

Considered Judgement Form

This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations.

Meeting date: 12th of August 2005.

Topic: *The effectiveness of Ergys – A functional Electrical Stimulation Device used to improve the health and wellbeing of persons with spinal cord injuries.*

Background and Purpose:

In recent years there has been a growing awareness of the need for physical exercise in Spinal Cord Injured (SCI) patients. One of the leading causes of death in the SCI population is cardiovascular disease which is associated with exercise inactivity. There is strong confirmation that functional electrical stimulation (FES) can significantly improve cardiovascular function in individuals with SCI (Wilder *et al*, 2002).

FES is stimulation of the neuromuscular system by small electrical currents in functional or therapeutic applications. The FES cycle ergometer (Ergys2) is one of the newer technologies on the market, and is used to enhance the health of patients suffering from SCI. The main goal of the FES cycle ergometer is to aid in the treatment of the cardiopulmonary and circulatory systems, muscles and bones which are severely affected due to injury by SCI.

Currently ACC does not fund FES-cycle ergometer equipment for SCI patients and a request for evidence which supports the appropriateness of ACC funding for these claimants was requested by a branch manager.

<p>1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency</p> <p>Comment here on the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible, any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand Population, and the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence</p> <p>A total of 29 papers met the selection criteria and were included in the review. All studies included adults only with either tetraplegia or paraplegia with varying post injury times. The quality of the studies was moderate with only four papers graded with a 1- rating, indicating that there is some evidence of effectiveness of FES-cycle ergometry. Three papers were controlled trials and hence were graded a level 2. The majority of other studies were case series or pre post tests where intervention measures were observed before and after intervention.</p> <p>Overall, there was moderate evidence for FES cycle ergometry. It appears beneficial for Spinal Cord Injured (SCI) users in terms of cardiovascular and muscle outcomes, given there is consistent use for a 3 month period or greater. There is insufficient evidence to suggest that FES-cycle ergometry reduces bone demineralisation.</p>
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2. Cost

Comment on any economic costs associated with this service, product or procedure

Currently the ERGYS 2 costs \$15,665.00 (USD), (~\$22,050.80 NZD). All papers suggest that use must be consistent and a plan for ongoing regular exercise is required for maintenance of therapeutic effects. (www.musclepower.com/patientpricing.htm).

3. Clinical impact

Comment on the clinical impact e.g. size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit.

The evidence from RCT's, controlled trials, and case series indicate that FES-cycle ergometry maybe effective in improving cardiopulmonary and circulatory function as well as lower extremity muscle atrophy. There is limited evidence as to whether these positive outcomes translate to functional improvement.

There is insufficient evidence to suggest that bone mass reduction is halted or stopped as a result of FES-cycling.

There has been no direct comparison between the "hand cycle" which is currently used in New Zealand, or other forms of rehabilitation versus the ERGYS system.

Use of the FES cycle is not recommended for individuals with the following conditions: implanted pacing devices, high or abnormal heart rate, high blood pressure, heart disease, possible blood clots, types of tumour, pregnancy, unhealed wounds, infection in the area of treatment, denervated muscle, severe osteoporosis, limited range of motion in joints where treatment is to occur, abnormal bone formation in treatment areas, severe muscle spasticity, autonomic dysreflexia, history of joint disarticulation of treatment limb, and high fever (Wilder et al, 2002).³⁷.

Few adverse effects were reported in the 29 studies included in this review. Fatigue was the most commonly reported safety issue. In these instances, cycling was slowed or stopped to allow the subject to recover. FES-cycling appears to be a reasonably safe intervention when practiced appropriately by properly trained therapists.

4. Equity, Maori Health, Pacific Health, Acceptability

Comment on the extent to which the service, product or procedure reduces disparities in health status (equity of access, resources, health outcome), is consistent with the treaty of Waitangi and encourages Maori/ Pacific participation in providing and using service, product and procedures, and is consistent with values and expectations of New Zealanders.

The purchasing recommendation should be applied equally across Maori, Pacific and ethnic populations.

5. Possible Purchasing Options

List the possible purchasing options.

Option 1: Don't purchase, at this time. Wait for more evidence to become available relating to overall functional improvement after using the ERGYS device. Wait for evidence that compares the currently used treatment such as the "Hand Cycle" with the Ergys device.

Option 2: Purchase on a case by case basis, where a clear exercise regime is stipulated over a 3 month or greater period and that the individual meets all of the criteria required for the safe use of such a piece of equipment.

Option 3: Purchase FES cycle ergometers for communal use in spinal injury units such as Burwood Spinal Unit in Christchurch or Otara Spinal Unit in Auckland.

6. Evidence Statement

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

On the basis of the studies reviewed, FES cycle ergometry appears beneficial for SCI users in terms of physiological outcomes, given there is consistent use for a three month period or greater. There is insufficient evidence to suggest that FES-cycle ergometry reduces bone demineralisation.

FES-cycling therefore appears to be a reasonably safe intervention when practiced appropriately by properly trained therapists.

7. Purchasing Recommendations

What recommendation(s) does the advisory group draw from this evidence?

The PGAG are unable to make a purchasing recommendation because there is insufficient evidence.

References

Wilder RP, Jones EV, Wind TC, Edlich RF. Functional electrical stimulation cycle ergometer exercise for spinal cord injured patients. [Review] [44 refs]. *Journal of Long-Term Effects of Medical Implants*. 2002;12(3):161-74.

PGAG Discussion

It is not clear if the physiological benefits attributable to this device would translate into functional improvement for the claimant with spinal cord injury, or whether this device offers any benefit over usual treatments.

It was not clear why ERYS wasn't being used in other countries.