The feasibility of determining the effectiveness and cost-effectiveness of medication organisation devices compared with usual care for older people in a community setting: systematic review, stakeholder focus groups and feasibility randomised controlled trial

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Declared competing interests of authors: Debi Bhattacharya reports funding from the University of East Anglia throughout the duration of the study. Clare F Aldus reports grants, personal fees and non-financial support from the University of East Anglia. Garry Barton, Sathon Boonyaprapa, Richard Holland, Christina Jerosch-Herold, Charlotte Salter, Lee Shepstone, Steven Waton and David Wright report grants and personal fees from the University of East Anglia. Christine Bond reports non-financial support from the University of Aberdeen. Christine Walton reports grants and personal fees from NHS Anglia Commissioning Support Unit.

Published July 2016
DOI: 10.3310/hta20500

Scientific summary

Effectiveness and cost-effectiveness of MODs compared with usual care

Health Technology Assessment 2016; Vol. 20: No. 50
DOI: 10.3310/hta20500

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Medication organisation devices (MODs) are a box or blister pack divided into days of the week with several compartments per day to allow for different dose timings. They are intended to organise a patient's medication to facilitate correct medication taking. MODs are most frequently provided to older people, often supported by NHS funds. Definitive evidence for either clinical effectiveness or cost-effectiveness is lacking. A trial to fill this evidence gap presents design challenges; thus preliminary research is required.

Objectives

The aim was to design and test the feasibility of conducting a randomised controlled trial (RCT) of the clinical effectiveness and cost-effectiveness of MODs. The objectives were to:

1. identify the most effective method of participant recruitment
2. estimate the prevalence of intentional non-adherence within an older population
3. estimate the prevalence and magnitude of unintentional non-adherence within a 3-week period within an older population
4. describe the functional abilities of an older population
5. provide a point estimate of the effect size of MODs relative to usual packaging
6. describe the feasibility and participant acceptability of trial participation
7. describe the feasibility of collecting the data necessary to conduct an economic evaluation.

Methods

The study comprised two phases: trial design and trial testing. Trial design included a systematic review, supplementary literature searching and focus groups. The systematic review included MOD studies of any design reporting any of the following outcomes: medication adherence, health outcomes, health-related quality of life, health or social care utilisation, dispensing or administration errors or prescribing- or medicine supply-related costs. Search terms comprising medical subject headings, free text and trade names were applied to electronic databases. Duplicate independent data extraction was undertaken. Supplementary searches informed characteristics of the study tested in phase 2. Focus groups with patients, carers and health-care professionals refined the proposed study design prior to testing.

The trial undertaken in phase 2 was a randomised 2 × 2 factorial design to test the effect of MODs compared with medication dispensed in usual packaging and of weekly compared with monthly medication supply. Two methods of recruitment were trialled: passive postal recruitment by a medical practice and active recruitment by a researcher placed in a medical practice. Six medical practices and the 11 neighbouring pharmacies were recruited. The six medical practices were matched by patient list size and equally allocated to the recruitment methods, each of which was trialled for 3 weeks, after which all practices undertook passive recruitment. Patients were eligible for the study if they were aged ≥ 75 years, were prescribed three or more solid oral dosage form medications [of which at least two were from a defined list that was intended for electronic adherence monitoring (EAM)] and were capable of providing informed consent. Patients with a life expectancy of less than 12 months, current other clinical trial involvement, experience of using a MOD or a diagnosis of Parkinson's disease, a severe mental health disorder or other situation deemed inappropriate by the health-care team were excluded. Those not self-administering their medication, who were using a medication organisation strategy incompatible with trial participation or who were intentionally non-adherent

were also excluded. Intentionally non-adherent participants were excluded by using their responses to a questionnaire. A 3-week dosage unit count was undertaken for the remaining participants and those demonstrating perfect adherence were excluded. The remaining unintentionally non-adherent participants were randomised to one of the four arms. The primary outcome was percentage adherence, as defined by dosage unit count. Other outcomes explored were self-reported health and quality of life, autonomy and satisfaction, mortality and costs.

Evaluation of the feasibility and acceptability of the interventions and trial design was undertaken using questionnaires and group discussions with participants and health-care professionals involved in the study.

Results

The systematic review identified that studies on MODs are largely of poor quality and that the evidence regarding the effects of MODs is contradictory. The majority of studies reported adherence but no health outcomes. Those studies reporting both adherence and health outcomes did not unequivocally report a positive relationship; some studies reported increased hospitalisation associated with MODs. No study reported any humanistic outcomes such as health-related quality of life.

The literature searches determined the validated tools that would be used for assessing patient functional ability and identified three potential candidates for EAM during the RCT element of the feasibility study. However, none of these manufacturers was able to produce a working version in the duration of the study.

The pre-trial focus groups largely considered the proposed trial design feasible and acceptable, the three MODs selected were Nomad™ (Surgichem Ltd, Cheshire, UK), Nomad XL™ (Surgichem Ltd, Cheshire, UK) and Venalink™ (Venalink, Flintshire, UK). Disparity between the focus groups and literature was greatest regarding the minimum age for patient recruitment, with the suggested minimum age ranging from 50 years (health-care professionals) to 75 years (literature). Furthermore, pharmacists reported that the frequency with which MODs are initiated increases from the age of 70 years. The RCT element of the feasibility study retained the 75 years threshold that was determined a priori.

Active recruitment yielded a higher consent rate but passive recruitment was more cost-effective at a cost of £2528 and £506 per participant recruited, respectively. The most significant attrition during recruitment was at the stage of determining eligibility for electronic medication adherence monitoring, which excluded 64.9% of the potentially eligible sample, followed by ineligibility because patients already used a MOD, which removed 45.6% from the remaining sample.

The prevalence of intentional non-adherence was 24.7% (95% CI 19.7% to 29.6%). Of the remaining 76 participants, 46.1% (95% CI 34.8% to 57.3%) were unintentionally non-adherent after 3 weeks of monitoring. The population was not cognitively impaired and the majority had adequately corrected vision. Manual dexterity varied, with 41.4% (95% CI 23.4% to 59.3%) having poorer function than normative values for their age and sex.

Mean adherence over the 8-week monitoring period exceeded 95% for all study arms and there was no indication of a difference between the study arms. Similarly, the post-trial participant questionnaire identified a relatively high level of satisfaction with all trialled methods and frequency of medication supply. The majority of participants and carers reported no change in confidence and autonomy. There was no indication of a difference between study arms in any of these outcomes. Five adverse events (AEs) or serious adverse events were identified in the MOD study arms, compared with none in the usual packaging arms. These comprised three falls, one hypoglycaemic episode and one temporary incapacitation.

Data to estimate health economic outcomes were successfully collected from participants and health and social care organisations. There was no discernible difference between the four study arms; the mean intervention cost was £20 per month greater for MOD monthly relative to usual supply monthly. Given the lower cost of monthly usual care, it dominated other study arms.

Conclusions

- Medication organisation devices were initiated for participants identified as unintentionally non-adherent and are widely used in routine practice for this purpose. The AEs observed in the MOD arms indicate that they may be associated with an increase in medication dose-related AEs.
- As a feasibility study, the implications for a future study are that maintaining the minimum recruitment age at 75 years resulted in over one-third of patients being ineligible for study participation because they already used a MOD. It is clear, therefore, that a subsequent study must have a lower age threshold in order to include participants of the age at which MODs are initiated in usual care. The ethical restriction of being unable to recruit patients already receiving a MOD means that the patients most likely to demonstrate benefit may have been excluded. It is therefore likely that the results of this feasibility study and any definitive trial provide a conservative estimate of any MOD benefits.
- Electronically monitoring adherence in the usual-care environment remains a technological challenge.
- Recruitment using invitation letters is more cost-effective than personal recruitment by researchers.

Recommendations for research

1. The relationship between MODs and AEs requires further exploration as adherence may not be the most appropriate primary outcome measure; a health outcome such as quality of life or health and social care use may be more appropriate.
2. A trial fully examining the costs and effects of MODs (both positive and negative) is necessary. Such a study should stratify participants by history of hospital admissions or by health and social care use.
3. Further work to develop an EAM system compatible with usual medication packaging is necessary.
4. The relationship between MODs, medication adherence and health outcomes requires further investigation.

Funding

This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 20, No. 50. See the NIHR Journals Library website for further project information.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/34/03. The contractual start date was in July 2011. The draft report began editorial review in November 2013 and was accepted for publication in October 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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