

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-017623
Article Type:	Research
Date Submitted by the Author:	06-May-2017
Complete List of Authors:	Wickstrom, Hanna; Lund University, Clinical Sciences Malmo; Landstinget Blekinge, Blekinge Wound Healing Centre Öien, Rut; Blekinge Wound Healing Center, Blekinge Centre of Competence Fagerstrom, Cecilia; Blekinge Center of Competence, Department of Health and Caring Sciences Anderberg, Peter; Blekinge Institute of Technology Jakobsson, Ulf; Lund University, Clinical Sciences Malmo Midlöv, Patrik ; Lund University, Clinical Sciences Malmo
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Health services research, Communication
Keywords:	eHealth, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Leg Ulcer, Registries, Wound Healing

SCHOLARONE™
Manuscripts

only

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.

Authors

Hanna Wickström, Rut F Öien, Cecilia Fagerstrom, Peter Anderberg, Ulf Jakobsson, Patrik Midlöv

Corresponding author

Wickstrom, Hanna Linnea

Lund University

Clinical Sciences Malmo

Jan Waldenstromsg 35

Malmo, SE 205 02

Sweden

hanna.wickstrom@med.lu.se

+46702728294

+46454733479

Co-authors:

Öien Rut Frank
Blekinge Wound Healing
Center
Blekinge Centre of
Competence
Karlskrona
Sweden

Anderberg Peter
Blekinge Institute of
Technology
Karlskrona
Sweden

Midlöv Patrik John
Lund University
Clinical Sciences Malmo
Malmo
Sweden

Fagerstrom Cecilia
Blekinge Center
of Competence
Department of Health and
Caring Sciences
Karlskrona
Sweden

Jakobsson Ulf
Lund University
Clinical Sciences Malmo
Malmo
Sweden

Keywords:

eHealth; Telemedicine; Leg Ulcer; Registries; Wound Healing

Word count:

3246

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.

1
2
3 **Results:** Median healing time was 60 days in the study group and 84 days in the control group
4
5 (p=0.001). Median waiting time was 25 days in the study group and 32 days for patients
6
7 diagnosed through in-person assessment (p=0.017). There were no significant differences
8
9 between the study group and the control group regarding gender, age, or ulcer size.
10

11 **Conclusions:** Healing time and waiting time were significantly shorter for patients diagnosed
12
13 through video consultation compared with those diagnosed through in-person assessment.
14
15

16 17 18 19 20 **Strengths and limitations of this study**

- 21 • The use of a large, nationally representative sample of patients with hard-to-heal
22
23 ulcers gives increased generalizability.
- 24 • A well-known technical system was used for video communication.
- 25 • All patients diagnosed through video consultation were assessed by the same GP,
26
27 following standardized clinical routines for ulcer assessment.
- 28 • The study group was consecutively included and rather limited in size (n=100).
29
30
31
32
33
34
35
36
37
38
39
40

41 **Introduction**

42
43
44 Patients with hard-to heal ulcers have long been considered a neglected patient group in
45
46 which treatment is often given without diagnosis, thus prolonging ulcer healing time¹. The
47
48 estimated prevalence of leg ulcers in the adult population is 1–2%². Leg ulcers constitute the
49
50 largest part of all hard-to-heal ulcers. The majority of these patients are elderly and suffer
51
52 from other conditions such as diabetes and heart and lung diseases^{3,4}. In addition to these
53
54 comorbidities, these patients may experience extreme pain^{5,6}. Treatment is carried out by
55
56
57
58
59
60

1
2
3 different caregivers within different medical specialties, and so a multidisciplinary team of
4
5 professionals is often necessary to establish the ulcer aetiology and provide the proper
6
7 diagnosis⁷.
8
9

10
11
12
13 In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care^{1, 8}.

14
15 Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful
16
17 of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-
18
19 centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000
20
21 inhabitants). BWHC is divided into two health care centres, BWHC West and BWHC East,
22
23 which are comparably organized in terms of staff and patients, and which work within the
24
25 same clinical establishment.
26
27

28
29
30
31 At BWHC, patients are treated according to a structured wound management based on the
32
33 Swedish national quality registry for ulcer diagnosis, treatment, and documentation (RUT)⁸.
34
35 Patients often stress the importance of continuity of care⁹, which is also crucial for healing¹⁰.
36
37 This is guaranteed by an assigned nurse who is responsible for following the patient until
38
39 ulcer healing. The team at BWHC collaborates with community and district nurses and staff
40
41 from different medical specialties within the county.
42
43
44
45
46
47

48 **The Swedish Registry of Ulcer Treatment**

49
50 RUT is a web-based tool for clinical assessment of hard-to-heal ulcers, treatment strategies,
51
52 and continuity of care. Solid clinical research data based on RUT has shown improved quality
53
54 of life as well as reduction of healing time, treatment costs, and antibiotic treatment^{1, 11, 12}.
55
56
57
58
59

1
2
3 There were more than 7000 registrations in RUT in 2016, meaning that the register covers
4 more than one fifth of the patients with hard-to-heal ulcers in Sweden.
5
6
7

8
9 Patients are registered by a nurse or physician on two occasions. The first registration includes
10 variables for assessment of ulcer diagnosis and treatment strategies, while the second includes
11 data on ulcer healing or negative clinical events such as amputation or death. Each patient
12 with a non-healing ulcer remains in the registry until the follow-up is completed. Since 2012,
13 it has been mandatory to register each patient treated at BWHC, and this is also the case for
14 some of the larger dermatological departments and well known wound healing centres in
15 Sweden.
16
17
18
19
20
21
22
23
24

25 26 27 **Telemedicine for wound management**

28
29 Telemedicine is the use of information technology and electronic communication to allow
30 health care professionals to evaluate, diagnose, and treat patients at a distance. It typically
31 includes various forms of video consultation or digital transmission of medical imaging and
32 other clinical data.
33
34
35
36
37
38
39

40 Transmission of digital photographs has been used within ulcer care in Denmark since 2005,
41 resulting in the reduction of waiting time, ulcer healing time, and transportation, the latter of
42 which can often be uncomfortable or painful for the patient¹³. Another example is the
43 telemedicine wound care model from the Home Hospital Wound Healing Network in
44 Languedoc-Roussillon, France. This model has produced reductions in both hospital
45 admissions and patient transportations¹⁴. The use of three-dimensional images has shown high
46 concordance with in-person consultation for assessment and measurement of wounds¹⁵.
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 Video communication is widely used within different medical specialties today, though
4 thorough documentation and evaluation is insufficient¹⁶. However, there is a lack of use of
5 this technology for ulcer care, even though its focus on the visual is considered ideal for
6 wound management¹⁷. Video communication could be a useful tool, especially in primary
7 care, where there is a need for national guidelines⁴ as well as dedicated doctors and nurses for
8 wound management.
9
10
11
12
13
14
15
16
17

18 In Sweden, like in many other countries worldwide, a challenging obstacle for health care is
19 the presence of different systems of electronic medical records. This makes communication
20 between caregivers more difficult. Video communication might be a feasible way to surmount
21 this obstacle, and in combination with the national database, RUT, seems to be a good future
22 solution for wound management.
23
24
25
26
27
28
29
30
31

32 The aim of this study was to compare video consultation with in-person assessment for
33 patients with hard-to-heal ulcers, in terms of healing time and waiting time.
34
35
36
37
38
39
40

41 **Methods**

42 **Study population and variables**

43
44 The healing time study was an analysis of healing time for patients with hard-to-heal ulcers
45 diagnosed through video consultation at BWHC West (study group) compared with patients
46 diagnosed through in-person assessment based on data from RUT (control group) (Table 1).
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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 weeks³. 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 RUT⁸. 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 (cm²), 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

1
2 multiplied by width, according to the established routines in different registration units.

3
4
5 Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers,
6
7 pressure ulcers, neuropathic ulcers, traumatic ulcers, malignant ulcers, ulcers due to
8
9 inflammatory vessel diseases such as vasculitis, and other ulcers.
10

11
12
13
14
15 Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of
16
17 diagnosis by a doctor.
18

19
20
21 Ulcer healing time (in days) was defined as the interval between the consultation with a
22
23 doctor and complete ulcer healing.
24

25
26
27
28 Waiting time (in days) was defined as the interval between referral and consultation with a
29
30 doctor at the BWHC.
31

32 33 34 35 36 **Data analysis**

37
38 Statistical analysis was performed using version 24 of IBM SPSS Statistics. Continuous
39
40 variables were expressed as mean values, ranges, and standard deviations (SD), and compared
41
42 using the two-sample Student t-test. Categorical variables were compared between groups
43
44 using Pearson's chi-squared test. Differences in groups were analysed using the two-sample
45
46 Wilcoxon rank-sum test (Mann-Whitney U-test). Healing time was assessed with Kaplan-
47
48 Meier analysis. A log-rank test was used for equality of survivor function. A p-value of less
49
50 than 0.05 was considered to indicate statistical significance.
51
52
53
54
55
56
57
58
59
60

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 cm² 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 cm² 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.

1
2
3 The median healing time was 60 days (mean: 78 days; range: 0–334 days) in the study group
4 and 84 days (mean: 134 days; range: 0–2540 days) in the control group ($p=0.001$) (Table 2).

5
6
7 The median healing time and healing rate are illustrated in Figure 2, using Kaplan-Meier
8
9 analysis.

10
11
12
13
14 **Figure 2** Healing rate and ulcer healing time for the study group compared with the control group.

15 16 17 18 **Waiting time**

19
20 The median waiting time was 25 days (mean: 24.8 days; range: 1–83 days) in the study group
21 and 32 days (mean: 43.4 days; range: 3–294 days) for the patients at BWHC East. There was
22 a significant difference in waiting time between the groups ($p=0.017$), with the shortest
23
24
25
26
27 waiting time seen in the study group (Figure 3).

28
29
30
31
32
33 **Figure 3** Waiting time for a doctor's consultation for patients in the study group compared with patients at
34 BWHC East.

35 36 37 38 39 40 **Discussion**

41
42
43 The main finding in this study was the significantly reduced ulcer healing time for patients
44 with hard-to-heal ulcers diagnosed by video consultation (60 days) compared with patients
45 diagnosed by in-person assessment (84 days). We also found that the waiting time was
46
47
48 significantly reduced for patients diagnosed by video consultation (25 days) compared with
49
50
51 patients diagnosed by in-person consultation (32 days).

1
2
3 Reduced ulcer healing time results in improved quality of life, less pain, lower treatment
4 costs, and less time spent on transportation^{5, 16}. The two major determinants of ulcer healing
5 time are ulcer duration and ulcer size^{18, 19}. Patients with shorter ulcer duration (1-6 months)
6 and smaller ulcer size (<10 cm²) have a shorter healing time than patients with longer ulcer
7 duration (>6 months) and larger ulcer size (≥10 cm²)^{18, 19}.
8
9
10
11
12
13
14
15
16

17 In the study group, the ulcer duration before diagnosis was 124 days and healing time was 60
18 days, while the corresponding figures in the control group were 84 days and 84 days
19 respectively. One explanation for this could be that the patients in the study group lived in
20 remote and mostly rural areas, and could not easily reach the health care centre for assessment
21 of the ulcer. The video consultation made it possible to reach these patients who might have
22 been undiagnosed and without adequate treatment for a long time. Nevertheless, a reduced
23 ulcer healing time was found in the study group, despite the longer ulcer duration, which
24 could demonstrate the importance of a short waiting time.
25
26
27
28
29
30
31
32
33
34
35
36
37

38 We found no significant difference in ulcer size between the study group and the control
39 group, even when different techniques for area measurements were used. Planimetry is more
40 accurate than length multiplied by width, which overestimates the real ulcer area²⁰.
41 Smartphone-based methods for wound measurements are considered accurate and precise²¹.
42
43
44
45
46
47
48
49

50 The health care system has a strong economic incentive to reduce patients' waiting time. In
51 the industrialized world, costs for wound management consume about 2-4% of the annual
52 expenditure on health care, and these costs will rise in the future because of longer life
53
54
55
56
57
58
59
60

1
2
3 expectancy and a larger proportion of patients with diabetes⁴. A recent study¹² found that staff
4 costs accounted for 87% of the total costs for wound management. Reduced waiting and
5 healing times^{10, 22} are strongly related to reduced costs.
6
7
8
9

10
11
12 Previous studies have shown that telemedicine using digital images provides rapid diagnosis
13 and ulcer care due to reduced waiting time^{13, 23}. We found that this is also true for real-time
14 video consultation, which has not previously been studied thoroughly. Video consultation
15 seems to be an effective tool to shorten waiting time. One perspective is the more efficient use
16 of the operating room. As the doctor does not need any facilities other than a tablet and
17 internet access to carry out the video consultation, the operating room is freed up for other
18 patients to undergo dressing changes at the same time, thus increasing the number of patients
19 diagnosed and treated per day. The lack of requirement for specialist equipment also means
20 that the doctor is independent of any specific health care centre.
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35

36 The healing rate in the study group was 82%, compared with 52% in the control group. The
37 figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks¹⁸ and 83% in
38 30 weeks²⁴. The lower healing rate in the control group could partly be explained by a
39 possible delay in follow-up in the registry.
40
41
42
43
44
45
46
47

48 Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers
49 who are unable to attend clinical visits due to other medical conditions, pain, disability, or
50 reduced mobility^{3, 5, 6}, as well as being an alternative for patients who are abroad.
51
52
53
54
55
56
57
58
59
60

1
2
3 Our results indicate that video consultation can effectively transmit sufficient ulcer data to
4 allow a remote specialist in wound care to establish diagnosis and an ideal treatment strategy.
5
6 This is in line with an earlier study²⁵ of diabetic foot ulcers, which showed no prolonged
7
8 healing time when comparing telemedical assessment with in-person clinic visits.
9
10
11 Concordance of the telemedicine consultation with in-person assessment was also found when
12
13 a three-dimensional camera was used in a study of diabetic foot ulcers¹⁵. Video consultation
14
15 provides a useful communication tool, allowing the specialist wound team to support and
16
17 educate the assigned nurses in primary care and community care in an easy and secure
18
19 manner. This could be compared with an earlier study²⁶ which showed that telemedicine
20
21 could effectively transmit sufficient wound data to allow a remote specialist in wound care to
22
23 provide support to local health professionals working in nursing homes. Telemedicine has
24
25 also been shown to be a useful communication tool in a home care setting²⁷. The modern
26
27 technique of video communication through iPad or smartphone is easy to use and is now
28
29 widely available in both rural and urban societies.
30
31
32
33
34
35
36

37 RUT covers wound management in primary care, community care, private care, and in-patient
38
39 hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up,
40
41 meaning that the dataset is large and reliable. An earlier study found that departments which
42
43 registered their patients in RUT reported reduced ulcer healing times after the introduction of
44
45 the registry¹. Patients not registered in RUT thus probably have a longer ulcer healing time. If
46
47 the results from our study were to be compared with unregistered patients, the difference in
48
49 healing time would be even more marked, making our findings somewhat understated.
50
51
52
53
54
55
56
57
58
59
60

1
2
3 The GP in charge of the BWHC is the first author of this study (HWI), which could be
4 considered a bias, but on the other hand it could be considered a strength that all patients
5 diagnosed through video consultation were assessed by the same GP following standardized
6 clinical routines for ulcer assessment. One limitation of our study is its lack of the perspective
7 of patients and staff. There is a need for future studies which focus on patient and staff
8 perceptions of the new technology, the patient's quality of life, and cost savings for the health
9 care system. Further well-designed randomized controlled studies are necessary to understand
10 how best to deploy telemedicine services in ulcer treatment.
11
12
13
14
15
16
17
18
19
20
21
22

23
24 Our study seems to provide sufficient evidence that video consultation is as feasible for
25 wound management as traditional in-person assessment for evaluating healing and waiting
26 time, and so a more widespread use can be recommended in clinical practice.
27
28
29
30
31
32
33

34 **Conclusion**

35
36
37 The findings from this study illustrate the immediate impact of video consultation with a
38 doctor for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and
39 waiting time. The results demonstrate the potential for improved ulcer diagnosis, treatment,
40 and healing by using video consultation as a complement to in-person assessment.
41
42
43
44
45
46
47
48
49

50 **Acknowledgements**

51
52 The authors wish to thank registered nurse Charlotta Prah and assistant nurse Anna Davnert
53 at Blekinge Wound Healing Centre.
54
55
56
57
58
59
60

References

1. Oien RF, Forssell H. Ulcer healing time and antibiotic treatment before and after the introduction of the Registry of Ulcer Treatment: an improvement project in a national quality registry in Sweden. *BMJ Open* 2013;**3**:e003091.
2. Alavi A, Sibbald RG, Phillips TJ, *et al.* What's new: Management of venous leg ulcers: Approach to venous leg ulcers. *J Am Acad Dermatol* 2016;**74**:627-40.
3. Nelzén O, Bergqvist D, Lindhagen A, *et al.* Chronic leg ulcers: an underestimated problem in primary health care among elderly patients. *J Epidemiol Community Health* 1991;**45**:184-7.
4. Swedish Council on Health Technology Assessment (SBU). Chronic Ulcers in the Elderly – Prevention and Treatment. Stockholm; 2014 Aug. SBU Yellow Report No. 226.
5. Akesson N, Oien RF, Forssell H, *et al.* Ulcer pain in patients with venous leg ulcers related to antibiotic treatment and compression therapy. *Br J Community Nurs* 2014;**19** (Suppl 9):S6-S13.
6. Hellstrom A, Nilsson C, Nilsson A, *et al.* Leg ulcers in older people: a national study addressing variation in diagnosis, pain and sleep disturbance. *BMC Geriatrics* 2016;**16**:25.
7. Mooij MC, Huisman LC. Chronic leg ulcer: does a patient always get a correct diagnosis and adequate treatment? *Phlebology* 2016;**31** (Suppl 1):68-73.
8. Registry of Ulcer Treatment (RUT). www.rut-europe.eu.
9. Törnvall E, Wilhelmsson S. Quality of nursing care from the perspective of patients with leg ulcers. *J Wound Care* 2010;**19**:388-95.

- 1
2
3 10. Petursson P. GPs' reasons for "non-pharmacological" prescribing of antibiotics: a
4
5 phenomenological study. *Scand J Prim Health Care* 2005;**23**:120-5
6
7
- 8 11. Oien RF, Ragnarson Tennvall G. Accurate diagnosis and effective treatment of leg ulcers
9
10 reduce prevalence, care time and costs. *J Wound Care* 2006;**15**:259-62.
11
12
- 13 12. Oien RF, Forssell H, Ragnarson Tennvall G. Cost consequences due to reduced ulcer
14
15 healing times – analyses based on the Swedish Registry of Ulcer Treatment. *Int Wound J*
16
17 2015;**13**:957-62.
18
19
- 20 13. Jelnes R. Telemedicine in the management of patients with chronic wounds. *J Wound*
21
22 *Care* 2011;**20**:187-90.
23
24
- 25 14. Sood A, Granick MS, Trial C, *et al.* The role of telemedicine in wound care: a review and
26
27 analysis of a database of 5,795 patients from a mobile wound-healing center in Languedoc-
28
29 Roussillon, France. *Plast Reconstr Surg* 2016;**138 (Suppl 3)**:248S-256S.
30
31
- 32 15. Bowling FL, King L, Paterson JA, *et al.* Remote assessment of diabetic foot ulcers using a
33
34 novel wound imaging system. *Wound Repair Regen* 2011;**19**:25-30.
35
36
- 37 16. Nordheim LV, Haavind MT, Iversen MM. Effect of telemedicine follow-up care of leg
38
39 and foot ulcers: a systematic review. *BMC Health Serv Res* 2014;**14**:565. doi:
40
41 10.1186/s12913-014-0565-6.
42
43
- 44 17. Chittoria RK. Telemedicine for wound management. *Indian J Plast Surg* 2012;**45**:412-7.
45
46
- 47 18. Moffatt CJ, Franks PJ, Oldroyd M, *et al.* Community clinics for leg ulcers and impact on
48
49 healing. *BMJ* 1992;**305**:1389-92.
50
51
- 52 19. Skene AI, Smith JM, Doré CJ, *et al.* Venous leg ulcers: a prognostic index to predict time
53
54 to healing. *BMJ* 1992;**305**:1119-21.
55
56
57
58
59
60

- 1
2
3 20. Oien RF, Håkansson A, Hansen BU, *et al.* Measuring the size of ulcers by planimetry: a
4 useful method in the clinical setting. *J Wound Care* 2002;**11**:165-8.
5
6
7
8 21. Foltynski P, Ladyzynski P, Wojcicki JM. A new smartphone-based method for wound
9 area measurement. *Artif Organs* 2014;**38**:346-52.
10
11
12
13 22. Vowden K, Vowden P, Posnett J. The resource costs of wound management in Bradford
14 and airedale primary care trust in the UK. *J Wound Care* 2009;**18**:93-4.
15
16
17
18 23. Chanussot-Deprez C, Contreras-Ruiz J. Telemedicine in wound care. *Int Wound J*
19
20 2008;**5**:651-4.
21
22
23 24. Rybak Z, Franks PJ, Krasowski G, *et al.* Strategy for the treatment of chronic leg wounds:
24 a new model in Poland. *Int Angiol* 2012;**31**:550-6.
25
26
27
28 25. Rasmussen BS, Froekjaer J, Bjerregaard MR, *et al.* A randomized controlled trial
29 comparing telemedical and standard outpatient monitoring of diabetic foot ulcers. *Diabetes*
30
31 *Care* 2015;**38**:1723-9.
32
33
34
35 26. Vowden K, Vowden P. A pilot study on the potential of remote support to enhance wound
36 care for nursing-home patients. *J Wound Care* 2013;**22**:481-8.
37
38
39
40 27. Terry M, Halstead LS, O'Hare P, *et al.* Feasibility study of home care wound management
41 using telemedicine. *Adv Skin Wound Care* 2009;**22**:358-64.
42
43
44
45
46
47

48 **Contributors:** Hanna Wickström led the research project and played the main role in the
49 research design and initial manuscript. Rut Öien contributed to the research design and
50 provided knowledge of RUT. Ulf Jakobsson contributed to the data analysis and interpretation
51
52
53
54
55
56
57
58
59
60

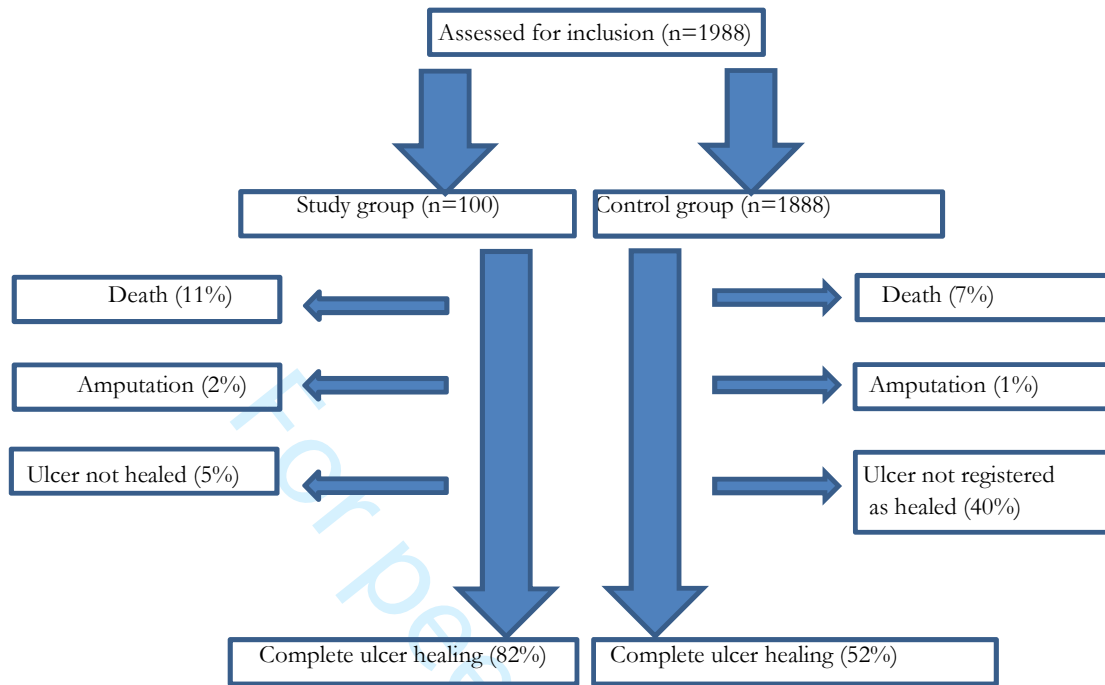
1
2
3 of results. Patrik Midlöv, Cecilia Fagerström, and Peter Anderberg contributed to the research
4
5 design. All authors reviewed and revised the manuscript.
6
7
8
9

10
11 **Funding:** The study was partly funded by the Scientific Committee of Blekinge County
12
13 Council's Research and Development Foundation as part of a PhD studentship.
14
15

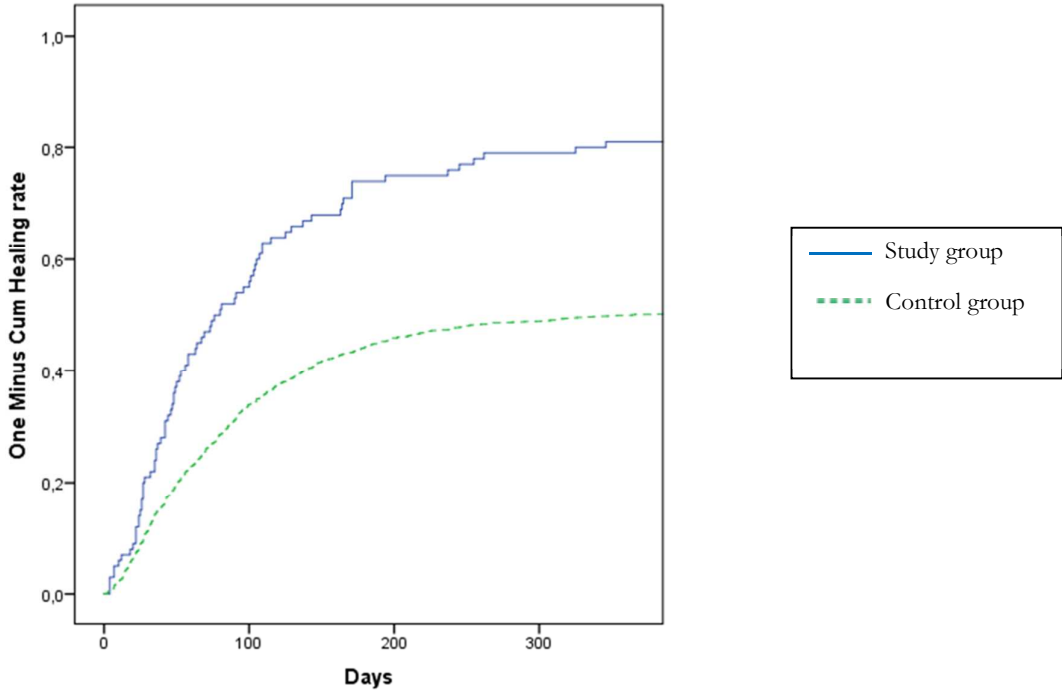
16
17
18
19 **Competing interests:** None
20
21
22

23
24
25 **Ethics approval:** The study was approved by the Regional Ethical Review Board of Lund,
26
27 Sweden (ref: 2014/228).
28
29
30

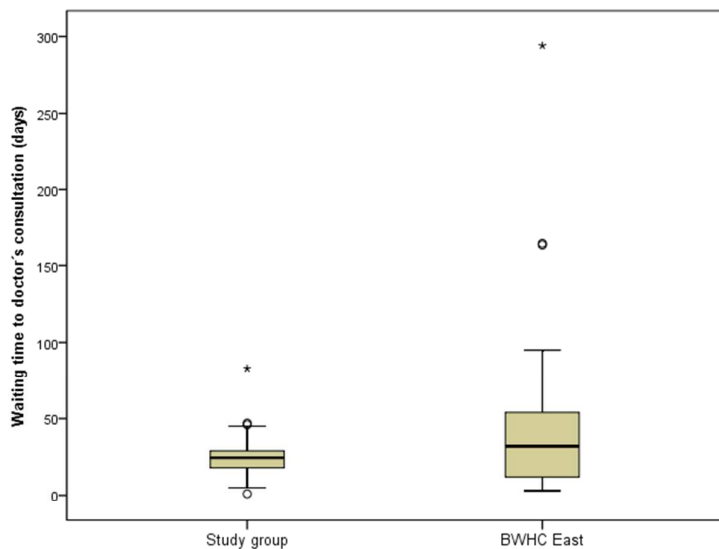
31
32
33 **Data sharing statement:** No additional data available.
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



For review only



Peer review only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-017623.R1
Article Type:	Research
Date Submitted by the Author:	31-Aug-2017
Complete List of Authors:	Wickstrom, Hanna; Lund University, Clinical Sciences Malmo; Landstinget Blekinge, Blekinge Wound Healing Centre Öien, Rut; Blekinge Wound Healing Center, Blekinge Centre of Competence Fagerstrom, Cecilia; Blekinge Center of Competence, Department of Health and Caring Sciences Anderberg, Peter; Blekinge Institute of Technology Jakobsson, Ulf; Lund University, Clinical Sciences Malmo Midlöv, Patrik ; Lund University, Clinical Sciences Malmo
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Health services research, Communication
Keywords:	eHealth, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Leg Ulcer, Registries, Wound Healing

SCHOLARONE™
Manuscripts

only

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.

Authors

Hanna Wickström, Rut F Öien, Cecilia Fagerström, Peter Anderberg, Ulf Jakobsson, Patrik Midlöv

Corresponding author

Wickström, Hanna Linnea

Lund University

Clinical Sciences Malmo

Jan Waldenstromsg 35

Malmo, SE 205 02

Sweden

hanna.wickstrom@med.lu.se

+46702728294

+46454733479

Co-authors:

Öien Rut Frank
Blekinge Wound Healing
Center
Blekinge Centre of
Competence
Karlskrona
Sweden

Anderberg Peter
Blekinge Institute of
Technology
Karlskrona
Sweden

Midlöv Patrik John
Lund University
Clinical Sciences Malmo
Malmo
Sweden

Fagerström Cecilia
Blekinge Center
of Competence
Department of Health and
Caring Sciences
Karlskrona
Sweden

Jakobsson Ulf
Lund University
Clinical Sciences Malmo
Malmo
Sweden

Keywords:

eHealth; Telemedicine; Leg Ulcer; Registries; Wound Healing

Word count:

3682

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.

1
2
3 **Primary and secondary outcome measures:** Differences in ulcer healing time were
4 analysed using the log-rank test. Differences in waiting time were analysed using Mann-
5 Whitney U-test.
6
7

8
9
10 **Results:** Median healing time was 59 days in the study group and 82 days in the control group
11 (p<0.001). Median waiting time was 25 days in the study group and 32 days for patients
12 diagnosed through in-person assessment (p=0.017). There were no significant differences
13 between the study group and the control group regarding gender, age, or ulcer size.
14
15
16

17
18
19 **Conclusions:** Healing time and waiting time were significantly shorter for patients diagnosed
20 through video consultation compared with those diagnosed through in-person assessment.
21
22
23

24 25 26 27 **Strengths and limitations of this study**

- 28 • The use of a large, nationally representative sample of patients with hard-to-heal
29 ulcers gives increased generalizability.
 - 30 • A well-known technical system was used for video communication.
 - 31 • All patients diagnosed through video consultation were assessed by the same GP,
32 following standardized clinical routines for ulcer assessment.
 - 33 • The study group was consecutively included and rather limited in size (n=100).
- 34
35
36
37
38
39
40
41
42
43
44
45
46
47

48 **Introduction**

49
50
51 Hard-to-heal ulcers are defined as ulcers which have not healed within 6 weeks¹. Patients with
52 these ulcers have long been considered neglected, as treatment is often given without
53 diagnosis, thus prolonging ulcer healing time². The majority of these patients are elderly and
54
55
56
57

1
2
3 suffer from other conditions such as diabetes and heart and lung diseases^{1,3}. In addition to
4 these comorbidities, these patients may experience extreme pain^{4,5}. Treatment is carried out
5 by different caregivers within different medical specialties, and so a multidisciplinary team of
6 professionals is often necessary to establish the ulcer aetiology and provide the proper
7 diagnosis⁶.
8
9
10
11
12
13
14
15
16

17 In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care^{2,7}.
18 Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful
19 of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-
20 centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000
21 inhabitants). It is divided into two health care centres within the same clinical establishment,
22 BWHC West and BWHC East, which are comparably organized in terms of patient
23 population and staff. Both centres have the same expenditure of time for doctors'
24 consultations and nurses' dressing changes, capacity for patient assessment and treatment, and
25 facilities in terms of operating rooms, dressing materials, and computer services.
26
27
28
29
30
31
32
33
34
35
36
37
38
39

40 At BWHC, patients are treated according to a structured wound management based on a
41 Swedish national quality registry, the Registry of Ulcer Treatment (RUT)⁷. The clinical
42 routines provided by BWHC are the same as those provided by all the other units which
43 register their patients in RUT, and so data from these other units are comparable with data
44 from BWHC.
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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 patient¹⁰. Another example is a telemedicine wound care model, which has produced reductions in both hospital admissions and patient transportations¹¹. The use of three-dimensional images has shown high concordance with in-person consultation for assessment and measurement of wounds¹².

1
2
3 Video communication is widely used within different medical specialties today, though
4 thorough documentation and evaluation is insufficient¹³. However, there is a lack of use of
5 this technology for ulcer care, even though its focus on the visual is considered ideal for
6 wound management¹⁴. Video communication could be a useful tool, especially in primary
7 care, where there is a need for national guidelines³ as well as dedicated doctors and nurses for
8 wound management.
9
10
11
12
13
14
15
16
17

18 The aim of this study was to compare video consultation with in-person assessment for
19 patients with hard-to-heal ulcers, in terms of healing time and waiting time.
20
21
22
23
24
25

26 **Methods**

27 **Study population and variables**

28
29 The first study was an analysis of healing time for patients diagnosed through video
30 consultation at BWHC West (study group) compared with patients diagnosed through in-
31 person assessment based on data from RUT (control group) (Table 1).
32
33
34
35
36
37
38
39
40

41 The second study was a supplementary analysis of the waiting time for a doctor's consultation
42 for patients diagnosed through video consultation at BWHC West (study group) compared
43 with patients diagnosed through in-person assessment at a comparable clinic (BWHC East)
44 (Table 1). The reason this supplementary analysis was needed is that waiting time is not
45 recorded in RUT.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 Hard-to-heal ulcers include different diagnostic groups such as venous, arterial and venous-
4 arterial leg ulcers; neuropathic ulcers; pressure ulcers; traumatic ulcers; malignant ulcers;
5 ulcers due to inflammatory vessel disease; and some ulcers of rare aetiology. This study
6 included ulcers of any aetiology, severity, size, and duration. It is possible to register ulcers in
7 RUT from the day they occur (day 0) if patients or staff believe that there will be a prolonged
8 total healing time.
9
10
11
12
13
14
15
16
17
18

19 The number of patients in the study group was chosen according to the expected number of
20 new undiagnosed patients seeking treatment at BWHC West and BWHC East, respectively,
21 over two years.
22
23
24
25
26
27
28

29 Every patient in the study group (n=100) gave their written consent. Every patient in the
30 control group (n=1888) gave their oral consent consistent with the principles of Swedish
31 national quality registries.
32
33
34
35
36
37
38

39 **Table 1** Study population and setting
40

	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 RUT⁸. 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.

1
2
3 Each video consultation took place in the patient's home or in the primary health care centre.
4
5 During this consultation, the doctor established the ulcer diagnosis and an appropriate
6
7 treatment strategy which could be carried out by the assigned nurse under supervision. The
8
9 patient and the treatment strategy were followed up according to general clinical routines.
10
11 Documentation of the video consultation was transferred to the patient's medical record.
12
13
14
15
16

17 Each patient was followed to ulcer healing or to the end of the study period, whichever
18
19 occurred first. If amputation or death occurred during the study period, the date of this event
20
21 was registered and the patient was not followed further.
22
23
24
25
26

27 Control group

28
29
30 All patients were diagnosed by in-person consultation and registered in RUT. The same
31
32 measurements were used in both the control group and the study group, except for
33
34 measurement of ulcer size. For patients in the control group, this was done either by a
35
36 planimeter or as length multiplied by width, according to different clinical routines.
37
38
39
40

41 As with the study group, each patient was followed to ulcer healing or the end of the study
42
43 period, and if amputation or death occurred, the date was registered and the patient was not
44
45 followed further.
46
47
48
49

50 **The waiting time study**

1
2
3 In Sweden, waiting time is considered clinically important as an indicator of cost effective
4 health care. Age, gender, ulcer size, and ulcer duration were not considered to affect the
5 waiting time for a doctor's consultation, and so were not analysed in this study.
6
7
8
9

10 11 12 13 Study group

14
15 The same study group was used as for the healing time study.
16
17
18
19

20 Patients at BWHC East

21
22 All patients with hard-to-heal ulcers were diagnosed by in-person assessment at BWHC East.
23 These patients were likewise assessed according to RUT and followed to ulcer healing or to
24 the end of the study period, whichever occurred first.
25
26
27
28
29
30
31

32 Variables

33
34 Age (years), gender, ulcer size (cm²), ulcer aetiology, and diabetes (yes or no) were analysed
35 in both the study group and the control group. Ulcer size was measured by planimeter
36 (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) or by length
37 multiplied by width, according to the established routines in different registration units.
38
39
40
41
42

43 Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers,
44 pressure ulcers, neuropathic ulcers, traumatic ulcers, malignant ulcers, ulcers due to
45 inflammatory vessel diseases such as vasculitis, and other ulcers.
46
47
48
49
50
51
52

53 Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of
54 diagnosis by a doctor.
55
56
57
58
59
60

1
2
3
4
5 Ulcer healing time (in days) was defined as the interval between the consultation with a
6
7 doctor and complete ulcer healing.
8
9

10
11 Waiting time (in days) was defined as the interval between referral and consultation with a
12
13 doctor at the BWHC.
14
15

16 17 18 19 **Data analysis**

20
21 Statistical analysis was performed using version 24 of IBM SPSS Statistics. Normally
22
23 distributed variables were expressed as mean values, standard deviations (SD), and ranges,
24
25 and compared using Student's t-test. Not normally distributed variables were expressed as
26
27 median values and ranges, and differences in groups were analysed using Mann-Whitney U-
28
29 test. Categorical variables were compared between groups using Pearson's Chi-square test.
30
31 Healing time was analysed with Kaplan-Meier curve. A log-rank test was used for equality of
32
33 survivor function. A Cox regression analysis was used to explore the effect of age, gender,
34
35 diabetes, ulcer size and ulcer duration on ulcer healing time. A p-value of less than 0.05 was
36
37 considered to indicate statistical significance.
38
39
40
41
42
43

44 **Results**

45 **Patient demographics**

46
47 Basic data on the study group and the control group are presented in Table 2.
48
49
50
51
52

53 The study group had a mean age of 77 years, the median ulcer size was 3.4 cm², and the
54
55 median ulcer duration was 124 days. The control group had a mean age of 75 years, the
56
57
58
59
60

1
2
3 median ulcer size was 3.8 cm², and the median ulcer duration was 84 days. In the study group
4
5 13% of the patients were registered as smokers, compared with 14% in the control group.
6
7
8
9

10 **Table 2.** Patient demographics: the healing time study.

	Study group	Control group	p-value
	n=100	n=1888	
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

28 ^A Student's t-test

29 ^B Chi-square test

30 ^C Mann-Whitney U-test

31 ^D Log-rank test

32
33
34
35
36
37
38 There was no significant difference in gender, age, ulcer size, or diabetes between the patients
39
40 in the study group and the patients in the control group (Table 2).
41
42
43

44 In both the study group and the control group, 71% (70.8% and 71.3% respectively) of the
45
46 ulcers were smaller than 10cm² and the remaining 29% (29.2% and 28.7% respectively) were
47
48 larger than 10 cm². The Mann-Whitney U-test showed no significant difference in ulcer size
49
50 between the study group and the control group when analysing only the small ulcers
51
52 (p=0.053) or only the larger ulcers (p=0.132).
53
54
55
56
57
58
59
60

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.

1
2
3 **Figure 1** Flow of participants through the trial.
4
5
6
7

8 After censorship of unhealed ulcers, deaths, and amputations, the median healing time was 59
9 days (mean: 78 days; 95% CI: 40-78) in the study group and 82 days (mean: 118 days; 95%
10 CI: 75-89) in the control group ($p < 0.001$; Table 2). Cox regression analysis showed that there
11 was no significant influence of gender, age, ulcer size, diabetes or ulcer duration on healing
12 time.
13
14
15
16
17
18
19
20
21
22

23 The healing time and healing rate are illustrated in Figure 2 using Kaplan-Meier analysis,
24 again censored for unhealed ulcers, deaths, and amputations and also adjusted for age, gender,
25 diabetes, ulcer size and ulcer duration.
26
27
28
29
30
31
32

33 **Figure 2** Healing rate and ulcer healing time for the study group compared with the control group. Figure
34 adjusted for age, gender, diabetes, ulcer size and ulcer duration.
35
36
37
38

39 **Waiting time**

40 The median waiting time was 25 days (mean: 25 days; range: 1–83 days) in the study group
41 and 32 days (mean: 43 days; range: 3–294 days) for the patients at BWHC East. There was a
42 significant difference in waiting time between the groups ($p = 0.017$), with the shortest waiting
43 time seen in the study group (Figure 3).
44
45
46
47
48
49
50
51
52

53 **Figure 3** Waiting time for a doctor's consultation for patients in the study group compared with patients at
54 BWHC East.
55
56
57
58
59
60

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 researchers¹⁵ have noted that the two methods have a high degree of

1
2
3 agreement with each other for ulcers with an area of up to approximately 10 cm². In this
4
5 study, most patients (71%) had an ulcer area smaller than 10 cm², and we found no significant
6
7 difference in ulcer size in the proportion of smaller ulcers between the study group and the
8
9 control group. We therefore consider that the use of the two different techniques for
10
11 measuring ulcer size could be justifiable in this setting. The remaining 29% of the ulcers were
12
13 larger than 10 cm², but even for these larger ulcers we found no significant difference in ulcer
14
15 size between the study group and the control group.
16
17
18
19
20

21
22 The health care system has a strong economic incentive to reduce patients' waiting time. In
23
24 the industrialized world, costs for wound management consume about 2-4% of the annual
25
26 expenditure on health care, and these costs will rise in the future because of longer life
27
28 expectancy and a larger proportion of patients with diabetes³. A recent study⁹ found that staff
29
30 costs accounted for 87% of the total costs for wound management. Reduced waiting and
31
32 healing times^{16, 17} are strongly related to reduced costs. We did not analyse the number of
33
34 nurse visits before and after the video consultation, but there were no changes in the clinical
35
36 routines and so we can assume that the frequencies of dressing changes were not altered.
37
38
39
40
41

42
43 Previous studies have shown that telemedicine using digital images provides rapid diagnosis
44
45 and ulcer care due to reduced waiting time^{10, 18}. We found that this is also true for real-time
46
47 video consultation, which has not previously been studied thoroughly. Video consultation
48
49 seems to be an effective tool to shorten waiting time. One perspective is the more efficient use
50
51 of the operating room. As the doctor does not need any facilities other than a tablet and
52
53 internet access to carry out the video consultation, the operating room is freed up for other
54
55 patients to undergo dressing changes at the same time, thus increasing the number of patients
56
57
58
59
60

1
2
3 diagnosed and treated per day. The lack of requirement for specialist equipment also means
4
5 that the doctor is independent of any specific health care centre.
6
7
8
9

10
11 The healing rate in the study group was 82%, compared with 52% in the control group. The
12
13 figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks¹⁹ and 83% in
14
15 30 weeks²⁰. The lower healing rate in the registry (i.e. in the control group) could be
16
17 explained by a possible delay in follow-up data being added to the registry. The difficulty of
18
19 obtaining follow-up data in a timely fashion is a well-known phenomenon for most Swedish
20
21 quality registries.
22
23
24
25
26

27
28 Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers
29
30 who are unable to attend clinical visits due to other medical conditions, pain, disability, or
31
32 reduced mobility^{1, 4, 5}, as well as being an alternative for patients who are abroad. Our results
33
34 indicate that video consultation can effectively transmit sufficient ulcer data to allow a remote
35
36 specialist in wound care to establish diagnosis and an ideal treatment strategy. This is in line
37
38 with an earlier study²¹ of diabetic foot ulcers, which showed no prolonged healing time when
39
40 comparing telemedical assessment with in-person clinic visits. Concordance of the
41
42 telemedicine consultation with in-person assessment was also found when a three-
43
44 dimensional camera was used in a study of diabetic foot ulcers¹². Video consultation provides
45
46 a useful communication tool, allowing the specialist wound team to support and educate the
47
48 assigned nurses in primary care and community care in an easy and secure manner. This could
49
50 be compared with an earlier study²² which showed that telemedicine could effectively
51
52 transmit sufficient wound data to allow a remote specialist in wound care to provide support
53
54 to local health professionals working in nursing homes. Telemedicine has also been shown to
55
56
57
58
59
60

1
2
3 be a useful communication tool in a home care setting²³. The modern technique of video
4 communication through iPad or smartphone is easy to use and is now widely available in both
5
6 rural and urban societies.
7
8
9

10
11
12 RUT covers wound management in primary care, community care, private care, and in-patient
13 hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up,
14 meaning that the dataset is large and reliable. One challenge for GPs and nurses in primary
15 care in Sweden is to provide adequate diagnosis and treatment to each patient with a hard-to-
16 heal ulcer in this unselected patient group. RUT was developed in order to deal with this
17 issue, and hence includes hard-to-heal ulcers of any aetiology even when there are different
18 healing trajectories. An earlier study found that departments which registered their patients in
19 RUT reported reduced ulcer healing times after the introduction of the registry². Patients not
20 registered in RUT thus probably have a longer ulcer healing time. If the results from our study
21 were to be compared with unregistered patients, the difference in healing time would be even
22 more marked, making our findings somewhat understated.
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39

40 The GP in charge of the BWHC is the first author of this study (HWI), which could be
41 considered a bias and a possible explanation for the lower dropout frequency in the study
42 group. However, it could be considered a strength that all patients diagnosed through video
43 consultation were assessed by the same GP following standardized clinical routines for ulcer
44 assessment. One limitation is the lack of blinded outcome assessment, but a register-based
45 study gives the opportunity to analyse large study populations, which is hard to accomplish
46 with blinded outcome studies. Another limitation is the exclusion of patients with dementia in
47 the study group, which was done as recommended by the Ethical Review Board. There is a
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 need for future studies which focus on patient and staff perceptions of the new technology, the
4 patient's quality of life, and cost savings for the health care system. Further well-designed
5
6 randomized controlled studies are necessary to understand how best to deploy telemedicine
7
8 services in ulcer treatment.
9

10
11
12
13
14
15 In Sweden, RUT stands for a structured wound management and a way to document the
16
17 wound healing process. Video consultation is one complementary communication tool, which
18
19 together with RUT allows an easy ulcer assessment, especially for patients who are unable to
20
21 attend clinical visits due to severe medical conditions, pain, disability, or reduced mobility.
22
23 Video consultation in parallel with the clinical practice in RUT seems to lead to a more
24
25 efficient use of resources when reducing healing time and waiting time for this neglected
26
27 patient group.
28
29
30
31
32
33

34 **Conclusion**

35
36
37 The findings from this study illustrate the possible impact of video consultation with a doctor
38
39 for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and
40
41 waiting time. Using video consultation as a complement to in-person assessment has the
42
43 potential to improve ulcer diagnosis, treatment, and healing.
44
45
46
47
48
49

50 **Acknowledgements**

51
52 The authors wish to thank registered nurse Charlotta Prahl and assistant nurse Anna Davnert
53
54 at Blekinge Wound Healing Centre.
55
56
57
58
59
60

References

1. Nelzén O, Bergqvist D, Lindhagen A, et al. Chronic leg ulcers: an underestimated problem in primary health care among elderly patients. *J Epidemiol Community Health* 1991;45:184-7.
2. Oien RF, Forssell H. Ulcer healing time and antibiotic treatment before and after the introduction of the Registry of Ulcer Treatment: an improvement project in a national quality registry in Sweden. *BMJ Open* 2013;3:e003091.
3. Swedish Council on Health Technology Assessment (SBU). Chronic Ulcers in the Elderly – Prevention and Treatment. Stockholm; 2014 Aug. SBU Yellow Report No. 226.
4. Akesson N, Oien RF, Forssell H, et al. Ulcer pain in patients with venous leg ulcers related to antibiotic treatment and compression therapy. *Br J Community Nurs* 2014;19 (Suppl 9):S6-S13.
5. Hellstrom A, Nilsson C, Nilsson A, et al. Leg ulcers in older people: a national study addressing variation in diagnosis, pain and sleep disturbance. *BMC Geriatrics* 2016;16:25.
6. Mooij MC, Huisman LC. Chronic leg ulcer: does a patient always get a correct diagnosis and adequate treatment? *Phlebology* 2016;31 (Suppl 1):68-73.
7. Registry of Ulcer Treatment (RUT). www.rut-europe.eu.
8. Oien RF, Ragnarson Tennvall G. Accurate diagnosis and effective treatment of leg ulcers reduce prevalence, care time and costs. *J Wound Care* 2006;15:259-62.
9. Oien RF, Forssell H, Ragnarson Tennvall G. Cost consequences due to reduced ulcer healing times – analyses based on the Swedish Registry of Ulcer Treatment. *Int Wound J* 2015;13:957-62.

- 1
2
3 10. Jelnes R. Telemedicine in the management of patients with chronic wounds. *J Wound*
4
5 *Care* 2011;20:187-90.
6
- 7
8 11. Sood A, Granick MS, Trial C, et al. The role of telemedicine in wound care: a review and
9
10 analysis of a database of 5,795 patients from a mobile wound-healing center in Languedoc-
11
12 Roussillon, France. *Plast Reconstr Surg* 2016;138 (Suppl 3):248S-256S.
13
- 14
15 12. Bowling FL, King L, Paterson JA, et al. Remote assessment of diabetic foot ulcers using a
16
17 novel wound imaging system. *Wound Repair Regen* 2011;19:25-30.
18
- 19
20 13. Nordheim LV, Haavind MT, Iversen MM. Effect of telemedicine follow-up care of leg
21
22 and foot ulcers: a systematic review. *BMC Health Serv Res* 2014;14:565. doi:
23
24 10.1186/s12913-014-0565-6.
25
- 26
27 14. Chittoria RK. Telemedicine for wound management. *Indian J Plast Surg* 2012;45:412-7.
28
- 29
30 15. Oien RF, Håkansson A, Hansen BU, et al. Measuring the size of ulcers by planimetry: a
31
32 useful method in the clinical setting. *J Wound Care* 2002;11:165-8.
33
- 34
35 16. Petursson P. GPs' reasons for "non-pharmacological" prescribing of antibiotics: a
36
37 phenomenological study. *Scand J Prim Health Care* 2005;23:120-5
38
- 39
40 17. Vowden K, Vowden P, Posnett J. The resource costs of wound management in Bradford
41
42 and airedale primary care trust in the UK. *J Wound Care* 2009;18:93-4.
43
- 44
45 18. Chanussot-Deprez C, Contreras-Ruiz J. Telemedicine in wound care. *Int Wound J*
46
47 2008;5:651-4.
48
- 49
50 19. Moffatt CJ, Franks PJ, Oldroyd M, et al. Community clinics for leg ulcers and impact on
51
52 healing. *BMJ* 1992;305:1389-92.
53
54
55
56
57
58
59
60

1
2
3 20. Rybak Z, Franks PJ, Krasowski G, et al. Strategy for the treatment of chronic leg wounds:
4 a new model in Poland. *Int Angiol* 2012;31:550-6.
5
6

7
8 21. Rasmussen BS, Froekjaer J, Bjerregaard MR, et al. A randomized controlled trial
9 comparing telemedical and standard outpatient monitoring of diabetic foot ulcers. *Diabetes*
10 *Care* 2015;38:1723-9.
11
12

13
14
15 22. Vowden K, Vowden P. A pilot study on the potential of remote support to enhance wound
16 care for nursing-home patients. *J Wound Care* 2013;22:481-8.
17
18

19
20 23. Terry M, Halstead LS, O'Hare P, et al. Feasibility study of home care wound management
21 using telemedicine. *Adv Skin Wound Care* 2009;22:358-64.
22
23
24
25
26
27

28 **Contributors:** Hanna Wickström led the research project and played the main role in the
29 research design and initial manuscript. Rut Öien contributed to the research design and
30 provided knowledge of RUT. Ulf Jakobsson contributed to the data analysis and interpretation
31 of results. Patrik Midlöv, Cecilia Fagerström, and Peter Anderberg contributed to the research
32 design. All authors reviewed and revised the manuscript.
33
34
35
36
37
38
39
40
41
42

43 **Funding:** The study was partly funded by the Scientific Committee of Blekinge County
44 Council's Research and Development Foundation as part of a PhD studentship.
45
46
47
48
49
50

51 **Competing interests:** None
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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.

For peer review only

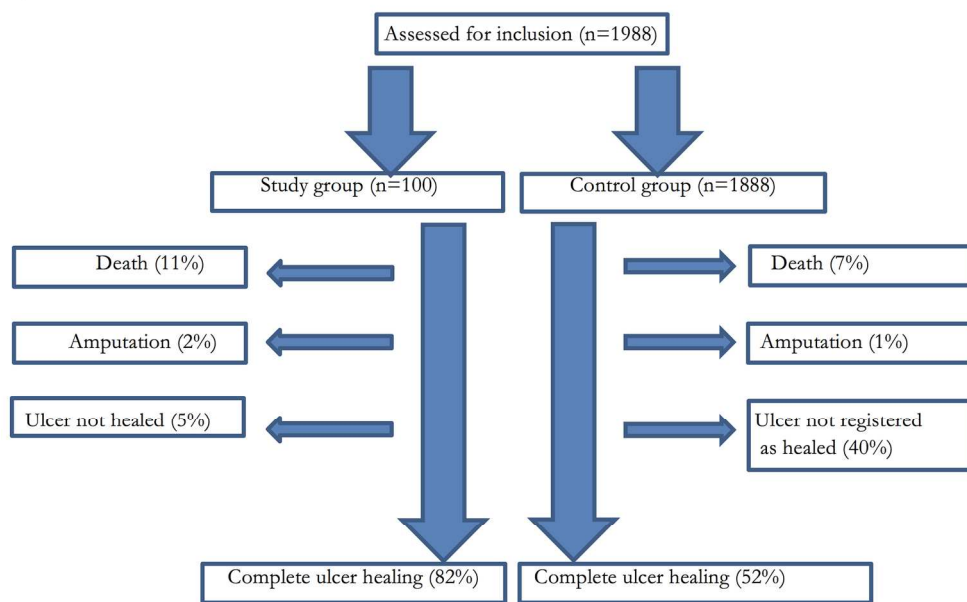


Figure 1 Flow of participants through the trial.

173x110mm (300 x 300 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

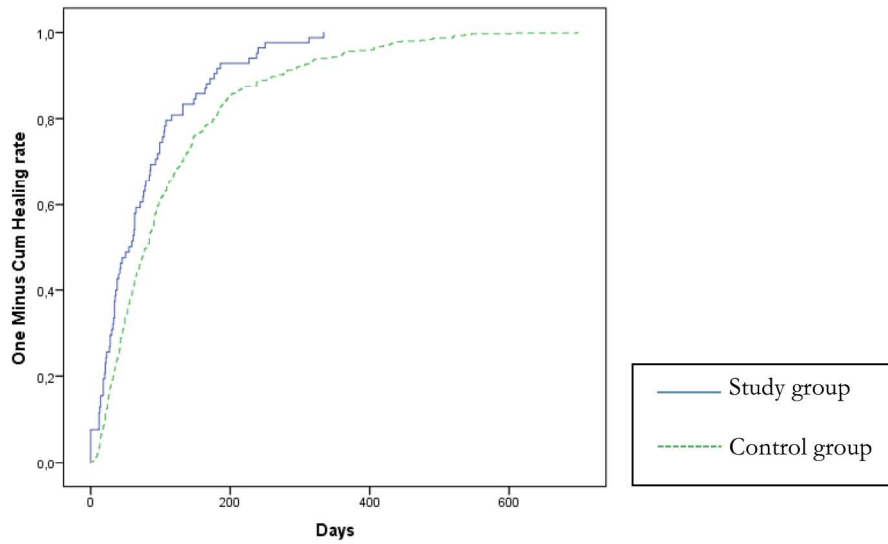


Figure 2 Healing rate and ulcer healing time for the study group compared with the control group. Figure adjusted for age, gender, diabetes, ulcer size and ulcer duration.

222x125mm (300 x 300 DPI)

Review only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

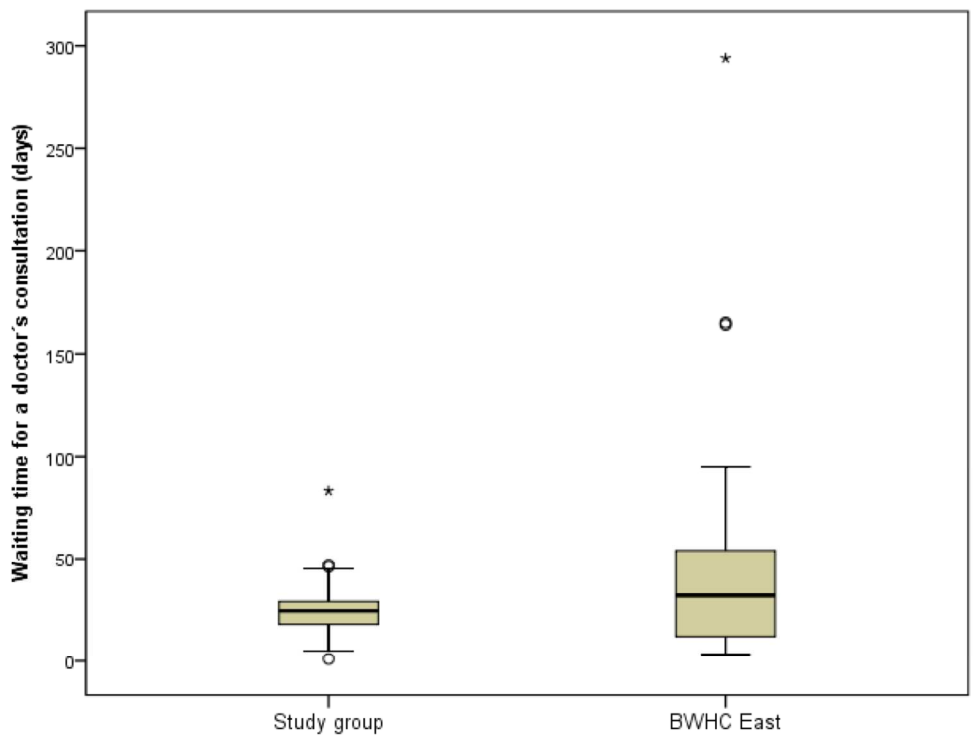


Figure 3 Waiting time for a doctor's consultation for patients in the study group compared with patients at BWHC East.

250x188mm (300 x 300 DPI)

Peer Review Only

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-017623.R2
Article Type:	Research
Date Submitted by the Author:	17-Oct-2017
Complete List of Authors:	Wickstrom, Hanna; Lund University, Center of Primary Health Care Research, Clinical Sciences Malmo; Blekinge Wound Healing Centre Öien, Rut; Blekinge Wound Healing Centre, Blekinge Centre of Competence Fagerstrom, Cecilia; Blekinge Centre of Competence, Department of Health and Caring Sciences; Linnaeus University Anderberg, Peter; Blekinge Institute of Technology, Department of Health Jakobsson, Ulf; Lund University, Center of Primary Health Care Research, Clinical Sciences Malmo Midlöv, Patrik ; Lund University, Center of Primary Health Care Research, Clinical Sciences Malmo
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Health services research, Communication
Keywords:	eHealth, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Leg Ulcer, Registries, Wound Healing

SCHOLARONE™
Manuscripts



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.

Authors

Hanna Wickström, Rut F Öien, Cecilia Fagerström, Peter Anderberg, Ulf Jakobsson, Patrik Midlöv

Corresponding author

Wickström, Hanna Linnea

Lund University

Center of Primary Health Care Research

Clinical Sciences Malmo

Jan Waldenstromsg 35

Malmo, SE 205 02

Sweden

hanna.wickstrom@med.lu.se

+46702728294

+46454733479

Co-authors

Öien Rut Frank
Blekinge Wound Healing
Centre
Blekinge Centre of
Competence
Karlskrona
Sweden

Kalmar
Sweden

Anderberg Peter
Blekinge Institute of
Technology
Department of Health
Karlskrona
Sweden

Fagerström Cecilia
Blekinge Centre of
Competence
Karlskrona
Linnaeus University

Jakobsson Ulf
Lund University

Center of Primary Health
Care Research
Clinical Sciences Malmo
Malmo
Sweden

Midlöv Patrik John
Lund University
Center of Primary Health
Care Research
Clinical Sciences Malmo
Malmo
Sweden

Keywords

eHealth; Telemedicine; Leg Ulcer; Registries; Wound Healing

Word count

3935

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.

1
2
3 **Primary and secondary outcome measures:** Differences in ulcer healing time were
4 analysed using the log-rank test. Differences in waiting time were analysed using the Mann-
5 Whitney U-test.
6
7

8
9
10 **Results:** Median healing time was 59 days (95% CI: 40–78) in the study group and 82 days
11 (95% CI: 75–89) in the control group ($p < 0.001$). Median waiting time was 25 days (range: 1–
12 83 days) in the study group and 32 days (range: 3–294 days) for patients diagnosed through
13 in-person assessment ($p = 0.017$). There were no significant differences between the study
14 group and the control group regarding gender, age, or ulcer size.
15
16

17
18
19 **Conclusions:** Healing time and waiting time were significantly shorter for patients diagnosed
20 through video consultation compared with those diagnosed through in-person assessment.
21
22

23 24 25 26 27 28 29 **Strengths and limitations of this study**

- 30 • The use of a large, nationally representative sample of patients with hard-to-heal
31 ulcers gives increased generalizability.
32
- 33 • A well-known technical system was used for video communication.
34
- 35 • All patients diagnosed through video consultation were assessed by the same GP,
36 following standardized clinical routines for ulcer assessment.
37
- 38 • The study group was consecutively included and rather limited in size ($n = 100$).
39
40
41
42
43
44
45
46
47
48
49

50 **Introduction**

51
52
53 A hard-to-heal (or chronic) ulcer is defined as a break in the skin which has not healed within
54 4–6 weeks^{1, 2, 3, 4}. This definition is independent of the wound type and aetiology⁵. Examples
55
56
57

1
2
3 of hard-to-heal ulcers are venous, arterial, or venous-arterial leg ulcers; diabetic foot ulcers;
4 pressure ulcers; burns⁶; and ulcers due to trauma, rheumatoid arthritis, and malignancy³.
5
6 Patients with these ulcers have long been considered neglected, as treatment is often given
7 without diagnosis, thus prolonging ulcer healing time⁷. The majority of these patients are
8 elderly and suffer from other conditions such as diabetes and heart and lung diseases^{1,8}. In
9 addition to these comorbidities, these patients may experience extreme pain^{9,10}. Treatment is
10 carried out by different caregivers within different medical specialties, and so a
11 multidisciplinary team of professionals is often necessary to establish the ulcer aetiology and
12 provide the proper diagnosis¹¹.
13
14
15
16
17
18
19
20
21
22
23
24
25

26 In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care^{7,12}.
27 Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful
28 of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-
29 centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000
30 inhabitants). It is divided into two health care centres within the same clinical establishment,
31 BWHC West and BWHC East, which are comparably organized in terms of patient
32 population and staff, and with equal resource allocation. Both centres have the same
33 expenditure of time for doctors' consultations and nurses' dressing changes, capacity for
34 patient assessment and treatment, and facilities in terms of treatment rooms, dressing
35 materials, and computer services.
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50

51 At BWHC, patients are treated according to a structured wound management based on a
52 Swedish national quality registry, the Registry of Ulcer Treatment (RUT)¹². The clinical
53 routines provided by BWHC are the same as those provided by all the other units which
54
55
56
57
58
59
60

1
2
3 register their patients in RUT, and so data from these other units are comparable with data
4
5 from BWHC.
6
7
8
9

10 **The Swedish Registry of Ulcer Treatment**

11
12 RUT is a web-based tool for clinical assessment of hard-to-heal ulcers, treatment strategies,
13
14 and continuity of care. Solid clinical research data based on RUT has shown improved quality
15
16 of life as well as reduction of healing time, treatment costs, and antibiotic treatment^{7, 13, 14}.
17
18 There were more than 7000 registrations in RUT in 2016, giving a coverage rate of
19
20 approximately 25% of all patients with hard-to-heal ulcers in Sweden.
21
22
23
24
25

26 Patients are registered by a nurse or physician on two occasions. The first registration includes
27
28 variables for assessment of ulcer diagnosis and treatment strategies, while the second includes
29
30 data on ulcer healing or negative clinical events such as amputation or death. Each patient
31
32 with a non-healing ulcer remains in the registry until the follow-up is completed.
33
34
35
36

37 **Telemedicine for wound management**

38
39 Telemedicine is the use of information technology and electronic communication to allow
40
41 health care professionals to evaluate, diagnose, and treat patients at a distance. It typically
42
43 includes various forms of video consultation or digital transmission of medical imaging and
44
45 other clinical data.
46
47
48
49

50 Transmission of digital photographs has been used within ulcer care in Denmark since 2005,
51
52 resulting in the reduction of waiting time, ulcer healing time, and transportation, the latter of
53
54 which can often be uncomfortable or painful for the patient¹⁵. Another example is a
55
56
57
58
59

1
2
3 telemedicine wound care model, which has produced reductions in both hospital admissions
4 and patient transportations¹⁶. The use of three-dimensional images has shown high
5
6 concordance with in-person consultation for assessment and measurement of wounds¹⁷.
7
8
9

10
11 Video communication is widely used within different medical specialties today, though
12 thorough documentation and evaluation is insufficient¹⁸. However, there is a lack of use of
13
14 this technology for ulcer care, even though its focus on the visual is considered ideal for
15
16 wound management¹⁹. Video communication could be a useful tool, especially in primary
17
18 care, where there is a need for national guidelines⁸ as well as dedicated doctors and nurses for
19
20 wound management.
21
22
23
24
25

26 The aim of this study was to compare video consultation with in-person assessment for
27
28 patients with hard-to-heal ulcers, in terms of healing time and waiting time.
29
30
31
32
33

34 **Methods**

35 **Study population and variables**

36
37
38 The first study was an analysis of healing time for patients diagnosed through video
39
40 consultation at BWHC West (study group) compared with patients diagnosed through in-
41
42 person assessment based on data from RUT (control group) (Table 1).
43
44
45
46
47
48
49

50 The second study was a supplementary analysis of the waiting time for a doctor's consultation
51
52 for patients diagnosed through video consultation at BWHC West (study group) compared
53
54 with patients diagnosed through in-person assessment at a comparable clinic (BWHC East)
55
56
57
58
59
60

(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 RUT¹². 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

1
2
3 treatment strategy which could be carried out by the assigned nurse under supervision. The
4
5 patient and the treatment strategy were followed up according to general clinical routines.
6
7 Documentation of the video consultation was transferred to the patient's medical record.
8
9

10
11
12 All patients were included and followed during the study period (1 October 2014 – 30
13
14 September 2016). Patients with ulcers that healed had different follow-up times, depending on
15
16 the date of ulcer healing, which was documented. Patients with ulcers that did not heal were
17
18 followed to the end of the study period. If amputation or death occurred during the study
19
20 period, the date of this event was registered and the patient was not followed further. Healing
21
22 was confirmed clinically by a nurse or a doctor.
23
24
25
26
27
28

29 30 Control group

31
32 All patients were diagnosed by in-person consultation and registered in RUT. The same
33
34 measurements were used in both the control group and the study group, except for
35
36 measurement of ulcer size. For patients in the control group, this was done either by a
37
38 planimeter or as length multiplied by width, according to different clinical routines.
39
40
41
42
43

44 As with the study group, each patient was included and followed during the study period (1
45
46 October 2014 – 30 September 2016). Again, patients with ulcers that healed had different
47
48 follow-up times, depending on the date of ulcer healing, which was registered in RUT.
49
50 Patients with ulcers that did not heal were followed to the end of the study period. If
51
52 amputation or death occurred during the study period, the date of this event was registered
53
54
55
56
57
58
59
60

1
2
3 and the patient was not followed further. Healing was confirmed clinically by a nurse or a
4
5 doctor at follow-up registration.
6
7
8
9

10 **The waiting time study**

11
12 In Sweden, waiting time is considered clinically important as an indicator of cost effective
13
14 health care. Age, gender, ulcer size, and ulcer duration were not considered to affect the
15
16 waiting time for a doctor's consultation, and so were not analysed in this study.
17
18
19
20
21
22

23 **Study group**

24
25 The same study group was used as for the healing time study.
26
27
28
29

30 **Patients at BWHC East**

31
32 All patients with hard-to-heal ulcers were diagnosed by in-person assessment at BWHC East.
33
34 These patients were likewise assessed according to RUT and followed to ulcer healing or to
35
36 the end of the study period, whichever occurred first.
37
38
39
40
41

42 **Variables**

43
44 Age (years), gender, ulcer size (cm²), ulcer aetiology, and diabetes (yes or no) were analysed
45
46 in both the study group and the control group. Ulcer size was measured by planimeter
47
48 (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) or by length
49
50 multiplied by width, according to the established routines in different registration units.
51
52
53 Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers,
54
55
56
57
58
59
60

1
2
3 pressure ulcers, neuropathic ulcers (diabetic foot ulcers), traumatic ulcers, malignant ulcers,
4
5 ulcers due to inflammatory vessel diseases such as vasculitis, and other ulcers.
6
7
8
9

10
11 Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of
12
13 diagnosis by a doctor.
14
15

16
17 Ulcer healing time (in days) was defined as the interval between the consultation with a
18
19 doctor and complete ulcer healing. A healed ulcer was defined as an ulcer covered by
20
21 epithelial regeneration, beneath which there may be scarring and absence of glands or
22
23 appendages²⁰.
24
25

26
27
28 Waiting time (in days) was defined as the interval between referral and consultation with a
29
30 doctor at the BWHC.
31
32
33
34
35

36 **Data analysis**

37
38 Statistical analysis was performed using version 24 of IBM SPSS Statistics. Normally
39
40 distributed variables were expressed as mean values, standard deviations (SD), and ranges,
41
42 and compared using Student's t-test. Non-normally distributed variables were expressed as
43
44 median values and ranges, and differences in groups were analysed using the Mann-Whitney
45
46 U-test. Categorical variables were compared between groups using Pearson's chi-square test.
47
48 Healing time was analysed with Kaplan-Meier curves. A log-rank test was used for equality
49
50 of survivor function. A Cox regression analysis was used to explore the effect of age, gender,
51
52 diabetes, ulcer size, and ulcer duration on ulcer healing time. A p-value of less than 0.05 was
53
54 considered to indicate statistical significance.
55
56
57
58
59
60

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 cm², 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 cm², 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 cm² and the remaining 29% (29.2% and 28.7% respectively) were larger than 10 cm². 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

1
2
3 of the ulcer. The video consultation made it possible to reach these patients who might have
4
5 been undiagnosed and without adequate treatment for a long time. Nevertheless, a reduced
6
7 ulcer healing time was found in the study group, despite the longer ulcer duration, which
8
9 could demonstrate the importance of a short waiting time.
10

11
12
13
14
15 In clinical practice in Sweden, the main technique for measuring ulcer size is multiplication of
16
17 length by width, while in specialized clinics such as BWHC, staff use digital planimetry to
18
19 measure ulcer size. The use of these different measurement techniques is one limitation of this
20
21 study, but earlier researchers²¹ have noted that the two methods have a high degree of
22
23 agreement with each other for ulcers with an area of up to approximately 10 cm². In this
24
25 study, most patients (71%) had an ulcer area smaller than 10 cm², and we found no significant
26
27 difference in ulcer size in the proportion of smaller ulcers between the study group and the
28
29 control group. We therefore consider that the use of the two different techniques for
30
31 measuring ulcer size could be justifiable in this setting, although it remains a weakness. The
32
33 remaining 29% of the ulcers were larger than 10 cm², but even for these larger ulcers we
34
35 found no significant difference in ulcer size between the study group and the control group.
36
37
38
39
40
41

42
43 The health care system has a strong economic incentive to reduce patients' waiting time. In
44
45 the industrialized world, costs for wound management consume about 2-4% of the annual
46
47 expenditure on health care, and these costs will rise in the future because of longer life
48
49 expectancy and a larger proportion of patients with diabetes⁸. A recent study¹⁴ found that staff
50
51 costs accounted for 87% of the total costs for wound management. Reduced waiting and
52
53 healing times^{22, 23} are strongly related to reduced costs. The present study cannot show
54
55 whether a one-week reduction in waiting time could lead to reduced costs, and so further
56
57
58
59
60

1
2
3 studies are needed to evaluate the cost-effectiveness implications. We did not analyse the
4
5 number of nurse visits before and after the video consultation, but there were no changes in
6
7 the clinical routines and so we can assume that the frequencies of dressing changes were not
8
9 altered. The doctor's video consultation took place together with the assigned nurse during a
10
11 regular dressing change, which means no additional costs in nurse time.
12
13

14
15
16
17 Previous studies have shown that telemedicine using digital images provides rapid diagnosis
18
19 and ulcer care due to reduced waiting time^{15,24}. We found that this is also true for real-time
20
21 video consultation, which has not previously been studied thoroughly. Video consultation in
22
23 this setting seems to be an effective tool to shorten waiting time. One perspective might be the
24
25 more efficient use of the treatment room. As the doctor does not need any facilities other than
26
27 a tablet and internet access to carry out the video consultation, the treatment room is freed up
28
29 for other patients to undergo dressing changes at the same time, thus increasing the number of
30
31 patients diagnosed and treated per day. The lack of requirement for specialist equipment also
32
33 means that the doctor is independent of any specific health care centre, which may lead to
34
35 increased doctor availability.
36
37
38
39
40
41
42

43 The healing rate in the study group was 82%, compared with 52% in the control group. The
44
45 figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks²⁵ and 83% in
46
47 30 weeks²⁶. The lower healing rate in the registry (i.e. in the control group) could be
48
49 explained by a possible delay in follow-up data being added to the registry. The difficulty of
50
51 obtaining follow-up data in a timely fashion is a well-known phenomenon for most Swedish
52
53 quality registries, even though follow-up registration is mandatory and reminders are sent to
54
55
56
57
58
59
60

1
2
3 the registering units. Another limitation of register-based studies is that there is no assurance,
4
5 other than trust, that a lack of healing date in the registry means that the ulcer has not healed.
6
7
8
9

10
11 Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers
12
13 who are unable to attend clinical visits due to other medical conditions, pain, disability, or
14
15 reduced mobility^{1, 9, 10}, as well as being an alternative for patients who are abroad. Our results
16
17 indicate that video consultation can effectively transmit sufficient ulcer data to allow a remote
18
19 specialist in wound care to establish diagnosis and an ideal treatment strategy. This is in line
20
21 with an earlier study²⁷ of diabetic foot ulcers, which showed no prolonged healing time when
22
23 comparing telemedical assessment with in-person clinic visits. Concordance of the
24
25 telemedicine consultation with in-person assessment was also found when a three-
26
27 dimensional camera was used in a study of diabetic foot ulcers¹⁷. Video consultation provides
28
29 a useful communication tool, allowing the specialist wound team to support and educate the
30
31 assigned nurses in primary care and community care in an easy and secure manner. This could
32
33 be compared with an earlier study²⁸ which showed that telemedicine could effectively
34
35 transmit sufficient wound data to allow a remote specialist in wound care to provide support
36
37 to local health professionals working in nursing homes. Telemedicine has also been shown to
38
39 be a useful communication tool in a home care setting²⁹. The modern technique of video
40
41 communication through iPad or smartphone is easy to use, and is now widely available in
42
43 both rural and urban societies.
44
45
46
47
48
49
50

51 RUT covers wound management in primary care, community care, private care, and in-patient
52
53 hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up,
54
55 meaning that the dataset is large and reliable. One challenge for GPs and nurses in primary
56
57

1
2
3 care in Sweden is to provide adequate diagnosis and treatment to each patient with a hard-to-
4 heal ulcer in this unselected patient group. RUT was developed in order to deal with this
5 issue, and hence includes hard-to-heal ulcers of any aetiology even when there are different
6 healing trajectories. An earlier study found that departments which registered their patients in
7 RUT reported reduced ulcer healing times after the introduction of the registry⁷. Patients not
8 registered in RUT thus probably have a longer ulcer healing time. If the results from our study
9 were to be compared with unregistered patients, the difference in healing time would be even
10 more marked, making our findings somewhat understated.
11
12
13
14
15
16
17
18
19
20
21
22

23 The GP in charge of the BWHC (HW) is the first author of this study, which could be
24 considered a bias and a possible explanation for the lower dropout frequency in the study
25 group. However, it could be considered a strength that all patients diagnosed through video
26 consultation were assessed by the same GP following standardized clinical routines for ulcer
27 assessment. The lack of blinded outcome assessment is one limitation, but a register-based
28 study gives the opportunity to analyse large study populations, which is hard to accomplish
29 with blinded outcome studies. Another limitation is the exclusion of patients with dementia in
30 the study group, which was done as recommended by the Ethical Review Board. We cannot
31 exclude the possibility that there were systematic differences between the study group and the
32 control group concerning patients with dementia and organization of the clinics involved.
33
34
35
36
37
38
39
40
41
42
43
44

45 There is a need for future studies which focus on patient and staff perceptions of the new
46 technology, specific patient groups including patients with dementia, the patient's quality of
47 life, and cost savings for the health care system. Further well-designed randomized controlled
48 studies are necessary to understand how best to deploy telemedicine services in ulcer
49 treatment.
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6 In Sweden, RUT stands for a structured wound management and a way to document the
7
8 wound healing process. Video consultation is one complementary communication tool, which
9
10 together with RUT allows an easy ulcer assessment, especially for patients who are unable to
11
12 attend clinical visits due to severe medical conditions, pain, disability, or reduced mobility.

13
14 Video consultation in parallel with the clinical practice in RUT seems to lead to a more
15
16 efficient use of resources when reducing healing time and waiting time for this neglected
17
18 patient group.
19
20
21
22
23

24 **Conclusion**

25
26
27 The findings from this study illustrate the possible impact of video consultation with a doctor
28
29 for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and
30
31 waiting time. Using video consultation as a complement to in-person assessment has the
32
33 potential to improve ulcer diagnosis, treatment, and healing.
34
35
36
37
38
39

40 **Acknowledgements**

41
42 The authors wish to thank registered nurse Charlotta Prahl and assistant nurse Anna Davnert
43
44 at Blekinge Wound Healing Centre. We would also like to thank Kake Pugh at the language
45
46 editing service Proper English AB.
47
48
49
50
51
52
53
54
55
56
57
58
59
60

References

1. Nelzén O, Bergqvist D, Lindhagen A, et al. Chronic leg ulcers: an underestimated problem in primary health care among elderly patients. *J Epidemiol Community Health* 1991;45:184-7.
2. Clarke-Moloney M, Lyons GM, Burke PE, et al. A review of technological approaches to venous ulceration. *Crit Rev Biomed Eng* 2005;33:511-56.
3. Moffatt CJ, Franks PJ, Doherty DC, et al. Prevalence of leg ulceration in a London population. *QJM* 2004;97(7):431-7.
4. Harding K, Aldons P, Edwards H, et al. Effectiveness of an acellular synthetic matrix in the treatment of hard-to-heal leg ulcers. *Int Wound J* 2014;11(2):129-37.
5. Vowden P. Hard-to-heal wounds Made easy. *Wounds International* 2011;2(4): Available from <http://www.woundsinternational.com>.
6. Chadwick P, Acton C. The use of amelogenin protein in the treatment of hard-to-heal wounds. *Br J Nurs* 2009;8;18(6):S22, S24, S26.
7. Oien RF, Forssell H. Ulcer healing time and antibiotic treatment before and after the introduction of the Registry of Ulcer Treatment: an improvement project in a national quality registry in Sweden. *BMJ Open* 2013;3:e003091.
8. Swedish Council on Health Technology Assessment (SBU). Chronic Ulcers in the Elderly – Prevention and Treatment. Stockholm; 2014 Aug. SBU Yellow Report No. 226.
9. Akesson N, Oien RF, Forssell H, et al. Ulcer pain in patients with venous leg ulcers related to antibiotic treatment and compression therapy. *Br J Community Nurs* 2014;19 (Suppl 9):S6-S13.

- 1
2
3 10. Hellstrom A, Nilsson C, Nilsson A, et al. Leg ulcers in older people: a national study
4 addressing variation in diagnosis, pain and sleep disturbance. *BMC Geriatrics* 2016;16:25.
5
6
- 7
8 11. Mooij MC, Huisman LC. Chronic leg ulcer: does a patient always get a correct diagnosis
9 and adequate treatment? *Phlebology* 2016;31 (Suppl 1):68-73.
10
11
- 12
13 12. Registry of Ulcer Treatment (RUT). www.rut-europe.eu.
14
15
- 16
17 13. Oien RF, Ragnarson Tennvall G. Accurate diagnosis and effective treatment of leg ulcers
18 reduce prevalence, care time and costs. *J Wound Care* 2006;15:259-62.
19
20
- 21
22 14. Oien RF, Forssell H, Ragnarson Tennvall G. Cost consequences due to reduced ulcer
23 healing times – analyses based on the Swedish Registry of Ulcer Treatment. *Int Wound J*
24 2015;13:957-62.
25
26
- 27
28 15. Jelnes R. Telemedicine in the management of patients with chronic wounds. *J Wound*
29 *Care* 2011;20:187-90.
30
31
- 32
33 16. Sood A, Granick MS, Trial C, et al. The role of telemedicine in wound care: a review and
34 analysis of a database of 5,795 patients from a mobile wound-healing center in Languedoc-
35 Roussillon, France. *Plast Reconstr Surg* 2016;138 (Suppl 3):248S-256S.
36
37
- 38
39 17. Bowling FL, King L, Paterson JA, et al. Remote assessment of diabetic foot ulcers using a
40 novel wound imaging system. *Wound Repair Regen* 2011;19:25-30.
41
42
- 43
44 18. Nordheim LV, Haavind MT, Iversen MM. Effect of telemedicine follow-up care of leg
45 and foot ulcers: a systematic review. *BMC Health Serv Res* 2014;14:565. doi:
46 10.1186/s12913-014-0565-6.
47
48
49
- 50
51 19. Chittoria RK. Telemedicine for wound management. *Indian J Plast Surg* 2012;45:412-7.
52
53
54
55
56
57
58
59
60

- 1
2
3 20. Medical Dictionary, Farlex Partner Medical Dictionary. (2012). Retrieved 26 September
4 2017 from <http://medical-dictionary.thegreedictionary.com/healed+ulcer>
5
6
7
8 21. Oien RF, Håkansson A, Hansen BU, et al. Measuring the size of ulcers by planimetry: a
9
10 useful method in the clinical setting. *J Wound Care* 2002;11:165-8.
11
12
13 22. Petursson P. GPs' reasons for "non-pharmacological" prescribing of antibiotics: a
14
15 phenomenological study. *Scand J Prim Health Care* 2005;23:120-5
16
17
18 23. Vowden K, Vowden P, Posnett J. The resource costs of wound management in Bradford
19
20 and Airedale primary care trust in the UK. *J Wound Care* 2009;18:93-4.
21
22
23 24. Chanussot-Deprez C, Contreras-Ruiz J. Telemedicine in wound care. *Int Wound J*
24
25 2008;5:651-4.
26
27
28 25. Moffatt CJ, Franks PJ, Oldroyd M, et al. Community clinics for leg ulcers and impact on
29
30 healing. *BMJ* 1992;305:1389-92.
31
32
33 26. Rybak Z, Franks PJ, Krasowski G, et al. Strategy for the treatment of chronic leg wounds:
34
35 a new model in Poland. *Int Angiol* 2012;31:550-6.
36
37
38 27. Rasmussen BS, Froekjaer J, Bjerregaard MR, et al. A randomized controlled trial
39
40 comparing telemedical and standard outpatient monitoring of diabetic foot ulcers. *Diabetes*
41
42 *Care* 2015;38:1723-9.
43
44
45 28. Vowden K, Vowden P. A pilot study on the potential of remote support to enhance wound
46
47 care for nursing-home patients. *J Wound Care* 2013;22:481-8.
48
49
50 29. Terry M, Halstead LS, O'Hare P, et al. Feasibility study of home care wound management
51
52 using telemedicine. *Adv Skin Wound Care* 2009;22:358-64.
53
54
55
56
57
58
59
60

1
2
3 **Contributors:** Hanna Wickström led the research project and played the main role in the
4 research design and initial manuscript. Rut Öien contributed to the research design and
5 provided knowledge of RUT. Ulf Jakobsson contributed to the data analysis and interpretation
6 of results. Patrik Midlöv, Cecilia Fagerström, and Peter Anderberg contributed to the research
7 design. All authors reviewed and revised the manuscript.
8
9
10
11
12
13
14
15
16

17 **Funding:** The study was partly funded by the Scientific Committee of Blekinge County
18 Council's Research and Development Foundation as part of a PhD studentship.
19
20
21
22
23
24

25 **Competing interests:** None
26
27
28
29
30

31 **Ethics approval:** The study was approved by the Regional Ethical Review Board of Lund,
32 Sweden (ref: 2014/228).
33
34
35
36
37
38

39 **Data sharing statement:** No additional data available.
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

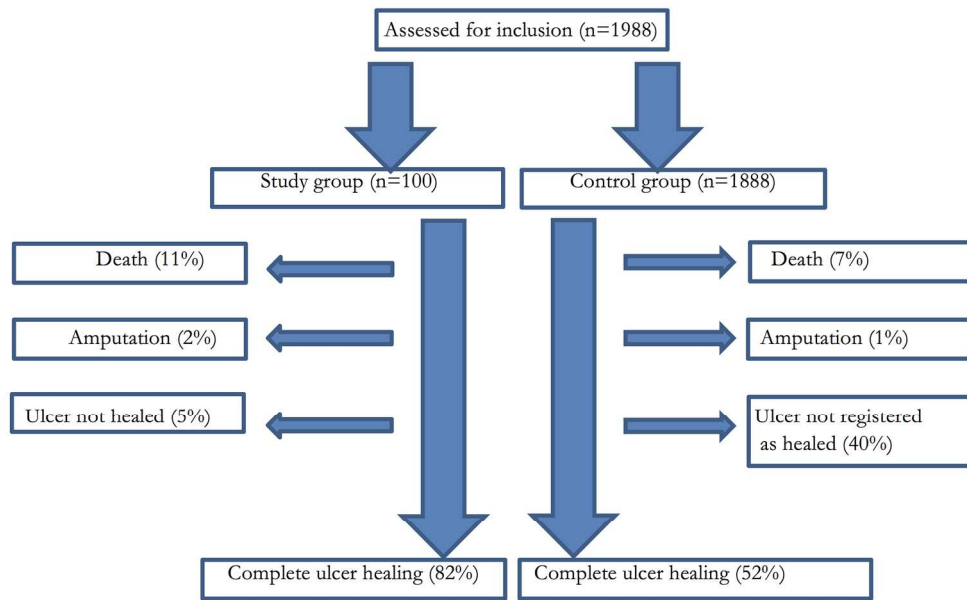


Figure 1 Flow of participants through the trial.

173x110mm (300 x 300 DPI)

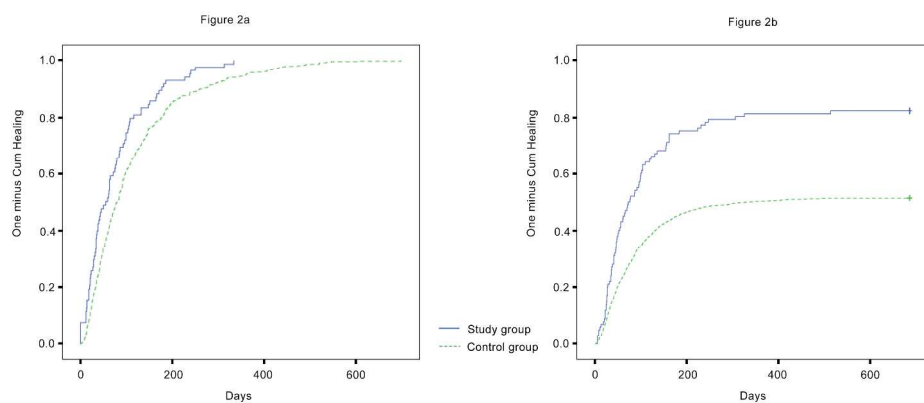


Figure 2a (to the left) illustrates ulcer healing time for the study group compared with the control group, censored for unhealed ulcers, deaths, and amputations. **Figure 2b** (to the right) illustrates ulcer healing time for the study group compared with the control group, uncensored for unhealed ulcers,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

335x149mm (300 x 300 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

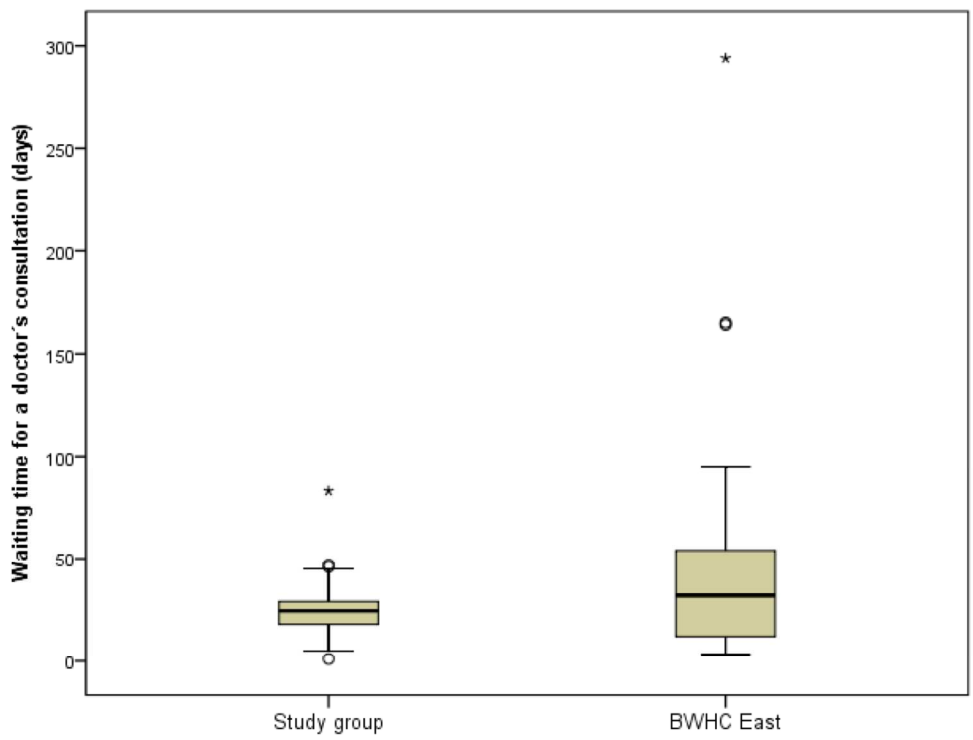


Figure 3 Waiting time for a doctor's consultation for patients in the study group compared with patients at BWHC East.

250x188mm (300 x 300 DPI)

View only

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			

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-017623.R3
Article Type:	Research
Date Submitted by the Author:	30-Nov-2017
Complete List of Authors:	Wickstrom, Hanna; Lund University, Center of Primary Health Care Research, Clinical Sciences Malmo; Blekinge Wound Healing Centre Öien, Rut; Blekinge Wound Healing Centre, Blekinge Centre of Competence Fagerstrom, Cecilia; Blekinge Centre of Competence, Department of Health and Caring Sciences; Linnaeus University Anderberg, Peter; Blekinge Institute of Technology, Department of Health Jakobsson, Ulf; Lund University, Center of Primary Health Care Research, Clinical Sciences Malmo Midlöv, Patrik ; Lund University, Center of Primary Health Care Research, Clinical Sciences Malmo
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Health services research, Communication
Keywords:	eHealth, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Leg Ulcer, Registries, Wound Healing

SCHOLARONE™
Manuscripts



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.

Authors

Hanna Wickström, Rut F Öien, Cecilia Fagerström, Peter Anderberg, Ulf Jakobsson, Patrik Midlöv

Corresponding author

Wickström, Hanna Linnea

Lund University

Center of Primary Health Care Research

Clinical Sciences Malmö

Jan Waldenströmsg 35

Malmö, SE 205 02

Sweden

hanna.wickstrom@med.lu.se

+46702728294

+46454733479

Co-authors

Öien Rut Frank
Blekinge Wound Healing
Centre
Blekinge Centre of
Competence
Karlskrona
Sweden

Kalmar
Sweden

Anderberg Peter
Blekinge Institute of
Technology
Department of Health
Karlskrona
Sweden

Care Research
Clinical Sciences Malmö
Malmö
Sweden

Fagerström Cecilia
Blekinge Centre of
Competence
Karlskrona
Linnaeus University

Jakobsson Ulf
Lund University
Center of Primary Health

Midlöv Patrik John
Lund University
Center of Primary Health
Care Research
Clinical Sciences Malmö
Malmö
Sweden

Word count

3986

Keywords

eHealth; Telemedicine; Leg Ulcer; Registries; Wound Healing

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.

1
2
3 **Results:** Median healing time was 59 days (95% CI: 40–78) in the study group and 82 days
4 (95% CI: 75–89) in the control group ($p < 0.001$). Median waiting time was 25 days (range: 1–
5 83 days) in the study group and 32 days (range: 3–294 days) for patients diagnosed through
6 in-person assessment ($p = 0.017$). There were no significant differences between the study
7 group and the control group regarding age, gender, or ulcer size.
8
9

10
11
12
13
14 **Conclusions:** Healing time and waiting time were significantly shorter for patients diagnosed
15 through video consultation compared with those diagnosed through in-person assessment.
16
17
18

19 20 21 22 **Strengths and limitations of this study**

- 23 • The use of a large, nationally representative sample of patients with hard-to-heal
24 ulcers gives increased generalizability.
- 25 • A well-known technical system was used for video communication.
- 26 • All patients diagnosed through video consultation were assessed by the same GP,
27 following standardized clinical routines for ulcer assessment.
- 28 • The study group was consecutively included and rather limited in size ($n = 100$).
- 29 • The difficulty of obtaining follow-up data in a timely fashion from national quality
30 registries could have influenced our results on healing time.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45

46 **Introduction**

47
48
49 A hard-to-heal (or chronic) ulcer is defined as a break in the skin which has not healed within
50 4–6 weeks^{1, 2, 3, 4}. This definition is independent of the wound type and aetiology⁵. Examples
51 of hard-to-heal ulcers are venous, arterial, or venous-arterial leg ulcers; diabetic foot ulcers;
52 pressure ulcers; burns⁶; and ulcers due to trauma, rheumatoid arthritis, and malignancy³.
53
54
55
56
57
58
59
60

1
2
3 Patients with these ulcers have long been considered neglected, as treatment is often given
4 without diagnosis, thus prolonging ulcer healing time⁷. The majority of these patients are
5 elderly and suffer from other conditions such as diabetes and heart and lung diseases^{1,8}. In
6 addition to these comorbidities, these patients may experience extreme pain^{9,10}. Treatment is
7 carried out by different caregivers within different medical specialties, and so a
8 multidisciplinary team of professionals is often necessary to establish the ulcer aetiology and
9 provide the proper diagnosis¹¹.
10
11
12
13
14
15
16
17
18
19
20

21 In Sweden, the majority of patients with hard-to-heal ulcers are treated in primary care^{7,12}.
22 Dedicated wound healing centres in primary care are scarce, but Sweden does have a handful
23 of such centres, including Blekinge Wound Healing Centre (BWHC), providing patient-
24 centred care with a holistic approach. BWHC covers the whole of Blekinge county (150 000
25 inhabitants). It is divided into two health care centres within the same clinical establishment,
26 BWHC West and BWHC East, which are comparably organized in terms of patient
27 population and staff, and with equal resource allocation. Both centres have the same
28 expenditure of time for doctors' consultations and nurses' dressing changes, capacity for
29 patient assessment and treatment, and facilities in terms of treatment rooms, dressing
30 materials, and computer services.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

47 At BWHC, patients are treated according to a structured wound management based on a
48 Swedish national quality registry, the Registry of Ulcer Treatment (RUT)¹². The clinical
49 routines provided by BWHC are the same as those provided by all the other units which
50 register their patients in RUT, and so data from these other units are comparable with data
51 from BWHC.
52
53
54
55
56
57
58
59
60

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 patient¹⁵. Another example is a telemedicine wound care model, which has produced reductions in both hospital admissions and patient transportations¹⁶. The use of three-dimensional images has shown high concordance with in-person consultation for assessment and measurement of wounds¹⁷.

1
2
3
4
5 Video communication is widely used within different medical specialties today, though
6 thorough documentation and evaluation is insufficient¹⁸. However, there is a lack of use of
7 this technology for ulcer care, even though its focus on the visual is considered ideal for
8 wound management¹⁹. Video communication could be a useful tool, especially in primary
9 care, where there is a need for national guidelines⁸ as well as dedicated doctors and nurses for
10 wound management.
11
12
13
14
15
16
17
18
19

20 The aim of this study was to compare video consultation with in-person assessment for
21 patients with hard-to-heal ulcers, in terms of healing time and waiting time.
22
23
24
25
26
27

28 **Methods**

29 **Study population and variables**

30
31
32 The first study was an analysis of healing time for patients diagnosed through video
33 consultation at BWHC West (study group) compared with patients diagnosed through in-
34 person assessment based on data from RUT (control group) (Table 1).
35
36
37
38
39
40
41
42
43

44 The second study was a supplementary analysis of the waiting time for a doctor's consultation
45 for patients diagnosed through video consultation at BWHC West (study group) compared
46 with patients diagnosed through in-person assessment at a comparable clinic (BWHC East)
47 (Table 1). The reason this supplementary analysis was needed is that waiting time is not
48 recorded in RUT.
49
50
51
52
53
54
55
56
57
58
59
60

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 RUT¹². 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.

1
2
3
4
5
6 All patients were included and followed during the study period (1 October 2014 – 30
7
8 September 2016). Patients with ulcers that healed had different follow-up times, depending on
9
10 the date of ulcer healing, which was documented. Patients with ulcers that did not heal were
11
12 followed to the end of the study period. If amputation or death occurred during the study
13
14 period, the date of this event was registered and the patient was not followed further. Healing
15
16 was confirmed clinically by a nurse or a doctor.
17
18
19
20
21

22 Control group

23
24 All patients were diagnosed by in-person consultation and registered in RUT. The same
25
26 measurements were used in both the control group and the study group, except for
27
28 measurement of ulcer size. For patients in the control group, this was done either by a
29
30 planimeter or as length multiplied by width, according to different clinical routines.
31
32
33
34
35

36
37 As with the study group, each patient was included and followed during the study period (1
38
39 October 2014 – 30 September 2016). Again, patients with ulcers that healed had different
40
41 follow-up times, depending on the date of ulcer healing, which was registered in RUT.
42
43 Patients with ulcers that did not heal were followed to the end of the study period. If
44
45 amputation or death occurred during the study period, the date of this event was registered
46
47 and the patient was not followed further. Healing was confirmed clinically by a nurse or a
48
49 doctor at follow-up registration.
50
51
52
53
54

55 **The waiting time study**

1
2
3 In Sweden, waiting time is considered clinically important as an indicator of cost effective
4 health care. Age, gender, ulcer size, and ulcer duration were not considered to affect the
5 waiting time for a doctor's consultation, and so were not analysed in this study.
6
7
8
9

10 11 12 13 Study group

14
15 The same study group was used as for the healing time study.
16
17
18
19

20 Patients at BWHC East

21
22 All patients with hard-to-heal ulcers were diagnosed by in-person assessment at BWHC East.
23 These patients were likewise assessed according to RUT and followed to ulcer healing or to
24 the end of the study period, whichever occurred first.
25
26
27
28
29
30
31

32 Variables

33
34 Age (years), gender, ulcer size (cm²), ulcer aetiology, and diabetes (yes or no) were analysed
35 in both the study group and the control group. Ulcer size was measured by planimeter
36 (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) or by length
37 multiplied by width, according to the established routines in different registration units.
38
39
40
41
42

43 Ulcers were categorized by diagnosis: venous ulcers, arterial ulcers, venous-arterial ulcers,
44 pressure ulcers, neuropathic ulcers (diabetic foot ulcers), traumatic ulcers, malignant ulcers,
45 ulcers due to inflammatory vessel diseases such as vasculitis, and other ulcers.
46
47
48
49
50
51
52

53 Ulcer duration (in days) was defined as the period from when the ulcer occurred to the date of
54 diagnosis by a doctor.
55
56
57
58
59
60

1
2
3
4
5 Ulcer healing time (in days) was defined as the interval between the consultation with a
6
7 doctor and complete ulcer healing. A healed ulcer was defined as an ulcer covered by
8
9 epithelial regeneration, beneath which there may be scarring and absence of glands or
10
11 appendages²⁰.
12

13
14
15 Waiting time (in days) was defined as the interval between referral and consultation with a
16
17 doctor at the BWHC.
18
19
20
21
22

23 **Data analysis**

24
25 Statistical analysis was performed using version 24 of IBM SPSS Statistics. Normally
26
27 distributed variables were expressed as mean values, standard deviations (SD), and ranges,
28
29 and compared using Student's t-test. Non-normally distributed variables were expressed as
30
31 median values and ranges, and differences in groups were analysed using the Mann-Whitney
32
33 U-test. Categorical variables were compared between groups using Pearson's chi-square test.
34
35 Healing time was analysed with Kaplan-Meier curves. A log-rank test was used for equality
36
37 of survivor function. A Cox regression analysis was used to explore the effect of age, gender,
38
39 diabetes, ulcer size, and ulcer duration on ulcer healing time. A p-value of less than 0.05 was
40
41 considered to indicate statistical significance.
42
43
44
45
46
47

48 **Results**

49 **Patient demographics**

50
51 Basic data on the study group and the control group are presented in Table 2.
52
53
54
55
56
57
58
59
60

The study group had a mean age of 77 years, the median ulcer size was 3.4 cm², 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 cm², 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 cm² and the remaining 29% (29.2% and 28.7% respectively) were larger than 10 cm². The Mann-Whitney U-test showed no significant difference in ulcer size

1
2
3 between the study group and the control group when analysing only the small ulcers
4
5 (p=0.053) or only the larger ulcers (p=0.132).
6
7

8
9 There was a significant difference in ulcer duration between the study group and the control
10
11 group (p<0.001), with the shortest ulcer duration seen in the control group (Table 2).
12
13

14
15
16 The aetiology of the ulcers is presented in Table 3. A chi-square test was performed
17
18 concerning the difference in ulcer aetiology between the groups, but the analysis showed that
19
20 the groups were too small for a comparison.
21
22

23
24
25 **Table 3** Ulcer aetiology (%)
26

	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

27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54 **Healing time**

55
56 The flowchart in Figure 1 illustrates the outcome for the participants in the healing time study.
57
58

1
2
3 Healing rate was 82% (n=82) in the study group and 52% (n=978) in the control group. In the
4 study group, 74% of the patients were followed for <6 months, 8% for 6–12 months, and 18%
5 for >12 months. In the control group, 38% of the patients were followed for <6 months, 8%
6 for 6–12 months, and 54% for >12 months.
7
8
9
10

11 12 13 14 **Figure 1**

15
16
17
18
19
20 After censorship of unhealed ulcers, deaths, and amputations, the median healing time was 59
21 days (mean: 78 days; 95% CI: 40-78) in the study group and 82 days (mean: 118 days; 95%
22 CI: 75-89) in the control group (p<0.001; Table 2). Cox regression analysis showed that there
23 was no significant influence of age, gender, ulcer size, diabetes, or ulcer duration on healing
24 time.
25
26
27
28
29
30

31
32
33
34 Healing time is illustrated in Figures 2a and 2b using Kaplan-Meier analysis. Figure 2a is
35 unadjusted for age, gender, diabetes, ulcer size, and ulcer duration, while Figure 2b is adjusted
36 for age, gender, diabetes, ulcer size, and ulcer duration. Both figures are censored for
37 unhealed ulcers, deaths, and amputations.
38
39
40
41
42
43
44
45
46

47 **Figure 2a-2b**

48 49 50 **Waiting time**

51
52
53 The median waiting time was 25 days (mean: 25 days; range: 1–83 days) in the study group
54 and 32 days (mean: 43 days; range: 3–294 days) for the patients at BWHC East. There was a
55
56
57
58
59
60

1
2
3 significant difference in waiting time between the groups ($p=0.017$), with the shortest waiting
4
5 time seen in the study group (Figure 3).
6
7
8
9

10 **Figure 3**

16 **Discussion**

19 The main finding in this study was the significantly reduced ulcer healing time for patients
20 with hard-to-heal ulcers diagnosed by video consultation (59 days) compared with patients
21 diagnosed by in-person assessment (82 days). We also found that the waiting time was
22 significantly reduced for patients diagnosed by video consultation (25 days) compared with
23 patients diagnosed by in-person consultation (32 days). This study focused on ulcer healing
24 time, as earlier research has shown that reduced ulcer healing time results in improved quality
25 of life, less pain, lower treatment costs, and less time spent on transportation^{9, 18}.
26
27
28
29
30
31
32
33
34
35
36
37

38 In the study group, the ulcer duration before diagnosis was 124 days and healing time was 59
39 days, while the corresponding figures in the control group were 84 days and 82 days
40 respectively. One explanation for this could be that the patients in the study group lived in
41 remote and mostly rural areas, and could not easily reach the health care centre for assessment
42 of the ulcer. The video consultation made it possible to reach these patients who might have
43 been undiagnosed and without adequate treatment for a long time. Nevertheless, a reduced
44 ulcer healing time was found in the study group, despite the longer ulcer duration, which
45 could demonstrate the importance of a short waiting time.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6 In clinical practice in Sweden, the main technique for measuring ulcer size is multiplication of
7 length by width, while in specialized clinics such as BWHC, staff use digital planimetry to
8 measure ulcer size. The use of these different measurement techniques is one limitation of this
9 study, but earlier researchers²¹ have noted that the two methods have a high degree of
10 agreement with each other for ulcers with an area of up to approximately 10 cm². In this
11 study, most patients (71%) had an ulcer area smaller than 10 cm², and we found no significant
12 difference in ulcer size in the proportion of smaller ulcers between the study group and the
13 control group. We therefore consider that the use of the two different techniques for
14 measuring ulcer size could be justifiable in this setting, although it remains a weakness. The
15 remaining 29% of the ulcers were larger than 10 cm², but even for these larger ulcers we
16 found no significant difference in ulcer size between the study group and the control group.
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32

33 The health care system has a strong economic incentive to reduce patients' waiting time. In
34 the industrialized world, costs for wound management consume about 2-4% of the annual
35 expenditure on health care, and these costs will rise in the future because of longer life
36 expectancy and a larger proportion of patients with diabetes⁸. A recent study¹⁴ found that staff
37 costs accounted for 87% of the total costs for wound management. Reduced waiting and
38 healing times^{22, 23} are strongly related to reduced costs. The present study cannot show
39 whether a one-week reduction in waiting time could lead to reduced costs, and so further
40 studies are needed to evaluate the cost-effectiveness implications. We did not analyse the
41 number of nurse visits before and after the video consultation, but there were no changes in
42 the clinical routines and so we can assume that the frequencies of dressing changes were not
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 altered. The doctor's video consultation took place together with the assigned nurse during a
4
5 regular dressing change, which means no additional costs in nurse time.
6
7
8
9

10 Previous studies have shown that telemedicine using digital images provides rapid diagnosis
11
12 and ulcer care due to reduced waiting time^{15,24}. We found that this is also true for real-time
13
14 video consultation, which has not previously been studied thoroughly. Video consultation in
15
16 this setting seems to be an effective tool to shorten waiting time. One perspective might be the
17
18 more efficient use of the treatment room. As the doctor does not need any facilities other than
19
20 a tablet and internet access to carry out the video consultation, the treatment room is freed up
21
22 for other patients to undergo dressing changes at the same time, thus increasing the number of
23
24 patients diagnosed and treated per day. The lack of requirement for specialist equipment also
25
26 means that the doctor is independent of any specific health care centre, which may lead to
27
28 increased doctor availability.
29
30
31
32
33
34
35

36 The healing rate in the study group was 82%, compared with 52% in the control group. The
37
38 figure of 82% is in line with earlier reports of a healing rate of 81% in 24 weeks²⁵ and 83% in
39
40 30 weeks²⁶. The lower healing rate in the registry (i.e. in the control group) could be
41
42 explained by a possible delay in follow-up data being added to the registry. The difficulty of
43
44 obtaining follow-up data in a timely fashion is a well-known phenomenon for most Swedish
45
46 quality registries, even though follow-up registration is mandatory and reminders are sent to
47
48 the registering units. Another limitation of register-based studies is that there is no assurance,
49
50 other than trust, that a lack of healing date in the registry means that the ulcer has not healed.
51
52
53
54
55
56
57
58
59
60

1
2
3 Video consultation could be more accessible and suitable for patients with hard-to-heal ulcers
4 who are unable to attend clinical visits due to other medical conditions, pain, disability, or
5 reduced mobility^{1, 9, 10}, as well as being an alternative for patients who are abroad. Our results
6 indicate that video consultation can effectively transmit sufficient ulcer data to allow a remote
7 specialist in wound care to establish diagnosis and an ideal treatment strategy. This is in line
8 with an earlier study²⁷ of diabetic foot ulcers, which showed no prolonged healing time when
9 comparing telemedical assessment with in-person clinic visits. Concordance of the
10 telemedicine consultation with in-person assessment was also found when a three-
11 dimensional camera was used in a study of diabetic foot ulcers¹⁷. Video consultation provides
12 a useful communication tool, allowing the specialist wound team to support and educate the
13 assigned nurses in primary care and community care in an easy and secure manner. This could
14 be compared with an earlier study²⁸ which showed that telemedicine could effectively
15 transmit sufficient wound data to allow a remote specialist in wound care to provide support
16 to local health professionals working in nursing homes. Telemedicine has also been shown to
17 be a useful communication tool in a home care setting²⁹. The modern technique of video
18 communication through iPad or smartphone is easy to use, and is now widely available in
19 both rural and urban societies.

20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43 RUT covers wound management in primary care, community care, private care, and in-patient
44 hospital care throughout Sweden, and provides a validated tool for diagnosis and follow-up,
45 meaning that the dataset is large and reliable. One challenge for GPs and nurses in primary
46 care in Sweden is to provide adequate diagnosis and treatment to each patient with a hard-to-
47 heal ulcer in this unselected patient group. RUT was developed in order to deal with this
48 issue, and hence includes hard-to-heal ulcers of any aetiology even when there are different
49 healing trajectories. An earlier study found that departments which registered their patients in

1
2
3 RUT reported reduced ulcer healing times after the introduction of the registry⁷. Patients not
4 registered in RUT thus probably have a longer ulcer healing time. If the results from our study
5 were to be compared with unregistered patients, the difference in healing time would be even
6 more marked, making our findings somewhat understated.
7
8
9

10
11
12
13
14
15 The GP in charge of the BWHC (HW) is the first author of this study, which could be
16 considered a bias and a possible explanation for the lower dropout frequency in the study
17 group. However, it could be considered a strength that all patients diagnosed through video
18 consultation were assessed by the same GP following standardized clinical routines for ulcer
19 assessment. The lack of blinded outcome assessment is one limitation, but a register-based
20 study gives the opportunity to analyse large study populations, which is hard to accomplish
21 with blinded outcome studies. Another limitation is the exclusion of patients with dementia in
22 the study group, which was done as recommended by the Ethical Review Board. We cannot
23 exclude the possibility that there were systematic differences between the study group and the
24 control group concerning patients with dementia and organization of the clinics involved.
25
26 There is a need for future studies which focus on patient and staff perceptions of the new
27 technology, specific patient groups including patients with dementia, the patient's quality of
28 life, and cost savings for the health care system. Further well-designed randomized controlled
29 studies are necessary to understand how best to deploy telemedicine services in ulcer
30 treatment.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50

51 The use of a large, representative sample of patients with hard-to-heal ulcers means that the
52 results of the study are generalizable, but the organization of health care systems in different
53 countries may have an impact. Video consultation in this setting can be applied worldwide
54
55
56
57

1
2
3 within all kinds of health care systems, and offers an opportunity for improvement in ulcer
4
5 treatment.
6
7
8
9

10 In Sweden, RUT stands for a structured wound management and a way to document the
11
12 wound healing process. Video consultation is one complementary communication tool, which
13
14 together with RUT allows an easy ulcer assessment, especially for patients who are unable to
15
16 attend clinical visits due to severe medical conditions, pain, disability, or reduced mobility.
17
18 Video consultation in parallel with the clinical practice in RUT seems to lead to a more
19
20 efficient use of resources when reducing healing time and waiting time for this neglected
21
22 patient group.
23
24
25
26
27
28
29

30 **Conclusion**

31
32
33 The findings from this study illustrate the possible impact of video consultation with a doctor
34
35 for patients with hard-to-heal ulcers, resulting in significantly reduced healing time and
36
37 waiting time. Using video consultation as a complement to in-person assessment has the
38
39 potential to improve ulcer diagnosis, treatment, and healing.
40
41
42
43
44

45 **Acknowledgements**

46
47 The authors wish to thank registered nurse Charlotta Prah and assistant nurse Anna Davnert
48
49 at Blekinge Wound Healing Centre. We would also like to thank Kake Pugh at the language
50
51 editing service Proper English AB.
52
53
54
55
56
57
58
59
60

References

1. Nelzén O, Bergqvist D, Lindhagen A, et al. Chronic leg ulcers: an underestimated problem in primary health care among elderly patients. *J Epidemiol Community Health* 1991;45:184-7.
2. Clarke-Moloney M, Lyons GM, Burke PE, et al. A review of technological approaches to venous ulceration. *Crit Rev Biomed Eng* 2005;33:511-56.
3. Moffatt CJ, Franks PJ, Doherty DC, et al. Prevalence of leg ulceration in a London population. *QJM* 2004;97(7):431-7.
4. Harding K, Aldons P, Edwards H, et al. Effectiveness of an acellular synthetic matrix in the treatment of hard-to-heal leg ulcers. *Int Wound J* 2014;11(2):129-37.
5. Vowden P. Hard-to-heal wounds Made easy. *Wounds International* 2011;2(4): Available from <http://www.woundsinternational.com>.
6. Chadwick P, Acton C. The use of amelogenin protein in the treatment of hard-to-heal wounds. *Br J Nurs* 2009;8;18(6):S22, S24, S26.
7. Oien RF, Forssell H. Ulcer healing time and antibiotic treatment before and after the introduction of the Registry of Ulcer Treatment: an improvement project in a national quality registry in Sweden. *BMJ Open* 2013;3:e003091.
8. Swedish Council on Health Technology Assessment (SBU). Chronic Ulcers in the Elderly – Prevention and Treatment. Stockholm; 2014 Aug. SBU Yellow Report No. 226.
9. Akesson N, Oien RF, Forssell H, et al. Ulcer pain in patients with venous leg ulcers related to antibiotic treatment and compression therapy. *Br J Community Nurs* 2014;19 (Suppl 9):S6-S13.

10. Hellstrom A, Nilsson C, Nilsson A, et al. Leg ulcers in older people: a national study addressing variation in diagnosis, pain and sleep disturbance. *BMC Geriatrics* 2016;16:25.
11. Mooij MC, Huisman LC. Chronic leg ulcer: does a patient always get a correct diagnosis and adequate treatment? *Phlebology* 2016;31 (Suppl 1):68-73.
12. Registry of Ulcer Treatment (RUT). www.rut-europe.eu.
13. Oien RF, Ragnarson Tennvall G. Accurate diagnosis and effective treatment of leg ulcers reduce prevalence, care time and costs. *J Wound Care* 2006;15:259-62.
14. Oien RF, Forssell H, Ragnarson Tennvall G. Cost consequences due to reduced ulcer healing times – analyses based on the Swedish Registry of Ulcer Treatment. *Int Wound J* 2015;13:957-62.
15. Jelnes R. Telemedicine in the management of patients with chronic wounds. *J Wound Care* 2011;20:187-90.
16. Sood A, Granick MS, Trial C, et al. The role of telemedicine in wound care: a review and analysis of a database of 5,795 patients from a mobile wound-healing center in Languedoc-Roussillon, France. *Plast Reconstr Surg* 2016;138 (Suppl 3):248S-256S.
17. Bowling FL, King L, Paterson JA, et al. Remote assessment of diabetic foot ulcers using a novel wound imaging system. *Wound Repair Regen* 2011;19:25-30.
18. Nordheim LV, Haavind MT, Iversen MM. Effect of telemedicine follow-up care of leg and foot ulcers: a systematic review. *BMC Health Serv Res* 2014;14:565. doi: 10.1186/s12913-014-0565-6.
19. Chittoria RK. Telemedicine for wound management. *Indian J Plast Surg* 2012;45:412-7.

- 1
2
3 20. Medical Dictionary, Farlex Partner Medical Dictionary. (2012). Retrieved 26 September
4 2017 from <http://medical-dictionary.thegreedictionary.com/healed+ulcer>
5
6
7
8 21. Oien RF, Håkansson A, Hansen BU, et al. Measuring the size of ulcers by planimetry: a
9
10 useful method in the clinical setting. *J Wound Care* 2002;11:165-8.
11
12
13 22. Petursson P. GPs' reasons for "non-pharmacological" prescribing of antibiotics: a
14
15 phenomenological study. *Scand J Prim Health Care* 2005;23:120-5
16
17
18 23. Vowden K, Vowden P, Posnett J. The resource costs of wound management in Bradford
19
20 and Airedale primary care trust in the UK. *J Wound Care* 2009;18:93-4.
21
22
23 24. Chanussot-Deprez C, Contreras-Ruiz J. Telemedicine in wound care. *Int Wound J*
24
25 2008;5:651-4.
26
27
28 25. Moffatt CJ, Franks PJ, Oldroyd M, et al. Community clinics for leg ulcers and impact on
29
30 healing. *BMJ* 1992;305:1389-92.
31
32
33 26. Rybak Z, Franks PJ, Krasowski G, et al. Strategy for the treatment of chronic leg wounds:
34
35 a new model in Poland. *Int Angiol* 2012;31:550-6.
36
37
38 27. Rasmussen BS, Froekjaer J, Bjerregaard MR, et al. A randomized controlled trial
39
40 comparing telemedical and standard outpatient monitoring of diabetic foot ulcers. *Diabetes*
41
42 *Care* 2015;38:1723-9.
43
44
45 28. Vowden K, Vowden P. A pilot study on the potential of remote support to enhance wound
46
47 care for nursing-home patients. *J Wound Care* 2013;22:481-8.
48
49
50 29. Terry M, Halstead LS, O'Hare P, et al. Feasibility study of home care wound management
51
52 using telemedicine. *Adv Skin Wound Care* 2009;22:358-64.
53
54
55
56
57
58
59
60

1
2
3 **Contributors:** Hanna Wickström led the research project and played the main role in the
4 research design and initial manuscript. Rut Öien contributed to the research design and
5 provided knowledge of RUT. Ulf Jakobsson contributed to the data analysis and interpretation
6 of results. Patrik Midlöv, Cecilia Fagerström, and Peter Anderberg contributed to the research
7 design. All authors reviewed and revised the manuscript.
8
9
10
11
12
13
14
15
16

17 **Funding:** The study was partly funded by the Scientific Committee of Blekinge County
18 Council's Research and Development Foundation as part of a PhD studentship.
19
20
21
22
23
24

25 **Competing interests:** None
26
27
28
29
30

31 **Ethics approval:** The study was approved by the Regional Ethical Review Board of Lund,
32 Sweden (ref: 2014/228).
33
34
35
36
37
38

39 **Data sharing statement:** No additional data available.
40
41
42
43
44

45 **Figure legends:**
46
47

48 Link text: Figure 1
49
50

51 Legend: Flow of participants through the trial.
52
53
54
55
56
57
58
59
60

1
2
3 Link text: Figures 2a-2b

4
5 Legend: Figure 2a (on the left) illustrates ulcer healing time for the study group compared
6 with the control group, unadjusted for age, gender, diabetes, ulcer size, and ulcer duration.
7 Figure 2b (on the right) illustrates ulcer healing time for the study group compared with the
8 control group, adjusted for age, gender, diabetes, ulcer size, and ulcer duration. Both figures
9 are censored for unhealed ulcers, deaths, and amputations.
10
11
12

13
14 Link text: Figure 3

15
16 Legend: Waiting time for a doctor's consultation for patients in the study group compared
17 with patients at BWHC East.
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

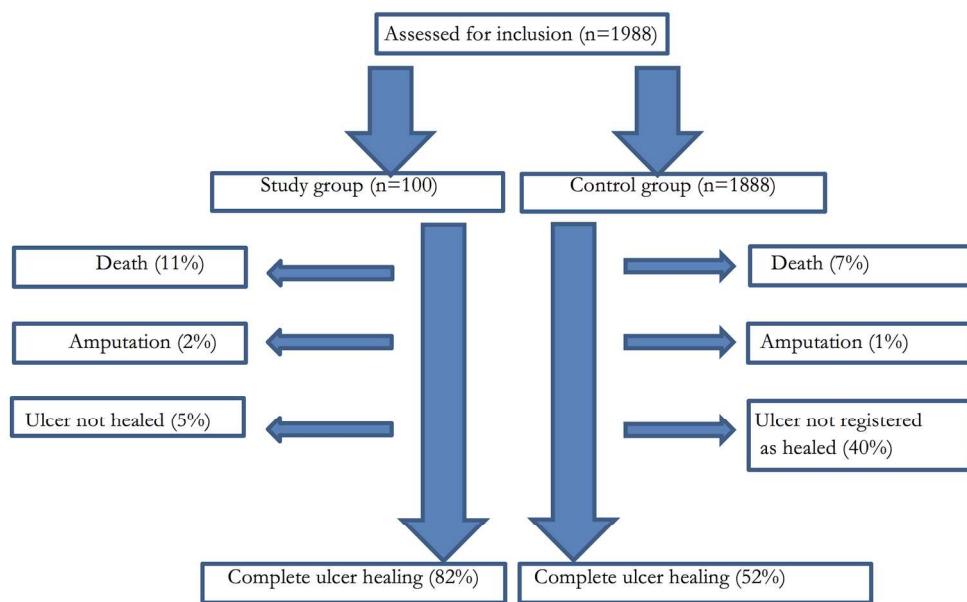


Figure 1 Flow of participants through the trial.

173x110mm (300 x 300 DPI)

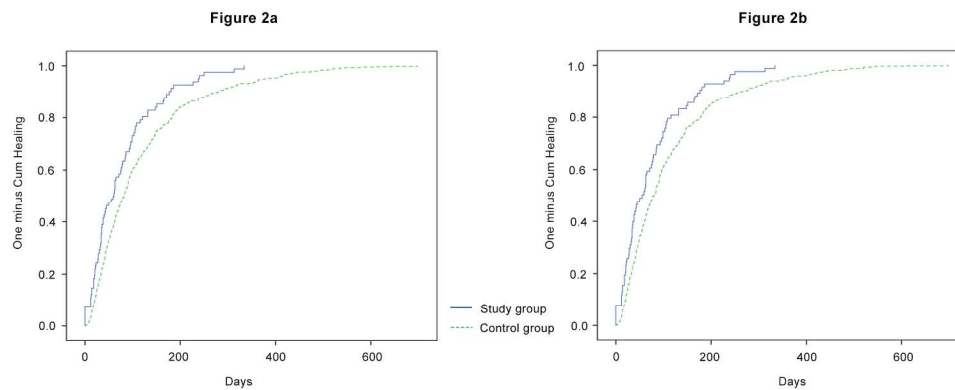


Figure 2a (on the left) illustrates ulcer healing time for the study group compared with the control group, unadjusted for age, gender, diabetes, ulcer size, and ulcer duration. **Figure 2b** (on the right) illustrates ulcer healing time for the study group compared with the control group, adjusted for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

215x89mm (300 x 300 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

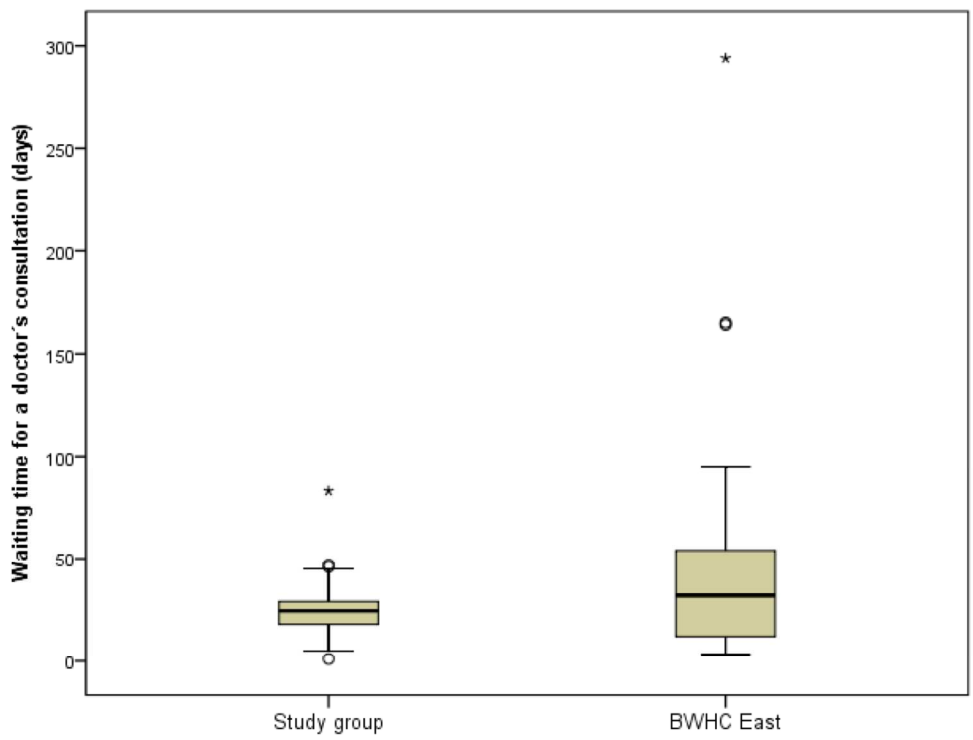


Figure 3 Waiting time for a doctor's consultation for patients in the study group compared with patients at BWHC East.

250x188mm (300 x 300 DPI)

www only

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

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.