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Pilot Study of Massage in Veterans with Knee Osteoarthritis

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Abstract

Objectives: To (1) assess the feasibility and acceptability of Swedish massage among Department of Veterans Affairs (VA) health care users with knee osteoarthritis (OA) and (2) collect preliminary data on efficacy of Swedish massage in this patient group.
Design: Experimental pilot study.
Setting: Duke Integrative Medicine clinic and VA Medical Center, Durham, North Carolina.
Patients: Twenty-five veterans with symptomatic knee OA.
Interventions: Eight weekly 1-hour sessions of full-body Swedish massage.
Outcome measures: Primary: Western Ontario and McMaster University Osteoarthritis Index (WOMAC) and global pain (Visual Analog Scale [VAS]). Secondary: National Institutes of Health Patient Reported Outcomes Measurement Information System-Pain Interference Questionnaire 6b (PROMIS-PI 6b), 12-Item Short-Form Health Survey (SF-12 v1) and the EuroQol health status index (EQ-5D-5L), knee range of motion (ROM), and time to walk 50 feet.
Results: Study feasibility was established by a 92% retention rate with 99% of massage visits and 100% of research visits completed. Results showed significant improvements in self-reported OA-related pain, stiffness and function (30% improvement in Global WOMAC scores; $p = 0.001$) and knee pain over the past 7 days (36% improvement in VAS score; $p < 0.001$). PROMIS-PI, EQ-5D-5L, and physical composite score of the SF-12 also significantly improved ($p < 0.01$ for all), while the mental composite score of the SF-12 and knee ROM showed trends toward significant improvement. Time to walk 50 feet did not significantly improve.
Conclusions: Results of this pilot study support the feasibility and acceptability of Swedish massage among VA health care users as well as preliminary data suggesting its efficacy for reducing pain due to knee OA. If results are confirmed in a larger randomized trial, massage could be an important component of regular care for these patients.

Introduction

Osteoarthritis (OA) affects nearly 27 million Americans, and its prevalence is expected to rise considerably in the next several decades.[1] Knee OA is particularly common, with a lifetime risk of 45%.[2] OA in general, and knee OA in particular, is more common in U.S. military veterans than in the general population, and Department of Veterans Affairs (VA) health care users are at particularly high risk.[3] In addition, VA health care users with arthritis (most commonly knee OA) have more severe symptoms and activity limitations.[4] In veterans, OA (including knee OA) commonly co-occurs with other chronic pain conditions, post-traumatic stress disorder, and substance abuse.[5]

Currently, a variety of conventional treatment options for knee OA are available, including pain medication, corticosteroid injections, physical therapy, exercise, weight management, and joint replacement surgery.[6] When traditional treatment approaches are used, many patients with knee OA continue to experience symptoms such as chronic pain and

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functional limitations that reduce quality of life.[7] Accordingly, there remains a pressing need to identify additional effective, conservative treatments for knee OA that improve pain, functioning, and overall well-being in these patients.

Massage therapy is effective for musculoskeletal disorders, such as chronic back and neck pain,[8] and is an effective treatment for managing pain associated with knee OA.[9] For massage to be integrated into a comprehensive pain management program, a systematic approach and dosage of massage therapy needs to be established. A prior study demonstrated the efficacy of a specific manualized protocol of Swedish massage for improving pain, stiffness, and functioning due to knee OA in non-veterans.[9] A subsequent study established an optimal dosage for the protocol: eight weekly 1-hour sessions.[10]

Although there is promising evidence for massage as an effective treatment for knee OA, further studies must evaluate its effectiveness in diverse patient groups. VA health care users are an important patient group for studying this treatment for several reasons. First, given VA health care users' particularly high risk for activity-limiting knee OA, it is important to identify effective interventions for this vulnerable patient group. Second, the demographic profile of VA health care users differs substantially from that of participant samples in previous studies of massage for knee OA.[9,10] Most of these patients are men, and the acceptability of massage in this group has not been sufficiently evaluated. Third, VA health care users with knee OA have higher levels of physical and psychological comorbidities that could influence or be affected by massage.[5] This pilot study evaluated a previously established massage therapy protocol in a new population: VA health care users with knee OA. Core objectives of this study were to (1) assess the feasibility and acceptability of Swedish massage among VA health care users with knee OA and (2) collect preliminary data on the efficacy of Swedish massage in this patient group.

Materials and Methods

This was a single group pilot study, with all participants receiving a 1-hour-per-week intervention of Swedish massage for 8 weeks. Assessments were conducted before and after the intervention. The institutional review boards of Duke University and the Durham VA Medical Center reviewed and approved the study.

Participants

Primary eligibility requirements included (1) VA health care users; (2) age ≥ 35 years; (3) written confirmation of OA of the knee per American College of Rheumatology criteria[6] provided by the participant's physician; (4) radiographically established OA of the knee; and (5) a prerandomization score in a specified range on the Visual Analog Scale (VAS; ≥ 40 mm and ≤ 90 mm on a 40–100 mm scale). For patients with bilateral knee involvement, the study knee was determined by the patient as being the more problematic/painful knee. Exclusion criteria included (1) any intra-articular knee depo-corticosteroid within the last 3 months, (2) intra-articular hyaluronate within the past 6 months, (3) arthroscopy within the past year, (4) knee replacement surgery, (5) significant injury within the past 6 months, and (6) presence of a rash or open wound over the knee. Participants missing the research visit or three or more massage visits could be withdrawn from the study at the discretion of the study principal investigator.

Patients with knee OA at the Durham VA Medical Center were recruited by using two methods. First, posters were displayed in clinic waiting rooms and other common areas of the medical center. Second, invitation letters were sent to patients who were identified as having knee OA from Durham VA electronic medical records. These letters provided basic information about the study and invited patients to call if they were interested in participating. The first 25 eligible participants to send a letter from their physician verifying their diagnosis of knee OA were enrolled in the study. Participants meeting all criteria gave written informed consent before enrolling in the study.

Study design and treatment

Participants received eight weekly 1-hour Swedish massages at Duke Integrative Medicine's clinical facilities, 1 mile from the Durham VA Medical Center. Massage therapists were certified by the National Certification Board for Therapeutic Massage & Bodywork adhered to a manualized massage protocol previously tested to treat OA of the knee.[10] Therapists announced their next technique or position in order to minimize potential client startle in a population with high prevalence of post-traumatic stress disorder. Each study therapist signed a form attesting to adherence to the study protocol after each massage session.

The primary outcome measure used to assess OA-related pain, stiffness, and function was the Western Ontario and McMaster University Arthritis Index (WOMAC) global score (VAS version). The WOMAC has been subject to numerous validation studies to assess reliability and responsiveness to change in therapy, including physical forms of therapy.[11] In addition, participants were asked to respond to the question, ''How much pain have you had because of your knee in the past week?'' using a 100-point VAS.

Secondary outcomes included measures of other domains of high relevance to patients with knee OA: the National Institutes of Health Patient Reported Outcomes Measurement Information System-Pain Interference Questionnaire 6b (PROMIS-PI 6b).[12] This instrument consists of six questions that follow the format, ''In the past 7 days, how much did pain interfere with [*insert category*]?'' and allows responses on a 5-point scale (1 = not at all/never, 5 = very much/always). The six categories include enjoyment of life, ability to concentrate, day-to-day activities, enjoyment of recreational activities, doing tasks away from home (e.g., getting groceries, running errands), and socializing with others. Measures used to assess change in perceived health status included EQ-5D-5L,[13] a non–disease-specific instrument for describing and valuing health-related quality of life, and the Short Form-12 (SF-12), version 1.[14] The SF-12 Health Survey is a 12-item subset of the SF-36 that measures the same eight domains of health as the longer scale. It is a brief, reliable measure of overall health status which is useful in large population health surveys and has been used extensively as a screening tool. Knee range of motion (ROM), measured manually with a goniometer to the onset of stiffness, and 50-foot walk test were also measured. Maximal walking speed is a more reliable and predictive

Table 1. Patient Characteristics

Characteristic	*Value*
Total sample (*n*)	25
Mean age at baseline (yr)	56.96 ± 11.98
Mean BMI (kg/m^2)	31.58 ± 7.71
Men, *n* (%)	17 (68)
Hispanic ethnicity, *n* (%)	0 (0)
Race, *n* (%)	
American Indian/Alaska Native	0 (0)
Asian	1 (4)
Black or African American	13 (52)
Native Hawaiian or other Pacific Islander	0 (0)
White	11 (44)
Currently employed (working for pay), *n* (%)	8 (32)

Values are expressed as the mean ± standard deviation or number (percentage) of patients.
BMI, body–mass index.

measure of walking ability than walking at a comfortable pace.[15,16] Participants were asked to walk as fast as they safely could with or without a walking aid. They were timed from a standing start until the point at which they walked through the 50-foot (15.24-meter) marker. Additional post-study questions were asked of all participants during the final visit to assess study acceptability (Appendix 1).

Statistical analysis

Paired-samples *t* tests were used to examine the effects of treatment on change in outcomes at baseline and immediately after the intervention. In all analyses, statistical significance is reported using a two-tailed α level of 0.05 or less, and the 95% confidence interval for all parameter estimates are provided. All analyses were carried out by using SAS software, version 9.3 (SAS Institute, Cary, NC).

Results

Feasibility and participant characteristics

Of the 104 potential participants completing the telephone screening, 56 were determined to be eligible (41 were ineligible and 7 declined participation), and the first 25 ($n=25$) to submit a letter from their physician confirming the diagnosis of OA by radiography were enrolled. Among the 25 study participants, the mean age was 57.0 (standard deviation, 12.0); most participants were men (68%), 52% were black or African American, and 68% were not employed (Table 1). During the study, 1 participant withdrew, and another participant was withdrawn by the principal investigator after missing three consecutive appointments. The remaining 23 participants (92%) completed the study. Study feasibility was established by the 92% retention rate with 99% of massage visits and 100% of research visits completed.

Primary outcome measures

Participants' mean WOMAC global score improved by 30% ($p=0.001$), as shown in Table 2. Significant improvement was observed on all subscales of the WOMAC index, including the pain subscale ($p<0.001$), stiffness subscale ($p=0.006$), and the function subscale ($p<0.001$). Participants' VAS scores also showed an average improvement of 36% ($p<0.001$).

Secondary outcome measures

Perceived health status as measured with the EQ-5D-5L and the SF-12 also improved significantly (Table 3). Improvements in the SF-12 physical composite score reached statistical significance ($p<0.01$). However, improvements in the SF-12 mental component score only exhibited a trend toward improvement ($p=0.080$). The PROMIS-PI 6b (Table 3) showed a 15% improvement ($p<0.01$). A trend in the expected direction was observed for knee ROM, but this did not reach statistical significance ($p=0.087$). There was no significant change in the 50-foot walk test ($p=0.121$).

Responses to post-study questions confirmed acceptability, feasibility, and a positive response to the treatment (full questions and responses listed in Appendix 1; $n=23$ for all questions). These questions were not part of a standardized instrument but were developed specifically for this study to assess aspects of patient satisfaction that were important to evaluate in the context of this pilot/feasibility study. An overwhelming majority of respondents answered ''yes'' to the following questions: ''Would you like to continue massage as part of the on-going management of your knee arthritis?'' (91%) and ''Was the schedule of visits (60 minutes/week) convenient for you?'' (96%).

When asked about the likelihood that other veterans would want to try massage if it were offered at the VA, 87% responded that it was very likely or somewhat likely, and 83% of respondents answered ''yes'' to the post-study question: ''Did you notice any other changes in your health or other aspects of your life since starting the massage?''

Table 2. Changes in Primary Outcome Measures

Variable	*Mean before (SD)*	*Mean after (SD)*	*Mean paired difference (95% CI)*	p-*Value*	*Percent improvement*
WOMAC					
Global	66.4 (13.8)	45.4 (22.6)	−21.0 (−32.2 to −9.9)	0.001*	30
Pain	63.0 (14.8)	42.0 (27.3)	−22.5 (−33.6 to −11.4)	<0.001*	37
Stiffness	69.1 (18.0)	52.8 (24.0)	−16.3 (−27.5 to −5.2)	0.006*	21
Function	65.0 (13.7)	41.5 (21.0)	−23.6 (−35.0 to −12.2)	<0.001*	32
VAS	69.4 (13.8)	43.0 (25.1)	−26.4 (−38.5 to −14.2)	<0.001*	36

*Indicates significance at level $p < 0.05$.
CI, confidence interval; SD, standard deviation; VAS, visual analog scale; WOMAC, Western Ontario and McMaster University Osteoarthritis Index.

Table 3. Changes in Secondary Outcome Measures

Variable	*Pre*	*Post*	*Patients* (n)	p-*Value*	*Change (95% confidence interval)*
EQ-5D-5L	0.60 ± .16	0.68 ± .15	23	0.002[a]	0.08 (0.03 to 0.1)
SF-12, PCS	28.1 ± 7.5	33.6 ± 10.5	13[b]	0.002[a]	5.5 (2.4 to 8.6)
SF-12, MCS	43.7 ± 18.3	50.7 ± 14.9	6[b]	0.080[c]	7.0 (−1.2 to 15.3)
PROMIS-PI	20.1 ± 5.0	17.0 ± 5.9	23	0.005[a]	−3.2 (−5.3 to −1.1)
Knee range of motion (degrees)	113.9 ± 13.0	117.5 ± 15.0	23	0.087	3.6 (−0.6 to 7.8)
50-ft walk (sec)	13.5 ± 2.2	12.8 ± 2.4	23	0.121	−0.7 (−1.7 to 0.2)

Values expressed with a plus/minus sign are the mean ± standard deviation. Negative values for mean paired difference for PROMIS Pain Interference and time to walk 50 feet indicate improvement on these measures.

[a]Significant at $p < 0.05$.

[b]Standard scoring of the SF-12 specifies that participants with any missing data be dropped from the analysis.

[c]Trend in expected direction at $p < 0.10$.

EQ-5D-5L, the EuroQol health status index; SF-21, 12-Item Short-Form Health Survey; MCS, Mental Composite Score; PCS, Physical Composite Score; PROMIS-PI, Patient Reported Outcomes Measurement Information System-Pain Interference.

Discussion

This pilot study confirmed the feasibility of delivering a manualized protocol of Swedish massage for treating VA health care users with knee OA, with no significant recruitment barriers and both retention and treatment session completion rates over 90%. Only two participants failed to complete the full massage intervention, and neither case was due to perceived inefficacy of the massage therapy. Acceptability of the intervention was high in this largely male veteran population, with over 90% of participants indicating they would like to continue to receive massage as part of their treatment plan for knee OA.

Although preliminary, the data strongly supported the potential efficacy of this treatment protocol for improving outcomes in VA health care users with knee OA. Results were consistent with findings from our previous studies in a general population.[9,10] Percentages of improvements in WOMAC scores were well above the minimal clinically important differences (17%–22%) reported by Angst et al. in their prospective cohort study of 192 patients with lower limb OA,[17] with a 30% improvement in the global score, 37% improvement on the pain subscale, and 32% improvement on the function subscale. Pain interference and perceived health status also significantly improved over the course of the study.

This study's findings raise important considerations for future studies of massage therapy for chronic pain conditions, such as knee OA. Its strong recruitment, retention, and feasibility outcomes suggest that veterans need and are largely receptive to massage as an intervention for pain due to knee OA. It appears that no study has demonstrated the feasibility and acceptability of providing professional outpatient massage for veterans with chronic pain due to knee OA (or OA in any other joint) and simultaneously provided strong preliminary results of significant pain reduction. These combined findings warrant a large-scale randomized controlled trial to establish the clinical efficacy of massage for veterans' knee OA.

Prior studies have also documented the strong interest of VA patients, providers, and administrators to make massage therapy available across the VA for patients with chronic pain. In one large-scale study ($n = 401$) conducted across five VA primary care clinics, 202 participants reported having sought massage for their chronic pain, and 387 participants (97%) reported willingness to try massage therapy; thus, massage was the most preferred of the complementary and alternative medicine modalities studied (massage therapy, chiropractic care, herbal medicines, and acupuncture).[18,19] A recent qualitative study of 28 patient care providers and administrators at a large VA facility rated massage as the top priority for promotion within the VA over 18 other modalities.[19] In this same study, although many participants saw lack of funding as a barrier to providing massage within the VA, others thought funding was available in response to a well-planned request.

Several strategies for reducing long-term cost of massage for chronic pain warrant further study. Home-based massage programs are cost-effective and have demonstrated significant reductions in self-reported pain and anxiety in veterans for conditions that include a substantial mental component in addition to chronic pain, such as cancer and reintegration after return from active duty in Iraq or Afghanistan.[20,21] Another pilot study in non-veterans recently showed that home-based massage resulted improved symptoms among patients with knee OA.[22] Larger studies are needed to evaluate whether home-based massage, either alone or as an adjunct to professional massage therapy, has benefit for veterans and others with knee OA. In addition, it would be useful to evaluate the potential combined effects of massage therapy (professional or home-based) with other therapies that could help to sustain benefits, such as mindfulness-based stress reduction, which is more effective and longer lasting for mood improvement than massage therapy.[23]

Finally, this study has several limitations common to pilot studies, including a small sample size ($n = 25$), relatively short intervention duration, and lack of control group. However, this study provides important preliminary data about the feasibility and efficacy of Swedish massage in a vulnerable and understudied patient group. In addition, this study was limited to Swedish massage techniques. Although this precludes generalizability to other possible techniques, it confers the advantage of standardizing the intervention in a health care system such as the VA.

In conclusion, this pilot study supports the feasibility and acceptability of Swedish massage among VA health care users with knee OA. Preliminary data suggest the potential efficacy of 8 weeks of 1-hour weekly massage for reduced

pain and interference of pain on other aspects of one's life. If results are confirmed in a larger randomized trial, massage could be an important component of regular care for these patients.

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Author Disclosure Statement

No competing financial interests exist.

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(*Appendix follows* →)

Appendix 1. Study Acceptability: Responses to Closed-Ended Post-Study Questions ($N=23$)

Question	*No*	*Yes*	*% Yes*
1. ''Was the schedule of visits (60 minutes/week) convenient for you?''	1	22	96
2. ''Would you like to continue massage as part of the ongoing management of your knee arthritis?''	2	21	91
3. ''Did you notice any other changes in your health or other aspects of your life since starting the massage?''	4	19	83
4. ''If the VA were to offer massage for knee arthritis, how likely do you think it is that other veterans you know would want to try this treatment?''			
• Very likely		18	78
• Somewhat likely		2	9
• Not at all likely		0	0
• Don't know		3	13

VA, Department of Veterans Affairs.