INPLASY PROTOCOL

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None.

3D printing-assisted for developmental dysplasia of the hip：protocol of a systematic review and meta-analyses

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Review question / Objective: **This systematic review aims to evaluate the effectiveness and safety of 3D printing-assisted for Developmental dysplasia of the hip.**
Condition being studied: **Developmental dysplasia of the hip (DDH) is a common clinical hip disease. The pathological changes of the hip joint will gradually aggravate with age, and the condition will become more complicated, which often brings greater difficulties to the treatment. As an emerging technology of rapid prototyping, 3D printing can directly generate a model of the diseased part through image generation software to understand the situation of the diseased part more intuitively, facilitate preoperative planning, and make the operation more accurate. This is also confirmed by a large number of studies. The purpose of this study is to evaluate the effectiveness and safety of 3D printing-assisted for DDH, and to provide the latest evidence for clinical applications.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 January 2021 and was last updated on 17 January 2021 (registration number INPLASY202110064).

INTRODUCTION

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As an emerging technology of rapid prototyping, 3D printing can directly generate a model of the diseased part through image generation software to understand the situation of the diseased part more intuitively, facilitate preoperative planning, and make the operation more accurate. This is also confirmed by a large number of studies. The purpose of this study is to evaluate the effectiveness and safety of 3D printing-assisted for DDH, and to provide the latest evidence for clinical applications.

METHODS

Participant or population: All the patients included in the study were diagnosed as DDH, regardless of age, sex, race and course of disease.

Intervention: The treatment group was treated with 3D printing-assisted, which was not limited by specific surgical methods, such as proximal femoral osteotomy, hip replacement, and pelvic osteotomy.

Comparator: There was no restriction of intervention in the control group. Studies of 3D printing-assisted and other treatments were included in this study if other treatments were used in the treatment group as well as in the control group.

Study designs to be included: All randomized controlled trials (RCTs) on 3D printing-assisted and moxibustion for DDH will be included. Other designs, such as animal studies, case reports, reviews, and non-randomized controlled trials will be excluded. There are no restrictions on language and publication date.

Eligibility criteria: 2.2.Type of studies All randomized controlled trials (RCTs) on 3D printing-assisted and moxibustion for DDH will be included. Other designs, such as animal studies, case reports, reviews, and non-randomized controlled trials will be excluded. There are no restrictions on language and publication date. 2.3.Types of patients All the patients included in the study were diagnosed as DDH, regardless of age, sex, race and course of disease. 2.4.Types of interventions. 2.4.1.Experimental interventions. The treatment group was treated with 3D printing-assisted, which was not limited by specific surgical methods, such as proximal femoral osteotomy, hip replacement, and pelvic osteotomy. 2.4.2.Control interventions. There was no restriction of intervention in the control group. Studies of 3D printing-assisted and other treatments were included in this study if other treatments were used in the treatment group as well as in the control group. 2.5.Types of outcome measures 2.5.1.Primary outcomes. (1)Harris hip score. Harris Hip Score is evaluated from 4 aspects: pain, function, deformity, and mobility, with a full score of 100. (2)Operation time . (3)Intraoperative blood loss. 2.5.2. Secondary outcomes. (1) Postoperative drainage. (2)acetabular abduction angle. (3)acetabular anteversion angle. (4)Hospitalization time. (5)Number of radiation.

Information sources: We will search the following databases by computer: PubMed, Web of Science,, Cochrane Library, Cochrane Central controlled Trials Registry (CENTER), EMBASE, China National knowledge Infrastructure (CNKI), Wanfang data, Chinese Biomedical Literature Database (CBM), VIP Database (VIP). Search from the establishment of the database to January 2021. Search for combinations of subject words and free words. Search terms include 3D printing, Three-dimensional printing,Developmental dysplasia of the hip,DDHand randomization controlled trials. There are no restrictions on language, country and population. We also search articles related to 3D printing and Developmental dysplasia of the hip to replace or supplement some reference lists, such as systematic reviews. At the same time, search conference papers and related clinical trial registries, such as the World Health Organization (WHO) International Clinical trial Registry ((ICTRP)), the US National Institutes of Health Clinical trial Registry, Australia and New Zealand Clinical trial Registry and China Clinical trial Registry.

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Main outcome(s): (1)Harris hip score. Harris Hip Score is evaluated from 4 aspects: pain, function, deformity, and mobility, with a full score of 100. (2)Operation time. (3)Intraoperative blood loss.

Additional outcome(s): (1)Postoperative drainage. (2)acetabular abduction angle. (3)acetabular anteversion angle. (4)Hospitalization time. (5)Number of radiation.

Quality assessment / Risk of bias analysis: In the aspect of inclusion of literature bias risk, Cochrane Collaboration's bias risk tool will be used to evaluate the quality of inclusion. It includes the following seven items: random sequence generation; allocation concealment; blinding of participants; blinding of outcome; incomplete outcome data; selective result report; and other sources of bias. All of the above projects will be evaluated independently by two researchers (Fo Yang,Tao Xu). If there are differences, we will resolve them by discussing or consulting a third researcher(Huan Liu). The bias risk of each project is rated as low, high or unclear risk.

Strategy of data synthesis: 3.3. Measures of treatment effect. RevMan software was used for comprehensive analysis. The results of dichotomy data are expressed by the risk ratio of 95%CI, and the continuous data are expressed by mean difference (MD) or standardized mean difference (SMD). 3.4.Missing data dealing with. If the research data is lost, the author will be contacted by email or telephone to obtain the appropriate information. If the data we need is not available, it will be analyzed through the existing data to assess whether it is included in the study. 3.5.Assessment of heterogeneity X2 test according to Cochrane manual, $P < 0.10$ will be considered significant. At the same time, the I2 value will be calculated. If $I2 \leq 50\%$, the statistical heterogeneity in this study is acceptable, and the effect will be estimated by the fixed-effects model. If $I2 > 50\%$, there is significant heterogeneity, using random-effects model. 3.6. Publication bias. When more than 10 trials were included in this study, the funnel chart was used to judge the report bias. If there is asymmetry in the funnel diagram, the Egge test of Stata software will be used for quantitative analysis. 3.7.Data synthesis. We will use Revman 5.4 software for statistical analysis. First of all, to judge whether there is statistical heterogeneity between the results, if there is statistical heterogeneity, the source of heterogeneity should be analyzed. After excluding the influence of obvious clinical heterogeneity, random-effects model should be used for meta-analysis. If not, the fixed-effects model is used for analysis. If there is significant clinical heterogeneity, subgroup analysis or sensitivity analysis are performed.

Subgroup analysis: If there is large heterogeneity, we will conduct subgroup analysis based on different control measures.

Sensibility analysis: We will eliminate the "high-risk" low-quality articles for sensitivity analysis to judge the robustness of the results.

Country(ies) involved: China.

Keywords: 3D printing,developmental dysplasia of the hip,protocol, systematic review and meta-analysis.

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