ORIGINAL ARTICLE

Stimulation of Acupoint ST-34 Acutely Improves Gait Performance in Geriatric Patients During Rehabilitation: A Randomized Controlled Trial

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ABSTRACT. Hauer K, Wendt I, Schwenk M, Rohr C, Oster P, Greten J. Stimulation of acupoint ST-34 acutely improves gait performance in geriatric patients during rehabilitation: a randomized controlled trial. Arch Phys Med Rehabil 2011;92:7-14.

Objective: To determine whether a specific regimen of acupoint stimulation improved gait performance in geriatric patients.

Design: Multiple-blinded, randomized, controlled intervention trial.

Setting: Geriatric ward rehabilitation.

Participants: 60 geriatric patients during rehabilitation.

Interventions: Both groups received a 1-time acupoint stimulation according to randomization. Stimulation of a verum acupoint (verum treatment) according to principles of traditional Chinese medicine was compared with a technically identical needle application on a nonacupoint (control treatment) in the control group.

Main Outcome Measures: Descriptive parameters were documented by valid, established tests. Gait performance was objectively measured by an electronic walkway before needling and after needling.

Results: All gait parameters showed statistically significant improvement after verum treatment compared with control treatment (velocity, cadence, stride length, cycle time, step time, single support, double support: *P* values all $<.05$) except for the base of support ($P=.163$). Effect sizes achieved by 1-time stimulation of an acupoint were low and ranged from .08 to .24. No severe adverse clinical events related to the intervention occurred.

Conclusions: Study results showed that a 1-time administration of a specific acupoint stimulation regimen statistically significantly improved gait performance during geriatric ward rehabilitation. If sustainability of effects can be documented, acupuncture may prove to be an inexpensive intervention that may mildly improve motor performance in frail geriatric patients.

Key Words: Acupuncture therapy; Aged; Gait; Rehabilitation.

ADEQUATE GAIT MOBILITY is an important quality of life issue in older patients and important to preserve functional independence.[1] Gait disorders represent high-impact risk factors for falls/fall injuries,[2,3] severe mobility limitation, hospitalization, and mortality[4] in older people.

Rehabilitation strategies to improve walking performances in older persons have been developed based on established training programs such as progressive resistance or functional training,[5,6] which have been shown to be effective in reducing falls in older people.[7] However, participation in strenuous physical exercise is limited in frail older persons for a number of different reasons. Limitations relate to medical causes such as adverse training-associated events including musculoskeletal impairment and pain,[5,8] fatigue and decreased functional capacity because of progressed frailty or multiple morbidities, or psychological reasons such as the perception of negative health status and the perception of future health problems.[9]

Alternative therapeutic approaches such as acupuncture after TCM principles may hold options for those who cannot follow strenuous training regimens or may fortify benefits already achieved by established rehabilitative programs. However, despite the widespread use of acupuncture in recent years, its efficacy remains controversial in different areas of application. Furthermore, methodologic deficiencies such as a lack of adherence to international recommendations for quality of research,[10-12] insufficient sample size,[13] and publication bias[14] reduce the credibility of published results. A major concern has been the insufficient blinding of patients, assessors, and therapists. Patient blinding seems especially important because patient beliefs on the effect of acupuncture may be more strongly related to pain perception rather than specific effects of acupuncture.[15] A recent review of clinical trials using sham devices to allow blinding of patients and therapists showed that effects of acupuncture may relate to a placebo response.[10] Further methodologic pitfalls are the lack of standardization, the large number of different therapeutic approaches, and the different control treatments used in RCTs.[10,16] It remains controversial whether acupuncture's clinical benefits are caused by nonspecific physiologic effects of needling or the effects of

List of Abbreviations

ADLs	activities of daily living
GDS	Geriatric Depression Scale
MMSE	Mini-Mental State Examination
RCT	randomized controlled trial
TCM	traditional Chinese medicine
VAS	visual analog scale

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Supported by the Dietmar Hopp Stiftung.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

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0003-9993/11/9201-00523$36.00/0
doi:10.1016/j.apmr.2010.09.023

stimulating specific acupoints selected based on TCM diagnostic methods[16] as beneficial clinical effects of treatment have been documented in verum and sham acupuncture groups.[12] Therefore, effective sham acupuncture has been regarded as a lower-grade or minimal acupuncture.[12] Other methodologic aspects of acupuncture such as the length of time for needle insertion; optimal/minimal frequency of therapeutic sessions; or intensified stimulation by manual, laser, or electric stimulation increase the diversity of interventions.[16] Acupuncture's underlying mechanisms are incompletely understood.

Although some studies support neuronal mechanisms caused by analgesia-related effects, other mechanisms suggest hormonal, anti-inflammatory, or other pathways.[10,16,17] Studies have shown contradictory results for acupuncture's effects on alpha motor neurons, whereas an increase of excitability of alpha motor neurons has been proposed as a mechanistic model of motor effects of acupuncture.[18,19] Placebo response has been discussed as a relevant cause of treatment effects.[10,20] Despite those methodologic flaws and controversial study results, there is evidence for the beneficial effects of acupuncture in 28 medical conditions.[10,12,21]

Motor effects induced by acupuncture such as improved strength, endurance, or functional performance have so far not undergone rigorous research despite the fact that acupuncture has been used for improving motor performances in older persons[22] and has been suggested to improve results in high-performance sports.[23] In poststroke rehabilitation, overall improvements because of acupuncture on balance, mobility, activities of daily living, quality of life, and length of hospital stay have been found[24,25] although other studies[18,26,27] could not confirm the improvement in functional and motor outcome nor spasticity. Interventions targeted at physical performance capacity and hemodynamic parameters related to endurance performances have also shown inconsistent results.[28,29] Positive effects of acupuncture on muscle strength have been reported for young, unimpaired persons[30] and on functional status of middle-aged persons with lower back pain.[31] To our knowledge, only 1 small study[22] reported on the long-term effect of acupuncture on gait performance in older people; no study has been performed on the acute effects of acupoint stimulation in impaired, older patients on geriatric wards.

Therefore, the objective of the present study was to observe the acute effects of a single acupoint stimulation based on TCM criteria in frail, multimorbid patients during geriatric rehabilitation. A rigorous multiple blinding design and objective technical measurements were used to ensure that any effects of intervention were free of bias of patients, therapists, or assessors. Based on the study hypothesis, we expected significant effects on different parameters of gait performances only in the group undergoing the real acupoint stimulation as defined by TCM criteria (verum) in comparison to nonacupoint skin stimulation (control).

METHODS

Study Design

The study was designed as a multiple-blinded, randomized, placebo-controlled intervention trial. The study protocol was based on the declaration of Helsinki and approved by the ethics committee of the medical department of the local university. Written informed consent either of the participant or legal representative was obtained.

Participants

Patients were consecutively recruited during rehabilitation at a geriatric hospital. Inclusion criteria were the following: written informed consent, older than 65 years of age, ability to walk 5m without support, no amputation of lower limbs, no leg casts or braces restricting mobility, full weight bearing status, no use of vitamin K antagonists, and no cognitive impairment (MMSE$>$24).[32] Patients meeting the inclusion criteria were randomly assigned to either the intervention group or the control group using an urn design for clinical trial (numbered containers), not stratified for subgroups.[33] The sequence was concealed until interventions were assigned after baseline measurements. A person unrelated to the study performed the randomization procedure and assigned participants to their study group.

Measurements

Descriptive parameters such as age (years), functional status (ADLs, Barthel score),[34] mobility status (independent outdoors vs indoors), psychological status (GDS),[35] fear of falling,[36] cognitive status (MMSE),[32] social status (dependent vs independent), comorbidity (number of diagnoses documented at discharge in patient charts), and pain (VAS)[37] were assessed by valid, established tests. All assessments had been interview based for the descriptive parameters described earlier.

Gait Measurement

For objective assessment, we used an electronic walkway (GAITRite-System[a]). The GAITRite is an electronic gait analysis system (4.9-m length) based on embedded pressure sensors that show high concurrent validity relative to a 3-dimensional motion analysis system.[38] Maximal gait speed was chosen as the primary study endpoint. Other temporal and spatial gait performances related to dynamic postural control and performance-based measures were used as secondary outcomes. The mean of 2 consecutive pre- and postinterventional trials was used in data analysis. No use of assistive devices was allowed during testing.

Test Proceeding/Blinding

For maximal blinding, we used a blinding and assessment procedure as developed in previous studies.[39] In step 1 (blinding of the patient), a trained acupuncturist marked nonacupoint (control treatment) and real acupoints (verum treatment) on the patients' skin by using 2 different colors. Patients were informed that all patients would receive an effective, new treatment. In step 2 (blinded assessor, baseline measurement), the type of intervention was invisible to the GAITRite operator, resulting in the blinding of the test assessor. After 2 test walks, the baseline measurement was performed. In step 3 (randomization), an independent randomization center then allocated the participant to 1 of the 2 study groups. In step 4 (blinding of the acupuncturist), a person not trained in TCM and being a novice to acupuncture performed the treatment using the skin point marked with the respective color according to the randomization code. In step 5 (postintervention measurement), 2 walks were performed to document effects of the intervention (fig 1).

Treatment

Commercially available sterile standard disposable injection needles (BD Micro-Fine+,[b] 0.30mm [30G] $\times$ 8mm) were used for treatment of the acupoints. Bilateral needling was performed on both the verum and control acupoints in the so-called sparrow-pecking technique, which basically consists of 5 rapid skin penetrations within approximately 3 seconds within a line of 2 cun (Chinese inches, equivalent to the width of the thumb of the patient) downward from the real acupoint

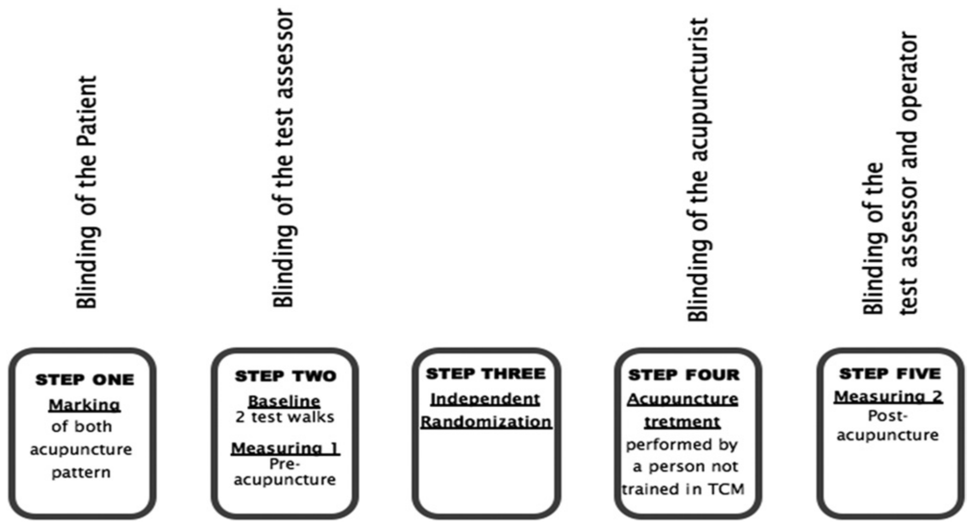

Fig 1. Illustration of test proceeding and blinding: multiple blinding according to a 5-step test procedure.

or the nonacupoint, respectively. The depth of skin penetration was 0.5 cm and limited by the shape of the needles. This type of technique is also known as the leopard spot technique and belongs to the "5 kinds of punctures" as named in the classic textbook *Ling Shu* and is recommended for the "numbness of muscles."[40]

Intervention

For verum treatment, the acupuncture point stomach 34 (梁丘穴, liáng-qiū-xué, monticulus septi) was used, located 2 cun proximal the superior lateral border of the patella. This acupoint was chosen according to the theory of Chinese Medicine as described by the Heidelberg Model of TCM.[41] This point, besides its analgetic effect, has traditionally been used for weakness of the legs and neurologic deficits in the lower extremities as induced by palsy or hemiplegia. Control treatment was performed at a nonspecific skin point with no direct relation to any conduit (meridian) between the felleal conduit (gallbladder meridian) and the lateral posterior border of the femur and at the same height as the verum point (fig 2).

The sample size was calculated for the increase of maximum gait speed after acupuncture using results of a pilot study (unpublished data, Hauer 2008) based on a statistical power of 80% and a significance level of 0.05 to verify a significant intervention effect.

Statistical Analysis

Statistical procedures were performed on SPSS 17.0 for Windows[c] by an intention-to-treat analysis. Exploratory analysis determined the variability and distribution of outcome variables. Unpaired *t* tests, Mann-Whitney *U* tests, and chi-square tests were used for baseline comparison as appropriate. Effects of intervention between group were analyzed by 2-way analysis of variance for repeated measures (group × time). A 2-sided *P* value ≤0.05 indicated statistical significance. Effect sizes for change within groups were calculated as mean changes between groups divided by pooled standard deviation at baseline.[42] Effect sizes represent a method for reporting the magnitude of change without unit of measurement.[43] Data are presented as means (standard deviation) or medians (range).

RESULTS

Recruitment

Sixty older patients were consecutively recruited between November 2008 and July 2009 and tested within the last 2 days of their 3-week geriatric ward rehabilitation (fig 3). Study participants represented a sample of multimorbid, older per-

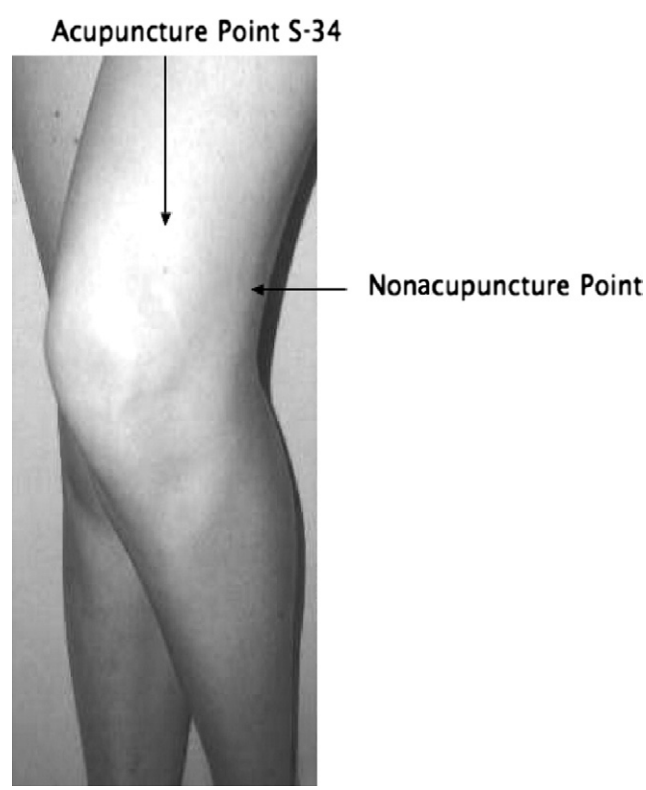

Fig 2. Location of acupoint ST-34 and the nonacupoint used for control treatment.

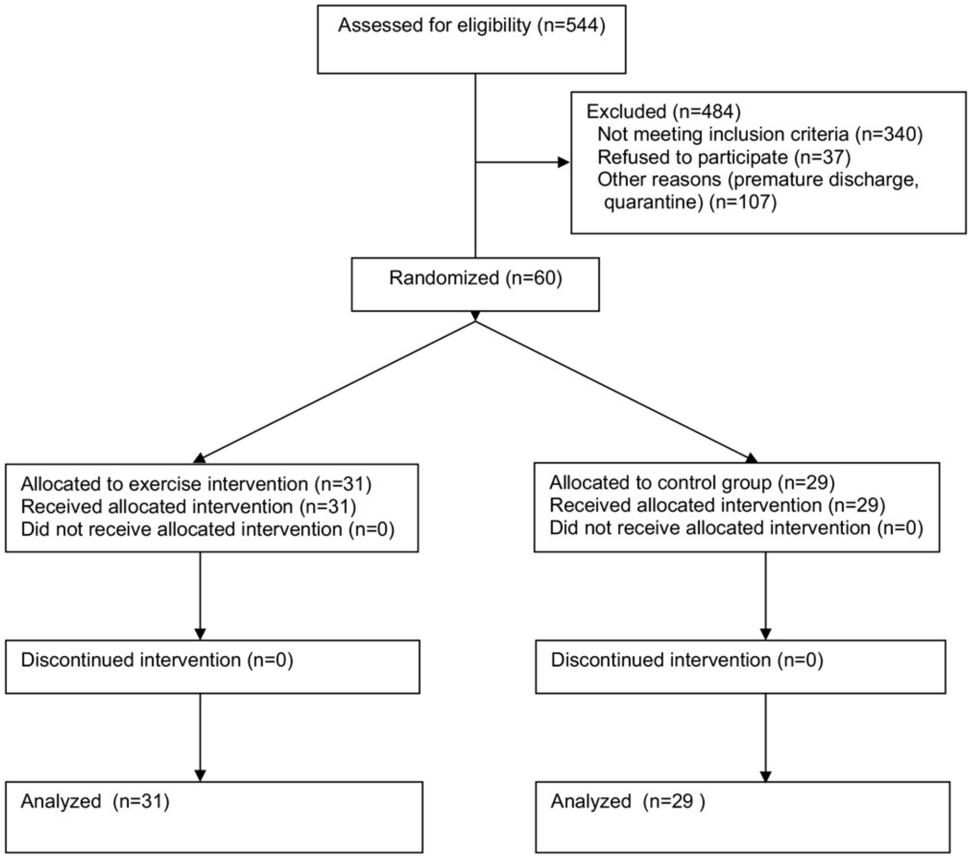

Fig 3. Flow chart for patient screening and randomization.

sons with limited gait performance typical for patients of a geriatric rehabilitation ward. The main causes of admission were falls/fall-related fractures/orthopedic impairment (n=31, 52%), acute cardiovascular events (n=21, 35%), or internal diseases (n=8, 13%).

Patients were excluded because of gait performance less than 5m without support (31%), vitamin K antagonist medication (27%), premature discharge home or transfer to another medical department (14%), acute infection/quarantine (6%), and MMSE less than 24 (6%). Of those patients who met inclusion criteria (17% of the total population screened), 62% took part in the intervention. The reasons not to take part included inconvenience of treatment, general unwillingness to participate in an intervention study, unwillingness to sign the participant's agreement, and a lack of interest. Study groups according to randomization did not significantly differ with respect to

Table 1: Comparison of Baseline Characteristics

Characteristic	Intervention Group (n=31)	Control Group (n=29)	*P*
Age (y)	79.87±6.94	81.90±4.39	.180
Sex, female, n (%)	22 (71.0)	21 (72.4)	.901
GDS (scores)	4.68±3.29	4.07±2.88	.450
MMSE (scores)	26.61±1.93	26.62±2.01	.988
ADLs (scores)	83.55±9.76	80.00±11.42	.200
VAS (scores)	3.48±3.00	2.31±2.14	.085
Fear of falling, n (%)	23 (74.2)	17 (58.6)	.201
Use of ambulatory device, n (%)	14 (45.2)	14 (48.3)	.809
Numbers of diagnosis	8.26±3.07	9.45±4.36	.223
Mobility before rehabilitation, n (%)	22 (71.0)	23 (79.3)	.556
Social status (independent), n (%)	17 (54.8)	22 (75.9)	.098
Cardiovascular disease, n	13	8	.493
Internal disease, n	4	4	
Fractures/orthopedic impairment, n	14	17	

NOTE. Data are presented for mean values ± SD or as otherwise indicated. For fear of falling, categories are dichotomized as no fear versus some to very much fear. *P* values are given for baseline differences between groups.

Table 2: Baseline Comparison of Gait Parameters

Characteristic	Intervention Group (n=31)	Control Group (n=29)	*P*
Velocity (cm/s)	79.57±26.13	87.93±33.78	.287
Cadence (ms)	107.39±19.99	112.84±21.09	.308
Stride length (cm)	89.02±22.72	91.72±27.23	.678
Cycle time (cm)	1.15±0.22	1.11±0.27	.449
Step time (ms)	0.58±0.13	0.57±0.19	.861
HH base support (cm)	11.97±4.19	12.76±4.85	.505
Single support (% of GC)	34.82±4.82	34.60±6.08	.917
Double Support (% of GC)	30.46±8.05	30.71±10.70	.402

NOTE. Data are presented as means of 2 consecutive tests ± SD. *P* values are given for baseline differences between groups.
Abbreviations: GC, gait cycle; HH, heel to heel.

baseline descriptive parameters (table 1) as well as baseline gait parameters (table 2). No patient randomized dropped out, and all patients remained in the intention-to-treat analysis.

Effect of Intervention

The single stimulation of the acupoint ST-34 increased gait performance in all documented gait parameters including the primary study endpoint (maximal gait speed), except for the width of the base of support. The stimulation of the nonacupoint produced no effects (ie, gait performance measures remained unchanged in the control group. However, the effect sizes achieved by the intervention were low. More pronounced effects were found for temporal (such as cadence) compared with spatial parameters (such as stride length) (table 3).

No adverse effects of needling occurred except minor bleeding, which required no specific treatment. The intervention was well accepted and feasible in frail older patients during rehabilitation, and no participant discontinued the assessment or intervention. The application was easy to deliver, did not require any special treatment location, was low-cost, used commercial needles, and took only minutes to administer.

DISCUSSION

Effects of Intervention

The results showed a significant improvement in gait performance in the verum treatment group compared with control treatment in multimorbid, frail patients at the end of geriatric rehabilitation. These beneficial effects were not caused by placebo effects because the assessor, therapist, and patients had all been blinded. Therefore, the effect of the selected acupoint (ST-34) can be regarded as a specific effect of this point in comparison to the nonacupoint skin region taken as placebo control. The results indicate an overall impact on the different dimensions of gait including performance-based measures such as gait speed or step frequency as well as gait parameters related to dynamic postural control such as increased single support and decreased double support. The latter results suggest an enhanced efficiency of balance control during gait.[44]

Significant changes could be obtained for all temporospatial gait parameters in the intervention group. Changes in gait speed averaged 0.056 m/s, representing a low but meaningful change in physical performance. Previous studies[45-47] in different samples of older, partly impaired people indicated similar changes as clinically meaningful ranging from .04 to .10 m/s depending on the methodology and population included. As in the present study, older, impaired persons were included; thus, even a lower value for meaningful change might be used for comparison, indicating clinical relevance of the achieved gait improvements.

Interestingly, larger effects were found for temporal compared with spatial parameters. Temporal gait parameters such as cadence are related to power, mechanical work, and the total energy generated and absorbed by the individual joint.[48] After the treatment, cadence was increased by 5.5 steps/min, indicating that acupuncture may also have positively influenced the energy generation of joints during walking.

The design used in this study did not allow deeper exploration into the underlying mechanisms, which have been discussed controversially for other positive effects of acupuncture.[10,16] However, acupuncture is widely regarded as a reflex therapy with involvement of both local and central as well as vegetative mechanisms. Studies[18,19] have reported contradictory results of acupuncture's effects on motor neurons, including increased excitability of alpha motor neurons. Activated alpha neurons in quadriceps motor units may result in the improved control of posture and movement and increased power generation. Increased microcirculation and augmented oxygen in different tissues induced by acupuncture[49,50] may have contributed to the documented functional improvement.

Methodologic Aspects

To avoid such controversial methodologies and results as mentioned previously, here we developed a methodology and design presenting solid methodologic evidence for the effects of the described intervention. Needling was brief, and only upper tissue layers (skin) were targeted to prevent adverse or

Table 3: Effects of Intervention

Characteristic	Intervention Group (n=31)		Control Group (n=29)		*P*	Effect Size
	T1	T2	T1	T2		
Velocity (cm/s)	79.57±26.13	85.19±26.68	87.93±33.78	86.99±35.40	.002	0.21
Cadence (steps/min)	107.39±19.99	112.24±20.44	112.84±21.09	112.83±21.04	.014	0.24
Stride length (cm)	89.02±22.72	90.88±21.52	91.72±27.23	90.61±28.50	.025	0.08
Cycle time (cm)	1.15±0.22	1.10±0.20	1.11±0.27	1.11±0.26	.005	0.24
Step time (ms)	0.58±0.13	0.55±0.11	0.57±0.19	0.57±0.19	.045	0.19
HH base support (cm)	11.97±4.19	11.13±4.41	12.76±4.85	12.74±4.51	.163	0.20
Single support (% of GC)	34.82±4.82	35.68±4.47	34.60±6.08	34,52±5.75	.046	0.18
Double support (% of GC)	30.46±8.05	29.07±7.19	30.71±10.70	31.03±10.60	.020	0.17

NOTE. Data are presented as means of 2 consecutive tests ± SD. *P* values for time × group effects and effect sizes are given for differences between groups.
Abbreviations: HH, heel to heel base support; GC, gait cycle; T1, baseline values before intervention; T2, postinterventional values.

unspecific effects in both groups not related to specific acupuncture mechanisms, such as activation, irritation, or harm of body structures.[23,51]

No additional stimulus such as laser or electrical stimulation was administered to keep the intervention as feasible and easy to apply as possible. We selected a high-impact acupoint for motor effects according to classic TCM criteria although not specified on an individualized TCM diagnosis.

Multiple categorization of individual impairment types represent a major feature of TCM diagnosis but is not yet strictly standardized. A previous study[52] showed limited interobserver reliability. With the use of 1 common acupuncture point for all patients of the intervention group, we prevented effects of unclear or unreliable individualized diagnosis. This strategy was chosen because the study participants were frail geriatric patients with different admission diagnoses for rehabilitation and high comorbidity.

Study results confirmed the study hypothesis that stimulation of a specific acupoint is superior to stimulation to a nonspecific skin region (nonacupoint) and are in line with the results of a previous study[22] on effects on gait and ADLs using less advanced and less detailed motor assessment. In accordance with a previous study,[53] in this investigation we could not identify a significant effect of needling the nonacupoint because the gait performance remained unchanged in the control group.

Placebo effects may be caused by increased patient-physician contact[54] or patient belief in the effectiveness of treatment,[10,15] which have been postulated to relate to insufficient blinding.[10,16,20] To address this issue, we used robust and multiple blinding of patients as well as assessors/therapists in the present study. Both study groups received identical contact, standardized treatment, and objective motor assessment. With this study protocol, we were able to exclude placebo effects in patients and contamination by assessors.

Sustainable acupuncture applied repeatedly over a certain time period, additional stimulation of needles, or specific needle location based on individual TCM diagnosis may enhance the effects of acupuncture.[16,55] In this study, we chose a 1-time application to document the acute effects of a feasible, low-impact, easy-to-administer acupuncture treatment not based on a comprehensive individual diagnosis. Therefore, our results may represent a lower estimate bound for the effectiveness of acupuncture to improve gait performances in older people. Although TCM is not commonly used by older, impaired people, almost two thirds of the geriatric population who met this study's inclusion criteria chose to participate in the protocol. As reviewed for previous studies,[10] the treatment in this study had no serious adverse effects including patients with vitamin K antagonists.[56] No participant discontinued the application when initial informed consent was given. Study results may confirm attitudes reported in observational studies that acupuncture is perceived as a serious alternative for conventional therapies in the general population[57] and that it is recommended as an effective therapy by almost a quarter of physicians in the United States and the United Kingdom.[58,59]

Because no specialized location or equipment is needed and the needling takes little time and training, the acupuncture could be administered during regular rounds on the rehabilitation ward. Depending on medical effectiveness and cost-evaluation models, this methodology may therefore represent a cost-effective treatment as documented in recent studies.[60,61]

Study Limitations

Based on the study design and sample size, we could not document underlying mechanisms of the intervention or report on the effects of potentially associated factors such as fear of falling and pain, which may have influenced study results. Although effects were achieved by a single-application treatment only, representing lower-bound estimates, low effect sizes limit the clinical relevance of the improved gait performances. The sustainability of effects was not followed up within this first study and should be measured in consecutive studies. However, the significant improvements as achieved by a 1-time application, which so far have limited clinical relevance, need to be confirmed by a sustainable application to guarantee an impact on function and quality of life in older persons.

CONCLUSIONS

This is the first double-blind study to show statistically significant and potentially clinically relevant effects of needle acupuncture on gait performance in unselected geriatric patients on a rehabilitation ward. It will be a worthwhile research goal to relate clinical research to applied TCM practice to unveil underlying mechanisms and optimize intervention strategies by a prolonged time period of application and modified frequency, duration, and quality of stimulation or acupuncture based on individual TCM diagnosis for different indications.

Acknowledgments: We thank Andrew Remppis, MD, and Arne Stroehlein, MD, for support in design of the study and preparation of the manuscript.

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Suppliers

a. CIR Systems Inc, 60 Garlor Dr, Havertown, PA 19083.
b. Becton Dickinson GmbH, Tullastrasse 8-12, 69126 Heidelberg, Germany.
c. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.