Geriatrics & Gerontology International
Medline Indexed

Geriatr Gerontol Int 2013; **13:** 393–397

ORIGINAL ARTICLE: EPIDEMIOLOGY, CLINICAL PRACTICE AND HEALTH

Short-term effect of low-intensity, pulsed, electromagnetic fields on gait characteristics in older adults with low bone mineral density: A pilot randomized-controlled trial

Andrea Giusti,[1] Massimo Giovale,[2] Marco Ponte,[2] Francesco Fratoni,[4] Umberto Tortorolo,[3] Armando De Vincentiis[4] and Gerolamo Bianchi[2]

[1]Department of Gerontology and Musculoskeletal Sciences, Bone Clinic, Galliera Hospital, [2]Department of Rheumatology, "La Colletta" Hospital – ASL3, Arenzano-Genova, [3]Opera Don Orione – Paverano, Genova, and [4]THS-Therapeutic Solutions Srl, Milano, Italy

Aim: To evaluate the short-term effects of a 10-min exposure to low-intensity, pulsed, electromagnetic fields (PEF) on gait characteristics in older adults with low bone mineral density.

Methods: In a single-center, double-blind, randomized-controlled trial, community-dwelling older adults aged ≥70 years were randomized (3:2 ratio) to receive a 10-min treatment with PEF (mean intensity 1.5 mW) or placebo. The following gait parameters were assessed at baseline and just after the intervention/placebo with the GAITRite Portable Walkway system: self-selected gait speed (cm/s), stride length (cm), support base (cm) and double support phase (s).

Results: In the intervention group (25 patients), both self-selected gait speed and stride length increased significantly from baseline, whereas the double support phase decreased. In the placebo group, all gait parameters except for support base remained unchanged. The mean percent increase (±standard deviation) of self-selected gait speed was significantly ($P = 0.010$) greater in the intervention group (20.1 ± 15.6) compared with the placebo group (10.5 ± 13.1), whereas no significant difference in the mean percent variation of the other parameters was found between the two groups. During the intervention, no adverse event was observed. A similar proportion of patients in the two groups reported one fall in the 30 days after the intervention/placebo.

Conclusions: This is the first randomized-controlled trial showing the potential beneficial effects of PEF on gait characteristics in older adults. Further phase III randomized trials are warranted to establish their potential benefits (e.g. fall prevention) on fall-related health outcomes in elderly patients. **Geriatr Gerontol Int 2013; 13: 393–397**.

Keywords: electromagnetic fields, falls, gait.

Introduction

Adequate gait mobility is essential to preserve functional independence in older adults. Gait disorders can represent relevant risk factors for falls and fall-related injury (e.g. hip fractures), severe mobility limitations, hospitalization and mortality in elderly people.[1–3] Thus, rehabilitation strategies to improve walking performances in older adults might have a relevant and positive impact on their quality of life, survival and functional status.

The biological properties and clinical effects of low-intensity, pulsed, electromagnetic fields (PEF), which are generally considered safe, have not been fully investigated. Nevertheless, PEF have been successfully used, in experimental trials to improve fracture healing and bone-implant osteo-integration for the treatment of inflammation and depression, and in neurorehabilitation.[4–8]

Available evidence from *in vitro* models suggest that electromagnetic fields might exert positive effects on human cells and tissues when administered with specific ranges of frequency and intensity. Such effects disappear when the same stimuli are applied with higher or lower values. A possible explanation for these phenomena is that every cell or cell aggregate expresses their own specific frequency band and that externally-provided electromagnetic fields, to be effective, must be able to harmonically "resonate" with them.[9–11] Pulsed electromagnetic fields have been shown to enhance physical performance in patients affected by Parkinson's disease

Accepted for publication 7 June 2012.

Correspondence: Dr Gerolamo Bianchi MD, Division of Rheumatology, Azienda Sanitaria Genovese 003, Via Bertani 4, 16120 Genova, Italy. Email: gerolamo_bianchi@tin.it

doi: 10.1111/j.1447-0594.2012.00915.x

and other neurological conditions/abnormalities.[12–16] To date, the effect of low-intensity PEF on gait characteristics in older adults has never been tested.

We carried out an exploratory randomized-controlled trial (RCT) to determine whether a 10-min low-intensity PEF exposure would improve gait parameters assessed with the GAITRite Portable Walkway system (CIR System, Havertown, PA, USA) in a sample of community-dwelling osteoporotic/osteopenic older adults.[17,18] The main objective of the present pilot study was to evaluate the immediate effects of PEF on gait performance, in order to provide a background for further RCT designed to assess and investigate the potential benefits of PEF in older adults.

Methods

In a single-center, double-blind, randomized, placebo-controlled trial, 41 patients aged ≥70 years were randomly assigned to receive a low-intensity PEF intervention or placebo. Details of the enrolment and allocation phases are shown in Figure 1. Briefly, participants were enrolled in the local community, and were recruited and referred from general practitioners. Five general practitioners were involved in the enrolment phase of the study. They were asked to identify all the consecutive patients potentially eligible for inclusion in the trial, evaluated within 1 week in their general practice, and to refer them to the senior researcher (GB) for further evaluation and assessment of eligibility.

Participants were included in the study if they were community-living males or females, presented with a femoral neck bone mineral density T-score below –2 (assessed within 6 months from eligibility screening), were able to walk with or without aids, had at least one fall in the last 3 years and were not cognitively impaired (age-adjusted Mini-Mental State Examination score above 27).[19] Exclusion criteria included: a previous diagnosis of dementia, multiple sclerosis, Parkinson's disease or brain neoplasm; other neurological, orthopedic or medical conditions that would limit the participation; concurrent or previous use (1 week before) of drugs for vertigo; and alcohol abuse. The study was approved by the ethics committee of the Local Health Agency 3 (ASL3, Genova, Liguria, Italy), and all study participants provided written informed consent.

Patients were assessed at baseline, just before receiving the intervention or the placebo, and immediately after. Gait characteristics were evaluated using the GAITRite Portable Walkway System, which automates the acquisition, analysis and reporting of objective parameters of gait as the subject walks the walkway with embedded sensors.[17,18] The following parameters were considered: self-selected gait speed (cm/s), stride length (cm), support base (cm) and double support phase (s).[17,18]

Low-intensity, pulsed, electromagnetic fields were supplied by the THS 280 E device (THS-Therapeutic Solutions Srl, Milan, Italy). It provides a new therapeutic approach, named TEPS (Triple Energy Postural Stabilization), and represents an evolution of physical therapy based on contemporary use of low-potency laser technology, infrared light and transcutaneous electrical nerve stimulation (TENS), all supplied under specific and patented wave lengths and shapes, at low/very low frequencies:

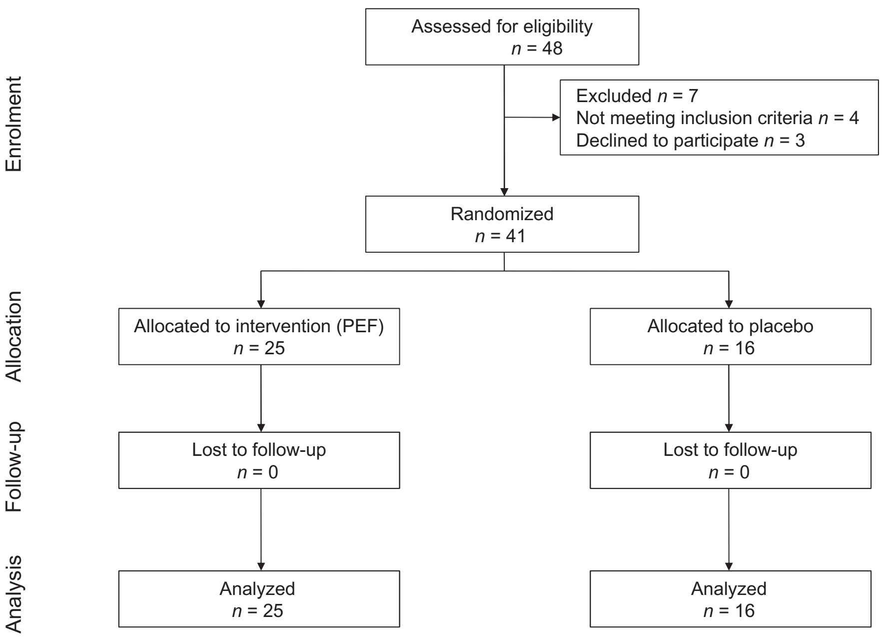

Figure 1 Consolidated Standards of Reporting Trials flow diagram of the progress through the phases of the trial. Abbreviations: PEF, low-intensity pulsed electromagnetic fields.

- low-power laser: wave length 500 to 700 nm;
- low-energy infrared pulsed light: wave length 700–1050 nm;
- TENS: maximum amplitude 200 V.

After the baseline assessment, patients were seated, connected with six skin electrodes to the THS 280 E and randomized with a 3 : 2 ratio to receive a 10-min treatment with low-intensity (mean intensity 1.5 mW) PEF or placebo. Figure 2 shows the THS 280 E device (Fig 2a) and the positioning of the electrodes (Fig. 2b), which was determined following the experience of acupuncture therapy in vertigo.

The randomization was carried out directly by the software of the device, so that both patients and observers were blinded to the treatment allocation. During the treatment, adverse events were observed and recorded by a physician.

One month after the intervention/placebo, patients were contacted by telephone interview and were asked to report any falls and/or episodes of dizziness. Dizziness was defined by one of the following: vertigo, disequilibrium, pre-syncope or lightheadedness.[20]

The primary outcome was the mean percent change from baseline of gait parameters in the intervention and placebo groups.

The characteristics of the two groups and the mean percent change of the gait parameters in the two groups were compared. Categorical data were analyzed using Fisher's exact test. Continuous variables were compared using the independent samples *t*-test or the nonparametric Mann–Whitney *U*-test. Statistical inferences were made on the basis of a two-sided significance level of $P < 0.05$. All analyses were carried out in R version 2.13.1 for Windows (The R Foundation for Statistical Computing, http://www.r-project.org).

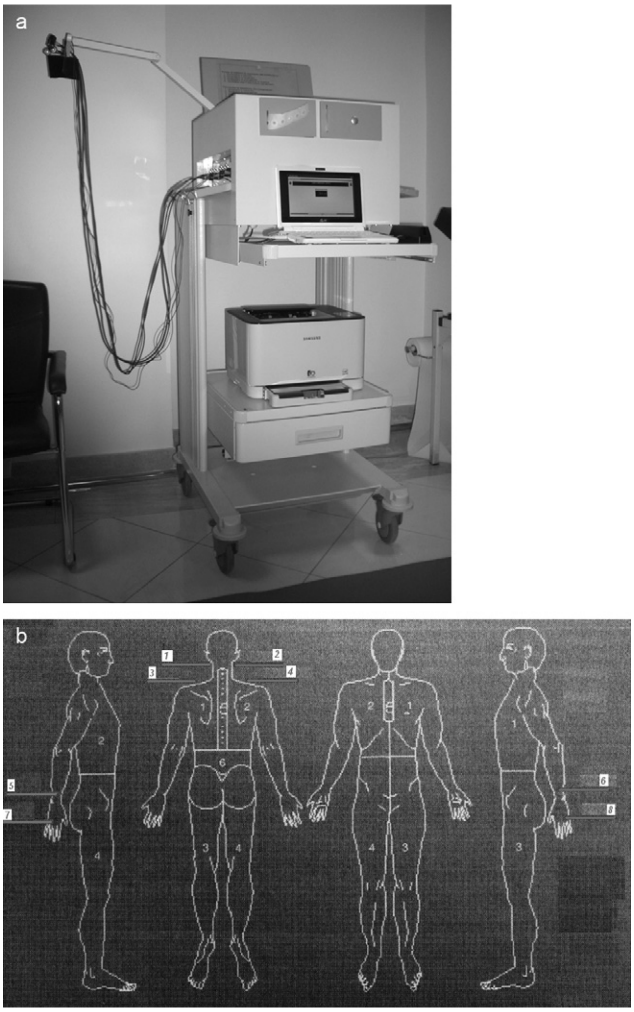

Figure 2 (a) THS 280 E device and (b) positioning of electrodes. The device was originally designed with eight electrodes. In the present study, just six electrodes were positioned.

Results

Overall, 48 participants were referred by general practitioners and assessed for eligibility. Of these, 41 were included in the study and allocated to the intervention or placebo group (Fig. 1).

Table 1 shows baseline characteristics of the intervention and placebo groups, and the mean percent changes from baseline of the gait parameters. In the intervention group, both self-selected gait speed (mean ± standard deviation [SD], from 45.3 ± 13.6 to 54.4 ± 13.4 cm/s, $P < 0.001$) and stride length (mean ± SD, from 29.9 ± 6.9 to 33.2 ± 6.9 cm, $P < 0.001$) increased significantly from baseline, whereas double support phase decreased (mean ± SD, from 0.51 ± 0.1 to 0.45 ± 0.2 s, $P = 0.006$). In the placebo group, all gait parameters except for support base (mean ± SD, from 11.3 ± 4.3 to 12.0 ± 4.8 cm, $P = 0.009$) remained unchanged. The mean percent increase of self-selected gait speed was significantly greater in the intervention group compared with the placebo, whereas no significant difference in the mean percent variation of the other parameters was found between the two groups (Table 1). During the intervention/placebo, no adverse event was observed.

One patient in the intervention group and one patient in the placebo group reported one fall in the 30 days after the treatment. The corresponding figures for any episode of dizziness were five and seven participants.

Discussion

Electromagnetic fields have been experimentally investigated for the treatment of different conditions, including fracture healing, knee osteoarthritis, cardiovascular disorders, pain, bone-implant osteo-integration and depression.[4–8,21] They have been also used in neurorehabilitation programs.[8,12–16] In most of the cases, their

Table 1 Baseline characteristics and mean percentage changes of gait parameters from baseline in the intervention and placebo groups

	Intervention (n = 25)	Placebo (n = 16)	P-value
Baseline characteristics			
Mean age, years (range)	84 (74–96)	87 (75–100)	0.345
No. men (%)	2 (8)	1 (6)	0.554
Gait speed baseline (mean cm/s ± SD)	45.3 ± 13.6	39.2 ± 9.6	0.123
Stride length baseline (mean cm ± SD)	30.0 ± 6.9	30.4 ± 7.5	0.657
Support base baseline (mean cm ± SD)	8.6 ± 4.8	11.9 ± 4.2	0.098
Double support phase baseline (mean s ± SD)	0.51 ± 0.13	0.59 ± 0.20	0.763
Mean percent change (±standard deviation) of gait characteristics			
Gait speed	20.1 ± 15.6	10.5 ± 13.1	0.010
Stride length	10.8 ± 9.9	6.4 ± 11.8	0.244
Support base	12.2 ± 9.7	6.0 ± 9.8	0.167
Double support phase	–11.3 ± 15.6	–2.1 ± 17.9	0.732

beneficial effects have been shown in animal models or small studies.

Despite these favorable therapeutic effects of PEF, there is a general agreement on the fact that the biophysical interactions between these signals and biological tissues are still not well understood.[21–23] Among other hypotheses, it has been suggested that external magnetic stimuli, when applied with adequate characteristics of frequency and intensity, interact with cells either through transmembrane receptors or ion channels, thereby initiating one or more signal transduction cascades or cell functions.[23]

During the past decades the popularity of PEF therapies has been growing. The most frequent indications were musculoskeletal disorders, including osteoarthritis and rheumatoid arthritis, as well as healing of bone fractures. Minor experiences in patients with Parkinson's disease have strongly encouraged their application in the rehabilitation of neurological diseases and abnormalities.[12–16]

In this scenario, the beneficial effect of PEF on gait and balance has never been tested.[4–7]

In the present RCT, older adults who received a single 10-min intervention with PEF experienced a significantly greater improvement in gait speed compared with those who received placebo, whereas no significant difference was found between the two groups in the mean percent changes of other gait parameters. The small sample size and the single exposure to PEF might account for the fact that only gait speed changes reached significance between the two groups, and represent the main limitations of the RCT.

Recent evidence has shown a strong association between self-selected gait speed (and other gait parameters), and survival, quality of life, functional status and clinical outcomes in older adults.[2] Our preliminary data suggest that PEF is a safe, inexpensive and easy to use intervention, and it might have some beneficial effects on gait speed.

Although our data are interesting, the small sample size and the lack of a sample size calculation are major limitations of the study.

In conclusion, the present findings support the design of RCT on larger samples and different populations (e.g. frequent fallers, patients with severe osteoporosis) to establish the benefits of PEF on gait characteristics and, most importantly, on short- and long-term outcomes in older adults. Furthermore, additional studies are warranted to better understand the biological mechanism underlying the beneficial effects of PEF.

Disclosure statement

Dr Giusti has received honoraria and/or consulting fees from Novartis, Procter & Gamble, InFoMed (CME provider, Milano, Italy), Local Health Agency 3 (ASL3, Genova, Liguria, Italy), Arcispedale Santa Maria Nuova (ASMN, Reggio Emilia, Italy), Roche/GSK, Abiogen, Chiesi, Eli Lilly, Merck & Co and Stroder. Dr Bianchi has received honoraria and/or consulting fees from Abbott, Amgen, Eli Lilly, GlaxoSmithKline, Merck Sharp & Dohme, Novartis, Pfizer, Roche, Schering Plough and Servier. Dr De Vincentiis and Dr Fratoni are affiliated to THS-Therapeutic Solutions Srl (Milano, Italy). All other Authors declare no conflict of interest.

Francesco Fratoni and Armando De Vincentiis declare that they have affiliation with THS-Therapeutic Solutions Srl (Milano, Italy), an organization with a potential financial interest in the subject matter discussed in the manuscript.

All other authors certify that no party (including THS-Therapeutic Solutions) having a direct financial interest in the results of the research supporting this article has or will confer a benefit on them or on any organization with which they are associated.

References

1 Verghese J, Holtzer R, Lipton RB *et al*. Quantitative gait markers and incident fall risk in older adults. *J Gerontol A Biol Sci Med Sci* 2009; **64**: 896–901.

2 Studenski S, Perera S, Patel K *et al*. Gait speed and survival in older adults. *JAMA* 2011; **305**: 50–58.

3 Bischoff-Ferrari HA. The role of falls in fracture prediction. *Curr Osteoporos Rep* 2011; **9**: 116–121.

4 Guo L, Kubat NJ, Isenberg RA. Pulsed radio frequency energy (PRFE) use in human medical applications. *Electromagn Biol Med* 2011; **30**: 21–45.

5 Griffin XL, Costa ML, Parsons N *et al*. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. *Cochrane Database Syst Rev* 2011; (4): CD008471.

6 Rohde C, Chiang A, Adipoju O *et al*. Effects of pulsed electromagnetic fields on interleukin-1 beta and postoperative pain: a double-blind, placebo-controlled, pilot study in breast reduction patients. *Plast Reconstr Surg* 2010; **125**: 1620–1629.

7 Selvam R, Ganesan K, Narayana Raju KV *et al*. Low frequency and low intensity pulsed electromagnetic field exerts its antiinflammatory effect through restoration of plasma membrane calcium ATPase activity. *Life Sci* 2007; **80**: 2403–2410.

8 Hashmi JT, Huang YY, Osmani BZ, Sharma SK, Naeser MA, Hamblin MR. Role of low-level laser therapy in neurorehabilitation. *PM R* 2010; **2**: S292–S305.

9 Blackman CF, Benane SG, Rabinowitz JR, House DE, Joines WT. A role for the magnetic field in the radiation-induced efflux of calcium ions from brain tissue in vitro. *Bioelectromagnetics* 1985; **6**: 327–337.

10 Goodman EM, Greenebaum B, Marron MT. Effects of electromagnetic fields on molecules and cells. *Int Rev Cytol* 1995; **158**: 279–338.

11 Giuliani A, Lorenzini L, Gallamini M, Massella A, Giardino L, Calzà L. Low infra red laser light irradiation on cultured neural cells: effects on mitochondria and cell viability after oxidative stress. *BMC Complement Altern Med* 2009; **15**: 8–18.

12 Sandyk R. Brief communication: electromagnetic fields improve visuospatial performance and reverse agraphia in a parkinsonian patient. *Int J Neurosci* 1996; **87**: 209–217.

13 Sandyk R. Freezing of gait in Parkinson's disease is improved by treatment with weak electromagnetic fields. *Int J Neurosci* 1996; **85**: 111–124.

14 Sandyk R. Reversal of visuospatial deficit on the Clock Drawing Test in Parkinson's disease by treatment with weak electromagnetic fields. *Int J Neurosci* 1995; **82**: 255–268.

15 Sandyk R. Treatment with electromagnetic fields improves dual-task performance (talking while walking) in multiple sclerosis. *Int J Neurosci* 1997; **92**: 95–102.

16 Ikeguchi M, Touge T, Nishiyama Y, Takeuchi H, Kuriyama S, Ohkawa M. Effects of successive repetitive transcranial magnetic stimulation on motor performances and brain perfusion in idiopathic Parkinson's disease. *J Neurol Sci* 2003; **209**: 41–46.

17 Shore WS, deLateur BJ, Kuhlemeier KV *et al*. A comparison of gait assessment methods: Tinetti and GAITRite electronic walkway. *J Am Geriatr Soc* 2005; **53**: 2044–2045.

18 van Uden CJ, Besser MP. Test-retest reliability of temporal and spatial gait characteristics measured with an instrumented walkway system (GAITRite). *BMC Musculoskelet Disord* 2004; **5**: 13–17.

19 Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975; **12**: 189–198.

20 Reilly BM. Dizziness. In: Walker HK, Hall WD, Hurst JW, eds. *Clinical Methods: The History, Physical, and Laboratory Examinations*, 3rd edn. Boston, MA: Butterworths, 1990; 949–953.

21 Hug K, Röösli M. Therapeutic effects of whole-body devices applying pulsed electromagnetic fields (PEMF): a systematic literature review. *Bioelectromagnetics* 2012; **33**: 95–105.

22 Markov MS. Expanding use of pulsed electromagnetic field therapies. *Electromagn Biol Med* 2007; **26**: 257–274.

23 Bachl N, Ruoff G, Wessner B, Tschan H. Electromagnetic interventions in musculoskeletal disorders. *Clin Sports Med* 2008; **27**: 87–105.

Research

EFFECT OF REPEATED APPLICATION OF LOW-INTENSITY PULSED ELECTROMAGNETIC FIELDS (PEMF) ON GAIT SPEED IN OLDER ADULTS WITH A HISTORY OF FALLS

To the Editor: Falls in older adults are a major healthcare issue worldwide, being associated with significant mortality, disability, costs and reduction of quality of life.[1,2] In the last 2 decades, several tools have been developed to improve clinician's ability to predict falls and to identify individuals at high risk of falling.[3,4] Gait speed has been demonstrated to be a particularly useful tool.[3,4]

A spectrum of rehabilitative and physical interventions have been shown to improve gait speed and gait parameters in older adults, potentially reducing fall risk.[5] Low-intensity pulsed electromagnetic fields (PEMFs) have been used successfully for fracture healing and bone-implant osteointegration and are being investigated in the management of inflammation and other conditions.[6,7] In an exploratory randomized placebo-controlled trial, a single 10-minute PEMF exposition was found to improve gait parameters in older adults.[7]

To further clarify the beneficial effects of PEMF over the long term, the effect of repeated PEMF exposure on self-selected gait speed was retrospectively assessed in a population of older adults at risk of falls consecutively treated in an outpatient clinic.

METHODS

From the population of subjects treated from February 2012 to January 2013, 266 community-living older adults (91% female, mean age 77.1 ± 5.6) without cognitive impairment (age-adjusted Mini-Mental State Examination score >27)[8] who had fallen at least once in the previous year and were not using drugs for vertigo were selected.

Subjects were assessed at baseline, just before the intervention, and immediately after. Gait characteristics were evaluated using a portable walkway system, which automates the acquisition, analysis, and reporting of objective parameters of gait as the subject walks the walkway with embedded sensors.[3] Self-selected gait speed (cm/s) was considered for the present analysis.

After the baseline assessment, low-intensity pulsed electromagnetic fields, transmitted using a low-power laser (wave length 500–700 nm), low-energy infrared pulsed light (wave length 700–1,050 nm), and transcutaneous electrical nerve stimulation (maximum amplitude 200 V) were administered according to specific characteristics of wave length and shape (TEPS–Triple Energy Postural Stabilization), through six skin electrodes connected to the subject. A detailed description of the procedure has been reported elsewhere.[7] The treatment lasted approximately 10 minutes and was repeated every 2 months for 1 year.

Gait analysis was performed before and after every intervention, and at each visit, subjects were interviewed about falls, clinical events, and new drugs.

Data on self-selected gait speed were described as means ± standard deviations and were compared before and after the treatment for each exposure to PEMF. Categorical data were analyzed using the Fischer exact test, and continuous variables were compared using the dependent-samples *t*-test (paired *t*-test) or the nonparametric asymptotic Wilcoxon signed rank test. Statistical inferences were made on the basis of a two-sided significance level of $P < .05$. All analyses were performed in R version 3.0.1 for Windows (R Foundation for Statistical Computing, www.r-project.org).

RESULTS

Subjects underwent six treatments over 1 year. Gait speed increased significantly after each treatment with respect to baseline as follows: first treatment, from 73.9 ± 31.5 cm/s to 81.3 ± 31.1 cm/s ($P < .001$); second treatment, from 80.2 ± 32.9 cm/s to 88.4 ± 29.8 cm/s ($P < .001$); third treatment, from 77.8 ± 28.3 cm/s to 86.1 ± 30.5 cm/s ($P < .001$); fourth treatment, from 84.4 ± 24.7 cm/s to 90.6 ± 26.4 cm/s ($P < .001$); fifth treatment, from 91.5 ± 23.8 cm/s to 98.4 ± 25.5 cm/s ($P < .001$); sixth treatment, from 94.1 ± 25.5 cm/s to 102.7 ± 25.9 cm/s ($P < .001$). After 1 year, subjects with a baseline gait speed less than 80 cm/s had a mean percentage increase (60.1%) significantly greater than that of those with a baseline value greater than 80 cm/s (8.1%) ($P < .001$).

No subjects reported any falls during the year, and no adverse events were reported.

CONCLUSIONS

These results suggest that continuous exposure to PEMF improves self-selected gait speed in older adults at risk of falling. Although encouraging, these data need to be confirmed in large-scale randomized placebo-controlled trials lasting at least 1 year.

Andrea Giusti, MD
Department of Gerontology and Musculoskeletal Sciences, Bone Clinic, Galliera Hospital, Genoa, Italy

Armando De Vincentiis, MD
Francesco Fratoni, BioSci
THS-Therapeutic Solutions Srl, Milan, Italy

JAGS 62:1185–1211, 2014

0002-8614/14/$15.00

Massimo Giovale, MD
Gerolamo Bianchi, MD
Department of Rheumatology, "La Colletta" Hospital—ASL3, Arenzano-Genoa, Italy

ACKNOWLEDGMENTS

Conflict of Interest: Dr. Giusti has received honoraria or consulting fees from Novartis, Procter & Gamble, In&Fo&Med (ECM provider, Milan, Italy), Local Health Agency 3 (Genoa, Liguria, Italy), Arcispedale Santa Maria Nuova (Reggio Emilia, Italy), Roche/GSK, Abiogen, Chiesi, Eli Lilly, Merck & Co., and Stroder. Dr. Bianchi has received honoraria or consulting fees from Abbott, Amgen, Eli Lilly, GlaxoSmithKline, Merck Sharp & Dohme, Novartis, Pfizer, Roche, Schering Plough, and Servier.

Author Contributions: Giusti, De Vincentiis: study design, interpretation of data, preparation and critical review of manuscript. Giovale: acquisition of subjects and data, interpretation of results, critical review of manuscript. Fratoni: analysis and interpretation of data, critical review of manuscript. Bianchi: study concept and design, interpretation of data, preparation and critical review of manuscript.

Sponsor's Role: None.

REFERENCES

1. Verghese J, Holtzer R, Lipton RB et al. Quantitative gait markers and incident fall risk in older adults. J Gerontol A Biol Sci Med Sci 2009;64A:896–901.
2. Studenski S, Perera S, Patel K et al. Gait speed and survival in older adults. JAMA 2011;305:50–58.
3. Shore WS, deLateur BJ, Kuhlemeier KV et al. A comparison of gait assessment methods: Tinetti and GAITRite electronic walkway. J Am Geriatr Soc 2005;53:2044–2045.
4. van Uden CJ, Besser MP. Test-retest reliability of temporal and spatial gait characteristics measured with an instrumented walkway system (GAITRite). BMC Musculoskelet Disord 2004;5:13.
5. El-Khoury F, Cassou B, Charles MA et al. The effect of fall prevention exercise programmes on fall induced injuries in community dwelling older adults: Systematic review and meta-analysis of randomised controlled trials. BMJ 2013;347:6234.
6. Guo L, Kubat NJ, Isenberg RA. Pulsed radio frequency energy (PRFE) use in human medical applications. Electromagn Biol Med 2011;30:21–45.
7. Giusti A, Giovale M, Ponte M et al. Short-term effect of low-intensity, pulsed, electromagnetic fields on gait characteristics in older adults with low bone mineral density: A pilot randomized-controlled trial. Geriatr Gerontol Int 2013;13:393–397.
8. Folstein MF, Folstein SE, McHugh PR. 'Mini-mental state'. A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res 1975;12:189–198.

ASSOCIATION BETWEEN HEARING IMPAIRMENT AND FRAILTY IN OLDER ADULTS

To the Editor: Frailty is characterized by low physiological reserve and vulnerability to stressors and has been defined in epidemiological studies as being present when three or more of the following criteria are met: unintentional weight loss, slow walking speed, weakness, exhaustion, and low physical activity.[1] Frailty is independently associated with falls, disability, hospitalization, cognitive impairment, and death.[1,2] Whether hearing impairment, which is independently associated with physical and cognitive decline, is also associated with frailty is unknown. An exploratory cross-sectional study was conducted to investigate the association between self-reported hearing impairment and frailty.

METHODS

Data were analyzed from 2,109 individuals aged 70 and older in the 1999 to 2002 cycles of the National Health and Nutrition Examination Survey (NHANES), a nationally representative cross-sectional study that is representative of the noninstitutionalized, civilian U.S. population.

Hearing impairment was measured according to self-report, and individuals were classified as having good to a little trouble hearing versus a lot of trouble hearing. Frailty was defined according to a previous study that investigated frailty in NHANES using the following criteria: 5% or greater unintentional weight loss in the last year or body mass index less than 18.5 kg/m^2, 20-foot gait speed in the lowest sex-adjusted quintile, self-reported weakness (some or much difficulty lifting or carrying an object as heavy as 10 pounds or unable to do), self-reported exhaustion (some or much difficulty walking from one room to another or unable to do), and self-reported low physical activity (participant report of being less active than individuals of the same age).[3] Participants with three or more criteria were classified as frail, those with one or two criteria were classified as prefrail, and those with no criteria were classified as not frail. Individuals were classified in analyses as being not frail versus prefrail or frail. Trained technicians evaluated gait speed while participants completed a 20-foot usual-pace walk.

Differences in demographic and general health characteristics according to hearing status were analyzed using chi-square tests. The association between self-reported hearing impairment and frailty was examined using stepwise logistic regression models adjusted for demographic factors, cardiovascular risk factors, health status, and hearing aid use. Effect modification by sex was explored in stratified analyses Table 1.

Sample weights we used to account for the complex sampling design according to National Center for Health Statistics guidelines. Analyses were performed using Stata (StataCorp, College Station, TX), and statistical significance was defined as two-sided $P < .05$.

RESULTS

Demographic characteristics differed according to hearing status, with individuals with greater hearing impairment more likely to be older, male, Caucasian, and frail. The association between self-reported hearing impairment and frailty was analyzed using stepwise logistic regression. Self-reported hearing impairment was associated with frailty in a fully adjusted model (odds ratio (OR) = 1.68, 95% confidence interval (CI) = 1.00–2.82). When stratified according to sex, hearing was significantly associated with frailty in women (OR = 3.79, 95% CI = 1.69–8.51) but not men (OR = 0.85, 95% CI = 0.44–1.66). Hearing aid use was not significantly associated with frailty in men (OR = 0.82,

G GERONTOL 2015;63(03):192-195

ARTICOLO ORIGINALE
ORIGINAL ARTICLE

(Geriatria clinica)

Efficacia dei campi magnetici a bassa intensità sulla velocità del cammino negli anziani con storia di cadute

Efficacy of low intensity pulsed electromagnetic fields (pemf/teps) on gait velocity in elderly fallers

M. GIOVALE[1], P. SESSAREGO[2], P. MONTEFORTE[1], A. DE VINCENTIIS[3], A. UNGAR[4], B. RESTELLI[5], A. GIUSTI[6], G. BIANCHI[1]

[1] UO Reumatologia, ASL3 Genovese, Genova; [2] Istituto Riabilitazione, IRCCS Fondazione Salvatore Maugeri, Genova Nervi; [3] THS-Therapeutic Solutions srl, Milano; [4] Medicina e Cardiologia Geriatrica, Dipartimento Medico-Geriatrico, Azienda Ospedaliera Universitaria Careggi e Università di Firenze; [5] CDI-Centro Diagnostico Italiano, Medicina Interna; [6] Dipartimento d Gerontologia, Ospedale Galliera, Genova

Falls in older adults are a major healthcare issue worldwide, being associated with significant mortality, disability, costs and reduction of quality of life, mainly due to fractures.
Gait speed has been demonstrated to be particularly useful to predict falls and to identify individuals at high risk of falling. We previously demonstrated that a single 10-minute PEMF exposition was found to improve gait parameters in older adults.
In this study, PEMF (TEPS) was administered to 266 older adults (91% female, mean age 77) every two months for 1 year. Gait speed increased significantly after each treatment with respect to baseline (P < .00.1). Subjects with a baseline gait speed less than 80 cm/s had a mean percentage increase (60.1%) significantly greater than that of those with a baseline value greater than 80 cm/s (8.1%) (P < .001).
These results suggest that continuous exposure to PEMF improves self-selected gait speed in older adults at risk of falling.

***Key words*: Falls, Gait velocity, PEMF, TEPS**

INTRODUZIONE

Le cadute degli anziani sono responsabili di una significativa mortalità, disabilità, costi sociali e di una ridotta qualità di vita.
Le cadute, soprattutto quelle favorite dalla perdita della competenza posturale, caratteristica fisiologica dell'invecchiamento del soggetto [1 2], rappresentano il problema sanitario più comune e serio tra gli Anziani [3]. Le cadute complicano spesso la sensazione di instabilità posturale (dizziness): questa sintomatologia comprende qualsiasi condizione di alterata percezione della stabilità del corpo nello spazio. Negli USA la 'dizziness' è stata identificata come la prima causa che induce un ultra settantacinquenne a recarsi dal proprio medico [4].
Tra tutte le altre sindromi geriatriche (le reazioni avverse da farmaci, il decadimento cognitivo, la sindrome da immobilizzazione e l'incontinenza urinaria), le cadute rappresentano certamente una evenienza clinica comune e ricorrente, dove maggiormente si percepisce l'urgenza e la necessità di trovare soluzioni assistenziali innovative.
In questi ultimi vent'anni numerosi lavori hanno evidenziato che il 75% delle fratture si verifica

■ Corrispondenza: Massimo Giovale, via Privata Bastia 3, 16036 Recco (GE) – E-mail: massimogiovale@gmail.com

in pazienti oltre i 65 anni, che il 90% delle fratture è causato da una caduta e che il 95% delle fratture di femore è dovuto a un evento caduta [5]. Le cadute sono responsabili dei 2/3 delle morti accidentali e sono la quinta causa di morte negli over 60. 1/3 degli anziani che vivono in casa cade almeno una volta l'anno (50% degli over 80), un paziente su 40 richiede l'ospedalizzazione. Rappresentano inoltre la prima causa di ricovero ospedaliero degli anziani, che purtroppo durante la degenza incorrono nelle tipiche complicanze dell'ospedalizzazione [5], ed è tra le prime cause di ricovero in RSA (e tra gli ospiti residenti in struttura tra i deambulanti, le cadute rappresentano una evenienza molto frequente).
È noto e calcolato anche l'incremento progressivo avvenuto in questi anni in ambito europeo dell'occupazione dei posti letto ospedalieri da parte di soggetti fratturati a seguito di eventi caduta: si passa dal 25% nel 2000 al 35% previsto nel 2020, fino al 50% nel 2050 (*Summary Report on Osteoporosis in the European Action for Prevention*) [6].
L'evento frattura, indipendentemente dalla sede ossea coinvolta, compromette fortemente l'autonomia del soggetto interessato causandogli dolore, modificazioni dell'aspetto fisico, disabilità, riduzione dell'indipendenza, ulteriore perdita dell'autonomia funzionale residua con aumento della morbilità e mortalità.
La valutazione del rischio di caduta è per questo fondamentale nell'inquadramento del paziente anziano e può essere in grado di identificare i soggetti a maggior rischio per attuare interventi di prevenzione. Sarà quindi necessario saper valutare correttamente nella pratica clinica quotidiana il rischio di caduta [7]. L'analisi del cammino consente anch'essa di raccogliere diversi parametri e misure; tra tutti i markers misurabili, la velocità del cammino è ormai universalmente considerata quella più sensibile e correlata al rischio di caduta [8] e alla sopravvivenza dell'individuo [9] nei pazienti autonomi, ma è risultata analisi efficace anche in anziani fragili ricoverati in Residenza Sanitaria Assistenziale [10].
Dai dati disponibili in letteratura la velocità fisiologica di un individuo adulto sano è di 100 cm/s indipendentemente dall'età. Al di sotto di 70 cm/s aumenta il rischio di caduta di una volta e mezza e per ogni ulteriore riduzione di 10 cm/s il rischio di caduta aumenta di 7 volte. Dunque, misurare la velocità del cammino di un paziente permette di raccogliere rapidamente una misura altamente predittiva del suo rischio di caduta [11 12].
I campi magnetici a bassa intensità (PEMF) sono stati utilizzati con successo nella guarigione delle fratture, nella osteo-integrazione degli impianti protesici e ne è stato proposto l'utilizzo nelle patologie infiammatorie [13]. In un precedente studio, noi abbiamo dimostrato come una singola esposizione ai PEMF abbia migliorato la velocità del cammino in soggetti anziani [14]. In questo studio abbiamo valutato l'effetto di stimolazioni ripetute con PEMF sulla velocità del cammino in una popolazione di soggetti ambulatoriali valutati retrospettivamente.

MATERIALI E METODI

Sono stati valutati 266 soggetti anziani (91% femmine - età media 77 anni), senza deficit cognitivi e con storia di cadute nell'anno precedente, dei quali sono state valutate le caratteristiche del cammino con un sistema portatile (Free4Act, Loran Engineering, Bologna), subito prima e subito dopo il trattamento con PEMF; noi riportiamo qui i dati relativi alla velocità del cammino.
Il trattamento con PEMF, utilizzando contemporaneamente un laser a bassa energia (lunghezza d'onda 500-700 nm), luce infrarossa pulsata a bassa energia (lunghezza d'onda 700-1,050 nm), e TENS (max 200 V), è stato somministrato con specifiche caratteristiche di lunghezza e forma dell'onda (TEPS – *Triple Energy Postural Stabilization*®), tramite sei elettrodi cutanei connessi al soggetto, per una durata di 10 minuti, e con cadenza bimestrale per un anno.
La velocità del cammino è stata valutata, prima e dopo il trattamento, a ciascuna visita bimestrale, durante la quale sono stati raccolti i dati relativi ad eventuali cadute, eventi clinici e trattamenti farmacologici.

RISULTATI

La velocità del cammino è aumentata in maniera significativa dopo ciascun trattamento rispetto al basale, come segue: primo trattamento da 73,9 ± 31,5 cm/s a 81,3 ± 31,1 cm/s ($P < .001$); secondo trattamento, da 80,2 ± 32,9 cm/s a 88,4 ± 29,8 cm/s ($P < .001$); terzo trattamento, da 77,8 ± 28,3 cm/s a 86,1 ± 30,5 cm/s ($P < .001$); quarto trattamento, da 84,4 ± 24,7 cm/s a 90,6 ± 26,4 cm/s ($P < .001$); quinto trattamento, da 91,5 ± 23,8 cm/s a 98,4 ± 25,5 cm/s

Tab. I. Velocità del cammino (cm/s) prima e dopo il trattamento, ai vari tempi di trattamento.

	Velocità prima-	Velocità dopo	*P*-value
Primo trattamento	73.9 ± 31.5	81.3 ± 31.1	< .001
Secondo trattamento	80.2 ± 32.9	88.4 ± 29.8	< .001
Terzo trattamento	77.8 ± 28.3	86.1 ± 30.5	< .001
Quarto trattamento	84.4 ± 24.7	90.6 ± 26.4	< .001
Quinto trattamento	91.5 ± 23.8	98.4 ± 25.5	< .001
Sesto trattamento	94.1 ± 25.5	102.7 ± 25.9	< .001

(P < .001); sesto trattamento, da 94,1 ± 25,5 cm/s a 102,7 ± 25,9 cm/s (P < .001) (Tab. I).
I soggetti con una velocità del cammino al basale minore di 80 cm/s hanno avuto un miglioramento medio percentuale (60,1%) significativamente maggiore dei soggetti con velocità del cammino al basale maggiore di 80 cm/s (8,1%) (P < .001). Nei soggetti studiati non si sono verificate cadute e/o eventi avversi, durante l'intero anno di studio.

DISCUSSIONE

Questi risultati, che andranno confermati con ulteriori studi, suggeriscono come il trattamento con PEMF sia in grado di aumentare la velocità del cammino in soggetti anziani con una storia di cadute.

Le cadute degli anziani sono responsabili di una significativa mortalità, disabilità, costi sociali e di una ridotta qualità di vita, eventi correlati alle fratture da esse causate.
La velocità del cammino è il marker più sensibile del rischio di caduta e ne consente la predizione. Noi abbiamo in passato dimostrato come una singola esposizione ai PEMF abbia migliorato la velocità del cammino in soggetti anziani. In questo studio, un trattamento con PEMF (*Pulsed ElectroMagnetic Fields*), TEPS (*Triple Energy Postural Stabilization*), somministrato ogni 2 mesi per un anno, ha significativamente migliorato, dopo tutti i tempi di trattamento, la velocità del cammino di 266 soggetti anziani (91% femmine – età media 77 anni) (P < .001). I soggetti con una velocità del cammino al basale minore di 80 cm/s hanno avuto un miglioramento medio percentuale (60,1%) significativamente maggiore dei soggetti con velocità del cammino al basale maggiore di 80 cm/s (8,1%) (P < .001). Questo studio suggerisce come il trattamento con PEMF sia in grado di aumentare la velocità del cammino in soggetti anziani con una storia di cadute.

***Parole chiave*: Cadute, Velocità cammino, PEMF, TEPS**

Bibliografia

1 Iosa M Fusco A, Morone G, et al. *Development and decline of upright gait stability*. Front Aging Neurosci 2014;6:14.

2 Shumway-Cook A, Woollacott MH. *Aging and postural control*. In: Shumway-Cook A, Woollacott MH, eds. *Motor Control, Translating Research into Clinical Practice*. Lippincott Williams & Wilkins 2007, pp. 212-295.

3 Fuzhong Li, Fisher KJ, Harmer P, et al. *Fear of Falling in Elderly Persons: Association With Falls,Functional Ability and Quality of Life*. J Gerontol B Psychol Sci Soc Sci 2003;58:283-90.

4 Senin U, Cherubini A, Mecocci P. *Le sindromi Geriatriche Sensazione di instabilità*. In:. Senin U, Cherubini A, Mecocci P, eds. *Paziente Anziano Paziente Geriatrico Medicina della Complessità*. Edises 2011, pp. 23-330.

5 Bischoff-Ferrari HA. *The role of falls in fracture prediction*. Current Osteoporos Rep 2011;9:116-21.

6 *Report on Osteoporosis in the European Community, Action for Prevention*. 1988.

7 Bartoccioni F, Bartoccioni S, Margiacchi Z. *Malattie delle Ossa. Miscellanea Osteoporosi*. In: Bartoccioni F, Bartoccioni S Margiacchi Z, eds. *Terapia 2015* . Libreria Universo 2015, pp. 751-759.

8 Studenski S, Perera S, Patel K, et al. *Gait speed and survival in older adults*. JAMA 2011;305:50-8.

9 Gerald J, Seung-uk Ko, l Kauffman D, et al. *Gait characteristics associated to walking speed decline in older adults. Results frorn the Baltimore longiyìtudinal study of Aging*. Arch Gerontol Geriatr 2015;60:239-43.

10 Kuys SS, Peel NM, Klein K, et al. *Gait speed in ambulant older people in long term care: a systematic review and*

meta-analysis. J Am Med Dir Assoc 2014;15:194-200.

11 Verghese J, Holtzer R, Lipton RB, et al. *Quantitative gait markers and incident fall risk in older adults*. J Gerontol A Biol Sci Med Sci 2009;64:896-901.

12 Shore WS, DeLateur BJ, Kuhlemeier KV, et al. *A comparison of gait assessment methods: Tinetti and GAITRite electronic walkway*. J Am Geriatr Soc 2005;53:2044-5.

13 Guo L, Kubat NJ, Isenberg RA. *Pulsed radio frequency energy (PRFE) use in human medical applications*. Electromagn Biol Med 2011;30:21-45.

14 Giusti A, Giovale M, Ponte M, et al. *Short-term effect of low-intensity, pulsed, electromagnetic fields on gait characteristics in older adults with low bone mineral density: A pilot randomized-controlled trial*. Geriatr Gerontol Int 2012;13:393-7.