PROTOCOL FOR RANDOMIZED CONTROLLED TRIALS TO DETERMINE THE EFFICACY OF NEUROMUSCULAR TRAINING VS. CONTROL AS THE PREVENTION FOR PHYSICAL ACTIVITY- RELATED INJURIES IN ADOLESCENT BASKETBALL AND FOOTBALL PLAYERS

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Physical activity-related injuries prevention in adolescents
PARIPRE

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PHYSICAL ACTIVITY-RELATED INJURIES PREVENTION IN ADOLESCENTS (PARIPRE)
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INTRODUCTION

Abstract

Regular physical activity and sport are the most recognized determinants of health protection, particularly for the prevention of major chronic non-communicable diseases. In adolescents, physical activity and sport contribute to healthy musculoskeletal, cardiovascular, respiratory, immune, and metabolic development and help maintain physical fitness and appropriate body mass. It is also associated with several psychological and social benefits. Appropriate physical and sporting activity has no harmful effects, but there is an increased risk of injury during exercise, especially in high-intensity sports. No less than 47% of children are injured at least once in a year, with 50 % of injuries occurring in sports clubs, 30 % in recreational activities and 20 % at school. Sports club membership is therefore an underlying risk factor for hospitalization of children after injury, which must be considered as a logical cause-effect relationship. Disregarding COVID-19 era, we have observed an increase in the number of people involved in sports clubs Therefore, the prevention of physical activity and sport- related injuries (PARI) and the identification of risk factors must be an integral part of the promotion of physical activity and sport. Neuromuscular training (NMT) is widely recognized as an effective injury preventive program. NMT programs are typically coach or trainer led programs that are designed to improve balance, strength, agility, coordination, and movement control. NMT programs are often implemented as a part of a structured warm-up program, including running, agility, balance, plyometrics, and strengthening exercises where the intensity of warm-up is moderate, and the focus is on proper movement technique. Therefore, the aim of this study is to evaluate adherence, maintenance, and acceptance of 3-month NMT with 3-month follow-up in adolescent basketball and football teams. Furthermore, we are interested in physiological, biological and cognitive benefits of NMT.

Primary hypothesis

We hypothesized that neuromuscular training is acceptable for adolescent basketball and football teams yielding a positive outcome for injury incidence, neuromuscular properties, motor and cognitive abilities.

Purpose of the study protocol

The purpose of the study is to evaluate adherence, acceptance, and maintenance of neuromuscular training during 15-minute warm-up in adolescent basketball and football teams and to evaluate the effectiveness of 3-month neuromuscular training on injury incidence, and selected player performance indicators.

BACKGROUND

Theoretical background

Although regular physical activity (PA) has undisputed health benefits, such as reduced risk of premature mortality and many diseases (Warburton, 2006); however, also increased risk of injuries. The risk of injury and long-term disability can diminish the health benefits of regular and high-intensity PA (Mattila et al., 2008; Whittaker et al., 2015a). The consequences of PA-related injuries (PARI) do not appear only in short-term. Adolescent athletes after having sustained a severe injury are more prone to reinjury, have functional deficits, decreased quality of life, and are at increased risk of obesity compared to uninjured athletes (Whittaker et al., 2015a).

Approximately 20% of injuries treated at emergency departments in hospitals is related to sporting activities. Highest prevalence of injuries (around 50%) has been reported in organized sports (Räisänen et al., 2018). Repetitive activities such as running, jumping, or throwing without sufficient rest between such high load activities increase the risk of injuries (DiFiori et al., 2014). Adolescents are at inherent risk of PARI. The health benefits of PA need to be optimised by effective injury prevention strategies that should be applied in all spheres of PA, not excluding the training process.

Although it is impossible to eliminate all PARI, injury prevention strategies can unquestionably reduce the number and severity of PARI. Training strategies targeting modifiable and intrinsic (person related) risk factors are the most studied methods.

Rationale

Neuromuscular training (NMT) improves balance, strength, agility, coordination, and movement control without high intensity movement, emphasizing proper movement technique (Emery & Pasanen, 2019). NMT has been demonstrated a 37 % reduction in overall injury risk, 33 % reduction in acute injury risk, and 47% reduction in overuse injury risk in various sports and age groups (Lauersen et al., 2014). Even larger reductions have been reported with programs focusing on balance/proprioception and strength, where 45 % and 66 % reductions in overall injury risk have been reported, respectively (Lauersen et al., 2014; Leppänen et al., 2014).
The PARIPRE project recently issued the Recommendations for the prevention of physical activity-related injuries in adolescents (2021_PARIPRE_Recommendations.

pdf). Stating the NMT programs are typically coach or trainer led In youth sports, NMT has shown to reduce the risk of lower extremity injury by 35 % (Emery & Pasanen, 2019). Furthermore, NMT training has shown to reduce the risk of ankle injuries by 44–86 % and the risk of knee injuries by 45–83 % in youth athletes (Emery et al., 2015). NMT training is extremely effective to reduce the risk of anterior cruciate ligament (ACL) injury, which is one of the most common severe sport related injury leading to long absence from sports and is associated with permanent disabilities in knee function and high risk of early osteoarthritis (Whittaker et al., 2015b, 2019). It has been estimated that implementing NMT programs to 12–25-year-old youth athletes participating in high-risk sports could reduce the prevalence of ACL injuries by at least 40% (Lewis et al., 2018). In addition to preventive effect, NMT warm-up programs have shown to improve sports performance including strength, sprint abilities, agility, leg power, balance, and stability as well as sport-specific skills, especially among youth athletes (Pomares-Noguera et al., 2018; Rössler et al., 2016). The effectiveness of NMT warm-up has also been studied in school PE context. Increasing number of studies have shown that NMT warm-up is effective to reduce the risk of PARI in a school PE across different age groups of children and adolescents (Collard et al., 2010; Emery et al., 2020; Richmond et al., 2016).

Therefore, the study aims to investigate: (i) what is the level of adherence, maintenance, and acceptance of 3-month 15-minute NMT implemented in organized PA in warm-up period?; (ii) what is the effectiveness of the NMT on the characteristics of injury incidence in organized PA?; and (iii) what is the effect of NMT on the characteristics of muscle contractile properties, motor and cognitive abilities?

STUDY OBJECTIVES

Primary aim

To evaluate adherence, maintenance, and acceptance of 15-minute neuromuscular training warm-up in adolescent basketball and football teams during their training practice and competition. We will expose representative number of athletes (experimental group) to 3-month intervention being followed by 3-month follow-up period and compare the data to classical warm-up (control group).

Secondary aims

Additionally, we will evaluate effectiveness of 3-month neuromuscular training intervention on injury incidence, neuromuscular performance, motor and cognitive outcomes.

Rationale for the selection of outcome measures

NMT programs are typically coach or trainer led programs that are designed to improve balance, strength, agility, coordination, and movement control. NMT programs are often implemented as a part of a structured warm-up program, which includes running, agility, balance, plyometrics, and strengthening exercises. The intensity of warm-up is moderate, and the focus is on proper movement technique (Emery & Pasanen, 2019). NMT has been demonstrated a 37 % reduction in overall injury risk, 33 % reduction in acute injury risk, and 47% reduction in overuse injury risk in various sports and age group (Lauersen et al., 2014). Even larger reductions have been reported with programs focusing on balance/proprioception and strength, where 45 % and 66 % reductions in overall injury risk have been reported, respectively (Lauersen et al., 2014; Leppänen et al., 2014).

INTERVENTION

Previous research

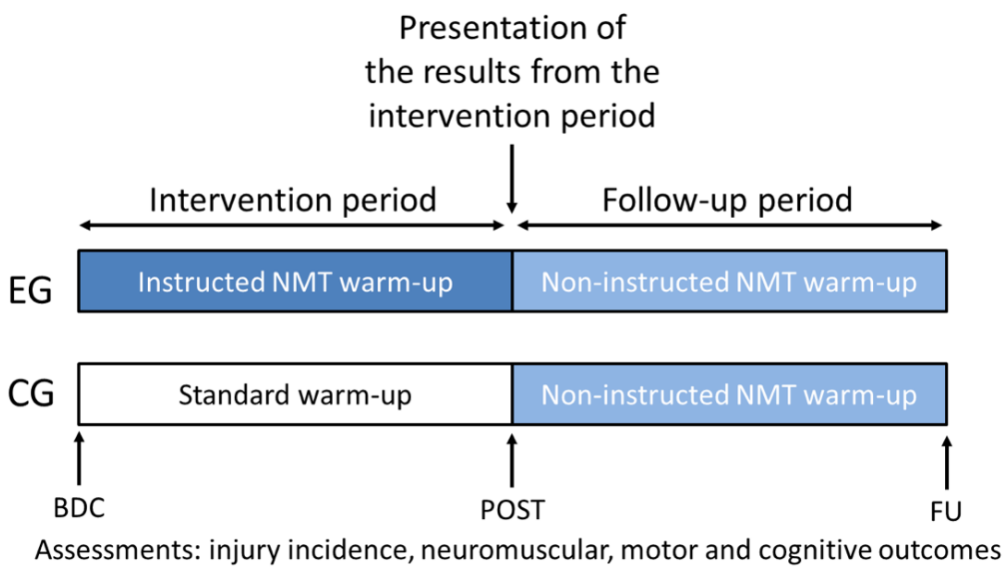
Effectiveness of neuromuscular training (NMT) in reducing the risk of sports injuries has been studied in several systematic reviews and meta-analyses, where data are combined from multiple prospective studies (2021_PARIPRE_Recommendations.pdf). NMT programs are typically coach or trainer led programs that are designed to improve balance, strength, agility, coordination, and movement control. NMT programs are often implemented as a part of a structured warm-up program, which includes running, agility, balance, plyometrics, and strengthening exercises. The intensity of warm-up is moderate, and the focus is on proper movement technique (Emery & Pasanen, 2019). NMT has been demonstrated a 37 % reduction in overall injury risk, 33 % reduction in acute injury risk, and 47 % reduction in overuse injury risk in various sports and age groups(Lauersen et al., 2014). Even larger reductions have been reported with programs focusing on balance/proprioception and strength, where 45 % and 66 % reductions in overall injury risk have been reported, respectively (Lauersen et al., 2014; Leppänen et al., 2014). In youth sports, NMT has shown to reduce the risk of lower extremity injury by 35 % (Emery & Pasanen, 2019). Furthermore, NMT training has shown to reduce the risk of ankle injuries by 44–86 % and the risk of knee injuries by 45–83 % in youth athletes (Emery et al., 2015). NMT training is extremely effective to reduce the risk of anterior cruciate ligament (ACL) injury, which is one of the most common severe sport related injuries leading to long absence from sports and is associated with permanent disabilities in knee function and high risk of early osteoarthritis (Whittaker et al., 2015b, 2019). It has been estimated that implementing NMT programs to 12–25-year-old youth athletes participating in high-risk sports could reduce the prevalence of ACL injuries by at least 40 % (Lewis et al., 2018). In addition to preventive effect, NMT warm-up programs have shown to improve sports performance including strength, sprint abilities, agility, leg power, balance, and stability as well as sport-specific skills, especially among youth athletes (Pomares-Noguera et al., 2018; Rössler et al., 2016).

STUDY DESIGN

Overview of study design

Figure 1 presents the graphical overview of the study design. In summary, two randomized control trials will be carried out, basketball in Slovenia and football in Slovakia. Each trial will consist of randomly formed experimental and control group of 10 teams. Intervention period will last 3 months being followed by follow-up period of 3 months. During intervention period participants in experimental group will follow 15-minute NMT per training/competition instead of classical warm-up being followed in control group. Assessment will be carried out at baseline (BDC), at the end of the intervention period (POST) and at the end of the follow-up period (FU). Injury and adherence to NMT intervention will be carried out also on monthly level.

Figure 1: Graphical presentation of the research design.



Subject selection

Inclusion criteria

For the randomized control trial, the following inclusion criteria will apply:

- male,
- age: 12-15 years,
- >2 years training basketball/football,

- member of the basketball/football (talented young teams) club,
- signed written consent by parents.

Exclusion criteria

For the randomized control trial, the following exclusion criteria will apply:

- recreational athlete,
- injured,
- acutely sick.

Ethical consideration

Both randomized control trials obtained ethical approvals from national or institutional ethical committees:

- Basketball: approved by Ethical committee at Science and Research Center Koper (No. 0624-9/22; 2.2.2022),
- Football: approved by the Ethics commission of the University of Prešov in Prešov (No. ECUP032022PO; 7.3.2022).

Recruitment and consent

Non-recreational youth sport clubs will be contacted via a phone call and/or email with basic information about the study. In each club, a U13 and U15 teams will be invited to participate in the study. If agreed for potential enrolment, a short online presentation will be given to the clubs with an official invitation for recruitment. To all interested clubs we will send a document with all essential study data for parents to give their informed written consent.

Randomization

The aim is to have at least 20 teams in each sport. Afterwards, we will randomly divide those teams in two groups: experimental and control group. All athletes from the same team will be allocated into the same group. The randomization in two groups will be done by a blind drawing piece of paper from an envelope with as many papers as there is enrolled clubs. If even number of clubs/papers, half of the papers will have "intervention" and other half "control" written on it. In case of odd number of clubs/papers, one more paper with "intervention" than "control" will be in the envelope.

Withdrawal

A participant enrolled in the study may decide to withdraw from the research at any time by notifying the coach of the club. The coach of the club than notifies the researcher during monthly reporting on intervention adherence. Data of withdrawn participant will be reported separately in the analysis (The proportion of withdrawals). Other data collected prior to participant withdrawal may be retained and used consistent with the study purpose and procedures, unless the study participant notifies the primary investigator that all participant information must be removed from the study.

STUDY PROCEDURES

Schedule of measurement

The data collection points will be focused in three time points (Figure 1): (i) at baseline (BDC); (ii), at the end of the intervention period (POST); and (iii) at the end of the follow-up period (FU). The collection of data (body characteristics, neuromuscular properties, balance, and cognition) will be carried out in the facilities of the sport club in the pipeline manner. First, a body characteristics will be examined, being followed by Tensiomyography and body composition, balance and cognition. The cognitive testing will be performed in a quiet room. One training practice before the assessment coaches will instruct athletes to arrive six per hour to enter the pipeline of the assessment. Then each athlete will enter per 10 minutes. After the last assessment athletes will be released home or to training session.

Injury rate will be assessed by be-weekly phone interviews with coaches and/or players. Each injury will be assessed in FIFA Injury Reporting Protocol using an electronic form.

Adherence, maintenance, and acceptance will be assessed by be-weekly phone interviews with coaches.

Study outcome measurements

<u>Basic anthropometry (BDC, POST):</u> body height and mass, lower limb length of both legs.

Body height and mass should be measured to nearest 5 mm and 0.1 kg, respectively. Lower limb length is assessed barefoot from the iliac crest to the lateral malleolus.

<u>Tensiomyography (BDC, POST):</u> contractile properties of vastus lateralis (VL), biceps femoris (BF), and gastrocnemius medialis (GM) muscles, of both legs.

TMG measurements will be performed during electrically evoked maximal isometric twitch contractions. For VL, participants will be in a supine position with the knee angle at 30° flexion (where 0° represents a fully extended knee joint). For the

BF they will be in a prone position with the knee at 5° flexion. For the GM they will be also in a prone position with the ankle in neutral. Foam pads will be used to support the joints. A single 1-ms maximal monophasic electrical impulse will be used to elicit a twitch that caused the muscle belly to oscillate and enlarge. These oscillations will be recorded using a sensitive digital displacement sensor (TMG-BMC Ltd, Slovenia) that will be placed on the surface of the skin over the mid belly of the muscle of interest. If needed, the measuring point and electrode positions will be adjusted to obtain maximal amplitude (Dm) of the muscle belly response. Initially, the stimulation amplitude will be set just above the contraction threshold and then gradually increased until the Dm of the radial twitch displacement increased no further. From two maximal twitch responses, a contraction time (Tc), delay time (Td) and radial velocity (Vc) will be calculated, and the average used for further analysis. Td is defined as a time from electrical impulse to 10% of Dm. Tc is defined as the time for the amplitude to increase from 10 % to 90 % of Dm. The Vc is calculated as a ratio between Dm and the sum of Td and Tc.

Bioimpedance analysis of body composition (BDC, POST): fat and muscle mass by bioimpedance.

The body composition should be measured using the same technology and technique at every time point. We propose assessment using tetrapolar bioimpedance device (e.g. BIA 101, Akern Ltd. Slovenia) after participants were laying supine for 30 minutes. The proportion of fat mass (FM in %) and fat free mass (FFM in %) will be recorded.

Balance test (BDC, POST): Y balance test: normalized anterior, posteromedial, and posterolateral distances.

The lower-quarter Y-balance test has the patient stand on one leg while reaching out in 3 different directions with the other lower extremity. They are anterior, posteromedial and posterolateral. After the recorded distance a normalization by the leg length will be done. The assessment protocol consists of: (1) warm up; (ii) measurement follows these steps (right anterior, left anterior, right posteromedial, left posteromedial, right posterolateral, left posterolateral. Hands are placed on the hips, subject reaches as far as possible and return to the starting point. Reach distance should be recorded to the nearest 0.5 cm. The participant should repeat one measurement with the same foot three times and then move on to the next one. A best result is taken for further consideration.

Cognitive abilities (BDC, POST): Simple & choice reaction time, CORSI, TMT-A and TMT-B.

The computerized Simple (sRT) and Choice reaction times (cRT) known as the Deary-Liewald task are recorded using the PsyToolkit platform. In the sRT task, a single white square is presented in the center of the screen against the blue background. Whenever a black "X" appears within the square, a subject must respond as quickly as possible by pressing a spacebar key on a standard keyboard with the index finger of their dominant hand. Eight practice trials preceded the twenty test stimuli, which were then averaged for the final sRT score. Similarly, in the cRT task, four white squares ordered in a row are presented in the center of the screen. A black "X" appears in one of the squares per trial, and participants must indicate the correct answer by pressing one of the four keys, each corresponding to one of the spatial positions of the squares on the screen. From the leftmost to the rightmost square position, the following keys had to be pressed, respectively: the "z" key with the left middle finger, the "x" key with the left index finger, the "," key with the right index finger, and the "." key with the right middle finger. After eight practice trials, forty test stimuli were sequentially presented and the response times to the correct positions averaged for the final score. Both speed and accuracy of the responses are encouraged.

The CORSI Block-Tapping task obtained through the PsyToolkit is used to assess the visuospatial working memory. Nine pink squares are randomly positioned on the screen and (some of them) flash yellow in a certain order (different each run). A participant is instructed to repeat the observed sequence by clicking on the squares in the same order as presented before. With each iteration, the sequence is becoming longer, starting with 2 and increasing by one each time. If a mistake is made, a second trial with the same sequence-length but different square distribution is offered. The task is finished after two consecutive fails or when the longest sequence of 9 items is successfully demonstrated. The score reflects the longest correctly reproduced sequence and ranges from 2-9.

The Trail-making test is used to assess the speed of processing and executive function. In TMT-A, 25 randomly distributed encircled numbers on a sheet of paper must be sequentially connected with a single line in an increasing fashion from 1 – 25. Similarly, In TMT-B a participant is required to draw a line connecting numbers (1 – 12) and letters (A – L) in an alternating and increasing fashion (1-A-2-B-3-C...12-L). If a mistake is made, the participant is warned, and they must correct it. The scores for each parts represent the time (in seconds) until completion.

Injury incidence (bi-weekly during intervention and follow-up periods): injury prevalence, distribution by body site, contact/non-contact, place.

A phone interview with club coaches or medical staff will be done bi-weekly. During the phone interview an electronic form of FIFA Injury Reporting Protocol will be filled for each injury.

Adherence, maintenance, and acceptance (monthly).

Adherence and maintenance will be assessed during intervention (only EG) and follow-up (EG and CG) periods by this form:

For monthly assessment of Adherence and Maintenance	Trainings	Competitions
How many sessions were performed?		
How many NMT warm-ups were done during these sessions?		
In average, how much time was used for NMT?		
In average, how many NMT exercises were used?		
Name players that missed more than 5 training sessions?		

Acceptance will be assessed only once, after the follow-up period by this form:

	Strongly disagree	Disagree	Neither	Agree	Strongly agree
PARI are preventable					
PARI prevention is important					
PARI decrease after NMT warm-up					
I will use NMT warm-up in the future					

And these two questions:

- Which barriers prevented you to use the NMT warm-up?
- Do you perform any additional systematical PARI prevention program?

STATISTICAL PLAN

Sample size determination

We based our sample size estimate on assumptions for our primary aim, as this is the most important aim. As we expected 30 – 40 % lower injury prevalence in EG, when compared to CG, a small samples were calculated (e.g. 50 per group in Sample Size Calculator (sruc.ac.uk)). However, secondary aims demanded higher sample sizes (e.g. 100 in G-power) and this was followed in our study. For the main aim the targeted study power was 0.9 while for the secondary aims the targeted study power was lower, 0.7.

Analysis plan

Analysis was done separately for each sport (basketball and football). Before the analysis, an agreement needs to be done for every specific issue in both sports. An expert in statistics will be perform all the statistical decisions in SPSS software. All main outcomes (body characteristics, neuromuscular performance, motor and cognitive outcomes) will be analyzed by classical statistical methods. Injury prevalence will be reported in percentages, normalized by group size for the period of the study. Whereas adherence, maintenance and acceptance will be reported descriptively.

Statistical methods

After confirming normality and homogeneity of the data distribution a mixed linear modelling will be used for every outcome. A histogram, QQ plot and Shapiro-Wilk test will be used to confirm normality of the data. Afterwards a Leven test will confirm homogeneity of the distribution. Since we expect approx. 20-30 % drop off, we plan to apply intention to treat protocol. Therefore, all outcome variables comparisons will be done using mixed linear model where normality of residuals will be confirmed by the same procedures as for the main variables. Participants will be classified as random factor, whereas Group (EG and CG) and Time (BDC, POST) will be classified as fixed factors. If significant main interaction effect (Time * Group), we will apply a post-hoc analysis with Bonferroni correction of p-value to compare time effects in each group separately. All statistical decisions will be made at $p \leq .05$. AS mixed linear model does not provide standard deviations, we will report 95 % confidential intervals for the variance of the distribution.

Missing outcome data

A Mixed linear modelling will be used to treat missing data.

DATA HANDLING AND RECORD KEEPING

Confidentiality and security

The authors confirm that all data obtained in the study will be confidential. In the process of conducting the study, necessary personal data will be recorded from the participants due to the need for future pairing (BDC, POST and FU measurements). After the data collection and tabulation process will be completed, all data will be anonymized and personal data known only to one designated researcher for each sport. The data will be stored in electronically password-protected on a protected server and accessible only to the study investigators without third-party access. There is a designated person in the research team responsible for maintaining the confidentiality of the data.

Training

All examiners will be instructed on the process for ensuring valid assessments, the confidentiality of the results of the investigation, and the rules for their further use. There will be one designated person in the research team responsible for maintaining the confidentiality of the data.

STUDY ADMINISTRATION

Organization and participating centers

The ERASMUS+ Sport project Physical activity-related injuries prevention in adolescents (PARIPRE) is led by UNIVERSITY OF PREŠOV, Faculty of Sports, Prešov, Slovakia. They are also a leading center for the study on effectiveness of NMT in adolescent football players.

SCIENCE AND RESEARCH CENTRE KOPER, Institute for Kinesiology Research, Koper, Slovenia and SPORTS UNION OF SLOVENIA, Ljubljana, Slovenia are leading centers for the study on effectiveness of NMT in adolescent basketball players.

Funding source and conflict of interest

The study was supported by the research grant 622594-EPP-1-2020-1-SK-SPO-SCP from the Education, Audiovisual and Culture Executive Agency (EACEA) ERASMUS+ Sport Collaborative Partnerships Program within the project titled "Physical activity-related injuries prevention in adolescents (PARIPRE)". The funder was not involved in the study design, collection, analysis, interpretation of data, the writing outputs.

Participant payments

The authors declare that no payments were made to participants involved in the research activity in the study.

Study timetable

Recruitment and randomisation

- January - February 2022

BDC assessment

- March 2022

Beginning of the RCT (intervention period)

- March 2022

POST assessment

- June 2022

Presentation of the results to both groups

- June/July 2022

Continuation of the RCT (follow-up period)

- July 2022

End of RCT

- September 2022

PUBLICATION PLAN

We plan to publish two manuscripts in per review journals:

- The effectiveness of three-month NMT in adolescent basketball players.
- The effectiveness of three-month NMT in adolescent football players.

However, if sufficient number of homogenous injuries will be obtained (in each sport) also an injury prediction could be estimated and published.

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