

|                        |                   |
|------------------------|-------------------|
| <b>Critique author</b> | <b>Ed Whitney</b> |
|------------------------|-------------------|

|                               |                                                                                     |
|-------------------------------|-------------------------------------------------------------------------------------|
| <b>Bibliographic Data</b>     |                                                                                     |
| Authors                       | Sherman KJ, Cook AJ, et al.                                                         |
| Title                         | Five-Week Outcomes From a Dosing Trial of Therapeutic Massage for Chronic Neck Pain |
| PMID                          | 24615306                                                                            |
| Citation                      | Ann Fam Med 2014;112-120. doi: 10.1370/afm.1602                                     |
| Other information if relevant |                                                                                     |

|                |                                                                             |
|----------------|-----------------------------------------------------------------------------|
| <b>Methods</b> |                                                                             |
| Aim of study   | To evaluate the optimal dose of massage for patients with chronic neck pain |
| Design         | Randomized clinical trial with six intervention arms                        |

|                                                                  |                                                                                                                                                                                                           |
|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Participants</b>                                              |                                                                                                                                                                                                           |
| Population from which participants are drawn                     | Enrolees in Group Health of Seattle, a large integrated health system with 500,000 beneficiaries in greater Seattle                                                                                       |
| Setting (location and type of facility)                          | Treatment clinics at various Group Health facilities                                                                                                                                                      |
| Age                                                              | 46.75                                                                                                                                                                                                     |
| Sex                                                              | 185 women, 43 men                                                                                                                                                                                         |
| Total number of participants for whom outcome data were reported | 228                                                                                                                                                                                                       |
| Inclusion criteria                                               | Age 20 to 64 with symptoms consistent with non-specific, uncomplicated neck pain of at least moderate level of pain for at least three months<br>Lives or works within Greater Seattle WA geographic area |

|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Exclusion criteria            | <p>Cervical Radiculopathy</p> <p>History of cancer (other than nonmelanoma skin cancer)</p> <p>Severe disk problems</p> <p>Unstable medical conditions</p> <p>Previous neck surgery</p> <p>Physically unable to get on and off of a massage table</p> <p>Has had massage within the last year</p> <p>Currently in litigation for neck pain</p> <p>Seeking other treatment for neck pain</p> <p>Potential contraindications for massage</p> <p>Unable to give informed consent</p> |
| Other information if relevant |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

### Intervention Groups

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| <b>Group 1</b>                     |                                                                                     |
| Group name                         | Waiting list control                                                                |
| Number in group                    | 37                                                                                  |
| Description of intervention        | Waiting list which was followed for outcomes but not treated                        |
| Duration of treatment period       | 4 weeks of no massage                                                               |
| Co-interventions if reported       | No self-care of the neck was permitted during the study period                      |
| Additional information if relevant | The authors forbade neck self-care in order to isolate the effects of massage alone |

|                              |                                                            |
|------------------------------|------------------------------------------------------------|
| <b>Group 2</b>               |                                                            |
| Group name                   | Massage level 1                                            |
| Number in group              | 38                                                         |
| Description of intervention  | Weekly 60-minute massage for 4 weeks (60 minutes per week) |
| Duration of treatment period | 4 weeks                                                    |

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| Co-interventions if reported       | No self-care of the neck was permitted during the study period                      |
| Additional information if relevant | The authors forbade neck self-care in order to isolate the effects of massage alone |

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| <b>Group 3</b>                     |                                                                                     |
| Group name                         | Massage group 2                                                                     |
| Number in group                    | 38                                                                                  |
| Description of intervention        | Massage twice weekly for 30 minutes (60 minutes per week)                           |
| Duration of treatment period       | 4 weeks                                                                             |
| Co-interventions if reported       | No self-care of the neck was permitted during the study period                      |
| Additional information if relevant | The authors forbade neck self-care in order to isolate the effects of massage alone |

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| <b>Group 4</b>                     |                                                                                     |
| Group name                         | Massage group 3                                                                     |
| Number in group                    | 39                                                                                  |
| Description of intervention        | Massage twice weekly for 60 minutes (120 minutes per week)                          |
| Duration of treatment period       | 4 weeks                                                                             |
| Co-interventions if reported       | No self-care of the neck was permitted during the study period                      |
| Additional information if relevant | The authors forbade neck self-care in order to isolate the effects of massage alone |

|                 |                 |
|-----------------|-----------------|
| <b>Group 5</b>  |                 |
| Group name      | Massage group 4 |
| Number in group | 37              |

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| Description of intervention        | Massage thrice weekly for 30 minutes (90 minutes per week)                          |
| Duration of treatment period       | 4 weeks                                                                             |
| Co-interventions if reported       | No self-care of the neck was permitted during the study period                      |
| Additional information if relevant | The authors forbade neck self-care in order to isolate the effects of massage alone |

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| <b>Group 6</b>                     |                                                                                     |
| Group name                         | Massage group 5                                                                     |
| Number in group                    | 39                                                                                  |
| Description of intervention        | Massage thrice weekly for 60 minutes (180 minutes per week)                         |
| Duration of treatment period       | 4 weeks                                                                             |
| Co-interventions if reported       | No self-care of the neck was permitted during the study period                      |
| Additional information if relevant | The authors forbade neck self-care in order to isolate the effects of massage alone |

|                                          |                                                                                                                                                                                                     |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Primary outcome</b>                   |                                                                                                                                                                                                     |
| Outcome name and criteria for definition | Clinically relevant decrease in the Neck Disability Index as indicated by a 5 point decline from baseline when assessed at 5 weeks after randomization                                              |
| Time points measured and/or reported     | Baseline and 5 weeks<br>Because clinically relevant response either did or did not occur, the outcomes are reported as “relative risks” of success compared to the waiting list controls at 5 weeks |

|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Differences between groups         | <ul style="list-style-type: none"> <li>- Each of the massage groups had higher response rates than the waiting list</li> <li>- For three of the massage groups (1x60 minutes per week, 2x30 minutes per week, and 3x30 minutes per week), the “relative risks” of improvement did not attain statistical significance</li> <li>- For two of the groups, the “relative risks” did attain statistical significance</li> <li>- The group with 2x60 minutes per week had a RR of 3.41, with 95% confidence interval 1.05 to 11.08</li> <li>- The group with 3x60 minutes per week had a RR of 4.98, with 95% CI 1.64 to 15.17</li> </ul> |
| Additional information if relevant | <ul style="list-style-type: none"> <li>- Treatment adherence, defined as attending at least 75% of the assigned dose, was 95% in the first 4 massage groups and 84% in a fifth group (that had 3x30 minutes per week)</li> <li>- Only 6 of 184 patients who received massage reported doing self-care activities which were prohibited in the study protocol</li> <li>- The NDI in the control group worsened during the waiting period, increasing by an average of 1.85 points</li> <li>- Some analyses were done as well treating the NDI as a continuous variable, but these were not the primary outcome</li> </ul>             |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Secondary outcomes</b>                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Outcome name and criteria for definition | Clinically relevant decrease in neck pain, indicated by an improvement of at least 30% at 5 weeks after randomization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Time points measured                     | Baseline and 5 weeks                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Differences between groups               | <ul style="list-style-type: none"> <li>- The pattern for the Neck Disability Index was similar for neck pain intensity</li> <li>- Each of the massage groups had lower neck pain intensity than the control group</li> <li>- For the 1x60 minute group and for the 3x30 minute group, the neck pain difference from the control group was not statistically significant</li> <li>- For three of the groups, the mean neck pain did attain statistical significance compared to the control group</li> <li>- The group with 2x30 minutes per week had a mean pain difference of 1.02 points; the group with 2x60 minutes had a mean pain difference of 1.56 points, and the group with 3x60 minutes had a mean pain difference of 2.07 points</li> </ul> |

|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Additional information if relevant | <ul style="list-style-type: none"> <li>- The authors also analyzed four groups with respect to the number of 60 minute sessions they had per week (0, 1, 2, and 3)</li> <li>- On these four groups with different “doses” of hour-long massage sessions, the authors did a linear test for dose-response trend for both NDI and neck pain intensity</li> <li>- Both outcomes did show a dose-response trend</li> <li>- For NDI, each additional weekly massage was associated with an incremental improvement of 1.81 points (95% CI 1.10 to 2.52)</li> <li>- For neck pain, each additional weekly massage was associated with an incremental improvement of 0.75 points (95% CI 0.47 to 1.01)</li> </ul> |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Conclusions</b>               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Key conclusions of study authors | <ul style="list-style-type: none"> <li>- Although 30 minute massages, either two or three times per week, failed to provide significant benefits compared to no massage, there were benefits associated with 60 minute massages twice or three times per week, and the response rate was higher with three than with two weekly massage sessions</li> <li>- Multiple weekly hour-long massage sessions for the first four weeks of treatment are more beneficial than a single weekly massage session</li> </ul> |

| <b>Risk of bias assessment</b>                                      |                                  |          |
|---------------------------------------------------------------------|----------------------------------|----------|
| Domain                                                              | Risk of bias<br>Low High Unclear | Comments |
| Random sequence generation<br><i>(selection bias)</i>               | Low                              |          |
| Allocation concealment<br><i>(selection bias)</i>                   | Low                              |          |
| Blinding of participants and personnel<br><i>(performance bias)</i> | High                             |          |

|                                                           |         |  |
|-----------------------------------------------------------|---------|--|
| Blinding of outcome assessment<br><i>(detection bias)</i> | Unclear |  |
| Incomplete outcome data<br><i>(attrition bias)</i>        | Low     |  |
| Selective outcome reporting?<br><i>(reporting bias)</i>   | Low     |  |
| Other bias                                                |         |  |

|                                                  |                                                                       |  |
|--------------------------------------------------|-----------------------------------------------------------------------|--|
| <b>Sponsorship if reported</b>                   |                                                                       |  |
| Study funding sources if reported                | National Center for Complementary and Alternative Medicine at the NIH |  |
| Possible conflicts of interest for study authors |                                                                       |  |
| Notes:                                           |                                                                       |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Comments by DOWC staff</b></p> <ul style="list-style-type: none"> <li>- The prohibition of self-care measures during massage treatment is a departure from ordinary care among massage therapists</li> <li>- For this reason, the authors' conclusion that 30 minute sessions of massage were not more beneficial than no massage is questionable, since a distinct benefit could have been observed if the lower dose massage groups had been permitted to do self-care</li> <li>- The linear test for trend in NDI and in neck pain intensity scores, although not the designated primary outcome, is more helpful in interpreting the study data than trying to compare "relative risks" of response rates in Table 2</li> </ul> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                 |  |
|---------------------------------|--|
| <b>Assessment by DOWC staff</b> |  |
|---------------------------------|--|

|                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Overall assessment as suitability of evidence for the guideline</p> <p><input type="checkbox"/> High quality</p> <p><input checked="" type="checkbox"/> Adequate</p> <p><input type="checkbox"/> Inadequate</p> | <p>The study supports a statement that there is some evidence that in the setting of chronic neck pain, four weeks of weekly hour-long massage leads to benefits with both pain and function, and that there incremental benefits from multiple massage sessions per week (up to three sessions) over a single massage session</p> |
| <p>If inadequate, main reasons for recommending that the article not be cited as evidence</p>                                                                                                                      |                                                                                                                                                                                                                                                                                                                                    |

|                                                 |
|-------------------------------------------------|
| <p><b>Additional references if relevant</b></p> |
| <p>-</p>                                        |