

**Introduction:** Chronic mechanical low back pain (CMLBP) can be caused by impaired neuromuscular control and degeneration of the multifidus muscles resulting in functional instability of the lumbar spine. Available treatment options often lack long-term effectiveness and prognosis is unfavourable. An implantable Restorative Neurostimulation system (ReActiv8® by Mainstay Medical), that stimulates the L2 medial branches of the dorsal rami to reactivate neuromuscular control, received FDA Premarket Approval based on evidence from the ReActiv8-B pivotal trial (clinicaltrials.gov/show/NCT02577354). Here we report the two-year results of the open-label phase of this trial.

**Methods:** Participants had refractory, activity limiting CMLBP with average low back pain VAS $\geq$ 6cm, Oswestry Disability Index ODI $\geq$ 21 points, evidence of multifidus inhibition (prone-instability-test) and no indication for spine surgery. Participants self-administered up to 60-minutes of stimulation per day and were followed-up through two years.

**Results:** At baseline (N=204), participants were 47 $\pm$ 9 years of age, had backpain for 14 $\pm$ 11 years, average LBP-VAS of 7.3 $\pm$ 0.7cm, ODI of 39.1 $\pm$ 10.3 points, EQ-5D (quality-of-life) of 0.585 $\pm$ 0.174 and had LBP on 97 $\pm$ 8% of days during the year before enrolment.

At two-years (N=159), all prespecified outcome measures showed statistically significant (P<0.0001) and clinically substantial improvements compared to baseline. Average LBP-VAS improved by -4.8 $\pm$ 2.4cm (-65.9 $\pm$ 32.6%), ODI by -21.7 $\pm$ 16.8points

(-54.7 $\pm$ 39.2%) and EQ-5D by 0.215 $\pm$ 0.215; 71% of participants had  $\geq$ 50% LBP-VAS improvement; 66% had VAS $\leq$ 2.5cm (LBP-resolution); 62% had  $\geq$ 20points ODI improvement; 77% had  $\geq$ 50% improvement in LBP-VAS and/or ODI; 80% were "Definitely satisfied" with the treatment and 59% voluntarily eliminated or reduced opioid consumption. The overall safety profile is favourable, and no lead migrations were observed.

**Discussion:** Long-term restorative neurostimulation is an effective and durable treatment option with an encouraging safety profile for patients with refractory, activity limiting CMLBP, impaired multifidus motor control and no indications for spine surgery. Clinically substantial improvements, which progressively accrue through two years, are consistent with the restorative mechanism of action.

**Conflicts of Interest Statement:** The ReActiv8-B study was sponsored by Mainstay Medical, who paid the study sites to perform study-related activities, including Assoc Prof Bruce Mitchell's site.

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## S13

### The effect of a neuromuscular neck exercise program on head impact magnitude during heading: A pilot randomised controlled trial

J. Anderson<sup>a</sup>, A. Gardner<sup>e</sup>, I. Gilchrist<sup>c</sup>, M. McKay<sup>a</sup>, T. Meyer<sup>d</sup>, K. Peek<sup>a</sup>, T. Versteegh<sup>b</sup>

<sup>a</sup>University Of Sydney, Australia

<sup>b</sup>School of Physical Therapy, Western University, Canada

<sup>c</sup>School of Kinesiology and Health Studies, Queen's University, Canada

<sup>d</sup>Institute of Sports and Preventive Medicine, Medical Faculty, Germany

<sup>e</sup>Priority Research Centre for Stroke and Brain Injury, School of Medicine and Public Health, The University of Newcastle, Australia

**Introduction:** Football is the only sport where the head is deliberately used to strike a ball. While heading has always been an integral part of football, there is growing research and public concern that retired footballers have an increased risk for neurodegenerative disease due to changes to brain tissue from repeated ball-head impacts. Any impact to the head has the potential to cause a transmission of force to the brain. Whether this results in detrimental stress and strain to brain tissue is likely related to head impact magnitude. Head impact magnitude (including peak linear acceleration and angular velocity of the head) may be attenuated by player neck strength.

**Objectives:** The primary objectives were to explore the effect of a neuromuscular neck exercise program on a) isometric neck flexor, extensor and side flexor strength, and b) head impact magnitude during purposeful heading in male and female adolescent football players. A secondary objective was to explore the acceptability of the exercise program.

**Design:** Pilot randomised controlled trial.

**Methods:** Male and female players (aged 12-17 years) were randomised by team to the intervention (five-week supervised neuromuscular neck exercises integrated into Part 2 of the FIFA 11+) or control (Part 2 of the FIFA 11+ but no neck exercises). Outcomes included isometric neck strength and head impact magnitude (linear head acceleration and angular velocity) during standardised heading (baseline and six-weeks) plus an anonymous evaluation survey.

**Results:** From a total of 88 eligible players, 52 players (n=31 intervention; n=21 control) completed the study. Repeated MANOVAs revealed significant differences in neck strength variables (p<0.001) and peak linear acceleration (p<0.01) between the intervention and control groups over time. A trend towards significance was reported for peak angular velocity (p=0.05). Intervention players demonstrated significant increases in mean composite neck strength (53.8% intervention versus 15.6% control) as well as significant decreases in mean linear head acceleration during heading (-11.8% v -5.0%) from baseline to follow-up. Reduction in angular velocity was more pronounced in female (-27.7%) than male players (-11.5%) in the intervention arm. Players who completed neck exercises reported this as a positive experience which was beneficial to them and their team.

**Conclusion:** Players who completed neuromuscular neck exercises demonstrated an increase in isometric neck strength and decrease in head impact magnitude during heading. The addition of neuromuscular neck exercises into Part 2 of the FIFA 11+ was feasible and accepted by players.

**Conflict of Interest:** My co-authors and I acknowledge that we have no conflict of interest of relevance to the submission of this abstract.

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## S29

### Time-efficient physical activity intervention for older adolescents: the Burn 2 Learn cluster randomised controlled trial

S. Costigan<sup>a,g</sup>, N. Eather<sup>a</sup>, P. Gyawali<sup>i</sup>, C. Hillman<sup>e,f</sup>, E. Holliday<sup>h</sup>, S. Kennedy<sup>a</sup>, A. Leahy<sup>a</sup>, C. Lonsdale<sup>b</sup>, D. Lubans<sup>a</sup>, M. Mavilidi<sup>a</sup>, P. Morgan<sup>a</sup>, M. Nilsson<sup>c</sup>, M. Noetel<sup>b,d</sup>, R. Plotnikoff<sup>a</sup>, T. Shigeta<sup>e,f</sup>, J. Smith<sup>a</sup>, S. Valkenborghs<sup>a</sup>, N. Weaver<sup>h</sup>

<sup>a</sup>Priority Research Centre in Physical Activity and Nutrition, University of Newcastle, Australia

<sup>b</sup>Institute for Positive Psychology and Education, Australian Catholic University, Australia

<sup>c</sup>Faculty of Health and Medicine, University of Newcastle, Australia

<sup>d</sup>School of Behavioural and Health Sciences, Faculty of Health Sciences, Australian Catholic University, Australia

<sup>e</sup>Department of Psychology, Northeastern University, United States of America

<sup>f</sup>Department of Physical Therapy, Movement and Rehabilitation Sciences, Northeastern University, United States of America

<sup>g</sup>School of Exercise and Nutrition Sciences, Deakin University, Australia

<sup>h</sup>School of Medicine and Public Health, University of Newcastle, Australia

<sup>i</sup>School of Biomedical Sciences and Pharmacy, University of Newcastle, Australia

**Introduction:** Time-efficient physical activity interventions are needed for older adolescents ( $\geq$ 16 years) in the senior school years (i.e., Grades 11 and 12) where there is a heavy focus on academic performance and physical education is not mandatory. The aim of our study was to evaluate the impact of a time-efficient school-based intervention designed to improve older adolescents' cardiorespiratory fitness (CRF) by integrating high-intensity activity breaks into curriculum time.