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Effects of dry needling intervention on lower limb dysfunction after stroke: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Lower limb dysfunction is among the common sequelae of patients who had a poststroke and often results in the reduction of the quality of life. This study aims to assess the short and interim-term efficacy of dry needling (DN) intervention on lower extremity function, balance and gait in lower limb dysfunction after stroke.

Methods and analysis This protocol entails an assessor and statistician-blinded, single-centre study with a randomised controlled trial. Forty-four patients who had a poststroke will be randomly allocated (1:1) to either the conventional treatment group (n=22) or the DN group (n=22). The conventional treatment group will receive conventional rehabilitation treatment once a day for 40 min each time. The treatment will be performed five times a week for 2 weeks. In the DN group, participants will be treated with DN on the basis of the conventional treatment. The intervention will be performed thrice a week for 2 weeks. The primary outcome that determines the efficacy of lower limb dysfunction will be the change in the Fugl-Meyer Assessment of Lower Extremity scale. The secondary indicators include the range of motion of knee and ankle joints, limits of stability, modified Clinical Test of Sensory Interaction on Balance, Timed Up and Go test, Modified Ashworth Scale and Barthel Index. Results will be evaluated at baseline, at 24 hours after intervention, at 2 weeks after intervention and at 3-month follow-up. Data will be released after the completion of the study. Adverse events will be reported.

Ethics and dissemination The experiment was approved by the Ethical Committee of Shanghai Tong Ren Hospital in October 2021 (approval number: 202105702). The results of this study will be published in peer-reviewed journals.

Trial registration number ChiCTR2000040754.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will focus on myofascial trigger points (MTrPs) of the quadriceps, in addition to focusing on MTrPs of the gastrocnemius to examine the efficacy of dry needling on lower limb dysfunction after stroke.
⇒ This study will explore if performing more than one session weekly (current recommendations) may have any potential adverse effects.
⇒ This trial will be the short intervention period because of short hospital stays.
⇒ There will be no sham control group.

INTRODUCTION

Stroke is a serious clinical disease and is the main cause of long-term disability in patients.[1] Stroke results in lower limb motor dysfunction, abnormal posture control, increased muscle tone and decreased balance function.[2 3] Lower limb dysfunction is a factor that directly affects the rehabilitation of patients who had a poststroke and is also the focus of rehabilitation treatment.[4] These clinical manifestations often affect the daily life of patients who had a poststroke, as well as their ability to walk; they reduce the quality of life and increase the economic burden on family and society.

Myofascial trigger points (MTrPs) are hyperirritable painful spots in taut bands of skeletal muscles. 'Spot tenderness', 'referred pain' and 'local twitch response' are the three most popular diagnosis criteria of MTrPs.[5] They have a high prevalence in patients who had a poststroke and are moderately associated with pain and function.[6] MTrPs can cause sensory symptoms and dyskinesias. Sensory symptoms associated with MTrPs include referred pain and hyperalgesia, whereas dyskinesias include increased muscle fatigue or increased synergistic activation of antagonist muscles.[7] Inactivating the hypersensitive points can alleviate the sensory symptoms and dyskinesias.

Dry needling (DN) is a minimally invasive technique that uses a disposable sterile stainless steel needle to penetrate the skin and to directly stimulate MTrPs.[8] It is one of the effective ways to inactivate MTrPs. One study found that regeneration would begin on day 3 after DN caused muscle fibre damage and intramuscular nerve damage. Satellite cells

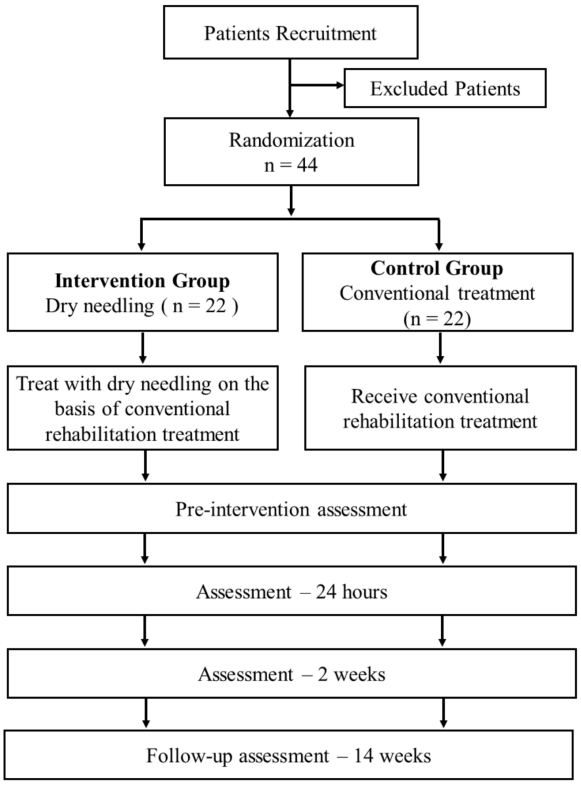

Figure 1 Flow chart of the trial shows the patient recruitment, intervention and assessment.

repair muscle damage by activating muscle fibres and triggering rounds of muscle degeneration followed by regeneration.[9] In previous studies, the effect of DN application on upper limb dysfunction in patients who had a poststroke has been observed.[10 11] Mendigutia-Gómez *et al*[12] found that DN can reduce local pressure pain sensitivity and enlarge the shoulder's range of motion in patients who had a poststroke after 3-week DN application (once per week). Lu *et al* found that DN intervention on the trigger points of the patients' superficial flexor muscle leads to the immediate increase in the active range of motion, the reduction of finger spasticity and the decrease in the frequency of motor unit action potential (MUAP) spikes.[13] In addition, DN application for the upper extremity in patients who had a poststroke appears to be cost-effective.[14 15] DN has benefits on patients' function, quality of life in the treatment of upper limb dysfunction after stroke, which is related to the rationale of lower limbs in this study, but has not been adequately validated.[11]

A meta-analysis suggests a positive effect of DN for decreasing spasticity on lower limb dysfunction after stroke (moderate evidence) while the effect on motor function is inconclusive when DN applied once in one muscle, which may limit the applicability of the results.[16] New randomised controlled trials are needed to investigate the effect of a greater number of DN applications on function, balance and gait in patients with lower limb dysfunction. Previous studies have focused more on the MTrPs in calf muscles of patients who had a poststroke. Salom-Moreno *et al* conducted a DN intervention on the MTrPs of gastrocnemius and tibialis anterior muscle of patients who had a poststroke and found that spasticity decreased in patients with poststroke, and plantar pressure changed, that is, the support surface increased, and the mean pressure decreased.[17] Another research found that after DN intervention on gastrocnemius medialis, lateralis and soleus muscles, the individuals showed short-term effects, that is, reduced spasticity and improved gait.[18] Ghannadi *et al* performed DN intervention on the gastrocnemius of patients after stroke. The passive ankle range of motion, walking speed and activities of daily living significantly improved.[19]

However, no studies have observed the effect of DN intervention performed on the MTrPs of the quadriceps muscle on the lower limb dysfunction of patients who had a poststroke. It has been reported that 40%–68% of patients who had a poststroke have abnormal gait related to knee hyperextension. From the perspective of knee kinematics analysis, the causes of knee hyperextension include knee extensor muscle weakness or spasm, gastrocnemius spasm or proprioception disorder. Simons[20] found that the quadriceps knee extension dysfunction may be related to trigger points.

We hypothesise that DN intervention on MTrPs in quadriceps femoris, gastrocnemius and tibialis anterior muscles may have beneficial effects on lower extremity function, range of motion, balance, gait and activities of daily living in patients who had a poststroke. Moreover, this study will analyse if performing DN sessions in the same MTrPs more than once weekly, which is the recommended practice to respect tissue repair, may have any adverse effects. This present trial aims to assess the short, interim-term efficacy, safety when performing DN more than once weekly on the MTrPs of the quadriceps femoris, gastrocnemius and tibialis anterior muscles on lower extremity function, balance and gait in lower limb dysfunction after stroke.

METHODS

Study design

An assessor and statistician-blinded, single-centre study with a randomised controlled design will be conducted according to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines at one municipal tertiary hospital (Shanghai Tong Ren Hospital). Forty-four stable patients who had a poststroke will be recruited and randomly assigned to a conventional treatment group or a DN group at a ratio of 1:1. The flow chart of the trial is displayed in figure 1. The experimental process and evaluation are listed in table 1. This trial has used the SPIRIT reporting guidelines.[21] The SPIRIT Checklist is attached as online supplemental file 1. This study commenced in October 2021 at Tong Ren

Table 1 Study design schedule

Period	Screening	Baseline assessment	Assessment (24 hours)	Assessment (2 weeks)	Assessment (14 weeks)
Inclusion and exclusion criteria	√				
Informed consent	√				
Physical examination	√				
Medical history	√				
Allocation	√				
FMA-LE		√	√	√	√
ROM		√	√	√	√
MMAS		√	√	√	√
mCTSIB		√	√	√	√
LOS		√	√	√	√
TUG		√	√	√	√
BI		√	√	√	√
SAS and SDS		√		√	√
Patient compliance		√	√	√	√
Dropout reasons			√	√	√
Adverse events			√	√	√

BI, Barthel Index; FMA-LE, Fugl-Meyer Assessment of Lower Extremity; LOS, limits of stability; mCTSIB, modified Clinical Test of Sensory Interaction on Balance; MMAS, Modified Modified Ashworth Scale; ROM, range of motion; SAS, Self-rating Anxiety Scale; SDS, Self-rating Depression Scale; TUG, Timed Up and Go test.

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Patient and public involvement

This will be a randomised controlled trial inspired by physical therapist awareness of limited choices for treating patients with MTrPs, and desire by patients for effective treatments. Patients and the public will not further be involved in the design or conduct of the study. Participants will be acknowledged at the end of publication.

Participant recruitment

Participants will be recruited from the Department of Rehabilitation Medicine at Shanghai Tong Ren Hospital. All patients who had a stroke will be screened for eligibility by their physiotherapist. Participants who meet the inclusion criteria and express interest in participating in the trial will be introduced to the trial protocol by the researchers in writing or verbally.

Inclusion criteria

1. Diagnosis of unilateral stroke was made according to neurologists using the WHO stroke diagnostic criteria and combined with neuroimaging data.[22]
2. At least 3 months after stroke.
3. No further deterioration of neurological deficits.
4. Able to walk (auxiliary equipment available).
5. No cognitive impairment with Mini-Mental State Examination score of ≥25.[23]
6. Volunteered to participate in this study and signed the informed consent form.

Exclusion criteria

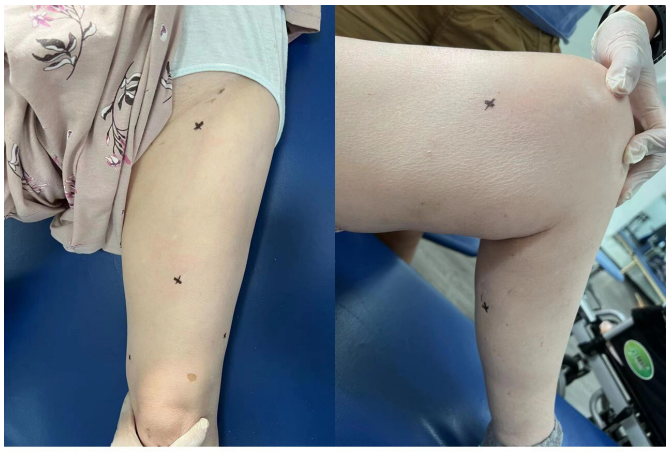
1. Recurrent stroke (ischaemic and/or haemorrhagic).
2. Botulinum toxin injections to the lower extremities in the past 3 months.
3. Severe cognitive impairment or inability to communicate.
4. Unstable hypertension.
5. Lower extremity fracture.
6. With fear of needles.

Termination criteria

1. Serious adverse events (SAEs).
2. The need for additional treatments.
3. Voluntary withdrawal.
4. Non-compliance.
5. Continued participation in the experiment is inappropriate, as judged by investigators.

Randomisation, concealment of allocation and blinding

Participants who meet the inclusion criteria will sign an informed consent form issued by the researcher and will be randomly assigned to the conventional treatment group or to the DN group (including conventional treatment) in 1:1 ratio through a random sequence. The random sequence will be generated on the random number generator (randomizer.org) by researcher A. Therapists B and C will treat the participants according to their group based on the random sequence. It will not be feasible to maintain the blinding of invention and the therapist because of the particularity of DN. Therapists will not collect or process the data. Data will be collected and maintained by a data manager who has received professional training. Participant retention and follow-up will be collected and recorded truthfully, including any outcome data for participants who discontinue or deviate from intervention protocols. An



A B

Figure 2 Treatment sites. (A) Myofascial trigger points (MTrPs) on the quadriceps of the lower extremity. (B) MTrPs on the gastrocnemius of the lower extremity.

independent statistician who does not know the allocation will analyse the data.

Interventions

Control group

Participants in the control group will receive conventional rehabilitation treatment, which includes the following: controlling the patient's abnormal posture; strengthening the motor function of the hemiplegic limbs through neurophysiological therapy; and promoting the sensory recovery of the hemiplegic limbs through multisensory stimuli once a day (40 min each time) five times a week for 2 weeks.

Intervention group

Participants in the intervention group will be treated with DN on the basis of conventional rehabilitation treatment. A quiet, single-patient privacy room will be used for DN treatment. A trained therapist who have 10 years of experience will identify a sensitive spot in a taut band of muscles through palpation (figure 2). After cleaning the skin surface, disposable sterile stainless steel needles (size, 0.30 mm × 45 mm; China) will be used on the MTrPs of the lower limb muscles (quadriceps, gastrocnemius and tibialis anterior) on the patient's hemiplegic side with fast-in and fast-out techniques in order to elicit local twitch responses. During treatment, the needle should be kept in a straight track to avoid damage to the muscle fibres as much as possible. The intervention will be performed thrice a week for 2 weeks.[24]

Outcome measures

Primary outcome

Lower limb motor function

The primary outcome that determines the efficacy of the treatment in alleviating lower limb dysfunction will be the change in the Fugl-Meyer Assessment of Lower Extremity (FMA-LE). The scale is a cumulative numerical scoring system divided into four domains, namely motor function, sensory function, balance and joint range of motion; 17 items are included.[25] All items will use a three-level scoring method ranging from 0 to 2 points, with a total score of 34. The higher the score is, the better the lower limb motor function on the hemiplegic side is.Intra-class correlation coefficient (ICC)is the principal measurement of reliability. The FMA-LE has been shown to have excellent intrarater reliability (ICC=0.93) and good test–retest reliability (ICC=0.868) in patients who had a poststroke.[26] The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Secondary outcomes

Range of motion

Active joint mobility of the lower limbs will be measured by the assessor. This includes the following: hip flexion, extension, abduction, adduction, internal rotation and external rotation; and knee flexion, ankle dorsiflexion and plantar flexion. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Muscle spasticity

The Modified Modified Ashworth Scale (MMAS) is a five-grade rating scale for evaluating spasticity. This scale's intrarater reliability was verified to be good and very good for the knee extensors and ankle plantar flexors.[27] In MMAS, the scale will be as follows: 0=no increase in muscle tone; 1=slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension; 2=marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but affected part(s) easily moved; 3=considerable increase in muscle tone and difficult passive movement; and 4=affected part(s) rigid in flexion or extension.[27] The higher the grade is, the more severe the muscle tone is.

The muscle tones of the quadriceps and gastrocnemius muscles in the affected side will be measured. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Sensory interaction on balance

The modified Clinical Test of Sensory Interaction on Balance (mCTSIB) is a test with four different conditions. Previous study has shown that mCTSIB has good test–retest reliability (ICC=0.91) in patients who had a poststroke.[28] It is used to assess how well the participant uses sensory inputs. All participants will be tested while standing with the head in a neutral position. Under condition 1, the participant's somatosensory, visual and vestibular will be available to maintain balance. The participant's eyes will remain open while standing on a firm surface. Under condition 2, the participant will rely on somatosensory and vestibular to maintain balance with eyes closed while standing on a firm surface. Under condition 3, a foam

cushion as big as the platform will be placed on the force plate, and the participant will stand on this foam cushion. At this time, proprioception will be removed, and the participant will only rely on vision and vestibular perception to maintain balance. Under condition 4, the participant will primarily use vestibular perception to maintain balance with eyes closed and while standing on a foam surface. The test will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Stability limits

A computerised posturography device (NeuroCom Clinical Research System, USA) is a quantitative method that can be used for assessing individuals' limits of stability (LOS). The device consists of an electronic screen and a force plate. When the participant stands on the plate, the track of centre of gravity (COG) will be displayed on the screen in real time. Before the formal test, all subjects will practise thrice. During the test, the participant will stand barefoot on the plate and will hold the COG in the centre area in a quiet environment. When the signal prompt is given, the participant will move the COG towards the target direction immediately. There are eight directions in this test, namely (1) front, (2) front right, (3) right, (4) rear right, (5) rear, (6) rear left, (7) left, and (8) front left. The movement towards each target direction will be performed in a single trial. The LOS correlates with the Berg Balance Scale in patients who had a stroke.[29]

This parameter includes reaction time (RT; s), movement velocity (MVL; °/s), end-point excursion (EPE; %), maximum excursion (MXE; %) and directional control (DCL; %). RT represents the time from hearing the signal to reacting. MVL is the average speed of COG movement per second in a specific direction. EPE is the distance that the COG travels from the initial position to the target point. MXE is the longest distance the COG travels in the test. DCL is the amount of movement in the predetermined direction minus the amount of the offset direction. DCL scores reflect the subjects' movement coordination. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Functional mobility

The Timed Up and Go (TUG) test will be used to evaluate functional mobility in patients with chronic stroke. The test–retest correlation coefficient for TUG scores was 0.95, and correlated well with plantar flexor strength, gait performance and walking endurance in subjects with chronic stroke.[30] The participant will sit on an armchair. The time it takes for a participant to walk 3 m forward, turn around, walk back and sit on the chair will be recorded by the assessor on completion of the test. This test will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Activities of daily living

The Barthel Index of activities of daily living will be used to assess the participant's dependency in daily life. This scale contains 10 items and has 100 points in total. During the assessment process, questions pertaining to the degree of self-care in terms of feeding, moving from wheelchair to bed, personal toilet (washing, using a shaver or using a comb), using the toilet, bathing, walking on a level surface, ascending and descending the stairs, dressing, controlling bowels and controlling bladder will be asked. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Mood

Negative psychology often occurs after a stroke.[31] Thus, it is necessary to monitor mood disorders after a stroke.[32] The Self-rating Anxiety Scale is a self-reported test containing 20 items. Each item is divided into four levels. The total score is 80 points. A score higher than 50 points indicates mild anxiety. The higher the score is, the more severe the anxiety is. The 20-item Self-rating Depression Scale will be used to evaluate participants' affective, psychological and somatic symptoms, which are associated with depression, based on their past week's experience. Each item will be divided into four levels that indicate the frequency of the item as follows: a little of the time, some of the time, a good part of the time and most of the time. The higher the score is, the more severe the depression is. These two scales will be employed at baseline, at 2 weeks after treatment and at 3-month follow-up.

Sample size

G*Power V.3.1.9.7 software was used for sample size calculation. In this trial, participants will be divided into two groups and evaluated at four different time points. Time is the within-subjects variable, and group is the between-subjects variable. Partial eta squared was set to 0.06 as a medium effect size. The estimated sample size was 36 individuals. With this sample size, the 95% statistical value and the 5% significance level are met. The sample size was finally determined to be 44 cases (22 per group) in consideration of the 20% dropout rate.

Data management and monitoring

Electronic data will be input into an encrypted electronic table, whereas the paper data of subjects will be stored in a locked file cabinet. Regular monitoring tests will be performed by the Clinical Research Center of Shanghai Tong Ren Hospital to ensure the integrity and authenticity of all data, including participants' informed consent forms, pathological report forms and possible adverse event (AE) records.

Statistical analysis

SPSS V.22.0 statistical software will be used for the statistical analysis. The normality of the distribution of quantitative variables will be determined using the Shapiro-Wilk test. All tests will be bilateral, and $p<0.05$ will be considered

as statistically significant. Qualitative variables will be described by frequencies and percentages; quantitative variables will be reported by the mean and SD or the median and IQR. Baseline information and demographic characteristics of the 28 participants will be analysed statistically. A two-way repeated measures analysis of variance will be conducted to analyse the data within factors (time: 0, 24 hours, 2 weeks and 3 months) and between factors (conventional rehabilitation treatment and DN intervention) to identify the difference among participants who suffered from stroke.

Adverse events

The AEs will be monitored and recorded throughout the study. Haematoma or muscle soreness at the treatment site after DN will be classified as an AE. Participants' syncope caused by fear of needles and other major medical events will be classified as serious adverse events (SAEs). Medical services will be provided if participants experience these AEs. The intervention will be immediately stopped if participants want to withdraw, and their rights and interests will not be affected.

Ethics and dissemination

The experiment has been approved by the Ethical Committee of Shanghai Tong Ren Hospital in October 2021 (approval number: 202105702). It has been registered in the Chinese Clinical Trial Registry in December 2020 (registration number: ChiCTR2000040754). Any modification of the protocol will be documented at www.chictr.org.cn. This research conforms to the Helsinki Declaration. Demographic data (age, gender, height, weight, type of stroke, affected side and time of stroke) will be gathered and stored properly. The results of this study will be published in peer-reviewed journals.

DISCUSSION

This study will be the first to focus on MTrPs of the quadriceps, in addition to focusing on MTrPs of the gastrocnemius and tibialis anterior. Quadriceps femoris plays an important role in lower limb function. Akbas *et al* found that excessive quadriceps activation may result in the decreased knee flexion in patients with stroke.[33] DN has been shown to decrease MUAP spikes and increase active range of motion. However, previous DN studies focused more on patients' calf. We found that latent trigger points may exist in the quadriceps muscle. Therefore, we wanted to evaluate whether DN intervention on MTrPs of thigh and calf could have a better impact on patients with stroke. DN interventions will be performed by therapists with extensive clinical experience. This study may help analyse the short-term and long-term efficacy of DN intervention on lower limb through the individuals' lower limb motor function, range of motion, balance, gait and mood in patients who had a poststroke. The new treatment site will provide new therapeutic ideas and may improve the efficacy of dry acupuncture in the treatment of lower limb dysfunction after stroke based on previous studies. The limitations of this study are as follows. First, the duration of the intervention in this study will only be 2 weeks due to the limited number of hospital stays. In addition, this study will not include a sham DN group. Lower limb dysfunction after stroke affects the daily life of many patients. This study may provide an efficient and safe method to improve lower limb function. Results may be used to support the development of an evidence-based physical therapy practice in patients who had a poststroke.

Contributors LT and SL conceived and designed the study protocol. YL, Q-MH and FG provided advice and revised the protocol. LT and SL drafted the protocol. LG and HD contributed to data acquisition. All authors read and approved the final manuscript.

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Disclaimer The funders have no role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

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. Refer to the Methods section for further details.

Patient consent for publication Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

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