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Assessment of redundancy, methodological and reporting quality, and potential discrepancies of results of systematic reviews of early mobilisation of critically ill adults: a meta-research protocol

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ABSTRACT

Introduction Several systematic reviews (SRs) have been conducted to determine the effectiveness of early mobilisation in critically ill adults with heterogeneous methodology and results. Redundancy in conducting SRs, unclear justification when leading new SRs or updating, and discordant results of SRs on the same research question may generate research waste that makes it difficult for clinicians to keep up to date with the best available evidence. This meta-research aims to assess the redundancy, methodological and reporting quality, and potential reasons for discordance in the results reported by SRs conducted to determine the effectiveness of early mobilisation in critically ill adult patients.

Methods and analysis A meta-research of early mobilisation SRs in critically ill adult patients will be conducted. A search of MEDLINE (Ovid), Embase (Ovid), CINAHL (EBSCOhost), Cochrane Library, Epistemonikos and other search resources will be conducted. Two independent reviewers will perform study selection, data extraction and quality appraisal. Discrepancies will be resolved by consensus or a third reviewer. The redundancy of SRs will be assessed by the degree of overlap of primary studies. In addition, the justification for conducting new SRs will be evaluated with the 'Evidence-Based Research' framework. The methodological quality of the SRs will be assessed with the A MeaSurement Tool to Assess systematic Reviews 2 tool, and the quality of the reports through compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. To assess the potential reasons for discordance in the results of the SRs considering divergence in results and their interpretation.

Ethics and dissemination As meta-research, this study does not involve the participation of people whose rights may be violated. However, this overview will be developed rigorously and systematically to achieve valid and reliable results. The findings of this meta-research study will be presented at conferences and published in a peer-reviewed journal related to rehabilitation, critical care or research methodology.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This meta-research will conduct a search of MEDLINE (Ovid), Embase (Ovid), the Cochrane Database of Systematic Reviews (Cochrane Library) and Epistemonikos, and registers of evidence synthesis study protocols to identify systematic reviews (SRs) for the early mobilisation of critically ill adults.

⇒ To assess redundancy, methodological and reporting quality, and potential causes of discrepancies between SRs, robust and contemporary tools and frameworks will be used, such as the corrected covered area, A MeaSurement Tool to Assess systematic Reviews 2, updated Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement and the Evidence-Based Research framework.

⇒ Because we will conduct a content analysis, a potential limitation could derive from our interpretation of what the authors report in the introduction and discussion of the SRs.

Trial registration number osf.io/kxwq9.

INTRODUCTION

Critically ill adult patients may present with complications from hospitalisation in an intensive care unit (ICU) stay.[1 2] Mechanical ventilation, sedation, neuromuscular blockade and the mobility restrictions imposed by the context of critical illness, as well as barriers derived from invasive devices in critically ill patients,[3–5] create an environment that can facilitate cognitive[6] and neuromusculoskeletal complications,[7] among others.

One of the main ones is ICU-acquired weakness (ICU-AW).[8 9] The prevalence of

ICU-AW is variable[10]; however, it is a problem that should be considered a priority in managing critically ill patients. ICU-AW is associated with other structural and functional impairments that may lead to patient activities and participation restrictions. Decreased quality of life, reduced participation in social activities and low frequency of return-to-work activities in the postdischarge setting have been reported.[11–13]

This health condition typically appears generalised and symmetrical, affecting limb and respiratory muscles. This weakness may be due to altered nerve stimulus conduction (critical illness polyneuropathy), altered muscle contraction due to myogenic disturbance (critical illness myopathy) or a mixture of both pathophysiological processes (critical illness neuromyopathy).[14 15] The diagnosis of ICU-AW can be performed in different ways.[16] The most used in clinical practice is the manual assessment of muscle strength of the four limbs using the Medical Research Council sum score scale (MRC-SS).[17]

Early mobilisation is one of the central non-pharmacological interventions studied to prevent or recover from ICU-AW. While the definition of early mobilisation is not agreed on,[18] it is expected that this intervention should be applied as early as possible to critically ill patients, starting with passive mobilisation of limbs and other body segments, continuing with active mobilisation as early as possible and with functional transitional exercises to higher positions including assisted ambulation. In addition, devices to support passive and active mobilisation, such as cycles or cycle ergometers, can be added.[19]

Positive effects on muscle strength, length of ICU and hospital stay, and duration of mechanical ventilation, among others, have been reported.[20–23] However, the evidence from primary studies on the effectiveness of early mobilisation is inconsistent. Therefore, several systematic reviews (SR) have been conducted to determine the effect of this intervention through pooled data analysis (meta-analysis (MA)) and the level of evidence by assessing the quality or risk of bias of the primary studies.

SRs are considered to have the highest level of evidence to establish the effectiveness and safety of any intervention in different health conditions.[24] This type of secondary study is the basis for developing recommendations in clinical practice guidelines.[25] However, the number of SRs published recently has increased exponentially,[26] and some SRs seeks to answer the same research question, finding limited methodological quality among them.

Redundancy in SRs,[27] the unclear justification provided when conducting a new SR or updating a previous one,[28] and the discordant results of SRs on the same research question may lead to difficulties for clinicians to keep up to date and identify the best available evidence.[29–31] Therefore, this meta-research aims to assess the redundancy, methodological and reporting quality, and potential reasons for discordance in the results reported by SRs conducted to determine the effectiveness of early mobilisation in critically ill adult patients on different clinical outcomes. In addition, this meta-research aims to explore the reasons given by the authors of SRs when justifying the conduct of a new SR for the same research question, the use of previous SRs to guide the design of their studies, and whether the findings of their SRs are discussed based on previously published SRs.

MATERIALS AND METHODS

There are no standard guidelines that can be used for meta-research studies. However, in many aspects, our work will resemble an overview of SRs of interventions. Thus we will follow the recommendations proposed by the Cochrane Handbook for Systematic Reviews of Interventions where appropriate.[32] Furthermore, this protocol was reported according to Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols statement, where appropriate,[33] and was registered in Open Science Framework (OSF). The findings of this meta-research will be guided by the Preferred Reporting Items for Overviews of Reviews statement.[34]

The SRs identified in our overview on the effectiveness of physical rehabilitation interventions on neuromusculoskeletal function in critically ill patients will be considered the basis of this meta-research.[35] However, different eligibility criteria will be applied for the population and intervention studied.

Eligibility criteria

Type of studies

Intervention SRs, with or without MA, that have considered primary studies with a randomised (RCTs) or quasi-randomised clinical trial (quasi-RCTs) design will be included. SRs that perform only network meta-analyses without including pairwise comparative analyses of interventions (conventional meta-analyses) will be excluded.

Considering that there are different definitions of SRs,[36] for this meta-research, intervention SRs will be defined as an evidence synthesis study that aims to answer predefined research questions using explicit, reproducible methods to identify, critically appraise and combine results of primary research studies aimed at determining the effectiveness of any intervention on different health conditions.[37]

Type of participants

SRs that consider studies of adult patients, with the majority (>50%) being on invasive or non-invasive mechanical ventilation at least once during the stay in the ICU, will be included. The illness or health condition that led to the need for critical care shall not limit inclusion.

In contrast to the eligibility criteria of our overview of SRs protocol,[35] only the adult population will be considered because it is in this population that most SRs have been conducted.

Type of interventions

SRs that consider early mobilisation as an intervention, as defined by the authors of the SRs, will be included. They

may have but are not limited to the passive mobilisation of limbs or another body segment,[38 39] exercises involving active patient participation,[40] and the use of assistive devices such as upper and lower extremity cycling or cycle ergometer.[19 38 39]

Type of comparators

SRs that consider any intervention in the control groups of the primary studies will be included. These interventions may include usual care, placebo, sham, delayed mobilisation or other physical rehabilitation interventions.

Types of outcomes

SRs that have addressed the effectiveness of early mobilisation on at least one of the following outcomes will be included:

- Mobility: outcome that can be measured with any generic or specific scale to assess functionality in ICU, such as Functional Status Score for the Intensive Care Unit,[41] ICU Mobility Scale,[42] the Chelsea Critical Care Physical Assessment Tool[43] or any other measure to assess mobility.
- Muscle strength: outcome that can be measured using a manual scale, for example, MRC-SS,[44] or using a device that allows the assessment of handgrip strength[45] or the pressures generated by the respiratory muscles,[46] among others.
- Muscle mass: outcome which can be measured by muscle circumference measurement, ultrasonography, dual-energy X-ray absorptiometry, CT scan,[47] among others.
- Duration of mechanical ventilation: number of days patients remain on invasive ventilatory support.
- ICU length of stay: days between admission to the ICU and discharge to a less complex unit.
- Mortality: due to any cause and which can be reported according to different follow-up points, for example, mortality in ICU, hospital, 90 days, 180 days, 360 days, the number of deaths due to a given cause.
- Incidence and duration of delirium: outcome that can be measured with a scale such as the Confusion Assessment Method for the Intensive Care Unit,[48] among others.
- Unwanted safety events: outcome that can be measured as the incidence of any unwanted safety events associated with delivering physical rehabilitation interventions reported by SRs.

The analysis will be conducted based on all outcomes considered by the SRs, both those listed above and those not listed.

Search strategy

A systematic search will be conducted in different electronic databases and other search resources. MEDLINE (through Ovid), Embase (through Ovid), CINAHL (through EBSCOhost), Cochrane Library and Epistemonikos will be searched using controlled language (ie, MeSH, Emtree and CINAHL Subject Headings) and key terms. In addition, the International Prospective Register of Systematic Reviews, International Platform of Registered Systematic Review and Meta-analysis Protocols and OSF registries will be reviewed.

In addition, the references of the SRs included in this overview will be manually searched using the Citationchaser tool,[49] and experts in critical patient rehabilitation will be consulted to identify potential SRs that meet the eligibility criteria of this overview.

The search strategy for MEDLINE (Ovid) (table 1) was constructed following the Peer Review of Electronic Search Strategies (PRESS) statement.[50] The search strategy for MEDLINE (Ovid) was built following the PRESS statement, which will be adapted for the other electronic databases and search resources. The Canadian Agency for Drugs and Technologies in Health filter was used to identify studies with an SR design.[51]

Study selection

Two reviewers will independently check records identified by the search strategy for compliance with the eligibility criteria. Before the screening, duplicates will be removed using the Mendeley reference manager (Mendeley Desktop V.1.19.8) and the Rayyan application.[52] Irrelevant documents will be excluded by reading the title and abstract and then determining the inclusion of SRs by reading the full text. Disagreements will be resolved by consensus or by a third reviewer. The Rayyan application will be used to improve the efficiency of this metaresearch stage.[52]

Data extraction

Two reviewers will independently extract data from the SRs. An extraction form explicitly created for this study will be piloted with data extraction from >3 SRs, and then adapted according to the reviewers' feedback in the piloting. This form will seek to extract data to describe the characteristics of the publication, general characteristics of the SRs, reported outcome data, quality or risk of bias of the primary studies included, and certainty of evidence (table 2). In addition, the methodological and reporting quality of the SRs will be rated in the data extraction form. Disagreements will be resolved by consensus or by the involvement of a third reviewer.

Methodological appraisal

Two reviewers will independently assess the methodological quality of the SRs included in this overview using 'A MeaSurement Tool to Assess systematic Reviews 2' (AMSTAR 2).[53] Disagreements will be resolved by consensus or by the involvement of a third reviewer.

This tool includes 16 items and considers 7 as critical:

- Protocol registered before the commencement of the review.
- Adequacy of the literature search.
- Justification for excluding individual studies.
- Risk of bias from individual studies being included in the review.

Table 1 Search strategy for MEDLINE (Ovid)

N°	Search term
1	Exercise/
2	exp Exercise Therapy/
3	exp Rehabilitation/
4	exp Physical Therapy Modalities/
5	Occupational Therapy/
6	"Physical Therapy (Specialty)"/
7	"activities of daily living"/
8	early ambulation/
9	recovery of function/ or movement/ or locomotion/ or walking/ or motor activity/ or exercise movement techniques/
10	exercis$.tw.
11	(mobilizat$ or mobilisat$ or mobility).tw.
12	(therap$ adj3 (physical or occupation$)).tw.
13	((bed or daily living) adj3 activit$).tw.
14	(training or pregait or pre-gait or walk$ or adl or physiotherap$ or ambulation).tw.
15	((cycle or bicycle) adj2 ergomet$).tw.
16	or/1–15
17	Critical Illness/
18	exp Intensive Care Units/
19	exp Critical Care/
20	(intensive care or intensive-care or critical care or critical-care).tw.
21	(icu or icuaw or icu-aw).tw.
22	(critical$ adj3 (ill$ or care$)).tw.
23	((intubat$ or ventilat$) adj5 patient$).tw.
24	or/17–23
25	16 and 24
26	(systematic review or meta-analysis).pt.
27	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/
28	((systematic$ adj3 (review$ or overview$)) or (methodologic$ adj3 (review$ or overview$))).ti,ab,kf.
29	((quantitative adj3 (review$ or overview$ or synthes$)) or (research adj3 (integrati$ or overview$))).ti,ab,kf.
30	((integrative adj3 (review$ or overview$)) or (collaborative adj3 (review$ or overview$)) or (pool$ adj3 analy$)).ti,ab,kf.
31	(data synthes$ or data extraction$ or data abstraction$).ti,ab,kf.
32	(handsearch$ or hand search$).ti,ab,kf.
33	(mantel haenszel or peto or der simonian or dersimonian or fixed effect$ or latin square$).ti,ab,kf.
34	(met analy$ or metanaly$ or technology assessment$ or HTA or HTAs or technology overview$ or technology appraisal$).ti,ab,kf.
35	(meta regression$ or metaregression$).ti,ab,kf.
36	(meta-analy$ or metaanaly$ or systematic review$ or biomedical technology assessment$ or bio-medical technology assessment$).mp,hw.
37	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.
38	(cochrane or (health adj2 technology assessment) or evidence report).jw.
39	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.
40	(outcomes research or relative effectiveness).ti,ab,kf.
41	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison$).ti,ab,kf.
42	(meta-analysis or systematic review).mp.
43	(multi$ adj3 treatment adj3 comparison$).ti,ab,kf.
44	(mixed adj3 treatment adj3 (meta-analy$ or metaanaly$)).ti,ab,kf.
45	umbrella review$.ti,ab,kf.
46	(multi$ adj2 paramet$ adj2 evidence adj2 synthesis).ti,ab,kf.
47	(multiparamet$ adj2 evidence adj2 synthesis).ti,ab,kf.
48	(multi-paramet$ adj2 evidence adj2 synthesis).ti,ab,kf.
49	or/26–48
50	25 and 49

- Appropriateness of meta-analytical methods.
- Consideration of risk of bias when interpreting the results of the review.
- Assessment of presence and likely impact of publication bias.

SRs will be classified according to the overall confidence in their results as high, moderate, low and critically low, according to the following criteria:

- High: no or one non-critical weakness. The SR provides an accurate and comprehensive summary of the results of the available studies that address the question of interest.
- Moderate: more than one non-critical weakness. The SR has more than one weakness but no critical flaws. It may provide an accurate summary of the results of the available studies that were included in the review.
- Low: one critical flaw with or without non-critical weaknesses. The SR has a critical flaw and may not provide an accurate and comprehensive summary of the available studies that address the question of interest.
- Critically low: more than one critical flaw with or without non-critical weaknesses. The SR has more than one critical flaw and should not be relied on to provide and accurate and comprehensive summary of the available studies.

Reporting quality

Two reviewers will independently assess SR authors' adherence to the Preferred Reporting Items for Systematic

Table 2 Data to extract

Domain	Data to extract
Bibliometric characteristics	1. Title 2. Authors 3. Countries involved in the SR 4. Year of publication 5. Journal 6. Journal impact factor at the time of publication of the SR 7. Protocol registration 8. Date of manuscript submission and publication
General characteristics of the SRs	1. Inclusion and exclusion criteria for primary studies according to the acronym PICO 2. Population description 3. Definition of early mobilisation proposed by the SRs' authors 4. Electronic databases and other search resources considered by the SR 5. Search timeframe 6. Study designs included by the SR 7. Publication status 8. Reasons for exclusion of primary studies reviewed in full text 9. Previous early mobilisation SRs cited in introduction* 10. Previous early mobilisation SRs cited in discussion* 11. Qualitative or survey-based studies of the preferences or values of the end-users of the SRs cited in the introduction*
Reported outcome data	1. Outcomes initially considered by SRs 2. Outcomes reported by SRs 3. Scales, questionnaires or instruments used to assess different outcomes 4. Type of synthesis of results (meta-analysis or narrative) 5. Results data for each outcome reported
Quality or risk of bias of the primary studies	1. Instrument for assessing the methodological quality or risk of bias of included primary studies 2. Results of the assessment of the methodological quality or risk of bias of the included studies
Certainty of evidence	1. Instruments or framework used to assess the certainty of the evidence 2. Results of the assessment of the certainty of the evidence
Conclusion	1. Conclusions on the effectiveness of early mobilisation 2. Recommendations for clinical practice 3. Recommendations for research

The search strategy will not use language, date or publication status restrictions.
*Together with the sentences or paragraphs mentioned.
PICO, population, intervention, comparison, outcomes; SR, systematic review.

Reviews and Meta-Analyses (PRISMA) statement when reporting their findings. Compliance will be assessed for the updated version.[54] Disagreements between the reviewers will be resolved by consensus or by a third reviewer.

Data analysis and evidence synthesis

The SR selection process will be reported in narrative form with a PRISMA-type flow chart.[54]

To assess the redundancy of SRs, a matrix will be created that cross-references the SRs identified by the search strategy with the primary studies included by these SRs. This will be done at the SR and outcome level. In addition, from these matrices, the corrected covered area (CCA)[55] will be calculated without considering any structural missing data and considering the chronological (primary studies published after the last search date for a specific SR) and primary study design (primary studies with a different research design than the one included in a specific SR. For example, an observational study would be a structural loss of an SR that includes only RCTs) structural missing data.[56] The ccaR package (https://github.com/thdiakon/ccaR) will be used.[57] The crossover matrix of the SRs and primary studies included will be reported. In addition, heat map graphics will be presented to inform the degree of overlap of primary studies at the SR and outcome level.

In addition, the Evidence-Based Research framework will be used to assess whether, as new SRs were published, preceding SRs were cited or used to (1) justify the conduct of a new evidence synthesis study, (2) contribute to the design of new evidence synthesis studies and (3) discuss the findings of new SRs considering preceding evidence synthesis studies.[58–60] For this purpose, five questionable research practices will be assessed through content analysis based on what is reported in the SRs' articles (table 3).[28]

An exploratory analysis will be carried out to assess possible reasons for discordance in SR results to consider divergences in the results or their interpretation. The following characteristics will be assessed where possible

Table 3 Evaluation of research practices in the evidence-based research framework

Research practices	Type of response	Section to review	Qualifying conditions
Authors use the results of a systematic and transparent collection of earlier similar studies when justifying a new study	Dichotomous (Yes/No)	Introduction	It will be considered compliant if the authors cite at least one previous SR on early mobilisation in critically ill adult patients. If the authors cite at least one previous SR on early mobilisation in critically ill adults. In addition, if they mention any overview of SRs that consider this research topic, it will also be regarded as compliant
Authors of a scientific study refer to all earlier similar studies	Dichotomous (Yes/No) Quantitative (Proportion)	Introduction	Suppose the authors cite all previous SRs (considering as the cut-off point the most current date of the conduct of the search strategy) on early mobilisation in critically ill adult patients. In that case, it will be regarded as compliant. In addition, the citation fraction of each SR will be calculated by dividing all potential cited SRs (considering as the cut-off point the most updated date of the conduct of the search strategy), and the number of cited SRs
Authors use the results of a systematic and transparent collection of earlier similar studies when designing a new study	Dichotomous (Yes/No)	Introduction and Methods	If authors discuss and critique the design of previously published SRs in the introduction (based on the definitions of the population, intervention, comparison, outcomes (PICO), and methods of the included studies) and implement improvements in their SR design, they will be considered compliant
Authors use the results of a systematic and transparent collection of the new research projects' end user's perspectives to inform the justification and design of the new study	Dichotomous (Yes/No)	Introduction	It will be considered a dichotomous variable. If the authors cite qualitative or survey-based studies on the perspectives or preferences of end-users of SRs (clinicians, decision-makers, patients, etc), it will be considered compliant
Authors systematically and transparently place new results in the context of existing evidence	Dichotomous (Yes/No) Quantitative (Proportion)	Discussion and Conclusion	Suppose the authors cite all previous SR (considering as the cut-off point the most current date of the conduct of the search strategy) on early mobilisation in critically ill adult patients. In that case, it will be regarded as compliant. In addition, if they cite any overview of SRs that consider this research topic, it will also be regarded as compliant. In addition, the citation fraction of each SR will be calculated by dividing all potential cited SRs (considering as the cut-off point the most updated date of the conduct of the search strategy) and the number of awarded SRs

SR, systematic review.

depending on the type of evidence synthesis (narrative vs MA).

Divergent results

A divergent result is the variation between the SRs of the effect estimators' values and their 95% CIs. The potential causes of variation to be explored will be:

- Search date: the most recent search date reported by the SRs shall be considered.
- Search resources: electronic databases and other search resources used by SRs will be considered.
- Eligibility criteria: the definitions of eligibility criteria according to the population, intervention, comparison, outcomes framework and the primary study designs included by the SRs will be considered.
- Publication status: consideration will be given to whether SRs included studies published only as abstracts in conference proceedings.
- Excluded studies: reasons for excluding primary studies evaluated in the full text will be considered.
- Synthesis of outcome data: statistical methods for conducting meta-analyses (eg, random effects vs fixed effects) and data used to estimate the effect of the intervention (eg, final scores vs changes in scores from baseline) will be considered.

Divergent interpretations

The divergent interpretation shall be understood as variation in the conclusions regarding the language used. This analysis will be performed by grouping SRs that determine that the effect estimator calculated using MA is (1) in favour of the intervention, (2) in favour of the comparator and (3) neither in favour of the intervention nor the comparator. The potential causes of variation to be explored will be:

- Risk of bias: the tool or scale used to assess the risk of bias of the included studies and the rating of the included studies will be considered.
- Certainty of the evidence: consideration will be given to whether any framework was used to assess the certainty of the body of evidence (eg, Grading of Recommendations, Assessment, Development and Evaluations framework) and the grading of the evidence.

- Statistical versus clinical significance: we will consider whether the interpretation of the effectiveness of the studies was made based on the statistical significance or by considering the minimally important clinical difference (clinical significance).
- Conclusion: consideration will be given to whether the authors' conclusions were made based on the risk of bias or certainty of evidence.

Patient and public involvement

None.

DISCUSSION

The methods proposed for conducting this meta-research have strengths. First, the search for SRs will take a sensitive approach, consulting four major databases, such as MEDLINE (Ovid), Embase (Ovid), The Cochrane Database of Systematic Reviews (Cochrane Library), and Epistemonikos, and other search resources. In addition, robust and contemporary tools and frameworks will be used to assess redundancy, methodological and reporting quality, and potential discrepancies, such as the CCA, AMSTAR 2, updated PRISMA statement and the Evidence-Based Research framework.

However, potential limitations should be taken into consideration. The evaluation of SRs under the Evidence-Based Research framework will be assessed through a content analysis. This strategy could be challenging because it depends on the judgement and interpretation of the research team conducting this meta-research.

ETHICS AND DISSEMINATION

As meta-research, this study does not involve the participation of people whose rights may be violated. However, this overview will be developed rigorously and systematically to achieve valid and reliable results.

The findings of this meta-research study will be presented at conferences and published in a peer-reviewed journal related to rehabilitation, critical care, or research methodology.

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Contributors RG-A, DP, PN and PS contributed to the conception and design of the study. RG-A developed the search strategies, which all authors reviewed. RG-A, DP, PN and PS designed the data analysis. RG-A drafted the manuscript and all authors read it critically.

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