

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

Submission date 23/09/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/06/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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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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 will 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

Sponsor details

Singleton Park

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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