A randomised controlled clinical trial comparing the effectiveness of bandaging compared to the JuxtaCuresTM device in the management of people with venous ulceration: Feasibility Study

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Abstract

Introduction: The mainstay of treatment for venous ulceration remains compression therapy. Velcro Wrap devices are being increasingly used in these patients despite limited evidence. This feasibility study aimed to compare standard bandaging to the JuxtaCuresTM Velcro wrap device.

Methods: A single centre, unblinded RCT compared participants with venous ulceration randomised to either the JuxtaCuresTM device or short stretch bandaging. Participants were followed up for 26 weeks.

Results: 160 participants were screened with 40 randomised. 3 participants in bandaging and 1 in JuxtaCuresTM didn't complete the study. 60% in JuxtaCuresTM healed v 55% in bandaging despite larger ulcers in the JuxtaCuresTM arm (9.33 cm2 v 6.97 cm2). There was no significant difference in time to healing (12.17 v 13.64 weeks). JuxtaCuresTM showed improved ulcer reduction for those that didn't heal (14.91–5.00 cm2 v 14.20–8.62 cm2; P ¼ 0.06). JuxtaCuresTM had more consistent sub-bandage pressure dropping from 39–36 mmHg versus 41–25 mmHg in bandaging between application and removal (P < 0.001). Quality of life (EQ5D) was improved in JuxtaCures at 3 months (mean difference 0.14, p ¼ 0.04), but not at 1 and 6 months, or in disease specific quality of life. Cost was lower in JuxtaCuresTM £842.47 v £1064.68. Duration of appointment was significantly shorter in JuxtaCuresTM (41 minutes v 53 minutes; P ¼ 0.003). Conclusion: This study has shown the feasibility and necessity of running a multicentre trial to evaluate the use of Velcro wrap devices for venous ulceration. It highlights the potential benefits of more consistent pressure, increased selfcare, and potential with regards to ulcer healing, cost, nursing resource and quality of life.

Keywords

Venous ulceration, wound care, compression bandaging

Introduction

Chronic venous ulceration affects approximately 1% of the population, increasing in the elderly, and is often associated with a prolonged period of healing and a high recurrence rate.[1] As such, venous ulceration significantly affects patient quality of life and represents a major drain on NHS and social services of approximately £1 billion per annum. First line treatment for the management of uncomplicated venous ulceration is multi-layered compression bandaging.[2] This serves to increase venous return and reduce venous hypertension. There is evidence that compression reduces pain, increases healing rate, and improves quality of life and functional status, when compared to using simple wound dressings alone.[3,4]

Although the ESCHAR[5] and EVRA[6] studies have highlighted the additional benefit of endovenous therapy to reducing time to ulcer healing and ulcer recurrence, this is adjunctive therapy rather than curative, as patients will still require compression. Many patients will also either be unwilling or unable to have endovenous surgery, and maximising ulcer free days and cost effectiveness with the optimum compression therapy therefore remains important.

It has been predicted that up to 51% of patients do not comply with their multilayer bandaging.[7] There are many potential reasons for this, including: skin irritation, bandage slippage, pain, malodour, inability to maintain hygiene, discomfort and inability to wear normal footwear. It is also thought that the effect of the compression is compromised by differing leg shapes and skin consistencies.[8]

JuxtaCuresTM is an adjustable compression device with a Built-In-Pressure System (BPS), which allows patients to adjust it throughout the day, that may be used for the treatment of open venous stasis ulcers (NICE advice [MIB25]). It is a compression wrap around device with a Built-In-Pressure SystemTM (BPS), which allows patients adjust it throughout the day. Due to the adjustability the device has the potential to provide more constant pressure than bandaging, which typically loses 50% of its initial compression during a week.[9] In addition it may be more tolerable, allowing patients more autonomy and assist with maintaining personal hygiene.

There is limited evidence from initial small-scale series and a single randomised controlled trial indicating that JuxtaCuresTM may provide economical and effective compression for venous ulcer (VU) healing.[10] Due to the ability to self apply, the number of visits for dressing changes and length of appointments can also be reduced in patients using Velcro Wrap devices, which has a potential cost-saving implication. As such, there is a need for better evidence to evaluate the use of JuxtaCuresTM.

Aims and objectives

The primary outcomes for this study are to evaluate the feasibility of conducting a powered multicentre trial into the use of Velcro Wrap devices. This will specifically assess the number of eligible patients per 100,000 population, the percentage of eligible patients accepted for randomisation, patient compliance with trial protocol, measured as days without compression

in trial period, the percentage of patients completing study, and preliminary secondary outcome data.

Secondary outcomes, which have not been powered for within the feasibility study include ulcer healing (in terms of surface area, and time to healing in days), quality of life measured by EuroQol-5D-5L and VEINESqol/sym, cost effectiveness, and sub-bandage pressure.

Methods

Trial design and oversight

This was a single centre, parallel-group, 1:1, randomised controlled trial that was funded by Medi UK (Hereford, UK). The trial was approved by the East of England -Essex Research Ethics Committee (16/EE/ 0271) and registered with www.clinicaltrials.gov (NCT02790593). The trial was sponsored by Colchester Hospital University Foundation Trust. Data was uploaded by trial staff to a web-based electronic data capture system, MACRO EDC and monitored by the trial staff and Anglia Ruskin Clinical Trial Unit. Medi UK had no participation in trial design, analysis or publication.

Trial setting and patients

The trial was run from January 2017 to July 2019. Patients with venous leg ulcers were identified through advertisement in primary care, referrals to vascular clinics, and leg ulcer clinics. All participants were screened by the trial team and assessed and identified as having a likely venous ulcer clinically and from duplex scan. Informed consent was obtained from all participants.

Eligibility criteria

Inclusion criteria for patients were age >18 years old, active venous ulcer for >2 weeks, 2:1cm squared surface area, venous incompetence confirmed by clinical assessment and duplex ultrasound scan, no evidence of arterial disease (Arterial Duplex OR Ankle Brachial Pressure Index 2:0.80 OR toe pressure index 2:0.70), patients able to complete trial procedures, and patients with a life expectancy of greater than 1 year. Exclusion criteria included acute deep vein thrombosis, patient unable or unwilling to have high compression (30 mmHg minimum), patients with dexterity insufficiency of hands, peripheral neuropathy, leg ulcers of another underlying cause, and patients unable or unwilling to provide written, informed consent

Randomisation

Participants were randomised using a web based independent service after stratification for ulcer size < or > 10 cm2. This was conducted through the Anglia Ruskin University Clinical Trials Unit.

Randomisation was 1:1 random block stratified by ulcer size using an online system, TENALEA.

Blinding

Due to the nature of the trial being a visible bandage or wrap it was not possible to blind the participant. As this was a feasibility study the statistician was also not blinded.

Data collected

Collected baseline data included age, gender, first four digits of participants postcode, ethnicity, medical comorbidities, medications, smoking status, previous ulceration, duration of ulcer, location of ulcer in relation to the ankle, previous compression therapy, and surface area of ulcer. Additional data collected throughout the duration of the trial is as outlined in the trial interventions and flow diagram (Figure 1).

Trial interventions

The participant was reviewed in the leg ulcer clinic every week for the first four weeks when they underwent pressure monitoring using the PicoPressVR (Microlab Italia, Padua, Italy). The PicoPress was positioned 10 cm above the medial malleolus and left in place until the participants next visit. Dressings were changed and the ulcer measured with standard 1 cm squared grids, and the SilhoutteVR 3D wound imaging system (ARANZ Medical Ltd, Christchurch, New Zealand). The type of dressings applied and length of appointment were recorded.

Compression bandages included either Actico Short Stretch or K2. Bilateral participants were allocated a single treatment, rather than randomisation of individual limbs. Dressings underneath the bandage or wrap were applied at the discretion of the treating clinician and recorded for cost analysis purposes.

For the initial 4 weeks of the study the compression was applied by the trial research team, prior to this being undertaken in the community or by the patient. This was undertaken between 1 and 3 times per week depending on wound exudate. Patients were advised to apply 40 mmHg pressure when adjusting the JuxtaCuresTM device. The sub-bandage pressure monitor was not used to adjust either type of compression unless there was a patient safety issue, and this was only used for the initial 4 weeks of the study.

At baseline, 1 month, 3 months and 6 months participants were invited to complete health related quality of life questionnaires. The disease specific VEINESqol/ sym, and generic Euroqol-5D-5L surveys were used. The study period for the randomised-control trial was up to 26 weeks for each participant, or until they had healed.

Flow diagram

See Figure 1.

Statistical analysis

Statistical analysis was undertaken using the Stata sta- tistical package. The Shapiro-Wilk W test was used for normality. As this is a feasibility study no formal power calculation was undertaken. An initial aim for 50 participants was reduced to 40 due to poor initial recruitment and ongoing costs of the trial.

The primary outcomes were reported through use of the screening log with population data based on the reported population served by the hospital in the 2017 Care Quality Commission report of 370,000.

Secondary outcomes were performed using t-tests or Mann-Whitney U tests for comparing the differences between two independent groups, paired t-tests were used for comparing the differences between pre-post groups and the KM estimator was used to show the survival curves.

The disease specific quality of life questionnaire was analysed with three items (Q3, Q6 and Q7) coded reversely. Q2 provided descriptive information, which was not included in the summary score calculation. The standard method for scoring scales was used for the analysis because of the questionnaire items with different responses. Raw scores are transformed to Z score first and then are transformed to T score. The mean scores were used in the analysis.

Health economic analysis

Cost analysis was assessed by comparing the accumulated expenditure on patients in each cohort for their venous ulcer management. Data was collected on: number, type and cost of dressings under compression; number, type and cost of compression treatment (JuxtaCuresTM or compression bandaging); and nursing costs, including duration of appointment.

Results

Descriptive analysis

A total of 160 potential participants were screened and assessed for eligibility. Reasons for exclusion are shown in Figure 2. A total of 40 participants were randomised into the study, 20 in each arm.

Due to the number of participants it was not possible to analyse for differences in comorbidities. These are recorded in Table 1.

Primary outcome measures

Eligibility. A total number of 160 patients were screened for this study. Of these, 75 were deemed to be eligible, 81 not eligible, and in 4 patients the researchers were unable to determine eligibility. Reasons for exclusion are shown in the CONSORT diagram (Figure 2). The percentage of eligible patients that were included in the study was 47%. It was estimated that the number of eligible patients per 100,000 of the population was 22 (75/370,000).

Compliance data. Participants were asked to complete a daily diary for the duration they were wearing compression. Of the 4559 diary entries completed (33%) were recorded as removing the bandaging or device, 63% reported that they did not remove the bandaging or device and the remaining 4% were left blank. Of those who reported removal 78% were in the JuxtaCuresTM arm and 22% were in the bandaging arm. The most common reasons for removal of com- pression was for washing (72%) and pain (4%). In addition, 219 episodes were recorded in the JuxtaCuresTM arm and 8 in the bandaging arm where the dressing was not changed.

Complications. Appendix 1 lists the complications that participants reported in both arms. Overall there were more complications reported for the bandaging arm (1918) than in the JuxtaCuresTM arm (1726). The most commonly cited complication for both arms was 'Pain', followed by 'Discomfort'. The report of 'Unpleasant smell' was higher in the bandaging arm (231 v 72 reports).

Study completion. 90% of participants completed the study as per the study protocol, with 95% of the JuxtaCuresTM arm and 85% of the bandaging arm.

Secondary analysis

Percentage healed, time to healing and surface area measurements. Of 40 patients in the study, 23 were healed (12 (60%) in the JuxtaCuresTM group and 11 (55%) in the Bandaging group) at study completion. A single participant had bilateral ulcers which healed at week 8 and week 14. The week 14 healing time was therefore used. The mean time to healing was 12.67 weeks (SD 6.11) in the JuxtaCuresTM group and 13.64 weeks (SD 6.98) in the Bandaging group. There was no significant difference in time to healing between the groups.

Ulcer sizes were initially larger in the JuxtaCuresTM arm in both the healed (9.33cm2 v 6.97cm2) and nonhealed participants (14.91cm2 v 14.20cm2). 7 participants in the JuxtaCuresTM group and 6 in the Bandaging group did not heal. The JuxtaCuresTM arm showed better reduction in ulcer size at the end of the trial (mean diameter at end of trial 5.00cm2 v 8.62cm2) which trended towards significance (P¼0.06) (Tables 2 and 3 and Figure 3).

EQ5D-5L quality of life. In the study, 40 patients (20 for each group) completed the questionnaire at baseline. The results showed that patients had better QoL at 3 months in the JuxtaCuresTM group compared with those in the Bandaging group (the mean difference in the mean scores of QoL-5D was -0.14 (95%CI: -0.28, 0.01), p ¼ 0.04). No differences were found at 1 month (-0.07 95%CI -0.21–0.06; P ¼ 0.27) and 6 months (-0.06 95%CI -0.21–0.08; P ¼ 0.49).

Disease specific questionnaire – VEINES. There was no difference in the median scores of disease specific quality of life between the two treatments at 1 month, 3 months and 6 months (Table 4). The summary statistics of the scores between the two groups are shown in Appendix 2.

Pressure. The pressure underneath the compression was recorded at application and removal for the first 3 weeks. This resulted in 94 paired readings (43 in the JuxtaCuresTM arm and 51 in the Bandaging arm) as several participants removed their compression prior to attending the appointment. There was a significant drop in pressure from Bandage application to removal (41 mmHg v 25 mmHg; P < 0.001), which was not the case in the JuxtaCuresTM group (39 mmHg v 36 mmHg; P ¼ 0.26). There was also a significant difference in pressure drop between the JuxtaCuresTM and Bandaging groups (P < 0.001) (Figure 4).

Cost analysis. The cost of each arm was calculated from data gathered on appointment length, dressings and intervention. An average for each arm was calculated. For those participants who healed or completed the study as per protocol, the cost of the JuxtaCuresTM was £842.47, and the costs of the bandaging arm was £1064.48 for the duration of the study. This shows a saving of £222.01 per participant for the JuxtaCuresTM arm. For participants that healed there was a cost saving of £183.33 per patient in the JuxtaCuresTM arm, with the trial arms crossing at 8 weeks. For those that did not heal the cost saving in the JuxtaCuresTM arm was £312.93 per patient with the trial arms crossing at 6 weeks of treatment. Figure 5 shows cost over time for both those that did and those that did not heal.

Nursing time. The mean duration of appointment for patients in the JuxtaCuresTM arm was 41.7 minutes (SD 13.1 minutes) versus 53.9 minutes (SD 6.6 minutes) which was significantly different (P = 0.003).

Sample size calculation. The data was used to determine the group sample sizes required to adequately power the study for time to ulcer healing. Sample sizes of 319 in each arm would be needed to achieve 80% power to detect the difference of 1.47 weeks with a significance level (alpha) of 0.05 using a two-sided two-sample t-test. Assuming mean (SD)¼12.17 (6.24) for JuxtaCuresTM and 13.64 (6.97) for bandaging. Adverse events. Adverse events were recorded as per the study protocol. No Serious Adverse Events occurred in the duration of this study.

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Discussion

This feasibility study has identified that randomising patients to standard compression therapy or a Velcro wrap device is acceptable, with recruitment and retention similar to or higher than in other venous trials.6,11 In addition, sample size calculations have identified that 319 participants in each cohort would be required to sufficiently power a study into healing times, necessitating a multicentre trial.

The percentage of patients within the study which healed within 6months was similar to previous venous trials.11,12 Despite the mean ulcer area in the JuxtaCuresTM arm being higher, there was a faster healing time, and greater reduction in ulcer area in both the healed and non-healed participants, although the study was not powered to reach significance. This could be due to the more consistent pressure that was applied by the JuxtaCuresTM device compared to bandaging, which is likely secondary to patient readjustment of the device when they feel it getting loose, or patients removing and replacing the device at the appropriate pressure.

It is well documented that compression bandaging loses pressure over time, with one study identifying a loss of interface pressure of at least 23.8% but up to 47.5% with 7 days of usage of a variety of bandages.

Pressure underneath Velcro devices has previously been studied by Kline et al.14 who identified that more accurate pressure was applied when using a built in pressure system which the JuxtaCuresTM includes. It is unknown whether this is due to repeated manipulation by the patient, or due to the material used, however the ability of the patient to manipulate the JuxtaCuresTM is likely to be a major reason for this. Further investigation using Velro wrap devices without a built-in pressure system are needed as the majority of devices on the market do not contain this function. A significant proportion of participants removed their compression during this study (although the duration of this was not documented), with 78% of those that removed the device in the JuxtaCuresTM arm, 96% when the dressing was not changed. This not only enabled patients to maintain hygiene and selfcare but does not appear to have adversely affected ulcer healing.

Quality of life surveys were undertaken within this feasibility study identifying a significantly improved quality of life at 3 months in the JuxtaCuresTM group according to EQ5D, however there was no significant difference at 1 or 6 months, and no difference in the disease specific scores. Looking at the EQ5D graphs (Appendix 1) it can be seen that patients in the JuxtaCuresTM arm were more self-caring, were more comfortable and had less anxiety and depression. One potential explanation for these results could be that at the 1 month timepoint both arms of the trial were being seen weekly and still getting used to their compression, whereas at the 3 month timepoint clinic visits were less frequent, and participants were accustomed to their treatment. The number of respondents was reduced in the 6 month quality of life surveys and the majority of patients at this point had healed. Quality of life, or patient satisfaction has previously been reported in Velcro wrap devices, but without the use of validated tools. Blecken et al.[15] found higher satisfaction rates in the JuxtaCureTM arm, with additional studies highlighting advantages for self-care, wearing your own shoes, patient compliance, empowerment, and reduced pain.[16–21] It is therefore prudent that quality of life is assessed further in both of these compression systems to further validate and investigate these findings with a greater sample size.

It is a common belief that clinicians are reluctant to use Velcro wrap devices due to the high upfront cost, despite previous reports that Velcro wrap devices have a reduced overall cost due to the reduction in clinic appointments and reduced nursing time required during these appointments.22 Although this was in a trial setting, the cost saving in the JuxtaCuresTM arm in this study was £222.01, with a break even point between the arms of the study between weeks 6 and 8 This certainly warrants further in-depth investigation as this could provide a

large cost saving. It also highlights the importance of identifying patients requiring an extending period of compression and those likely to rapidly heal to ensure that the most cost-effective treatment method is used. It is also important to consider the total number and length of appointments due to the burden of venous disease on the health service. Although this trial has identified a reduction in duration of appointment by 12.2 minutes, this does not take into account that typically fewer visits will also be required by patients in the JuxtaCuresTM device due to the ability to selfcare. In addition, both appointments would likely be of shorter duration due to the time spent on trial specific documentation rather than direct clinical care, therefore the proportion reduction in appointment is likely to be greater still. Given the significant cost of nursing time this is an important aspect to reduce cost in this cohort of patients.

This study is limited primarily by patient numbers in view that it is a single centre feasibility study. This has been sufficient to examine the primary outcomes, however the number of participants means that secondary outcomes should be interpreted with caution. In addition, the initial aim of recruiting 50 participants was reduced to 40 due to poor initial recruitment. This highlighted the importance of running a venous trial through dedicated leg ulcer clinics as well as secondary care particularly for a dressings only trial. The authors also accept that a proportion of patients will now also undergo venous intervention following the results of the EVRA trial,6 which could confound these results, however a significant proportion of patients still use compression therapy as their primary treatment, and all will require compression even if venous surgery is undertaken, therefore optimising compression therapy must remain a priority.

The results from this study show the potential for Velcro Wrap Devices to significantly alter the management of patients with venous ulceration. Further data is required to establish these results, however with equivocal healing rates, a potential for reduction in healing times, savings in cost, a reduction in clinic appointments, shorter clinic appointments, and potentially improved quality of life, Velcro Wrap Devices may enable improved care for patients with venous ulceration. This study has now been further developed and will progress into a multi-centre randomised controlled trial for which funding has been approved.

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Tables and Figures

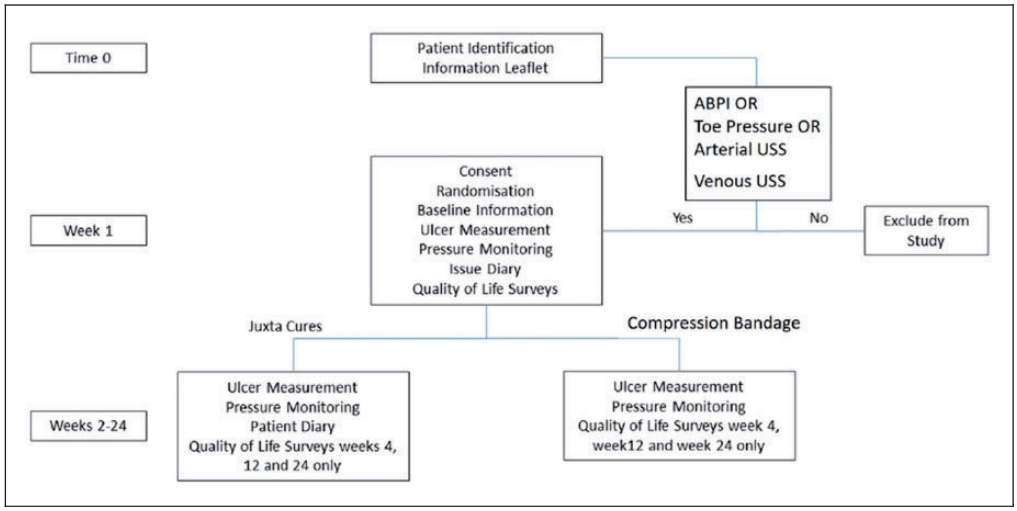

Figure 1. Flow diagram outlining the patient pathway.

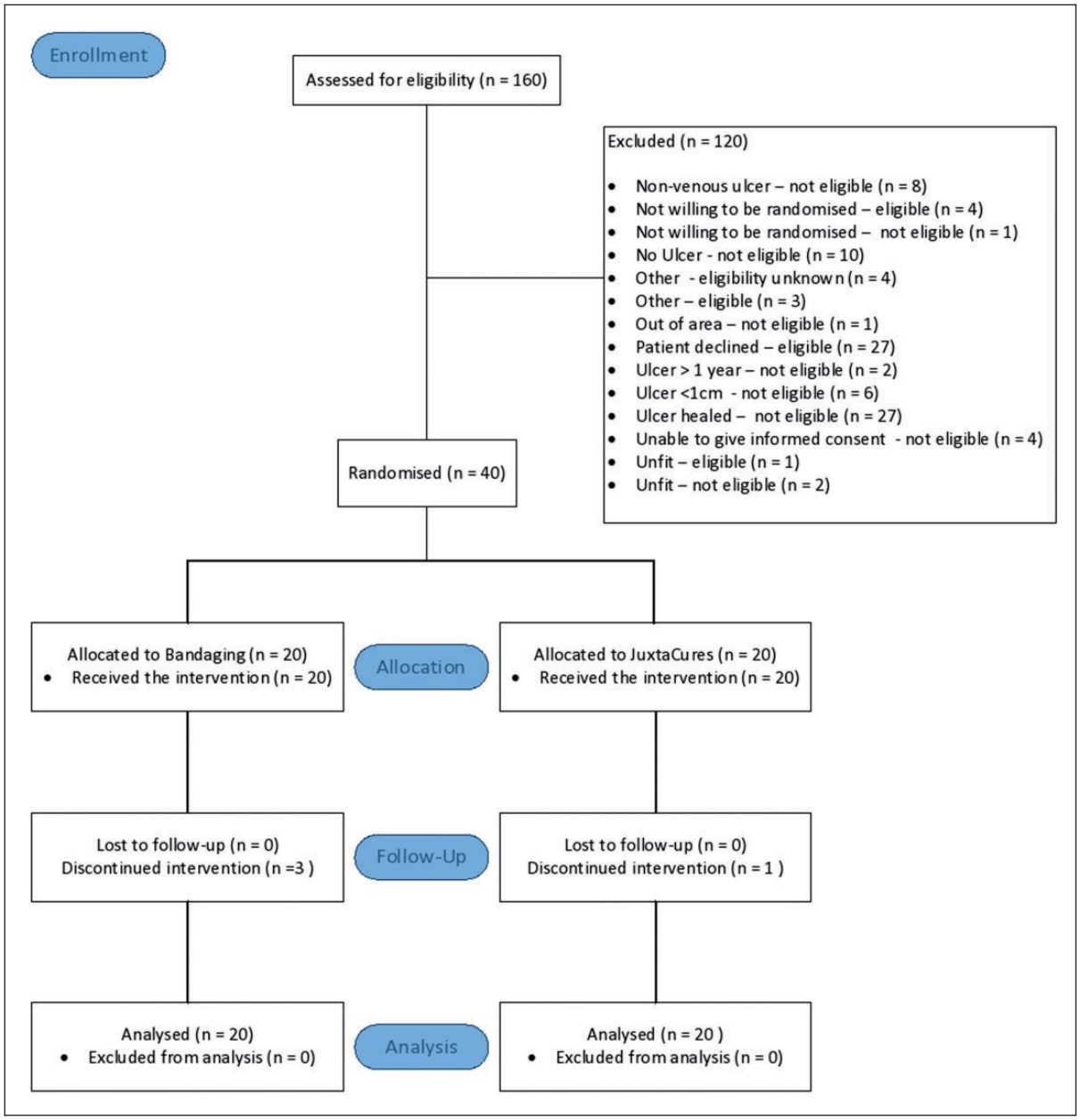

Figure 2. Consort diagram.

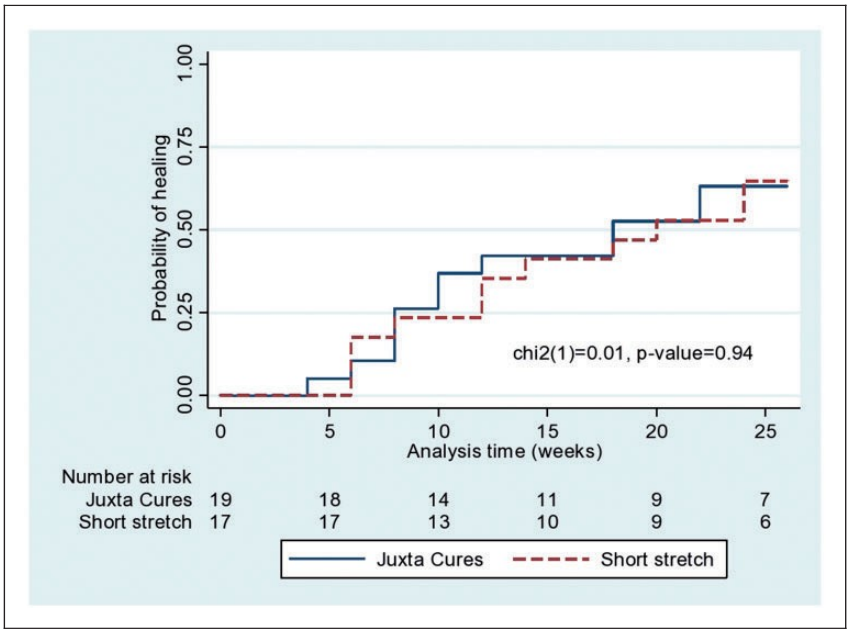

Figure 3. Kaplan Meier per protocol analysis reporting time to healing for all participants.

Table 1. Baseline data (mean (SD), or n (%)) below.

	Juxta-Cures™ (n ¼ 20)	Bandaging (n ¼ 20)
Age (yrs)	70 (11)	75 (9)
Male – n(%)	7 (35%)	11 (55%)
Smoker – n(%)		
Current smoker	4 (20%)	2 (10%)
Ex-smoker	4 (20%)	8 (40%)
COPD	0	2 (10%)
Cardiac History	0	1 (5%)
Stroke	1 (5%)	2 (10%)
Hypertension	6 (30%)	10 (50%)
Diabetes	2 (10%)	2 (10%)

Table 2. Ulcer surface area (cm^2) in participants that healed over time.

Arm	Stats	Baseline	1 month	3 months	6 months
Bandaging	N	11	11	6	0
	Mean	6.97	3.38	2.35	
	Sd	10.28	3.37	1.73	
	Min	1.1	0.01	0.1	
	Max	36.8	10.4	4.5	
Juxta-Cures™	N	12	11	5	0
	Mean	9.33	9.07	1	
	Sd	13.02	14.20	1.21	
	Min	0.9	0.6	0.1	
	Max	44.6	44.3	2.6	

Table 3. Ulcer surface area (cm^2) in participants that did not heal over time.

Arm	Stats	Baseline	1 month	3 months	6 months
Bandaging	N	6	6	6	6
	Mean	14.20	15.07	7.7	8.62
	Sd	3.83	6.10	5.65	6.97
	Min	7.8	6.6	2	1.6
	Max	17.8	21.5	16.2	19.6
Juxta-Cures™	N	7	7	7	7
	Mean	14.91	17.24	11.70	5.00
	Sd	15.58	20.99	16.57	8.05
	Min	1.7	1	0.6	0.3
	max	42	51.4	39.2	22.9

Table 4. The differences in median scores (t-score) between the JuxtaCures™ and Bandaging arm for each month.

Mean score	No. (JuxtaCures/bandage)	JuxtaCures	Bandage	P-value (Mann-Whitney U test)
DSQ_1-month	19/18	51.7 (47.4–53.2)	48.7 (45.2–55.7)	0.64
DSQ_3-month	16/14	51.0 (47.5–55.9)	49.6 (44.9–51.2)	0.38
DSQ_6-month	13/17	51.6 (47.1–53.3)	52.1 (49.6–54.8)	0.39