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

TABLE OF CONTENTS

1. ABBREVIATIONS

NIHR	National Institute of Health Research
HTA	Health Technology Assessment
RCT	Randomised Controlled Trial
MOD	Medication Organisation Device
RFID	Radio frequency identification
OSDF	Oral solid dose form
OtCM™	Objective therapy Compliance Monitoring
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 all 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 medicines are those in tablet or capsular format.

5. RESPONSIBILITY

Project management, assessment of participant ability, patient home 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 01603 593944 or 07538835530) or Chief Investigator (Debi Bhattacharya 01603 593391).

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	01603 593944
Researcher	Sathon Boonyaprapa	01603 592020
Researcher	Trish Boyton	01603 592020

6.2 Recruitment processes

These include patient database searches, GP verification of potential eligible participants, letters of invitation to participate and letters of reminder for non-responders.

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 Recruitment packs

Practices will be provided with recruitment packs and a template letter of invitation (Letter 2, Appendix 4). The letter of invitation should be prepared on headed paper and individual Practice Manager or Practice Researcher contact details must be added to the letter as appropriate. This letter should then be added to the recruitment pack, with the address of the patient positioned at the window in the envelope, and the pack sent to potential participants.

Recruitment packs will contain Letter 2 (inserted at the medical practice), a patient information leaflet (PIL), consent form, questionnaire 1, prescription request and collection application form and a stamped addressed envelope.

Recruitment packs will be posted to all GP-verified eligible patients. Postage costs will be refunded by UEA.

6.2.4 Reminder letter sent to non-responders

Researchers will identify responders to the surgery. From this the GP practice can identify non-responders. A reminder letter (Letter 9; Appendix 6) should be prepared on headed paper, to be sent to non-responding potential recruits. The letter of reminder should be prepared on headed paper with individual Practice Manager or Practice Researcher contact details added as appropriate. Postage and stationery costs will be refunded by UEA.

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 is essential to the design of a future definitive trial to obtain both positive and negative feedback concerning the design and execution of the trial. Health care professionals involved in the trial will be 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.

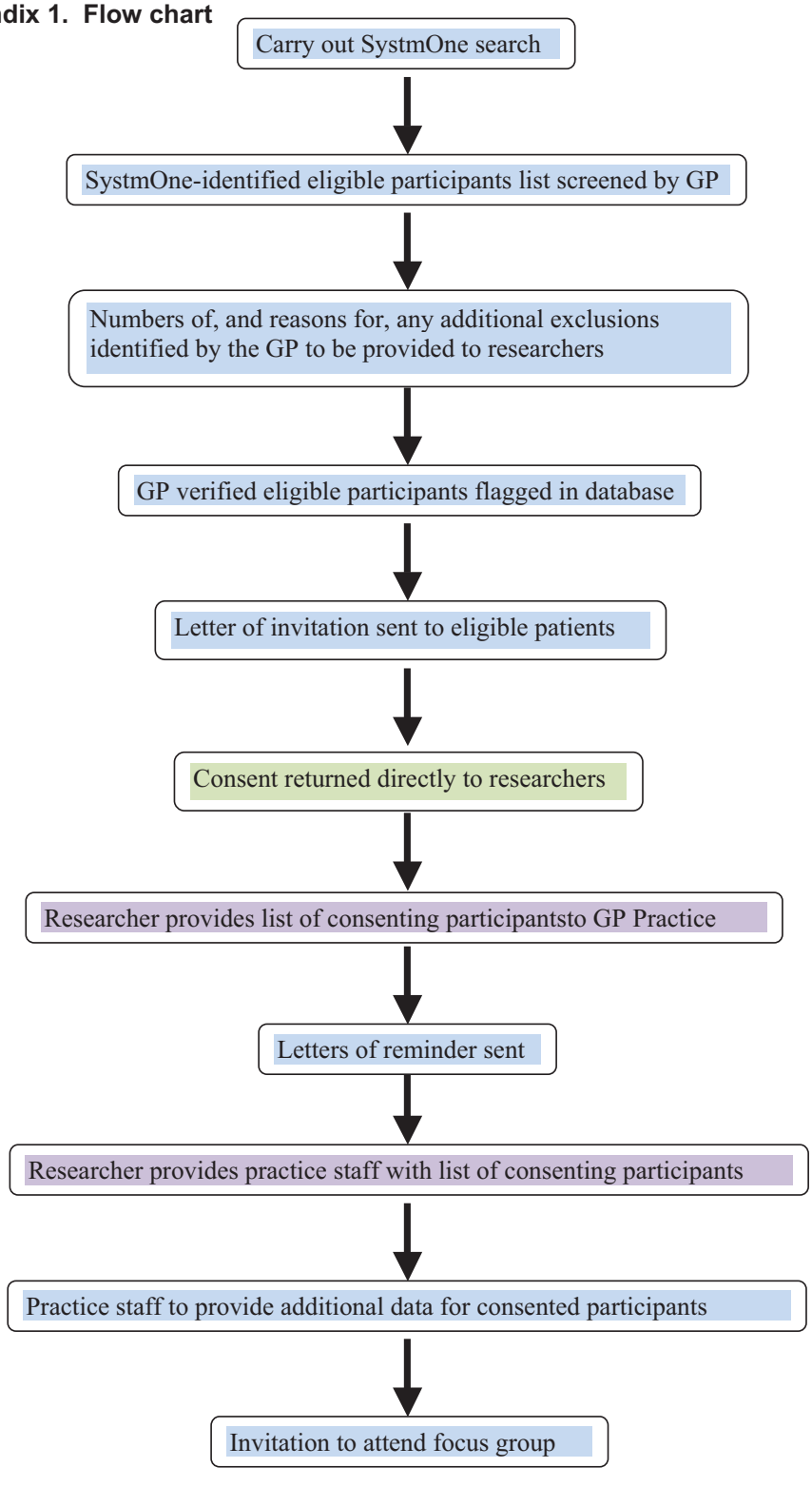
7. REFERENCES

PCRN RISP agreement

Project protocol

PIL (Patient Information Leaflet)

Appendix 1. Flow chart



Appendix 2. Process for identifying eligible patients for MODs

Search 1			75 years				
Age	Current age	over					
Repeat templates	Drug name	Aspirin 75	Report only current repeats	last issued	After	10th May 2012	
Search 2			75 years				
Age	Current age	over					
Repeat templates	Drug name	simvastatin 40	Report only current repeats	last issued	After	10th May 2012	
Search 3			75 years				
Age	Current age	over					
Repeat templates	Exact drugs	Ramipril 5mg capsules and ramipril 10mg capsules	Report only current repeats	last issued	After	10th May 2012	
Search 4			75 years				
Age	Current age	over					
Repeat templates	Drug name	Bendroflumethiazide 2.5	Report only current repeats	last issued	After	10th May 2012	
Search 5			75 years				
Age	Current age	over					
Repeat templates	Exact drugs	Amlodipine 5mg tablets and Amlodipine 10mg tablets	Report only current repeats	last issued	After	10th May 2012	
Search 6			75 years				
Age	Current age	over					
Repeat templates	Exact drugs	Atenolol 25mg tablets and Atenolol 50mg tablets	Report only current repeats	last issued	After	10th May 2012	
Search 7			75 years				
Age	Current age	over					
Repeat templates	Exact drugs	tablets	Report only current repeats	last issued	After	10th May 2012	
Search 8			75 years				
Age	Current age	over					
Repeat templates	Exact drugs	Metformin 500mg tablets	Report only current repeats	last issued	After	10th May 2012	
Search 9			75 years				
Age	Current age	over					
Repeat templates	Exact drugs	Omeprazole 20mg gastro-resistant capsules	Report only current repeats	last issued	After	10th May 2012	
Search 10			75 years				
Age	Current age	over					
Repeat templates	Drug name	Levothyroxine sodium	Report only current repeats	last issued	After	10th May 2012	
Search 11			75 years				
Age	Current age	over					
Repeat templates	Exact drugs	Lansoprazole 30mg gastro-resistant capsules and 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	XaIWQ **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 repontone 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 lis 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

Appendix 4. Example letter of invitation

GP practice letter head

<Patient name>

<Patient address1>

<Patient address2>

<Patient address3>

<Patient postcode>

<Date>

Dear <Patient name>

An invitation to take part in a research project to study the effects of pillboxes

We are one of six medical practices that are involved in a research project to test the effects of pillboxes. You have been identified as someone who could help with this project.

Please find enclosed a leaflet providing more detailed information about the project, a consent form and a questionnaire.

You do not have to participate but if you decide to take part, please fill in the consent form and questionnaire and send them to the researchers using the prepaid envelope supplied within two weeks of receiving this letter. The researchers have not been provided with any information about you and will only contact you if you provide consent. If you have any questions relating to this letter please contact (named contact at medical practice).

Yours sincerely,

<Contact name within practice>

Letter 2 invitation v3 13 06 2012

Appendix 5. Example letter of reminder

GP practice letter head

UEA letter head

<Patient name>

<Patient address1>

<Patient address2>

<Patient address3>

<Patient postcode>

<Date>

Dear <Patient name>

We recently sent you a letter inviting you to take part in a study to test the effects of pill boxes. If you would like to accept our invitation to take part, please read the enclosed leaflet providing more detailed information about the study. If you then decide you would like to take part in the study, please complete the enclosed consent form and return it in the prepaid envelope provided as soon as possible.

We will only contact you with further information if we hear from you. If you have any questions relating to this letter please contact <named person> on <contact telephone number>).

Yours sincerely,

<Contact name within practice>

Letter 10 invitation v2 13 06 2012