

Written information providing first aid advice for patients presenting to the Emergency Department

Submission date
10/02/2014

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/03/2014

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
08/03/2018

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Background and study aims

Emergency Department (ED) attendances are an excellent opportunity for education interventions. A variety of written information is given to patients in EDs. There is some evidence of this working well in other areas but it is unproven in first aid. The study seeks to question if there is an improvement in confidence in the first aid treatment of injuries if patients are given written information while in the ED.

Who can participate?

Adult patients coming to the ED with limb injuries, wounds and head injuries

What does the study involve?

Patients are randomly allocated to one of two groups: the intervention or the control group. Intervention group patients will be asked to complete two questionnaires: first, in person in the ED while waiting to be seen by a doctor or nurse practitioner, and second, 4 weeks later a questionnaire is completed by phone. Control group patients receive normal care.

What are the possible benefits and risks of participating?

The possible benefit to participants would be an improved confidence in managing first aid problems. There is minimal risk to the patients. The questionnaire is designed to be simple and take very little time. Research team members will not have clinical commitments while recruiting patients so ED staffing levels will not be affected. Should a patient be identified as in significant distress or pain, the researchers will inform the clinical staff responsible in preference to completing the study consent and survey. During the follow-up questionnaire, should clinical advice be sought by the patient, they will be directed to their own GP, out of hours services, or ED. This is because the research team may not be familiar with giving clinical advice by phone, and the inability to generate medical documentation from these discussions. Should any complaint be raised by the patient during follow-up questioning, the patient will be directed to the Patient Advice Liaison Service.

Where is the study run from?

The ED at the Northern General Hospital, Sheffield (UK) and the Minor Injuries Unit at the Royal Hallamshire Hospital, Sheffield (UK)

When is the study starting and how long is it expected to run for?

It is due to recruit in March-April 2014 with follow-up questionnaires in April-May 2014 and records checked for re-attendances to the ED in June-July 2014

Who is funding the study?

The British Red Cross (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 1.1

Study information

Scientific Title

Written information providing first aid advice for patients presenting to the Emergency Department: a randomised controlled trial

Study objectives

Giving written first aid information will result in an improvement of patients' confidence in managing injuries in future. This may lead to better self-care and potentially even fewer attendances to the Emergency Department.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East of England - Cambridge South, 28/02/2014, REC ref: 14/EE/0072

Study design

Single-centre randomised controlled interventional trial questionnaire study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information can be found at <https://docs.google.com/file/d/0BxEofEMwq3fNQVVDZkJoMUk2ZzA/edit?pli=1>

Health condition(s) or problem(s) studied

Minor injuries: wounds, limb injuries, and head injuries

Interventions

Patients will be randomised in clusters by the day they attend the ED to either the intervention arm or the control arm. The intervention group will receive an additional information leaflet giving information on first aid for the injury they have sustained; this will be in addition to normal care which would not be altered. The control group will receive all normal care, including any other verbal or written information they would normally receive about the after-care for their injury. Both arms will be followed up at 4 weeks by telephone. ED records will be checked at 3 months for reattendances for both arms.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Confidence in first aid management if the patient were to suffer the an injury again, assessed at baseline and follow-up

Secondary outcome measures

1. Confidence of first aid management to someone else. Confidence in first aid will be measured on a scale of 0 to 10 with 0 being 'Not confident' and 10 being 'Very confident' with half measures being accepted.
2. Improvement in the correct knowledge of first aid. Correct knowledge of first aid will be assessed based on an answer to an open question; answers will be marked correct if key words or phrases are used in the absence of any treatments which would be harmful.
3. How useful the written information was rated. Use of the material will be assessed using a series of yes/no questions and asking them to rate its usefulness on a scale of 0 ('not useful') to 10 ('very useful').
4. The use of other first aid information; related and unrelated reattendances to the Emergency Department within 3 months. The reattendance outcomes will be measured at 3 months by reviewing ED records at that time.

Most outcomes will be measured during the patients' attendance to the ED by a researcher in person, and at 4 weeks by telephone. Questionnaires will be used.

Overall study start date

01/03/2014

Completion date

01/08/2014

Eligibility

Key inclusion criteria

1. Presenting to the Emergency Department at the Northern General Hospital, or Minor Injury Unit at the Royal Hallamshire Hospital during the study period between 9am and 8pm.
2. Book in to reception with the presenting complaint of a head injury, limb injury, or wound between the hours of 9am and 8pm during the study period.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

248

Key exclusion criteria

1. Patients who do not themselves read English
2. Patients who are unable to consent

3. Patients who are resident in a care home
4. Patients with self-inflicted injuries
5. Patients with serious injury requiring immediate resuscitation or treatment
6. Patients over the age of 65 with suspected fractured neck of femur
7. Healthcare professionals

Date of first enrolment

01/03/2014

Date of final enrolment

30/04/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Northern General Hospital**

Sheffield Teaching Hospitals NHS Foundation Trust

Herries Road

Sheffield

United Kingdom

S5 7AU

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Trust (UK)

Sponsor details

Clinical Research Office Sheffield

11 Broomfield Road

Sheffield

England

United Kingdom

S10 2SE

Sponsor type

Hospital/treatment centre

Website

<http://www.sheffieldclinicalresearch.org/clinical-research-office>

ROR

<https://ror.org/018hjpz25>

Funder(s)

Funder type

Charity

Funder Name

British Red Cross (UK)

Results and Publications

Publication and dissemination plan

No current plans for further publication.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study are not expected to be made available due to lack of consent of the participants (the study took place before recent guidelines about data sharing, and participants were informed that their data would be kept confidential).

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	abstract	01/12/2015		No	No
HRA research summary			28/06/2023	No	No