Bone Reports 15 (2021) 101099

Contents lists available at ScienceDirect

Bone Reports

journal homepage: www.elsevier.com/locate/bonr

Feasibility of simple exercise interventions for men with osteoporosis – A prospective randomized controlled pilot study

Franca Genest, Sarah Lindström, Sophia Scherer, Michael Schneider, Lothar Seefried *

Clinical Trial Unit, Orthopedic Department, University of Wuerzburg, Germany

A R T I C L E I N F O

Keywords:
Osteoporosis
Sarcopenia
Resistance training
Whole Body Vibration
Spinal Orthosis
Qi gong

A B S T R A C T

Background: Aging is associated with progressive loss of musculoskeletal performance. Exercise interventions can improve physical function in the elderly but there is a paucity of comparative assessments in order to understand what specific goals can be achieved particularly with less demanding exercise interventions readily accessible for untrained men.

Methods: Prospective randomized, controlled, single center exploratory trial to compare four distinct exercise interventions, i.e. Resistance Training (RT), Whole Body Vibration Exercise (WBV), Qi Gong (QG) and wearing a Spinal orthosis (SO) for 6 months in men at risk for osteoporosis aged 65–90 years. Primary endpoint was change in isometric one repetition maximum force trunk strength for extension (TSE) and flexion (TSF) compared to baseline, secondary endpoints covered key parameters of geriatric functional assessment, including Handgrip Strength (HS), Chair-Rise-Test (CRT), Usual Gait Speed (UGS) and Timed-Up-and-Go (TUG).

Results: Altogether 47 men (mean age 77 ±6.1 years) were randomized to RT, ($n = 11$) WBV ($n = 13$), QG ($n = 10$) and SO($n = 13$). RT, defined as reference exercise intervention, lead to significant improvements for TSE ($p = 0.009$) and TSF ($p = 0.013$) and was significantly superior in the between-group analysis for TSE ($p = 0.038$). Vibration exercise caused sign. Improvements in TSE ($p = 0.014$) and CRT ($p = 0.005$), the Spinal orthosis improved CRT ($p = 0.003$) and Gait Speed ($p = 0.027$), while the QG intervention did not attain any sig. Developments.

Subgroup analyses revealed most pronounced musculoskeletal progress in vulnerable patients (age ≥ 80 years, pre-sarcopenia, multimorbidity ≥3chronic diseases). Irrespective of the type of exercise, participants ≥80 years experienced significant gains in TSE ($p = 0.029$) and CRT ($p = 0.017$). Presarcopenic subjects (Skeletal muscle Index (SMI) ≤10.75 kg/m^2) improved in TSE ($p = 0.003$), CRT ($p = 0.001$) and UGS ($p = 0.016$). Multimorbid participants achieved sig. Gains in TSE ($p < 0.001$), TSF ($p = 0.002$), UGS ($p = 0.036$) and HS ($p = 0.046$).

Conclusions: In this exploratory trial we found that simple exercise interventions are feasible in elderly men eliciting specific benefits, i.e. improvements are attained in those tasks addressed with the respective exercise modality. While targeted resistance training is superior in increasing TSE, alternative simple exercise interventions also appear to elicit beneficial effects, even in vulnerable patients, i.e. those with low muscle mass, above 80 years of age or multimorbidity.

1. Introduction

Osteoporosis and sarcopenia both are critical determinants for impaired health outcomes and functional decline in aging (Cruz-Jentoft et al., 2010a; Cruz-Jentoft et al., 2010b; Hirschfeld et al., 2017; Fischer et al., 2017; Landi et al., 2012; Uemura et al., 2018). Specifically, reduced bone quality and quantity along with decreased muscle mass and function elevate the risk for falls and fractures, entailing restrictions in mobility and subsequent morbidity and mortality (Van Der Klift et al., 2002). In addition to osteoporosis, sarcopenia is a critical factor of

Abbreviations: TSE, trunk strength for extension; TSF, trunk strength for flexion; HS, handgrip strength; CRT, Chair-Rise-Test; UGS, usual gait speed; SB, static balance; TUG, timed up and go test; SPPB, Short Physical Performance Battery; 6MW, 6 min walk test; RT, resistance training; QG, Qi Gong training; SO, spinal orthosis training; WBV, Whole Body Vibration training; SMI, skeletal muscle index; ROM, range of motion; BIA, bioimpedance analysis.

* Corresponding author at: Clinical Trial Unit, Orthopedic Department, University of Wuerzburg, Brettreichstrasse 11, 97074 Wuerzburg, Germany.

E-mail addresses: f-genest.klh@uni-wuerzburg.de (F. Genest), Sophia.scherer@stud-mail.uni-wuerzburg.de (S. Scherer), l-seefried.klh@uni-wuerzburg.de (L. Seefried).

https://doi.org/10.1016/j.bonr.2021.101099
Received 16 November 2020; Received in revised form 3 June 2021; Accepted 11 June 2021
Available online 24 June 2021

progressive immobility and functional decline with aging (Landi et al., 2012; Scott et al., 2017). Sarcopenia is commonly defined by reduced muscle mass combined with reduced muscle strength and/or impaired physical performance (Cruz-Jentoft et al., 2019; Landi et al., 2018). Growing evidence supports the perception of sarcopenia and functional decline being critical factors of elevated fracture risk, commonly reflected in approaches to define a condition of osteosarcopenia (Chalhoub et al., 2015; Zanker and Duque, 2020). Current literature confirms that individuals with both conditions are at higher risk for decreased mobility, general health issues and increased mortality (Scott et al., 2017; Wagner et al., 2018; Tarantino et al., 2016). In this context, functional decline and impaired mobility or dysmobility appear to be of particular clinical significance in aging men (Buehring et al., 2018; Ebeling et al., 2019).

Concurrently, growing scientific data propose exercise interventions as effective measures to mitigate or even partially reverse this age associated decay and prevent adverse outcomes (Nawrat-Szoltysik et al., 2018; Wisdom et al., 2015; Cesari et al., 2015; Cadore et al., 2014; Chen et al., 2018; Moore et al., 2018; Seldeen et al., 2018). Importantly, different exercise modalities in that regard exhibit a very distinct profile regarding both feasibility in the elderly as well as efficacy in terms of achieving meaningful training results and overall improvements. However, a critical appraisal of available evidence also reveals that despite the high number of studies in the field, there is a paucity of comparative analyses of distinct intervention modalities in randomized controlled studies with prespecified outcome parameters (Moore et al., 2019; Sherrington et al., 2019). Currently, machine-supported or augmented, professionally supervised resistance training is a well-established, reliable and effective exercise intervention strategy to regain muscle mass and strength in the elderly (Moore et al., 2018; Pippa et al., 2007; Song et al., 2018; Vergara-Diaz et al., 2018) and can be considered gold standard. However, real world feasibility and sustainability of such an intervention is limited by costs, accessibility, adherence, and the motivation of untrained seniors to familiarize with this type of exercise modality. Hence, easy-accessible, technically simple training concepts requiring less personal engagement were attractive alternatives, particularly for previously non-athletic, mobility-restricted individuals. There is data suggesting that low impact training modalities like e.g. group-based Qi Gong may be safe, widely accepted and still effective (Pippa et al., 2007). Growing evidence also supports Whole Body Vibration as being both an effective as well as efficient and safe exercise modality in vulnerable patients at risk for muscular deficits (Seefried et al., 2017; Bogaerts et al., 2007; Bautmans et al., 2005). Furthermore, there is also literature reporting effectiveness of a specific trunk supporting, flexible back brace in terms of increasing muscular performance by regular use without the need for a specific workout routine. This Spinal orthosis is a back brace approved for supportive treatment of osteoporosis with kyphosis and/or back pain (long-term care). Considering well-known difficulties with encouraging (not only) older people to attend regular workout sessions, this appears a low-threshold alternative, specifically for individuals severely limited with regards to performing conventional physical training (Dionyssiotis et al., 2015; Valentin et al., 2014; Pfeifer et al., 2011; Kaijser Alin et al., 2019).

So far there are no comparative data to advise which of these alternative exercise modalities is preferable regarding both efficacy in terms of different functional outcome parameters on the one hand as well as safety and feasibility including acceptance on the other hand. In addition, there is a need to understand to what extend these alternative exercise interventions can keep up with the gold standard of a professionally supervised conventional resistance exercise intervention program regarding functional outcome.

2. Methods

2.1. Study design

This is an exploratory prospective randomized controlled single center pilot trial to compare efficacy, feasibility and safety of four different exercise modalities over 6 months in community-dwelling elderly men at risk for osteoporosis.

2.2. Study population

Main inclusion criteria included male subjects ≥65 years with one of the following indicators of relevant osteoporosis: Preexisting DXA-Scan with T-Score ≤−2.5 at the hip or spine, previously diagnosed osteoporosis or ongoing osteoporosis treatment or 10-year fracture risk probability ≥20% according to applicable national guidelines (Thomasius et al., 2018). Exclusion criteria mirrored contraindications to Whole Body Vibration according to the manufacturer's specifications and a full list can be found in the supplementary material.

Participants were identified from a previous study evaluating coincidence and potential interference of osteoporosis and sarcopenia in a large, community-derived cohort of elderly men (Genest et al., 2021). Out of 507 participants evaluated in that former study, 268 had risk factors warranting further assessment for osteoporosis according to applicable national guidelines and were therefore invited for a comprehensive musculoskeletal exam, including assessment of clinical risk factors for osteoporosis, DXA measurement and laboratory workup (Pfeil et al., 2018; Neuerburg et al., 2017). Out of 113 who accepted that offer, 57 were willing to participate in this six months exercise intervention study. Treatment group allocation was based on a predefined randomization list which was created using block randomization with a block size of 20, set up by an independent biostatistician. Ten men canceled participation before starting the intervention. A total of 47 participants completed the study per protocol (see Fig.1 for details).

2.3. Exercise intervention

Exercise interventions were supervised Resistance Training (RT) as a reference, Whole Body Vibration Exercise (WBV) as externally stimulated muscle activation, Qi Gong (QG) classes as a low impact training modality and wearing a Spinal orthosis (SO) as an effortless, almost passive modality.

2.3.1. Resistance training

Professionally supervised, individually adjusted conventional resistance training with special focus on trunk strength comprising 8 different exercises was conducted for 30 min twice weekly in a high-level gym facility for professional athletes (Predia, Wuerzburg, Germany).

2.3.2. Qi Gong training

Instructed group sessions 2x45min per week comprising various exercises of coordinated body-posture, low-impact movements, breathing and meditation rather than muscle power and strength training.

2.3.3. Whole Body Vibration training

Supervised WBV training sessions on a side alternating vibration platform (Galileo®, Novotec Medical GmbH, Pforzheim, Germany) with vibration frequencies up to 25.5 Hz. Exercises focusing on trunk strength and lower extremities were performed for 2 × 20 min per week.

2.3.4. Spinal orthosis

Participants were provided with an off-the-shelf orthosis (Spinomed active, Medi GmbH, Bayreuth, Germany) customized at the beginning of the study. Subjects were requested to wear the back brace for at least 3 h per every day throughout the study, preferentially while being active.

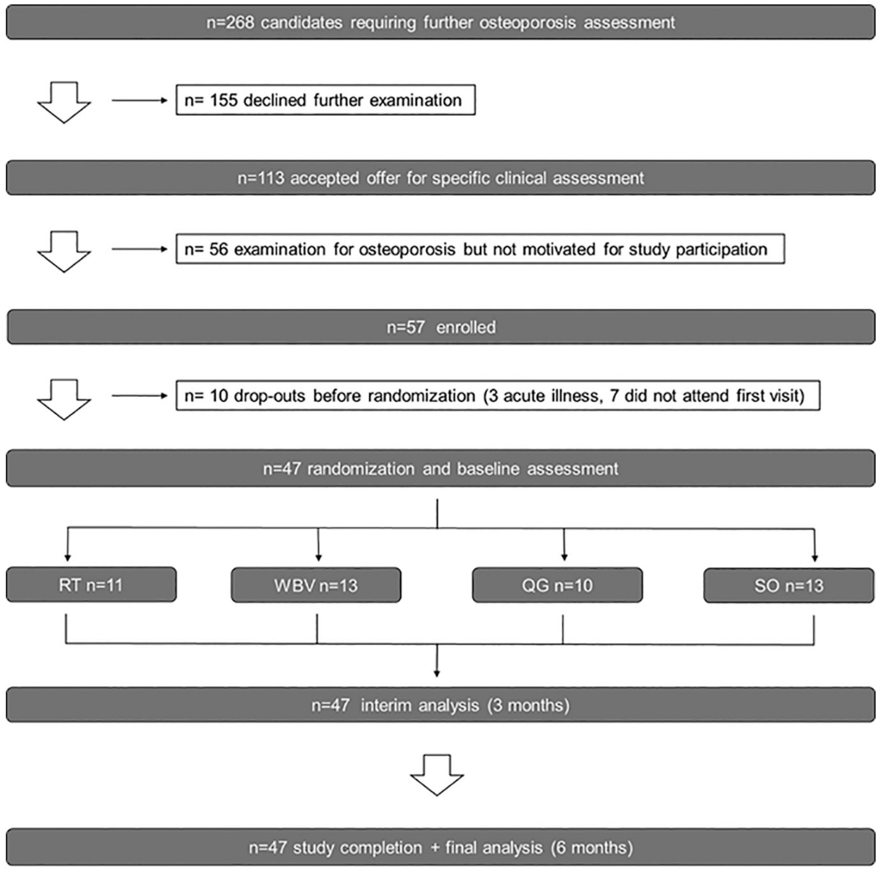

Fig. 1. Study population flow.

Wearing time of the orthosis and tolerability had to be documented on a daily basis.

A detailed description of all the interventions can be found in the supplementary material.

For RT, WBV and QG, training adherence was calculated as the percentage of sessions attended in relation to the sessions planned per protocol. For the spinal orthosis, adherence was defined as the percentage of days when participants wore the brace for at least 3 h as defined in the protocol.

2.4. Assessments and endpoints

Baseline assessment of physical performance was scheduled before starting exercise intervention, an interim evaluation was performed at 3 months and final assessment was scheduled after 6 months of training. Tests were accomplished by independent staff not involved in treatment group allocation and scientific evaluation.

Primary endpoint was one repetition maximum force isometric measurement of trunk strength for extension (TSE) and flexion (TSF) on a stationary machine (Typus FPZ Systems developed by Schnell Ltd. Peutenhausen, Germany). Secondary endpoints comprised key diagnostic parameters of geriatric functional assessment. Handgrip Strength (HS) was measured with a handheld dynamometer (DynEx1, Akern srl, Florence, Italy) in a seated position, the elbow flexed at 90°. Best performance value out of three per side was used for further analyses. The three components of the Short Physical Performance Battery (SPPB) including Chair-Rise-Test (CRT), Usual Gait Speed (UGS) and static Balance (SB) were assessed as described previously in literature (Guralnik et al., 1994; Beaudart et al., 2016). For distinct analysis of individual tests SB results were calculated summing up total standing time, i.e. max 10s side-by-side, 10s semi-tandem and 10s tandem stance, yielding 30s as max result for best performance. In addition, the Timed-Up and Go (TUG) (Mathias et al., 1986), the 6 min walk test (6 MWT) and the Skeletal Muscle Index (SMI, skeletal muscle mass by height squared, kg/m^2) derived from Bioelectrical Impedance Analysis (BIA, BIA 101 Anniversary, Akern srl, Florence, Italy) according to the formula established by Janssen et al. (Janssen et al., 2000) were assessed.

2.5. Statistical analysis

Descriptive statistical analysis comprised absolute frequencies and corresponding proportions, arithmetic means and median analyses along with standard deviation (SD) and interquartile range (IQR), respectively. Between-group differences were assessed using Kruskal-Wallis Test, since actual number of participants was considerably lower than expected thus limiting the validity of between group comparisons, additional longitudinal analyses were accomplished to evaluate within-group changes from baseline to the 6 month visits using Friedman's test with post-hoc Bonferroni correction. Effect sizes were calculated using Pearsons correlation coefficient $r = |z/\sqrt{n}|$ and Cohen's classification applied for estimating effect sizes ($r = 0.1$ small effect; $r = 0.3$ medium effect, $r = 0.5$ strong effect). P values of less than 0.05 were considered statistically significant. All statistical analyses were performed using SPSS ver. 25 statistical software package (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

In order to learn about feasibility and usefulness of simple exercise interventions in particularly vulnerable patients, three subgroups were defined based on low muscle mass, in this case SMI $< 10.75\ kg/m^2$, high age as ≥ 80 years and multimorbidity, meaning ≥ 3 chronic medical conditions (Schafer et al., 2009) and subgroup analyses were performed in these patients.

The study protocol was approved by the competent ethics committee at Wuerzburg University (N. 111/14) and registered with the German Register for Clinical Studies (DRKS00013262).

3. Results

Altogether 57 men were enrolled of whom10 did not attend the baseline and randomization visit, 3 due to acute illness, 7 without giving feedback.) Deducting these drop-outs before randomization., $n = 47$ men were eventually randomized and all of them completed the study. Mean age of all participants was 77.0 years (SD 6.1) at baseline. Of all n = 47 patients, $n = 11$ were randomized into the conventional RT group, $n = 13$ in the WBV group, $n = 10$ in the QG group and n = 13 in the SO group. For a detailed overview on anthropometrics at baseline see also Table 1.

All $n = 47$ patients completed 6 months of training.

3.1. Training adherence

Overall mean training adherence was on average ≥ 75% for all groups together, with the highest adherence for the SO-group (85.2%), then WBV group (83.2%), then RT group (71.3%) and the lowest for the QG group (65.1%). All $n = 47$ patients completed 6 months of training and attended the 3 months interim analyses as well as the final assessment after 6 months.

3.2. Physical performance

Across all groups, at 6 months vs baseline average trunk strength increased substantially by 16.8% from 247.0 nm to 288.5 nm for TSE (p = 0.003; $r = 0.12$) and by 10.7% from 136.0 nm to 150.5 nm for TSF (p < 0.001; $r = 0.16$). This increase was most pronounced and statistically significant for TSE with +39% from 240 nm to 333.5 nm ($p = 0.008$; $r = 0.47$) and with 31.9% from 135 nm to 178 nm for TSF ($p = 0.008$; $r = 0.47$) in the RT group. Trunk strength also increased in the SO group for TSE by 19.1% ($p = 0.223$) and for TSF by 27.5% ($p = 0.072$) and WBV group by 11.6% for TSE ($p = 0.103$) and 4.8% for TSF ($p = 0.115$), respectively, although these improvements were not statistically significant. In the QG group, trunk strength remained largely unaltered (also see Figs. 2 and 3 and Table 2).

HS improved significantly in the WBV group by 2.8% from 31.9 kg to 32.8 kg ($p = 0.023$; $r = 0.30$) while there was no relevant change in all other groups. Regarding SB testing, none of the training interventions elicited a significant improvement. While USG increased significantly only in the RT by 8.2% from 1.22 m/s to 1.32 m/s ($p = 0.015$; $r = 0.36$) group, improvements in the CRT were most pronounced and statistically significant in the SO group with 9.0% from 8.62 s to 7.84 s ($p = 0.003$; $r = 0.33$) and the WBV group with 8.9% from 8.81 s to 8.03 s ($p = 0.007$; $r = 0.34$). There were no significant changes in the overall SPPB-Score, the 6 MWT or the TUG test in any of the exercise groups scrutinized, see also Table 2.

In addition, there was no significant change in the lumbar bending total range of motion (ROM) in any exercise group, even though improvements in this parameter with 5.3% from 47.0° to 49.5° ($p = 0.053$) and the 6 MWT with 3.4% from 553 m to 572 m ($p = 0.061$;) were borderline significant in the QG group, see also Table 2.

Constitutional parameters including height, weight and along with that BMI and SMI determined by BIA did not change significantly during the course of the study in any of the groups.

3.3. Safety and feasibility

All 47 participants starting the exercise intervention adhered to the study protocol and concluded the study as intended. Moreover, throughout the conduct of the study, there were no adverse events associated with the interventions.

3.4. Between group comparisons

Comparative between-group analyses regarding changes attained during 6 months with the 4 different exercise interventions revealed a statistically significant difference ($p = 0.038$) with regards to the co-primary endpoint trunk strength extension (Table 3) and the post hoc analysis revealed a sig. Difference between RT and QG ($p = 0.027$; $r = 0.62$, see also Fig. 4). For all other tests regarding between group comparisons including to co-primary endpoint trunk strength flexion, there was no statistically significant difference.

3.5. Subgroup analysis

In order to evaluate training responses in participants at particularly high risk, subgroup analyses were performed considering the following three at-risk cohorts: All participants ≥80 years of age ($n = 19$; 40.4% of all participants), patients with low baseline SMI ≤ 10.75 kg/m^2 as assessed by BIA ($n = 30$; 63.8%) and men with three or more chronic medical conditions ($n = 27$; 57.4%) fulfilling the definition of multimorbidity (Schafer et al., 2009). Results for these subgroups were evaluated in an aggregated way irrespective of the assigned exercise group.

After 6 months of exercise intervention, the subgroup of patients ≥80 years exhibited sig. Improvements in trunk strength by 11.2% from 125 nm to 139 nm for TSF ($p = 0.017$; $r = 0.21$). In addition, there was a significant reduction of the time required time to perform the TUG by 11.1% from 9.78 s to 8.69 s ($p = 0.036$; $r = 0.18$).

Participants with a reduced SMI of ≤10.75 kg/m^2 attained significant improvements for TSF by 9.3% from 129 nm to 141 nm ($p = 0.035$; $r = 0.12$), HG by 3.8% from 31.6 kg to 32.8 kg ($p = 0.026$; r = 0.12) and the CRT by 7.7% from 8.66 s to 7.99 s ($p = 0.002$; r = 0.18) after 6 months of exercise intervention. Multimorbid men achieved significant improvements regarding TSE with 21.9% from 246.5 nm to 300.5 nm ($p < 0.001$; $r = 0.28$) and TSF with 20.5% from 127 nm to 153 nm ($p = 0.001$; $r = 0.17$), HG with 11.9% from 29.4 kg to 32.9 kg ($p = 0.034$; $r = 0.14$) and CRT with 7.6% from 8.81 s to 8.14 s ($p = 0.004$; $r = 0.18$) at the end of the study. Detailed results for baseline, 3 and 6 months are provided in a dedicated table in the supplements, results for TSF are visualized in Fig. 5.

Additional subgroup analyses within the at-risk groups did not reveal one exercise modality being superior above all others (data not shown).

4. Discussion

To our knowledge this is the first prospective randomized study evaluating efficacy of alternative, less demanding training concepts in elderly men at risk for osteoporosis. Considering both transferability of the results into a real world setting, as well as applicability and feasibility in large, general population based studies, we selected three

Table 1
Means and SD for anthropometrics at baseline for all participants and exercise subgroups.

Mean (SD)	All n = 47	RT n = 11	WBV n = 13	QG n = 10	SO n = 13
Age (y)	77.02 (6.1)	75.91 (5.6)	77.85 (6.2)	77.00 (7.9)	77.15 (5.5)
Height (cm)	174.77 (7.5)	176.09 (7.2)	171.46 (6.7)	174.40 (9.3)	177.23 (6.7)
Weight (kg)	84.83 (12.1)	87.09 (12.2)	77.92 (9.1)	85.00 (9.9)	89.69 (14.1)
BMI (kg/m^2)	27.78 (3.5)	28.20 (4.4)	26.45 (2.0)	28.13 (4.1)	28.47 (3.4)
SMI (kg/m^2)	10.19 (1.0)	10.60 (1.3)	10.09 (0.7)	10.18 (0.9)	9.96 (0.9)

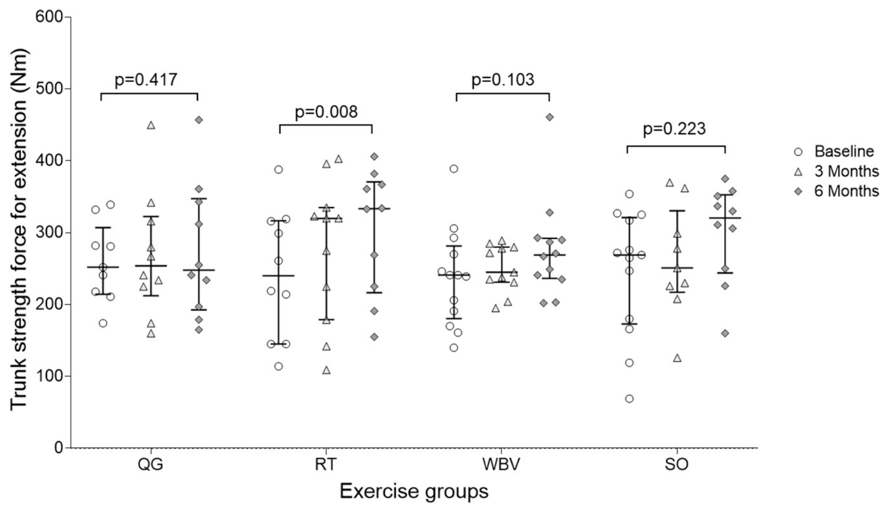

Fig. 2. Changes in trunk strength for extension in all 4 exercise groups.

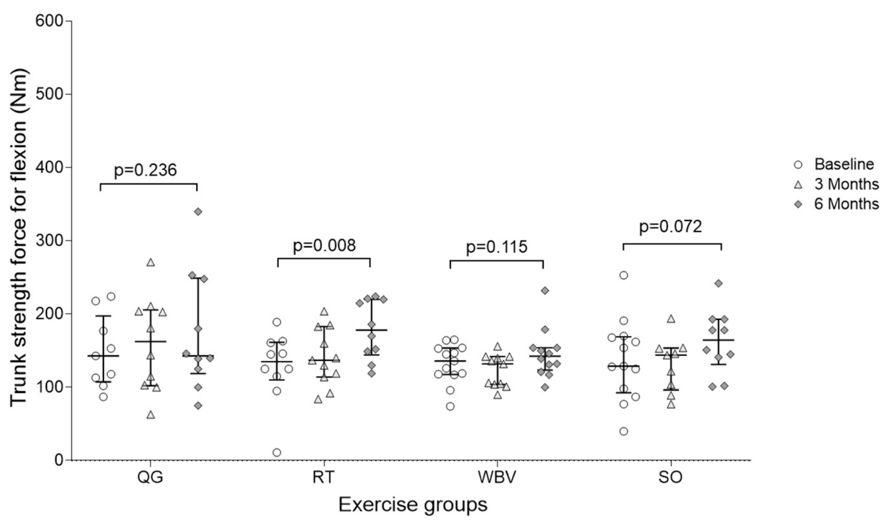

Fig. 3. Changes in trunk strength for flexion in all 4 exercise groups.

simple exercise modalities that neither require any previous sports experience nor a high level of motivation and compared these to professionally guided resistance exercise as a gold standard.

As expected, resistance exercise intervention clearly met the primary endpoint by yielding significant improvements in both trunk strength extension and flexion. This is in line with current literature (Lichtenberg et al., 2019) and reassuring in terms of the overall study setting and more importantly, it also confirms that appropriate exercise intervention can consistently improve muscular force and performance in a cohort of elderly men, although it has to be stated that due to the small sample size, these results have a more exploratory purport and might therefore serve as a first database to generate further hypotheses and trigger larger studies to investigate this matter.

Even though improvements achieved with the three alternative interventions were not statistically significant regarding the primary endpoint, the extent of improvements and evaluation of secondary endpoints surely supports distinct beneficial effects for each of these concepts. Specifically, the improvement of trunk strength by 19.1% for extension and 27.5% for flexion by wearing a specific, flexible, customized off-the-shelf back brace is encouraging. Essentially, these results confirm previous reports stating that despite tenacious concerns about potential muscle atrophy due to trunk bracing, this particular device rather enhances muscle strength (Dionyssiotis et al., 2015; Valentin et al., 2014; Pfeifer et al., 2011; Li et al., 2015). Similarly, WBV exercise over 6 months was also associated with non-significant but still considerable numerical improvements in trunk strength (TSE +11.6% / TSF +4.8%). In addition, both WBV and wearing the orthosis were associated with significant improvements regarding the time required to perform the CRT. While this has been reported before in conjunction with WBV exercise (Beck and Norling, 2010) and appears obvious considering how WBV exercise impacts thigh musculature, it is surely a novel and interesting finding with regards to the SO that deserves further attention in forthcoming studies to see if this is due to an interventional effect extending further down the back including gluteal and/or ischiocrural musculature or if this is an indirect effect of encouraging subjects to be more active while wearing the brace. Not surprisingly, the QG group did not attain significant improvements in established measures of strength and power. Still, lumbar ROM improved numerically after 6 months and in line with previous literature, we also observed a trend to increased 6 MWT distance (Pippa et al., 2007).

In line with established principles for exercise intervention, it can be considered a general finding of this study, that improvements were observed in those functions specifically addressed by the respective intervention with no relevant off-target effects in the overall analysis, i. e. resistance exercise focusing on trunk strength is proficient in that

Table 2
Musculoskeletal assessment results in dependence of exercise modality (median/IQR – except mean/SD for SPPB and balance).

Median (IQR)	0 months	3 months	6 months	*p*-Value
Lumbar extension (nm)				
Overall	**247.0 (117.0)**	**267.0 (93.0)**	**288.5 (113.0)**	**0.003**
Qi Gong	252.0 (92.5)	254.0 (110.3)	248.0 (155.0)	0.417
Resistance training	**240.0 (171.8)**	**320.0 (156.0)**	**333.5 (154.3)**	**0.008**
Whole Body Vibration	241.0 (101.0)	245.0 (49.0)	269.0 (55.8)	0.103
Lumbar orthosis	269.0 (92.5)	251.0 (110.25)	320.5 (155.0)	0.223
Lumbar flexion (nm)				
Overall	**136.0 (48.5)**	**137.0 (54.0)**	**150.5 (62.3)**	**<0.001**
Qi Gong	143.0 (90.0)	162.5 (103.5)	143.0 (130.5)	0.236
Resistance training	**135.0 (51.5)**	**137.0 (69.0)**	**178.0 (76.0)**	**0.008**
Whole Body Vibration	136.0 (36.0)	132.0 (38.0)	142.5 (30.5)	0.115
Spinal orthosis	129.0 (90.0)	144.0 (103.5)	164.5 (130.5)	0.072
Lumbar Ext/Flex. total ROM (°)				
Overall	50.0 (14.5)	55.0 (18.5)	53.5 (16.5)	0.951
Qi Gong	47.0 (19.0)	45.0 (25.8)	49.5 (16.0)	0.053
Resistance training	57.50 (22.3)	60.0 (19.0)	60.5 (14.3)	0.135
Whole Body Vibration	56.0 (29.5)	55.0 (20.0)	54.5 (15.0)	0.931
Spinal orthosis	48.0 (19.0)	56.0 (25.8)	48.5 (16.0)	0.072
Grip strength (kg)				
Overall	**32.4 (9.2)**	**33.1 (10.2)**	**32.9 (8.7)**	**0.006**
Qi Gong	27.0 (17.6)	27.65 (14.4)	29.0 (14.3)	0.122
Resistance training	34.6 (7.5)	37.4 (11.1)	32.9 (5.7)	0.178
Whole Body Vibration	**31.9 (6.7)**	**32.5 (8.8)**	**32.8 (6.3)**	**0.023**
Spinal orthosis	33.8 (17.6)	35.5 (14.4)	34.2 (14.4)	0.794
Balance overall (sec)				
Overall	27.9 (4.7)	27.8 (4.8)	27.3 (6.0)	0.738
Qi Gong	27.1 (6.2)	27.3 (4.5)	26.2 (6.6)	0.601
Resistance training	27.0 (6.2)	27.2 (4.0)	27.1 (4.3)	0.991
Whole Body Vibration	27.8 (4.1)	28.8 (2.2)	29.7 (0.9)	0.177
Spinal orthosis	29.3 (2.0)	27.6 (7.2)	26.1 (8.9)	0.283
Gait speed (m/s)				
Overall	**1.22 (0.2)**	**1.18 (0.3)**	**1.25 (0.2)**	**0.023**
Qi Gong	1.25 (0.4)	1.18 (0.3)	1.20 (0.2)	0.452
Resistance training	**1.22 (0.1)**	**1.32 (0.3)**	**1.32 (0.3)**	**0.015**
Whole Body Vibration	1.22 (0.2)	1.18 (0.3)	1.26 (0.2)	0.942
Spinal orthosis	1.16 (0.4)	1.07 (0.3)	1.23 (0.2)	0.199
CRT (s)				
Overall	**8.81 (2.6)**	**8.96 (2.3)**	**8.03 (2.6)**	**<0.001**
Qi Gong	9.27 (3.8)	9.86 (6.5)	8.70 (5.2)	0.497
Resistance Training	8.18 (2.9)	8.69 (2.1)	8.14 (2.0)	0.441
Whole body vibration	**8.81 (2.3)**	**8.57 (1.8)**	**8.03 (2.0)**	**0.007**
Spinal orthosis	**8.62 (3.8)**	**10.28 (6.5)**	**7.84 (5.2)**	**0.003**
SPPB score (points)				
Overall	11.2 (1.6)	11.1 (4.6)	11.3 (1.3)	0.743
Qi Gong	10.9 (2.0)	10.8 (1.8)	10.9 (1.9)	0.927
Resistance training	11.3 (1.6)	11.4 (1.0)	11.3 (1.1)	0.959
Whole Body Vibration	11.3 (1.1)	11.7 (0.5)	11.8 (0.4)	0.163
Spinal orthosis	11.1 (1.8)	10.5 (2.3)	11.3 (1.6)	0.424
6MW (m)				
Overall	**544.0 (127.0)**	**548.0 (122.0)**	**524.0 (154.0)**	**0.017**
Qi Gong	553.0 (189.8)	579.5 (179.0)	572.0 (193.0)	0.061
Resistance training	590.0 (240.0)	548.0 (127.0)	524.0 (154.0)	0.076
Whole Body Vibration	544.0 (118.5)	549.0 (118.0)	512.0 (180.0)	0.735
Spinal orthosis	528.0 (189.8)	538.0 (179.0)	527.0 (193.0)	0.484
TUG (s)				
Overall	8.31 (2.6)	8.09 (1.8)	8.16 (8.2)	0.273
Qi Gong	8.10 (3.2)	8.28 (4.3)	8.19 (3.4)	0.741
Resistance training	8.31 (1.9)	7.87 (2.4)	7.91 (1.2)	0.307
Whole Body Vibration	8.18 (2.9)	7.71 (0.9)	7.97 (1.3)	0.232
Spinal orthosis	8.56 (3.2)	8.81 (4.3)	9.00 (6.2)	0.368

P-values are showing the longitudinal development from baseline to 6 months with sig. assessment developments in bold characters.

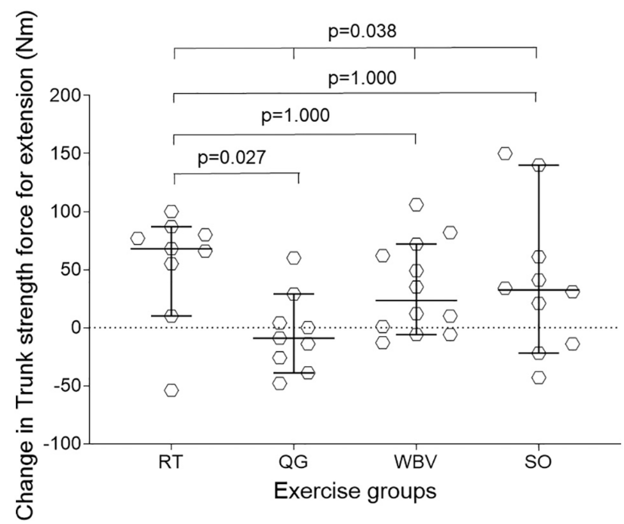

Fig. 4. Comparison of the changes in TSE between all 4 exercise groups.

regard without substantially improving other measures of physical performance. Accordingly, WBV typically involving the thigh muscles and requiring the participant to firmly hold on to the handrail entails improvements in the CRT and HG while wearing a flexible, elastic back brace continuously stimulates and trains trunk muscles. Another finding was that patients' motivation to participate in a volunteer active exercise program was very low. Therefore our initial aim to include more elderly men in this study could not be met entirely, even though these exercises were very simple and time-efficient. Consequently only 47 elderly men could be enrolled and the overall small sample size is surely one of the main limitations of this pilot study which has to be kept in mind with regards to drawing further conclusions.

Along with that, lack of statistical significance and small effect sizes for several of the improvements and effects attained with regards to the primary and some key secondary endpoints are surely attributable to the piloting nature and small sample size of this study and this explanation in combination with some heterogeneity in baseline data also applies to the lack of significance for between group comparisons.

Importantly, all 4 training interventions were well accepted by the participants, notwithstanding them being on average 77 years old and generally not completely healthy and none of the investigated exercise modalities was completely inferior to the others comparing changes in test results after 6 months. Specifically, adherence over time was particularly encouraging with all 47 subjects (100%) completing the program. With regards to the available sessions attended, our result of ≥75% is in line with literature date reporting 58 to 77% (Picorelli et al., 2014). Similarly, the spinal orthosis was well accepted and perceived as being comfortable with >80% of days meeting minimum wearing time.

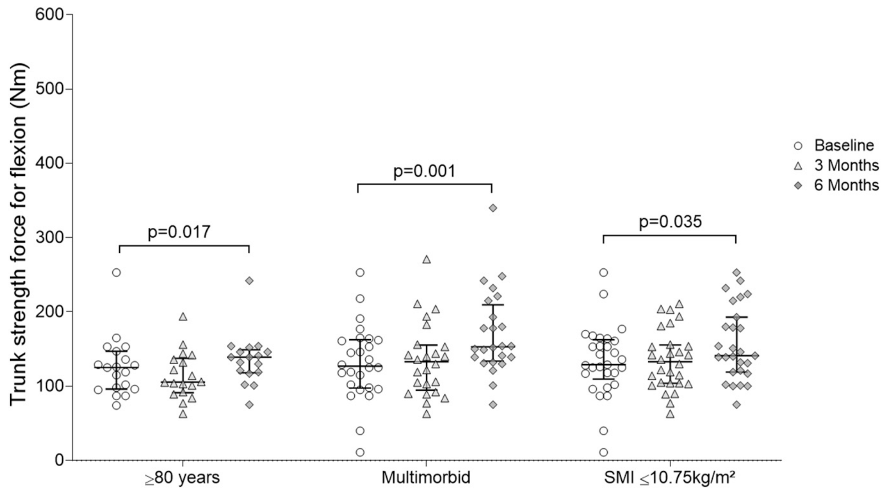

Fig. 5. Changes in TSF in men at risk for osteoporosis following exercise intervention.

Main reasons for individual downtimes in wearing the back brace were acute health related issues and traveling.

Subgroup analyses revealed particularly pronounced and encouraging improvements for high-risk subjects (Age $\geq$ 80 years, SMI $\leq$ 10.75 kg/m^2, $\geq$ 3 chronic diseases) irrespective of the applied intervention and all 3 vulnerable subgroups achieved significant improvements specifically in their lumbar flexion strength, various lower extremity performance measures (CRT, TUG, 6 MW) and HG.

Taken together, these results indicate that the low impact training-concepts scrutinized in this study are particularly suitable for very old, multimorbid and presarcopenic subjects with restricted mobility and elevated fracture risk. Future studies with more participants are needed to further substantiate these results. Data presented here should be considered a starting point for targeted evaluations if and how these simple exercise modalities can be effectively implemented in routine care for long term prevention of age associated functional decline.

5. Conclusions

Within this exploratory trial we found that exercise interventions are safe and feasible in elderly men, eliciting specific benefits and that improvements are attained in those parameters addressed with the respective exercise modality. While specific resistance training of trunk strength appeared superior in increasing that task, alternative simple exercise interventions also appear beneficial in terms of attaining specific improvements.

Ethics approval and consent to participate

The study protocol was approved by the competent ethics committee at Wuerzburg University (N. 111/14).

Every participant gave written informed consent to participate and for publication before any study related procedures.

Availability of data and materials

All data and study material is stored at the Departments of Orthopedics at the University of Wuerzburg for 10 years. The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Funding

Parts of this work have been supported by the Bayerische Forschungsstiftung, Munich Germany, Predia Institute, Wuerzburg, Germany; medi Bayreuth, Bayreuth, Germany, SMT medical, Wuerzburg, Germany; Novotec Medical, Pforzheim, Germany. This publication was supported by the Open Access Publication Fund of the University of Wuerzburg.

Author contributions

Study design: LS.
Study lead investigator: LS.
Enrolled and studied patients: LS, FG.
Collection and assembly of data: FG, SL, SS, MS.
Data analysis: LS, FG,
Data interpretation: LS, FG.
Manuscript preparation: LS, FG.
Manuscript content review and revisions: All authors.
Approval of the final Manuscript: All authors.

Transparency document

The Transparency document associated with this article can be found, in online version.

Declaration of competing interest

LS has received honoraria for lectures and advice from Abbvie, Amgen, Alexion, KyowaKirin, Lilly, Medi, MSD, Novartis, Servier and UCB and research grants to the Institution (University of Wuerzburg) from Alexion, Kyowa Kirin and Novartis.

FG has received honoraria for lectures from Abbvie, Alexion and Lilly.

SL, SS, and MS report no COI during the course of the study.

Acknowledgements

The authors acknowledge Prof. Franz Jakob for organizational support.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bonr.2021.101099.

References

Bautmans, I., Van Hees, E., Lemper, J.C., Mets, T., 2005. The feasibility of whole body vibration in institutionalised elderly persons and its influence on muscle

performance, balance and mobility: a randomised controlled trial [ISRCTN62535013]. BMC Geriatr. 5, 17.
Beaudart, C., McCloskey, E., Bruyere, O., et al., 2016. Sarcopenia in daily practice: assessment and management. BMC Geriatr. 16, 170.
Beck, B.R., Norling, T.L., 2010. The effect of 8 mos of twice-weekly low- or higher intensity whole body vibration on risk factors for postmenopausal hip fracture. Am. J. Phys. Med. Rehabil. 89 (12), 997–1009.
Bogaerts, A., Verschueren, S., Delecluse, C., Claessens, A.L., Boonen, S., 2007. Effects of whole body vibration training on postural control in older individuals: a 1 year randomized controlled trial. Gait Posture 26 (2), 309–316.
Buehring, B., Hansen, K.E., Lewis, B.L., Cummings, S.R., Lane, N.E., Binkley, N., et al., 2018. Dysmobility syndrome independently increases fracture risk in the osteoporotic fractures in men (MrOS) prospective cohort study. J. Bone Miner. Res. 33 (9), 1622–1629.
Cadore, E.L., Casas-Herrero, A., Zambom-Ferraresi, F., Idoate, F., Millor, N., Gomez, M., et al., 2014. Multicomponent exercises including muscle power training enhance muscle mass, power output, and functional outcomes in institutionalized frail nonagenarians. Age (Dordr.) 36 (2), 773–785.
Cesari, M., Vellas, B., Hsu, F.C., Newman, A.B., Doss, H., King, A.C., et al., 2015. A physical activity intervention to treat the frailty syndrome in older persons-results from the LIFE-P study. J. Gerontol. A Biol. Sci. Med. Sci. 70 (2), 216–222.
Chalhoub, D., Cawthon, P.M., Ensrud, K.E., Stefanick, M.L., Kado, D.M., Boudreau, R., et al., 2015. Risk of nonspine fractures in older adults with sarcopenia, low bone mass, or both. J. Am. Geriatr. Soc. 63 (9), 1733–1740.
Chen, H.T., Wu, H.J., Chen, Y.J., Ho, S.Y., Chung, Y.C., 2018. Effects of 8-week kettlebell training on body composition, muscle strength, pulmonary function, and chronic low-grade inflammation in elderly women with sarcopenia. Exp. Gerontol. 112, 112–118.
Cruz-Jentoft, A.J., Baeyens, J.P., Bauer, J.M., Boirie, Y., Cederholm, T., Landi, F., et al., 2010a. Sarcopenia: European consensus on definition and diagnosis: report of the European Working Group on Sarcopenia in Older People. Age Ageing 39 (4), 412–423.
Cruz-Jentoft, A.J., Landi, F., Topinkova, E., Michel, J.P., 2010b. Understanding sarcopenia as a geriatric syndrome. Curr Opin Clin Nutr Metab Care 13 (1), 1–7.
Cruz-Jentoft, A.J., Bahat, G., Bauer, J., Boirie, Y., Bruyere, O., Cederholm, T., et al., 2019. Sarcopenia: revised European consensus on definition and diagnosis. Age Ageing 48 (1), 16–31.
Dionyssiotis, Y., Trovas, G., Thoma, S., Lyritis, G., Papaioannou, N., 2015. Prospective study of spinal orthoses in women. Prosthetics Orthot. Int. 39 (6), 487–495.
Ebeling, P.R., Cicuttini, F., Scott, D., Jones, G., 2019. Promoting mobility and healthy aging in men: a narrative review. Osteoporos. Int. 30 (10), 1911–1922.
Fischer, S., Kapinos, K.A., Mulcahy, A., Pinto, L., Hayden, O., Barron, R., 2017. Estimating the long-term functional burden of osteoporosis-related fractures. Osteoporos. Int. 28 (10), 2843–2851.
Genest, F., Schneider, M., Zehnder, A., Lieberoth-Leden, D., Seefried, L., 2021. Differential impact of osteoporosis, sarcopenia and obesity on physical performance in aging men. Endocr. Connect. 10 (3), 256–264.
Guralnik, J.M., Simonsick, E.M., Ferrucci, L., Glynn, R.J., Berkman, L.F., Blazer, D.G., et al., 1994. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. J. Gerontol. 49 (2), M85–M94.
Hirschfeld, H.P., Kinsella, R., Duque, G., 2017. Osteosarcopenia: where bone, muscle, and fat collide. Osteoporos. Int. 28 (10), 2781–2790.
Janssen, I., Heymsfield, S.B., Baumgartner, R.N., Ross, R., 2000. Estimation of skeletal muscle mass by bioelectrical impedance analysis. J. Appl. Physiol. 89 (2), 465–471.
Kaijser Alin, C., Uzunel, E., Grahn Kronhed, A.C., Alinaghizadeh, H., Salminen, H., 2019. Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: a randomized controlled trial. Arch. Osteoporos. 14 (1), 5.
Landi, F., Liperoti, R., Russo, A., Giovannini, S., Tosato, M., Capoluongo, E., et al., 2012. Sarcopenia as a risk factor for falls in elderly individuals: results from the ilSIRENTE study. Clin. Nutr. 31 (5), 652–658.
Landi, F., Calvani, R., Cesari, M., Tosato, M., Martone, A.M., Ortolani, E., et al., 2018. Sarcopenia: an overview on current definitions, diagnosis and treatment. Curr. Protein Pept. Sci. 19 (7), 633–638.
Li, M., Law, S.W., Cheng, J., Kee, H.M., Wong, M.S., 2015. A comparison study on the efficacy of SpinoMed(R) and soft lumbar orthosis for osteoporotic vertebral fracture. Prosthetics Orthot. Int. 39 (4), 270–276.
Lichtenberg, T., von Stengel, S., Sieber, C., Kemmler, W., 2019. The favorable effects of a high-intensity resistance training on sarcopenia in older community-dwelling men with Osteosarcopenia: the randomized controlled FrOST study. Clin. Interv. Aging 14, 2173–2186.
Mathias, S., Nayak, U.S., Isaacs, B., 1986. Balance in elderly patients: the “get-up and go” test. Arch. Phys. Med. Rehabil. 67 (6), 387–389.
Moore, D.R., Kelly, R.P., Devries, M.C., Churchward-Venne, T.A., Phillips, S.M., Parise, G., et al., 2018. Low-load resistance exercise during inactivity is associated with greater fibre area and satellite cell expression in older skeletal muscle. J. Cachexia. Sarcopenia Muscle 9 (4), 747–754.
Moore, S.A., Hrisos, N., Errington, L., Rochester, L., Rodgers, H., Witham, M., et al., 2019. Exercise as a treatment for sarcopenia: an umbrella review of systematic review evidence. Physiotherapy 107, 189–201.
Nawrat-Szoltysik, A.J., Polak, A., Malecki, A., Piejko, L., Grzybowska-Ganszczyk, D., Krecichwost, M., et al., 2018. Effect of physical activity on the sequelae of osteoporosis in female residents of residential care facilities. Adv. Clin. Exp. Med. 27 (5), 633–642.
Neuerburg, C., Mittlmeier, L., Schmidmaier, R., Kammerlander, C., Bocker, W., Mutschler, W., et al., 2017. Investigation and management of osteoporosis in aged trauma patients: a treatment algorithm adapted to the German guidelines for osteoporosis. J. Orthop. Surg. Res. 12 (1), 86.
Pfeifer, M., Kohlwey, L., Begerow, B., Minne, H.W., 2011. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. Am. J. Phys. Med. Rehabil. 90 (10), 805–815.
Pfeil, A., Lehmann, G., Lange, U., 2018. Update DVO guidelines 2017 on "Prophylaxis, diagnostics and treatment of osteoporosis in postmenopausal women and men" : What is new, what remains for rheumatologists? Z. Rheumatol. 77 (9), 759–763.
Picorelli, A.M., Pereira, L.S., Pereira, D.S., Felício, D., Sherrington, C., 2014. Adherence to exercise programs for older people is influenced by program characteristics and personal factors: a systematic review. Aust. J. Phys. 60 (3), 151–156.
Pippa, L., Manzoli, L., Corti, I., Congedo, G., Romanazzi, L., Parruti, G., 2007. Functional capacity after traditional Chinese medicine (qi gong) training in patients with chronic atrial fibrillation: a randomized controlled trial. Prev. Cardiol. 10 (1), 22–25.
Schafer, I., Hansen, H., Schon, G., Maier, W., Hofels, S., Altiner, A., et al., 2009. The German MultiCare-study: patterns of multimorbidity in primary health care - protocol of a prospective cohort study. BMC Health Serv. Res. 9, 145.
Scott, D., Seibel, M., Cumming, R., Naganathan, V., Blyth, F., Le Couteur, D.G., et al., 2017. Sarcopenic obesity and its temporal associations with changes in bone mineral density, incident falls, and fractures in older men: the Concord Health and Ageing in Men Project. J. Bone Miner. Res. 32 (3), 575–583.
Seefried, L., Genest, F., Luksche, N., Schneider, M., Fazeli, G., Brandl, M., et al., 2017. Efficacy and safety of whole body vibration in maintenance hemodialysis patients - a pilot study. J. Musculoskelet. Neuronal Interact. 17 (4), 268–274.
Seldeen, K.L., Lasky, G., Leiker, M.M., Pang, M., Personius, K.E., Troen, B.R., 2018. High intensity interval training improves physical performance and frailty in aged mice. J. Gerontol. A Biol. Sci. Med. Sci. 73 (4), 429–437.
Sherrington, C., Fairhall, N.J., Wallbank, G.K., Tiedemann, A., Michaleff, Z.A., Howard, K., et al., 2019. Exercise for preventing falls in older people living in the community. Cochrane Database Syst. Rev. 1, Cd012424.
Song, Q., Li, L., Zhang, C., Sun, W., Mao, D., 2018. Long-term Tai Chi practitioners have superior body stability under dual task condition during stair ascent. Gait Posture 66, 124–129.
Tarantino, U., Baldi, J., Scimeca, M., Piccirilli, E., Piccioli, A., Bonanno, E., et al., 2016. The role of sarcopenia with and without fracture. Injury 47 (Suppl. 4), S3-S10.
Thomasius, F., Baum, E., Bernecker, P., Böcker, W., Brabant, T., Clarenz, P., et al., 2018. DVO Leitlinie 2017 zur Prophylaxe, Diagnostik und Therapie der Osteoporose bei postmenopausalen Frauen und Männern, 27 (03), 154–160.
Uemura, K., Makizako, H., Lee, S., Doi, T., Lee, S., Tsutsumimoto, K., et al., 2018. The impact of sarcopenia on incident homebound status among community-dwelling older adults: a prospective cohort study. Maturitas 113, 26–31.
Valentin, G.H., Pedersen, L.N., Maribo, T., 2014. Wearing an active spinal orthosis improves back extensor strength in women with osteoporotic vertebral fractures. Prosthetics Orthot. Int. 38 (3), 232–238.
Van Der Klift, M., Pols, H.A., Geleijnse, J.M., Van Der Kuip, D.A., Hofman, A., De Laet, C. E., 2002. Bone mineral density and mortality in elderly men and women: the Rotterdam Study. Bone 30 (4), 643–648.
Vergara-Diaz, G., Osypiuk, K., Hausdorff, J.M., Bonato, P., Gow, B.J., Miranda, J.G., et al., 2018. Tai chi for reducing dual-task gait variability, a potential mediator of fall risk in Parkinson’s disease: a pilot randomized controlled trial. Glob. Adv. Health Med. 7, 2164956118775385.
Wagner, P., Chapurlat, R., Ecochard, R., Szulc, P., 2018. Low muscle strength and mass is associated with the accelerated decline of bone microarchitecture at the distal radius in older men: the prospective STRAMBO study. J. Bone Miner. Res. 33 (9), 1630–1640.
Wisdom, K.M., Delp, S.L., Kuhl, E., 2015. Use it or lose it: multiscale skeletal muscle adaptation to mechanical stimuli. Biomech. Model. Mechanobiol. 14 (2), 195–215.
Zanker, J.J., Duque, G., 2020. Osteosarcopenia: the Path Beyond Controversy. Curr. Osteoporos. Rep. 18 (2), 81–84.