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Minimal interventions to improve medication adherence in people with multiple long-term conditions (MINIMA) study

Submission date
24/04/2014

Recruitment status
No longer recruiting

Registration date
24/07/2014

Overall study status
Completed

Last Edited
13/04/2017

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

As people live longer, the numbers living with long-term conditions is increasing in the UK and worldwide. In fact, a substantial proportion of the UK population now live with more than one long-term condition, the likelihood that someone will do so increasing with age. Many people with long-term conditions are now managed in primary care with referral to specialist care only when strictly necessary and for short periods e.g. for specific diagnostic assessments, for surgical interventions or specialist treatments. Medication plays an important role in the way many patients with long-term conditions manage their conditions day to day. However, many people with long-term conditions have problems taking their medication as prescribed. These difficulties can have significant negative impacts on the longer term health of the individual. Poorer adherence has been shown to be associated with increased mortality and poorer quality of life, and can also be costly for the NHS through greater service use and increased hospital admissions among those whose adherence is poor. People with more than one long-term condition are particularly likely to have difficulties in taking medication as prescribed as their medication regimes are more likely to be complex and patients may prioritize one condition over another.

Although there are some methods that have been shown to be effective in improving adherence to medication in patients with long-term conditions, the down-side is that these are often complex and require significant professional time and support. This reduces their usefulness in a resource-constrained healthcare system. There is therefore a need to complement these existing methods with ones that are simpler, more efficient and have sufficient 'reach' into the population to support the large number of patients with long-term conditions. Research has suggested that a psychological method known as 'self-affirmation' may be effective at improving adherence to medications among those with long-term health problems. Self-affirmation is a way of bolstering the individual against the threat posed by negative personally-relevant health messages (e.g. a message about the importance of taking medication as prescribed if you have a long-term condition) so that individuals are more receptive to that information. In practice self-affirmation involves activities such as writing an essay about ones positive personal characteristics or constructing a plan to remember one's positive attributes or personal values when feeling anxious or stressed. Self-affirmation has been shown to be

effective at getting people who are chronically ill (people with end-stage renal failure) to adhere better to their medication. However, it has not yet been tested with people with the kind of long-term conditions typically managed in primary care (e.g. coronary heart disease, chronic obstructive pulmonary disease, depression, type 2 diabetes, arthritis).
Before undertaking a larger-scale study to look at the effectiveness of self-affirmation for improving adherence to prescribed medication in primary care patients with multiple long-term conditions, it is necessary to ensure that self-affirmation is acceptable to this patient group and that the study methods employed will be suitable. We are therefore undertaking a small-scale pilot study to explore these issues.

Who can participate?
Participants will be recruited through their GP (primary care) practice in Greater Manchester, UK. To be eligible to take part in the study, a person will need to be aged 50+ and have two or more of five long-term conditions commonly managed in primary care (depression, chronic obstructive pulmonary disease, type 2 diabetes, arthritis and coronary heart disease).

What does the study involve?
Participants will be randomly allocated to either a self-affirmation (intervention) group or a no self-affirmation control group. Participants will be sent an invitation letter and study pack containing the first study questionnaire from their practice. As well as study measures, the first questionnaire will contain the self-affirmation task (for the intervention group only) and a health message about the importance of taking medication as prescribed (for both groups). One month later participants will be sent a second questionnaire to complete.

What are the possible benefits and risks of participating?
The information participants provide in this study will be useful in exploring the possibilities of a method that could help support people living with long-term conditions to take their medication as prescribed. Participants will also receive accurate health information about the possible detrimental effects of not taking their medication as prescribed. The study also provides an opportunity for participants to reflect on this issue. Risks to participants in the study are relatively slight. There is a slight risk of mild distress in response to the questionnaires which contain the health message, questions on adherence or physical health, and questions on mood. We have been upfront about this content in the participant information sheet and provided information about where to seek further help to manage this risk. A second risk relates to the fact that it is not possible to go into detail upfront about the nature of self-affirmation with participants as evidence indicates that this might undermine the effectiveness of the method. To avoid any unnecessary distress this may cause we are providing a full debrief to participants as soon as possible with a full explanation of self-affirmation and why it was not possible to go into more detail prior to this point and also reminding participants that they reserve the right to pull out even at that late stage in the study. Previous studies of self-affirmation with similar methodologies have gone ahead successfully with no reported problems so we do not anticipate that this will be a major issue.

Where is the study run from?
University of Manchester (UK).

When is the study starting and how long is it expected to run for?
The study started in May 2014 and will run until August 2014.

Who is funding the study?
The study is being funded by the NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre (GM PSTRC).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Minimal Interventions to Improve Medication Adherence in Multimorbidity (MINIMA) study

Acronym
MINIMA

Study objectives

The aim of this study is to investigate the acceptability of a self-affirmation intervention for improving medication adherence in people with multiple long-term conditions and the feasibility of methods that could be used in a randomised controlled trial of effectiveness of the intervention in this patient group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Liverpool Central NRES Committee, 07/05/2014, ref: 14/NW/0282

Study design
Randomized controlled feasibility and acceptability pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Common long-term conditions (depression, coronary heart disease, chronic obstructive pulmonary disease, type 2 diabetes and arthritis [osteo and rheumatoid]), specifically multimorbidity of these

Interventions
Condition 1: Intervention group: Self-affirmation task plus health message
Condition 2: Control group: Health-message only control group

1 month follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Acceptability of the intervention and feasibility of study methods will be assessed by looking at:
1. Recruitment

2. Retention
3. Characteristics of responders versus non-responders
4. Engagement with the intervention (intervention group only)
5. The proportion of positive to negative comments made in response to questions asked about the experience of the intervention (intervention group only), and of taking part in the study (both groups)
6. Proportion of questionnaire correctly completed

Secondary outcome measures
No secondary outcome measures

Overall study start date
12/05/2014

Completion date
31/08/2014

Eligibility

Key inclusion criteria
1. Primary care patients aged 50+
2. Two or more of five common long-term conditions (depression, chronic obstructive pulmonary disease [COPD], type 2 diabetes, arthritis [osteo and rheumatoid] and coronary heart disease)
3. Participants must be fluent in written English

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
Patients suffering from a condition which impairs their ability to provide informed consent or otherwise means that they are considered unsuitable to approach by their primary care team

Date of first enrolment
12/05/2014

Date of final enrolment
31/08/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Manchester Centre for Health Psychology
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

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Sponsor type
University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name

NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre (GM PSTRC) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No