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# A trial of a brief intervention to improve emotional distress after thrombosis

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| **Submission date**<br>23/09/2015 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>29/09/2015 | **Overall study status**<br>Completed | |
| **Last Edited**<br>06/06/2018 | **Condition category**<br>Circulatory System | |

## Plain English summary of protocol

Background and study aims
Venous thromboembolism (VTE) is a medical condition where a blood clot forms in a vein. It is a serious condition that is potentially fatal. VTE can refer to a deep vein thrombosis (DVT), which is a blood clot in one of the deep veins in the body (most commonly a leg) or pulmonary embolism, which is a blood clot in the blood vessel that transports blood from the heart to the lungs. Many patients who have suffered a VTE experience a significant amount of anxiety and post-trauma stress afterwards. This study investigates a brief intervention (or programme) that has been developed to reduce this distress and help patients cope better. The intervention is brief, easy for patients to use in their own home and consists of information and self-help tools known to be of benefit , including information about the illness and treatment as well as cognitive behavioural and mindfulness strategies for managing anxiety.

Who can participate?
Adults (aged 18-70) that have had a VTE within the last 4 weeks.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are provided with the brief intervention. Those in group 2 (control) are not. They are all asked to complete a series of questionnaires. After one month all participants are asked to complete the questionnaires again, measuring how anxious they feel and how they feel that their VTE has affected them. Participants in group 1 are also asked to give feedback on the intervention.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Nevill Hall Hospital, Abergavenny (Wales, UK)

When is the study starting and how long is it expected to run for?
October 2015 to May 2016

Who is funding the study?
Nevill Hall Thrombosis Research Alliance (Wales, UK)

Who is the main contact?
1. Dr Rachael Hunter (public)
2. Professor Paul Bennett (scientific)

# Contact information

### Type(s)
Public

### Contact name
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### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

## Scientific Title
Improving psychological outcomes after venous thromboembolism (VTE): a pilot randomised control trial (RCT) of a brief intervention

## Study objectives
The psychological outcomes for patients using the intervention after a venous thromboembolism (as assessed by measures of illness perceptions, health anxiety, post-trauma stress, anxiety and depression) will be improved compared to patients not receiving the intervention.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Wales REC 6, 09/11/2015, ref: 15/WA/0382

## Study design
Single-centre pilot randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format

## Health condition(s) or problem(s) studied
Venous thromboembolism (VTE) and its impact on patients emotional and psychological well-being.

## Interventions
A psycho-educational tool to reduce distress and improve psychological outcomes. It includes information about VTE and self-help tools for managing anxiety and low mood.

Participants are randomly allocated into one of two groups. Those in the intervention group are provided with the brief intervention. Those in the control group are not.

After one month patients we be asked to complete post-intervention outcome measures and provide feedback on the intervention if they received it. The results will be analysed to identify any effect or impact of the intervention.

## Intervention Type
Other

### Primary outcome measure
Pre and post intervention questionnaires will be completed by patients. The questionnaire incorporates robust, standardised measures widely used in psychological research and include:
1. The Hospital Anxiety and Depression Scale (HADS)
2. Impact of Events Scale (IES) – Fear & dissociation Subscale
3. Brief illness perception questionnaire (IPQ)
4. Health Anxiety Inventory (HAI)
Measured at baseline and after one month

### Secondary outcome measures
Qualitative and verbatim feedback from participants on the usefulness of the intervention, measured at one month post-intervention

### Overall study start date
01/10/2015

### Completion date
30/05/2016

## Eligibility

### Key inclusion criteria
1. 18-70 years
2. Either gender
3. Experienced a VTE in the previous 4 weeks

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
Both

### Target number of participants
24

### Key exclusion criteria
Patients diagnosed with serious comorbidities such as terminal cancer

### Date of first enrolment
01/10/2015

**Date of final enrolment**
30/05/2016

# Locations

**Countries of recruitment**
United Kingdom

Wales

**Study participating centre**
**Nevill Hall Hospital**
Brecon Road
Abergavenny
Monmouthshire, Wales
United Kingdom
NP7 7EG

# Sponsor information

**Organisation**
Swansea University

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**Sponsor type**
University/education

**ROR**
https://ror.org/053fq8t95

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**

# Results and Publications

## Publication and dissemination plan

This research will be submitted as part of a student PhD at Swansea University. It is hoped articles derived from the data will be published in peer reviewed journals and that this the results will also enable the development of a full RCT of the intervention.

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |