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Title

Ulcer healing time and waiting time for patients with hard-to-heal ulcers: a comparison between patients diagnosed through video consultation and in-person assessment.

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Abstract

Objectives: To investigate differences in ulcer healing time and waiting time between video consultation and in-person assessment for patients with hard-to-heal ulcers.

Setting: Patients treated at Blekinge Wound Healing Centre, a primary care centre covering the whole of Blekinge county (150 000 inhabitants), were compared with patients registered and treated according to the Registry for Ulcer Treatment (RUT), a Swedish national web-based quality registry.

Participants: The study group consisted of 100 patients diagnosed through video consultation between October 2014 and September 2016. The control group for analysing healing time consisted of 1888 patients registered in RUT during the same period. For analysing waiting time, 100 patients diagnosed through in-person assessment were compared with the study group.

Primary and secondary outcome measures: Differences in ulcer healing time and waiting time were analysed using the two-sample Wilcoxon rank-sum test.

Results: Median healing time was 60 days in the study group and 84 days in the control group (p=0.001). Median waiting time was 25 days in the study group and 32 days for patients diagnosed through in-person assessment (p=0.017). There were no significant differences between the study group and the control group regarding gender, age, or ulcer size.

Conclusions: Healing time and waiting time were significantly shorter for patients diagnosed through video consultation compared with those diagnosed through in-person assessment.

Strengths and limitations of this study

- The use of a large, nationally representative sample of patients with hard-to-heal ulcers gives increased generalizability.
- A well-known technical system was used for video communication.
- All patients diagnosed through video consultation were assessed by the same GP, following standardized clinical routines for ulcer assessment.
- The study group was consecutively included and rather limited in size (n=100).

Introduction

Patients with hard-to heal ulcers have long been considered a neglected patient group in which treatment is often given without diagnosis, thus prolonging ulcer healing time[1]. The estimated prevalence of leg ulcers in the adult population is 1–2%[2]. Leg ulcers constitute the largest part of all hard-to-heal ulcers. The majority of these patients are elderly and suffer from other conditions such as diabetes and heart and lung diseases[3, 4]. In addition to these comorbidities, these patients may experience extreme pain[5, 6]. Treatment is carried out by

different caregivers within different medical specialties, and so a multidisciplinary team of professionals is often necessary to establish the ulcer aetiology and provide the proper diagnosis[7].

In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care[1, 8]. Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000 inhabitants). BWHC is divided into two health care centres, BWHC West and BWHC East, which are comparably organized in terms of staff and patients, and which work within the same clinical establishment.

At BWHC, patients are treated according to a structured wound management based on the Swedish national quality registry for ulcer diagnosis, treatment, and documentation (RUT) [8]. Patients often stress the importance of continuity of care[9], which is also crucial for healing[10]. This is guaranteed by an assigned nurse who is responsible for following the patient until ulcer healing. The team at BWHC collaborates with community and district nurses and staff from different medical specialties within the county.

The Swedish Registry of Ulcer Treatment

RUT is a web-based tool for clinical assessment of hard-to-heal ulcers, treatment strategies, and continuity of care. Solid clinical research data based on RUT has shown improved quality of life as well as reduction of healing time, treatment costs, and antibiotic treatment[1, 11, 12].

There were more than 7000 registrations in RUT in 2016, meaning that the register covers more than one fifth of the patients with hard-to-heal ulcers in Sweden.

Patients are registered by a nurse or physician on two occasions. The first registration includes variables for assessment of ulcer diagnosis and treatment strategies, while the second includes data on ulcer healing or negative clinical events such as amputation or death. Each patient with a non-healing ulcer remains in the registry until the follow-up is completed. Since 2012, it has been mandatory to register each patient treated at BWHC, and this is also the case for some of the larger dermatological departments and well known wound healing centres in Sweden.

Telemedicine for wound management

Telemedicine is the use of information technology and electronic communication to allow health care professionals to evaluate, diagnose, and treat patients at a distance. It typically includes various forms of video consultation or digital transmission of medical imaging and other clinical data.

Transmission of digital photographs has been used within ulcer care in Denmark since 2005, resulting in the reduction of waiting time, ulcer healing time, and transportation, the latter of which can often be uncomfortable or painful for the patient[13]. Another example is the telemedicine wound care model from the Home Hospital Wound Healing Network in Languedoc-Roussillon, France. This model has produced reductions in both hospital admissions and patient transportations[14]. The use of three-dimensional images has shown high concordance with in-person consultation for assessment and measurement of wounds[15].

Video communication is widely used within different medical specialties today, though thorough documentation and evaluation is insufficient[16]. However, there is a lack of use of this technology for ulcer care, even though its focus on the visual is considered ideal for wound management[17]. Video communication could be a useful tool, especially in primary care, where there is a need for national guidelines[4] as well as dedicated doctors and nurses for wound management.

In Sweden, like in many other countries worldwide, a challenging obstacle for health care is the presence of different systems of electronic medical records. This makes communication between caregivers more difficult. Video communication might be a feasible way to surmount this obstacle, and in combination with the national database, RUT, seems to be a good future solution for wound management.

The aim of this study was to compare video consultation with in-person assessment for patients with hard-to-heal ulcers, in terms of healing time and waiting time.

Methods

Study population and variables

The healing time study was an analysis of healing time for patients with hard-to-heal ulcers diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment based on data from RUT (control group) (Table 1).

The waiting time study was a supplementary analysis of the waiting time for a doctor's consultation for patients with hard-to-heal ulcers diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment at a comparable clinic (BWHC East) (Table 1).

Hard-to-heal ulcers were defined as ulcers which had not healed within 6 weeks[3]. The number of patients in the study group was chosen according to the expected number of new undiagnosed patients seeking treatment at BWHC West and BWHC East, respectively, over two years.

Table 1 Study population and setting

	Healing time study		**Waiting time study**	
Participants	Study group n=100	Control group n=1888	Study group n=100	Patients at BWHC East n=100
Assessment	Video consultation	In-person assessment	Video consultation	In-person assessment
Setting	Patients at BWHC West	Patients from RUT	Patients at BWHC West	Patients at BWHC East
Inclusion	Consecutively included	All patients registered in RUT during the study period	Consecutively included	Consecutively included
Inclusion criteria	Age >18; women and men; ulcers of any aetiology, severity, size, and duration			
Exclusion	Age < 18	Age <18	Age <18	Age <18

criteria	Patients with dementia	*	Patients with dementia	*
Study period	1 October 2014 – 30 September 2016			
Consent	Written consent mandatory		Written consent mandatory	

*Dementia is not recorded in the registry, and so it was not possible to exclude these patients from the control group. Patients diagnosed with dementia and patients from whom it was impossible to obtain a valid consent were excluded from the study group, as written consent was mandatory.

The healing time study

Study group

The patients were initially assessed during a nurse visit, with measurements taken according to RUT[8]. During this visit, the patient received an iPad programmed with Skype for the upcoming video consultation between the general practitioner at BWHC and the patient accompanied by the assigned nurse.

The video consultation took place in the patient's home or in the primary health care centre. During this consultation, the doctor established the ulcer diagnosis and an appropriate treatment strategy which could be carried out by the assigned nurse under supervision.

Documentation of the video consultation was transferred to the patient's medical record. Each patient was followed to ulcer healing or to the end of the study period, whichever occurred first.

Control group

All patients were diagnosed by in-person consultation and registered in RUT. The same measurements were used in both the control group and the study group, except for measurement of ulcer size. For patients in the control group, this was done either by planimeter or as length multiplied by width, according to different clinical routines.

The waiting time study

As the waiting time for a doctor's consultation is not recorded in the registry, a supplementary analysis was carried out with patients at BWHC East.

Study group

The same study group and the same measurements were used as for the healing time study.

Patients at BWHC East

All patients were diagnosed by in-person assessment at BWHC East. These patients were likewise assessed according to RUT and followed to ulcer healing or to the end of the study period, whichever occurred first. Age, gender, ulcer size, and ulcer duration were not considered to affect the waiting time for a doctor's consultation, and so were not analysed in this study.

Variables

Age (years), gender, ulcer size (cm^2), ulcer aetiology, and diabetes (yes or no) were analysed in both the study group and the control group. Ulcer size was measured by planimeter (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) or by length

multiplied by width, according to the established routines in different registration units. Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers, pressure ulcers, neuropathic ulcers, traumatic ulcers, malignant ulcers, ulcers due to inflammatory vessel diseases such as vasculitis, and other ulcers.

Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of diagnosis by a doctor.

Ulcer healing time (in days) was defined as the interval between the consultation with a doctor and complete ulcer healing.

Waiting time (in days) was defined as the interval between referral and consultation with a doctor at the BWHC.

Data analysis

Statistical analysis was performed using version 24 of IBM SPSS Statistics. Continuous variables were expressed as mean values, ranges, and standard deviations (SD), and compared using the two-sample Student t-test. Categorical variables were compared between groups using Pearson's chi-squared test. Differences in groups were analysed using the two-sample Wilcoxon rank-sum test (Mann-Whitney U-test). Healing time was assessed with Kaplan-Meier analysis. A log-rank test was used for equality of survivor function. A p-value of less than 0.05 was considered to indicate statistical significance.

Results

Patient demographics

Basic data on the study group and the control group are presented in Table 2.

The study group (n=100) had a mean age of 77 years (range: 37–98 years). The mean ulcer size was 9.8 cm^2 and the mean ulcer duration was 332 days. The control group (n=1888) had a mean age of 75 years (range: 23–104 years). The mean ulcer size was 18.1 cm^2 and the mean ulcer duration was 210 days.

Table 2. Patient demographics: the healing time study.

	Study group n=100	Control group n=1888	p-value
Age, median (SD) [A]	79 years (13)	78 years (14)	0.231
Female [B]	54%	56%	0.744
Diabetes [B]	27%	28%	0.798
Ulcer size, median (range) [C]	3.4 cm^2 (0.1-131.6)	3.8 cm^2 (0.01-1196.0)	0.192
Ulcer duration, median (range) c	124 days (7-3657)	84 days (0 to 5839)	**<0.001**
Healing time, median (range) [C]	60 days (0-334)	84 days (0-2540)	**0.001**

[A] Student's t-test

[B] Chi-squared test

[C] Mann-Whitney U-test

There was no significant difference in gender, age, ulcer size, or diabetes between the patients in the study group and the patients in the control group (Table 2).

There was a significant difference in ulcer duration between the study group and the control group ($p<0.001$), with the shortest ulcer duration seen in the control group (Table 2).

The aetiology of the ulcers is presented in Table 3.

Table 3 Ulcer aetiology (%)

	Study group n=100	Control group n=1888
Venous ulcer	37	35
Arterial ulcer	19	8
Venous-arterial ulcer	8	5
Pressure ulcer	16	14
Neuropathic ulcer	6	4
Traumatic ulcer	11	14
Malignant ulcer	1	1
Inflammatory vessel disease	0	1
Other	2	9
Missing	0	9

Healing time

The flowchart in Figure 1 illustrates the outcome for the participants in the healing time study. Healing rate was 82% (n=82) in the study group and 52% (n=978) in the control group.

Figure 1 Flow of participants through the trial.

The median healing time was 60 days (mean: 78 days; range: 0–334 days) in the study group and 84 days (mean: 134 days; range: 0–2540 days) in the control group (p=0.001) (Table 2). The median healing time and healing rate are illustrated in Figure 2, using Kaplan-Meier analysis.

Figure 2 Healing rate and ulcer healing time for the study group compared with the control group.

Waiting time

The median waiting time was 25 days (mean: 24.8 days; range: 1–83 days) in the study group and 32 days (mean: 43.4 days; range: 3–294 days) for the patients at BWHC East. There was a significant difference in waiting time between the groups (p=0.017), with the shortest waiting time seen in the study group (Figure 3).

Figure 3 Waiting time for a doctor's consultation for patients in the study group compared with patients at BWHC East.

Discussion

The main finding in this study was the significantly reduced ulcer healing time for patients with hard-to-heal ulcers diagnosed by video consultation (60 days) compared with patients diagnosed by in-person assessment (84 days). We also found that the waiting time was significantly reduced for patients diagnosed by video consultation (25 days) compared with patients diagnosed by in-person consultation (32 days).

Reduced ulcer healing time results in improved quality of life, less pain, lower treatment costs, and less time spent on transportation[5, 16]. The two major determinants of ulcer healing time are ulcer duration and ulcer size[18, 19]. Patients with shorter ulcer duration (1-6 months) and smaller ulcer size (<10 cm^2) have a shorter healing time than patients with longer ulcer duration (>6 months) and larger ulcer size (≥10 cm^2)[18, 19].

In the study group, the ulcer duration before diagnosis was 124 days and healing time was 60 days, while the corresponding figures in the control group were 84 days and 84 days respectively. One explanation for this could be that the patients in the study group lived in remote and mostly rural areas, and could not easily reach the health care centre for assessment of the ulcer. The video consultation made it possible to reach these patients who might have been undiagnosed and without adequate treatment for a long time. Nevertheless, a reduced ulcer healing time was found in the study group, despite the longer ulcer duration, which could demonstrate the importance of a short waiting time.

We found no significant difference in ulcer size between the study group and the control group, even when different techniques for area measurements were used. Planimetry is more accurate than length multiplied by width, which overestimates the real ulcer area[20]. Smartphone-based methods for wound measurements are considered accurate and precise[21].

The health care system has a strong economic incentive to reduce patients' waiting time. In the industrialized world, costs for wound management consume about 2-4% of the annual expenditure on health care, and these costs will rise in the future because of longer life

expectancy and a larger proportion of patients with diabetes[4]. A recent study[12] found that staff costs accounted for 87% of the total costs for wound management. Reduced waiting and healing times[10, 22] are strongly related to reduced costs.

Previous studies have shown that telemedicine using digital images provides rapid diagnosis and ulcer care due to reduced waiting time[13, 23]. We found that this is also true for real-time video consultation, which has not previously been studied thoroughly. Video consultation seems to be an effective tool to shorten waiting time. One perspective is the more efficient use of the operating room. As the doctor does not need any facilities other than a tablet and internet access to carry out the video consultation, the operating room is freed up for other patients to undergo dressing changes at the same time, thus increasing the number of patients diagnosed and treated per day. The lack of requirement for specialist equipment also means that the doctor is independent of any specific health care centre.

The healing rate in the study group was 82%, compared with 52% in the control group. The figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks[18] and 83% in 30 weeks[24]. The lower healing rate in the control group could partly be explained by a possible delay in follow-up in the registry.

Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers who are unable to attend clinical visits due to other medical conditions, pain, disability, or reduced mobility[3, 5, 6], as well as being an alternative for patients who are abroad.

Our results indicate that video consultation can effectively transmit sufficient ulcer data to allow a remote specialist in wound care to establish diagnosis and an ideal treatment strategy. This is in line with an earlier study[25] of diabetic foot ulcers, which showed no prolonged healing time when comparing telemedical assessment with in-person clinic visits. Concordance of the telemedicine consultation with in-person assessment was also found when a three-dimensional camera was used in a study of diabetic foot ulcers[15]. Video consultation provides a useful communication tool, allowing the specialist wound team to support and educate the assigned nurses in primary care and community care in an easy and secure manner. This could be compared with an earlier study[26] which showed that telemedicine could effectively transmit sufficient wound data to allow a remote specialist in wound care to provide support to local health professionals working in nursing homes. Telemedicine has also been shown to be a useful communication tool in a home care setting[27]. The modern technique of video communication through iPad or smartphone is easy to use and is now widely available in both rural and urban societies.

RUT covers wound management in primary care, community care, private care, and in-patient hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up, meaning that the dataset is large and reliable. An earlier study found that departments which registered their patients in RUT reported reduced ulcer healing times after the introduction of the registry[1]. Patients not registered in RUT thus probably have a longer ulcer healing time. If the results from our study were to be compared with unregistered patients, the difference in healing time would be even more marked, making our findings somewhat understated.

The GP in charge of the BWHC is the first author of this study (HWI), which could be considered a bias, but on the other hand it could be considered a strength that all patients diagnosed through video consultation were assessed by the same GP following standardized clinical routines for ulcer assessment. One limitation of our study is its lack of the perspective of patients and staff. There is a need for future studies which focus on patient and staff perceptions of the new technology, the patient's quality of life, and cost savings for the health care system. Further well-designed randomized controlled studies are necessary to understand how best to deploy telemedicine services in ulcer treatment.

Our study seems to provide sufficient evidence that video consultation is as feasible for wound management as traditional in-person assessment for evaluating healing and waiting time, and so a more widespread use can be recommended in clinical practice.

Conclusion

The findings from this study illustrate the immediate impact of video consultation with a doctor for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and waiting time. The results demonstrate the potential for improved ulcer diagnosis, treatment, and healing by using video consultation as a complement to in-person assessment.

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Contributors: Hanna Wickström led the research project and played the main role in the research design and initial manuscript. Rut Öien contributed to the research design and provided knowledge of RUT. Ulf Jakobsson contributed to the data analysis and interpretation

of results. Patrik Midlöv, Cecilia Fagerström, and Peter Anderberg contributed to the research design. All authors reviewed and revised the manuscript.

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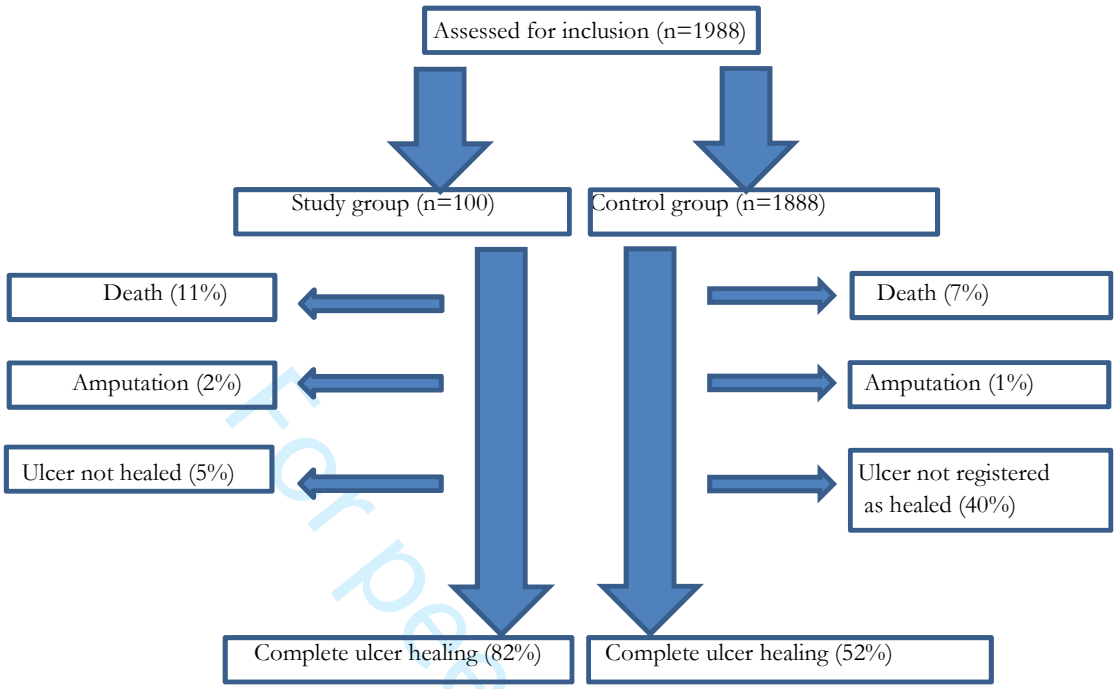
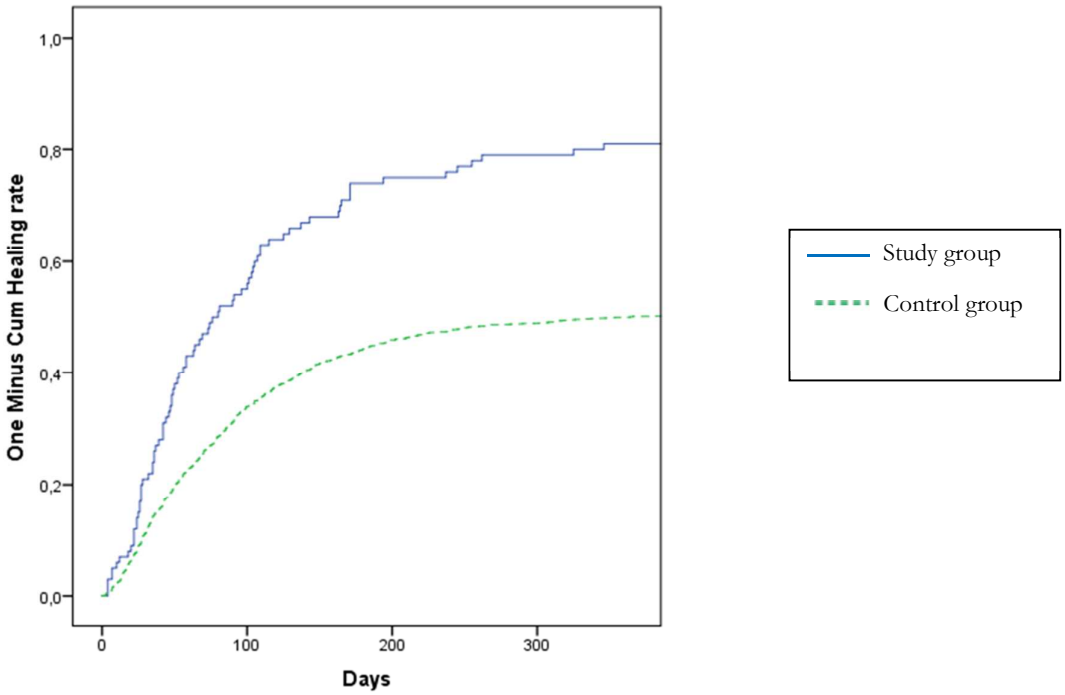
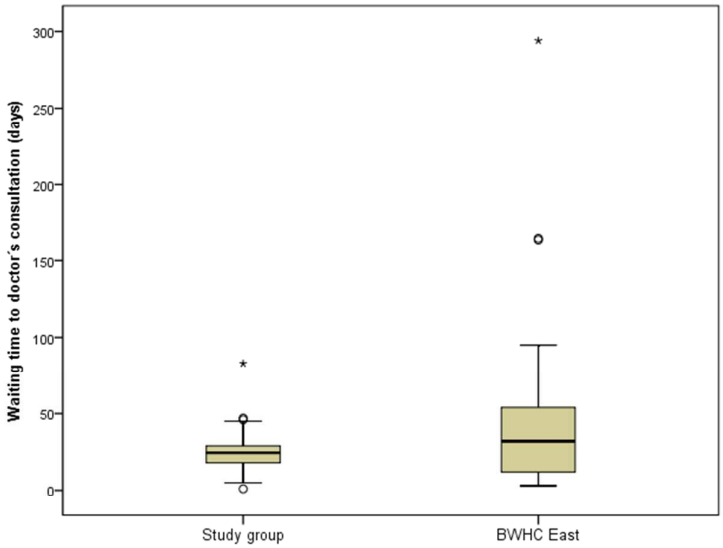
Competing interests: None

Ethics approval: The study was approved by the Regional Ethical Review Board of Lund, Sweden (ref: 2014/228).

Data sharing statement: No additional data available.







STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *case-control studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1, 2, 3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2, 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-8
Participants	6	*(*a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	7-9
		(*b*) For matched studies, give matching criteria and the number of controls per case	Not relevant
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	17
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		© Explain how missing data were addressed	12 Flow chart – no missing data
		(*d*) If applicable, explain how matching of cases and controls was addressed	Not relevant
		(*e*) Describe any sensitivity analyses	Not relevant
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12 Flow chart
		(b) Give reasons for non-participation at each stage	7-8 Consecutively included in the study group = no missing data, see Flow chart page 12; Data from RUT shows healed ulcers why there were no missing data relevant for this study
		(c) Consider use of a flow diagram	12
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11-12
		(b) Indicate number of participants with missing data for each variable of interest	No missing data in the study group
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	12-13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11-13
		(*b*) Report category boundaries when continuous variables were categorized	11-13
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Comparing video consultation with in-person assessment for Swedish patients with hard-to-heal ulcers: registry-based studies of healing time and of waiting time.

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Title

Comparing video consultation with in-person assessment for Swedish patients with hard-to-heal ulcers: registry-based studies of healing time and of waiting time.

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Abstract

Objectives: To investigate differences in ulcer healing time and waiting time between video consultation and in-person assessment for patients with hard-to-heal ulcers.

Setting: Patients treated at Blekinge Wound Healing Centre, a primary care centre covering the whole of Blekinge county (150 000 inhabitants), were compared with patients registered and treated according to the Registry for Ulcer Treatment (RUT), a Swedish national web-based quality registry.

Participants: In the study for analysing ulcer healing time, the study group consisted of 100 patients diagnosed through video consultation between October 2014 and September 2016. The control group for analysing healing time consisted of 1888 patients diagnosed through in-person assessment during the same period. In the study for analysing waiting time the same study group (n=100) was compared with 100 patients diagnosed through in-person assessment.

Primary and secondary outcome measures: Differences in ulcer healing time were analysed using the log-rank test. Differences in waiting time were analysed using Mann-Whitney U-test.

Results: Median healing time was 59 days in the study group and 82 days in the control group ($p<0.001$). Median waiting time was 25 days in the study group and 32 days for patients diagnosed through in-person assessment ($p=0.017$). There were no significant differences between the study group and the control group regarding gender, age, or ulcer size.

Conclusions: Healing time and waiting time were significantly shorter for patients diagnosed through video consultation compared with those diagnosed through in-person assessment.

Strengths and limitations of this study

- The use of a large, nationally representative sample of patients with hard-to-heal ulcers gives increased generalizability.
- A well-known technical system was used for video communication.
- All patients diagnosed through video consultation were assessed by the same GP, following standardized clinical routines for ulcer assessment.
- The study group was consecutively included and rather limited in size (n=100).

Introduction

Hard-to-heal ulcers are defined as ulcers which have not healed within 6 weeks[1]. Patients with these ulcers have long been considered neglected, as treatment is often given without diagnosis, thus prolonging ulcer healing time[2]. The majority of these patients are elderly and

suffer from other conditions such as diabetes and heart and lung diseases[1, 3]. In addition to these comorbidities, these patients may experience extreme pain[4, 5]. Treatment is carried out by different caregivers within different medical specialties, and so a multidisciplinary team of professionals is often necessary to establish the ulcer aetiology and provide the proper diagnosis[6].

In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care[2, 7]. Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000 inhabitants). It is divided into two health care centres within the same clinical establishment, BWHC West and BWHC East, which are comparably organized in terms of patient population and staff. Both centres have the same expenditure of time for doctors' consultations and nurses' dressing changes, capacity for patient assessment and treatment, and facilities in terms of operating rooms, dressing materials, and computer services.

At BWHC, patients are treated according to a structured wound management based on a Swedish national quality registry, the Registry of Ulcer Treatment (RUT) [7]. The clinical routines provided by BWHC are the same as those provided by all the other units which register their patients in RUT, and so data from these other units are comparable with data from BWHC.

The Swedish Registry of Ulcer Treatment

RUT is a web-based tool for clinical assessment of hard-to-heal ulcers, treatment strategies, and continuity of care. Solid clinical research data based on RUT has shown improved quality of life as well as reduction of healing time, treatment costs, and antibiotic treatment[2, 8, 9]. There were more than 7000 registrations in RUT in 2016, giving a coverage rate of approximately 25% of all patients with hard-to-heal ulcers in Sweden.

Patients are registered by a nurse or physician on two occasions. The first registration includes variables for assessment of ulcer diagnosis and treatment strategies, while the second includes data on ulcer healing or negative clinical events such as amputation or death. Each patient with a non-healing ulcer remains in the registry until the follow-up is completed.

Telemedicine for wound management

Telemedicine is the use of information technology and electronic communication to allow health care professionals to evaluate, diagnose, and treat patients at a distance. It typically includes various forms of video consultation or digital transmission of medical imaging and other clinical data.

Transmission of digital photographs has been used within ulcer care in Denmark since 2005, resulting in the reduction of waiting time, ulcer healing time, and transportation, the latter of which can often be uncomfortable or painful for the patient[10]. Another example is a telemedicine wound care model, which has produced reductions in both hospital admissions and patient transportations[11]. The use of three-dimensional images has shown high concordance with in-person consultation for assessment and measurement of wounds[12].

Video communication is widely used within different medical specialties today, though thorough documentation and evaluation is insufficient[13]. However, there is a lack of use of this technology for ulcer care, even though its focus on the visual is considered ideal for wound management[14]. Video communication could be a useful tool, especially in primary care, where there is a need for national guidelines[3] as well as dedicated doctors and nurses for wound management.

The aim of this study was to compare video consultation with in-person assessment for patients with hard-to-heal ulcers, in terms of healing time and waiting time.

Methods

Study population and variables

The first study was an analysis of healing time for patients diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment based on data from RUT (control group) (Table 1).

The second study was a supplementary analysis of the waiting time for a doctor's consultation for patients diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment at a comparable clinic (BWHC East) (Table 1). The reason this supplementary analysis was needed is that waiting time is not recorded in RUT.

Hard-to-heal ulcers include different diagnostic groups such as venous, arterial and venous-arterial leg ulcers; neuropathic ulcers; pressure ulcers; traumatic ulcers; malignant ulcers; ulcers due to inflammatory vessel disease; and some ulcers of rare aetiology. This study included ulcers of any aetiology, severity, size, and duration. It is possible to register ulcers in RUT from the day they occur (day 0) if patients or staff believe that there will be a prolonged total healing time.

The number of patients in the study group was chosen according to the expected number of new undiagnosed patients seeking treatment at BWHC West and BWHC East, respectively, over two years.

Every patient in the study group (n=100) gave their written consent. Every patient in the control group (n=1888) gave their oral consent consistent with the principles of Swedish national quality registries.

Table 1 Study population and setting

	Healing time study		**Waiting time study**	
Participants	Study group n=100	Control group n=1888	Study group n=100	Patients at BWHC East n=100
Assessment	Video consultation	In-person assessment	Video consultation	In-person assessment
Setting	Patients at BWHC West	Patients from RUT	Patients at BWHC West	Patients at BWHC East

Inclusion	Consecutively included	All patients registered in RUT during the study period	Consecutively included	Consecutively included
Inclusion criteria	Age >18; women and men; ulcers of any aetiology, severity, size, and duration			
Exclusion criteria	Age < 18 Patients with dementia	Age <18 *	Age <18 Patients with dementia	Age <18 *
Study period	1 October 2014 – 30 September 2016			
Consent	Written consent mandatory	Oral consent according to Swedish registries	Written consent mandatory	Oral consent according to Swedish registries

* Patients in the control group (the registry) were included regardless of dementia status, since dementia is not recorded in the registry.

The healing time study

Study group

The patients were initially assessed during a nurse visit, with measurements taken according to RUT[8]. Ulcer size was measured by a planimeter. During this visit, the patient received an iPad programmed with Skype for the upcoming video consultation between the general practitioner at BWHC and the patient accompanied by the assigned nurse. All iPads had mobile internet access to avoid any need to use the patients' home Wi-Fi.

Each video consultation took place in the patient's home or in the primary health care centre. During this consultation, the doctor established the ulcer diagnosis and an appropriate treatment strategy which could be carried out by the assigned nurse under supervision. The patient and the treatment strategy were followed up according to general clinical routines. Documentation of the video consultation was transferred to the patient's medical record.

Each patient was followed to ulcer healing or to the end of the study period, whichever occurred first. If amputation or death occurred during the study period, the date of this event was registered and the patient was not followed further.

Control group

All patients were diagnosed by in-person consultation and registered in RUT. The same measurements were used in both the control group and the study group, except for measurement of ulcer size. For patients in the control group, this was done either by a planimeter or as length multiplied by width, according to different clinical routines.

As with the study group, each patient was followed to ulcer healing or the end of the study period, and if amputation or death occurred, the date was registered and the patient was not followed further.

The waiting time study

In Sweden, waiting time is considered clinically important as an indicator of cost effective health care. Age, gender, ulcer size, and ulcer duration were not considered to affect the waiting time for a doctor's consultation, and so were not analysed in this study.

Study group

The same study group was used as for the healing time study.

Patients at BWHC East

All patients with hard-to-heal ulcers were diagnosed by in-person assessment at BWHC East. These patients were likewise assessed according to RUT and followed to ulcer healing or to the end of the study period, whichever occurred first.

Variables

Age (years), gender, ulcer size (cm^2), ulcer aetiology, and diabetes (yes or no) were analysed in both the study group and the control group. Ulcer size was measured by planimeter (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) or by length multiplied by width, according to the established routines in different registration units. Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers, pressure ulcers, neuropathic ulcers, traumatic ulcers, malignant ulcers, ulcers due to inflammatory vessel diseases such as vasculitis, and other ulcers.

Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of diagnosis by a doctor.

Ulcer healing time (in days) was defined as the interval between the consultation with a doctor and complete ulcer healing.

Waiting time (in days) was defined as the interval between referral and consultation with a doctor at the BWHC.

Data analysis

Statistical analysis was performed using version 24 of IBM SPSS Statistics. Normally distributed variables were expressed as mean values, standard deviations (SD), and ranges, and compared using Student´s t-test. Not normally distributed variables were expressed as median values and ranges, and differences in groups were analysed using Mann-Whitney U-test. Categorical variables were compared between groups using Pearson's Chi-square test. Healing time was analysed with Kaplan-Meier curve. A log-rank test was used for equality of survivor function. A Cox regression analysis was used to explore the effect of age, gender, diabetes, ulcer size and ulcer duration on ulcer healing time. A p-value of less than 0.05 was considered to indicate statistical significance.

Results

Patient demographics

Basic data on the study group and the control group are presented in Table 2.

The study group had a mean age of 77 years, the median ulcer size was 3.4 cm^2, and the median ulcer duration was 124 days. The control group had a mean age of 75 years, the

median ulcer size was 3.8 cm^2, and the median ulcer duration was 84 days. In the study group 13% of the patients were registered as smokers, compared with 14% in the control group.

Table 2. Patient demographics: the healing time study.

	Study group n=100	Control group n=1888	p-value
Age, mean (SD, range) [A]	77 years (13, 37-98)	75 years (14, 23–104)	0.231
Female [B]	54%	56%	0.744
Diabetes [B]	27%	28%	0.798
Ulcer size, median (range) [C]	3.4 cm^2 (0.1-131.6)	3.8 cm^2 (0.01-1196.0)	0.192
Ulcer duration, median (range) [C]	124 days (7-3657)	84 days (0-5839)	**<0.001**
Healing time, median (95% CI) [D]	59 days (40-78)	82 days (75-89)	**<0.001**

[A] Student's t-test

[B] Chi-square test

[C] Mann-Whitney U-test

[D] Log-rank test

There was no significant difference in gender, age, ulcer size, or diabetes between the patients in the study group and the patients in the control group (Table 2).

In both the study group and the control group, 71% (70.8% and 71.3% respectively) of the ulcers were smaller than 10cm^2 and the remaining 29% (29.2% and 28.7% respectively) were larger than 10 cm^2. The Mann-Whitney U-test showed no significant difference in ulcer size between the study group and the control group when analysing only the small ulcers (p=0.053) or only the larger ulcers (p=0.132).

There was a significant difference in ulcer duration between the study group and the control group ($p<0.001$), with the shortest ulcer duration seen in the control group (Table 2).

The aetiology of the ulcers is presented in Table 3. A Chi-square test was performed concerning the difference in ulcer aetiology between the groups, but the analysis showed that the groups were too small for a comparison.

Table 3 Ulcer aetiology (%)

	Study group n=100	Control group n=1888
Venous ulcer	37	35
Arterial ulcer	19	8
Venous-arterial ulcer	8	5
Pressure ulcer	16	14
Neuropathic ulcer	6	4
Traumatic ulcer	11	14
Malignant ulcer	1	1
Inflammatory vessel disease	0	1
Other	2	9
Missing	0	9

Healing time

The flowchart in Figure 1 illustrates the outcome for the participants in the healing time study. Healing rate was 82% (n=82) in the study group and 52% (n=978) in the control group.

Figure 1 Flow of participants through the trial.

After censorship of unhealed ulcers, deaths, and amputations, the median healing time was 59 days (mean: 78 days; 95% CI: 40-78) in the study group and 82 days (mean: 118 days; 95% CI: 75-89) in the control group ($p<0.001$; Table 2). Cox regression analysis showed that there was no significant influence of gender, age, ulcer size, diabetes or ulcer duration on healing time.

The healing time and healing rate are illustrated in Figure 2 using Kaplan-Meier analysis, again censored for unhealed ulcers, deaths, and amputations and also adjusted for age, gender, diabetes, ulcer size and ulcer duration.

Figure 2 Healing rate and ulcer healing time for the study group compared with the control group. Figure adjusted for age, gender, diabetes, ulcer size and ulcer duration.

Waiting time

The median waiting time was 25 days (mean: 25 days; range: 1–83 days) in the study group and 32 days (mean: 43 days; range: 3–294 days) for the patients at BWHC East. There was a significant difference in waiting time between the groups ($p=0.017$), with the shortest waiting time seen in the study group (Figure 3).

Figure 3 Waiting time for a doctor's consultation for patients in the study group compared with patients at BWHC East.

Discussion

The main finding in this study was the significantly reduced ulcer healing time for patients with hard-to-heal ulcers diagnosed by video consultation (59 days) compared with patients diagnosed by in-person assessment (82 days). We also found that the waiting time was significantly reduced for patients diagnosed by video consultation (25 days) compared with patients diagnosed by in-person consultation (32 days). This study focused on ulcer healing time, as earlier research has shown that reduced ulcer healing time results in improved quality of life, less pain, lower treatment costs, and less time spent on transportation[4, 13].

In the study group, the ulcer duration before diagnosis was 124 days and healing time was 59 days, while the corresponding figures in the control group were 84 days and 82 days respectively. One explanation for this could be that the patients in the study group lived in remote and mostly rural areas, and could not easily reach the health care centre for assessment of the ulcer. The video consultation made it possible to reach these patients who might have been undiagnosed and without adequate treatment for a long time. Nevertheless, a reduced ulcer healing time was found in the study group, despite the longer ulcer duration, which could demonstrate the importance of a short waiting time.

In clinical practice in Sweden, the main technique for measuring ulcer size is multiplication of length by width, while in specialized clinics such as BWHC, staff use digital planimetry to measure ulcer size. The use of these different measurement techniques is one limitation of this study, but earlier researchers[15] have noted that the two methods have a high degree of

agreement with each other for ulcers with an area of up to approximately 10 cm^2. In this study, most patients (71%) had an ulcer area smaller than 10 cm^2, and we found no significant difference in ulcer size in the proportion of smaller ulcers between the study group and the control group. We therefore consider that the use of the two different techniques for measuring ulcer size could be justifiable in this setting. The remaining 29% of the ulcers were larger than 10 cm^2, but even for these larger ulcers we found no significant difference in ulcer size between the study group and the control group.

The health care system has a strong economic incentive to reduce patients' waiting time. In the industrialized world, costs for wound management consume about 2-4% of the annual expenditure on health care, and these costs will rise in the future because of longer life expectancy and a larger proportion of patients with diabetes[3]. A recent study[9] found that staff costs accounted for 87% of the total costs for wound management. Reduced waiting and healing times[16, 17] are strongly related to reduced costs. We did not analyse the number of nurse visits before and after the video consultation, but there were no changes in the clinical routines and so we can assume that the frequencies of dressing changes were not altered.

Previous studies have shown that telemedicine using digital images provides rapid diagnosis and ulcer care due to reduced waiting time[10, 18]. We found that this is also true for real-time video consultation, which has not previously been studied thoroughly. Video consultation seems to be an effective tool to shorten waiting time. One perspective is the more efficient use of the operating room. As the doctor does not need any facilities other than a tablet and internet access to carry out the video consultation, the operating room is freed up for other patients to undergo dressing changes at the same time, thus increasing the number of patients

diagnosed and treated per day. The lack of requirement for specialist equipment also means that the doctor is independent of any specific health care centre.

The healing rate in the study group was 82%, compared with 52% in the control group. The figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks[19] and 83% in 30 weeks[20]. The lower healing rate in the registry (i.e. in the control group) could be explained by a possible delay in follow-up data being added to the registry. The difficulty of obtaining follow-up data in a timely fashion is a well-known phenomenon for most Swedish quality registries.

Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers who are unable to attend clinical visits due to other medical conditions, pain, disability, or reduced mobility[1, 4, 5], as well as being an alternative for patients who are abroad. Our results indicate that video consultation can effectively transmit sufficient ulcer data to allow a remote specialist in wound care to establish diagnosis and an ideal treatment strategy. This is in line with an earlier study[21] of diabetic foot ulcers, which showed no prolonged healing time when comparing telemedical assessment with in-person clinic visits. Concordance of the telemedicine consultation with in-person assessment was also found when a three-dimensional camera was used in a study of diabetic foot ulcers[12]. Video consultation provides a useful communication tool, allowing the specialist wound team to support and educate the assigned nurses in primary care and community care in an easy and secure manner. This could be compared with an earlier study[22] which showed that telemedicine could effectively transmit sufficient wound data to allow a remote specialist in wound care to provide support to local health professionals working in nursing homes. Telemedicine has also been shown to

be a useful communication tool in a home care setting[23]. The modern technique of video communication through iPad or smartphone is easy to use and is now widely available in both rural and urban societies.

RUT covers wound management in primary care, community care, private care, and in-patient hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up, meaning that the dataset is large and reliable. One challenge for GPs and nurses in primary care in Sweden is to provide adequate diagnosis and treatment to each patient with a hard-to-heal ulcer in this unselected patient group. RUT was developed in order to deal with this issue, and hence includes hard-to-heal ulcers of any aetiology even when there are different healing trajectories. An earlier study found that departments which registered their patients in RUT reported reduced ulcer healing times after the introduction of the registry[2]. Patients not registered in RUT thus probably have a longer ulcer healing time. If the results from our study were to be compared with unregistered patients, the difference in healing time would be even more marked, making our findings somewhat understated.

The GP in charge of the BWHC is the first author of this study (HWI), which could be considered a bias and a possible explanation for the lower dropout frequency in the study group. However, it could be considered a strength that all patients diagnosed through video consultation were assessed by the same GP following standardized clinical routines for ulcer assessment. One limitation is the lack of blinded outcome assessment, but a register-based study gives the opportunity to analyse large study populations, which is hard to accomplish with blinded outcome studies. Another limitation is the exclusion of patients with dementia in the study group, which was done as recommended by the Ethical Review Board. There is a

need for future studies which focus on patient and staff perceptions of the new technology, the patient's quality of life, and cost savings for the health care system. Further well-designed randomized controlled studies are necessary to understand how best to deploy telemedicine services in ulcer treatment.

In Sweden, RUT stands for a structured wound management and a way to document the wound healing process. Video consultation is one complementary communication tool, which together with RUT allows an easy ulcer assessment, especially for patients who are unable to attend clinical visits due to severe medical conditions, pain, disability, or reduced mobility. Video consultation in parallel with the clinical practice in RUT seems to lead to a more efficient use of resources when reducing healing time and waiting time for this neglected patient group.

Conclusion

The findings from this study illustrate the possible impact of video consultation with a doctor for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and waiting time. Using video consultation as a complement to in-person assessment has the potential to improve ulcer diagnosis, treatment, and healing.

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Contributors: Hanna Wickström led the research project and played the main role in the research design and initial manuscript. Rut Öien contributed to the research design and provided knowledge of RUT. Ulf Jakobsson contributed to the data analysis and interpretation of results. Patrik Midlöv, Cecilia Fagerström, and Peter Anderberg contributed to the research design. All authors reviewed and revised the manuscript.

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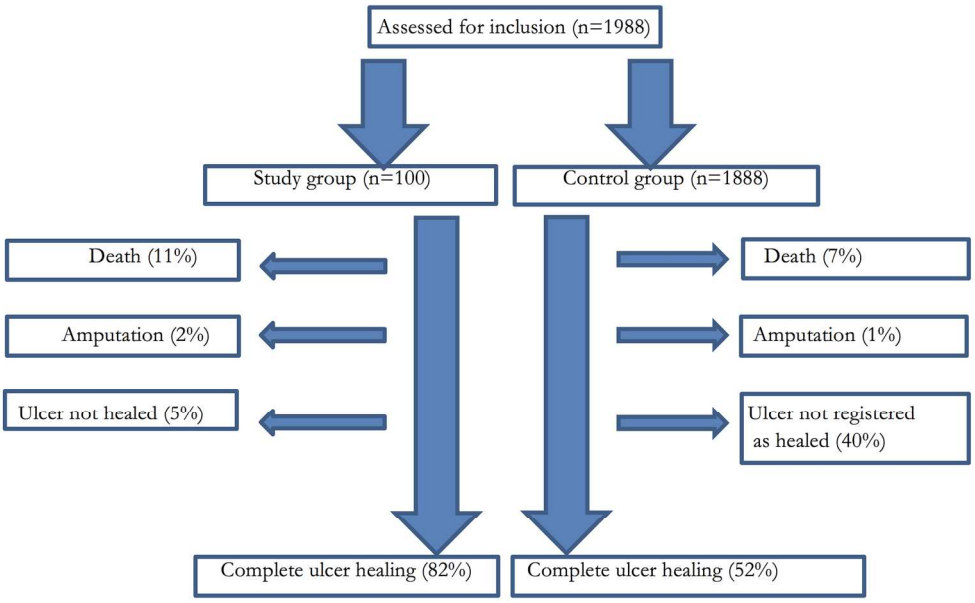

Figure 1 Flow of participants through the trial.

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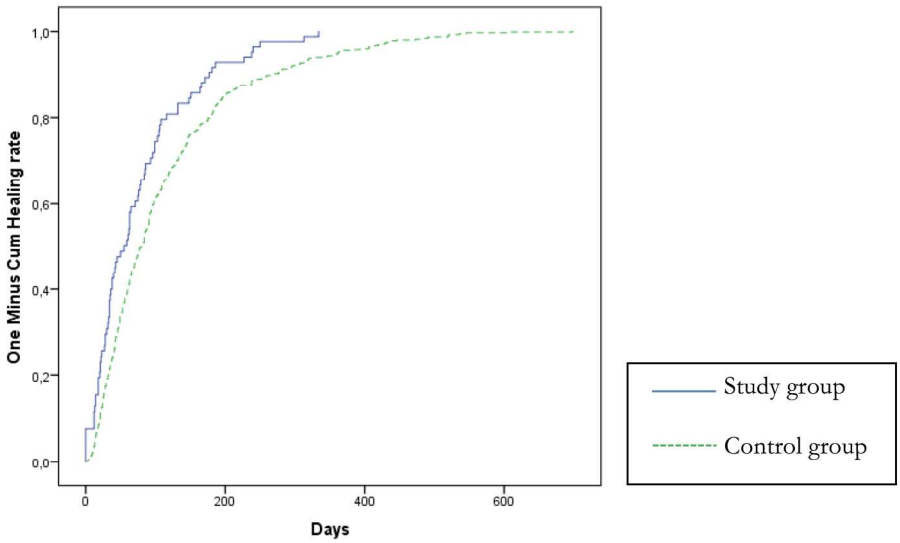

Figure 2 Healing rate and ulcer healing time for the study group compared with the control group. Figure adjusted for age, gender, diabetes, ulcer size and ulcer duration.

222x125mm (300 x 300 DPI)

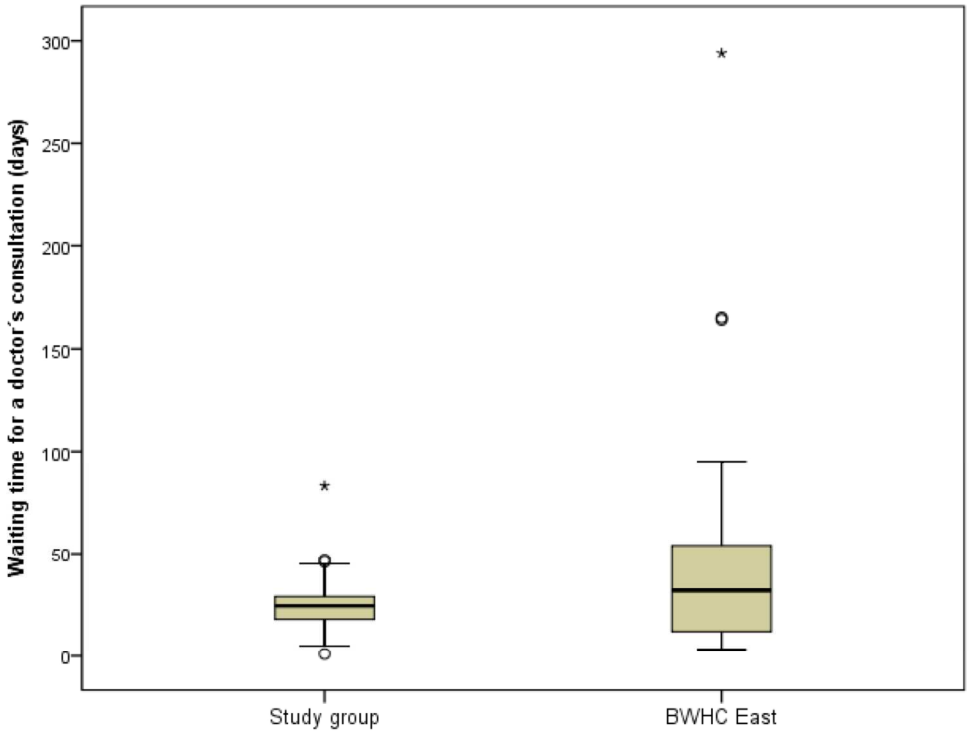

Figure 3 Waiting time for a doctor´s consultation for patients in the study group compared with patients at BWHC East.

250x188mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *case-control studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1, 2, 3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2, 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-8
Participants	6	*(*a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	7-9
		(*b*) For matched studies, give matching criteria and the number of controls per case	Not relevant
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	17
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		© Explain how missing data were addressed	12 Flow chart – no missing data
		(*d*) If applicable, explain how matching of cases and controls was addressed	Not relevant
		(*e*) Describe any sensitivity analyses	Not relevant
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12 Flow chart
		(b) Give reasons for non-participation at each stage	7-8 Consecutively included in the study group = no missing data, see Flow chart page 12; Data from RUT shows healed ulcers why there were no missing data relevant for this study
		(c) Consider use of a flow diagram	12
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11-12
		(b) Indicate number of participants with missing data for each variable of interest	No missing data in the study group
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	12-13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11-13
		(*b*) Report category boundaries when continuous variables were categorized	11-13
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Comparing video consultation with in-person assessment for Swedish patients with hard-to-heal ulcers: registry-based studies of healing time and of waiting time.

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Title

Comparing video consultation with in-person assessment for Swedish patients with hard-to-heal ulcers: registry-based studies of healing time and of waiting time.

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Abstract

Objectives: To investigate differences in ulcer healing time and waiting time between video consultation and in-person assessment for patients with hard-to-heal ulcers.

Setting: Patients treated at Blekinge Wound Healing Centre, a primary care centre covering the whole of Blekinge county (150 000 inhabitants), were compared with patients registered and treated according to the Registry for Ulcer Treatment (RUT), a Swedish national web-based quality registry.

Participants: In the study for analysing ulcer healing time, the study group consisted of 100 patients diagnosed through video consultation between October 2014 and September 2016. The control group for analysing healing time consisted of 1888 patients diagnosed through in-person assessment during the same period. In the study for analysing waiting time the same study group (n=100) was compared with 100 patients diagnosed through in-person assessment.

Primary and secondary outcome measures: Differences in ulcer healing time were analysed using the log-rank test. Differences in waiting time were analysed using the Mann-Whitney U-test.

Results: Median healing time was 59 days (95% CI: 40–78) in the study group and 82 days (95% CI: 75–89) in the control group ($p<0.001$). Median waiting time was 25 days (range: 1–83 days) in the study group and 32 days (range: 3–294 days) for patients diagnosed through in-person assessment ($p=0.017$). There were no significant differences between the study group and the control group regarding gender, age, or ulcer size.

Conclusions: Healing time and waiting time were significantly shorter for patients diagnosed through video consultation compared with those diagnosed through in-person assessment.

Strengths and limitations of this study

- The use of a large, nationally representative sample of patients with hard-to-heal ulcers gives increased generalizability.
- A well-known technical system was used for video communication.
- All patients diagnosed through video consultation were assessed by the same GP, following standardized clinical routines for ulcer assessment.
- The study group was consecutively included and rather limited in size (n=100).

Introduction

A hard-to-heal (or chronic) ulcer is defined as a break in the skin which has not healed within 4–6 weeks[1, 2, 3, 4]. This definition is independent of the wound type and aetiology[5]. Examples

of hard-to-heal ulcers are venous, arterial, or venous-arterial leg ulcers; diabetic foot ulcers; pressure ulcers; burns[6]; and ulcers due to trauma, rheumatoid arthritis, and malignancy[3]. Patients with these ulcers have long been considered neglected, as treatment is often given without diagnosis, thus prolonging ulcer healing time[7]. The majority of these patients are elderly and suffer from other conditions such as diabetes and heart and lung diseases[1, 8]. In addition to these comorbidities, these patients may experience extreme pain[9, 10]. Treatment is carried out by different caregivers within different medical specialties, and so a multidisciplinary team of professionals is often necessary to establish the ulcer aetiology and provide the proper diagnosis[11].

In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care[7, 12]. Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000 inhabitants). It is divided into two health care centres within the same clinical establishment, BWHC West and BWHC East, which are comparably organized in terms of patient population and staff, and with equal resource allocation. Both centres have the same expenditure of time for doctors' consultations and nurses' dressing changes, capacity for patient assessment and treatment, and facilities in terms of treatment rooms, dressing materials, and computer services.

At BWHC, patients are treated according to a structured wound management based on a Swedish national quality registry, the Registry of Ulcer Treatment (RUT) [12]. The clinical routines provided by BWHC are the same as those provided by all the other units which

register their patients in RUT, and so data from these other units are comparable with data from BWHC.

The Swedish Registry of Ulcer Treatment

RUT is a web-based tool for clinical assessment of hard-to-heal ulcers, treatment strategies, and continuity of care. Solid clinical research data based on RUT has shown improved quality of life as well as reduction of healing time, treatment costs, and antibiotic treatment[7, 13, 14]. There were more than 7000 registrations in RUT in 2016, giving a coverage rate of approximately 25% of all patients with hard-to-heal ulcers in Sweden.

Patients are registered by a nurse or physician on two occasions. The first registration includes variables for assessment of ulcer diagnosis and treatment strategies, while the second includes data on ulcer healing or negative clinical events such as amputation or death. Each patient with a non-healing ulcer remains in the registry until the follow-up is completed.

Telemedicine for wound management

Telemedicine is the use of information technology and electronic communication to allow health care professionals to evaluate, diagnose, and treat patients at a distance. It typically includes various forms of video consultation or digital transmission of medical imaging and other clinical data.

Transmission of digital photographs has been used within ulcer care in Denmark since 2005, resulting in the reduction of waiting time, ulcer healing time, and transportation, the latter of which can often be uncomfortable or painful for the patient[15]. Another example is a

telemedicine wound care model, which has produced reductions in both hospital admissions and patient transportations[16]. The use of three-dimensional images has shown high concordance with in-person consultation for assessment and measurement of wounds[17].

Video communication is widely used within different medical specialties today, though thorough documentation and evaluation is insufficient[18]. However, there is a lack of use of this technology for ulcer care, even though its focus on the visual is considered ideal for wound management[19]. Video communication could be a useful tool, especially in primary care, where there is a need for national guidelines[8] as well as dedicated doctors and nurses for wound management.

The aim of this study was to compare video consultation with in-person assessment for patients with hard-to-heal ulcers, in terms of healing time and waiting time.

Methods

Study population and variables

The first study was an analysis of healing time for patients diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment based on data from RUT (control group) (Table 1).

The second study was a supplementary analysis of the waiting time for a doctor's consultation for patients diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment at a comparable clinic (BWHC East)

(Table 1). The reason this supplementary analysis was needed is that waiting time is not recorded in RUT.

Our study included ulcers of any aetiology, severity, size, and duration. It is possible to register ulcers in RUT from the day they occur (day 0) if patients or staff believe that there will be a prolonged total healing time. The number of patients in the study group was chosen according to the expected number of new undiagnosed patients seeking treatment at BWHC West and BWHC East, respectively, over two years.

Every patient in the study group (n=100) gave their written consent. Every patient in the control group (n=1888) gave their oral consent consistent with the principles of Swedish national quality registries.

Table 1 Study population and setting

	Healing time study		**Waiting time study**	
Participants	Study group n=100	Control group n=1888	Study group n=100	Patients at BWHC East n=100
Assessment	Video consultation	In-person assessment	Video consultation	In-person assessment
Setting	Patients at BWHC West	Patients from RUT	Patients at BWHC West	Patients at BWHC East
Inclusion	Consecutively included	All patients registered in RUT during the	Consecutively included	Consecutively included

		study period		
Inclusion criteria	Age >18; women and men; ulcers of any aetiology, severity, size, and duration			
Exclusion criteria	Age < 18 Patients with dementia	Age <18 *	Age <18 Patients with dementia	Age <18 *
Study period	1 October 2014 – 30 September 2016			
Consent	Written consent mandatory	Oral consent according to Swedish registries	Written consent mandatory	Oral consent according to Swedish registries

* Patients in the control group (the registry) were included regardless of dementia status, since dementia is not recorded in the registry.

The healing time study

Study group

The patients were initially assessed during a nurse visit, with measurements taken according to RUT[12]. Ulcer size was measured by a planimeter. During this visit, the patient received an iPad programmed with Skype for the upcoming video consultation between the general practitioner at BWHC and the patient accompanied by the assigned nurse. All iPads had mobile internet access to avoid any need to use the patients' home Wi-Fi. The iPads had a one-time cost of 325 GBP (439 USD) per unit; the software (Skype) was free, and there was a negligible cost for internet access.

Each video consultation took place in the patient's home or in the primary health care centre. During this consultation, the doctor established the ulcer diagnosis and an appropriate

treatment strategy which could be carried out by the assigned nurse under supervision. The patient and the treatment strategy were followed up according to general clinical routines. Documentation of the video consultation was transferred to the patient's medical record.

All patients were included and followed during the study period (1 October 2014 – 30 September 2016). Patients with ulcers that healed had different follow-up times, depending on the date of ulcer healing, which was documented. Patients with ulcers that did not heal were followed to the end of the study period. If amputation or death occurred during the study period, the date of this event was registered and the patient was not followed further. Healing was confirmed clinically by a nurse or a doctor.

Control group

All patients were diagnosed by in-person consultation and registered in RUT**.** The same measurements were used in both the control group and the study group, except for measurement of ulcer size. For patients in the control group, this was done either by a planimeter or as length multiplied by width, according to different clinical routines.

As with the study group, each patient was included and followed during the study period (1 October 2014 – 30 September 2016). Again, patients with ulcers that healed had different follow-up times, depending on the date of ulcer healing, which was registered in RUT. Patients with ulcers that did not heal were followed to the end of the study period. If amputation or death occurred during the study period, the date of this event was registered

and the patient was not followed further. Healing was confirmed clinically by a nurse or a doctor at follow-up registration.

The waiting time study

In Sweden, waiting time is considered clinically important as an indicator of cost effective health care. Age, gender, ulcer size, and ulcer duration were not considered to affect the waiting time for a doctor's consultation, and so were not analysed in this study.

Study group

The same study group was used as for the healing time study.

Patients at BWHC East

All patients with hard-to-heal ulcers were diagnosed by in-person assessment at BWHC East. These patients were likewise assessed according to RUT and followed to ulcer healing or to the end of the study period, whichever occurred first.

Variables

Age (years), gender, ulcer size (cm^2), ulcer aetiology, and diabetes (yes or no) were analysed in both the study group and the control group. Ulcer size was measured by planimeter (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) or by length multiplied by width, according to the established routines in different registration units. Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers,

pressure ulcers, neuropathic ulcers (diabetic foot ulcers), traumatic ulcers, malignant ulcers, ulcers due to inflammatory vessel diseases such as vasculitis, and other ulcers.

Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of diagnosis by a doctor.

Ulcer healing time (in days) was defined as the interval between the consultation with a doctor and complete ulcer healing. A healed ulcer was defined as an ulcer covered by epithelial regeneration, beneath which there may be scarring and absence of glands or appendages[20].

Waiting time (in days) was defined as the interval between referral and consultation with a doctor at the BWHC.

Data analysis

Statistical analysis was performed using version 24 of IBM SPSS Statistics. Normally distributed variables were expressed as mean values, standard deviations (SD), and ranges, and compared using Student's t-test. Non-normally distributed variables were expressed as median values and ranges, and differences in groups were analysed using the Mann-Whitney U-test. Categorical variables were compared between groups using Pearson's chi-square test. Healing time was analysed with Kaplan-Meier curves. A log-rank test was used for equality of survivor function. A Cox regression analysis was used to explore the effect of age, gender, diabetes, ulcer size, and ulcer duration on ulcer healing time. A p-value of less than 0.05 was considered to indicate statistical significance.

Results

Patient demographics

Basic data on the study group and the control group are presented in Table 2.

The study group had a mean age of 77 years, the median ulcer size was 3.4 cm^2, and the median ulcer duration was 124 days. The control group had a mean age of 75 years, the median ulcer size was 3.8 cm^2, and the median ulcer duration was 84 days. In the study group 13% of the patients were registered as smokers, compared with 14% in the control group.

Table 2. Patient demographics: the healing time study.

	Study group n=100	Control group n=1888	p-value
Age, mean (SD, range) [A]	77 years (13, 37–98)	75 years (14, 23–104)	0.231
Female [B]	54%	56%	0.744
Diabetes [B]	27%	28%	0.798
Ulcer size, median (range) [C]	3.4 cm^2 (0.1-131.6)	3.8 cm^2 (0.01-1196.0)	0.192
Ulcer duration, median (range) [C]	124 days (7-3657)	84 days (0-5839)	**<0.001**
Healing time, median (95% CI) [D]	59 days (40-78)	82 days (75-89)	**<0.001**

[A] Student's t-test

[B] Chi-square test

[C] Mann-Whitney U-test

[D] Log-rank test

There was no significant difference in gender, age, ulcer size, or diabetes between the patients in the study group and the patients in the control group (Table 2).

In both the study group and the control group, 71% (70.8% and 71.3% respectively) of the ulcers were smaller than 10 cm^2 and the remaining 29% (29.2% and 28.7% respectively) were larger than 10 cm^2. The Mann-Whitney U-test showed no significant difference in ulcer size between the study group and the control group when analysing only the small ulcers ($p=0.053$) or only the larger ulcers ($p=0.132$).

There was a significant difference in ulcer duration between the study group and the control group ($p<0.001$), with the shortest ulcer duration seen in the control group (Table 2).

The aetiology of the ulcers is presented in Table 3. A chi-square test was performed concerning the difference in ulcer aetiology between the groups, but the analysis showed that the groups were too small for a comparison.

Table 3 Ulcer aetiology (%)

	Study group n=100	Control group n=1888
Venous ulcer	37	35
Arterial ulcer	19	8
Venous-arterial ulcer	8	5
Pressure ulcer	16	14
Neuropathic ulcer	6	4
Traumatic ulcer	11	14
Malignant ulcer	1	1
Inflammatory vessel disease	0	1
Other	2	9

Missing	0	9

Healing time

The flowchart in Figure 1 illustrates the outcome for the participants in the healing time study. Healing rate was 82% (n=82) in the study group and 52% (n=978) in the control group. In the study group, 74% of the patients were followed for <6 months, 8% for 6–12 months, and 18% for >12 months. In the control group, 38% of the patients were followed for <6 months, 8% for 6–12 months, and 54% for >12 months.

Figure 1

After censorship of unhealed ulcers, deaths, and amputations, the median healing time was 59 days (mean: 78 days; 95% CI: 40-78) in the study group and 82 days (mean: 118 days; 95% CI: 75-89) in the control group (p<0.001; Table 2). Cox regression analysis showed that there was no significant influence of gender, age, ulcer size, diabetes, or ulcer duration on healing time.

Healing time is illustrated in Figure 2a using Kaplan-Meier analysis, again censored for unhealed ulcers, deaths, and amputations and also adjusted for age, gender, diabetes, ulcer size, and ulcer duration. Figure 2b illustrates healing time and healing rate, without censoring for unhealed ulcers, deaths, and amputations.

Figure 2a-2b

Waiting time

The median waiting time was 25 days (mean: 25 days; range: 1–83 days) in the study group and 32 days (mean: 43 days; range: 3–294 days) for the patients at BWHC East. There was a significant difference in waiting time between the groups (p=0.017), with the shortest waiting time seen in the study group (Figure 3).

Figure 3

Discussion

The main finding in this study was the significantly reduced ulcer healing time for patients with hard-to-heal ulcers diagnosed by video consultation (59 days) compared with patients diagnosed by in-person assessment (82 days). We also found that the waiting time was significantly reduced for patients diagnosed by video consultation (25 days) compared with patients diagnosed by in-person consultation (32 days). This study focused on ulcer healing time, as earlier research has shown that reduced ulcer healing time results in improved quality of life, less pain, lower treatment costs, and less time spent on transportation[9, 18].

In the study group, the ulcer duration before diagnosis was 124 days and healing time was 59 days, while the corresponding figures in the control group were 84 days and 82 days respectively. One explanation for this could be that the patients in the study group lived in remote and mostly rural areas, and could not easily reach the health care centre for assessment

of the ulcer. The video consultation made it possible to reach these patients who might have been undiagnosed and without adequate treatment for a long time. Nevertheless, a reduced ulcer healing time was found in the study group, despite the longer ulcer duration, which could demonstrate the importance of a short waiting time.

In clinical practice in Sweden, the main technique for measuring ulcer size is multiplication of length by width, while in specialized clinics such as BWHC, staff use digital planimetry to measure ulcer size. The use of these different measurement techniques is one limitation of this study, but earlier researchers[21] have noted that the two methods have a high degree of agreement with each other for ulcers with an area of up to approximately 10 cm^2. In this study, most patients (71%) had an ulcer area smaller than 10 cm^2, and we found no significant difference in ulcer size in the proportion of smaller ulcers between the study group and the control group. We therefore consider that the use of the two different techniques for measuring ulcer size could be justifiable in this setting, although it remains a weakness. The remaining 29% of the ulcers were larger than 10 cm^2, but even for these larger ulcers we found no significant difference in ulcer size between the study group and the control group.

The health care system has a strong economic incentive to reduce patients' waiting time. In the industrialized world, costs for wound management consume about 2-4% of the annual expenditure on health care, and these costs will rise in the future because of longer life expectancy and a larger proportion of patients with diabetes[8]. A recent study[14] found that staff costs accounted for 87% of the total costs for wound management. Reduced waiting and healing times[22, 23] are strongly related to reduced costs. The present study cannot show whether a one-week reduction in waiting time could lead to reduced costs, and so further

studies are needed to evaluate the cost-effectiveness implications. We did not analyse the number of nurse visits before and after the video consultation, but there were no changes in the clinical routines and so we can assume that the frequencies of dressing changes were not altered. The doctor's video consultation took place together with the assigned nurse during a regular dressing change, which means no additional costs in nurse time.

Previous studies have shown that telemedicine using digital images provides rapid diagnosis and ulcer care due to reduced waiting time[15, 24]. We found that this is also true for real-time video consultation, which has not previously been studied thoroughly. Video consultation in this setting seems to be an effective tool to shorten waiting time. One perspective might be the more efficient use of the treatment room. As the doctor does not need any facilities other than a tablet and internet access to carry out the video consultation, the treatment room is freed up for other patients to undergo dressing changes at the same time, thus increasing the number of patients diagnosed and treated per day. The lack of requirement for specialist equipment also means that the doctor is independent of any specific health care centre, which may lead to increased doctor availability.

The healing rate in the study group was 82%, compared with 52% in the control group. The figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks[25] and 83% in 30 weeks[26]. The lower healing rate in the registry (i.e. in the control group) could be explained by a possible delay in follow-up data being added to the registry. The difficulty of obtaining follow-up data in a timely fashion is a well-known phenomenon for most Swedish quality registries, even though follow-up registration is mandatory and reminders are sent to

the registering units. Another limitation of register-based studies is that there is no assurance, other than trust, that a lack of healing date in the registry means that the ulcer has not healed.

Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers who are unable to attend clinical visits due to other medical conditions, pain, disability, or reduced mobility[1, 9, 10], as well as being an alternative for patients who are abroad. Our results indicate that video consultation can effectively transmit sufficient ulcer data to allow a remote specialist in wound care to establish diagnosis and an ideal treatment strategy. This is in line with an earlier study[27] of diabetic foot ulcers, which showed no prolonged healing time when comparing telemedical assessment with in-person clinic visits. Concordance of the telemedicine consultation with in-person assessment was also found when a three-dimensional camera was used in a study of diabetic foot ulcers[17]. Video consultation provides a useful communication tool, allowing the specialist wound team to support and educate the assigned nurses in primary care and community care in an easy and secure manner. This could be compared with an earlier study[28] which showed that telemedicine could effectively transmit sufficient wound data to allow a remote specialist in wound care to provide support to local health professionals working in nursing homes. Telemedicine has also been shown to be a useful communication tool in a home care setting[29]. The modern technique of video communication through iPad or smartphone is easy to use, and is now widely available in both rural and urban societies.

RUT covers wound management in primary care, community care, private care, and in-patient hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up, meaning that the dataset is large and reliable. One challenge for GPs and nurses in primary

care in Sweden is to provide adequate diagnosis and treatment to each patient with a hard-to-heal ulcer in this unselected patient group. RUT was developed in order to deal with this issue, and hence includes hard-to-heal ulcers of any aetiology even when there are different healing trajectories. An earlier study found that departments which registered their patients in RUT reported reduced ulcer healing times after the introduction of the registry[7]. Patients not registered in RUT thus probably have a longer ulcer healing time. If the results from our study were to be compared with unregistered patients, the difference in healing time would be even more marked, making our findings somewhat understated.

The GP in charge of the BWHC (HW) is the first author of this study, which could be considered a bias and a possible explanation for the lower dropout frequency in the study group. However, it could be considered a strength that all patients diagnosed through video consultation were assessed by the same GP following standardized clinical routines for ulcer assessment. The lack of blinded outcome assessment is one limitation, but a register-based study gives the opportunity to analyse large study populations, which is hard to accomplish with blinded outcome studies. Another limitation is the exclusion of patients with dementia in the study group, which was done as recommended by the Ethical Review Board. We cannot exclude the possibility that there were systematic differences between the study group and the control group concerning patients with dementia and organization of the clinics involved. There is a need for future studies which focus on patient and staff perceptions of the new technology, specific patient groups including patients with dementia, the patient's quality of life, and cost savings for the health care system. Further well-designed randomized controlled studies are necessary to understand how best to deploy telemedicine services in ulcer treatment.

In Sweden, RUT stands for a structured wound management and a way to document the wound healing process. Video consultation is one complementary communication tool, which together with RUT allows an easy ulcer assessment, especially for patients who are unable to attend clinical visits due to severe medical conditions, pain, disability, or reduced mobility. Video consultation in parallel with the clinical practice in RUT seems to lead to a more efficient use of resources when reducing healing time and waiting time for this neglected patient group.

Conclusion

The findings from this study illustrate the possible impact of video consultation with a doctor for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and waiting time. Using video consultation as a complement to in-person assessment has the potential to improve ulcer diagnosis, treatment, and healing.

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Data sharing statement: No additional data available.

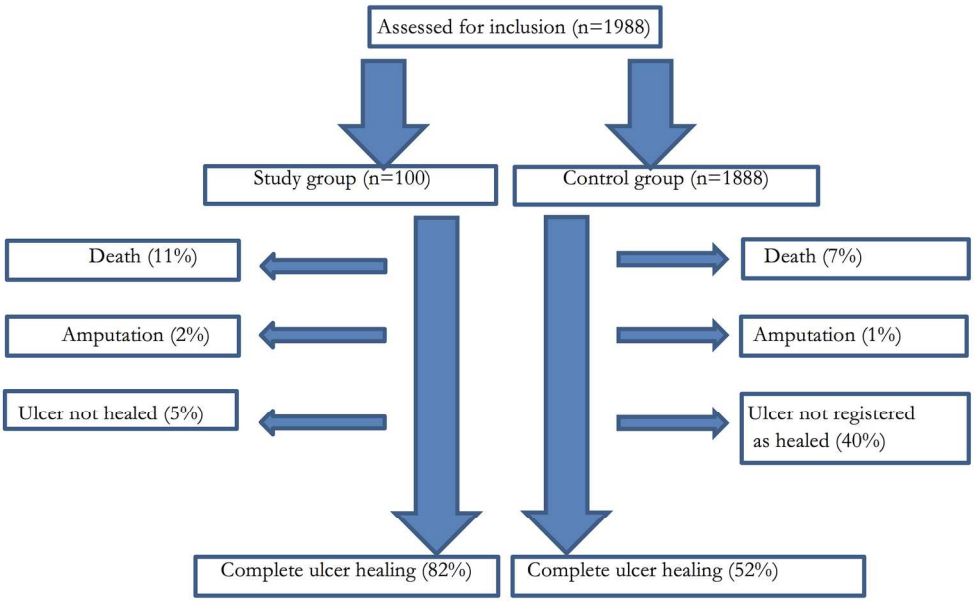

Figure 1 Flow of participants through the trial.

173x110mm (300 x 300 DPI)

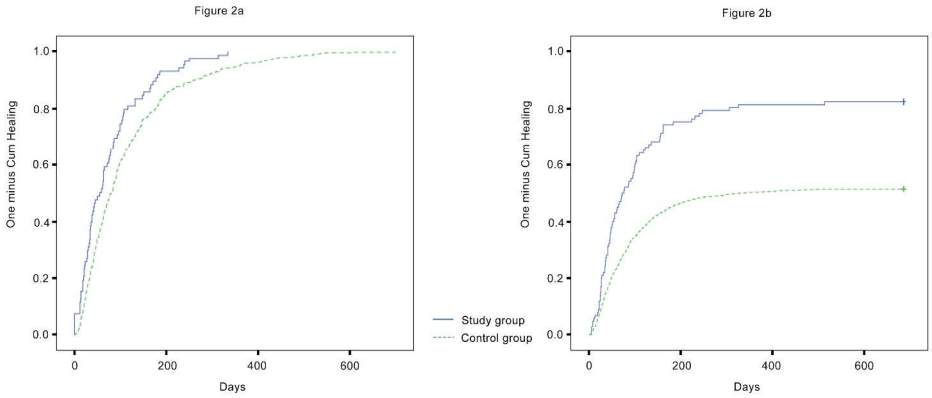

Figure 2a (to the left) illustrates ulcer healing time for the study group compared with the control group, censored for unhealed ulcers, deaths, and amputations. **Figure 2b** (to the right) illustrates ulcer healing time for the study group compared with the control group, uncensored for unhealed ulcers, deaths and amputations. Both figures adjusted for age, gender, diabetes, ulcer size and ulcer duration.

335x149mm (300 x 300 DPI)

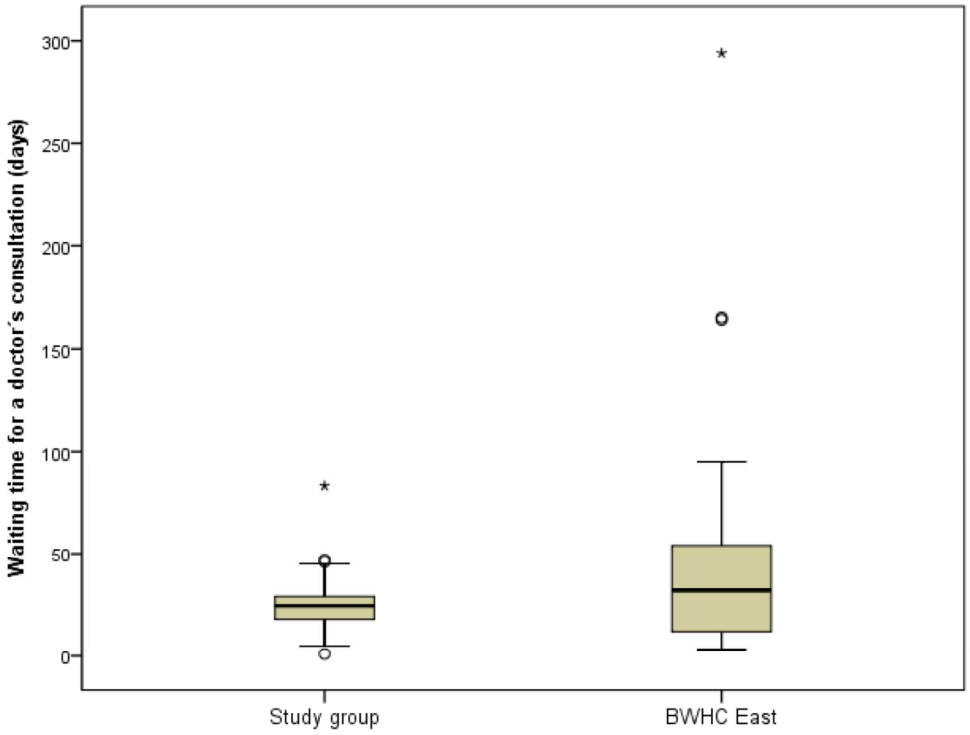

Figure 3 Waiting time for a doctor´s consultation for patients in the study group compared with patients at BWHC East.

250x188mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *case-control studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1, 2, 3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2, 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-8
Participants	6	*(*a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	7-9
		(*b*) For matched studies, give matching criteria and the number of controls per case	Not relevant
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	17
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		© Explain how missing data were addressed	12 Flow chart – no missing data
		(*d*) If applicable, explain how matching of cases and controls was addressed	Not relevant
		(*e*) Describe any sensitivity analyses	Not relevant
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12 Flow chart
		(b) Give reasons for non-participation at each stage	7-8 Consecutively included in the study group = no missing data, see Flow chart page 12; Data from RUT shows healed ulcers why there were no missing data relevant for this study
		(c) Consider use of a flow diagram	12
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11-12
		(b) Indicate number of participants with missing data for each variable of interest	No missing data in the study group
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	12-13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11-13
		(*b*) Report category boundaries when continuous variables were categorized	11-13
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Comparing video consultation with in-person assessment for Swedish patients with hard-to-heal ulcers: registry-based studies of healing time and of waiting time.

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Keywords:	eHealth, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Leg Ulcer, Registries, Wound Healing

Title

Comparing video consultation with in-person assessment for Swedish patients with hard-to-heal ulcers: registry-based studies of healing time and of waiting time.

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Abstract

Objectives: To investigate differences in ulcer healing time and waiting time between video consultation and in-person assessment for patients with hard-to-heal ulcers.

Setting: Patients treated at Blekinge Wound Healing Centre, a primary care centre covering the whole of Blekinge county (150 000 inhabitants), were compared with patients registered and treated according to the Registry for Ulcer Treatment (RUT), a Swedish national web-based quality registry.

Participants: In the study for analysing ulcer healing time, the study group consisted of 100 patients diagnosed through video consultation between October 2014 and September 2016. The control group for analysing healing time consisted of 1888 patients diagnosed through in-person assessment during the same period. In the study for analysing waiting time the same study group (n=100) was compared with 100 patients diagnosed through in-person assessment.

Primary and secondary outcome measures: Differences in ulcer healing time were analysed using the log-rank test. Differences in waiting time were analysed using the Mann-Whitney U-test.

Results: Median healing time was 59 days (95% CI: 40–78) in the study group and 82 days (95% CI: 75–89) in the control group (p<0.001). Median waiting time was 25 days (range: 1–83 days) in the study group and 32 days (range: 3–294 days) for patients diagnosed through in-person assessment (p=0.017). There were no significant differences between the study group and the control group regarding age, gender, or ulcer size.

Conclusions: Healing time and waiting time were significantly shorter for patients diagnosed through video consultation compared with those diagnosed through in-person assessment.

Strengths and limitations of this study

- The use of a large, nationally representative sample of patients with hard-to-heal ulcers gives increased generalizability.
- A well-known technical system was used for video communication.
- All patients diagnosed through video consultation were assessed by the same GP, following standardized clinical routines for ulcer assessment.
- The study group was consecutively included and rather limited in size (n=100).
- The difficulty of obtaining follow-up data in a timely fashion from national quality registries could have influenced our results on healing time.

Introduction

A hard-to-heal (or chronic) ulcer is defined as a break in the skin which has not healed within 4–6 weeks[1, 2, 3, 4]. This definition is independent of the wound type and aetiology[5]. Examples of hard-to-heal ulcers are venous, arterial, or venous-arterial leg ulcers; diabetic foot ulcers; pressure ulcers; burns[6]; and ulcers due to trauma, rheumatoid arthritis, and malignancy[3].

Patients with these ulcers have long been considered neglected, as treatment is often given without diagnosis, thus prolonging ulcer healing time[7]. The majority of these patients are elderly and suffer from other conditions such as diabetes and heart and lung diseases[1, 8]. In addition to these comorbidities, these patients may experience extreme pain[9, 10]. Treatment is carried out by different caregivers within different medical specialties, and so a multidisciplinary team of professionals is often necessary to establish the ulcer aetiology and provide the proper diagnosis[11].

In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care[7, 12]. Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000 inhabitants). It is divided into two health care centres within the same clinical establishment, BWHC West and BWHC East, which are comparably organized in terms of patient population and staff, and with equal resource allocation. Both centres have the same expenditure of time for doctors' consultations and nurses' dressing changes, capacity for patient assessment and treatment, and facilities in terms of treatment rooms, dressing materials, and computer services.

At BWHC, patients are treated according to a structured wound management based on a Swedish national quality registry, the Registry of Ulcer Treatment (RUT) [12]. The clinical routines provided by BWHC are the same as those provided by all the other units which register their patients in RUT, and so data from these other units are comparable with data from BWHC.

The Swedish Registry of Ulcer Treatment

RUT is a web-based tool for clinical assessment of hard-to-heal ulcers, treatment strategies, and continuity of care. Solid clinical research data based on RUT has shown improved quality of life as well as reduction of healing time, treatment costs, and antibiotic treatment[7, 13, 14]. There were more than 7000 registrations in RUT in 2016, giving a coverage rate of approximately 25% of all patients with hard-to-heal ulcers in Sweden.

Patients are registered by a nurse or physician on two occasions. The first registration includes variables for assessment of ulcer diagnosis and treatment strategies, while the second includes data on ulcer healing or negative clinical events such as amputation or death. Each patient with a non-healing ulcer remains in the registry until the follow-up is completed.

Telemedicine for wound management

Telemedicine is the use of information technology and electronic communication to allow health care professionals to evaluate, diagnose, and treat patients at a distance. It typically includes various forms of video consultation or digital transmission of medical imaging and other clinical data.

Transmission of digital photographs has been used within ulcer care in Denmark since 2005, resulting in the reduction of waiting time, ulcer healing time, and transportation, the latter of which can often be uncomfortable or painful for the patient[15]. Another example is a telemedicine wound care model, which has produced reductions in both hospital admissions and patient transportations[16]. The use of three-dimensional images has shown high concordance with in-person consultation for assessment and measurement of wounds[17].

Video communication is widely used within different medical specialties today, though thorough documentation and evaluation is insufficient[18]. However, there is a lack of use of this technology for ulcer care, even though its focus on the visual is considered ideal for wound management[19]. Video communication could be a useful tool, especially in primary care, where there is a need for national guidelines[8] as well as dedicated doctors and nurses for wound management.

The aim of this study was to compare video consultation with in-person assessment for patients with hard-to-heal ulcers, in terms of healing time and waiting time.

Methods

Study population and variables

The first study was an analysis of healing time for patients diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment based on data from RUT (control group) (Table 1).

The second study was a supplementary analysis of the waiting time for a doctor's consultation for patients diagnosed through video consultation at BWHC West (study group) compared with patients diagnosed through in-person assessment at a comparable clinic (BWHC East) (Table 1). The reason this supplementary analysis was needed is that waiting time is not recorded in RUT.

Our study included ulcers of any aetiology, severity, size, and duration. It is possible to register ulcers in RUT from the day they occur (day 0) if patients or staff believe that there will be a prolonged total healing time. The number of patients in the study group was chosen according to the expected number of new undiagnosed patients seeking treatment at BWHC West and BWHC East, respectively, over two years.

Every patient in the study group (n=100) gave their written consent. Every patient in the control group (n=1888) gave their oral consent consistent with the principles of Swedish national quality registries.

Table 1 Study population and setting

	Healing time study		**Waiting time study**	
Participants	Study group n=100	Control group n=1888	Study group n=100	Patients at BWHC East n=100
Assessment	Video consultation	In-person assessment	Video consultation	In-person assessment
Setting	Patients at BWHC West	Patients from RUT	Patients at BWHC West	Patients at BWHC East
Inclusion	Consecutively included	All patients registered in RUT during the study period	Consecutively included	Consecutively included
Inclusion criteria	Age >18; women and men; ulcers of any aetiology, severity, size, and duration			
Exclusion	Age < 18	Age <18	Age <18	Age <18

criteria	Patients with dementia	*	Patients with dementia	*
Study period	1 October 2014 – 30 September 2016			
Consent	Written consent mandatory	Oral consent according to Swedish registries	Written consent mandatory	Oral consent according to Swedish registries

* Patients in the control group (the registry) were included regardless of dementia status, since dementia is not recorded in the registry.

The healing time study

Study group

The patients were initially assessed during a nurse visit, with measurements taken according to RUT[12]. Ulcer size was measured by a planimeter. During this visit, the patient received an iPad programmed with Skype for the upcoming video consultation between the general practitioner at BWHC and the patient accompanied by the assigned nurse. All iPads had mobile internet access to avoid any need to use the patients' home Wi-Fi. The iPads had a one-time cost of 325 GBP (439 USD) per unit; the software (Skype) was free, and there was a negligible cost for internet access.

Each video consultation took place in the patient's home or in the primary health care centre. During this consultation, the doctor established the ulcer diagnosis and an appropriate treatment strategy which could be carried out by the assigned nurse under supervision. The patient and the treatment strategy were followed up according to general clinical routines. Documentation of the video consultation was transferred to the patient's medical record.

All patients were included and followed during the study period (1 October 2014 – 30 September 2016). Patients with ulcers that healed had different follow-up times, depending on the date of ulcer healing, which was documented. Patients with ulcers that did not heal were followed to the end of the study period. If amputation or death occurred during the study period, the date of this event was registered and the patient was not followed further. Healing was confirmed clinically by a nurse or a doctor.

Control group

All patients were diagnosed by in-person consultation and registered in RUT**.** The same measurements were used in both the control group and the study group, except for measurement of ulcer size. For patients in the control group, this was done either by a planimeter or as length multiplied by width, according to different clinical routines.

As with the study group, each patient was included and followed during the study period (1 October 2014 – 30 September 2016). Again, patients with ulcers that healed had different follow-up times, depending on the date of ulcer healing, which was registered in RUT. Patients with ulcers that did not heal were followed to the end of the study period. If amputation or death occurred during the study period, the date of this event was registered and the patient was not followed further. Healing was confirmed clinically by a nurse or a doctor at follow-up registration.

The waiting time study

In Sweden, waiting time is considered clinically important as an indicator of cost effective health care. Age, gender, ulcer size, and ulcer duration were not considered to affect the waiting time for a doctor's consultation, and so were not analysed in this study.

Study group

The same study group was used as for the healing time study.

Patients at BWHC East

All patients with hard-to-heal ulcers were diagnosed by in-person assessment at BWHC East. These patients were likewise assessed according to RUT and followed to ulcer healing or to the end of the study period, whichever occurred first.

Variables

Age (years), gender, ulcer size (cm^2), ulcer aetiology, and diabetes (yes or no) were analysed in both the study group and the control group. Ulcer size was measured by planimeter (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) or by length multiplied by width, according to the established routines in different registration units. Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers, pressure ulcers, neuropathic ulcers (diabetic foot ulcers), traumatic ulcers, malignant ulcers, ulcers due to inflammatory vessel diseases such as vasculitis, and other ulcers.

Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of diagnosis by a doctor.

Ulcer healing time (in days) was defined as the interval between the consultation with a doctor and complete ulcer healing. A healed ulcer was defined as an ulcer covered by epithelial regeneration, beneath which there may be scarring and absence of glands or appendages[20].

Waiting time (in days) was defined as the interval between referral and consultation with a doctor at the BWHC.

Data analysis

Statistical analysis was performed using version 24 of IBM SPSS Statistics. Normally distributed variables were expressed as mean values, standard deviations (SD), and ranges, and compared using Student's t-test. Non-normally distributed variables were expressed as median values and ranges, and differences in groups were analysed using the Mann-Whitney U-test. Categorical variables were compared between groups using Pearson's chi-square test. Healing time was analysed with Kaplan-Meier curves. A log-rank test was used for equality of survivor function. A Cox regression analysis was used to explore the effect of age, gender, diabetes, ulcer size, and ulcer duration on ulcer healing time. A p-value of less than 0.05 was considered to indicate statistical significance.

Results

Patient demographics

Basic data on the study group and the control group are presented in Table 2.

The study group had a mean age of 77 years, the median ulcer size was 3.4 cm^2, and the median ulcer duration was 124 days. The control group had a mean age of 75 years, the median ulcer size was 3.8 cm^2, and the median ulcer duration was 84 days. In the study group 13% of the patients were registered as smokers, compared with 14% in the control group.

Table 2. Patient demographics: the healing time study.

	Study group n=100	Control group n=1888	p-value
Age, mean (SD, range) [A]	77 years (13, 37–98)	75 years (14, 23–104)	0.231
Female [B]	54%	56%	0.744
Diabetes [B]	27%	28%	0.798
Ulcer size, median (range) [C]	3.4 cm^2 (0.1-131.6)	3.8 cm^2 (0.01-1196.0)	0.192
Ulcer duration, median (range) [C]	124 days (7-3657)	84 days (0-5839)	**<0.001**
Healing time, median (95% CI) [D]	59 days (40-78)	82 days (75-89)	**<0.001**

[A] Student's t-test

[B] Chi-square test

[C] Mann-Whitney U-test

[D] Log-rank test

There was no significant difference in age, gender, ulcer size, or diabetes between the patients in the study group and the patients in the control group (Table 2).

In both the study group and the control group, 71% (70.8% and 71.3% respectively) of the ulcers were smaller than 10 cm^2 and the remaining 29% (29.2% and 28.7% respectively) were larger than 10 cm^2. The Mann-Whitney U-test showed no significant difference in ulcer size

between the study group and the control group when analysing only the small ulcers (p=0.053) or only the larger ulcers (p=0.132).

There was a significant difference in ulcer duration between the study group and the control group (p<0.001), with the shortest ulcer duration seen in the control group (Table 2).

The aetiology of the ulcers is presented in Table 3. A chi-square test was performed concerning the difference in ulcer aetiology between the groups, but the analysis showed that the groups were too small for a comparison.

Table 3 Ulcer aetiology (%)

	Study group n=100	Control group n=1888
Venous ulcer	37	35
Arterial ulcer	19	8
Venous-arterial ulcer	8	5
Pressure ulcer	16	14
Neuropathic ulcer	6	4
Traumatic ulcer	11	14
Malignant ulcer	1	1
Inflammatory vessel disease	0	1
Other	2	9
Missing	0	9

Healing time

The flowchart in Figure 1 illustrates the outcome for the participants in the healing time study.

Healing rate was 82% (n=82) in the study group and 52% (n=978) in the control group. In the study group, 74% of the patients were followed for <6 months, 8% for 6–12 months, and 18% for >12 months. In the control group, 38% of the patients were followed for <6 months, 8% for 6–12 months, and 54% for >12 months.

Figure 1

After censorship of unhealed ulcers, deaths, and amputations, the median healing time was 59 days (mean: 78 days; 95% CI: 40-78) in the study group and 82 days (mean: 118 days; 95% CI: 75-89) in the control group ($p<0.001$; Table 2). Cox regression analysis showed that there was no significant influence of age, gender, ulcer size, diabetes, or ulcer duration on healing time.

Healing time is illustrated in Figures 2a and 2b using Kaplan-Meier analysis. Figure 2a is unadjusted for age, gender, diabetes, ulcer size, and ulcer duration, while Figure 2b is adjusted for age, gender, diabetes, ulcer size, and ulcer duration. Both figures are censored for unhealed ulcers, deaths, and amputations.

Figure 2a-2b

Waiting time

The median waiting time was 25 days (mean: 25 days; range: 1–83 days) in the study group and 32 days (mean: 43 days; range: 3–294 days) for the patients at BWHC East. There was a

significant difference in waiting time between the groups (p=0.017), with the shortest waiting time seen in the study group (Figure 3).

Figure 3

Discussion

The main finding in this study was the significantly reduced ulcer healing time for patients with hard-to-heal ulcers diagnosed by video consultation (59 days) compared with patients diagnosed by in-person assessment (82 days). We also found that the waiting time was significantly reduced for patients diagnosed by video consultation (25 days) compared with patients diagnosed by in-person consultation (32 days). This study focused on ulcer healing time, as earlier research has shown that reduced ulcer healing time results in improved quality of life, less pain, lower treatment costs, and less time spent on transportation[9, 18].

In the study group, the ulcer duration before diagnosis was 124 days and healing time was 59 days, while the corresponding figures in the control group were 84 days and 82 days respectively. One explanation for this could be that the patients in the study group lived in remote and mostly rural areas, and could not easily reach the health care centre for assessment of the ulcer. The video consultation made it possible to reach these patients who might have been undiagnosed and without adequate treatment for a long time. Nevertheless, a reduced ulcer healing time was found in the study group, despite the longer ulcer duration, which could demonstrate the importance of a short waiting time.

In clinical practice in Sweden, the main technique for measuring ulcer size is multiplication of length by width, while in specialized clinics such as BWHC, staff use digital planimetry to measure ulcer size. The use of these different measurement techniques is one limitation of this study, but earlier researchers[21] have noted that the two methods have a high degree of agreement with each other for ulcers with an area of up to approximately 10 cm^2. In this study, most patients (71%) had an ulcer area smaller than 10 cm^2, and we found no significant difference in ulcer size in the proportion of smaller ulcers between the study group and the control group. We therefore consider that the use of the two different techniques for measuring ulcer size could be justifiable in this setting, although it remains a weakness. The remaining 29% of the ulcers were larger than 10 cm^2, but even for these larger ulcers we found no significant difference in ulcer size between the study group and the control group.

The health care system has a strong economic incentive to reduce patients' waiting time. In the industrialized world, costs for wound management consume about 2-4% of the annual expenditure on health care, and these costs will rise in the future because of longer life expectancy and a larger proportion of patients with diabetes[8]. A recent study[14] found that staff costs accounted for 87% of the total costs for wound management. Reduced waiting and healing times[22, 23] are strongly related to reduced costs. The present study cannot show whether a one-week reduction in waiting time could lead to reduced costs, and so further studies are needed to evaluate the cost-effectiveness implications. We did not analyse the number of nurse visits before and after the video consultation, but there were no changes in the clinical routines and so we can assume that the frequencies of dressing changes were not

altered. The doctor's video consultation took place together with the assigned nurse during a regular dressing change, which means no additional costs in nurse time.

Previous studies have shown that telemedicine using digital images provides rapid diagnosis and ulcer care due to reduced waiting time[15, 24]. We found that this is also true for real-time video consultation, which has not previously been studied thoroughly. Video consultation in this setting seems to be an effective tool to shorten waiting time. One perspective might be the more efficient use of the treatment room. As the doctor does not need any facilities other than a tablet and internet access to carry out the video consultation, the treatment room is freed up for other patients to undergo dressing changes at the same time, thus increasing the number of patients diagnosed and treated per day. The lack of requirement for specialist equipment also means that the doctor is independent of any specific health care centre, which may lead to increased doctor availability.

The healing rate in the study group was 82%, compared with 52% in the control group. The figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks[25] and 83% in 30 weeks[26]. The lower healing rate in the registry (i.e. in the control group) could be explained by a possible delay in follow-up data being added to the registry. The difficulty of obtaining follow-up data in a timely fashion is a well-known phenomenon for most Swedish quality registries, even though follow-up registration is mandatory and reminders are sent to the registering units. Another limitation of register-based studies is that there is no assurance, other than trust, that a lack of healing date in the registry means that the ulcer has not healed.

Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers who are unable to attend clinical visits due to other medical conditions, pain, disability, or reduced mobility[1, 9, 10], as well as being an alternative for patients who are abroad. Our results indicate that video consultation can effectively transmit sufficient ulcer data to allow a remote specialist in wound care to establish diagnosis and an ideal treatment strategy. This is in line with an earlier study[27] of diabetic foot ulcers, which showed no prolonged healing time when comparing telemedical assessment with in-person clinic visits. Concordance of the telemedicine consultation with in-person assessment was also found when a three-dimensional camera was used in a study of diabetic foot ulcers[17]. Video consultation provides a useful communication tool, allowing the specialist wound team to support and educate the assigned nurses in primary care and community care in an easy and secure manner. This could be compared with an earlier study[28] which showed that telemedicine could effectively transmit sufficient wound data to allow a remote specialist in wound care to provide support to local health professionals working in nursing homes. Telemedicine has also been shown to be a useful communication tool in a home care setting[29]. The modern technique of video communication through iPad or smartphone is easy to use, and is now widely available in both rural and urban societies.

RUT covers wound management in primary care, community care, private care, and in-patient hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up, meaning that the dataset is large and reliable. One challenge for GPs and nurses in primary care in Sweden is to provide adequate diagnosis and treatment to each patient with a hard-to-heal ulcer in this unselected patient group. RUT was developed in order to deal with this issue, and hence includes hard-to-heal ulcers of any aetiology even when there are different healing trajectories. An earlier study found that departments which registered their patients in

RUT reported reduced ulcer healing times after the introduction of the registry[7]. Patients not registered in RUT thus probably have a longer ulcer healing time. If the results from our study were to be compared with unregistered patients, the difference in healing time would be even more marked, making our findings somewhat understated.

The GP in charge of the BWHC (HW) is the first author of this study, which could be considered a bias and a possible explanation for the lower dropout frequency in the study group. However, it could be considered a strength that all patients diagnosed through video consultation were assessed by the same GP following standardized clinical routines for ulcer assessment. The lack of blinded outcome assessment is one limitation, but a register-based study gives the opportunity to analyse large study populations, which is hard to accomplish with blinded outcome studies. Another limitation is the exclusion of patients with dementia in the study group, which was done as recommended by the Ethical Review Board. We cannot exclude the possibility that there were systematic differences between the study group and the control group concerning patients with dementia and organization of the clinics involved. There is a need for future studies which focus on patient and staff perceptions of the new technology, specific patient groups including patients with dementia, the patient's quality of life, and cost savings for the health care system. Further well-designed randomized controlled studies are necessary to understand how best to deploy telemedicine services in ulcer treatment.

The use of a large, representative sample of patients with hard-to-heal ulcers means that the results of the study are generalizable, but the organization of health care systems in different countries may have an impact. Video consultation in this setting can be applied worldwide

within all kinds of health care systems, and offers an opportunity for improvement in ulcer treatment.

In Sweden, RUT stands for a structured wound management and a way to document the wound healing process. Video consultation is one complementary communication tool, which together with RUT allows an easy ulcer assessment, especially for patients who are unable to attend clinical visits due to severe medical conditions, pain, disability, or reduced mobility. Video consultation in parallel with the clinical practice in RUT seems to lead to a more efficient use of resources when reducing healing time and waiting time for this neglected patient group.

Conclusion

The findings from this study illustrate the possible impact of video consultation with a doctor for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and waiting time. Using video consultation as a complement to in-person assessment has the potential to improve ulcer diagnosis, treatment, and healing.

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Contributors: Hanna Wickström led the research project and played the main role in the research design and initial manuscript. Rut Öien contributed to the research design and provided knowledge of RUT. Ulf Jakobsson contributed to the data analysis and interpretation of results. Patrik Midlöv, Cecilia Fagerström, and Peter Anderberg contributed to the research design. All authors reviewed and revised the manuscript.

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Competing interests: None

Ethics approval: The study was approved by the Regional Ethical Review Board of Lund, Sweden (ref: 2014/228).

Data sharing statement: No additional data available.

Figure legends:

Link text: Figure 1

Legend: Flow of participants through the trial.

Link text: Figures 2a-2b

Legend: Figure 2a (on the left) illustrates ulcer healing time for the study group compared with the control group, unadjusted for age, gender, diabetes, ulcer size, and ulcer duration. Figure 2b (on the right) illustrates ulcer healing time for the study group compared with the control group, adjusted for age, gender, diabetes, ulcer size, and ulcer duration. Both figures are censored for unhealed ulcers, deaths, and amputations.

Link text: Figure 3

Legend: Waiting time for a doctor´s consultation for patients in the study group compared with patients at BWHC East.

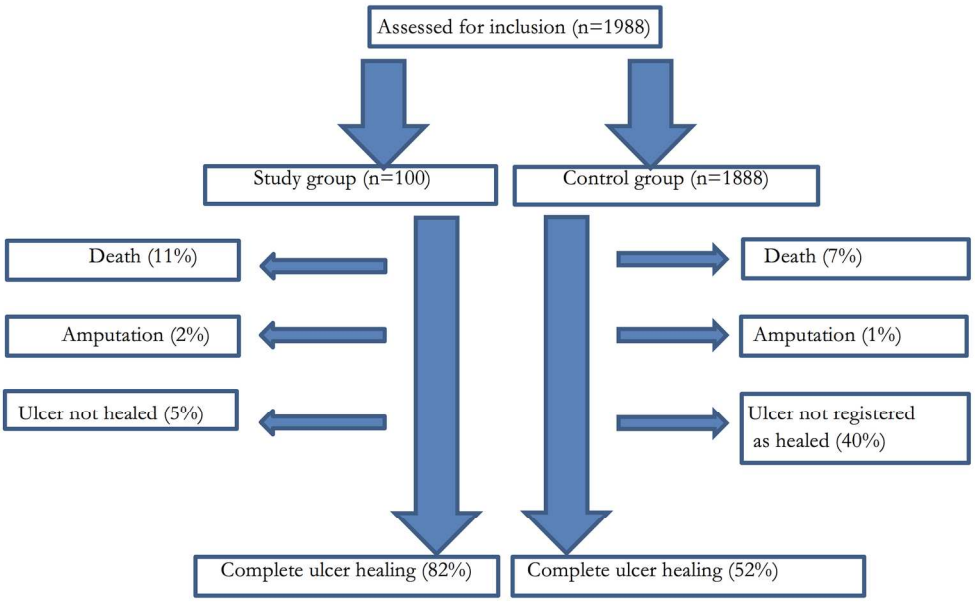

Figure 1 Flow of participants through the trial.

173x110mm (300 x 300 DPI)

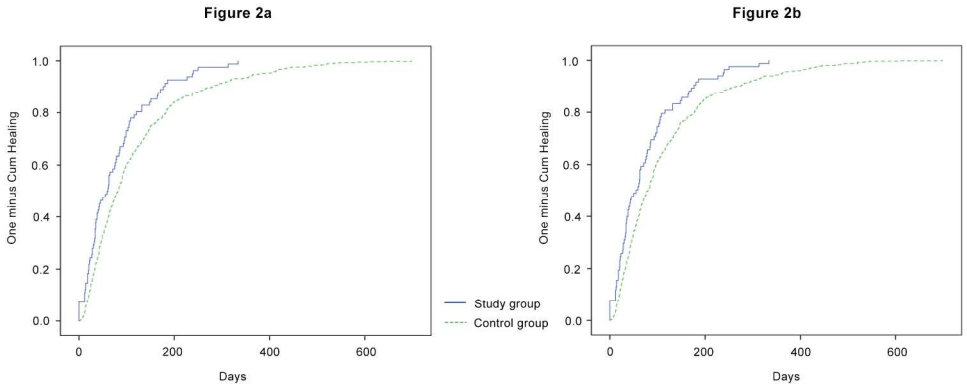

Figure 2a (on the left) illustrates ulcer healing time for the study group compared with the control group, unadjusted for age, gender, diabetes, ulcer size, and ulcer duration. **Figure 2b** (on the right) illustrates ulcer healing time for the study group compared with the control group, adjusted for age, gender, diabetes, ulcer size, and ulcer duration. Both figures are censored for unhealed ulcers, deaths, and amputations.

215x89mm (300 x 300 DPI)

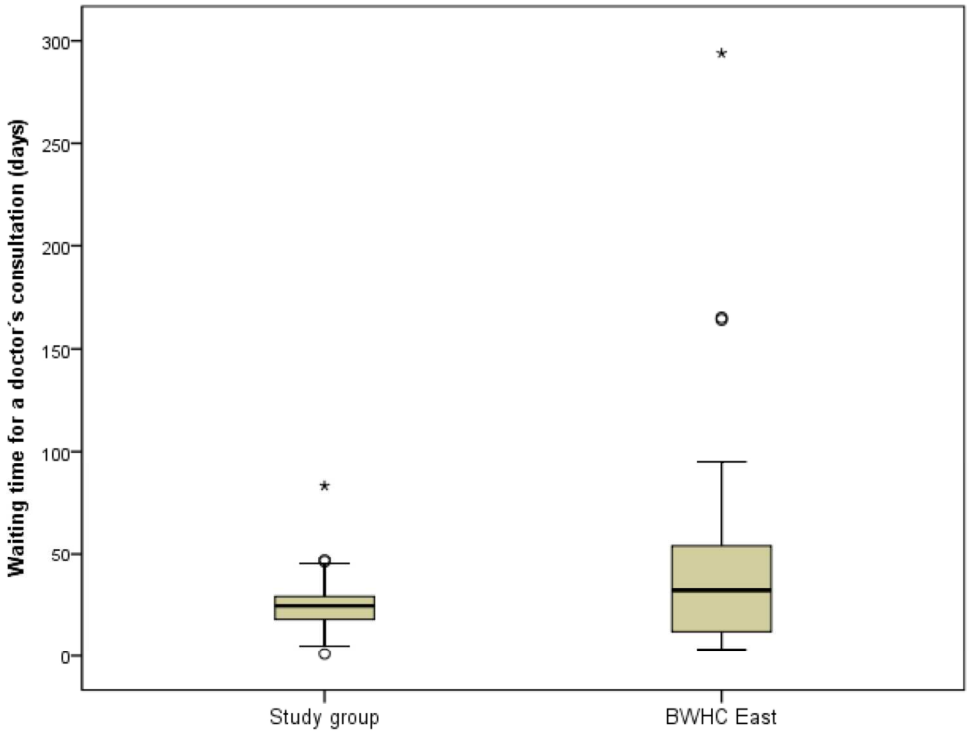

Figure 3 Waiting time for a doctor´s consultation for patients in the study group compared with patients at BWHC East.

250x188mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *case-control studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1, 2, 3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2, 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-8
Participants	6	*(*a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	7-9
		(*b*) For matched studies, give matching criteria and the number of controls per case	Not relevant
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	17
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		© Explain how missing data were addressed	12 Flow chart – no missing data
		(*d*) If applicable, explain how matching of cases and controls was addressed	Not relevant
		(*e*) Describe any sensitivity analyses	Not relevant
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12 Flow chart
		(b) Give reasons for non-participation at each stage	7-8 Consecutively included in the study group = no missing data, see Flow chart page 12; Data from RUT shows healed ulcers why there were no missing data relevant for this study
		(c) Consider use of a flow diagram	12
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11-12
		(b) Indicate number of participants with missing data for each variable of interest	No missing data in the study group
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	12-13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11-13
		(*b*) Report category boundaries when continuous variables were categorized	11-13
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.