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Nurse-facilitated adherence therapy for haemophilia

Submission date
27/02/2014

Recruitment status
No longer recruiting

Registration date
01/04/2014

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Haematological Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Haemophilia is an inherited condition that affects the blood's ability to clot, causing the patient to bleed for longer than usual. Clotting factor treatment is the most effective method for preventing both life-threatening bleeding and long-term damage to the muscles and skeleton. Non-adherence to treatment is a major problem faced by doctors treating haemophilia. Research suggests that up to 20% of people living with haemophilia do not fully follow their prescribed treatment. Therefore, we need to find methods to improve patient adherence to treatment. The aim of this study is to find out if nurse-facilitated Adherence Therapy for haemophilia improves patient adherence to treatment.

Who can participate?
Patients over 12 years of age with haemophilia A or B being treated at one of the participating centres

What does the study involve?
Half of the participants are randomly allocated to receive Adherence Therapy for Haemophilia and half continue to receive their usual treatment. Participants are initially asked to complete a short questionnaire. The answers given on this questionnaire help the research team decide if Adherence Therapy may be useful. Nurses based in the Adherence Therapy groups are provided with 5 days training in Haemophilia Adherence Therapy and apply the techniques learnt within patient review appointments with identified and consenting patients. Participants are offered six 20-30 minute Adherence Therapy sessions; this may be face-to-face or via the telephone as preferred. The participant is also asked to complete some short treatment-related work books. Adherence therapy is a brief individual approach aimed at facilitating a process of shared decision making where service users and doctors work toward agreed goals. The intervention consists of six phases which form the core of the therapy: assessment, treatment problem solving, treatment timeline, exploring ambivalence, discussing beliefs and concerns about treatment, and treatment in the future. The aim is to achieve a mutual decision about medication between the individual and the doctor.

What are the possible benefits and risks of participating?
Adherence Therapy aims to help people with haemophilia make the best use of their prescribed

treatments and therefore hopefully improve the use of treatment and reduce the occurrence of bleeds. Although Adherence Therapy has not been used in haemophilia before, in some other disorders such as high blood pressure it has helped people use their treatment better and helped them control their health problems. By taking part in this study there are no risks of physical injury or harm. It is also unlikely that taking part in the study would result in any emotional or psychological distress as it is conducted by Nurse Specialists who have experience in dealing with the participants.

Where is the study run from?
The study is being run by researchers at Canterbury Christ Church University in the UK. The trial will take place at 10 haemophilia comprehensive care centres across the UK.

When is the study starting and how long is it expected to run for?
The study started recruiting patients in October 2014 and will run for 18 months from this date.

Who is funding the study?
Pfizer (UK)

Who is the main contact?
Mr Martin Bedford
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13/SC/0549

Study information

Scientific Title
Nurse-facilitated Adherence Therapy for Haemophilia (AnTHem Trial): a cluster randomised controlled trial

Acronym
AnTHem

Study objectives
Haemophilia nursing staff trained in adherence therapy can improve patient adherence to clotting factor replacement therapy.

A secondary aim is to explore the patient's perception of adherence therapy and its impact upon their perceptions about their prescribed treatment (through the patient workbook).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS NRES Committee South Central - Oxford A, REC ref: 13/SC/0549, IRAS project ID: 139940

Study design
Prospective parallel group cluster randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Martin.Bedford@canterbury.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Haemophilia A or B

Interventions
Ten nurse specialists based at 10 different UK NHS Haemophilia Comprehensive Care Centres will be randomised into either intervention or control groups; partcipants in the control group will be offered treatment as usual. Nurses based in the intervention groups will be provided with 5 days training in Haemophilia Adherence Therapy and will apply the techniques learnt with identified and consenting patients within patient review appointments. Treatment adherence

will be measured using the VERITASpro measure at baseline, immediately post intervention and at six months follow-up. Levels of patient treatment adherence in the intervention group will be compared with the control group. The aim is to recruit a total of at least 158 patients.

Patients being treated by nurses in the intervention group will be offered 6 x 20-30 minute Adherence Therapy sessions; this may be face to face or via the telephone as preferred. The participants will also be asked to complete some short treatment-related work books, which will be used to gather qualitative data about their experiences of the intervention. Adherence therapy is a brief individual therapy approach aimed at facilitating a process of shared decision making where service users and clinicians work toward agreed goals. The intervention consists of six phases which form the core of the therapy. The aim is to achieve a mutual decision about medication between the individual and the clinician.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Adherence to haemophilia therapy will be measured at baseline, post intervention and at 6 months follow-up using the 24-item VERITASpro tool (terminology adapted to suit the UK setting). The VERITASPro is a reliable and valid measure of adherence to prophylactic treatment of haemophilia. Internal consistency for the total VERITASPro score and all subscales was good to excellent; test-retest reliability correlations were very strong. Validation measures were strongly correlated with VERITASPro scores. This self-reported tool allows measurement of overall adherence to therapy, but also through the use of six subscales: differential scoring of timing, dosing, planning, remembering, skipping and communicating. Low scores represent greater levels of adherence to therapy. The literature utilising VERITASpro indicates a population range with 45 point median and 57 point high score (indicating a significant level of nonadherence). The study will therefore identify and recruit patients with a score of 57 and measure their adherence at the three time points. Participants will be asked to return the completed measures (at time points two and three) to a member of the research team who is blinded to treatment allocation.

Secondary outcome measures
Clinician ratings of adherence will be measured at the three time points using Kemp's Composite measure of compliance. Kemp et al.'s (1998) observer rating of compliance uses a seven-point scale, ranging from 1 (complete refusal) to 7 (active participation in treatment). Concurrent validity has been established by correlating scores with the Hogan Drug Attitude Inventory (DAI30; Hogan, Awad, & Eastwood, 1983; Kemp et al., 1998).
This quantitative data will be supplemented with thematically analysed qualitative excerpts from patient work books and staff logs in order to gain insights into both patient and clinician experiences of the AnTHem intervention.

Overall study start date
01/03/2014

Completion date
01/09/2015

Eligibility

Key inclusion criteria
1. Patients with Haemophilia A or B being treated at one of the 10 haemophilia comprehensive care centres included in the trial
2. Aged 12 years or over who have been self-infusing clotting factor for a minimum of 6 months
3. Able to provide informed consent (or able to consent with parental/guardian agreement and signature)
4. With identified nonadherence issues (as determined by a score of ≥57 on the VERITASpro assessment measure)
5. English speaking and literate to a degree necessary to understand the PIS and the VERITASpro assessment measure and to complete the AnTHem workbook

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
158

Key exclusion criteria
1. Patients that do not meet the abovementioned criteria
2. Patients identified as having nontransient inhibitors to factor VIII or IX
3. Patients who during the period of the research develop nontransient inhibitors to factor VIII or IX

Date of first enrolment
01/10/2014

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Canterbury Christ Church University
Canterbury
United Kingdom
CT1 1QU

Sponsor information

Organisation
Canterbury Christ Church University (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/0489ggv38

Funder(s)

Funder type
Industry

Funder Name
Pfizer UK - Ref. WI174071

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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