NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Functional electrical stimulation to stimulate muscle recovery in non neurological chronic diseases**

Name of Professional Expert: Christine Singleton

Job title: Clinical Specialist (FES) Physiotherapist

Professional Regulatory Body: GMC ☐

Other (specify) X☐

Registration number: PH29851

Specialist Society: Chartered Society of Physiotherapist

Nominated by (if applicable):

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

☐**X** Yes.

☐ No – please answer no more questions and return the form

Comments:

As a physiotherapist I have used and developed the clinical application of Functional Electrical Stimulation (FES) since 1995. Currently manage and clinically lead a specialist FES service which I developed for the West Midlands region in 2002.

1.2 Is this procedure relevant to your specialty?

☒ **X** Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

I use FES on a daily basis mostly for neurological and some non neurological conditions

1.3 Is this procedure performed by clinicians in specialities other than your own?

☒ **X** Yes – please comment

☐ No

Comments:

The National FES Centre use FES for both neuro and non neurological conditions. It is also used for muscular skeletal conditions to strengthen muscles and encourage active movement. Sports injury clinics and private practices use FES

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

☒ **X** I do this procedure regularly.

Comments:

1.5 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☒ **X** I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

1.6 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☐**X** I have done bibliographic research on this procedure.

☐X I have done research on this procedure in laboratory settings (e.g. device-related research).

☐X I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

The majority of my research relates to use of FES for neurological conditions

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☐ Fewer than 10% of specialists engaged in this area of work.

☐**X** Cannot give an estimate.

Comments:

Medical doctors do not perform this procedure as it is usually the Physiotherapist or Medical Engineers/Scientists

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☐ Yes

☐**X** No - If no, please suggest alternative titles.

Comments:

Functional electrical stimulation to stimulate muscle activity and recovery in non neurological chronic diseases

2.2 Which of the following best describes the procedure (choose one):

☒ **X** Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

Electrical stimulation of muscle has been around for many years with Slendertone (abdominals), faradic stimulation (foot baths), being examples

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Resisted muscle activity using weights or machinery, gym exercise, cardio-vascular exercises, walking

2.4 Are there any major trials or registries of this procedure currently in progress? If so, please list.

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Work relating to circulation (preventing DVTs) and chronic constipation treatment

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

Please list any adverse events and major risks (even if uncommon) and, if possible, estimate their incidence:

Adverse events reported in the literature (if possible please cite literature)

Anecdotal adverse events (known from experience)

Intolerance to sensation of stimulation, skin reaction to electrodes used in FES

Theoretical adverse events

Pacemaker/defibrillator present, pregnancy is considered as a contraindication, poor skin condition, uncontrolled epilepsy

3.2 Please list the key efficacy outcomes for this procedure?

Facilitation of muscle activity, strengthening of muscle function, improving physiology of muscles, facilitation of normal activity, pain management, realignment of joints

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

No concerns other than good instructions

3.4 What clinician training is required to do this procedure safely?

Reading instruction booklets, training in applications for best outcome, sharing practice

3.5 What clinical facilities are needed to do this procedure safely?

This procedure can be done by the patient in their home environment so no special clinical facilities are required other than privacy of consulting room when teaching patients

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

None known although it is taking time to be considered as a treatment option eg: muscular skeletal conditions as a pre op training

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

Daily treatment of 30 mins for 6 weeks should show a change in condition

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

If no benefit after 3 months of daily treatment then should be discontinued

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☐**X** Rapidly (within a year or two).

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

Depends on how the procedure is used eg: pre/post surgery

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

☐ Most or all district general hospitals.

☐ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐**X** Cannot predict at present.

Comments:

The community is also an appropriate place for this treatment, GP practices, rehabilitation centres, community physio, patients can self treat following screening and instruction

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐**x** Major.

☐ Moderate.

☐ Minor.

Comments:

This is an under-utilised self treatment with training

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

Electrical stimulation has potential to allow patients to treat themselves with guidance

7 Data protection and conflicts of interest

7.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The professional expert questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our privacy notice

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7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
none			

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Functional electrical stimulation to stimulate muscle recovery in non neurological chronic diseases**

Name of Professional Expert: Edward Tobias (Toby) Pring BSc MBChB MRCS

Job title: Clinical Research Fellow

Professional Regulatory Body: GMC ☒

Other (specify) ☐

Registration number: 7042088

Specialist Society: ESCP, ACPGBI

Nominated by (if applicable): N/A

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please answer no more questions and return the form

Comments:

I am a clinical research fellow and general surgery registrar. I am conducting research into functional electrical stimulation in the context of advanced colorectal cancer and post surgical recovery. I have over 2 years experience of FES in complex cancer surgical patients and am currently principle investigator on a single centre

RCT using Neuro Muscular Electrical Stimulation (NMES) in the pre and post-operative setting of advance colorectal cancer.
We consider cancer to be a chronic disease which has a profound effect on muscle mass, patients with poor muscle mass have worse post-surgical and oncological outcomes. Surgery and subsequent immobility and malnutrition compound muscle loss. Our unit has a specific interest in muscle preservation and functional recovery following surgery for colorectal cancer. We believe, in a subset of patients with advanced disease and poor postoperative mobility, that FES/NMES may provide benefit by the reduction of post-operative cancer induced muscle loss (myopenia/sarcopenia). We do believe that this has to be done in combination with nutritional support and more importantly standard physiotherapy – FES is an adjunct to, not a replacement for, physiotherapy.

1.2 Is this procedure relevant to your specialty?

☒ Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

FES is of great interest in my field as there is a greater appreciation of prehabilitation and rehabilitation especially in patients incapacitated as a result of surgery. There have been multiple previous trials looking at NMES/FES in the cancer population – usually palliative, our interest is in the curative surgical population. This latter group has received little interest regarding FES to date but we believe this is an ideal group who could benefit from FES treatment (due to removal of cancer i.e. the main initial stimulus of muscle loss, high rates of poor mobility, young and motivated group).

1.3 Is this procedure performed by clinicians in specialities other than your own?

☒ Yes – please comment

☐ No

Comments:

FES is used in multiple specialties including critical care and neurological rehab

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

☒ I do this procedure regularly.

Comments:

We are using FES as part of a randomised clinical trial as described above.

1.5 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☒ I take part in patient selection or refer patients for this procedure regularly.

Comments:

1.6 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☒ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☒ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

RCT currently recruiting at St Mark's Hospital LNWUH NHS Trust
See clincaltrials.gov trial NCT04065984 for further details
https://clinicaltrials.gov/ct2/show/NCT04065984?term=nmes&draw=2&rank=8

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☒ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

This is a novel method however it has been used in cancer patients before – we are currently the only individuals using it in the post operative cancer surgery setting

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☐ Yes

☒ No - If no, please suggest alternative titles.

Comments:

Functional electrical stimulation to stimulate muscle recovery in non neurological acute rehabilitation and chronic diseases

2.2 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☒ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Standard physiotherapy without NMES/FES

2.4 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Multiple trials – see https://clinicaltrials.gov/ct2/results?term=nmes&Search=Search

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a

comprehensive reference list but it will help us if you list any that you think are particularly important.

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

Please list any adverse events and major risks (even if uncommon) and, if possible, estimate their incidence:

- FES is not to be used by people who have implanted electronic devices (pacemakers etc.) unless under specialised medical supervision.
- Persons with uncontrolled epilepsy.
- The safety of electrical stimulation in pregnancy has not been determined and therefore contraindicated in this study.
- Some high level spinal cord lesion patients may suffer autonomic effects after or during electrical stimulation.

Adverse events reported in the literature (if possible please cite literature)

- A slight reddening of the skin under the electrode is normal. This should fade after about an hour once the electrodes are removed.
- Reaction to electrode gel – allergy or irritation
- Pain – pulled muscle/muscle injury

Anecdotal adverse events (known from experience)

Theoretical adverse events

- There is a potential risk that handling the electrodes while the stimulator is on can lead to stimulation current affecting other areas of the body. There is a theoretical possibility that the electrical stimulation may affect the heart if the current path is directly across the chest, although there are no reported incidences of this.

3.2 Please list the key efficacy outcomes for this procedure?

Change in muscle mass (measurable on CT scanning)
Muscle mass measure on bioimpedance analysis
Functional improvement (Berg Balance Scale, 6 minute walk test, sit to stand test)
Functional Quality of life measure on validated questionnaires – see below.

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

Efficacy has not been proven to date in this patient population.

3.4 What clinician training is required to do this procedure safely?

Very little training required, explanation of theory and device training can be completed in 2 to 3 hours.

3.5 What clinical facilities are needed to do this procedure safely?

No extra clinical facilities are required and the procedure can be undertaken independently by the patient at home following appropriate training.

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

None in this field but is a novel procedure

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

CT muscle and body composition measurements in cancer paitens undergoing routine CTs
Bio-impedance analysis – muscle mass pre and post usage
Functional measures as described aboveQoL measures include standard Quality of life validated questionnaires especially relating to function – we use ED-5Q-5L & EORTC QLQ – CR29 at 6 months and 12 months following surgery

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Any adverse events – including pain, irritation, and more serious adverse events e.g. seizures

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☐ Rapidly (within a year or two).

☒ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

☒ Most or all district general hospitals.

☐ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

There would potentially be call for this procedure in chronic surgical inpatients who have either had complex postoperative courses or complications resulting in significant catabolism and muscle loss be it from infection, muscle disuse of malnutrition. It should be used in combination with nutritional support and standard physiotherapy and is very much a rehabilitation adjunct rather than a panacea. The devices are relatively cheap, easy to use, safe and generally well tolerated. Compliance in some patients appears to be an issue, both in published literature and from our own experience, anecdotally from our own experience other patients seem to enjoy the experience and use the device religiously.

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☒ Moderate.

☐ Minor.

Comments:

This device if efficacious has the potential to reduce hospital stay by allowing self-directed physiotherapy in a complex patient group. It potentially increases patient

autonomy giving them an active role in there rehabilitation process. It is cheap but should not be used at the expense of or replacement for other resources i.e. standard physiotherapy.

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

Compliance with treatment is a major potential barrier to efficacy, treatment is time consuming and if patients are mobile they are reluctant to use the device in addition to day to day exercise. NICE should take into account compliance data within studies as this will have a potentially significant effect on efficacy and outcome.

7 Data protection and conflicts of interest

7.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The professional expert questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☐ X I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our privacy notice

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7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
No pecuniary interest or otherwise to declare			

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Functional electrical stimulation to stimulate muscle recovery in non neurological chronic diseases**
Name of Professional Expert:	Ian Swain
Job title: Professor	
Professional Regulatory Body:	GMC ☐
	Other (specify) HCPC ☐
Registration number: CS03644	
Specialist Society: IPEM	
Nominated by (if applicable):	IPEM

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

x☐ Yes.

☐ No – please answer no more questions and return the form

Comments:

I have worked in the field of FES for over 35 years.

1.2 Is this procedure relevant to your specialty?

x☐ Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

x☐ Yes – please comment It is performed by doctors, physios and OTs as well as Clinical Engineers and Scientists.

☐ No

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

x☐ I do this procedure regularly. I have personally assessed over 3000 patients

Comments:

1.5 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

x☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

See answer to1.4

1.6 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

x☐ I have done bibliographic research on this procedure.

x☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

x☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

x☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

x☐ Yes

☐ No - If no, please suggest alternative titles.

Comments:

2.2 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

x☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

Physiotherapists often used exercise to strengthen muscles. Also FES is widely used in neuro patients. The use of FES in increasing strength in MSK patients is merely an extension of these two.

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Standard physiotherapy without the use of FES

2.4 Are there any major trials or registries of this procedure currently in progress? If so, please list.

We are just commencing a trial looking at the role of FES in people undergoing THR. We have published our literature reviews prior to the trial which we are just about to start.

Burgess L, Immins T, Swain I, Wainwright T. **Effectiveness of neuromuscular electrical stimulation for reducing oedema: A systematic review** Journal of Rehabilitation Medicine 26 Feb 2019 (Journal article)

Louise C. Burgess,mailto:lburgess@bournemouth.ac.uk Ian D Swain, Paul Taylor, Thomas W. Wainwright

Strengthening Quadriceps Muscles with Neuromuscular Electrical Stimulation Following Total Hip Replacement: a Review Current Physical Medicine and Rehabilitation Reports First Online: 09 May 2019 Musculoskeletal Rehabilitation (B Schneider, Section Editor)

A previous trial some years ago looked at TKR.

Avramidis K, Strike PW, Taylor PN, Swain ID. Effectiveness of electrical stimulation of the vastus medialis muscle in the rehabilitation of patients after total knee arthroplasty. *Archives of Physical Medicine and Rehabilitation,* 84: 1850-1853, 2003.

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a

comprehensive reference list but it will help us if you list any that you think are particularly important.

Electrical stimulation for strengthening weakened muscles.

1. Doucet BM, Lam A, Griffin L. Neuromuscular electrical stimulation for skeletal muscle function. Yale J Biol Med. 2012; 85: 201-15.
2. Kramer JF, Mendryk SW. Electrical stimulation as a strength improvement technique: a review. J Orthop Sports Phys Ther. 1982; 4: 91-8.
3. Yue C, Zhang X, Zhu Y, Jia Y, Wang H, Liu Y. Systematic Review of Three Electrical Stimulation Techniques for Rehabilitation After Total Knee Arthroplasty. J Arthroplasty. 2018; 33: 2330-7.
4. Dehail P, Duclos C, Barat M. Electrical stimulation and muscle strengthening. Ann Readapt Med Phys. 2008; 51: 441-51.
5. Watson T. Electrotherapy: Evidence-Based Practice. 12th Edition ed. Philadelphia: Churchstone Livingstone Elsevier, 2008.
6. (ATPA) APTA. Clinical Electrophysiology. Electrotherapeutic Terminology in Physical Therapy. Alexandria, VA: American Physical Therapy Association, 1990.
7. Rushton DN. Functional electrical stimulation and rehabilitation--an hypothesis. Med Eng Phys. 2003; 25: 75-8.
8. Eriksson E, Haggmark T. Comparison of isometric muscle training and electrical stimulation supplementing isometric muscle training in the recovery after major knee ligament surgery. A preliminary report. Am J Sports Med. 1979; 7: 169-71.
9. Williams JG, Street M. Sequential faradism in quadriceps rehabilitation. Physiotherapy. 1976; 62: 252-4.
10. Millard JB. The use of electrical stimulation in the rehabilitation of knee injuries. Proc Int Congr Phys Med 1952; London; 1952.
11. Curwin S SWD, Valiant G. . Clinical applications and biochemical effects of high frequency electrical stimulation. Can Athl Ther Assoc 1980; 7: 15-6.
12. Hartsell HD. Electrical muscle stimulation and isometric exercise effects on selected quadriceps parameters*. J Orthop Sports Phys Ther. 1986; 8: 203-9.
13. Selkowitz DM. High frequency electrical stimulation in muscle strengthening. A review and discussion. Am J Sports Med. 1989; 17: 103-11.
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3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

Please list any adverse events and major risks (even if uncommon) and, if possible, estimate their incidence:

Adverse events reported in the literature (if possible please cite literature)

The most likely adverse event is a reaction to the electrodes used. This is far more likely in neurological patients where the system is used, often on a daily basis for many years. Reddening often occurs under the electrodes but this quickly fades.

The safety of electrical stimulation in patients with pacemakers and implantable cardioverter defibrillators: A systematic review

Badger J, Taylor, P , Swain I (10.1177/2055668317745498)
Journal of Rehabilitation and Assistive Technologies Engineering **4**:2055668317745498 2018

Influence of electrical stimulation therapy on permanent pacemaker function.
Egger F, Hofer C, Hammerle FP, Löfler S, Nürnberg M, Fiedler L, Kriz R, **Kern H**, Huber K.
Wien Klin Wochenschr. 2019 Jul;131(13-14):313-320. doi: 10.1007/s00508-019-1494-5. Epub 2019 Apr 25.
PMID:

31025164

If however FES is being used to strengthen denervated muscles then there are far more problems as the energy needed is many times that required for innervated muscles. Denervated muscles occur after damage to peripheral nerves, the spinal cord below T12 or in certain conditions such as polio and MND. The leading group in this field is in Vienna. Kern et al.

To Reverse Atrophy of Human Muscles in Complete SCI Lower Motor Neuron Denervation by Home-Based Functional Electrical Stimulation.
Kern H, Gargiulo P, Pond A, Albertin G, Marcante A, Carraro U.
Adv Exp Med Biol. 2018;1088:585-591. doi: 10.1007/978-981-13-1435-3_27.
PMID:

30390271

Similar articles

Select item 29686823 7.
Two years of Functional Electrical Stimulation by large surface electrodes for denervated muscles improve skin epidermis in SCI.
Albertin G, **Kern H**, Hofer C, Guidolin D, Porzionato A, Rambaldo A, Caro R, Piccione F, Marcante A, Zampieri S.
Eur J Transl Myol. 2018 Mar 6;28(1):7373. doi: 10.4081/ejtm.2018.7373. eCollection 2018 Jan 12.

PMID:

29686823

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Anecdotal adverse events (known from experience)

CONTRINDICATIONS AND PRECAUTIONS

The list below are those often provided with FES equipment.

1. Avoid handling the electrodes while the stimulator is on. This is to prevent the stimulation current affecting other areas of the body. There is a theoretical possibility that the electrical stimulation may affect the heart if the current path is directly across the chest, although there are no reported incidences of this. Always remember to turn OFF the stimulator before you remove the electrodes!

2. **Do not** immerse in water. Clean using a damp cloth. **Do not** use spirit based cleaners unless required for infection control.

3. Always wash and dry the skin carefully when the electrodes have been removed. **Do not** use skin creams near the electrode sites.

4. A slight reddening of the skin under the electrode is normal. This should fade after about an hour once the electrodes are removed. If stimulation causes long term marking of the skin, discontinue use and seek medical advice.

5. **Do not** place electrodes over broken skin or shave the area under the electrodes as this may cause skin irritation.

6. Spastic tone may be affected by electrical stimulation. If you notice any adverse change in the spasticity, discontinue use and seek medical advice.

7. **Do not** operate dangerous machinery or drive whilst using the stimulator.

8. **Do not** use the stimulator within three meters of physiotherapy short wave diathermy equipment.

9. The safety of electrical stimulation in pregnancy has not been determined.

10. Some high level spinal cord lesion patients may suffer autonomic effects after or during electrical stimulation. If head aches or sweating occur, or if blood pressure, bowel or bladder are affected, discontinue the use of the stimulator and seek medical advice.

11. The stimulator is **not** to be used by people who have implanted electronic devices (pacemakers etc.) unless under specialised medical supervision. See article in previous section. Badger et al.

12. Persons with epilepsy **should not** use the stimulator unless their fits are well controlled with drug treatment.

Theoretical adverse events

See above.

3.2 Please list the key efficacy outcomes for this procedure?

Increase muscular strength, blood flow and associated benefits.

Taylor, P.N., Ewins,D.J., Fox,B., Grundy,D., Swain,I.D., Limb Blood Flow, Cardiac Output and Quadriceps Muscle Bulk following Spinal Cord Injury and the Effect of Training for the Odstock Functional Electrical Stimulation Standing System. Paraplegia, 31 (1993) 303-310.

Muscle and skin improve by home-based FES and full-body in-bed gym.

U C, G A, P G, B R, F P, S Z, H K, Pond A.

Biol Eng Med. 2018 Jun;3(3). doi: 10.15761/BEM.1000S1003. Epub 2018 May 24.

PMID:

30820477

Free PMC Article

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Gerontol Geriatr Med. 2018 Apr 10;4:2333721418768998. doi: 10.1177/2333721418768998. eCollection 2018 Jan-Dec.

4 Effects of Electrical Stimulation on Skeletal Muscle of Old Sedentary People.

Mosole S[1,2], Zampieri S[1,2], Furlan S[3], Carraro U[4], Löefler S[2], Kern H[2,5], Volpe P[1], Nori A[1].

4.1 Please list any uncertainties or concerns about the *efficacy* of this procedure?

Like a lot of physiotherapy compliance is a problem. Again the great variety in dosage makes for uncertainty in the treatments efficacy.

4.2 What clinician training is required to do this procedure safely?

Most physios will cover the basic in their first degree. However few have any real experience. There are a number of courses available but the majority are for neurological patients . See https://www.odstockmedical.com/course-types

4.3 What clinical facilities are needed to do this procedure safely?

Standard physiotherapy equipment plus access to equipment as one of the advantages of the technique is that is can, and should, be carried out by the patient at home in order to be able to provide a sufficient dose. It is something that needs to be done either daily or alternate days at least.

4.4 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Yes, little structured training at a postgraduate level. A lot of commercial equipment is over complex and hence clinical staff are often uncertain of the parameters to use. Many companies make unrealistic claim and often have very complex waveforms designed primarily to sell their equipment rather than being based on sound scientific and clinical principles.

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

Prof Taylor and I have this for neuro patients where we have extensive data on over 7000 people but we do not have such data on musculoskeletal patients. We are happy to share that data with you as it does determine the long term use of FES systems, albeit not for the category of patients specified here . The effects on muscle function, skin problems etc are still however relevant.

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

The most obvious early adverse outcome measure is that the patient does not like the sensation and is hence non-compliant with treatment. This is known at the time of assessment. Skin problems are often detected after several months. However most MSK patients would use the system for less than 6 months at the longest.

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

x☐ Rapidly (within a year or two).

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

x☐ Most or all district general hospitals.

☐ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

It will probably being in a hub and spoke arrangement with regional centres starting and then rolling out services. However the numbers of patients who could benefit, given the number of THR/TKR etc, would need the service to be provided at a DGH level. Specialist course s would be needed for MSK physios sop that the use of the equipment is based on scientific principles rather than company literature.

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

x☐ Major. – but could be provided as part of standard physio care. It is not a miracle cure but something which should be used to enhance current treatment

where clinically relevant. For staff to be able to determine this requires greater staff training.

☐ Moderate.

☐ Minor.

Comments:

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

I am sorry that I was unable to be able to come to the meeting in person although I would be very willing to be involved further in this process as I feel my clinical experience in the field would be very beneficial to the group.

7 Data protection and conflicts of interest

7.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The professional expert questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our privacy notice

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7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director