ISRCTN12674490 https://doi.org/10.1186/ISRCTN12674490

New medicines service pilot

Submission date 11/11/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 21/11/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 27/10/2022	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Between 30% and 50% of prescribed medicines are not taken as recommended. This means that a lot of medicines are wasted or are not as effective as they could be. This study is looking at patients who have been prescribed a new medicine by their doctor for a specific condition and trying to understand why they take their new medicine as recommended (treatment adherence). All patients who get medicines from their community pharmacist receive counseling on how to take their medicines when they collect the prescription. The aim of this study is to find out whether additional counseling with a pharmacist about medication use can help improve treatment adherence.

Who can participate?
Adults who have been prescribed a new medicine for asthma, lung conditions, type 2 diabetes, high blood pressure, anti-clotting medications, medications to lower cholesterol or long-term pain.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a telephone call from the pharmacist after 7-14 days or are asked to come back to the pharmacy and the pharmacist asks some questions about how they are getting on with their new medicine, find out if theyyou are having problems and give information and support as needed. After one month, the pharmacist again make contact, either over the phone or when the participant comes in to collect their next prescription, to ask some further questions about how patients are getting on with their medicine. Those in the second group only receive contact from the pharmacist after one month, either over the phone or when they come in to collect their next prescription.

What are the possible benefits and risks of participating?
Participants who take part in the counseling program benefit from having extra contact from their community pharmacist which may help them better understand their new medicine. There are no notable risks involved with participating.

Where is the study run from?
The study is run by the Irish Pharmacy Union and takes place in 50 community pharmacies in Ireland (Ireland)

When is the study starting and how long is it expected to run for?
November 2016 to April 2017

Who is funding the study?
1. Pfizer Healthcare Ireland (Ireland)
2. Irish Pharmacy Union (Ireland)

Who is the main contact?
1. Ms Pamela Logan (public)
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2. Dr Gerry Molloy (scientific)
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3. Ms Sinead McCool (scientific)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IPU1

Study information

Scientific Title
IPU New Medicine Service Pilot: a randomised control pilot to explore the operation of the NMS, the complexity and nature of consultations and determine acceptability to stakeholders

Study objectives
The aim of this study is to:
1. Explore the operation of the NMS, in particular the complexity and nature of resulting consultations in terms of patient engagement, age range, advice-giving and support
2. Determine acceptability to stakeholders, reasons for success or lack of success and feasibility within the service delivery environment

Ethics approval required
Old ethics approval format

Ethics approval(s)
National University of Ireland (NUI) Galway Research Ethics Committee, 27/01/2017, ref: 16-Dec-17

Study design
Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Long-term medication

Interventions
Patients presenting with a new prescription for a medicine within one of the identified conditions will be asked if they wish to participate in a pilot service. They will be informed that this will either involve:
1. A telephone or face-to-face consultation within 7-14 days followed by a short survey after one month; or
2. A short survey after one month.
The patient will be asked to sign a consent form. The pharmacist will input the patient details into the Pharmapod platform (a web-based platform that will collate data from pharmacies and anonymise and aggregate) and Pharmapod will randomly allocate the patient to the active (NMS service) or control arm (current practice service). Patient selection would not be dependent on disease area. Adherence will be measured by the collection of the patient's prescription over 3 months. Patients will have an option to opt out of the study at any time.

Those patients who have been selected for the NMS service will receive a telephone or face-to-face consultation within 7-14 days and will be asked a number of questions to find out if they are having any problems with their medicine. The patients in the control arm will not receive this consultation.

After one month, all patients who consented to participate, and who were allocated either the NMS service or the current practice service, will be asked to complete a survey, either face-to-face or by telephone. The survey will consist of the Morisky Eight Item Medication Adherence Scale (MMAS-8).

The pharmacist will input all data collected from the consultation and survey into the Pharmapod platform along with data on prescription collection over a 3-month period. A selection of anonymised and aggregated reports will be produced by Pharmapod to evaluate the pilot. Pharmacists will also be required to complete an online survey to determine acceptability of the service, the reasons for success or lack of success and the feasibility within the service delivery environment.

Intervention Type
Behavioural

Primary outcome measure
Acceptability of the NMS service to pharmacists is measured using a pharmacist survey created for the purpose of this study at the end of the pilot (after 3 months).

Secondary outcome measures
Patient adherence levels are measured by reviewing how often the patient collects their prescription from the pharmacy over a 3-month period.

Overall study start date
06/11/2016

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Patients aged 18 years and older
2. Presenting with a new prescription for a medicine within one of the identified conditions /therapy areas
3. Living independently at home

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Under 18 years of age
2. Living in care home or residential home
3. Using compliance aid or involved in any other adherence programme
4. Under the care of psychiatric services
5. Unable to participate in the study due to language difficulties

Date of first enrolment
25/01/2017

Date of final enrolment
17/02/2017

Locations

Countries of recruitment
Ireland

Study participating centre
Irish Pharmacy Union
Butterfield Avenue
Rathfarnham
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14

Sponsor information

Organisation
Irish Pharmacy Union

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Sponsor type
Other

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ROR
https://ror.org/048q77b60

Funder(s)

Funder type
Industry

Funder Name

Pfizer Healthcare Ireland

Funder Name
Irish Pharmacy Union

Results and Publications

Publication and dissemination plan
Planned publication of the study results in a report which will be sent to all community pharmacies and Department of Health officials.

Intention to publish date
30/05/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Pamela Logan (pamela.logan@ipu.ie)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	15/11/2016	21/11/2016	No	Yes
Funder report results		01/01/2017	27/10/2022	No	No