will include the authors' names, the title of the article, year of publication, study design, country of publication, and the number of participants (include age, sex, race), diseases originally treated, study period, thread type used for TEA, and concomitant treatment. In addition, the number of AE cases, type of AEs, AE coding or terminology system, severity of AEs, seriousness of AEs, and suspected causality will be conducted.
Outcomes and prioritization	13	The primary outcomes will be the incidence (or frequency) and the types of AEs associated with TEA. The secondary outcomes will be severity, causality, and follow-up information.
Risk of bias in individual studies	14	Two reviewers will independently assess the risk of bias using McMaster tool for assessing quality of harms assessment

		and reporting in study reports (McHarm). The answers to each question are "yes (implying a less risk of bias)", "no (implying a high risk of bias)", and "unsure". Any disagreement between the two reviewers will be resolved through discussion. If the two reviewers fail to reach a consensus, a third reviewer will make the final decision.
Data synthesis	15a	The relative risk (RR) calculated by incidence of AEs will be quantitatively synthesised.
	15b	The I^2 statistic(significance level = 0.1) will be used to measure heterogeneity between studies. A random-effect model or fixed-effect model with a 95% confidence interval (CI) will be used to calculate the pooled estimates of the effect size. A meta-analysis will be performed using fixed-effect model if the I^2 value is 50% or less. If the I^2 value is higher than 50%, a random-effect model will be used for data pooling.
	15c	We will perform subgroup analyses. Subgroup analyses will be performed using variables that have high homogeneity, such as target disease, implanted-thread type, and operating conditions (administrative site and depth, etc).
	15d	If a quantitative synthesis is appropriate, we will conduct a meta-analysis, but if not, we will conducted a narrative analysis.
Meta-bias(es)	16	Not applicable
Confidence in cumulative evidence	17	Not applicable

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.