

A randomised controlled trial comparing graded exercise treatment and usual physiotherapy for patients with non-specific neck pain (the GET UP neck pain trial).

MCLEAN, Sionnadh <a href="http://orcid.org/orcid.org/0000-0002-9307-8565">http://orcid.org/orcid.org/0000-0002-9307-8565</a>, KLABER MOFFETT, Jennifer A, SHARP, Donald M and GARDINER, Eric

Available from Sheffield Hallam University Research Archive (SHURA) at:

https://shura.shu.ac.uk/7035/

This document is the Accepted Version [AM]

### Citation:

MCLEAN, Sionnadh, KLABER MOFFETT, Jennifer A, SHARP, Donald M and GARDINER, Eric (2013). A randomised controlled trial comparing graded exercise treatment and usual physiotherapy for patients with non-specific neck pain (the GET UP neck pain trial). Manual therapy, 18 (3), 199-205. [Article]

# **Copyright and re-use policy**

See http://shura.shu.ac.uk/information.html

# A Randomised Controlled Trial Comparing Graded Exercise Treatment and Usual Physiotherapy for Patients with Non-specific Neck Pain (The GET UP Neck Pain Trial)

# **Authors:**

Sionnadh M McLean Senior Lecturer of Physiotherapy School of Health and Well Being, Sheffield Hallam University, Broomhall Road, Sheffield, S10 2BP

Jennifer A Klaber Moffett Deputy Director Institute of Rehabilitation, 215 Anlaby Road, Hull, East Yorkshire, HU3 2PG

Donald M Sharp Clinical Psychologist Institute of Rehabilitation, 215 Anlaby Road, Hull, East Yorkshire, HU3 2PG

Eric Gardiner Statistician Institute of Rehabilitation, 215 Anlaby Road, Hull, East Yorkshire, HU3 2PG

<u>Number of text pages including figures and tables:</u> 16 (11 pages of text, 5 tables and figures)

# **Corresponding Author:**

Sionnadh McLean School of Health and Well Being, Sheffield Hallam University, Broomhall Road, Sheffield, S10 2BP

Telephone : 0114-2252271

E:mail : s.mclean@shu.ac.uk

# **Abstract**

Evidence supports exercise-based interventions for the management of neck pain, however there is little evidence of its superiority over usual physiotherapy. The aim of this study was to investigate the effectiveness of a group neck and upper limb exercise programme compared with usual physiotherapy for patients with non-specific neck pain. A total of 151 eligible adult patients were randomised to either a graded neck and upper limb exercise class (GET) or usual physiotherapy (UP). The primary measure was the Northwick Park Neck pain Questionnaire (NPQ) score at six weeks, six months and 12 months. Mixed modelling identified no difference in neck pain and function between patients receiving GET and those receiving UP at any follow-up time point. Both interventions resulted in modest significant and clinically important improvements on the NPQ score with a change score of around 9% between baseline and 12 months. Both GET and UP are appropriate clinical interventions for patients with non-specific neck pain, though GET had a particularly high attrition rate. Consideration of patients' preferences for treatment and specific targeted strategies to address barriers to adherence may be needed in order to maximise the effectiveness of the approach.

#### Acknowledgements

Arthritis Research UK and Hull and East Yorkshire Hospitals NHS Trust funded this research. We declare that there are no conflicts of interests.

# INTRODUCTION

Neck pain is a costly problem which affects around 50% of people at some point in their lives (Borghouts et al., 1999; Fejer et al., 2006). The role of different conservative treatments for managing neck pain is not clear. Evidence from systematic reviews supports the use of exercise for managing neck pain (Hurwitz et al., 2008). In particular, general neck and upper limb endurance training, dynamic strengthening programmes and cervical stabilisation exercises appear to be more favourable exercise options than stretching, return to normal activity or no intervention (Jull et al., 2002; Sarig-Bahat, 2003). However, exercise is not superior to other conservative treatment approaches (Viljanen et al., 2003). For example, multimodal treatments such as those usually offered by physiotherapy may also be effective for patients with neck pain (Hurwitz et al., 2008). Usual physiotherapy offers a broad range of treatments which are normally tailored to individual patients needs. Interventions commonly include specifically tailored exercises such as McKenzie exercises in combination with manual therapy, other passive treatments, advice and education (Klaber Moffett et al., 2005).

This study aimed to investigate, at six weeks, six months and 12 months, the effectiveness of a graded neck and upper limb exercise programme, based on stabilisation, endurance and strengthening principles, compared with usual physiotherapy for patients with non-specific neck pain.

### **METHODS**

# Study design

This multi-centre, pragmatic, randomised controlled trial (RCT) recruited patients with non-specific neck pain. Patients were randomised to either a graded neck and upper limb exercise class (GET) or usual physiotherapy (UP). Ethics approval was gained from Hull & East Riding Research & Ethics Committee.

### Recruitment of participants

Patients were recruited from waiting lists of four secondary care physiotherapy departments in England between February 2004 and July 2005. Patient follow-up proceeded until July 2006. Referral letters were used to identify potentially eligible patients aged 18 years or over, with sub-acute or chronic mechanical neck pain. A letter was sent to potentially eligible patients inviting them to take part in the study. Patients

who were happy to be contacted, were telephoned by a trial co-ordinator who explained the study to them. Patients verbally consenting to participate in the trial were given a face-to-face appointment where the trial co-ordinator confirmed the patient's eligibility for the trial. Patients were thoroughly screened by trained assessors and excluded from the study if they had serious neck or upper limb problems or any other potentially serious pathology e.g. systemic disease, progressive or worsening neurological disorders, inflammatory conditions, major trauma which would affect their ability to participate safely in the trial or if they had received physiotherapy for neck pain in the three months prior to trial entry. The aim of screening was to ensure that only patients classified as having non-specific neck pain and who were safe to participate in the GET programme were recruited to the study. Finally, patients who were eligible and consented, completed the self-report baseline questionnaires and were then randomised to one of the interventions.

### Randomisation and blinding

Patients were randomised to the interventions using consecutively numbered, sealed, opaque envelopes compiled by a statistician who was not involved in subject recruitment or data collection. The two interventions were randomised in blocks of three and four. Patients were stratified by treatment centre and high or low Northwick Park Neck Pain Questionnaire (NPQ) scores, where high scores were  $\geq 15$  and low scores were  $\leq 14$ . Allocation of patients was concealed from trial co-ordinators until after the end of the recruitment process when baseline data questionnaires had been completed.

Blinding of patients and therapists was not possible, however, to maintain a position of equipoise, patients were made aware that both interventions were considered active physiotherapy treatments and that neither treatment was known to be better than the other. Treating physiotherapists were not involved in recruitment of subjects, data collection or analysis. To ensure assessor blinding, baseline data was collected through patient-completed questionnaires by trial co-ordinators who remained independent of data analysis processes. Thereafter follow-up data was collected via the postal system and data was anonymized and scanned electronically into computer software using an independent data scanning service.

#### Treatment protocols

Graded exercise treatment (GET)

Patients randomised to GET were asked to attend a minimum of six and a maximum of 12 sessions over a six week period; on average they attended six sessions (range 0 to 11). Sessions took place in the physiotherapy departments of participating hospitals and class sizes ranged from six to 10 patients. The exercise class consisted of warm-up exercises, range of movement exercises for neck, trunk and upper limb and endurance training for the upper limb, trunk and lower limbs. Patients began each session with warm-up exercises and range of movement exercises. In this phase patients learned how to control compensatory spinal movement patterns in various postures and activities e.g. controlling trunk lateral flexion or flexion when pedalling a stationary bike or controlling chin poke when elevating the upper limbs through flexion or abduction. The protocol for the exercise class, examples of possible compensatory strategies employed by patients and possible corrections are outlined in a supplementary electronic file. Varying levels of physical ability and confidence were expected, so patients were encouraged by the physiotherapist to progress to the endurance phase of training when the patient felt ready. In this phase there were eight simple exercises which were conducted for one minute each (one set), with a weight of the patients choice, at a speed of the patient's choosing. With support from the physiotherapist, patients progressed from one set of endurance exercises to a maximum of three sets as they felt able. Each session varied between 30-60 minutes as the patient's individual ability allowed, but patients were encouraged to gradually increase the amount and intensity of exercise over the six week period. Within the framework of the class structure, physiotherapists were encouraged to provide advice regarding progression, regression or modification of all exercises as necessary to allow patients to perform exercise in a pain-free manner and to respond to any patient's individual queries and concerns.

The treating physiotherapists were volunteers who stayed with this treatment arm through the course of the trial. They received standardised training of three 2 hour training sessions which included practical and theoretical principles of employing cervical stabilisation within the exercise class, training about the phases and purpose of the exercise class and observation of a class to check fidelity of the treatment delivery. Further adhoc sessions at each centre were an opportunity to further check the fidelity of the treatment and an opportunity for physiotherapists to ask questions informally.

Usual physiotherapy interventions were at the discretion of the treating physiotherapist. Possible options included manual therapy, neural and muscle treatments, modalities, individualised exercise, advice and education. Table 1 provides a breakdown of actual treatments delivered. Assessment sessions lasted between 40-60 minutes and follow-up treatment lasted 20-30 minutes. On average patients were seen approximately six times (range 0 to 13). Patients randomised to UP were not eligible to participate in GET.

# Outcome measures

The primary measure of neck pain and disability was the NPQ (Leak et al., 1994). This nine item questionnaire measures level of symptoms and functional disability. Each item scores between 0 and 4. The resultant score is summated and converted to a percentage score (Leak et al., 1994). The secondary measure of upper limb disability was measured using the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (Hudak et al., 1996). These questionnaires are valid, reliable and appropriate for use in this population. Follow-up data were collected at six weeks, six months and 12 months using postal questionnaires. Non-responders received reminders first by post then by telephone as necessary. All participants were subject to standardized data collection procedures throughout the life of the trial.

A range of psychological, sociodemographic and clinical baseline characteristics were also measured for the purposes of secondary analysis (to be reported elsewhere).

#### Statistical analysis

Sample size calculations were based on detecting a difference in mean NPQ scores of 2.5 points (6.9%) between the groups after six months (Klaber Moffett et al., 2005). Based on previous research (Klaber Moffett et al., 2005), the within-group standard deviation was predicted to be 5.00 points (13.9%). Therefore, for two-tailed, two-sample t-tests carried out with a 5% significance level, 64 patients were required in each group to achieve 80% power (Machin et al., 1997). Adjusting for planned analysis of covariance and assuming a within-patient correlation of 0.5, led to a requirement of 48 patients in each group. However, allowing for possible attrition and further secondary analysis using regression techniques, we proposed to recruit 150 patients in total.

To obtain an intention-to-treat analysis we used a method of multiple imputation to correct for missing data (Mohlenberghs and Kenward, 2007). Data from the NPQ at six weeks, six months and 12 months were analysed jointly using a mixed model, assuming no structure for the matrix of correlations for outcomes at the three time points. Baseline NPQ and hospital site were adjusted for as covariates, as these had been used as stratification variables. The same process was then used for analysing the DASH measure.

# **RESULTS**

# Study population

The CONSORT flow-chart (see fig. 1) shows that a total of 483 patients with neck pain were referred for possible inclusion into the study, with 151 patients eventually being recruited (GET n=75, UP n=76). The participants in this study were similar to non-participants except on age; {participants mean age 54.25 (14.63), non-participants mean age 49.98 (16.09), p=0.006}. At six weeks, six months and 12 months respectively 31 (20.5%), 34 (22.5%) and 36 (23.8%) patients were lost to follow-up with losses being higher in the GET group at each follow-up period. Losses were related to drop-outs or withdrawals with no reports of serious adverse events. One subject in the GET group and two subjects in the UP group inadvertently received the wrong intervention.

The groups were similar on all baseline demographic variables indicating that randomisation procedures worked well (see Table 2). However, positive Townsend scores indicate that the trial population was more socially and materially deprived than the average UK population which has an average Townsend score of zero (Townsend et al., 1988). In addition, the study population presented with high mean anxiety and depression scores, where an individual subject score of between eight to 10 points from a maximum 21 indicates the probable presence of the mood disorder (Snaith, 2003).

### Treatment effects

Means and standard deviations for the NPQ and DASH scores by intervention group and time point are presented in Table 3. Mean improvements in NPQ score between baseline and six week follow-up were 1.5 % and 5.1% respectively for the GET and UP group respectively. At six month follow-up these improvements were 5% and 7.7% respectively, whilst at 12 month follow-up this improvement was 9.1% and 9.4% respectively for the

GET and UP group. Mean DASH score improvements, compared with baseline, in the UP group at six weeks was 5.4% which remain unchanged at six and 12 month follow-up. In the GET group, there was a small but non-significant deterioration in DASH scores at six week follow-up which returned to approximately baseline levels at six month and 12 month follow-up.

Treatment main effects were found to be non-significant: {NPQ GET minus UP estimated difference 1.91 (95% confidence interval (-3.14,6.96); p=0.74); DASH GET minus UP estimated difference 4.54 (95% CI (-1.10,10.2); p=0.16)}. The time main effect was significant for NPQ (p=0.005) but not for DASH (p=0.80) with estimates: {NPQ six week minus 12 month difference 5.62 (95% CI (3.16,8.09)); NPQ six month minus 12 month difference 3.12 (95% CI (0.768,5.47)); DASH six week minus 12 month difference 2.07 (95% CI (-0.480,4.62); DASH six month minus 12 month difference 1.39 (95% CI (-0.676,3.46))}. Estimates of treatment effects from mixed modelling of the original non-imputed data were qualitatively similar to those reported above, giving some confidence that statistical inferences are not sensitive to the choice of analysis method.

There is no evidence that one treatment provides greater benefit than the other for neck pain or upper limb disability. However, for both treatment groups there was a statistically significant reduction in NPQ over time, estimated to be around 5.5% from six weeks to six months and around 3% from six months to 12 months. There was no statistically significant reduction in DASH score over time.

### Treatment adherence

Fifty four (36%) patients were non-adherent with treatment i.e. they either did not attend treatment (DNA) or did not complete treatment as per protocol (DNCT)(see Table 4 and 5). The definition of adherence was attending six or more sessions from a maximum of 12 sessions in the GET treatment arm or a patient-therapist negotiated discharge at any time point within the UP treatment arm. Non-adherers came mainly from GET (n=35), compared with UP (n=19). Non-adherers were significantly different from adherers on two baseline variables; non-adherers were younger (p=0.042) and had higher Townsend scores (p=0.007), indicating that they originated from more deprived areas.

#### **DISCUSSION**

This paper reports the findings from an RCT investigating the effectiveness of a neck and upper limb exercise class (GET) compared with usual physiotherapy (UP). The GET intervention was found to be similarly effective as the UP intervention. No significant between group differences in neck pain and function were found at six weeks, six months or 12 months between patients receiving GET and those receiving UP. Both interventions reduced NPQ scores by a statistically significant amount over time. With respect to baseline measures, the mean improvement of NPQ score varied between 5.0-7.8% at 6 month follow-up and between 9.0-9.4% at twelve months, which is a small but clinically important change (Dziedzic et al., 2005; Klaber Moffett et al., 2005). DASH scores did not change significantly in either intervention group during the follow-up period.

Though modest, the findings of our study are comparable with previous RCTs investigating usual physiotherapy for the management of neck pain. In comparison with a brief physiotherapy intervention Klaber Moffett et al. (2005) found that the usual physiotherapy group improved by about 6% at three months and 7.8% at 12 months. Dziedzic et al. (2005) demonstrated that (1) advice and neck exercises, (2) advice, neck exercises and manual therapy and (3) advice, neck exercises and pulsed shortwave diathermy, achieved improvements of approximately 10-11% at six months.

Our study also provides evidence supporting exercise approaches involving strengthening, endurance training or cervical stabilisation for the management of neck pain. This is in line with a best evidence synthesis that exercise based approaches are recommended for the management of neck pain (Hurwitz et al. 2008). They concluded that supervised exercise interventions are more effective than no treatment or alternative interventions such as spinal manipulation alone, TENS, or usual General Practitioner care. They further concluded that there were no short-term or long-term differences between endurance exercises and strengthening exercises in female workers with sub-acute, chronic, or recurrent neck pain.

### Strengths and limitations of the study

This RCT was designed, conducted, analysed and interpreted in accordance with the recommendations of the CONSORT statement (Schulz et al., 2010). This study achieved its recruitment target of 150 patients and had a good rate of follow-up. Randomization procedures and concealed allocation minimized the likelihood of selection bias. Outcomes

were self-assessed using postal questionnaires, thus reducing the likelihood of therapist or assessor bias. The use of broad inclusion criterion ensured that trial participants were broadly representative of patients referred to the physiotherapy departments involved with this trial.

The participants in GET were asked to attend between six and 12 sessions of treatment. In general the influence of exercise intensity, frequency of exercise, number of sessions and programme duration on outcome remains unknown. However, 12 sessions of exercise may not have been sufficient to create optimal change in pain or function. For patients with chronic low back pain it has been shown that a longer, more intensive programme of exercise i.e. four days per week for 16 weeks continued to accumulate benefits over time and was significantly more effective than less intensive programmes of two or three days per week over the same period of time (Kell et al., 2011).

Adherence with both treatments was relatively poor, with only 47% of patients in the GET group completing treatment as per protocol. This is common in trials investigating exercise (Pavey et al., 2012) and may have impacted on the effectiveness of treatment (Vermeire et al., 2001; WHO, 2003). Several factors could account for this low level of adherence. For example, subjects in our study presented with low prior levels of physical activity, low self-efficacy and high levels of anxiety and depression (see table 2). These are recognised predictors of non-adherence (Jack et al., 2010). In addition, subjects from our study who were from more materially deprived areas were less likely to adhere with treatment than those from less materially deprived areas (see table 5). This finding is consistent with previous studies which indicate that high levels of deprivation are linked with low treatment adherence (Kim et al., 2004; Self et al., 2005). The relatively deprived status of subjects in our study may partly explain the low levels of adherence with both interventions.

Non-adherence and deprivation may also influence the outcome of treatment (Carr and Moffett, 2005; Hayden et al., 2005). Patients who are adherent have been found to have better treatment outcomes than patients who are non-adherent (Boyette et al., 1997; van Gool et al., 2005). Several high quality studies indicate that deprivation predicts poor treatment outcome in patients with back or neck pain (Carr et al., 2005; McLean, 2007;

Klaber Moffett et al., 2008). These factors may explain the modest treatment outcomes achieved in our study.

# <u>Implications for clinical practice</u>

Our study demonstrated that GET and UP were similarly effective interventions for patients with non-specific neck pain, therefore such patients should be assessed to see whether exercise-based interventions or usual physiotherapy are appropriate to meet their clinical need. The criteria for making decisions about the appropriateness of either intervention in clinical practice are lacking, however since patients' preferences for treatment are likely to impact upon the effectiveness of that treatment (Preference Collaborative Review Group, 2008) it is important to establish whether patients themselves have a preference for either of the approaches.

Due to the potentially high levels of non-adherence, asking patients to initiate and adhere to an exercise programme is a challenge. However it is a challenge which cannot be ignored since adhering to exercise has been shown to improve pain and function in a range of musculoskeletal conditions (Hayden et al., 2005; van Gool et al., 2005). In addition, there is strong evidence that adhering to regular ongoing physical activity protects people with neck pain from progression to severe, disabling or recurrent neck pain (McLean et al., 2007). Eliciting changes in exercise behaviour either in the short-term or long-term is difficult (Holtzman et al., 2004; Hayden et al., 2005). Nevertheless, health professionals involved with exercise-based interventions could begin by being aware of the range of possible cognitive, behavioural, demographic, organisational and practical barriers which may impact on patient adherence with exercise (Jack et al., 2010). The opportunity to discuss exercise options and elicit any concerns that patients might have may allow health professionals to identify and overcome specific barriers facing individual patients.

### <u>Implications for research</u>

The exercise programme used in this study might be improved in two possible ways. Firstly, combining exercise-based rehabilitation with usual physiotherapy may enhance effectiveness of conservative cervical management (Miller et al., 2010). This combination has also been identified as being potentially beneficial for other musculoskeletal conditions such as knee osteoarthritis (Medlicott and Harris, 2006), temperomandibular disorders (Jansen et al., 2011) and cervicogenic headache and neck pain (Jull et al., 2002).

Secondly, the addition of adherence strategies to either of the interventions may lead to improved treatment outcomes. However recent systematic reviews reveal considerable uncertainty about which adherence strategies may work best for increasing adherence with exercise in patients with musculoskeletal disorders (Jordan et al., 2010; McLean et al., 2010). There are indications from the wider literature that treatment adherence can be improved (Holtzman et al., 2004) and may be linked to improved treatment outcomes (Roter et al., 1998; Haynes et al., 2008). Strategies with potential to improve exercise adherence are worthy of further investigation.

#### **CONCLUSIONS**

This study demonstrated that GET and UP produced modest but significant reductions in pain and disability for patients with non-specific neck pain at six and 12 month follow-up. Both approaches are appropriate for use in clinical practice although both interventions had high levels of non-adherence. Patients should be assessed to establish whether either of these interventions is likely to meet their clinical needs and whether they have a preference for either of the interventions. Health professionals should attempt to identify possible cognitive, behavioural, demographic, organisational or practical barriers which may impact on patient adherence with treatment. Supporting patients to overcome their barriers may help patients to optimise treatment outcome, though strategies to improve adherence require further investigation.

- Borghouts JA, Koes BW, Vondeling H, Bouter LM. Cost-of-illness of neck pain in the Netherlands in 1996. Pain 1999; 80(3): 629-636.
- Boyette LW, Sharon BF, Brandon LJ. Exercise adherence for a strength training program in older adults. The Journal of Nutrition, Health & Aging 1997; 1(2): 93-97.
- Carr JL, Klaber Moffett JA, Howarth E, Richmond SJ, Torgerson DJ, Jackson DA, et al. A randomized trial comparing a group exercise programme for back pain patients with individual physiotherapy in a severely deprived area. Disability and Rehabilitation 2005; 27(16): 929-937.

- Carr JL, Moffett JA. The impact of social deprivation on chronic back pain outcomes. Chronic Illness 2005; 1(2): 121-129.
- Dziedzic K, Hill J, Lewis M, Sim J, Daniels J, Hay EM. Effectiveness of manual therapy or pulsed shortwave diathermy in addition to advice and exercise for neck disorders: A pragmatic randomized controlled trial in physical therapy clinics. Arthritis and Rheumatism 2005; 53(2): 214-222.
- Fejer R, Kyvik KO, Hartvigsen J. The prevalence of neck pain in the world population: A systematic critical review of the literature. European Spine Journal 2006; 15(6): 834-848.
- Hayden JA, van Tulder MW, Tomlinson G. Systematic review: Strategies for using exercise therapy to improve outcomes in chronic low back pain. Annals of Internal Medicine 2005; 142(9): 776-785.
- Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence. Cochrane Database of Systematic Reviews 2008; Issue 2. Art. No.: CD000011. DOI: 10.1002/14651858.CD000011.pub3.
- Holtzman J, Schmitz K, Babes, G, Kane, RL, Duval, S, Wilt TJ, et al. Effectiveness of behavioral interventions to modify physical activity behaviors in general populations and cancer patients and survivors. Evidence report/technology assessment no. 102 (Prepared by the Minnesota Evidence-based Center, under contract no. 290-02-0009) AHRQ publication no. 04-E027-2, Agency for Healthcare Research and Quality, Rockville, M.D., 2004
- Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: The DASH (disabilities of the arm, shoulder and hand). The upper extremity collaborative group (UECG). American Journal of Industrial Medicine 1996; 29(6): 602-608.
- Hurwitz EL, Carragee EJ, van der Velde G, Carroll LJ, Nordin M, Guzman J, et al. Treatment of neck pain: Noninvasive interventions: Results of the Bone and Joint Decade 2000-2010 Task Force on neck pain and its associated disorders. Spine 2008; 33(4 Suppl): S123-52.
- Jack K, McLean SM, Moffett JK, Gardiner E. Barriers to treatment adherence in physiotherapy outpatient clinics: A systematic review. Manual Therapy 2010; 15(3): 220-228.
- Jansen MJ, Viechtbauer W, Lenssen AF, Hendriks EJ, de Bie RA. Strength training alone, exercise therapy alone, and exercise therapy with passive manual mobilisation each reduce pain and disability in people with knee osteoarthritis: A systematic review Journal of Physiotherapy 2011; 57(1): 11-20.
- Jordan JL, Holden ME, Mason EEJ, Foster NE. Interventions to improve adherence to exercise for chronic musculoskeletal pain in adults. Cochrane Database of Systematic Reviews 2010 Issue 1.Art.No.:CD005956.DOI: 10.1002/14651858.CD005956.pub2. 2010.

- Jull G, Trott P, Potter H, Zito G, Niere K, Shirley D, et al. A randomized controlled trial of exercise and manipulative therapy for cervicogenic headache. Spine 2002; 27(17): 1835-43.
- Kell RT, Risi AD, Barden JM. The response of persons with chronic nonspecific low back pain to three different volumes of periodized musculoskeletal rehabilitation. Journal of Strength & Conditioning Research 2011; 25(4): 1052-1064.
- Kim LG, Thompson SG, Marteau TM, Scott RA, for Multicentre Aneurysm Screening Study Group. Screening for abdominal aortic aneurysms: The effects of age and social deprivation on screening uptake, prevalence and attendance at follow-up in the MASS trial. Journal of Medical Screening 2004; 11(1): 50-53.
- Klaber Moffett JA, Jackson DA, Richmond S, Hahn S, Coulton S, Farrin A, et al. Randomised trial of a brief physiotherapy intervention compared with usual physiotherapy for neck pain patients: Outcomes and patients' preference. British Medical Journal 2005; 330(7482): 75-80.
- Klaber Moffett JA, Underwood M, Gardiner E. Socioeconomic status predicts functional disability in patients participating in a back pain trial. Disability and Rehabilitation 2008; 31(1): 1-790.
- Leak AM, Cooper J, Dyer S, Williams KA, Turner-Stokes L, Frank AO. The Porthwick park neck pain questionnaire, devised to measure neck pain and disability. British Journal of Rheumatology 1994; 33(5): 469-474.
- Machin D, Campbell M, Fayers P, Pinol A. Sample size tables for clinical studies. London: Blackwell Science 1997.
- McLean S. Conservative management of non-specific neck pain: Effectiveness of treatment, predictors of treatment outcome and upper limb disability. Hull; University of Hull; 2007a.
- McLean S, Burton, M., Bradley, L., Littlewood C. Interventions for enhancing adherence with physiotherapy: A systematic review. Manual Therapy 2010; 15(6): 514-521.
- McLean SM, May S, Klaber Moffett J, Sharp D, Gardiner E. Prognostic factors for progressive non-specific neck pain. Physical Therapy Reviews 2007b; 12(3): 207-220.
- Medlicott MS, Harris SR. A systematic review of the effectiveness of exercise, manual therapy, electrotherapy, relaxation training, and biofeedback in the management of temporomandibular disorder. Physical Therapy 2006; 86(7): 955-973.
- Miller J, Gross A, D'Sylva J, Burnie SJ, Goldsmith CH, Graham N, et al. Manual therapy and exercise for neck pain: A systematic review. Manual Therapy 2010; 15(4): 334-354.
- Mohlenberghs G, Kenward MG. Missing data in clinical studies. Chichester: Wiley 2007.

- Pavey T, Taylor A, Hillsdon M, Fox K, Campbell J, Foster C, et al. Levels and predictors of exercise referral scheme uptake and adherence: A systematic review. Journal of Epidemiology and Community Health 2012; doi:10.1136/jech-2011-200354.
- Preference Collaborative Review Group. Patients' preferences within randomised trials: Systematic review and patient level meta-analysis. British Medical Journal 2008; 337a1864, doi:1136/bmj.a1864.
- Roter DL, Hall JA, Merisca R, Nordstrom B, Cretin D, Svarstad B. Effectiveness of interventions to improve patient compliance: A meta-analysis. Medical Care 1998; 36(8): 1138-1161.
- Sarig-Bahat H. Evidence for exercise therapy in mechanical neck disorders. Manual Therapy 2003; 8(1): 10-20.
- Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. BMC Medicine 2010; doi:10.1186/1741-7015-8-18.
- Self R, Oates P, Pinnock-Hamilton T, Leach C. The relationship between social deprivation and unilateral termination (attrition) from psychotherapy at various stages of the health care pathway. Psychology and Psychotherapy 2005; 78(1): 95-111.
- Snaith RP. The hospital anxiety and depression scale. Health and Quality of Life Outcomes 2003; 129.
- Townsend P, Phillimere P, Beattie A. Health and deprivation inequality and the north. London: Routledge 1988.
- van Gool CH, Penninx BW, Kempen GI, Rejeski WJ, Miller GD, van Eijk JT, et al. Effects of exercise adherence on physical function among overweight older adults with knee osteoarthritis. Arthritis and Rheumatism 2005; 53(1): 24-32.
- Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: Three decades of research. A comprehensive review. Journal of Clinical Pharmacy and Therapeutics 2001; 26(5): 331-342.
- Viljanen M, Malmivaara A, Uitti J, Rinne M, Palmroos P, Laippala P. Effectiveness of dynamic muscle training, relaxation training, or ordinary activity for chronic neck pain: Randomised controlled trial. British Medical Journal 2003; 327(7413): 475-479.
- WHO. Adherence to long term therapies evidence for action. Geneva: World Health Organisation 2003.

Fig. 1 CONSORT flow-chart of participants through the GET UP neck pain trial

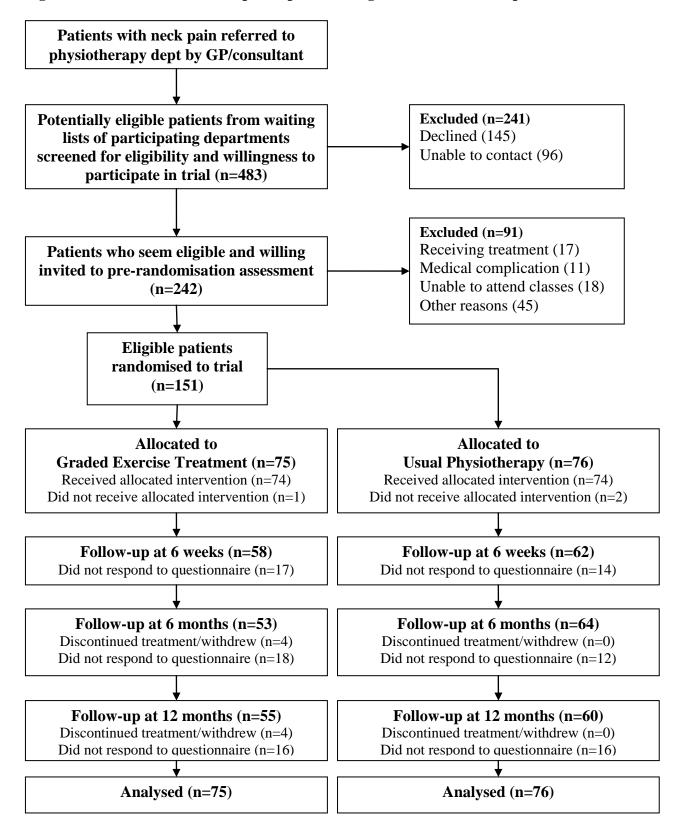


Table 1 Components of usual physiotherapy treatment

Treatment	Specific	No. of patients who
	•	received this treatment
Home exercise	McKenzie exercises	31
	Neck strengthening	0
	Stretches	$25^{1}$
	Cervical stabilisation	24
	Upper limb strengthening	4
	Other specific exercises	$33^{2}$
	General exercise	3
Manual Therapy	Manipulation	0
	Mobilisation	42
	Neural biased	4
	Muscle biased	20
	Massage	1
Modalities	Traction	3
	Shortwave diathermy	7
	Ultrasound	3
	Interferential	0
	TENS	2
	Acupuncture	4
	Ice/heat	15
	Collar	1
	Taping	1
	Ergonomic advice	1

<sup>&</sup>lt;sup>1</sup>Stretches were either active range of motion exercises or muscle stretches
<sup>2</sup>Other specific exercises included scapular, thoracic, postural exercises, relaxation etc.

Table 2 Baseline characteristics of participants in each intervention of the GET UP neck pain trial. Values are means (standard deviations) unless otherwise indicated

	Frequency	Graded Exercise Treatment (GET)(n=75)	Usual Physiotherapy (UP)(n=76)	
Age	151	54.2 (13.8)	53.5 (15.1)	
Female (frequency)	90	44	46	
Male (frequency)	61	31	30	
Smoking status (frequency)				
• smokers	43	22	21	
non-smokers	107	53	54	
Exercise levels <sup>1</sup>	-1			
more than once per week	60	29	31	
never exercise	84	44	40	
Social deprivation score	150	2.0416 (4.300)	1.044 (3.989)	
Treatment (frequency)				
Expressed a preference	82	38	44	
Preferred UP	41	17	24	
Preferred GET	34	18	16	
No preference	67	34	33	
NPQ score (0-100)	151	39.1 (14.4)	38.4 (15.6)	
DASH score (0-100)	141	31.0 (18.2)	31.1 (20.1)	
QVAS (0-100)	150	62.0 (15.9)	59.8 (17.4)	
PSE (0-100)	145	36.9 (15.1)	37.4 (15.6)	
HADS-Anxiety (0-21)	151	9.4 (1.7)	9.0 (1.8)	
HADS-Depression (0-21)	149	9.9 (2.6)	9.8 (2.5)	
TSK (17-68)	139	36.1 (8.2)	35.1 (6.7)	
CSQ-diverting attention (0-42)	143	14.5 (8.2)	13.7 (9.0)	
CSQ-reinterpreting pain sensation (0-42)	142	9.8 (7.8)	9.7 (8.1)	
CSQ-catastrophising (0-42)	141	10.7 (7.2)	10.2 (7.4)	
CSQ-ignoring sensations (0-42)	148	17.2 (8.0)	16.5 (8.1)	
CSQ-praying and hoping (0-42)	141	15.9 (9.5)	17.6 (8.5)	
CSQ-coping self statements (0-42)	143	24.4 (5.9)	23.6 23.7(7.0)	
CSQ-increased behaviour (0-42)	143	17.3 (7.6)	17.5 (7.3)	

Notes: NPQ=Northwick Park Neck Pain Questionnaire, DASH=Disabilities of Arm, Shoulder and Hand Questionnaire, QVAS=Quadruple Visual Analogue Scale, PSE=Pain Self Efficacy, HADS=Hospital Anxiety and Depression Scale, TSK=Tampa Scale of Kinesiophobia, CSQ=Coping Strategies Questionnaire

1. Any form of exercise or activity which raises the heartbeat or gets the patient slightly out of breath

Table 3 Mean NPQ, DASH scores and mean change scores (and standard deviations) at each time point, using all available data

	Graded Exercise Treatment (GET)		Usual Physiotherapy (UP)	
	NPQ score	DASH score	NPQ score	DASH score
	mean (SD)	mean (SD)	mean (SD)	mean (SD)
Baseline	39.1 (14.4)	31.0 (18.2)	38.4 (15.6)	31.5 (20.1)
	(n=75)	(n=69)	(n=76)	(n=73)
6 week follow-up	37.6 (18.2)	35.3 (22.3)	33.3 (19.3)	26.1 (19.4)
	(n=58)	(n=57)	(n=62)	(n=61)
Mean change score at 6 weeks	1.5 (19.7)	-4.3 (23.3)	5.1 (21.9)	5.4 (19.9)
6 month follow-up	34.1 (18.6)	32.8 (21.0)	30.7 (21.5)	27.6 (21.9)
	(n=53)	(n=49)	(n=64)	(n=60)
Mean change score at 6 months	5.0 (21.7)	-1.8 (22.1)	7.7 (19.4)	3.9 (18.9)
12 month follow-up	30.0 (20.6)	29.5 (22.5)	29.0 (20.1)	26.4 (21.3)
	(n=55)	(n=55)	(n=60)	(n=61)
Mean change score at 12 months	9.1 (21.6)	1.5 (22.1)	9.4 (18.9)	5.1 (21.4)

Note: NPQ=Northwick Park Neck Pain Questionnaire, DASH=Disabilities of Arm, Shoulder and Hand Questionnaire, SD=standard deviation Range for both scores=0-100; lower scores indicate less disability. Mean change scores are provided relative to baseline

Table 4 Frequency of adherers versus non-adherers by intervention group.

	Treatment completed as protocol (adherers)	Treatment begun but not completed (DNCTs) (non-adherers)	Did not attend treatment (DNA) (non-adherers)	Others	Total
GET group	35	23	12	5 <sup>1</sup>	75
UP group	55	12	7	$2^2$	76

Notes: DNCTs=Did Not Complete Treatment; DNA=Did Not Attend
<sup>1.</sup> Four patients withdrew from the trial and one received UP inadvertently
<sup>2.</sup> Two patients received GET inadvertently

**Table 5 Baseline characteristics of adherers versus non adherers.** Values are means (standard deviations) unless otherwise stated

	Adherers (n=90)	Non-adherers (n=54)	p value of independent samples t-test or $\chi^2$ test	
Age	55.7 (14.2)	50.8 (13.4)	0.042*	
Female (frequency)	51	35	0.224	
Male (frequency)	39	19	0.334	
• smokers	25	16		
<ul> <li>non-smokers</li> </ul>	64	38	0.844	
Exercise levels <sup>1</sup>				
<ul> <li>exercise more than once per week</li> </ul>	36	22	0.922	
<ul> <li>never exercise</li> </ul>	49	31		
Townsend social deprivation score	0.8310 (3.7035)	2.7687 (4.6478)	0.007*	
Treatment preference (frequency)				
Expressed a preference	50	28		
Preferred UP	29	9		
Preferred GET	18	15	0.187	
<ul> <li>No preference</li> </ul>	38	25		
NPQ score (0-100)	39.6 (15.6)	37.5 (14.6)	0.445	
DASH score (0-100)	32.5 (20.2)	28.9 (17.8)	0.276	
QVAS (0-100)	60.6 (17.4)	60.3 (15.4)	0.934	
PSE (0-100)	37.9 (16.2)	35.8 (14.4)	0.432	
HADS- Anxiety (0-21)	9.2 (1.8)	9.3 (1.9)	0.795	
HADS- Depression (0-21)	9.8 (2.6)	10.0 (2.5)	0.642	
TSK (17-68)	35.0 (6.7)	35.8 (8.3)	0.576	
CSQ-diverting attention (0-42)	14.4 (9.0)	13.4 (8.0)	0.518	
CSQ-reinterpreting pain sensation (0-42)	10.4 (8.2)	9.1 (7.5)	0.366	
CSQ-catastrophising (0-42)	9.6 (7.1)	12.0 (7.5)	0.065	
CSQ-ignoring sensations (0-42)	17.5 (8.3)	16.0 (7.9)	0.285	
CSQ-praying and hoping (0-42)	17.4 (9.4)	15.7 (8.1)	0.252	
CSQ-coping self statements (0-42)	24.2 (6.7)	23.8 (6.0)	0.736	
CSQ-increased behaviour (0-42)	18.0 (8.0)	16.1 (6.5)	0.154	

\*significant at p<0.05

Notes: UP=Usual Physiotherapy, GET=Graded Exercise Treatment, NPQ=Northwick Park Neck Pain Questionnaire, DASH=Disabilities of Arm, Shoulder and Hand Questionnaire, QVAS=Quadruple Visual Analogue Scale, PSE=Pain Self Efficacy, HADS=Hospital Anxiety and Depression Scale, TSK=Tampa Scale of Kinesiophobia, CSQ=Coping Strategies Questionnaire

Any form of exercise or activity which raises the heartbeat or gets the patient slightly out of breath