ISRCTN17683580 https://doi.org/10.1186/ISRCTN17683580

Improving a bowel-care questionnaire for people with spinal cord injury using clinic feedback and digital follow-up

Submission date
22/08/2025

Recruitment status
No longer recruiting

Registration date
22/08/2025

Overall study status
Completed

Last Edited
22/08/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
People living with spinal cord injury often have ongoing bowel-management difficulties that affect daily life. This study tests whether adding structured digital feedback (brief weekly check-ins and tailored prompts) to a bowel-difficulty patient-reported measure makes care more effective over 12 weeks compared with standard clinic administration without digital prompts.

Who can participate?
Adults (18 years or older) with a spinal cord injury of at least 6 months' duration who use a stable bowel-care routine and can complete the bowel-difficulty questionnaire, and who provide written informed consent.

What does the study involve?
Participants join one of two groups at a single hospital. One group completes the bowel-difficulty measure with digital feedback via a secure mobile/web system plus usual care; the other completes the measure in the standard clinic way without digital prompts (usual care continues for both groups). Everyone completes the measure at the start and again at 12 weeks. Some may also complete a short mid-point check at week 6 and brief 7-day diaries about bowel events. No medicines, devices, or procedures are given by the study.

What are the possible benefits and risks of participating?
There may be no direct benefit, but the digital approach could help some people track symptoms and communicate with the clinic between visits. Risks are minimal and relate mainly to the time and possible discomfort of answering personal questions. Participation will not change usual medical care.

Where is the study run from?
Rehabilitation Department, Hebei Medical University Third Hospital, Shijiazhuang, Hebei, China.

When is the study starting and how long is it expected to run for?
September 2024 to September 2025.

Who is funding the study?
Guidance Topic of the Hebei Provincial Health Commission (20242297).

Who is the main contact?
Wei Jing, 38500659@hebmu.edu.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Feng Zhang

Contact details
Rehabilitation Department, Hebei Medical University Third Hospital
Shijiazhuang
China
050000
+86-0311-86265523
zhangfeng4134@163.com

Additional identifiers

Study information

Scientific Title
Adults with spinal cord injury: clinical feedback–integrated patient-reported bowel-difficulty measure versus standard administration for 12-week applicability and responsiveness

Acronym
REFINE-IMD

Study objectives
Objective: to optimise the Spinal Cord Injury Quality of Life Intestinal Management Difficulty scale by integrating structured clinical and digital feedback, revising and psychometrically recalibrating items (content validity indices and Rasch diagnostics), and then evaluating the tool' s sensitivity/responsiveness in longitudinal clinical use.

Primary hypothesis: adding structured clinical/digital feedback to scale administration will produce a greater 12-week improvement (decrease) in the bowel-difficulty total score compared with standard administration.

Secondary hypotheses: feedback-integrated administration will (i) show superior responsiveness (e.g., higher standardised response mean and larger effect size) and stronger anchor validity versus standard administration; (ii) demonstrate better construct validity with clinical anchors (patient global rating of change and bowel-diary metrics) at 12 weeks; and (iii) improve feasibility /acceptability (completion/adherence) without increasing adverse events.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 20/12/2024, Hebei Medical University Third Hospital Ethics Committee (Rehabilitation Department, Hebei Medical University Third Hospital, Shijiazhuang, Hebei 050000, China, Shijiazhuang, 050000, China; +86-0311-86265523; fad@hebmu.edu.cn), ref: AD2024-077

Primary study design
Interventional

Study design
Single-centre prospective interventional two-arm non-randomized controlled open-label study

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Bowel management difficulties in adults living with spinal cord injury.

Interventions
This single-centre, two-arm, non-randomised interventional study compares structured digital-feedback administration of a patient-reported bowel-difficulty measure with standard administration over 12 weeks. In the digital-feedback arm, participants complete the measure via a secure mobile/web platform at baseline and receive automated, tailored prompts and weekly check-ins; flagged responses are reviewed by the rehabilitation clinic team with feedback provided during routine visits or secure messages. In the standard arm, participants complete the measure per usual clinic practice (paper or clinic tablet) without digital prompts or interim feedback. Allocation is by clinic workflow and participant preference/technology access (no randomisation). All participants provide baseline demographics and injury details; outcomes are collected at baseline and Week 12 (with an optional mid-point check at Week 6 where feasible). Adverse events related to study procedures (e.g., distress from surveys) are monitored and documented; no changes to clinical care are mandated by the protocol.

Intervention Type
Behavioural

Primary outcome(s)
Patient-reported bowel-difficulty total score measured using the Spinal Cord Injury Quality of Life Intestinal Management Difficulty scale at baseline and Week 12; primary endpoint is the change from baseline to Week 12.

Key secondary outcome(s)
1. Patient Global Impression of Change (7-point PGIC) measured using a single-item global rating at Week 12.
2. Intestinal Management Difficulty (IMD) total score measured using the SCI-QOL IMD scale at baseline and Week 6; endpoint is the change from baseline to Week 6.
3. Minimal clinically important improvement (MCII) in IMD score measured using anchor-based calibration to PGIC (“much improved” or better) at Week 12; endpoint is the proportion achieving MCII.
4. Incontinence episodes per week measured using a 7-day bowel diary at baseline and Week 12; endpoint is the change baselineWeek 12.

5. Time required per bowel-care session (minutes) measured using a 7-day bowel diary at baseline and Week 12; endpoint is the change baselineWeek 12.
6. Completion/adherence rate to scheduled check-ins measured using platform analytics over Weeks 0–12; endpoint is the percentage of planned entries completed.
7. Usability/acceptability measured using the System Usability Scale (SUS) at Week 12; endpoint is the SUS total score.
8. Unscheduled clinic or emergency visits for bowel-related problems measured using hospital records over Weeks 0–12; endpoint is the number of visits.
9. Adverse events related to study procedures (e.g., distress from surveys) measured using a standard adverse-event log over Weeks 0–12; endpoint is any event and total events.

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years (adult patients).
2. Confirmed spinal cord injury sustained ≥6 months before enrolment, verified by neuroimaging and physician documentation.
3. Consistent bowel-care regimen for ≥3 months prior to baseline.
4. Neurogenic Bowel Dysfunction (NBD) Score ≥10 (moderate–severe bowel dysfunction).
5. Able to complete the SCI-QOL Intestinal Management Difficulty subscale independently.
6. Provides written informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Age <18 years.
2. Spinal cord injury <6 months since onset or progressive neurological disease (e.g., new demyelinating disorder).
3. Inability to provide informed consent or to complete study questionnaires in the study language (with or without reasonable assistance).
4. Unstable medical condition likely to preclude 12-week follow-up (e.g., planned major surgery affecting bowel function, anticipated prolonged hospitalisation elsewhere).
5. Active gastrointestinal infection or acute inflammatory bowel disease flare at baseline.
6. Permanent ostomy or other bowel diversion that makes the Intestinal Management Difficulty

scale inapplicable.
7. Concurrent enrolment in another interventional study targeting bowel or continence outcomes during Weeks 0–12.
8. Major change planned to bowel-care regimen (new medications, devices, or programmes) mandated by another protocol during Weeks 0–12.

Date of first enrolment
01/01/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
China

Study participating centre
Hebei Medical University Third Hospital – Rehabilitation Department
Shijiazhuang
China
050000

Sponsor information

Organisation
Third Hospital of Hebei Medical University

ROR
https://ror.org/004eknx63

Funder(s)

Funder type
Government

Funder Name
Hebei Provincial Health Commission — Guidance Topic (20242297) Type: Government health department

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from Wei Jing (Email: 38500659@hebmu.edu.com). De-identified IPD will include baseline demographics and injury characteristics, Intestinal Management Difficulty (IMD) scores at baseline/Week 6/Week 12, Patient Global Impression of Change at Week 12, 7-day bowel diary metrics, usability (SUS) at Week 12, adherence logs, and bowel-related healthcare visits and adverse events through Week 12. Data will become available 6 months after primary publication and remain available for 5 years. Access will be granted for methodologically sound, non-commercial projects with a prespecified analysis plan, evidence of local ethics approval, and a signed data-use agreement; dates will be offset and rare combinations suppressed to minimise re-identification risk. Where participant consent or local regulations limit sharing, only aggregate outputs will be provided.

IPD sharing plan summary

Available on request