Standard Operating Procedure: MEDICAL PRACTICE procedures (ACTIVE RECRUITMENT) for Medication Organisation Device project (NIHR HTA 09/34/03; Phase II Randomised controlled trial)

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1. ABBREVIATIONS

NIHR	National Institute of Health Research
HTA	Health Technology Assessment
RCT	Randomised Controlled Trial
MOD	Medication Organisation Device
RFID	Radio frequency identification
OtCM™	Objective therapy Compliance Monitoring
OSDF	Oral solid dose form
SOP	Standard Operating Procedure
RISP	Research Information Sheet for Practices
PIL	Patient Information Leaflet
UEA	University of East Anglia

2. INTRODUCTION

The aim of this study is to test whether Medication Organisation Devices (MODs) help patients to take their medication correctly. MODs are currently used by around 100,000 people in the UK, at a cost of several million pounds per year. Some MODs are supplied by the NHS under the Disability Discrimination Act, but in many cases patients or their carers bear the cost themselves. Although pharmacists, clinicians, patients and carers believe that MODs aid adherence to complex medication regimes; this proposal has not yet been tested in a randomised controlled trial (RCT).

Under this RCT, diverse measures will be used: Objective measures such as Objective therapy Compliance Monitoring (OtCM™) films which record when a pill has been removed from its packaging; subjective measures including questionnaires which ask patients about their medication-taking and attitudes towards their medication, quality of life, satisfaction with the trial and perceived changes in autonomy; and the views of their carer(s). In addition to this, post-RCT focus groups for participants and healthcare professionals will be arranged, with a view to using these qualitative data to further refine the design of the proposed definitive study. Data will be accessed in a number of formats including paper-based records, electronic audio recording, RFID-enabled devices, and computer-based data.

Six medical practices and their respective pharmacies will take part in this research project. Patients will be invited to participate by either passive (postal) or active means (introduction by GP then personal approach by researcher). The trial will take part in two main phases: a 3-week trial followed at exactly four weeks post initiation by a 3-month trial.
It is anticipated that 720 participants will be assessed for suitability, 576 will take part in the 3-week trial and 160 will go on to participate in a 3-month, 2 x 2 factorial trial comprising medication from: usual packaging weekly; MOD weekly; usual packaging monthly; MOD monthly. A simple flow chart is appended (Appendix 1).

3. SCOPE

This SOP is provided by the UEA Research team to each Medical Practice team to provide clear instruction for trial procedures; facilitate project management and ensure appropriate management and confidential storage of materials and data for the Medication Organisation Device project (NIHR HTA 09/34/03).

4. DEFINITIONS

MOD	Device used for organisation of medicines to facilitate correct taking of prescribed medicines. In this case MODs refer only to Nomad Clear, Nomad Clear XL and Venalink devices. Each of these is divided into compartments labelled with days of the week and times of the day.
RFID	Wireless non-contact system that uses radio-frequency electronic fields to transfer data from a tag attached to an object.
OtCM™	Clear plastic film with printed microcircuit which adheres to the foil backing of drug blister packs and which, when the circuit is broken, records electronically the time and date of medicine –removal events.
OSDF	Oral solid dose form medications are medications in tablet or capsular format

5. RESPONSIBILITY

Project management, recruitment, assessment of participant ability, patient visits and data collation will be the responsibility of researchers.

Participant recruitment and specified data collation will be facilitated by medical practice personnel and GPs
Medication supply, delivery and storage of removed medicines, attachment of monitoring devices, collection and storage of used monitoring devices and specific data collation and provision will be the responsibility of pharmacists in conjunction with researchers.

Individual researchers and project associated personnel are expected to behave in a professional manner and in accordance with NHS, Pharmacy and University rules and regulations and the project RISP agreement.

All parties should be aware that as 'persons receiving healthcare', the subjects of this trial must be considered 'vulnerable' under the Safeguarding Vulnerable Groups Act (2006).
If you have any concerns regarding individual participants or any procedures or safeguarding issues arising from this trial then you must immediately contact either the trial manager (Clare Aldus XXX or XXX) or Chief Investigator (Debi Bhattacharya XXX).

6. PROCEDURE

The following section provides detail for procedures to be used. Study procedures are also outlined in a flow diagram (Appendix 1).

6.1 Contact details

For any general queries, however seemingly trivial please contact us:

Project Manager	Clare Aldus	XXX XXX
Researcher	Sathon Boonyaprapa	XXX XXX
Researcher	Trish Boyton	XXX XXX

6.2 Recruitment processes

These include patient database searches, GP verification of potential eligible participants, introduction to the study by practice personnel and recruitment by researcher.

6.2.1 Database search

The patient database will be searched according to the SystmOne search procedure detailed in Appendix 2. Inclusion and exclusion criteria with the list of drug names and strengths relevant to the trial are detailed in Appendix 3. To be eligible to take part, patients should be prescribed at least two different solid oral dose forms at strengths indicated (Appendix 3).

6.2.2 GP verification of list

A list of patients fulfilling the stated criteria will be prepared and provided to the GP. The GP will identify any patients thought unsuited to inclusion for any other reason. For example, patient xxx should be excluded because he is known to be currently suffering from a severe depressive episode. Numbers of, and reasons for exclusion should be provided to researchers. The names of patients excluded in this way should not be revealed to researchers. Patients will be identified in the practice database if eligible for inclusion.

6.2.3 Accommodating the researcher at the GP Practice

Practices will facilitate the presence of the researcher by providing a desk or table and two chairs in patient waiting area. Researchers will provide all other study materials.

6.2.4 Introducing eligible patients to the study

When a patient 'flagged' on the patient database as eligible for the study, visits the surgery for a medical appointment at a time when a researcher is present at the practice, medical staff (this may be the receptionist, nurse or GP) will:

1. Explain that there is a study going on regarding medication organisation devices and that they may be eligible to take part.
2. Provide the patient with the patient information leaflet.
3. Tell the participant that there is a researcher in the waiting area who will be very pleased to provide more detail about the study without obligation.
4. 4. Note the name of the person to whom the PIL has been given so that person will not receive another copy of the PIL at a later date.

6.2.5 Further patient information required

Researchers will provide GP practices with details of participants who have consented to take part in the trial so that additional information pertaining to these participants can be provided to researchers. Additional information comprises:

1. Age
2. Co-morbidities
3. List of all medicines prescribed to participant
4. NHS number for access to Health Episode Statistics;
5. Details of use of practice services for the duration of the trial

For all consented patients we will ask for details listed (items 1-3). These data will be used to characterise the study population. For consented patients who proceed to randomisation we will ask for further details (listed items 1-5). The information required on the use of hospital and GP practice services will be used to determine differences in frequency and cost of healthcare utilisation for RCT intervention and control groups. We would like you to tell us:

- The number of contacts with a healthcare professional within the practice
- The type of healthcare professional e.g. nurse, GP or healthcare assistant
- Whether it was in person at the practice, by telephone or a home visit

Please note that we do not need to know why patients saw the healthcare professional.

6.3 Providing feedback to researchers

It would be beneficial to the design of a future definitive trial to obtain positive and negative feedback concerning the design and execution of the trial. Healthcare professionals involved with this trial will be invited to take part in a focus group after the trial. Other feedback can be provided by email, letter or telephone.

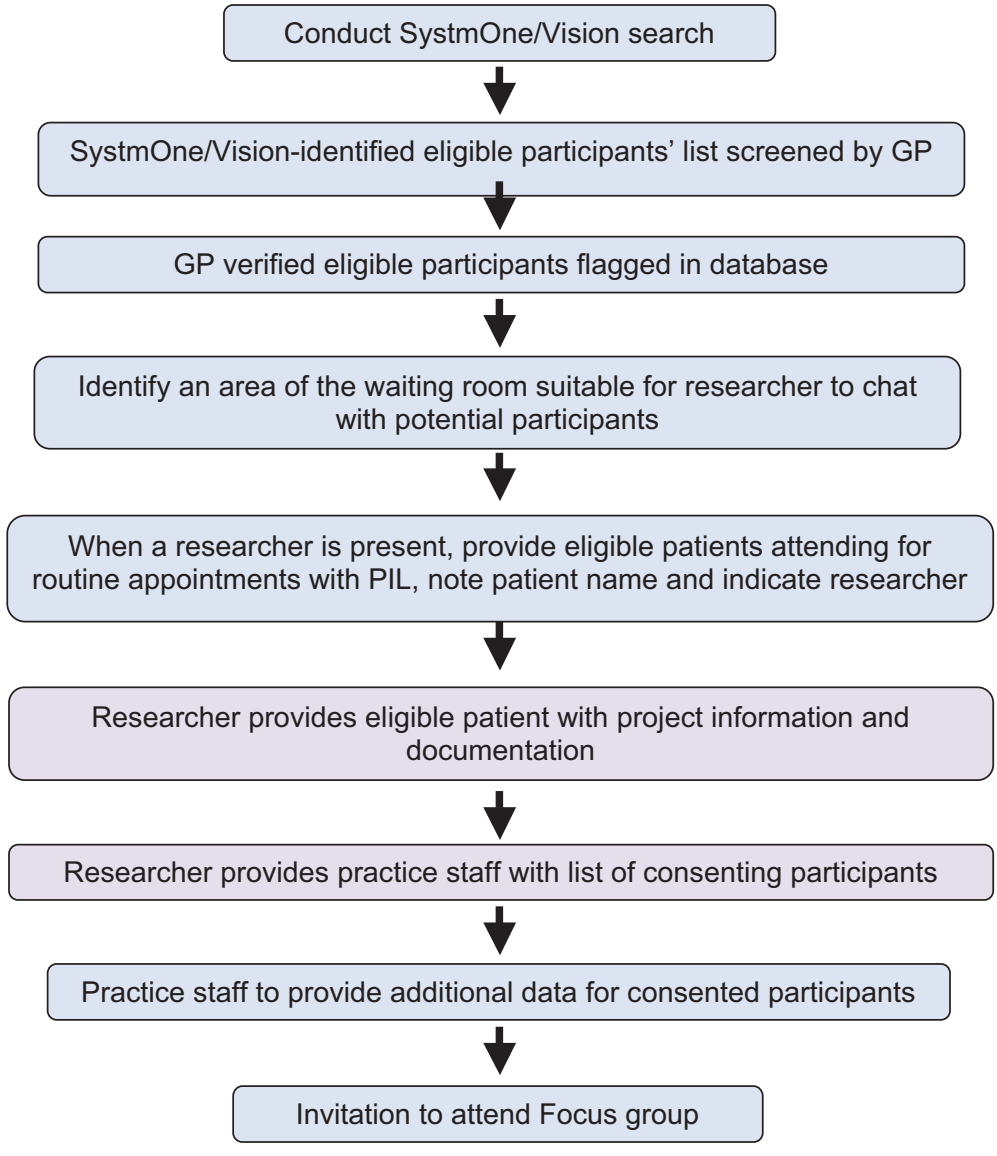
6.4 Post-trial discussion with participants

As a direct result of this trial, participants may feel that they would like to be assessed for suitability for receiving medicines in MODs. Researchers will refer participants expressing this wish to pharmacists for professional advice. GPs may wish to refer patients expressing this wish to the local pharmacist or to the Norfolk Medicines Support Service.

7. REFERENCES

PCRN RISP agreement
Project protocol NIHR HTA 09/34/03
PIL (Patient Information Leaflet)

Appendix 1. Flow chart



Appendix 2. Process for identifying eligible patients for MODs

Search 1							
Age	Current age	over	75	years			
Repeat templates	Drug name	Aspirin 75	Report only current repeats	last issued	After	10th May 2012	
Search 2							
Age	Current age	over	75	years			
Repeat templates	Drug name	simvastatin 40	Report only current repeats	last issued	After	10th May 2012	
Search 3							
Age	Current age	over	75	years			
Repeat templates	Exact drugs	Ramipril 5mg capsules and ramipril 10mg capsules	Report only current repeats	last issued	After	10th May 2012	
Search 4							
Age	Current age	over	75	years			
Repeat templates	Drug name	Bendroflumethiazide 2.5	Report only current repeats	last issued	After	10th May 2012	
Search 5							
Age	Current age	over	75	years			
Repeat templates	Exact drugs	Amlodipine 5mg tablets and Amlodipine 10mg tablets	Report only current repeats	last issued	After	10th May 2012	
Search 6							
Age	Current age	over	75	years			
Repeat templates	Exact drugs	Atenolol 25mg tablets and Atenolol 50mg tablets	Report only current repeats	last issued	After	10th May 2012	
Search 7							
Age	Current age	over	75	years			
Repeat templates	Exact drugs	tablets	Report only current repeats	last issued	After	10th May 2012	
Search 8							
Age	Current age	over	75	years			
Repeat templates	Exact drugs	Metformin 500mg tablets	Report only current repeats	last issued	After	10th May 2012	
Search 9							
Age	Current age	over	75	years			
Repeat templates	Exact drugs	Omeprazole 20mg gastro-resistant capsules	Report only current repeats	last issued	After	10th May 2012	
Search 10							
Age	Current age	over	75	years			
Repeat templates	Drug name	Levothyroxine sodium	Report only current repeats	last issued	After	10th May 2012	
Search 11							
Age	Current age	over Lansoprazole 30mg gastro-resistant capsules and	75	years			
Repeat templates	Exact drugs	Lansoprazole 15mg gastro-resistant capsules	Report only current repeats	last issued	After	10th May 2012	
Search 12							
Join searches 1 to 11 (Only report on patients found in at least a specified number of the selected reports)	"Patients must be found in at least"	2 of the join groups					This will give you all patients prescribed any 2 of the medicines from the provided list
Search 13							
Age	Current age	over	75	years			
Clinical	Read coded entries	Xalw/Q **or as appropriate for psychoses**					This will identify patients with psychotic disorders
Search 14							
Age	Current age	over	75	years			
Clinical	Read coded entries	F12 **or as appropriate for Parkinson's disease**					This will identify patients with Parkinson's disease
Search 15							
Join searches 13 to 14 (report on patients found in either of the selected reports)							This will identify patients having Parkinson's disease or psychoses
Search 16							
Join search 12 to search 15	Assign search 12 as report one and search 15 as report two	Report on patients found in report one but not in report two					This will give you all patients prescribed any 2 of the medicines from the provided list and NOT having Parkinson's disease or diagnosed with psychotic disorders. Please save this search.
Please now give the patient list of search 16 for a GP to review to ensure that no inappropriate patients get sent an invitation							
Once the list has been finalised:	1) Record the number of patients excluded by the GP						
	2) Record the reason(s) why any patients are excluded by the GP						
	3) Read code every patient that is eligible for study participation and sent an invitation letter (use any read code that you wish but please make sure that you						
	4) 'Flag' eligible participants so that they can be easily identified when visiting surgery						

Appendix 3. Inclusion and exclusion criteria to be applied in the selection of participants and tabulated drug names and concentrations

The search criteria for your patients should include ALL patients:

- aged 75 years or over
- prescribed two or more oral solid dose form (OSDF) medications for the management of a chronic condition from those tabulated (Table 1)
- a life expectancy equal to or in excess of one year
- capable of providing informed consent

The search criteria should exclude ALL patients

- in receipt of a prescribed MOD or with a history of having received a MOD
- resident in a care home
- currently or recently involved in medication intervention trials
- diagnosed with Parkinson's disease, a severe mental health disorder such as schizophrenia or other clinical contraindications which in the opinion of the healthcare team renders the patient inappropriate for trial participation*

ALL PATIENTS MUST BE TAKING AT LEAST THREE OSDF MEDICINES

*Please record the number of patients excluded due to the clinical team deeming them inappropriate for trial participation. Please also document the specific reason for exclusion.

Table 1. Most commonly prescribed medicines for persons aged 75 and older

Medicine name	Strength
Simvastatin	40mg
Aspirin dispersible	75mg
Levothyroxine	25mcg, 50mcg, 100mcg
Ramipril	5mg, 10mg
Bendroflumethiazide	2.5mg
Omeprazole	20mg
Amlodipine	5mg, 10mg
Lansoprazole	15mg, 30mg
Atenolol	25mg, 50mg
Metformin	500mg
Furosemide	20mg, 40mg