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Understanding adherence to blood pressure treatment and statins

Submission date
09/12/2019

Recruitment status
No longer recruiting

Registration date
14/01/2020

Overall study status
Completed

Last Edited
01/02/2024

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
High blood pressure (hypertension) is the largest contributor to global mortality and a major risk factor for heart disease and stroke. About 30% of the UK population suffer from hypertension. A direct association has been found between survival and adherence to medication for high blood pressure (statin therapy). However, medication adherence is a significant problem with around 50% of patients with cardiovascular disease or its major risk factors not regularly taking their medications (adherence) one year after starting treatment.

The aim of this research is to assess adherence to high blood pressure and statin medication in a UK population through direct (urine testing) and self-report measures (questionnaire). These results can be combined with data from a survey we have designed and validated, to identify psychological barriers and facilitators to adherence. The findings will inform the design and deployment of new interventions based on behavioural science to improve adherence and thus patient outcomes.

Who can participate?
Patients at the GP surgery who are taking statins, or medication for high blood pressure

What does the study involve?
Taking part in the study will involve providing a small amount of personal information, most of which is collected routinely by the doctor. Participants will be asked to give a urine sample to check if the medicines prescribed are having the expected effect. Finally, participants will complete a simple questionnaire which will ask about experiences of taking blood pressure medications or statins and reasons why this may be difficult or easy. This will take approximately 20 minutes to complete. If necessary, medical notes may be accessed by members of the research team to check certain details.

What are the possible benefits and risks of participating?
There are no direct benefits but the study will allow us to design ways to help people to take their medications and improve their blood pressure or cholesterol control in the future.

Taking part in the study involves providing a minimal amount of personal information, giving a urine sample and answering a simple questionnaire. There is no reasonable expectation that any harm will arise from this.

Where is the study run from?
Imperial College Healthcare NHS Trust, UK

When is the study starting and how long is it expected to run for?
April 2016 to January 2023

Who is funding the study?
1. Robert Luff Foundation, UK
2. NIHR Imperial Patient Safety Translational Research Centre, UK

Who is the main contact?
Dr Gaby Judah
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
200751

Protocol serial number
38504

Study information

Scientific Title
Understanding the psychological determinants of medication adherence in patients taking anti-hypertensive and statin medication in the United Kingdom

Study objectives
Current study hypothesis as of 29/01/2020:
Research questions:
- What is the self-reported and objectively measured rate of anti-hypertensive and statin medication non-adherence in a UK patient population?
- What are the psychological barriers to medication adherence?
- What are the psychological facilitators of medication adherence?
- Can identified psychological constructs be used to predict medication non-adherence?

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Previous study hypothesis:
Research questions:

- What is the self-reported and objectively measured rate of anti-hypertensive and statin medication non-adherence in a UK patient population?
- What are the psychological and behavioural barriers to medication adherence?
- What are the psychological and behavioural facilitators of medication adherence?
- Can identified behavioural and psychological constructs be used to predict medication non-adherence?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/03/2016, East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44(0)207 104 8036; NRESCommittee.EastMidlands-Derby@nhs.net), ref: 16/EM/0106

Study design
Observational; Design type: Cross-sectional

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypertension

Interventions
Current interventions as of 29/01/2020:
The research project takes place in three distinct but linked phases - each of which will be conducted at a different time sequentially and involve a different cohort of patients from the study population.

1) Semi-structured interviews - formalised semi-structured interviews of patients attending the Peart Rose clinic will be performed. Whilst the focus will be on allowing patients to freely express their experience of taking medication, a structured topic guide will be used to direct the interviews as required to help elicit barriers and facilitators of adherence. Patients will be recruited until saturation (<10% statement duplication), which from previous similar studies is likely to be approximately 15 patients. The interviews will be analysed thematically to guide questionnaire item generation in conjunction with an appropriate literature review. Each interview will take approximately 20 mins.

2) Questionnaire design and piloting - following analysis of the semi-structured interviews and a thorough systematic literature review questionnaire items will be generated and constructively aligned to the validated Health Belief Model and Theoretical Domains Framework of behaviour. The pilot questionnaire will then be tested on a sample patient population of 30 patients and subsequently refined via calculation of ceiling and floor effects, inter-item correlation and Cronbach's Alpha internal consistency measures. The pilot questionnaire items will also be assessed for readability and comprehensibility using a validated method to ensure it is appropriate for the target
population. Completion of the pilot questionnaire will take approximately 15 minutes and

recruitment of participants will be from the same population and via the same methodology as will be adopted with the final definitive questionnaire study.

3) Principal data collection and testing - in order to validate the new questionnaire, and to assess the association between medication adherence and its' psychological determinants approximately 500 patients from primary care will be recruited into a cross-sectional evaluative study (approximately 300 patients taking antihypertensives and 200 patients taking statins). Participants will complete the questionnaire which will include routine demographic information including age, sex, martial status, co-morbidities, medication history and socio-economic metrics. Participants will also be asked to complete validated measures of self-reported medication adherence (Extent of nonadherence scale) and habit (Self-Report Behavioural Automaticity Index (SRBAI)). Patients will also be asked to give urine samples to allow objective measurement of medication adherence within the past 24 hours, which can be used to help validate the self-report measure.

All results will then be assimilated and appropriately analysed prior to publication and dissemination - hopefully providing a new validated questionnaire for assessing barriers to medication adherence in a UK secondary care hypertensive population, together with providing evidence for development of a short assessment tool and further studies in other patient populations e.g. General Practice.

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Previous interventions:
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1) Semi-structured interviews - formalised semi-structured interviews of patients attending the Peart Rose clinic will be performed. Whilst the focus will be on allowing patients to freely express their experience of taking medication, a structured topic guide will be used to direct the interviews as required to help elicit barriers and facilitators of adherence. Patients will be recruited until saturation (<10% statement duplication), which from previous similar studies is likely to be approximately 15 patients. The interviews will be analysed thematically to guide questionnaire item generation in conjunction with an appropriate literature review. Each interview will take approximately 20 mins.

2) Questionnaire design and piloting - following thematic analysis of the semi-structured interviews and a thorough systematic literature review questionnaire items will be generated and constructively aligned to the validated Health Belief Model and Theoretical Domains Framework of behaviour. The pilot questionnaire will then be tested on a sample patient population of 30 patients and subsequently refined via calculation of ceiling and floor effects, inter-item correlation and Cronbach's Alpha internal consistency measures. The pilot questionnaire items will also be assessed for readability and comprehensibility using a validated method to ensure it is appropriate for the target
population. Completion of the pilot questionnaire will take approximately 15 minutes and recruitment of participants will be from the same population and via the same methodology as will be adopted with the final definitive questionnaire study.

3) Principal data collection and testing - in order to validate the new questionnaire, and to assess the association between medication adherence and its' behavioural and psychological determinants approximately 200 patients from the Peart Rose Hypertension Clinic will be recruited into a cross-sectional evaluative study. During routine clinic attendance participants will complete the questionnaire. In addition routine demographic information including age, sex,

martial status, co-morbidities, medication history and socio-economic metrics will be collected. Participants will also be asked to complete validated measures of self-reported medication adherence (Moresby Medication Adherence Scale (MMAS-8), and the Self-Report Behavioural Automaticity Index (SRBAI)) in order to aid in the validation of the new questionnaire. Patients give urine samples on a regular basis as part of their routine care in the clinic; results of direct measures of medication adherence will be collected and utilised to validate the questionnaire.

All results will then be assimilated and appropriately analysed prior to publication and dissemination - hopefully providing a new validated questionnaire for assessing medication adherence in a UK secondary care hypertensive population, together with providing evidence for development of a short assessment tool and further studies in other patient populations e.g. General Practice.

Intervention Type
Other

Primary outcome(s)
Measured during the data collection session:
1. Urine test of medication adherence. A urine sample will be tested for anti-hypertension and statin metabolites to give a valid and reliable direct measure of medication adherence within the past 24hrs.
2. Self-reported medication adherence. Using 3 item Likert scale from Voils 2012

Key secondary outcome(s))
Measured during the data collection session:
1. Habit, measured using the Self Report Automaticity Index, a 4-item Likert scale from Gardner 2012

Completion date
31/01/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/01/2020:
All patients attending a primary or secondary care service for the treatment of hypertension or taking statins that are willing to take part

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Previous inclusion criteria:
All patients attending a primary or secondary care service for the treatment of hypertension that are willing to take part

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
491

Key exclusion criteria
In the opinion of the investigator unsuitable or unable to adequately complete questionnaire e. g. due to inadequate level of English comprehension

Date of first enrolment
27/04/2016

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St. Mary's Hospital
Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Robert Luff Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Imperial College London

Alternative Name(s)
Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Following the publication of the results, the anonymised datasets generated by the study will be available on request from Gaby Judah (g.judah@imperial.ac.uk). Any requests for data access will be considered by the study management team including discussion of the proposed use of the data, and storage of the data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		01/02/2024	01/02/2024	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version V1.7	06/08/2019	14/01/2020	No	No