

### **Best Evidence from the Cochrane Library**

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### **Exercise Interventions for Smoking Cessation**

Michael H Ussher, Adrian Taylor, Guy Faulkner

**Background:** Taking regular exercise may help people give up smoking by moderating nicotine withdrawal and cravings, and by helping to manage weight gain.

**Objective:** To determine whether exercise-based interventions alone, or combined with a smoking cessation program, are more effective than a smoking cessation intervention alone.

**Result:** We identified 15 trials, seven of which had fewer than 25 people in each treatment arm. They varied in the timing and intensity of the smoking cessation and exercise programs. Three studies showed significantly higher abstinence rates in a physically active group versus a control group at end of treatment. One of these studies also showed a significant benefit for exercise versus control on abstinence at the three-month follow-up and a benefit for exercise of borderline significance ( $p=0.05$ ) at the 12-month follow-up. One study showed significantly higher abstinence rates for the exercise group versus a control group at the three-month follow up but not at the end of treatment or 12-month follow-up. The other studies showed no significant effect for exercise on abstinence.

**Conclusion:** Only one of the 15 trials offered evidence for exercise aiding smoking cessation at a 12-month follow-up. All the other trials were too small to reliably exclude an effect of intervention, or included an exercise intervention, which was insufficiently intense to achieve the desired level of exercise. Trials are needed with larger sample sizes, sufficiently intense interventions, equal contact control conditions, and measures of exercise adherence and change in physical activity in both exercise and comparison groups.

### **Disposable Surgical Face Masks for Preventing Surgical Wound Infection in Clean Surgery**

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**Background:** Surgical facemasks were originally developed to contain and filter droplets

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containing microorganisms expelled from the mouth and nasopharynx of healthcare workers during surgery, thereby providing protection for the patient. However, there are several ways in which surgical facemasks could potentially contribute to contamination of the surgical wound, e.g. by incorrect wear or by leaking air from the side of the mask due to poor string tension.

**Objective:** To determine whether disposable surgical facemasks worn by the surgical team during clean surgery prevent postoperative surgical wound infection.

**Result:** Three trials were included, involving 2113 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials.

**Conclusion:** From the limited results, it is unclear whether the wearing of surgical facemasks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery.

### **Intracutaneous or Subcutaneous Sterile Water Injection Compared with Blinded Controls for Pain Management in Labor**

Sheena Derry, Sebastian Straube, R Andrew Moore, Heather Hancock, Sally L Collins

**Background:** Intracutaneous or subcutaneous injection of sterile water is rapidly gaining popularity as a method of pain relief in labor and it is therefore essential that it is properly evaluated. Adequate analgesia in labor is important to women worldwide. Sterile water injection is inexpensive, requires basic equipment, and appears to have few side effects. It is purported to work for labor pain.

**Objective:** To determine the efficacy of sterile water injections for relief of pain (both typical contraction pain and intractable back pain) during labor compared to placebo (isotonic saline injections) or non-pharmacological interventions, and to identify any relevant effects on mode and timing of delivery, or safety of both mother and baby.

**Result:** We included seven studies, with 766 participants: four used intracutaneous injections, two subcutaneous, and one both. All reported on low back pain in labor only. Methodological quality was good, but four studies were at high risk of bias due to small size of treatment groups, incomplete outcome data, and performance bias.

All studies reported treatment group mean or median scores, finding greater reduction in pain for sterile water. However, failure to demonstrate a normal distribution for pain intensity or relief, and use of different scales, meant meta-analysis was inappropriate. No study reported primary dichotomous efficacy outcomes. One reported the number self-scoring 4/10 cm or more reduction in pain; significantly more had this outcome with sterile water (50% to 60%) than with placebo (20% to 25%).

There was no significant difference between sterile water and saline for rates of caesarean section (risk ratio (RR) 0.58, 95% confidence interval (CI) 0.33 to 1.02), instrumental delivery (RR 1.31, 95% CI 0.79 to 2.18), rescue analgesia (RR 0.86, 95% CI 0.44 to 1.69), timing of delivery, or Apgar scores. Two studies reported that more women treated with sterile water would request the same analgesia in future.

No study reported on women's satisfaction with pain relief, women's sense of control in labor, women's satisfaction with the childbirth experience, mother/baby interaction, rates of breastfeeding, maternal morbidity, infant long-term outcomes, or cost. No adverse events were reported other than transient pain with injection, which was worse with sterile water.

**Conclusion:** The outcomes reported severely limit conclusions for clinical practice. We found little robust evidence that sterile water is effective for low back or any other labor pain. Neither did we find any difference in delivery or other maternal or fetal outcomes. Further large, methodologically rigorous studies are required to determine the efficacy of sterile water to relieve pain in labor.

### **Intramedullary Nailing for Tibial Shaft Fractures in Adults**

Xin Duan, Mohammed Al-Qwbani, Yan Zeng, Wei Zhang, Zhou Xiang

**Background:** Intramedullary nailing is commonly used for treating fractures of the tibial shaft. These fractures are one of the most common long bone fractures in adults.

**Objective:** To assess the effects (benefits and harms) of different methods and types of intramedullary nailing for treating tibial shaft fractures in adults.

**Result:** Nine randomized and two quasi-randomized clinical trials, involving 2093 participants with 2123 fractures, were included. The evidence was dominated by one large multicentre trial of 1319 participants. Both quasi-randomized trials were at high risk of selection bias. Otherwise, the trials were generally at low or unclear risk of bias. There were very few data on functional outcomes and often incomplete data on re-operations. The trials evaluated five different comparisons of interventions: reamed versus non-reamed intramedullary nailing (six trials); ender nail versus interlocking nail (two trials); expandable nail versus interlocking nail (one trial); interlocking nail with one distal screw versus with two distal screws (one trial); and closed nailing via the trans-tendinous approach versus the para-tendinous approach (one trial).

No statistically significant differences were found between the reamed and non-reamed nailing groups in 'major' re-operations (66/789 versus 72/756; risk ratio (RR) 0.88, 95% confidence interval (CI) 0.64 to 1.21; 5 trials), or in the secondary outcomes of nonunion, pain, deep infection, malunion and compartment syndrome. While inconclusive, the evidence from a subgroup analysis suggests that reamed nailing is more likely to reduce the incidence of major re-operations related to non-union in closed fractures than in open fractures. Implant failure, such as broken screws, occurred less often in the reamed nailing group (35/789 versus 79/756; RR 0.42, 95% CI 0.28 to 0.61).

There was insufficient evidence established to determine the effects of interlocking nail with one distal screw versus with two distal screws, interlocking nail versus expandable nail and para-tendinous approach versus trans-tendinous approach for treating tibial shaft fractures in adults.

Ender nails when compared with an interlocking nail in two trials resulted in a higher re-operation rate (12/110 versus 3/128; RR 4.43, 95% CI 1.37 to 14.32) and more malunion. There were no statistically significant differences between the two devices in the other reported secondary outcomes of nonunion, deep infection, and implant failure.

One trial found a lower re-operation rate for an expandable nail when compared with an interlocking nail (1/27 versus 9/26; RR 0.11, 95% CI 0.01 to 0.79). The differences between the two nails in the incidence of deep infection or neurological defects were not statistically significant.

The trial comparing one distal screw versus two distal screws found no statistically significant difference in nonunion between the two groups. However, it found significantly more implant failures in the one distal screw group (13/22 versus 1/20; RR 11.82, 95% CI 1.70 to 82.38).

One trial found no statistically significant differences in functional outcomes or anterior knee pain at three-year follow-up between the trans-tendinous approach and the para-tendinous approach for nail insertion.

**Conclusion:** Overall, there is insufficient evidence to draw definitive conclusions on the best type of, or technique for, intramedullary nailing for tibial shaft fractures in adults. 'Moderate' quality evidence suggests that there is no clear difference in the rate of major re-operations and complications between reamed and non-reamed intramedullary nailing. Reamed intramedullary nailing has, however, a lower incidence of implant failure than non-reamed nailing. 'Low' quality evidence suggests that reamed nailing may reduce the incidence of major re-operations related to non-union in closed fractures rather than in open fractures. 'Low' quality evidence suggests that the Ender nail has poorer results in terms of re-operation and malunion than an interlocking nail.

## **Conservative Management for Post Prostatectomy Urinary Incontinence**

Susan E Campbell, Cathryn MA Glazener, Kathleen F Hunter, June D Cody,  
Katherine N Moore

**Background:** Urinary incontinence is common after both radical prostatectomy and transurethral resection of the prostate (TURP). Conservative management includes pelvic floor muscle training with or without biofeedback, electrical stimulation, extra-corporeal magnetic innervation (ExMI), compression devices (penile clamps), lifestyle changes, or a combination of methods.

**Objective:** To assess the effects of conservative management for urinary incontinence after prostatectomy.

**Result:** Thirty-seven trials met the inclusion criteria, 33 amongst men after radical prostatectomy, three trials after transurethral resection of the prostate (TURP) and one trial after either operation. The trials included 3399 men, of whom 1937 had an active conservative intervention. There was considerable variation in the interventions, populations and outcome measures. Data were not available for many of the pre-stated outcomes. Men's symptoms improved over time irrespective of management. Adverse effects did not occur or were not reported.

There was no evidence from eight trials that pelvic floor muscle training with or without biofeedback was better than control for men who had urinary incontinence after radical prostatectomy (e.g. 57% with urinary incontinence versus 62% in the control group, risk ratio (RR) for incontinence after 12 months 0.85, 95% confidence interval (CI) 0.60 to 1.22) as the confidence intervals were wide, reflecting uncertainty. However, one large multicentre trial of one-to-one therapy showed no difference in any urinary or quality of life outcome measures and had narrower confidence intervals. There was also no evidence of benefit for erectile dysfunction (56% with no erection in the pelvic floor muscle-training group versus 55% in the control group after one year, RR 1.01, 95% CI 0.84 to 1.20). Individual small trials provided data to suggest that electrical stimulation, external magnetic innervation or combinations of treatments might be beneficial but the evidence was limited.

One large trial demonstrated that there was no benefit for incontinence or erectile dysfunction from a one-to-one pelvic floor muscle training based intervention to men who were incontinent after transurethral resection of the prostate (TURP) (e.g. 65% with urinary incontinence versus 62% in the control group, RR after 12 months 1.05, 95% CI 0.91 to 1.23).

In eight trials of conservative treatment of all men after radical prostatectomy aimed at both treatment and prevention, there was an overall benefit from pelvic floor muscle training versus control management in terms of reduction of UI (e.g. 10% with urinary incontinence after one year versus 32% in the control groups, RR for urinary incontinence 0.32, 95% CI 0.20 to 0.51). However, this finding was not supported by other data from pad tests. The findings should be treated with caution, as most trials were of poor to moderate quality and confidence intervals were wide.

Men in one trial were more satisfied with one type of external compression device, which had the lowest urine loss, compared to two others or no treatment. The effect of other conservative interventions such as lifestyle changes remains undetermined as no trials involving these interventions were identified.

**Conclusion:** The value of the various approaches to conservative management of post prostatectomy incontinence after radical prostatectomy remains uncertain. It seems unlikely that men benefit from one-to-one pelvic floor muscle training therapy after transurethral resection of the prostate (TURP). Long-term incontinence may be managed by external penile clamp, but there are safety problems.

## **Progressive Resistance Strength Training for Improving Physical Function in Older Adults**

Chiung-ju Liu, Nancy K Latham

**Background:** Muscle weakness in old age is associated with physical function decline. Progressive resistance strength training (PRT) exercises are designed to increase strength.

**Objective:** To assess the effects of PRT on older people and identify adverse events.

**Result:** One hundred and twenty one trials with 6700 participants were included. In most trials, PRT was performed two to three times per week and at a high intensity. PRT resulted in a small but significant improvement in physical ability (33 trials, 2172 participants; SMD 0.14, 95% CI 0.05 to 0.22). Functional limitation measures also showed improvements: e.g. there was a modest improvement in gait speed (24 trials, 1179 participants, MD 0.08 m/s, 95% CI 0.04 to 0.12); and a moderate to large effect for getting out of a chair (11 trials, 384 participants, SMD -0.94, 95% CI -1.49 to -0.38). PRT had a large positive effect on muscle strength (73 trials, 3059 participants, SMD 0.84, 95% CI 0.67 to 1.00). Participants with osteoarthritis reported a reduction in pain following PRT (6 trials, 503 participants, SMD -0.30, 95% CI -0.48 to -0.13). There was no evidence from 10 other trials (587 participants) that PRT had an effect on bodily pain. Adverse events were poorly recorded but adverse events related to musculoskeletal complaints, such as joint pain and muscle soreness, were reported in many of the studies that prospectively defined and monitored these events. Serious adverse events were rare, and no serious events were reported to be directly related to the exercise program.

**Conclusion:** This review provides evidence that PRT is an effective intervention for improving physical functioning in older people, including improving strength and the performance of some simple and complex activities. However, some caution is needed with transferring these exercises for use with clinical populations because adverse events are not adequately reported.

## **Physical Activity and Enhanced Fitness to Improve Cognitive Function in Older People without Known Cognitive Impairment**

Maaïke Angevaren, Geert Aufdemkampe, HJJ Verhaar, A Aleman, Luc Vanhees

**Background:** Physical activity is beneficial for healthy ageing. It may also help maintain good cognitive function in older age. Aerobic activity improves cardiovascular fitness, but it is not known whether this sort of fitness is necessary for improved cognitive function. Studies in which activity, fitness and cognition are reported in the same individuals could help to resolve this question.

**Objective:** To assess the effectiveness of physical activity, aimed at improving cardiorespiratory fitness, on cognitive function in older people without known cognitive impairment.

**Result:** Eight out of 11 studies reported that aerobic exercise interventions resulted in increased cardiorespiratory fitness of the intervention group (an improvement on the maximum oxygen uptake test which is considered to be the single best indicator of the cardiorespiratory system) of approximately 14% and this improvement coincided with improvements in cognitive capacity. The largest effects on cognitive function were found on motor function and auditory attention (effect sizes of 1.17 and 0.50 respectively). Moderate effects were observed for cognitive speed (speed at which information is processed; effect size 0.26) and visual attention (effect size 0.26).

**Conclusion:** There is evidence that aerobic physical activities, which improve cardiorespiratory fitness, are beneficial for cognitive function in healthy older adults, with effects observed for motor function, cognitive speed, auditory and visual attention. However, the majority of comparisons yielded no significant results.

The data are insufficient to show that the improvements in cognitive function, which can be attributed to physical exercise, are due to improvements in cardiovascular fitness, although the temporal association suggests that this might be the case. Larger studies are still required to confirm whether the aerobic training component is necessary, or whether the same can be achieved with any type of physical exercise. At the same time, it would be informative to understand why some cognitive functions seem to improve with (aerobic) physical exercise while other functions seem to be insensitive to physical exercise.

Clinicians and scientists in the field of neuropsychology should seek mutual agreement on a smaller battery of cognitive tests to use, in order to render research on cognition clinically relevant and transparent and heighten the reproducibility of results for future research.