CHAPTER 5

Study III: Effectiveness of physiotherapy treatment in elders with frequent intermittent headache: A randomized controlled study

5.1 Introduction

Headache is a common health problem affecting quality of life and imposes substantial medical cost. There is evidence suggesting that headache changes with age (1, 2). Headache in the elderly becomes less typical and more often associated with neck pain in the elderly population (1, 2). A recent study has demonstrated that cervical musculoskeletal impairments are not specific to cervicogenic origin but other frequent headaches (i.e. migraine and tension-type headache) in the elderly population (5). Cervical musculoskeletal dysfunction (CMD) associated with neck pain in elder populations might be the source of headache (cervicogenic headache), or changes in the headache features of primary headache could be an additional peripheral source of nociceptive as part of the changes in the nature of headache, which are a consequence of increasing age. The effective management of older persons with headache in particular of those with atypical features of headache remains a challenge. Evidence indicates that physiotherapy management methods such as manual therapy and therapeutic exercise are effective management approaches for headache associated with the neck (15, 16). This may suggest that physiotherapy treatment would have a beneficial effect for elders with other intermittent headache who have neck pain and concomitant cervical musculoskeletal dysfunction. This is particular relevant as there are widespread concerns about medication overuse, adverse drug events and drug interaction in elders (17, 18). At present, there has been no trial to date which has investigated the effectiveness of physiotherapy treatment specifically for elders with various types of headaches with associated neck pain and cervical musculoskeletal impairment. A clinical trial of treatment of cervical musculoskeletal impairment in elders with various frequent intermittent headaches may help guide management of headache in attempts to

lesson medication use and cost in this population. Physiotherapy may be a worthy treatment option particularly in elders with headache who do not respond well to medication.

5.2 Methods

5.2.1 Sample size calculation

In a previous randomized controlled trial of headache (15), 76% of the participants who received either manipulative therapy, therapeutic exercise or a combination of manipulative therapy and therapeutic exercise gained 50% or better reduction in headache frequency. There was up to a 10% better chance of achieving a good or excellent outcome with the combined therapies. Medium to large sized effects (0.68-0.87) of all treatments on headache frequency were demonstrated. However the results of the previous study were conducted in a general population. Since there are no results of similar studies available in the elderly population, the sample size calculation was based on the following assumptions: (a) a power of 0.8; (b) alpha level of 0.05; (c) a medium effect size of 0.25; (d) an intraclass correlation of 0.5. (e) ANOVA-repeated measures within-between interaction model. A minimal sample size of 17 participants per group was required. To account for dropouts (10%), a group size of 20 was recruited, with a total sample size of 40.

5.2.2 Participants

Thirty-nine male and female participants, aged range 60-75 years were recruited both from the headache clinic at Maharaj University Hospital and from the local community through advertising on local radio, in newspaper and flyers. Participants were eligible if they met the inclusion and none of the exclusion criteria. Participants had persistent intermittent headaches (migraine, tension-type headache, cervicogenic headache or mixed headache) at least one per week over the past year with associated neck pain and CMD (restriction in active range of cervical motion in extension or rotation and symptomatic joint dysfunction of the upper cervical spine) (5), a score of $\geq$ 3 on a 0-10 numeric rating scale (NRS) of neck pain and neck disability $\geq$ 10 out of 100 as measured by the Neck Disability Index (NDI). Exclusion criteria were

headache diagnosed as temporal arteritis (giant cell arteritis), trigeminal neuralgia, cluster headache or chronic paroxysmal hemicranias (s) continua; temporomandibular joint dysfunction; sinus disease; neurological disorders (e.g. Parkinson disease, stroke); cognitive disturbance; previous history of serious head and neck trauma; any condition that contraindicated cervical mobilization; or receiving either physiotherapy or chiropractic treatment for headache and/or neck pain in previous 12 months.

A research assistant conducted preliminary screening telephone interview with participants responding to advertisements. The participants were scheduled to determine the eligible for the trial by neurologist and experienced physiotherapist. The neurologist diagnosed all potential participants (recruited from advertisements or the headache clinic) as migraine, tension-type headache and other headache type according to the criteria of the International Headache Society (104), or for cervicogenic headache according to Cervicogenic Headache International Study Group (105). The physical examination of the neck was performed by physiotherapist who was blinded to type of headache, to identify the presence or absence of CMD and clinical rating of greater or lesser and measuring cervical range of motion. The participants were asked to rate any pain provoked on palpation on a numeric rating scale. The physical therapist rated the perceived tissue resistance during manual palpation as normal, slight, moderate, or marked resistance. The symptomatic joint dysfunction was classified as pain provoked by manual palpation $\geq$ 2 of 10 in combination with the physical therapist rating of moderately or markedly abnormal tissue compliance (6). Participants were classified as greater CMD if they had at least two levels of symptomatic joint dysfunction and limit range of cervical extension and rotation. If participants presented musculoskeletal dysfunction, but rated to lesser degree were classified as lesser CMD. If participants had pain free and within normal limit range of cervical motion were classified as no CMD.

The study was approved by the ethical review committee for research in humans, Faculty of Medicine, Chiang Mai University. The study was conducted in accordance with the Declaration of Helsinki. All participants provide written informed consent prior to commencement of the study.

5.2.3 Randomization and allocation

All eligible participants were randomly by an independent research assistant who did not involve in the study. A sequence of random numbers was generated using a computer-generated permuted blocks with a block size of four. Randomized sequence was stratified into a greater or lesser physical impairment based on the presence of the cervical musculoskeletal impairment. Allocation concealed in sequentially numbered, sealed, opaque envelopes. The envelopes were opened by the research assistant allocating patients to the respective intervention. The assessor was blinded the subject conditions collecting at baseline and follow-up of physical measures and entered questionnaire data.

5.2.4 Interventions

5.2.4.1 Physiotherapy treatment

The intervention was delivered by two physiotherapists experienced in the trial treatments. The treatment period was 10 weeks and commenced within 1 week of baseline assessment. The intervention consists of two visits per week for the first four weeks (8 treatments) and one visit per week for the last six weeks (6 treatments). Each treatment session lasted approximately 45 minutes. The physiotherapy treatment consists of cervical joint mobilization and the therapeutic exercise program, a regime that has proven successful in previous trials of headache management (15, 16, 218). The physiotherapy treatment includes the use of and high-velocity thrust (manipulation) is considered inappropriate for older persons and was not used in the study. The low-velocity cervical mobilization technique described by Maitland et al (219) was performed. The selection of mobilization technique based on therapists' clinical reasoning which considered about the nature and direction of movement dysfunction, behavior and severity of pain of the patients. The progression of treatment techniques is based on a basic assessment of the effects of the treatment. The steps to be taken in the progression of the treatment's technique are driven primarily by the symptomatic response felt by the patient during the performance of the technique and the effects of the treatment over the following day or so (219). The therapeutic exercise program was used low load endurance exercises to train muscle control of the axioscapular region in

both lying and sitting positions. All participants received the same essential elements of exercise as well as health education programs. The elements of the treatment program were given at the discretion of a therapist, based on the initial and progressive assessment of participant's cervical musculoskeletal dysfunctions.

The therapeutic exercise program consisted of low load exercise for the craniocervical flexor (15, 220) and axioscapular muscles (221) and postural correction exercise (220, 222). Participants were first taught to perform a slow and controlled craniocervical flexion action and then a holding capacity. The pressure biofeedback (Stabilizer^{TM}, Chattanooga Group Inc., Chattanooga, TN) was used to monitor participant's ability to perform and hold a precise upper cervical flexion. Training was commenced at the pressure level that the participant is able to achieve and hold steadily with a good craniocervical flexion pattern, without dominant use or substitution by the superficial flexor muscles. The participants then trained to progressively increase the various incremental levels of pressure (22 to 30 mmHg). For each target pressure level, the participants were instructed to hold for 10 seconds for 10 repetitions with 3-5 second rest between each contraction (training the holding capacity of the deep neck flexors). Once the patient shows improvement in deep cervical flexor activation, training progresses to the sitting position. The exercise consists of a controlled eccentric action of the flexors to the cervical extension range, followed by a concentric action of these muscles to return the head to the neutral upright position. Then, the patient practices eccentric control of the head into flexion, followed by concentric control back to the neutral position in a 4 point kneeling position to train the coordination of the deep and superficial cervical extensors. Further, co-contraction of the neck flexors and extensors is facilitated with rotation. The patient uses self-resisted isometric rotation while looking into the palm of the hand, using a resistance of about 10-20% while in a correct upright sitting posture. A final and late stage element of the training addresses any strength deficits in the neck flexor synergy. Resistance is provided with gravity and head load, incorporating, first a craniocervical flexion, followed by a head lift from the bed. The therapeutic exercise intervention was also included specific exercises for axioscapular muscles control by activating particularly the coordinated contraction of the serratus anterior and lower trapezius, using inner range holding exercise of scapular adduction and retraction. Precision of the scapular in

a correct orientation was required with emphasis placed on relaxation of unwanted muscle activity. Training was commenced in side lying position and progressed to the prone position. Once the correct scapular orientation was achieved, endurance capacity of the scapular muscles was performed in a set of 10 repetitions with a 10 second hold. Muscle lengthening exercise could also be given to address any muscle tightness present. For the postural correction exercise, re-education of control of posture begins from the first treatment. Participants are instructed initially in sitting and correction is initiated from the lumbopelvic region while sitting up straight. The scapular is corrected and a final element of the postural exercise is to ask the patient to add a gentle lift of the base of the skull from the top of the neck.

Participants were instructed to practice their exercise once daily (10-20 minutes) during the intervention period, without aggravating pain. To monitor compliance and adverse events, participants were asked to record an exercise diary and any adverse events. The adverse effects were defined of any increase in headache and neck pain, loss of neck motion and loss of function as a consequence of intervention.

5.2.4.2 Usual care

Participants were asked to maintain their routine or appropriate primary care receiving by participants such as medication or other treatments for relief from headache, the exception for these are not to receive physiotherapy treatment. For preventing of behavioral changes during 10-week treatment period, all participants in this group were asked not to receive additional information involving condition and treatment for their headache. Participants were asked to record adverse event effects in the diary during 10-week intervention.

5.2.5 Outcome measures

Primary outcome measure

- Headache frequency: the frequency was recorded in a headache diary as the number of headache days in 1 week before assessment dates and the total number of the day of headache per week was used for analysis.

Secondary outcome measures

- Headache intensity: the intensity in the past week was recorded in headache diary using a 0-10 numerical rating scale.

- Headache duration: the average number of hours of headache for each day in the past week was recorded using a headache diary

- Neck pain intensity: intensity of neck pain in the past week was measured using a VAS. The participants indicated their average neck pain intensity over the past week by making a 100-mm line.

- Neck pain and disability: neck pain and disability in the past week was measured using the NDI-TH

- Medication intake: type and dose of all medications taken by the participants were recorded using a medication diary for 1 week before baseline and follow-up period. The medication consumption was converted to define daily dose (DDD) by multiplying the units dispended field with the DDD conversion (223). For example, the strength of one tablet is 500 mg and DDD is 3 g for paracetamol. Each one table of 500 mg is equivalent to 0.17 DDD. The DDD of paracetamol derived from multiplying the quantity dispensed (ten tablets) by a conversion factor of 0.17 equal a total of 1.7 DDDs. The sum of DDDs of all medication in 1 week was used for analysis.

- Range of cervical motion: range of cervical motion was measured in flexion-extension, right-left lateral flexion, right-left rotation and right-left upper cervical rotation with full flexion using CROM (Performance Attainment Associates, Roseville, MN) (224) (Figure 5.1). The CROM device is reliable tool to assess cervical range of motion (225). Cervical range of motion was measured in the upright sitting position. The cervical movement was instructed to be actively performed in each direction with manual guidance provided by an examiner to ensure the correct

movement, if necessary. Average of three times measure was used for analysis.

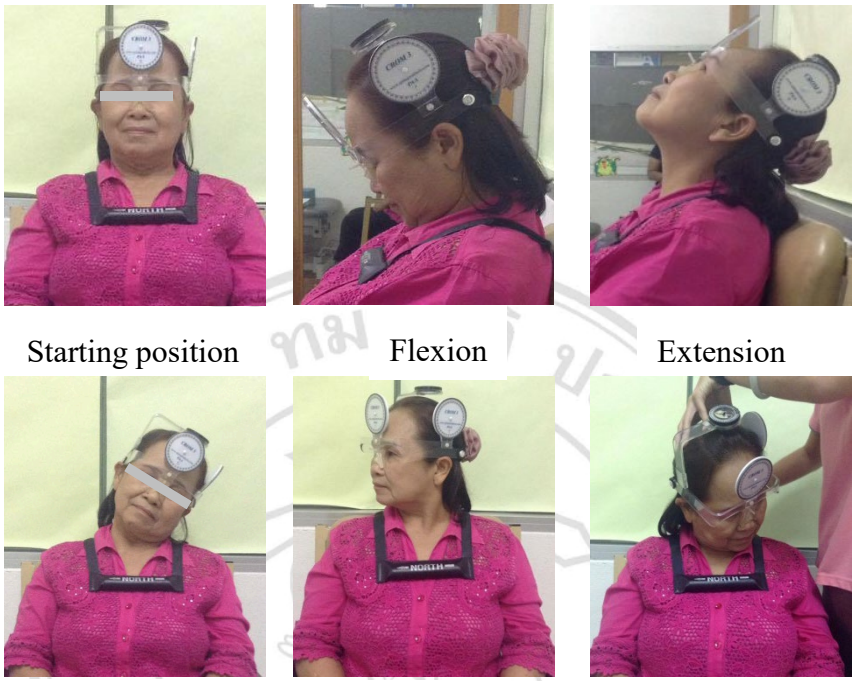

Figure 5.1 Measurement of cervical range of motions

- Global assessment of treatment benefit: patient perceived benefit of treatment was measured on a 0-10 scale, where 0 represents no benefit and 10 represents maximum benefit

5.2.6 Procedure

Participants were initially screened for the inclusion and exclusion criteria. Participants' headache types were made by a neurologist. All eligible participants were stratified according to cervical musculoskeletal dysfunction and randomly allocated into the usual care or 10-week physiotherapy treatment groups. All eligible participants were asked to record their medication intake (type and dose of all medication) and headaches features (frequency, intensity and duration) on each day for the week before each assessment date. Participants were asked to note that it is typical of their headache or difference headache, for example associated with a cold or flu. On the assessment day at baseline and follow-up at week 11, all eligible participants completed the headache,

NDI, global assessment of treatment benefit and VAS questionnaires (details of the questionnaires are provided in Appendices B-D and F). Participants were then measured active range of cervical motion (a reliability study of the CROM measure is provided in Appendix K). The measurements were obtained by an assessor blind to participant's treatment group allocation throughout the whole study period. Participants in the physiotherapy treatment were asked to refrain from seeking other treatments for relief of headache during trial. For the ethical considerations, usual medication was not withheld from any participant, regardless of group allocation and follow-up assessment days. For maintained high retention of participants in the usual care group was conducted by reminder telephone calls during the 10-week intervention.

5.2.7 Statistical analysis

Independent t-test and chi-square were used to compare demographic characteristics between participants. Univariate analyses of covariance were used to determine differences in primary and secondary outcomes between groups and baseline data was used as a covariate. The effect size was determined by partial eta squared (η^2) and can be interpreted as small (0.01), medium (0.06) and large (0.14) (226). Dichotomous of responder was calculated for determine clinically significant improvement in headache frequency as defined by $\geq$ 50% reduction in the number of headache days post treatment. The results are presented as relative risks with 95% CI. Data were analyzed with the SPSS statistical package (version 17). Significance was set at $p < 0.05$.

5.3 Results

5.3.1 Participant characteristics

The process of participant recruitment began in January 2013 and was completed in December 2014. The flow diagram throughout the trial is presented in Figure 5.1. One hundred and five older adults with headache were recruited for the study, 50 elders did not meet the inclusion criteria, and 16 declined to participate. Thirty-nine participants were recruited for the study and none were lost to follow-up. Participant characteristics at baseline are presented in Table 5.1. There were no

significant differences between groups in their baseline characteristics ($p > 0.05$), except in the physiotherapy treatment group, which had headaches of longer duration than with usual care ($p < 0.05$).

5.3.2 Interventions

All participants in the physiotherapy group received 14 sessions over 10 weeks. Exercise adherence was recorded in an exercise diary and participants in the physiotherapy treatment group practiced their exercises an average of 63.3 (standard deviation, 9.5) of the 70 treatment days. Two participants in the usual care group reported using massage, and one participant reported using a balm for relief of their headache. Some adverse effects were reported in the physiotherapy group, amounting to 11% reporting discomfort around their neck after the first treatment, with the discomfort disappearing within 24 hours. No adverse effects were reported in the control groups.

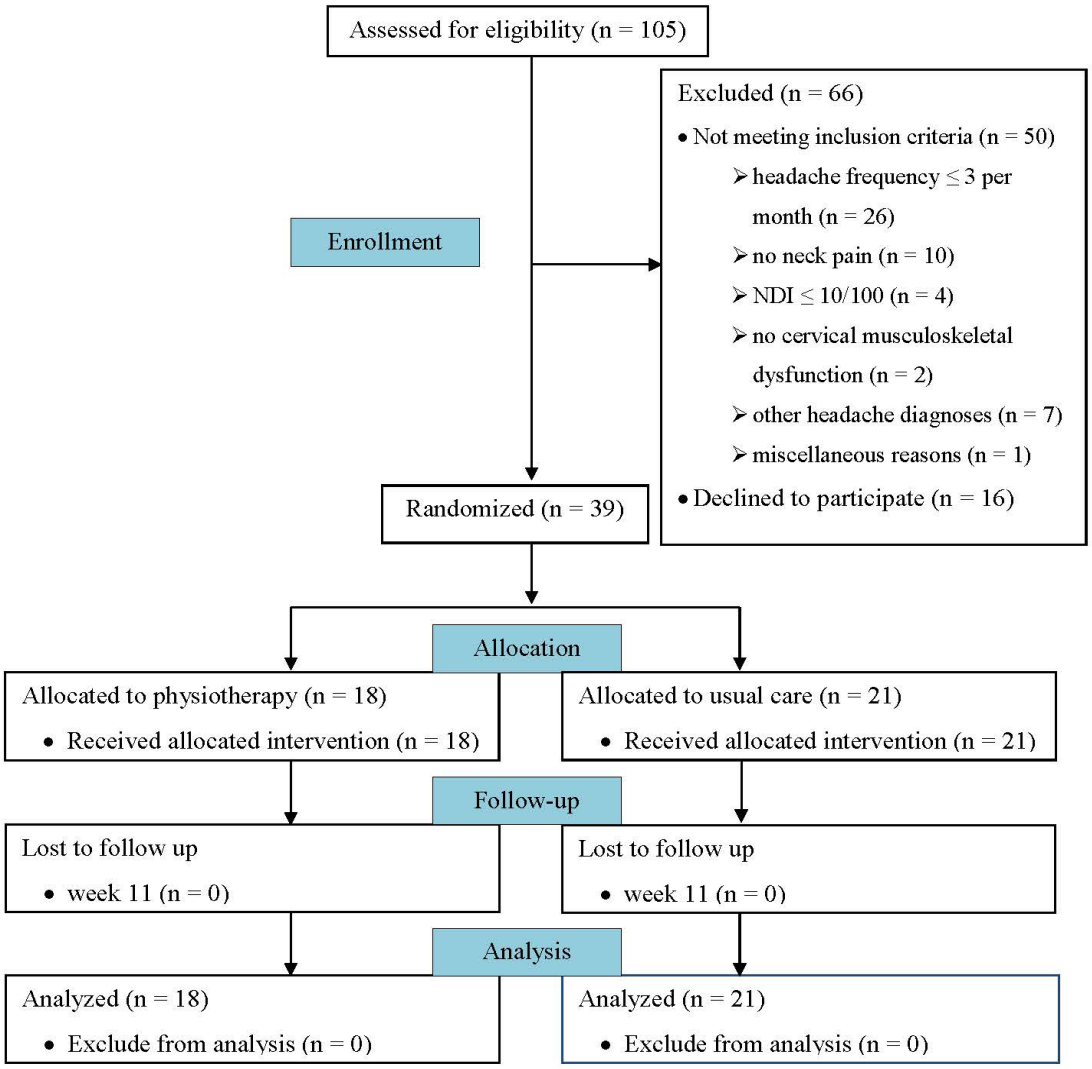

Figure 5.2 Flow diagram of the trial

Table 5.1 Demographic characteristics of participants

Variables	Participants		
	Physiotherapy (n = 18)	Usual care (n = 21)	*p*-value
Age (y)	65.11 ± 4.10	64.62 ± 2.97	0.67
Gender (female), %	88.89	95.24	0.46
BMI (kg/m^2)	23.79 ± 3.63	25.47 ± 2.89	0.12
Employment status, n			
Retired	9	7	
Full-time employment	2	7	
Self-employed	2	4	
Housewife	5	3	
History of headache (y), (mean ± SEM)	9.73 ± 2.28	3.55 ± 0.79	**0.02**
Headache diagnosis (type), n			
Migraine	3	4	
Tension-type headache	1	0	
Cervicogenic headache	13	16	
Mixed headache	1	1	
CMD (greater), %	66.67	66.67	1.0

Data are mean ± SD unless otherwise indicated.

CMD, cervical musculoskeletal dysfunction; SEM, standard error of the mean; BMI, body mass index

5.3.3 Primary outcome

The results of changes between groups for primary outcomes are presented in Table 5.2. The participants who received physiotherapy treatment demonstrated significantly reduced headache frequency immediately after treatment compared with usual care ($p < 0.01$). The effect of physiotherapy treatment indicates a large effect on headache frequency (Table 5.3). The effectiveness of physiotherapy treatment was also determined by the number of participants who responded to treatment. The participants in the physiotherapy treatment group had a significantly higher proportion of participants who experienced $\geq$ 50% reduction in headache frequency than the usual care group, we also found that 55% of participants in the treatment groups had complete relief of headache at follow-up at week 11 ($p < 0.05$) (Table 5.4).

5.3.4 Secondary outcomes

The results of changes between groups for secondary outcomes are summarized in Table 5.2. There were significant reductions in headache intensity and duration, neck pain, neck disability (NDI) and medication use immediately after treatment (11 weeks), compared with the usual care group (all $p < 0.05$). The participants with physiotherapy treatment groups showed significant increased cervical range of motion and treatment benefit after treatment (11 weeks) than the usual care group (all $p < 0.05$), except for upper cervical rotation ($p > 0.05$).

Table 5.2 Findings of outcome variables between the physiotherapy and usual care groups

Outcome variables	Physiotherapy (n = 18)		Usual care (n = 21)		
	Baseline	11 weeks	Baseline	11 weeks	*p*-value[a]
Primary outcome					
Headache frequency (d/wk)	3.56 ± 2.15	1.39 ± 2.06	2.95 ± 2.29	2.24 ± 2.10	**0.005**
Secondary outcomes					
Headache intensity (0-10 NRS)	4.65 ± 1.64	1.29 ± 1.83	4.58 ± 2.44	5.10 ± 2.48	**< 0.001**
Headache duration (h/d)	6.38 ± 6.30	2.18 ± 3.27	3.86 ± 5.32	4.01 ± 5.82	**0.01**
Neck pain intensity (0-10 VAS)	4.98 ± 1.40	1.42 ± 1.33	5.77 ± 1.26	5.04 ± 1.28	**< 0.001**
Neck pain disability (%)	30.74 ± 10.88	8.99 ± 6.43	27.51 ± 11.80	26.23 ± 9.35	**< 0.001**
Cervical range of motion (degrees)					
Flexion-extension	107.06 ± 8.49	114.67 ± 11.37	107.63 ± 8.43	107.16 ± 7.84	**0.002**
Lateral flexion (right-left)	61.43 ± 7.38	65.65 ± 8.57	58.87 ± 10.08	58.48 ± 8.71	**0.02**
Rotation (right-left)	116.37 ± 12.89	123.74 ± 9.10	115.11 ± 12.10	113.62 ± 13.64	**0.005**
Upper cervical rotation	50.07 ± 5.75	54.30 ± 4.72	48.95 ± 5.25	51.14± 5.81	0.10

Table 5.2 Findings of outcome variables between the physiotherapy and usual care groups

Outcome variables	Physiotherapy (n = 18)		Usual care (n = 21)		
	Baseline	11 weeks	Baseline	11 weeks	*p*-value[a]
Treatment benefit (0-10 VAS)	4.46 ± 3.54	9.34 ± 0.95	3.70 ± 3.61	6.44 ± 2.73	**< 0.001**
Medication (DDD per week)	2.96 ± 11.74	0.05 ± 0.14	0.34 ± 0.72	0.34 ± 0.74	**0.003**

Data are mean ± SD.

[a] Differences between groups were tested using univariate analysis of covariance, controlling for baseline

NRS, numerical rating scale; VAS, visual analog scale; DDD, defined daily dose

Table 5.3 Effect size estimates for group differences

Outcome	Effect size (η^2)
	Baseline to after treatment
Headache frequency	0.20
Headache intensity	0.67
Headache duration	0.16

Table 5.4 The number of participants (%) with a greater than 50% and 100% reduction in headache frequency after treatment (week 11)

	50% reduction				100% reduction			
Headache frequency	Physiotherapy n = 18	Usual n = 21	*p*-value	Relative risk (95% CI)	Physiotherapy n = 18	Usual care n = 21	*p*-value	Relative risk (95% CI)
11 weeks	14 (77.78)	7 (33.33)	0.01	2.33 (1.21-4.48)	10 (55.55)	1 (4.76)	< 0.001	11.67 (1.65-82.57)

CI, confidence interval

5.4 Discussion

The purpose of this study was to determine the effectiveness of physiotherapy treatment in elders with frequent headache associated with neck pain and concomitant cervical musculoskeletal dysfunction. This randomized controlled trial provides evidence that physiotherapy treatment of the neck, including cervical mobilization and therapeutic exercise, demonstrated significantly reduced headache frequency after treatment (week 11), compared with usual care. Also, improvements in headache intensity and duration, neck pain, neck disability, cervical range of motion, treatment benefits and medication use were found after 10 weeks of physiotherapy treatment. Adverse event effects did not show significant differences between the two groups. Therefore, these findings demonstrate beneficial effects of physiotherapy after 10 weeks of treatment. The results suggest that physiotherapy treatment of the neck is an appropriate intervention for elderly patients with frequent intermittent headache in association with neck pain and CMD.

The effects of treatment in this study showed large sized effects in all headache features (headache frequency, duration and intensity). According to IHS (227), a reduction of 50% in headache frequency is considered to be clinically relevant. In the present study, participants who were treated at the neck achieved a clinically relevant reduction in headache frequency, which was approximately twice as effective, compared with usual care, immediately after treatment. Approximately 55% of participants who were treated for the neck reported complete relief of their headache, compared with 5% for the usual care group, immediately after treatment. Participants receiving physiotherapy had $\geq$ 50% reduction of headache frequency, which was 2.33 times that of the participants receiving usual care, and their being headache free was 11.67 times that of the usual care group. About two-thirds of participants were diagnosed with cervicogenic headache, the remaining 70% presented with migraine. This may reflect the primary inclusion criteria of the presence of neck pain and CMD. This finding further supports the previous evidence that the prevalence of cervicogenic headache is more frequent in older persons with an age of more than 50 years (26, 228). Due to our strict eligibility criteria, only one-third of participants selected into this study

indicated the internal validity of the study. However, these results might not be generalized to the entire population.

A recent study showed that physiotherapy treatment (cervical mobilization and muscle stretching) did not provide an additive effect in reducing headache frequency in migraine patients, more than receiving medication alone. It also found no improvement in cervical range of motion (CROM) (160). A treatment effect of physiotherapy could be expected if the presence of neck pain is concomitant with CMD. Our results showed that participants who were allocated to the treatment group had improved CROM, greater than the minimal detectable changes (MDC) of 6.5° in any direction as previously reported (225), except for upper cervical rotation with full flexion. Previous studies have demonstrated that upper cervical rotation does not change with age, and limitations in lower cervical movement with age may compensate with an increased range of upper cervical motion (55). It is possible that non-significance between groups in upper cervical rotation might be explained by this compensation. A clinically meaningful change (minimal clinical important difference, MCID) in neck disability is presented by changes in the neck disability index score of $\geq$ 20% (229). This study demonstrated that regardless of headache, eligible headache patients who had neck pain and CMD demonstrated the effectiveness of treatment of the neck, suggesting CMD played an active role in the headache. Our trial provides evidence that cervicogenic headache is responsive to local treatment of the neck. Also, elderly patients with primary headache presenting with neck pain and CMD, which is an additional peripheral source of nociceptive, were responsive to local treatment of the neck. This study suggests that it is important to include a pragmatic approach to the management of elders with frequent headaches who have neck pain and concomitant cervical musculoskeletal dysfunction.

Although the present study demonstrates the beneficial effects of the treatment of the neck in elderly patients with frequent intermittent headaches, there are some limitations. Blinding of the physiotherapists and participants was not possible. Additionally, the physiotherapy group received more attention during their 10-week treatment, and therefore may result in an increased chance of positive outcomes, possibly reflecting a performance bias. Headache type was diagnosed according to

classification criteria for migraine, tension-type headache, or cervicogenic headache, but the participants did not perform nerve or joint blocks to confirm cervicogenic headache. In this study, the headache features were recorded in the headache diary, but patients did not use an electronic diary to record headache symptoms during a headache attack. Thus, the participant may have fulfilled headache features from recall memory, which may reflect a recall bias.

5.5 Conclusion

This study shows that physiotherapy treatment using cervical mobilization and therapeutic exercise is effective for reducing headache and neck symptoms in older persons with frequent intermittent headaches associated with neck pain and CMD, regardless of the type of headache. Headache is more frequent in older populations, because of concerns about medication overuse and drug interactions, management associated with CMD might result in positive effects to a multimodal headache intervention strategy for this group.