Can large scale randomised controlled trials be delivered within a community pharmacy environment in a timely, efficient and robust manner?

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Introduction

Background

- The aim of this poster is to demonstrate that a randomised controlled trial can be delivered in community pharmacy in a timely and robust way, using the *New Medicine Service Randomised Controlled Trial* (NMS RCT) as an example
- The NMS RCT tested an innovative, simple, low cost behavioural 'nudge' intervention delivered within community pharmacy with the aim of improving patients' adherence to their medicines
- The Department of Health Behavioural Insights Team (BIT) wanted to trial a behavioural intervention to improve medicines adherence
- Working together with independent academic researchers, the BIT and community pharmacy, the study protocol was developed and implemented, allowing operational insights from pharmacy to be considered from an early stage

Study aim	Improve medicines adherence		
Method	Robust evaluation of intervention		
Tools	Behavioural Insights	RCTs	Community Pharmacy
Stakeholders	Department of Health	Community Pharmacy	Academic partners

Behavioural Insights

- Discipline that draws from behavioural economics, psychology and other sciences
- Behavioural insights can provide simple and low cost strategies to close the gap between people's intentions (in this case, to take their medications) and their actions (not doing so)
- A proven concept from other settings is the use of a 'commitment device' to help bridge this intentions-to-actions gap
- In one study, 3,500 patients were sent either a standard letter or a simplified letter as a reminder for attending an NHS Health Check appointment. The new letter increased attendance by 13%[1]

Methods

Free NHS New Medicine Service
Let's help you manage your medicines

A randomised controlled trial of a behavioural 'nudge' intervention delivered within community pharmacies to increase medicines adherence as part of the NHS New Medicine Service (NMS).

- The study methodology was developed to take into account the busy environment of a community pharmacy and ensure as little disruption to this as possible
- The intervention was kept simple and designed to bolt on to the existing NMS service and take a matter of minutes
- It used existing data capture methods
- It involved a simple update to the usual NMS leaflet
- Randomisation was clustered (at the pharmacy level) to one of four trial arms: three variants of a sticker (see to right) or control (no sticker), to minimise contamination between groups
- The number of pharmacies was chosen to ensure patient recruitment and data capture could be completed within a 9 month timeframe to give sufficient sample size for analysis
- Patients were asked to make a non-enforceable commitment (by signing the sticker) to either take their medicines as prescribed or seek advice
- Medicines adherence was measured using the four item Morisky adherence[2] scale at intervention (2 weeks) and follow-up (4 weeks) after the initial consultation
- Anonymised data were collated by each pharmacy onto an electronic template which were collected centrally for analysis

Commitment only

I will take this medication as prescribed. NHS

I commit to taking this medication exactly as prescribed, or I will speak to my GP or Pharmacist if I have a concern.

Signed: .....

Date: .....

Commitment + health message

Not taking my medication as prescribed could risk my health. NHS

I want to do all I can to improve my health, so I commit to taking this medication exactly as prescribed, or I will speak to my GP or Pharmacist if I have a concern.

Signed: .....

Date: .....

Commitment + cost message

The NHS loses £300 million per year from wasted medication. NHS

I want to do my bit to support the NHS, so I commit to taking this medication exactly as prescribed, or I will speak to my GP or Pharmacist if I have a concern.

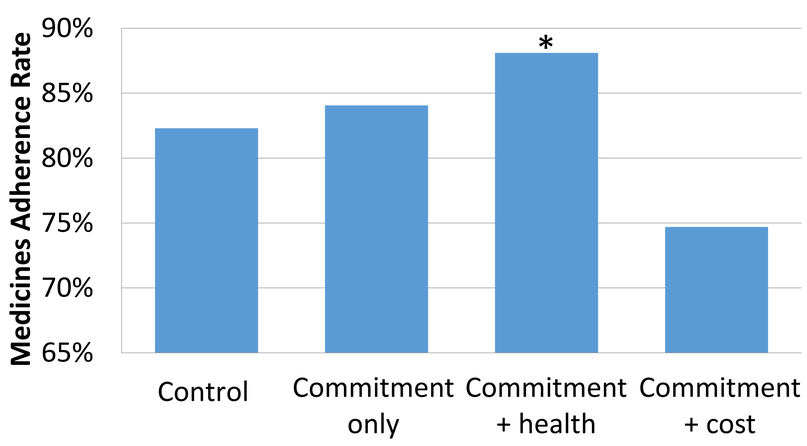
Signed: .....

Date: .....

Results

- Ethics approval was granted from the NRES Research Ethics Committee on June 26th 2015 (ref 15/WM/0225)
- Implementation and data collection occurred between July 2015 and March 2016
- The trial was successfully undertaken in 242 pharmacies across London
- Complete datasets for 10,904 patients (45.1 per pharmacy) recruited to the trial were collected for analysis over the 9 month period
- For participants who signed the commitment only sticker, there was no change to their medication adherence levels vs control
- Participants who signed the commitment + health message were significantly more likely to adhere to their medication than the control group (OR=1.59, CI95% [1.02; 2.48])

Reported adherence (MMAS-4) across experimental groups in comparison to the control group.
*p=0.043



Conclusions

- This is an example of a robust, academic trial that came about as a collaboration between Government, pharmacies and academics
- This research shows that high quality evidence could be generated through partnership working in shorter timescales than is usually associated with randomised controlled trials
- More trials of this kind could continue to build the evidence base to extend the role of community pharmacists in supporting patients with their health

References

1. Sallis A, Bunten A, Bonus A, James A, Chadborn T, Berry D: The effectiveness of an enhanced invitation letter on uptake of National Health Service Health Checks in primary care: a pragmatic quasi-randomised controlled trial. BMC Fam Pract. 2016 17:35
2. Morisky DE, Green LW, Levine DM Concurrent and predictive validity of a self-reported measure of medication adherence. 1986 Med Care 24(1):67–74

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