

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

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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

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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.

Methods: We evaluated the Burn 2 Learn (B2L) intervention using a cluster randomised controlled trial with older adolescents (N=670) from 20 secondary schools in New South Wales, Australia. We utilised a range of implementation strategies to support teachers to facilitate the delivery of 2-3 high intensity interval training (HIIT) sessions/week during lesson-time. The B2L intervention included the following: (i) information seminar for students delivered by school champions, (ii) school-based HIIT sessions delivered during lesson time, (iii) purpose-built smartphone application (app) and heart rate monitors designed to quantify individual and group heart rate and support self-monitoring, and (iv) information newsletters for parents. The HIIT sessions involved a combination of aerobic and muscle-strengthening exercises, designed to be enjoyable and vigorous in nature. Teachers and students in the control group continued with their usual practice. Outcomes were assessed at baseline, 6 and 12-months. The primary outcome was CRF (multi-stage fitness test). Secondary outcomes included physical activity (ActiGraph GT9X Link accelerometers), hair cortisol concentrations, muscular fitness (push-up and standing long jump tests), body composition (body mass index), mental health and HIIT self-efficacy (questionnaires). Data were analysed using linear mixed models, accounting for clustering of effects at the class level. Potential moderators of effects were identified a priori and sub-group analyses were conducted if interaction tests were significant ($p < 0.1$).

Results: At the primary endpoint (6-months), we found a significant difference between groups (in favour of B2L) for the primary outcome CRF [4.0 laps (95% CI, 1.7 to 6.4)] and a range of secondary outcomes. Moderator analyses revealed reduced stress and internalising problems among adolescents in the intervention group who were identified as 'at-risk' of poor mental health at baseline.

Discussion: Implementing high intensity breaks during curricular time improved CRF and muscular endurance among the full sample of older adolescents, and mental health among the 'at-risk' sub-sample. Our findings highlight the health benefits of re-allocating a small amount of curriculum time to physical activity during the final years of secondary school.

Trial registration: ACTRN12618000293268

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S32

Physical literacy & early childhood executive function and language development: Active Early Learning randomised controlled trial

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Background: Executive function involves a number of cognitive processes that are integral to the self-regulation of behaviour and developing social and cognitive competence in young children. Physical activity is increasingly recognised as an important determinant of cognitive functioning among older populations but less is known about these relationships in early childhood. In younger populations, it has been suggested that interventions aiming to increase physical activity should focus on children's physical literacy. Physical literacy can be defined as developing capabilities in the physical, psychological, cognitive and social domains that facilitate and promote an active lifestyle across the life course. The contribution of physical literacy programs to the healthy development of language and executive function during early childhood is yet to be fully investigated. In this randomised controlled trial, we examined the effect of a physical literacy curriculum, delivered in an early learning centre setting on

child executive function and language development.

Methods: 321 children aged 3-5 years from 16 early learning centres were randomly assigned to the intervention (8 centres; n=169 children) or control group (7 centres, n=152 children). The intervention group received 20 weeks of the physical literacy curriculum, while the control group received usual practice care. Executive function (inhibition [Go/NoGo]; visual spatial working memory [Mr Ant]; shifting [Card Sort]) and expressive vocabulary was assessed using the Early Years Tool Box. Linear mixed effects models were used to determine differences in groups, adjusting for clustering of children within centres.

Results: Children receiving the intervention had greater improvements on measures of inhibition ($\beta = 1.97$, $p = .001$) and expressive vocabulary ($\beta = 0.5$, $p = .033$), compared to control group children. No significant differences were observed for visual-spatial working memory or shifting.

Discussion: A physical literacy curriculum that aligns with the Australian Early Years Learning Framework and is fully integrated into early learning centre practices is beneficial in improving aspects of young children's executive function and language development. These data support the case for greater investment in physical literacy professional development for educators working in early learning centres.

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S33

Hormone therapy and exercise as interventions for post-menopausal women with greater trochanteric pain syndrome. A randomised clinical trial

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Background: Greater trochanteric pain syndrome (GTPS) is a debilitating condition, prevalent in post-menopausal women. A positive association between high oestrogen levels and tendon health may exist. Menopausal hormone therapy (MHT) could reduce the incidence of tendon abnormality in post-menopausal women, particularly when combined with exercise. This blinded 2 x 2 factorial randomised clinical trial (GLOBE Hip Trial) aimed to determine the effect of MHT and exercise on tendon pain and function in post-menopausal women with GTPS.

Methods: A total of 132 post-menopausal women (mean age 61.1 ± 6.4 years, BMI 28.6 ± 5.43) with GTPS were randomised into either MHT (oestradiol 50mcg and norethisterone acetate 140mcg) or placebo transdermal cream groups and either tendon-specific/GLOBE or sham exercise groups for a 12-week intervention period. All groups received education on avoiding gluteal tendon compression. Primary (Victorian Institute of Sport Assessment - Gluteal Tendon (VISA-G)) and secondary (Assessment of Quality of Life, Hip Disability and Osteoarthritis Outcome Score, Oxford Hip Score, Global Rating of Change) outcomes were measured at baseline, 12 and 52 weeks. A linear mixed effects model (of best fit) was used to compare groups at each time point and changes over time. Body mass index (BMI) was included as a covariate.

Results: All groups improved over time, regardless of intervention. There was no difference between targeted or sham exercise or MHT and placebo creams (raw unadjusted and including BMI as covariate) at each timepoint. VISA-G outcome was significantly associated with BMI ($p = 0.003$) and there was a significant interaction effect between cream and BMI ($p = 0.03$). The population was therefore stratified based on BMI (<25, <30, ≥ 30). The MHT groups (with exercise and education) had