INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The effect of Kinesio taping in patients with spastic cerebral palsy A protocol of systematic review and meta-analysis

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Review question / Objective: **The purpose of this study was to provide credible evidence for the intervention of kinesio taping efficacy combined with rehabilitation therapy in patients with spastic cerebral palsy and to provide basis for the treatment of spastic cerebral palsy. P:Inclusion criteria for study populations will be all patients with spastic cerebral palsy. No restrictions will be applied in terms of gender, race, and education status. No other cardiovascular disease, no skin breakage and no allergy to kinesio taping. I: Our research will include studies that took routine rehabilitation therapy(exercise therapy, neuro developmental therapy and physical factor therapy) or other ways(massage, neuromuscular electrical stimulation, etc.) as the main treatment in the intervention group, and the kinesio taping as auxiliary therapy. C: the control group only use routine rehabilitation therapy or other ways (pharmacological treatments, placebo). O:The primary outcome will be set to evaluate lower extremity muscle tension and gross motor function, including foot flexion angle and Gross Motor Function Measure, GMFM-88. The foot flexion angle includes left and right food flexion angle. Gross motor function includes standing (GMFM-88D) and walking、running and jumping(GMFM-88E).S: Randomized controlled trials (RCTs).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 August 2021 and was last updated on 25 August 2021 (registration number INPLASY202180098).

INTRODUCTION

Review question / Objective: **The purpose of this study was to provide credible evidence for the intervention of kinesio taping efficacy combined with rehabilitation therapy in patients with spastic cerebral palsy and to provide basis for the treatment of spastic cerebral palsy. P:Inclusion criteria for study populations**

will be all patients with spastic cerebral palsy. No restrictions will be applied in terms of gender, race, and education status. No other cardiovascular disease, no skin breakage and no allergy to kinesio taping. I: Our research will include studies that took routine rehabilitation therapy(exercise therapy, neuro developmental therapy and physical factor therapy) or other ways(massage, neuromuscular electrical stimulation, etc.) as the main treatment in the intervention group, and the kinesio taping as auxiliary therapy. C: the control group only use routine rehabilitation therapy or other ways (pharmacological treatments, placebo). O:The primary outcome will be set to evaluate lower extremity muscle tension and gross motor function, including foot flexion angle and Gross Motor Function Measure, GMFM-88. The foot flexion angle includes left and right food flexion angle. Gross motor function includes standing (GMFM-88D) and walking、running and jumping(GMFM-88E).S: Randomized controlled trials (RCTs).

Condition being studied: The incidence of cerebral palsy(CP) is high, while spastic cerebral palsy accounts for a large proportion of cerebral palsy. At present, routine rehabilitation methods are used in the treatment of spastic cerebral palsy. At the same time, some studies have shown that the kinesio taping is applied to the treatment of cerebral palsy, which can improve the lower extremity muscle tension and gross motor function. The purpose of this study was to provide credible evidence for the intervention of kinesio taping efficacy combined with rehabilitation therapy in patients with spastic cerebral palsy and to provide basis for the treatment of spastic cerebral palsy.

METHODS

Search strategy: The following electronic databases will be searched from inception to Dec 2020: Web of Science, the Cochrane Library (Central), EMBASE, MEDLINE, Allied and Alternative Medicine and Chinese National Knowledge Infrastructure(CNKI), Wanfang data and Chinese Scientific Journals Database(VIP). To ensure literature saturation, we will scan the reference lists of included studies or relevant reviews identified through the search. We will also search the authors personal files to make sure that all relevant material has been captured.

Participant or population: Inclusion criteria for study populations will be all patients with spastic cerebral palsy. No restrictions will be applied in terms of gender, race, and education status. No other cardiovascular disease, no skin breakage and no allergy to kinesio taping. Excludes patient with severe cardiovascular and/or liver and/or kidney disease, patients with severe disgnosia.

Intervention: Our research will include studies that took routine rehabilitation therapy(exercise therapy, neuro developmental therapy and physical factor therapy) or other ways(massage, neuromuscular electrical stimulation, etc.) as the main treatment in the intervention group, and the kinesio taping as auxiliary therapy.

Comparator: The control group only use routine rehabilitation therapy or other ways (pharmacological treatments, placebo).

Study designs to be included: We will include researches related to kinesio taping of patients suffering from spastic cerebral palsy. Due to language restrictions, we will search for articles in English and Chinese.All studies must meet the following two conditions:(1)complete documents; (2)the type is randomized controlled trial.

Eligibility criteria: (1)No Chinese or English; (2)Lack of outcome data; (3)Duplicate studies;(4)Studies with incomplete datas and abstracts without full texts.

Information sources: (1) The following electronic databases will be searched from inception to Dec 2020: Web of Science, the Cochrane Library (Central), EMBASE, MEDLINE, Allied and Alternative Medicine

and Chinese National Knowledge Infrastructure(CNKI), Wanfang data and Chinese Scientific Journals Database(VIP). To ensure literature saturation, we will scan the reference lists of included studies or relevant reviews identified through the search. (2)We will also search the authors personal files to make sure that all relevant material has been captured.

Main outcome(s): The primary outcome will be set to evaluate lower extremity muscle tension and gross motor function, including foot flexion angle and Gross Motor Function Measure(GMFM-88). The food flexion angle includes left and right food flexion angle. Gross motor function includes standing (GMFM-88D)and walking, running and jumping (GMFM-88E).

Quality assessment / Risk of bias analysis: The retrieved studies will be imported in Endnote software 9.1 to remove duplicates. Two researchers (LN and KDZ) will screen the titles and abstracts independently according to the preestablished inclusion and exclusion criteria. After that, the full text will be screened as a second filtration. Two researchers will crosscheck the included studies, and the third researcher (TH) will be involved if disagreements occur. The other 2 researchers (TH and XXL) will extract data independently to fill out the predesigned form. The information includes author, country, publication year, methodological quality, characteristicsof participants, the details of intervention and comparisons, outcomes, the specific data, results, conclusions, follow-up, adverse events, conflicts of interest, sources of funds, and ethical approval. The extracted data will be crosschecked by the 2 researchers. A third researcher (LN) will be involved if a disagreement occurs. The authors of the studies included will be contacted for further information when necessary. According to the guidance from the Cochrane Handbook of Systematic Reviews of Interventions, 2 researchers (FZH and KDZ) will evaluate the risk of bias of the included RCTs independently. We will evaluate from the following 6 parts: selection, performance, attrition, detection, reporting, and other sources of bias. We will rate the risk of bias into 3 levels: when meets none of the criteria, it will be regarded as high; when meets all criteria, it will be regarded as low; when study without sufficient information to determine, it will be regarded as unclear. After the assessment, it will be crosschecked by 2 researchers. The third researcher (LWN) will be involved if a disagreement occurs.

Strategy of data synthesis: Review Manager software (RevMan5.4) will be used to conduct all data analyses if it is possible to perform a meta-analysis. Effect calculation: a study using the same results, the mean difference (Mean Difference MD), and the corresponding 95% confidence interval (Confidence Intervals CI). Thetest will be used to test whether the combined statistics of multiple similar studies have significant significance, and the probability P-value of the statistic will be worth according to the. If P0.05, the combined statistics of multiple studies will be not significant. Heterogeneity test: the heterogeneity of intervention effect will be inevitable, because of the differences in the design of the study. The heterogeneity among the results will be analyzed bytest (P=0.10), at the same time, combined with I^2 quantitative judgment of heterogeneity. If P>0.10, $I^2$50%, which will indicate heterogeneity among the studies, a random effect model should be selected for analysis. The level of Meta-analysis will be set to P<0.05. For obvious heterogeneity, subgroup analysis or sensitivity analysis will be used, or only descriptive analysis.

Subgroup analysis: It is possible that individual studies may consist of multiple treatment groups, subgroup analysis will be performed to explain heterogeneity if possible. Factors such as following will be considered: (1)Patients characteristics (age, sex and course of disease); (2)Types of other interventions (massage, neuromuscular electrical stimulation, etc.); (3) Intervention time.

Sensitivity analysis: Based on the risk of bias, insufficient data, and sample size, we will perform a sensitivity analysis to

evaluate the robustness if significant statistical heterogeneity existed.

Country(ies) involved: China.

Keywords: kinesio taping; spastic cerebral palsy; Meta analysis; protocol; systematic review.

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