WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

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Prof Suzanne Hagen
Programme Director
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NMAHP Research Unit
Glasgow Caledonian University
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Glasgow
G4 0BA

Date 13 March 2013
Direct line 0141-211-1722
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e-mail evelyn.jackson@ggc.scot.nhs.uk

Dear Professor Hagen

Study title: **Multicentre randomised trial of the effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence (OPAL-Optimal PFMT for Adherence Long-term)**
REC reference: **13/WS/0048**
IRAS project ID: **120377**

The Research Ethics Committee reviewed the above application at the meeting held on 1 March 2013. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Ms Evelyn Jackson, evelyn.jackson@ggc.scot.nhs.uk.

Ethical opinion

Ethical issues raised by the Committee in private discussion, together with responses given by the researcher when invited into the meeting:

1. The Committee asked where the interviews will take part and Professor Hagen explained that the first interview will take place in a place that is convenient to participants then the rest will be on the telephone.

2. The Committee were not sure how the EMG Biofeedback unit to be used at home would work and Professor Hagan explained that this unit is the same as the one used in the clinic setting. This has a screen and gives a reading of contraction strength and the information is stored in the unit and can be accessed when the unit is connected to the computer in the clinic.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

1. In the Participant Information Sheet (PIS):

(a) The Committee suggested that a lay title be added and EMG Biofeedback be explained,

or refer to the leaflet which describes this.

(b) Give details of the voucher to be given to participants.

(c) In the Electromyography Biofeedback Information Leaflet, section headed “Home EMG Biofeedback”, more explicit information to be given as to how the EMG Biofeedback unit will be used in the patient's home.

(d) In the section headed “Who has reviewed the study “East local NHS Board Ethics Committee to be removed from all of the PISs.

(e) The letters relating to the 12 month and 24 month questionnaire must be printed on appropriate letter headed paper and contact details to be printed at the top of the page.

(f) Give details that as part of the bladder diary, urine passed will be measured and recorded.

(g) Add a statement that all audio recordings will be destroyed following transcription.

2. In the Consent Form:

(a) Instead of tick boxes against each statement, the participant should initial against each statement.

(b) Must be printed on appropriate letter headed paper and contact details printed at the top of the page.

3. The Committee suggested that women suffering from mixed UI incontinence should not be included in the study as this could be caused by other factors not associated to the pelvic floor muscles.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The documents reviewed and approved at the meeting were:

Document	***Version***	***Date***
Covering Letter	-	14 February 2013
REC application	-	13 February 2013
Protocol	1.0	12 February 2013
Investigator CV	-	-
Letter of invitation to participant	1.0	12 February 2013
Participant Information Sheet: General	1.0	13 February 2013
Participant Information Sheet: EMG Biofeedback Leaflet	1.0	12 February 2013
Participant Information Sheet: Interview Study	1.0	12 February 2013
Participant Consent Form: General	1.0	12 February 2013
Participant Consent Form: Interview Study	1.0	07 February 2013

GP/Consultant Information Sheets	1.0	30 January 2013
Evidence of insurance or indemnity	-	10 July 2012
Letter from Sponsor	-	-
Other: Best Contact Form	-	-
Other: First Appointment Date Letter	1.0	12 February 2013
Other: Interview Study Letter	1.0	12 February 2013
Other: Pre-Treatment Interview (A)	1.0	12 February 2013
Other: Post Treatment Interview (B)	1.0	12 February 2013
Other: 12 month Follow-up Interview	1.0	12 February 2013
Other: 6 month appointment date letter	1.0	12 February 2013
Other: 6 month questionnaire - reminder letter	1.0	12 February 2013
Other: 6 month questionnaire - 2nd reminder letter	1.0	12 February 2013
Other: Post intervention delivery interview (by phone)	1.0	12 February 2013
Other: 12 month questionnaire letter	1.0	12 February 2013
Other: 12 month questionnaire - reminder letter	1.0	12 February 2013
Other: 24 month questionnaire letter	1.0	12 February 2013
Other: 24 month questionnaire - reminder letter	1.0	12 February 2013
Other: 24 month follow-up interview (D)	1.0	12 February 2013
Other: Letter from Professor John Norrie, CHaRT	-	20 April 2012
Other: Letter from National Institute for Health Research re. funding	-	06 November 2012
Other: Bladder Diary	1.0	13 February 2013
Other: Therapy Assessment and Treatment Form	1.0	13 February 2013
Other: Clinical Assessment Form	1	13 February 2013
Other: EMG home diary	1.0	13 February 2013
Other: PFM home diary	1.0	13 February 2013
Questionnaire: Participant Costs and Travel	1.0	13 February 2013
Questionnaire: Baseline Questionnaire	1.0	12 February 2013
Questionnaire: 6/12/24 month questionnaire	1.0	12 February 2013

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/WS/0048 Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

***For* Dr Brian Neilly**
Chair

Enclosures: *List of names and professions of members who were present at the meeting*
"After ethical review – guidance for researchers"

Copy to: *Veronica James, Glasgow Caledonian University*
Dr Maureen Travers, R&D Office, Tennent Building, Western Infirmary

West of Scotland REC 4

Attendance at Committee meeting on 01 March 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Lynda Brown	Public Health Adviser	No	
Thomas Duncan Byrne		Yes	
Dr Andrew Clark	Consultant Haematologist	No	
Ms Cristina Coelho	Pharmacist	Yes	
Dr Clair Evans	Consultant Paediatric and Perinatal Pathologist	Yes	
Dr Kenneth James	Consultant Anaesthetist	Yes	
Dr Grace Lindsay	Reader	No	
Miss Fiona Mackelvie	(Retired) Lay member	Yes	
Ms Margaret McDonald	Retired (Lay Member)	No	
Mrs Cynthia Mendelsohn	Retired (Lay member)	No	
Dr Brian Neilly	Consultant Physician	Yes	
Dr Jackie Riley	Statistician	Yes	
Dr Ihab Shaheen	Consultant Paediatric Nephrologist	Yes	
Mrs Kathleen Tuck	Retired Teacher	Yes	
Mr Iain Wright	Consultant Engineer (Lay member)	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Dr Judith Godden	Scientific Adviser
Ms Evelyn Jackson	
Dr Laura Strachan	Trainee Anaesthetist
Dr S Viswanathan	Consultant GI Radiologist

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Professor Suzanne Hagan
Research Programme Director
Nursing, Midwifery and Allied Health
Professions Research Unit
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Cowcaddens Road
Glasgow
G4 0BA

Date 14 October 2013
Direct line 0141-211-1722
Fax 0141-211-1847
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Dear Professor Hagan

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REC reference:	**13/WS/0048**
IRAS project ID:	**120377**

Thank you for your letter of 1 October 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 13 March 2013

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Covering Letter	-	01 October 2013
Participant Information Sheet: General: Leaflet	2.0	26 September 2013
Participant Consent Form	2.0	01 October 2013

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Covering Letter	-	14 February 2013
Covering Letter	-	01 October 2013
Protocol	1.0	12 February 2013
REC application	-	13 February 2013
Investigator CV	-	-
Letter of invitation to participant	1.0	12 February 2013
Participant Information Sheet: EMG Biofeedback	1.0	13 February 2013
Participant Information Sheet: Interview Study	1.0	12 February 2013
Participant Information Sheet: General: Leaflet	2.0	26 September 2013
Participant Consent Form: Interview Study	1.0	07 February 2013
Participant Consent Form	2.0	01 October 2013
Evidence of insurance or indemnity	-	10 July 2012
GP/Consultant Information Sheets	1.0	30 January 2013
Letter from Sponsor	-	-
Other: Best Contact Form	-	-
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Questionnaire: Participant Costs and Travel	1.0	13 February 2013
Questionnaire: Baseline Questionnaire	1.0	12 February 2013
Questionnaire: 6/12/24 month questionnaire	1.0	12 February 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/WS/0048 **Please quote this number on all correspondence**

Yours sincerely

Ms Evelyn Jackson
Committee Co-ordinator

Copy to: *Professor Valerie Webster, Glasgow Caledonian University*
Dr Maureen Travers, R&D Office, Tennent Building, Western Infirmary