THE UNIVERSITY of York

CONFIDENTIAL

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VenUS IV Leg ulcer study

Baseline Questionnaire

| Participant ID I | Number |
|------------------|-------------------------------------------------------------------------------------------------|
| | umber will be allocated to the patient when the nurse telephones the randomisation service. |
| | enter the number in the boxes above after you have en given it by the randomisation service. |
| Today's Date | Day Month Year |

VenUS IV (Venous Ulcer Study IV - Compression hosiery for venous leg ulcers) A multicentre randomised trial, funded by the NIHR Health Technology Assessment Programme (International Standardised Randomised Controlled Trial No:ISRCTN49373072)

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study.

We would like to find out a little about your health.

Please answer ALL the questions. Although some of the questions may not seem relevant to yourself, they do give us valuable information.

If you find it difficult to answer a question, please do the best you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example, in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

| Do you drive a car? | Yes | \times |
|---------------------|-----|----------|
| | No | |

PLEASE USE A BLACK OR BLUE PEN FOR ALL OF THE QUESTIONS.

Please do not use a pencil or any other coloured pen.

Please read all the instructions for each section.

Section 1

This section asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Do not cross more than one box in each group.

Mobility

| I have no problems in walking about | |
|-------------------------------------------------|--|
| I have some problems in walking about | |
| I am confined to bed | |
| Self-Care | |
| I have no problems with self-care | |
| I have some problems washing or dressing myself | |

I am unable to wash or dress myself

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

Pain/Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

Anxiety/Depression

I am not anxious or depressed I am moderately anxious or depressed I am extremely anxious or depressed

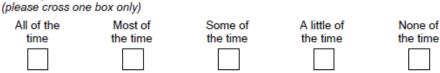
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| | Section 2 | | | | |
|----|-------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------|
| | | | | | |
| | keep track of I Answer every | now you feel and question by mar | riews about your he how well you are a king a cross in the a estion, please give | ble to do your us appropriate box. | sual activities. If you are |
| 1. | In general, would (please cross one | you say your hea e box only) | lth is: | | |
| | Excellent | Very Good | Good | Fair | Poor |
| 2. | | /acuum cleaner, b | alth limit you in mode owling or playing gol | | |
| | Yes, limited | a lot | Yes, limited a little | No, not li | mited at all |
| 3. | During a typical d If so, how much? (please cross one | | Ith limit you in climbi | ing several flights | of stairs? |
| | Yes, limited | a lot | /es, limited a little | No, not li [| mited at all |
| 4. | | ly activities as a r | ch of the time have yo esult of your physic | | ess than you would |
| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
| 5. | | her regular daily a | ch of the time have yo activities as a result o | | |
| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
| | | | | | |
| 6. | would have liked | in your work or ar e ms (such as feel | ch of the time have yo ny other regular daily ing depressed or any | activities as a res | |
| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
| | | | | | |
| | | | | | |

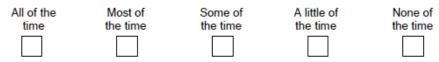
7. During the past 4 weeks, how much of the time have you done work or other activities less carefully than usual as a result of any emotional problems (such as feeling depressed or anxious)?



 During the past 4 weeks, how much did pain interfere with your normal work (both outside the home and housework)? (please cross one box only)



9. This question is about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that comes closest to the way you have been feeling. How much during the past 4 weeks have you felt calm and peaceful ? (please cross one box only)



10. This question is about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that comes closest to the way you have been feeling. How much during the past 4 weeks did you have a lot of energy ? (please cross one box only)





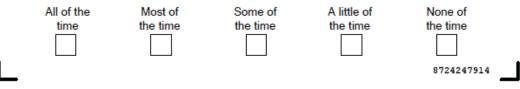
| Some of | A little of |
|----------|-------------|
| the time | the time |
| | |

| N | one of |
|----|--------|
| th | e time |
| | |

11. This question is about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that comes closest to the way you have been feeling. How much during the past 4 weeks have you felt downhearted and depressed? (please cross one box only)



12. During the past 4 weeks how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)? (please cross one box only)



Section 3

This section asks you some questions specifically about your legs Below are some questions about your views about your legs. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

 During the <u>past 4 weeks</u>, how often have you had any of the following leg problems? (For each question, please place a cross in one box ONLY)

| a. | Heavy legs | Every day | Several times a week | About once a week | Less than once a week | Never |
|----|-----------------------------------------------|--------------|----------------------------|-------------------------|-----------------------------|-------|
| b | Aching legs | | | | | |
| C. | Swelling | | | | | |
| d. | Night cramps | | | | | |
| e. | Heat or burning sensation | | | | | |
| f. | Restless legs | | | | | |
| g. | Throbbing | | | | | |
| h. | Itching | | | | | |
| i. | Tingling sensation (e.g. pins and needles) | | | | | |

| • | | | | • |
|----|---------------------------------------------------------------------------------------------|----------------------|---------------------------|--------|
| 2. | At what time of day is your leg problem <u>mo</u> (Please place a cross in one box ONLY) | st intense? | | |
| | | | On waking | |
| | | | At mid-day | |
| | | | At the end of the da | у |
| | | | During the night | |
| | | | At any time of day | |
| | | | Never | |
| 3. | <u>Compared to one year ago</u> , how would you (Please place a cross in one box ONLY) | rate your leg proble | m in general <u>now</u> ? | |
| | | Much better now th | an one year ago | |
| | | Somewhat better n | ow than one year ag | 0 |
| | | About the same no | w as one year ago | |
| | | Somewhat worse n | ow than one year ag | 0 |
| | | Much worse now th | nan one year ago | |
| | | l did not have any l | eg problem last year | |
| L | | | 0615; | 247915 |

4. The following items are about activities that you might do in a typical day. Does your <u>leg</u> <u>problem now limit you</u> in these activities? If so, how much? (Please place a cross in one box ONLY)

| | | l do not work | YE S , limited a lot | YE S , limited a little | NO, not limited at all |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------------------|--------------------------------------|------------------------------|
| a. | Daily activities at work | | | | |
| b. | Daily activities at home (e.g. house- work, ironing, doing odd jobs/repairs around the house, gardening etc) | | | | |
| C. | Social or leisure activities in which you are <u>standing</u> for long periods (e.g. parties, weddings, taking public transportation, shopping, etc.) | | | | |
| d. | Social or leisure activities in which you are <u>sitting</u> for long periods (e.g. going to the cinema or the theatre, travelling, etc.) | | | | |

 During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your leg problem</u>? (For each question, please place a cross in either the YES or NO box)

| a. | Cut down the amount of time you spent on work or other activities | YES | NO |
|----|--------------------------------------------------------------------------------------------|-----|----|
| b. | Accomplished less than you would like | | |
| C. | Were limited in the kind of work or other activites | | |
| d. | Had difficulty performing the work or other activities (for example, it took extra effort) | | |
| | | | |

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|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------|---|
| 6. | During the <u>past 4 weeks</u> , to what extent has your <u>leg problem</u> interfered w normal social activities with family, friends, neighbours or groups? (<i>Please place a cross in one box ONLY</i>) | vith your | | |
| | | Not at all | | |
| | | Slightly | | |
| | | Moderately | | |
| | | Quite a bit | | |
| | | Extremely | | |
| 7. | How much <u>leg</u> pain have you had during the <u>past 4 weeks</u> ? (Please place a cross in one box ONLY) | | | |
| | | None | | |
| | | Very mild | | |
| | | Mild | | |
| | | Moderate | | |
| | | Severe | | |
| | | Very severe | | |
| L | | 158624 | 17913 | ┛ |

8. These questions are about how you feel and how things have been with you <u>during the past 4 weeks as a result of your leg problem</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>:
(Please a creater in one hav ONLY)

(Please place a cross in one box ONLY)

| | | All of the Time | Most of the Time | A Good Bit of the Time | Some of the Time | A Little of the Time | None of the Time |
|----|-----------------------------------------------------------------------------|-----------------------|------------------------|------------------------------|------------------------|----------------------------|------------------------|
| a. | Have you felt concerned about the appearance of your leg(s)? | | | | | | |
| b. | Have you felt irritable? | | | | | | |
| C. | Have you felt a burden to your family or friends? | | | | | | |
| d. | Have you been worried about bumping into things? | | | | | | |
| e. | Has the appearance of your leg(s) influenced your choice of clothing? | | | | | | |

Section 4

We would now like to ask you about the pain related to your leg ulcer(s)

Instructions for completing the scale:

Place a cross in one of the boxes below to indicate the intensity of pain from your ulcer(s) over the last 24 hours, ranging from no pain to the worst pain imaginable.

1. How intense has the pain from your leg ulcer(s) been over the past 24 hours?

| | | | | | | | | | | | | | | | | | | | | | _ |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------|--------------|------------|---------------|-------------------------|-------------|--------------|-------------|-------|------|------|--------|-------|---------|-------|-------------|---------------------|----------------|-----|
| | 05 | 10 | 15 | 20 | 25 | 30 | 35 4 | 40 | 45 | 50 | 55 | 60 | 65 | 70 | 75 | 80 | 85 | 90 | 95 | 100 | |
| | No Pain | | | | | | | | | | | | | | | | | | | Worst imagi | |
| | (For office use only) | | | | | | | | | | | | | | | | | | | | |
| | Instruc Place a last 24 | a cros | s in | the | box | whic | h bes | stid | escri | bes t | | | | of p | ain f | from | you | r ulce | er(s) |) over t | the |
| 2. | How in | ntens | e ha | is th | e pa | in fi | rom y | you | ır leg | ulce | er(s) | be | en o | ver | the | pas | st 24 | hou | rs? | | |
| | No p | ain | | Ve | ery m | ild p | ain | | Mil [| d pai | 'n | | Se | ever | e pa | in | Ve | ery se [| ever | e pain | |
| | Section 5. In order to accurately measure the cost of different leg ulcer treatments, we would like to know the number of times you have seen a health professional (i.e. doctor or nurse). If the health care you received was related to your leg ulcers, record this in the 'leg ulcer' column. If the health care was for any other reason, enter this in the 'other' column. Please answer every question, even if the answer is "0". | | | | | | | | | | | | | | | | | | | | |
| | Please | e fill ir | n bot | th bo | oxes, | for | exam | ple | ∷if se | een t | hree | tim | es | 0 | 3 | | | | | | |
| | | | | | | | | | | lf se | en O | tim | ies | 0 | 0 | | | | | | |
| | Care fr | | | | | | | | | | | | | | | | | | | | |
| 1. | In the I health | | | | | | ny tir | nes | s hav | e yoi | u cor | nsul | | Beca | - | e of | he fo | | ng N Oth reas | er | |
| | Genera (please | al Pra e <i>reco</i> | actiti ord t | oner he n | (GP umb |) at er of | docto f <i>tim</i> e | or's sii | surge the | ery boxe | s) | | | | | nter '0 | 00' | | | enter '0 | 0' |
| | Genera (please | | | | | | | | | boxe | es) | | | lf noi | ne en | nter 'C | 00' | f ı | none | enter '0 | 0' |
| | | | | | | | | | | | | | | | | | | | 7610 | 24791 | 7 |
| | | | | | | | | | | | | | | | | | | | | | |

| A NURSE at your doctor's surgery (please record the number of times in the boxes) | Because of leg ulcer | Other reason |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|
| A NURSE in your home (please record the number of times in the boxes) | If none enter '00' | If none enter '00' |
| A DOCTOR in a hospital out-patient clinic or other location (please record the number of times in the boxes) | If none enter '00' | If none enter '00' |
| A NURSE in a hospital out-patient clinic or other location (please record the number of times in the boxes) | If none enter '00' | If none enter '00' |
| In the last <u>3 months</u> how many times have you: Been admitted to hospital without staying overnight (i.e. for a minor procedure or day surgery)? | Because of leg ulcer | Other reason |
| Been admitted to hospital as an in-patient (i.e. stayed for 1 or more nights)? | If none enter '00' | If none enter '00' |
| If, over the last 3 months, you have been a hospital in-patient, please record how many nights you stayed in hospital. If you have stayed in hospital more than once please add the nights you stayed for each visit together and record the total. | If none enter '00' | If none enter '00' |

2.

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any general comments about your ulcer, the study, or this questionnaire, please write them below.