ISRCTN23560818 https://doi.org/10.1186/ISRCTN23560818

Evaluation of the New Medicine Service

Submission date 05/07/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2012	**Overall study status** Completed	
Last Edited 27/10/2022	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.nmsevaluation.org.uk

Contact information

Type(s)
Scientific

Contact name
Dr Matthew Boyd

Contact details
School of Pharmacy
University Park
Nottingham
United Kingdom
NG7 2RD
+44 (0)115 9515061
matthew.boyd@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01635361

Secondary identifying numbers
12494

Study information

Scientific Title
Understanding and appraising the New Medicine Service in the NHS in England

Study objectives
About 25% medicines prescribed for longterm conditions are not taken as directed, and approximately 15% people receiving a new medicine take few, if any, doses. The New Medicines Service (NMS) is a community pharmacy service that started in England in October 2011 which involves the pharmacist providing additional support to patients starting a new medicine for some breathing problems (asthma & chronic obstructive pulmonary disease [COPD]), high blood pressure, adult onset diabetes or medicines which reduce blood clotting. It aims to improve the way patients take their medicines improving outcomes and reducing costs to the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 02/05/2012 ref: 12/WM/0096

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
All diseases

Interventions
The effectiveness and cost effectiveness of the NMS will be assessed using a research study where some people will receive the NMS, and some wont, in order to look at the effect of the NMS on problems with their medicines, medicines taking and use of the NHS in general. Data will be collected in the East Midlands, South Yorkshire and London areas. 500 patients will be recruited from a range of different pharmacies and follow them up at 6, 10 and 26 weeks after starting their new medicine to assess effects on medicines taking behaviour, patients reported

problems with medicines, referrals to their GP and use of NHS resources. The data gathered will be compared with that being collected routinely by all pharmacies in England to provide wider estimates of cost-effectiveness.

The study will also explore how the NMS service is being implemented by pharmacies. A sample of patients from the main study will be followed in more detail. This will involve recording the consultations with the pharmacist and also interviewing patients about their experience of the service. The patients GPs will be interviewed to investigate their views of the service. The trialists will also try to understand why people decline the invitation for the NMS.

Follow Up Length: 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Medicines adherence measured at 6, 10 and 26 weeks

Secondary outcome measures
1. Cost effectiveness measured at 6 months
2. Operation of the NMS measured 1 year from first recruited patient
3. Patients understanding of their medicines measured at 10 weeks
4. Pharmacovigilance measured 1 year from first recruited patient
5. Professional relationships measured 1 year from first recruited patient
6. Stakeholder experience measured 1 year from first recruited patient

Overall study start date
16/07/2012

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. They are community dwelling patients eligible for NMS (i.e. aged from 14 years starting a new medicine for asthma/COPD, diabetes (Type 2), antiplatelets/anticoagulants or hypertension).
2. There is no upper age limit for providing the NMS hence there is no upper limit for patients taking part in the trial
3. They are able to understand patient/participant study documents
4. They are able and willing to provide informed assent/consent
5. The pharmacist will provide the patient with details of the study to in order to allow the patient to make an informed decision to take part into the study or not
6. Male and female participants

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 500; Description: The study requires 200 patients in each arm. The sample is calculated to allow for an attrition rate of 20%

Key exclusion criteria
1. Younger patients who may not be able to understand the NMS service and/ or consenting procedure
2. Patients collecting a repeat prescription for a medicine for asthma/COPD, type 2 diabetes mellitus (T2DM), antiplatelets/anticoagulants or hypertension
3. Patients collecting a medicine where the only change from the previous medicine involves a dosage or formulation change only
4. Participants who are unable to understand patient/participant study documents
5. Participants who are unable and unwilling to provide assent/consent

Date of first enrolment
16/07/2012

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details

School of Pharmacy
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - Central Commissioning Facility (UK)

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2013		Yes	No
Results article	10-week follow-up	01/10/2016		Yes	No
Results article	cost effectiveness results	01/12/2017		Yes	No
Results article	26-week follow-up	15/11/2019	27/10/2022	Yes	No