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Effect of online physical therapy on workplace accident-related outcomes in nursing care worker: study protocol of a multicentre randomised controlled trial

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ABSTRACT

Introduction According to the 2017 data, occupational accidents are more common in social welfare facilities compared with other industries; in particular, the number of occupational accidents resulting in four or more days of absence from work due to low back pain (LBP) or falls has increased and is considered problematic. Although physical therapy has been demonstrated to be effective in preventing LBP and falls in older adults living in the community, no randomised controlled trials have examined whether individual online physical therapy can prevent LBP and falls in nursing care workers (NCW).

Methods and analysis A total of 120 NCW aged 20 years or older will be randomly assigned to an online individualised therapy group (ITG) or usual group (UG) after obtaining informed consent. We defined an NCW as a person who assists disabled and elderly persons with eating, bathing and toileting activities in social welfare facilities. We will follow-up the participants 12 months after the start of the intervention and compare the results at 3, 6 and 12 months. The primary endpoint will be the Oswestry Disability Index (ODI); ITG participants will receive professional advice on LBP and musculoskeletal problems from a physical therapist via online interview and email as often as they wish over a 6-month period; UG participants will only have access to brochures and video feeds related to LBP and fall prevention. Owing to the nature of the study, blinding the participants and interventionists is not possible; however, the outcomes will be assessed via a web-based questionnaire to prevent detection bias. The null hypothesis is that there is no clinically important difference in the primary outcome between the two treatment groups and that a decrease in the ODI score of at least 20% is clinically meaningful.

Ethics and dissemination The Ethics Committee of the Japanese Society of Occupational Medicine approved the protocol of this study. The results of this study will be disseminated through peer-reviewed journals and conference presentations.

Trial registration number jRCT1070210128.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Recruitment of the participants from multiple sites.
⇒ Difficulty in introducing researcher bias in the evaluation of the outcomes.
⇒ Only cooperative participants will be included, which reduces generalisability.
⇒ Lack of blinding of the participants and interveners, which does not exclude the possibility of bias.

INTRODUCTION

Japan's population is ageing owing to the decline in the birth rate and increase in life expectancy; it is estimated that by 2025, those aged 65 and over will account for 30% of Japan's total population, and the working-age population will decrease by 10 million people by 2040.[1] As of 2016, there will be a shortage of 0.55 million nursing care workers working (NCW) in social welfare facilities[2]; thus, securing the NCW workforce is an urgent issue.[1 2] Data from 2017 show that social welfare facilities in Japan have more occupational accidents than other industries, and the percentage of occupational accidents requiring four or more days of absence from work among all industries is increasing every year. This has become a major problem resulting in a shortage of human resources for NCW.[3] Back injuries and falls are particularly common in occupational accidents, accounting for nearly half of the cases and mostly occurring in social welfare facilities.[3] Low back pain (LBP) and falls have generally been shown to be events that increase in frequency with age; the same trend has been observed in the NCWs.[4] Particularly among workers in their 40s and older, occupational accidents have occurred owing to the physically burdensome assistance unique to NCWs and work in areas with poor footholds.[4] This situation may lead to a decrease in the workforce of NCWs at social welfare facilities, which could reduce productivity and the quality of care, thereby warranting countermeasures.

Several studies have reported on the factors associated with LBP and falls among workers. A study examining the causes of LBP among NCW in social welfare facilities in Japan found that human lifting movements and improper posture during bathing were some of the problems.[5] Inappropriate posture generally includes excessive forward bending and twisting movements of the lower back.[6] Studies focusing on the factors that cause workers to fall on the job have found that in addition to being female and over the age of 45, poor balance and lower extremity muscle strength are risk factors for falls.[7–9] The internal factors that contribute to falls and LBP are familiar territory for physical therapists, and systematic reviews of community-dwelling elderly patients have shown that exercise therapy by physical therapists can prevent falls and LBP.[10 11] In recent years, individualised exercise instruction by physical therapists to workers has been shown to improve physical function.[12] however, it is not clear whether physical therapist interventions for workers ultimately contribute to work-related outcomes and work-related injury prevention. Therefore, this study aimed to examine whether individual instruction by physical therapists to NCW in social welfare facilities has an impact on the outcomes related to occupational accidents.

Box 1 Inclusion and exclusion criteria used in the randomised controlled trial

Inclusion criteria

1. Age: 20 years and older, but less than 60 years of age at the start of the study.
2. Sex: Any sex possible.

Exclusion criteria

1. Persons with severe visual impairment (disability levels 1–6) or hearing impairment (grade 2–6 disability level, *those with a normal hearing level on one side are included in this category).
2. Those who have a history of spinal disease (surgery).
3. Those who have already received rehabilitation treatment and guidance by physical therapists, etc.
4. Those who wish to retire within 1 year at the start of the study, or those who are likely to retire during the intervention period or are likely to reach.
5. Those who have been advised against participating in the study by their physicians due to medical reasons.
6. Those who did not provide consent to participate in the study.

Discontinuation criteria

1. Criteria for discontinuation: Those who wish to discontinue participation in the study and request to opt out.
2. Those who have health reasons that make it difficult to participate in the LBP and fall prevention Programme

LBP, low back pain.

METHODS AND ANALYSIS

Checklist

The protocol for this study was drafted as per the checklist from the Standard Protocol Items for Clinical Trials.[13]

Patient and public involvement

There was no involvement of the general public or patients in the development of this study.

Study setting

This is a multicentre, randomised, controlled trial comparing a study group that received only pamphlet distribution and video delivery on LBP and falls with a control group that received individualised management by a physical therapist online. Participating facilities and candidates were recruited through the website of the Department of Rehabilitation Medicine and Development of Rehabilitation Medicine, School of Occupational and Environmental Medicine. In addition, flyers were distributed to social welfare facilities in Kitakyushu City, Fukuoka Prefecture, through interested parties.

Eligibility criteria

Members of the study group will assess the eligibility of the institutions and candidates (20 years of age or older) for participation in the study. Eligibility and exclusion criteria are presented in box 1. Eligibility for participation in the study is defined as NCW working in a social welfare facility and who provide assistance with eating, bathing and toileting activities for disabled and elderly persons. All the participants who meet the eligibility criteria would be provided with detailed information regarding the study, and consent will be obtained via a signed informed consent form.

Interventions

Individual therapy groups (ITG): Online training by physical therapists on LBP and fall prevention would be provided on the study start date. Training sessions will be prerecorded and distributed to participants via chat or email on the study start date, 3 months and 6 months, and viewing completion will be verified by the facility manager. The training session will last approximately 1 hour and will be related to the prevention of physical fitness, falls, LBP, lifestyle-related diseases and depression. After the course, pamphlets on falls and LBP prevention would be distributed. The content of the pamphlet consists mainly of the muscle strengthening and stretching exercises for the trunk and lower extremities. Based on the results of the baseline (T1) assessment, the physical therapist will provide individualised online instruction according to the exercise guidelines. During the intervention period, the participant will be required to perform the exercises and stretches following the instructions of an online physical therapist at least once a week. The type and frequency of exercises and stretches will be tailored to each participant owing to the highly individualised nature of the programme. Participants will have unrestricted access to their assigned physical therapist via online meetings, video streaming or chat and email for 6 months after attending the online seminar.

Usual group (UG): An online seminar on LBP and fall prevention will be provided by a physical therapist. The delivery method and content will be the same as for the ITG. The pamphlet distributed after the workshop will also be the same as the one distributed at the ITG. A physical therapist not involved in the study would select 3–5 exercises and stretches related to LBP and fall prevention once a week and simultaneously allocate them to the participants via chat and email. This process would continue for up to 6 months after attending the online seminar; however, the participants would not receive advice from the physical therapist.

Outcomes

We chose patient subject-reported outcomes other than absenteeism because we believe that there would be no assessment bias by the physical therapy interventionists and that appropriate effectiveness determinations can be assessed in a short period of time and with a realistic sample size. The effectiveness of the interventions will be assessed at 3, 6 and 12 months. Absenteeism will be evaluated at similar time points and reported by the facility administrator or the individual, along with a physician's diagnosis.

Baseline data

After registration of the study participants, data such as sex, educational background, employment status, work experience as an employee, type of facility, overtime hours per week, workplace accident-related injury or experience in the previous year, and site of injury will be collected through questionnaires.

Primary outcome

The primary outcome measure of this study is the Oswestry Disability Index (ODI). The primary time point is at 6 months.

Oswestry Disability Index

The ODI is used to measure the outcomes of occupation-related disabilities. The Japanese version of ODI has been validated and is the most widely used LBP assessment method in the world. It is characterised by the inclusion of items related to social life.[14 15] Primary outcomes will be assessed at baseline (T1), 3 months postintervention (T2), 6 months postintervention (T3) and 1-year postintervention (T4).

Secondary outcome

Secondary outcomes are measured by the participants self-administered subjective ratings and self-reports. The list of measures of secondary outcomes is shown in box 2. Participants will be asked to fill out questionnaires concerning the fear of falling and decreased productivity. They will also be asked to self-report the number of days of absence from work due to LBP and falls, along with a physician's note. These assessments will be tabulated at each follow-up visit.

Box 2 Outcome measures

Measurements are recorded at 3, 6 and 12 months

Primary outcome measure

1. ODI* at 6 months.

Secondary outcome measures

1. FES-I.*
2. HPQ.*
3. Absenteeism.

*See text definition
FES-I, International Falls Evaluation Scale; HPQ; WHO Health and Work Performance Questionnaire; ODI, Oswestry Disability Index.

International Falls Evaluation Scale

The International Falls Evaluation Scale (FES-I) will be used as an outcome measure for occupation-related disability, and a Japanese version of the FES-I has been developed to verify its reliability and validity.[16] The questionnaire consists of two items: fear of falling and falls self-efficacy. Those who have a fear of falling tend to be more eligible for hospitalisation attributed to falls than those who are not, which is consistent with the purpose of this study.[17]

WHO Health and Work Performance Questionnaire

The WHO Health and Work Performance Questionnaire (HPQ) will be used to investigate the impact of the intervention on the presenteeism of the workers; the reliability and validity of the Japanese version of the HPQ have been validated.[18 19]

Absenteeism

In this study, absenteeism due to falls was defined as the frequency of absenteeism of 4 or more days attributed to falls. In addition, absenteeism due to LBP was defined as absenteeism of 4 or more days attributed to LBP. In addition, the frequency of occurrence and the total number of 4 or more days will be recorded as occupation-related injuries, including falls and LBP, and will be monitored during the follow-up period from the start point of the intervention.*

Participant timeline

The timelines for enrolment, assessment and intervention of this study are shown in table 1. A flow diagram of the study is shown in figure 1.

Sample size

The sample size was calculated using G*Power V.3.1. In this study, the primary endpoint was the ODI after 6 months of intervention, with alpha and beta levels set at 0.05 and 0.2, respectively. Based on previous studies examining the effects of individual physical therapy on workers in manufacturing industries,[12] the effect size of individual physical therapy on physical function was estimated to be approximately 0.5. ODI has been found to be associated with items included in the Short Physical

Table 1 Schedule of the enrolment, interventions and assessments

	Study period				
	Enrolment	Allocation	Postallocation		
Time point			3 months	6 months	12 months
Enrolment:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions:					
(Individual therapy group)		◆	----------	◆	
(Usual group)		◆	◆	◆	
Assessments:					
Baseline data	X				
ODI, FES-I, HPQ	X		X	X	X
Absenteeism			X	X	X

*See text definition of absenteeism in this trial.

Performance Battery (SPPB).[20] The SPPB was validated in a random sample of 5000 individuals aged 70 years and above from three regions of the United States-East Boston, Massachusetts and Washington, D.C, USA. Although originally developed to assess lower extremity function in the elderly, the SPPB has proven to be a

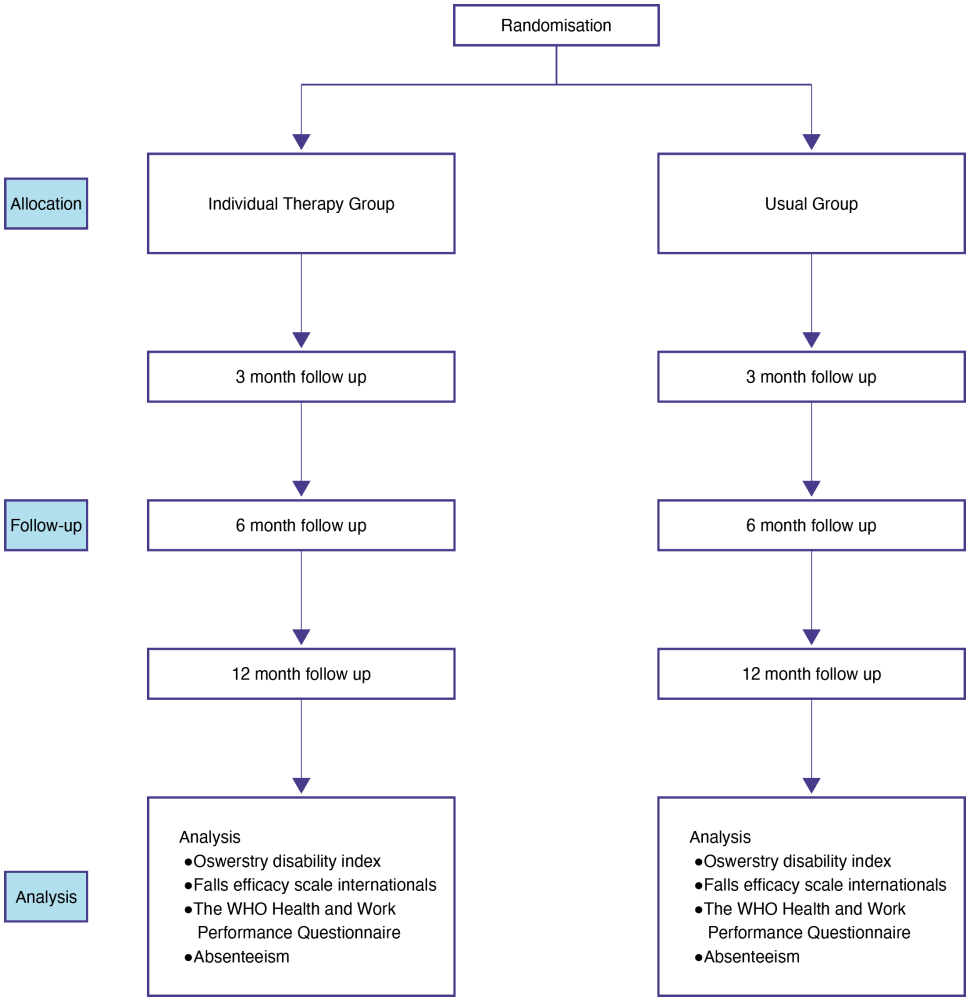

Figure 1 Flow chart of the trial. Individual therapy group (ITG) and usual group (UG).

feasible assessment of physical function of workers in the manufacturing industry.[12 21] We determined that the ODI could indirectly reflect the physical function of the participants because the SPPB has been shown to be a valid assessment battery that characterises physical function, primarily muscle strength, balance function and walking ability.[21] Although a drop-out rate of 20% is often estimated over the course of a study, it was expected that the participants in this study would be easier to track than in studies involving outpatients since they were healthcare workers. Therefore, we estimated a dropout rate of 10% and set the number of study participants required for this study as 60 in each group.

Allocation

Sequence generation and concealment

After the baseline measurements were completed, a third party not involved in the study would assign the participants to either ITG or UG using a computer random number function in R.

Stratification

Participants randomised to the ITG or UG would be stratified by sex, and subsequent subgroup analyses will examine the effect sizes by sex. Several reports have revealed a higher prevalence and severity of LBP and poorer postoperative outcomes in women compared with men,[22–25] The difference in the distribution of the number of women in each group could render the primary outcome, the ODI score, more severe.

Implementation of randomisation

The order of allocation would be decided by a physical therapist affiliated with the University of Occupational and Environmental Health (UOEH), who will not be involved in the study. After obtaining informed consent from the participants, the physical therapist will distribute individual interventions or pamphlets according to the treatment allocation.

Blinding

The evaluation in this survey will be performed through a questionnaire. The participants can freely choose whether to respond on paper or via the digital questionnaire. The number of incidences of LBP and falls, as well as the number of workdays lost due to LBP and falls, will be reported by the participants and their facility administrators. Owing to the nature of the study, blinding of the participants to the physical therapist conducting the intervention is challenging. Therefore, there is a potential for bias in the projected effects of this research. We will mention them as research limitations when discussing this study's findings.

Data collection methods

The questionnaires used in this study, from the baseline assessment to 1 year after participation in the study, can be completed by the participants either on paper or via a Google form. Participants who have not responded for more than 1 week will be listed, contacted, and encouraged to respond. The number of occurrences of LBP and falls and the number of days of absence related to LBP and falls will be self-reported by the study participants and evaluated by facility administrators, while the absence rates will be tabulated as outcomes.

Participant retention

Participants may contact the principal investigator directly or through the facility administrator at any time during the study period if they have any questions or concerns about the study, thereby preventing participants from dropping out due to dissatisfaction with the study content. Contact information for the principal investigator is provided in the study description. To ensure compliance of the participants assigned to each group with the study protocol, the ITG will receive at least one follow-up email per week from the assigned physical therapist throughout the study period, documenting the frequency and duration of interventions and exercise instruction as they occur.

Data management

Data will be entered and coded in duplicate by two third parties who will not be involved in the study to prevent erroneous data entry. The completed database will be stored at the Department of Rehabilitation Medicine, University of Occupational and Environmental Health.

Statistical methods

Strict randomisation is used to address differences in the number of confounders randomly assigned to the two groups, but covariate adjustments are made as appropriate depending on the distribution of confounders. Regarding confounding factors, a study of healthcare workers, primarily nurses, found that the OR of developing LBP increased by 1.06 for every 1-year increase in age. Previous studies have also found that being female increases the risk of developing LBP by 1.79 ORs. Based on previous studies and discussions with researchers, we decided to consider age and sex as confounding factors, considering that these two variables ensure convenient information collection and are likely to influence outcomes.[26–28] Other confounders, such as high body mass index,[28] premenstrual tension,[29] number of manual patient lifts per day, and low job satisfaction,[30] were considered in previous studies to be associated with LBP and were therefore treated as potential confounders in this study. Furthermore, if the distribution of baseline data other than age and sex is not equal, it is up to the experts, including the coauthors, to decide whether to treat them as confounders. Statistical significance will not be used to determine confounding factors, and experts will discuss only the presence or absence of significance based on the descriptive distribution of the data. If confounders were found after assignment, analyses would be conducted in models with and without adjustment for confounders as covariates. Intervention effects would also be presented separately for each model. For the primary endpoint,

two-way analysis of variance will be used to compare the groups at 6 months post-intervention. Intention-to-treat and per-protocol analyses will be used for group differences. If there is a significant difference in the primary endpoint at 6 months post-intervention, the primary and secondary endpoints will be compared at 3 months, 6 months, and 1-year postintervention. In addition, a subgroup analysis will be performed between males and females to identify the differences in the magnitude of the treatment effect by sex. Any missing values for follow-up results during the study period will be supplemented by multiple assignment. Owing to the difficulty in strictly controlling the intervention time for participants assigned to the ITG group and the video viewing time in the UG group in this study, we did not consider the differences in the amount of individual intervention in our analysis.

Data monitoring and auditions

This is not applicable to the study since it is not an invasive intervention study.

Harm

Muscle pain is expected after performing the LBP and fall prevention exercises that are included in the course content. However, these risks are clearly outweighed by their benefits.

ETHICS AND DISSEMINATION

Research ethics approval

Approval was obtained from the Research Ethics Committee of the University of Occupational and Environmental Health. (Approved on 25 November 2021, reception number R3-058). Subsequently, the enrolment in the clinical trial was completed. https://jrct.niph.go.jp/search (jRCT1070210128).

Protocol amendments

After approval by the Ethics Committee, the progress and results of the research at the end of each year will be reported to the University Ethics Committee. If during the research, the expected risk is judged higher than the expected benefit, or in case sufficient results cannot be obtained, the research will be terminated, and if sufficient results are obtained, the research will be terminated even during the research period.

Consent or assent

The significance, purpose and methods of this study, as well as the possible disadvantages and risks that the participants may face would be explained verbally and in writing, and the participants will be asked to sign a consent form. The contents of the consent form, as well as the study protocol, are published in the Japan registry of clinical trials (https://jrct.niph.go.jp/search (jRCT1070210128)) (online supplemental file 1).

Confidentiality

No biological samples will be collected in this study; however, the data obtained will be kept in a locked vault in the Department of Rehabilitation Medicine under the supervision of the principal investigator. The data obtained in this study will be stored for 5 years after the completion of the study or 3 years from the date of reporting the study results, whichever is later, and then all the data will be disposed after confirming anonymisation.

Data sharing

Deidentified individual participant data collected in this study that support the study results will be shared. These data will also be available for up to 3 years after publication. Access to the data will be granted only to those who intend to conduct research that also addresses topics related to this study. In addition, a predesigned research plan must be presented, and analysis to achieve the objectives of the application approved as a research plan by the ethics committee will be permitted. For data access applications, permission to use the data must be requested from reha@mbox.med.uoeh-u.ac.jp. The applicant must execute a data access agreement. Information on submitting an application and data access can be obtained by visiting the following site and following the contact link. (https://www.uoeh-u.ac.jp/kouza/rihabiri/homepage/contact.html)

Ancillary and post-trial care

Emergency contact information for this research will be made available to the participants so that they can ask questions at any time during and after the research, and the principal investigators and research staff will have a system in place to respond appropriately.

Dissemination policy

We will disseminate our findings through publication in a peer-reviewed journal and conference presentation, and our study will support the development of international clinical practice guidelines.

Twitter Shuto Higuchi @shuto_higuchi

Collaborators n/a.

Contributors SH, KF, KN, SK, YF and SS were involved in major parts of the study design, and SH was the principal investigator. The manuscript was prepared by SH, and all members actively participated and contributed to the writing of the manuscript; KF, KN and YF were responsible for the preparation of figures and tables and statistical analysis. All authors reviewed the text and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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同　意　書

産業医科大学　学長 殿

私は、西暦2022年1月から西暦2024年12月までの期間、産業医科大学医学部リハビリテーション医学講座で実施される「社会福祉施設の介護従事者に対するオンライン転倒・腰痛プログラムの有効性に関する研究」について、事前に説明文書を受け取り、研究実施担当者から、説明文書に基づいて、研究の目的、意義、方法、対象者が受ける不利益及び危険性、個人情報の保護などに関して、十分な説明を受けました。

また、私が、研究参加に同意した後も、何時でも自らの意思で研究参加を取止めることができること、及び研究参加を取止めた後も何ら不利益を受けないことについても説明を受けました。

以上のことを理解した上で、私の意思により、この研究に参加することに同意します。

説明を受け理解した項目　（　確認欄にご自身で〇を記入してください。）

確認欄	項　　目	説明文書項目
	研究の目的、意義及び方法	４，５
	研究対象者として選定された理由	６
	予測される利益、リスクと不利益	７
	研究参加の任意性とその同意の撤回の自由	８，９
	研究に関する情報公開の方法	１０，１１
	個人情報の保護	１２
	個人情報などの保管及び廃棄方法	１３
	研究の資金源と利益相反	１４
	研究により得られた結果等の取扱い	１５
	研究対象者等からの相談等への対応	１６
	費用の負担に関すること	１７
	通常の診療を超える研究について	１８，１９
	研究業務の一部を委託する場合の業務内容と監督方法について	２０
	研究対象者の健康等への影響について	２１
	研究対象者から得た情報などの将来的活用	２２
	モニタリング及び監査方法	２３
	知的財産の発生について	２４
	その他	２５

（本人）
同意年月日　西暦　　年　　月　　日

ご署名＿＿＿＿＿＿＿＿＿＿＿＿

（代諾者）・・・必要な場合のみ
同意年月日　西暦　　年　　月　　日

ご署名＿＿＿＿＿＿＿＿＿＿（続柄　　）

上記の研究について私が説明をしました。
説明年月日　西暦　　年　　月　　日

所属名＿＿＿＿＿＿＿＿　氏名＿＿＿＿＿＿＿＿＿＿

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