A Qualitative Phase 1 Study to Development a New Patient-Reported Outcome Instrument for Acute and Chonic Wounds: The WOUND-Q

Published: 02-02-2017
Last updated: 15-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45641

Source
ToetsingOnline

Brief title
The WOUND-Q Phase 1

Condition

- Procedural related injuries and complications NEC
- Epidermal and dermal conditions
- Vascular disorders NEC

Synonym
chronic wounds

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute wound, Chronic wound, patient reported outcome measure, Qualitative study

Outcome measures

Primary outcome

Interviews, coding and item generation: The study RA will conduct the interviews (see Table 3 for Interview Guide), which will be tape recorded and transcribed verbatim. The data will be coded using a line-by-line approach where all concepts are labelled with a major and minor COI. Coding will take place as soon as possible after an interview so that findings can inform subsequent interviews in an iterative fashion. Item generation will also take place concurrently with data collection. This process will occur within Excel. Codes (patient quotes) and their major and minor COI will be moved from the Word document into Excel columns. Patient characteristics (e.g., age, health condition, wound type, healing phase) will also be inserted into Excel columns. These characteristics will make it possible for us to identify potential core items (common across wound type) and unique items (specific to a wound type). For each code, preliminary items will be generated and each will be assigned a descriptor to capture the essence of what it measures. Items will retain the wording used by patients and have the lowest possible grade reading level to ensure the content resonates with patients and is comprehensible.

Secondary outcome

After completing phase 1 we will continue with phase 2 and 3 (not part of this application). We anticipate that the WOUND-Q will provide the international medical community with meaningful, precise and reliable feedback on important patient-centered outcomes and the potential for widespread use in both clinical and research settings.

Study description

Background summary

Each year, millions of individuals require treatment for acute and chronic wounds. Wounds represent an important health problem and challenge to patients, healthcare professionals and healthcare systems alike. Wounds vary greatly in terms of their impact on patients* in terms of recovery and return to usual activities and health-related quality of life (HRQL). Currently, there is scope to develop a comprehensive patient-reported outcome (PRO) instrument for acute and chronic wounds to measure patient outcomes and experience of wound care. A PRO instrument is needed because outcomes, such as how a patient feels and functions, are concepts of interest (COI) best assessed by the patient. Patients also have important things to say about their experience of wound care. Such information can serve as quality metrics.

Study objective

The aim of our study is to develop a new PRO instrument for acute and chronic wounds. Our 3-phased approach involves a qualitative study, an international field-test and a psychometric study. Patients, healthcare providers and other stakeholders will be integrally engaged in content development and evaluation. The current proposal is for the phase 1 qualitative study only. We will conduct patient interviews to identify important COI and to create a conceptual framework and set of independently functioning scales for this new PRO instrument, i.e., WOUND-Q. The new questionnaire will be shown to patients in a series of cognitive interviews. We will use the findings to ensure the scales are as easy as possible to understand and cover all important issues from the patient perspective. Healthcare providers will be invited to provide feedback to ensure all clinically important issues are captured. The scales will be revised and pilot tested prior to finalizing. In phase 2 (not part of this application), we will field-test the WOUND-Q in a large cross-sectional heterogeneous sample of patients. Data will be analyzed to identify the best subset of items to retain in each scale, based on their performance against a

standardized set of psychometric criteria. At this point, the WOUND-Q will be available for distribution. In phase 3, we will perform a supplementary psychometric study to examine responsiveness.

Study design

This is a qualitative study that involves the following steps:
1) semi-structured interviews with patients to collect data to inform the development of a hypothesized conceptual framework and set of scales with items;
2) input from healthcare providers who care clinically for the patients of interest, in order to ensure the scales reflect all clinically important issues from their perspective; and
3) cognitive interviews with patients to refine the preliminary set of scales and items ensuring they contain maximum content validity and are easy to comprehend. Our study takes an applied health services research approach called Interpretive Description.
This approach aims to generate knowledge relevant for the clinical context and presumes there is theoretical knowledge, clinical knowledge and a scientific basis informing a study.

Interviews: Given that qualitative research aims to investigate what underlies aspects of behavior, and that it is concerned about richness rather than representativeness of data, it requires smaller, focused samples instead of large, random samples. For qualitative interviews, evidence suggests that data saturation can occur within 12 interviews, with themes arising as early as six interviews. Given clinical differences in our sample, we plan to conduct approximately 60 interviews (15 in the Netherlands) or as many as are necessary to reach saturation, i.e., no new content identified. We will purposely recruit a heterogeneous sample of patients.

Cognitive interviews using think-aloud method: Sample size requirements for cognitive interviews are variable, with the number of interviews a function of the complexity of the PRO instrument and the diversity of the population. Willis suggests up to 10 participants are sufficient, but we will conduct 30 interviews or as many as are necessary to reach saturation. The interviews will be conducted in three rounds of 10 participants to provide the investigative team the opportunity to make changes between rounds.

Study burden and risks

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients aged 18 and older with any type of chronic wound (> 3 months) anywhere on their body;Patients will be recruited from the out-patient clinic of the Plastic Surgery department, Catharina Hospital Eindhoven. Sampling will be purposeful and will consist of a heterogeneous maximum variation sample to ensure we hear as many patient stories as possible. Included patients will have are those who have received treatment for an acute or chronic wounds. ;We will strive to recruit a sample that varies by gender, age, ethnicity, type of acute or chronic would, location of wound on body, phase in the wound healing process and risk of poor outcome including older age, smoking having diabetes or being obese.

Exclusion criteria

Patients who do not speak Dutch and/or have cognitive or developmental delay will be excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2017
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58696.100.16