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Intervention fidelity for a complex behaviour change intervention in community pharmacy addressing cardiovascular disease risk

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Abstract

Background: Delivery of cardiovascular disease (CVD) prevention programs by community pharmacists appears effective and enhances health service access. However, their capacity to implement complex behavioural change processes during patient counselling remains largely unexplored. This study aims to determine intervention fidelity by pharmacists for behavioural components of a complex educational intervention for CVD prevention. After receiving training to improve lifestyle and medicines adherence, pharmacists recruited 70 patients aged 50–74 years without established CVD, and taking antihypertensive or lipid lowering therapy. Patients received five counselling sessions, each at monthly intervals. Researchers assessed biomedical and behavioural risk factors at baseline and six months. Pharmacists documented key outcomes from counselling after each session. Most patients (86%) reported suboptimal cardiovascular diets, 41% reported suboptimal medicines adherence, and 39% were physically inactive. Of those advised to complete the intervention, 85% attended all five sessions. Pharmacists achieved patient agreement with most recommended goals for behaviour change, and overwhelmingly translated goals into practical behavioural strategies. Barriers to changing behaviours were regularly documented, and pharmacists reported most behavioural strategies as having had some success. Meaningful improvements to health behaviours were observed post-intervention. Findings support further exploration of pharmacists' potential roles for delivering interventions with complex behaviour change requirements.

Background

Cardiovascular Disease (CVD) is the leading cause of death worldwide [1]. Promoting healthy behaviours to reduce risk for those without established CVD, is a key population strategy for reducing its burden [2, 3]. Patients at elevated CVD risk have regular pharmacy visits, making it a natural setting for engaging them about their health [4]. Correspondingly, there is a strong argument, supported by research, that more extensive pharmacist involvement in the detection and management of cardiovascular risk factors might improve equity of health service access and patient outcomes [5–11]. This may be driving increased community

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pharmacist involvement with delivery of cardiovascular health promotion programs [12].

While most pharmacy research examines the screening or management of risk factors by pharmacists on an individual basis [5–10, 12, 13], more recent public health guidelines underscore the need to embrace comprehensive multiple risk factor interventions (MRFI) [14–17]. The PAART study was one of the first pharmacist-led prevention studies designed to assess overall CVD risk, and then develop a comprehensive risk reduction strategy with patients based on behavioural change theory [18]. This cohort study observed a 25% relative reduction in the risk of CVD, including improvements to adherence with medicines and several key lifestyle parameters.

While the efficacy of multifaceted disease management interventions by pharmacists has been demonstrated, the implementation of health behaviour change components of the intervention is rarely examined. This makes it difficult to verify that improved outcomes or health behaviours, whether directly measured or participant-reported, are primarily and directly a result of education and behaviour change support by pharmacists. Plausible alternative explanations include that: pharmacy interventions might facilitate uptake of other services to support behaviour change; intensively treated patients are more likely to report improvements for social desirability reasons; or improved behaviour is simply a result of closer monitoring. Demonstrable intervention fidelity is an important component of verifying a cause–effect relationship within complex intervention studies [19]. It also indicates the likelihood of delivering a consistent intervention during wider implementation, explains variation in outcomes and identifies intervention components that require better development. There is no detailed evidence to demonstrate intervention fidelity during lifestyle modification support by pharmacists

The aim of this study is therefore to determine the appropriateness and extent of community pharmacist support for patients to modify key health behaviours during the PAART CVD trial. By documenting intervention fidelity for the delivery of behavioural support of patients, this study will identify pharmacists' capacity to deliver complex lifestyle interventions, and the likelihood of a genuine cause–effect relationship between the intervention and behavioural outcomes.

Methods

Setting and participants

Methods for the PAART CVD trial intervention have been described in detail previously [18, 20]. Summarising the methods in accordance with the TIDieR framework [21], 12 experienced pharmacists from 10 community pharmacies in Victoria and Tasmania (5 rural, 5 metropolitan), most of whom owned or managed their pharmacy, were recruited and provided intensive training on the assessment and management of overall CVD risk using MRFI approaches. Equal focus was placed on optimisation of medicines use for CVD risk factors, medicines adherence and lifestyle modification. Pharmacists were instructed in health education and behaviour change processes according to the Health Action Process Approach (HAPA) [22]. Lifestyle intervention trials for similar populations have demonstrated HAPA efficacy in facilitating patient behaviour change [23, 24].

Recruited patients were aged 50–74 years, took medication for dyslipidaemia or high blood pressure (BP) or both, and did not have a self-reported history of CVD or diabetes. Treating General Practitioners (GPs, equivalent to Family Physicians) were informed of patients' desire to participate and asked to inform researchers if patients did not meet criteria.

Measuring health status

At baseline and 6 months, research assistants measured BP (using Omron 1A1B automated BP monitors), weight, height, waist and hip circumference, in accordance with established protocols [25–27], and lipid profile and blood glucose in accordance with manufacturer protocols using Cholestech LDX Analyzers (Cholestech Corporation, Hayward, CA).

Data on medical history, medication use, medication adherence, health behaviours (smoking, diet,

weight management, alcohol intake, physical activity) and psychosocial health were collected via an interviewer administered questionnaire, which incorporated several validated scales [20]. Key behavioural assessment scales are specified in Appendix 1.

The intervention

The objective of the intervention was to reduce patients' 5-year risk of CVD onset, estimated using the Framingham CVD risk score [28]. To avoid excessive workload for community pharmacists, pharmacists with formal accreditation to undertake home-based pharmacotherapy management reviews ('home medicine reviews', HMRs—see www.aacp.com.au/) were engaged to write a clinical report and action plan based on baseline data. This plan was supplied to the patient's community pharmacist and GP, and a summary given to the patient. This report highlighted the patient's overall CVD risk, adjusting the score upwards (+5%) in accordance with guidelines if the Framingham equation was thought to underestimate individual risk (if obese, family history of CVD or relevant ethnicity) [14, 28]. Evidence-based targets for treatment, suggested treatment priorities, and strategies for improving CVD risk through medication use, medication adherence, and lifestyle modification were documented according to a template. The accredited HMR pharmacists were asked to suggest 3–4 priority goal areas in each patient's report that were likely to deliver most cardiovascular benefit. Priorities consisted of both treatment goals and behavioural goals. Raw data regarding baseline dietary habits was also provided to pharmacists, following early feedback that was very helpful for understanding patient needs.

Community pharmacists offered five sessions to each patient at monthly intervals in a private counselling area. Pharmacists were advised that the initial visit should take about 30 min, and that subsequent visits should take 15–20 min. The initial visit required education to be delivered covering CVD risk and suggested goals, confirmation that proposed goals were acceptable to patients, and modification of these goals if appropriate. Subsequent visits included ongoing review of goals, and corresponding further education, planning and self-efficacy support. GP and patient involvement in decision-making was encouraged and incorporated into clinical protocols. This included provision to GPs of written information about the process and recommendations for care on at least three occasions. Patients at low risk of CVD onset (less than 5% over five years) were given the option of withdrawing or reducing the intervention intensity. All patients, including these low-risk patients, were invited to receive follow-up assessment, regardless of extent of participation in the intervention.

Implementation data collection

The accredited HMR pharmacist reports were obtained by researchers to enable documentation of the advice and suggested priority goals provided to community pharmacists. Community pharmacists in turn documented issues about each session to monitor the nature of counselling provided. Specifically, patient agreement with suggested goals, progress towards behavioural goals and barriers experienced, and agreed changes to goals were documented. In sessions 2–5, pharmacists were asked to rate, as a binary outcome (yes/no), if any success had been achieved for each agreed patient strategy noted in the previous session. At the end of the intervention, pharmacists were asked to document those areas where they felt patients had made major achievements, what they felt were outstanding challenges for the patient, and whether or not they felt competent in treating that patient. The scheduled time and duration of each visit was also recorded.

Measuring intervention fidelity: key measures

We defined intervention fidelity for each patient using different perspectives:

1. Process indicators examining appropriateness and suitability of the intervention structure (all

taken from pharmacist documentation of the intervention):
- Retention of patients within the program;
- Time taken to deliver the intervention; and

2. Process indicators to determine appropriate targeting and delivery of lifestyle interventions:
- Recruitment of patients with uncontrolled risk factors (from baseline data collection);
- Recommendation of goals that directly address the identified risk factors (from baseline reporting sent to community pharmacists);
- Patient agreement to pursue recommended behavioural goals and strategies (as documented by pharmacists);
- Development of strategies to address risk factors/goals (as documented by pharmacists); and
- Identification of barriers and enablers to behaviour change initiation and maintenance (as documented by pharmacists).

Goals and strategies were only included if they were clearly related to modifying health behaviours. For example, written strategies simply to involve another health professional, and not explain the purpose of referral, might be seeking a diagnosis or prescription, and may not seek to address any behaviours.

The following were also documented by pharmacists to gain additional insight into process-related outcomes:

- Perceived success of behaviour strategies agreed at or continued from the previous session. This was a binary outcome (yes/no) documented during Sessions 2–5 for all active strategies. Any 'yes' ticked to indicate strategy success during Sessions 2–5 was considered as 'a strategy success' and was indicative only of some progress being made (as opposed to goal attainment).
- Self-assessed perceived competence by pharmacists to deliver the intervention was documented for each patient by pharmacists as a binary outcome (yes/no) after Session 5.
- Pharmacist-perceived need for further patient support at completion of the intervention.

The general expected outline of each session is described in Table I. Each of the above domains requiring pharmacist documentation involved specific open or multiple choice questions for completion as part of their documentation of care.

The study was approved by relevant university ethics committees and is registered on the Australia and New Zealand Clinical Trials Registry (Trial Number ACTRN12609000677202).

Statistical analysis

Analysis was performed using IBM SPSS Statistics 20 (SPSS Inc., Chicago IL.). Univariable proportion data and continuous normally distributed variables were reported as percentages (*n*) or as percentages (95% CI). Non-parametric data were reported as medians (interquartile range). Where data for one or more cases was missing when calculating a statistic, a new denominator was specified.

Results

Recruitment and retention

Seventy eligible patients from the 10 pharmacies were recruited and received baseline assessment. Three patients were advised to consider not proceeding beyond the initial session following advice that they had low CVD risk and may not benefit from intervention—all three declined further treatment. Three further patients withdrew prior to completion of the final assessment. Overall, 81% (56/69) with data available completed all five sessions, 85% (56/66) among those recommended the full intervention. The initial session lasted a mean of 34 min, dropping to a mean of 22 min for the second session and 15–20 min for subsequent sessions (Table I). For some participants whose sessions ran considerably behind schedule, pharmacists condensed the content of multiple sessions into one.

Participant characteristics

Demographic characteristics are summarised in Table II. The majority of participants were Australian-born (90%), female (73%) and the

Table I. *Content and duration of PAART counselling sessions*

Session	Number (%) completing session ($n = 69$)	Number with documented session duration	Mean duration (SD), min	Discussion topics
1	66 (96)	64	34 (19)	A. Intervention objectives, their role as pharmacist, and involvement of their GP including sharing of the pharmacy care plan B. Interpretation of the patient's cardiovascular risk C. Any issues identified as urgent on the baseline report, if relevant D. Medication management issues identified in the baseline report, if relevant
2	62 (90)	58	22 (10)	A. Follow up from previous session undertaken to establish progress and confirm action on urgent issues B. Patient priority goals confirmed via consensus, following cost/benefit of change discussion, motivation discussion C. Medication management discussed [if relevant] including adherence and development of tailored strategies, via consensus, to address goals D. Lifestyle modification discussed including discussion of potential strategies, potential barriers and agreement on strategies
3	59 (86)	58	18 (10)	A. Progress of strategies assessed (and ongoing assessment of attitudes/knowledge/motivation to change) B. Modification of strategies [if relevant]
4	57 (83)	54	16 (8)	A. Progress of strategies assessed (and ongoing assessment of attitudes/knowledge/motivation to change) B. Modification of strategies [if relevant]
5	56 (81)	52	18 (7)	A. Progress of strategies assessed (and ongoing assessment of attitudes/knowledge/motivation to change) B. Modification of strategies [if relevant] C. Maintaining behaviour change

mean age was 60 years (Table II). Almost half had a concession card allowing access to government-subsidised prescription medicine with a small co-payment. They had a median (IQR) of 4 (3–5) self-reported chronic conditions and used a median of 6 (4–7) medicines (including non-prescription). At baseline, most (88%) used at least one antihypertensive medicine and the majority (57%) used a lipid-lowering medicine. The overall 5-year CVD risk was a mean of 6.7% (95% CI 5.6–7.7%) and the mean BMI was 30.1 (95% CI 28.5–31.7). More than one third (37%) were obese (BMI $\geq$ 30), and half (51%) had BP of 140/90 mmHg or higher (Table II). Participants had a median of six (IQR 6–10) visits to their pharmacist in the 6 months prior to baseline, compared with two visits (IQR 1–3) to their GP.

Targeting key behaviours

The health behaviours most commonly failing to meet targets at baseline were diet-related (Table III). Most (86%) had an overall diet that was suboptimal for cardiovascular health, and almost three quarters added salt to food while cooking or eating. Related to this, almost 9 out of 10 participants did not meet guidelines for a healthy waist circumference. Approximately two in five participants failed to meet goal criteria for one of the following: alcohol intake; medicines adherence; or physical activity. Relevant priority goals were

documented for all smokers and obese individuals at baseline (Table III). This was also reported in those with insufficient physical activity or lower quality diets. Among those with reported medication non-adherence at baseline, only a third had it recommended as a priority goal.

Table II. *Baseline characteristics of recruited participants*

	Overall ($N = 70$)
Social/demographic characteristic	
Number (%) women	51 (73)
Mean (SD) age, years	60.1 (5.9)
Number (%) aged 60 years plus	38 (54)
Number (%) with high CVD risk ethnic background (Aboriginal or Torres Strait Islander, Maori, Polynesian, Indian)	3 (4)
Mean number of years full-time education	11.3 (3.0)
Number (%) recruited from rural pharmacies	46 (66)
Number (%) with concession card	31 (44)
Number (%) reporting family history of premature coronary heart disease before age 60 years	30 (43)
Clinical characteristics	
Mean (95% CI) five-year CVD risk (%)	6.7 (5.6–7.7)
Mean (95% CI) systolic BP (mmHg)	137.7 (133.6–141.8)
Mean (95% CI) diastolic BP (mmHg)	85.6 (83.4–87.8)
Number (%) with uncontrolled BP ($\geq$ 140/90 mmHg)	36 (51)
Median (IQR) total cholesterol (mmol/L) *	4.83 (4.31–5.43)
Median (IQR) LDL cholesterol (mmol/L) †	2.60 (2.31–3.32)
Median (IQR) HDL cholesterol (mmol/L)*	1.28 (1.01–1.47)
Median (IQR) triglycerides (mmol/L)*	1.39 (1.02 –2.12)
Mean (95% CI) BMI	30.1 (28.5–31.7)
Median (IQR) waist circumference (men, cm)	98.5 (94.2–111.4)
Median (IQR) waist circumference (women, cm)	92.3 (84.2–99.5)

* $N = 66$ (no lipid panel available).
† LDL cholesterol values were unable to be detected for eight patients when tested.

Confirming goals and developing strategies

Almost all patients agreed with the priorities suggested at the baseline review (Table IV). Similarly, almost all patients who agreed with goals ended up with relevant documented strategies to address each goal (Table IV). The exceptions to this were for medicines adherence, and for reduced alcohol intake, where 5/11 and 2/7, respectively, had no documented strategy.

Identification of barriers and enablers

Pharmacists documented common barriers to addressing lifestyle goals (59/70 patients), which were: family or personal issues including other priorities (27, 46%); co-morbidities (24, 41%); time restrictions generally (14, 24%); unsuitable weather for exercise (9, 15%); and poor attitude (7, 12%). Musculoskeletal problems were the principal cited co-morbidities; occasionally, respiratory conditions also prevented physical activity from being undertaken. Pharmacists identified co-morbidities as a barrier to exercise for the majority of patients reporting musculoskeletal conditions at baseline (23/35, 71%). Reported enablers included: positive attitude (25, 42%); decreased stress levels (5, 9%); improved energy levels from lifestyle modification (2, 3%); improved pain management (2, 3%); concern over BP elevation (1, 2%); increased awareness (4, 7%); good weather (3, 5%): and program involvement (1, 2%).

Perceived accomplishments and remaining challenges

Pharmacists identified what they felt the major achievements were for each patient over the intervention (51/70 patients). They identified successful dietary changes for the majority of patients (37, 73%), followed by increased physical activity (20, 39%), generally improved cardiovascular awareness (14, 28%), weight loss (10, 20%), improved medicines adherence (8, 16%), smoking cessation (1, 2%) and reduction in alcohol intake (1, 2%). In addition to these perceived health and behavioural achievements, more positive attitudes (5, 10%), finding time to address health (2, 4%)

Table III. *Baseline prevalence of key lifestyle risk factors and recommendations from baseline assessment to target those risk factors with a relevant priority goal*

Lifestyle-related Risk factor	Risk factor definition	Number (%) patients at-risk*		Priority goal recommendation to address risk	Number (%) at-risk patients with appropriate priority goal recommended	
Central obesity	Waist circumference ≥ 80 cm (F) or ≥ 94 cm (M) ††	59	(84)	Reduce weight, BMI or waist	55	(93)
Obese	BMI ≥ 30	26	(37)	Reduce weight, BMI or waist	26	(100)
Physical inactivity	Lifescript score < 3	27	(39)	Increase physical activity	26	(96)
Poor quality diet	Scores < 104/130 on DQT‡	56/65	(86)	Improve diet (excl. specific salt advice)	51	(91)
	Scores < 20/20 on DQT added salt subscale	50/68	(74)	Reduce salt intake (specific salt advice)	8	(16)
				Improve diet (excluding specific salt advice)	44	(88)
Poor medicines adherence	MMAS-4† score > 0	29	(41)	Improve adherence	9	(31)
High alcohol intake	Confirmed high risk (AUDIT C score > 6)	9	(13)	Reduce alcohol use	6	(67)
	Possible high risk (score 4–5)	18	(26)	Reduce alcohol use	3	(17)
Smoking	Smoked in past month	6	(9)	Smoking cessation	6	100

* $n = 70$ unless otherwise stated due to missing data.
† MMAS=Morisky Medicines Adherence Scale (4-items).
‡ DQT = Diet Quality Tool.
†† Australian guideline-indicated ideal weight.

and improved well-being (1, 2%) were also noted as accomplishments in this regard. Pharmacists indicated what they felt were the key remaining health behaviour challenge(s) for 54 of the 56 patients who attended session 5. Among these, they identified maintaining diet changes for 17 (32%) and further diet modifications for five patients (9%), maintenance of physical activity levels for 21 (39%) and further increasing physical activity for 13 (24%), weight loss for 14 (26%), general motivation for 13 (24%), decreasing alcohol intake for 5 (9%), quitting smoking for 2 (4%) and medication adherence for 2 (4%). Related to this, 50/55 (91%) with strategy documentation in Session 5 were recommended lifestyle strategies to facilitate maintenance and further change of behaviours beyond the intervention. Three patients were provided an extra (sixth) visit.

Table V reports on pharmacists' perceptions of any success with individual strategy throughout the intervention period relating to those key health behaviour. Success was documented for each strategy agreed or continued, when reviewed at the following session. A documented 'success' indicated only that

Table IV. *Prevalence of participant agreement with priority goals and development of relevant strategies to address goals*

	All participants		Those with a relevant goal recommended for adoption as a priority	Those who agreed with their pharmacist to target a goal
	Number (%) with a goal recommended for adoption as a priority *	Number (%) with a documented strategy to address the goal ($n = 64$)	Number (%) who agree with pharmacist to pursue a goal related to this**	Number (%) with a related written strategy**
Target behaviour				
Weight loss	53/63 (84)	(Dietary) 58 (91) (Alcohol) 11 (17)[#] (Physical activity) 56 (88) (Other weight) 15 (23)	53 (100)	(Dietary) 47/53 (89) (Alcohol) 10/52 (18) (Physical activity) 48/53 (91) (Other weight) 15/53 (28)
Increase physical activity	47/63 (75)	56 (88)	44 (94)[‡]	40 (91)[‡]
Improve diet (generally) [†]	52/62 (84)	58 (91)	51 (98)	46 (90) [†]
Reduce salt intake [†]	8/62 (13)	58 (91)	8 (100)	8 (100)
Improve medicines adherence	11/62	17 (27) [#]	11 (100)	6 (55)
Lower risky alcohol intake (based on AUDIT C)	8/62	11 (17) [#]	8 (100)	5/7 (72)[‡‡]
Quit smoking	6/62	3 (5) [#]	5[‡]	3 (60)[‡]

* Some participants at target for individual behaviours (e.g. quit smoking in the recent past) were also given goals; only defined at-risk individuals were considered in Table III, hence numbers will vary between the two Tables.
** Variation in participant numbers identified in data columns 1 as adopting goals reflect exclusion of individuals with missing data around goal agreement from column 3 analysis, and also strategy data in column 4. # n = 63, data missing for one participant.
[†] 'Improve diet (generally)' refers to broad dietary goals that would typically incorporate salt reduction also.
[‡] Statistic assumes goal agreement for a small number of participants—one for physical activity, two for smoking cessation—who initially declined a behavioural goal in Session 2 but subsequently agreed to strategies to address that behaviour.
[‡‡] Data missing on development of strategy for one or more participants has resulted in a different denominator to Column 2

some progress was made from the pharmacists' perspectives, and does not reflect sustained success or changed behaviour overall. Most or all of the strategies were deemed by pharmacists to have been successful across all key behaviours. For comparison, Table V also reports researcher-measured changes to behaviour-related outcomes, in the same group with at least one strategy developed for that behaviour. Applying benchmarks that would constitute a clinically relevant change, this suggests that improvements to health behaviours were widespread, and that very few had worse health behaviours. In particular, a majority self-reported improvements to both diet and physical activity, and half had significant weight reduction. However, the proportions achieving a measured significant change were consistently and considerably lower that the proportion deemed to have made some level of progress. In particular, large proportions with strategies to improve adherence, alcohol intake and weight did not achieve overall substantial improvements.

Upon completion of the intervention, pharmacists indicated that they had felt competent to deliver the intervention for most (50/53, 94%) patients. The issues identified as challenging their competency included instances of having to manage expert patients, patient denial of suboptimal behaviour and, on several occasions, lack of sufficiently extensive knowledge on the pharmacist's part.

Table V. *Pharmacist perceptions and measured success among those who had behaviour change strategies*

Behaviour	Pharmacist documentation of individual strategies to achieve behavioural goals			Researcher-assessed changes to overall behaviours using standardises measures*			
	Number with outcome information for a behavioural strategy	Number perceived by pharmacist as having had some success	%	Level of change between baseline and six months suggesting clinical relevance	Number (%) improved	Number (%) unchanged	Number (%) worse
Medicine adherence	16	16	100	MMAS,† one points or more	6 (38)	10 (63)	0 (0)
Diet	54	51	94	DQT,‡ five points or more (n = 51)	33 (65)	12 (24)	6 (12)
Weight	10	10	100	Weight, 2 kg or more	5 (50)	5 (50)	0 (00)
Alcohol	10	8	80	AUDIT C, one point or more	4 (40)	5 (50)	1 (1)
Physical activity	50	44	88	Lifescripts score, one point or more	25 (50)	12 (24)	13 (26)
Smoking	3	2	NA	Smoked (or not) in the past month	0 (0)	3 (100)	NA

* Researcher administered surveys to patients for all behaviours except weight, which was directly measured by researchers.
† MMAS = Morisky Medicines Adherence Scale (4-items).
‡ DQT = Diet Quality Tool

Discussion

This study provides evidence that community pharmacists successfully implemented an evidence-based behaviour change intervention for multiple CVD risk factors, which translated to improved health behaviours for a substantial proportion of participants. More specifically, the study's community pharmacists recruited appropriate at-risk patients and then recommended suitable goals in collaboration with patients for improving relevant health behaviours. With the notable exception of medicines adherence, strategies were largely developed to address these goals for most patients. Barriers and enablers to change were identified as part of this process and there appears to have been a substantial degree of improvement to most health behaviours among relevant participants. A greater understanding of pharmacists' competencies to deliver behaviour change interventions, patient needs, feasibility of intervention delivery within the anticipated timeframe, and patient adherence to the intervention all justify the incorporation of rigorous process evaluation into health service trials. Our findings justify the development and evaluation of further funding and practice models that enable pharmacists to apply lifestyle modification and medicines adherence support programs more routinely. Findings add support to the hypothesis that previously reported improvements to biomedical risk factors in this cohort are a result of the PAART CVD intervention [18].

Demonstration of pharmacists' abilities to implement such behavioural support processes has been lacking in previous literature, despite indirect evidence to this effect. Many RCTs examining disease management interventions have demonstrated clear benefits from pharmacist interventions, but tended to document only the overall effect of complex interventions [5–7, 29–31]. The absence of rigorous process evaluations from RCTs means that the implementation of behaviour change processes

within such complex interventions cannot be confirmed. Consequently, the independent effects of behaviour change components on outcomes cannot be separated from those of other intervention components, such as medication changes and referral to medical practitioners. RCT interventions to promote pharmacists' routine uptake of ostensibly straightforward patient education and support strategies for single risk factors demonstrate quite mixed success [32–34]. It is therefore inappropriate to simply assume implementation by pharmacists of complex behavioural change protocols, and our results provide reassurance as to the capacity for pharmacists to deliver such interventions.

While there are some studies examining behavioural interventions in pharmacy, few offer clarity around implementation of behaviour change processes or directly related outcomes for lifestyle modification. Jolly et al. undertook an RCT of six different UK commercial and primary care weight loss interventions, including one in pharmacy [35]. Significant weight loss was achieved after a 12-week program in the community pharmacy arm, a non-significant improvement compared with the general practice arm which had an identical intervention framework. However, these two arms demonstrated the least weight loss overall, and were the only study arms that failed to maintain significant weight loss at 12 months. Notably, these two arms also had the lowest rates of program attendance—about half the subjects attended less than 25% of the 12 sessions, suggesting shortcomings with implementation and a reduced intervention dose. Hence, pharmacists would have been unable to apply the intervention with many patients. Low rates of program adherence for this and other trials contrast strongly with our findings.

Most pharmacist studies with a focus on behavioural intervention involve smoking cessation [36, 37]. Although implementation of processes are not documented in detail, and outcomes may be attributable to nicotine replacement therapy or improved adherence following closer monitoring, these RCTs at least demonstrate improved cessation outcomes where pharmacists are trained to deliver structured interventions with a behavioural focus [36, 37]. Conversely, a more recent US study of smoking cessation by Prokhorov et al. [38] which examined implementation of the '5As' principles for supporting behaviour change, underscores the potential for poor implementation. This study documented very low baseline levels of '5As' counselling for behaviour change, and no improvements following targeted training of pharmacists.

Medicines adherence was a notable and unexpected exception to the near-universal development of goals for other health behaviours. It may be that pharmacists determined some individuals' nonadherence to be less of a priority, for various reasons, compared with other behaviours. This includes the possibility that some participants downplayed the extent of their nonadherence to pharmacists. Because pharmacists might consider themselves more experienced in the management of medicine adherence relative to other health behaviours, they may also have been more confident to adopt a 'wait and see' approach, or to make judgments as to the clinical relevance of the situation for individual patients. However, the fact that pharmacists developed medicines adherence strategies for a number patients who did not have this recommended as an initial goal, coupled with the considerable improvements to medicines adherence overall, supports the idea that pharmacists applied appropriate professional discretion rather than overlooking its importance. There was considerable discrepancy between researcher-collected adherence improvements and pharmacist-assessed strategy success among those with adherence strategies (Table V)—this may reflect pharmacist bias in recording, transient successes that were not sustained to follow up data collection, or possible inability to detect partial behavioural improvements using the Morisky 4-item scale for some patients [39].

Because community pharmacists are often the most visited health care professional for patients at elevated risk of CVD [4], are available and accessible in most communities, and offer support that may impart an independent positive effect on patient self-management in addition to GP care [11], it is important for future research to establish what behavioural interventions are effective and how they

can be implemented. This would also help to address a well-documented lack of confidence that many pharmacists have about providing formal professional services [40, 41]. Future research might also place more emphasis on how pharmacists can facilitate longer-term maintenance of behaviour change, overcoming barriers for patients with comorbidities, and on ensuring the quality with which counselling techniques are applied.

Limitations

While this study did provide important evidence regarding pharmacists' ability to implement complex social interventions, we did not demonstrate a conclusive link with health outcomes. There is a clear need for controlled trials to carefully measure the effects of behavioural interventions by pharmacists. Our study was unable to demonstrate the actual quality of counselling and education provided (e.g. via audio or video-recording of interviews to assess counselling skills), only the nature and extent to which essential steps were reported as undertaken. The level of detail documented about strategies was highly variable, and was potentially subject to recorder bias from pharmacists. Hence, only a broad assessment of appropriateness could be provided. Finally, our patient group was disproportionately rural and most had previously established relationships with their pharmacist. This may have contributed to the high level of program retention, trust in their pharmacists, and willingness to agree on behaviour change targets and strategies. Our findings might not be representative of outcomes with other participant populations.

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Conflict of interest statement

None declared.

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Appendix 1

Description of health behaviour terms and self-report scales used

A. Self-report scales used for health and health behaviour assessment

- AUDIT C screening tool for alcohol misuse [42].
- CES-D 10-item scale to screen for depression [43].
- CVAR (Cardiovascular Absolute Risk) scores are an estimate of the probability of developing CVD over the next five years. These are calculated using validated Framingham algorithms based on demographics and key risk factor information [27].
- DQT (Diet Quality Tool) to assess the quality of diet in terms of cardiovascular health [44]
- 'Lifescripts' physical activity assessment tool [45]
- Morisky Medicines Adherence Scale (4-items) to assess medication adherence [39]