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Text messages for pressure ulcer prevention in spinal cord injury

Submission date
05/06/2017

Recruitment status
Suspended

Registration date
09/06/2017

Overall study status
Completed

Last Edited
21/12/2020

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pressure ulcers (also known as pressure sore) are described as an area of damage to the skin caused by prolonged loading (pressure) in bony area. Up to 85% of spinal cord injury (SCI) patients' form a pressure sore at some point during their lifetime, usually a result of sitting in a wheelchair. When a pressure sore forms after a SCI, patients usually have to stay in hospital longer and delay their rehabilitation programme and loss of independence, which add extra burdens to the psychological (mental) trauma of the injury and reduced quality of life. Sometimes surgery is necessary for severe ulcers, as patients can die from complications of infected pressure sores. Pressure sores are also expensive to treat. Therefore, preventing pressure sores is very important in the SCI population. Currently, people with SCI are provided with prevention education programmes at the hospital, are prescribed expensive cushions, and are told to preform pressure relief exercises every day. Still, the rate of pressure sores remains high. Recent research has found that patients with SCI did not learn much about skin care to prevent pressure sores while in hospital, and many patients lost motivation or were unsure how to perform the pressure relief exercises they were told to do. Interestingly, using text messaging as a reminder has been reported to improve adherence to medication and exercise regimen. The aim of this study is to look at whether the text message as a reminder would improve patients' concordance (consistency) with the 'pressure relief' exercise as well as reduce the pressure sore incidence in people with SCI.

Who can participate?
Adults aged 18 to 70 years old who are scheduled to be discharged from hospital with SCI.

What does the study involve?
Participants are allocated to one of two groups. Those in the first group receive education and reminder text messages twice a week for six months after their discharge from hospital. Those in the second group do not receive text messages. Participants receive standard follow-up rehabilitation care. Participants complete questionnaires before they are discharged from hospital, and again three and six months after they are discharged to assess participants' concordance with pressure-relief regimen, quality of life and the number of skin related problems.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
London Spinal Cord Injury Centre, Royal National Orthopaedic Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2021

Who is funding the study?
Rosetrees Trust (UK)

Who is the main contact?
Dr Liang Qin Liu

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
219199

ClinicalTrials.gov number

Secondary identifying numbers
34112, IRAS 219199

Study information

Scientific Title
Educational text messaging for pressure ulcer prevention in people with spinal cord injury who are newly discharged from hospital: a pilot study

Study objectives
The aim of this study is to assess whether using text messages as a reminder would improve patients' concordance with the 'pressure relief' regimen, and quality of life as well as reduce the pressure Ulcer (PrU) incidence in people with spinal cord injury (SCI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Bristol Research Ethics Committee, 26/04/2017, ref: 17/SW/0097

Study design
Randomised; Interventional; Design type: Prevention, Education or Self-Management, Management of Care, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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
Spinal cord injury

Interventions
Participants are randomly allocated to either the 'text message group' or the 'no text message group' using block randomisation. A random number generator is used to produce numbers and the randomisation list is concealed using individual opaque envelopes before patients are screened and consent to take part in the study.

Text message group: Participants receive a welcome text message on the day after they consent to join the study. They also receive some educational text messages twice per week during the first four weeks after they are discharged from hospital, then text message reminders twice per week for the duration of the six month trial.

No text message group: Participants do not receive any text messages after their discharge from hospital.

Participants in both arms continue to receive standard pressure ulcer prevention education and follow- up as per the standard hospital protocol.

Participants are asked to complete two short questionnaires before they are discharged from the hospital, and at three and six months after they are discharged from the hospital. The first questionnaire called the Pressure relief concordance questionnaire assesses concordance to pressure relief and skin inspection. The second questionnaire is the brief illness perception questionnaire that assesses participants views on pressure sores. Each questionnaire takes around five to ten minutes to complete. There are no study visits, as participants fill out hard copies of the questionnaires and return them in a stamped addressed envelope to the researcher.

Intervention Type
Other

Primary outcome measure
Concordance with 'pressure-relief' regimen is measured using the 'Pressure relief' concordance questionnaire at baseline, three and six months after discharge.

Secondary outcome measures
1. The number of any grade of skin problem or numbers of seeing GP/nurse/hospital for skin concerns are reported by the participants using the Brief Illness Perception questionnaire at baseline (immediately after the consent and or/ shortly before discharged from the hospital), three and six months after discharge
2. Acceptability and satisfactory of receiving educational text message is assessed using a questionnaire at six months after discharge

Overall study start date
01/01/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Aged 18 to 70 years old
3. Supra-sacral spinal cord injury at any spine level with complete or incomplete lesion, and are scheduled to be discharged from hospital after their first admission to London Spinal Injury Centre, Royal National Orthopaedic Hospital;
4. Can read English and complete questionnaires (due to lack of interpreter resource for this project, patients who can't read English to complete the questionnaires will be not eligible)
5. Individuals who didn't complete the standard pressure sore prevention education program at the LSCIC

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Key exclusion criteria
1. Patients who are younger than 18 years old
2. Patients who are older than 70 years old
3. Patients who have difficulties in adequately understanding written or verbal information in English
4. Patients who did not complete the standard pressure sore prevention education program at the LSCIC

Date of first enrolment
06/06/2017

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London Spinal Cord Injury Centre
Royal National Orthopaedic Hospital NHS Trust
Brockley
United Kingdom
HA7 4LP

Sponsor information

Organisation

Middlesex University

Sponsor details
School of Health and Education
Hendon Campus
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NW4 4BT

Sponsor type
University/education

ROR
https://ror.org/01rv4p989

Funder(s)

Funder type
Charity

Funder Name
Rosetrees Trust

Alternative Name(s)
Teresa Rosenbaum Golden Charitable Trust, Rosetrees

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and setting the intent to publish date around one year after the overall trial end date.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No