### Resistance band training or general exercise in multidisciplinary rehabilitation of low back pain? A randomized trial

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**Multidisciplinary biopsychosocial rehabilitation has been recommended for chronic low back pain (LBP), including physical exercise. However, which exercise modality that is most advantageous in multidisciplinary biopsychosocial rehabilitation is unclear. In this study, we investigated whether multidisciplinary biopsychosocial rehabilitation could be more effective in reducing pain-related disability when general physical exercise was replaced by strength training in the form of progressive resistance training using elastic resistance bands. In this single-blinded (researchers), randomized controlled trial, 99 consenting adults with moderate-to-severe non-specific LBP were randomized to three weeks of multidisciplinary biopsychosocial rehabilitation with either general physical exercise or progressive resistance band training and were then instructed to continue with their respective home-based programs for nine additional weeks, in which three booster sessions were offered. The primary outcome was between-group difference in change on the Oswestry Disability Index (ODI) at 12 weeks. Due to early dropouts, data from 74 participants (mean age: 45 years, 57% women, mean ODI: 30.4) were obtained at baseline, 61 participants were followed-up at 3 weeks, and 46 at 12 weeks. There was no difference in the change in ODI score between groups at 12 weeks (mean difference 1.9, 95% CI: −3.6, 7.4, \( P = .49 \)). Likewise, the change in secondary outcomes did not differ between groups, except for the patient-specific functional scale (0-10), which favored general physical exercise (mean difference 1.4, 95% CI: 0.1, 2.7, \( P = .033 \)). In conclusion, this study does not support that progressive resistance band training compared to general physical exercise improve outcomes in multidisciplinary biopsychosocial rehabilitation for patients with non-specific LBP.**

**KEYWORDS**
biopsychosocial, chronic pain, disability evaluation, function, muscle strength, musculoskeletal disorders, randomized controlled trial

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### 1 | INTRODUCTION

Low back pain (LBP) is one of the most significant contributors to disability worldwide.\(^1\) The current evidence indicates that a multidisciplinary biopsychosocial rehabilitation (MDR) approach is slightly more effective than a unimodal approach for treating and managing chronic LBP.\(^2\)\(^–\)\(^4\) Physical exercise is usually included in MDR,\(^2\) but numerous exercise modalities exist and we are not aware of studies investigating whether a particular form of exercise can improve outcomes...
from MDR more than another. In the specialist health services in Norway, the physical exercise-component of MDR for LBP typically entails an introduction to various physical activities and exercises based on the patients’ interests and the therapists’ recommendations (i.e., general physical exercise, GPE).

For persons with chronic LBP, exercise has been found to provide a small, but significant effect on function and pain.5-7 However, Hayden and colleagues found strength training to be more effective for improving function in chronic LBP patients than aerobic training, mobilizing exercises and coordination exercises, and other specific exercise therapies (e.g., McKenzie exercise therapy and functional restoration).6 Similarly, Searle and colleagues found strength and coordination programs to be most effective, while no beneficial effects were demonstrated for aerobic and combined exercise programs.7 It has also been suggested that strength training should be performed as progressive resistance training, starting out with low load and high number of repetitions, and progressing to high load and low number of repetitions.7-9 This way of exercising has been recognized as a promising treatment for other musculoskeletal disorders as well.8,10-13

Resistance training machines and free weights are commonly used for progressive resistance training, but such equipment is expensive, space-consuming, and not easily available for all patients. A viable alternative that easily can be implemented in home-based programs is training with elastic resistance bands (ERB). Studies have showed that elastic resistance bands can provide similar muscle activation to exercises performed with resistance training machines or free weights.14,15

This randomized clinical trial (RCT) investigated whether a 3-week MDR program could be more effective in reducing LBP-related disability when GPE was replaced with progressive resistance training using ERBs. After the MDR program, the respective exercise modalities were continued and performed as home-based training for 9 weeks. We hypothesized that MDR with ERB would reduce LBP-related disability, as well as other health-related outcomes, more than MDR with GPE in patients with chronic LBP.

2 | MATERIAL AND METHODS

2.1 | Study design, setting and participants

The study protocol has been published elsewhere.16 In brief, the study is a single-blinded (researchers), single-center RCT. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (REK midt 2014/1157) and registered in ClinicalTrials.gov (NCT02420236). The trial is reported in accordance with the CONSORT statement.17

The study was carried out in an outpatient hospital back and neck pain clinic (Department of Physical Medicine and Rehabilitation, St. Olavs Hospital, Trondheim University Hospital, Norway). Study participants were recruited from the clinic. A physician at the clinic assessed study eligibility during a routine screening session. Eligible patients willing to participate in the trial were randomized (1:1, block-randomization with unknown block sizes varying between 10 and 20, third party) to the ERB-intervention group or the comparative GPE group (see Figure 1 for flowchart). Exercise was only one of the components in the more comprehensive MDR program. All patients received both written and oral information and signed an informed consent prior to participating in the study.

Inclusion criteria for the study were as follows: (a) chronic (≥3 months) or recurrent (≥2 periods with duration ≥4 weeks the past year) non-specific LBP, (b) strongest LBP the last 2 weeks ≥4 on numerical pain rating scale (NRS: 0-10), and (c) age 16-70 years. Patients were excluded from the study if they: (a) had a severe somatic condition (e.g., cancer, inflammatory rheumatic disease, severe osteoporosis) or psychiatric condition that would severely impair group functioning, (b) had insufficient comprehension of Norwegian language to participate in group sessions and fill out questionnaires, (c) were awaiting surgery of the lumbar spine, (d) had alcohol or drug abuse, (e) had an ongoing compensation claim or were applying for disability pension due to LBP, (f) had been engaged in high-intensity resistance training on a regular basis during the last 6 months, or (g) had contra-indications for high-intensity resistance training (e.g., shoulder complications severely limiting the ability to conduct the training program). Additionally, physicians only referred participants to MDR if considered beneficial based on the clinical history, the motivation of the patient, and whether sufficient treatment had been attempted in primary care. The physician also compared MRI results with findings from the clinical examination. Patients with a dominating pain mechanism requiring specific treatment (e.g., surgery) or further medical examination were not included in the study.

Patients who participated in the usual MDR program, but declined to participate in the study or were excluded from study participation, were asked to participate in a reference group to assess the generalizability of the results. Participants in this group signed informed consent and completed the baseline questionnaire only.

2.2 | Intervention and comparative group

More detailed information, including illustrations of the ERB-exercises, is available in the study protocol.16 All participants were scheduled for MDR at the clinic. The MDR involved two full weeks (5 days per week) of rehabilitation with a 1-week break in between, and included patient education, GPE, and
Participants in the ERB-group performed three sessions of ERB per week during the 3-week MDR period (supervised in week one and three) and were instructed to perform home-based ERB three times per week in the 9 weeks after completion of the MDR program (12 weeks in total). The exercises used were squats, stiff-legged deadlifts, flies, unilateral rows, reversed flies, unilateral shoulder abduction, and lateral pulldown. All exercises were performed with Theraband Elastic resistance bands (Performance Health, Akron, OH, USA). The resistance loading was progressively increased during the intervention, with the program sequenced into four periods, weeks 1-2: two sets of 15-20 repetitions, weeks 3-5: two sets of 12-15 repetitions, weeks 6-8: three sets of 10-12 repetitions, and weeks 9-12: three sets of 8-10 repetitions. All sets were to be performed to failure; thus, the intensity of the first and last period corresponds to approximately 60%-70% and 75%-80% of one repetition maximum, respectively.
Participants were instructed to record all ERB sessions in a standardized training diary.\textsuperscript{16}

Participants in the comparative group performed GPE sessions four times in week one and five times in week three, as practiced in the ongoing MDR program at the clinic, and were recommended to stay active during the week in between. Participants in the ERB-group also received one session of GPE in week one and two sessions in week three to have the same exercise frequency as the comparative group. The GPE sessions included activities such as endurance training, ball games, body awareness, stretching, circle training, walks, relaxation techniques, and low-intensity resistance exercises. After completing the MDR at the clinic, the patients in the comparative group were provided with a home-based GPE program based on their interests and the physiotherapists’ recommendation.

All participants in the ERB and GPE groups were offered three booster sessions in the period between the end of the MDR program and the 12-week follow-up. These sessions focused on improving technique, making individual adjustments (including resistance loadings for the ERB group), and ensuring adherence and compliance to the exercise programs.

### 2.3 | Outcome measures

Questionnaires and strength tests were administered at baseline, at completion of the MDR (end of week 3), and after the home-based exercise period at week 12. The primary outcome was between-group difference in change on the Oswestry Disability Index (ODI: 0-100, higher score indicate more disability)\textsuperscript{19} at 12-week follow-up. Secondary outcomes included between-group difference in change on the ODI at 3-week follow-up, and differences at 3- and 12-week follow-up for LBP-intensity (current, and worst pain last 2 and 4 weeks; Numerical Pain Rating Scale, NRS: 0-10, higher score indicate more pain\textsuperscript{20}), number of additional pain sites indicated on a pain drawing (0-11),\textsuperscript{21} work ability (one item from the Work Ability Index: current workability vs. lifetime best, WAI: 0-10, higher score indicate better work ability),\textsuperscript{22} anxiety and depressive symptoms assessed with the 25-item Hopkins Symptom Checklist (HSCL-25: 1-4, higher score indicate more symptoms),\textsuperscript{23} health-related quality of life assessed with EQ-5D-3L (0-1, higher score indicate better health),\textsuperscript{24} fear-avoidance beliefs related to physical activity and work assessed with the Fear Avoidance Beliefs Questionnaire (FABQ physical; 0-24, and FABQ work; 0-42, higher score indicate worsening),\textsuperscript{25} patient-specific functional limitation assessed with the Patient-Specific Functional Scale (PSFS: 0-10, higher score indicate more limitation),\textsuperscript{26} patient-rated treatment efficacy at 3 and 12 weeks using the Global Rating of Change Scale (GRC: 1-7, very much improved to very much worse),\textsuperscript{27} as well as isometric back extension and grip strength.\textsuperscript{16}

### 2.4 | Sample size

The sample size calculation was taken for the mixed linear models analysis of the primary outcome, ODI. The minimal detectable change for ODI has been proposed to be 9.5 (0-100 scale),\textsuperscript{28} but as both groups participated in a comprehensive MDR program in the specialist care, the sample size was calculated to detect a 5-point difference between groups. With a power of 80% (\(\alpha = 0.05\)) and a marginal standard deviation of 9,\textsuperscript{29,30} a study sample of 100 participants, accounting for 20 dropouts, was required.

### 2.5 | Statistical analysis

Primary and secondary outcomes were analyzed in accordance with the intention-to-treat principle. The between-group differences (except global rating of change) were assessed using mixed linear model.\textsuperscript{31} All outcomes were analyzed separately using the outcome variable as the dependent variable with an interaction term of time (baseline, 3 weeks, 12 weeks) and intervention (GPE, ERB). Baseline level for the outcome variables was set by merging data from the two groups.\textsuperscript{32} To account for baseline variation and regression to the mean, we included a random intercept for participant (allowing different levels for participants in the analysis). The estimates from the mixed linear models were used to compute Cohen’s \(d\) effect sizes for changes from baseline to 12 weeks, within and between groups. 0.2, 0.5, and 0.8 were considered small, medium, and large effects, respectively. Global rating of change was dichotomized as improved (scores 1 and 2) and not improved (scores 3-7)\textsuperscript{33} and analyzed using multilevel, mixed-effect logistic regression. The EQ-5D score was converted to an indexed value (ranging from 0 (death) to 1 (perfect health)) using a crosswalk calculator, based on Danish national scoring algorithms.\textsuperscript{34}

Per-protocol analysis was performed by excluding participants in the ERB group who trained less than 60% of the total sessions. A sensitivity analysis was performed by dichotomizing all participants according to strength gain, using median percentage increase in back extension strength as cutoff. The per-protocol and sensitivity analyses were only done for the primary outcome. In these scenarios, baseline data were not merged. We also adjusted for fear avoidance related to physical activity in the sensitivity analysis.

\(t\) tests or Fisher’s exact tests, as appropriate, were used to assess differences in baseline characteristics between study participants and reference participants, and differences between participants completing the study and participants dropping out. Results with \(P\)-values <.05 (two-tailed) was considered statistically significant. STATA/IC 13.1 (StataCorp LP, USA) and R version 2.13.1 (the R foundation, Austria) was used for analyses.
Recruitment started in December 2014 and continued until September 2016. The follow-up data collection ended January 2017. Participant flow throughout the study is presented in Figure 1. Of 99 included participants, 74 participants were tested at baseline and included in the intention-to-treat analysis. Sixty-one and 46 participants were followed up at 3 and 12 weeks, respectively. The dropout rates from
inclusion and from baseline to 12 weeks were 53.5% and 37.8%, respectively.

### 3.1 Participants’ characteristics

Table 1 shows characteristics of the study sample at baseline. The mean age was 45 years (SD 12), and the majority (79%) had experienced LBP for more than 1 year. Seventy-nine percent were employed, 58% were sick listed, 22% had disability pension or were on work assessment allowance (a work reimbursement option in Norway after having been on sick leave for 1 year), and 52% had used analgesics for their LBP during the last week. The leisure time exercise index (i.e., an index from 0.78-3 based on the questions “How frequently do you exercise,” “How long does each session last,” and “How hard do you push yourself”) indicated that the participants were moderately active in their leisure time.35

Overall, the mean ODI score (30.4, SD: 11.4) and the NRS score for the last 2 weeks (6.8, SD: 2.0) indicated that the participants had moderate disability and moderate-to-severe pain at baseline. No significant baseline differences were observed between participants in the RCT and the reference group, except for a higher proportion of people being sick listed in the RCT. There was no significant difference between participants that completed and those who dropped out.

### 3.2 Outcomes

Figure 2 shows changes in the ODI from baseline to 3- and 12-week follow-up. There was no significant difference between groups in the change from baseline to 12-week follow-up (mean difference: 1.6 [95% CI: −3.9, 7.0] \( P = .570 \)). From baseline (mean: 30.4 [95% CI: 27.7, 33.0]), the ODI

| Table 2 | Secondary outcomes, estimated means, and 95% confidence intervals from baseline to 12 weeks |
|---------|----------------------------------|
| **Outcome** | **Baseline** | **12 weeks** | **Between-group comparison** |
| | **GPE** | **ERB** | **Mean (95% CI)** | **Difference** | **Mean (95% CI)** | **P-value** |
| LBP (NRS; 0-10) | | | | | | |
| Current | 4.6 (4.2, 5.1) | 3.4 (2.7, 4.2) ** | 4.0 (3.3, 4.8) | 0.6 (−0.4, 1.6) | .266 |
| Worst last 2 wks | 6.8 (6.4, 7.4) | 4.9 (4.0, 5.7) ** | 5.7 (4.8, 6.5) ** | 0.8 (−0.3, 2.0) | .168 |
| Worst last 4 wks | 7.0 (6.5, 7.5) | 5.5 (4.7, 6.3) ** | 6.2 (5.4, 7.0) ** | 0.7 (−0.4, 1.8) | .184 |
| Additional pain sites (0-10) | 1.9 (1.4, 2.4) | 1.6 (0.7, 2.5) | 2.5 (1.7, 3.4) | 0.9 (−0.2, 2.1) | .113 |
| WAI (0-10) | 4.3 (3.7, 4.9) | 5.6 (4.7, 6.5) ** | 5.5 (4.7, 6.4) ** | −0.1 (−1.3, 1.1) | .925 |
| HSCL-25 (1-4) | 1.74 (1.64, 1.85) | 1.46 (1.31, 1.62) ** | 1.56 (1.41, 1.71) ** | 0.10 (−0.08, 0.30) | .291 |
| EQ-5D | 0.709 (0.685, 0.733) | 0.717 (0.676, 0.758) | 0.730 (0.680, 0.753) | 0.013 (−0.043, 0.068) | .649 |
| FABQ A (0-24) | 7.7 (6.6, 8.7) | 5.2 (3.7, 6.8) ** | 5.4 (3.7, 7.1) ** | 0.5 (−1.6, 2.6) | .637 |
| FABQ B (0-42) | 18.6 (15.8, 21.4) | 16.4 (12.8, 20.0) | 16.0 (12.4, 19.7) | −0.4 (−4.8, 4.1) | .880 |
| GRC (improved) | N/A | 52% (32%, 79%) | 40% (23%, 59%) | OR: 0.62 (0.2, 1.97) | .408 |
| PSFS (0-10) | 6.8 (6.2, 7.4) | 4.0 (3.0, 5.0) ** | 5.4 (4.4, 6.3) ** | 1.4 (0.1, 2.7) | .033 |
| Back extension strength (N) | 685 (627, 742) | 762 (680, 844) * | 838 (759, 919) ** | 77 (−21, 175) | .125 |
| Grip strength (kg) | 37.8 (35.0, 40.9) | 39.5 (36.1, 43.0) | 40.5 (37.1, 43.9) * | 0.9 (−1.7, 3.6) | .489 |

GPE, General physical exercise group; ERB, Elastic resistance band group; NRS, Numerical pain rating scale; LBP, Low back pain; WAI, Work ability index; HSCL-25, Hopkins symptom checklist 25; FABQ A, Fear avoidance beliefs questionnaire in relation to physical activity; FABQ B, Fear avoidance beliefs questionnaire in relation to work; GRC, Global rating of change scale; PSFS, Patient-specific functioning scale; OR, Odds ratio. Significant change from baseline within group, \(* P < .05; ** P < .01\).
within the GPE group decreased to 26.4 (95% CI: 22.8, 30.0) at 3-week follow-up and to 21.1 (95% CI: 17.0, 25.3) at 12-week follow-up. The corresponding ODI values within the ERB-group was 28.1 (95% CI: 24.4, 31.9) at 3-week follow-up and 22.7 (95% CI: 18.7, 26.7) at 12-week follow-up. The improvement from baseline to 12 weeks was statistically significant for both groups and from baseline to 3 weeks for the GPE group.

Table 2 shows changes in secondary outcomes from baseline to 12-week follow-up. The change for the PSFS was significantly larger for the GPE group compared to the ERB group (mean [95% CI): 1.4 (0.1, 2.7), P = .033). There were no other significant differences between groups in changes from baseline to 3- (Table S1) or 12-week follow-up (Table 2).

For between-group changes from baseline to 12 weeks, effect sizes were small or very small, with the exception of PSFS which was of medium magnitude in favor of GPE. Between- and within-group effects sizes are presented in Table S2.

### 3.3 | Per-protocol and sensitivity analysis

Fourteen of the 24 participants in the ERB group with follow-up at 12 weeks completed at least 60% of the prescribed training sessions and were included in the per-protocol analysis. There was no significant difference on ODI at 12 weeks between the GPE group and those with more than 60% completed training sessions (mean −2.5 [95% CI: −9.9, 4.8], P = .50; favoring ERB). Twelve participants from the ERB group and eight from the GPE group increased their back extension strength above the median and were included in the sensitivity analysis. There was no difference in change for the ODI between participants who increased strength above the median compared to those who did not (mean 0.6 [95% CI: −5.8, 7.0], P = .85; favoring increased strength).

### 4 | DISCUSSION

This study found no additional effect of replacing GPE with ERB for patients with chronic LBP enrolled in a MDR program in the specialist health services. The ERB and the GPE group improved their ODI score from baseline to 12-week follow-up with 7.7 and 9.3 points, respectively, with no significant difference between groups. Furthermore, there were no significant differences between groups for any of the secondary outcomes, except that PSFS improved more from baseline to 12-week follow-up in the GPE compared to the ERB-group. Both groups had improved in most of the health-related outcomes at 12 weeks.

Although the ERB intervention used in this study followed the current recommendations for resistance training for novices, we observed little difference in back extension strength between the groups after the intervention. This made us question the adherence to the home-based ERB program, and if adherence was related to improvement in ODI. Only 14 of the 24 patients, who participated at 12-week follow-up, performed at least 60% of the scheduled home-based training sessions. However, the per-protocol analysis demonstrated that even for those completing more than 60% of the training sessions, ERB was not more effective than GPE in improving ODI. A possible reason for the lack of difference in strength gain could be that some participants trained with lower intensity than prescribed during the home-based training period, as suggested by inspection of the training diaries. Patients, with a history of pain and fear-avoidance behavior, might benefit from closer follow-up during a home-based training period. Further, we cannot exclude the possibility that some of the participants in the GPE group performed some sort of resistance training during the home-based training period. Therefore, we performed a sensitivity analysis to assess whether patients who increased back extension strength, regardless of group allocation, had greater improvements on the ODI compared to patients who did not increase their strength. However, we found no difference between these two subgroups which strengthens our main findings.

There are several possible explanations for the lack of a differential effect of the two exercise modalities. ERB or GPE was provided in combination with MDR, limiting the room for additional improvements induced by a particular exercise method. We are unaware of studies comparing different exercise modalities within MDR; therefore, it is difficult to directly compare our results with previous studies investigating resistance-exercise interventions for patients with LBP. Furthermore, physical exercise can be perceived less important for patients enrolled in MDR in a specialist care unit, as they might be more affected by psychological and social factors compared to patients in primary health care. This assumption is supported by the average HSCL-baseline score in our study sample, which was around the cutoff level for anxiety and depression (i.e., HSCL-25 > 1.75) (Table 1). Further, back examination with reassurance, as provided in the initial screening session, resembles brief intervention which previously has been found effective in reducing sick leave for workers with LBP. The screening session was performed prior to baseline testing, and this may to some extent explain the low baseline scores on FABQ. Higher FABQ scores have been reported for a similar population when FABQ was answered before to the screening session. Finally, although some studies have shown promising results for ERB, our findings are in line with a systematic review, showing that improvements in physical capacity (including muscular strength) are weakly correlated.
with improvements in pain and disability in patients with chronic LBP.

Our finding of improvement on the PSFS for the GPE group compared to the ERB group indicates that there might be some beneficial effects of exposure to various exercises, which also may involve a larger degree of tailoring. Considering that PSFS relates to activities rated important by the participant, it might be that the GPE was more suitable for improving this outcome than a general ERB program, as the participants in collaboration with therapists chose which exercises to include in the home-based GPE program. The participants’ influence on the GPE program might have resulted in better adherence than in the ERB program; however, this remains speculative as the GPE group did not record activity in a diary. It should also be noted that the difference between groups was relatively small (mean difference 1.4, 95% CI: 0.1, 2.7, \( P = .033 \)) and, considering the number of tests performed, we cannot exclude the possibility of a type I error. Thus, this finding should be interpreted with caution.

This study had some limitations. Participants were enrolled in MDR in a specialist back and neck pain clinic. Caution should be shown in generalization of the results to other settings. Although we followed recommended measures to increase compliance and adherence,\(^{16}\) we experienced a considerable number of dropouts limiting statistical power. However, as dropouts were evenly distributed between the groups, we consider the risk of selective attrition bias to be low. Therefore, we contend it is unlikely that the conclusion would be altered with additional participants or a lower dropout rate. Moreover, there were no differences in baseline characteristics for patients who completed the intervention and those who dropped out. Further, patients who took part in the study were similar to those in the reference group, that is, patients enrolled for MDR at the clinic but who refused to participate or who were excluded from the study. This indicates that the patients who completed the intervention are a representative sample of the population. While both the ERB and GPE group improved on most outcomes from baseline to 12 weeks, we cannot distinguish the effects from the programs and the effects of time. Despite forming clear procedures for management of the groups, we cannot exclude the occurrence of a potential carryover effect as the same team of physiotherapists provided both the ERB and GPE interventions. Finally, it was not possible to blind participants or therapists managing the interventions, but test leaders and researchers conducting the analyses were blinded, and participants were blinded to the researchers’ hypotheses.

In summary, our findings provide no support that replacing GPE with ERB in MDR will improve LBP-related disability in patients with chronic non-specific LBP.

## 5 | PERSPECTIVES

Low back pain is a leading cause of disability in most countries across the world.\(^1\) While numerous treatment options exist, none have been found to provide more than small-to-moderate effects.\(^{3,42}\) MDR including exercise is considered more effective than unimodal treatments for chronic LBP, but it is unclear which exercise modality that should be incorporated in MDR. Recent evidence suggests that resistance training could be a promising treatment option for persons with chronic LBP. This study investigated whether patients participating in MDR could have greater benefits when replacing the usual general physical exercise with progressive resistance training using elastic resistance bands. However, we observed similar changes for both groups and encourage clinicians to advice patients’ to choose between these exercise options based on their interests and motivation.

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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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