REVIEW



The effects of person-centered or other supportive interventions in older women with osteoporotic vertebral compression fractures—a systematic review of the literature

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Abstract Vertebral compression fracture (VCF) is a common fragility fracture and the starting point of a lasting, painful, disabling condition. The aim was to summarize evidence of person-centered/non-medical interventions supporting women with VCF. Results show small numbers of studies with only probable effect on function, pain, QoL, fear of falling, and psychological symptoms. The vertebral compression fracture (VCF) caused by osteoporosis is the third most common fragility fracture worldwide. Previously, it was believed that the pain caused by VCF was self-subsiding within weeks or a few months post-fracture. However, this positive prognosis has been refuted by studies showing that, for the great majority of patients, the VCF was the starting point of a long-lasting, severely painful, and disabling condition. The low number of studies focusing on the experience of the natural course of VCF, and what support is available and how it is perceived by those affected, calls for further investigation. Strengthening older patients' sense of security and increasing confidence in their own abilities are of great importance for successful rehabilitation following VCF. More research is needed to identify

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resources, possibilities, and strategies that can assist older patients to reach their goals to improve well-being. The purpose of this systematic review was to identify and summarize the current evidence of person-centered or other structured nonmedical/non-surgical interventions supporting older women after experiencing an osteoporotic VCF. A systematic literature search was conducted on the MeSH terms encompassing osteoporosis and vertebral compression fractures in the PubMed-MEDLINE and Cumulative Index for Nursing and Allied Health Literature (CINAHL) databases during March through June 2015. The initial search identified 8789 articles. but only seven articles (six randomized controlled trials and one observational study with a control group) met the inclusion criteria. It became evident from the current study that the availability of evidence on the effects of non-medical interventions aiming to support older women with VCF is limited, to say the least. The trials included in this review have few limitations and were mainly considered to be of moderate quality. This systematic literature review suggests that nonmedical interventions aiming to support older women with VCF might decrease levels of pain and use of analgesic as well as promote improved physical mobility and function. These interventions would probably result in an improved difference in experiences of fear of falling and perceived psychological symptoms, but would only slightly improve quality of life. However, given the nature of the seven studies, potential biases in patient selection, issues around precision with small cohorts, and failure to control for confounders, makes it difficult to draw a definitive conclusion about the significant effects of non-medical interventions. Incurring a VCF is a complex and diverse event, necessitating equally complex interventions to identify new ways forward. However, to date, interventions struggle with a risk of selection bias in that only

the needs of the healthiest of the population are addressed and the voices of the remaining majority of the people affected by VCF are unheard.

Keywords Nursing · Osteoporotic vertebral compression fracture · Supportive interventions

Introduction

Vertebral compression fracture (VCF) caused by osteoporosis refers to the collapse/compression/wedging of a vertebral body and is the third most common fragility fracture world-wide [1]. In the global estimate of 9 million new osteoporotic fractures each year, VCFs amount to 1.4 million, whereas, in Sweden, VCF accounts for approximately 16,000 of a total of 107,000 new fractures each year [2]. Many VCF are missed or even neglected and are therefore never diagnosed for a variety of reasons. One reason might be the limited knowledge and awareness of the condition by healthcare providers, which, together with undefined and unclear areas of responsibility, leads to low rates of referral to the appropriate osteoporosis services [3–5].

Despite the large number of persons affected by VCF, both with and without X-ray-verified diagnosis, surprisingly little is known about the experience of its natural course. Previously, it was believed that the pain caused by VCF was selfsubsiding within weeks or a few months post-fracture. However, this positive prognosis was refuted by studies showing that, for the great majority of patients, the acute VCF was the starting point of a long-lasting, severely painful, and disabling condition [6]. It has also been shown that health-related quality of life (HRQoL) in older women with VCF was considerably lower compared with controls up to 7 years postfracture, and that they experienced increased fear of pain and falling, as well as decreased self-esteem [7]. In a recent study by Svensson et al. (2015) [8], the experience of older women with VCF is described as a painful never-ending story accompanied by fear and concerns of becoming dependent. Regardless of the length of time that has passed since the initial injury, the experience of facing an uncertain future with decreased self-confidence endures, but it is also accompanied by a belief in individual capability and capacity for improvement [8]. In most cases, the acute VCF is painful and will consequently reduce the person's ability to be physically active and thus accelerate further bone mineral loss, leading to aggravated bone fragility [9]. This pain-induced inactivity will also affect the musculature, resulting in muscle hypotrophy and weakness, factors that all in all will multiply the risk of falls with subsequent new fractures [4, 6, 10, 11]. Moreover, there are studies showing a decreased independence, loss of roles and isolation due to the imminent threat of becoming a burden on close family. In addition, the pain in itself has been shown to have an inhibitory effect on motivation and confidence in their own ability suggesting a substantial impact on these women's social life [7–9]. Kanis et al. (2004) [3] argues that this significant effect on the patient's social life together with the subsequent disability of VCF, that well exceeds that of other fragility fractures, are considerably underestimated in the reports of increased mortality within the first year after a VCF [3].

In Sweden, and in most other western countries, treatment after an acute VCF is said to be early mobilization, usually combined with pharmacological pain management and antiresorptive bone medication (bisphosphonates); however, there are several challenges in the care and rehabilitation of older persons with VCF [12, 13]. Although the individual motivation for rehabilitation might be present, high age, along with comorbidity and chronic illness, adds to their already reduced capacity for physical rehabilitation. Old and frail persons are at high risk of a downward trajectory in their physical state as well as in their general health status after a fracture [4]. The beneficial effects of multicomponent exercise programs, such as posture, balance, and muscle strengthening exercises, have been suggested to reduce levels of pain and prevent falls with subsequent fractures [14]. However, in most cases, patients with VCF are discharged with insufficient pain relief and without any plan for organized support or follow-up to initiate and pursue a healthy transition towards a renewed phase of stability and acceptance [8, 15].

Surgery to treat VCF is presented with several difficulties due to the low bone density related to the underlying osteoporosis. A meta-analysis of the current evidence of the use of two different surgical techniques (i.e., percutaneous vertebroplasty and percutaneous balloon kyphoplasty) showed a significant reduction of pain and an increase in quality of life, as well as improvement in physical function [16]. However, other studies indicate the contrary and describe the invasive treatment alternative as being less promising than anticipated in VCF management [12, 13]. The National Board of Health and Welfare in Sweden stated in 2012 that there is no indication for surgery in the management of VCF due to the moderate or low quality of evidence of its effect on pain, quality of life, and physical function [17].

As described, osteoporosis, with its subsequent fragility fractures, primarily affects women after menopause and research has shown that women need to express a higher level of symptoms to get the attention of healthcare providers [18]. In this context, a question of double jeopardy might be raised; that is to say, not only being an older woman, but also having to endure osteoporosis and VCF, which amplifies their ongoing vulnerability and frailty in everyday life [19]. However, in several qualitative studies, women affected by osteoporosis are portrayed not only as frail, but also as able and engaged in their own health by devising strategies to overcome barriers in daily life, despite having received inadequate or inaccurate

information from indifferent healthcare providers [8, 9, 20–26]. Patients' own resources and confidence in their own abilities are of utmost importance for successful rehabilitation. By establishing a partnership based on the individual's narrative about their everyday life, abilities, goals, views, obstacles, desires, fears, and perceptions of their abilities, healthcare providers could empower confidence in their own abilities and encourage their patients to become more actively involved in their care and rehabilitation [27–29].

Purpose

The purpose of this systematic review was to identify and summarize the current evidence of person-centered or other structured non-medical/non-surgical interventions supporting older women after an osteoporotic VCF.

Methods

A systematic review (SR) of the literature was performed and the findings were reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement [30].

Inclusion criteria

The inclusion criteria are shown in Table 1.

Search method

Information sources and search

The systematic literature search was conducted by the first author with the support of a library staff. Search terms were identified as follows: "osteoporosis" OR "osteoporotic" AND "vertebral" AND "fracture" OR "fractures" and language (English). Terms were combined as MeSH terms or terms and Title/Abstract in PubMed, and as text words in the Cumulative Index for Nursing and Allied Health Literature (CINAHL) database. The search had no restrictions or limitations with regards to publication date, publications status, length of follow-up, or study design, because further limitations would increase the risk of overlooking relevant articles. The search was applied from March through June 2015 and repeated in February 2016, with the aim of including an unbiased and complete set of relevant studies. A search by hand was also performed to review the references in the studies included.

Study selection

All published randomized clinical trials and other study designs comparing interventions with conventional treatment were included. Reviews, recommendations, epidemiological studies, case-reports, letters, commentaries, abstracts, and unpublished articles were excluded. We included studies published in English, with female participants aged \geq 65 years living with osteoporosis and one or several subsequent vertebral compression fractures in the lumbar or thoracic spine. Primary outcomes were formulated as pain, quality of life, fear of falling, and social and physical isolation, with physical activity as a secondary outcome.

In the preliminary stage, the search strategy was designed to be as comprehensive as possible in order to include the greatest number of studies and then it was gradually narrowed according to the inclusion and exclusion criteria. Duplicated studies were removed from the list. Studies were excluded in the assessment phase and were done so in terms of the study purposes and design, or study participants (men regardless of age or women other than those >65 years). The primary focus was on person-centered interventions or equivalent supporting interventions aiming to support and strengthen the women in their everyday lives (Table 1) [31]. Three authors independently reviewed the titles and abstracts of all citations that were identified. After all abstract were reviewed, data comparisons between investigators were conducted to ensure completeness and reliability. Studies were categorized into four groups: (1) eligible study, as it was considered pertinent according to the inclusion and exclusion criteria; (2) feasibly eligible study, required to be read in full to determine whether it was considered pertinent to the study aims; (3) ineligible for this review, where it was not possible to detect from the title or the abstract its pertinence with regard to the inclusion/ exclusion criteria adopted, but the reference list would be reviewed as it might uncover relevant articles; and (4) ineligible for this review, where it was not possible to detect from the title or the abstract its pertinence with regard to the inclusion/ exclusion criteria adopted. Differing decisions were resolved by discussing and reaching a consensus.

| Р | Women, ≥65 years, living with osteoporosis and one or several vertebral compression fractures |
|-------|---|
| I^1 | Person-centered interventions |
| I^2 | Other supporting interventions |
| С | Conventional treatment |
| 0 | Primary—pain, quality of life, fear of falling, social and physical isolation Secondary—physical mobility |
| S | RCT and observational studies |

Data extraction

Three authors independently reviewed the text of each study in full and then came to a mutual decision on which studies would be included. Any disagreements between authors were resolved in discussions until a consensus was reached.

Specific outcome definitions were used to appropriately conceptualize people's experiences of improvement in their health and well-being from a nursing science perspective, and to avoid the risk of producing data-driven analysis. These included the ability to maintain physical activity, experiences of pain, and quality of life. According to the literature, maintaining physical activity is of major importance and, for the purposes of this review, was defined as the ability to sustain the current level of physical function (i.e., any bodily movement produced by skeletal muscles that result in energy expenditure) with a normal decrement due to high age and comorbidity [4, 32]. The experiences of pain were defined as self-reported decrease using validated instruments such as the visual analog scale (VAS), and social and physical isolation were defined as a self-reported sense of being trapped and not being able to engage in any social activities or to leave their residence [8, 33]. Quality of life was defined as the individual's perception of their life situation, based on cultural context, in terms of physical well-being, functional ability, emotional well-being, and social well-being; and the values they placed on personal goals, expectations, standards, and concerns [34]. The research questions guiding the data collection process were the following: (1).what kind of personcentered or other supportive interventions have been tried and investigated in a population of older women with osteoporosis and VCF? (2) What is the current state of the scientific knowledge on person-centered or other supportive interventions for maintaining physical function, decreasing pain, and increasing quality of life in older women living with osteoporotic VCF? (3) What is our knowledge regarding reducing social and physical isolation among older women suffering from a vertebral compression fracture using person-centered or other supportive interventions?

Assessment of risk of bias

The quality of the studies was assessed using the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) checklists on risk of selection, performance, assessment, attrition, and reporting bias [35]. This assessment also constituted the basis for the subsequent classification of the strength of scientific evidence using Grading of Recommendations Assessment, Development and Evaluation (GRADE), which reflects on study quality, consistency/conformity, transferability/relevance, precision in the data, and risk of publication bias. The strength of scientific evidence is specified based on four levels: high (++++), moderate (+++0), low (++00), and very low (+000) [36].

Results

The initial search identified 8789 articles (Fig. 1) [37]. After eliminating duplicates (3918 articles), an additional 4736 articles were excluded based on their titles; thus, 135 articles remained and were screened on their abstracts. We excluded studies evaluating the effects of surgery and pharmacological treatment and a further 104 articles were thus excluded. The full text of each of the remaining 31 articles was read in full by three authors independently and an additional 26 articles were excluded (Table 2) [4–6, 14, 33, 38–58]. The reference lists of all eligible articles were screened and an additional two articles were included.

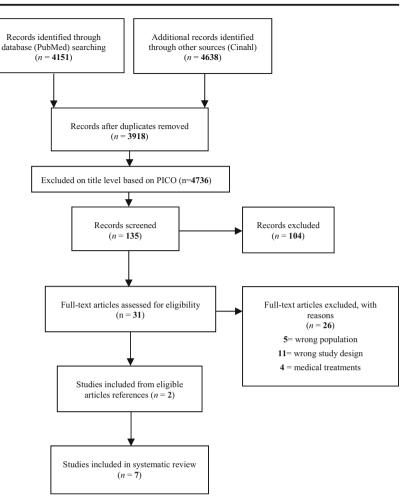
Study characteristics

Seven peer-reviewed articles (six randomized controlled trials and one observational study with a control group) met the inclusion criteria [59–65]. The study characteristics are presented in Table 3.

The studies originated from the USA [59, 60], Norway [61-63], Italy [65], Denmark [62], and Canada [64], and included both continuing care retirement communities (CCRC) and outpatient clinics. Study population sizes ranged from 50 participants [59] to 185 participants [60]. Inclusion criteria in all of the seven studies were established osteoporosis assessed with dual-energy X-ray absorptiometry (DEXA); data were valued based on the WHO's range in terms of T-scores and history of one or more VCF. In addition to these criteria, there was a complement of specific criteria in terms of age, antiosteoporotic medical treatment, and the appearance and localization of the fracture. Exclusion criteria in the majority of the studies were major cognitive impairment assessed with mini mental state examination (MMSE) or described as an inability to answer questionnaires; the presence of comorbidity, such as pulmonary, cardiac, or neurological diseases (6/7); and secondary causes of osteoporosis, i.e., metastatic cancer or metabolic bone disease. In some of the studies, smokers and/or persons suffering from alcohol abuse were also excluded.

In five of the seven studies included in this review, the intervention consisted of various physical exercise programs aiming to maintain or even increase physical function compared with participants who sustained current exercise levels [60–64]. One study evaluated the effect of two different electric stimulation applications on reducing pain compared with "sham" stimulation [65]. In one study, an educational program that aimed to support the participants in everyday life and in

Fig. 1 PRISMA-flow chart



promoting increased quality of life was evaluated [59]. The intervention periods ranged from 8 weeks to 6 months.

The primary outcomes were mobility [61, 63], quality of life [59, 64], trunk extension [60], pain with activity [60], psychological symptoms [60], chronic low back pain [62, 65], and use of analgesic [62].

The secondary outcomes were fear of falling [63], physical function [64], mobility [61], balance [61], quality of life [61, 62], muscle strength [62], and bone density [64].

Risk of bias within studies

An overview of the assessment of the individual studies on risk of selection, performance, assessment, attrition, and reporting bias are presented in Table 4.

Gold et al. (2004) [60] reported a clear description of the randomization process. Randomization was made by site and also by masking the intervention status and study hypotheses to the researchers and personnel involved in the trial (apart from the biostatistician) as well as the participants, in that they were unaware of the content of the intervention in the other sites during phase 1. There were no descriptions of sample size calculations; however, the recruitment process was well defined with clear descriptions of how inclusion and exclusion criteria were employed. The primary outcome measures were clearly defined; however, there was some uncertainty about whether other variables were also collected. The measurements used to assess the effects of the intervention were described, but the effects of the participant drop-out rate were vague, and whether these were taken into account in the analyses was unclear. The intervention itself was complex and comprised many elements, and was described without any reference to a study protocol or any discussion relating to the need for a wash-out period to prevent contamination [60].

Papaioannou et al. (2002) applied randomization blocks of six within four strata, defined by age and number of fractures, but provided no rationale for adopting this strategy. It is unclear how many patients were eligible for inclusion in the study and, although the authors report a drop-out rate of 23% at 12 months and adherence of 46% at 12 months, there is no description as to how they incorporated these results in the analysis. At baseline, the intervention group reportedly rated their physical function better within the physical domain of the QoL instrument than the control group (p = 0.048);

Table 2 Excluded publications

| First author | Year/country | Reason for exclusion |
|--------------------------------|-------------------|--|
| Barker K. L. et al. [36] | 2014 UK | Design and study protocol |
| Bennell K. L. et al. [37] | 2010 Australia | Population of both men and women |
| Ekström H. et al. [38] | 2013 Sweden | Multiple fractures included |
| Giangregorio L. M. et al. [14] | 2014 Canada | Recommendations |
| Giangregorio L. M. et al. [39] | 2013 Canada | Review |
| Gran Kronhed A. C. et al. [40] | 2009 Sweden | Exclusively osteoporosis |
| Hall S. E. et al. [41] | 1999 Australia | No intervention |
| Hongo M. et al. [42] | 2006 Japan | Exclusively osteoporosis |
| Hoshino M. et al. [43] | 2013 Japan | Population of both men and women |
| Hübscher M. et al. [44] | 2010 Germany | Descriptive |
| Kaffashian S. et al. [45] | 2011 France | Compilation of health-related costs |
| Kammerlander C. et al. [4] | 2014 Austria | Epidemiology and screening |
| Klazen C. A. et al. [32] | 2010 Netherlands | Descriptive |
| Lukert B. P. et al. [46] | 1994 USA | Recommendations of pain relief |
| Majumdar S. R. [47] | 2012 Canada | Intervention targeting treatment complianc |
| Papa J. A. [48] | 2012 Canada | Descriptive |
| Pratelli E. et al. [49] | 2010 Italy | Recommendations |
| Riccio I. et al. [50] | 2013 Italy | Recommendations |
| Schröder G. et al. [51] | 2012 Germany | Exclusively osteoporosis |
| Suzuki N. et al. [6] | 2008 Japan/Sweden | Descriptive |
| Suzuki N. et al. [52] | 2009 Japan/Sweden | Descriptive |
| Suzuki N. et al. [53] | 2010 Japan/Sweden | Descriptive |
| Varacallo M. A. [5] | 2014 USA | Medical treatment |
| Venmans A. et al. [54] | 2014 Netherlands | Descriptive pain |
| Wang L. Y. et al. [55] | 2013 Taiwan | Descriptive balance |
| Yoon S. P. et al. [56] | 2014 Korea | Descriptive |

however, there is no explanation of how this might have influenced the results. The results in terms of QoL were presented based on each domain of the instruments, which enables the reader to follow the effects, but it is unclear whether the Sickness Impact Profile (SIP) and force-plate were measured at 6 or at 12 months. The control group was contacted by phone once a month, but the purpose of this was not disclosed and might have affected the participants' reporting. Reference to a study protocol was also missing [64].

Zambito et al. (2007) gave a clear description of the recruitment process with the inclusion and exclusion criteria well stated as well as in which way they were applied. The randomization process and the steps taken in the blinding process, in terms of both participants and treating personnel, were fully disclosed. However, the reason for the randomization by blocks of 15 was not stated, nor the suitability of this strategy, as each study group comprised 35 participants. The outcomes were defined, although they were not classified into primary or secondary, and they did use validated instruments in their assessments of the effects. The results were clearly presented in graphs. The time-span under which the treatments lasted was not described and there is a risk of confounders in that all participants in the three groups were instructed to exercise during the intervention period. The authors reported no drop-out rate, therefore implying that there was no need for any description of the analysis based on intention-to-treat (ITT) or per protocol (PP), and there were no reference to the use of a study protocol [65].

The main purpose of the randomized controlled trial conducted by Malmros et al. was to detect the effects of physiotherapy on chronic pain and performance (1998). An overview of the demographic data and the number of patients who were eligible for inclusion was missing, as well as a description of which outcomes were primary and which were secondary. There are some ambiguities in terms of the use of questionnaires that were modified or designed by the authors to better suit the population without any discussion of their validation. They reported a small drop-out rate, yet the cohort itself was small (n = 53), and there was no description of how this was incorporated in the analysis. No reasons were stated for the block randomization and no reference was made to the completion of a power calculation or the intention of the analysis (ITT or PP). Reference to the study protocol was missing; however, the randomization process and the masking of the

| Table 3 Characteristics of included publications | ncluded publicati | ons | | | | | | |
|---|---|------------------------------------|---|---|-----------------------------|---|---|--|
| Authors | Year Country Patients Mean ag (year) | Patients | Mean age (year) | Study design | Study duration | Outcome variables | Intervention vs control | Discontinuation |
| Olsen C.F. & Bergland A. [61] 2014 Norway | | IT, 47; CT, 42 | 71.1 | RCT | 12 months | P, mobility; S, fear of falling | Exercise program 60 min/3 months vs. maintaining current | IT, 19% (9) discontinued; CT, 24% (10) discontinued |
| Papaioannou A., Adachi J. D., 2003 Canada Winegard K., Ferko N., Parkinson, W., Cook, R J., Webber, C & McCartney N. | 2003 Canada | IT, 37; CT, 37 | 71.6 | RCT | 12 months | P, QoL; S, function; S, bone mineral density | Home-based exercise program 60 min 3 days/week 6 months vs. maintaining current exercise | Home-based exercise program CT + IT, 19% (14) discontinued 60 min 3 days/week 6 months; 6 months vs. maintaining 23% (17) discontinued 12 months current exercise |
| Gold D.T., Shipp K.M., Pieper 2004 USA C.F., Duncan P. W., Martinez S. & Lyles K.W. [58] | 2004 USA | IT, 94; CT, 91 | 81 | RCT/cross-over | 12 months (6 + 6 months) | P, trunk extension; P, pain with activities; P, psychological symptoms | Exercise and coping classes 45 min 2 times/week 6 months vs. health education 6 months | IT, 10% (9) discontinued phase 1; 23% (22) discontinued phase 2; CT, 5, 5% (5) discontinued phase 1; 15% (14) discontinued phase 2 |
| Bergland A., Thorsen H. & Kåresen R. [59] | 2011 Norway | IT, 47; CT, 42 | 71.4 | RCT | 12 months | P, mobility (walking speed); S, mobility (up and go); S, HROOL | Circuit exercise and coping class 1 h 2 times/week in 3 months vs. maintaining current lifestyle | IT, 20% (9) discontinued; CT, 24% (10) discontinued |
| Malmros B., Mortensen L., Jensen M. B. & Charles P. [60] | 1998 Denmark IT, 27; CT, 25 | IT, 27; CT, 25 | IT, 65; CT, 68 | RCT | 22 weeks | Pain, Pain, use of analgesics; functional status, QoL, muncle errordth | Physiotherapeutic training 2 times/week 10 weeks vs. no training | IT, 11% (3) discontinued; CT, 8% (2) discontinued |
| Zambito A., Bianchini D., Gatti D., Rossini M., Adami S. & Viapiana O. [63] | 2007 Italy | HT, 35; IFT, 35; SHAM, 35 | IFT, 70.8; HT, 70.5; HT sham, 70.5 | RCT | 14 weeks | P, chronic low back pain | IFT therapy vs. HT therapy vs. sham HT therapy | P, chronic low back pain IFT therapy vs. HT therapy vs. HT (35) + IFT (35) + HT sham (35) P, chronic low back pain IFT therapy 0% discontinued |
| Kessenich C.R., Guyatt G.H., 2000 USA Patton C.L., Griffith., Hamlin A. & Rosen C.J. [57] | 2000 USA | IT, 25; CT,25 | IT, 71.7; CT, 69.6 | Observational study/cross sectional | 8 weeks | P, QoL | Support and educational group IT, 0% discontinued; 90 min 1 time/week in CT, 0% discontinued 8 weeks vs. usual clinical care | IT, 0% discontinued; CT, 0% discontinued |

Table 4 Assessment of risk of bias

| | Selection bias | Performance bias | Assessment bias | Attrition bias | Reporting bias |
|---------------------|----------------|------------------|-----------------|----------------|----------------|
| Olsen 2014 | + | + | + | + | ? |
| Papaioannou 2003 | + | ? | + | + | + |
| Gold 2004 | + | + | + | + | ? |
| Bergland 2011 | + | + | + | + | + |
| Malmros 1998 | ? | + | ? | ? | + |
| Zambito 2007 | + | ? | + | + | + |
| Kessenich 2000 | - | + | ? | + | + |

? unclear risk, + low risk, - high risk

testing personnel were well reported, as was the structure of the various questionnaires. The results were presented as median (25:75 percentiles) values, both in the tables and graphical models, which made it difficult to assimilate the correlation and impact of the results [62].

The randomized controlled trial implemented and reported by Bergland et al. (2011) [61], also reported by Olsen et al. (2014), had few ambiguities. The randomization process was well described in both articles, but the purpose of adopting an eight-block randomization was specified in neither. The demographic data differed between the two articles, in regards to mean age, falls during the last year, and use of analgesic, among other variables. The authors accounted for a relatively large drop-out rate (21%). Primary and secondary outcomes were well stated in both articles and were described based on clear definitions, with the use of validated instruments to evaluate the effects. The researchers discussed the potential risk of selection bias, in that only the healthiest were included in the study, and that there might be additional cofounders affecting the results, such as the effects on social contacts and attitudinal aspects. The study was registered at clinicaltrials. com [61, 63].

In the observational study by Kessenich et al. (2000) [59], there were ambiguities in terms of the selection of participants in the use of a convenience sample. The participants were assigned to the different study groups based on their personal preference, which could give distinct differences in the baseline variables. However, the study delivered a clear description of the recruitment process and the instruments used in assessing primary outcome of QoL. The study sample was small (n = 50) and no power calculations were described. The results were clearly illustrated and, although no significant differences could be shown, the authors discussed trends and possible clinical implication for the content of the intervention. The discussion section could be seen as sparse, but the authors discussed cofounders, which might explain the absence of significant differences [59].

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Results of individual studies

Physical mobility

Five randomized trials, representing altogether 489 participants, evaluated various exercise and/or educational programs designed to improve physical mobility (including these outcomes; mobility, function, balance, trunk extension, and muscle strength). These studies used various measurements when assessing the effects and each had some weaknesses in regards to study limitations, uncertain precision in the reporting, and publication bias (Table 5).

Bergland et al. (2011) [61] used maximum walking speed (seconds/min over 20 m) for assessing mobility before and after an exercise intervention aimed at improving balance, coordination, and posture to prevent falls and subsequent fractures. They found a significant improvement at follow-up at both 3 and 12 months. In assessing the effect on level of mobility, they used the Time Up and Go test (TUG), where the participant is asked to rise from a sitting position, walk a distance of 3 m, and then turn around again and sit down (seconds/min), and found improvement in the IT group at the 3- and 12-month follow-up [61]. This test was also used by Papaioannou et al. (2003) [64], but there were no significant differences found in their study [64]. The functional reach test (FR) is a way of identifying differences in balance by asking participants to stand up straight with one arm extended at a 90-degree angle and then extend as far as they can without taking a step. The effect is measured in centimeters from the difference between the upright and forward-leaning position. It was used by Bergland et al. (2011) [61] and showed significant differences at the 3-month follow-up, but the effects were lost at 12 months [61]. Olsen et al.'s (2014) publication is based on the same data as Bergland et al., and therefore describes the same findings in regards to their results from measuring maximum walking speed and the functional reach test [63]. The use of a force-plate measurement to detect differences in postural adjustment by measuring participants' balance on one or two legs was used in two studies;

| | Measurements | Intervention | Control | Comments |
|--|--|--|---|--|
| Physical mobility Olsen et al. 2014 | Maximum walking speed (sec/min over 20 m) | 3 months, −1.3 (95% CI −2.0, −0.6), between groups <i>p</i> < 0.01 12 months, | 3 months, 0.6 (95% CI -0.3, 1.4) 12 months, | Participants and administrator of the intervention was not blinded for allocation, but this is difficult given the nature of the intervention. The authors report a discontinuation of 21%, which can be seen as moderate. Assessment of mobility and balance can be seen as sensitive to |
| | Functional reach (cm) | -0.5 (95% CT -1.4, -0.3), between groups $p = 0.02$ 3 months, 1.6 (95% CT 0.1, 3.1), between groups $p < 0.01$ 1.2 months, 1.0 (95% CT -0.6, 2.6), | 05% CI -0.5, 1.8) (95% CI -0.5, 1.8) -2.2 (95% CI -3.8, -0.7) 12 months, 0.3 (95% CI -1.0, 1.6) | assessment blas in the nature of the testing. |
| Papaioannou et al. 2003 [64] | OQLQ (physical function) (range 1–7) | between groups $p = 0.49$ 6 months, 0.22 (95% CI -0.08, 0.52), between groups $p = 0.15$ 12 months, 0.16 (95% CI -0.35, 0.68), | | In the section on describing the management of the participants, it is unclear whether they or the practitioners were blinded or not, which may not be possible considering the nature of the intervention. The use of assessing mobility can be seen as sensitive to assessing bias. The randomization process was briefly described without reason for |
| | Stance test (balance) (sec) Time up and go (function) (sec) | between groups $p = 0.18$ 6 months, 0.80 (95% CT -1.45, -0.15), between groups $p = 0.01$ 6 months, -0.01 (95% CT -1.58, 1.56) Between groups | | using stratified and blocked limitations. |
| Gold et al. 2004 [60] | Trunk extension (B-200 isostation) (range 0–80 ft_ib) | p = 0.99 $p = 0.99$ Phase 1, 6.628, between groups 10.68, (95% CI 6.98–14.39), p = <0.01 Phase 2, -3.60 (95% CI -6.40–1.71), (95% CI -6.40–1.71), | Phase 1, -4.560 Phase 2, 15.02 (95% CI 10.80-19.27), | The assessment tool for trunk extension can be seen as sensitive to assessment bias due to its nature. In regards to the reporting of discontinuation, and the reasons for this, is unclear in the publication and also how they have incorporated this in the analysis |
| Bergland et al. 2011 [61] | Maximum walking speed (sec/min over 20 m) | within groups $p = 0.02$ 3 months, -1.3 (95% CI - 2.0, -0.6), between groups $p = 0.001$ 12 months, -0.9 (95% CI - 1.4, 0.3). | 3 months, $p = <0.01$ 3 months, $p = <0.01$ 0.6 (95% CI -0.3 , 1.4) 12 months, 0.6 months, 0.6 months, 0.6 | The process of randomization was implemented with a block of 8, for which the purpose is not stated. Assessment of mobility can be seen as sensitive for assessing bias. Due to the nature of the intervention, neither the practitioners nor the participants were blinded to the allocation of group. |
| | Time up and go (sec/min sitting-walk 3 m-sitting) | between groups $p = 0.019$ 3 months, 0.5 | 3 months, 0.4 | |

 Table 5
 Outcome physical mobility

| | Measurements | Intervention | Control | Comments |
|--------------------------|--|---|---|---|
| | Functional reach (cm) | (95% CI -0.9 , -0.01), between groups $p = 0.026$ 12 months, -0.6 (95% CI -1.0 , -0.2), between groups $p = 0.021$ 3 months, 1.7 (95% CI 0.1 , 3.1), between groups $p = 0.001$ 12 months, 1.1 (95% CI -0.7 , 2.7), between grounts $p = 0.001$ 12 months, | (95% CI0.2, 1.1) 12 months, 0.2 (95% CI -0.4, 0.7) 3 months, -2.2 (95% CI -3.8, -0.7) 12 months, -0.3 (95% CI -1.0, -1.6) | |
| | Qualeffo-41 physical function (range 0–100) | 3 months, -2.1 (95% CI -4.9, 0.8), between groups $p = 0.40$ 12 months, -2.5 (95% CI -5.0, -0.03), between grouns $p = 0.047$ | 3 months, -0.6 (95% CI -2.6, 1.5) 12 months, -1.0 (95% CI -1.5, 3.4) | |
| Malmros et al. 1998 [62] | Daily level of function (Oswestry questionnaire) (score 0–74) Balance (Chattecx balance system) (sway index) Arm strength (kg) | 10 weeks, Ca 15% Ca 15% 5 weeks, 5 weeks, 17.6 (95% CI 15.6, 20.1), between groups $p = 0.08$ 17.8 (95% CI 14.9, 19.3), between groups $p = 0.08$ 5 weeks, 5 weeks, 10 weeks, 10 weeks, 5 weeks, 10 weeks, | 10 weeks, Ca 45% Ca 50% 5 weeks, 5 weeks, 20.4 (95% CI 17.4, 25.4) 10 weeks, 21.1 (95% CI 16.4, 25.5) 5 weeks, 23.2 (95% CI 19.1, 27.3) 10 weeks, 23.6 (95% CI 20.2, 28.2) | There is a low risk of selection bias, but an explanation for using block limitation of 12 is not described. The study participants and the physiotherapist were not blinded to allocation due to the nature of the intervention; however, the evaluators were. The instrument used for assessing daily level of function was not validated after modification. |
| | | between groups $p = 0.08$ | | |

 Table 5 (continued)

Papaioannou et al. found a significant difference in balance between groups after 6 and 12 months, after implementation of an intervention comprising a home-based exercise program of 60 min/day 3 days a week [64]. However, Malmros et al. (1998) [62] did not find any significant differences, but were still able to show a trend of improvement in balance in the intervention group after a 10-week exercise program [62]. Gold et al. (2004) [60] reported the findings of a randomized cross-over intervention study. The content of the intervention was either a physical therapist-led exercise class addressing trunk weakness, reduced trunk flexibility, and difficulties with erect posture, or a psychiatric social worker-led coping class undertaken for 45 min 2 times/week, addressing coping skills, stress reduction and relaxation, networking skills, and lifestyle modifications. The primary outcome of trunk extension was assessed using B-200 Isostation, which is a standard protocol for measuring strength. The results show a significant difference between groups after phase 1 (p = 0.01) and phase 2 (p < 0.01) [60]. There were also questionnaires employed, which were found to be relevant in assessing function and mobility. The Quality of Life Questionnaire issued by the European Foundation for Osteoporosis (QUALEFFO-41) is a diagnosis-specific quality-of-life instrument, consisting of 41 questions arranged in five domains: pain, physical function, social function, general health perception, and mental function, and was used in one of the studies [61]. The various exercise and/or educational programs reported in these five studies probably improve physical mobility and the quality of evidence was rated as moderate (GRADE +++0) for each.

Pain

The outcome of pain was divided into two different assessments of quality of evidence due to the diversity of the interventions. Two randomized trials, including a total of 237 participants, explored exercise versus no intervention, or coping classes focusing on stress reduction and lifestyle modifications. One randomized trial explored the effects of electric stimulation versus "sham" stimulation (Table 6). All three studies had some study limitations and uncertainty of precision, and the two studies exploring exercise also showed some inconsistencies and indirectness in population selection.

Various scales were commonly applied in the assessment of pain. Malmros et al. (1998) [62] used an 11-point box scale (0=no pain, 10= maximal pain) to describe the effect of a 10week exercise intervention on pain. They found a decrease in pain in the training group, whereas the control group showed little change over time and the differences between groups were significant. The use of analgesic was also assessed, using an instrument developed by Manniche et al. (1994), as an indicator of intensity of pain and showed a decrease in the training group compared with the control [62]. Another study used a sub-scale of the Functional Status Index (FSI) to assess pain with activity after a two-phase (6 months) cross-over intervention study which suggested a worsening in the control group but no significant differences between groups [60]. The results show that exercise and/or coping classes may slightly improve levels of pain and the quality of evidence was rated as low (GRADE ++00).

Zambito et al. 2007 used a standard VAS scale with an additional functional questionnaire to describe the results of their intervention of electric stimulation applied in a standard dermatomal pattern (interferential therapy (IFT)) or lumbar zone and posterior site of thighs (horizontal therapy (HT)) versus "sham" stimulation, i.e., placement of pads at the same sites but without electric stimulation. By using the Backhill questionnaire, the authors could show results, with 100% attendance, of a significant improvement in perceived pain in all of the three groups at 6 and 14 weeks, with a small but not significantly better effect of the HT. After the initial improvement, the placebo group slowly became worse in their VAS scores during follow-up, whereas the two treatment groups continued to improve [65]. The results imply that electric stimulation probably improves pain and the quality of evidence was graded as moderate (GRADE +++0).

Social and physical isolation

No study reported the outcome of social and physical isolation.

Quality of life

The outcome of quality of life/health-related quality of life was reported in three randomized trials and one observational study, making it difficult to perform a general GRADE classification without differentiating study design in the analysis. The assessment of three randomized trials, with a total of 215 participants, on the effects of exercise classes and/or coping classes (focusing on body awareness, osteoporosis, nutrition, pain control, and ergonomic advice in everyday situations) versus current level of exercise, showed few study limitations but some uncertainty in terms of precision and directness (Table 7). Bergland et al. used QUALEFFO-41 and a generic questionnaire, the General Health Questionnaire (GHQ-20), to detect the effects of their intervention. The level of general health showed significant improvement at 3 months, but not at 12 months, whereas the results for QUALEFFO-41 indicated the opposite, with more significant differences at 12 months rather than 3 months [61]. Papaioannou et al. (2003) [64] described the findings of a home-based exercise intervention, aiming to integrate short exercise sessions in the participants' daily lives. The primary outcome of QoL was assessed using the diagnosis-specific Osteoporosis Quality of Life Questionnaire (OQLQ) and a general HRQoL questionnaire, the Sickness Impact Profile (SIP). The results of the scores

| Table 6 Outcome pain | | | | 552 |
|----------------------------------|---|---|---|--|
| | Measurements | Intervention | Control | Comments |
| Pain Malmros et al. 1998 [62] | Pain level (range 0–10) Use of analgesic (0–20; 20 – no analgesic) | 5 weeks, 70% < 3 score, between groups $p = 0.02$ 10/22 weeks, Ca $80\% < 3$ score, between groups $p = 0.02$ 5 weeks, ca $60\% 20$ score 10/22 weeks, ca $60/55\% 20$ score | 5 weeks, 60% <3 score 10/22 weeks, Ca 60% <3score 5 weeks, 40% 20 score 10/22 weeks, 45/40% 70 score | The use of PP or ITT was not described The study participants and the physiotherapist were not blinded to allocation due to the nature of the intervention; however, the evaluators were. |
| Gold et al. 2004 [60] | Pain with activity FSI (range 1–4) | Phase 1, -0.022, between groups-0.03, (95% CI -0. 14, -0.08), p = 0.64 Phase 2, -0.03 (95% CI -0.11, -0.06), within ground s = 0.64 | Phase 1, 0.004 Phase 2, -0.03 (95% CI -0.11 , -0.17), within groups $p = 0.70$ | • An in-advance published study protocol is missing and chosen outcomes cannot be audited. |
| Zambito et al. 2007 | Pain score (VAS) (range 0–10) | waim groups $p = 0.54$ 2 weeks, HT 6 score, FT ca 7 score 6 weeks, HT ca 5.5 score, IFT 5 score, between groups $p \le 0.01$ 14 weeks, HT ca 4.5 score, IFT ca 5.5 score, between groups | 2 weeks, sham HT ca 6 score 6 weeks, sham HT 6.2 score 14 weeks, sham HT ca 7 score | The randomize process is well described but without but without any given explanation to the block limitation. Both the participants and the physicians that evaluated the patients and administered the questionnaires where blinded to the allocation of treatment. There is a lack of clarity on which outcomes were primary and if there were any other primary and pri |
| | Backhill (range 0–40) | p = 0.01 2 weeks, HT ca 27 score, IFT ca 27 score 6 weeks, HT ca 29 score, IFT ca 28 score, between groups p = <0.01 14 weeks, HT ca 32 score, IFT ca 29 score, between groups p = <0.01 | 2 weeks, sham HT 25 score 6 weeks, sham HT ca 25 score 14 weeks, sham HT 25 score | • There was neither any report of adverse events due to the treatment. |

| Table 7 Outcome quality of life | fe | | | |
|--|--|--|--|--|
| | Measurements | Intervention | Control | Comments |
| Quality of life Bergland et al. 2011 [61] | GHQ-20 (range 0-3) QUALEFFO-41 total (range | 3 months, -3.7 (95% CI -5.5, -1.9), between groups $p = 0.009$ 12 months, -2.8 (95% CI -4.6, -1.0), between groups $p = 0.17$ 3 months, | 3 months, -0.2 (95% CI -2.1, 1.7) 12 months, -1.1 (95% CI -2.8, 0.7) 3 months, | There is no description of how the authors balanced baseline variables, even though the discontinuation was small. There are no reports of an in-advance published study protocol. |
| Papaioannou et al. 2003 [64] | 0–100) OQLQ (mean changes) (range1–7) | -2.1 (95% CI -4.2, -0.02), between groups $p = 0.15$ 12 months, -3.3 (95% CI -5.2, -1.3), between groups $p = 0.019$ Between groups Symptoms 6 months, 0.44 | 0.2 (95% CI -2.2, 2.5) 12 months, -0.4 (95% CI -2.0, -2.7) | It is unclear whether they or the practitioners were blinded or not, which may not be possible considering the nature of the intervention. There is also a question regarding reporting as they did not |
| | | (95% CI 0.16, 0.73), p = 0.003; 12 months, 0.38 0.38 (95% CI $-0.05, 0.81$), p = 0.02 Emotion, 6 months, 0.34 (95% CI 0.02, 0.66), p = 0.01; 12 months, 0.30 | | refer to any published study protocol and there were no structured descriptions of adverse events or complications occurring during the intervention. |
| | | (95% CI -0.21, 0.81), p = 0.10 Leisure/social, 6 months, 0.39 (95% CI -0.02, 0.81), p = 0.03; 12 months, 0.26 (95% CI -0.22, 0.74), p = 0.09 6 months, | | |

| | Measurements | Intervention | Control | Comments |
|----------------------------|--|--|--|---|
| | SIP (mean changes) (range 0–68) | 0.55 (95% CI $-1.81, 2.91$), between grouns $n = 0.54$ | | |
| Kessenich et al. 2000 [59] | Cantril ladder (range 0–10, mean changes) | 8 weeks, 7.4, between groups -0.32 (95% CT -0.94, 0.30), <i>n</i> = 0.30 | 8 weeks, 6.8 | In this study, there is a high risk for selection bias since the participants were allocated through own preferences. This will contribute to a difference between groups at baseline, nerhans not in demographic data but on level of motivation |
| | SF-36 (physical) (range 0–100, mean change) | 8 weeks, 38.4, between groups 2.06 (95% CI -0.76, 4.89), p = 0.15 | 8 weeks, 36.7 | and physical function. • No previously published study-protocol was described. |
| | SF-36 (mental) (range 0–100, mean changes) | 8 weeks, 52.8, between groups 2.00 (95% CI -1.82, 5.82), p = 0.30 | 8 weeks, 51.7 | |
| | OQLQ (range 1–7, mean changes) | 8 weeks, Symptoms, 5.0, between groups 0.15 (95% CI -0.26, 0.56), <i>p</i> = 0.46 | 8 weeks, Symptoms, 5.1 | |
| | | Emotion, 5.1, between groups 0.08 (95% CI -0.27, 0.43) p = 0.64 Leisure/social, 5.3, between groups 0.2 (95% CI -0.26, 0.66), n = 0.38 | Emotion, 5.3 Leisure/social, 5.5 | |
| Malmros et al. 1998 [62] | QoL (own questionnaire) (range 0-20) | 5 weeks, 5 weeks, 65% > 120 score, between groups $p = 0.01$ 10 weeks, 85% > 120 score, between groups $p = 0.0001$ 22 weeks, 75\% > 120 score, between groups $p = 0.0008$ | 5 weeks, 35% >120 score 10 weeks, 15% >120 score 22 weeks, 25% >120 score | An in-advance published study protocol was not described and which outcomes were primary or secondary is unclear. In this publication, there are some unclear risks of bias in that the instruments used for assessing QoL were not validated. |

Table 7 (continued)

showed an improvement in the intervention group compared with the control group regarding quality of life symptoms and social activity (at both 6 and 12 months), and emotion and leisure only at 6 months but not at 12 months [64]. Malmros et al. (1998) [62] also showed significant effects on QoL at all follow-ups using an instrument of their own design to better fit the Danish population [62]. Exercise and/or coping classes were found to probably improve quality of life and the quality of evidence was graded as moderate (GRADE +++0).

The assessment of the observational study by Kessenich et al. revealed serious study limitations, including selection bias, and uncertainty of directness and precision. In assessing the effects of educational support, Kessenich et al. (2000) [59] used a generic and well-used instrument, the Medical Outcome Survey short form (SF-36), with the addition of the 10-step Cantril Ladder, assessing perception of health, and OQLQ. However, their 8-week follow-up observational study showed no effects on quality of life between the intervention group and control group [59]. It is uncertain whether educational support has any effect on quality of life and this study holds a very low quality of evidence (GRADE +000).

Fear of falling

The audit of one randomized trial on the effects of an exercise/ educational program on fear of falling showed some uncertainty of directness. Olsen et al. (2014) described an exercise intervention with an additional 3-h education and guidance session held by a physiotherapist with the focus on coping techniques, body awareness, and ergonomic advice in everyday situations (Table 8). They used the Falls Efficacy Scale International (FES-I) measure, and the results showed a significant reduction within the intervention group and also a significant difference between intervention and control group at 3 and 12 months. They also reported an increase of fear of falling within the control group, where 38% went from low to high level of concerns related to falling [63]. The results of this study imply that exercise and education probably decrease

Table 8 Outcome fear of falling

fear of falling, and the study was assessed as having a moderate quality of evidence (GRADE +++0).

Psychological symptoms

Gold et al.'s (2004) [60] randomized trial evaluated a 12month cross-over intervention study with both physical therapist-led exercise class addressing trunk weakness, reduced trunk flexibility and difficulties with erect posture and coping classes addressing stress reduction, relaxation and lifestyle modifications. The review revealed that this study had some limitations as well as ambiguities regarding directness. They used the Global Severity Index (GSI), which comprises 90 questions designed to measure how a person believes they have felt mentally and physically over the past week based on a five-point scale (0-4). Divided into nine subscale, somatization, obsessive compulsive, interpersonal sensitivity, depression, anxiety, hostility/anger, phobic anxiety, paranoid thinking, and psychopathy, the results are calculated and presented in an index (Table 9). They showed a significant difference (p < 0.01) between intervention and control group during phase 1 as well as during phase 2 (p = 0.0064) [60]. The results of this study showed that exercise and coping classes probably decrease psychological symptoms and the quality of evidence was graded as moderate (GRADE +++0).

Syntheses of results

The trials included in this review have several limitations and were mainly considered to be of moderate quality. In general, all of the studies provided a clear description of the allocation of concealment, and, if relevant, the randomization process. Across trials, the mean age of participants ranged from 65 to 81 years, and follow-up time points ranged from 8 weeks to 12 months from baseline. The outcomes were clearly defined in all of the trials; however, only two referred to the use of a previously published study protocol. Adherence across trials was reported as high, with an average drop-out and withdrawal rate of 21%, but only three of the RCTs performed power

| | Measurements | Intervention | Control | Comments |
|-------------------|---|--|---|---|
| Fear of falling | | | | |
| Olsen et al. 2014 | FES-1 (range 16–64 (1–4), mean change) | 3 months, -2.5 (95% CI -4.2, -0.7), between groups <i>p</i> = 0.004 12 months, -2.7 (95% CI -4.4, -0.9), between groups <i>p</i> < 0.01 | 3 months, 0.8 (95% CI 0.6, 2.1) 12 months, 2.8 (95% CI 1.0, 4.5) | • Participants and administrator of the intervention was not blinded for allocation, but this is difficult given the nature of the intervention. |

| Table 9 | Outcome | psychological | symptoms |
|---------|---------|---------------|----------|
|---------|---------|---------------|----------|

| | Measurements | Intervention | Control | Comments |
|-----------------------|---|--|---|---|
| Psychological symptor | ns | | | |
| Gold et al. 2004 [60] | Psychological symptoms GSI (range 0–4) | Phase 1, -0.018, between groups -0.08 (95% CI -0.2, -0.10), $p < 0.01$ Phase 2, -0.01 (95% CI -0.06-0.03), within groups $p = 0.60$ | Phase 1, 0.062 Phase 2, -0.11 (95% CI 10.19–13.3), within groups $p = 0.006$ | • Participants and administrator of the intervention was not blinded for allocation, but this is difficult given the nature of the intervention. |

analyses to ensure that the sample sizes were sufficient to detect differences between the study populations. In five of the randomized trials, the analysis was based on ITT and they all reported relatively homogeneous groups at baseline. Three trials used statistical correction, adjusting for the small imbalances between groups. Four trials reported the source of funding and only two disclosed no conflict of interest.

Because the study interventions and reported outcome measures, to a great extent, varied, we focused on narrative assessment of the studies, their results, their applicability, and their limitations, as well as the quality of the study based on a qualitative synthesis level rather than on a meta-analysis.

Risk of bias across studies

The limited number of studies eligible for inclusion in this review prevents further analysis of assessing the risk of bias across studies.

Discussion

This systematic review suggests that non-medical interventions aimed at supporting older women with VCF might decrease levels of pain and the use of analgesic as well as improve physical mobility and function. The interventions probably result in differences in experiences of fear of falling and perceived psychological symptoms, but only slightly improve quality of life. However, given the nature of the seven studies, potential biases in patient selection, precision with small cohorts, and failure to control for confounders, makes it difficult to draw a definitive conclusion about the significant effects of the studied non-medical interventions.

It becomes clear from this review that the availability of evidence on the effects of non-medical interventions aimed at supporting older women with VCF is limited, to say the least. In addition, studies addressing the sense of entrapment and of being disregarded, which have been shown to be prominent features for this population, were missing. The included intervention studies mainly evaluated concrete and measurable variables, but incurring a VCF is a complex and extensive process that not only affects physical ability but also raises mental and social issues that must be addressed in order to be better able to support these women.

The available intervention studies showed low to moderate quality according to GRADE criteria due to several reasons: one being that the studies evaluated the effects of complex interventions in a patient population with multifaceted functional limitations and care needs. According to Craig et al. (2008) [66], complex interventions can be defined based on the number of interacting components, the degree of flexibility among these components, the number of organizational levels targeted, and the level of difficulty of the implementation. They depend on clear definitions of context (which differ not only by site but also by time), the problem being examined, the population most at risk, and an understanding of how the intervention is likely to work. By their very nature, complex interventions include both known and unknown confounders and mediators which might make it difficult to detect "true" effects. When studies report negative results [59], one could ask whether the intervention really did not have any effect or whether it rather suggests that the intervention was improperly designed, conducted in the wrong way in the wrong context, or whether it is a fragile design in group composition with inappropriate timing of follow-up and outcome measurement. In the same way, studies that report mainly positive results [61, 63] may be challenged in their ability to apply the results in other contexts due to individual differences in the performance of the intervention and the unfeasibility of replication. The use of complex interventions is increasing within the field of healthcare and guidelines on how to avoid major methodological difficulties have been formulated. However, the use of complex interventions places high demands on transparency and clarity in the presentation of the study results to create possibilities for replication [66-68].

Regardless of the variety in design, all of the studies targeted similar participants with comparable inclusion and exclusion criteria. On the other hand, all of the studies can been seen as having a risk of selection bias in that the content of the interventions requires a certain level of physical activity and may only include women who have the strength to participate, thus overlooking those with the most severe disability and adverse symptoms. This provides problems in generalization of the results to the wider population and makes it difficult to comment on the true effects of the group at large. Therefore, there is a risk that the findings provide a biased description, even perhaps an underestimation of the effects of a given intervention, and that the vast number of ineligible and unreported women remain unheard and unseen.

The studies that included physical activity as part of the intervention used training programs that were tailored to the population and considered some individual differences in ability, which could be seen as individualized or person-centered to some degree [60-64]. However, more research is needed to explore the possibilities of designing person-centered interventions aimed at supporting and motivating women to move forward in managing their condition instead of letting them enter a negative transition towards increased isolation and loneliness with subsequent diminished self-esteem and confidence in their own ability. Previous research has shown that these women are resourceful and have a high level of engagement and willingness to find ways forward, an attribute which should be considered as the point of departure in their rehabilitation and care plan. In immediate and close collaboration with the patient and the relatives, the care can be tailored according to each person's needs, preferences, ambitions, and resources in defining their short- and long-term goals [27-29, 69]. Traditionally, healthcare professionals have decided what is best for the patients and which form of rehabilitation and care that is appropriate, but from an objective point of view [70]. By including the person in the planning of their own rehabilitation and care, it becomes possible to enter a partnership between care-givers and care-users to empower their confidence in their own ability, which is the key to a successful recovery process [27-29, 71].

Agreements and disagreements

In a Cochrane review published in 2013, Giangregorio et al. (2013) [72] analyzed and rated seven studies (four of which are included in the present review) with the aim of describing the state of the research on exercise and its impact on outcomes after a vertebral fracture [72]. The focus of the present study lies within the field of nursing sciences and includes both the effects of interventions targeting VCF on physical functions as well as its effects on psychological and social aspects. These outcomes should also involve the impact of the effects of any given intervention on lived experience of bodily limitations, changes in self-image and life situation, and altered ability to social interaction. To our knowledge, little is known of the effects of person-centered care or supportive interventions for patients affected by VCF, not only those aimed at improving well-being and strengthening the

sense of security, but also at increasing an individual's confidence in their own ability to maintain physical mobility levels and thereby reduce frailty.

Method discussion

In the search for eligible publications for this review, we used a small number of restrictions, as further limitations were likely to exclude suitable studies. Additionally, there were no limitations in relation to publication dates, which one might argue could affect the outcome of the review. However, because the search resulted in such a sparse number of interventions, this might rather reinforce the findings that surprisingly few studies have been conducted in this population. The studies included had a publication date ranging from the year 1998 to 2014, which may underline the fact that there has not been any considerable development within the field of non-medical support for older women living with osteoporotic vertebral compression fractures.

In the present review, we used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, developed by the GRADE Working Group, in assessing the quality of evidence within the defined research field. This method provides a transparent and structured assessment of quality and strength of recommendations, although the subjective judgment of the individual reviewers remains as an underlying reason for potential variation in the assessment [73–79].

Limitations

The included trials used various methods of measurement to assess the effects of the same or similar outcomes. The clinical heterogeneity of the studies makes it impossible to compile, collate, and visualize the results in a meta-analysis and/or summary of findings and also to comment on the combined effects of the results. In the assessment of quality of evidence of the outcome of physical mobility, we merged five outcomes (mobility, functional status, balance, trunk extension, and muscle strength) to be able to comment on the probability of the effects on a richer dataset with more participants.

Future research

Given the nature of the studies and the multiple biases that could have affected the results and related assumptions, it would be of utmost importance to conduct further randomized controlled studies. These should have well-defined interventions, taking into account the population's fragility, with wellchosen outcomes measured at appropriate follow-up times to detect long-lasting and meaningful differences. Also, future research should include those with the most prominent symptoms to find pathways to promising care transitions and to provide optimal healthcare and rehabilitation for these women.

Conclusion

Because the experience of incurring a VCF is such a complex and diverse event, it needs equally complex interventions to identify new ways forward in the treatment pathway. However, the interventions to date struggle with a risk of selection bias in that only the needs of the healthiest of the population are addressed and the voices of the remaining majority of the people affected by VCF are unheard. To be able to reach this frail and vulnerable population, healthcare providers need to incorporate the person's needs, preferences, ambitions, and resources, despite their infirmities, to attain a successful rehabilitation and a healthy transition towards a phase of stability and acceptance.

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Compliance with ethical standards

Funding Funding sources had no involvement in the design, methods, data collection, analysis or preparation of this manuscript, or the decision to submit for publication. The corresponding author had full access to the data in this study and final responsibility for the decision to submit for publication. All authors meet the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

Conflicts of interest None.

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