Co-designing dietary weight management in spinal cord injury

Submission date	Recruitment status	[X] Prospectively registered
09/07/2025	Recruiting	☐ Protocol
Registration date 22/08/2025	Overall study status Ongoing	Statistical analysis plan
		Results
Last Edited	Edited Condition category	Individual participant data
09/09/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Following Spinal Cord Injury (SCI) there is loss of muscle below the level of the injury. This can change body composition and may adjust how much energy a person with SCI needs. Someone with SCI has about 20% more fat in their body than the same person, of the same weight, without an SCI. This increases the risk of problems associated with being overweight such as diabetes and coronary heart disease. It can mean the person needs wider wheelchairs that are more difficult to push around. When people need less energy, it is more difficult to prevent them gaining weight or having an ideal body weight.

There is little knowledge about how best to help these patients. There are 11 UK Specialist Spinal Injury Centres, each covering large geographical areas. For Sheffield, patients come from Yorkshire, Lincolnshire, Nottinghamshire, Leicestershire, and Norfolk. We need to try and find new ways, including the use of technology, to help patients with their weight who live a distance from their Specialist Spinal Injury Centre.

Aim

We will work with patients and health care professionals to develop a new way of providing weight management support to people with SCI within Specialist Spinal Injury Centres. We will request feedback from the people involved and together we will test out the support package we create.

Who can participate?

People with spinal cord injuries, aged 18 or over, who are able to give informed consent may be invited to take part. Healthcare staff who work with spinal cord injury patients may also be involved. Participants will be selected based on different stages of recovery and care.

What does the study involve?

Making a new intervention I will follow a three-stage process for developing a new intervention (Hawkins 2017).

Stage 1 – Evidence base and stakeholder consultation.

1. We will do a 'mapping exercise' to consider how different SCI Centres are supporting their patients with weight management. We will do this by discussing current weight management practices with the dietitians that work at the specialist spinal centres around the country. We will also go and visit any weight management service that is being delivered to see how it works

and what is involved.

2. We will interview 20-36 staff and patients in one SCI Centre about their knowledge of weight changes following SCI, and when and how they feel weight management information should be provided.

Stage 2: Co-production

We will meet with a group of both patients and staff regularly and work together to develop a new intervention to support patients to manage their weight. We will start by looking at the information gathered in Stage 1.

We will discuss what an ideal weight management programme for people with SCI could look like, which may include teaching and support during admission and following discharge.

Stage 3: Prototyping

We will test the new weight management programme with 5-7 patients in one SCI Centre. We will ask both patients receiving and staff delivering the programme about their experiences of the programme.

What are the possible benefits and risks of participating?

For the participants who are involved in Stage 1 and 2, there is unlikely to be any personal benefit. However, it is expected that their involvement will help to establish a suitable intervention for supporting weight management for people living with SCI.

For patient participants involved in Stage 3, they will benefit from receiving support from the clinical team to help with managing their weight. The staff participants will also gain experience of supporting people with SCI in their weight management journey.

There are only limited risks in participating in the research. Patients will only be asked to participate in the research if they have been injured more than 3 months. They may find it upsetting talking about their weight management journey and if this happens then suitable support will be offered. The researcher is asking for a time commitment to be attend meetings and interviews. However, their time will be reimbursed.

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? July 2025 to August 2028

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact? Sarah Wilkinson, sarah.wilkinson71@nhs.net Carolyn Taylor, carolyn.taylor1@nhs.net

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

392354

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 56454. NIHR303573

Study information

Scientific Title

A co-design project to develop, and assess the acceptability and feasibility of, an intervention to support prevention of weight gain and/or encourage weight reduction in people with spinal cord injury within specialist spinal injury centres

Study objectives

Hypothesis:

Is it possible to co-design a feasible and acceptable weight management intervention for people with Spinal Cord Injury?

Objectives:

- 1. Co-design a weight management programme with patients and health care professionals that we will provide from the spinal centre for people in the hospital and when they go home
- 2. Develop a training package for staff in Specialist Spinal Injury Centres to help them provide the programme
- 3. Check if the programme can be successfully delivered

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 22/08/2025, London - Dulwich Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8290; dulwich.rec@hra.nhs.uk), ref: 25/LO/0535

Study design

Co-production / qualitative

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Weight management in spinal cord injury

Interventions

The project will use the Hawkins et al 2017 framework for co-design. This is made up of three stages which are explained below.

Stage 1: Evidence base and stakeholder consultation.

We will have an online workshop with the dietitians that work at the 11 UK Specialist Spinal Injury Centres. We will ask them to tell us about the weight management services they provide for their patients. This will allow us to learn what is currently available within the UK. We will also ask them about any training they give to patients, carers or staff, and any service they give to patients once they go home. We will ask them if they have any ideas for future improvements that could be made to weight management services for people with an SCI.

We will visit two different weight management services that are currently happening at specialist SCI centres. We will watch what they do and take notes so that we can learn from them.

We will speak to staff and patients at the Sheffield Specialist Spinal Injury Centre to hear their thoughts and experiences of patients managing their weight. We will speak to about 8–10 members of staff. We will make sure that we speak to members of staff from different professions. This will include community liaison nurses, ward staff, physios and occupational therapists, dietitians and medical. We will also speak to approximately 12–16 patients. This will include patients who are currently in hospital, some who have recently gone home and some who are coming to out-patients and had their injury a few years ago. We will aim to include all genders, different ages, people with different types of injuries, and from different ethnic groups. It will include people with overweight and obesity but also those who have a healthy

weight. Patients will be able to choose to have the talk either face-to-face, online or by telephone.

The discussion with both staff and patients will look at what they know about how someone with an SCI can have a healthy weight. We will also ask them if they know what will happen if the person is overweight or has obesity. We will also ask them what a good weight management programme would look like to them. All the discussions will be recorded so that we can listen to them back and make notes. From these notes we will then group ideas together.

Finally, we will talk to up to 6 Managers. This will include Service Managers, Dietetic Managers and Nurse Managers within the Sheffield Specialist Spinal Injury Centre. We will ask them their ideas on how we can provide a weight management service for our patients.

The learning from this first stage will be taken forward to the co-production stage.

Stage 2: Co-production

We will run up to 4 co-design workshops. The workshops will include approximately 8 patients (and their carers) who are living at home. It will also include approximately 6 staff who work within the centre. By working with both staff, patients and carers the workshops will get the ideas from people with different knowledge, experiences and views. This will help to produce a programme that will meet the needs of different people. By including patients who have been sent home after their initial injury we will be able to understand how their life has changed. They will also have had time to think about how their time in hospital might have affected their weight. Patients with overweight or obesity or a healthy weight will be able to take part. This will make sure that people who have struggled to keep to a healthy weight and those that have been successful in weight maintenance are able to give us their views. Staff invited to take part in the workshops will include discharge liaison nurses, community support nurses and physiotherapists. We have chosen these staff members so we can include experiences of those who work closely with patients living at home and who provide information on exercise and activity.

At an initial 3-hour workshop we will present the information we have gathered from stage 1. This workshop will be in person, although people will be able to attend online if they want to.

We will talk to people about the following points:

- a. If we need to focus on an intervention to prevent weight gain or promote weight loss b. Is it possible to have group sessions for patients either delivered within the Specialist Spinal Injury Centre or online
- c. Is there any digital technologies available for online reviews and support for patients to access at home
- d. How often we should be reviewing patients
- e. How patients could link with health professionals for help
- f. Can we look at how to increase physical activity to help with the weight programme
- g. How can people check their weight when at home
- h. Should we be measuring how their muscle and fat is changing within their body
- i. What education we need to give to staff about the changes in energy needs following SCI
- j. When the right time is to talk to people about the likely changes to weight following SCI. Is it too early to talk to them about it when they are first injured
- k. Would it be good to have the weight management clinics at the same time as an outpatient appointment

At the end of the first workshop we will ask everyone to decide which part of the list are the first things we need to look at when developing the weight management programme. We will run up to three more co-production workshops to continue to develop the weight management programme. At these workshops we will present the ideas from the previous workshop, ask for feedback, make changes to the programme and then present back at the next workshop. If we have found a suitable programme that already exists that can be adapted to use with the SCI population, we will look at how we can make these changes.

Stage 3: Prototyping

We will create a first draft version of the programme, including a training package for staff. Four staff at Sheffield Specialist Spinal Injury Centre will use the programme with 5–7 patients for 3 months. We will choose patients who have not been involved in the workshops. Some patients will start when they are in hospital, and some will start once they are at home. At 3 months we will talk to the four staff involved with delivering the intervention and the 5–7 patients who have used it. We will ask them how they found the programme and what changes we need to make.

Intervention Type

Behavioural

Primary outcome(s)

Outcomes for stage 1 will be measured following thematic analysis of semi-structured interviews and workshops. It will relate to participants views on suitable weight management practices within SCI. It will include reflections on their own experiences and possible interventions that could be designed to improve available support for this patient population.

Outcomes from stage 2 will be the design of a weight management programme for the SCI population. This will be taken to stage 3 for testing.

Outcomes from stage 3 will be thematic analysis of the experiences of patient and staff participants who have tested the developed intervention. Due to the limited sample size there will be no formal assessment of feasibility and acceptability but it is planned that this feedback will provide information of any future changes to the intervention prior to developing a suitable feasibility and acceptability evaluative study.

Key secondary outcome(s))

There are no secondary outcome measures

Completion date

31/08/2028

Eligibility

Key inclusion criteria

- 1. Work Package 1: Evidence-Based and Stakeholder Consultation
- 1.1 Dietetic staff at spinal injuries centres in the UK and Ireland
- 1.2 STH staff will be recruited if they offer care to people with a spinal cord injury
- 1.3 STH managers will be recruited if their service might provide weight management care
- 1.4 Patient participants will be spinal cord injured adults
- 1.4.1 Newly injured in-patients who are at least 3 months post injury and have been admitted to the Sheffield spinal injuries centre for more than 4 weeks

- 1.4.2 Patients seen as outpatients who have been discharged from their acute admission
- 1.4.3 Adults over the age of 18
- 1.4.4 Able to give informed consent
- 1.4.5 Patient participants will include any level of spinal cord injury with any ASIA (American Spinal Injury Association Impairment Scale) score of A-D
- 1.4.6 Patients will not be excluded based on their weight history. Both those with a healthy weight and those living with overweight or obesity will be approached
- 1.5 Patient participants will be able to have carers to support them if required
- 1.6 Two specialist spinal injury centres that currently offer a weight management service to their spinal cord injured patients will be invited to participate in the non-participant observation element of the study
- 2. Work Package 2: Co-Production
- 2.1 Patient participants who have been discharged following their initial acute spinal cord injury admission at Sheffield but remain under follow-up review by the Sheffield Spinal Injury Centre
- 2.1.1 Patients will need to have been 1 year post spinal cord injury to allow time to reflect on their inpatient stay and offer practical solutions to support that could be required post discharge
- 2.1.2 Patients will not be excluded based on their weight history
- 2.1.3 Patients will be adults over the age of 18
- 2.1.4 Patient participants will include any level of spinal cord injury with any ASIA score of A-D
- 2.1.5 Able to give informed consent
- 2.2 Carers of patient participants will be allowed to participate
- 2.3 Staff participants will be recruited if they offer care to people with a spinal cord injury
- 3. Work Package 3: Prototyping
- 3.1 Patient participants who are either current inpatients or outpatients from the Sheffield Spinal Cord Injury Centre
- 3.1.1 Patients diagnosed with a spinal cord injury under the care of Sheffield Spinal Cord Injury Centre
- 3.1.2 Patients who are interested in receiving support for managing their weight
- 3.1.3 Patients will be adults over the age of 18
- 3.1.4 Patient participants will include any level of spinal cord injury with any ASIA score of A-D
- 3.1.5 Able to give informed consent
- 3.2 Staff participants will be recruited if they offer weight management support to people with a spinal cord injury

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Work Package 1: Evidence-Based and Stakeholder Consultation
- 1.1 Any staff participants with no experience of supporting people with spinal cord injury
- 1.2 Any patient without a spinal cord injury
- 1.3 Anyone under 18 years of age
- 1.4 Anyone unable to provide informed consent
- 1.5 Patients who have been injured less than 3 months or admitted to Sheffield Spinal Injuries Centre for less than 4 weeks
- 2. Work Package 2: Co-Production
- 2.1 Any staff participants with no experience of supporting people with spinal cord injury
- 2.2 Any patient without a spinal cord injury
- 2.3 Anyone under 18 years of age
- 2.4 Anyone unable to provide informed consent
- 2.5 Any patient who sustained their spinal cord injury less than 1 year ago
- 3. Work Package 3: Prototyping
- 3.1 Any staff participants who are not supporting the weight management programme for people with spinal cord injury
- 3.2 Any patient without a spinal cord injury
- 3.3 Anyone under 18 years of age
- 3.4 Anyone unable to provide informed consent
- 3.5 Any patient who has been included in the co-production element of Work Package 2

Date of first enrolment

23/09/2025

Date of final enrolment

31/08/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital Herries Road Sheffield United Kingdom S5 7AU

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust

ROR

https://ror.org/018hjpz25

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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?

Participant information sheet 11/11/2025 No Yes