

# Clinical and cost effectiveness of different emergency department healthcare professionals in soft tissue management

**Submission date**  
20/08/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
07/10/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
01/11/2013

**Condition category**  
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Clinical and cost effectiveness of different emergency department healthcare professionals in soft tissue management: a randomised trial

## Acronym

MISTi Trial - Management In Soft Tissue injury Trial

## Study objectives

This research is a trial of equivalence and investigates two null hypotheses:

1. The clinical outcome of adult patients presenting to the Emergency Department (ED) with a soft tissue injury (STI) is different between healthcare professionals
2. A doctor, Emergency Nurse Practitioner (ENP) and Extended Scope Physiotherapist (ESP) are not equally cost-effective in treating ED patients with soft tissue injuries

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by:

1. The Salisbury and South Wiltshire Ethics Committee, obtained on the 4th May 2006 (ref: 06/Q2008/10)
2. The Faculty of Health and Social Care Ethics Committee at the University of the West of England, obtained on the 10th July 2006 (ref: HSC/06/07/57)

## Study design

Pragmatic multicentre three-arm blinded randomised controlled trial of equivalence

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Acute peripheral musculoskeletal soft tissue injury

## **Interventions**

Active control: Doctors (of all grades)

Intervention under investigation: Extended Scope Physiotherapist (ESP) and Emergency Nurse Practitioners (ENP). The intervention is the care provided by ESPs and ENPs compared to routine treatment by Doctors.

The patients are being followed up at 14 days and 8 weeks post treatment.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

The primary aspect of the study will evaluate the clinical outcome of STIs following attendance at an emergency department, and the impact on quality of life. This will be done at baseline, and at 2 and 8 weeks using telephone interviews. The trial is powered to detect differences at the 8-week follow up.

Two validated and reliable functional outcome measures will be used in the trial: the Lower Extremity Functional Scale (LEFS) and the Quick Disabilities of the Arm, Shoulder and Hand (Quick DASH) questionnaire. Quality of life will be measured using the Short Form-12 Health Survey Questionnaire, Version 2 (SF-12v2).

## **Secondary outcome measures**

The secondary aspect of the study will be an economic analysis identifying, quantifying and comparing the costs of both the emergency department visit and subsequent costs to the individual, NHS and society. Process measures associated with the three different types of healthcare practitioner (e.g. number of patients treated per hour and referral rate) will also be considered.

## **Overall study start date**

01/10/2006

## **Completion date**

01/10/2008

# **Eligibility**

## **Key inclusion criteria**

1. Adults (17 years or older), male or female
2. Patients presenting to an ED with a peripheral soft tissue injury with no immediately apparent fracture and is eligible for management by any of the three professional groups
2. Patients who consent to the study
3. All three practitioners working concurrently when the patient is admitted to the emergency department, to enable randomisation
5. A traumatic injury
6. Soft tissue injury less than 72 hours old
7. Patients will be included if they have minor grazes or wounds that require no treatment

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

17 Years

**Sex**

Both

**Target number of participants**

900

**Key exclusion criteria**

1. Systemic disease
2. Recent surgery
3. Previous ongoing injury to extremity
4. Intoxicated patients
5. Patients unable to give informed consent (e.g. dementia)
6. Open wounds/wounds (patient will be included if minor and insignificant)
7. Major deformities
8. Patients requiring opiate analgesia
9. Systemic disease (e.g. rheumatoid arthritis)
10. Healing fracture (less than 3 months)
11. Recent soft tissue injury
12. Head injuries (patient will be included if minor and insignificant)
13. Chest/rib injuries (patient will be included if minor and insignificant)
14. Neurovascular deficits
15. Less than 17 years of age
16. Obvious associated fractures
17. Patients who attend the ED when there is no ESP, ENP, doctor service running concurrently
18. Prisoners

**Date of first enrolment**

01/10/2006

**Date of final enrolment**

01/10/2008

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

England

United Kingdom

**Study participating centre**  
The Academic Department of Emergency Care,  
Bristol  
United Kingdom  
BS2 8HW

## **Sponsor information**

**Organisation**  
University of the West of England (UK)

**Sponsor details**  
Faculty of Health and Social Care  
Glenside Campus  
Blackberry Hill  
Stapleton  
Bristol  
England  
United Kingdom  
BS16 1DD  
deb.joy@uwe.ac.uk

**Sponsor type**  
University/education

**Website**  
<http://www.uwe.ac.uk>

**ROR**  
<https://ror.org/02nwg5t34>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
University of the West of England (UK) - funded as part of a PhD bursary

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration

### **Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results of pilot study	01/05/2006		Yes	No
<a href="#">Results article</a>	results	08/11/2012		Yes	No
<a href="#">Results article</a>	results	03/01/2013		Yes	No