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The use of health belief derived interventions to improve the ability of patients to take medicines for pulmonary arterial hypertension

Submission date
09/10/2018

Recruitment status
No longer recruiting

Registration date
16/10/2018

Overall study status
Completed

Last Edited
24/10/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Pulmonary Arterial Hypertension (PAH) is a rare, incurable disease of the heart and lungs, causing significant shortness of breath and tiredness to patients. Patients living with PAH face the burden of having to take complex medication with significant limiting side effects. It is known from other studies that medicines are not always taken by patients as instructed. This is termed non-adherence. It is thought that at least 50% of patients with chronic diseases do not adhere to their medication instructions. Failure to correctly take medicines limits the achieved benefits. Additionally, the doctor often needs to escalate therapies to control symptoms, putting the patient at unnecessary side effects. The cost of wasted and ineffective therapies due to non-adherence is very significant. Other studies using simple interventions have resulted in limited success. Recent studies have sought to uncover patients inner beliefs about medicines in order to more accurately understand an individuals circumstances and barriers to taking medicines. Interventions derived from this have been shown to improve medication taking. The aim of this study is to interview patients on health beliefs and medication-taking behaviours, in order to produce a personalised action plan to improve their ability to take medicines.

Who can participate?
Adults with pulmonary arterial hypertension currently being treated in the Belfast Hospitals in Northern Ireland

What does the study involve?
The study does not require any additional blood tests or medicines. Each participant will be asked to complete study questionnaires each month for a period of 12 months. Every three months each participant will be seen by a specialist pharmacist who will assess their medicines. At month 3, the pharmacist will interview participants on how they take their medicines. This will take approximately one hour and be completely confidential. Information obtained from this interview will result in several interventions that is aimed at improving participants ability to take medicines and improve confidence with these medicines.

What are the possible benefits and risks to participants?
The study has been designed to understand how patients take medicines, and their thoughts and views on medicines. The potential benefits include more dedicated time with a researcher and nurse with expertise in PAH to discuss all issues, and more information on their medicines with the opportunity to discuss their expectations of medicines. Participants will gain the opportunity to discuss their beliefs about medicines with a researcher. This will help identify any difficulties they may have with taking medicines as instructed. The researcher will not be judgmental. It is to help participants gain full potential from taking medicines. Participants will be provided with a personalised set of recommendations (known as the 'ACTION PLAN') to further improve how they take medicines. This is planned to improve not only participants understanding of PAH medicines but all their medicines. This may help participants become more confident in reducing the burden of future treatments.
There are no major disadvantages and risks of taking part in this study. The need to attend a 3 monthly PAH clinic could be more frequent than participants are currently attending. There is a possibility of becoming upset or distressed when discussing the condition with the researcher, and whilst completing the questionnaires. Participants may find that having someone they know with them can help.

Where is the study run from?
1. Royal Victoria Hospital, Belfast (UK)
2. Belfast City Hospital, Belfast (UK)
This will be the same hospital as the one participants are currently attend for their PAH clinic appointments.

When is the study starting and how long is it expected to run for?
October 2016 to May 2019

Who is funding the study?
Heart Trust Fund (UK)

Who is the main contact?
Michael Jackson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
17/NI/0038

Study information

Scientific Title
Evaluating the use of a theory-based intervention to improve medication-taking behaviours: s longitudinal study in patients with pulmonary arterial hypertension

Study objectives
Primary research question:
Does the use of a health belief derived intervention improve medication-taking behaviours in patients with pulmonary hypertension?

The statement 'health belief derived intervention' refers to using a theoretical plan that enables the pharmacist to uncover patients ability and barriers to taking medicines, so that a personalised action plan can be introduced to overcome any barriers. The statement 'medication-taking behaviours' refer to how patients take medicines. This is assessed by understanding their beliefs through interview in addition to whether or not they actually take their medicines (measured as adherence).

The objectives of this study are as follows:
1. To measure patients ability to take Pulmonary Hypertension (PH) medicines each month
2. To interview patients on medication behaviours at month 3 so that any issues can be identified
3. To formulate a personalised set of recommendations that are agreed between patient and pharmacist
4. To monitor any change in medication adherence before and after the intervention has been provided to the patient
This will assess the impact of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for research Ethics Committees Northern Ireland (ORECNI), 08/05/2017, REC ref: 17/NI /0038, IRAS project ID: 211692

Primary study design
Interventional

Study design
Interventional mixed methods non-randomised longitudinal study

Study type(s)
Other

Health condition(s) or problem(s) studied
Pulmonary arterial hypertension (PAH)

Interventions
As this is a longitudinal study, all participants will act as their own control. Medication adherence (defined using the medicines adherence rating scale (MARS), and PAH medication counts) will be assessed 6 months before and after the study interventions. Each intervention will be personalised to participants own beliefs, aimed at improving a component of medication-taking behaviours. Examples of interventions include correction of negative and incorrect beliefs in disease or medication, delivery of medication and disease education, optimisation of medication, use of medication compliance aids, use of mobile phone medication reminder apps, and use of motivational techniques.
All participants will compete a beliefs about medicines questionnaire (BMQ) at month 3 which will be used to inform discussion though a semi-structured interview. Transcribed patient interview transcripts will be coded using phenomenological methodology and thematic analysis based on a modified health belief model.
Interventions are to be individualised to participants medication-taking behaviours and medication beliefs. The ranking of interventions will be undertaken by two researchers based on three principles:
1. Likely impact on medication-taking behaviours
2. Patient acceptability
3. Ease of administration
Examples of interventions will include correction of negative and incorrect beliefs in disease or medication, delivery of medication and disease education, optimisation of medication, use of medication compliance aids, use of mobile phone medication reminder apps and use of motivational techniques.
Each participant will discuss the interventions with one researcher at month 6. During this meeting the participant will agree to complete the recommendations over a stated period of time. This length of time will be dependent upon the intervention. Participants will be followed up for a further 6 months to ascertain the impact of the interventions on medication-taking behaviours and medication adherence.

Intervention Type
Behavioural

Primary outcome(s)
1. Changes in medication adherence, assessed using the Medication Adherence Rating Scale (MARS). MARS is assessed each month by participant. The analysis will compare the average score of MARS from months 0-3 with the average MARS score from months 9-12
2. Change in patient medication beliefs, assessed using the following between months 3 and 12:
2.1. Changes in thematic outcomes obtained from the patient population of a semi-structured interviews between the two time points using interpretive phenomenological analysis (IPA)
2.2. Changes in Beliefs about Medication Questionnaire (BMQ) between the two time points. This will be analysed as intra-patient differences in addition to population differences and as differences in beliefs between high adherent and low adherent groups

Key secondary outcome(s)
1. Relationship between patient psychological wellbeing and medication adherence, assessed over the 12 month study period. Psychological wellbeing is assessed using the Depression, Anxiety, Stress Scale (DASS) and medication adherence is assessed using the Medication Adherence Rating Scale (MARS).). Each participant will complete both questionnaire each month for a total of 12 months. The analysis will examine the relationship between the two scales
2. Change in participant medication burden, assessed using a bespoke study scale over the 12 month period. Medication burden is collected at the baseline and at months 3, 6, 9 and 12. The

study will examine whether there is a relationship between variations in medication adherence and other study measures (medication adherence, disease parameters, DASS-21 score)
3. Change in medication adherence, assessed using monthly MARS over the 12 month period
4. The relationship between quality of life measurements at the baseline and at months 3, 6, 9 and 12 with other study parameters (medication burden, disease burden, medication adherence, DASS-21), assessed using the following:
4.1. Short Form Health Survey (SF-36) questionnaire to capture global quality of life
4.2. EMPHASIS-10 questionnaire to capture disease specific indices

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Diagnosis of pulmonary arterial hypertension (PAH)
2. Attending the regional outpatient pulmonary hypertension clinic in the Belfast Trust hospitals (UK)
3. Aged 18 years or over
4. Have a life-expectancy of at least 1 year (assessed by consultant within clinic)
5. Receiving at least one targeted medicine for PAH
6. No significant dementia or learning disability (assessed by consultant within study)
7. Ability to provide full and informed consent
8. Fluent in verbal and written English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. No capacity to consent
2. Patients in whom there is reason to believe will not complete study
3. Current illicit drug use or dependency

Date of first enrolment
01/10/2017

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Royal Victoria Hospital
Grosvenor Road
Belfast
United Kingdom
BT126BA

Study participating centre
Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Sponsor information

Organisation
University of Bradford

ROR
https://ror.org/00vs8d940

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Heart Trust Fund, Royal Victoria Hospital

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to a stipulation in the original ethics submission. Participants data will be held at the local study hospital for a maximum of five years

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet		16/10/2018	16/10/2018	No	Yes