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Evaluating quality of life measurement in patients with surgical wounds healing by secondary intention using the WoundQoL-14 questionnaire

Submission date
23/09/2024

Recruitment status
Recruiting

Registration date
25/11/2024

Overall study status
Ongoing

Last Edited
25/11/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Wounds present a significant healthcare challenge in the United Kingdom, with an estimated annual treatment cost of approximately £8.3 billion for the National Health Service. Following surgical procedures, the conventional practice is to suture or staple wounds closed. Nevertheless, this approach is not universally suitable or advisable. In select cases, patients' wounds are left to heal from the base up, known as Surgical Wound Healing by Secondary Intention (SWHSI). Living with a SWHSI can significantly affect the patient's well-being. Researchers and medical professionals are dedicated to enhancing treatment and care for this patient group but there is no current good way of measuring the impact of SWHSIs on quality of life. This study aims to test a method for assessing the quality of life within the SWHSI population - the WoundQoL-14 questionnaire. This study will rigorously assess the WoundQoL-14 questionnaire's ability to accurately and consistently measure the quality of life in individuals with SWHSI in the UK for use in research and clinical settings.

Who can participate?
Adult patients aged 18 years old and over with one or more SWHSI can participate in the study as long as they are recruited within 21 days of surgery or 7 days of wound dehiscence. Patients need to have a good understanding of English as we are testing an English-language questionnaire. Patients also need to be legally able to consent to being involved in a research study.

What does the study involve?
The first part of the study:
At the first visit, the researchers will need to check that the patient meets the criteria to join the study; only patients with SWHSIs will be eligible. After that, they will collect some information about the patient’s background and medical history. They will then ask the patient to complete a

group of questionnaires. They will also ask if the patient would be happy for them to take a photograph of the wound site, though this part will be completely optional as they know not everyone will be comfortable with this.

For the second visit, the researchers will contact the participant again by telephone or email up to 7 days after the first contact and ask them to complete the questionnaires again either over the telephone or electronically. Finally, they will contact the participant 3-4 months after the first visit. At this time, they will ask the participant again about their SWHSI and any changes in their medical conditions. They will then ask the participant to complete the group of questionnaires again. This can be done over the telephone or in person. At the second and third visits, they may also ask the participant to send them an updated photograph of the SWHSI to a secure email address, but this will be completely optional and all participants can decline to do this if they wish without affecting their participation in the rest of the study.

The second part of the study:
If participants have previously agreed to be contacted for the second part of the study, they may receive an invitation to attend an interview or focus group meeting with the study team. They will be asked some questions that will help the team understand how participants feel about using the WoundQoL-14. They will likely ask questions about how easy, understandable, and relevant the participants feel the questionnaire was to their experience. The interview or focus group may be completed remotely using telephone or video-calling programs like Zoom, or they may be in-person. Each participant will be asked which method they would prefer

What are the possible benefits and risks of participating?
Though participation is very helpful in improving care generally for patients with SWHSIs, there are no direct benefits to the individual participant for taking part in the study. As this is a questionnaire study, participation does not have any direct risks to participants.

Where is the study run from?
The study is run from the Academic Vascular Surgery Unit at Hull York Medical School. Hull University Teaching Hospitals NHS Trust (the Sponsor) is responsible for the conduct of this study.

When is the study starting and how long is it expected to run for?
August 2022 to March 2027

Who is funding the study?
This research is being undertaken as part of a PhD with Hull York Medical School. This study is funded by the NIHR Doctoral Fellowship programme.

Who is the main contact?
Dr Misha Sidapra, NIHR Doctoral Fellow, misha.sidapra1@nhs.net

Study website
https://swhsi3.my.canva.site/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321703

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR303688, R4128; CPMS 57587

Study information

Scientific Title
Psychometric evaluation of the WoundQoL-14 health-related quality of life tool in patients with surgical wounds healing by secondary intention (SWHSI) – The SWHSI-QoL Study

Acronym
SWHSI-QoL

Study objectives
Rationale: To evaluate the ability of the WoundQoL-14 questionnaire in measuring wound-specific quality of life in patients with surgical wounds healing by secondary intention (SWHSI) using psychometric methodology.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/09/2024, London - City & East Research Ethics Committee (Research Ethics Committee Centre, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8124; cityandeast.rec@hra.nhs.uk), ref: 24/PR/0943

Study design
Single centre prospective longitudinal observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital, Internet/virtual, Telephone

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Surgical wounds healing by secondary intention (SWHSI)

Interventions
Observational study.

Quantitative Study:
Participants recruited into the study will be asked to complete a suite of questionnaires and information relating to their wound, general health and impact on quality of life at 3 time points during their postoperative journey - baseline (at time of recruitment), 2-7 days after recruitment, and 12-16 weeks after recruitment.

Qualitative Study:
Participants will be recruited from patient and clinician groups to complete a standalone interview with the study team regarding the feasibility, acceptability and accessibility of the target measurement tool (WoundQoL-14).

Intervention Type
Other

Primary outcome measure
The validity, reliability and responsiveness of Wound-QoL measured using a quantitative psychometric evaluation, guided by the COSMIN guidelines for validation of patient-reported outcome measures, at 3 time points during their postoperative journey - baseline (at the time of recruitment), 2-7 days after the recruitment, and 12-16 weeks after recruitment

Validity and reliability are measured by assessing dimensionality, reliability of scales, limits of agreement, measurement error, convergent and discriminative validity and test-retest reliability

Responsiveness is measured by assessing correlation relationships between scores at time points 1 and 3 and clinical information with subgroup analysis for healed and unhealed wounds

Secondary outcome measures
1. Interpretability measured using an assessment of minimal clinically important difference at time point 1
2. Acceptability measured using a visual analogue scale of acceptability at all time points and a qualitative investigation
3. Accessibility measured qualitatively using interviews at 1 time point
4. Usefulness measured qualitatively using interviews at 1 time point

Overall study start date
01/08/2022

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Patients over 18 years of age with one or more SWHSI at the time of assessment will be eligible for inclusion in the study.
2. SWHSIs will be defined as:
2.1. Surgical wounds intentionally left open to heal by secondary intention within 21 days from the time of operation, or
2.2. Primarily closed surgical wounds that have since dehisced and are being managed thereafter by secondary intention. For dehisced primarily closed wounds, the time of enrolment in the study must be within 7 days of the wound dehiscence.
3. All participants must be capacitous to make decisions about their healthcare and be sufficiently literate in English to engage with the study information and instruments. As this study aims to evaluate the validity of the UK English-language version of the Wound-QoL questionnaire, eligible participants must have an appropriate level of spoken or written English to be reasonably able to complete the test instrument.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
308

Key exclusion criteria

1. Patients who cannot freely consider enrollment in the trial are not eligible to participate in the trial.
2. Patients who cannot communicate in spoken or written English are not eligible for this study as it is a validation of an English-language questionnaire.

Date of first enrolment
01/10/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull University Teaching Hospitals NHS Trust

Sponsor details
Hull Royal Infirmary, Anlaby Road
Hull
England
United Kingdom
HU3 2JZ
+44 (0)1482 875875
hyp-tr.development.research@nhs.net

Sponsor type
Hospital/treatment centre

Website

https://www.hull.nhs.uk/

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/03/2028

Individual participant data (IPD) sharing plan
Data will be made available upon request by contacting the study lead (Dr Misha Sidapra, misha.sidapra1@nhs.net), with the details of the request discussed with the trial management group. Any release of data will adhere to GDPR 2018 regulations, ensuring that data is shared securely and in an anonymised format.

IPD sharing plan summary
Available on request