Critical issues in the transition of FES technology from research laboratory to clinical practice: a study of subject presentation and recruitment.

R Marshall[1,2], H Rischbieth[2], JM Clark[2], JM Jelbart[2], S Donohoe[2], J Strayer[1,2], M Sharpe[3]

The Royal Adelaide Hospital[1]; The Hampstead Rehabilitation Centre[2]; The University of South Australia[3].

Abstract

Aim

We sought to define patterns and trends in recruitment of patients in FES research programmes.

Method

137 subjects were approached for recruitment in four separate studies over 10 years (FES-walking, exercise, upper limb neuroprosthesis, wound healing). Reasons for exclusion or withdrawal were divided into four categories - Emotional/ Social, Medical, Physical and FES Criteria - which varied between the studies.

Results

Of the 137 patients approached, 33 (24%) were eligible for inclusion, and 18 (13%) completed the studies. Success rates of recruitment to the studies appear to be related to characteristics of the potential sample as much as to the effects of the stimulation, and varied from 6% for the upper limb neuroprosthesis to 33% for the FES-exercise study. Statistical power was low in these four studies because matched controls and double-blind research designs are inappropriate.

Conclusion

Recruiting and retaining SCI subjects to FES research studies requires access to a large sample population. Many factors limit successful recruitment to FES treatment programmes. Overcoming these factors is essential if FES is to increase its role in the rehabilitation of persons with SCI.

The quality and quantity of FES research in recent years has provided evidence for the resurgence of FES in clinical practice. Health professionals familiar with FES technologies readily identify potential beneficiaries within cohorts with neurological impairment. However further research is needed to substantiate the wider use of FES applications and increase acceptance of technology-based interventions in the management of acute and chronic neurological disorders. Furthermore trustworthy evidence is the antecedent step for transfer from research to clinical practice. Significantly in the pathway from research to practice, FES technology has encountered a number of impediments to momentum and progress.

Eligibility for inclusion in a research sample from a spinal cord injured population is determined by level and completeness of injury, physical status and current medical status. Thus a subject may be excluded on one or more of those criteria, according to the study requirements.

We examined the recruitment of cohorts of SCI volunteers against these criteria. All had completed rehabilitation at the same centre and were residing in the community. Subjects presented with:

1. Chronic neurological impairment (SCI) and attended the laboratory on an outpatient basis (Groups 1a & 1b) – predominantly paraplegic subjects;
2. Chronic neurological impairment (SCI), the subjects were evaluated

against criteria for prescription of a neuromuscular prosthesis (Group 2) – tetraplegic subjects.

3. Chronic neurological impairment (SCI) requiring hospital admission for management of delayed wound healing (Group 3)

Methods

Four separate FES studies with very dissimilar objectives were completed between 1990 and 1999. We designed a recruitment algorithm for use with FES research (Figure 5), and examined recruitment patterns against the algorithm.

Standardized FES criteria excluded persons with known cardiac or cardiovascular disorders, active bone or joint disease or osteoporosis > moderate and pregnancy.

Studies 1 and 2

These studies recruited fit and healthy subjects with thoracic paraplegia (ASIA A). Study 1 evaluated standing and stepping following to the Kralj and Bajd method; Study 2 assessed combined electrically stimulated leg cycling and active arm cranking (using the Power Trainer) to enhance fitness.

Inclusion

- Males and females with Thoracic SCI > 1 year
- Skeletally mature and < 70 years

Exclusion

- Medical debility / insufficient physical capacity
- Musculoskeletal deformity – fracture / contracture
- Skin breakdown
- Psychological or emotional disorder

Table 1 – Stand and Step (Study 1)

Status	*Number*
Approached	26
Screened	18
Eligible	16
Completed	4

Rate of completion of study = 15%

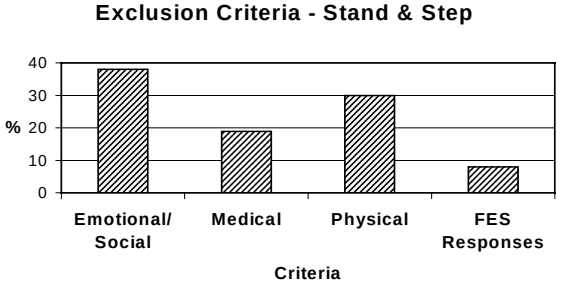

Figure 1 – Exclusion criteria for Study 1

Table 2 – Electrically stimulated cycling (Study 2).

Status	*Number*
Approached	21
Screened	16
Eligible	9
Completed	7

Rate of completion of study = 33%

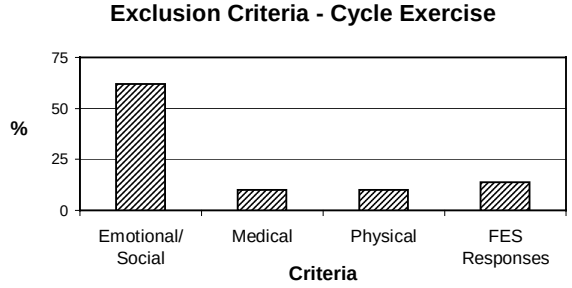

Figure 2 – Exclusion criteria for Study 2

Study 3 (Upper limb Neuroprosthesis multi-centre trial).

Inclusion

- Males and females with C6-7 SCI (ASIA A)
- Medically and physically appropriate: proximal upper limb function and antigravity wrist extension
- Stimulation response and tolerance

Exclusion

- Usual FES contraindications including autonomic dysreflexia
- Emotional, social and cognitive function.

Table 3 – Upper limb neuroprosthesis (Study 3)

Status	*Number*
Approached	60
Screened	29
Eligible	5
Accepted	5
Completed	4

Rate of completion of study = 6%

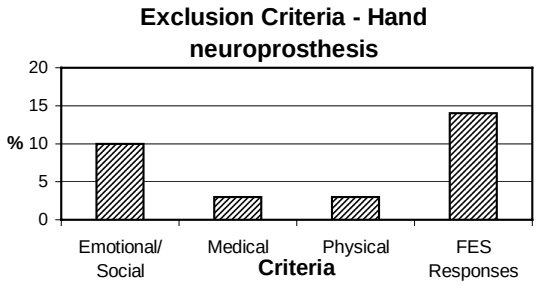

Figure 3 – Exclusion criteria for Study 3

Study 4 (Wound management)

Inclusion

- Males and females with SCI (ASIA A-D) admitted for wound management
- Age 18-55 years
- Wound morphology (10-100 cm^3)

Exclusion

- Chronic medical illness
- Emotional and social function
- Wound criteria and compliance with wound care

Table 4 – Wound management (Study 4)

Status	*Number*
Approached	30
Screened	30
Eligible	2
Completed	2

Rate of completion of study = 6.6%

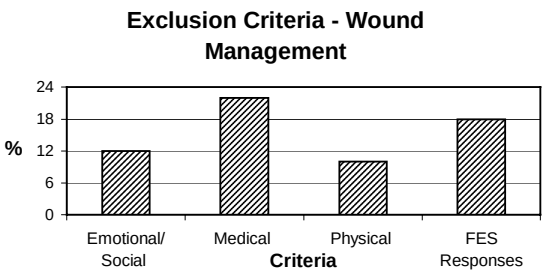

Figure 4 – Exclusion criteria for Study 4

Discussion

There are clear prerequisites for safe and timely transition of technologies from the laboratory to the clinic, and clinical research is an essential step in this process. Safe and effective prescription of technology is determined by evidence from such research.

Rates for completion of a study ranged from 3% (debilitated) to 33% (fit and healthy). Reasons for the variation changed with each study. Although neurological presentations were similar for all subjects, health status varied considerably. Success of the recruiting decreased with increasing specificity of application and with increasing debility of the target sample.

Statistical power was consistently low in these studies because matched controls and double-blind research designs are inappropriate. Multi-centre trials can improve study power, but pose a number of other difficulties with regard to ethos, ethical, political, social economic and logistic considerations.

Conclusion

Many factors limit successful recruitment to FES trials and treatment programmes. Overcoming these factors is essential if FES is to increase its role in the rehabilitation of persons with SCI.

The future of successful clinical application of FES may rely on transfer of technology from the laboratory through collaboration between research establishments (Figure 6).

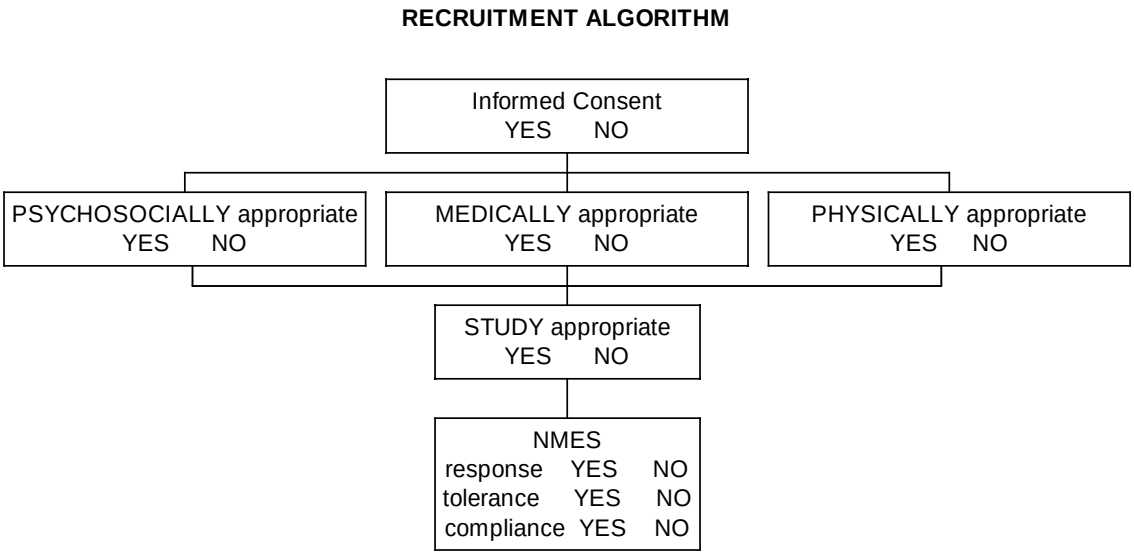

Figure 5. Recruitment Algorithm

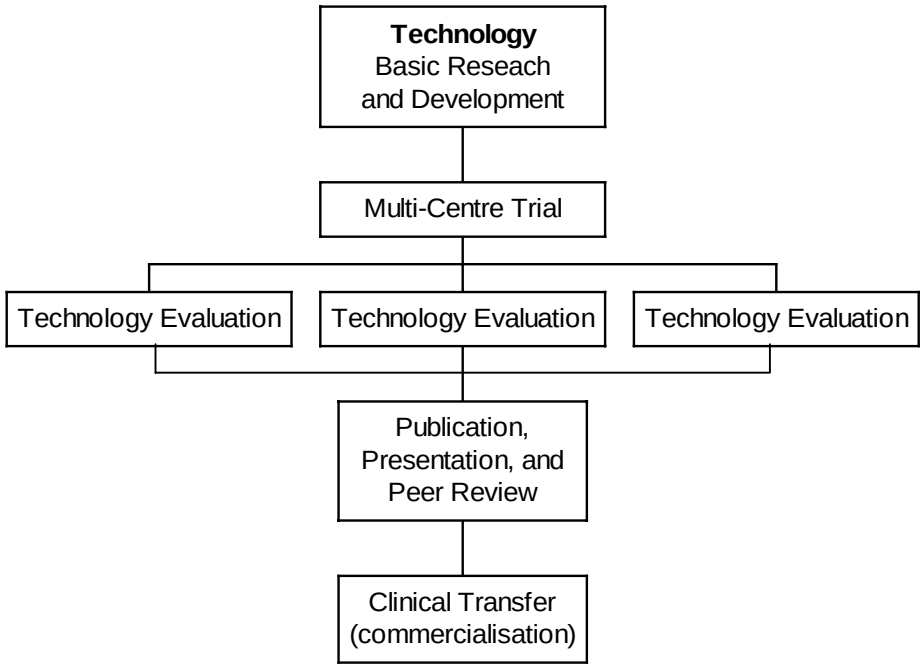

Figure 6 Technology transfer algorithm