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Pain in spinal cord injuries: investigating associated factors

Submission date	Recruitment status	[X] Prospectively registered
25/04/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/12/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/08/2017	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is estimated that there are 40,000 people living with a spinal cord injury (SCI) in the UK, with 1,200 being paralysed from a SCI every year. Of these, over 62% experience chronic pain. It is known that adaptation to the significant changes in health and lifestyle for SCI patients is limited by the experience of persistent pain and yet in the UK there is currently no tailored pain management programme available. This study aims to get more information about the different things that contribute to the chronic pain experienced by people with a spinal cord injury. It is known that psychological factors are involved. These include things such as the way we think about the pain, whether we believe we can do anything about it and how bad we think it is. Stress might also affect how bad the pain feels and even our social relationships may play a part. This research will investigate all of these areas to see which aspects are important on their own and which aspects combine with other things to affect the pain we feel. Additionally, the study will look at whether these things change over a nine month period. The information will be used to design a pain management programme specifically for people with a spinal cord injury and to increase our knowledge about this area.

Who can participate?
English speaking in-patients and out-patients of the National Spinal Injuries Centre (NSIC), Stoke Mandeville, aged 18 and over who are experiencing chronic pain. In-patients can participate three months after being admitted to hospital. Out-patients can participate if it has been a minimum of two years since they were discharged from hospital.

What does the study involve?
In-patients are asked to complete a set of 8 questionnaires at three, six and twelve months after admission to the NSIC and to provide saliva samples on each occasion. This is done by wiping a cotton bud around the inside of their mouth for a couple of minutes. The saliva sample is analysed to see how much of a substance called cortisol they are producing. Cortisol is produced when people feel stressed. It takes about 35 minutes to answer the questionnaires and provide the saliva sample. Out-patients are asked to complete the same set of questionnaires and provide a saliva sample but only on one occasion. They are given the option of filling in paper questionnaires or of completing them online.

What are the possible benefits and risks of participating?
There may not be any direct benefits from taking part in this study. However, the information obtained will influence the design of a pain management programme, which spinal cord injured patients could benefit from. Taking part in the study will help to improve understanding of the nature of chronic pain experienced by people with a spinal cord injury. Because the questions ask participants to think about how they are feeling there is a chance they may find some of them upsetting. Participants can stop and have a break at any time or they can choose not to answer any questions they don't like. Participants can stop taking part in the study at any time without any consequences.

Where is the study run from?
The National Spinal Injuries Centre, Stoke Mandeville Hospital, Aylesbury (UK)

When is the study starting and how long is it expected to run for?
June 2013 to June 2015

Who is funding the study?
The University of Buckingham (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A longitudinal (in-patient) study and a cross-sectional (out-patient) study investigating the contribution of cortisol, psychological and social factors in the experience of chronic pain in spinal cord injured patients

Study objectives
1. Negative appraisals, mental defeat and pain catastrophising will individually and in combination increase pain intensity and disability
2. Mental defeat will trigger catastrophising, which in turn will trigger further catastrophic thinking
3. Higher levels of cortisol will negatively mediate pain intensity, disability and duration and will predict higher levels of depression and anxiety
4. Greater acceptance of pain will predict lower psychological distress, less catastrophic thinking and mental defeat and lower cortisol levels
5. Interpersonal factors will be associated with pain disability and pain behaviours

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. School of Science and Medicine Ethical Approval Committee, University of Buckingham, 15/04/2013
2. Berkshire Research Ethics Committee, 09/10/2013, ref: 13/SC/0457
3. NRES Committee South Central Oxford C, 09/10/2013, ref: 13/SC/0457
4. Buckinghamshire Healthcare NHS Trust Research and Development Office, 25/02/2014, ref: RXQ584

Study design
Longitudinal design using questionnaires and cortisol sampling with in-patients
Cross-sectional design using questionnaires and cortisol sampling with out-patients

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Chronic pain in patients with a spinal cord injury

Interventions
A longitudinal, multiple assessment-point design will be used with spinal cord injured in-patients at the National Spinal Injuries Centre (NSIC), Stoke Mandeville. Participants will be asked to complete a set of two pain assessment questionnaires and six psychological assessments at 3, 6 and 12 months after admission to the NSIC and to provide salivary cortisol samples on each occasion. Additionally, a cross-sectional study, using the same questionnaires and cortisol sampling, will be undertaken with out-patients of the NSIC who have been out of hospital for a minimum of two years.

The following questionnaires will be used:
Multidimensional Pain Inventory - Spinal Cord Injury
Leeds Assessment of Neuropathic Symptoms and Signs
Pain Self-Perception Scale
Perceived Stress Scale
Hospital Anxiety and Depression Scale
Pain Catastrophising Scale

Appraisals of Disability: Primary and Secondary Scale
Chronic Pain Acceptance Questionnaire

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Pain intensity, measured using the Multidimensional Pain Inventory - Spinal Cord Injury and the Leeds Assessment of Neuropathic Pain at 3, 6 and 12 months following injury for in-patients and on one occasion with out-patients

Key secondary outcome(s))
Measure at 3, 6 and 12 months after admission to the NSIC:
1. Catastrophising, measured using Pain Catastrophising Scale
2. Appraisals, measured using Appraisals of Disability: Primary and Secondary Scale
3. Pain acceptance, measured using Chronic Pain Acceptance Questionnaire
4. Cortisol concentration, analysed using salivary samples and enzyme-linked immunosorbent assay
5. Perceived stress, measured using Perceived Stress Scale
6. Mental defeat, measured by the Pain Self-Perception Scale
7. Anxiety and depression, measured using Hospital Anxiety and Depression Scale
8. Disability, measured using the Multidimensional Pain Inventory-SCI

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Men and women with a spinal cord injury
2. English speaking
3. Experiencing chronic pain
4. Aged 18 years or over
5. Considered by health professionals/ward staff to be well enough to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. A significant head injury or communication disorder that would impair their ability to complete questionnaires
2. Illiterate

Date of first enrolment
01/05/2014

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
National Spinal Injuries Centre
Stoke Mandeville
United Kingdom
HP21 8AL

Sponsor information

Organisation
University of Buckingham (UK)

ROR
https://ror.org/03kd28f18

Funder(s)

Funder type
University/education

Funder Name
University of Buckingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The 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