

REVIEW

Completeness of exercise reporting among randomized controlled trials on pelvic floor muscle training for women with pelvic organ prolapse: A systematic review

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Abstract

Aims: This systematic review aimed to assess the completeness of exercise reporting in randomized controlled trials (RCTs) on pelvic floor muscle training (PFMT) for women with pelvic organ prolapse (POP).

Methods: MEDLINE, Cochrane Central, CINHALL, Embase, SCOPUS, and PEDro databases were searched up to October 2020. Full-text RCTs comparing PFMT to any type of intervention among women with any type and stage of POP were eligible for inclusion. Completeness of intervention was evaluated with t20he template for intervention description and replication (TIDieR) and the consensus on exercise reporting template (CERT). Inter-rater agreement for each item of the tools was calculated.

Results: Twenty-six RCTs were included. None of the studies completely reported all intervention descriptors. On average 57.1% (6.8 ± 2.4 ; out of 12) of the overall TIDieR items and 35.3% (6.7 ± 2.9 ; out of 19) of the CERT were well described. In particular, 7 and 5 items were completely reported more than 50% of the time for the TIDieR and CERT, respectively. Frequent shortcomings were the undetailed reporting of information regarding tailoring and modifications of exercises and their adherence. Detailed descriptions of exercise repetitions to enable replication were missing in 53.8%. According to the CERT, only 11.5% of the RCTs sufficiently described the main providers' characteristics.

Conclusion: The completeness of PFMT reporting for women with POP is still below desirable standards and it is insufficient to ensure transferability into practice. The present results may add relevant knowledge and contribute to improving adequate reporting of exercise.

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KEYWORDS

cystocele, exercise therapy, pelvic organ prolapse, rectal prolapse, rehabilitation, uterine prolapse

1 | INTRODUCTION

Pelvic organ prolapse (POP) is described as the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix), or the apex of the vagina (vaginal vault or cuff scar after hysterectomy).¹ It may be associated also with the subjective perception of a falling, slipping or downward displacement of a part or organ.¹

Evidence suggests that pelvic floor muscle training (PFMT)² has a potential positive effect for prolapse symptoms and severity³ and it should be the first-line treatment^{3–5} for women with POP. PFMT consists of a series of exercises to improve pelvic floor muscle strength, endurance, power, relaxation, or a combination of these parameters.² This intervention is usually combined with other treatments, such as lifestyle modifications and vaginal pessaries and it could be also administered before and/or after surgery.

To implement and transfer effective interventions from single trials to daily clinical practice, a detailed description of the treatment should be provided by authors. Completeness of therapeutic interventions reporting is necessary for at least another two reasons⁶: to reproduce the intervention in subsequent trials and to provide sufficient information for evidence synthesis and comparison. All three mentioned reasons are important for the advancement of clinical knowledge and practice.

Although different tools have been developed to help and guide researchers during the reporting of non-pharmacological⁷ and exercise studies,⁸ trial descriptions are often suboptimal, leaving readers uncertain about the content of effective programs and missing important details ensuring the reproducibility of the interventions.⁸ Over the years, several studies in different physical therapy fields revealed evident gaps and clear deficiencies in reporting on exercise-based interventions.^{9–13}

To our knowledge, the reporting of PFMT in women with POP has not been explored.

Considering this framework, the primary objective of this systematic review was to:

1. Assess the completeness of exercise reporting among all published randomized controlled trials (RCTs) on PFMT in women with POP.

2 | MATERIAL AND METHODS

Given that the specific reporting checklist is currently under development,¹⁴ The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist¹⁵ was used for the reporting of the manuscript. The systematic review protocol was registered in PROSPERO (CRD42020215186).

2.1 | Search strategy

To identify eligible studies, a search strategy was developed according to the PICO framework with the help of an information specialist. MEDLINE, Cochrane Central, CINAHL, SCOPUS, and PEDro databases were searched. A detailed search strategy for each database was established to find all relevant studies published (Supplementary File 1).

Additional records were identified through gray literature (Google Scholar and direct contact with experienced researchers in the field). We checked the reference lists of all relevant studies. Search was conducted up to October, 24th 2020 with no date restriction.

2.2 | Study selection criteria

2.2.1 | Inclusion criteria

Full-text RCTs comparing PFMT to any type of intervention among women with any type and stage of POP¹ were eligible for inclusion. Trials could include PFMT provided to participants in any setting (e.g., outpatient, at home, or in the community) and should have involved the prescription of a supervised or unsupervised exercise program, with or without the addition of other components or treatments (e.g., biofeedback, lifestyle modification, use of pessaries or surgery). We included only articles published in English.

2.2.2 | Exclusion criteria

Data only published as abstracts or conference proceedings were excluded. Besides, given the aim of this

review, we excluded RCTs that provided secondary analysis or follow-up of the original article already included.

2.3 | Study selection process

The records retrieved from the searching of the database were collected and imported to EndNote V.X9 (Clarivate Analytics). Duplicates were removed through Endnote deduplicator tool. The study selection process consisted of two levels of screening using Rayyan QCRI online software¹⁶: (1) a title and abstract and (2) full-text screening. For both levels, two authors independently screened the articles with any disagreement resolved by a third author. The study selection process and the reasons for the exclusion were recorded and presented in the PRISMA flow diagram.

2.4 | Data extraction and assessment

Data extracted from each study included general study details (e.g., year of publication, population, POP) and characteristics of the PFMT (e.g., setting, intervention described by authors) were electronically tabulated (Excel worksheet) by two independent trained reviewers. One of them was a PhD candidate and physical therapist with experience in pelvic floor rehabilitation, the other was a PhD gynecologist with research and practice experience. The training was provided by a third physical therapist expert in research methodology.

For each included study, the same two independent authors assessed the completeness of PFMT description with two tools:

- The Template for Intervention Description and Replication (TIDieR) checklist.⁷ TIDieR is based on a 12-item checklist with a total possible score of 12.
- The Consensus on Exercise Reporting Template (CERT).¹⁷ This checklist is based on a 16-item resulting in a total possible score of 19.

According to the explanation and elaboration statements of both guidelines, each item was marked with “1” if it was completely described by authors, incomplete or missing items with “0,” and not applicable items with “NA.” Any disagreement was resolved by the author expert in research methodology.

Any possible mentioned information source and materials for the intervention reporting (e.g., supplementary data files, registered protocol) were considered.

To investigate the completeness of PFMT interventions reporting, the authors of the included studies have not been contacted for missing information. Summary tables and graphics of extracted data of all included studies and narrative synthesis were provided.

2.5 | Data analysis

The total score and the individual item scores from the TIDieR and the CERT tools were calculated. For the final analysis, we considered the “NA” items as items not reported and described by authors. Data were analyzed descriptively using IBM SPSS Statistics software (Version 24.0; SPSS Inc.).

Before the final consensus, the inter-rater agreement for each item of the tools was calculated.

3 | RESULTS

Of the 3918 studies identified by the initial literature searches, 3891 were excluded and 26 RCTs published in English were included.^{18–43} The reasons for exclusion and the corresponding references are reported in the online supplementary file (Supplementary File 2). A complete overview of the study selection process is provided in the PRISMA flow diagram (Figure 1).

3.1 | Characteristics of studies

Studies were published between 2003 and 2020. This systematic review evaluated the PFMT interventions provided to 4076 women with POP. Considering the type of POP, 38.5% ($n = 10$ studies) of patients presented with anterior, posterior, and/or apical POP while one of the included studies investigated women with an isolated anterior vaginal wall prolapse.³² However, it should be considered that 34.6% ($n = 9$) of the RCTs did not report the type of POP. Considering the stage of the condition evaluated with the POP-Q, stage II–III was the most frequent one ($n = 7$; 26.9%).

Table 1 shows a summary of the main characteristics of the included RCTs (Table 1). For more details, Supplementary File 3 provides complete data.

3.2 | Template for Intervention Description and Replication

According to the TIDieR checklist, Supplementary File 4 provides the completeness of the intervention-reporting

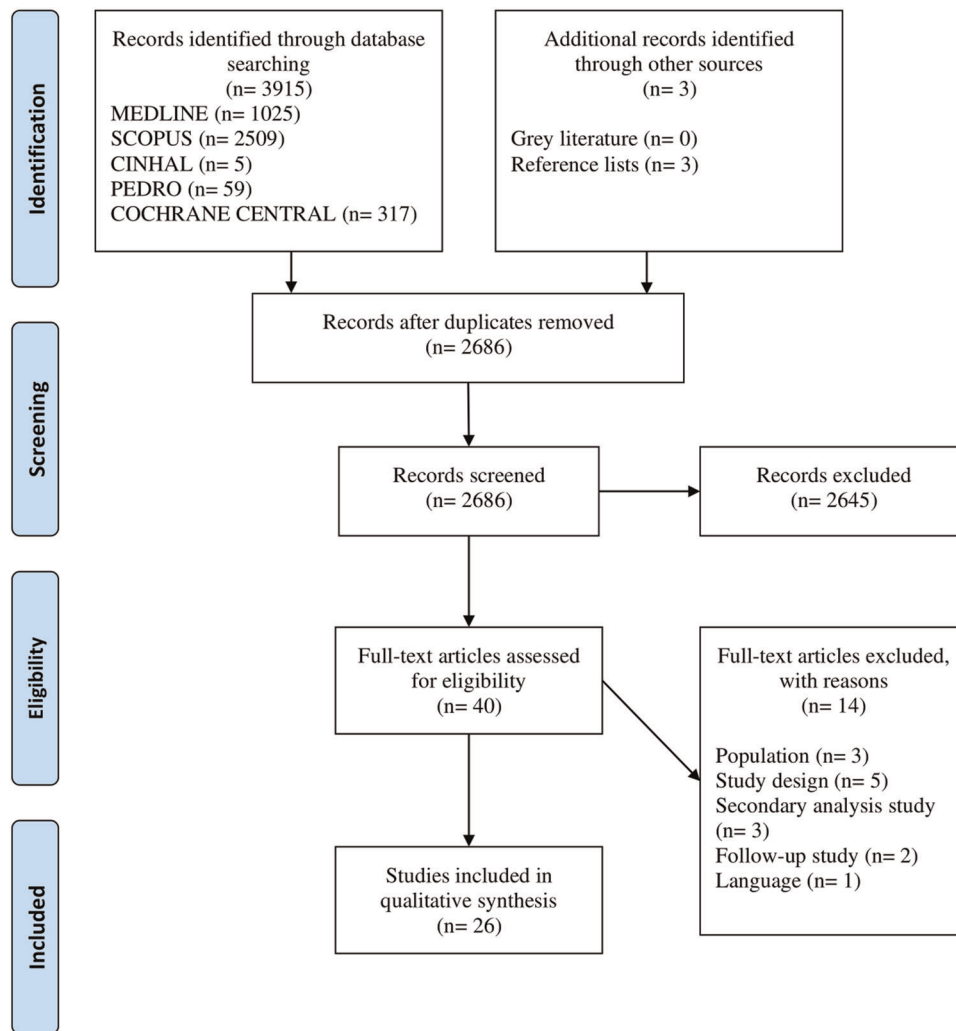


FIGURE 1 PRISMA flow-diagram. PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses

of each study divided for its items. The overall completeness of descriptors is illustrated in Figure 2.

Considering the whole included literature, 57.1% of the 12-checklist items were adequately reported (6.8 ± 2.4). The greatest adherence to the TIDieR reached the 83.3%. The most frequently described items were: item 1 (Brief name of the intervention; $n = 26$, 100% of the studies) and item 4 (Procedures; $n = 25$, 96.2% of the studies).

On the contrary, items 9 (Tailoring) and 10 (Modifications) were the least frequently reported ($n = 7$; 26.9% and $n = 0$; 0%).

Seven items were completely reported more than 50% of the time. More specifically, these were items 1, 4, 7 (Where), 8 (When and how much), 11, and 12 (How well).

Only in 2 RCTs the core intervention components, represented by items 3 to 9,⁷ were completely reported.

Considering item 8 (When and how much), complete descriptors are provided in 16 studies (61.5%).

The agreement between reviewers before consensus for each item is shown in the supporting documents online (Supplementary File 5). Items on the TIDieR with the lowest and highest agreement were items 9, 10 (57.7%), and 1 (100%), respectively.

3.3 | Consensus on Exercise Reporting Template

The mean score of the completely reported items was 6.7 ($SD = 2.9$) out of 19, ranging from 0 to 12, representing the 35.3%. In particular, Supplementary File 6 shows the completeness of the exercise-reporting of each study divided according to items. Figure 3 illustrates the overall completeness of exercise reporting.

TABLE 1 Summary. Characteristics of the included RCTs (n=26)

Variable	No. of studies (%)
Characteristics of the included RCTs (n = 26)	
Year of publication	
2003–2009	3 (11.5)
2010–2019	20 (76.9)
2020 (up to October)	3 (11.5)
Characteristics of POP	
Type	
Anterior	1 (3.8)
Anterior, posterior (and/or combination)	6 (23.1)
Anterior, posterior, apical (and/or a combination)	10 (38.5)
Not reported	9 (34.6)
Stage	
0, I, II	1 (3.8)
I, II	4 (15.4)
II	4 (15.4)
≥II	1 (3.8)
II, III	3 (11.5)
I, II, III	7 (26.9)
II, III, IV	2 (7.7)
Mild, severe	1 (3.8)
Not reported	3 (11.5)
PFMT	
Conservative treatment	17 (65.4)
Preoperative	2 (7.7)
Perioperative	5 (19.2)
Postpartum	1 (3.8)
Preoperative or conservative treatment	1 (3.8)

Abbreviations: PFMT, pelvic floor muscle training; POP, pelvic organ prolapse.

None of the analyzed trials provided a detailed description of PFMT as required by the 19 CERT items.

Item 14a (generic description if the exercise was tailored or not), and item 14b (detailed descriptors of how exercises were tailored) were the most and the least frequently and completely described items respectively.

Five items were completely described in more than 50% of cases: item 3 (how: individually or group), 5 (adherence),

10 (non-exercise components), 12 (where), and 14a. Only 9 (34.6%) out of the 26 RCTs described if adverse effects (item 11) of PFMT were present or not.

Analyzing item 13 data (Dosage of the exercise), the adherence was less than 50%. Data regarding PFMT providers (item 2) were largely missing. More details are provided in Supplementary File 7, which displays information by authors.

Supplementary File 5 shows the agreement between reviewers before consensus for each item: item 16a (how well, 50%) presented the lowest agreement, while items 4 (supervised/unsupervised), 10 (non-exercise components), and 11 (adverse effect) were had the highest one (100%).

4 | DISCUSSION

The aim of the present systematic review was to assess the completeness of PFMT reporting among all published RCTs for women with POP. To the author's knowledge, this is the first review to provide an evaluation of exercise reporting in this field of rehabilitation.

Describing exercise-based and complex interventions is challenging. Anyway, if the goal of clinical research is to provide evidence-based and reliable interventions, detailed descriptors are necessary.⁴⁴ The lack of details can compromise the reproducibility and the comparability of the research thus reducing its empirical and practical significance.

To help and guide researchers during the reporting of the trials, different tools have been developed and are currently available. In particular, the TIDieR checklist⁷ has been recommended for nonpharmacological intervention trials and the CERT⁸ has been specifically designed for an adequate description of exercise interventions.

For the first time, in the present review, we analyzed the extent of the lack of implementation of both checklists in this study field. Even if 100% of the included studies provided the name or a short sentence describing the intervention (TIDieR, item 1), this can not be considered sufficient for replicability.

In particular, the analysis of the 26 RCTs showed that no trials met all the descriptors developed in the CERT and TIDieR checklist. On average, each RCTs completely reported 6.8 items out of 12 (57.1%) for the TIDieR and 6.7 items out of 19 (35.3%) for the CERT. The difference in the percentage of adherence to the check-lists is justified by the fact that CERT is more specific and it requires more detailed information.

These results are consistent with previous reviews on PFMT in male¹¹ and female¹² participants with urinary incontinence.

In more detail, CERT and TIDieR items are characterized by poor reporting highlighted issues in the

FIGURE 2 Template for Intervention Description and Replication (TIDieR) percentage of RCTs that completely reported items. RCT, randomized controlled trial

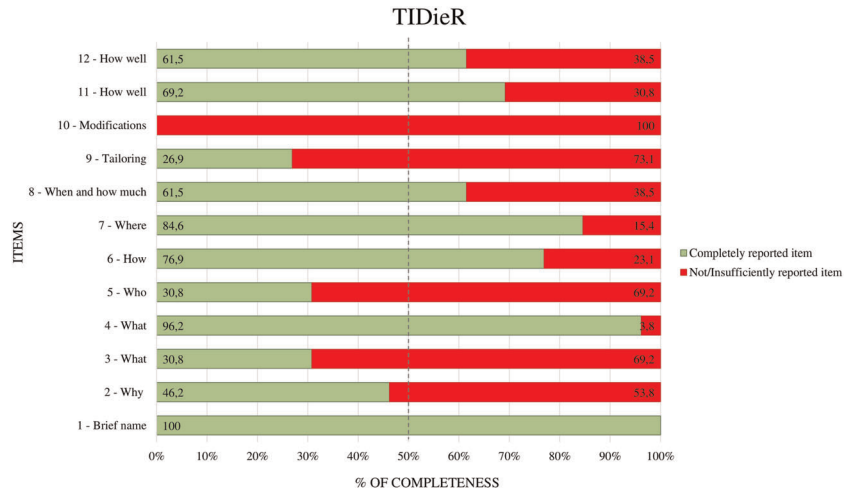
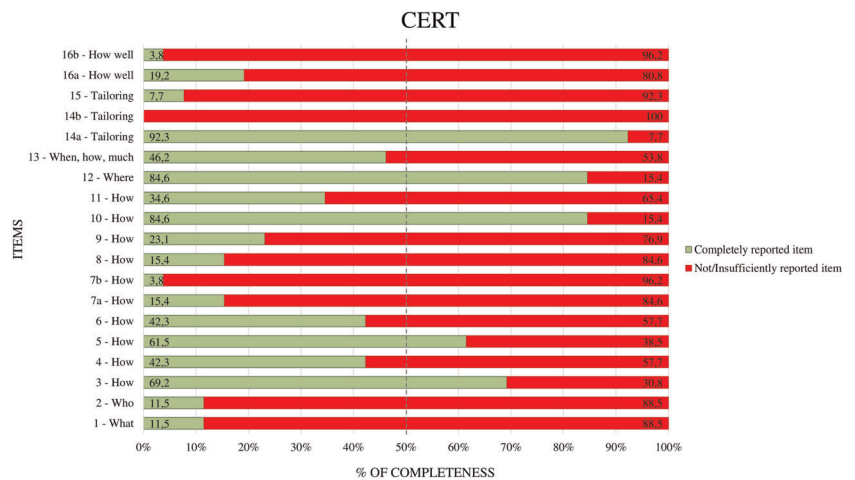


FIGURE 3 Consensus on Exercise Reporting Template (CERT): percentage of RCTs that completely reported items. RCT, randomized controlled trial



description of treatment's providers and PFMT tailoring. Indeed, PFMT should be adapted and tailored to the specific individual's conditions and environmental factors¹² and subsequently modified according to functional improvements. However, item 9 of the TIDieR, item 14b, and 15 of the CERT were often not reported. Charette et al.¹² found a similar percentage of adherence to those items.

Exercise progression descriptors, assessed with item 7b of the CERT, were lacking in the majority of RCTs (96.2%). As already explored in a qualitative study,⁴⁵ clinicians need explicit, comprehensive exercise descriptions and also rules guiding exercise progression. Lack of details leads them to rely on personal and professional experience, not replicating a potentially effective intervention.

Addressing the description of the characteristics of PFMT providers, we found that 30.8% (item 5, TIDieR) and 11.5% (item 2, CERT) of the included studies reported the knowledge, training, and expertise of the professionals. Even if we found better reporting comparing to the results shown by Charette,¹² these data remain suboptimal if we consider that, in rehabilitative intervention, providers' characteristics, such

as experience and education, may deeply influence intervention results.

Further considerations for the dosage of exercise (mode of exercise, frequency, intensity, volume, and duration of training) and adherence are needed. In 65.4% of all PFMT interventions, the modalities in which exercises were carried out were not clearly stated. For example, the intensity, frequency, times of hold/rest, number of repetitions, and positions were usually not simultaneously reported. Detailed descriptions of each exercise to enable replication (item 8, CERT) were presented in only 4 articles. Even if usually there is no need for specific equipment or materials for PFMT, adherence to item-1 of the CERT was also very low.

Similar to other rehabilitation fields, adherence or fidelity to the exercise is one of the major barriers, especially for the home-based interventions and it may contribute to the success of the treatment. The differences between TIDieR and CERT score are evident: CERT can distinguish two different types of adherence, the adherence of the patient (item 5; 61.5%) and the provider (item 16b, 3.8%). As underlined by Hall,¹¹ the lack of this information could compromise the results and the consequent interpretation.

Incomplete reporting of effective programs may be overcome by using appropriate tools when constructing, submitting, reviewing, and publishing articles.⁴⁶ More specifically, aligning with previous studies,^{13,46} we also recommend that authors and reviewers should use and evaluate the completeness of reporting of exercise interventions in trial protocols and reports.

Considerations regarding the journal's policy are necessary as word count limitations could preclude the completeness of the reporting. However, detailed contents should be reported by authors as protocol and/or supplementary files (e.g., photographs, videos, websites links).

Anyway, it is important to underline that the results of this review are referred to the completeness of the reporting and not to the quality of the interventions for patients with POP themselves. A well-documented exercise intervention can still be of low therapeutic quality and vice-versa. To assess the quality of interventions the recently created "i-CONTENT" tool⁴⁷ is the more appropriate one.

Further research may evaluate the association between the quality or effectiveness of the exercise-based interventions and the completeness of its reporting.

Alongside studies conducted by Charette et al.¹² and Hall et al.¹¹ our review provides a clear scenario of the PFMT reporting for patients with pelvic floor dysfunction. In RCTs involving people with POP undergoing PFMT, we highlighted that the completeness of exercise reporting is still below desirable standards.

4.1 | Strengths and limitations

Differently to other studies with similar scope, the sample of the present review is highly representative as we chose to include and evaluate the content of PFMT in all RCTs published on PFMT interventions among women with POP, without any type of restrictions. Besides, we evaluated the RCTs not only with the CERT tool, which is the most recent and specific for the exercise reporting, but also with the TIDieR.

When mentioned by authors, missing intervention details were obtained by sourcing reference materials. The two independent reviewers were specifically trained, and inter-agreement was calculated.

Even if the inter-review agreement was good, before the consensus some disagreements concerning certain items are relevant. It should be noted that (a) especially for the CERT checklist, items are composed of different descriptors that should be reported completely to mark the score "1"¹² and (b) both checklists were developed as reporting tools and not as assessment ones.

Besides, we included RCTs only published in English; this review may have lost potentially relevant studies.

5 | CONCLUSION

This systematic review showed that PFMT interventions for women with POP were not sufficiently and adequately reported to ensure transferability into practice. Frequent shortcomings were the reporting of detailed information regarding the exercise dosage, tailoring, adherence, and modifications as well as the providers' characteristics.

To enable adequate replication, comparison, and transferability into clinical practice, researchers should apply the existing intervention reporting tools, while peer-reviewers and journal editors should check the relative adherence.

The results of this review may add relevant knowledge and contribute to further improving the reporting of exercise in clinical research.

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PROTOCOL REGISTRATION

PROSPERO (CRD42020215186).

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTORS

Silvia Giagio proposed the review project and identified the framework. Silvia Giagio and Tiziano Innocenti proposed the methodology. Tiziano Innocenti identified the search strategy. Silvia Giagio, Lami Alessandra, and Giulia Gava extracted and analyzed the data. Paolo Pillastrini, Maria Cristina Meriggiola, Stefano Salvioli, and Tiziano Innocenti supervised the methodology. All authors conducted the review and developed the first and subsequent drafts of the manuscript.

DATA AVAILABILITY STATEMENT

The data that supports the findings of this study are available in the supplementary material of this article.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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