

# Randomised controlled trial of Early biofeedBAck PhysioTherapy versus pelvic floor exercises in patients who sustain third degree tears

<b>Submission date</b> 23/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/05/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/08/2011	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Colm O Herlihy

### Contact details

UCD School of Medicine and Medical Science  
National Maternity Hospital  
Dublin  
Ireland  
2

## Additional identifiers

### Protocol serial number

2

## Study information

### Scientific Title

**Acronym**

EBAPT

**Study objectives**

Women who sustain third or fourth degree tears are at risk of subsequent faecal incontinence. Our hypothesis is that women who sustain a third degree tear who have early intervention with home biofeedback physiotherapy will have fewer symptoms and better manometry pressures than those advised to perform standard pelvic floor exercises.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the National Maternity Hospital on the 21st January 2007

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Anal sphincter injury leading to anal incontinence

**Interventions**

We propose to randomise patients who have sustained a third or fourth degree tear into two groups. One group receives current management of laxatives, antibiotics and analgesia and is advised on pelvic floor exercises. The other group is shown how to perform biofeedback exercises using a machine at home. Both groups will be followed up at the specialised perineal clinic and will be evaluated using endo-anal ultrasound and anorectal manometry.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Manometry scores at three months.

**Key secondary outcome(s)**

Symptoms and continence scores at three months.

**Completion date**

31/01/2008

**Eligibility**

**Key inclusion criteria**

Patients who have sustained a third degree tear in labour

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Patients who sustained a third degree tear in a previous delivery
2. Patients whose babies are in the special care baby unit
3. Infectious blood borne disease: Human Immunodeficiency Virus (HIV) and hepatitis B and C
4. Patients who have drug and alcohol addiction problems and would not be likely to be able to follow the home programme
5. Patients who do not have a fluent command of English

**Date of first enrolment**

01/02/2007

**Date of final enrolment**

31/01/2008

**Locations****Countries of recruitment**

Ireland

**Study participating centre**

UCD School of Medicine and Medical Science

Dublin

Ireland

2

**Sponsor information****Organisation**

National Maternity Hospital (Ireland)

**ROR**

<https://ror.org/03jcx214>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Maternity Hospital, Health Research Board of Ireland (Ireland)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration