

Inviting patients to make a commitment to take their medication as prescribed, as a way to increase medications adherence

Submission date 26/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/05/2021	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Medicines play a crucial role in maintaining health, managing long term health conditions and curing disease. One aspect of optimising the use of medication is 'medications adherence', patients taking their medication as prescribed, or seeking support if they have questions or concerns. Estimates vary, but non-adherence is common. Non-adherence impacts patients health. It is also wasteful to the NHS. In England, the estimated cost to the NHS from wasted medication in primary care is £300 million per year. Other credible estimates calculate the full opportunity cost to the NHS at many times this amount. A wide range of factors affect adherence. These include forgetting, missing windows of opportunity and intentional non-adherence. Lots of help is already in place. for example, advice from pharmacists and GPs or reminder charts. An area where there may be new things to do is to close the gap between people's good intentions (to take their medications) and their actions (not doing so). A proven concept from a range of settings is to encourage people to self-commit to achieve a particular goal. In addition, to use simple messages to motivate people to take their medication or to seek advice or help if they have concerns. The aim of this study is to test a simple and non-enforceable commitment device designed to help close the gap between someone's good intention to take their medication as prescribed, and their actions of non-adherence.

Who can participate?

Patients that have agreed to participate in an existing NHS Medicine service and have been prescribed a medicine to treat a long-term condition for the first time.

What does the study involve?

In a pharmacy, shortly after receiving a new course of medication for a long term condition, a participant may be invited by the pharmacist to sign a sticker. This is a commitment to take their medication as prescribed, or to seek advice if they have questions. The patient is then invited to attach this to their medications package, as a reminder of this good intention every time they see the package. The participant is randomly selected to receive one of three stickers. One sticker contains the aforementioned commitment to take the medication and message to seek advice if the participant has any questions (sticker A). A another sticker contains these messages

and, in addition, another message reminding the patient that the NHS spends £300 million every year on wasted medication (sticker B). A third sticker (sticker C) has the same message as A but with an additional message reminding the patient that not taking medication can harm their health. Some participants do not receive a sticker, but are instead allocated to the control group and they receive their usual service. The sticker is tested as part of a small change to an existing NHS service, called the New Medicines Service and investigates if accompanying wording on the sticker - about the cost to the NHS from wasted medication or about the benefits to the patient's own health - can further encourage adherence. At two weeks and again at four weeks after the start of the study, the patient speaks on the phone to their pharmacist to receive verbal advice about their medication. For example, the pharmacist may help with side effects. At these discussions, the pharmacist asks a few short questions about how the patient is getting on with taking their medication. This research uses this information - self-reported by patients - to measure if the new sticker has an effect.

What are the possible benefits and risks of participating?

The benefit of taking part in the study may be in helping the participating patient who wants to take their medication to be motivated to take it; or for patients who have queries or concerns to feel motivated to speak to their GP or pharmacist. We have not identified any risks of taking part in the study.

Where is the study run from?

All Boots UK pharmacies in London, UK

When is the study starting and how long is it expected to run for?

July 2015 to December 2015

Who is funding the study?

UK Department of Health (UK)

Who is the main contact?

1. Mr Daniel Berry
2. Ms Laura Freeman

Contact information

Type(s)

Public

Contact name

Mr Daniel Berry

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

REC 15/WM/0225

Study information

Scientific Title

Inviting patients to make a commitment to take their medication as prescribed, as a way to increase medications adherence: a cluster randomised controlled trial

Study objectives

A wide range of psychological factors affect 'adherence': i.e. whether patients take their medications as prescribed. These include simply forgetting, missing windows of opportunity, and intentional non-adherence. An under-explored area in medication adherence research is the use of behavioural insights. This term covers disciplines that draw from behavioural economics and other sciences. Behavioural insights can help to close the gap between people's good intentions (in this case, to take their medications) and their actions (not doing so). A proven concept from a range of settings is the use of a 'commitment device' to help bridge this intentions-to-actions gap.

The hypothesis is therefore that a simple and non-enforceable commitment device may help close the gap between someone's good intention to take their medication as prescribed, and their actions of non-adherence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Research Ethics Committee, 26/06/2015, ref: 15/WM/0225

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Medications adherence

Interventions

11,292 patients who have already agreed to participate in a NHS service to support patients to take their medications will be randomly assigned as follows:

A: To be invited to sign a sticker committing to take their medication as prescribed, or to seek advice if they have any concern. The patients may then attach this to their medications package.

B: To be invited to sign a sticker as at A, but with an additional message reminding the patient that the NHS spends £300 million every year on wasted medication

C: To be invited to sign a sticker as at A, but with an additional message reminding the patient that not taking medication can harm their health

D: To receive the usual service (this is the control group)

Intervention Type

Behavioural

Primary outcome measure

Whether the patient takes their medication as prescribed. This is measured by the patient self-reporting this to the pharmacist. This research uses common set of questions about adherence, called the Morisky scale. These are the four questions:

1. Do you ever forget to take your medicine? Yes/No
2. Are you careless at times about taking your medicine? Yes/No
3. Sometimes if you feel worse when you take the medicine, do you stop taking it? Yes/No
4. When you feel better do you sometimes stop taking your medicine? Yes/No

Secondary outcome measures

N/A

Overall study start date

20/07/2015

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Patients who have already consented to participate in an existing NHS service, called the New Medicines Service
2. Patients who are prescribed a medicine to treat a long-term condition for the first time

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

11,292

Total final enrolment

16191

Key exclusion criteria

1. Anyone who has opted to not participate in the NHS New Medicine service
2. Any patients who opt-out from the trial component of the Service

Date of first enrolment

20/07/2015

Date of final enrolment

30/11/2015

Locations

Countries of recruitment

United Kingdom

Study participating centre

Boots UK

All Boots UK pharmacies in London, UK.

London

United Kingdom

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Sponsor information

Organisation

Department of Health

Sponsor details

79 Whitehall
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Sponsor type

Government

Website

<https://www.gov.uk/government/organisations/department-of-health>

ROR

<https://ror.org/03sbpja79>

Funder(s)**Funder type**

Government

Funder Name

UK Department of Health

Results and Publications**Publication and dissemination plan**

Peer reviewed journal and dissemination through the NHS

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2021	12/05/2021	Yes	No
HRA research summary			28/06/2023	No	No