

Dear

A STUDY OF PATIENTS' VIEWS ON RECOVERY FROM TREATMENT FOR VARICOSE VEINS

We approached you today to ask if you would be willing to take part in a discussion group. In these discussion groups we are speaking to people who have recently had treatment for varicose veins to find out about what was important to them during in their recovery. The discussion group would take place in a few weeks time. For a couple of days after the discussion group we are asking participants to fill in a diary. As you have recently been treated for varicose veins, we are asking you to consider participating and sharing your views.

We enclose a leaflet giving you further information about the study. It explains why the study is being done and what you would need to do if you were willing to take part in the study. After you have read this letter and the information leaflet, if you would like to take part, please fill in the form at the bottom of this letter and return it in the envelope provided (no stamp is needed). Travelling expenses to and from the discussion group will be reimbursed, together with any parking or child-care costs. If you would like to participate but cannot travel to the discussion group (which would be held in Aberdeen) we would still like to speak with you and get your opinions by telephone or in a face-to-face interview.

Although we would be very pleased if you did join a discussion group or agree to be interviewed, we stress that you are under no obligation to participate in the study.

If you have any questions about the study, please contact the researcher by telephone on 01224 XXXXXXX or myself on 01224 XXXXXXX.

Yours sincerely
Dr Julie Brittenden

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Name
Address
Tel no

Yes, I would like to take part in a discussion group or an interview. I give permission for a member of the research team to contact me to arrange this.

Please return this in the envelope provided. No stamp is needed.



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The **BRAWO** Study

A STUDY OF PATIENTS' VIEWS ON RECOVERY FROM TREATMENT FOR VARICOSE VEINS

Patient Information Leaflet

Introduction

You are being invited to take part in a research study. In this study, we are interviewing people who have recently had treatment for varicose veins to find out about what was important to them during their recovery. As you have had treatment for varicose veins, we are asking you to consider participating and sharing your views. We are using the information from the interviews to develop a questionnaire to use in another research study of people having treatment for varicose veins. Collecting information from people like yourself who have had treatment for varicose veins will help us make sure that this questionnaire will ask the appropriate questions.

Information sheet for patients approached at clinic, Version 1, 21 August 2008

What is the purpose of this study?

As someone who has recently had treatment for varicose veins, you might be able to help us. We are keen to hear from people like you about their experiences and thoughts about the treatment and their recovery.

The information from interviews and discussion groups will tell us what is important for people during their recovery from treatment for varicose veins. From this information, we will develop a questionnaire to use in a larger study of treatments for varicose veins.

What will I have to do to take part?

If you agree to take part in our study, we would ask you to participate in a discussion group with between five and seven other people who have had treatment for varicose veins. In total, we hope that approximately twenty-one people will take part in this study. The discussion group would take place a few weeks after your treatment.

A member of the study team will lead the discussion group and ask some questions. The discussion will last about one hour and thirty minutes, and will include a refreshment break. The discussion will take place in the Health Sciences Research Unit at the University of Aberdeen, and travel, parking and child-care expenses will be reimbursed.

The discussion will be tape-recorded. The tape recording will be treated confidentially.

If you want to take part in the study but cannot manage to attend a discussion group, it might be possible to organise a one-to-one interview with you, either in person or over the telephone.

After the discussion group or interview we will ask you to fill in a diary for a couple of days. We will give you a pre-paid envelope to return this to the study office.

What will be done with what I say?

We will use the transcript of the discussion to create a summary of all the opinions that were expressed. The tape and transcript will be stored safely and will be destroyed after the end of the study.

The only people who will be able to hear the tape-recorded discussion will be the research team and a secretary at the Health Services Research Unit at the University of Aberdeen (who will transcribe the tape). No information will be published that could identify you.

What will be done with what I write in my diary?

We will create a summary of the information contained in all the diaries. The diary will be stored safely and destroyed at the end of the study.

What are the possible risks of taking part?

We do not think that taking part in the discussion will have any risks for your health. Your health care will not be affected.

What are the possible benefits of taking part?

We hope that you will enjoy taking part in the discussion. You might find it interesting to meet and talk with other people who have had treatment for varicose veins. By participating in a discussion, you will also be helping the research team to understand issues from the perspectives of people who have had treatment for varicose veins. If you enjoy taking part in this research, there may be an opportunity for you to continue advising the research team by joining our panel of service users.

Will I be able to find out the results of the study?

If you wish, the researcher will send you a written summary of the findings.

Do I have to take part?

No. If you do not want to take part in a discussion that is fine. You do not have to give a reason. If you agree to join a discussion group, but later change your mind, you can withdraw your consent at any time. Your care will not be affected.

What should I do if I do NOT want to take part?

If you do not want to take part in a discussion, you do not need to do anything. Thank you for reading about the study.

What should I do if I DO wish to take part?

If you might like to take part in a discussion group, you can let us know by filling in the form at the bottom of your letter, and returning it to us in the envelope provided (you do not need a stamp). If you do participate we will ask you to sign a consent form when you come to the discussion group. You will be given a copy of this consent form to keep.

Who has reviewed the study?

This study has been reviewed by the research team and the North of Scotland Research Ethics Committee.

Any questions?

If you have any questions at all about the study, you can contact a member of the research team on the telephone numbers below.



The **BRaVO** Study

A study of patients' views on recovery from treatment for varicose veins

Study No

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CONSENT FORM

Name of Researcher:

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PLEASE INITIAL BOX

1. I confirm that I have read and understand the information sheet dated May 2008 (version 1) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that the discussions I have about the study may be tape recorded but that these will be kept confidentially and I will not be identified individually.
4. I agree to take part in the study on views of patients about recovery from treatment for varicose veins.

Name of patient

Date

Signature

Name of person taking consent

Date

Signature

1 for patient; 1 for researcher

INTERVIEW TOPIC GUIDE, BRAVVO STUDY

1. Introductions and Review

- Introduce people in the room
- Objective of BRAVVO study
- What is asked of participants inc length of interview
- Intention to audiotape
- Confidentiality procedures
- Participants' rights – to withdraw, ask for tape to be switched off etc

2. Check

- Any questions
- Procedures for reimbursement of costs

3. Sound check

- Audibility of tape
- Sound quality of each participant's voice (for transcriber)

4. Interview

Let's begin. First of all can you please tell us about your experience of the treatment itself.

(PROMPTS - Can you remember...

- What happened?
- Who was there?
- How you felt?
- How you were told to care for the leg after treatment?
- How long after the treatment did you keep the support stockings on for?

As I've said, we are interested in the **milestones** you have achieved throughout your recovery from treatment.

A. So can you tell us some of the *things that you looked forward to doing for the first time* immediately after your treatment for varicose veins?

(PROMPTS AS NEEDED PRESENTED AS DOT POINTS BELOW):

- While you were still at the hospital? After you returned home?
- After the first week?
- Anything that you had not been able to do before your treatment?
- When did you do these activities – how long after your treatment?

B. Are there any activities that you *were worried about doing for the first time* after your treatment?

- What activities were painful?
- Were there any activities that you were worried might do damage?
- When did you do these activities – how long after your treatment?
- What happened when you did them?

C. Are there any activities that you *felt particularly pleased that you had achieved when you did them for the first time, after your treatment*?

- When did you do these activities – how long after your treatment?
- How did it feel?

- D. You all had treatment a few weeks ago – is that right? Are there any *further milestones that you are still looking forward to doing or expecting to do* that you've not been able to do yet?
- Anything else?
- E. Is there anything else you remember about your recovery that you would like to mention?

Thank you very much for your help. I will also be talking to patients who had different treatments and we will write to you to let you know what we find out in this study. If you have got any comments about the focus group, or anything else about your treatment or recovery that you would like to tell us about, there are feedback sheets on the table. You can fill one of these in now, or if you want to take a copy home we will give you a reply paid envelope to send them back