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Implementing a medication review and deprescribing intervention for older people living with frailty and polypharmacy in General Practice: a feasibility study.

Eloise Radcliffe* ^{1,2}, Ngianga Kandala², Tracey Sach¹, Sara McCloskey¹, Clare Howard³, Claire Sheikh⁴, Katherine Bradbury^{2,8}, Sue Latter⁶, Alejandra Recio Saucedo⁹, Mark Lown¹, Lawrence Brad⁷, Simon D.S. Fraser^{1,2} Kinda Ibrahim^{1,2}

Author affiliations

1. School of Primary Care, Population Sciences and Medical Education, Faculty of Medicine, University of Southampton,
2. NIHR Applied Research Collaboration ARC Wessex, University of Southampton, Southampton, UK
3. Health Innovation Wessex, Science Park, Chilworth, Southampton, UK
4. Living Well Partnership, Southampton, UK
5. School of Pharmacy and Biomedical Sciences, Portsmouth University, Portsmouth, UK
6. School of Health Sciences, University of Southampton, Southampton, UK
7. Westbourne Medical Centre, Westbourne, Bournemouth, UK
8. School of Psychology, University of Southampton, Southampton, UK
9. School of Healthcare Enterprise and Innovation, Trials and Studies Coordinating Centre, National Institute of Health Research Evaluation, University of Southampton, Southampton, UK

* Corresponding author: Eloise Radcliffe- e.radcliffe@soton.ac.uk

Abstract

Background: Polypharmacy in older adults with frailty increases risks of adverse outcomes. Evidence supports proactive structured medication reviews (SMRs) for medicines optimisation, including deprescribing, however challenges exist in general practice.

Aim: To test the implementation of a co-designed multidisciplinary SMR intervention (MODIFY) for this high-risk group.

Design and Setting: A non-randomised pre-post feasibility study was conducted across five general practices in England. The multidisciplinary intervention comprised five components including patient and health care professional (HCP) preparation.

Method: Patients aged ≥ 75 with moderate-to-severe frailty (eFI > 0.25) and ≥ 5 medications were identified and invited to participate. Primary outcomes were recruitment, retention, and completion of outcome measures. Secondary outcomes included medication-related outcomes, healthcare utilisation, adverse drug reactions, and acceptability to patients and HCPs based on qualitative interviews.

Results: Of 479 patients invited, 48 were recruited (10% rate); 47 received the intervention, 43 completed three-month follow-up (92% retention). Medication changes occurred in 87% of participants; 72% had at least one medication stopped and 26% had a dose reduced. The mean number of medications decreased slightly by 0.27 (SD:1.44) without significant change in clinical and patient-reported outcomes (including function, frailty status, treatment burden) and no reported adverse events. Qualitative interviews with 10 patients, 1 carer, and 8 HCPs, indicated high acceptability and perceived value, and suggested improvements. Economic data was well completed. SMRs cost £28.50 per patient. Participants' reported quality of life improved slightly over three months.

Conclusion: The MODIFY intervention is feasible and acceptable for deprescribing in primary and support progression to a definitive trial.

How this fits in: Polypharmacy and inappropriate prescribing are common among older people with frailty, yet structured deprescribing is inconsistently delivered in general practice. This study shows that a pharmacist-led, patient-centred deprescribing intervention is feasible and acceptable within routine primary care. It highlights the importance of structured tools, multidisciplinary collaboration, and follow-up planning to support high-quality medication reviews. These findings provide a clear rationale for a definitive randomised controlled trial to assess clinical and cost effectiveness in general practice.

Background

Polypharmacy (taking five or more regular medications on daily basis) affects nearly half of people in England aged 65 and over (1, 2). Polypharmacy in older people is associated with increased potentially inappropriate medications (PIMs) (3) leading to increased risk of falls, cognitive impairment, functional decline, hospital admission and death (4-6). In older people living with frailty medications harm can be amplified and can outweigh benefits or the known time to benefit exceeds projected life expectancy e.g. statins (7). Additionally, the goals of drug treatment in this population may change from reducing the risk of disease and prolonging life to reducing the burden of treatment and maintaining quality of life (8). Frailty may influence factors such as drug pharmacokinetics and pharmacodynamics, toxicity, and therapeutic efficacy. In turn, these factors may be involved in the development of frailty (9).

Therefore, it has been recommended that people living with frailty and those with complex and problematic polypharmacy should receive a structured medication review (SMR) annually by their general practice team, specifically a clinical pharmacist (10, 11) referred to throughout as a 'pharmacist'. An important aspect of SMR is deprescribing which involves tapering /dose reduction, stopping, or switching drugs with the goal of improving outcomes (12). Deprescribing has been shown to be feasible and safe across a wide range of conditions, medications, settings and with the use of different deprescribing tools (13-18). Deprescribing can lead to a reduction in polypharmacy and PIMs and for those living with frailty, can result in important benefits in relation to depression, function and frailty status (7, 19).

Implementing deprescribing in primary care can be challenging, but several facilitating factors have been identified (20). These include collaboration within well-integrated multidisciplinary teams (MDTs) with clear roles, where pharmacists lead with input from other professionals as needed. Effective digital and face-to-face communication, co-location, access to patient records, systems to identify high-risk patients, and use of tools to support SMRs further facilitate deprescribing (20). Face-to-face consultations are particularly valuable for discussing deprescribing, although communication should be tailored to patient and carer needs (20). Patient and carer education, shared decision-making, and trust in HCPs are also key facilitators (21-23). Clear plans for monitoring and follow-up after SMRs support continuity of care [for example (24)]. Despite this growing evidence, no intervention has yet been developed and tested that integrates these facilitators and is feasible for implementation in routine primary care.

To address this, a complex intervention to support medication review and deprescribing in primary care for older people living with frailty and polypharmacy was co-developed with key stakeholders, including patients, carers and health care professionals (HCPs) (MODIFY). This was achieved through three iterative stages of: reviewing the evidence; collecting and analysing primary qualitative data; and collaborating with stakeholders, guided by the principles of realist synthesis and the person-based approach (25, 26). This paper presents the research conducted which aimed to assess the feasibility and acceptability of implementing the intervention in general practice among older people living with frailty, to inform a future substantive trial.

Methods

Study design

This was a non-randomised pre-post quasi experimental study testing the feasibility of implementing the MODIFY intervention in general practice in England (25). The Medical Research Council's framework (27) for developing complex interventions underpinned the study. The framework recommends that a feasibility study should be designed to assess predefined progression criteria that relate to the evaluation design or the intervention itself, to determine whether an evaluation, for example a randomised controlled trial (RCT), is feasible, whether it can be carried out at a reasonable cost, and by which methods. Although this study is not an RCT, the results of the study will be reported in accordance with the CONSORT 2010 Statement: extension to randomised pilot and feasibility trials but only in relation to those elements of the statement that are appropriate for a study of this type (28) (refer to supplementary file B).

The MODIFY intervention


The intervention involved five key components (see figure 1 and refer to our previous publication for further details (25)).

Figure 1: MODIFY intervention stages


The MODIFY intervention for Structured Medication Review (SMR) and deprescribing

The five main stages:


1 Proactive identification of patients for targeted medication review
focusing on frailty (using e-FI>0.25, age (>=75 years), taking =>10 regular medications)




2 Patients and carers preparation
sending "Reviewing your medicines" leaflet prior to SMR appointment to explain the purpose of SMR, rationale for deprescribing and empower them to prepare and ask questions about medicines




3 Health Care professional preparation
use the PresQIPP IMPACT online tool** to identify and prioritise high-risk medications for deprescribing, save in patient record, review patients notes, discuss with GP or other HCPs if necessary



4 Person-centred medication review, multidisciplinary team involvement as and when necessary
use evidence-based deprescribing sheets and IMPACT data alongside person-centred approach to discuss and agree any potential deprescribing recommendations



5 Clear, tailored, documented follow-up plans
use "Safely stopping your medicines" to summarise any agreed changes to medication (e.g. reduce doses, tapering protocols, symptoms to monitor, instructions for restarting medications if needed) and agree follow-up plans with the patient (e.g. further appointment, or follow-up text message)



*Resources to support patients having a Structured Medication Review - The Health Innovation Network
**Bulletin 268: IMPACT (prescqipp.info)

Recruitment

Practices and staff: Four general practices took part in the intervention development phase, where staff who had indicated willingness to test the intervention were approached (25). An additional fifth practice expressed an interest in taking part after recruitment had begun, and they were subsequently enrolled. Practices were located across the South-East of England and included three practices in predominantly rural/coastal areas and two in urban areas. Practices were located in areas with a range of deprivation levels, including one within 10% of most deprived areas in England (29). To be eligible for participating in the study, practices had to have at least one

pharmacist (prescribers and non-prescribers) and one GP who agreed to work together to deliver the intervention. Staff in the five practices (including pharmacists, GPs, administration staff) attended an online research initiation meeting to present the evidence behind the intervention and to establish the research process.

Patients: Patient inclusion criteria were as follows: age 75 and over and taking five or more regular medications with a frailty score >0.25 using the Electronic Frailty Index (moderate to severe frailty) (30). Patients were excluded if they lived in a care/nursing home, had received an SMR within the last 6 months, were at end of life (palliative care), or lacked the capacity to give informed consent, as judged by their GP (eg. diagnosis of dementia). Patient participant lists were generated from each General Practice database, using a search developed based on the inclusion criteria. Each practice then selected a proportion of patients (usually the first 50 patients in an alphabetical list to begin with) and sent them an invitation via text message that included a link to an invitation letter, participant information sheet and consent form. Patients were invited to either call a study phone number or complete an online form with their contact details (phone number/ email/ address, depending on their preference) if interested. Written consent to take part in the feasibility study was obtained from all participants.

Sample size

Recruitment ran between April and July 2024, with the aim of recruiting approximately 50 patients in total (10 patients in each of the 5 practices). As this is a feasibility study, no formal power calculation was required. The sample of 50 participants allows for sufficiently precise estimation of key feasibility parameters. Specifically, an observed recruitment proportion of 0.50 would yield a 95% confidence interval of ± 0.15 , which provides adequate precision to assess whether recruitment is likely to meet the $\geq 75\%$ progression threshold for a full trial.

Data collection and outcome

Data at baseline included patients' demographics (age, gender, level of educational attainment, marital status, usual residence, and ethnicity), number of comorbidities, cognition using the Abbreviated Mental Test Score (AMTS) (31) and self-reported alcohol consumption were collected.

Patient data were collected between April and October 2024, at baseline (at the point of recruitment) and 3-month follow-up from the date of baseline) from the patient's clinical records by research delivery staff, and also collected from patients by a researcher (ER) via telephone or in-person, depending on patient/carer preference and needs. Patients were invited to complete a diary to record any adverse drug events or changes to their medications.

Data on all medications prescribed were extracted from the patient medical records, supplemented by self-reported data obtained from the patients at baseline and 3-months follow-up. The number and therapeutic classes of medications included in the BNF (British National Formulary) chapters 1-4 and 6-10 (32) were recorded which are used for chronic conditions excluding topical and acute medications. Focusing on these medications has been recommended in several systematic reviews (15, 33).

A number of further outcome measures were collected from the patients by a researcher (ER) at baseline and 3-months: PRISMA7 questionnaire for frailty (34), the SARC-F questionnaire to measure risk of sarcopenia (35), the modified Barthel index activities of daily living to measure function (36), self-reported falls and fractures in previous 3-months, the Multimorbidity Treatment Burden Questionnaire (MTBQ) for treatment burden (37), the EUROQOL ED-5D-5L for quality of life (38), healthcare utilisation (number of visits to GP/specialists and number of unplanned hospitalisations), and self-reported adverse drug events (ADEs).

Primary outcomes: the primary focus of this feasibility study was to estimate

- proportion of eligible patients in each practice,
- patient recruitment rates,
- patient follow-up rates,
- completion of health and patient-related outcome measures (e.g. PRISMA-7, SARC-F, modified Barthel index modified Bartal, MTQB)

Secondary outcomes

Medication-related outcomes: these included the total number of medications (BNF chapters 1-4 and 6-10) at both baseline and 3-month follow-up. Medication changes between baseline and 3-month follow-up were evaluated for each patient by a pharmacist and included stopping medication, reducing dose, and starting new medication. Deprescribing for this study was defined as a medication stopped or dose reduced, the proportion of patients who had at least: one medication stopped, one medication dose reduced, or new medication started. The therapeutic classes of medications stopped, reduced and restarted were also recorded.

Health economic data: Participants' primary, community, secondary care, and prescription resource use was recorded at baseline and 3-months for the previous three month periods

. Health-related quality of life was elicited using the EUROQOL EQ-5D-5L instrument (38).

Acceptability outcomes: These were based on participant feedback on acceptability of the intervention in interviews with a sample of patients who received the intervention, purposively sampled according to gender and general practice to ensure all five practices were represented. HCPs involved in the intervention implementation were interviewed, purposively sampled according to general practice to ensure all five

practices were represented. Two topic guides were co-developed with the study patient and public involvement group to explore patients' and carers' experiences of participating in the feasibility study, any barriers or facilitators experienced and any further feedback to refine and optimise the intervention design (see appendix 1 and 2, supplementary file A). A topic guide was developed to explore HCP experiences of intervention delivery, barriers or facilitators to implementation and any other feedback to refine and optimise intervention design (see appendix 3, supplementary file A). All interviews were recorded and transcribed verbatim, with any identifying data anonymised. Additionally, an online questionnaire measuring confidence in deprescribing (39) was completed by participating HCPs at baseline and after study completion.

Data analysis

Quantitative data analysis: Data were entered on Qualtrics. The number and characteristics of participants recruited were summarised using descriptive statistics. For categorical data, results are reported as frequencies and proportions, whereas for continuous data, the mean, mean difference, and their associated 95% confidence intervals are presented. Outcome measures including PRISMA-7 (frailty), SARC-F (sarcopenia), EQ5D (quality of life), MTBQ (medication adherence) are reported first on their continuous scale, providing full distributional information, and then categorised using definitions and cut-off points to aid interpretability. Prior to the analysis, the distribution of changes in continuous outcome measures at baseline and after 3-months was assessed, and paired t-tests were utilised. Changes in proportions for categorical outcome measures were analysed using the McNemar test. All statistical tests were two-sided, employing a 5% significance level ($p < 0.05$). As the primary aim of this feasibility study is not to assess statistical significance, p-values are presented merely for reference, to support the interpretation of trends. All analyses were conducted using SAS software, version 9.4 (SAS Institute Inc., Cary, NC, USA).

Economic analyses: Completeness was explored for all cost and outcome measures. Visits were valued using published unit costs for 2023/24 (40, 41), and prescriptions were costed at the mean price of all prescriptions listed on the Prescription Cost Analysis (PCA). UK utility values for the EQ-5D-5L were derived using the approach recommended by the National Institute for Health and Care Excellence (NICE) (42). Descriptive analyses were undertaken to calculate mean (SD) cost by resource use item and utility at baseline and 3-months, as well as mean difference (95% CI) in cost and utility between time periods. Quality-Adjusted Life Years (QALYs) were also estimated at 3-months.

Qualitative data were analysed using the Person-Based Approach (26). This consisted of coding the transcripts, and developing a 'table of changes' based on the codes. This systematically tabulated positive and negative intervention feedback, and any possible changes or refinements, and factors that may have influenced patient,

carer and HCP engagement at different intervention stages (35). Three members of the research team (ER, KI, AR) coded the data separately and met several times to discuss and refine the analysis and ensure a consistent and rigorous approach.

Results

Feasibility outcomes

A total of 1505 eligible patients were identified across all five practices (see table 1). Of these, 479 were randomly invited to participate; 62 patients then contacted the researcher through the online form or by phone. Of these, 48 patients were recruited, one patient withdrew (prior to baseline data collection) due to ill-health, resulting in a recruitment rate of 10% (see figure 2). Number of participants recruited from each practice ranged between 2-17.

An overview of participants' characteristics at baseline is presented in table 2. The participants mean age was 81 years (range 75–92) with 51% male participants. Most were married or widowed and 70% lived at home with family or friends. Almost half of the participants left their education after finishing secondary school at the age of 16 and all except reported their ethnicity as white British background. The mean number of long-term medications was 9.93 (± 2.82) at baseline.

Baseline data collection was completed with all patients; 41 (87%) collected over the phone and six (13%) in-person at patient's homes, based on patient preference, mainly due to hearing difficulties. All patients attended their SMR appointment within 28 days of recruitment (range 4-43 days). The majority had face-to-face SMRs (n=42, 89%) with only five having their SMR appointments over the phone, due to patient preference or lack of clinic space. Of the 47 patients who completed baseline data, only 4 were lost at the 3-months follow-up (follow-up rate of 92%); due to ill health (n=1), loss of interest (n=1) and loss of contact with patient (n=2). No adverse events were reported.

Table 1. feasibility of recruitment and follow-up rates.

Practice ID	Total practice population	No. eligible patients identified from the search	% eligible patients	No. patients invited to the study	No. Patients recruited	No. patients attended the medication review appointment	No. patients completed 3-month follow-up
1	45,000	670	1.49	70	11	11	11
2	8,161	162	1.99	100	13	13	11
3	21,003	297	1.41	203	5	5	5
4	8,800	376	4.27	70	17	17	15

5	14,000	45	0.32	36	2	1	1
Total	-	1505	-	479	48	47	43

Collecting health and patient-related outcome measures (e.g. PRISMA-7, SARC-F, modified Barthel index modified Bartal, MTQB) was feasible and complete from all patients at both baseline and three month follow-up. At baseline 68% of patients were frail according to PRISMA-7 and 34% had potential sarcopenia according to SARC-F. Approximately 70% of patients lived independently according to Barthel and the rest had slight or moderate dependence. All patients had no (36%) or low treatment burden (64%). As shown in table 3, there was no statistically significant change in these outcomes between baseline and follow-up.

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Figure 2: Consort Diagram for the study procedures

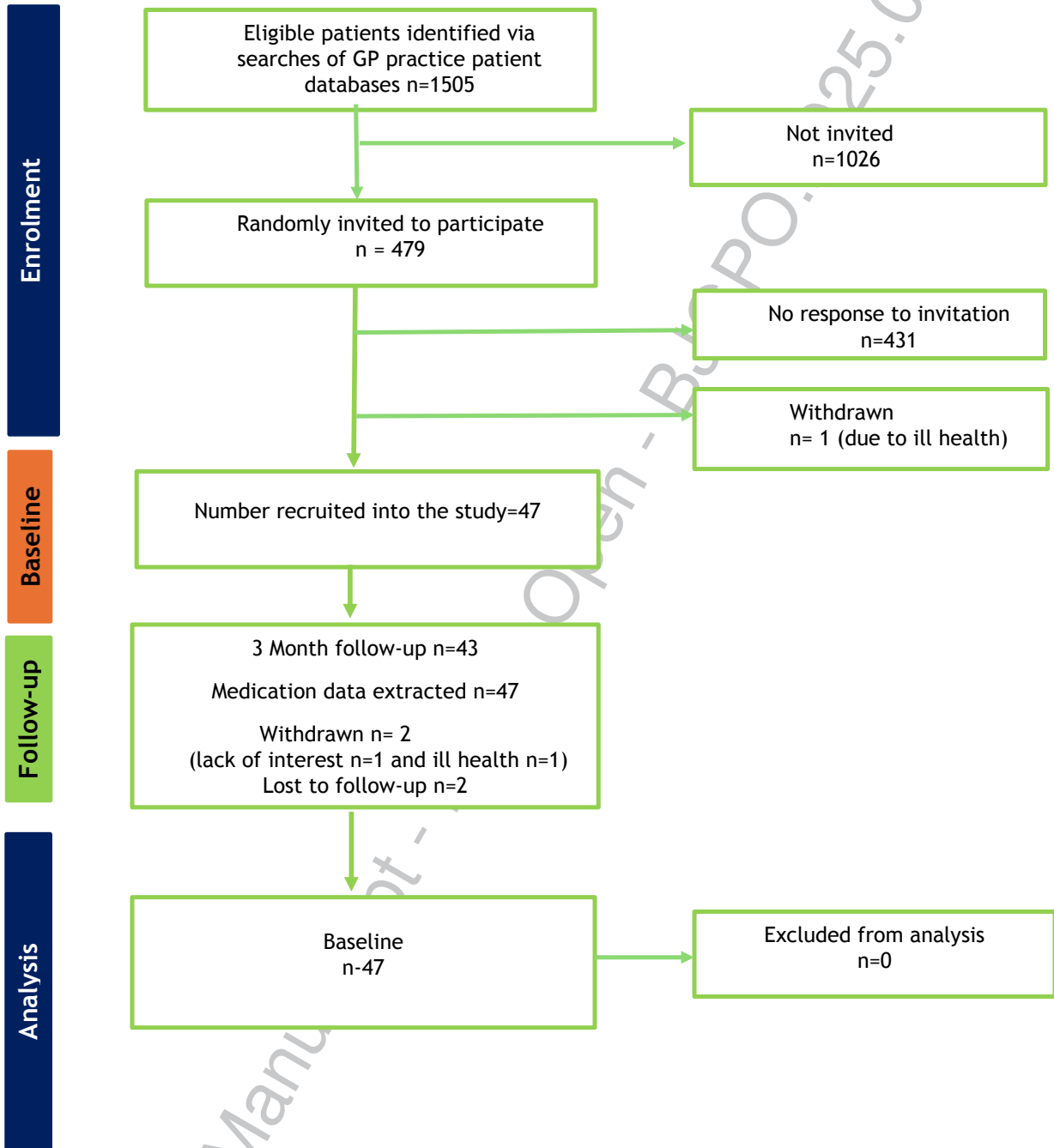


Table 2. Patient baseline characteristics.

Variable	Number(n)	Percentage(%)
Gender		
Female	23	49
Male	24	51
Age in years, Mean (SD) [Min – Max]	81(5)	[75 -92]
Number of Medications Mean (SD) [Min – Max]	9.93 (3)	[5-19]
Number of comorbidities Median [Min – Max]	4[3 – 5]	
AMT Median [Min – Max]	10 [9-10]	
Marital status		
Single	5	11
Married	32	68
Divorced or separated	2	4
Widowed	8	17
Residency		
Private home living alone	13	28
Private home living with friends or relatives	33	70
Sheltered accommodation	1	2
Ethnicity		
White	46	98
Mixed	1	2
Education		
Secondary school up to 16 years	22	47
Higher or secondary or further education (A-level, BTEC, etc)	12	25
College or University	10	21
Postgraduate degree	3	6
Do you normally drink alcohol?		
No	21	45
Yes	26	55
Number. of Falls in previous 12 months -Median (Lower, Upper Quartiles)	1(1, 2)	[1 , 18]
	[Min ,Max]	
Fractures in the previous 12 months?		
No	45	96
Yes	2	4

Table 3. Outcome measures comparisons – At baseline and three months, figures are mean and standard deviation unless otherwise stated.

Variable	Baseline	At 3 months	Means difference	P-value
			Mean (95% CI)	
PRISMA-7	3.26(1.36)	3.28(1.61)	-0.02(-0.39 - 0.39)	0.996 [!]
Frail=Score of 3 or higher	32(68%)	29(67%)		0.995*
Robust=Score <3	15 (32%)	14(33%)		
SARC-F	2.98(2.58)	2.93(2.25)	0.05(-0.34 - 0.81)	0.421 [!]
Sarcopenia: score of 4 or higher	16(34%)	16 (37%)		0.995*
Robust: Score <4	31(66 %)	27 (63%)		
Barthel	96.85(7.03)	95.23(13.44)	1.62(-2.8 - 5.63)	0.501 [!]
Total dependence (Score of 0–20)	0 (0 %)	1(2%)		0.111*
Severe dependence (Score of 21–60)	0 (0 %)	0 (0%)		
Moderate dependence (Score of 61–90)	7 (15%)	7 (17%)		
Slight dependence (Score of 90–99)	7 (15%)	1 (2%)		
Independent (Score of 100 or more)	33 (70%)	34 (79%)		
MTBQ	1.66(1.82)	1.74(1.95)	-0.08(-0.45 - 0.59)	0.788 [!]
No burden (score 0)	17 (36)	15 (35%)		0.563*
Low burden (score <10)	30 (64%)	28 (65%)		
Medium burden (10-22)	0 (0%)	0 (0%)		
High burden (>=22)	0 (0%)	0 (0%)		
Hospital admission at least once in the previous 3 months	40 (87%)	40 (87%)	0.00	
No	6 (13%)	6 (13%)		
Yes				

*McNemar's Test, [!] Paired t-test

Medication-related outcomes

The mean number of medications included in the BNF chapters 1-4 and 6-10 reduced slightly by 0.27(SD:1.44) from 9.93 (± 2.82) at baseline to 9.66(± 2.77) at 3-month follow-up. All patients apart from six (13%) had at least one medication change (medication stopped, started or dose reduction) following the SMR, with an average of 1.5 medication changes per patient. A total of 53 medications were stopped, with 72% of patients having at least one medication stopped following the SMR and 15 medication doses were reduced among 26% of patients. The most common medications reduced or stopped were antihypertensive medications (n=20), medications for gastro-intestinal systems such as PPI (n=9), followed by central nervous system medications (n=7) and medications for respiratory disease (n=7). However, 60% of patients also started at least one new medication following the SMR, most commonly anti-diabetics (n=7) and antihypertensives (n=7). Reasons for changing medications were not recorded.

Health economic data

Participants' resource use and EQ-5D-5L data were completed at for all patients at baseline, and for 87% at 3-months (see Appendix 4, supplementary file A). Unit costs are reported in Appendix 5 and resource use in Appendix 6 of supplementary file A. Key health economic outcomes are reported in Table 4.

SMRs were assumed to take 30 minutes and cost £28.50. Participants had an average of 1.40 (1.04) SMR appointments during the 3-month period, equating to a mean (SD) cost of £40.02 (29.51). Prescriptions, GP visits, nurse visits, pharmacist visits for SMR, outpatient/other secondary care visits, and inpatient visits appear to be the major cost drivers. Given the available data, medications could not be costed individually. The future trial should collect more detailed data on medication use. Mean (SD) utility scores were 0.623 (0.268) at baseline and 0.665 (0.181) at 3-months.

Table 4. Health economic costs (UK 2023/24 £s) and outcomes, based on available cases

Resource Items	Baseline Mean (SD)	N (%)	3-month Mean (SD)	N (%)	Mean (95% CI) difference
Intervention					
MODIFY intervention-SMR	£0 (0)	47 (100%)	£40.02 (29.51)	47 (100%)	40.02 (31.36; 48.69)
Primary and community care					
General Practitioner clinic visit	£39.36 (37.32)	47 (100%)	£41.72 (45.39)	47 (100%)	£2.36 (-12.04; 16.76)
Practice nurse clinic visit	£3.74 (5.15)	47 (100%)	£16.00 (9.18)	46 (98%)	£12.26 (9.32; 15.18)
Practice pharmacist visit (non-SMR)	£1.21 (3.77)	47 (100%)	£1.41 (3.95)	47 (100%)	£0.20 (-1.49; 1.90)
NHS Walk in centre	£1.87 (12.84)	47 (100%)	£1.87 (12.84)	47 (100%)	0 (-5.39; 5.39)
NHS out of hours visit	£0 (0)	47 (100%)	£5.81 (39.82)	47 (100%)	£5.81 (-5.88; 17.50)
NHS 111 service (call service)	£0 (0)	47 (100%)	£1.17 (3.89)	47 (100%)	£1.17 (0.03; 2.32)
Health visitor(HV)	£0 (0)	47 (100%)	£0 (0)	46 (98%)	N/A
Physiotherapist (PH)	£0 (0)	47 (100%)	£0.89 (6.05)	46 (98%)	£0.89 (-0.90; 2.69)
Occupational therapist (OT)	£0 (0)	47 (100%)	£0 (0)	46 (98%)	N/A
Dietician (D)	£0 (0)	47 (100%)	£0 (0)	46 (98%)	N/A
Speech and language (SLT)therapist	£0 (0)	47 (100%)	£0 (0)	46 (98%)	N/A
Geriatric medical services (GMS)	£0 (0)	47 (100%)	£0 (0)	46 (98%)	N/A
Frailty practitioner (FP)	£0 (0)	47 (100%)	£0 (0)	46 (98%)	N/A
Older persons specialist (OPS)nurse	£0 (0)	47 (100%)	£0 (0)	46 (98%)	N/A

Other primary care	£4.12 (25.75)	47 (100%)	£23.96 (83.96)	47 (100%)	£19.84 (-6.13; 45.81)
Secondary Care					
A&E	£0 (0)	47 (100%)	£15.21 (44.57)	47 (100%)	£15.21 (2.13; 28.30)
Outpatient appointments	£3.75 (25.67)	47 (100%)	£146.04 (221.17)	47 (100%)	£142.30 (77.08; 207.52)
Falls clinic	£0 (0)	47 (100%)	£0 (0)	47 (100%)	N/A
Syncope clinic	£0 (0)	47 (100%)	£0 (0)	47 (100%)	N/A
Other secondary care	£125.28 (172.67)	47 (100%)	£94.16 (133.18)	47 (100%)	-£31.11 (-85.39; 23.16)
Inpatient visits	£362.54 (1005.08)	46 (98%)	£241.70 (630.95)	47 (100%)	-£120.85 (-390.48; 148.78)
Medications					
Prescribed Medications	£100.64 (24.23)	47 100%	£103.33 (27.79)	47 100%	£2.68 (-2.58; 7.94)
Total Cost	£641.63 (1021.07)	46 (98%)	£710.38 (741.74)	45 (96%)	£115.68 (- 158.27; 389.63)
Outcomes	Baseline mean (sd), (Min, Max)	N (%)	3-month Mean (sd), (Min, Max)	N (%)	Mean (95% CI) difference
EQ-5D-5L index (utility)	0.623 (0.268) (-0.037, 0.989)	47 (100%)	0.665 (0.181) (0.150, 0.989)	41 (87%) 4 missing completely and 2 partial missingness	0.046 (-0.011; 0.103)
QALYs	N/A	N/A	0.161 (0.051) (0.043, 0.239)*	42 (87%)	N/A
EQ-5D-5L VAS	71.6 (21.4) (25, 100)	47 (100%)	72.6 (18.8) (20, 100)	43 (91.5%)	0.814 (-6.63; 8.26)
Correlation between index and VAS	0.6079 (p<0.000)	47 (100%)	0.4239 (p=0.0057)	41 (87%)	N/A

*Minimum value represents 17.3% of perfect health and maximum value represents 95.6% of perfect health over 3 months

Intervention acceptability

We aimed to conduct qualitative interviews with approximately 10 patients and their carers (if applicable) and 10 HCPs delivering the intervention. Interviews were conducted with 10 patients (5 female, 5 male), one carer (a husband), Seven were phone interviews, and four (3 patients, 1 carer) in-person at patient's homes, based on participant preference. Online interviews were conducted with 8 HCPs (6 pharmacists, 2 GPs) involved in the intervention implementation across all five practices. Of the seventeen HCPs who took part in delivering the intervention thirteen

(77%) completed the baseline questionnaire measuring confidence in deprescribing and 10 repeated the same questionnaire at the end of the intervention (see Appendix 7, supplementary file A).

Healthcare professionals' perspectives

The intervention was broadly considered acceptable by staff. Both senior (independent prescribers working in primary care for 3 years or more) and junior pharmacists (non-prescriber and independent prescribers, working in primary care for less than 3 years) delivered the SMRs, supported by GPs or more experienced pharmacists. The proportion of staff reporting “feeling supported making decisions about stopping medicines where I work” (Q17) increased following the intervention, as did the proportion reporting that “priorities do not get in the way of me being able to stop medicines” (Q19). Pharmacists found the preparation time (approximately 15 minutes per patient) using the PrescQIPP IMPACT tool helpful in prioritising medications for deprescribing, particularly for complex patients. The tool was credited with improving clinicians’ knowledge, confidence, and capability in negotiating medication discontinuation, supporting shared decision-making, especially among less experienced pharmacists. This was reflected in increased staff-reported knowledge and confidence in stopping medication safely between baseline and follow-up surveys (Q1–3, Q9–10, Q12–13, Q21).

Training materials, including the IMPACT tool video and online study briefing, were regarded as effective in preparing staff. This was reflected in increased willingness to use e-resources to support decision-making following the intervention (Q16). Some pharmacists also found the deprescribing tip sheets helpful, although a few reported forgetting to use them. One practice without an existing proactive SMR process found the intervention particularly beneficial, as reflected in this pharmacist’s comment:

“I found the resources incredibly helpful and have incorporated them into my work. This has allowed me to engage with polypharmacy-related reviews in a way I wasn’t doing before.” — Pharmacist, ID 51

However, several areas for improvement were identified:

- improve the format and visual presentation of the IMPACT tool
- embed the tool into existing GP clinical systems (e.g. SystmOne, EMIS)
- provide clearer guidance on post-SMR documentation and follow-up actions

Patients’ perspectives

Patients responded positively to the SMRs, appreciating the consultation duration (up to 30 minutes) and face-to-face format. Most found it valuable to understand the purpose of their medications, ask questions, and engage in shared decision-making.

The patient information leaflet helped some prepare for appointments and manage expectations, although not all patients reported reading it. Aspects of the intervention that patients particularly appreciated were:

- opportunities to discuss whether medications remained necessary or beneficial and clear explanations about any changes
- inclusion of carers or family members in discussions, where relevant.
- follow-up support, especially when provided via planned phone calls or written summaries. However not all patients received a written summary of their SMR, and follow-up support varied across practices.

One participant reflected on how the intervention changed her view of medication reviews:

“Participating [in MODIFY] gave me food for thought. Before, a medication review was a tick-box exercise, but this made me think I have every right to say what I thought... [The pharmacist] listened to what I said about what I was taking and what I wasn't getting any benefits from... We made a plan... and she would call me on a regular basis.” — Female, age 82, lives alone, ID 103

Discussion

Summary

This feasibility study evaluated the implementation of the MODIFY intervention, a structured, person-centred SMR and deprescribing intervention for older people with frailty and polypharmacy in general practice.

The intervention was feasible and acceptable to patients, carers, and HCPs, with SMRs delivered to all recruited patients, high follow-up rates (92%), and complete patient-reported outcome data. Pharmacists reported increased confidence in safe deprescribing, reflected in 72% of patients having at least one medication stopped and 26% having a dose reduction, with no reported adverse events. The intervention was particularly valued in practices without established deprescribing processes. Some patients described feeling more actively involved in medication decisions and gaining a better understanding of their medicines. Areas for improvement included digital integration of the deprescribing tool, streamlining its interface, and improving follow-up documentation.

Feasibility for progression to a definitive trial was assessed using recruitment, retention, and outcome completion. Retention (92%) and data completeness (100%) exceeded commonly used feasibility thresholds, and all progression criteria met “green” status. Recruitment was 10% of those invited (48/479), consistent with trials involving older adults with multimorbidity or frailty, reflecting the complexity of this population and real-world recruitment conditions. These data provide valuable estimates for future trial planning.

Comparison with existing literature

All five intervention components were implemented, although fidelity assessment relied on qualitative evaluation. Practices successfully identified eligible patients using eFI and polypharmacy criteria, indicating feasibility within routine data systems. Previous qualitative research has shown that SMRs in UK primary care are often rushed and that deprescribing is delayed due to workload and limited preparation time (43). In this study, protected preparation time was integral, with pharmacists using the IMPACT tool and reporting increased confidence in identifying medications suitable for deprescribing. Patient and carer preparation was also important and addressed through pre-SMR information materials (44, 45), aligning with NICE guidance that patients and carers should be informed and able to contribute to SMRs (46). Patients valued longer appointments (approximately 30 minutes), which supported trust, discussion of medication concerns, and shared decision-making. This is consistent with evidence that advance communication improves patient engagement with SMRs (47). Although most participants did not receive written summaries of medication changes despite available templates, many reported valued follow-up phone support from HCPs.

Nearly three-quarters of patients had at least one medication stopped (72%), and a quarter had a dose reduction (26%), which is encouraging given the clinical complexity of the population. However, the small sample size limits firm conclusions. Sixty per cent of patients also started a new medication post-SMR, reflecting real-world practice where deprescribing may coincide with treating previously unrecognised or undertreated conditions. The net reduction in medication burden was small (mean 0.27 medications) and may not capture clinically meaningful changes in risk–benefit profiles. Future studies should assess medication appropriateness (e.g. STOPPFrail) or patient satisfaction to better evaluate impact. Patient-reported outcomes and adverse events did not change over three months; this may be viewed positively, as deprescribing without harm can reduce costs and patient burden (48, 49). The short follow-up period limits interpretation, and longer-term effects should be assessed in future research.

Pharmacists taking the lead-role in delivering the SMR is supported by the evidence on pharmacist-led deprescribing (50). Junior pharmacists in our study expressed growing confidence using the structured tool and collaborative discussions with GPs or senior pharmacists. This highlights the importance of mentorship and MDT collaboration, particularly in complex decision-making scenarios. Studies have shown that multidisciplinary involvement enhances the quality and safety of medication reviews (51).

Strengths and Limitations

A key strength of this study lies in its rigorous co-design of the intervention using the Person-Based Approach and realist synthesis, which incorporated input from patients, carers, and clinicians. This approach likely contributed to the high acceptability observed across stakeholder groups. Additionally, the study was successfully implemented across a diverse range of practices in terms location type (rural, urban and coastal areas) size of practice, and socioeconomic context, suggesting potential generalisability. The use of mixed methods, quantitative outcome tracking alongside

rich qualitative feedback, provides a comprehensive understanding of the intervention's feasibility. The study also demonstrated high participant retention and completion rates for outcome measures, among an older population with high levels of frailty.

However, this study has several limitations. As a non-randomised feasibility study without a control group, it cannot provide definitive evidence of clinical effectiveness. Plus, follow-up was short and not powered to detect efficacy. The study was conducted in one region in England with limited participant ethnic diversity, which may limit the generalisability of findings. While medication changes were well documented, the reasons behind initiating new medications post-SMR were not consistently recorded. In addition, due to logistical reasons we were unable to record and measure "switching medications" between baseline and follow-up, to reflect the general definition of deprescribing (12). This limits interpretation of the net impact of the intervention on the number of medications and medication burden. Practices involved in intervention development may be more motivated than average; broader testing is needed. Variation in implementation, particularly around follow-up and documentation, suggests that standardisation will be essential in a definitive trial.

Implications and future research

The findings support the growing consensus that deprescribing interventions for older adults with frailty are not only necessary but feasible and acceptable when well-structured and patient-centred. Importantly, our findings suggest that embedding structured tools into routine care can improve the quality of medication reviews, particularly when supported by training, multidisciplinary collaboration between pharmacists and GPs, and patient education. However, sustained implementation will require digital integration of tools into existing clinical systems, clear protocols for follow-up planning and documentation, and system-level support for adequate consultation time. Future iterations of the intervention should address these practical needs to enhance fidelity and scalability. The results of this study indicate that a definitive RCT of the MODIFY intervention is both warranted and feasible, to assess its clinical effectiveness on relevant outcomes including falls, hospital admissions, medication appropriateness, quality of life and cost-effectiveness.

Conclusion

This study demonstrates that a complex, pharmacist-led deprescribing intervention is both feasible and acceptable in general practice for older people with frailty. While recruitment rates were modest, retention and engagement were high. The intervention facilitated meaningful deprescribing, with strong endorsement from patients and clinicians. To optimise and scale the intervention, further work is needed to improve tool usability, ensure consistent follow-up, and identify sensitive outcome measures. These findings support progression to a definitive trial to evaluate clinical and cost effectiveness.

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Ethical approval and study registration

This study received ethical approval from the UK Health Research Authority (Research Ethics Committee reference 22/PR/0580).

This study has been registered on Clinicaltrials.gov on 22nd March 2022, reference: NCT05705284

(URL:<https://clinicaltrials.gov/study/NCT05705284?term=Older%20People&intr=Depr+escribing%20Intervention&page=2&rank=12>).

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