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RCSI Royal College of Surgeons in Ireland *Coláiste Ríoga na Máinleá in Éirinn*

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IRISH SOCIETY OF CHARTERED PHYSIOTHERAPISTS

A Randomised Controlled Trial of Multimodal **P**hysiotherapy for Patients with **A**cute / Sub-acute **Ce**rvical **R**adiculopathy – the **PACeR** Trial Protocol

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ISCP Annual Conference
Galway 2017

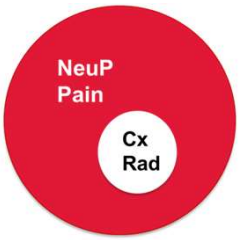
Definition

- **Pain in a radicular pattern** in one or both upper extremities related to **compression and/or irritation** of one or more cervical nerve roots.
- Frequent signs and symptoms include varying degrees of sensory, motor and reflex changes as well as dysesthesias and paresthesias related to nerve root(s) without evidence of spinal cord dysfunction (myelopathy)

NASS Work Group Consensus Statement 2011

- **Radiating pain** in the arm with motor, reflex and/or sensory changes (such as paraesthesiae or numbness), **provoked by neck posture(s) and /or movement(s)**

Thoomes et al 2012



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Background

- Prevalence **3.5 per 1000**
- Annual incidence **83 per 100,000**

Salemi et al 1996, Radhakrishnan et al 1994

- **Taskforce on Neck Pain**
  - Research Gap exists in CR ***Hurwitz et al 2008***
  - Higher levels of pain, disability & healthcare costs ***Haldeman et al 2008***
- **Systematic Reviews**
  - **Conservative Mgmt:** low quality evidence but collar or Physio promising in ST ***Thoomes et al 2013***
  - **Exercise:** low quality evidence for small benefit for immediate pain ↓ post treatment with cervical stretch / strengthening / stabilization in acute CR ***Gross et al 2015***

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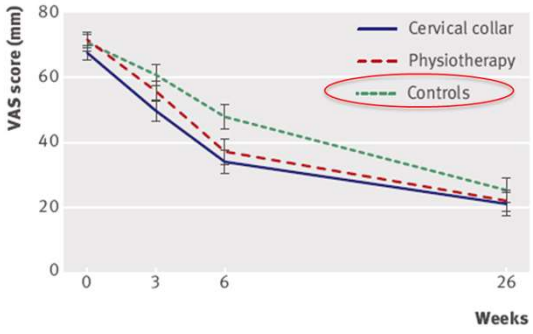
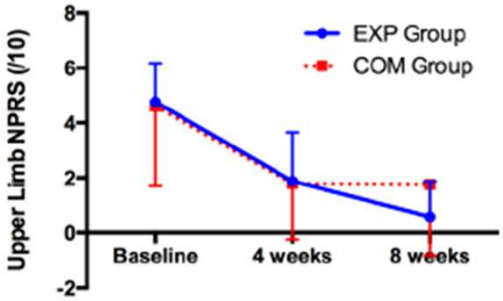
Background

Acute / sub-acute

- **RCTs**
  - **Kuijper** et al 2009
  - **Langevin** et al 2015





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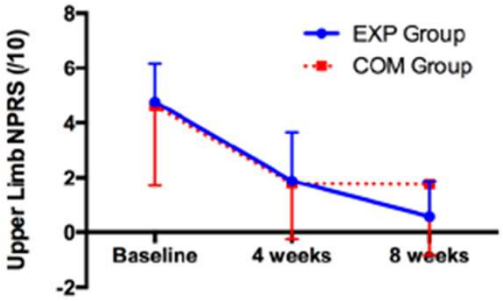
Background

Acute / sub-acute

- **RCTs**
  - Kuijper et al 2009
  - Langevin et al 2015



- **Predictors** of good response to conservative Rx at 4/52
  - age greater than 54 years,
  - non-dominant arm,
  - cervical flexion not aggravating symptoms,
  - multimodal physiotherapy: MT, cervical traction and DNF strengthening at half of clinical visits

Cleland et al 2007

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New Clinical Guidelines

- **Danish** National Clinical Guidelines for recent onset CR

Kjaer et al 2017

- **Canada** - OPTIMa Clinical Guidelines for recent onset Neck pain, including CR

Cote et al 2016

- **APTA** Revised Neck Pain Guidelines

Blanpied et al 2017

Kjaer, P et al (2017). *Eur Spine J*. doi: 10.1007/s00586-017-5121-8
Cote, P et al (2016). *Eur Spine J,* 25**,** 22.
Blanpied et al (2017). *J Orthop Sports Phys Ther,* 47**,** A1-A83.

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Research Questions

- *Clinical Course*
  - Does early stage CR tend to improve with medication & advice over 12 weeks?
- *Early Physiotherapy Intervention*
  - Can early non-provocative physiotherapy reduce pain and disability better than medication & advice alone?
  - What predicts a good outcome?

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Aims & Objectives

- **Primary aim**
  - to investigate the effects of a 4 week multimodal physiotherapy (MP) programme on pain (neck and arm) and disability in patients with acute / sub-acute cervical radiculopathy
    - Co-primary outcome measures are **NDI & NPRS** for neck and arm pain.
    - Primary study end point is **4/52** assessment

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Aims & Objectives 2

- **Secondary Objectives**
  - to investigate the effects of the MP programme on the following additional biopsychosocial outcome measures
    - **Cervical range of motion** measured with a CROM 3 device (Performance Attainment Associates, USA)
    - **Mechanosensitivity** using Pressure Pain Thresholds (PPT) measured with pressure algometry (Walton et al., 2011), and ULNT 1 (Elvey, 1994)
    - **Quality of Life** using the SF-12v2 (Ware et al, 2002)
    - **Anxiety and depression** using the HADS (Zigmond and Snaith, 1983)
    - **Fear Avoidance** beliefs using the FABQ (Waddell et al, 1993, Landers et al, 2008)
    - **Patient rating of recovery** using the Global Rating of Change scale (Jaeschke et al., 1989)

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Aims & Objectives 3

- **Secondary Objectives**
  - to identify whether any of the following can predict outcome at 3/12
    - Biopsychosocial outcome measures from baseline
    - PainDETECT (Freynhagen et al., 2006)
    - Aetiological type of radiculopathy (concordant MRI)
    - Group allocation

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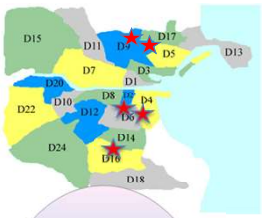
Trial Design



POPN: Adults with Acute / Sub-acute CR

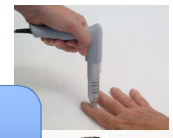
SAMPLE: Untreated Acute / Sub-acute CR (Dx with CPR)

Control: Advice & Meds **n= 32**

Intervention: Multimodal Physio & Meds **n=32**

Outcome

1° - Pain (neck & arm) Disability



Randomisation
Allocation concealment
Blinded Assessment

Baseline — 4wks — 12wks — 6mo*

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Eligibility

- **Recruitment**
  - Neurosurgery OPD wait list (routine appt.), Beaumont Hospital
  - GPs in Greater Dublin
- **Inclusion criteria**
  - Subjects aged 18 years or older
  - Meets criteria for cervical radiculopathy diagnosis on a CPR for at least 3 of the 4 clinical tests ***Wainner et al 2003***
  - Complaints of neck / periscapular pain in addition to radicular pain, paraesthesia or numbness in the upper limb; aggravated by neck posture or movement ***Thoomes et al 2012***
  - Symptom duration must be greater than 2 weeks and less than 3 months
  - Mean of Numerical Pain Rating Scale (NPRS) scores for both neck and arm pain must be ≥ 3/10
  - Fluent in spoken & written English

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Eligibility

- **Exclusion criteria**
  - Bilateral / multi-level CR
  - Previous treatment
    - physiotherapy / manual treatment to cervical spine within 6 months
    - Prior surgery / epidural injection
  - Myotomal paresis < 4 / 5 on MRC scale
  - Co-morbidities –
    - Spondylotic Myelopathy
    - Generalised neuro disorder
    - Peripheral neuropathy affecting either upper limb e.g. carpal tunnel syndrome, thoracic outlet syndrome
    - Fibromyalgia
    - Psychiatric diagnosis within 6 months
  - Medical red flags
  - Ongoing litigation

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Trial schedule

	Enrolment		Allocation	Post-allocation						
TIMEPOINT	$-t_2$	$-t_1$	0	t_1 week 1	t_2 week 2	t_3 week 3	t_4 week 4	f_1 4 weeks	f_2 12 weeks	$f_{3\ (Phone)}$ 24 weeks
ENROLMENT:										
Eligibility phone screen	X									
Eligibility physical screen		X								
Informed consent		X								
Allocation			X							
INTERVENTIONS:										
Multimodal physiotherapy				←	—	—	→			
Control advice phone calls				X	X	X	X			
ASSESSMENTS:										
Primary - NPRS (Neck & Arm) and NDI		X						X	X	X
HADS, FABQ, SF12v2 questionnaires		X						X	X	
ROM, ULNT, PPT measures, Neuro exam		X						X	X	
painDETECT		X								
Participant Beliefs		X								
GROC								X	X	X

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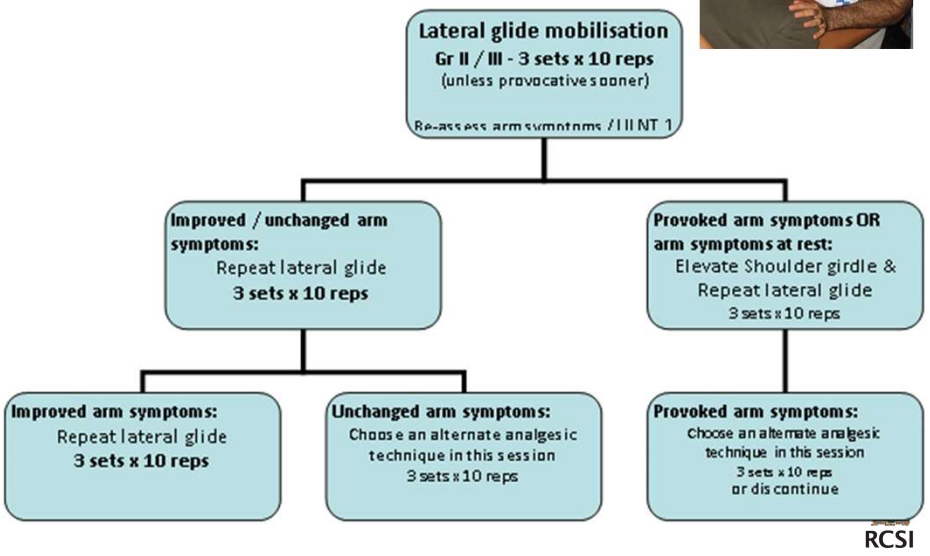
Intervention

- **6-8 sessions**
  - **Manual Therapy**: lat glide at mechanical interface, C2-T4 mobilisation
  - **Exercise**: mobility, DNF, scapular control
  - **Neural unloading tape** (UL)

Lateral Glide algorithm

modified from Nee et al (2011)



Exercise

DNFs

- **10reps x 10 sec holds twice per day**
  - short of fatigue to avoid activity of the superficial muscles

Mobility

- **AROM – Rotation**
  - **sitting / supine**
- **AROM – Flex**
- **AROM – Ext**
  - **10 reps twice a day**

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Scapular Rehab
based on Scapular Dyskinesis Tests

- **Scapula dyskinesis tests** *Kibler and Sciascia, 2010*
  - scapula not elevated at rest and active scapular depression does not increase arm symptoms ➔resolution of significant neuromechanosensitivity

- **Rehab Phases**
  - Phase 1 – Scapular Orientation low load endurance
  - Phase 2 – Training Scapular Orientation with movement and load
  - Phase 3 – Strength & Endurance training

Jull et al 2008, Ekstrom et al 2003, Cools et al 2014, McCreesh 2015

- Progression to overhead movements / load only occurs if symptom free phase 1 and 2 exercises with a good motor control pattern around the scapula

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Scapular Rehab – Phase 2




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Scapular Rehab – Phase 3




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No.	Compulsory Exercises	Options	Non-compulsory Exercises	Options	Conditions
1	**AROM**	Rotation - supine			***Non-provocative direction of movement***
		Rotation - sitting			
		Flexion			
		Extension			
2	**Scapular Orientation (Phase 1)**	Sitting			***No provocation of arm symptoms***
		Sidelying			*Optimal motor pattern*
		Sidelying in 140degs elevation			
			Self-mobilising CT Junction	Rotation	***No provocation of arm symptoms***
				Extension	
			Muscle Stretches	Levator Scapula stretch	***No provocation of arm symptoms***
				Upper Trapezius stretch	
				Pec Minor stretch	
3	**DNF training**	Supine			***No provocation of neck or arm symptoms***
		Prone on elbows			
		Prone with rotn			
			Cervical Extensor training	Neutral to ext	***No provocation of neck or arm symptoms***
				Full range flex to ext	
				Isometric	
			Scapular Training (Phase 2)	Elevation	***No provocation of arm symptoms***
				Concentric ER	*After Scapula Dyskinesis tests only*
				Isometric ER	*1) Scapula not elevate at rest*
					2) Active Scapula Depression does not provoke arm symptoms
				ER with theraband	*Restrict range to symptom free rotation*
				ER with theraband @ 45degs abd	
			Scapular Strengthening (Phase 3)	Unilateral Prone Row	***No provocation of arm symptoms***
				Sidely with UL lift	*Once arm symptoms are not provoked by elevation*
				Unilateral Prone W	
				Unilateral Prone Y	

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Data Analysis Plan

- **Intention to treat analysis**
  - Baseline differences - Linear / Poisson regression
  - Adjusted mean differences between groups (95% CI)
  - ANOVAs & MANOVAs (treatment x time)
  - Per protocol analysis
  - Compliers: 80% Rx received

Thabane et al 2010

- **Predictors of outcome**
  - Multivariable regression analysis
  - Linear / logistic

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Pilot Results

- **Retention**
  - Successful strategy
- **Recruitment**
  - Target n=1 per week not achieved

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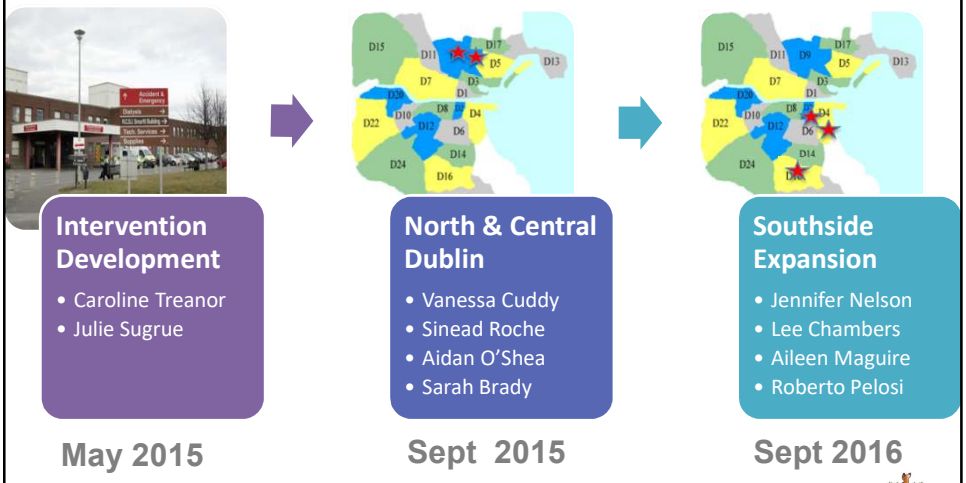
PACeR Trial Evolution



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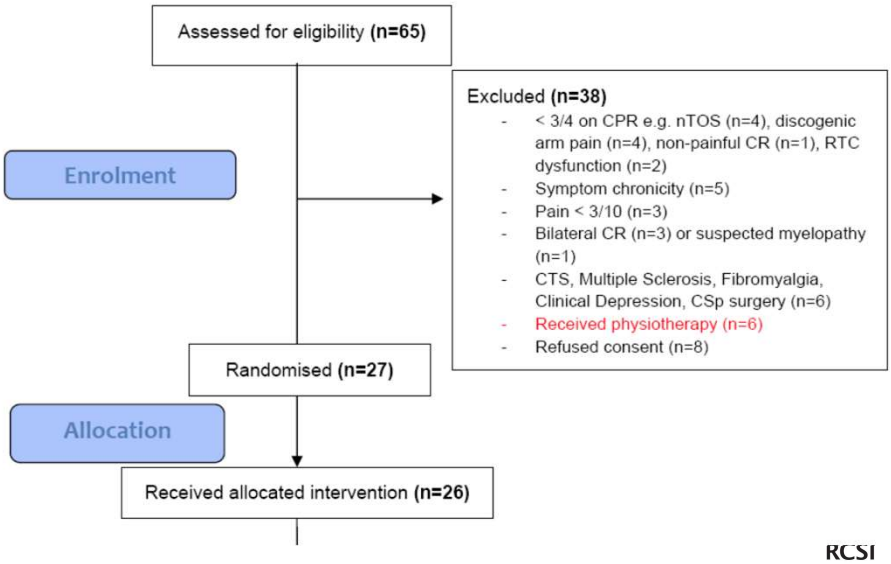
CONSORT Flow Diagram



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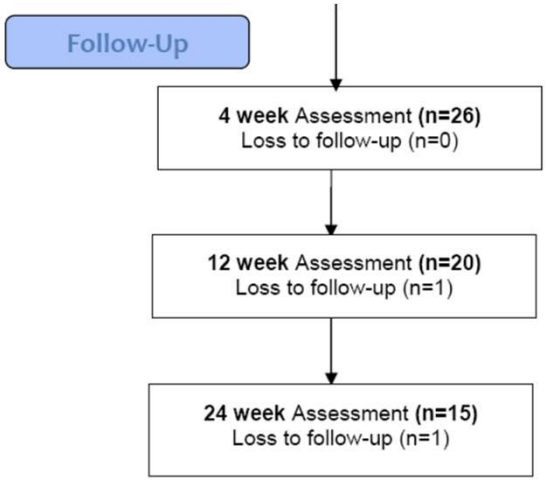

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Challenges

- **Recruitment**
- **Recruitment**
- **Recruitment**

HEALTH RESEARCH BOARD
Primary Care CTNI
CLINICAL TRIALS NETWORK IRELAND

- GP engagement
  - ICGP Faculty & CME mtgs
  - HRB CTNI
- Primary Care Physio Waitlist
- Private Neurosurgeon referrals
- Social media / Radio / print media campaign

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IRISH SOCIETY OF CHARTERED PHYSIOTHERAPISTS

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- Dr. Catherine Doody, UCD

Control Group Physios

- Grace Corcoran,
- Siobhan Magner, Beaumont Hosp

Participants

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References

- BONO, C. M., GHISELLI, G., GILBERT, T. J., KREINER, D. S., REITMAN, C., SUMMERS, J. T., BAISDEN, J. L., EASA, J., FERNAND, R., LAMER, T., MATZ, P. G., MAZANEC, D. J., RESNICK, D. K., SHAFFER, W. O., SHARMA, A. K., TIMMONS, R. B. & TOTON, J. F. 2011. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. *Spine J,* 11**,** 64-72.
- CLELAND, J. A., CHILDS, J. D. & WHITMAN, J. M. 2008. Psychometric properties of the Neck Disability Index and Numeric Pain Rating Scale in patients with mechanical neck pain. Arch Phys Med Rehabil, 89, 69-74.
- GROSS A, et al, Cervical Overview Group. Exercises for mechanical neck disorders. Cochrane Database of Systematic Reviews 2015, Issue 1. Art. No.: CD004250. DOI: 10.1002/14651858.CD004250.pub5.
- HALDEMAN, S., CARROLL, L., CASSIDY, J., SCHUBERT, J. & NYGREN, A. 2008. The Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders - Executive Summary. *Spine (Phila Pa 1976),* 33**,** S5-7.
- HURWITZ, E. L., CARRAGEE, E. J., VELDE, G., CARROLL, L. J., NORDIN, M., GUZMAN, J., PELOSO, P. M., HOLM, L. W., CÔTÉ, P., HOGG-JOHNSON, S., CASSIDY, J. D. & HALDEMAN, S. 2008. Treatment of Neck Pain: Noninvasive Interventions. *European Spine Journal,* 17**,** 123-152.
- KUIJPER, B., TANS, J. T., BEELEN, A., NOLLET, F. & DE VISSER, M. 2009. Cervical collar or physiotherapy versus wait and see policy for recent onset cervical radiculopathy:randomised trial. BMJ, 339, b3883.
- LANGEVIN, P., DESMEULES, F., LAMOTHE, M., ROBITAILLE, S, & ROY, J. S. 2015. Comparison of 2 Manual Therapy and Exercise Protocols for Cervical Radiculopathy: A Randomized Clinical Trial Evaluating Short-Term Effects. *J Orthop Sports Phys Ther* ;45(1):4-17. Epub 24 Nov 2014. doi:10.2519/jospt.2015.5211
- NEE, R. J., VICENZINO, B., JULL, G. A., CLELAND, J. A. & COPPIETERS, M. W. 2012. Neural tissue management provides immediate clinically relevant benefits without harmful effects for patients with nerve-related neck and arm pain: a randomised trial. *Journal of Physiotherapy,* 58**,** 23-31.
- RADHAKRISHNAN, K., LITCHY WJ, O' FALLON WM & LT., K. 1994. Epidemiology of cervical radiculopathy. A population-based study from Rochester, Minnesota, 1976 through 1990. *Brain,* 117**,** 325-35.
- SALEMI G, S. G., MENEGHINI F ET AL. 1996. Prevalence of cervical spondylotic radiculopathy: a door-to-door survey in a Sicilian municipality. . *Acta Neurol Scan. ,* 93**,** 184-88.
- THOOMES, E. J., SCHOLTEN-PEETERS, G. G., DE BOER, A. J., OLSTHOORN, R. A., VERKERK, K., LIN, C. & VERHAGEN, A. P. 2012. Lack of uniform diagnostic criteria for cervical radiculopathy in conservative intervention studies: a systematic review. Eur Spine J, 21, 1459-70.
- WAINNER, R. S., FRITZ, J. M., IRRGANG, J. J., BONINGER, M. L., DELITTO, A. & ALLISON, S. 2003. Reliability and diagnostic accuracy of the clinical examination and patient self-report measures for cervical radiculopathy. *Spine (Phila Pa 1976),* 28**,** 52-62.
- WARE, J. J., KOSINSKI, M., TURNER-BOWKER, D. & GANDEK, B. 2002. User's Manual for the SF-12v2TM Health Survey with a Supplement Documenting SF-12.5 Health Survey. Quality Metric Incorporated.

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