UTS UNIVERSITY OF TECHNOLOGY SYDNEY

Minor ailment services from community pharmacy

by Sarah Michelle Dineen-Griffin

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Doctor of Philosophy

under the supervision of Prof Kylie Williams and Dr Victoria Garcia Cardenas

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Minor ailment services from community pharmacy

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Certificate of original authorship

I, *Sarah Michelle Dineen-Griffin*, declare that this thesis, is submitted in fulfilment of the requirements for the award of Doctor of Philosophy, in the Discipline of Pharmacy, Graduate School of Health at the University of Technology Sydney, Australia. This thesis is wholly my own work unless otherwise reference or acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis. This document has not been submitted for qualifications at any other academic institution. This research is supported by the Australian Government Research Training Program.

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Abstract

Background: Governments including the United Kingdom and Canada endeavour to optimise health care systems through investment in primary care reform. Community pharmacists are moving, encouraged by policy, to deliver self-care support in pharmacy. International studies indicate the role and scope of pharmacists in primary care could be expanded with clinical and economic savings.

Methods: Chapter 1 presents a systematic review of randomized controlled trials evaluating self-management support interventions following the Cochrane handbook and PRISMA guidelines. Chapter 4 describes the qualitative research (a focus group with stakeholders, working meetings with general practitioners (GPs) to develop treatment pathways, and semi-structured interviews with community pharmacists) to co-design an Australian model minor ailment service (MAS) applicable to the Australian setting. Chapter 5 presents a protocol for a cluster-randomized controlled trial (cRCT) quantitatively evaluating the clinical, humanistic and economic effectiveness of MAS. MAS pharmacists were trained in treatment pathways pre-agreed with GPs and communication systems with GPs, and received monthly practice facilitator support. Control patients received usual pharmacist care (UC). Chapter 6 details the statistical analysis undertaken using modified Poisson regression. Chapter 7 details the cost utility analysis (CUA) conducted alongside the cRCT. Deterministic and probabilistic sensitivity analysis were performed.

Results: A theoretical model was developed providing structure to self-management in practice (Chapter 1). Chapter 4 presents the community pharmacy MAS model with the following elements: (1) In-pharmacy consultation, (2) treatment protocols on a technology platform (HealthPathways), (3) communication channels between pharmacy and GPs (HealthLink), (4) educational training, and (5) practice change support. Chapter 6 highlights findings from the cRCT. Patients (n=894) were recruited from 30 pharmacies and 82% (n=732) responded to follow up. Patients receiving MAS were 1.5 times more likely to receive an appropriate referral (relative rate (RR)=1.51; 95% confidence interval (CI)=1.07-2.11; p=0.018), and were 5 times more likely to adhere to referral, compared with UC patients (RR=5.08; 95%CI=2.02-12.79; p=0.001). MAS pharmacists were 2.6 times more likely to perform a clinical intervention (RR=2.62, 95%CI=1.28-5.38; p=0.009), compared with UC. MAS patients (94%) achieved symptom resolution or relief at follow up, while this was 88% with UC (RR=1.06; 95%CI=1-1.13; p=0.035). MAS patients had a greater mean difference in EQ-VAS at follow up (4.08; 95%CI=1.23-6.87; p=0.004). No difference in reconsultation was observed (RR=0.98; 95%CI=0.75-1.28; p=0.89). The CUA revealed MAS as cost-effective. MAS patients gained an additional 0.003 QALYs at an incremental cost of AUD $7.14, compared to UC. The resulting ICER was AUD $2,277/ QALY. The probabilistic SA revealed ICERs between AUD -$1,150 and $5,780/ QALY.

Conclusion: Findings suggest MAS should be implemented within the Australian context. A series of recommendations are made including the development of self-care policy in Australia to provide a policy framework for MAS.

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Dissemination of Research

The research described within this thesis has been disseminated as follows.

Peer reviewed publications

1. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Helping patients help themselves: a systematic review of self-management support in primary health care. PloS one. 2019;14(8): e0220116.
2. **Dineen-Griffin, S**., Benrimoj, S. I., Williams, K. A. & Garcia-Cardenas, V. Co-design of a minor ailment service: Involving service users and healthcare professionals. BMC Health Services. 2020 **(Submitted – Under Review)**
3. **Dineen-Griffin, S**., Garcia-Cardenas, V., Rogers, K., Williams, K. A. & Benrimoj, S. I. Evaluation of a collaborative protocolized approach by community pharmacists and general medical practitioners for an Australian Minor Ailments Scheme: Protocol for a cluster randomized controlled trial. JMIR Res Protoc. 2019;8(8): e13973.
4. **Dineen-Griffin, S**., Benrimoj, S. I., Rogers, K., Williams, K. A. & Garcia-Cardenas, V. A cluster randomized controlled trial evaluating the clinical and humanistic impact of a pharmacist-led minor ailment service. BMJ Qual Saf 2020;0:1–11.
5. **Dineen-Griffin, S**., Williams, K. A., Vargas, C., Benrimoj, S. I., & Garcia-Cardenas, V. Cost utility of a minor ailment service provided in the community pharmacy setting. Cost Effectiveness and Resource Allocation**.** 2020. **(Submitted – Under Review)**

Reports

1. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. An Australian Minor Ailments Scheme: Evaluation of a collaborative protocolized approach by community pharmacies and general medical practitioners; 2019. ISBN-13: 978-0-646-80883-3.
2. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Evaluation of a collaborative minor ailment service in community pharmacy: Findings from a pilot study in Western Sydney primary health network. 2018.

Conference proceedings

1. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. A Collaborative approach for an Australian Minor Ailments Scheme. What's New in Practice. *79th FIP World Congress of Pharmacy and Pharmaceutical Sciences*. Abu Dhabi. 2019. (Oral and Poster Presentation).
2. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Enhancing self-management support in primary health care: a systematic review of randomized controlled trials. *FIP Pharmacy Practice Research Symposium* Lisbon, Portugal. 2019. (Oral Presentation).

3. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Innovative practice: Minor Ailments – triage to treatment. *Pharmaceutical Society of Australia 2018 Conference* Sydney, Australia. 2018. (Oral Presentation – invited speaker).
4. **Dineen-Griffin, S.** Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Innovation of collaborative healthcare models: minor ailment services in community pharmacy. *UTS Annual Research Showcase.* University of Technology Sydney, Australia. 2018. (Oral Presentation – invited speaker).
5. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Evaluation of an integrated model of minor ailment care in the Australian health care system. *Congreso Simpodader Annual Conference*. Granada, Spain. 2018. (Poster Presentation).
6. **Dineen-Griffin, S.** Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. (2017). Session: Primary Health Networks. *Pharmaceutical Society of Australia 2017 Conference.* Sydney, Australia. (Panel Interview – guest panellist).
7. **Dineen-Griffin, S**., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. A model of collaborative primary health care: integrating consumer self-care, community pharmacy and general practice in the management of minor ailments and usage of non-prescription medications. *Pharmaceutical Society of Australia (PSA) Annual Conference*. Sydney, Australia. 2017. (Poster Presentation).
8. **Dineen-Griffin, S.** Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. An Australian Minor Ailment Scheme. *Pharmaceutical Society of Australia Annual Seminar.* Western Australia, Australia. 2016. (Oral Presentation – invited speaker).

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Preface

This thesis is presented in fulfilment of the doctoral requirements for UTS. The thesis is structured as a PhD by compilation. Eight chapters are presented throughout the thesis, comprising a coherent suite of published works where copies of peer reviewed publications form chapters of the manuscript. To meet journal requirements for manuscript submission spelling varies between US English and British English. Sarah M Dineen-Griffin is the primary author of each publication. Coauthors include supervisors and collaborators who contributed to the concept, design, data collection, data analysis, data interpretation, and revision of manuscripts.

Chapter 1 describes a systematic review of published literature (1). The review was undertaken as part of the early exploratory work to capture the breadth of literature around self-management support interventions to identify and describe the main components of self-management support from a large body of published literature. Early insights from the review suggested a dearth of published evidence relating to self-management in community pharmacy. It was then decided to expand the review to include published literature from other primary care disciplines. The findings captured and synthesized the overarching components of self-management into a theoretical model. The model consists of a one-on-one consultation with a health care professional, such as a community pharmacist. The preliminary work contributed to understanding and investigating how self-management services could be practised in community pharmacy.

Chapter 2 presents the contextual background information of this research by examining self-care and self-care models in community pharmacy. The role of the community pharmacist in relation to self-care and minor ailment services is described. The chapter concludes by highlighting the gaps and opportunities in practice and international literature detailing the premise for undertaking the research.

Chapter 3 provides the aim and objectives of individual studies within the thesis and provides a description of the methodological approach to meet objectives. A detailed description of methods is presented under the relevant chapters of this thesis.

Chapters 4-7 discusses the empirical studies undertaken, each addressing specific objectives. Chapter 4 details a qualitative study undertaken with the aim of co-designing a MAS relevant to Australian community pharmacy (2). The co-design process involved an initial focus group with stakeholders to agree on service model elements and semi-structured interviews with community pharmacists during feasibility testing of the service. Chapter 5 details the protocol for a cRCT to evaluate the clinical, humanistic and economic impact of the community pharmacist delivered MAS (developed in chapter 4) compared to UC, in the Australian setting (3). Chapter 6 describes the clinical and humanistic evaluation results obtained from the cRCT (4). Chapter 7 details the results of the economic evaluation undertaken alongside the cRCT (5).

Chapter 8 discusses the overall research. The chapter focuses on describing how the research methods addressed the overall objectives and discusses contributions to existing knowledge in community pharmacy and the wider literature. The chapter reflects on the overall strengths and limitations of the research, describes the implications of the research findings and areas for future research. The chapter concludes by drawing conclusions from the overall research and provides recommendations for practice and policy.

Appendices provided at the end of this thesis include copies of ethics approval, a summary of abbreviations, and a declaration outlining authors contributions to co-authored papers.

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Chapter 1: Self-management

Self-management support

Self-management

Self-management is defined by Barlow and co-authors as a patient's ability to manage symptoms, treatment, physical or psychosocial consequences and lifestyle changes inherent in living with a chronic condition" (6, 7). Self-management is considered essential to disease management and secondary prevention (8). The terms self-care and self-management are used interchangeably and have been used in literature as concepts with similar and overlapping meanings (9). Jordan and co-authors note the distinction between self-care (taking responsibility for the health of self or family) and self-management (attitudes, behaviours and skills that the patient directs towards managing the impact of a condition) (10). Self-care is more commonly applied to minor illness, while self-management is used in relation to chronic disease (9). Most self-management activities are disease-specific (11) and involve increasing patients' confidence to manage their symptoms and disease (self-efficacy) (11-13). Self-management support is viewed as a portfolio of tools which help patients to choose healthy behaviours, and transformative in the patient-provider relationship to a collaborative partnership (14). The pivotal objective of self-management support is to change behaviours to produce sustainable positive health effects. This may be achieved by increasing patients' skills and confidence in managing their disease through regular assessment, goal setting, and problem-solving support (13).

Self-management support in pharmacy

Community pharmacists, alongside GPs, are typically the first point of contact for patients into the health system (15). Community pharmacists are continuing contacts for patients collecting their prescription medicines and therefore can facilitate self-management in practice. Community pharmacy based self-management initiatives are in the early stages of being developed and implemented. An example would be a small scale, locally commissioned service such as the Self-care Management Support Program (16) for patients with chronic diseases in the United Kingdom (UK). Patients with certain chronic conditions are directed to their community pharmacy for three sessions over twelve weeks with a trained pharmacist (16).

Self-management support is not terminology often used in community pharmacy. Aspects of self-management support are generally carried out opportunistically by community pharmacists, either during dispensing of prescribed medicines and conducting specific services such as a medication review, or lifestyle services. Self-management support is a comprehensive and multidimensional concept that looks at how care is provided holistically to the patient, not just as separate episodic

interventions. An examination of many of the self-management support interventions in literature do not mention or involve community pharmacy. This may mean that community pharmacy is generally seen as having little or no value in supporting self-management of chronic conditions or that their potential has not been realised. None of the published literature appears to include any theoretical framework or structure for pharmacists to provide self-management support or the training and system changes needed. A key issue to be addressed is how community pharmacists can deliver self-management services which are structured and evidence-based. Furthermore, a need exists to understand the clinical, humanistic and economic outcomes that can be achieved. Pharmacists should acquire the competencies to ensure patients obtain the skills to successfully self-manage. There should be emphasis on upskilling pharmacists to deliver self-management services as it appears not to be comprehensively covered in most university pharmacy courses.

Systematic review

The chapter hereon presents the work that was undertaken at the beginning of this PhD as part of a wider review, mapping published literature to understand the self-care and self-management in community pharmacy and capture the breadth of literature (1). Early insights from the review suggested a dearth of published evidence on self-management within the community pharmacy literature. The roles of health professionals and primary care teams in self-management support are explored extensively in medicine and nursing fields. It was then decided to expand the review to include published literature from other primary health disciplines. Therefore, the review was undertaken to provide clarity on existing research evidence in self-management, synthesize the evidence on effective interventions that facilitate positive clinical and humanistic outcomes, and develop a service model. The findings from the review led to the development of a theoretical framework which may be applied to pharmacy practice. Details on the search strategy, electronic databases, inclusion and exclusion criteria, the appraisal and synthesis techniques are presented in the following peer-reviewed publication[1].

[1] **Citation:** Dineen-Griffin, S., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Helping patients help themselves: a systematic review of self-management support in primary health care. PloS one. 2019;14(8): e0220116. https://doi.org/10.1371/journal.pone.0220116

PLOS ONE

RESEARCH ARTICLE

Helping patients help themselves: A systematic review of self-management support strategies in primary health care practice

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Abstract

Background

Primary health professionals are well positioned to support the delivery of patient self-management in an evidence-based, structured capacity. A need exists to better understand the active components required for effective self-management support, how these might be delivered within primary care, and the training and system changes that would subsequently be needed.

Objectives

(1) To examine self-management support interventions in primary care on health outcomes for a wide range of diseases compared to usual standard of care; and (2) To identify the effective strategies that facilitate positive clinical and humanistic outcomes in this setting.

Method

A systematic review of randomized controlled trials evaluating self-management support interventions was conducted following the Cochrane handbook & PRISMA guidelines. Published literature was systematically searched from inception to June 2019 in PubMed, Scopus and Web of Science. Eligible studies assessed the effectiveness of individualized interventions with follow-up, delivered face-to-face to adult patients with any condition in primary care, compared with usual standard of care. Matrices were developed that mapped the evidence and components for each intervention. The methodological quality of included studies were appraised.

Results

6,510 records were retrieved. 58 studies were included in the final qualitative synthesis. Findings reveal a structured patient-provider exchange is required in primary care (including

a one-on-one patient-provider consultation, ongoing follow up and provision of self-help materials). Interventions should be tailored to patient needs and may include combinations of strategies to improve a patient's disease or treatment knowledge; independent monitoring of symptoms, encouraging self-treatment through a personalized action plan in response worsening symptoms or exacerbations, psychological coping and stress management strategies, and enhancing responsibility in medication adherence and lifestyle choices. Follow-up may include tailored feedback, monitoring of progress with respect to patient set healthcare goals, or honing problem-solving and decision-making skills. Theoretical models provided a strong base for effective SMS interventions. Positive outcomes for effective SMS included improvements in clinical indicators, health-related quality of life, self-efficacy (confidence to self-manage), disease knowledge or control. An SMS model has been developed which sets the foundation for the design and evaluation of practical strategies for the construct of self-management support interventions in primary healthcare practice.

Conclusions

These findings provide primary care professionals with evidence-based strategies and structure to deliver SMS in practice. For this collaborative partnership approach to be more widely applied, future research should build on these findings for optimal SMS service design and upskilling healthcare providers to effectively support patients in this collaborative process.

Introduction

Internationally, healthcare systems are challenged with the rising rates of chronic and complex illness and the clinical and economic burden associated represents a major challenge to the optimal provision of healthcare [1]. Health systems need to accommodate changes to meet the increasing need for health services. Evidence suggests that leveraging the potential of people to care for themselves and involving patients in decisions affecting their health is beneficial, particularly on the increasing rates of primary care consultations and health system pressures [2]. A key issue that needs to be addressed is how primary health care professionals (HCPs) can support self-management in an evidence-based, structured way and how self-management processes can be integrated into clinical practice, as models of care evolve to deliver a person-centred approach. Patient participation is suggested to narrow the gap between the dichotomous roles of patient and HCP [3]. Patient participation involves being engaged in the planning of care and exchanging knowledge, setting own goals and carrying out self-management activities [3]. This partnership has been suggested as valuable in the support of the management and control of symptoms, particularly for patients with chronic health conditions [4]. Self-management strategies are increasingly recognized as an essential component of chronic disease management and secondary prevention [5], individually tailored to patient preferences, prior knowledge and circumstances, supporting patient participation in their care [6].

Self-management support (SMS) is viewed in two ways: (1) as a portfolio of techniques and tools that help patients choose healthy behaviours, and (2) as a fundamental transformation of the patient-professional relationship into a collaborative partnership [7]. SMS encompasses more than a didactic, instructional program and goes beyond simple dissemination of information or disease state management. The pivotal objective of SMS is to change behaviour

within a collaborative arrangement to produce sustainable effects. This can be achieved by increasing patients' skills and confidence in managing their disease state through regular assessment of progress and problems, goal setting, and problem-solving support [8]. Simply put, patients and HCPs work to develop tangible and realistic healthcare goals, while HCPs can assist with the development of the skill set necessary to achieve these goals and monitor for improvements in patient health [9]. Lorig and Holman [10] identify a generic set of skills proven successful for effective self-management, including (1) problem-solving; (2) decision-making; (3) resource utilization; (4) forming a patient-health care provider partnership; and (5) taking action. Acquisition of these skills leads to increased self-efficacy. Self-efficacy refers to beliefs in one's capabilities to execute a behaviour or course of action necessary to reach a desired goal [10, 11].

There is a growing body of evidence that shows supporting people to self-manage their health and care can lead to improvements in clinical and humanistic outcomes [12–18], reducing the economic impact of chronic disease and a means of contributing to the sustainability of the global healthcare system. Supporting people to self-manage has resulted in reduced use of general practitioners, reduced admissions to hospital, significant gains in health status and increased symptom control [19, 20]. Interventions have targeted patients with arthritis [21], asthma [22], chronic heart failure (CHF) [23], chronic obstructive pulmonary disease (COPD) [24], type 2 diabetes mellitus (T2DM) [25, 26], hypertension (HT) [27] and patients on oral anticoagulation [28]. Self-management support interventions vary in the literature with increasing evaluations of peer-led, lay-led, or non-health professional-led, web-based and group-based interventions. For example, the generic Chronic Disease Self-Management Program, a non-health professional group-delivered intervention remains the most widely adopted self-management support program internationally [29].

Primary HCPs are typically an individuals' first point of contact with the health system [30], and are continuing contacts for people with chronic disease. This opens up substantial opportunities to effect sustainable changes through supporting self-management and delivery of more personalized healthcare services. There is an increasing number and uptake of primary care services which require HCPs to be patient-oriented however none of the education provided appears to include any theoretical framework or evidence-based structure for providers to effectively support self-management and facilitate patient behaviour change. Importantly, HCPs need to acquire the competencies not only to identify the techniques and tools for specific patients but to ensure that patients acquire the skills to self-manage. Kennedy et al. recommends a whole systems approach, which integrates SMS at the level of the patient, HCP, and service organizations, which has proven effective in improving outcomes for patients [31]. Effective implementation is profoundly important to ensure viability and sustainability, and potential scale-up. In some countries, governments have developed health policy and funding alignment for self-management support with the aim of improving health outcomes and alleviating pressures on the wider health system [32].

While the role of primary HCPs in delivering SMS is highlighted in the literature, there remains a gap in research regarding the specific strategies and active components of interventions used by providers resulting in better health outcomes for patients. A need exists to better understand how these might be delivered within primary care, what outcomes can be achieved, and the training and system changes needed as a result. This gap increases the challenge of providing consistent SMS in primary care, and enabling the appropriate evaluation of SMS trials. Therefore, the objective of this systematic review is to summarize the evidence of effectiveness for SMS interventions delivered face-to-face in primary care practice, and identify evidence-based strategies with active components facilitating positive clinical and humanistic patient outcomes.

Methods

A systematic review of randomized controlled trials evaluating SMS interventions was conducted following the Cochrane Handbook for Systematic Reviews of Interventions. We have reported the review according to PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines [33, 34]. Details of the protocol for this systematic review can be found in the PROSPERO international prospective register of systematic reviews database (registration CRD42017062639).

Search strategy

The research question (using PICO) and search strategy were developed and reviewed by three authors (SDG, VGC, SB) to identify studies for this review. In a preliminary scoping search of databases, we as a group of authors identified ten key papers which were suitable to be included in the review. In the multiple search strategies all authors were involved. We tested and refined our strategies as a group, which ensured reproducibility of key papers within search results and a robust search strategy. The detailed search strategy for different electronic databases can be found in S1 Table. A comprehensive search was undertaken in three databases using PubMed, Scopus and Web of Science and search strategies were refined for each individual database. Multiple databases were searched to adequately identify all literature relevant to the research question. Published literature was systematically searched from inception to June 2019. Neither publication date nor publication type filters were used. Citation searching was also conducted to find articles cited by other publications. Searches of grey literature and reference lists of previous systematic reviews complemented our literature search to ensure all relevant studies were captured. The complete results from all databases were imported and managed in a unique EndNote X9 library upon search completion and saved without duplication.

Data extraction, management and synthesis

The review team were responsible for assessing the trials' eligibility using the methods outlined. The lead reviewer (SDG) screened by title and abstract to select relevant publications. A second and third reviewer (VGC, SB) were consulted throughout this process if an article could not be rejected with certainty. Any disagreement among the reviewers throughout this process were resolved by discussion and consensus. All authors (SDG, VGC, KW, SB) agreed on the final texts for inclusion. Full texts were assessed for eligibility according to inclusion and exclusion criteria. Eligible studies were randomized controlled trials (RCTs) and cluster-randomized controlled trials (c-RCTs) assessing SMS interventions with follow-up, delivered by primary HCPs, face-to-face to adult patients with any condition, compared to usual standard of care. The types of interventions included in the review were multicomponent interventions aimed at supporting patient self-management. Jonkman et al's definition of SMS interventions was applied for the purposes of selection of interventions for inclusion in this review [35]. This definition includes the wide range of components considered for 'self-management interventions'. Self-management interventions are defined as [35]:

"*Interventions that aim to equip patients with skills to actively participate and take responsibility in the management of their chronic condition. This includes knowledge acquisition, and a combination of at least two of the following: (1) stimulation of independent sign and/or symptom monitoring; (2) medication management; (3) enhancing problem-solving and decision-making skills for treatment or disease management; (4) or changing physical activity, dietary and/or smoking behaviour*".

Excluded studies were: (1) non-randomized controlled study designs; (2) interventions not meeting Jonkman's definition of self-management support; (3) interventions not delivered face-to-face (i.e. web-based interventions); (4) group-delivered interventions; (5) study

populations under 18 years of age; (6) interventions delivered in settings other than primary care; (7) interventions delivered by non-HCPs (i.e. lay, peer-led); (8) studies without usual standard of care as comparator; (9) studies written in a language other than English or Spanish; or (10) non-primary research articles (i.e. literature reviews, study protocols).

Authors kept a record of the number of trials included or excluded from the review at each stage of the assessment process. Multiple papers of the same study were linked together. Study design, setting, methods, participant characteristics, type of intervention, content, duration and intensity of components, follow up, and study findings were extracted using a tailored data extraction form developed for data retrieval using the Cochrane Handbook for Systematic Reviews of Interventions [36] and the Cochrane Effective Practice and Organisation of Care Group (EPOC) data collection form [37] and checklist [38].

Matrices were developed mapping both evidence and active components for each self-management intervention. Outcome indicators were independently extracted, tabulated and grouped using the following categories of outcome measures, including (1) disease specific indicators; (2) self-efficacy; (3) health-related quality of life; (4) functional status and disability; (5) psychological functioning; (6) disease knowledge; (7) behaviours and self-management activities. Components were categorized according to Jonkman's definition of SMS interventions [35], including strategies for: (1) condition or treatment knowledge acquisition; (2) active stimulation of symptom monitoring; (3) self-treatment through the use of an action plan; (4) enhancing resource utilization; (5) enhancing problem-solving and/ or decision-making skills; (6) enhancing stress management or emotional coping with condition; (7) enhancing physical activity; (8) enhancing dietary intake; (9) enhancing smoking cessation; and (10) medication management or adherence. Given the heterogeneity of the studies regarding participants, varying healthcare setting, strategies and outcome measures, no formal quantitative synthesis or meta-analysis could be conducted.

Assessment of risk of bias

The methodological quality of studies were appraised using the 'Suggested risk of bias criteria for EPOC reviews' tool in accordance with the Cochrane Handbook [39]. Domains of bias included in the final assessment, were: (1) random sequence generation; (2) allocation concealment; (3) similarities on baseline outcome measurements; (4) similarities on baseline characteristics; (5) completeness of outcome data; (6) blinding (participants, personnel); (7) protection against contamination; (8) selective outcome reporting; and (9) other risks of bias. Studies were assessed by domain as 'low risk' or 'high risk' of bias. Domains were 'unclear risk' if too few details were available to make an acceptable judgement of 'high' or 'low' risk. A second and third reviewer (VGC, SB) were consulted throughout this process if decisions could not be made with certainty. Any disagreement among the reviewers throughout this process were resolved by discussion and consensus. Three categories of study quality were identified by study authors according to each study's methodological characteristics. In high-quality studies, the majority of criteria were fulfilled and done well (low risk of bias in at least six criterion), while in low-quality studies, the majority of criteria were not done or done poorly (high risk of bias in at least five criterion); other situations were considered medium quality [40]. No papers were excluded as a result of quality assessment.

Results

Study selection

6,510 citations were retrieved. After the removal of duplicates, 4,831 records were screened by title and abstract. After review of full texts, fifty-eight RCTs/c-RCTs (reported in 80 citations) fulfilled the review criteria and were included in this systematic review (see flow diagram in

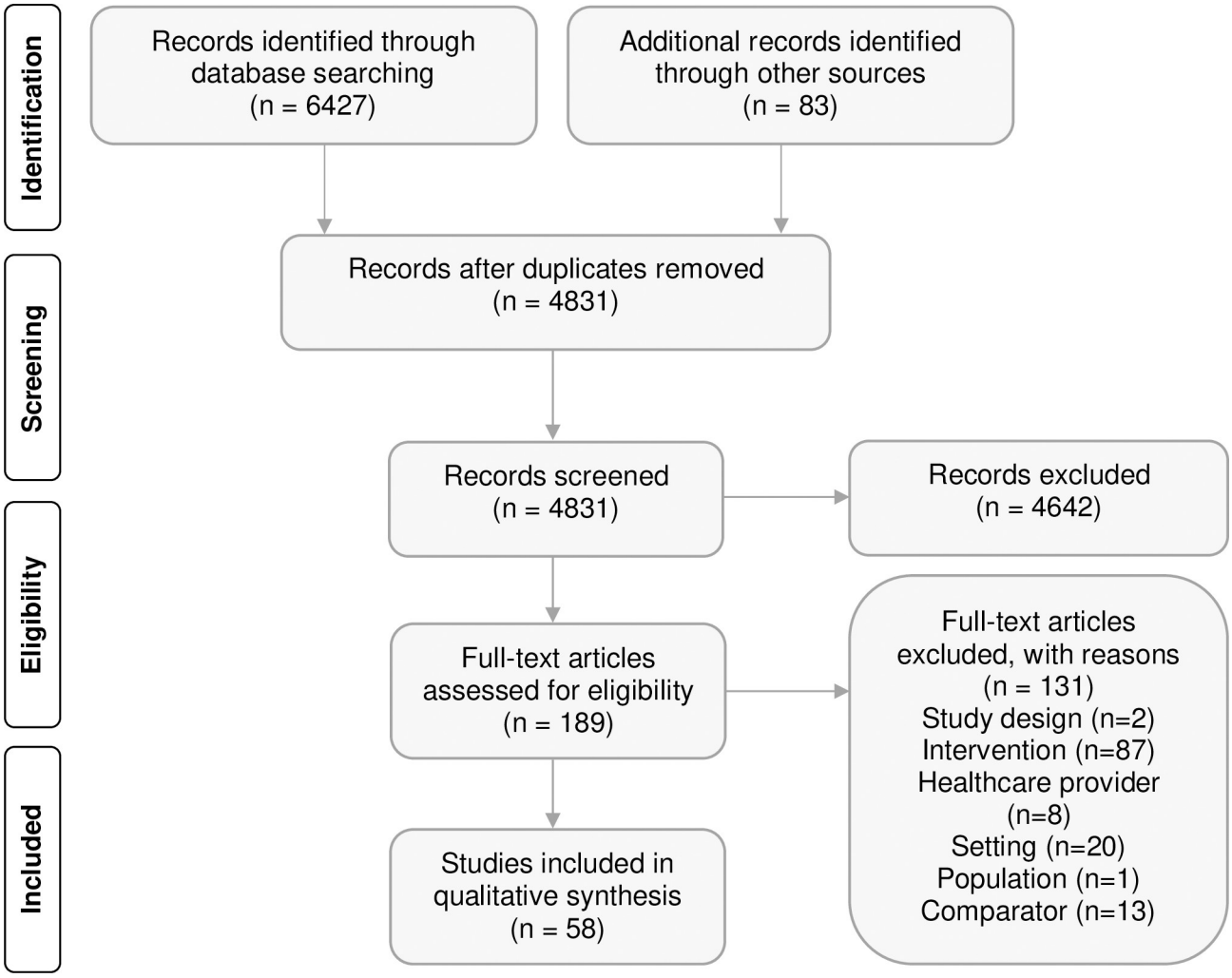

Fig 1. PRISMA diagram of search results and screening.

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Fig 1). A completed PRISMA checklist can be found in S2 Table. Descriptive characteristics of individual studies are provided in S3 Table.

Description of studies

The included studies originated from 18 countries, predominantly the United Kingdom (UK) and the United States (US). The conditions most frequently targeted included T2DM (37.9%; n = 22), COPD (20.7%; n = 12) and depression (13.8%; n = 8) (Table 1). Settings primarily reported were general practice (48.3%; n = 28), primary care clinics (25.9%; n = 15) and community pharmacies (10.3%; n = 6). Interventions were delivered largely by general practitioners or nurses, commonly specialising in areas such as respiratory, diabetes and mental health. SMS interventions in fourteen studies were delivered in primary care teams involving more than one health care professional from different disciplines (24.1%; n = 14).

Study outcomes

Ninety-three different outcome measures were adopted by studies. Clinical outcome measures associated with a particular condition were typically reported (e.g. clinical outcomes such as

Table 1. Classification of self-management support studies by condition.

Condition	Frequency (N)	Associated references
Diabetes	22	[31, 41–63]
COPD	12	[31, 58, 59, 61–71]
Depression	8	[47, 58, 72–77]
Coronary heart disease	5	[47, 58, 76, 78, 79]
Asthma	5	[59, 62, 63, 80–82]
Osteoarthritis (OA)	4	[58, 83–87]
Low back pain	2	[88, 89]
Irritable bowel syndrome (IBS)	3	[31, 61, 90, 91]
Cardiovascular disease (CVD)	3	[55, 59, 62, 63]
Recurrent binge eating/ binge eating disorder	2	[92, 93]
Unexplained chronic fatigue & chronic fatigue syndrome	2	[94, 95]
Anxiety	2	[73, 74]
Chronic dizziness	1	[96]
Bulimia nervosa	1	[97]
Hypertension	1	[58]
Migraine/ headache	1	[98]
Oral hygiene	1	[99]
Low self-esteem	1	[100]
Psychosocial problems	1	[101]
Schizophrenia	1	[58]
Bipolar	1	[58]
Congestive heart failure	1	[58]
Hyperlipidaemia	1	[62, 63]
Prediabetes	1	[62, 63]

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changes in blood pressure or HbA1c levels). Humanistic outcomes sought to measure physical, social and psychological functioning and changes in health-related quality of life (HRQOL). Others captured changes in self-efficacy. Results were classified by outcome and method of assessment (summarised in S4 Table relative to key findings).

Impact of interventions on outcomes

The overall impact of interventions on clinical and humanistic outcomes are illustrated in Table 2.

Disease specific outcomes. Forty four RCTs examined the impact of interventions on disease specific outcomes [42–57, 60, 70, 71, 76, 78, 79, 82, 85–87, 102, 106, 107, 109, 110, 112, 114, 115, 118]. Disease specific outcomes were most commonly reported in studies evaluating interventions targeting patients with T2DM (e.g. changes in HbA1c, weight, blood pressure and lipids), COPD (e.g. changes in Peak Expiratory Flow (PEF)), courses of antibiotics, oral corticosteroids and frequency of exacerbations), asthma (e.g. PEF, symptoms, inhalation technique, number of exacerbations and nocturnal awakenings), binge eating disorders (e.g. frequency of episodes and purging) and osteoarthritis (OA) (e.g. pain intensity, level of fatigue and use of pain medication). Seventeen studies targeting diabetes reported mean changes in HbA1c, with seven reporting significant improvements in the intervention compared to usual care [42, 46, 47, 50, 52, 53, 56, 109, 112]. Goudswaard et al. [42] reported a decrease in HbA1c at six weeks by 0.7% more (95% CI 0.1, 1.4) in those receiving the intervention when compared with control. The intervention evaluated by Adachi et al. [50] for patients with T2DM resulted

Table 2. Evidence of SMS interventions on desired outcomes.

	Disease specific outcomes	Self-efficacy	Quality of life	Physical and social functioning	Psychological functioning	Disease knowledge	Health behaviours	Self-management activities
Adachi et al. [50]	±							
Banasiak et al. [97]	±			+	+			
Barbanel et al. [80]	+							
Barley et al. [76]	NEA	NEA	NEA	NEA	NEA			
Bartels et al. [58]				NS				±
Bischoff et al. [69]	NS	NS	NS					
Broderick et al. [84]	±	±	NS	±	+			
Browning et al. **[54, 102]**	±	NS	NS		+			±
Chalder et al. [95]	+			+				
Cherkin et al. [88]	NS			NS		+	+	
Clark et al. [41, 103]	NEA						NS	+
Clarkson et al. [99, 104]	±	+						
Doucette et al. [45]	NS							±
Dziedzic et al. [85–87]	NS	+		NS	NS			
Efraimsson et al. [66]			+			+	+	
Eikelenboom et al. [59, 105]		NS					NS	
Farmer et al. [48, 106, 107]	NS							
Ferrone et al. [71]	+		+			+		
Fortin et al. [62, 63]				+				+
Freund et al. [101]			±					
Friedberg et al. [94, 108]	+		NS		NS			
Gabbay et al. [43]	±				+			
Gabbay et al. [60]	±		NS		NS			NS
Goudswaard et al. [42]	+							
Grilo et al. [93]	NS				NS	NS		
Heitkemper et al. [91]			+		+			
Hill et al. [67]						+		
Hoffmann et al. [98]	NS	NS	±					
Huang et al. [46, 109]	±							
Ismail et al. [49]	NS							
Jaipakdee et al. [56]	±		+		NS			
Kennedy et al. [31, 61]		NS	NS	NS	NS			NS
McGeoch et al. [64]	NS		NS		NS			±
McLean et al. [82]	+		+			+		
Mehuys et al. [81]	±		NS			NS	±	
Mehuys et al. [52]	+					+		±
Meland et al. [78, 110]	NS	NS					NS	

(*Continued*)

Table 2. (Continued)

	Disease specific outcomes	Self-efficacy	Quality of life	Physical and social functioning	Psychological functioning	Disease knowledge	Health behaviours	Self-management activities
Mitchell et al. [68, 111]	±	NS			±	+		
Morgan et al. [47, 112]	±				+			
Moss-Morris et al. [90, 113]	+		+		NS			
Murphy et al. [79, 114, 115]	NS			NS				
Olry de Labry Lima et al. [53]	±							
Partapsingh et al. [51]	NS							
Richards et al. [74]			NS		NS			
Rosemann et al. [83]			NS				NS	
Smit et al. [77, 116]		NS						
Striegel-Moore et al. [92, 117]	+		+		+			
Sturt et al. [44]	NS	+			+			
Tiessen et al. [55, 118]	NS						NS	
van Dijk-de Vries et al. [57]	NS	NS	NS	NS	NS	NS		
Von Korff et al. [89]	NS			NS	NS			
Waite et al. [100]					+			
Watkins et al. [72]	+				+			
Watson et al. [70]	NS							
Williams et al. [75]					+			
Wood-Baker et al. [65]	±		NS				NS	
Yardley et al. [96]	+		+	NS	NS			
Zimmermann et al. [73]	NS	+	NS		NS			

(+): positive findings; (±): mixed findings; (NS): non-significant findings; NEA: no evidence available

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in a 0.7% decrease in HbA1c at six months in the intervention group (n = 100) compared with a 0.2% decrease in the control group (n = 93) (difference −0.5%, 95% CI: -0.2%, −0.8%; p = 0.004).

Three RCTs reported on the level of asthma control and symptoms [80–82]. Mehuys et al. measured the level of asthma control using the Asthma Control Test (ACT), a clinically validated measure [81]. While mean ACT scores did not change from baseline for both study groups, a subgroup analysis of patients having insufficiently controlled asthma at baseline showed the intervention group had significantly increased ACT scores after six months (mean ACT change from baseline in the intervention group was +2.3 and +0.3 in the control group (mean difference 2.0, 95% CI: 0.1, 3.9; p = 0.038). The need for rescue medication was reduced in both groups from baseline, however a significantly higher reduction in the intervention group (-0.56 and -0.57 inhalations per day at three and six-month follow-up, respectively) was reported against control (-0.03 and -0.43 inhalations per day at three and six-month follow-up, respectively; p = 0.012) [81]. Six studies reported on COPD-specific outcomes [64, 65, 68–71,

111]. McGeoch et al. [64] reported no significant change in St. George's Respiratory Questionnaire (SGRQ) as the primary outcome measure. The intervention also showed no effect on self-reported outcomes including the frequency of use of antibiotic courses and oral corticosteroids over 12 months [64].

Interventions targeting eating disorders were evaluated in four RCTs [41, 92, 93, 97, 103, 117]. Banasiak et al. [97] explored primary outcome measures of eating pathology derived from the Eating Disorder Examination Questionnaire (EDE-Q). Intention-to-treat (ITT) analyses revealed significant improvements in psychological symptoms at the end of the intervention compared with control, reduction in mean frequency of binge-eating episodes by 60% in intervention and 6% in control, and remission from all binge-eating and compensatory behaviours in 28% of the intervention and 11% of control. Treatment gains were maintained at three and six-month follow-up [97].

An intervention targeting patients with OA measured primary outcomes of pain intensity, physical functioning, self-efficacy, psychological distress, use of pain coping strategies, catastrophizing and HRQOL [84]. ITT analyses were performed on primary outcomes at baseline, post-treatment, 6 and 12 month follow-up which yielded significant group differences, indicating improvement in pain intensity ($F(3,233) = 2.75$, $p = 0.044$), physical functioning ($F(3,233) = 3.11$, $p = 0.027$), psychological distress ($F(3,233) = 2.83$, $p = 0.039$), use of pain coping strategies ($F(3,233) = 4.97$, $p = 0.002$), and self-efficacy ($F(3,232) = 10.59$, $p < 0.001$) in intervention, compared with control. All outcomes, except for self-efficacy, were maintained at 12-month follow-up while effects on self-efficacy degraded over time [84].

Health-related quality of life. Twenty-four RCTs examined the impact of interventions on HRQOL [31, 54, 56, 57, 60, 61, 64–66, 69, 71, 73, 74, 76, 81–84, 90–92, 94, 96, 98, 101, 102, 108, 113, 117]. The method of assessment varied and included general HRQOL questionnaires such as the SF-12 survey questionnaire and EuroQoL EQ-5D questionnaire. Disease specific QOL measures were also identified including the Arthritis Impact Measurement Scales Short Form questionnaire (AIMS2-SF) [119], Irritable Bowel Syndrome Quality of Life Questionnaire (IBSQOL) [120], Audit of Diabetes Dependent Quality of Life (ADDQOL) [121] and the standardised Asthma Quality of Life Questionnaire (AQLQ) [122]. Eight studies reported significant improvements in HRQOL [56, 66, 71, 82, 90–92, 96, 113, 117]. Efraimsson et al. [66] evaluated the effects of COPD self-management delivered at a nurse-led primary health care clinic. HRQOL, measured using the SGRQ, was improved by an average value of 8.2 units (from 30.6) in the intervention group, whereas no change was noted in control. Differences between groups were clinically relevant and statistically significant ($p = 0.00030$) [66]. Heitkemper et al. [91] examined the effect of an IBS SMS intervention on HRQOL using the Irritable Bowel Syndrome Quality of Life questionnaire (IBSQOL), a 30-item questionnaire. Compared to usual care, participants receiving the intervention demonstrated statistically significant improvements in QOL, increasing by 10.6 units, 12.8 units and 12.2 units at nine weeks, six and twelve-months, respectively. Changes persisted at 12-month follow-up ($p<0.001$) [91].

Physical, psychological or social functioning. Physical, mental or social functioning were measured in 25 RCTs [31, 43, 44, 47, 54, 56–58, 60–64, 68, 72–76, 79, 84–97, 100, 102, 108, 111–115, 117]. Psychological symptoms and social functioning using the CORE-OM scale [123] were measured in three studies [74, 75, 100]. Psychological functioning was measured using the Beck Depression Inventory (BDI) and Beck Depression Inventory-II (BDI-II) scale [124] in eight studies [72, 75, 84, 92–94, 97, 100, 108, 117]. Williams et al. [75] reported lower mean BDI-II scores in the intervention group at four months (2.6 to 7.9; mean difference 5.3 points, $p<0.001$). At twelve-month follow-up, there were also significantly higher proportions of participants achieving a 50% reduction in BDI-II in the intervention arm compared to

control [75]. The Problem Areas in Diabetes Scale (PAID), a brief self-report scale [125], was used to evaluate diabetes-related distress. Sturt et al. [44] reported a reduction by 4.5 points in mean PAID scores at follow-up (95% CI: −8.1, −1.0), indicating lowered diabetes-related distress after a nurse-delivered intervention compared with control ($p = 0.012$), however this difference was considered a small effect [44]. Physical functioning was assessed with the SF-36PF scale [126] by Friedberg et al. [94, 108] evaluating a chronic fatigue self-management intervention. No significant changes in scores by time, treatment group, or diagnostic group were revealed ($p>0.05$) [94, 108].

Patient self-efficacy. Self-efficacy was assessed using a number of validated instruments including the General Self Efficacy Scale (GSES-12) [127], Diabetes Management Self Efficacy Scale (DMSE) [128] and the Arthritis Self Efficacy Scale (an eight item scale measuring patients' perceived ability to perform specific behaviours aimed at controlling arthritis pain and disability) [129], the COPD self-efficacy scale (CSES) [130], among others. Self-management and patient enablement were measured by the Patient Enablement Instrument (PEI) [87]. Changes in perceived self-efficacy were reported in 14 studies [31, 44, 54, 57, 68, 69, 73, 76–78, 84, 87, 98, 99, 102, 104, 110, 111, 116]. Sturt et al. showed self-efficacy scores were 11.2 points higher on the DMSE (95% CI: 4.4, 18.0) in the intervention group compared with the control group following a structured intervention delivered by practice nurses in the UK ($p = 0.0014$) [44]. Broderick et al. [84] reported significant improvement in self-efficacy ($F(3,232) = 10.59$, $p = 0.001$) following a nurse-practitioner delivered intervention for OA patients, however this was not maintained at 12-month follow up ($p = 0.158$). Seven RCTs reported non-significant improvements in self-efficacy [54, 57, 59, 68, 69, 77, 78, 98, 102, 105, 110, 111, 116]. Bischoff et al. found no statistically significant changes in CSES scores at 24 months [69]. Smit et al. [77, 116] assessed self-efficacy in controlling depressive symptoms and preventing future episodes, using the Depression Self-Efficacy Scale (DSES) [131]. No statistically significant differences between groups were revealed at 12-month follow-up [77, 116]. Eikelenboom et al. reported no significant difference in PAM-13 scores (measure of patient activation [132]) between control and intervention arms at six-month follow-up [59, 105].

Self-management behaviours. Behaviours commonly measured were diet, physical activity, medication adherence and smoking. Five studies reported on level of physical activity [41, 59, 83, 88, 103, 105]. A range of measures included the International Physical Activity Questionnaire short form (IPAQ-SF) [133], Rapid Assessment of Physical Activity questionnaire (RAPA) [134] and The Physician-based Assessment and Counselling for Physical Activity (PACE) questionnaire [135]. No significant between group differences were reported for physical activity in 4 RCTs [41, 59, 65, 83, 103, 105]. There was evidence in one study to suggest self-reported exercise participation was higher 1-week post-intervention ($p<0.001$) however differences were no longer significant at seven-week follow-up [88]. Self-care activities within 7 days were measured in 4 RCTs [41, 52, 54, 60, 102, 103] using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire, a brief self-report instrument for measuring levels of self-management in diabetes ('general diet', 'specific diet', 'physical exercise', 'foot care' and 'smoking') [136]. Mehuys et al. reported significant improvements in self-management activities in the domains of 'specific diet' (+0.5 day/week, $p = 0.008$), 'physical exercise' (+0.4 day/week, $p = 0.006$), and 'foot care' (+1.0 day/week, $p<0.001$) for intervention patients. There were significant between-study group differences in the domains 'physical exercise' ($p = 0.045$) and 'foot care' ($p<0.001$), however the between-group difference for 'specific diet' were non-significant [52].

Disease knowledge. Nine studies reported disease knowledge as an outcome [52, 66–68, 71, 81, 82, 88, 93, 111]. Two RCTs [67, 68, 111], measured COPD disease knowledge using the Bristol COPD Knowledge Questionnaire (BCKQ) [137]. Hill et al. reported the results of the

BCKQ for each domain in both groups. Compared with baseline measures, the total Bristol COPD knowledge Questionnaire score increased from 27.6 ± 8.7 to 36.5 ± 7.7 points ($p<0.001$) in the intervention group, and unchanged in the control group (29.6 ± 7.9 to 30.2 ± 7.2; $p = 0.51$) [67].

Intervention components and theoretical underpinnings

Each of the studies described interventions including multiple core components (see S5 Table for full component breakdown). Providing knowledge about the condition or treatment (100%; n = 58), enhancing patients role in making lifestyle changes (71.9%; n = 41), development of a self-management or action plan (45.6%; n = 26), keeping logs of self-monitoring (43.9%; n = 25), strategies for psychological coping with conditions (43.9%; n = 25), enhancing problem-solving and/or decision-making skills (42.1%; n = 24) and medication adherence or management (36.8%; n = 21) were most prominently detected (Table 3). Interventions targeting heart disease, irritable bowel disease (IBD) and asthma reported the highest number of self-management components. Self-treatment through the use of an action plan, enhancing medication adherence and smoking cessation components were frequently seen in studies evaluating interventions targeting COPD. Similarly, SMS components targeting T2DM commonly included strategies to stimulate symptom monitoring, making positive lifestyle improvements with physical activity or dietary improvements. In contrast, interventions for depression included components focusing on patients' role in managing stress, problem-solving and strategies for coping with conditions.

Overall, sixteen studies explicitly reported a theoretical framework underpinning the intervention (28.1%; n = 16) including Cognitive Behavioural Theory (17.5%; n = 10) [58, 74, 75, 84, 90–94, 100], Social Cognitive Theory (3.5%; n = 2) [79, 104], Prochaska and DiClementes' Transtheoretical model of the Stages of Change (3.5%; n = 2) [51, 55, 66, 82], Social Learning Theory (1.8%, n = 1) [44], Normalization Process Theory [31] and Implementation Intention Theory (1.8%; n = 1) [104]. Intervention fidelity was reported in 21 studies (27.6%; n = 16).

Training of primary care provider to deliver SMS. 70.7% (n = 41) of studies included upskilling of HCPs to deliver the intervention. Training aimed at enhancing aspects of patient self-efficacy including mastery achievements, positive learning, adjustment to stress, verbal encouragement and outcome expectations. Intervention approaches were underpinned by the use of core communication skills to build trust and rapport in the patient-provider

Table 3. Frequency of self-management components of included interventions.

Components	Number of studies in which this strategy is mentioned N (%)
Providing knowledge about condition or treatment	58 (100.0)
Stimulation of physical activity	27 (47.4)
Enhancing problem-solving and/ or decision-making skills	27 (47.4)
Self-treatment through use of self-management or action plan	26 (45.6)
Active stimulation of symptom monitoring	25 (43.9)
Emotional coping with condition or stress management	25 (43.9)
Enhancing dietary intake	24 (42.1)
Medication management or adherence	21 (36.8)
Encouraging use of other health services or support resources	13 (22.8)
Enhancing smoking cessation	13 (22.8)

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relationship, and as such providers were trained in areas including active listening, non-verbal communication, reflection, empathy and affirmation. Studies reported the provision of HCP resources to support self-management, e.g. written material or manuals, feedback on care reports, video demonstrations or case studies, and tools to assess patient support needs and priorities (PRISMS).

Interventions reporting positive findings for clinical and humanistic measures

Thirteen RCTs targeting a range of conditions including asthma, T2DM, COPD, recurrent binge eating, chronic fatigue, major depression, low self-esteem, IBS and depression reported positive findings for all clinical and humanistic outcome measures (Table 4) [42, 66, 67, 72, 75, 80, 91, 92, 95, 100, 117].

A mean of five self-management components (SD 1.7) were included in effective interventions. Elements most frequently reported to enhance the patient's role in self-management included information provision (100.0%; n = 13), enhancing problem-solving or decision-making skills (76.9%; n = 10), active stimulation of symptom monitoring (46.2%; n = 6), medication management or adherence (46,2%; n = 6), strategies for stress or psychological

Table 4. RCTs showing positive findings for all outcome measures.

	Transfer of information	Self-treatment through use of an action plan	Active stimulation of symptom monitoring	Stress or psychological management	Enhancing problem solving/ decision-making	Resource utilization	Enhancing physical activity	Enhancing dietary intake	Enhancing smoking cessation	Enhancing medication adherence
Barbanel et al. [80]	✓	✓	✓	✗	✓	✗	✗	✗	✓	✓
Chalder et al. [95]	✓	✗	✓	✗	✓	✗	✗	✗	✗	✗
Efraimsson et al. [66]	✓	✓	✗	✗	✓	✗	✓	✓	✓	✓
Ferrone et al. [71]	✓	✓	✗	✓	✓	✗	✓	✓	✓	✓
Fortin et al. [62, 63]	✓	✗	✗	✗	✗	✗	✓	✓	✓	✗
Goudswaard et al. [42]	✓	✗	✓	✗	✗	✗	✓	✓	✗	✓
Heitkemper et al. [91]	✓	✓	✓	✓	✓	✗	✗	✓	✗	✗
Hill et al. [67]	✓	✗	✗	✗	✗	✗	✓	✗	✓	✓
McLean et al. [82]	✓	✓	✓	✗	✓	✗	✗	✗	✗	✓
Striegel-Moore et al. [92, 117]	✓	✗	✓	✓	✓	✓	✗	✓	✗	✗
Waite et al. [100]	✓	✗	✗	✓	✓	✗	✗	✗	✗	✗
Watkins et al. [72]	✓	✗	✗	✓	✓	✗	✗	✗	✗	✗
Williams et al. [75]	✓	✗	✗	✓	✓	✗	✗	✗	✗	✗
Total	**13**	**5**	**6**	**6**	**7**	**1**	**5**	**6**	**5**	**6**

Summary: (✓) component present; (✗): component absent/ unclear/ not specified

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management of condition (46.2%; n = 6) or enhancing dietary intake (46.2%; n = 6). The total duration of interventions ranged from 4 to 52 weeks. Initial consultations were on average 62 minutes (SD 13.8). Follow-up was delivered face-to-face in 11 interventions (84.6%; n = 11), and two studies reported telephone follow up (15.4%; n = 2). Studies reported mean of five follow-up sessions (SD 3.6) on average, ranging from 1 to 12 sessions. Mean duration of follow up sessions were 57 minutes (SD 18.5). Individuals were provided self-help support materials or resources in majority of interventions (92.3%; n = 12). Accompanying patient materials provided in addition to face-to-face sessions included manuals, information or educational booklets to work through at home, personalized treatment or action plans, devices and diaries for self-monitoring, goal setting forms or individualized dietary plans. Six RCTs incorporated a theoretical underpinning in their intervention: cognitive behavioral theory (30.8%; n = 4) and Prochaska and DiClementes' transtheoretical model of the stages of change (15.4%; n = 2). Five integrated cognitive behavioral therapy (CBT) into their intervention (38.5%; n = 5).

Barbanel et al. [80] and Goudswaard et al. [42] targeted asthma and T2DM respectively and produced positive improvements in clinical outcomes. The SMS intervention evaluated by Barbanel et al. [80] examined the impact of a self-management program delivered by community pharmacists on asthma control. Intervention participants received self-management support from the pharmacist with weekly telephone follow-up for 3 months. This included a review of inhaler technique, skills including monitoring of peak flow, and a personalized action plan for worsening symptoms or exacerbations. Symptom scores improved in the intervention group and marginally worsened in the control group to 20.3 (4.2) and 28.1 (3.5), respectively ($p<0.001$; adjusted difference = 7.0 (95% CI: 4.4, 9.5). Goudswaard et al. [42] evaluated long-term effects of nurse-delivered self-management education in type 2 diabetics. The intervention focused on medication adherence, enhancing physical exercise, dietary intake and self-monitoring blood glucose at home. Six sessions were provided at intervals of 3–6 weeks, resulting in contact time of approximately 2.5 hours with HCPs over 6 months. HbA1c levels improved from 8.2% to 7.2% in the intervention group and 8.8% to 8.4% in usual care at 6 weeks, however this result was not sustained at 18 months [42].

Efraimsson et al. [66] examined effects of nurse-led COPD intervention. Patients received education on self-care ability to cope with disease and treatment. Patients were scheduled for two visits with nurses lasting 60 minutes during a 5-month period. A statistically significant increase was noted in the intervention group on QOL, the proportion of patients who ceased smoking, and patients' knowledge about COPD at 3–5 month follow up, compared with usual care. Heitkemper et al. [91] examined an intervention delivered to women with IBS. Women in the intervention received eight weekly 1-hour individual sessions. The intervention included education, dietary counselling, symptom monitoring, relaxation training and cognitive-behavioral strategies including anger management, cognitive restructuring, assertiveness and social skills training [91]. Hill et al. [67] examined an intervention in people with COPD. Intervention participants attended two one-to-one 60-minute sessions, focusing on enhancing self-efficacy. Sessions were accompanied by a written manual adapted from the "Living Well with COPD" program. COPD knowledge increased from 27.6 (+/- 8.7) to 36.5 (+/- 7.7) in the intervention group, which was greater than any difference seen in the control group. Waite et al. [100] examined an individualized intervention for patients with low self-esteem. This included goal setting, learning skills to re-evaluate anxious and self-critical thoughts and beliefs through cognitive techniques. All participants were given a three-part self-help workbook in addition to individual treatment sessions. The intervention showed significantly better functioning than control on measures of overall functioning and depression and had fewer psychiatric diagnoses at the end of treatment. All treatment gains were maintained at follow-up assessment. Williams et al. [75] evaluated a guided self-help intervention for depression in

primary care. The first appointment focused on an introduction to the use of the self-help materials. Three additional face-to-face support sessions of approximately 40 minutes were provided on a weekly or fortnightly basis. Mean Beck Depression Inventory (BDI-II) scores were lower in the intervention group at 4 months by 5.3 points, compared with control (2.6 to 7.9, p = 0.001). There were also significantly higher proportions of intervention participants achieving a 50% reduction in BDI-II scores at 4 and 12 months.

McLean et al. [82] involved a pharmacist-delivered intervention for asthma self-management. The intervention involved education surrounding the basic concepts of disease, medications, trigger identification and avoidance, and an asthma action plan. Patients were taught to use a peak flow meter, spacer devices, calendars/diaries were provided and asked to record peak expiratory flow rates (PEFRs) regularly for the course of the study period. Patients received appointments of approximately one hour in length with a pharmacist in a private counselling area every two to three weeks for at least three appointments, and then follow-up appointments at least quarterly for 12 months [82]. Symptom scores decreased by 50% ($p<0.05$) and peak flow readings increased by 11% (p = 0.0002) for intervention patients, compared to those receiving usual care. Chalder et al. [95] evaluated the efficacy of a self-help booklet and advice delivered by a nurse in reducing chronic fatigue in adult patients. The intervention reiterated self-monitoring and maintaining symptom diaries. Basic cognitive techniques such as identifying and challenging unhelpful thoughts were also introduced. The self-help group showed significantly greater improvements in fatigue (p = 0.01) and psychological distress ($p<0.01$) than controls. Striegel-Moore et al. [92, 117] evaluated cognitive behavioural guided self-help for the treatment of recurrent binge eating. Intervention participants received 8 sessions over 12 weeks. The primary focus of this intervention was on developing a regular pattern of moderate eating using self-monitoring and problem-solving. The main outcome, abstinence from binge eating differed significantly between the groups: the initial improvement in abstinence from baseline was greater for the intervention group than usual care ($p<0.001$). Watkins et al. [72] evaluated guided self-help concreteness training as an intervention for major depression. During the initial session of the self-help intervention, psychoeducation and training exercises were provided. During the follow-up telephone sessions, feedback, guidance and encouragement was provided to ensure accurate use of exercises, and progress monitored. The intervention resulted in significantly fewer depressive symptoms post-treatment, relative to treatment as usual (ITT, p = 0.006, effect size d for change in Hamilton Rating Scale for Depression (HAMD) = 0.76; PP, $p<0.0001$, d = 1.06).

Quality risk of bias assessment of individual studies

The overall methodological quality was considered high (lower risk of bias) in 41.4% of studies (n = 24 RCTs), and of medium quality in 58.6% of studies (n = 34 RCTs). The domains considered lowest risk of bias were selective reporting (96.6%; n = 56), baseline outcome measures (84.5%; n = 49), random sequence generation (79.3%; n = 46) and baseline characteristics (79.3%; n = 46). The domains with higher risk of bias were 'blinding of outcome assessment' (25.9% of studies; n = 15). Reporting bias was judged low for more than 95% of studies. Half of studies (51.7%; n = 30) presented low risk for the domain 'other bias'. Reasons for other risk of bias included not meeting recruitment targets for assumed power. Fig 2 shows aggregate appraisal of risk of bias of included studies and visual representation of each domain.

Discussion

This systematic review has synthesized evidence from 58 randomized controlled trials examining the effectiveness of primary HCP delivered self-management support interventions for

adult patients, with any condition, compared to usual standard of care. We describe effective SMS interventions and have highlighted their active elements, identified trends in combinations of intervention strategies, range of outcomes measured and the magnitude of effect size. This review demonstrates that SMS interventions delivered face-to-face by primary HCPs, which are multicomponent and tailored to explicitly enhance patient self-management skill set can lead to improvements in clinical and humanistic outcomes. The various tools and strategies that provide a structure to interventions delivered face-to-face include adapting interventions according to patients' readiness to change, action planning and goal setting by collaboratively breaking down individual health goals into small achievable actions. The effectiveness of multicomponent SMS interventions is not surprising. But it raises the question of how to focus efforts on the best combination of active components within interventions. The variation in context, outcome measures, training methodology used across the 58 studies, in addition to the high degree of autonomy given to providers, deem the evaluation of SMS interventions more difficult.

Ninety-three different outcome measures were adopted to demonstrate evaluated impact of the various interventions and presumably were selected to reflect expected outcomes or processes of self-management. These include different measures of health-related quality of life, overall functioning, self-efficacy, health behaviours, disease knowledge, symptoms and disease control. Disease specific clinical indicators were mostly included as primary outcomes, and QoL indicators generally served as secondary or ancillary outcomes to primary outcome criteria. Generic HRQOL measures varied across different types of diseases, interventions and groups (i.e. EQ5D, SF-12), and specific HRQOL disease measures were also utilized. (i.e. IBS-QOL questionnaire was used to measure changes in HRQOL for IBS patients). Further examination of studies producing positive improvements in HRQOL revealed use of disease specific measures (i.e. Ferrone et al. [71] reported positive changes in HRQOL using the Clinical COPD Questionnaire (CCQ)—a 10-item, health-related quality of life questionnaire). Interestingly, studies using more generic HRQOL measures (i.e. EQ5D, SF scales) mostly reported insignificant differences in their interventions. S4 Table provides a summary of the various instruments used in studies.

Our findings reveal a structured patient-provider exchange is required in primary care (including a one-on-one patient-provider consultation, ongoing follow up and provision of self-help materials). A systematic and tailored patient-primary care provider exchange is needed to provide individuals with the portfolio of techniques and tools to effectively self-manage. Various combinations of strategies were used to achieve this and adapted to the individuals' condition, health literacy, skills and confidence in managing their own health. Strategies containing several interacting components and varying dimensions of complexity produce favourable effects when tailored to the individual. No one intervention solution is suitable for all patient groups and the selection of combinations of strategies should support patients' needs relevant to both primary care and HCP. The strategy of enhancing the patient's decision-making skills or ability to problem-solve was reported in the highest percentage of studies (53.8%) with positive results, after knowledge acquisition. Active stimulation of symptom monitoring (46.2%) and having specific, clear and accepted treatment or healthcare goals was also commonly identified. This involved setting measurable, clear and accepted treatment or healthcare goals on a per patient basis with a specific action or self-management plan detailing these. Tailored, written information and care plans that are mutually agreed upon have previously been identified as helpful [138]. Strategies to improve responsibility in medication adherence and lifestyle choices were also reported within effective interventions.

Interestingly, strategies for stress or psychological coping of conditions (46.2%) were commonly identified in effective interventions. Changing the patient's cognitive approach to their

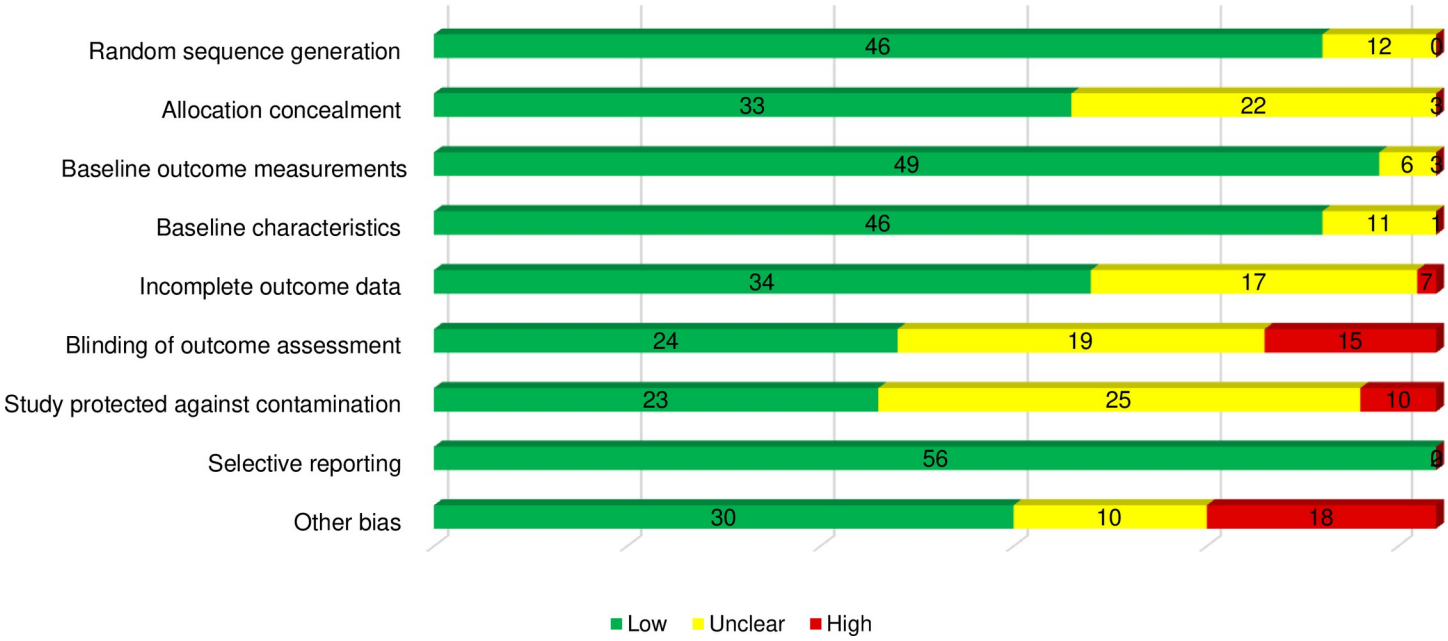

Fig 2. Risk of bias graph.

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illness was commonly incorporated into the intervention to deal with the physical and emotional symptoms resulting from a chronic illness. Effective interventions integrated cognitive behavioral therapy (CBT) into the intervention in 40% of studies. Multiple cognitive strategies were raised, such as identifying and challenging unhelpful thoughts [95], relaxation training and cognitive-behavioral strategies including anger management, cognitive restructuring, assertiveness and social skills training [91]. A 2014 systematic review of qualitative literature identified patients often express difficulties in dealing with the physical and emotional symptoms of their chronic conditions [138]. As such, undesirable physical and emotional symptoms and impaired physical functioning can directly prevent patients from carrying out normal daily activities, including tasks required to appropriately and successfully self-manage [139–141]. Self-management of chronic conditions should therefore be examined not only from the clinical perspective, but also the patient perspective with a focus on humanistic outcomes. Importantly, the theory of SMS drawn for effective studies included Cognitive Behavioral Theory and Prochaska and DiClementes' transtheoretical model of the stages of change. Follow-up by HCPs included tailored feedback, monitoring of progress with respect to patient set healthcare goals, or honing problem-solving and decision-making skills. Self-help tools and assistance with locating resources were commonly provided during the patient-provider exchange.

The scope of the terms 'self-management', 'self-management support' and 'self-management support interventions' in literature and the large heterogeneity in terminology has repeatedly been highlighted in previous systematic reviews and meta-analyses [27, 142–144]. This is a key limitation, as very broad or very narrow definitions of what constitutes "self-management support" have been applied. Lorig and Holman [10] previously underlined the need to explore interventions beyond the label of self-management to define if interventions actually address the necessary support strategies required to change behaviour. Subtle variations in self-management definitions can result in substantial differences in selected studies. Using Jonkman's operational definition [35] to define our interventions has shown highly important

in distinguishing self-management interventions from other types of interventions (ie. patient education or disease management) without being too restrictive. The definition clearly defines the elements or strategies that constitute a self-management support intervention, with the pivotal objective of changing behaviour. This has guided the selection of studies on which our review conclusions have been based.

A notable gap identified in the literature was a lack of focus on multimorbidity. This is understood to pose challenges for self-management, as many individuals have more than one health condition [138]. The effects of multimorbidity on a person are not always linear. Interestingly enough, some studies have found that patients with multimorbidity consider themselves better at self-management because they had already developed skills such as self-monitoring and self-advocacy [145].

In acknowledging that SMS is a multidimensional topic, we aimed to create a broader picture of the landscape of SMS in primary care. This was achieved by evaluating the patterns of intervention components comprehensively across all conditions, by not limiting our research to a clinical condition, or specific intervention strategies. Although including different clinical conditions in the review may be considered as a drawback due the potential heterogeneity induced, in our research, there was a clear distinction of strategies across the conditions studied. Findings from this review add further detail to this body of knowledge, while providing HCPs with a number of evidence-based strategies that can be utilized in practice. These findings pave the way to explore further SMS strategies targeting patient's behaviour change, effective patterns of strategies, and develop a more evidence-based model for optimum SMS service design. Primary care providers (e.g. general practitioners, nurses, pharmacists) can play a foundational role in supporting patient self-management, especially for people with multiple chronic conditions. Fig 3 sets the foundation for an evidence-based SMS primary care model for face-to-face interventions, allowing for a more efficient and effective process to evaluate and implement SMS interventions in primary care.

For this collaborative partnership approach to be more widely applied, there should be a strong focus on upskilling primary care providers to deliver SMS strategies in health care, which are both integrated and coordinated to improve the patient-provider encounter in practice [5]. The total duration of the intervention and the correlation of intervention duration with the number of strategies delivered are important aspects when considering the sustainability within primary care. Policy and funding alignment will also be a major determinant for future sustainability. Therefore, we must determine where the best compromise in SMS interventions lie for cost-effective and resource-limited approaches. Future high-quality evaluations of consistent interventions will be of value to practitioners, policy-makers and researchers in terms of collecting clinical, humanistic and economic outcome measures to generate a robust evidence base of primary care providers impact in the area. This will also allow determination of ineffective combinations of strategies.

Future research efforts should continue to expand on this landscape to (1) examine the patterns of strategies within effective multicomponent interventions for various conditions; (2) examine the weighting of each strategy (ie. determine intervention components which are more or less effective) within effective multicomponent interventions; (3) determine if certain types of patient populations could be targeted most effectively by certain combinations of strategies; (4) develop a core SMS outcome set in primary care; (5) examine the patient's ability to self-manage over time as well as aiming to achieve the goal of long-term sustainability for improved self-management; and (6) determine training requirements for the upskilling of health care providers for sustained patient behaviour change.

Furthermore, sustainability of improved SMS first requires an understanding of the implementation of SMS enhancing interventions [146]. Sustainability can be challenging if not

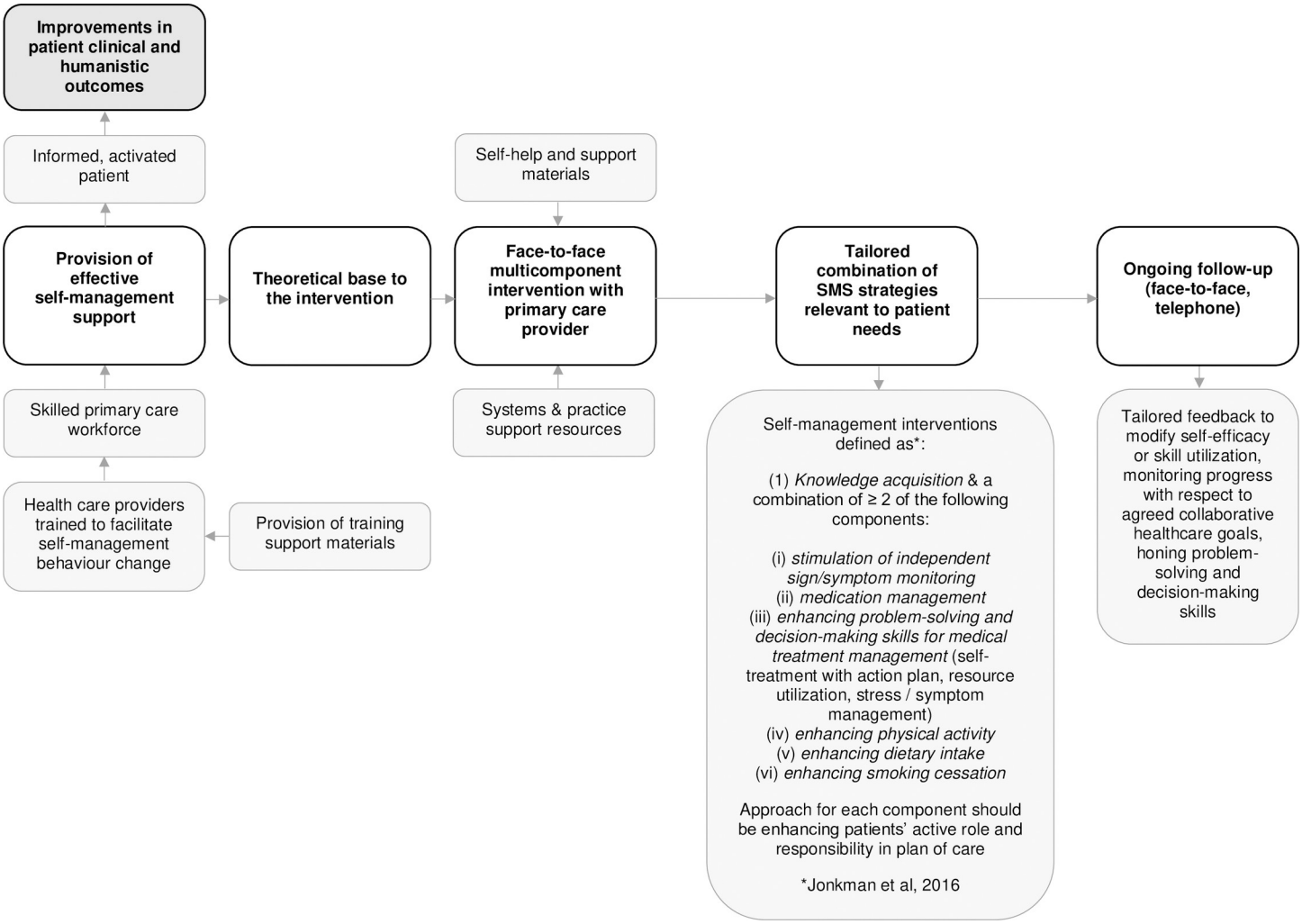

Fig 3. Elements for a practical approach for HCPs in supporting face-to-face SMS multi-component strategies, individually tailored for patients in primary care. Modelled on the definition of self-management interventions by Jonkman et al. 2016 [35].

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embedded into everyday clinical practice [31], and achieving the potential of primary care as a platform to effectively deliver SMS and achieve the stated outcomes means overcoming known barriers, such as limited time, skills and confidence among health professionals [31, 147]. We know changes in health care professional practice requires exhaustive planning and testing to increase the probability that they are successfully and sustainably implemented. The adoption of Intervention Mapping has been widely used in health care settings to plan changes in the behaviour and practice of health care professionals, and should be applied to ensure SMS interventions are both effective and successfully implemented in practice [148].

There are limitations to this review. A number of studies did not report sufficient detail to their interventions which hampered the assessment of possible effective combinations of strategies being evaluated. The methodological quality domains of the included trials were in a lot of cases unclear, with a lack of poor description of the study methodology and intervention fidelity in evaluations. This was mitigated by contacting authors for further relevant information, searching for study protocols or further examining supplementary data online. With the growing recognition of the importance of assessing treatment fidelity in multicomponent

interventions [149–151] (ie. compliance to treatment protocols by HCPs, or compliance to treatment by patients), it is important to note most trials (72%) did not include this in their design and few provided data on treatment fidelity to the intervention. Only 38% of effective interventions reported an assessment of intervention fidelity. The methodological quality domains of the included trials were in a lot of cases unclear. Four high-quality studies provided positive evidence that SMS interventions delivered in primary care dominate usual standard of care, by improving patients' clinical outcomes, HRQOL or psychological functioning [72, 91, 92, 100]. Similar trends have been found in existing literature in several contexts that self-management is essential to optimizing clinical and humanistic outcomes for patients with chronic conditions [13, 15, 18, 152–155].

Although multiple databases were extensively searched using clear, specific and appropriate terms, the search may not have yielded all published relevant studies given the ambiguity of what constitutes "self-management support" and the variation in terminology for "self-management" identified in the literature. Unsurprisingly, with the rising burden of chronic disease, the nomenclature of "self-management" has become more prevalent in both published and grey literature. We recognize the use of different search terms and definitions to guide the development of the search strategy may lead to variation in the identification of studies, and affect a review's conclusions. This is identified as a limitation of our review. Search terms were sourced from previous systematic reviews, primary studies and grey literature. Our search included general terms for "self-management" and was not limited to specific illnesses or outcomes.

Systematic reviews are at risk for bias from a number of sources [156]. We sought to reduce potential sources of bias within the inclusion and synthesis of studies. One of our main goals was developing inclusion criteria to minimize ambiguity and reduce bias in study selection decisions. We have defined our inclusion and exclusion criteria by PICO clearly and have documented and reported all decisions made in the study selection process for transparency. Since we restricted our review to face-to-face interventions, there may be other SMS interventions that may be effective that are not covered by this review. We decided to categorize the comparator as usual standard of care and understand the definition of usual standard of care may vary by country or healthcare system.

Conclusion

In conclusion, this review highlights core components of successful interventions showing positive clinical and/or humanistic outcomes. Whilst it was difficult to directly correlate individual strategies to outcomes and effectiveness, there was a clear distinction of strategies across the conditions studied. This review provides encouraging groundwork for the design and evaluation of practical strategies for evidence-based practice and the construction of self-management support processes in primary healthcare practice. This review may assist in determining the breadth and focus of the support primary care professionals provide. Application of a theoretical perspective provides a strong base for the development of SMS interventions. The developed model sets the foundation for the design and evaluation of practical strategies for the construct of self-management support in primary healthcare practice. These results may be used to justify additional research investigating self-management interventions delivered in the primary care setting. In response, primary care providers can begin to deeply reflect on current practice and become involved in a dialogue to improve self-management support. Critically, these results should stimulate informed discussion for the future delivery of self-management support in primary care and the requirements for upskilling healthcare providers to effectively support patients in this collaborative process.

Supporting information

S1 Data. Database.
(XLS)

S1 Table. Search strategy.
(PDF)

S2 Table. PRISMA checklist.
(PDF)

S3 Table. Descriptive characteristics of included studies.
(PDF)

S4 Table. Summary of findings and extracted outcomes.
(PDF)

S5 Table. Mapping of intervention components.
(PDF)

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2

Chapter 2: Self-care in pharmacy

Self-care in pharmacy

While self-management support has emerged as a concept and models exist in the literature for the management of chronic conditions in primary care, it was found that community pharmacy is yet to be fully engaged in adopting these principles and models into usual practice. Most of the published evidence suggests that the concept of self- management is synonymous with self-care in community pharmacy. Self-care, in turn, is associated with self-medication and is more widely recognised as a concept that applies to minor ailments (17-20).

Self-care

Self-care[2] is highlighted by the World Health Organization (WHO) as integral to primary health care (21). As models of care evolve to deliver patient-centred care, a key issue needing to be addressed is how primary health care professionals can support self-care in an evidence-based, structured manner and how processes can be integrated into usual clinical practice. Many health services and providers have moved toward incorporating ways to increase patient involvement in managing their own health (22-24), and embedding patient-centred care principles. Self-care has the potential to make significant contributions to health care system efficiency (25-27). A policy statement released in 2019 by the International Pharmaceutical Federation and the Global Self-Care Federation, states the intention of the profession and industry to further develop self-care as a "pillar of sustainable healthcare systems" (28, 29).

Self-care is usually the primary method for managing minor ailments (30). Minor ailments have been defined in the international literature as "common or self-limiting or uncomplicated conditions which may be diagnosed and managed without medical (ie. GP) intervention" (31-33). In Australia, the PSA has defined minor ailments as "conditions that are self-limiting, with symptoms easily recognized and described by the patient and falling within the scope of pharmacist's knowledge and training to treat" (34). This may include, but not limited to, conditions such as common colds, strains and sprains, acute diarrhoea, constipation, muscle aches and pains, allergies, headache, rash, dermatitis and eczema, fevers, foot conditions such as corns and callouses and others (35). Questions exist in Australia surrounding how the health care system can address minor ailments more efficiently by delivering care at the appropriate level in an integrated capacity (36).

[2] This is a summary of the introduction taken from a report as first author:
Citation: Dineen-Griffin, S., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. An Australian Minor Ailments Scheme: Evaluation of a collaborative protocolized approach by community pharmacies and general medical practitioners; 2019. ISBN-13: 978-0-646-80883-3. https://www.uts.edu.au/sites/default/files/2019-11/Full%20Report%20%28wl%29.pdf

Self-medication

Self-medication is a fundamental component of self-care, and is defined by WHO as “the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms” (37). Australia’s nonprescription medicine market is a $5.4 billion industry (Australian dollars) (2016), growing at 2.5% per annum (38). It provides access to approximately 16,000 medicines on the Australian Register of Therapeutics Goods (39). Community pharmacy is the primary channel of access for nonprescription medicines. Legislation in Australia requires these medicines to be supplied under the supervision of a pharmacist (Schedule 2 medicines or “pharmacy medicines”) or supplied by pharmacists themselves (Schedule 3 medicines or “pharmacist only medicines”) (40). Community pharmacists are positioned to facilitate responsible self-medication (41, 42).

Trends in self-medication and the increasing availability of nonprescription medicines increases the need for sharing information between pharmacists and GPs to ensure continuity of care (41). There is a need for a structured communication approach, addressing both content (ensuring the required items for referral, assessment and management) and timeliness of information sharing. Community pharmacists are often required to make recommendations based on incomplete symptom information, other medical conditions, and other medications. Irrespective of pharmacist involvement, GPs too may not be aware of the vast amount of self-care and self-medication occurring. Suboptimal communication between providers has been highlighted as an area for improvement (43, 44) as it is associated with limited or inappropriate outcomes (44-46).

International policy response

International governments have been investing in supporting pharmacists to take on an expanded role in supporting self-care and self-medication (47-49). This is partially prompted by increases in GP and emergency department (ED) presentations (49-53). Canada and the UK are arguably the most advanced countries in terms of the profession enhancing its role in areas such as minor ailment services and prescribing. The 2013 NHS urgent and emergency care review highlighted the role of community pharmacy in providing accessible care for minor ailments in the UK. Minor ailment accounted for 18-20% of GP presentations (50, 51, 54). A study in the UK demonstrated that pharmacists could manage up to 8% ED presentations (55). With additional training, such as a 12-month diploma in clinical examination skills and diagnostics, a further 28% of presentations could be managed by a pharmacist (55). Since 2006, pharmacists in the UK have been able to undertake further training to become independent prescribers (56). The extended role is not intended to replace the existing workforce, but as a complementary group of health professionals who can diversify and become part of a fully integrated team to clinically manage patients (57).

International MASs were implemented with various objectives as part of their general health policy and include (53):

- Contributing to the sustainability of health systems and optimising costs, through treating patients with minor ailments at an appropriate level with nonprescription medicines.
- Improving accessibility by providing treatment for patients with minor ailments through the community pharmacy network in both urban and rural areas.
- Increasing primary care capacity and availability of general practice for medical provision in chronic or complex patients, through the transfer of minor ailment presentations from general practice to community pharmacy.
- Relieving pressure on existing emergency and urgent care services.
- Improving collaboration among health professionals through consensus of standardised protocols of work, particularly the referral of patients.
- Empowering patients to self-care and increasing their skills to responsibly self-medicate through community pharmacy.

International minor ailment initiatives

Ninety-four MASs are identified in literature, in the UK (England, Scotland, Northern Ireland and Wales) and regions of Canada (known as pharmacists prescribing for minor ailments (PPMA)) (58, 59). Countries including Spain (60) and New Zealand (NZ) (61) are evaluating the feasibility of introducing similar services. Paudyal and co-authors in a systematic review published in 2013 of international MASs recognised the patient and economic benefits (53). The review shows high symptom-resolution rates, and low reconsultation, suggesting minor ailments are being dealt with appropriately in pharmacy (53). The proportion of patients reporting symptom resolution ranged between 68% and 94.4% (53), while the rate of reconsultation ranged from 2.4% to 23.4% (53).

Scotland

Scotland was the first country to implement the national ‘Pharmacy First’ scheme in 2006 (62, 63). The scheme was introduced for use by children, patients aged over 60 years, those with a medical exemption certificate, or people on certain benefits. The Scottish service treats 25 minor ailments and allows pharmacists to supply certain prescription-only medicines for conditions under Patient Group Directions (PGDs) (58). Examples include chloramphenicol 0.5% eye drops or fluconazole 150mg capsules. Reimbursement is by capitation fee dependant on the number of patients registered per month per pharmacy under MAS. Additional reimbursement is provided for the cost of medicines (62, 64, 65). In 2018, the Scottish government announced expansion of the ‘Pharmacy First’ scheme,

available to all patients irrespective of age or social circumstance (66). The national service is expected to cover a wider range of conditions such as uncomplicated urinary tract infections and impetigo (66). Funding remains at £1.1 million (British pound) per year (66). The Scottish government announced an additional £2.6 million (British pound) in community pharmacy funding in the 2019/20 financial year (67).

England

Eighty-nine MASs are commissioned by clinical commissioning groups (CCGs) or area teams (ATs) in England. The variety of minor ailments covered under services vary up to 47 conditions (58). Usually MAS is only open to patients who would otherwise be eligible for free prescriptions (ie. over 60 years, under 16 years, or pregnant women). Community pharmacies are remunerated by the NHS (68, 69). Certain MASs are associated with PGDs allowing pharmacists to treat minor ailments with specific prescription medicines (58). Examples include oral antivirals or antibiotics, chloramphenicol eye drops or fusidic acid cream (70). The remuneration structure is determined at a local level and typically uses combinations of payment structures. (58). These include banded capitation, a one-off payment, retainer fees, pharmacist consultation fees or remuneration for the number of medicines supplied (58).

Since 2017, there has been emphasis on further integrating community pharmacy into local NHS urgent care pathways through the community pharmacy consultation service (CPCS) (71, 72). This model involves a digital referral from NHS111 (emergency telephone helpline) or general practices to the community pharmacy following assessment by a call advisor (73). The CPCS is intended to improve patient access to treatment for minor ailments and relieve pressure on the wider NHS (71, 74). The CPCS is nationally commissioned and roll out commenced in October 2019. The service is a component of the five-year community pharmacy contractual framework (75). Pharmacies are paid £14 (British pound) per completed consultation (76).

Northern Ireland

MAS was introduced in Northern Ireland in 2005. However, this service was withdrawn because of disputes regarding pharmacy reimbursements between the Department of Health, Social Services, Patient Safety, and the Pharmaceutical Contractors Committee of Northern Ireland (34). MAS was reintroduced in 2009 as a national service. MAS is available to patients, registered with a general practice, over three months of age (77). A maximum of two medicines may be issued per consultation at no cost to the patient. Pharmacies are remunerated under a banded capitation model and for medicines supplied (34). Between 2013-17, the total cost of MAS was £14,196,513 (British pound). This sum comprised £7,830,424 (British pound) in pharmacy fees to provide the service and £6,366,089 (British pound) for the cost of medicines (78). In 2019, it was announced the government would channel £2.1m (British pound) in funding, up to March 2020, for community pharmacies to deliver MAS (79).

Wales

Wales implemented the ‘Choose Pharmacy’ scheme in 32 pharmacies in the Betsi Cadwaladr and Cwm Taf areas in 2016, with the intention of implementing a national service (34, 80). It also piloted a NHS111

service, which is hoped to be rolled out nationally (80). The Welsh government channelled an extra £1.4 million (British pound) in funding to community pharmacy in 2019 (80), and £100,000 (British pound) for pharmacists' training in minor ailments (80).

Canada

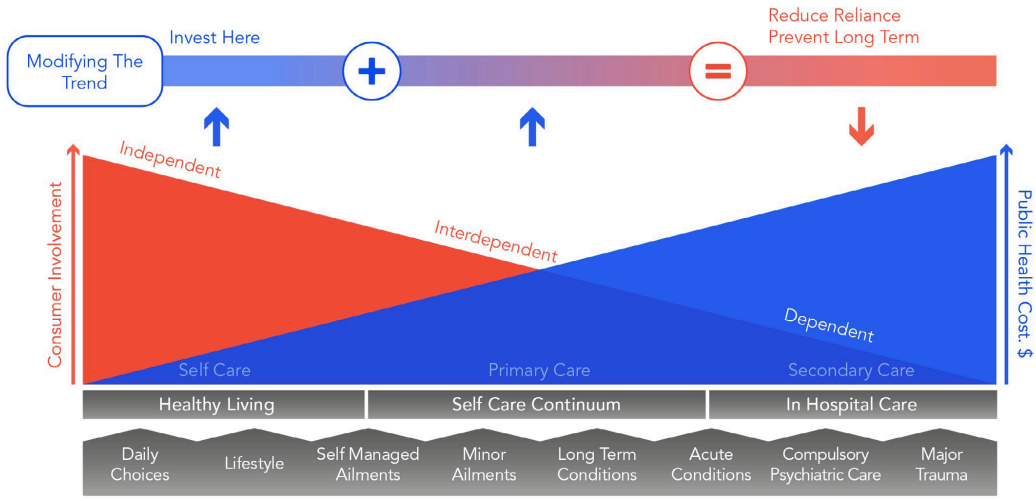
Eight of thirteen provinces in Canada operate a program known as "Pharmacists Prescribing for Minor ailments" (PPMA) or similar (58), allowing pharmacists to prescribe certain medicines for the treatment of self-limiting conditions. Alberta became the first province allowing pharmacists to prescribe medicines in 2007 (59). The remaining provinces have since adopted various degrees of prescriptive authority (81). The variety of conditions treated under PPMA varies from 12 to 34 conditions including vaginal thrush, seasonal allergic rhinitis, or haemorrhoids (58). Nova Scotia gave pharmacists authority to prescribe certain medicines in 2011. Saskatchewan became the first province to remunerate for PPMA services for conditions such as mild acne, thrush, cold sores, diaper dermatitis, and insect bites. An $18 (Canadian dollar) fee is offered for services resulting in a prescription (58). For example, valacyclovir for cold sores or intranasal mometasone for allergies (82). Pharmacists in New Brunswick were given the ability to manage 32 ailments following mandatory training in 2008 (83). Pharmacists in Alberta obtained additional authority to prescribe medicines in areas they can demonstrate clinical competency (58). PPMA is soon to be among the responsibilities of community pharmacists in Ontario (83). The Ontario government indicated in 2019 they will support pharmacists to practice to the full extent of their expertise to alleviate the growing economic burden on ED and GP services (83).

Policy context in Australia

The Australian federal and state/ territory governments have made substantial policy progress to deliver integrated care (84). Multiple strategies have been employed including reforms such as implementation of integrated service models and targeted community-based programs (53, 85-88). A substantial investment was made with the introduction of Primary Health Networks (PHNs) in 2015 (89, 90). Thirty one PHNs were funded by $900 million (Australian dollars), replacing 61 Medicare Locals (91). PHNs were established to lead improvements in the quality of primary health care and align with local hospital networks to drive efficiencies and better direct funding to the delivery of frontline health services (92). The principles that underpin PHNs are fundamental to strong primary care (93).

In Australia, reform is limited by the lack of national policy and strategic effort to promote self-care (47). Whilst there is increasing evidence that self-care is beneficial, self-care in Australia is not an established policy concept. The Global Access Partners report describes "the role of pharmacies and nonprescription medicines in supporting self-care and reducing government expenditure for a more efficient health system" (94). Enhancing the ability of the population to self-care requires whole-system policy development and action. Figure 1 illustrates the ways in which policy reform and targeted investment in self-care is required to modify trends in health service utilisation (47).

Figure 1 Modifying health service utilisation through investment in self-care



Source: Figure adapted from Duggan et al. Australian Health Policy Collaboration (47).

Contextualizing in Australia

The profession is broadening the scope of practice of pharmacists through professional services (95-98). This is driven primarily by leadership of professional organizations, government policies, innovative practitioners, education, remuneration and patient needs (99). Professional services have been defined as, “a set of actions undertaken in or organised by a pharmacy, delivered by a pharmacist or other health practitioner, applying specialized health knowledge to optimise the process of care, with the aim of improving health outcomes and the value of healthcare” (100). Implementation of professional services continues to remain a crucial aspect of the professional and economic viability of community pharmacy (101). The focus on new services suggests the profession continues to realise the benefit of service implementation and its integrated role within the health system (102).

Community pharmacists in Australia are increasingly collaborating with other health professionals to ensure medicines-related management is part of a more collaborative approach (103, 104). Collaboration is driven by the need for greater efficiency and cost-effective health outcomes (103, 105). The PSA’s *Pharmacists in 2023* report envisages pharmacists practising at their full scope to drive greater efficiencies (106). The Pharmacy Guild of Australia’s *Community Pharmacy 2025* report identifies community pharmacies as health hubs facilitating the provision of cost-effective and integrated health services to patients (103, 107).

Rationale for an Australian minor ailments service

Community pharmacists providing self-care and advice on self-medication is a well-established activity in Australian pharmacy practice (108). National pharmacy standards exist (109), however within these standards there is no structured approach to assessment, no agreed protocols with GPs for evidence-based management, or pathways to appropriately refer patients to general practice or ED settings (109). There is minimal integration with general practice systems and no formal method of GP-pharmacist communication relating to minor ailments (110). The potential for pharmacists to meet patients' needs for the management of minor ailments and alleviate health system pressure in Australia has been recognised (111). The following issues contribute to a lack of integration, collaboration and cost inefficiency in the Australian health care system:

- There is no self-care policy within Australian health care policy.
- Patients are seeking care for minor ailments at an inappropriate level (ie. general practice and EDs with resource implications).
- Accessibility to primary care is limited in rural and remote regions of Australia.
- Some patients may be self-medicating inappropriately with nonprescription medicines leading to safety and efficacy issues.
- Health care providers may be unaware of self-medication practices and inappropriate use of nonprescription medicines may go undetected.
- Provision of pharmacist care for minor ailments is not standardized which results in unstructured patient-pharmacist exchanges.
- There are no agreed pathways facilitating appropriate referral when necessary for timely care from pharmacy to the rest of the health system.
- There is no requirement for patient follow up or documentation in community pharmacy.
- GP-pharmacist communication around referral and use of nonprescription medicines is inconsistent.
- There is no national data documenting the frequency of clinical interventions performed by community pharmacists.
- There are no substantial local, state or national campaigns directing patients to the appropriate level of entry into the health care system.
- There is no data on cost savings (estimated or potential cost avoidance) for patients not going to emergency, after-hours, or general practice settings for the same minor ailment symptoms.

The implication of this lack of evidence is that community pharmacists cannot demonstrate their clinical impact on a larger national scale.

There are no MAS models in Australia and consequently no literature in the Australian context. It is evident that pharmacists could contribute to the Australian healthcare system in a way that is cost-efficient and clinically effective through an integrated approach to self-care. Community pharmacists are underutilized in the health care system, and are potentially part of the solution for containing healthcare costs (112). National implementation of MAS in Australian primary care, underpinned by national and state self-care policy, could have many benefits including:

- Coordination of services (increased collaboration, use of health technologies, improved flow of patients and information between settings to ensure health outcomes for patients at the best cost).
- Efficiencies (greater accessibility, cost-effective treatment, increased capacity of primary care, optimization of costs through use of less expensive settings).
- Effectiveness (best clinical outcome for patients at an accessible point of entry into the health care system).

However, evidence is needed before large-scale implementation could be considered in Australia.

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Chapter 3: Objectives and research overview

Objectives and research overview

The thesis hereon presents a series of studies addressing the overarching aim of designing and evaluating a community pharmacist delivered MAS in Australia. The research consisted of 'Work Streams' embedded within a mixed methods design (Figure 1). The design combined elements of both qualitative and quantitative research methodologies. Work Stream one ("co-design") was undertaken using qualitative methods (2). The findings from the qualitative research undertaken informed the design of the research in Work Stream two ("pilot study") (113) and Work Stream three ("impact study") (3-5, 114). The methodological grounding for the individual studies within this body of work are presented and discussed in the relevant chapters.

The aims of each Work Stream of the research included:

Co-design: To investigate stakeholder perspectives for the design of a MAS model, and reach agreement on service elements and operational characteristics of MAS in Australia.

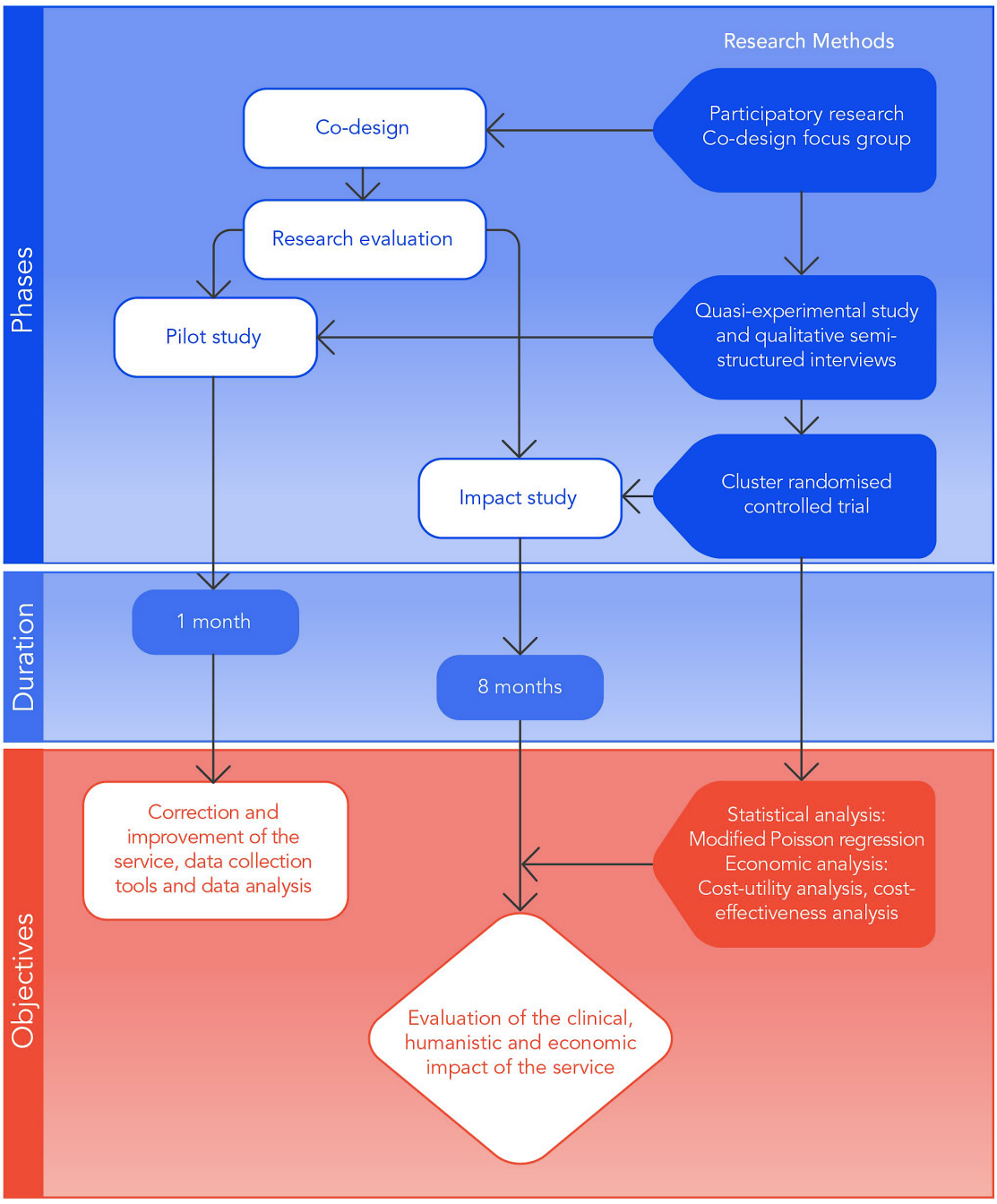
Pilot study: (i) To assess the feasibility of MAS and research methods for the impact study and (ii) To explore preliminary data trends on clinical, humanistic and economic outcomes of MAS, compared with usual pharmacist care, in Australia.

Impact study: To evaluate the clinical, humanistic and economic impact of MAS, compared to usual pharmacist care, in Australia.

The specific study objectives of the impact study were:

(1) To evaluate the clinical and humanistic impact of MAS for adult patients presenting to the community pharmacy with a symptom-based or product-based presentation for specific minor ailments, compared to usual pharmacist care.
(2) To evaluate the economic impact of MAS, compared to usual pharmacist care:
    i. Assess the cost utility and cost effectiveness of MAS, from a societal perspective, in Australia.
    ii. Assess uncertainty by deterministic and probabilistic sensitivity analysis.

Figure 1 Flow chart of study Work Streams and methods



Ethics approval to undertake Work Stream one was granted by the UTS Human Research Ethics Committee (HREC) (ref ETH17-1348) on the 18th of May 2017. For Work Stream two (pilot study) and three (impact study), HREC approval was received on the 24th of May 2017 (ref ETH17-1350). Approval by the HREC indicates that the research meets the requirements of the NHMRC National Statement of Ethical Conduct in Human Research (2007).

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Chapter 4: Service co-design

[3] **Citation:** Dineen-Griffin, S., Benrimoj, S. I., Williams, K. A. & Garcia-Cardenas, V. Co-design of a minor ailment service: Involving service users and healthcare professionals. BMC Health Services. 2020 **(Submitted – Under Review)**

Co-design of a minor ailment service: Involving service users and healthcare professionals

Abstract

Background: Community pharmacies provide a suitable setting to deliver minor ailment services (MASs). Implementing services in community pharmacy is challenging and requires the participation of stakeholders, including patients, in service design.

Objectives: The aim of this study was to co-design a community pharmacy MAS relevant to Australia and reach stakeholder agreement on service model elements.

Methods: A three-step co-design process using qualitative methods was conducted. Phase one involved a focus group with stakeholders to identify service elements and allowed researchers to conceptualize the service model. Participant responses were digitally recorded, transcribed verbatim and content was analyzed using thematic analysis. Phase two involved an international literature review of treatment protocols and three working group meetings with general practitioners (GPs) to develop treatment and referral pathways for a number of minor ailment conditions. Phase three involved qualitative work comprising of observation, checklists and semi-structured interviews conducted by practice change facilitators during a pilot study.

Results: Nine stakeholders participated in the initial focus group. Following thematic analysis in phase one, five components of the pharmacy MAS model were determined, including (1) In-pharmacy consultation, documentation and follow-up, (2) treatment protocols on a technology platform (HealthPathways), (3) communication channels between pharmacy and general practice (HealthLink), (4) an educational training package, and (5) practice change support. Phase two led to the development of evidence-based referral pathways. Testing of the service in phase three revealed the main barriers to service delivery were time, remuneration, and patient acceptability. The main facilitators were the agreed referral pathways, interprofessional collaboration, external support and training.

Conclusions: The resulting service was collaboratively developed for the Australian health system. The study contributes to the literature with co-design methodology that may lead to successful implementation and sustainability of the pharmacy service in practice. Our approach was influenced by participatory design involving stakeholders and users.

Introduction

Co-design (also known as participatory design (PD), experience-based co-design, co-production, co-creation, or co-operative design) (1), is used in healthcare settings to increase participation and engagement of stakeholders in the development of health services (2-7). The co-design phase is seen as critical to buy-in and commitment from stakeholders (8-19). Stakeholders include individual potential users, groups, or organizations who may influence or be affected by decision-making on a particular aim or policy. Co-design challenges traditional understanding of healthcare development and places end-user value at its very heart, with implementation and broader dissemination strategies part of its design from gestation (20-22). Involving patients in the development of services is positively associated with clinical effectiveness and patient safety (23), improved service patient-provider relationships, communication and patient satisfaction (21). It encourages transparency in the service planning process and increases translation of research findings in practice (24-29). As a result, services are more efficiently developed, evaluated and implemented.

The literature is consistent in demonstrating that cooperation between professionals, patients, organizations and across disciplines leads to better health outcomes, enhanced satisfaction, and cost savings (12, 21, 30-32). An increasing number of healthcare services worldwide are using this approach (1, 4, 6) including the United Kingdom (33-35), Canada (36), New Zealand (37-39), Australia (40-43), and the United States of America (44). The projects addressed include a broad range of clinical areas spanning from cancer services (33), cardiovascular disease prevention services (12, 36), emergency medicine (45) and mental health care (46, 47).

Co-design is well-suited for the design of interventions in settings, such as community pharmacies (48). Community pharmacy services encompass a range of patient-focused services provided by pharmacists that aim to minimize the inherent risks associated with the use of medicines, ensure medicines are used appropriately and to optimise health outcomes (49). The implementation of new pharmacy services into pharmacy practice and systems has been challenging and may fail to create expected impact due to insufficient stakeholder involvement in the design process. The inherent complexity of both services and healthcare systems may be fundamental to this problem. Many pharmacy services have been previously developed intuitively without explicit knowledge of factors that may hinder or facilitate implementation (50-52). The co-design approach has only recently begun to be reported in community pharmacy service development in Canada, New Zealand and Australia (40, 53-55). It is recognised in literature that the development, evaluation and implementation of community pharmacy services requires stakeholder input in service design (12, 31, 56).

Community pharmacists are increasingly being integrated into the health system and increasingly collaborating with other health professionals to ensure that medicines-related management is part of a more collaborative approach to patient care. Collaboration of community pharmacists with other health professionals is driven by the need for greater efficiency, the provision of integrated care and cost-

effective outcomes (57). The implementation of services continues to remain a crucial aspect of the future professional and economic viability of the sector (58). The focus on new services suggests that the profession is changing its practices and continues to realise the professional and financial benefit of service implementation and its integrated role within the broader health system (59). A specific area in which community pharmacy services are seen to be particularly relevant is in the management of minor ailments. According to the World Health Organization, self-care interventions are the optimal approach to managing minor ailments, and reducing the use of health care resources (60). A 2019 joint policy statement from the International Pharmaceutical Federation with the Global Self-Care Federation, describes the united intention of the pharmacy profession and industry to further develop self-care as a "core pillar of sustainable health systems" (61, 62). The statement encourages pharmacists to prompt people to use health system resources responsibly, engage in self-care where appropriate, and document patients' medicines in a record (61, 62). Internationally, governments are investing in pharmacists, through established services, to support self-care and self-medication practices. Their positive impact on self-medication and in managing minor ailments has been shown (63-76).

In line with the international trend, Australian community pharmacies are eager to provide services and receive remuneration from the government for the provision of MAS. Patients and general practitioners (GPs) are key stakeholders who interact with or are affected by pharmacy services delivered in the community pharmacy setting and may be able to influence implementation of such services through co-design. Despite there being national professional guidelines (77), the impetus for this co-design research project is that there is no Australian community pharmacy service which utilizes a standardized approach to assess and triage patients, no agreed protocols with GPs for evidence-based management, and no agreed referral pathways. Furthermore, there is minimal integration with general practice systems and no formal method of GP-pharmacist communication relating to minor ailments and use of self-care products. This paper presents the development and execution of a process for applying co-design methods to develop MAS relevant to Australia and reach stakeholder agreement on service model elements.

Methods

A three-step co-design process using participatory methods sequentially engaged: (1) a mixed group of stakeholders, including potential service users, to work collaboratively and generate a preliminary model of the service, (2) GPs, for the development and agreement on treatment protocols and referral pathways following a literature review of international and national clinical guidelines, and (3) a group of community pharmacists delivering the service during a pilot study testing feasibility. An initial analysis of implementation factors (barriers and facilitators) through direct observation of the service being delivered, completing facilitator checklists and interviewing service providers (semi-structured interviews) conducted by a practice change facilitator (PCF). Each phase is described, as follows:

Phase 1: Develop a MAS model relevant to the Australian health system

A focus group was conducted in 2017 (June) at Western Sydney primary health network (PHN), Blacktown, Sydney, Australia. Stakeholders were purposively recruited with sufficient knowledge and understanding of the policy context (78), from the community of Western Sydney PHN (79). These included researchers, patients, GPs, community pharmacists, representatives of the PHN and professional pharmacy organizations. Participants were recruited through existing networks while PHN representatives facilitated local engagement with GPs, community pharmacists and patients located in Western Sydney. During the 2.5h discussion, 17 questions were posed to the group to ascertain what the service should look like, how the service would fit within existing GP and pharmacy systems to facilitate integration, and then generate a preliminary understanding of potential barriers and facilitators to service implementation. The international literature pertaining to pharmacy delivered care for minor ailments and MASs was studied to guide the development of the focus group guide (63, 64, 76, 80, 81). This ensured the structural features of international services were considered during this process (63). The guide is provided in supplementary file 1. One researcher (SB) with experience in qualitative research moderated the group discussion. Field notes were taken during the focus group by another researcher (SDG). Responses were audio recorded, with consent, and transcribed verbatim by a professional transcription company. Complete transcripts were obtained and the accuracy of the transcripts confirmed. The research was conducted and reported in accordance with the consolidated criteria for reporting qualitative studies (COREQ) checklist (82). Ethical approval was obtained by the Human Research Ethics Committee at the University of Technology Sydney (ref ETH17-1348). All participants provided written consent prior to research being conducted.

The method of analysis chosen was the qualitative approach of thematic analysis (83). Focus group data was managed in NVivo V.12 software (QSR International Pty; Victoria, Australia) (84). The conceptual framework of the thematic analysis was mainly built upon the theoretical positions of Braun and Clarke (85). A deductive approach was considered appropriate (86). A conceptual code structure was developed following the process of thematic analysis for sorting of the data. The analysis was undertaken by one researcher (SDG) and reported to co-investigators (SB, KW, VGC). Consensus was

attained regarding themes (theme verification). Verbatim quotes are used to present and support themes reflective of the overall findings.

To organize analyzed data and build the service model, the JeMa2 model by Sabater-Hernández et al was applied (31). The model shows pharmacists as agents who affect health by promoting changes in patients' behaviours (in this case, the ability to self-care) to improve clinical outcomes and quality of life (31). The model hypothesizes the relationship between MAS and the context it is to be implemented. It envisages the factors that may influence implementation. The result is a program comprised of the service and the strategies that may support implementation and overall impact (31).

Phase 2: Develop agreed clinical treatment pathways and referral points

A two-step process was performed. The first step involved a scoping review of international and national clinical guidelines for minor ailments. The second step involved agreement of treatment pathways with GPs on a technology platform (*HealthPathways* (87)), following PHN clinical governance processes.

Scoping review of clinical guidelines and quality appraisal

The aim was to systematically search and review literature for clinical guidelines for a number of minor ailment conditions, identify the characteristics of guidelines and appraise quality. Conditions included common cold, cough, reflux, headache (tension and migraine), primary dysmenorrhoea, and low back pain. Individual minor ailments were chosen based on their ability to be managed by a community pharmacist through self-care and nonprescription medicines. Search strategies were developed using MeSH terms and keywords. A preliminary search of published literature was undertaken in databases including PubMed, Scopus and Web of Science from inception to 2017 (July). Given these database searches yielded minimal results, searches of grey literature were subsequently conducted.

A systematic grey literature search was conducted using Google as the primary search tool. The search method was based on that by Godin et al. who demonstrated a robust method for applying systematic review search methods to grey literature (88). Clinical guidelines were defined as "systematically developed statements which assist practitioner and patient decisions about appropriate healthcare for specific clinical conditions". Guidelines were included if they proposed the assessment, management and referral of the indication, intended for the management of adult patients (≥18 years), published or reviewed in Australia, Canada and the United Kingdom within the last 5 years. If more than one version of the same clinical guideline was found, older versions were excluded.

The first one hundred weblinks from each grey literature search were imported and managed in Microsoft Excel and saved without duplication for each condition (91). Godin et al. (88) reported that screening one hundred websites was sufficient to capture the most relevant information while remaining a feasible volume to screen. Weblinks were screened by title against eligibility criteria by one reviewer (SDG). Potentially eligible guidelines were retrieved and independently screened against the inclusion and exclusion criteria. Reference lists of included guidelines were reviewed to identify any further

guidelines not retrieved in the initial search. The process was summarized using a PRISMA flow diagram. Data from each guideline was summarized in a pre-designed data extraction table in Microsoft Excel. Quality appraisal was undertaken using the international Appraisal of Guidelines for Research and Evaluation version II (AGREE II) instrument.

Development, localization and review of treatment pathways

Clinical pathways are defined as "a complex intervention for the decision making and organization of care processes*"* (89). Similarly, to clinical guidelines, clinical pathways are designed to be used to aid assessment and therapy. However, clinical pathways take this a step further by providing a specific algorithm for how to treat a condition, along with the aim of improving the coordination of care across disciplines and sectors. It is for this reason that clinical pathways are superior to clinical guidelines, focusing on providing quality coordinated care which can be tailored to a local population as opposed to a more general plan to manage a condition (90).

HealthPathways is the proprietary technology system of clinical pathways and is used in PHNs in Australia (87). *HealthPathways* are primarily used by GPs during consultation. However, there are no established pathways for minor ailment conditions and to our knowledge, none which are utilized by community pharmacists. The localization and review of each pathway was undertaken for each minor ailment condition following the literature review. This process was undertaken with the GP clinical lead and HealthPathways planning group at Western Sydney PHN in three working group meetings. The pathways were endorsed via PHN processes. For each *HealthPathway*, the same structure was followed including differential diagnosis and evidence-based management (self-care, and/or medicines for symptomatic relief, and/or referral for medical care).

Phase 3: Pilot test the co-designed MAS and examine the barriers and facilitators to service delivery

The service was pilot tested in four community pharmacies in 2017 (October). Qualitative work pursued the objective of exploring pharmacists' perceptions on overall service delivery, perceived facilitators and barriers to providing the service in community pharmacies (the use of technology systems, documentation and follow up procedures etc.) and examine why particular aspects of the service may have been feasible or not. A PCF performed weekly visits to pharmacies. An analysis of implementation factors (barriers and facilitators) was undertaken through direct observation of pilot sites. The checklist consisted of 49 predetermined implementation factors previously identified to enable or hinder the implementation of community pharmacy services.

Semi-structured interviews were conducted with community pharmacists during the pilot study using an interview guide (supplementary file 2) which was principally developed to explore the pharmacists' experience of delivering MAS, including barriers and facilitators. The interview guide was based on a previously designed and piloted interview guide used in the United Kingdom (80). Interviews were digitally recorded and transcribed verbatim by a transcription company. NVivo V.12 software (QSR

International Pty; Victoria, Australia) was used to manage and analyze the data (84). Ethics approval was granted for the pilot study by UTS HREC (ref ETH17-1350). Written consent was obtained from all pilot participants. Verbatim quotes are used to present and support themes reflective of the overall findings.

Coding involved summarizing checklist and semi-structured interview data into descriptive codes. The next stage involved grouping codes into themes. Themes were interpreted as factors that may positively (ie. facilitators) or negatively (ie. barriers) influence the delivery or implementation of MAS. The third stage involved organizing barriers and facilitators into four different levels including the patient, interpersonal, organizational and healthcare system level, using an adapted version of the Ecological Model (91). The model has been successfully applied for planning health services in a variety of settings (15, 92).

Results

Phase 1: Develop a MAS model relevant to the Australian health system

Nine individuals were included in the focus group (5 males and 4 females) including 2 patients, 2 community pharmacists, 2 GPs, 2 management leaders involved in PHN clinical governance, and 1 representative from a pharmacy organization. Thematic analysis identified five components to the service model, including: (1) In-pharmacy consultation, documentation and follow up, (2) evidence-based treatment pathways on a technology platform (*HealthPathways*), (3) agreed communication channels between pharmacy and general practice settings (*HealthLink*), (4) an educational training package, and (5) practice change support.

In-pharmacy consultation, documentation and follow up. Consultations in a private area of the community pharmacy (eg. the consultation room or similar) for patients presenting to the pharmacy requesting a medicine to self-treat or with minor ailment symptoms was proposed by stakeholders. Stakeholders acknowledged the value of the pharmacist interaction in facilitating responsible self-medication and referral. It was recommended to standardize the ways in which pharmacists deliver referrals to medical practitioners, and document the interaction. Follow-up of patients was suggested to be incorporated. This was particularly emphasized for patients referred to general practice or ED settings to confirm whether patients attended an appointment (Q15 and 16; supplementary file 1). This was a priority by GPs as there was concerns lack of follow-up may delay diagnosis, treatment or lead to other lapses in patient safety. Stakeholders were initially doubtful of the potential for success of follow-up as most tend not return to the pharmacy for their minor ailment (Q15; supplementary file 1).

> *"Nobody actually knows what happens to the patient after we consult with them. It would be important to follow up the patient to check if their symptoms have resolved or whether they've gone to see their doctor as recommended." [Pharmacist 1]*

It was seen as positive by stakeholders that consultation information be documented in a secure central database. Pharmacists were initially doubtful given the demanding nature of their current positions and the time required to document (Q3; supplementary file 1). Stakeholders considered self-care education to be fundamental to the interaction with patients. However, responses from patient participants noted the need to avoid medicalized language. Stakeholders also highlighted the need to use different methods (eg. by taking information home) and materials (eg. self-care fact cards, websites, diaries) in acknowledgement of different learning styles.

Technology platforms to promote collaboration. Strategies to facilitate collaborative practice were identified by stakeholders, including the use of existing GP technology platforms such as *HealthPathways* (Q13 and 14; supplementary file 1) and *HealthLink* (Q9 and Q10; supplementary file 1). From the health provider perspective, it was felt current mechanisms for communication were

insufficient. GPs were supportive of pharmacists using *HealthPathways* as a support tool during consultation.

> *"This program [HealthPathways] would help the pharmacist, I feel. The pharmacist would be able to say I've had a discussion with your GP about this in the past and this is what we've agreed we're going to do. It will give the pharmacist the ability to reassure the patient that their GP is also involved in their management." [GP 2]*

GPs agreed that a structured referral process would be beneficial to ensure patients continually self-medicating are being identified and referred. Moreover, they recognized that having support tools integrated with GP systems would encourage pharmacists to use technologies in practice.

> *"I think the other important thing is that these HealthPathways will be agreed between pharmacists and GPs. That agreement is really important for patient care". [PHN representative 1]*

It was seen as logical to use existing communication software as GPs are already accustomed to use these systems in their current practice (Q11; supplementary file 1).

> *"I'm consulting all these people now. Wouldn't it be good if I could consult them in a way that is consistent with expectations, and also in connection with the pharmacist?" [GP 1]*

Regular communication with GPs and a pre-existing relationship was emphasized as important to maximise the success of MAS. It was suggested communication methods would need to be agreed with GPs to facilitate the relationship (Q9; supplementary file 1).

> *"We're getting to the stage that it needs to be integrated. The consumer will get much better service from the pharmacy and much better service from the GP because everybody will know what's happening." [PHN representative 2]*

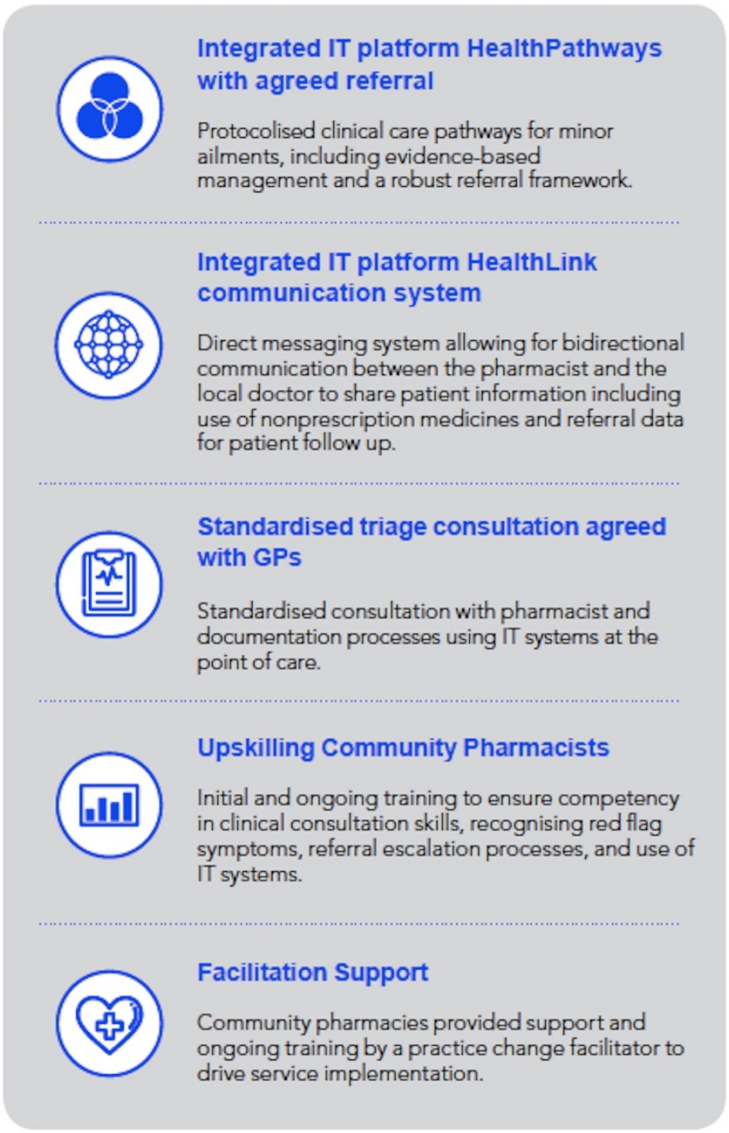
It was also important that patient privacy was upheld and information sharing between pharmacies and GPs is conducted only with patient permission (Q12; supplementary file 1).

> *"I think maybe some consumers might have issues with privacy. Perhaps it's something they didn't necessarily want their family GP to know." [Patient 2]*

An educational training package and practice change support. It was agreed pharmacists should receive training to ensure competency in clinical areas, consultation skills, recognizing red flags, use of technologies and referral. It was suggested that community pharmacies could be supported in the form of monthly visits and telephone support (Q2-5, supplementary file 1).

The resulting co-designed MAS model with the five service elements is depicted in Figure 1.

Figure 1 Co-designed MAS model



Abbreviations: IT: information technology.

Phase 2: Develop agreed clinical treatment pathways and referral points

The clinical guidelines identified as being of high quality provided clear management information tailored to pharmacist's scope in the Australian context. Seven pathways were formed. Pathways included assessment, management and referral. Each pathway was devised following the same structure (Table 1). An example is provided in supplementary file 3.

Table 1 Structure of HealthPathways

Red flag referral criteria	Signs, symptoms or events recognized as likely to be more serious in nature and point to the need for immediate referral for assessment.
Clinical assessment	Symptoms (duration, frequency and severity), past history of symptoms, medications used for this episode of symptoms or other health problems, known allergies and intolerances, other concomitant diseases or medicines.
Evaluation	Assessment of risk factors, contraindications and drug interactions.
Treatment	Evidence based nonpharmacological and pharmacological support recommendations.
Referral	Critical time of symptom evolution after which the pharmacist may suspect that it is not a minor ailment, as well as other symptoms or signs that point to the need for assessment by the GP or another health care provider, and the timeframe within which a patient is recommended to seek care.
Resources	Resources consulted in the preparation of the pathway and patient self-care.

Phase 3: Pilot test the co-designed MAS and examine the barriers and facilitators to service delivery

Nine semi-structured interviews were conducted with community pharmacists involved in the pilot study. Nineteen implementation factors were organized into four levels. These factors were found to exist as a barrier, facilitator, or both (Table 2).

Individual patient level. Factors at this level were related to the patients' needs, preferences, expectations, or previous experiences with community pharmacists and services. Pharmacists believed that time restraints of patients were a factor limiting receptibility to MAS.

> *"The patient's expectation I think is difficult. A quick response is expected for their minor ailment symptoms." [Pharmacist 7]*

Pharmacists expressed that the expectation of the patient was also a barrier (Q1; supplementary file 2). A few pharmacists mentioned those selecting a product to self-treat their symptoms were less likely to engage in consultation with the pharmacist. Pharmacists expressed that normalizing the service to the patient (ie. through advertising) may increase receptibility to the service.

Interpersonal level. A valued aspect of MAS was the ability of pharmacists to directly engage with GPs (Q14; supplementary file 2). The majority recognised that establishing communication channels were important to increase rapport with GPs and enhance information exchange.

> *"It's helping us move into the area where there is more communication and we're working alongside each other rather than as separate entities." [Pharmacist 2]*

Pharmacists reported a variety of views with regard to the level of communication and indicated that the level of collaboration with GPs was variable as part MAS. Some pharmacists expressed that

communicating with GPs had several barriers (for example, the patient did not have a regular GP, or there was no pre-existing relationship with the GP). Some pharmacists believed that it was helpful for the GP to be notified following each patient consultation while others believed that only consultations resulting in referral or complex patients should be relayed (Q13; supplementary file 2). Pharmacists commented that *HealthPathways* provided structure to consultation and was a positive development toward better collaboration with GPs, and the platform was easy to navigate (Q8; supplementary file 2). Pharmacists strongly indicated that the agreed pathways improved their confidence and knowledge to consult.

> *"I'm feeling more supported to say that the service I am providing as a pharmacist is in collaboration with GPs." [Pharmacist 3]*

Pharmacists identified the training resources were relevant and necessary for service delivery. Multidisciplinary education and training for healthcare professionals was suggested as a way to improve collaboration (Q12; supplementary file 2).

Organizational level. Most pharmacists agreed on the need for a private area (ie. a counselling room) to perform MAS, particularly if the service was expanded to include conditions of a more sensitive nature eg. vaginal thrush (Q6; supplementary file 2). This was viewed as difficult in some instances where a private room did not exist, particularly smaller independent pharmacies. Others believed that a semi-private cubicle or a separate area of the pharmacy was equally appropriate to maintain privacy during consults for conditions, such as cough or common cold.

> *"We have a counselling area which is appropriate for general conditions such as common cold. If the service was to be extended to other situations or ailments, such as patients presenting with thrush or for the morning after pill, it would be great to conduct the consultation in a private counselling room." [Pharmacist 1]*

Most pharmacists suggested that lack of staff (pharmacists or other staff) was a barrier to offering MAS (Q11; supplementary file 2). This was often related to the inability of the pharmacist to find time to offer MAS. It was agreed the service must be provided by a pharmacist with appropriate qualification and should not be delegated to a lesser-qualified staff member (Q3; supplementary file 2).

> *"I don't find we have sufficient time or staff to promote the service. If I really want to concentrate on the patient and make sure I've performed a proper consult, I need that block of time available." [Pharmacist 7]*

All pharmacists commented on the importance of documenting and recording clinical encounters and interventions for accountability and follow up purposes. This would especially be important to monitor if service outcomes are sustained longer term. Simplified documentation included refining data collection instruments, development of written procedures for data collectors and focused in-store training to assist with data collection (Q10 and Q22; supplementary file 2).

Community and healthcare system level. All pharmacists reported that pharmacy remuneration would be needed if they were to maintain MAS in future (Q15; supplementary file 2). Pharmacists had variable views towards reimbursement levels, however a consultation fee between $10-30 (Australian dollars) per patient irrespective of product sale was determined as appropriate (Q18; supplementary file 2). Pharmacists agreed remuneration should not be associated with the sale of a medicine, since not all consults would progress to sales and may include self-care only (Q19; supplementary file 2). All but one pharmacist agreed that the government should provide this remuneration, with many suggesting that the cost savings with MAS would cover remuneration (Q16; supplementary file 2).

> *"Definitely, how do we keep going? This is a service that we're already doing and we have the potential to be reimbursed for our time." [Pharmacist 4]*

Lastly, the JeMa2 model was used to organize the gathered data, including the implementation factors identified in this final phase. The detailed model, found in supplementary file 4, delineates the MAS model along with the causal chain that explains the relationship between the service and the final service outcomes.

Table 2 Implementation factors influencing MAS delivery during the pilot testing phase

Themes	Implementation factor
Patient level	Patients' availability or time to participate in the service
	Patients' understanding, perception and expectation of their own role in the service
	Patients' understanding, perceptions and expectations of the role of the GP associated to the service
	Patients' understanding, perceptions and expectations of collaboration between healthcare professionals
	Patients' language, communication and cultural issues
Interpersonal level	Knowledge, expertise, clinical and non-clinical skills (eg. cultural competency) of community pharmacist to adequately provide the service
	Willingness, interest and motivation to provide the service and/or participate in multidisciplinary collaboration
	Collaborative relationships between the pharmacist and other healthcare providers (eg. GPs) and their nature
	Referral mechanisms between healthcare professionals
	Communication channels and modes between pharmacists and other healthcare providers (eg. GPs)
	Education, training and practice change support for pharmacists and pharmacies
Organizational level	Structural characteristics of the pharmacy setting (ie. size of counselling rooms)
	Privacy of the setting, including the availability of a private consultation area
	Availability of suitable material resources to support the service (ie. self-care materials for patients, documentation systems)
	Sufficient staff to perform service
	Promotion of the service to facilitate its uptake
	Costs and duration of the service consultation for the patient
Health system level	Presence of agreed healthcare protocols to facilitate the delivery of the service
	Funding allocated to support service delivery

Discussion

The research summarizes a participatory co-design process that resulted in the development and testing for feasibility of a MAS model aimed at encouraging self-care in the Australian setting. The qualitative data gathered during each phase revealed the three-step approach as an effective means of ascertaining the needs of stakeholders and provided valuable input into service design. The main aim during development was fostering close collaboration between GPs and community pharmacists, where there is apparent limited collaboration for minor ailments. *HealthPathways*, and communication systems were agreed with GPs. The model offers pharmacists a consistent framework to operate, to differentially diagnose and manage a patient. The pathways and existing technologies provide a structure to consultation and documentation. The input of pharmacists and GPs into the co-design process was important for understanding the practical application of MAS and existing systems allowing pharmacists to better integrate with GPs.

Comparison to international models

Ninety-four international services are identified in literature, including the UK (England, Scotland, Northern Ireland and Wales) and regions of Canada (93). Countries such as Spain (65), New Zealand (39), and Ireland (94) are evaluating the feasibility of introducing similar services. While the international literature pertaining to MASs was studied to ensure the structural characteristics of services was considered during co-design (63, 64, 76, 80, 81), we did not duplicate international MAS models. We were cognisant on contextualization; thus, a model applicable to Australia was developed. The service model presents similarities (ie. consultation process), and differences (ie. training, pathways, communication platforms and external support by a practice change facilitator) to international models. Although some international initiatives require pharmacists to undertake additional training to deliver MASs, none have utilized a PCF to assist with service implementation in practice (63).

Previous challenges with implementation of international MASs

International initiatives report improved health outcomes and cost savings to health care systems. Nazar et al. note the challenges with MAS implementation and highlight the importance of service design for implementation success (96). Multiple reasons have been identified including lack of initial GP engagement (80) and poor service design (96). Aly et al. recommended involving GP stakeholders in service design (80). Our co-design process encouraged us to consider feasibility of implementation throughout the design period as well as appropriateness to the local context. We provide a theoretical model and have attempted to resolve the practical aspects of MAS and reach agreement with stakeholders on operational reality in practice. This model has the added value of being aligned with stakeholder needs and used to further develop the service in practice. The main facilitators to MAS were agreed pathways, interprofessional collaboration, and external support and training. Barriers, such as limited time and patient acceptability were also identified. Remuneration was described as essential for future service delivery and implementation. In its absence, the implementation of MAS may be

challenging. The need for remuneration is a theme that it represented internationally with continual calls to ensure that community pharmacists are paid for providing clinical services to patients (97-99). Previous theory and research on barriers and facilitators to community pharmacy service implementation (100, 101) may assist. Similarly, additional work is necessary to identify and precisely define implementation strategies (102, 103). Successful implementation will involve ongoing adaption and refinement of the MAS model (104).

Strengths and limitations

Several features strengthen our study including the co-design process and the views gained from stakeholders. The approach was an apparently effective means of ascertaining needs of service users and health providers. Positive group dynamics and interaction enhanced data collection. The use of interviews specifically to explore the influencing factors to MAS delivery presented consistency in the views which are similarly reflected in previous international studies (80). There were a number of limitations to this study. This study was conducted in a specific geographical region and there may be challenges in other regions not identified in this research. The qualitative study during pilot testing only examined views of community pharmacists. Future research efforts should continue to understand views and experiences of other stakeholders (GPs, patients, policy makers and organizations), barriers and facilitators to service delivery and improvements that could be made to the service model to ensure successful implementation in Australia. Views of these individuals have been examined in the UK and Canada with positive experiences and views being expressed by these groups (80, 105). It is also important to understand the impact of participatory research on service outcomes (ie. measure improvements in patient experience and clinical outcomes) (106). Further physician involvement in discussions are recommended to strengthen pathways and agree on referral processes and systems. Continued development and agreement on pathways for other minor ailments is recommended applying a similar co-design approach to the seven developed as part of this research.

Conclusion

This paper is a step in the co-design of a collaborative service to improve the future management of minor ailments in Australian primary care. The study may contribute to literature with co-design methodology that may lead to service implementation in practice. Community pharmacists can begin to deeply reflect on current practice and become involved in dialogue to improve self-care support in practice. These results should stimulate informed discussion for the future delivery of MAS. The success of the service to date, in our estimation, is due in large to the stakeholder co-design approach. Success in this context is measured in terms of the research ability to go from conception through development, to pilot, in the Australian context.

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Chapter 5: Research protocol

[4] **Citation:** Dineen-Griffin, S., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Evaluation of a collaborative protocolized approach by community pharmacists and general medical practitioners for an Australian Minor Ailments Scheme: Protocol for a cluster randomized controlled trial. JMIR Res Protoc. 2019; 8(8): e13973.
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Protocol

Evaluation of a Collaborative Protocolized Approach by Community Pharmacists and General Medical Practitioners for an Australian Minor Ailments Scheme: Protocol for a Cluster Randomized Controlled Trial

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Abstract

Background: Internationally, governments have been investing in supporting pharmacists to take on an expanded role to support self-care for health system efficiency. There is consistent evidence that minor ailment schemes (MASs) promote efficiencies within the health care system. The cost savings and health outcomes demonstrated in the United Kingdom and Canada open up new opportunities for pharmacists to effect sustainable changes through MAS delivery in Australia.

Objective: This trial aims to evaluate the clinical, economic, and humanistic impact of an Australian Minor Ailments Service (AMAS) compared with usual pharmacy care in a cluster randomized controlled trial (cRCT) in Western Sydney, Australia.

Methods: The cRCT design has an intervention group and a control group, comparing individuals receiving a structured intervention (AMAS) with those receiving usual care for specific health ailments. Participants will be community pharmacies, general practices, and patients located in Western Sydney Primary Health Network (WSPHN) region. A total of 30 community pharmacies will be randomly assigned to either intervention or control group. Each will recruit 24 patients, aged 18 years or older, presenting to the pharmacy in person with a symptom-based or product-based request for one of the following ailments: reflux, cough, common cold, headache (tension or migraine), primary dysmenorrhea, or low back pain. Intervention pharmacists will deliver protocolized care to patients using clinical treatment pathways with agreed referral points and collaborative systems boosting clinician-pharmacist communication. Patients recruited in control pharmacies will receive usual care. The coprimary outcomes are rates of appropriate recommendation of nonprescription medicines and rates of appropriate medical referral. Secondary outcomes include self-reported symptom resolution, health services resource utilization, and EuroQoL Visual Analogue Scale. Differences in primary outcomes between groups will be analyzed at the individual patient level accounting for correlation within clusters with generalized estimating equations. The economic impact of the model will be evaluated by cost-utility and cost-effectiveness analysis compared with usual care.

Results: The study began in July 2018. Thirty community pharmacies were recruited. Pharmacists from the 15 intervention pharmacies were trained. A total of 27 general practices consented. Pharmacy patient recruitment began in August 2018 and was completed on March 31, 2019.

Conclusions: This study may demonstrate the efficacy of a protocolized intervention to manage minor ailments in the community and will assess the clinical, economic, and humanistic impact of this intervention in Australian pharmacy practice. Pharmacists supporting patient self-care and appropriate self-medication may contribute to greater efficiency of health care resources and integration of self-care in the health system. The proposed model and developed educational content may form the basis of a national MAS service in Australia, using a robust framework for management and referral for common ailments.

Trial Registration: Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12618000286246; http://www.anzctr.org.au/ACTRN12618000286246.aspx

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KEYWORDS

pharmacy; pharmacists; general practitioners; primary health care; community pharmacy services; nonprescription drugs; self care; self medication; randomized controlled trial; Australia

Introduction

Integrated care is a possible solution to the rising demand in facilitating appropriate delivery of health services and limiting fragmentation between health care providers. Evidence indicates that health systems with strong integrated primary health care are effective in improving patient outcomes and efficient at delivering high-quality appropriate services [1,2]. Many countries have undergone major health reforms to deliver effective and efficient health care, moving toward sustainable health systems that are both durable and resilient to withstand impending and ongoing challenges [3-6]. As an example, the Australian health system has undertaken significant reform and restructuring to improve value for investment in health care [2,7] through the establishment of Primary Health Networks (PHNs). Their objectives are delineated as (1) delivering health care services that increase the efficiency and effectiveness for patients and (2) strengthening the degree of coordination and connectivity of care, ensuring patients receive the right care, in the right place, at the right time [8].

Major questions exist surrounding how health care systems can address minor ailments more efficiently through the use of administering care in less expensive settings such as community pharmacy [9,10]. Minor ailments have been defined as "conditions that are often self-limiting, with symptoms easily recognized and described by the patient and falling within the scope of pharmacist's knowledge and training to treat" [11]. It is already known that patients self-manage conditions to a large extent [12], and encouraging people to exercise greater levels of self-care, either for acute or chronic problems, has significant potential to directly affect demand for, and shift costs from, medical health care. Pharmacists are positioned to facilitate self-care and appropriate self-medication processes [13]. Undoubtedly, the expansion of nonprescription medicines has given patients greater choice, providing community pharmacy with an opportunity to demonstrate real and tangible benefits by facilitating this process [13]. Community pharmacy has been transforming to a service provider model driven primarily by leadership of professional organizations, government policies, remuneration, and patient needs. The community pharmacy sector has undergone changes such as enhancing the pharmacists' role in providing professional pharmacy services to optimize the process of care [14]. Community pharmacy provides a range of remunerated commissioned and noncommissioned professional pharmacy services that have shown to be cost-effective compared with other health care settings and contribute to improved health outcomes for patients [15-18]. Importantly, pharmacists can be better integrated within primary care. Effective collaboration between general medical teams and community pharmacies will be integral to achieve the highest level of patient care [8,19].

There is consistent evidence at an international level that pharmacy-based minor ailment schemes (MASs) promote efficiencies of use within the health care system [20]. MASs were introduced for patients to access professional support for conditions that can be self-managed with the objectives of increasing accessibility, providing the right level of care and mitigate funding and system inefficiencies [21]. A total of 94 international schemes are identified in the literature across 103 regions, including the United Kingdom (England, Scotland, Northern Ireland, and Wales) [20,22-26]. Minor ailment assessment and prescribing is the nomenclature used in Canada, representing a pharmacy service that allows pharmacists to prescribe certain drug groups for the treatment of minor, self-diagnosed, and/or self-limiting conditions. Of 13 provinces in Canada, 8 operate a Minor Ailments Prescribing Service [27-28]. Each of these services is slightly unique in its feature and structural design parameters [20]. MASs have been included in the policy agenda in Australia [29-31] and New Zealand [32]. Paudyal et al explored the effect of MAS on patient health and cost-related outcomes [21]. The review showed low reconsultation and high symptom resolution rates of up to 94% with MAS, suggesting minor ailments are being dealt with appropriately in pharmacy [21]. The positive economic impact has shown international MAS to be cost-effective compared with more expensive health care services, such as general practice and accident and emergency (A&E) departments [16]. There are different models of general practitioner (GP)-pharmacist collaboration offering the community pharmacy network to be better integrated into general practice or urgent and emergency care systems. One example in the United Kingdom is the provision of integrated out-of-hours services by community pharmacy, such as the Digital Minor Illness Referral Service [12]. The service evaluates the way in which patients with self-limiting minor ailments who are contacting urgent services can be supported by community pharmacists instead of being booked for an urgent GP appointment or signposted to their own GP.

Pharmacists treating patient's common ailments, the exclusive availability of nonprescription products through pharmacies to provide symptomatic relief, and referral to other health care professionals is a well-established activity within pharmacy practice. Unfortunately, in Australia, there is limited standardization and protocolization for consultations and procedures for escalating referral. There is minimal integration with general practice systems and no formal method of

physician-pharmacist collaboration or communication relating to minor ailments, and the nature and extent of collaboration may be seen as both episodic and informal. This invariably limits facilitated self-medication practices. In addition, there are no mechanisms to monitor or document patient interactions, resulting in missed opportunities to identify patients who require referral, limiting the ability to detect inappropriate or continued use of nonprescription medicines. The potential for community pharmacists to moderate patients' needs for the treatment and management of minor ailments and alleviate health system pressure in Australia has been recognized [33,34].

The Australian Minor Ailments Service (AMAS) is a practice model with key elements, such as agreed referral points, communication systems between pharmacists and general practitioners (GPs), and clinical treatment pathways, that is, *HealthPathways*. The conceptualized components of AMAS have been developed in consultation with key stakeholders including PHN leaders and, importantly, leading general medical professionals involved in PHN governance in Australia. Input into design and agreement with stakeholders have progressed the development of collaborative referral pathways, providing a robust framework for community pharmacists to deliver evidence-based minor ailment care. In essence, these pathways seek to improve the coordination and delineation of health care provider roles for minor ailments with sequencing of care through referral that is agreed between pharmacists and general practice for health system efficacy and optimal quality [1,12,35-39]. Specifically, assurance of quality in health service provision may be achieved through the evaluation of standardized condition management and differential diagnosis tools such as *HealthPathways* [40], robust referral processes for escalation, and service delivery by the pharmacist themselves.

In achieving the stated objectives, we may provide evidence that a scheme would be successful in Australia. Community pharmacists offering an enhanced self-care model can make a significant contribution to Australian health care and reduce the substantial burden on other primary care providers with pharmacists providing the appropriate level of care for minor ailments and checking on patients who are self-medicating. The integration of community pharmacists into primary health care would better enable primary care to be delivered in a structured manner. In addition, the systematization of clinical decision making and referrals through relatively easy-to-update protocols would improve service navigation and the patient journey. The development of new clinical pathways in the area of minor ailments seeks to standardize practice according to the best available evidence and reduce variations in current practice. Increased interprofessional teamwork and collaboration between GPs and community pharmacists for care coordination would increase the likelihood of reaching treatment goals and improving patient outcomes. Community pharmacists will gain from having evidence-based guidance, and the community will benefit from another mechanism to ensure that advice from a pharmacist is based on the latest available evidence. AMAS facilitates increased access to care for individuals to receive minor ailment treatment in a timely and efficient manner.

This paper describes a research protocol to evaluate a collaborative protocolized AMAS to improve the management of common ailments in Australia. The AMAS intervention outlined in this study protocol offers a unique and innovative approach to address self-medication and formalize triage processes in the Australian primary care system. The principal aim of this study is to evaluate the clinical, economic, and humanistic impact of AMAS on adult patients attending Australian community pharmacies compared with usual pharmacist care.

Methods

Study Design and Setting

The study will use a community pharmacy-based cluster randomized controlled trial (cRCT) design with an intervention group and a control group following the Standard Protocol Items: Recommendations for Interventional Trials checklist [41] (Multimedia Appendix 1). The study will be performed over 8 months in community pharmacies throughout Western Sydney Primary Health Network (WSPHN) region.

Recruitment of Study Participants

Participant recruitment will occur at 3 levels: community pharmacy, general practice, and patient level.

Pharmacy Level

Community pharmacies located in WSPHN region with a pharmacist available to attend specialized training to deliver the AMAS service will be eligible to participate in the study. Contact information of pharmacies will be retrieved from publicly available lists, and those meeting criteria for inclusion will be invited to join the study by telephone. The lead researcher will arrange face-to-face discussion for those expressing interest and to obtain written consent for participation. Randomization will be at the level of the community pharmacy. Pharmacies will be sequentially numbered according to their order of acceptance into the study. An independent researcher will assign the pharmacies (units of randomization) to either the intervention group or control group based on unrestricted random sampling using a computer-generated random number list with a ratio of 1:1 in Excel 2016 (Microsoft Corporation).

General Practice Level

Representatives from WSPHN will assist in the engagement and recruitment of general practices within WSPHN into the study. An expression of interest will be forwarded by a blast email to all practices located within the region. The WSPHN representative will provide follow-up information for those expressing interest, and consent will be sought at the practice level from GP practice managers overseeing the work of the surgery or group of surgeries. Each practice manager will be requested to ensure individual GPs within the consented practice are made fully aware of their role within the study before commencement. Study information will be circulated to individual practitioners detailing GP involvement, and given the option of contacting the research team with further questions. Signed practice consent forms will be forwarded to the lead

researcher. Informed consent will be essential to receive information from the pharmacist. The details of individual GP involvement in the study are provided below.

Patient Level

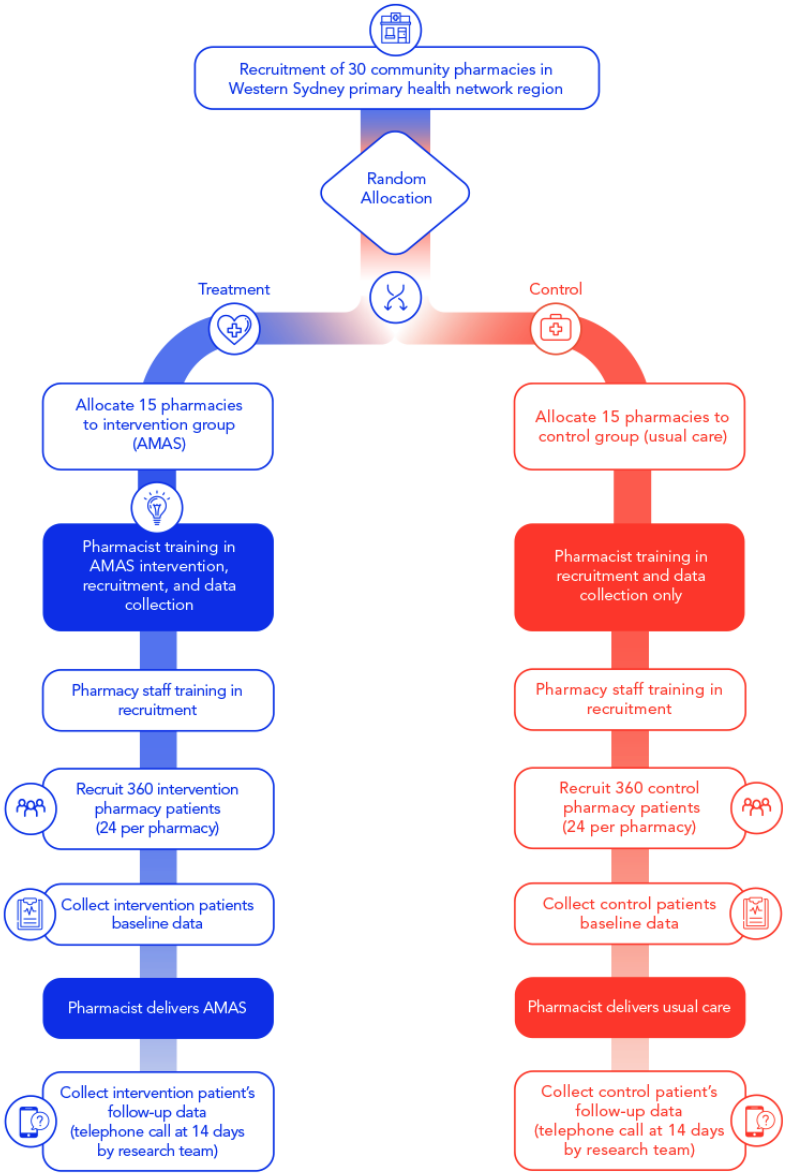
Patients will be recruited from participating pharmacies. Consecutive recruitment will be used. The recipients of the AMAS service or usual care will be patients who request management for their minor ailment symptoms (symptom-based request) and/or self-select a product to self-treat their ailment (product-based request). The patient may either initiate an interaction or wait to be approached by a member of pharmacy staff while self-selecting a product. The pharmacy team member will refer the patient to the pharmacist who will offer participation in the study if eligible to participate. Patients aged 18 years or older will be identified as eligible if meeting all the qualifying criteria, including (1) attending the pharmacy in person, (2) presenting with a symptom-based and/or product-based request for one of the included minor ailment conditions from 3 specific symptom groups (Table 1), (3) ability to provide written informed consent to participate in the study, and (4) accessible by telephone.

Eligible patients identified by the pharmacist will be provided a Participant Information and Consent Form (PICF) explaining the study and given the opportunity to ask questions. Further discussion will be conducted at a private area in the pharmacy or an area appropriate for the discussion to be performed in a confidential manner. Those agreeing to participate will be asked by the pharmacist to provide signed consent. On the basis of which pharmacy they attend, patients will receive the intervention or usual care (Figure 1).

Table 1. Minor ailment conditions.

Classification	Minor ailments to be included in the study
Gastrointestinal	Reflux or indigestion
Respiratory	Cough and common cold
Pain	Headache (tension or migraine), primary dysmenorrhea (period pain), and low back pain

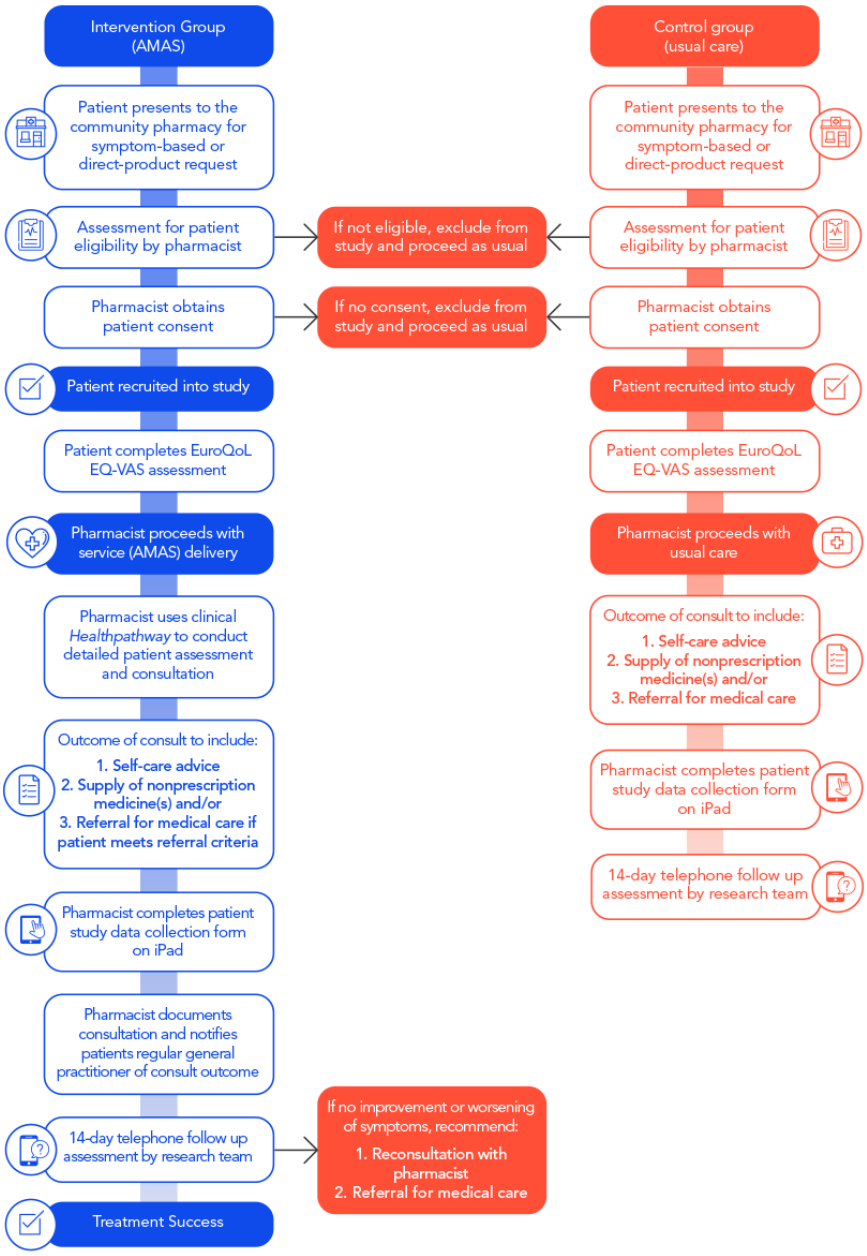
Figure 1. Study design. AMAS: Australian Minor Ailments Service.



Description of Intervention

As we are aiming to evaluate the impact of an enhanced service compared with the one that is already being delivered in routine practice, intervention patients will receive AMAS on presentation to the pharmacy. This will involve a protocolized face-to-face pharmacist-patient consultation. Pharmacists will follow a number of steps in the patient encounter (Figure 2). Patients will be followed up at 14 days after the initial patient-pharmacist consultation through telephone by the research team to assess for resolution of symptoms and health care utilization for the same ailment.

Figure 2. Usual care versus intervention: clinical management algorithm. AMAS: Australian Minor Ailments Service; EQ-VAS: EuroQoL Visual Analogue Scale.



We are proposing a number of innovative features to AMAS, which are described below.

Collaborative Treatment Pathways for Minor Ailments

Clinical pathways are "document-based tools that provide recommendations, processes, and time frames for the management of specific medical conditions or interventions" [42]. They define a process of care agreed by local clinicians and pharmacists and are informed by existing evidence, guidelines, and protocols. *HealthPathways* is a proprietary system of clinical pathways developed in New Zealand and adopted by clinicians throughout PHNs in Australia [40]. These pathways seek to serve as guidance for desired standards of practice and are ultimately intended to promote consistency and uniformity of care.

The collaborative clinical pathways for each minor ailment (Table 1) are intended for use by community pharmacists delivering AMAS. Each ailment has the same structure and format to make the process of finding and using the information easy and practical. These pathways include types of questions, assessment, management approach recommending a particular course of action including self-care, and/or a nonprescription medicine for symptomatic relief, specific to each ailment. Included is a robust framework for referral, indicating red flag criteria to trigger escalation processes, and the time frame within which a patient is recommended to seek care from a particular health care provider (ie, the patient is recommended to see a GP within 24 hours). A red flag is a symptom that is recognized as likely to be of a more serious nature and requires immediate referral. The research and writing of these clinical pathways followed a literature review of contemporary international and

national clinical guidelines in consultation with leading general medical professionals involved in PHN governance with comprehensive experience in *HealthPathways* development.

Pharmacist-Directed Care and Data Collection

Pharmacists will undertake a consultation with eligible patients for symptom-based and product-based requests in the community pharmacy. Intervention pharmacists will use the agreed clinical pathways to recommend a particular course of action, including self-care and/or nonprescription medicine recommendation for symptomatic relief and/or referral. In case of the need to refer, the pharmacist will appropriately escalate if the patient meets criteria for referral for further assessment and/or prescribing of prescription-only medicine.

Collaborative Approach to Management, Follow-Up, and Data Collection

The *HealthLink* system is used by clinicians in Australia [43]. This system allows for the encrypted transmission of clinical and patient confidential information securely and reliably between GPs and community pharmacists. For AMAS patients who have identified a regular GP during the patient-pharmacist consultation, the consultation will be documented and forwarded from the pharmacist to the GP, outlining clinical assessment undertaken, observations, presentation, and consult outcomes (ie, medication supply, pharmacist-directed self-care, and/or details of referral). Details of the consultation will not be provided if (1) the patient has not consented, (2) the patient has not identified a regular GP, (3) the practice has not consented to partake in the study, or (4) the practice is not using HealthLink software. Importantly, the use of this communication system has been agreed with local clinicians within WSPHN. The process of rolling out this system to pharmacies, set up, and licensing will be facilitated by the PHN and project team. If a patient's identified GP has not consented to the study or does not use this software in practice, the pharmacist will still provide the AMAS service (ie, following management pathways and referral if required), yet GPs will not receive feedback on details of their patient's consultation.

Training Pharmacists to Deliver Australian Minor Ailments Service

Intervention pharmacists will attend one of two 7.5-hour training workshops at WSPHN before delivery of AMAS. The aim of educational training is to ensure pharmacists competency in delivering the service. The 2016 National Competency Standards Framework for Pharmacists in Australia [44] and the Pharmaceutical Society of Australia's Professional Practice Standards (version 5) [15] informed the development of content emphasizing competencies to enhance the pharmacist's role in service provision. The training program will also be a refresher about current best practice in common ailments. The workshop will include a combination of lecture presentations and interactive sessions including role-play scenarios. Self-care information and resources for consumers, clinical treatment pathways, communication and data collection software are available on provided iPads to be used at the point of care. Given that pharmacy assistants are likely to be the very first point of contact in the pharmacy, a researcher will visit each intervention pharmacy to train pharmacy assistants in recruitment and will be given the opportunity to ask questions. During this visit, training materials will be revisited with a *champion* pharmacist who will have attended one of the training days before commencing recruitment.

Practice Change Facilitation to Support Intervention Pharmacies

Practice change facilitators (PCFs) will visit intervention pharmacies at least monthly to support the delivery of AMAS. The PCF will be involved in a range of change facilitation processes and activities during visits with the objective of ensuring recruitment targets are met, quality of service provision, quality of data entry, and adherence to the intervention protocol. PCFs will be trained to ensure these objectives are met. These include addressing any barriers to change using evidence-based strategies. PCFs will be collecting both quantitative and qualitative data on-site. This role works closely with the research team.

Control Group

Pharmacies randomized to the usual care arm will receive training in the use of data collection materials and recruitment only. One training night (2 hours) in data collection and recruitment will be provided at WSPHN. A researcher will visit each of the 15 control pharmacies to deliver study materials, and pharmacists unable to attend the training night will be trained in-store. Materials to be provided include study information detailed in the PICF, data collection software for use on provided iPads, and detailed instructions for data collection. Training will be provided to pharmacy staff to support recruitment for the pharmacist. Patient recruitment will begin immediately after this visit. The pharmacist will check patient eligibility, obtain informed consent, and will document control patients' baseline data and proceed with usual care using their own clinical judgment, processes, and resources. Patients will be followed up at 14 days after the initial patient-pharmacist consultation by the research team to assess for resolution of symptoms and health care utilization.

Data Collection Methods

Data will be collected at 2 time points in both intervention and control arms—baseline and 14 days after the consultation. All patients will complete a baseline questionnaire in the pharmacy, including demographic characteristics, and EuroQoL Visual Analogue Scale. Additional data about patient's ailment history, their contact details, and pharmacist intervention will be collected by pharmacists using forms on iPads provided for that purpose. The time taken per patient to deliver the intervention or usual care will be recorded to inform the economic analysis. Follow-up telephone questionnaires will be conducted by research assistants using forms provided for that purpose. Follow-up at 14-days is considered appropriate because of the nature and duration of minor health symptoms. Study data will be collected and managed using Research Electronic Data Capture (REDCap) tools hosted at the University of Technology Sydney (UTS) [45]. REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an interface for validated data entry, (2) audit trails for

tracking data manipulation and export procedures, (3) automated export procedures for data downloads to statistical packages, and (4) procedures for importing data from external sources [45]. All data collected in pharmacies will be returned to the research team on the day of recruitment to allow for timely follow-up. The chief investigator will have access to the trial data.

Study Measurements and Outcomes

The evaluation of MAS compared with usual care will be achieved by comparing the primary and secondary outcomes [46] as set out in Multimedia Appendix 2.

Sample Size

The primary joint outcome measures of the study are appropriate medical referral rate and appropriate recommendation of nonprescription medicines. Sample size calculation was based on an assumed baseline appropriate medical referral rate of 85% and assumed baseline appropriate recommendation of nonprescription medicines rate of 82% [47,48]. Pharmacies are the primary unit of randomization with individual patients nested within pharmacies. The rate of the joint outcomes will be compared between the treatment and control arms in the study. To test for a 10% absolute increase in primary outcomes (appropriate medical referral rate: 85%-95% and appropriate recommendation of nonprescription products 82%-92%) with ≥0.9 power, alpha of .05, equal allocation ratio, and assuming intracluster correlation is 0.01, we would need 30 pharmacies (15 in each arm) with 24 participants per pharmacy (allowing for 10% dropout) for an overall sample of 720 patients.

Blinding

Given the cluster design, it will not be possible for participating pharmacies to be blinded to group assignment. However, the patient, research assistants conducting follow-up, and the data analyst will be blinded to treatment assignment.

Postrecruitment Retention Strategies

All recruited pharmacies will be contacted by telephone in the first 2 weeks of commencing patient recruitment to address any teething issues with study procedures. Support to resolve any problems will be offered by PCFs (for intervention) or a study researcher (for control). Intervention fidelity will also be monitored by PCFs. Regular newsletters and emails will be sent to all pharmacies during the study period for encouragement, provision of feedback surrounding data quality, and strategies to enhance recruitment to meet desired targets. Pharmacies not meeting target recruitment will be offered additional in-pharmacy support by the study researcher. Recruited patients will be contacted by telephone. Attempts to contact nonresponders will continue until contact is made or for a maximum of either 1 week or 5 call attempts.

Statistical Methods and Analysis

Data will be analyzed using Stata 16 for Windows [49]. Baseline pharmacy and patient level information will be summarized by treatment arm. Continuous variables will be summarized with mean and standard deviation with median and interquartile range provided if the data are skewed. Categorical variables will be summarized by frequency and proportion. Generalized estimating equations will be used to account for within-cluster correlation [50] using an exchangeable correlation structure. A modified Poisson regression approach will be used for the analysis to estimate relative rates (RRs) [51,52]. If the estimation of RR is not computationally achievable, we will estimate odds ratios with logistic regression [50]. As a secondary analysis, we will adjust for key baseline covariates at both the pharmacy level (eg, pharmacy type) and the patient level (eg, age and sex). We plan to conduct an exploratory subgroup analysis by treatment classification (respiratory, pain, and gastrointestinal) and type of inquiry (symptom presentation, direct product request, and both). Standard model diagnostics will be conducted to check for model assumptions. All analyses will be intention-to-treat. Multiple imputation (MI) by chained equations [53] will be applied to account for missing patient outcomes. A total of 30 imputations (including using pharmacy type, age, and sex in the MI model) will be performed. A detailed statistical analysis plan will be developed by blinded investigators before unblinding and locking the study database.

A cost-utility analysis (CUA) and cost-effectiveness analysis (CEA) will be performed through examining the resource use of adult patients in the context of the randomized controlled study designed to investigate the efficacy of AMAS compared with the control group. A healthcare perspective will be applied for the analysis. Costs will be estimated in Australian dollars at the 2018-2019 financial year. Costs during the 2-week follow-up period will be analyzed for all patients included in the cRCT. Costs will be grouped into 4 main categories: (1) pharmacist time, (2) medications, (3) referrals and reconsultation, and (4) training and facilitation costs. The pharmacist cost will consider the working time for a community pharmacist and time consumption to deliver the service. Patient out-of-pocket costs (for all medicines supplied during the 14-day period) will be estimated by the average unit price across pharmacy banner groups. Health service utilization will be based on the cost of medical services recorded in the study, with unit prices sourced from Medicare Benefits Schedule prices, Australian National Hospital Cost Data [54], and the Pharmacy Industry Award [55]. Finally, capital costs for training of pharmacists, facilitation, information technology, and program setup will be counted.

The trial-based outcome measures used for the economic evaluation will be symptom resolution rates and appropriateness of pharmacy care (as a proxy of health gain). Utility values from the literature for symptom resolution and nonsymptom resolution of minor ailments will be used to estimate quality-adjusted life years (QALYs). Other intermediate outcomes will be used to adjust the utilization of resources including referral and reconsultation rates. A decision analytic modeling technique will be used. The model inputs will be informed by data from the trial supplemented with published literature. Results of the CUA will be expressed in terms of an incremental cost per QALY (incremental cost-effectiveness ratio), calculated by dividing the difference in total costs and QALYs between intervention and control groups (incremental costs/incremental QALYs). In addition to the CUA, 2 CEAs will be conducted where the clinical effect measure will be an extra episode of appropriate pharmacy care and extra patient achieving symptom

resolution for their ailment. The cost-effectiveness results will be expressed in terms of extra cost per additional episode of appropriate pharmacy care and extra cost per additional patient achieving symptom resolution.

Ethics Approval and Consent to Participate

This project has been approved by the UTS Human Research Ethics Committee (HREC) (UTS HREC approval number: ETH17-1350). All participants (pharmacies, general practices, and patients) will complete a consent form to participate in this research.

Results

Statistical and economic analyses will be completed in July 2019. Following this, research findings will be disseminated through peer-reviewed publication.

Discussion

Integrated Care

Globally, health care is changing to address a number of challenges including the needs of an aging population, escalation in consumer knowledge and their expectations of the health service, rapid advances in scientific and technical capacity, and the increasing cost of health care [56]. With this, a key issue that needs to be addressed is how to connect services and health care professionals to achieve integrated services for consumers and health professionals as models of care evolve to deliver a person-centered approach [57]. There are excellent services and health professionals all striving to deliver the best possible care, but it is often in a fragmented and siloed manner [2]. The increasing longitudinal care requires both effective oral and *technology-enabled* communication between health care team members.

Innovative thinking and tools are needed to deliver better and cost-effective care. This study is unique, as it enables and evaluates integrated electronic technology systems in Australian primary care for common ailments. This ensures health care providers have access to the best information available to deliver excellent patient care. Although the journey to integrated care is complex, technology can help to support it; this applies to care management and referral (*HealthPathways* [40]), collection of data (*REDCap* [45]), and interprofessional clinician-pharmacist communication (*HealthLink Messaging Software* [43]). This approach offers innovative technologies to move from the traditional health care delivery model, which centers on individual disciplines operating in isolation, to solutions that integrate systems to provide a centralized, complete patient view to health care providers.

This research supports an integrated approach in managing common minor ailments. Drawing on expertise from a range of stakeholders, an AMAS service has been co-designed to complement general practice and promotes collaboration between professions. With the development of agreed clinical *HealthPathways* for a number of common ailments [40], the service aims to standardize practice according to the best available evidence and reduce variations in current practice using a robust framework for referral and treatment. To our knowledge, there is no study investigation or published research relating to a protocolized MAS intervention delivered by community pharmacists for minor ailment presentations in Australian health care. This research will evaluate an Australian MAS reporting on patient outcomes, including health status, and resolution of symptoms and will provide full economic analyses. This evaluation focuses on specific minor ailments for relevant comparisons of both health-related and cost-related outcomes.

Comparison With Literature

The literature internationally suggests that minor ailment services enhance the delivery of primary care, promote efficiencies, and reduce overall health care costs [20]. Pharmacy-based minor ailment services were introduced internationally over a decade ago with the aim of supporting consumers to self-care and provide professional support for conditions that can be self-managed [20]. Previous evidence includes the studies by Paudyal et al [21], Watson et al [16], Aly et al [20], and Rafferty et al [58] reporting on minor ailment services. From the UK perspective, studies have compared outcomes of minor ailment management in settings such as pharmacy, emergency departments (EDs), and general practice [16]. The positive economic impact of MAS has been demonstrated through reduced pressure on other health services and cost-effectiveness compared with more expensive health care services, such as general practice and A&E [16]. Comparatively, Rafferty et al have identified community pharmacy as the most cost-effective option for minor ailment care in Saskatchewan, Canada [58]. The scope of complexity and the varied nature of conditions treated by pharmacists under MASs highlight their skills in being able to assist consumers to self-care, facilitating self-medication, ensuring appropriate use of medicines, and timely medical referral [20]. Comparative evaluations identified in the literature compare general practice or ED settings to the community pharmacy or interventions delivered by health care professionals in ED and GP (ie, physicians or nurses) as a comparator to community pharmacy-based MAS [16,59,60]. Within the various studies, there is no clear distinction between whether pharmacists or members of pharmacy staff deliver the MAS intervention. Our study delineates the role of pharmacist in delivering the MAS intervention, and is not delivered by support staff under pharmacist supervision in the pharmacy.

We report 2 primary outcome measures (appropriate medical referral and appropriate recommendation of nonprescription medicine by pharmacist). Referrals (and importantly, red flag referrals) were a critical point that came up in the codesign process with GPs. GPs wanted to see patients quickly if there were any doubts and ensure patients are being referred in an appropriate and timely manner to the correct health provider. We also wanted to assess pharmacist's impact of MAS on self-medication processes. Further strengths to the study include the adoption of clinical and humanistic outcomes (as secondary outcome measures) recommended by Paudyal et al in a systematic review published in 2018 [61]. Clinical outcomes identified in this international review included symptom status (such as resolution of symptoms, symptom severity, and pattern).

Reconsultation with the GP was identified as a surrogate follow-up measure of clinical outcome assessment. Our study will evaluate reconsultation with the pharmacist, GP, and other health professionals within 14 days for the same ailment. Quality of life outcomes using EuroQoL have also been previously collected in a number of studies [61,62]. Our intervention was developed using available evidence and theory, with key elements. Methods of recruitment, data collection, and study variables were tested during a feasibility and piloting stage. This helped to identify methods to improve recruitment rate, limit documentation time, and confirm relevance and appropriateness of study outcomes to Australian health care.

We present the design of a cRCT in international literature to determine the clinical, humanistic, and economic effectiveness of a protocolized intervention for minor ailments compared with usual care. This study improves on other research evaluating MAS directly using a randomized study design. The randomized controlled trial has a number of important features that make it the *gold-standard* evaluation method [63]. Our choice of cluster randomization at the level of the pharmacy decreases the potential for contamination, as each pharmacist in either the intervention group or the control group will only be providing either AMAS or control, not both. In this respect, the study is novel and will provide information on the impact of the service on clinical, economic, and humanistic outcomes and barriers to implementation compared with usual pharmacy care. However, some limitations to the study should be discussed. Although a cluster randomized design is being used to overcome contamination between study arms, the study design may be susceptible to some methodological biases. Cluster randomized trials often do not, or cannot, conceal treatment allocation. Participants awareness of the allocation can lead to biased recruitment [63]. The Hawthorne effect may also influence research subjects, that is, the consequent effect of being observed or awareness of being studied which can potentially impact on participants' behavior [63]. Finally, one of the main limitations of this type of study is that, by definition, a minor ailment is a self-limiting health problem and implicitly involves resolution, regardless of the intervention performed by the pharmacist. Careful attention has been placed to the design of our cluster trial to minimize the potential for biases.

Conclusions

Collectively, the findings from this study will act as the first stage of implementation of MAS in Australian pharmacy practice and may be extended to facilitate the growing prominence of self-care. The study may also provide groundwork for the optimal design of a MAS intervention tailored for greater patient autonomy and boost the clinician-pharmacist relationship for greater discussion surrounding both the appropriate and inappropriate use of nonprescription medicines. This study evaluates the best possible care to the current level of care provided by pharmacists to patients with common ailments in the Australian population. AMAS presents a key opportunity for pharmacists to intervene, as communication of patient-centric clinical information between health care providers will be essential to support effective patient management in Australian health care.

The delivery of safe and high-quality health services that are fully integrated into the health system are of high importance. Research from high-quality evaluations should be used to inform the strategic direction for health service delivery internationally. Implementation research may be applied to MAS to translate evaluation findings into practice for meaningful improvements in patient care outcomes. This paper is a key step in the dissemination process, outlining the aims and methodology that will be used. Along with providing community pharmacists a framework to patient management and the practical skills to engage patients to self-care and self-medicate appropriately, this study may also contribute to the literature with evidence that an intervention of this nature may lead to more efficient resource use in the provision of primary health care in Australia.

Dissemination Plan

To support this study's contribution to wider knowledge, the research findings will be disseminated through peer-reviewed publications and conferences, both nationally and internationally, targeting service users, health care providers, academics, service commissioners, and policymakers.

Trial Status

The study began in July 2018. A total of 30 community pharmacies were recruited. Pharmacists from the 15 intervention pharmacies were trained. 27 general practices consented. Patient recruitment began in August 2018 and was completed on March 31, 2019.

Protocol Amendments

Any protocol amendments will be submitted to the UTS HREC for approval and noted in the registered protocol at the Australian New Zealand Clinical Trials Registry. Trial participants will be notified should relevant protocol changes be made.

Acknowledgments

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Authors' Contributions

SDG contributed to background research, manuscript preparation, writing, and review. SDG, VGC, KW, and SB contributed extensively to study design, methodology, review, and editing. KR contributed extensively to the development of the statistical methods, statistical analysis plan, and sample size calculation. All authors have read and approved the final manuscript. The study funders did not have any influence on study design, writing of the manuscript, or decision to submit for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Standard Protocol Items: Recommendations for Interventional Trials checklist.
[PDF File (Adobe PDF File), 89KB - resprot_v8i8e13973_app1.pdf]

Multimedia Appendix 2

Summary of measurements and study outcomes.
[PDF File (Adobe PDF File), 43KB - resprot_v8i8e13973_app2.pdf]

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Abbreviations

A&E: accident and emergency
AMAS: Australian Minor Ailments Service
CRCT: cluster randomized controlled trial
CEA: cost-effectiveness analysis
CUA: cost-utility analysis
ED: emergency department
GPs: general practitioners

HREC: Human Research Ethics Committee
MAS: minor ailment schemes
MI: multiple imputation
PCF: practice change facilitator
PHN: primary health network
PICF: Participant Information and Consent Form
QALYs: quality-adjusted life years
REDCap: Research Electronic Data Capture
RR: relative rate
UTS: University of Technology Sydney
WSPHN: Western Sydney Primary Health Network

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Chapter 6: Clinical evaluation

[5] **Citation:** Dineen-Griffin, S., Benrimoj, S. I., Rogers, K., Williams, K. A. & Garcia-Cardenas, V. A cluster randomized controlled trial evaluating the clinical and humanistic impact of a pharmacist-led minor ailment service. BMJ Qual Saf 2020;0:1–11. http://qualitysafety.bmj.com/cgi/content/full/bmjqs-2019-010608

A cluster randomized controlled trial evaluating the clinical and humanistic impact of a pharmacist-led minor ailment service

Abstract

Background: Community pharmacists are well positioned to support patients' minor ailments. The objective was to evaluate the clinical and humanistic impact of a minor ailment service (MAS) in community pharmacy compared to usual pharmacist care (UC).

Methods: A cluster-randomized controlled trial was conducted. Intervention patients received MAS, which included a consultation with the pharmacist. MAS pharmacists were trained in clinical pathways and communication systems mutually agreed with general practitioners and received monthly support. Control patients received UC. All patients were followed up by telephone at 14 days. Clinical and humanistic impact were defined by primary (appropriate referral rate, appropriate nonprescription medicine rate) and secondary outcomes (clinical product-based intervention rate, referral adherence, symptom resolution, reconsultation, and EQ-5D visual analogue scale (VAS).

Results: Patients (n=894) were recruited from 30 pharmacies and 82% (n=732) responded to follow up. Patients receiving MAS were 1.5 times more likely to receive an appropriate referral (relative rate (RR)=1.51; 95% confidence interval (CI)=1.07-2.11; p=0.018), and were 5 times more likely to adhere to referral, compared with UC (RR=5.08; 95%CI=2.02-12.79; p=0.001). MAS patients (94%) achieved symptom resolution or relief at follow up, while this was 88% with UC (RR=1.06; 95%CI=1-1.13; p=0.035). MAS pharmacists were 1.2 times more likely to recommend an appropriate medicine (RR 1.20, 95% CI 1.1-1.3; p=0.000), and were 2.6 times more likely to perform a clinical product-based intervention (RR=2.62, 95%CI=1.28-5.38; p=0.009), compared with UC. MAS patients had a greater mean difference in VAS at follow up (4.08; 95%CI=1.23-6.87; p=0.004). No difference in reconsultation was observed (RR=0.98; 95%CI=0.75-1.28; p=0.89).

Conclusion: The study demonstrates improved clinical and humanistic outcomes with MAS. National implementation is a means to manage minor ailments more effectively in the Australian health system.

Trial Registration: Registered with Australian New Zealand Clinical Trials Registry (ANZCTR) and allocated the ACTRN: ACTRN12618000286246. Registered on 23 February 2018.

Introduction

Self-care is usually the primary method for managing minor ailments. Self-medication is a fundamental component of self-care and is defined by the World Health Organization as “the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms” (1). The public tend to self-medicate for their minor ailments before seeing a health care provider (2-5). However, many patients’ use pharmacies as a provider of advice for minor illness and access to nonprescription medicines. These medicines are often perceived by the public as being safer than prescription medicines (6), however many are known to contain potent pharmacological agents. Nonprescription medicines have the potential for adverse effects and frequent or continued inappropriate use of these medicines can be clinically unsafe (7-10). Inappropriate self-medication with nonprescription medicines has shown to contribute to hospital admissions (11). Community pharmacists are well positioned to support patient purchases of nonprescription medicines through the application of knowledge and skills, in an environment in which safety and quality are paramount (12, 13). Pharmacists play an important role in responsible self-medication and are a point of access for reliable information.

Internationally, governments have been investing in supporting pharmacists to support self-care and self-medication practices. Health policy has been developed in a number of countries to encourage self-care at the community pharmacy level. For example, through minor ailment services (MASs) in the United Kingdom, and pharmacists prescribing for minor ailment (PPMA) services in Canada (14, 15). Other countries, such as Spain (16), New Zealand (17) and Ireland (18) are evaluating the feasibility of introducing similar initiatives. These initiatives have been shown to produce positive clinical outcomes (14, 15). There are several studies reporting improvements in a range of clinical outcome indicators (15, 19-28). A systematic review published in 2013 of international services showed low reconsultation and high symptom resolution rates, suggesting minor ailments are being dealt with appropriately in community pharmacy (15). The proportion of patients reporting symptom resolution ranged between 68% and 94% (15).

Although the international literature is positive, the contextual application to the Australian health care system requires local data to ensure transferability. Pharmacists providing self-care advice for minor ailments and referral is a well-established activity in Australian pharmacy practice (29). National pharmacy standards exist (30), however within these standards there is no standardised approach to assessment and triage, no agreed protocols with general practitioners (GPs) for evidence-based management, no agreed referral pathways to appropriately refer patients to general practice or emergency department (ED) settings, no mechanisms to monitor or record patient interactions, and no follow up processes in place (30). The specific aim of this research was to evaluate the impact of MAS on adult patients requesting management for their symptoms (symptom-based presentation) and/or self-selecting a product (product-based presentation) for reflux, cough, common cold, headache

(tension or migraine), primary dysmenorrhoea or low back pain on clinical outcomes, compared with usual pharmacist care (UC) in Western Sydney, Australia (Supplementary file 1).

Methods

Study design & setting

The study used a community pharmacy-based cluster randomized controlled trial (cRCT) design, comparing individuals receiving MAS to UC. The duration of the trial was 8 months (July 2018 to March 2019). The study protocol has been previously published (31). Sites recruited were community pharmacies in the region covered by the primary health network (PHN) of Western Sydney (32). Community pharmacies were eligible to participate if located in the PHN with a pharmacist available to attend training. In total, 133 of 209 pharmacies in the designated area were contacted by telephone in alphabetical order until the required number of pharmacies were recruited. Consent was sought at the pharmacy level from pharmacy owners, as per ethics approval, prior to randomisation. Following consent to participate in the study, pharmacies were sequentially numbered according to their order of acceptance into the study. They were randomized by using a computer-generated random number list with a ratio of 1:1 in Excel 2016 (Microsoft Corporation). There was no stratification by pharmacy type or for regions within Western Sydney PHN. Representatives from the PHN assisted with recruitment of general practices into the study. An initial email was sent to all practices via a mailing list for expression of interest to participate in the study. Consent was sought at the general practice level from practice managers, as per ethics approval. As a result of the PHN recruiting the practices, there was no data on refusal to participate. Study information was circulated to individual GPs ensuring they were fully aware of their role within the study before commencement. Details of GP involvement are provided below.

Participants

Patients were consecutively recruited by community pharmacies. Patients were eligible if, (i) aged 18 or over; (ii) requesting a medicine or self-selecting a medicine to treat symptoms (product-based presentation) and/or presenting with symptoms and directly asking for pharmacists advice (symptom-based presentation) for reflux, cough, common cold, headache (tension or migraine), primary dysmenorrhoea or low back pain; (iii) attending the pharmacy in person; (iv) able to provide informed consent; and (v) willing to be contacted by telephone.

Description of the intervention (MAS)

As we were aiming to evaluate the impact of an enhanced service compared to current practice, we evaluated four features within the intervention that included:

Standardised consultation for pharmacist-patient intervention

Intervention patients received a structured face-to-face consultation on presentation to the pharmacy. Pharmacists followed a number of steps in the patient encounter, including:

(1) Service offering, during which the pharmacist explained the features of the service.
(2) Clinical assessment, where the pharmacist elicited relevant clinical information and checked for referral symptoms.
(3) Standardised management, where the pharmacist used agreed clinical pathways to proceed with a standardised management approach, including provision of self-care advice, non-prescription medicine(s) if appropriate, and/or referral to an appropriate healthcare provider.
(4) Documentation and follow up plan, where the pharmacist documented the consultation in the study data collection form, the patient completed the EuroQoL EQ-5D visual analogue scale (VAS) assessment and a direct message was sent to the patients' regular GP of the consultation outcome by the pharmacist (with patient consent) using HealthLink (34)

To deliver the standardised consultation, MAS group pharmacists were provided with:

Integrated technology platforms agreed with GPs

(1) **HealthPathways** (35): Protocolized evidence-based clinical care pathways specific to each ailment. The research and writing of these clinical pathways followed a literature review of contemporary international and national clinical guidelines in consultation with GPs involved in PHN governance with comprehensive experience in HealthPathways development. The pathways for each ailment were used by community pharmacists to guide consultation with their patient. Each pathway had the same structure and included assessment, and management specific to each ailment.
(2) **HealthLink** (34): A secure messaging system allowing for bidirectional communication between the community pharmacist and the GP.

Educational training program for pharmacists

Pharmacists delivering MAS were trained for 7.5-hours by researchers and GPs at Western Sydney PHN. Training aimed to ensure pharmacists competency in delivering the service, clinical areas, consultation skills, red flags and other referral criteria, documentation and technology systems. The workshop involved a lectures and interactive sessions.

Practice change support for pharmacists

Pharmacists delivering MAS were provided 1-hour monthly visits at the pharmacy consisting of support and on-site training by a practice change facilitator (PCF). The PCF monitored data quality, recruitment and intervention fidelity. PCFs were trained to ensure these objectives were met. PCFs also addressed barriers to change using evidence-based strategies and collected both quantitative and qualitative data.

Description of control (UC)

Patients received usual pharmacist care on presentation to the pharmacy. Pharmacists in the UC group followed their usual practices, according to national standards (30). Pharmacists in the UC group did not receive any of the interventions outlined above including practice change facilitator support. However, they attended a 2-hour training workshop on data collection systems and recruitment at Western Sydney PHN.

Data collection

Study data was collected and managed using the Research Electronic Data Capture (REDCap) tool on provided iPads (35). Community pharmacists completed the data collection form during consultation with each patient. Most pharmacists recorded data directly into the data collection software on the iPad during consultation. However, some anecdotally informed the PCF that this data was first recorded on provided data collection sheets and later transferred into the software the same day. PCFs weren't involved in any data collection relating to the pharmacist-patient consultation. Patients were contacted by the PCF at 14 days by telephone to complete a follow up questionnaire (Supplementary file 2). Attempts to contact non-responders continued until contact or up to five call attempts were made.

Blinding

It was not possible for pharmacies or pharmacists to be blinded to group assignment given the clustered study design. The data analyst was blinded to allocation status. Groups were renamed "1" and "2" by researchers prior to analysis.

Outcomes and assessment

Details of study outcomes are included in Table 1. A standardised approach was undertaken in assessing appropriateness. Appropriateness of a product recommendation was determined by the Therapeutic Goods Administration (TGA) (36) approved indication for use, dose, frequency, duration of use, and contraindications for each medicine. Appropriateness of referral was determined by pharmacist's adherence to referral criteria (including reason, timeframe and healthcare provider referred to) in the mutually agreed clinical protocols. SDG was responsible for assessing appropriateness using the criteria above. If there was any doubt throughout this process, a discussion ensued with VGC and SB to arrive at a consensus. SDG was not blinded to the process, but VGC and SB were.

Table 1 Study outcomes

Definition and assessment	Timepoint
Primary outcome [1]: Appropriate medical referral rate	Pharmacist-patient consultation using data collection record form completed by the pharmacist.
Defined as meeting the agreed referral criteria in the mutually agreed clinical protocols (HealthPathways) (34) for each minor ailment. Appropriate medical referral rate was calculated as the proportion of patients appropriately referred divided by the total number of patients referred during the consult.	
Primary outcome [2]: Appropriate nonprescription medicine recommendation rate	
Defined as meeting the entire requirement as approved in product information by the Therapeutic Goods Administration (TGA) of Australia (36) eg. indication for use, dose, frequency, duration, and contraindications. Appropriate nonprescription medicine recommendation rate was calculated as the proportion of patients receiving an appropriate product recommendation divided by the total number of patients who received a product during the consult.	
Secondary outcome 1: Clinical product-based intervention rate	
Defined as a professional activity resulting in the pharmacist making a recommendation to change the patients' medication therapy (ie. changing the medicine originally selected by the patient to a medicine with the correct indication or with no contraindications for use, changing an incorrect dose, frequency or duration of use. The clinical product-based intervention rate was calculated as the proportion of patients receiving an intervention divided by the total number of patients who presented to the pharmacy self-selecting or requesting a medicine for self-treatment.	
Secondary outcome 2: Self-reported symptom resolution or improvement rate	14-day telephone follow up using data collection record form completed by the practice change facilitator.
Defined as complete absence of symptoms or relief of symptoms. Patients were asked to indicate whether their symptoms had (1) completely resolved, (2) improved but not resolved, or (3) not improved or had worsened. Symptom resolution or improvement rate was calculated as the proportion of patients self-reporting symptom resolution or improvement at follow up divided by the total number of patients followed up.	
Secondary outcome 3: Adherence to referral advice rate	
Defined as adherence to the pharmacist's referral recommendation. Patients referred by the pharmacist during consultation were asked at follow up if they had adhered to the pharmacist's referral advice and sought medical care with another healthcare professional. Adherence to referral advice rate was calculated as the proportion of patients who were adherent to referral divided by the total number of referred patients followed up.	
Secondary outcome 4: Reconsultation rate to all health providers	
Defined as the patients use of health services in the two weeks following consultation with the pharmacist. Patients not referred by the pharmacist in consultation were asked at follow up if they had reconsulted with another healthcare professional, how many times and with whom. Reconsultation rate was calculated as the proportion of patients who had reconsulted with another health professional divided by the total number of non-referred patients followed up.	
Secondary outcome 5: Mean difference in EuroQoL EQ-5D visual analogue scale (VAS)	Pharmacist-patient consultation and repeated at 14-day telephone follow up (administered by the practice change
Defined as the mean difference in patient's self-reported health-related quality of life during consultation and at follow up. The assessment was undertaken using the EuroQoL **EQ-5D** VAS (37), a 20 cm vertical visual analogue scale with a grade ranging from 0 (the worst possible health	

status) to 100 (the best possible health status). Referred and non-referred patients were included in determining EuroQoL EQ-5D VAS as they all received pharmacist intervention.	facilitator, completed by the patient).

Abbreviations: TGA: Therapeutic Goods Administration, VAS: visual analogue scale.

Sample size

The sample size calculation tested for a 10% absolute increase in appropriate medical referral rate based on the agreed protocols (85% to 95%) and appropriate recommendation of nonprescription medicine rate based on TGA approved indications and dose (82% to 92%)) with ≥0.9 power, alpha of .05, equal allocation ratio, and assuming intra-cluster correlation is .01. The larger of the two calculations (that being, appropriate medical referral rate) was used to determine the overall sample size of 720 patients (allowing for 10% dropout) with 30 pharmacies (15 in each arm) (38, 39).

Statistical analysis

A modified Poisson regression approach in SAS/STAT 14.2 (40) was used to analyse the two primary outcomes and secondary outcomes (41, 42). Baseline covariates were adjusted for at the pharmacy level (eg. pharmacy type) and the patient level (eg. age and gender). A subgroup analysis by treatment classification (respiratory, pain, and gastrointestinal) and type of presentation (symptom-based, product-based, and both) was performed. Multiple imputation (MI) by chained equations (43) was undertaken to account for missing clinical outcomes for patients lost to follow-up. Thirty imputations were performed.

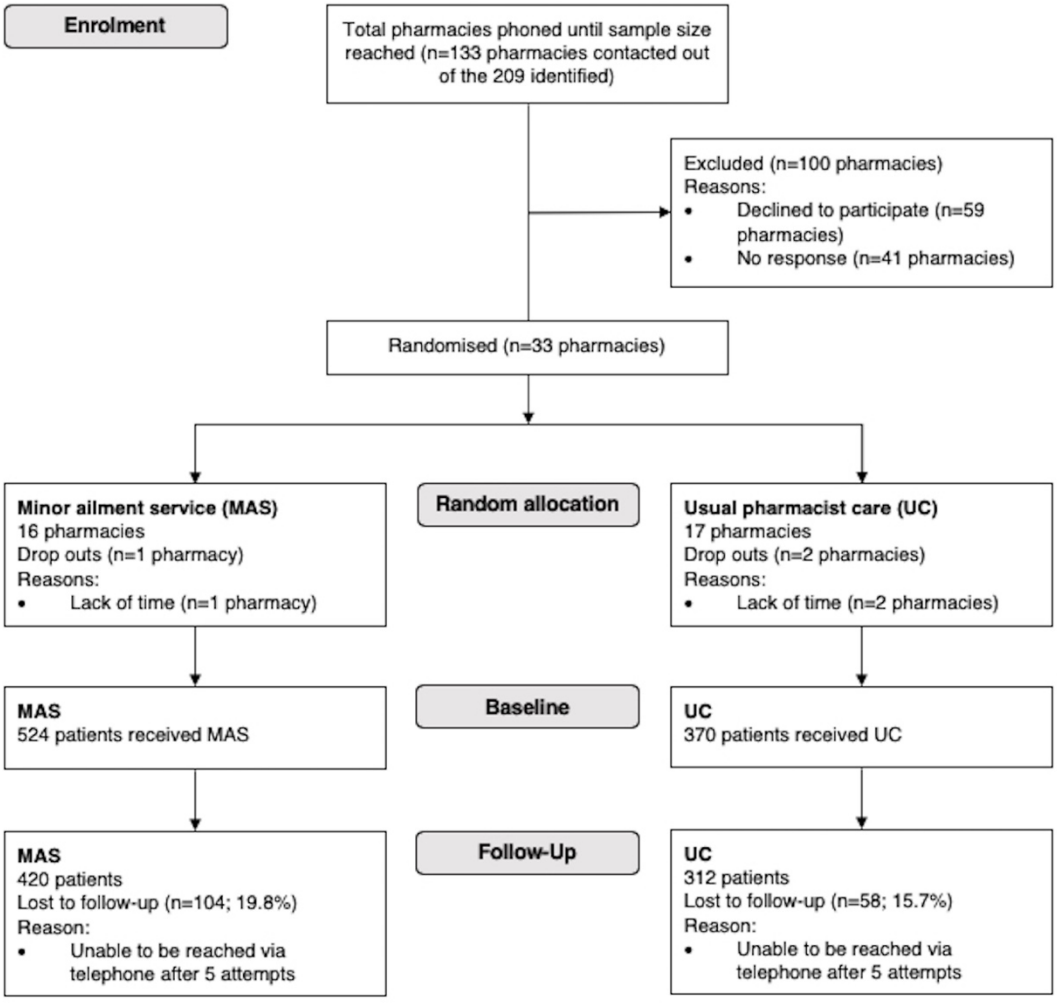
Ethical considerations

The research was registered with the Australian New Zealand Clinical Trials Registry: ACTRN12618000286246. The UTS Human Research Ethics Committee provided approval to undertake the study (ETH17-1350). Pharmacies delivering MAS were remunerated $10 Australian dollars (AUD) per patient for the estimated cost of pharmacists' time to consult and record data. UC pharmacies were reimbursed $5 AUD per patient to record data for research purposes only. Two iPads were offered to the highest recruiting pharmacist in each study arm. Community pharmacy sites, general practices and patients in the intervention and control arms were provided a written information and consent sheet detailing study objectives and a description of the study. Written consent was obtained for all participants.

Results

Thirty-three community pharmacies participated. Sixteen were randomly assigned to deliver MAS and 17 were assigned to provide UC (Figure 1). Three pharmacies withdrew during the first month of the study period. Thirty pharmacies with 55 pharmacists were included in the final analysis. Surrounding general practices consented to receive referral information and details of the pharmacy consultation (n=27 practices with 150 GPs). Results are reported in accordance with the CONSORT 2010 checklist (44) and the CONSORT 2010 extension for cRCTs (45).

Figure 1 CONSORT 2010 flow diagram



Abbreviations: MAS: minor ailment service; UC: usual pharmacist care.

Patient characteristics

In total, 894 patients were recruited with 524 (59%) receiving MAS and 370 (41%) receiving UC. Table 2 outlines baseline patient characteristics.

Table 2 Baseline patient characteristics

	Sample population n (%)	Minor ailment service group n (%)	Usual pharmacist care group n (%)
Total	**894 (100%)**	**524 (100%)**	**370 (100%)**
Gender			
Male	382 (42.7%)	233 (44.5%)	149 (40.3%)
Female	510 (57.1%)	290 (55.3%)	220 (59.4%)
Other	2 (0.2%)	1 (0.2%)	1 (0.3%)
Nationality *			
Australian	528 (59.1%)	248 (47.3%)	280 (75.7%)
Other	366 (40.9%)	276 (52.7%)	90 (24.3%)
Aboriginal and/or Torres Strait Islander origin			
Yes	30 (3.4%)	17 (3.2%)	13 (3.5%)
Highest educational attainment *			
Postgraduate Degree	105 (11.7%)	92 (17.6%)	13 (3.5%)
Graduate Diploma or Certificate	54 (6.0%)	31 (5.9%)	23 (6.2%)
Bachelor Degree	197 (22.0%)	139 (26.5%)	58 (15.7%)
Advanced Diploma or Diploma	119 (13.4%)	71 (13.5%)	48 (13.0%)
Year 12 or equivalent	216 (24.2%)	108 (20.6%)	108 (29.2%)
Year 10 or equivalent	154 (17.2%)	64 (12.2%)	90 (24.3%)
Year 9 or below	45 (5.0%)	16 (3.1%)	29 (7.8%)
Never attended school	4 (0.5%)	3 (0.6%)	1 (0.3%)
Employment status			
Employed, working full-time	458 (51.2%)	283 (54.0%)	175 (47.3%)
Employed, working part-time	167 (18.7%)	106 (20.2%)	61 (16.5%)
Unemployed, looking for work	44 (4.9%)	22 (4.2%)	22 (5.9%)
Not seeking to be in the labour force	225 (25.2%)	113 (21.6%)	112 (30.3%)
Presentation type *			
Product-based presentation	245 (27.4%)	114 (21.8%)	131 (35.4%)
Symptom-based presentation	598 (66.9%)	386 (73.7%)	212 (57.3%)
Both symptom and product-based presentation	51 (5.7%)	24 (4.5%)	27 (7.3%)
Conditions			
Common cold	340 (38.0%)	197 (37.6%)	143 (38.6%)
Cough	223 (24.9%)	136 (25.9%)	87 (23.6%)
Gastroesophageal reflux	106 (11.8%)	74 (14.1%)	32 (8.6%)
Non-specific low back pain	98 (11.0%)	64 (12.2%)	34 (9.2%)
Tension headache	55 (6.2%)	15 (2.9%)	40 (10.8%)
Migraine	42 (4.7%)	24 (4.6%)	18 (4.9%)
Primary dysmenorrhoea	30 (3.4%)	14 (2.7%)	16 (4.3%)
Duration experienced current episode of symptoms			
< 1 day	103 (11.5%)	58 (11.1%)	45 (12.2%)
> 1 day and 2 days	220 (24.6%)	119 (22.7%)	101 (27.3%)
> 2 days and 7 days	337 (37.7%)	203 (38.7%)	134 (36.2%)
> 7 days and 14 days	81 (9.1%)	48 (9.2%)	33 (8.9%)

> 14 days and 28 days	49 (5.5%)	32 (6.1%)	17 (4.6%)
> 28 days	104 (11.6%)	64 (12.2%)	40 (10.8%)
Experienced same or similar symptoms previously *			
Yes	725 (81.1%)	406 (77.5%)	319 (86.2%)
Symptoms spreading or worsening			
Yes	385 (43.1%)	234 (44.7%)	151 (40.8%)
Self-medicated for current episode of symptoms			
Yes	385 (43.1%)	248 (47.3%)	137 (37.0%)
Consulted another health care professional for previous episodes of symptoms			
Yes	376 (42.1%)	258 (49.2%)	118 (31.9%)
Other health conditions			
Yes	392 (43.8%)	211 (40.3%)	181 (48.9%)
Taking other prescribed or non-prescribed medicines			
Yes	430 (48.1%)	224 (42.7%)	206 (55.7%)
Follow up at 14 days			
Yes	732 (81.9%)	420 (80.2%)	312 (84.3%)

Legend: * Indicates baseline patient characteristics with statistically significant differences ($p<0.05$). Baseline differences were adjusted for in the analysis of study outcomes (see Table 3 for adjusted analysis).

Primary and secondary outcomes

The primary and secondary outcome results are presented in Table 3.

Table 3 Comparison of outcome measures

Outcome type	Outcome	Effect of the minor ailment service (MAS)/ usual pharmacist care (UC)	Adjusted relative rate estimate (95% confidence interval)	Adjusted p value
Primary	Appropriate medical referral rate #	Rate Ratio (MAS/ UC)	1.51 (1.07 – 2.11)	0.018
Primary	Appropriate nonprescription medicine recommendation rate	Rate Ratio (MAS/ UC)	1.20 (1.10 – 1.30)	0.000
Secondary	Clinical product-based intervention rate	Rate Ratio (MAS/ UC)	2.62 (1.28 – 5.38)	0.009
Secondary	Self-reported symptom resolution or improvement rate	Rate Ratio (MAS/ UC)	1.06 (1.00 – 1.13)	0.035
Secondary	Adherence to referral advice rate %	Rate Ratio (MAS/ UC)	5.08 (2.02 – 12.79)	0.001
Secondary	Reconsultation rate to all health providers *	Rate Ratio (MAS/ UC)	0.98 (0.73 – 1.33)	0.910
Secondary	Mean difference in EuroQoL EQ-5D VAS	Mean Difference (MAS/ UC)	4.08 (1.27 – 6.89)	0.004

Abbreviations: MAS: minor ailment service; UC: usual pharmacist care; VAS: visual analogue scale.

Applies to all presentation types (symptom-based, product-based, both).

% Patients referred during consultation who went to see the healthcare provider as advised.

* Providers include pharmacists, general practitioners, emergency departments, nurses, allied health, dentists and specialists.

Appropriate nonprescription medicine recommendation rate

Patients receiving MAS were 1.2 times more likely to receive an appropriate nonprescription medicine recommendation by their pharmacist, than patients receiving UC (RR 1.20, 95% CI 1.1 to 1.3; p=0.000). Pharmacists delivering UC supplied at least one nonprescription medicine to 95% of patients (n=350), compared with 84% (n=441) delivering MAS (p=0.10). Pharmacists delivering MAS provided self-care without the supply of a nonprescription medicine to 11% of patients (n=56), compared with 4% (n=15) receiving UC. Patients in the UC arm (35%; n=129) were much more likely to be supplied a medicine without self-care advice, compared to MAS (2%, n=12). The most common medicines supplied were for symptomatic relief of upper respiratory tract infections, including cold or cough preparations accounting for 63% of all medicines supplied (across both study arms). Oral analgesics, including NSAIDs, non-opioid analgesics alone or in combination (22%) were also commonly supplied for the symptomatic relief of pain. Medicines for reflux accounted for 10% of all medicines supplied and included combination antacids, histamine-2 receptor antagonists and proton pump inhibitors (PPIs).

Clinical product-based intervention rate

Pharmacists delivering MAS performed a clinical product-based intervention for 21% (n=29) of patients requesting a medicine or self-selecting a medicine to treat their symptoms, compared with 11% in the UC group (n=18) (RR 2.62, 95% CI 1.28 to 5.38; p=0.009). The reasons for recommending a change in the patients medication therapy in the MAS group included, (i) a more effective medicine was available (41%; n=12), (ii) the patient was self-medicating incorrectly or inappropriately (24%; n=7), (iii) the patient had contraindications to the requested medicine (17%; n=5), (iv) drug duplication was identified (7%; n=2), (v) the patient requested an inappropriate dosage form (7%; n=2) or (vi) toxicity or an adverse effect was present (4%; n=1).

Referral rate

Referral was provided to 20% (n=104) of patients receiving MAS, compared to 5% (n=19) in the UC arm. Ninety-four percent of MAS referrals (n=98) were considered appropriate meeting the agreed clinical protocols, compared to 74% in the UC arm (n=14). Patients receiving MAS were 1.5 times more likely to receive an appropriate referral, compared with patients receiving UC (RR 1.51; 95% CI 1.07 to 2.11; p=0.018).

MAS group pharmacists identified 2% (n=11) of patients with red flag referral symptoms. No patients with red flag symptoms were identified in the UC arm. The reasons for referral for these patients included, the patient had marked lethargy or shortness of breath (n=2), had trouble breathing or was feeling faint (n=1), severe or disabling pain (n=3), fever or neck stiffness (n=2), potentially a thunderclap headache with sudden onset (n=2) or monocular pain, red eye with visual disturbance (n=1).

Duration or frequency of symptoms was identified as the main reason for referral in the MAS group (38%; n=39). For example, referral for medical assessment was agreed for patients presenting with

persistent low back pain progressively worsening beyond four weeks (n=3), cough greater than two weeks or a recurrent cough (especially smokers with > 20-year pack history) (n=11), or reflux symptoms with no improvement after two weeks of PPI therapy (n=4). Patients were most commonly referred back to their GP within 1-3 days (37%; n=38), whereas patients receiving UC were referred within 2-3 weeks at their next appointment (42%; n=8).

Adherence to referral advice

Patients receiving MAS adhered to pharmacist's referral in 52% of cases (n=49), compared with 16% receiving UC (n=3) (RR 5.08; 95% CI 2.02 to 12.79; p=0.001).

Self-reported symptom resolution rate

The majority of patients receiving MAS achieved symptom resolution (62%; n=259) or relief (32%; n=134) at follow up, while this was 53% (n=164) and 35% (n=109) in the UC group (RR 1.06; 95% CI 1 to 1.13; p=0.035). Six percent of patients receiving MAS experienced no symptom improvement or worsening (n=27), compared with 13% receiving UC (n=39).

Reconsultation

Patients not referred had self-reported health service use within the two weeks following consultation with the pharmacist. MAS patients reconsulted with the same or another health care provider for their same symptom episode in 22% (n=70) of cases. The rate of reconsultation was similar in the group receiving UC (22%; n=60). No difference was observed between groups (RR 0.98; 95% CI 0.75 to 1.28; p=0.89) (Table 4).

Table 4 Reconsultation by health care provider

	Sample population n (%)	Minor ailment service group n (%)	Usual pharmacist care group n (%)
Total	**145* (100%)**	**74 (100%)**	**71 (100%)**
Pharmacist	23 (15.9%)	6 (8.1%)	17 (23.9%)
General practitioner	93 (64.1%)	49 (66.2%)	44 (62.0%)
Emergency department	3 (2.1%)	1 (1.4%)	2 (2.8%)
Nurse	2 (1.4%)	1 (1.4%)	1 (1.4%)
Specialist	8 (5.5%)	8 (10.7%)	0 (0.0%)
Allied health professional	14 (9.6%)	9 (12.2%)	5 (7.1%)
Hospitalisation (admission)	2 (1.4%)	0 (0.0%)	2 (2.8%)

Legend: *Some patients reconsulted with multiple healthcare professionals.

EuroQoL EQ-5D VAS

Patients receiving MAS self-reported a lower VAS assessment (59.5; SD 19.1) than the UC group (63.9; SD 21.4) during consultation with the pharmacist (Table 5). Patients receiving MAS had a greater mean difference in VAS scores, four points greater than that seen in the UC group (mean difference 4.08; 95% CI 1.23 to 6.87; p=0.004).

Table 5 Mean difference in EuroQoL EQ-5D VAS

	Sample population (n=732)	Minor ailment service group (n=420)	Usual pharmacist care group (n=312)
Mean EuroQoL EQ-5D VAS (initial consultation)	61.3	59.5	63.9
Standard deviation	20.2	19.1	21.4
Mean EuroQoL EQ-5D VAS (follow-up)	83.1	85.3	80.2
Standard deviation	14.6	14.8	13.9
Mean difference	**21.8**	**25.8**	**16.3**

Abbreviations: VAS: visual analogue scale.

Subgroup analysis

Results of the subgroup analysis showed that effects of MAS are consistent between subgroups for all study outcomes (Supplementary file 3).

Imputed analysis

The results of the imputed analysis accounting for patient data lost to follow up (n=162) were consistent with main study findings, confirming the effectiveness of MAS in improving clinical and humanistic outcomes (Supplementary file 4).

Discussion

The research evaluated the clinical and humanistic impact of a structured approach to managing symptom-based and product-based presentation types for minor ailments in Australian community pharmacies. MAS pharmacists may have been more likely to perform a clinical product-based intervention due to the assessment and management structured approach provided in the agreed clinical protocols and training provided. Interestingly, half of all patients were self-medicating for their current symptoms, 27% had experienced their current symptoms beyond seven days and 10% had experienced symptoms beyond four weeks prior to attending the community pharmacy. This certainly raises questions as to why patients are not seeking care sooner and are continuing to self-medicate for prolonged periods without medical assessment or re-assessment. When compared to current practice, MAS group pharmacists were referring four times as many patients to other parts of the health system when using the clinically agreed protocols. Several conditions, such as migraine, low back pain, reflux and dysmenorrhoea may also be chronic or recurrent in nature.

Pharmacists delivering MAS identified instances where patients were continuing to self-medicate for persistent symptoms without seeking medical assessment and were referred to a medical practitioner. The variability in referral rate between groups could be due to pharmacists in the UC group not having a standard approach to assessment and management, training or practice change support. Importantly, 2% of MAS patients were identified with red flag features requiring immediate referral. Patients receiving MAS were five times more likely to follow through with referrals, compared to current practice. Non-adherence to referral advice might delay identification of underlying disease while rapid recovery may lead to the perception that no further assessment or treatment is necessary (46).

Comparison to literature

The types of outcomes, methods of assessment and conditions considered as minor ailments in literature represents a challenge for comparison of results and data interpretation (28). Generally, the available literature reports pharmacy-based management of minor ailments, irrespective of whether they are delivering a minor ailment service or not. Our study reports three new outcomes including appropriate nonprescription medicine recommendation rate, appropriate medical referral rate and, referral adherence. Currently, there is no gold standard with regard to the type of outcomes and the method of assessment for interventions targeting minor ailment management (28).

Paudyal et al. in a systematic review undertaken in 2014 reported complete symptom resolution rates ranging from 68% to 94% (15). Our findings reveal complete symptom resolution rates of 62%, and symptom relief or improvement rates to be 32% with the service, compared with 53% and 35%, receiving UC respectively (RR 1.06; 95% CI 1 to 1.13; p=0.035). Studies identified in the literature however reported small sample sizes, do not use a randomized study design and in some instances do not specify the member of staff involved in management, to compare our results.

The Mary Seacole Research Centre evaluated the Pharmacy First minor ailment service in the UK where it was found 23% of the 145 consultations led to a GP reconsultation (47). The Minor Ailment study ('MINA' study) undertaken in the UK reported a reconsultation rate of 33% to all health settings, and an 18% reconsultation rate to GPs only (19). In contrast, our study found GP reconsultation rates to be 15% with MAS and 16% receiving UC, while to all health providers findings show a reconsultation rate of 22% in both groups. This indicates reconsultation rates obtained in this study are consistent with evaluations of pharmacy-based management of minor ailments in international literature.

Referral rate has been reported in a number of studies (48, 49). In England, a pilot evaluation of the north-east NHS111 consultation service reported a 22% referral rate to general practice, ED, or signposted to other services in the community (49). Comparatively, our results reveal a similar referral rate (to all health providers) with MAS at 20%.

Implications for practice

Community pharmacy is an integral part of the Australian primary health system and with the appropriate supporting systems and pre-agreement with GPs has the potential to facilitate an improved flow of patients and information within the health system. We have provided clinical and humanistic evidence that a national service would be successful in Australia. It is recommended that due consideration be given for community pharmacies nationwide to adopt and implement MAS. For this approach to be more widely applied, there should be a strong focus on upskilling community pharmacists to deliver MAS in an integrated and coordinated capacity. Policy and funding alignment will also be a major determinant for future sustainability.

In Australia, currently, there is limited discussion on pharmacists prescribing. Internationally, there has been policy changes resulting in increased scope of practice for pharmacists in the area of independent prescribing. However, these are subject to policies which have not been proposed by governments in Australia. Expanding community pharmacists' scope through training, as seen in the UK and Canada, for other clinical areas such as minor abrasions, wounds, strains and sprains, minor burns etc. or prescribing of certain prescription medicines within a collaborative model for certain conditions is likely to add further clinical and humanistic benefits.

Study limitations

One of the main limitations of this type of study is that, by definition, a minor ailment is a self-limiting problem and implicitly involves resolution regardless of the intervention performed by the pharmacist. This study was not powered to detect changes in symptom resolution (secondary outcome measure). While we saw a positive effect on symptom resolution rates, this might be of use in future studies to determine whether symptom resolution results in differences in patients who reconsult and those who do not. Although a cRCT is being used to overcome contamination between study arms, the study design may be susceptible to some methodological biases. Pharmacists awareness of the allocation can lead to biased recruitment (50). The Hawthorne effect may also influence research subjects, that

is, the consequent effect of being observed or awareness of being studied which can potentially impact on pharmacist's behavior (50).

Conclusion

The pharmacist's consultations followed evidence-based treatment protocols which were collaboratively designed specifically to ensure that referral points were agreed with GPs. Community pharmacists were in a strong position to facilitate responsible self-care and self-medication when provided the protocol for use during consultation. The project was successful in establishing a method of communicating the pharmacist's actions to the GP, thus providing GPs with additional information than that they may have had. Our evidence demonstrates improved clinical and humanistic outcomes as a result of MAS compared to current practice. Implementing a national service which is integrated and collaborative will set the foundation for improved medication safety and service sustainability in the Australian health system.

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Chapter 7: Economic evaluation

[6] Dineen-Griffin, S., Williams, K. A., Vargas, C., Benrimoj, S. I., & Garcia-Cardenas, V. Cost utility of a minor ailment service provided in the community pharmacy setting. Cost Effectiveness and Resource Allocation. 2020. **(Submitted – Under Review)**

Cost utility of a minor ailment service provided in the community pharmacy setting

Abstract

Background: A cluster randomised controlled trial (cRCT) performed from July 2018 to March 2019 in Australia, demonstrated the clinical impact of a community pharmacist delivered minor ailment service (MAS) when compared with usual pharmacist care (UC). We report the results of the economic evaluation.

Objectives: The aim of this research was to evaluate the economic impact of MAS compared to the alternative of UC. The objectives were to (i) assess the cost utility and cost effectiveness of the service, from a societal perspective, and (ii) assess uncertainty by conducting deterministic and probabilistic sensitivity analysis (SA).

Methods: A cost utility analysis (CUA) was performed alongside the cRCT. Participants recruited were patients of community pharmacies located in the primary health network of Western Sydney. Data were collected from adult patients (≥ 18 years) presenting to community pharmacies with one of seven minor ailment conditions. Patients received MAS (intervention) or UC (control) by their pharmacist depending on the pharmacy attended. Pharmacists delivered MAS to patients which consisted of a structured consultation. Evidence-based clinical pathways were used to guide assessment and management on a technology platform, and communication systems were collaboratively agreed with general practitioners. MAS pharmacists received 7.5 hours of training and were provided monthly in-pharmacy support by a practice change facilitator. Patients were followed up by telephone at 14 days in both arms. A decision analytic modelling technique was employed for the economic evaluation, undertaken from a societal perspective over a 14-day time horizon. Data from the trial and literature informed probabilities, utility values, and costs (Australian dollars). The outcome measure for the CUA was the incremental cost effectiveness ratio (ICER). Deterministic and probabilistic SA were performed. Results of the cost effectiveness analysis (CEA) were reported with the effect measures as extra cost per additional episode of appropriate pharmacist care and extra cost per additional patient achieving symptom resolution.

Results: Patients (n=894) recruited by thirty pharmacies were included in the analysis of costs. The majority (n=732; 82%) were followed up for whom both clinical and economic outcomes were available. MAS was more expensive but also more effective compared to UC. MAS patients (n=524) gained an additional 0.003 QALYs at an incremental cost of AUD $7.14 compared to UC (n=370). The resulting ICER was AUD $2,277/ QALY. The probabilistic SA revealed ICERs between AUD -$1,150 and $5,780/ QALY. Results of the CEA revealed an ICER of AUD $37.42 per additional patient receiving appropriate pharmacist care and an ICER of AUD $586.88 per additional patient achieving symptom resolution.

Conclusions: We found MAS demonstrated clinical and cost effectiveness. Findings suggest that implementation within the Australian context is cost effective. This is the first CUA and CEA in international literature, evaluating MAS compared with UC.

Registration: The trial was registered with Australian New Zealand Clinical Trials Registry on 23 February 2018 with the ACTRN number 12618000286246.

Introduction

Minor ailment presentations to emergency departments (EDs) and general practitioners (GPs) for conditions such as headaches, coughs, colds and earaches are an inefficient use of public resources [1, 2]. Minor ailments have been defined in the international literature as “common or self-limiting or uncomplicated conditions which may be diagnosed and managed without medical (ie. GP) intervention” [3-5]. The Pharmaceutical Society of Australia has defined minor ailments as “conditions that are self-limiting, with symptoms recognised and described by the patient and falling within the scope of pharmacist’s knowledge and training to treat” [6]. Self-care is the preferred method of managing minor ailments for many patients [7]. It is known that patients self-manage conditions [8] and encouraging people to exercise greater self-care has potential to shift costs from medical health care. A 2019 policy statement from the International Pharmaceutical Federation and the Global Self-Care Federation, describes the intention of the profession and industry to further develop self-care as a “pillar of sustainable healthcare systems” [9, 10]. The statement encourages pharmacists to encourage people to use health resources responsibly and engage in self-care where appropriate [9, 10]. International health systems, like the United Kingdom (UK), have been shifting to support self-care for minor ailments and chronic illness [11-13]. This is partially due to increases in GP and ED presentations driving governments to review policy to support self-care [13-18]. This has also resulted in the development and implementation of community pharmacy-based self-care programs, known as minor ailment services (MASs).

Ninety-four international services are identified in the UK (England, Scotland, Northern Ireland and Wales) and regions of Canada (known as pharmacist prescribing for minor ailments (PPMA)) [6, 19, 20]. Other countries, such as Spain [21], New Zealand [22] and Ireland [23] are evaluating the feasibility of introducing similar initiatives. These services have apparently shown positive economic impact through reduced pressure on other health services. This is demonstrated by reduced costs associated with unnecessary use of other more expensive healthcare services and encouraging care to be delivered at the appropriate level [24]. Watson and co-authors estimated the cost of community pharmacy-based care of minor ailments in the UK using a prospective cohort study design, compared with care provided in GP and ED settings. The results suggested similar clinical outcomes and lower costs with pharmacy care (£29.30) compared with the cost of GP (£82.34) and ED (£147.09) care [24]. In Canada, Rafferty et al. conducted an economic impact analysis measuring costs of a minor ailment program and the alternative scenario of usual care from a societal perspective, using primary data on pharmacists’ consultations in Saskatchewan [25]. The Saskatchewan PPMA program saved the province approximately Canadian dollars (CAD) $546,832 in 2014. Projected cumulative cost savings after five years of implementation was CAD $3.48 million. The study identified the community pharmacy program as the most cost-effective option for minor ailment care at CAD $18, compared with the cost of a GP appointment (CAD $66.40) and an ED visit (CAD $138) [25]. Similarly, the Ontario Pharmacists Association determined that implementation of a program aimed at five practice areas, including

smoking cessation services, flu vaccinations, adapting patients' drug therapy, renewing prescriptions for stable chronic conditions, and a minor ailments program could save the Ontario health system CAD $143 million over five years [26, 27]. With national implementation, it was estimated that an additional 2.4-4.7 million Canadian's could receive services and waiting times could be reduced by transferring up to 17 million medical consultations to community pharmacy [26, 27].

Much of the clinical and economic evaluative work in the international literature has focused on community pharmacist management of minor ailments in the UK and Canada [4, 24, 25, 28-34]. To our knowledge no studies offer a comparative viewpoint in terms of cost utility and cost effectiveness of a community pharmacist delivered MAS compared with usual pharmacist care (UC). Clinical and economic data were obtained alongside a cluster randomised controlled trial (cRCT) (https://www.anzctr.org.au ref: ACTRN12618000286246) evaluating the effectiveness of MAS in Australia [35, 36]. Our aim was to determine if the community pharmacist delivered MAS is a value for money intervention. This paper reports the economic evaluation, in the form of a CUA with corresponding deterministic and probabilistic SA.

Methods

Clinical and economic data were collected from adult patients (≥ 18 years) presenting to one of thirty community pharmacies located in the PHN region of Western Sydney, Australia [37]. Eligible patients were recruited by the pharmacist on requesting treatment or a product to self-treat one of the following minor ailments: common cold, low back pain, tension headache, migraine, primary dysmenorrhoea, cough or reflux. Patients received MAS (intervention) or UC (control) depending on allocation of the pharmacy to which they attended. All patients were followed up by telephone approximately 14 days after their interaction with the pharmacist. Ethics approval was received from the Human Research Ethics Committee of the University of Technology Sydney (ETH17-1350). Written consent was obtained from all participants.

The intervention

Patients attending pharmacies received MAS which consisted of an individual consultation with a trained pharmacist. Pharmacists utilised collaboratively agreed pathways (HealthPathways) to guide assessment, management (self-care, provision of nonprescription medicines) and/ or referral for medical care [38]. For patients identifying a regular GP, a summary of the consultation was sent electronically via secure messaging software. Full details of the intervention and study protocol have been published elsewhere [35].

Economic evaluation

A cost utility analysis (CUA) and cost effectiveness analysis (CEA) was performed alongside the cRCT (Table 1). The research is reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist [39].

Table 1 Key components of the economic evaluation

Types of analysis	CUA, CEA
Patient population	Adults that present at the pharmacy with common cold, cough, low back pain, tension headache, migraine, primary dysmenorrhoea and reflux
Intervention	Pharmacist-led minor ailment service
Comparator	Usual pharmacist care
Outcomes	Cost per quality adjusted life year, cost per appropriate pharmacist care, cost per symptom resolution (SR) case
Perspective	Societal
Time horizon	14 days
Method used to generate results	Decision tree
Quality of life	Utility values reported from the literature for SR and non-SR of minor ailments which used EuroQoL EQ-5D-3L
Resource utilisation sources	Trial based, Medicare Benefits Schedule, Australian Institute of Health and Welfare, Pharmacy Industry Award
Software	Microsoft Excel For Mac Version 16.16.10

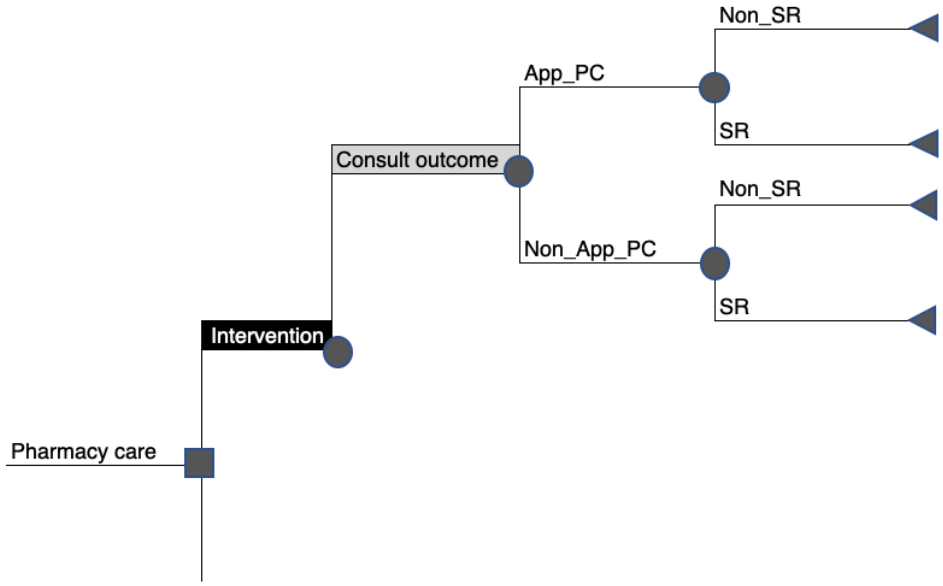
Abbreviations: SR: symptom resolution.

A decision analytic modelling technique was employed for the economic evaluation consisting of a decision tree conceptualized in Microsoft Excel for Mac 16.16.10 (Figure 1). The full model is depicted in Supplementary File 1. The two strategies (MAS and UC) are denoted by the branch emanating from the decision node (represented by a square in Figure 1). Appropriate pharmacist care was reported as an intermediate outcome measure for cost effectiveness (a proxy for health gain). This was defined as providing an appropriate nonprescription medicine recommendation and/or appropriate referral in line with the agreed treatment pathway (HealthPathway) for each condition [38]. The terminal node (represented by the triangle in Figure 1) represents the end point of the patient pathway whereby patients achieve symptom resolution or not at 14 day follow up [40]. It was assumed patients reporting partial resolution of symptoms would achieve complete resolution given the self-limiting nature of minor ailment conditions [41].

The model was populated with probabilities and costs using cRCT trial data (Supplementary File 2). The difference in patient outcomes and costs were generated to derive the total incremental impact of MAS in a cohort who received: (i) appropriate pharmacist care and the patient achieved symptom resolution, (ii) appropriate care and the patient did not achieve symptom resolution, (iii) pharmacist care

outside of the agreed pathways and the patient achieved symptom resolution, or (iv) care outside of the agreed pathways and the patient did not achieve symptom resolution.

Figure 1 Decision tree model structure



Intervention	Minor ailments service	MAS
	Usual pharmacist care	UC
Consult outcome	Self-care	SC
	Self-care plus nonprescription medicine	SC+NPM
	Self-care plus referral	SC+R
	Self-care plus nonprescription medicine plus referral	SC+NPM+R

Abbreviations: AppPC: appropriate pharmacist care meeting agreed protocols; Non_AppPC: pharmacist care outside agreed protocols; Non_SR: no symptom resolution; SR: symptom resolution.

Measures of outcomes

Health benefit was measured as quality adjusted life years (QALYs) (Table 2). Australia, similar to many other countries, accepts the use of the QALY as the unit of health measured in the context of economic evaluations for health decision-making [42]. QALYs were estimated by multiplying the duration of time spent in the health state (14 days), the utility value associated with that health state (symptom resolution or no symptom resolution), and the proportion of individuals within the trial achieving symptom resolution or not. Additionally, two CEAs were conducted where the clinical effect measure was an extra episode of appropriate pharmacist care and extra patient achieving symptom resolution. Results are

expressed in terms of cost per additional episode of appropriate pharmacist care and cost per additional patient achieving symptom resolution.

Table 2 Cost utility and cost effectiveness effect outcomes

Method	Effect measure	Outcome(s)	Source
CUA	Utilities	Quality adjusted life years	Refer to Watson study [24]
CEA	Natural units	Episode of appropriate pharmacist care Extra patient achieving symptom resolution	Trial data

Abbreviations: CEA: cost effectiveness analysis; CUA: cost utility analysis.

Results of the CUA and CEA are reported as the incremental cost effectiveness ratio (ICER). This was calculated by dividing the difference in total costs (incremental cost) by the difference in the health outcome or effect (incremental effect) reflecting the 'extra cost per extra unit of health effect' [43]. The ICER was considered against a willingness-to-pay threshold showing how much a decision-maker is willing to pay for one additional QALY. Australia has not yet defined an explicit threshold. However, a base-case reference ICER of $28,033/QALY Australian dollars (AUD) (95% CI AUD $20,758–$37,667) has been recommended to inform health care decision making in Australia [44].

Costs

Costs were identified, measured and valued using cRCT trial data and local sources. A societal perspective was applied for the analysis. Costs were estimated in AUD (2018-2019 values) [45]. Table 3 outlines the model parameters and sources used to populate the economic model. Mean estimates of costs per patient were compared between arms. Pharmacists wage was based on unit prices sourced from the Pharmacy Industry Award [46]. The hourly rate of a pharmacist was averaged according to position held and multiplied by the time consumption of MAS or UC. Patient out-of-pocket nonprescription medicine costs were determined by averaging the list price from three pharmacy groups (Priceline, Amcal, Chemist Warehouse). Referral and reconsultation costs consisted of costs of contacts with health practitioners. Costs were included for patients who had (i) adhered to referral (adherence was established at 14 day follow up by confirming whether the patient had reported visiting their healthcare provider), or (ii) reconsulted with a medical provider (reconsultation was established at 14 day follow up for patients not-referred by the pharmacist but had reported seeking care from a healthcare provider). The average cost of a consultation with a GP was determined through examination of Medicare Benefits Schedule (MBS) reports (in and out of hours). Costs were calculated by considering the average cost per consult and patient out-of-pocket costs for all medicines (including nonprescription and prescription) as a result of referral adherence or reconsultation. Prescription prices were determined using Pharmaceutical Benefits Scheme (PBS) and non-PBS prices. A cost related to training, technology and monthly facilitation was included for the MAS arm only. The average hourly wage was multiplied by total training time for MAS pharmacists who received training. The cost of

workshop facilitators and all training materials were incorporated. MAS pharmacies received monthly visits (1 hour) for the 8-month duration of the study. The hourly wage of the practice change facilitator was applied to calculate facilitation costs. A cost for the technology and an annual license cost per pharmacist for messaging software was included. We used an estimated nominal number of patients per pharmacy based on industry data [47] to estimate the average cost per patient for training, facilitation and technology. Details of this calculation are provided in Supplementary File 3.

Table 3 Summary of identified health resources and cost estimates

Health resources	Model parameter	Unit	Low range (AUD)	High range* (AUD)	Resource
Costs					
Pharmacist wage	$29.37	per hour	$24.04	$34.30	Australian Government Fair Work Ombudsman 2018 [46]
Training with MAS	1	training per year	0	2	Trial data
Facilitation visit with MAS	60	minutes per month	n/a	n/a	Trial data
Facilitator cost with MAS	$46.28	per hour	n/a	n/a	UTS Award level HEW5 Step1
Average training, facilitation and technology cost with MAS	$0.07	per patient	$0.00	$0.10	Purchase invoices
Time to deliver MAS	10.88	minutes per patient	10.52	11.23	Trial data
Time to deliver UC	3.29	minutes per patient	2.88	3.71	Trial data
Average nonprescription medicine price with MAS	$10.62	per patient	$10.20	$11.05	Amcal, Chemist Warehouse, Priceline 2019 data; trial data
Average nonprescription medicine price with UC	$9.76	per patient	$9.39	$10.14	
Average cost of medicines at reconsult	$9.79	per patient	$7.94	$11.64	PBS 2019; Amcal, Chemist Warehouse, Priceline 2019 data; trial data
GP reconsultation	$44.07	per consult	$30.85	$57.29	MBS 2019 [48]
Utilities					
Symptom resolution	0.91		0.88	0.94	Refer to Watson study [24]
No symptom resolution	0.77		0.73	0.81	

Abbreviations: AUD: Australian dollars; GP: general practitioner; HEW: Higher education worker; MAS: Minor ailment service; MBS: Medicare Benefits Schedule; NPM: nonprescription medicine; PBS: Pharmaceutical Benefits Scheme; UC: usual pharmacist care; UTS: University of Technology Sydney.

* Lower and upper bound values represent 95% confidence interval; or upper and lower range from trial data.

Utilities values were obtained from a prospective cohort study published in the UK (MINA study) by Watson et al (2015) [24]. Watson and co-authors estimated cost-related outcomes of pharmacy care, compared with care for the same minor ailments provided in GP and ED settings. Utility values were determined using the EQ-5D. The study reports a mean (95% CI) incremental QALY gain for pharmacy patients compared with GP and ED patients to be 0.001 (0.000 to 0.002) and 0.001 (−0.001 to 0.002), respectively [24].

Deterministic SA

Deterministic SA assessed the impact of individual parameters (one-way) and simultaneous changes in multiple parameters (multi-way) on the ICER and the extent to which the results vary when estimates of input variables are changed. For the one-way SA, all known variables (Table 3) were tested independently, *ceteris paribus*, using upper and lower limits owing to changes in assumptions made for the base-case analysis. For the multi-way SA, the impact of (i) the highest possible cost of a pharmacist consultation, and (ii) all patients adhering to referral advice, were assessed. A tornado diagram was produced showing varying effects on the ICER.

Probabilistic SA

A probabilistic SA was conducted applying Monte Carlo simulation [49]. The results were used to estimate the probability MAS is cost effective considering a total of 5,000 random simulations. The analysis was run in Microsoft Excel for Mac 16.16.10 and presented in a cost effectiveness plane and acceptability curve.

Results

Eight hundred and ninety-four patients were recruited by thirty community pharmacies between July 2018 and March 2019 and were included in the analysis of costs. Seven hundred and thirty-two patients (82%) were successfully followed up for whom both effectiveness and economic outcomes were available. Table 4 shows a summary of the mean cost of resource use categories for both arms. The descriptive results show the primary difference in expected cost arises from consultation time and referral adherence (due to the higher referral rate and higher adherence to referral seen in the MAS arm).

Table 4 Estimated mean costs for each cost category

	MAS Mean cost per patient (AUD)	UC Mean cost per patient (AUD)
Consultation time	$5.33	$1.61
Nonprescription medicine	$10.85	$10.36
Referral adherence (incl. medicines)	$5.59	$0.61
Reconsultation (incl. medicines)	$7.73	$9.70
Training, facilitation, technology set-up	$0.07	-
Total cost	$29.56*	$22.28*

Abbreviations: AUD: Australian dollars; MAS: Minor ailment service; UC: usual pharmacist care.

***Note:** The costs used in the cost utility and cost effectiveness evaluations are different as a result of the decision tree modelled analysis that considers the proportion of patients in each arm receiving an outcome.

CUA

Incremental cost and incremental QALYs are presented in Table 5. On average, MAS was more expensive but also more effective when compared to UC. Patients (n=524) receiving MAS gained an additional 0.003 QALYs at an incremental cost of AUD $7.14, compared to UC (n=370). The results indicate an ICER of AUD $2,277 per QALY.

Table 5 Incremental analysis

	Mean cost per patient (AUD)	Total QALY	Inc. cost (AUD)	Inc. QALY	ICER (AUD/QALY)
UC	$19.75	0.0264			
MAS	$26.88	0.0296	$7.14	0.003	$2,277

Abbreviations: AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; MAS: Minor ailment service; QALY: Quality adjusted life year; UC: usual pharmacist care.

Note: The costs used in the cost utility and cost effectiveness evaluations for MAS is AUD $26.88 rather than AUD $29.56 as a result of the decision tree modelled analysis that considers the proportion of patients in each arm receiving an outcome instead of the mean costs stated above. Similarly, UC is AUD $19.75 instead of AUD $22.28.

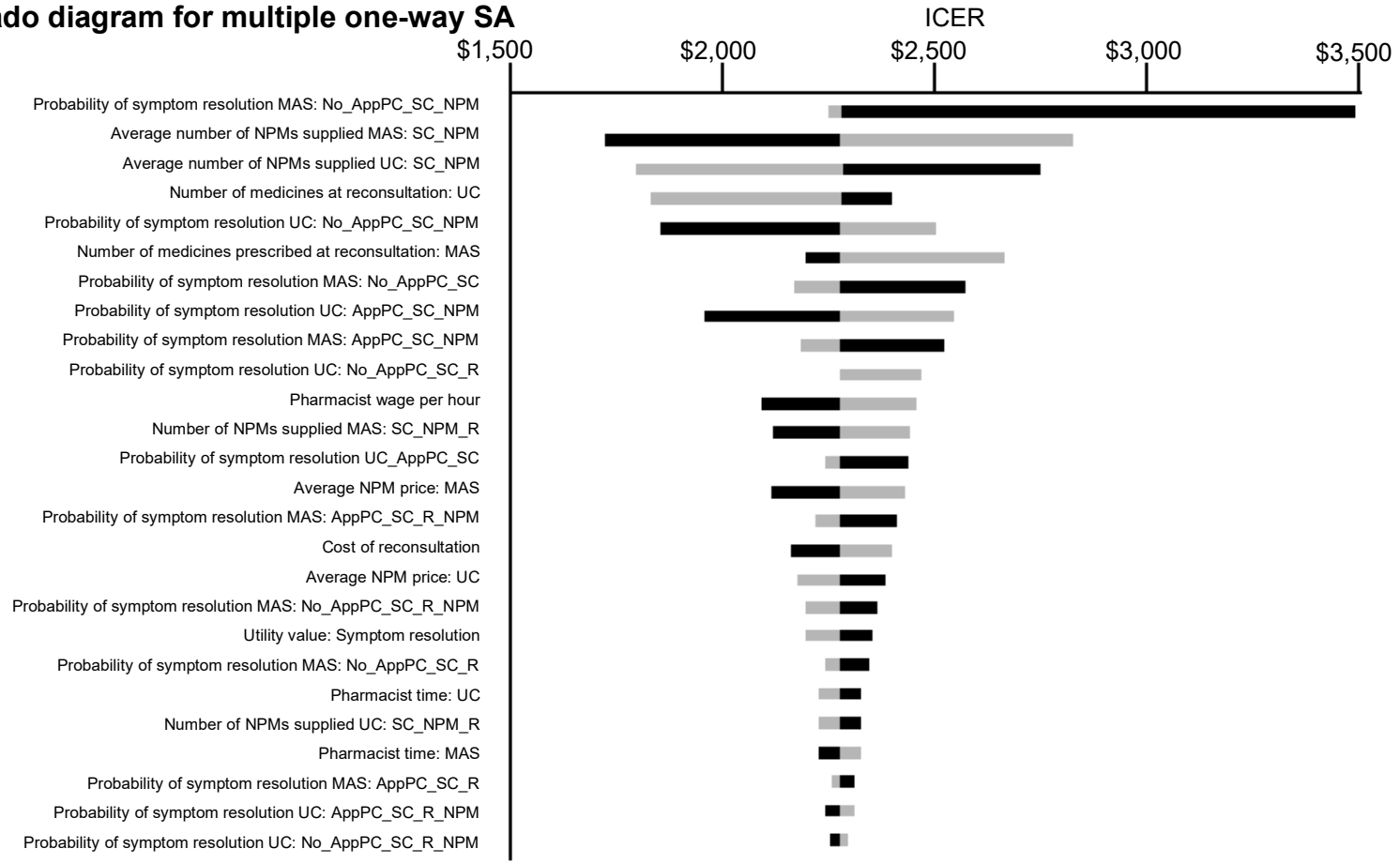
Deterministic SA

The tornado graph displays bars for each parameter depicting which variable has the greatest to smallest impact on the ICER measure (Figure 2). The ICER ranges from AUD $1,720 to $3,510 per QALY. The variable with the greatest impact on the ICER result was the probability of a patient achieving symptom resolution. The number of nonprescription medicines supplied had the second greatest impact on ICER results. The impact was almost null when the parameters of pharmacist wage, training costs, duration of consultation and reconsultation costs were changed. One-way SA results are tabulated in Supplementary File 4. The results of the multi-way SA are found in Supplementary File 5.

Probabilistic SA

The results of 5,000 simulations are presented in a cost effectiveness plane (Figure 3). Each point represents one ICER when model parameters take random values from specified probability distributions. The ICER ranged from AUD -$1,150 to $5,780 per QALY, primarily in the north east quadrant of the plane (higher costs with higher QALYs). The probability of MAS being cost-effective for a range of willingness-to-pay thresholds is presented in Figure 4. The curve shows that the service has a probability of being cost-effective ranging from 9% at a willingness to pay of AUD $1,000/QALY to 100% at a willingness to pay of AUD $6,000/QALY, compared with UC. The probability that the intervention was cost-effective at the recommended threshold of AUD $28,033 per QALY was 100%.

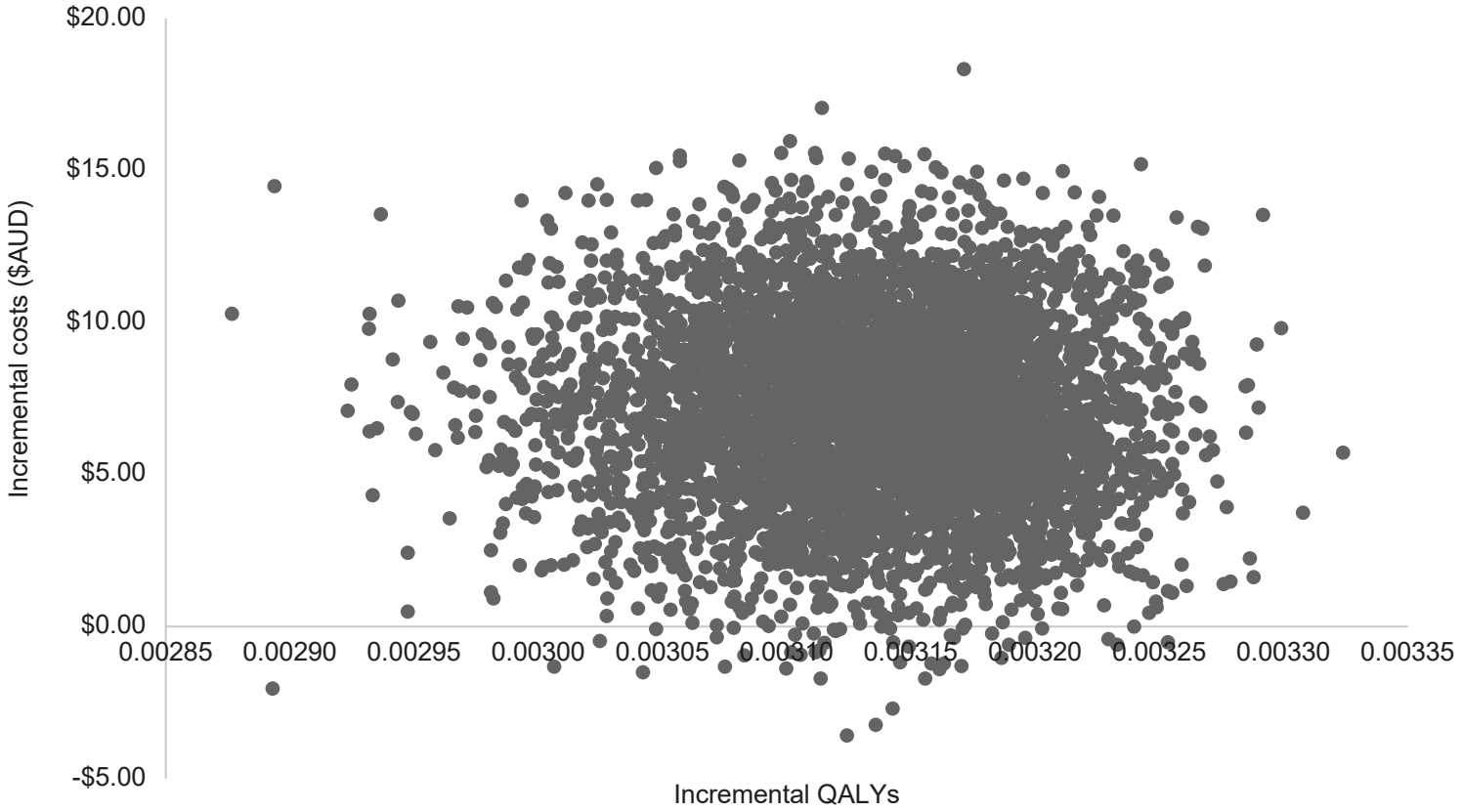
Figure 2 ICER tornado diagram for multiple one-way SA



Legend: Grey: indicates a lower value for each variable was applied. Black: indicates a higher value for each variable was applied.

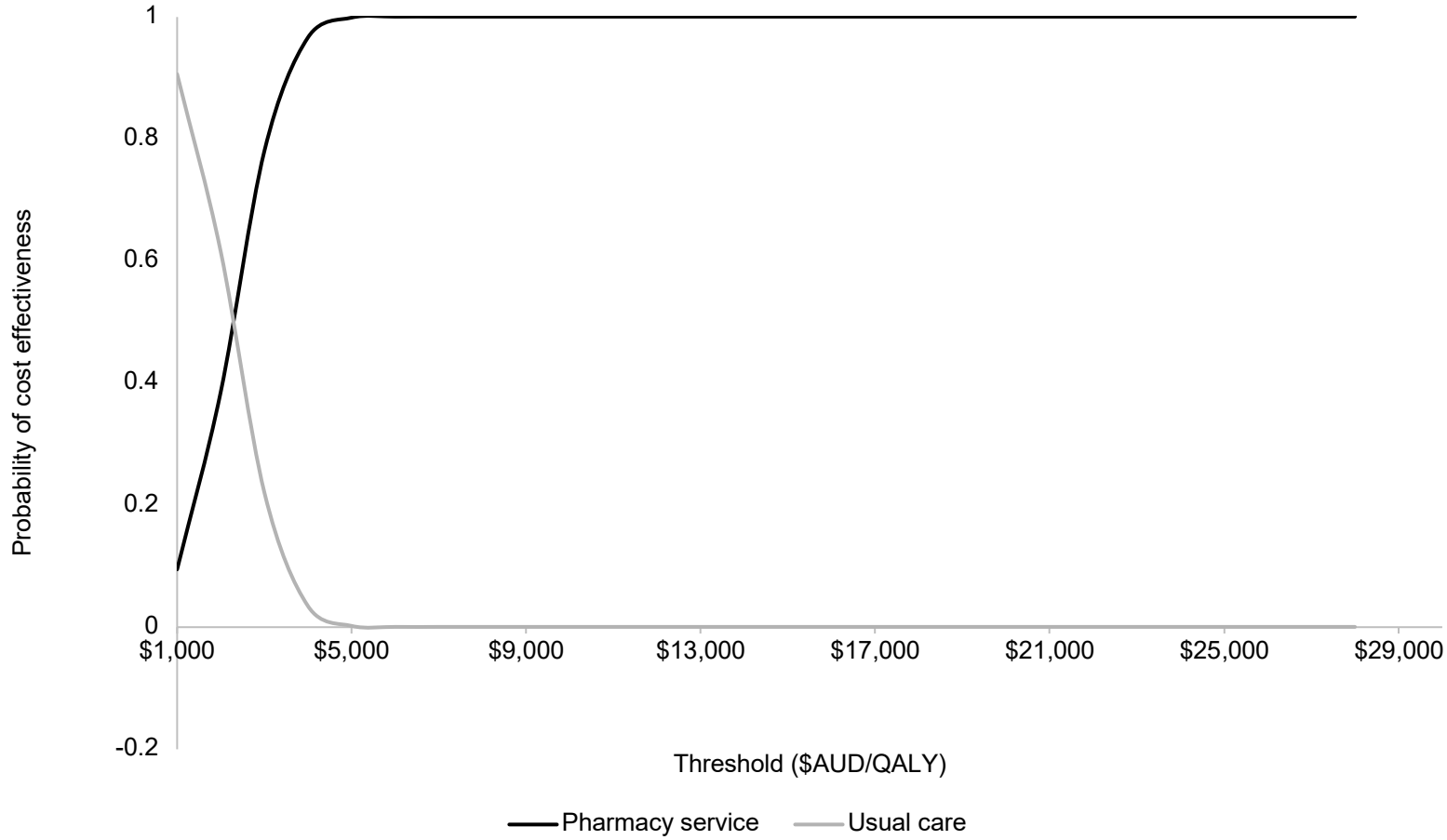
Abbreviations: AppPC: appropriate pharmacist care meeting agreed protocols; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; MAS: Minor ailment service; No_AppPC: pharmacist care outside agreed protocols; NPM: nonprescription medicine; QALY: Quality adjusted life year; R: referral; SA: sensitivity analysis; SC: selfcare advice; UC: usual pharmacist care.

Figure 3 Cost effectiveness plane for MAS over UC



Abbreviations: AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; MAS: Minor ailment service; QALY: Quality adjusted life year; UC: usual pharmacist care.

Figure 4 Cost effectiveness acceptability curve showing the probability of MAS being cost-effective at different willingness-to-pay thresholds



Abbreviations: AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; QALY: Quality adjusted life year.

Cost effectiveness analysis

For the effect measure of appropriate pharmacist care, the service resulted in an incremental score of 0.191 additional patients receiving appropriate pharmacist care, relative to UC, and an ICER of AUD $37.42 (Table 6). For the effect measure of symptom resolution, the service resulted in an incremental score of 0.012 additional patients achieving symptom resolution, relative to UC, and an ICER of AUD $586.88.

Table 6 Results of the CEA

	Mean cost per patient (AUD)	Total outcome	Inc. cost (AUD)	Inc. Outcome	ICER (AUD/outcome)
Outcome = appropriate pharmacist care (care meeting pre-agreed treatment pathways)					
UC	$19.75	0.676			
MAS	$26.88	0.866	$7.14	0.191	$37.42
Outcome = symptom resolution					
UC	$19.75	0.738			
MAS	$26.88	0.750	$7.14	0.012	$586.88

Abbreviations: AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; MAS: Minor ailment service; UC: usual pharmacist care.

Discussion

We report details of a CUA and CEA of pharmacy service (MAS) from a societal perspective. The uncertainty in model parameters was addressed by conducting a series of sensitivity analyses. The results of the CUA show slightly higher costs and higher QALYs with the service (ICER of AUD $2,277 per QALY). The service demonstrated clinical effectiveness when compared to current practice [35, 36]. Based on the reference threshold of AUD $28,033, findings suggest implementation of MAS in Australia is a value for money intervention. According to an international survey on cost effectiveness thresholds, AUD $64,000/QALY has also been proposed in Australia [50]. Previous decisions by the Pharmaceutical Benefits Advisory Committee to recommend a drug for reimbursement is associated with ICERs less than AUD $30,000/QALY [51]. Our results should be interpreted within the appropriate context compared to ICERs from previous studies of health services that were accepted (or not) at clinical and policy levels within the Australian setting [52].

Implications for practice

International literature suggests the implementation of MASs may lead to more efficient use of GP and ED services and health care spending. Australian healthcare expenditure was AUD $170 billion in 2016-17 [54]. Presentations to EDs are increasing on average by 2.7 percent per annum [55] with AUD $533 being the average cost of a non-admitted visit [56]. Thirty-seven percent (2.9 million) of all ED presentations in 2017-18 were for lower urgency care presentation types [57]. Similarly, increased

health spending is a result of gradual increases in GP services. There are 381,000 GP consultations made on average each day in Australia [58]. With the increase in GP services there has also been an increase in MBS expenditure. In 2016-17, 148 million GP services were provided to Australian's costing the health system approximately AUD $7.4 billion [56]. It has been estimated between 7 and 21 percent of all GP services nationally are partly or totally spent on minor ailments [59] including conditions such as acute upper respiratory tract infections, diarrhoea, low back pain, cough, headache and constipation [59].

Strengths and limitations

The majority of patients were followed up (82%) in the cRCT increasing the generalizability of results in this economic evaluation. There are some limitations to our study. While the decision tree model is a step forward in mapping minor ailment interactions, it is a simplification of reality and is subject to the trade-offs between data availability and assumptions made in constructing the model. We treated our study population as a full cohort and assumed patients lost to follow up behave similarly (ie. similar probability of adhering to referral advice or reconsulting within 14 days) and their health status resolves (ie. similar probability of achieving symptom resolution) in similarly to patients followed up. While we saw a positive effect on symptom resolution rates with MAS, the differences in symptom resolution were small compared with UC. A minor ailment is a self-limiting condition and implicitly involves symptom resolution regardless of pharmacist intervention. Given symptom resolution probabilities were incorporated into our economic model, this impacts the results of our economic evaluation.

Utility values were not available from our cRCT study data. We relied on utility values obtained from the 2015 prospective cohort study (MINA study) conducted across two geographic regions (East Anglia, England and Grampian, Scotland) by Watson et al [24] for estimation of QALYs in this evaluation. The transferability of utility scores between jurisdictions remains unclear and the utility weights may not represent Australian preferences. A review by Knies et al. [60] discusses the international transferability of utilities derived from EQ-5D questionnaires. The authors found differences between national EQ-5D value sets and discourages the application of utilities from other countries [60]. The MINA study did not evaluate MAS per se - it compared the management of similar ailments across health settings (community pharmacy, GP and ED). The evaluation examined multiple conditions including musculoskeletal aches and pains, eye discomfort, nausea, vomiting, diarrhoea, constipation, sore throat, cough, cold and sinus. It was assumed that the QALY gain for these conditions was equal to the QALY gain for all minor ailments as applied in our analysis.

We attempted to improve the transferability of results to wider Australia using nationally reported unit costs, and accounted for variation through SA. Local variation in practice, for example referral rates to general practice, can greatly influence the cost of providing MAS. Analysis of data from other trial sites would help address these limitations. Further refinement of the decision tree model and confirming transition probabilities in future evaluations would be useful to validate economic findings in this study.

Conclusion

We provide economic evidence, consisting of a CUA and CEA, alongside a cRCT evaluating MAS in international literature. There is significant potential to amplify self-care and self-medication in Australia. With national implementation in the Australian healthcare system there is potential for system efficiency gains, demonstrated through systematically delivering care that is optimally cost efficient and clinically effective at the appropriate level. The implicit assumption is that patients consulting GPs or EDs could be transferred, where appropriate, to the pharmacy setting with the aim of fully utilising primary health locations and professionals in Australia. Expanding community pharmacists' scope through training, as seen in the UK and Canada, for other clinical areas such as minor wounds or minor burns etc. or prescribing of certain prescription medicines within a collaborative model for certain conditions will likely add further economic benefits. While our findings are likely to have applicability to other healthcare systems, we also know that context is important in these types of analyses and hence as other countries consider implementing MASs, researchers should conduct their own evaluations to account for differences in health systems.

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Chapter 8: Overall discussion, conclusions and recommendations

Overall research discussion

Research summary

This chapter discusses the findings from the research work undertaken for this thesis. It focuses on describing how the research addressed objectives, and discusses the contributions it makes to existing knowledge in community pharmacy and the wider literature. First, a summary of the overall work is provided followed by a reflection on its methodological strengths and limitations. The findings and implications for practice are discussed in context of existing policy and research. This then leads to a discussion of key areas and recommendations for practice, policy and further research.

A systematic review was undertaken at the beginning of the PhD as part of a wider review and mapped published literature to understand the concepts of self-care and self-management in community pharmacy (1). Insights from the review suggested a dearth of published evidence relating to 'self-management support' within community pharmacy literature. In contrast, the role of other primary health professionals and teams are explored extensively in literature, particularly in medicine and nursing fields. The review showed that there is a body of literature describing the different components and aspects of self-management, however there appears to be no widely accepted frameworks incorporating the key elements of self-management support which facilitate improvement in outcomes. The findings from the review led to the development of a theoretical framework, which may be applied to practice. The model consists of a one-on-one consultation with tailored strategies such improving a patient's disease knowledge, monitoring of symptoms, self-treatment through use of an action plan, coping or stress management and enhancing responsibility in medication adherence or lifestyle.

While self-management support is an emerging concept in literature, it was found that community pharmacy is yet to be fully engaged in adopting these principles into usual practice. Most of the published literature uses the terminology of 'self-care' or 'self-care support' in pharmacy, focusing primarily on the management of minor ailments through provision of information and advice and/or treatment with non-prescription medicines (30, 41, 115, 116). While existing community pharmacy services embed aspects of self-management, there is opportunity for pharmacists to deliver 'self-management support' as a holistic and patient-centered concept in community pharmacy.

Chapter 2 provides an overview of the literature detailing the role of the community pharmacist in self-care and MASs, highlighting gaps and opportunities in practice providing the premise for undertaking the research in the Australian setting. The research work employed a mixed methods design consisting of qualitative and quantitative methods. Mixed methods were considered the appropriate approach since both qualitative and quantitative data were required in the various studies within Work Streams. Qualitative methods were employed in Work Stream one ("co-design") and two (pharmacists' interviews

during “pilot study”). These informed the quantitative methods employed in Work Stream three (“impact study”). Each of the work streams had specific aims and objectives that contributed to addressing the overall aim and objectives of the PhD work. The summary of the main findings from work streams are synthesized and summarized in the context of existing literature. The discussion is provided under the following broad sub-sections:

Co-design

The research[7] summarizes a participatory co-design process resulting in the development of a MAS model for the community pharmacy service aimed at increasing self-care for minor ailments in the Australian setting. The co-design process was used as it sequentially engaged (1) a group of stakeholders, including potential service users, to work collaboratively and generate a preliminary model of the MAS service, (2) GPs, for the development and agreement on treatment pathways following a literature review of international and national clinical guidelines, and (3) a group of community pharmacists delivering the service during feasibility testing. An initial analysis of implementation factors (barriers and facilitators) through direct observation of the service being delivered, completing facilitator checklists and interviewing service providers (semi-structured interviews) was conducted. The developed model met the principle of integration of self-care in primary health care unlike current Australian practice. It allowed the pharmacist, GP and patient to share information providing the potential for higher quality and safer service. As the model was mutually agreed with stakeholders, there is a higher probability of it being adopted in practice.

The qualitative data gathered during each phase revealed the approach as an effective means of ascertaining the needs of stakeholders. Nine stakeholders were involved in the initial focus group interview. Thematic analysis identified five components to the MAS model, including: (1) In-pharmacy consultation, (2) evidence-based treatment pathways (*HealthPathways*), (3) communication systems agreed between pharmacy and general practice settings (*HealthLink*), (4) educational training, and (5) practice change support. The service model offers pharmacists a consistent framework to operate within, through pre-agreed *HealthPathways*, to differentially diagnose and manage a patient. The systematization and standardization of clinical decision making and referrals was achieved through the developed protocols, expertise and collaborative agreement with other service providers. The input of both pharmacists and GPs into the co-design process was important for understanding practical application of the service and understanding existing systems which would allow pharmacists to better integrate with GPs.

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[7] This is a summary of the discussion taken from a report as first author:
Citation: Dineen-Griffin, S., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. An Australian Minor Ailments Scheme: Evaluation of a collaborative protocolized approach by community pharmacies and general medical practitioners; 2019. ISBN-13: 978-0-646-80883-3. https://www.uts.edu.au/sites/default/files/2019-11/Full%20Report%20%28wl%29.pdf

Nine semi-structured interviews were conducted with community pharmacists delivering MAS in Work Stream two ("pilot study"). Nineteen implementation factors were identified. Implementation factors were interpreted as elements that positively (ie. facilitators) or negatively (ie. barriers) influence service delivery. In synthesizing and organizing factors affecting service delivery during pilot testing, we aimed to optimize implementation in the Australian context. The main facilitators were the agreed pathways, interprofessional collaboration, external support and training. Barriers, such as time and patient acceptability were also identified. Remuneration for MAS provision was described as essential for future service delivery and implementation. The need for remuneration is a theme represented internationally with continual calls being made to ensure that pharmacists are paid for providing clinical services to patients (117-119). Previous theory and research on barriers and facilitators to pharmacy service implementation (120, 121) may assist in this regard. Similarly, additional work is necessary to identify and precisely define implementation strategies (122, 123). Successful implementation involves ongoing adaption and continual refinement of the MAS model to a changing context and feedback processes for implementation and sustainability (124).

Impact study

Work Stream three ("impact study") evaluated the clinical, humanistic and economic effectiveness of MAS for symptom-based and product-based presentation types for patients with minor ailments in Australian community pharmacies. The study used a community pharmacy cRCT design. The evidence demonstrated improved clinical and humanistic outcomes as a result of MAS compared to current practice. Variability in referral rate between groups may have been due to pharmacists in the UC group not having a standard approach to assessment and management, training or practice support. When compared to current practice, MAS group pharmacists were referring four times as many patients to other parts of the health care system when using the clinically agreed pathways. Patients receiving MAS were five times more likely to follow through with referral, compared to current practice. Findings of the economic evaluation suggest that implementation within the Australian context is cost effective. This is the first cost utility analysis in international literature evaluating the impact of MAS in the community pharmacy setting.

The types of outcomes, methods of assessment and conditions considered as minor ailments in literature represent a challenge for comparison of results and data interpretation (63). Currently, there is no gold standard with regard to the type of outcomes and the method of assessment for interventions targeting minor ailment management and is an area for future research (63).

Methodological reflections and limitations

The strengths and limitations relating to the individual Work Streams have already been discussed in the relevant chapters. Multiple methodologies were employed. Mixed methods research has gained increasing popularity and applications in social and health science research as it increases the overall strength of a study by capitalizing on the strengths and minimizing the weaknesses of both qualitative and quantitative methods (125-127). A pragmatic approach taken in this research aimed to use qualitative methods to uncover perspectives of stakeholders to the service, and use quantitative methods to deductively expand, triangulate and generalize the findings (128).

Co-design

The qualitative participatory methodologies employed allowed an exploration of the perspectives of participants, providing considerable breadth and richness to data (62, 129-133). Participatory research challenges traditional understanding of health development and places end-user value at its heart, with implementation and broader dissemination strategies as part of its design from gestation (134-136). An overarching strength of this qualitative work was that perspectives of GPs were included and provided an understanding of how MAS could be contextualized within the Australian health context to promote further integration. A second strength was the inclusion of the 'patient voice' in the focus group interview adding to the 'completeness' of the research. One-to-one interviewing with community pharmacists provided the platform to obtain personalized views rather than broad and generalizable perspectives (137). Facilitator observations and completing implementation checklists proved very useful in collecting data with the advantage of providing an understanding of the actions and interactions that occur in practice (138).

The method of analysis was the qualitative approach of thematic analysis (139). The conceptual framework of the thematic analysis was mainly built upon the theoretical positions of Braun and Clarke (140). According to them, thematic analysis is a method used for 'identifying, analysing, and reporting patterns (themes) within data' (140).This type of analysis has been found to be a useful analytical technique to interpret qualitative data in health services research, and is a flexible technique that can be used with inductive and deductive approaches (139, 141, 142). A deductive approach was considered appropriate, as we started with preconceived codes derived from prior international literature (141) to develop a conceptual code structure for preliminary sorting of the data following the process of thematic analysis. To organise the analyzed qualitative data, the JeMa2 model to conceptualize pharmacy-based services by Sabater-Hernández et al was applied (143). The pharmacy-oriented model shows pharmacist service providers as core environmental agents who affect health by promoting changes in patients' behaviours (in this case, the ability to self-care) to improve health outcomes (143). The model hypothesizes the relationships between pharmacy services and the context

in which services are to be implemented and envisages the factors that influence the implementation of the service in practice (143).

Impact study

The quantitative method of the research was informed by findings of the qualitative studies. Work Stream Three ("impact study", see Chapters 5-7) used a community-pharmacy based cRCT study design to address specific objectives. RCTs are considered the gold standard for effectiveness research (144). The act of randomization balances participant characteristics between groups allowing attribution of any differences in outcome to the study intervention (in this case, MAS) (144). There is lessened risk of experimental contamination as randomization eliminates much of the bias inherent with other study designs (144, 145). Given the clustered study design, however, pharmacists awareness of allocation may have led to biased recruitment (146). The Hawthorne effect may also influence research pharmacists', that is, the consequent effect of being observed or awareness of being studied, which can potentially impact behavior (146). Procedures were put in place to minimize the impact and to ensure rigor. For example, the data analyst was blinded to allocation status and groups were renamed "1" and "2" by researchers prior to statistical analysis.

CUA is the most sophisticated pharmacoeconomic analysis in that it considers the improvement in quality of life conferred by an intervention for resources expended (147). CUA, however, has its own limitations. A methodological controversy is the utility concept (148). Health effects are commonly expressed in QALYs gained. Although QALYs are a step forward, their use is not straightforward. The different methods available to estimate QALYs may also not provide identical results (149). Apart from the methodological inconsistencies, the interpretation of results of economic evaluations can also be troublesome (148). Partly, this is because of the aggregated nature of the outcome of a CUA. All economic and health aspects of interventions are comprised into one single ratio, the ICER (148).

Implications for policy and practice

This research was conceived and undertaken at a time of significant changes to the healthcare landscape in Australia (150). The Australian health system is faced with challenges of improving accessibility and quality of care for patients in the face of constrained funding and is exploring better models of care (150). Policy makers, at governmental and organizational levels, are increasingly interested in cost-effective, evidence-based, patient-centered services. The drivers of this interest are equally to save the health system money, improve patient outcomes and quality use of medicines. The Australian Government, in 2019, announced the development of a Primary Care 10-Year Plan (151). The plan aims to guide future primary health care reform to be more person-centred, integrated, efficient and equitable (151). Self-care and self-management are inseparable from the provision of high-quality primary health care.

Australian primary care will need to undergo reforms that incentivise community pharmacists to deliver self-care and self-management effectively, with clear responsibilities for contributing to the overall health outcomes of patients. There are already international models of care in community pharmacy that attempt to address these challenges. Scotland, for example, uses a capitation model of remuneration and provides pharmacists with the opportunity to take responsibility for the care of individual patients that register with their pharmacy (62, 64, 65). While there are ongoing debates as to the most efficient and effective ways of repositioning healthcare resources towards providing self-care and self-management support, an area of agreement is that the perspectives of patients are an underutilized resource. Patients should be incorporated into the development of any community pharmacy service.

The scope of pharmacy practice remains heavily focused on medicines dispensing and provision. This is despite pharmaceutical care and service delivery being seen as the future of community pharmacy for more than two decades. Pharmaceutical care, defined as the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (152), has played a part in extending the role of community pharmacy from predominantly dispensing of medicines to more patient-facing. The majority of community pharmacy services and interventions have also been underpinned by the philosophy of pharmaceutical care (152). While the philosophical foundations of pharmaceutical care advocates 'patient-centred' care, the definition which focuses on 'responsible provision of drug therapy' reflects a medicines-focused approach to patient care. The language, terminology and nomenclature used in some services and interventions underpinned by pharmaceutical care in community pharmacy, such as 'medication review', reflect a narrow focus on medicines. While it could be argued that pharmacy's traditional tenets around medicines is what makes community pharmacy practice different from other professions, it may also be argued that this is responsible for the lack of integration of community pharmacy into the wider multidisciplinary team. In order to be more widely accepted as a profession that is positioned to improve patient's overall health; its expertise on the use of medicines should be one of its many roles and responsibilities. Nomenclature in community pharmacy could reflect a holistic 'patient centered' approach to care by using terminologies such as self-care or self-management. This may have the benefit of aligning community pharmacy with other healthcare fields that are already adopting similar nomenclature to describe their services and interventions. There are some deficiencies in the way that current services are delivered. For example, didactic counselling practices provide little opportunity for pharmacists to explore and engage patients in identifying and resolving both medicines and non-medicines related issues. Similarly, lifestyle services such as smoking cessation and weight management interventions are generally provided as isolated interventions rather than as a holistic package designed to meet the individual needs of patients. Self-care and self-management support could be undertaken via a comprehensive package of care that focuses on involving community pharmacy in the ongoing management of individual patients, rather than the provision of one-off services and interventions.

The research presented in this thesis provides merit in implementing MAS in Australia. In addition, the development of an implementation program should be considered with the intention of scaling up nationally. A national Spanish study developed an implementation program for their medication review with follow-up service (153). The implementation study used a hybrid effectiveness design (153). Implementation strategies included stakeholder meetings, training of pharmacist owners and service providers, facilitation visits and assignment of an internal pharmacy champion to 'champion' implementation efforts as implementation progresses. The facilitators and champions role included analysing barriers and facilitators and tailoring strategies to overcome or utilize these. Implementation outcomes included the movement of pharmacies through implementation stages, service benefits, reach, fidelity and integration (153).

The extent of transferability of findings is dependent on the contextual environment surrounding design and implementation. A methodological consideration is the urban Australian community pharmacy setting this study was conducted. Future Australian studies to confirm or enhance implementation of MAS in other contexts would be beneficial. Future research efforts should also continue to consider the views of stakeholders, barriers and facilitators to service implementation and the improvements that could be made to the service model for successful implementation. Further insights into the perspectives of GPs will be important for change in policy and practice. Future work may also be undertaken to explore the perspectives of pharmacy team members, who have frequent contacts and interactions with patients. Lastly, it is important to understand the impact of co-design methodology on service outcomes (ie. measure improvements in patient experience and clinical outcomes).

Conclusion and recommendations

Community pharmacy is an integral part of the Australian primary health system and is effectively positioned to support self-care and self-management. This program of work resulted in both the development of a theoretical model to deliver self-management, and a community pharmacist delivered MAS model applicable to Australian healthcare. Testing of the service revealed clinical, humanistic and economic evidence in support of MAS implementation.

The recommendations from this program of work highlight the need for reforms and an evolution in how community pharmacy is currently structured to deliver care. Consideration should be given for the policy and legislative changes to promote and develop self-care. There should be a strong focus on upskilling community pharmacists to deliver MAS. Funding alignment will also be a major determinant for future sustainability.

A number of recommendations are presented for consideration by federal and state policy makers, primary care organizations, professional organizations, industry and practitioners:

Recommendation 1. Implement a national MAS in Australia

An important consideration for the government is how to enhance community pharmacy's role in supporting self-care and self-management, as part of a more integrated model. Patients seeking care from EDs for conditions, such as coughs and colds, are an inefficient use of resources. Similarly, increased healthcare spending in Australia is also a result of the gradual increase in GP services. It is estimated that 7 to 21.2 percent of all GP consultations and 2.9 to 11.5 percent of all ED services in Australia could be transferred to a community pharmacy as part of a national service (32, 65, 154-156). Building on the accessibility of community pharmacies in primary health care, it could be promoted that instead of going to ED or GPs, patients can visit their community pharmacist. The findings from this research reveal MAS as a cost effective alternative and demonstrate the potential clinical and economic impact if nationally implemented. With national implementation, there is huge potential for system efficiency gains, demonstrated through systematically delivering care at the appropriate level. Conceptually, the MAS model provides a framework for national roll out. Training, technology infrastructure, and agreed protocols have already been established.

Recommendation 1: Consideration should be given for community pharmacies nationwide to adopt and implement MAS.

Recommendation 2. Implement a national self-care strategy in Australia

There is significant potential to amplify self-care and self-medication in Australia. A crucial step is to strategically align the Australian health system so that responsibility for self-care is integral to the health system. A national strategy for self-care and a national lead are needed to provide leadership and coordinate work across primary and secondary care sectors for significant progress to be made. Implementation of policy in Australia should seek to promote self-care and self-medication capabilities, change the culture of dependency on more costly parts of the health system, and potentially allow the economic and professional practice resources to shift to practices with a preventative ethos. The Department of Health should ensure that, where appropriate, more medicines are made available without prescription to support more people to self-care.

Recommendation 2: The federal government in consultation with stakeholders develop a self-care policy within its national health policy.

Recommendation 3. Establish a funding model to reflect the quality, time and complexity of community pharmacist care

Resources need to be provided at a national level to ensure self-care is embedded across the Australian health system. Pertinent to a national MAS system in Australia is funding and having a legal and regulatory framework in place establishing the current and potential contribution community pharmacy can make as part of an integrated system. Remuneration needs to reflect quality and value and incentivise pharmacists to focus on care which is of higher value and impact to the health system. This may mean revising remuneration models for pharmacist interventions (ie. recognise higher significance interventions and quality recording), in addition to models of remuneration such as fee-for-service, or practice allowance. Funding should include time spent educating patients to self-care. Incentives to engage in health provider collaboration should also be considered. What is clear, is that a remuneration model should have the objective of achieving patient accessibility as well as supporting integration of community pharmacists into primary care.

National funding mechanisms include federal, state or territory governments and local PHNs who have shared responsibility for health governance in Australia. Federal government funding may fund MAS by inclusion in the 7th Community Pharmacy Agreement or as an MBS item (157). For example, a pharmacist consultation payment similar to GP MBS Item 3 would be a suitable fit, which provides a fee of $17.45 (Australian dollars) per GP consultation for patients presenting with 'an obvious problem characterised by a short patient history and limited examination and management if required' (158). Pharmacists services could be funded by PHNs which have the objectives of increasing the efficiency and effectiveness of services for patients at the local level. Alternatively, state and territory governments, primarily responsible for public hospitals may fund MAS with the specific objective of alleviating ED and hospital presentations for certain low-acuity conditions. Funding options may include a fee for consultation with or without reimbursement for the cost of the medicine for the patient, banded capitation fees, one off payments, or retainer fees. Medicine costs could be paid for by individuals as an out-of-pocket expense or by the health care system for specific patient classes. Importantly, there is a need to consider the patients that could access the service (ie. all Australians, within certain PHNs, special demographic or population groups (disadvantaged, elderly, children etc)).

Recommendation 3: A funding model be negotiated between federal and/or state governments with PSA and the Pharmacy Guild of Australia.

Recommendation 4. Promote a systems wide approach to further promote quality use of nonprescription medicines in Australia

Consideration should be placed on taking a systems wide approach toward national quality use of medicines. This would require the development of supportive infrastructure and alignment of resources, training and introducing agreed tools to support quality use of medicines. The MAS standardized consultation is a means to improve quality and safety in the health system. There is need for national reporting of community pharmacists' interventions. The documentation systems with MAS provide a needed framework for community pharmacists to actually document their clinical interventions for nonprescription medicines. National reporting would allow measurement of the contribution and impact of the community pharmacist. Simplified adverse event reporting processes would also support the safe and quality use of nonprescription medicines.

Recommendation 4: A systems wide approach, at a policy level, should be promoted toward quality use of nonprescription medicines in Australia.

Recommendation 5. National public awareness campaign

A public awareness campaign directed predominantly at potential and actual service users could be developed and funded by federal and state governments to encourage the use of community pharmacy as a site for minor ailment intervention. PHNs, in conjunction with relevant stakeholders including pharmacy organizations, can select and promote the types of conditions that are appropriate to be managed under MAS. Marketing campaigns may target specific populations and demographic groups. Similar strategies have been applied in the UK under the "Stay Well" pharmacy campaign to use the community pharmacy for advice and treatment for self-treatable conditions (159). The 3-month campaign targeted parents and carers of children under 5 years of age and patients over 65 years of age in winter. As a result, an additional 1.6 million visits were made to pharmacy and 13,500 less patients presented to ED in 2018 (159). A second wave of the campaign encouraged the use of community pharmacy as a source of advice and treatment for winter ailments, helping reduce GP and ED demand (160). Following on from the successful campaign, NHS England launched a promotional campaign in 2019 'Help Us Help You' (161).

Recommendation 5: A public awareness campaign should be instigated to inform consumers seeking care for minor ailments to do so at the appropriate level of care.

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Appendices

List of abbreviations

A&E	Accident and emergency
ACT	Asthma control test
ADDQOL	Audit of diabetes dependent quality of life
AGREEII	Appraisal of guidelines for research and evaluation version II
AIHW	Australian institute of health and welfare
AIMS2-SF	Arthritis impact measurement scales short form questionnaire
AMAS	Australian minor ailments scheme
ANZCTR	Australian New Zealand clinical trials registry
APPPC	Appropriate pharmacist care meeting agreed protocols
AQLQ	Asthma quality of life questionnaire
ATs	Area teams
AUD	Australian dollars
BCKQ	Bristol COPD knowledge questionnaire
BDI	Beck depression inventory
CAD	Canadian dollars
CBT	Cognitive behavioral therapy
CCGs	Clinical commissioning groups
CCQ	Clinical COPD questionnaire
CEA	Cost effectiveness analysis
CHEERS	Consolidated health economic evaluation reporting standards
CHF	Chronic heart failure
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
COREQ	Consolidated criteria for reporting qualitative studies
CPCS	Community pharmacy consultation service
CPS	Community Pharmacy Scotland
cRCT	Cluster randomized controlled trial
CSES	COPD self-efficacy scale
CUA	Cost utility analysis
CVD	Cardiovascular disease
DMSE	Diabetes management self-efficacy scale
DSES	Depression self-efficacy scale
ED	Emergency department
EDE-Q	Eating disorder examination questionnaire
EPOC	Effective practice and organization of care group
EQ-VAS	EuroQoL EQ-5D visual analogue scale
GEE	Generalized estimating equation
GPs	General practitioners
GSES-12	General self-efficacy scale
GSH	Graduate School of Health
HAMD	Hamilton rating scale for depression
HCPs	Health care professionals
HEW	Higher education worker
HREC	Human research ethics committee
HRQOL	Health-related quality of life
HT	Hypertension
IBD	Irritable bowel disease
IBS	Irritable bowel syndrome
IBSQOL	Irritable bowel syndrome quality of life questionnaire
ICER	Incremental cost effectiveness ratio
IG	Intervention group
IPAQ-SF	International physical activity questionnaire short form
ITT	Intention to treat
MAS	Minor ailment service

MBS	Medicare Benefits Schedule
MICE	Multiple imputation by chained equations
NOAPPPC	Pharmacist care outside agreed protocols
NONSR	No symptom resolution
NPM	Nonprescription medicine
NSAIDs	Non-steroidal anti-inflammatory drugs
NZ	New Zealand
OA	Osteoarthritis
OR	Odds ratio
PACE	Physician-based assessment and counselling for physical activity questionnaire
PAID	Problem areas in diabetes scale
PAM	Patient activation measure
PBS	Pharmaceutical Benefits Scheme
PCF	Practice change facilitator
PD	Participatory design
PEF	Peak expiratory flow
PEI	Patient enablement instrument
PGDs	Patient group directions
PH	Pharmacy
PHN	Primary health network
PPIs	Proton pump inhibitors
PPMA	Pharmacists prescribing for minor ailments
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
QALY	Quality adjusted life year
QOL	Quality of life
R	Referral
RAPA	Rapid assessment of physical activity questionnaire
RCT	Randomized controlled trial
REDCap	Research electronic data capture
RR	Relative rate
SA	Sensitivity analysis
SC	Self-care
SCNPM	Self-care plus nonprescription medicine
SCNPMR	Self-care plus nonprescription medicine plus referral
SCR	Self-care plus referral
SDSCA	Summary of diabetes self-care activities questionnaire
SGRQ	St. George’s respiratory questionnaire
SMS	Self-management support
SR	Symtom resolution
T2DM	Type 2 diabetes mellitus
TGA	Therapeutic Goods Administration
UC	Usual pharmacist care
UG	Usual care group
UK	United Kingdom
US	United States
UTS	University of Technology Sydney
VAS	Visual analogue scale
WHO	World Health Organization

Author's contributions

Paper 1:
Dineen-Griffin, S., Garcia-Cardenas, V., Williams, K. A. & Benrimoj, S. I. Helping patients help themselves: a systematic review of self-management support in primary health care. PloS one. 2019;14(8): e0220116.

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Paper 2:
Dineen-Griffin, S., Benrimoj, S. I., Williams, K. A. & Garcia-Cardenas, V. Co-design of a minor ailment service: Involving service users and healthcare professionals. Research in Social and Administrative Pharmacy. 2020

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Paper 3:
Dineen-Griffin, S., Garcia-Cardenas, V., Rogers, K., Williams, K. A. & Benrimoj, S. I. Evaluation of a collaborative protocolized approach by community pharmacists and general medical practitioners for an Australian Minor Ailments Scheme: Protocol for a cluster randomized controlled trial. JMIR Res Protoc. 2019;8(8): e13973.

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Paper 4:
Dineen-Griffin, S., Benrimoj, S. I., Rogers, K., Williams, K. A. & Garcia-Cardenas, V. A cluster randomized controlled trial evaluating the clinical and humanistic impact of a pharmacist-led minor ailment service. BMJ Quality & Safety. 2020.

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Paper 5:
Dineen-Griffin, S., Williams, K. A., Vargas, C., Benrimoj, S. I., & Garcia-Cardenas, V. Cost utility of a minor ailment service provided in the community pharmacy setting. The European Journal of Health Economics. 2020.

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Checklist 1 Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Checklist

S1 Appendix Search Query

Database	Search query
PubMed	("Self Efficacy"[Mesh] OR "Self Concept"[Mesh] OR "Self Care"[Mesh] OR "Self Efficacy"[Title/Abstract] OR "Self-Management"[Title/Abstract] OR "Self Care" [Title/Abstract] OR "Self Report"[Title/Abstract] OR "Self Medication"[Title/Abstract] OR "Self Concept"[Title/Abstract]) AND ("Primary Health Care"[Mesh] OR "Health Personnel"[Mesh] OR "Collaborative Care"[Title/Abstract] OR "Primary Care"[Title/Abstract] OR "Primary Health Care"[Title/Abstract] OR "Community Care"[Title/Abstract] OR "Primary Medical Care"[Title/Abstract] OR "Community Health Services" [Mesh]) AND ("Cluster Randomised"[Title/Abstract] OR "Controlled Trial"[Title/Abstract] OR "Randomized Controlled Trial"[Title/Abstract] OR "Randomised Controlled Trial"[Title/Abstract] OR "Clinical Trial"[Title/Abstract] OR "Clinical Study"[Title/Abstract] OR "Intervention Study"[Title/Abstract] OR "Randomized"[Title/Abstract] OR "Randomised"[Title/Abstract]) AND ("Patient Education as Topic"[Mesh] OR "Cognitive Therapy"[Mesh] OR "Patient Care Planning"[Mesh] OR "intervention" [Title/Abstract])
Scopus	KEY ("Community Care" OR "Patient Care" OR "Pharmacy" OR "General Practice" OR "Primary Medical Care") AND KEY ("Self Medication" OR "Self Concept" OR "Self Care" OR "Self-Management" OR "Self Report") AND KEY ("Health Program" OR "Patient Education" OR "Health Education" OR "Health program" OR "Health Service" OR "Health Care Management") AND KEY ("Randomized Controlled Trial" OR "Clinical Trial")
Web of Science	TS=("Self Efficacy" OR "Self-Management" OR "Self Care" OR "Self Report" OR "Self Medication" OR "Self Concept") AND TS=("Collaborative Care" OR "Primary Care" OR "Primary Health Care" OR "Community Care" OR "Primary Medical Care") AND TS =("Cluster Randomised" OR "Controlled Trial" OR "Randomized Controlled Trial" OR "Randomised Controlled Trial" OR "Clinical Trial" OR "Clinical Study" OR "Intervention Study" OR "Randomized" OR "Randomised" AND TS=("Patient Education" OR "Cognitive Therapy" OR "Patient Care Planning" OR "Intervention")

S2 Appendix PRISMA 2009 Checklist

Citation: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PloS Med 6(7): e1000097.

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4-6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	7-8
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8-9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	10
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	n/a
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	8-9

Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	11
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	S3 Appendix
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	26
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11-26
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	11-26
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	27
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	27
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	33
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	34-35
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	n/a

S3 Appendix Descriptive Characteristics of Included Studies

Author	Title, year, country	Study design, sample size	Condition	Intervention and control-group description	Healthcare professional	Study follow up (mode, time point)	Outcomes assessed
Adachi et al. (1)	Effects of lifestyle education program for type 2 diabetes patients in clinics: a cluster randomized controlled trial 2013, Japan	c-RCT 20 practices 193 participants (IG: 100; CG: 93)	Type 2 diabetes (T2DM)	IG: The intervention group received structured individual-based lifestyle education that encouraged the reduction in energy intake at dinner and an increase in vegetable intake at breakfast and lunch. Support for self-management of glycaemic control, such as by diet, exercise, and stress management, was provided in 3 or 4 sessions with trained registered dieticians during the study period. The program for the IG was structured in four steps: “Basic information on glycaemic control”, “Actions for glycaemic control”, “Daily activities for glycaemic control”, and “Management of stress for glycaemic control”. An assessment sheet, which was developed by consulting evidence-based practice guidelines for treatment of diabetes in Japan, was used. Patients decided on one or two short-term goals for glycaemic control to be achieved in the next month based on the results of	Dietician	Face-to-face 3 or 4 sessions delivered in 6 months	Clinical outcomes: Change in HbA1c levels Fasting plasma glucose Lipid profile Blood pressure Body mass index Energy Nutrient intakes Humanistic outcomes: NA

				the FFQW82 and advice by registered dieticians. Sedentary participants were encouraged to increase basal physical activity. A gradual increase in physical activity was recommended. CG: Usual care			
Banasiak et al. (2)	Guided self-help for bulimia nervosa in primary care: a randomized controlled trial 2005, Australia	RCT 109 participants (IG: 54; CG: 55)	Bulimia Nervosa	IG: The intervention group received direction and support from a general practitioner (GP) over a 17-week period while working through a manual by Cooper (1995), 'Bulimia Nervosa and Binge-Eating: A Guide to Recovery'. Part 1 presents psychoeducational information about bulimia nervosa and Part 2 presents a six step, sequential, self-treatment program which offers cognitive behavioural strategies and advice to assist patients to overcome their eating problem. Each participant received an initial 30 to 60-minute session with the GP, provided the manual and an outline of guided self-help, treatment rationale and goals and advised to work through the program at their own pace. The GP provided 9 treatment sessions in the course of normal clinical practice lasting 20-30 minutes each. Guidance sessions were weekly for the first 4 weeks, fortnightly for the following 6 weeks and then every	General practitioner	Face-to-face Weekly for the first 4 weeks, fortnightly for the following 6 weeks and then every 3 weeks for the remaining 6 weeks (total 9 sessions)	Clinical outcomes: Frequency over the past 28 days of episodes of: objective binge eating, subjective binge eating, vomiting, laxative, diuretic and enema misuse Body dissatisfaction Body size through direct measurements of weight and height Humanistic outcomes: Psychological functioning General functioning Attitudes towards treatment

				3 weeks for the remaining 6 weeks. Each session followed the general format (1) assessing and monitoring progress by reviewing homework (2) discussing and resolving identified difficulties (3) jointly setting homework. CG: Delayed treatment control			
Barbanel et al. (3)	Can a self-management program delivered by a community pharmacist improve asthma control? A randomized trial 2003, UK	RCT 24 participants (IG: 12; CG: 12)	Asthma	IG: Participants received a review of their inhaler technique and personal education from the pharmacist addressing the following topics: basic pathophysiology of asthma; recognition and avoidance of triggers; inhaler technique; self-management skills including monitoring of peak flow or symptoms; action in response to worsening symptoms; how to access emergency care appropriately; smoking cessation if relevant. Participants also received written personalized credit card self-management plans and educational leaflets. Self-management decision-making was based on peak expiratory flow readings if the participant could use and interpret readings from a peak flow meter; otherwise advice was based on symptoms. For self-management plans, the instructions were for patients to: 1. Double their inhaled	Pharmacist	Telephone Weekly for 12 weeks	Clinical outcomes: Asthma symptoms (using the North of England asthma symptoms scale)

				corticosteroid dose if their peak expiratory flow rate (PEFR) was 70-80% of best or they were waking at night with symptoms 2. Contact their doctor to arrange a course of oral corticosteroid treatment if their PEFR was 50-70% or breathlessness was increasing 3. Call their doctor urgently if their PEFR was below 50% of best or symptoms continued to worsen. CG: Usual care			
Barley et al. (4)	The UPBEAT nurse-delivered personalized care intervention for people with coronary heart disease who report current chest pain and depression: a randomized controlled pilot study 2014, UK	RCT 81 participants (IG: 41; CG: 40)	Coronary Heart Disease Chest pain & Depression	IG: A nurse conducted a standardized, face-to-face, bio-psychosocial assessment (including physical and mental health, difficulties with current treatment regimens, problems with daily activities and social problems). Patients were helped to identify up to three problems which they consider contribute to their depression and wanted to address. The nurse-case managers provided information, signposted patients to existing resources (e.g. leisure centers, social clubs, Improving Access to Psychological Therapy (IAPT) services) and use evidence-based behaviour change techniques to help patients set and achieve goals. The underlying intention of the intervention was to increase the patient's self-efficacy to achieve	Nurse	Telephone Weekly then variable according to patients need	Clinical outcomes: Mood Chest pain Humanistic outcomes: Functional status Wellbeing and psychological process variables

				desired goals (as opposed to goals determined by others such as symptom management or reduction of cardiac risk factors). Details of the assessment and action plan are recorded in a 'personalized health plan', which the patient held. CG: Treatment as usual			
Bartels et al. (5)	Integrated IMR for Psychiatric and General Medical Illness for Adults Aged 50 or Older with Serious Mental Illness 2014, United States	RCT 71 participants (IG: 36; CG: 35)	Schizophrenia spectrum, bipolar disorder, or major depression PLUS diabetes, chronic obstructive pulmonary disease (COPD), congestive heart failure, ischemic heart disease, hypertension, hyperlipidaemia, or osteoarthritis	IG: The I-IMR program integrated components of conventional IMR related to psychiatric illness self-management with strategies for self-management of general medical illness. The psychiatric component included psychoeducation about illness and treatment, cognitive-behavioural approaches to increase medication adherence, training in relapse prevention, instruction about coping skills to manage persistent symptoms, and social skills training. The general medical illness component consisted of an individually tailored curriculum that applied the same skills and strategies for self-management of psychiatric illness to the self-management of general medical illness. In addition, a nurse health care manager facilitated coordination of necessary preventive and ongoing health care. A primary care nurse was embedded one day per week at	Social worker Nurse	Face-to-face Weekly (social worker) for 8 months Fortnightly (nurse) for 8 months	Clinical outcomes: NA Humanistic outcomes: Self-management of psychiatric and general medical illness

				each mental health centre to coordinate health care appointments, medication adjustments, and transfer of information and to provide counselling on self-management and lifestyle changes for chronic health conditions. Participants met with the nurse health care manager twice per month to discuss progress and obstacles in meeting general medical and mental health goals. CG: Usual care			
Bischoff et al. (6)	Comprehensive self-management and routine monitoring in chronic obstructive pulmonary disease patients in general practice: randomized controlled trial. 2012, The Netherlands	RCT 165 participants (IG (1): 55; IG (2): 55; CG: 55)	COPD	IG: A comprehensive self-management program as an adjunct to usual care, consisting of four tailored sessions with ongoing telephone support by a practice nurse; routine monitoring as an adjunct to usual care, consisting of 2-4 structured consultations a year with a practice nurse; or usual care alone (contacts with the general practitioner at the patients' own initiative). Patients in the self-management group received a translated and modified version of the Canadian self-management program "Living well with COPD." The self-management program consisted of paper modules and a written exacerbation action plan. Topics covered in the modules were COPD disease knowledge,	Nurse	Face-to-face 60 minutes; 2-4 sessions over 4-6 weeks Telephone 6 sessions	Clinical outcomes: Chronic respiratory questionnaire domain scores Frequency and patients' management of exacerbations Humanistic outcomes: Change in COPD specific quality of life (QOL) (Chronic respiratory questionnaire total score) Self-efficacy (COPD self-efficacy scale)

	respiratory drugs, breathing techniques, managing exacerbations, maintaining a healthy lifestyle, managing stress and anxiety (optional), and home exercise (optional). The individualized written exacerbation action plan covered early recognition of and prompt action in the course of an exacerbation. Actions included increase in bronchodilator use; initiation of standing prescriptions for prednisolone, antibiotics (if applicable), or both; or contacting the practice nurse or general practitioner. The practice nurse of each participating practice acted as case manager and applied the program to the individual patient in two to four sessions of approximately one hour each, scheduled in four to six consecutive weeks. The sessions took place in the general practice. The number of sessions depended on the patient's needs, but it was at least two. Subsequently, the nurse called each patient six times during the rest of the study period to reinforce self-management skills. The nurse was available for advice during business hours. Before the study, all nurses were trained in how to apply the self-	

				management program. In addition, all nurses were observed at least once by a respiratory nurse who was a member of the study group and experienced in the self-management program. The respiratory nurse also coached the practice nurses by using a message board on a secured web-based application during the rest of the follow-up. CG: Usual care			
Broderick et al. (7)	Nurse practitioners can effectively deliver pain coping skills training to osteoarthritis patients with chronic pain: A randomized, controlled trial 2014, United States	RCT 256 participants (IG: 129; CG: 127)	Osteoarthritis	IG: Patients in the Pain Coping Skills Training (PCST) treatment condition received 10 sessions of individual PCST, which was designed to promote the use of cognitive-behavioural pain management coping skills. PCST interventions teach patients cognitive and behavioural skills to manage their pain and enhance their perception of pain control. Four broad coping skills were taught across the ten 30- to 45-minute sessions: relaxation response, attention diversion techniques, altering activity and rest patterns as a way of increasing activity level, and reducing negative pain-related thoughts and emotions. The sessions were outlined in detail in a treatment manual and followed a format of review of home practice assigned at the	Nurse practitioner	Face-to-face Weekly (total 10 sessions) Telephone Up to 4 sessions	Clinical outcomes: Pain intensity Fatigue Use of pain medication Humanistic outcomes: Physical functioning Psychological distress Self-efficacy Catastrophizing Use of coping strategies Health-related quality of life (HRQOL) Social functioning Health satisfaction

				last session, instruction in a new coping skill, guided practice in that skill, and a home practice assignment. Homework assignments are an integral component of PCST, followed by review and problem-solving in the subsequent session. Consistent with the goal of testing the effectiveness of nurse practitioners (NPs) delivering PCST in the patients' doctors' offices, all treatment sessions were conducted in the clinics or by telephone (phone sessions). Up to 4 sessions could be conducted via telephone with some discretion on the part of the NP and patient. The first 3 sessions and the last session had to be conducted in person. Patients were provided with a treatment binder divided into sections for each session. These sections included handouts and logs to record home practice of the skill and reviewed by the NP at each session. Treatment sessions with a patient were stopped if they were not completed within 20 weeks of randomization. CG: Usual care			
Browning et al. (8, 9)	Management of type 2 diabetes in China: The Happy Life Club, a	c-RCT 41 practices	T2DM	IG: Intervention group participants received a combination of telephone and face-to-face health coaching in	General practitioner Nurse Psychologist	Face-to-face 2 sessions monthly for	Clinical outcomes: HbA1c Systolic and

	pragmatic cluster randomized controlled trial using health coaches 2016, China	668 participants (IG: 372; CG: 296)	addition to usual care. Health coaches aimed to assist participants in achieving the treatment targets as outlined in the Chinese Guideline for Diabetes Prevention and Management, with the primary goal of treatment of HbA1c of less than 7.0%. An intervention manual that utilized existing local guidelines and recommendations (e.g. Dietary Guidelines for Chinese Residents) was used to guide health coaches. The initial step in each health coaching session was to set the agenda for the session with the participant. This was achieved by asking the participant to identify the most productive place to start the conversation, that is, 'What would be helpful to talk about today?' Once the participant identified a key issue for discussion, health coaches utilized their complex set of motivational interviewing (MI) skills by assessing current behaviour in relation to the issue and determined where the participant was in the change process. Health coaches then guided the conversation with the ultimate aim of strengthening the participants' own motivation and commitment for change. By stepping out of the expert role	3 months, then 1 session monthly until 12 months Telephone 2 calls monthly for 3 months, then 1 call monthly until 12 months	diastolic blood pressure Weight Body mass index Waist and hip circumference Fasting plasma glucose Total cholesterol; triglyceride; high-density lipoprotein; low-density lipoprotein Humanistic outcomes: Psychological distress QOL Diabetes self-care activities Diabetes management self-efficacy

				into a more guiding, collaborative role, health coaches engaged the person in the process of making significant, lasting changes in their own life. CG: Usual care			
Chalder et al. (10)	Self-help treatment of chronic fatigue in the community: A randomized controlled trial. 1997, United Kingdom	RCT 150 participants (IG: 70; CG: 80)	Chronic fatigue	IG: The experimental group was given a self-help booklet. The nurse spent between 10 and 15 minutes discussing its contents, focusing on information that seemed pertinent to the individual. All participants were asked to return to the practice for follow-up three months after recruitment. The booklet was divided into three sections. Part 1 provided general information about fatigue and outlined different factors which contribute to both onset and maintenance of fatigue. Part 2 described the importance of self-monitoring and how diary-keeping helps to build a clear picture of fatigue in relation to activities. Part 3, the largest section, described a variety of cognitive and behavioural techniques for overcoming fatigue. The booklet indicated that fatigue may be associated both with doing too much and with doing too little, and the emphasis was on achieving a balance between the two. As sleep problems are common in people who complain	Research Nurse	Face-to-face 3-month follow up	Clinical outcomes: Fatigue symptoms Humanistic outcomes: Mental health (12 item General Health Questionnaire)

				of fatigue a section on how to improve sleep was included. Basic cognitive techniques such as identifying and challenging unhelpful thoughts were introduced. CG: No treatment control			
Cherkin et al. (11)	Pitfalls of patient education: Limited success of a program for back pain in primary care 1996, United States	RCT 293 participants (IG (1): 95; IG (2): 102; CG: 97)	Low back pain	IG (1): Usual care plus an educational booklet. IG (2): Usual care plus a 15-minute educational session and an educational booklet 'Back in Action: A Guide to Understanding Your Low Back Pain and Learning What You Can Do About It'. The nurse answered subjects' questions, reviewed the booklets table of contents, set exercise goals, using an exercise log to monitor progress, and emphasized key points of the booklet. CG: Usual care	Registered nurse	Telephone 1-3 days after baseline assessment	Clinical outcomes: Symptom relief Humanistic outcomes: Perceived knowledge Functional status Satisfaction with care Participation in exercise
Clark et al. (12, 13)	Effects of a tailored lifestyle self-management intervention in patients with Type 2 diabetes 2004, UK	RCT 100 participants (IG: NA; CG: NA)	T2DM	IG: The key features of the intervention were assessment, patient participation in goal setting, selecting personalized strategies to overcome barriers and follow-up including evaluation and problem solving. Following the principles of MI, a personalized program was formulated in which management goals for lifestyle change were negotiated; specific intervention strategies to increase self-efficacy and decrease barriers to	Psychologist	Telephone 1,3,7 weeks	Clinical outcomes: Estimated daily grams of fat Binge eating severity among obese persons Humanistic outcomes: Self-care activities over the past 7 days Current physical activity status

				change were developed. The patient received a copy of the goal setting form and an appointment made for a follow up telephone call in 1 week to monitor progress. Before patients left they received booklets, which were specially prepared for the intervention reinforcing essentials of healthy eating and the importance of increasing physical activity. CG: Usual care			Number of days and amount of time spent in leisure time Household and work-related physical activity over the past 7 days Barriers to healthy eating and physical activity Confidence in performing physical activity and diet behaviours QOL (SF-12 survey) Self-esteem
Clarkson et al. (14, 15)	How to influence patient oral hygiene behaviour effectively 2010, UK	c-RCT 87 practices 478 participants (IG: 234; CG: 244)	Oral hygiene	IG: A powered toothbrush and behavioural advice on timing, method and duration of tooth brushing was framed to target oral self-efficacy and action plans to influence oral hygiene behaviour and therefore clinical outcomes. The content and the delivery of the intervention were standardized as a series of steps taking approximately 5 minutes. This included (1) recommendations for brushing twice a day, for 2 minutes, using an electric toothbrush, fluoride toothpaste. (2) Tooth-brushing	Dentist	Face-to-face At 8 weeks	Clinical outcomes: Percentage of surfaces with plaque and showing gingival bleeding on gentle probing Humanistic outcomes: Timing, duration and method Oral hygiene self-efficacy

				technique on model of mouth (3) Dentist assessment of technique and corrects if required (4) Dentist elicited action plan. CG: Routine care			
Doucette et al. (16)	Community pharmacist-provided extended diabetes care 2009, United States	RCT 78 participants (IG: 36; CG: 42)	T2DM	IG: Pharmacists role in the intervention involved a 5-step process of care: gathering information from patients and other sources, evaluating the information, formulating a plan, implementing the plan, monitoring the plan, and following up with the patient and physician to ensure optimal outcomes. Pharmacists were instructed to assess clinical parameters such as HbA1c, LDL and blood pressure and use these values to educate patients and recommend drug therapy changes. Pharmacists assessed self-care activities and made recommendations when appropriate. During the first visit, the study protocol recommended that pharmacists take a patient history, create a medication list, assess clinical markers, review medications and self-care behaviours and identify drug therapy problems. Subsequent visits were intended to allow pharmacists to follow up on previous problems, identify new problems, reassess clinical parameters such as blood	Pharmacist General practitioner	Face-to-face 3-monthly (up to 4 sessions)	Clinical outcomes: Changes in HbA1c; LDL; blood pressure Humanistic outcomes: Self-report of self-care activities

				glucose and blood pressure and discuss self-care activities. After the visits, pharmacists faxed a one-page progress note to patient's physicians describing the content of the visit. CG: Usual care			
Dziedzic et al. (17-19)	Implementing core NICE guidelines for osteoarthritis in primary care with a model consultation (MOSAICS): a cluster randomized controlled trial 2018, United Kingdom	c-RCT 8 practices 525 participants (IG: 234; CG: 288)	OA	IG: Practices delivered the MOAC which consisted of: an enhanced GP consultation to make, give and explain the diagnosis, and provide initial care for older adults presenting with peripheral joint pain; an OA Guidebook offered by the GP to patients to support OA self-management; advice on analgesia; and up to four follow-up practice nurse consultations to guide patients in self-management for OA with advice on weight management if required, general exercise, and physical activity, with goal-setting as appropriate. Briefly, the intervention followed the Whole Systems Informing Self-Management Engagement (WISE) model for guided self-management including provision of patient information (the OA guidebook), care responsive to patient needs, and good access to follow-up care (practice nurse consultations). The timing of the first appointment with the practice nurse was planned for a	General practitioner Nurses	Face-to-face 4 (at 2 weeks, then three visits in three months)	Clinical outcomes: Measures of pain (peripheral joint pain intensity, OMERACT/OARSI responder criteria) Humanistic outcomes: SF-12 physical component score (PCS); self-management and patient enablement; self-efficacy; physical activity; Global assessment of change; SF-12 mental health

	minimum of 2 weeks after the initial GP consultation. This gave patients time to read the guidebook and try those self-management strategies they felt were suitable. In the first consultation the practice nurse was asked to refer to the guidebook as a resource to answer questions and clarify issues, ascertain the advice from the GP consultation, negotiate and agree appropriate goals, discuss the need for pain relief and opportunities for healthy eating, physical activity and exercise as appropriate. The timing of up to three follow-up visits with the nurse was agreed between the patient and the practice nurse, but was scheduled to be delivered within 3 months following the GP consultation. The follow-up practice nurse consultations were tailored to the patient's individual needs and could focus on, for example, reviewing the self-management plan, demonstrating exercises (Arthritis Research UK Exercises for Arthritis leaflet), giving advice as to how this could be maintained longer-term or making any necessary referrals to the broader multidisciplinary team. The practice nurse	

				consultations were supported by a specifically tailored Case Report Form (available on request) and a nurse toolkit that included advice leaflets to give to patients (content of the toolkit available on request). CG: Usual care			
Efraimsson et al. (20)	Effects of COPD self-care management education at a nurse-led primary health care clinic 2008, Sweden	RCT 52 participants (IG: 26; CG: 26)	COPD	IG: Patients in the intervention group received education with an emphasis on self-care ability and how to support the individual based on their unique requirements and abilities to cope with disease and treatment. The educational visits were based on motivational dialogue, tailored for each patient based on the severity of illness, age, intellectual capacity and lifestyle, with the following main components: (1) Description of the anatomy and physiology of the airways and the effects of COPD (2) Measurement of respiratory function (spirometry) and explanation of the outcome to the patient (3) Optimization of pharmacological treatment and control of inhalation technique (4) Instructions on the coughing technique to prevent infections and exacerbations (5) Motivational dialogue on smoking cessation (6) Instructions on how to deal with acute exacerbations (7) Measurements of oxygen	Nurse General Practitioner Dietician, social worker, physiotherapist, OT were at times consulted	Face-to-face 4 sessions between 3-5 months	Clinical outcomes: NA Humanistic outcomes: QOL (St George's respiratory questionnaire) Knowledge about COPD and smoking habits

				saturation before and after exertion (8) Assessment and instruction of breathing technique and relation (9) Dialogue on physical activity and exercise (10) Dietary counselling (11) Psychosocial counselling and support (12) Counselling on infection prevention (13) Individual treatment plan in collaboration with the patient. CG: Standard care			
Eikelenboom et al. (21, 22)	Effectiveness of personalized support for self-management in primary care: a cluster randomized controlled trial 2016, The Netherlands	c-RCT 15 practices 644 participants (IG: 296; CG: 348)	Diabetes	IG: The intervention consisted of screening patients with the SeMaS questionnaire, producing a graphic profile with abilities or barriers for self-management. Patients received tailored feedback. Practice nurses were trained in using the profile to enhance self-management of the patient and provide personalized self-management support. The use of individual care plans and self-management interventions was stimulated. SeMaS assesses: perceived burden of disease, self-efficacy, locus of control, social support, coping, anxiety and depression. To guide the type of support, it contains items about computer skills, functioning in groups, and willingness to perform self-care. A 1-page graphic profile of the results was provided to support the patient and health	Nurse	Not specified	Clinical outcomes: Patient measures for lifestyle factors (exercise, nutrition, smoking) Humanistic outcomes: Level of patient activation (PAM-13)

				professional in counselling on self-management and make the results of SeMaS easy to use. This included education/ psychoeducation on how to cope with barriers, providing information about the condition, lifestyle, self-monitoring and providing an individual care plan. CG: Usual care			
Farmer et al. (23-25)	Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomized trial 2007, UK	RCT 48 practices 453 participants (IG (1): 150; IG (2): 151; CG: 152)	T2DM	IG (1) Less intensive monitoring: continued to use the goal setting and review techniques introduced at the assessment visit. In addition, they were given a blood glucose meter. They were asked to record three values daily on two days during the week (one after fasting and the other two before meals or two hours after meals) and to aim for glucose levels of 4-6mmol/L after fasting and levels of 6-8mmol/L two hours after meals. They were advised by the nurse to consider contacting their doctor if readings were consistently high (>15mmol/L) or low (<4mmol/L). They were not given information about how to interpret their blood glucose readings. Separate diaries were used to record identified goals and activity to record blood glucose results. IG (2) More intensive monitoring: continued to use goal setting and	Nurse	Face-to-face 1,3,6,9 months	Clinical outcomes: HbA1c Blood pressure Weight Total cholesterol level Ratio of total cholesterol to high density lipoprotein cholesterol Body mass index Humanistic outcomes: NA

				review and were also given a blood glucose meter. They were also given training and support in timing, interpreting and using the results of their blood glucose test to enhance motivation and to maintain adherence to diet, physical activity and drug regimens. They were encouraged to experiment with monitoring to explore the effect of specific activities, such as exercise on their blood glucose level and to reflect on abnormal values in an attempt to identify what might have contributed to them. A single diary was used to record goals, activities and blood glucose results. CG: Standardized usual care			
Ferrone et al. (26)	The impact of integrated disease management in high-risk COPD patients in primary care 2019, Canada	RCT 168 participants (IG: 84; CG: 84)	COPD	IG: Intervention subjects received on-site spirometry, case management, education, and skills training, including self-management education by a certified respiratory educator (CRE) at baseline (1 h), 3 months post-enrolment (45 min), and either a telephone contact or in-person visit at 6 and 9 months (15–30 min). All visits occurred in the primary care practice where the individual normally received care. The CREs involved were all regulated healthcare professionals whose scope of practice included patient	Certified respiratory educator	Face-to-face; telephone At 3 months (45 min), and either a telephone contact or in-person visit at 6 and 9 months (15–30 min)	Clinical outcomes: FEV1; number of exacerbations Humanistic outcomes: COPD specific QOL; COPD knowledge

				counselling and who have successfully completed a Canadian Network for Respiratory Care approved respiratory educator program. The CREs that were COPD certified for this project were experienced asthma educators who provided services in an established primary care asthma program. During patient encounters, CREs were supported by a scalable electronic point of service system (POSS) developed for the project that guided them through the standardized evidence-based interventions and recorded all care elements delivered. The IDM intervention identified patient-specific goals and emphasized shared decision making. The specific elements of IDM are categorized under case management, education, and skills training. The final management plan for each in-person visit was confirmed by the primary care physician during a 5–7 min encounter immediately following the CRE evaluation. CG: Usual care			
Fortin et al. (27, 28)	Integration of chronic disease prevention and management services	RCT 305 participants	Diabetes, cardiovascular disease, COPD, asthma,	IG: The principles guiding the intervention were based on self-management support and health education, a patient-centered approach, motivational approach	Nurse	Face-to-face (2 sessions, interval not specified)	Clinical outcomes: NA Humanistic outcomes:

	into primary care: a pragmatic randomized controlled trial (PR1MaC) 2016, Canada	(IG: 144; CG: 161)	tobacco smoking, obesity, hyperlipidaemia, prediabetes, sedentary lifestyle or any combination of these	and interprofessional collaboration. For each patient, the intervention started with a preliminary clinical evaluation by a trained nurse. then designed an individualized intervention plan in collaboration with the patient that could include encounters with 1 or more CDPM professionals in the following disciplines: nursing, physical activity, nutrition, respiratory therapy and smoking cessation therapy. The intervention plan was based on the patient's objectives as identified at the first encounter but could be further adapted by any professional in each discipline involved. Interventions were done by CDPM professionals who were recruited and trained by the research team and travelled from 1 organization to the other to deliver the services. CG: Delayed treatment control			Self-management; self-efficacy, health-related quality of life, psychological distress; lifestyle factors
Freund et al. (29)	The effect of preventive consultations on young adults with psychosocial problems: a randomized trial 2012, Denmark	RCT 495 participants (IG: 240; CG: 255)	Psychosocial problems	IG: GPs were recommended to skim the BQ and then start by asking the following questions 'How was it like to complete the questionnaire?' and 'What do you prefer to discuss?' Completing the BQ was supposed to facilitate insight into the relationship between social life, health, lifestyle, own reaction on stressors and resources and	General practitioner	Telephone At 3 months	Clinical outcomes: Blood pressure Body mass index Blood glucose level Cholesterol Humanistic outcomes: Change in HRQOL after 1

				barriers for gaining control and changing behaviour. At the end of the consultation, the GP and the patient together made a written report of their general impression of the consultation, general health, resources, network and lifestyle. The patient chose one or two goals. Goals setting, time schedule and specific resources and barriers for reaching the goals were discussed and shortly described in the three-page report. Needs for other interventions were discussed. CG: Usual care			year (SF-12 survey)
Friedberg et al. (30, 31)	Chronic fatigue self-management in primary care: a randomized trial 2013, United States	RCT 111 participants (IG: 37; CG (1): 38; CG (2): 36)	Unexplained chronic fatigue & chronic fatigue syndrome	IG: This two-session nurse conducted individual self-management intervention was based on a modified version of an efficacious 12-session cognitive-behavioural treatment program for chronic fatigue syndrome and a self-help book. A 61-page self-management booklet provided to these participants contained material discussed and assigned in therapy sessions for the three-month self-management period. Session 1: This session educated the participant about (1) diagnosis and possible causal factors in chronic fatigue (2) stress factors and behaviours that play a role in disturbed sleep	Nurse	Face-to-face At 2 weeks	Clinical outcomes: Fatigue impact on functioning (Fatigue Severity Scale) Humanistic outcomes: NA

	patterns, post-exertion symptoms, and push-crash activity cycles. Persistent fatigue was explained as a symptom associated with doing too much or too little. Optimal self-management was intended to achieve a healthy balance between mental and physical exertion and periods of rest. Assignments included the self-management booklet and a daily web diary to identify baseline activities, symptoms, and stress levels. Session 2: Scheduled two weeks after session 1, this session identified unhelpful behaviours and beliefs about the illness followed by development of more useful cognitive and behavioural coping strategies. With information gathered from the week 1 web diary, the scheduling of home-based activities, rest/sleep assignments, and cognitive coping skills was individualized for each participant. Walking, if included, was intended as a voluntary leisure activity, rather than a fitness regimen. For instance, a relatively low functioning individual might be assigned a regular sleep /wake schedule and gradual low effort walking to increase tolerance of physical activity. A higher	

				functioning participant might respond more favourably to pacing of activity and low effort pleasant activities. The final topic was post intervention planning for maintenance of new self-management skills which included recognizing and managing early symptoms of setbacks before they affected functioning. CG (1): Attention control. To control for therapist attention, homework assignments, and other non-specific effects, a two-session attention control condition was incorporated into this study. This condition included (1) in-session emotional support and (2) home-based self-monitoring of symptoms, affect and stress as recorded in web diaries. The two face-to-face sessions in this condition were separated by two weeks. CG (2): Usual care			
Gabbay et al. (32)	Nurse case management improves blood pressure, emotional distress and diabetes complication screening 2006, United States	RCT 332 participants (IG: 150; CG: 182)	Diabetes	IG: The nurse implemented specific diabetes management algorithms under the supervision of the patient's primary care physician. Goals were based on ADA recommendations: BP < 130/80mmHg, LDL < 100, HbA1c < 7%, quarterly HbA1C measurement, bi-annual lipid measurement, yearly ophthalmological and	Registered Nurse	Face-to-face 4-monthly	Clinical outcomes: Changes in blood pressure, HbA1c, and lipids Complication screening process measures

				monofilament exam, micro albumin/ creatinine ratio, flu vaccine, appropriate Pneumovax immunization, certified diabetes nurse educator and dietician visits. The nurse case manager used behavioural goal setting, established individualized care plan, provided patient self-management education and surveillance of patients, including phone calls to patients, referred patients to a diabetes nurse educator or a dietician where appropriate, ordered protocol driver laboratory tests, tracked the outcomes using the computerized data registry and made therapeutic recommendations based on ADA diabetes guidelines with approval from the primary care provider. An initial 45 to 60-minute baseline visit provided an opportunity for patient assessment and development of an individualized care plan to focus on specific shortcomings of clinical parameters and to establish patient centered behavioural goals. CG: Usual care			Humanistic outcomes: Diabetes-related distress
Gabbay et al. (33)	Diabetes nurse case management and motivational interviewing for change	RCT 545 participants	T2DM	IG: The visits typically included a review of patients' clinical laboratory test results, health-related lifestyle behaviour relevant to managing T2DM and	Nurse	Face-to-face 2,6,12 weeks, 6,12 months, and	Clinical outcomes: Blood pressure HbA1c Lipids

	(DYNAMIC): Results of a 2-year randomized controlled pragmatic trial 2013, United States	(IG: 232; CG: 313)		medication adherence. The nurses also checked whether the patient was due for complications screening and reminded them of follow-up specialist visits when they were due. Referrals to a certified diabetes nurse educator or a dietician were done where appropriate. Finally, nurses prompted the physicians for medication titrations when necessary. These were done via e-mail, in person, or phone call, depending on the PCP's preference. CG: Routine care		at least every 6 months Telephone; email Variable	Depression symptom scores (Centre for Epidemiologic Studies Depression (CES-D) scale) Humanistic outcomes: Diabetes-related distress (Problem Areas in Diabetes scale) Treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire) Self-care activities (Summary of Diabetes Self-Care Activities) QOL (Audit of Diabetes Dependent Quality of Life)
Goudswaard et al. (34)	Long-term effects of self-management education for patients with Type 2 diabetes taking maximal oral hypoglycaemics therapy: a	RCT 54 participants (IG: 25; CG: 29)	T2DM	IG: The educational program focused on: general information on diabetes; reinforcing compliance with actual medication; importance of physical exercise and losing body weight; and nutritional advice. All patients were also	Nurse	Face-to-face 3-6 weekly (total 6 sessions)	Clinical outcomes: HbA1c Weight Humanistic outcomes: NA

	randomized trial in primary care 2004, The Netherlands			taught how to control their blood glucose at home on a regular basis for which they were given a blood glucose meter and strips. CG: Usual care			
Grilo et al. (35)	Self-help for binge eating disorder in primary care: a randomized controlled trial with ethnically and racially diverse obese patients 2013, United States	RCT 48 participants (IG: 24; CG 24)	Binge-eating disorder	IG: Self-help cognitive behaviour therapy (CBT) was provided in addition to usual care and involved being given Overcoming Binge Eating a self-help program (self-help manual) which follows the professional CBT program and is considered to be the treatment of choice for Binge Eating Disorder. The self-help manual has 3 stages. The first stage consisted of: presentation of the CBT model including the structure, goals, and methods; education regarding binge eating, dieting, and health; introduction of self-monitoring techniques; and introduction of graded behavioural techniques for establishing normalized eating patterns. The second stage consisted of maintaining the normalized eating and self-monitoring procedures and integrates cognitive restructuring procedures and the development of coping skills for triggers of maladaptive eating. The third stage focused on consolidating progress, maintenance of changes, and relapse prevention methods. The manual provided	General practitioner	Face-to-face Monthly (total 4 sessions)	Clinical outcomes: Binge eating rates of “remission” during the previous 28 days Depression levels (BDI score) Body mass index Humanistic outcomes: Continuous measures of eating disorder psychopathology (EDE global score, EDE-Q global score)

				guidance as to when to move on to the next step of the program. CG: Usual care			
Heitkemper et al. (36)	Self-management for women with irritable bowel syndrome 2004, United States	RCT 132 participants (IG (1): 40; IG (2): 48; CG: 44)	Irritable bowel syndrome	IG (1): Comprehensive treatment. Session 1: Introduction and review baseline assessment, Session 2: Physiologic arousal and abdominal breathing, Session 3: Diet and automatic thoughts, Session 4: Automatic thoughts and active progressive muscle relaxation, Session 5: Cognitive restructuring and mini-relaxation, Session 6: Targeted problem-solving skills and passive relaxation, Session 7: Consolidate strategies and review goals, plan, and obstacles, Session 8: Maintenance and termination. Individual sessions included a review of homework assignments from the previous session, new strategies were presented, and homework based on the content of the session was assigned. Adherence strategies were integrated throughout the sessions (e.g., breaking tasks into small pieces, beginning with assignments that allow participants to succeed reinforcement, rehearsal of assignments). Assignments included symptom monitoring and other homework specific to	Nurse practitioner	IG (1) Face-to-face Weekly for 8 weeks IG (2) Face-to-face At 8 weeks	Clinical outcomes: Improvements in symptoms Humanistic outcomes: Psychological distress HRQOL Indicators of stress-related hormones

	the intervention. At the last session, an individualized management plan was developed. The intervention had the following 4 components. Education and reassurance. In addition to defining IBS and providing reassurance that IBS is not life threatening, this content also included a discussion of signs and symptoms for which it is important to consult a health care provider. Dietary counselling. The participants were first instructed on healthy eating strategies; for example, participants were encouraged to eat small frequent meals/ snacks and slowly increase their fibre intake to 20–25 g/day. In addition, participants were taught to recognize foods that were associated with their symptoms (e.g., coffee, fatty foods, raw vegetables) as well as situations when select foods were not tolerated (e.g., a time of high work stress). Homework included keeping a food diary to identify when they ate, what they ate, and what was happening in their environment. Relaxation training. Abdominal breathing, progressive muscle relaxation, and mini-relaxation were taught. Homework included abdominal breathing at least 3 times a day	

				(e.g., before each meal), use of the relaxation audiotape 3 times a week, and daily mini-relaxation with tension as a cue. Cognitive-behavioural strategies. Specific cognitive-behavioural strategies were selected on the basis of individualized assessment. These included anger management, cognitive restructuring, assertiveness and social skills training, and social support. Homework included writing down automatic thoughts and identifying and using alternative thoughts. IG (2): The Brief program attempted to cover the same material as the Comprehensive program, but it was condensed into one 90-minute session. Each participant was given the same workbook and relaxation tape; the nurse discussed how dietary changes, relaxation exercises, and cognitive strategies could be integrated into lifestyle. CG: Usual care			
Hill et al. (37)	Disease-specific education in the primary care setting increases the knowledge of people with chronic obstructive pulmonary disease:	RCT 93 participants (IG: 50; CG: 43)	COPD	IG: Individuals allocated to the intervention attended two one-to-one education sessions, the first of which was scheduled one month following randomization and the second one-month later. A certified COPD educator performed both 60-minute sessions as face-to-face	Certified COPD educator	Face-to-face At 4 weeks	Clinical outcomes: NA Humanistic outcomes: COPD knowledge (Bristol COPD

	A randomized controlled trial 2010, Canada			discussion at the primary care practice. The educational content was standardized. The sessions focused on enhancing self-efficacy in areas likely to be important to individuals recently diagnosed with COPD. Specifically, the following topics were addressed (1) normal lung function (2) how COPD affects the lungs (3) symptoms and what makes them worse (4) strategies for smoking cessation (5) respiratory medications (6) symptoms of an acute exacerbation (7) the role of regular exercise. A written teaching manual adapted from the "Living Well with COPD" program accompanied the oral information. Patients were given this after their second education session. CG: Usual care			Knowledge Questionnaire)
Hoffmann et al. (38)	Pharmaceutical care for migraine and headache patients: a community-based, randomized intervention 2008, Germany	c-RCT 83 practices 410 participants (IG: 201; CG: 209)	Migraine/ Headache	IG: The intervention included individual counselling with a defined extended time frame, usually provided in designated rooms. All specific steps of the intervention were documented by the pharmacist in semi-standardized forms including the number of consultations, demographic variables of the patient, medical history, nutrition, allergies, headache and migraine characteristics, past and present	Pharmacist	Face-to-face Up to 6 sessions Telephone At 4 months	Clinical outcomes: Number of days with headache Number and severity of headaches Humanistic outcomes: Self-efficacy HRQOL

				medication. Together with the patient, the intervention pharmacist prioritized problems, defined individual goals, and devised a plan to work toward them. CG: Usual care			
Huang et al. (39, 40)	Prospective randomized controlled trial to evaluate effectiveness of registered dietician-led diabetes management on glycaemic and diet control in a primary care setting in Taiwan 2010, Taiwan	RCT 154 participants (IG: 75; CG: 79)	T2DM	IG: Patients in the intervention group, in addition to receiving usual care, received ongoing instruction on the self-monitoring of glucose, medications, exercise, foot care and complication management. Patients in the intervention group were also provided individualized nutrition counselling and dietary plans to reinforce the concepts on controlling portion sizes of foods every 3 months. The registered dietician assessed patients understanding and practice of dietary plans and self-care skills and reinforced important knowledge throughout the study period. The physicians consulted with the registered dieticians based on medicines prescribed or patient's self-care related to adjustment of meal times and amount of food. During each intervention visit, the dietician obtained daily nutrient intake by asking patients to recall the foods consumer for the previous 24-hour period. Each patient received dietary	Dietician	Face-to-face 3-monthly for 12 months (total 4 sessions)	Clinical outcomes: Anthropometric measurements Clinical lab measurements after an 8 to 12 hour fast Dietary habits Humanistic outcomes: NA

				education recommended by the ADA. An individualized diet plan was created to maintain intake of protein, fat, and carbohydrate energy to ~15-20, 25-30 and 50-60%. CG: Routine care			
Ismail et al. (41)	Usage of glucometer is associated with improved glycaemic control in type 2 diabetes mellitus patients in Malaysian public primary care clinics: an open-label, randomized controlled trial 2013, Malaysia	RCT 105 participants (IG: 58; CG: 47)	T2DM	IG: All patients received similar health education, as recommended in the Malaysian Clinical Practice Guidelines on the management of diabetes mellitus, which highlighted the need for strict glycaemic control, diet control, blood glucose monitoring, and knowledge on how to adjust the dose of oral hypoglycaemic agents (OHA) or insulin, as well as treatment of hypoglycaemia. In addition, participants were offered two-day classes that included practical demonstrations of self-monitoring blood glucose, during which the usage of the glucometer was explained. Patients were supplied a glucometer with reagent test strips at no charge, after they demonstrated the skill needed to use the device. Patients were advised to monitor their blood glucose levels (either during fasting, two hours after breakfast, or two hours after meals) and to keep a record in their logbooks. If the test result was found to be above the set	Nurse	Face-to-face 2-monthly (total 3 sessions)	Clinical outcomes: Fasting blood glucose or two-hour postprandial blood glucose HbA1c Fasting cholesterol Triglycerides Serum creatinine Weight Blood pressure Humanistic outcomes: NA

				target value (i.e. fasting blood glucose > 6.0 mmol/L; postprandial blood glucose > 7.8 mmol/L), the patient was advised to adjust the dose of OHA/insulin accordingly and recheck the blood glucose level of that particular time (either during fasting or postprandial), after four to five days. CG: NA			
Jaipakdee et al. (42)	Effectiveness of a self-management support program for Thais with type 2 diabetes: Evaluation according to the RE-AIM framework 2015, Thailand	c-RCT 10 practices 403 participants (IG: 203; CG: 200)	T2DM	IG: The diabetes self-management support program was adapted from three strategies, including diabetes education, behaviour change support, and emotional support program comprised of two components: (I) diabetic educational section to help patients understand the disease process; and (II) proper skill learning to manage their condition and change their lifestyle. In Component I, a CAI was developed for use in the educational sessions. The CAI facilitated the DSMS delivery lesson by lesson according to the pre-set steps, while lesson repetition is also possible. Its video component included lessons on diabetes and pre- and post-tests (10-questions with three choice answers of each lesson). The lessons consisted of: (1) knowledge of diabetes; (2)	Nurse	Face-to-face 3,6 months	Clinical outcomes: HbA1c Humanistic outcomes: NA

	foods for diabetes; (3) physical activity; (4) foot care; (5) medication used to control diabetes; (6) reducing complications and stress management; (7) self-monitoring of clinical indicators and goals of diabetes control. The lessons were designed in various forms such as stories, graphics, animated images, interviews, and demonstrations to stimulate learners' interest and enjoyment. In Component II, the step-by-step approach for behaviour change and psychological support was in accordance with the 5C intervention and consisted of: (1) constructing a problem definition; (2) collaborative goal setting; (3) collaborative problem solving; (4) contracting for change; (5) continuing support. The nurse supporters performed as facilitators to help participants define their problem in a potentially useful way, set goals, identify barriers, and solve problems in achieving those goals. Participants were followed-up for their behaviour changes that were engaged in the previous session, such as dietary habits, exercise, foot care, medication, and blood glucose monitoring.	

				CG: Usual care			
Kennedy et al. (43, 44)	Implementation of self-management support for long term conditions in routine primary care settings: cluster randomized controlled trial 2013, United Kingdom	c-RCT 41 practices 5599 participants (IG: 2295; CG: 3304)	Diabetes, COPD, IBS	IG: The intervention (whole system informing self-management engagement, WISE) is based on accumulated evidence from multiple randomized controlled trials and an ongoing program of work grounded in primary care.7 28-31 The core aim was to take several components found to be effective in these previous studies and to deliver them as a comprehensive package under naturalistic conditions and using routine care providers to maximize real world applicability. The intervention was designed to be feasible to implement widely in primary care, which put practical limitations on the intensity of the intervention. Training (developed and piloted with two non-trial practices) was delivered in each practice over two sessions, which we estimated through informed feedback was the maximum feasible in UK primary care using current educational structures. Session 1 involved all practice staff (doctors, nurses, technicians, and administration staff) and session 2 focused on clinical staff. Fidelity checks and reinforcement sessions with trainers were scheduled after training. Two facilitators	General practitioners Practice nurses	Not specified	Clinical outcomes: NA Humanistic outcomes: Shared decision making; self-efficacy, generic health related quality of life; general health; social or role limitations; energy and vitality; psychological wellbeing; self-care activity; and enablement

				employed by the primary care trust delivered the training and also provided access to self-management support activities and resources in the primary care trust. The practices were provided with resources to support self-management, including a tool to assess patient support needs and priorities (PRISMS). In session 1, practices worked on ways to embed self-management tools in their systems; in session 2, clinicians practiced ways to use core self-management skills in consultations and ensure patients received, or were directed to, appropriate resources. Assessment of patient need was linked to appropriate support, including self help guidebooks based on published development methods, access to relevant community groups and programs. CG: Wait list comparator			
McGeoch et al. (45)	Self-management plans in the primary care of patients with chronic obstructive pulmonary disease 2006, New Zealand	c-RCT 159 participants (IG: 86; CG: 73)	COPD	IG: The intervention group received usual care and education on the use of a self-management plan. The plan and structured education included methods of early recognition of exacerbations and a range of appropriate self-initiated interventions including antibiotics and short course of oral	Practice nurse or respiratory educator General practitioner	Face-to-face 1 session at 12 months Telephone 3, 6, 9 months	Clinical outcomes: Symptoms (St Georges Respiratory Questionnaire) Courses of antibiotics Courses of oral steroids

				corticosteroids. In addition, patients were instructed to make early contact with their general practice during exacerbations. Standardized self-management plan education was delivered in an individual session of 1-hour duration from a practice nurse or respiratory educator in association with their general practitioner. The sessions covered the major points of the COPD self-management plan and the use of previously validated sputum colour charts. CG: Usual care			Humanistic outcomes: Self-report anxiety and depression (Hospital Anxiety and Depression Scale) Self-management (COPD Self-Management Interview)
McLean et al. (46)	The BC Community Pharmacy Asthma Study: A study of clinical, economic a nd holistic outcomes influenced by an asthma care protocol provided by specially trained community pharmacists in British Columbia Canada, 2003	c-RCT 18 pharmacie s 631 participant s (IG: 191; CG (1): 214; CG (2): 226)	Asthma	IG: Intervention (EC) involved soliciting all of the UC information plus the teaching of asthma self-management as outlined in the HOP Asthma Care Module. This involved instruction on the basic concepts of the disease, the medications being used and trigger identification and avoidance, as well as the development of the asthma action plan. In addition, the use of a peak flow meter was taught, calendars/diaries were provided and the patient asked to record PEFRs regularly for the course of the study period. Also, spacer devices were used by all patients requiring them for better utilization of their medications. Care in the EC group involved	Pharmacist	Face-to-face (Every 2-3 weeks, for at least three appointment s and then follow-up appointment s at least every three months)	Clinical outcomes: Peak expiratory flow rates; symptom scores (dyspnoea, cough, wheeze, chest tightness, phlegm production and nasal symptoms) Humanistic outcomes: Patient's knowledge; QoL

	appointments of approximately one hour in length with a pharmacist in a private counselling area every two to three weeks for at least three appointments, and then follow-up appointments at least every three months for the remainder of the study. Patients could request additional appointments or could see the pharmacist intermittently for short sessions without an appointment. An initial assessment of 'readiness for change' was completed using the Transtheoretical Model of Change and patients were reassessed at each appointment. Education did not begin until the patient was in 'contemplation' stage, and the new strategies were not begun until the patient was in 'preparation' stage. EC patients received 'pharmaceutical care'; thus, EC may be summarized as: • pharmacist assesses readiness to change and adjusts initiation date • pharmacist provides education on disease, helps identify triggers and works with patient to develop action plan • patient participates in all decisions • patient monitors own therapy (PEFRs, using calendar/diary)	

				• pharmacist takes responsibility for outcomes • pharmacist promotes evidence-based care • pharmacist-patient interaction based on appointment and occurs in private consultation area • physician informed or consulted regarding all results and interventions CG: Usual care			
Mehuys et al. (47)	Effectiveness of pharmacist intervention for asthma control improvement 2008, Belgium	RCT 201 participants (IG: 107; CG: 94)	Asthma	IG: Session 1: Participants received personal education from the pharmacist about the following topics (1) Correct use of the inhaler device (2) Understanding asthma, symptoms, triggers, early warnings (3) Understanding asthma medication, difference between controller and reliever, adherence to controller medication (4) Smoking cessation if required. Session 2 & 3: at 1 month and 3-month follow up: Pharmacist advice based on ACT score of the patient. If ACT score < 15 - immediate referral to GP or respiratory specialist. If ACT 15-19: review inhalation technique and check controller medication adherence. If ACT ≥ 20: no specific advice needed, inform patient asthma is well controlled. CG: Usual care	Pharmacist	Face-to-face 1, 3 months	Clinical outcomes: Level of asthma control Peak expiratory flow Rescue medication use Night-time awakenings due to asthma Inhalation technique Adherence to controller medication Severe exacerbations Humanistic outcomes: QOL Knowledge on asthma and smoking behaviour

Mehuys et al. (48)	Effectiveness of a community pharmacist intervention in diabetes care: a randomized controlled trial 2011, Belgium	c-RCT 66 practices 288 participants (IG: 153; CG: 135)	T2DM	IG: Patients in the intervention group received a protocol-defined intervention at the start of the study and at each prescription-refill visit (for hypoglycaemic medication) during the course of the study. The intervention consisted of several elements: (1) Education about T2DM and its complications; (2) Education about the correct use of oral hypoglycaemic agents (timing in relation to food); (3) Facilitation of medication adherence (by counselling); (4) Healthy lifestyle education (diet, physical exercise and smoking cessation); and (5) Reminders about annual eye and foot examinations. CG: Usual care	Pharmacist	Face-to-face At each prescription refill visit	Clinical outcomes: HbA1c Humanistic outcomes: NA
Meland et al. (49, 50)	Effectiveness of two preventive interventions for coronary heart disease in primary care 1997, Norway	c-RCT 22 participants 110 patients (IG: 58; CG: 52)	Coronary heart disease	IG: Participants were provided with self-help material based on cognitive behaviour change. A behavioural intervention was chosen by the patient at each consultation including cholesterol reduction, weight reduction, salt reduced diets, leisure time exercise, smoking cessation and stress management. The cholesterol lowering self-help brochure invited patients to self-monitor their everyday diet and make a contract on dietary changes. The smoking cessation program employed self-	General practitioner	Face-to-face Three-monthly	Clinical outcomes: Blood pressure Weight Resting pulse Total serum cholesterol Triglycerides Humanistic outcomes: Self-efficacy in diet, physical exercise and smoking Smoking status

				monitoring, gradually breaking smoking habits and addiction, and motivational behaviour change. Patients were also offered a stress-coping audiotape containing general relaxation and self-cognitive instructions. CG: Conventional care			
Mitchell et al. (51, 52)	A self-management program for COPD: a randomized controlled trial 2014, UK	RCT 184 participants (IG: 89; CG: 95)	COPD	IG: In addition to usual care, intervention participants received the self-management program structured around the SPACE FOR COPD manual (a 176-page workbook that individuals can follow independently at home). The manual, divided into four sections, contains educational material and a home exercise program. Acquisition of skills is promoted through goal-setting strategies, coping planning and case studies. It incorporates an exercise regime that consists of a daily walking program, and resistance training of the upper and lower limbs using free weights three times per week. The manual advises on training progression and includes an action plan for exacerbation management. Participants randomized to SPACE FOR COPD were introduced to the program by a physiotherapist during a 30–45-min consultation. MI techniques were used to	Physiotherapist	Telephone 2,4 weeks	Clinical outcomes: Symptom burden (Chronic Respiratory Questionnaire) Humanistic outcomes: Shuttle walking tests Disease knowledge Anxiety/ depression Self-efficacy Smoking status

				underpin the consultation in order to explore the patients' readiness to change and to enhance motivation for adopting new lifestyle behaviours. Participants' needs were discussed, and goal-setting strategies were introduced. Participants were advised how to use the manual at home and the exercise regime was described by the physiotherapist in detail. It was anticipated that participants would work through the manual in approximately 6 weeks; however, participants were advised the manual was theirs to keep, as it could be used as a resource for the future, and that the lifestyle changes it suggested should be lifelong. CG: Usual care			
Morgan et al. (53, 54)	The TrueBlue model of collaborative care using practice nurses as case managers for depression alongside diabetes or heart disease: a randomized trial 2013, Australia	c-RCT 11 practices 317 participants (IG: 170; CG: 147)	Depression Diabetes Heart Disease	IG: The nurse and patient identified possible barriers to achieving their goals and discussed enabling methods that may overcome these barriers. The nurse supplied educational material to assist patients in understanding their condition and meeting their goals. This information was then added to the GP management plan. The GP completed the consultation with the patient, providing the patient with a copy of the	Nurse General Practitioner	Face-to-face 3-monthly (total 4 sessions)	Clinical outcomes: Five-point reduction in depression scores for patients with moderate-to-severe depression Improvement in physiological measures Humanistic outcomes:

				completed management plan to follow at home. CG: Wait list control			NA
Moss-Morris et al. (55, 56)	A randomized controlled trial of a cognitive behavioural therapy-based self-management intervention for irritable bowel syndrome in primary care 2010, UK	RCT 64 participants (IG: 31; CG: 33)	Irritable bowel syndrome	IG: Participants received an IBS fact sheet after their diagnosis was confirmed. In addition, they were provided with a comprehensive self-management manual that included the provision of information, real life examples, and weekly homework sheets that they were encouraged to complete. The program was divided into seven chapters, one to be completed each week over a 7 to 8-week period. Participants received a 1-hour face-to-face session with a health psychologist at the beginning of the program. Participants received two 1-hour therapy sessions by telephone schedule midway and towards the end of the program. They were intended to give the patient an opportunity to go through any queries they might have, to clarify the appropriateness of the goals set, and to work through some of the more complex aspects of the program such as managing unhelpful thoughts. Chapter 1: IBS explained; Treatment rationale, which includes the following explanations: Illustrative physiology of the digestive	Psychologist	Telephone 2 sessions in 8 weeks	Clinical outcomes: Symptom severity (Irritable Bowel Syndrome Severity Scoring System) Self-report anxiety and depression (Hospital Anxiety and Depression Scale) Symptom relief (Subjects Global Assessment of Relief) Humanistic outcomes: Work and Social Adjustment

	system together with the functional changes that occur in the gut as a result of IBS; How the autonomic nervous system ('fight-or-flight' stress system) may interact with the enteric nervous system; The interaction between thoughts, feeling and behaviours and how these can impact on stress levels and gut symptoms. Chapter 2: Assessing symptoms and self-monitoring; Participants begin to make the link between their own symptoms, thoughts and behaviours. The pitfalls of becoming overly symptom focused are discussed; Participants keep daily diaries of the severity and experience of IBS symptoms in conjunction with stress levels experienced and eating routines/behaviours. Chapter 3: Managing IBS symptoms; Behavioural management of the symptoms of diarrhoea and constipation and common myths in this area are discussed. Goal setting is explained; The importance of healthy eating and exercise regimes is covered, and participants are encouraged to set goals for managing symptoms, exercise and diet. Goal setting, monitoring and evaluation continue weekly	

	through the program. Chapter 4: Managing unhelpful thoughts; The concept of negative automatic thoughts and how these can impact on IBS symptoms is introduced; Participants are asked to keep a daily thought record of unhelpful thoughts and to try and come up with alternative thoughts. Chapter 5: Personal expectations and activity patterns; The concept of perfectionism and unhelpful personal expectations is introduced. How these may lead to an all-or-nothing style of activity is addressed; Participants are asked to keep daily thought records of unhelpful thoughts related to personal expectations and patterns of over activity. Chapter 6: Relaxation and stress management; Basic stress management and sleep hygiene are discussed. A relaxation CD is provided, and participants are encouraged to set goals for relaxation and improving sleep over a 15-day period. Chapter 7: Managing flare-ups and the future; The probability of flare-ups is discussed, and patients are encouraged to develop achievable, long-term goals and to continue to use the skills they have learnt throughout the	

				manual to manage flare-ups and ongoing symptoms. CG: Treatment as usual			
Murphy et al. (57-59)	Effect of tailored practice and patient care plans on secondary prevention of heart disease in general practice: cluster randomized controlled trial 2009, UK	c-RCT 48 practices 903 participants (IG: 444, CG: 459)	Coronary heart disease	IG: A multifaceted intervention comprising care plans for both the practices and the patients. An action plan for each patient was agreed with the practice and regularly reviewed by the study research nurse and practice. The study nurse maintained regular contact with the practices through a 2-page study newsletter provided to practices every four months. The patient and practitioner together identified areas of management that could be improved, and the patient was invited to prioritize one particular aspect of his or her lifestyle for change. Possible ways of achieving targets reflecting optimal management were identified and action plans individualized so that small, realistic goals for change were agreed. Booklet containing information on all the key risk factors for coronary heart disease was used by practitioners in discussions on initial target setting and then given to the patients. Six sections of the book include medications, smoking, exercise, healthy eating, stress and community support.	General practitioners Practice Nurses	Face-to-face 4-monthly Telephone At 2 weeks	Clinical outcomes: Blood pressure Total cholesterol Humanistic outcomes: Physical and mental health status (SF-12 survey)

				CG: Usual care			
Olry de Labry Lima et al. (60)	Effectiveness of an intervention to improve diabetes self-management on clinical outcomes in patients with low educational level 2017, Spain	c-RCT 9 general practitioners 184 participants (IG: 90; CG: 94)	T2DM	IG (1): Face-to-face intervention carried out by GPs during the clinic visit and consisted of seven visits, one every three months. Each session consisted of completing a diabetes care record sheet (DCRS) together with the patient. The DCRS consisted of two parts: Five questions on self-care activities in the last three months and a graph with previously measured HbA1c levels. This information was completed at each session, resulting in a graph showing the evolution of glycaemic control related to self-care activities. The DCRS was explained to patients, emphasizing the relationship between self-care and glycaemic control. At the end of the session, patients were given a copy of the DCRS and suggested to show it and discuss it with their relatives. IG (2): Face-to-face intervention plus telephone reinforcement. In this group patients received the above described intervention plus a telephone reinforcement. It consisted of five telephone calls lasting about 10 minutes each, to provide advice on carrying out physical exercise and eating a balanced diet and to encourage the use of health	General practitioner	IG (1): Face-to-face 3-monthly (total 7 sessions) IG (2): Face-to-face 3-monthly (total 7 sessions) Telephone Variable (total 5 phone calls)	Clinical outcomes: HbA1c Blood pressure (systolic and diastolic) Lipids (triglycerides, high density lipoprotein and low-density lipoprotein) Body mass index Waist circumference Humanistic outcomes: NA

				services related to diabetes control. Telephone follow-up reinforced T2DM self-management and motivational interviewing techniques. CG: Standard care			
Partapsingh et al. (61)	Applying the Stages of Change model to Type 2 diabetes care in Trinidad: A randomized trial 2011, Trinidad	RCT 122 participants (IG: 61; CG: 61)	T2DM	IG: The intervention was 'stage-specific' and personalized. Care was delivered to Type 2 diabetics specific to the patient's current stage of change (SOC) and specific to the patient as a whole. These formats divided each consultation into sections specific for the named SOC. Each format was translated into a form, which was used at each patient-physician consultation. There were five forms in this study and each patient was exposed to the one appropriate to their present SOC with respect to diet, exercise and medication use. These forms were used as checklists for the physician to ensure all the sections of the consultation were attended to during the visit. CG: Routine care	General practitioner	Face-to-face At 48 weeks	Clinical outcomes: HbA1c Body mass index Blood pressure Plasma urea and creatinine Total cholesterol Triglycerides Blood glucose (random) Humanistic outcomes: Patients' readiness to change.
Richards et al. (62)	PHASE: a randomized, controlled trial of supervised self-help cognitive behavioural therapy in primary care 2003, UK	RCT 139 participants (IG: 75; CG: 64)	Anxiety/ depression	IG: PN-facilitated self-help. Practice nurses assisted patients in using a self-help book "Managing Anxiety and Depression" a booklet developed for primary care, based on CBT techniques. PNs assisted patients in using the booklet both	Nurse	Face-to-face Weekly for 2 weeks, then at 3 months (total 3 sessions)	Clinical outcomes: NA Humanistic outcomes: HRQOL Depth of relationship;

				within and between sessions. The program comprised up to three sessions based on a previous trial evaluating a 'two-plus-one' session model. The initial two sessions offered 1 week apart, focused on familiarization with the booklet and applying it to samples of the patients' problems. Patients then used the booklet at home and were offered a third review appointment ('plus-one') 3 months later. CG: Usual care			professional care and perceived time (using consultation satisfaction questionnaire)
Rosemann et al. (63)	Case management of arthritis patients in primary care: a cluster-randomized controlled trial 2007, Germany	c-RCT 75 practices 1021 participants (IG (1): 345; IG (2): 344; CG: 332)	Osteoarthritis	IG: GPs participated in 2 peer group meetings. GPs received written materials for patients: a leaflet providing information about the cause and the treatment possibilities as well as coping strategies. The leaflets also contained contact addresses for the 2 largest self-help groups for patients. GPs also received booklets and audio CDs with a detailed exercise program and were asked to provide these materials to every included patient. In intervention group II, a practice nurse conducted additional case management via telephone. CG: NA	General Practitioner	Telephone 4-weekly	Clinical outcomes: NA Humanistic outcomes: HRQOL (AIMS2-SF questionnaire) Physical activity
Smit et al. (64, 65)	Enhanced treatment for depression in primary care: first	RCT	Depression	IG (1): The Depression Recurrence Prevention (DRP) Program consisted of three	Nurse Psychologist	IG (1): Face-to-face	Clinical outcomes:

	year results on compliance, self-efficacy, the use of antidepressants and contacts with the primary care physician 2005, The Netherlands	267 participants (IG (1): 112; IG (2): 39; IG (3) 44; CG: 72)	individual face-to-face sessions with a trained prevention specialist, followed by four telephone contacts per year. DRP is a structured psycho-educational self-management intervention. Education on self-care management of depression is an integral part of the program. Prior to the first session, patients were handed a book and corresponding videotape containing information about depression, treatment options, relapse prevention and self-management strategies, and a two-page instruction booklet to prepare for the first session. In the first session, the prevention specialist gave an overview of the DRP-program. The potential benefits of self-monitoring of depressive symptoms and various stress reduction strategies were introduced and discussed. In the second session, the personal Recurrence Prevention Plan was prepared, with special attention to self-care and what could be learned from the patient's earlier episodes. Socializing and the scheduling of pleasant activities such as sports were encouraged. At the third and final session, depression specialist and patient drew up the final Prevention	3 individual sessions Telephone 4 phone calls yearly for 3 years IG (3): Face-to-face Weekly CBT for 12 weeks 3 individual sessions Telephone 4 phone calls yearly for 3 years	Use of antidepressant medication Humanistic outcomes: Patient evaluation of the information and care received for depression Effects on perceived self-efficacy

	Plan, with the following topics: personal warning signs; stress reduction strategies; an 'Emergency-plan', with the steps that the patient was planning to take once s/he feared a relapse or recurrence; and a medication plan for patients using antidepressants. During the first phase of the DRP-Program, the primary care physician regularly received written feedback about patient cooperation and progress, and about medication use including side effects. After the last session, a copy of the patients' Prevention Plan was sent to the physician with an accompanying letter in which specific elements of the plan were highlighted. IG (2): PC and DRP. The PC+DRP group was offered one 1-hour visit with one of two available psychiatrists prior to the DRP-intervention. The PCP provided the psychiatrist with information about the patients' health and treatment status. Afterwards, the psychiatrist reported and discussed his diagnostic findings and treatment advice with the PCP. A copy of this report was also made available to the prevention specialist.	

				IG (3): CBT and DRP. The CBT+DRP group was offered 12 weakly one-hour sessions of CBT treatment. The DRP-Program started after the final CBT session. The CBT-therapist informed the prevention specialist about the main themes that the CBT had addressed, and the progress achieved. To reinforce concepts and CBT techniques and to monitor their adherence to the protocol, regular supervision sessions were held. CG: Usual care			
Striegel-Moore et al. (66, 67)	Cognitive Behavioural Guided Self-Help for the Treatment of Recurrent Binge Eating 2010, United States	RCT 123 participants (IG: 59; CG: 64)	Recurrent Binge Eating	IG: Following randomization, all participants were mailed a flyer detailing relevant health plan sponsored services, such as regularly offered series of classes focused on non-diet approaches to health living and eating. Patients were also encouraged to contact their primary care physician for other potentially appropriate services within the health plan including visits with a nutritionist or mental health provider. The intervention group additionally received 8 sessions implemented over a 12-week period. The treatment was based on Fairburn's "Overcoming Binge Eating" (1995). The book's first part provides user-friendly information	Therapists (master's level)	Face-to-face Weekly for 4 weeks, then fortnightly (total 8 sessions)	Clinical outcomes: Abstinence from binge eating Humanistic outcomes: Eating related psychopathology Psychosocial functioning

				about binge eating; the second part comprised a six-step self-help program. The primary focus was on developing a regular pattern of moderate eating using self-monitoring, self-control strategies, and problem solving. To promote maintenance of behavioural change, relapse prevention was emphasized. CG: Treatment as usual			
Sturt et al. (68)	Effects of the Diabetes Manual 1:1 structured education in primary care 2008, UK	c-RCT 48 practices 245 participants (IG: 114; CG: 131)	Diabetes	IG: Practices nurses held a 15-minute face-to-face consultation to introduce the 12-week Diabetes Manual program. Patients worked independently through the workbook. Patient workbook was recommended at 1 hour per day over 12 weeks. Topics included diabetes facts/ metabolism/ goal setting and evaluation/ exercise/ nutrition/ blood glucose monitoring/ weight loss/ smoking cessation/ tests/ complications/ medication/ stress, anxiety and depression/ cholesterol/ quizzes to self-evaluate workbook topics/ other people's stories/ self-assessment record sheets to encourage personal evaluation of current and new behaviours. A relaxation audiotape was provided, and the patient was encouraged within the workbook to use it and to explore alternative relaxation methods. A question/ answer	Nurse	Telephone 1, 5, 11 weeks	Clinical outcomes: HbA1c Cardiovascular risk factors Humanistic outcomes: Diabetes-related distress Confidence to self-care measured

				audiotape was provided mirroring discussion between a general practitioner and patient used as a brief introduction to diabetes and its management. Practice nurse telephone support was provided to assess goal progress, promotion of self-evaluation and re-negotiation, offer support and problem solve. CG: Usual care			
Tiessen et al. (69, 70)	Randomized controlled trial on cardiovascular risk management by practice nurses supported by self-monitoring in primary care 2012, The Netherlands	RCT 201 participants (IG: 105; CG: 96)	Cardiovascular disease or diabetes	IG: All patients received counselling regarding cardiovascular risk from practice nurses trained in MI techniques and in the intervention group this counselling was based on self-monitoring results (pedometer, weighing scale and/ or blood pressure device). Treatment for all present risk factors was pro-actively offered. The order in which the treatments for the different risk factors were started depended on preference and SOC of the participant. Adapted MI was used to help participants recognize and change unhealthy behaviour. If applicable, quitting smoking was advised as the first treatment goal. Treatment for all risk factors that the participant was motivated for working on, had to start within three months. In case of several risk factors, these treatments could be combined within one visit. (1)	Nurse	Face-to-face Variable number of sessions over 12 months	Clinical outcomes: Anthropometric data Changes in medication and medical history Fasting blood glucose; lipids and creatinine Number and duration of visits Humanistic outcomes: Smoking behaviour Use of self-monitoring

				Overweight: Intensive counselling and feedback on energy intake and expenditure, supported by food diary, home weight scale, step diary and pedometer. (2) Smoking: Intensive counselling and feedback based on SOC, Minimal Intervention Strategy and Dutch GP guideline. (3) Physical Inactivity: Intensive counselling and feedback on increasing physical activity, supported by step diary and pedometer. (4) Hypertension/Hypercholesterolemia: same as control group except feedback based on home measurements. CG: For the control group, follow-up visits were planned according to the Dutch GP guideline in case of hypertension and/or hypercholesterolemia. Medication adjustments were made by the practice nurses under supervision of the GP. For each visit the practice nurses filled in a step by step treatment plan based on the Dutch GP guideline.			
van Dijk-de Vries et al. (71)	Lessons learnt from a cluster-randomized trial evaluating the effectiveness of Self-Management	c-RCT 77 practices 264 participants	T2DM	IG: SMS included a detection and follow-up phase. The detection phase of SMS started by exploring whether patients experienced problems in daily life. Patients who experienced	Nurse	Face-to-face or telephone 3-monthly	Clinical outcomes: Glycaemic control Humanistic outcomes:

	Support (SMS) delivered by practice nurses in routine diabetes care 2015, The Netherlands	(IG: 117; CG: 147)		problems of daily functioning and emotional health problems were offered consultations for SMS. These extra consultations delivered by PNs were aimed at supporting patients in their day-to-day management of diabetes and its emotional and social consequences. The intervention strategy derived from the principles of learning theory has been described elsewhere. PNs supported patients in the processes of defining problems and finding solutions themselves, by applying problem-solving and reattribution techniques. Problem solving consisted of seven stages that efficiently addressed problems and their possible solutions. The reattribution technique was applied to challenge patients to link feelings and cognition to consequent behaviour. Patients could use information from a diary in which they recorded symptoms, thoughts, worries, feelings, and behaviour. Both problem solving, and reattribution techniques were intended to result in action plans indicating how patients would achieve their personal goals. CG: Usual care			Perceived effect of diabetes on daily functioning Diabetes-related distress QOL Autonomy and participation Self-efficacy Self-management
Von Korff et al. (72)	A trial of an activating intervention for	RCT	Chronic back pain	IG: An initial 90-minute visit with a psychologist; identified and addressed patient fears about	Psychologist Physiotherapist	Face-to-face	Clinical outcomes:

	chronic back pain in primary care and physical therapy settings 2005, United States	240 participants (IG: 119; CG: 121)		back pain; discussing the relationship between resuming normal activities and QOL; setting activity or exercise goals to enhance QOL; and developed an action plan to achieve the goal. The second visit with a physical therapist conducted a standardized mechanical examination of the back, discussed unresolved patient concerns identified in the initial visit, taught stretches and exercises relevant to the action plan, and offered guidance in overcoming barriers the patient had encountered in carrying out the action plan. The third visit focused on the action plan and exercises relevant to the action plan. After a 2-week interval, a fourth visit (30 minutes) with the psychologist reviewed progress, encouraged use of relaxation, and developed plans for sustaining progress, managing flare ups and resuming activities when a flare up occurred. CG: Usual care		4 sessions over 4-5 weeks Telephone 2, 6, 12 and 24 months	Pain intensity Chronic pain grade Humanistic outcomes: Fear avoidance beliefs Mental health and social functioning
Waite et al. (73)	Cognitive behaviour therapy for low self-esteem: a preliminary randomized controlled trial in a primary care setting 2012, UK	RCT 22 participants (IG: 11; CG: 11)	Low self esteem	IG: The treatment was based on Fennell's (1997, 1999, 2006) CBT protocol for overcoming low self-esteem and included four phases: 1. Individualized formulation, goal setting and psycho-education (sessions 1-2) 2. Learning skills to re-evaluate	Psychologist	Face-to-face 10 sessions over 11 weeks	Clinical outcomes: Self-report measures of depression (Beck Depression Inventory-II)

				anxious and self-critical thoughts and beliefs through cognitive techniques and behavioural experiments (sessions 3-8) 3. Enhancing self-acceptance (sessions 4 - 8) 4. The development of more adaptive beliefs and rules and planning for the future (sessions 7-10). As well as individual treatment sessions, all participants were given a three-part self-help workbook and were asked to read the chapters and complete the exercises to tie in with the associated therapy sessions. CG: Wait list control			Humanistic outcomes: Self Esteem (Robson Self-concept Questionnaire) Overall psychological functioning and wellbeing (Routine Evaluation Outcome Measure)
Watkins et al. (74)	Guided self-help concreteness training as an intervention for major depression in primary care: A Phase II randomized controlled trial 2012, UK	RCT 121 participants (IG (1): 40; IG (2): 39; CG; 42)	Major depression	IG (1): Cognitive bias modification (CBM) training guided self-help intervention. During the initial session, the treatment rationale was explained, the psychologist provided psycho-education about depression, rumination and overgeneralization, and practiced training exercises with the patient. During the telephone sessions, feedback, guidance and encouragement was provided to ensure accurate use of the exercises, monitored progress and scheduled regular practice. The training exercises involved patients' identifying a recent mildly to moderately upsetting difficulty and working	Psychologist	Telephone 1 week after initial training, and fortnightly thereafter	Clinical outcomes: Self-report depression measures Humanistic outcomes: NA

	through standardized steps to facilitate concrete thinking: (1) using mental imagery to focus on sensory details during the difficult event, noticing what is specific about the event and the context in which it occurs; (2) noticing the process and sequence by which the difficult event unfolds ('How did it happen?'), including warning signs and actions that may have influenced its outcome; (3) focusing on how to move forward by specifying the particular steps and behaviours to do next (Watkins, 2009; Watkins et al. 2009). The practice CD included (a) 30 min repeating the original training exercise; (b) a 7-min First Aid exercise in which concrete thinking is applied to difficulties in real time as they occur (practiced in the first telephone session); (c) a 7-min 'absorption exercise' in which concrete thinking is used to enhance positive experiences (practiced in the second telephone session). IG (2): Treatment as usual plus relaxation training guided self-help. In relaxation training, the training exercises involved progressive relaxation skills including tensing and relaxing muscle groups and slowing breathing. The practice CD	

				included (a) a 30-min progressive relaxation exercise; (b) a 7-min First Aid exercise using relaxation; (c) a 7-min exercise in which patients practiced letting go of tension without prior tensing of muscles. CG: Treatment as usual			
Watson et al. (75)	Evaluation of a self-management plan for chronic obstructive pulmonary disease New Zealand, 1997	RCT 56 participants (IG: 29; CG: 27)	COPD	IG: Practice nurses were educated about the use of the Action Plan and booklet by a senior nurse from the hospital respiratory outreach service. The PN then introduced subjects to the Action Plan and booklet. The GP also saw each subject and gave them a prescription for a course of oral prednisone and a broad spectrum antibiotic appropriate for self-administration during an exacerbation. No attempt was made to supervise the adequacy of the instruction given to subjects. The COPD Action Plan and booklet evaluated in this study were developed by staff from Canterbury Respiratory Services. The format for the Action Plan was modelled on the asthma action plan produced by the Asthma Foundation of New Zealand. Feedback from workshops with GPs and PNs, and interviews with patients led to modifications to the Action Plan. The booklet, entitled "A	Nurses	Not specified	Clinical outcomes: Respiratory status; prednisone use; antibiotic use; contact with GP, PN, hospital specialist, pharmacist Humanistic outcomes: HRQOL

				Guide to Living Positively with Chronic Obstructive Pulmonary Disease", was developed to be used in conjunction with the Action Plan. Existing patient education material was reviewed together with appropriate scientific literature. The topics included in the booklet were: stopping smoking; controlling breathlessness; exercise; daily activities made easier; diet; sleep; clearing mucus from the lungs; planning for the future; medications; oxygen; and contact details for support services. Drafts of the booklet were circulated among patients, their families, respiratory health professionals and PNs for comment. CG: Usual care			
Williams et al. (76)	Guided self-help cognitive behavioural therapy for depression in primary care: a randomized controlled trial 2013, UK	RCT 281 participants (IG: 140; CG: 141)	Depression	IG: The first appointment focused on an introduction to the use of self-help materials. The patient was given a copy of Workbook 1 (‘‘Understanding depression’’) and instructed on how to use it. At session 2, the first workbook was reviewed before a joint decision identified additional 1–2 treatment workbooks to be used between sessions 2 and 3. These were chosen on the basis of the initial self-assessment in the Understanding depression workbook. At session 3, there	General practitioner Psychologist	Face to face Weekly to fortnightly (total 3-4 sessions)	Clinical outcomes: Psychological symptoms Humanistic outcomes: Social functioning Acceptability of the intervention (using the Client Satisfaction Questionnaire-CSQ)

	was a final review of their progress. The relapse prevention workbook and up to one or two additional workbooks were also offered at this final appointment. The workbooks aimed to communicate key CBT principles in a low jargon way. Case examples, illustrations, text and interactive worksheets encouraged users to self-assess, and then choose which topics (workbooks) they would work on. Each workbook included a Putting into Practice (homework) plan to encourage application in the reader's own life. The choice of workbooks followed a core/options approach where the initial workbook (self-assessment) helped identify what problem areas the person wished to work on. In the final support session, the focus was on the Planning for the Future (relapse prevention) workbook. At any time during treatment, patients could arrange to see their doctor or other health care practitioner as normal. The intervention by the psychology graduate was only to support the use of the self-help materials using a written support protocol and ''advice'' separate from the intervention was not offered. The	

				GP was informed that the participant had been seen and discharged at the end of GCBT-SH support. The support protocol focused on using and applying one to two workbooks per week. The support worker encouraged the participant to read, answer questions and plan how to put what was being learned into practice. Each session allowed progress or barriers to progress to be reviewed and plans to overcome these barriers to be discussed. CG: Treatment as usual			
Wood-Baker et al. (77)	Written action plans in chronic obstructive pulmonary disease increase appropriate treatment for acute exacerbations 2006, Australia	c-RCT 139 participants (IG: 67; CG: 72)	COPD	IG: All participants received a COPD information booklet and an individual educational session with a nurse experienced in managing respiratory disease. The nurse covered a range of topics including basic pathology of COPD, smoking cessation, immunization, nutrition, exercise, sputum clearance techniques, breathing control, stress management, medications, inhaler use and community support services. Participants in the intervention group were provided with a written self-management action plan, which was developed in consultation with their GP. The self-management plan listed the patient's maintenance	Nurse General Practitioner	Face-to-face 6, 12 months Telephone 3, 9 months	Clinical outcomes: Use of antibiotics Short courses of oral steroids Smoking status Humanistic outcomes: HRQOL

				medications and provided an individualized action plan based on the early recognition of symptoms associated with exacerbations of COPD. All participants in the action plan group were encouraged to make early contact with their GP during an exacerbation. CG: Routine care			
Yardley et al. (78)	Effectiveness of primary care-based vestibular rehabilitation for chronic dizziness 2004, UK	RCT 170 participants (IG: 83; CG: 87)	Chronic dizziness	IG: The nurse taught the patient exercises to be carried out daily at home, with the support of a treatment booklet. Nurses explained the rationale for vestibular rehabilitation, described and took the patient through the set of standard head and eye exercises, asked the patient to identify and record in the booklet, advised the patient how to monitor recovery using standardized exercises and dizziness ratings recorded weekly in the booklet; the nurse then taught the patient to tailor the intensity and difficulty of the exercises he or she carries out to their stage of recovery, helped the patient to select daily activities to encourage physical and psychological adaptation in everyday situations, suggested additional customized exercises to treat particular forms of dizziness or imbalance, provided advice on how to anticipate and	Nurse	Telephone At 1 and 3 weeks	Clinical outcomes: Self-reported spontaneous and provoked symptoms of dizziness Objective measurement of postural stability with eyes open and eyes closed Humanistic outcomes: Dizziness related QOL Anxiety and depression (Hospital Anxiety and Depression Scale) QOL (scores on the physical functioning scale of the Medical Outcomes Study Short Form-36

				cope with obstacles to adherence. The patient carried out exercises and activities daily at home; the patient monitored and adjusted the program as needed. CG: Usual care			quality of life questionnaire)
Zimmermann et al. (79)	Collaborative nurse-led self-management support for primary care patients with anxiety, depressive or somatic symptoms: Cluster-randomized controlled trial (findings of the SMADS study) 2016, Germany	c-RCT 20 practices 325 participants (IG: 191; CG: 134)	Anxiety Depression	IG: Case management and counselling techniques to promote self-management for patients. In cooperation with the patients, they developed specific objectives to be achieved over the course of the trial. Together, they decided on a hierarchy of goals, from smaller to larger ones, consented and recorded in written form. Subsequently, the nurses and the patients developed strategies on how to achieve these goals. The planning of the measures and concrete self-management support took place in close consultation with GPs. After reaching an agreement at the first session, further appointments were scheduled. Over the course of the trial, nurses could use the nine modules of intervention to support their patients or offer low-threshold, behavioural modules: problem-solving techniques, relaxation exercises or strengthening self-confidence activities – all promoting better	Nurse	Face-to-face Sessions delivered over 12 months	Clinical outcomes: NA Humanistic outcomes: Change in self-efficacy

	self-care, i.e. improving self-management. The counselling process ended with a final interview in order to get patients' feedback, check goal attainment and preview further developments. Nurses regularly met with the study GP (EP; GP and psychotherapist) for joint discussions. CG: Routine care	

Abbreviations: BMI: body mass index; CBM: cognitive bias modification; CBT: cognitive behaviour therapy; CG: control group; CHD: coronary heart disease; COPD: chronic obstructive pulmonary disease; c-RCT: cluster randomized controlled trial; DCRS: diabetes care record sheet; DRP: depression recurrence prevention; EQ-5D: EuroQoL-5D; GPs: general practitioners; HbA1c: glycated haemoglobin; HRQOL: health-related quality of life; IBS: irritable bowel syndrome; IG: intervention group; MI: motivational interviewing; NA: not available; NCMs: nurse case managers; NP: nurse practitioners; OT: occupational therapist; PCPs: primary care professionals; PCST: pain coping skills training; PEFR: peak expiratory flow rate; PNs: practice nurses; QOL: quality of life; RCT: randomized controlled trial; SOC: stage of change; SMS: self-management support; T2DM: type 2 diabetes mellitus; UC: usual care; UK: United Kingdom

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S4 Appendix Summary of Findings and Extracted Outcomes

Reported outcomes	Method of assessment	Findings in (c)-RCTs
Self-efficacy		
Changes in perceived self-efficacy	DMSES	(+) Sturt et al. (1)
	Questionnaire (Likert 7-point scale)	(+) Clarkson et al. (2, 3)
	Arthritis Self-Efficacy Scale (8 items) * adapted from Lorig et al. 1989	(+) (post-treatment); NS (6 months); NS (12 months) Broderick et al. (4)
	Arthritis Self-Efficacy pain subscale	NS Dziedzic et al. (5-7)
	GSE	(+) Zimmermann et al. (8)
	GSES-12	NEA Barley et al. (9) NS van Dijk-de Vries et al. (10)
	Questionnaire (28 item)	NS Hoffmann et al. (11)
	Self-administered questionnaire	NS Meland et al. (12, 13)
	PRAISE	NS Mitchell et al. (14, 15)
	CDMSES	NS Browning et al. (16, 17)
	COPD self-efficacy scale	NS Bischoff et al. (18)
	DSES	NS Smit et al. (19, 20)
	Short form healthcare climate questionnaire	NS Kennedy et al. (21, 22)
	Managing Chronic Disease 6-Item Scale	(+) Fortin et al. (23, 24)
Level of patient activation	PAM-13	NS Eikelenboom et al. (25, 26)
Self-management and patient enablement	Patient Enablement Instrument (PEI)	(+) Dziedzic et al. (5-7)
Quality of life		
Change in HRQOL	SGRQ	(+) Efraimsson et al. (27) NS Wood-Baker et al. (28) NS McGeoch et al. (29) NS Watson et al. (30)
	Dizziness Handicap Inventory (25 items)	(+) Yardley et al. (31)
	WSAS	(+) Moss-Morris et al. (32, 33) (+) Striegel-Moore et al. (34, 35)
	IBSQOL	(+) Heitkemper et al. (36)
	Brief clinical inventory category	(+) Jaipakdee et al. (37)
	AIMS2-SF	NS (Group 1); (+) (Group 2 symptom scale, the lower limb scale, and the social scale) Rosemann et al. (38) NS Broderick et al. (4)
	SF-12	NS (physical health); (+) (mental health) Freund et al. (39) NEA Barley et al. (9)

		NS van Dijk-de Vries et al. (10) (+) Fortin et al. (23, 24) NS (physical component score); NS (mental component summary) Dziedzic et al. (5-7)
	SF-36	NS (physical health); (+) (mental health) Hoffmann et al. (11)
	SF-36PF	NS Friedberg et al. (40, 41)
	EQ-5D	NS Richards et al. (42) NS Zimmermann et al. (8) NS Kennedy et al. (21, 22)
	ADDQoL	NS Gabbay et al. (43)
	CRQ	NS Bischoff et al. (18)
	AQLQ	NS Mehuys et al. (44)
	WHO QoL-BREF	NS Browning et al. (16, 17)
	Juniper questionnaire	(+) McLean et al. (45)
	CAT	(+) Ferrone et al. (46)
	CCQ	(+) Ferrone et al. (46)
Physical and social functioning		
General functioning	Satisfaction with life scale; SAS-SR	(+) Banasiak et al. (47)#
Physical and social functioning	WOMAC	(+) (post-treatment); NS (6 months); NS (12 months) Broderick et al. (4)
General health and physical functioning	GHQ Medical Outcome Study short form general health survey	(+) Chalder et al. (48) (+) Chalder et al. (48)
Physical functioning	SF-36	NS Yardley et al. (31)
Perceived effect of diabetes on daily functioning	DFT	NS van Dijk-de Vries et al. (10)
Changes in physical and mental health status	SF-12	NS Murphy et al. (49-51)
	Warwick-Edinburgh Mental Well-being Scale	NEA Barley et al. (9)
Functional status	RDQ (modified)	NS Cherkin (52)#
Symptoms and functioning	Brief psychiatric rating scale	NS Bartels et al. (53)
Social functioning	Social Functioning scale from the SF-36	NS Von Korff et al. (54)
Psychological functioning		
Overall psychological functioning and wellbeing	CORE-OM	(+) Waite et al. (55) NS Richards et al. (42) (+) Williams et al. (56)
Self-esteem	RSCQ	(+) Waite et al. (55)
Depression score	PHQ	(+) Morgan et al. (57, 58) (+) Watkins et al. (59) NS Jaipakdee et al. (37)

		NS Dziedzic et al. (5-7)
Anxiety score	GAD-7	(+) Watkins et al. (59) NS Dziedzic et al. (5-7)
Cognitive symptoms	CSFBD	(+) Heitkemper et al. (36)
Level of distress	SCL-90R	(+) Heitkemper et al. (36)
	K10	(+) Browning et al. (16, 17)
Psychological/ psychosocial functioning	BDI-II	NS Friedberg et al. (40, 41) (+) Waite et al. (55) (+) Williams et al. (56) (+) Banasiak et al. (47)# (+) Watkins et al. (59)
Psychological distress	Mental Health Inventory	NS Von Korff et al. (54)
	Kessler Psychological Distress Scale	(+) Fortin et al. (23, 24)
Diabetes-related distress	PAID	(+) Gabbay et al. (60)# NS Gabbay et al. (43) (+) Sturt et al. (1) NS van Dijk-de Vries et al. (10)
Level of anxiety and depression	HADS	NS Yardley et al. (31) NS McGeoch et al. (29) NS Moss-Morris et al. (32, 33)# (+) (HADS anxiety); NS (HADS depression) Mitchell et al. (14, 15) NEA Barley et al. (9)
	BDI	(+) Striegel-Moore et al. (34, 35) (+) (post-treatment); NS (6 months); (+) (12 months) Broderick et al. (4) NS Grilo et al. (61)
Coping	FQCI	NS Zimmermann et al. (8)
	CSQ	(+) Broderick et al. (4)
Knowledge		
Disease knowledge	Questionnaire (5-point scale)	(+) Cherkin et al. (52)
	Brief Diabetes Knowledge Test	(+) Mehuys et al. (62)
	Questionnaire (details not reported)	(+) Efraimsson et al. (27) (+) McLean et al. (45)
	BCKQ	(+) Hill et al. (63) (+) Mitchell et al. (14, 15) (+) Ferrone et al. (46)
	Knowledge of Asthma and Asthma Medicine questionnaire (updated version)	NS Mehuys et al. (44)
	KQ	NS Grilo et al. (61)
Self-management knowledge and behaviours	PIH-NL	NS van Dijk-de Vries et al. (10)
Self-management education	Health Education Impact Questionnaire (heiQ)	(+) Fortin et al. (23, 24)
Behaviours		
Exercise		

Level of exercise/ physical activity	Questionnaire (details not reported)	(+) Cherkin (52)
	IPAQ	NS Rosemann et al. (38) NS Dziedzic et al. (5-7)
	PACE	NS Clark et al. (64, 65)
	PASE	NS Dziedzic et al. (5-7)
	Rapid Assessment of Physical Activity questionnaire	NS Eikelenboom et al. (25, 26)
Physical activity over the past 7 days (steps/ day)	Self-report diary card and pedometer recordings	NS Wood-Baker et al. (28)
Smoking		
Mean number of cigarettes smoked per day	Questionnaire (details not reported)	NS Meland et al. (12, 13)
Smoking behaviour	Questionnaire	NS Tiessen et al. (66, 67)# (+) Efraimsson et al. (27)
Smoking status	Smoking status assessment questionnaire	NS Eikelenboom et al. (25, 26)
Diet		
Estimated daily grams of fat	The Block Fat Screener questionnaire (15 items)	NS Clark et al. (64, 65)
Dietary behaviour	Rapid Eating Assessment for Participants — short questionnaire	NS Eikelenboom et al. (25, 26)
Self-management activities		
Mean days per week engaging in 3 separate diet activities	Questionnaire (self-reported) *self-care items taken from Toobert et al. 2000.	(+) Doucette et al. (68)
Mean days per week engaging in 5 separate diabetes activities	Questionnaire (self-reported) *self-care items taken from Toobert et al. 2000.	(+) Doucette et al. (68)
Mean days per week engaging in 2 separate exercise activities	Questionnaire (self-reported) *self-care items taken from Toobert et al. 2000.	NS Doucette et al. (68)
Self-care activities	SDSCA	NS (general diet); (+) (specific diet); NS (physical exercise); NS (blood glucose monitoring); NS (foot care) Browning et al. (16, 17)
		NS (general diet); NS (specific diet); (+) (physical exercise); (+) (foot care); NS (smoking) Mehuys et al. (62)
		NS Gabbay et al. (43)
		(+) Clark et al. (64, 65)
General medical illness self-management	Stanford Chronic Disease self-efficacy scale	NS Bartels et al. (53)
Self-management	COPD-SMI	(+) (for all domains expect one) McGeoch et al. (29)
Psychiatric illness self-management	IMR scale	(+) Bartels et al. (53)
Adherence		

Adherence to medication (number of prescription refills; self-reported)	Questionnaire	(+); NS Mehuys et al. (62)
Technique		
Inhalation technique	Checklist	(+) Mehuys et al. (44)
Disease specific		
Diabetes / cardiovascular conditions		
Change in HbA1c / blood glucose	Clinical laboratory measurements	(+) Goudswaard et al. (69) (+) Huang et al. (70, 71) (+) Morgan et al. (57, 58) (+) Adachi et al. (72) (+) Olry de Labry Lima et al. (73) (+) Mehuys et al. (62) (+); NS Jaipakdee et al. (37) NS Gabbay et al. (60)# NS Sturt et al. (1) NS Doucette et al. (68) NS Farmer et al. (74-76) NS Ismail et al. (77) NS Browning et al. (16, 17) NS Tiessen et al. (66, 67)# NS van Dijk-de Vries et al. (10) NS Gabbay et al. (43) (-) Partapsingh et al. (78)#
Change in weight / BMI	Anthropometric measurements	(+) Goudswaard et al. (69) NS Gabbay et al. (60)# NS Huang et al. (70, 71) NS Morgan et al. (57, 58)# NS Ismail et al. (77) NS Adachi et al. (72) NS Partapsingh et al. (78) NS Olry de Labry Lima et al. (73)# NS Browning et al. (16, 17) NS Tiessen et al. (66, 67)#
Change in blood pressure	Blood pressure measurement	(+) Gabbay et al. (60) (+) (SBP); NS (DBP) Huang et al. (70, 71) (+) (SBP); NS (DBP) Browning et al. (16, 17) (+) (SBP); NS (DBP) Gabbay et al. (43) NS Meland et al. (12, 13) NS Doucette et al. (68) NS Morgan et al. (57, 58)# NS Murphy et al. (49-51) NS Ismail et al. (77) NS Adachi et al. (72) NS Partapsingh et al. (78) NS Olry de Labry Lima et al. (73) NS Tiessen et al. (66, 67)#
Change in lipids	Clinical laboratory test	NS Meland et al. (12, 13) NS Gabbay et al. (60)# NS Doucette et al. (68) NS Huang et al. (70, 71)

		NS Morgan et al. (57, 58)# NS Murphy et al. (49-51) NS Ismail et al. (77) NS Adachi et al. (72) NS Partapsingh et al. (78) NS Olry de Labry Lima et al. (73) NS Browning et al. (16, 17) NS Tiessen et al. (66, 67)# NS Gabbay et al. (43)
Chest pain	Modified Rose Angina Questionnaire	NEA Barley et al. (9)
Chronic obstructive pulmonary disease		
Pulmonary function	FEV1	NS Wood-Baker et al. (28)
		(+) Ferrone et al. (46)
Respiratory status	Diary (self-report)	NS Watson et al. (30)
Courses of antibiotics	COPD-SMI	NS McGeoch et al. (29)
	Diary (self-report)	(+) Wood-Baker et al. (28) (+) Watson et al. (30)
Courses of oral steroids	COPD-SMI	NS McGeoch et al. (29)
	Diary (self-report)	(+) Wood-Baker et al. (28) NS Watson et al. (30)
Symptom burden	CRQ-SR	(+) (6 weeks); NS (6 months) Mitchell et al. (14, 15) NS Bischoff et al. (18)
Frequency and patients' management of exacerbations	TEXAS	NS Bischoff et al. (18)
	Diary (self-report)	(+) Ferrone et al. (46)
Eating disorders		
Frequency over the past 28 days of episodes of objective binge eating	EDE; EDE-Q	(+) Banasiak et al. (47) NS Grilo et al. (61)
Frequency over the past 28 days of episodes of subjective binge eating	EDE; EDE-Q	(+) Banasiak et al. (47)#
Purging episodes score=primary purging behaviour (episodes of vomiting, or laxative, or diuretic or enema/suppository misuse).	EDE; EDE-Q	(+) Banasiak et al. (47)
Body mass index	Direct measurements of weight and height	NS Banasiak et al. (47)# NS Grilo et al. (61)
Binge eating severity	The Gormally binge eating scale (16 items)	NEA Clark et al. (64, 65)#
Abstinence from binge eating	PHQ-ED (modified)	(+) Striegel-Moore et al. (34, 35)
Asthma		
Level of asthma control	ACT	NS Mehuys et al. (44)
PEF	PEFR (self-measured)	NS Mehuys et al. (44) (+) McLean et al. (45)
Rescue medication use	Self-report diary	(+) Mehuys et al. (44)
Asthma symptoms	North of England asthma symptoms scale (10 items)	(+) Barbanel et al. (79)
	Self-report symptom scores	(+) McLean et al. (45)
Number of exacerbations	Self-report diary	NS Mehuys et al. (44)
Nocturnal awakenings over 14 days	Self-report diary	(+) Mehuys et al. (44)
Migraine		

Intensity of pain	Questionnaire (10-point scale)	NS Hoffmann et al. (11)
Number of days with headache	Kiel Headache Questionnaire	NS Hoffmann et al. (11)
Back pain		
Mean difference in pain intensity	Questionnaire (10-point scale)	NS Von Korff et al. (54)
Symptom relief	Questionnaire (10-point scale)	NS Cherkin (52)
Dizziness		
Change in spontaneous and provoked symptoms of dizziness	Vertigo Symptom Scale-Short Form	(+) Yardley et al. (31)
Oral hygiene		
Percentage of surfaces with plaque	Silness and Löe index	NS (RCT); (+) (cRCT) Clarkson et al. (2, 3)
Percentage sites bleeding	Silness and Löe index	NS Clarkson et al. (2, 3)
Timing, duration and method	Self-report (scale)	(+) Clarkson et al. (2, 3)
Irritable bowel syndrome		
Symptom severity	IBS-SSS	(+) Moss-Morris et al. (32, 33)#
Chronic fatigue syndrome		
Fatigue impact on functioning	FSS	(+) Friedberg et al. (40, 41) (+) Chalder et al. (48)
Depression		
Depressive symptoms	HAM-D	(+) Watkins et al. (59)
	CES-D	NS Gabbay et al. (43)
Symptom load	PHQ-D	NS Zimmermann et al. (8)
Osteoarthritis		
Pain intensity	BPI	(+) (post-treatment); NS (6 months); (+) (12 months) Broderick et al. (4)
Peripheral joint pain intensity	OMERACT/OARSI responder criteria	(+) Dziedzic et al. (5-7)
Fatigue	BFI	(+) (post-treatment); NS (6 months); (+) (12 months) Broderick et al. (4)
Use of pain medication	Diary (self-report)	(+) (post-treatment); NS (6 months); (+) (12 months) Broderick et al. (4)
Other		
Satisfaction	Questionnaire (questionnaire with two subscales, “Information and General care”)	(+) Cherkin (52)
Satisfaction with health	AIMS2-SF	(+) (post-treatment); NS (6 months); NS (12 months) Broderick et al. (4)
Depth of relationship; professional care and perceived time	Consultation satisfaction questionnaire	(+) Richards et al. (42)

Legend: (+): significant findings $p<0.05$; NS: non-significant findings; (-): negative findings; NEA: no evidence available; #: no p-value provided

Abbreviations: ACT: Asthma control test; ADDQoL: Audit of Diabetes Dependent Quality of Life; AIMS2-SF: Arthritis Impact Measurement Scales Short Form (78 items); AQLQ: Standardised Asthma Quality of Life Questionnaire; BCKQ: Bristol COPD Knowledge Questionnaire; BDI: Beck Depression Inventory (21 items); BDI-II: Beck Depression Inventory-II; BFI: Brief Fatigue Inventory; BMI: body mass index; BPI: Brief pain inventory; CAT: COPD assessment test; CCQ: Clinical COPD Questionnaire; CDMSES: Career Decision Making Self Efficacy Scale; CES-D: Centre for Epidemiologic Studies Depression scale; COPD-SMI: COPD-self management interview; CORE-OM: Clinical Outcomes in Routine Evaluation Outcome Measure; CRQ: Chronic respiratory questionnaire (20 items); CRQ-SR: Chronic Respiratory Questionnaire dyspnoea domain; CSFBD: Cognitive Scale for Functional Bowel Disorders; CSQ: Coping strategies questionnaire (42 items); DBP: diastolic blood pressure; DFT: Daily Functioning Thermometer; DMSES: Diabetes Management Self-efficacy Scale; DSES: Depression Self-Efficacy Scale (5 items); DTSQ: Diabetes Treatment Satisfaction Questionnaire; EDE: Eating Disorder Examination; EDE-Q: Eating Disorder Examination Questionnaire (EDE Q); EQ-5D: quality of life questionnaire (5 items); FEV1: Forced expiratory volume in one second; FQCI: Freiburg questionnaire of coping with illness; FSS: Fatigue Severity Scale; GAD-7: Generalized Anxiety Disorder-7; GHQ: General Health Questionnaire (12 items); GSE: general self-efficacy scale; GSES: General Self Efficacy Scale; HADS: Hospital Anxiety and Depression Scale (14 items); HAM-D: Depression rating scale (17 items); heiQ: Health Education Impact Questionnaire; HDL: high density lipoprotein; HRQOL: Health-related quality of life; IBSQOL: Irritable Bowel Syndrome quality of life questionnaire; IBS-SSS: Irritable Bowel Syndrome Severity Scoring System; IPAQ: Short form of the International Physical Activity Questionnaire; K10: Kessler 10 score; KQ: Knowledge Questionnaire (10 items); LDL: low density lipoprotein; PACE: The Physician-based Assessment and Counselling for Physical Activity (11 items); PAID: Problem Areas in Diabetes scale (20 items); PAM-13: Patient Activation Measure (13 items); PASE: Physical Activity Scale for the Elderly; PEF: Peak expiratory flow; PEFR: Peak expiratory flow rate; PEI: Patient Enablement Instrument; PHQ9: Patient Health Questionnaire-9; PHQ-D: Patient health questionnaire; PHQ-ED: Patient Health Questionnaire eating disorder module; PIH-NL: Partners in Health scale (12 items); PRAISE: Pulmonary Rehabilitation Adapted Index of Self-Efficacy; RDQ: Roland Disability Questionnaire (23 items); RSCQ: Robson Self-concept Questionnaire (30 items); SAS-SR: Overall adjustment score of the modified social adjustment scale; SBP: systolic blood pressure; SCL-90R: Symptoms checklist (90 items); SDSCA: Summary of Diabetes Self-Care Activities; SF-12: Short form survey (12 items); SF-36: Short form survey (36 items); SF-36PF: Short Form-36 Physical Function subscale; SGRQ: St George's Respiratory Questionnaire (50 items); TC: total cholesterol; TEXAS: Nijmegen telephonic exacerbation assessment system; TG: triglycerides; WHO QoL-BREF: World Health Organization Quality of Life-BREF; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index (24 items); WSAS: Work and Social Adjustment Scale (5 items)

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S5 Appendix Mapping of Intervention Components

	Transfer of information	Active stimulation of symptom monitoring	Self-treatment through use of self-management or action plan	Resource utilization	Strategies for psychological coping or stress management	Enhancing problem-solving or decision-making skills	Enhancing physical activity	Enhancing dietary intake	Enhancing smoking cessation	Enhancing medication adherence
Adachi et al. (1)	✓	×	×	✓	×	×	✓	✓	×	×
Banasiak et al. (2)	✓	×	×	×	✓	×	×	×	×	×
Barbanel et al. (3)	✓	✓	✓	×	✓	×	×	×	✓	✓
Barley et al. (4)	✓	✓	×	×	×	✓	×	×	×	×
Bartels et al. (5)	✓	×	×	✓	×	×	×	×	×	✓
Bischoff et al. (6)	✓	✓	×	✓	×	×	×	×	×	✓
Broderick et al. (7)	✓	×	✓	✓	✓	×	×	×	×	×
Browning et al. (8, 9)	✓	×	×	×	✓	×	×	×	×	×
Chalder et al. (10)	✓	×	✓	×	✓	×	×	×	×	×
Cherkin et al. (11)	✓	×	✓	×	×	×	✓	×	×	×
Clark et al. (12, 13)	✓	×	×	×	✓	×	✓	✓	×	×
Clarkson et al. (14, 15)	✓	✓	×	×	×	×	×	×	×	×
Doucette et al. (16)	✓	✓	×	×	×	×	×	×	×	✓
Dziedzic et al. (17-19)	✓	✓	×	×	×	✓	✓	✓	×	×
Efraimsson et al. (20)	✓	✓	×	×	×	✓	✓	✓	✓	✓
Eikelenboom et al. (21, 22)	✓	✓	✓	×	✓	×	×	×	×	×
Farmer et al. (23-25)	✓	×	✓	×	✓	×	✓	✓	×	✓
Ferrone et al. (26)	✓	✓	×	✓	✓	×	✓	✓	✓	✓
Fortin et al. (27, 28)	✓	×	×	×	×	×	✓	✓	✓	×
Freund et al. (29)	✓	✓	✓	×	✓	✓	×	×	×	×
Friedberg et al. (30, 31)	✓	✓	✓	✓	✓	×	✓	×	×	×
Gabbay et al. (32)	✓	✓	×	×	×	✓	×	×	×	×
Gabbay et al. (33)	✓	×	×	×	×	✓	×	×	×	✓
Goudswaard et al. (34)	✓	×	✓	×	×	×	✓	✓	×	✓

Grilo et al. (35)	✓	×	✓	✓	×	×	×	✓	×	×
Heitkemper et al. (36)	✓	✓	✓	✓	✓	×	×	✓	×	×
Hill et al. (37)	✓	×	×	×	×	×	✓	×	✓	✓
Hoffmann et al. (38)	✓	✓	×	×	×	×	×	×	×	×
Huang et al. (39, 40)	✓	✓	✓	×	×	×	✓	✓	×	✓
Ismail et al. (41)	✓	✓	✓	×	✓	×	×	✓	×	✓
Jaipakdee et al. (42)	✓	×	✓	✓	✓	×	✓	✓	×	✓
Kennedy et al. (43, 44)	✓	×	×	✓	×	✓	×	×	×	×
McGeoch et al. (45)	✓	✓	✓	×	×	×	×	×	×	×
McLean et al. (46)	✓	✓	✓	×	✓	×	×	×	×	✓
Mehuys et al. (47)	✓	×	×	×	×	✓	×	×	✓	✓
Mehuys et al. (48)	✓	×	×	×	×	✓	✓	✓	✓	✓
Meland et al. (49, 50)	✓	×	✓	✓	✓	×	✓	✓	✓	×
Mitchell et al. (51, 52)	✓	×	×	✓	×	×	✓	×	×	×
Morgan et al. (53, 54)	✓	✓	×	×	✓	×	×	×	×	×
Moss-Morris et al. (55, 56)	✓	×	✓	✓	×	×	✓	✓	×	×
Murphy et al. (57-59)	✓	✓	×	✓	×	✓	✓	✓	✓	✓
Olry de Labry Lima et al. (60)	✓	×	×	×	×	✓	✓	✓	×	×
Partapsingh et al. (61)	✓	×	×	×	×	×	✓	✓	×	✓
Richards et al. (62)	✓	×	×	✓	×	×	×	×	×	×
Rosemann et al. (63)	✓	×	×	✓	×	✓	✓	×	×	×
Smit et al. (64, 65)	✓	✓	✓	✓	×	×	×	×	×	×
Striegel-Moore et al. (66, 67)	✓	×	✓	✓	✓	✓	×	✓	×	×
Sturt et al. (68)	✓	×	✓	✓	✓	×	✓	✓	✓	✓
Tiessen et al. (69, 70)	✓	×	✓	×	×	×	✓	✓	✓	×
van Dijk-de Vries et al. (71)	✓	✓	✓	✓	✓	×	×	×	×	×
Von Korff et al. (72)	✓	✓	×	×	✓	×	✓	×	×	×
Waite et al. (73)	✓	×	×	✓	×	✓	×	×	×	×
Watkins et al. (74)	✓	×	×	✓	×	✓	×	×	×	×
Watson et al. (75)	✓	✓	✓	×	×	×	✓	✓	✓	✓
Williams et al. (76)	✓	×	×	✓	✓	×	×	×	×	×
Wood-Baker et al. (77)	✓	✓	×	✓	×	✓	✓	✓	✓	✓
Yardley et al. (78)	✓	✓	✓	×	✓	×	✓	×	×	×
Zimmermann et al. (79)	✓	×	×	✓	✓	×	×	×	×	×
Total	57	26	25	25	24	13	27	24	13	21

Legend: (✓) component present; (×): component absent/ unclear/ not specified

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Supplementary File 1 Focus Group Discussion Guide

Domain 1 Implementation and sustainability

1. How do you think the service would be best integrated into current practice in the beginning?
2. What are the facilitators to implementing the service?
3. What are the barriers to implementing the service?
4. What strategies would address the barriers to implementing the service you have identified?
5. What factors will ensure the sustainability of the service?

Domain 2 Collaboration with general practitioners

6. How should referrals between health providers take place (ie. pharmacists and GPs)?
7. What are your suggestions on method of referral (ie. letter given to patient)?
8. How should a relationship between the pharmacist and general practitioner be initiated?
9. How should communication between the pharmacist and general practitioner be performed?
10. When should communication between the pharmacist and general practitioner be performed?
11. What are your views on existing IT platforms for communication between community pharmacists and general practitioners?
12. What information do you think should be shared?

Domain 3 Treatment and referral pathways

13. What are your views on community pharmacists using agreed treatment protocols during consultation for assessment, management and referral for common minor ailments?
14. What are your views on existing eHealth platforms for pharmacists to access treatment protocols?

Domain 4 Documentation and follow up processes

15. Should follow up with patients be performed?
16. How and when should follow up with patients be performed?
17. Do you think should document their consultations? If so, what information should be documented?

Supplementary File 2 Semi Structured Interview Guide for Community Pharmacists

Domain 1 Acceptability and perceived benefits of the service

1. What are your views on minor ailment services?
    a. For the pharmacy as a business?
    b. For pharmacists as a healthcare professional?
    c. For the patient?
    d. For the healthcare system?
2. Do you believe that a minor ailment service is important? Why/ why not?
3. Do you think providing the service fits your role as a community pharmacist?
4. Do you think the service is appropriate for your pharmacy?
5. Do you think the service ensures the appropriate and safe provision of health care to patients? Why/ why not?

Domain 2 Service flow and elements

6. Do you think that the pharmacy offers adequate privacy to offer consultations for minor ailments? Can you suggest any improvements?
7. Have you adapted or modified the service or workflow in any way?
8. What are your views on the treatment protocols (HealthPathways)? Do they effectively support you?
9. What are your views on the referral points and processes? Are these adequate?
10. What are your views on the documentation and record keeping process?

Domain 3 Resources

11. Do you think there is enough resources (ie. time, space, staff) to deliver the service in this pharmacy?

Domain 4 Training and support

12. Do you believe the training and ongoing monthly in-store and telephone support is adequate to support you to deliver the service? Why/ why not?

Domain 5 Interprofessional collaboration

13. When an individual patient consults at the pharmacy, do you believe it is valuable for their GP to be informed or notified by an official channel (ie. HealthLink)? Why/ why not?
14. What are your views on the level of healthcare professional collaboration- is this adequate? Should there be more/ or less?

Domain 6 Remuneration

15. Do you believe pharmacies should be remunerated to provide the service in Australia?
16. Who should fund the service?
    a. Patient?
    b. Government?
    c. PHN?
17. Do you think there should be a cost associated with patients accessing the service?
18. What do you believe is an appropriate level of reimbursement?
19. Do you think the service would change if there was no monetary incentive other than associated sale revenue?

Domain 7 Implementation and sustainability

20. Are there any barriers or facilitators associated with your offering of the service in your pharmacy? Please describe (if any).
21. Do you believe that there are any factors (internal or external) that would influence your decision to implement the service?
22. What aspects of the service do you think could be improved?
23. Are there any aspects of the service that do/do not work well that haven't been covered?
24. Do you have any other views or experiences regarding the service?

Supplementary File 3 HealthPathways Example (Reflux)

HealthPathways

For Pharmacists-Reflux Pharmacy Protocol

This protocol is for community pharmacists participating in the trial of a collaborative minor ailments service. The protocol offers best practice advice on the care of adults aged ≥ 18 years with symptoms suggestive of reflux.

Disclaimer

About

About reflux

About Reflux

- Reflux of gastric contents into the oesophagus is a normal physiological process.
- Heartburn is a burning sensation rising from the epigastrium toward the neck. It is usually caused by reflux of acid into the oesophagus and may be associated with regurgitation.
- 15 to 20% of adults experiencing heartburn at least once a week.
- Persistent symptoms, occurring more than twice weekly, are considered to be gastroesophageal reflux disease (GORD).
- Causes may include:
  - relaxation of the lower oesophageal sphincter.
  - increased lower abdominal pressure
  - delayed gastric emptying
  - impaired oesophageal clearance

Red flags

Send to emergency department immediately if:

- Black, tarry stool
- Vomiting that is persistent, protracted, or contains blood.
- Crushing chest pain radiating to the back, neck, jaw or arms
- Chest discomfort exacerbated by exercise.
- Trouble breathing or feeling faint
- Severe or disabling pain

Consultation

1. Take a history:
   - symptoms

Symptoms

- Location and frequency of pain
- Nature and severity of pain. If gnawing, sharp, or stabbing it is unlikely to be reflux.
- Radiation: referred pain might indicate cardiovascular origin e.g., radiation to jaw, neck, or left arm.
- Associated symptoms: black and tarry stools (indicate a bleed in the gastrointestinal tract).

   - classification/severity

Classification or severity

- Severe: patient waking at night and symptoms significantly impact quality of life.

- Moderate: symptoms are frequent, intense and prolonged, and impacting quality of life.
- Mild: symptoms are not overly bothersome, although can occur frequently or infrequently.

- risk factors

Risk factors

- Overweight or obese
- Pregnancy
- Smoking
- Other medical conditions e.g., Crohn's disease, hypothyroidism, hypocalcaemia

- aggravating factors

Aggravating factors

Ask about:

- foods that can reduce lower oesophageal sphincter pressure e.g., fatty foods, garlic, onions, spearmint, peppermint, and alcohol.
- food and drinks that can make symptoms worse e.g., acidic or spicy food, caffeine, fruit juice.
- eating habits that can make symptoms worse e.g., overeating and eating "on the move".

- medications

Medications

- The use of medications which lower oesophageal pressure include:
  - calcium channel blockers
  - nitrates
  - anticholinergics e.g., benzhexol, benztropine, oxybutynin, tolterodine, tricyclic antidepressants, antipsychotics, and sedating antihistamines
  - dopaminergic medicines
  - nicotine replacement therapy (NRT)
  - progesterone
  - benzodiazepines
  - phosphodiesterase-5 (PDE-5) inhibitors e.g., sildenafil, tadalafil, vardenafil
  - beta-agonists e.g., salbutamol, terbutaline, eformoterol
- The use of medications which may cause or exacerbate oesophagitis include:
  - non-steroidal anti-inflammatory drugs (NSAIDS), including low-dose aspirin
  - bisphosphonates
  - iron
  - potassium chloride
  - tetracyclines
- The use of medications which may delay gastric emptying include:
  - narcotic analgesics
  - glucagon-like peptide-1 (GLP-1) analogues (e.g. exenatide, liraglutide)
  - anticholinergics.

2. Consider differential diagnosis.

Differential diagnosis

- Gastric or duodenal ulceration:
  - Can lead to gastrointestinal bleeding, perforation, and gastric obstruction.
  - Nearly 75 percent of the people who have gastric or duodenal ulcers don't have symptoms. In fact, these ulcers rarely cause severe symptoms.
  - Possible severe symptoms or signs include: black and tarry stool, vomiting blood, stabbing or gnawing pain, persistent and severe.
- Gastric cancer: Upper abdominal discomfort with other possible associated symptoms including nausea and vomiting, weight loss, black and tarry stool or vomiting blood.
- Oesophageal cancer: may present with symptoms of pain or difficulty swallowing, sensation of food sticking in oesophagus, unintended weight loss.
- Gallstones: Pain in right upper abdomen especially after a big meal.
- Ischaemic heart disease (IHD)
  - Nature of pain - tightness, burning, crushing, squeezing, constricting, vice-like, aching.
  - Location of pain: chest, shoulder(s), neck, arm(s), jaw, back
  - Associated symptoms: nausea, dizziness, cold sweat, shortness of breath, discomfort or pain in the upper abdomen (dyspepsia) and feeling unwell generally

3. Identify any concerning features and refer appropriately to general practitioner unless otherwise indicated.

Concerning features

- Anaemia
- Painful or difficult swallowing
- Sensation that food is 'sticking' in the throat
- Abdominal mass
- Severe or debilitating pain
- Treatment failure (using non-pharmacological and non-prescription measures)
- Adverse drug reaction suspected or suspected medication induced reflux e.g., from bisphosphonate
- Unexplained cough, dyspnoea, or hoarseness
- Long-standing change in bowel habit
- Aged < 18 years, or > 55 years with new onset or undiagnosed symptoms
- Unexplained weight loss associated with gastrointestinal symptoms
- Symptoms that are severe or frequent (such as awaking patient during night), or if symptoms have a significant impact on daily life

Treatment

1. For all patients provide non-pharmacological support.

Non-pharmacological support

- If symptoms are considered to be a minor ailment condition, proceed with a standardised management approach.
- Provide each patient a PSA Self-Care Fact Card.
- For all patients regardless of the severity or frequency:
  - Review and avoid trigger factors:
    - If patient is overweight or obese, advise weight loss.
    - Advise smoking cessation and alcohol intake reduction.
    - Refer to general practitioner to consider change or stop medicines known to cause or worsen reflux (as listed in the consultation).

- Provide nutrition advice:
  - Eat smaller, frequent meals.
  - Drink fluids between meals rather than with meals.
  - Not eating large meals near bedtime.
  - Avoid trigger foods/drinks.
  - Reducing alcohol intake.
- Simple measures:
  - Avoid lying down for up to 3 hours after eating.
  - Raising the bed head (if symptoms occur at night).

2. Consider pharmacological options and be aware of specific considerations.

Specific considerations

In elderly: avoid constipating products.

During pregnancy:

- Trial non-pharmacological recommendations initially.
- If drug therapy is required:
  - Antacids are pregnancy category A, and are the treatment of choice for pregnant women with GORD.
  - H2-antagonists, ranitidine is Category B1.
  - PPIs should only be used if antacids and H2-antagonists have not been effective.
  - Esomeprazole, lansoprazole, omeprazole, and pantoprazole are category B3, and rabeprazole is category B1.
  - If a PPI is required during pregnancy, omeprazole has the most data in humans and appears safe to use.

Manage medications according to symptom severity.

- mild infrequent (≤ 2 times a week)

Mild infrequent

- Antacids when required and/or H2-receptor antagonists (Ranitidine) for 14 days.
  - Combination antacids: dose according to label, up to 1 g elemental calcium daily. Liquid products are more effective, but less convenient, than solid products
  - Advise patient to:
    - Take between meals or at bedtime when symptoms occur or patient expects they might occur. Optimum antacid effect is achieved if taken 1 – 3 hours after meals.
    - Chew or suck before swallowing for the best effect.
    - Take antacids at least 2 hours away from other medicines by at least 2 hours.
  - Simple:
    - Sodium bicarbonate, potassium bicarbonate, calcium carbonate e.g., Quik-eze, Tums, Eno, Alka-seltzer.
    - Simple combinations: Rennie (calcium carbonate with magnesium carbonate).
    - Generally well tolerated but may experience some stomach distension, flatulence, belching.
  - Aluminium or Magnesium:
    - Aluminium hydroxide, magnesium hydroxide, magnesium trisilicate, magnesium sulfate, magnesium carbonate; e.g. Alu-tabs, Mylanta, Gaviscon Relief, Gastrogel.
    - Aluminium based side effect: Constipation.
    - Magnesium based side-effect: Diarrhoea.
  - Alginates: Combination with antacids e.g., Gaviscon, Mylanta heartburn relief.
- H2-receptor antagonist: If antacids do not give adequate relief, use Ranitidine:
  - 150 mg then repeat after 1 hour (Max daily dose 300 mg), or

- 300 mg once daily.
- Onset after 20-30min and last 4 to 12 hours.

- If symptoms:
  - resolve, continue lifestyle recommendations and medication as required.
  - do not resolve, treat as per mild frequent or moderate reflux.

- ⛔ mild and frequent (>2 times a week) or moderate

Mild and frequent or moderate

Trial a proton pump inhibitor (PPI) for 14 days.

- Dose: once daily 30 to 60 minutes before a meal.
- Advise patient:
  - Swallow whole with glass of water - do not crush or chew.
  - If their symptoms occur:
    - mainly during the day, to take the proton pump inhibitor before breakfast.
    - mainly at night, to take the proton pump inhibitor before the evening meal.
- It takes 2 to 3 days for the PPI to reach maximum effectiveness, and the patient may need adjuvant therapy with an antacid until then.
- Supply either:
  - Esomeprazole 20 mg daily.
  - Rabeprazole 10 mg daily.
  - Pantoprazole 20 mg daily.
  - Omeprazole 20 mg daily.

Referral

Arrange referral if symptoms are not considered to be a minor ailment condition or patient is presenting with red flags or concerning features. Determine patient's regular general practitioner or practice and arrange appropriate referral:

- Immediate emergency department referral:
  - Black, tarry stool
  - Blood in vomit
  - Vomiting that is persistent, protracted, or contains blood
  - Crushing chest pain radiating to the back, neck, jaw or arms
  - Chest discomfort exacerbated by exercise.
  - Trouble breathing or feeling faint
  - Severe or disabling pain
- Immediate general practitioner referral:
  - Known anaemia
  - Painful or difficult swallowing
  - Sensation that food is ‘sticking’ in the throat
  - Unexplained weight loss associated with gastrointestinal symptoms
  - Symptoms that are severe or frequent (such as awaking patient during night)
  - Significant impact on daily life
- 2 to 3 week general practitioner referral:
  - Unexplained cough, dyspnoea, or hoarseness
  - Longstanding change in bowel habit
  - Aged < 18 years, or > 55 years with new onset or undiagnosed symptoms
  - Adverse drug reaction suspected or suspected medication induced reflux e.g., from bisphosphonate
  - Symptoms that show no improvement after 2 weeks of proton pump inhibitor (PPI) therapy
  - Symptoms persist or relapse frequently

Documentation and general practitioner feedback

- Ensure that the patient:

- has read and signed the Patient Information and Informed Consent Form (to be kept at the pharmacy)
- has completed the EURO-QOL EQ-5D questionnaire (hard copy to be kept at the pharmacy)
- is informed of follow-up phone call conducted by the research team

- Provide date and time to patient of phone call (14 days after consultation in the pharmacy)
- Document the consultation by recording relevant information of the consultation on the data collection spreadsheet (for research purposes)
- Provide an electronic summary to the patient's regular general practitioner.

Provide an electronic summary to the patient's regular general practitioner.

- For all patients, provide a summary of the consultation, including non-prescription medicines provided.
- If referral was provided, indicate the criteria for referral.

Visit Health Link connect portal

Information

Patient information

- Gastroenterological Society of Australia – Heartburn (Oesophageal Reflux) Information Sheet
- Nice – GORD and Dyspepsia in Adults: Investigation and Management
- Healthdirect – GORD-Reflux
- Better Health Channel – Indigestion
- Choosing Wisely Australia – Heartburn and Reflux: Manage Your Medicine
- NPS – Your Heartburn and Reflux Management Plan
- Mothersafe – Heartburn in Pregnancy and Breastfeeding

Clinical resources

- Disorders of the oesophagus [revised 2017 Mar]. In: eTG complete [Internet]. Melbourne: Therapeutic Guidelines Limited; 2016 Mar.
- Australian Medicines Handbook 2017 (online). Adelaide: Australian Medicines Handbook Pty Ltd; 2017 Jan.
- National Institute for Health and Clinical Excellence (2014) - Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management. NICE guideline
- Rutter P, Newby D. Community pharmacy: symptoms, diagnosis and treatment. 2016; 3e
- Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol 2013;108(1):18–38
- Pharmaceutical Society of Australia. Guidance for provision of a pharmacist only medicine – proton pump inhibitors (PPIs). In: Sansom LN, ed. Australian pharmaceutical formulary and handbook. 23rd edn. Canberra: PSA; 2015.

Page Information

Information about this HealthPathways document (412706):

Document Owner: Not assigned (see Who's Who)
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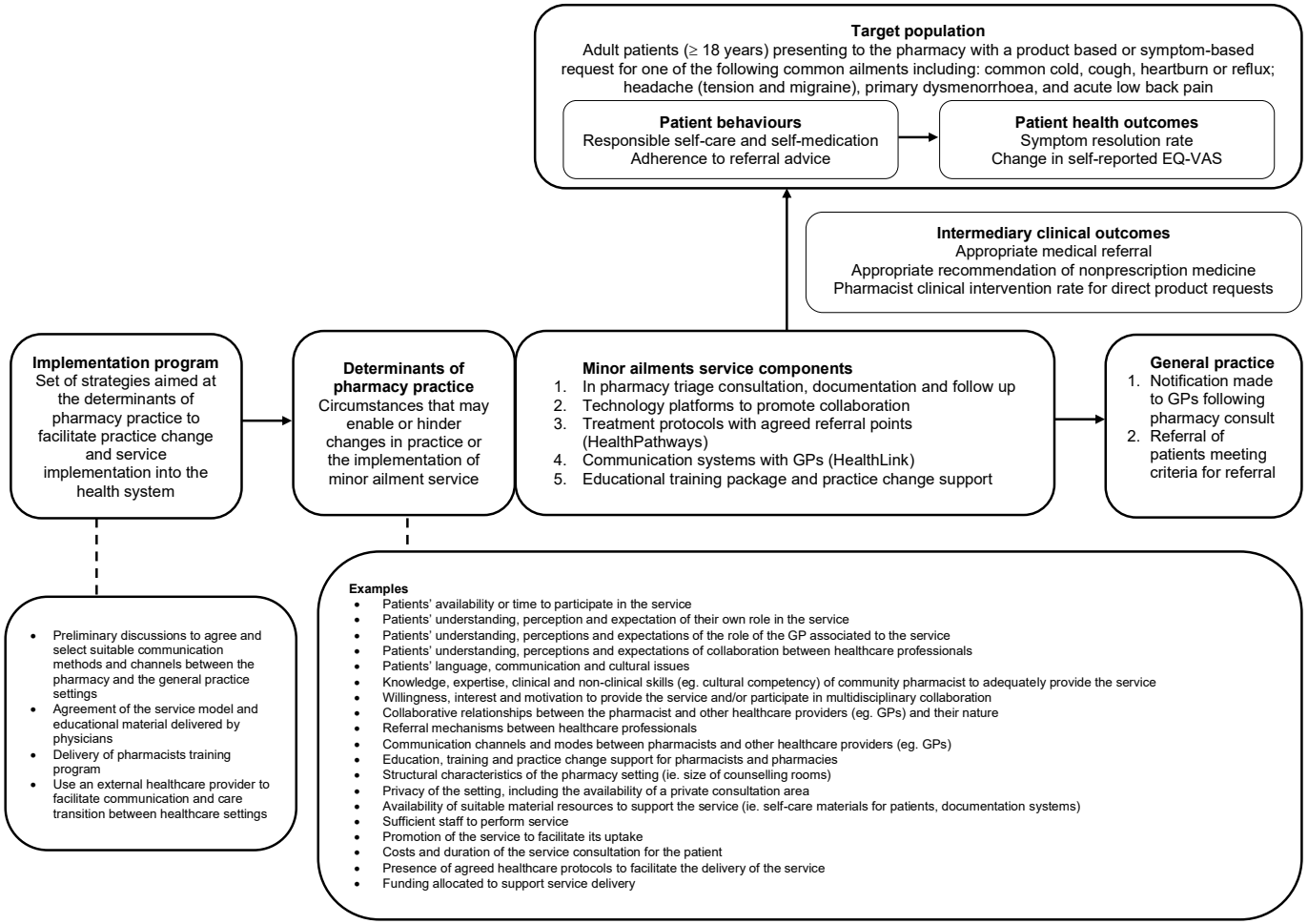
Have you read the disclaimer?

Supplementary File 4 Theoretical Service Model, based on the JeMa2 Model



Checklist 1 Consolidated Criteria for Reporting Qualitative Research (COREQ) Checklist

Citation: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007;19(6):349-357.

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	4
Credentials	2	What were the researcher's credentials? e.g. PhD, MD	4
Occupation	3	What was their occupation at the time of the study?	4
Gender	4	Was the researcher male or female?	4
Experience and training	5	What experience or training did the researcher have?	4
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	N/A
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	N/A
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	4
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	4
Sample size	12	How many participants were in the study?	7
Non-participation	13	How many people refused to participate or dropped out? Reasons?	N/A
Setting			

Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	4
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	N/A
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	7
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	4
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	4
Field notes	20	Were field notes made during and/or after the interview or focus group?	4
Duration	21	What was the duration of the inter views or focus group?	4
Data saturation	22	Was data saturation discussed?	N/A
Transcripts returned	**23**	**Were transcripts returned to participants for comment and/or correction?**	N/A
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	4
Description of the coding tree	25	Did authors provide a description of the coding tree?	N/A
Derivation of themes	26	Were themes identified in advance or derived from the data?	4
Software	27	What software, if applicable, was used to manage the data?	4
Participant checking	28	Did participants provide feedback on the findings?	N/A
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	7
Data and findings consistent	30	Was there consistency between the data presented and the findings?	7
Clarity of major themes	31	Were major themes clearly presented in the findings?	7
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	7

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18 May 2017

Professor Charlie Benrimoj
Graduate School of Health
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Charlie,

UTS HREC ETH17-1348 – Professor Charlie Benrimoj, Professor Kylie Williams, Dr Victoria Garcia Cardenas (for Ms Sarah Dineen-Griffin, PhD student) – "A model of collaborative primary health care: Integrating consumer self-care, community pharmacy and general practice in the management of minor ailments and usage of non-prescription medications (first phase - qualitative study)"

Thank you for your response to the Committee's comments for the above-titled project. Your response satisfactorily addresses the concerns and questions raised by the Committee who agreed that the application now meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). I am pleased to inform you that ethics approval is now granted.

Your approval number is UTS HREC REF NO. ETH17-1348
Approval will be for a period of five (5) years from the date of this correspondence subject to the provision of annual reports.

Please note that the ethical conduct of research is an on-going process. The *National Statement on Ethical Conduct in Research Involving Humans* requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9772.

Yours sincerely,

Production Note:
Signature removed
prior to publication.

Associate Professor Beata
Bajorek Chairperson
UTS Human Research Ethics Committee

UTS: PHARMACY

UTS UNIVERSITY OF TECHNOLOGY, SYDNEY

PARTICIPANT INFORMATION SHEET

STUDY TITLE	A model of collaborative primary health care: Integrating consumer self-care, community pharmacy and general practice in the management of minor ailments and usage of non-prescription medications (UTS Ethic Approval No. ETH 17-1348)
STUDY LOCATION	University of Technology Sydney (or alternatively, Western Sydney primary health network Blacktown)

Before you decide if you wish to participate we would like you to understand why the study is being done, what it will involve and how your information will be used. Please take time to read the following information carefully. One or more of our team will go through the information sheet with you and answer any questions you have. Please ask questions about anything that you do not understand or want to know more about. Participation in this research is voluntary. You will be given a copy of this Information Sheet to keep.

WHO IS DOING THE RESEARCH?

The study is being led by the research team at The University of Technology Sydney with chief investigator Prof Charlie Benrimoj, Sarah Dineen-Griffin, Prof Kylie Williams and Dr Victoria Garcia Cardenas. We have active collaboration with Western Sydney primary health network that will facilitate and support service delivery to local communities.

WHAT IS THIS RESEARCH ABOUT?

In order to enhance the provision of minor ailment services in Australia, we are conducting research to evaluate stakeholder perspectives in co-designing a community pharmacy service in the area of minor ailments, self-care and non-prescription medicines. The research aims to standardise care through agreed treatment pathways for use in routine pharmacy practice, provide formal arrangement for referral and communication with the GP and to integrate community pharmacists into the primary care team.

This qualitative study will use a focus group approach with 8-10 participants who have been selected by the research team to obtain an in-depth understanding of stakeholder perspectives in designing and delivering the service. The overall objectives of this qualitative research are to:

- To co-design a model of the service to be piloted and trialed in community pharmacies.
- To ensure the service meets the needs of stakeholders (general medical practitioners, patients and community pharmacists) and is responsive to local needs.
- To ensure successful implementation and sustainability of the service.

WHY HAVE I BEEN ASKED?

You have been invited to participate in this study because you have been identified as a valuable stakeholder to the service. The findings of this study will be critical in understanding the context in which the intervention will be applied and consequently, in formulating its key components.

IF I SAY YES, WHAT WILL IT INVOLVE?

Your participation in this project will involve:

- You will be asked to attend a focus group conducted at the University of Technology, Sydney (or alternatively Western Sydney primary health network, Blacktown).
- The focus group will take approximately three hours to complete plus travel time.
- You will be remunerated for your time at $50/hour and travel.

WHAT BENEFITS WILL I GET?
Findings of this study may be of potential benefit to you in the future.

ARE THERE ANY RISKS/INCONVENIENCE?
There are very few if any risks because the research has been carefully designed. Inconvenience may occur due to time away from usual work commitments. In addition, possible discomfort may occur based on the questions asked. Any information obtained in connection with this research that can identify you will remain confidential and will only be disclosed with your permission, except as required by law. The research team intend to publish and/ report the results of the research study in a variety of ways including peer reviewed journals, which will form part of a final thesis for a doctoral degree and communications in research conferences. All information published will be done in a way that will not identify you.

WHAT WILL HAPPEN IF I SAY NO?
Nothing. We will thank you for your time so far and won't contact you about this research again.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?
If you decide to participate in the focus group your comments along with other participants will be recorded during the focus group discussion. Because of the way in which the focus group discussions are recorded, the research team will not be able to withdraw or destroy individual participant responses. If you do not wish to be recorded, you will not be able to participate in the study.

Any information obtained in connection with this study project that can identify you will remain confidential. Your information will only be used for the purpose of this study project and it will only be disclosed with your permission. All participant information will be de-identified. You will be coded and referred to as a randomly assigned number in all published or unpublished data. All data collected will be stored in secure UTS premise and will only be accessible to authorised personnel with login and password details. Hard copies of data will be kept in locked in filling cabinets with restricted key access, at the Graduate School of Health, University of Technology Sydney.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?
If you would like any further information concerning this project or you have any questions you wish to be answered before consenting or during the course of the study, please feel free to contact Sarah Dineen-Griffin via email sarah.dineen-griffin@uts.edu.au or by phone on +61 2 9514 7256. Alternatively, you may contact Prof Charlie Benrimoj on shalom.benrimoj@uts.edu.au or +61 2 9514 4013.

If you would like to talk to someone not directly involved with the study for any further information regarding your rights or should you wish to make a complaint to people independent of the study team, you may contact the Ethics Secretariat on +61 2 9514 2478 or Research.Ethics@uts.edu.au and quote the UTS HREC reference number.

UTS: PHARMACY

UTS UNIVERSITY OF TECHNOLOGY, SYDNEY

PARTICIPANT CONSENT

I _____ (participant's name) agree to participate in the research project Pharmacy Service Model for Minor Ailments (UTS Ethic Approval No. ____) being conducted by Sarah Dineen-Griffin or Prof Charlie Benrimoj, +61 2 9514 4013 of the University of Technology Sydney. Funding for this research has been provided by the Pharmaceutical Society of Australia and the Research and Innovations Office, University of Technology Sydney.

1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I have been informed about the possible risks of taking part in this study.

4. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

5. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future relationship with the University of Technology Sydney.

6. I am aware this focus group will be audiotaped and transcribed, but this will be de-identified to ensure privacy and confidentiality.

7. I agree to keep confidential all information including all conversations and discussions, materials and methods provided to by the UTS research team.

8. I consent to any necessary and relevant information to be shared with the research group at the University of Technology Sydney for the purposes of this project. I understand that such information will remain confidential.

9. I agree that the research team has answered all my questions fully and clearly.

10. I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

_____ ____/____/____
Signature (participant)

_____ ____/____/____
Signature (researcher or delegate)

NOTE:
This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research, which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 2478 or Research.Ethics@uts.edu.au), and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

Multimedia Appendix 1 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Sequence generation	16a	Method of generating the allocation sequence (e.g., computer- generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant- level dataset, and statistical code
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

Multimedia Appendix 2 Study Outcomes

Variable	Operational definition	Group	Type	T0[a]	T2[b]	Data source	Completed by
Clinical							
Appropriate medical referral rate	Defined as meeting the action agreed in the HealthPathways for each patient referred. Each referral made will be independently assessed against the action outlined within the HealthPathways for each minor ailment indication (which were pre-agreed with GPs[c] in the codesign process). The referral is considered appropriate if it meets the reason for referral, recommended time frame to seek care, and health care provider referred to. In which case, the appropriateness of referral will be calculated as the proportion of patients appropriately referred divided by the total number of patients referred for treatment and control arms.	IG[d], UG[e]	1°[f]	X	—[g]	Patient consultation record	Pharmacist
Appropriate recommendation of nonprescription medicine rate	Defined as meeting the action agreed in the HealthPathways for each product recommended. Each product recommendation will be independently assessed against the action outlined within the HealthPathways for each minor ailment indication (which were pre-agreed with GPs in the codesign process). The recommendation is considered appropriate if it meets the entire requirement as approved in Product Information by the Therapeutic Goods Administration including correct indication for use, dose, frequency, duration of use, and contraindications. The appropriateness of medicine recommendation will be calculated as the proportion of patients receiving an appropriate medicine recommendation by the pharmacist divided by the total number of patients who received a medicine during the consult for treatment and control arms.	IG, UG	1°	X	—	Patient consultation record	Pharmacist
Pharmacist intervention rate (or clinical intervention rate) for direct product requests	Defined as the identification and attempted resolution of an actual or potential drug-related or symptom-related problem arising from a patient self-selecting a medicine to self-treat. An investigation of the pharmacist's identification and response (ie, change in product to a safer or more appropriate alternative) will be made. In which case, the clinical intervention rate will be calculated as the proportion of patients recommended an alternative product by the pharmacist divided by the total number of patients who present to the	IG, UG	1°	X	—	Patient consultation record	Pharmacist

	pharmacy directly requesting a product for self-treatment for treatment and control arms.						
Self-reported symptom resolution rate	Participants will be asked at follow-up to indicate whether their minor ailment symptoms have (1) completely resolved, (2) improved but not completely resolved, and (3) not improved or have worsened. Complete resolution has been defined as the complete absence of minor ailment symptoms at 14-day follow up. In which case, the symptom resolution rate will be calculated as the proportion of patients reporting complete symptom resolution at 14-day follow-up divided by the total number of patients successfully followed up for treatment and control arms.	IG, UG	2°[h]	—	X	Telephone data collection record	Research team member
Economic							
Health services resource utilization associated with the minor ailment	Defined as the individual's use of pharmaceutical, GP, hospital, and emergency department services within 14 days following the initial consultation with the pharmacist for treatment and control arms.	IG, UG	2°	X	X	Patient consultation record, telephone data collection record	Pharmacist and research team member
Time and resources of service delivery	Defined as the time and personnel consumptions for MAS[i] delivery and usual care.	IG, UG	2°	X	X	Patient consultation record, facilitators database	Pharmacist, research team member, and practice change facilitator
Humanistic							
Change in self-reported EQ-VAS[j]	Defined as patient's overall measure of health status at (1) the initial consultation with the pharmacist and (2) 14 days following the initial consultation with the pharmacist for treatment and control arms.	IG, UG	2°	X	X	EuroQoL Visual Analogue Scale	Patient

[a]T0: baseline, [b]T2: follow-up at 14 days, [c]GP: general practitioner, [d]IG: intervention group, [e]UG: usual care group, [f]1°: primary outcome, [g]—: not applicable, [h]2°: secondary outcome, [i]MAS: minor ailment service, [j]EQ-VAS: EuroQoL visual analogue scale.

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UTS CRICOS PROVIDER CODE 00099F

24 May 2017

Professor Charlie Benrimoj
Graduate School of Health
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Charlie,

UTS HREC ETH17-1350 – Professor Charlie Benrimoj, Professor Kylie Williams, Dr Victoria Garcia Cardenas (for Ms Sarah Dineen-Griffin, PhD student) – "A model of collaborative primary health care: Integrating consumer self-care, community pharmacy and general practice in the management of minor ailments and usage of non-prescription medications (Second Phase: Pilot and Cluster-Randomised Controlled Trial)"

Thank you for your response to the Committee's comments for the above-titled project. Your response satisfactorily addresses the concerns and questions raised by the Committee who agreed that the application now meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). I am pleased to inform you that ethics approval is now granted.

Your approval number is UTS HREC REF NO. ETH17-1350
Approval will be for a period of five (5) years from the date of this correspondence subject to the provision of annual reports.

Please note that the ethical conduct of research is an on-going process. The *National Statement on Ethical Conduct in Research Involving Humans* requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9772.

Yours sincerely,

Production Note:
Signature removed
prior to publication.

Associate Professor
Beata Bajorek
Chairperson
UTS Human Research Ethics Committee

PATIENT INFORMATION SHEET

STUDY TITLE	A model of collaborative primary health care: Integrating consumer self- care, community pharmacy and general practice in the management of minor ailments and usage of non-prescription medications (UTS Ethic Approval No. ETH17-1350)
STUDY LOCATION	Western Sydney primary health network

Before you decide if you wish to participate we would like you to understand why the study is being done, what it will involve and how your information will be used. Please take time to read the following information carefully. One or more of our team will go through the information sheet with you and answer any questions you have. Please ask questions about anything that you do not understand or want to know more about. You will be given a copy of this Information Sheet to keep.

WHO IS DOING THE RESEARCH?

The study is being led by the research team at The University of Technology Sydney with chief investigator Prof Charlie Benrimoj, Sarah Dineen-Griffin, Prof Kylie Williams and Dr Victoria Garcia Cardenas. We have active collaboration with Western Sydney primary health network and the Pharmaceutical Society of Australia that will facilitate and support service delivery to local communities.

WHAT IS THIS RESEARCH ABOUT?

In order to enhance the provision of minor ailment services in Australia, researchers at the University of Technology Sydney have co-designed an innovative pharmacy service, which draws on existing skills and technologies to address consumer self-care of minor ailments. The research aims to standardise care through agreed treatment pathways for use in routine pharmacy practice, provide formal arrangement for referral and communication with the GP and to integrate community pharmacists into the primary care team.

WHY HAVE I BEEN ASKED?

Pharmacies have been randomly chosen to trial a new method of service. You are being asked to participate because the pharmacy you are attending today is participating in the trial. Not all pharmacies will provide the new service; some will continue to provide usual care.

IF I SAY YES, WHAT WILL IT INVOLVE?

We will ask intervention participants to participate in:

- 5-10 minute pharmacist-patient consultation. In this consultation your pharmacist will ask you about your minor ailment symptoms. You will receive care from your pharmacist based on your symptoms. This may include educating you on how to self-manage your condition and provide you a non-prescription medicine if appropriate.
- 2 minutes to complete a questionnaire.
- 5 minute follow up telephone questionnaire 14 days after your visit to the pharmacy by the research team.
- Personal and health information will be transferred to your usual GP and the research team.

We will ask control participants to participate in:

- Usual care provided by your pharmacy
- 2 minutes to complete a questionnaire when usual care has been provided.
- 5 minute follow up telephone questionnaire 14 days after your visit to the pharmacy by the

research team.
- Personal and health information will be transferred to the research team only.

WHAT BENEFITS WILL I GET?
We cannot guarantee or promise that you will receive any benefits from this research; however findings of this study may be of potential benefit to you in the future.

ARE THERE ANY RISKS/INCONVENIENCE?
There are very few if any risks because the research has been carefully designed. Inconvenience may occur due to time taken to complete the consultation. There is a potential risk for an adverse drug reaction to a non- prescription medicine if supplied during the consultation with your pharmacist. If you experience any adverse drug reaction, please contact your pharmacy or the researchers immediately.

WHAT WILL HAPPEN IF I SAY NO?
Nothing. We will thank you for your time so far and won't contact you about this research again.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?
Any information obtained in connection with this study project that can identify you will remain confidential. Your information will only be used for the purpose of this study project and it will only be disclosed with your permission. All electronic data will be coded and kept in password-protected databases, separate from identifying information. Hard copies of data will be kept in locked in filling cabinets with restricted key access, at the Graduate School of Health, University of Technology Sydney. It is anticipated that the results of this study will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?
If you would like any further information concerning this project or you have any questions you wish to be answered before consenting or during the course of the study, please feel free to contact Sarah Dineen-Griffin via email sarah.dineen-griffin@uts.edu.au or by phone on +61 2 9514 7256.
Alternatively, you may contact Prof Charlie Benrimoj on shalom.benrimoj@uts.edu.au or +61 2 9514 4013.

If you would like to talk to someone not directly involved with the study for any further information regarding your rights or should you wish to make a complaint to people independent of the study team, you may contact the Ethics Secretariat on +61 2 9514 2478 or Research.Ethics@uts.edu.au and quote the UTS HREC reference number.

PATIENT CONSENT

I (participant's name) agree to participate in the research project Pharmacy Service Model for Minor Ailments (UTS Ethic Approval No. ETH17-1350) being conducted by Sarah Dineen- Griffin or Prof Charlie Benrimoj, +61 2 9514 4013 of the University of Technology Sydney. Funding for this research has been provided by the Pharmaceutical Society of Australia and the Research and Innovations Office, University of Technology Sydney.

1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I have been informed about the possible risks of taking part in this study.

4. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

5. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future relationship with the University of Technology Sydney.

6. I consent to any necessary and relevant information to be shared with the research group at the University of Technology Sydney for the purposes of this project. I understand that such information will remain confidential.

7. I agree that the research team has answered all my questions fully and clearly.

8. I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

_____ ___/___/___
Signature (participant)

_____ ___/___/___
Signature (researcher or delegate)

NOTE:
This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research, which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 2478 or Research.Ethics@uts.edu.au), and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

UTS: PHARMACY

UTS UNIVERSITY OF TECHNOLOGY, SYDNEY

GENERAL PRACTICE INFORMATION SHEET

STUDY TITLE	A model of collaborative primary health care: Integrating consumer self- care, community pharmacy and general practice in the management of minor ailments and usage of non-prescription medications (UTS Ethic Approval No. ETH17-1350)
STUDY LOCATION	Western Sydney primary health network

Before you decide if you wish to participate we would like you to understand why the study is being done, what it will involve and how your information will be used. Please take time to read the following information carefully. One or more of our team will go through the information sheet with you and answer any questions you have. Please ask questions about anything that you do not understand or want to know more about. You will be given a copy of this Information Sheet to keep.

WHO IS DOING THE RESEARCH?

The study is being led by the research team at The University of Technology Sydney with chief investigator Prof Charlie Benrimoj, Sarah Dineen-Griffin, Prof Kylie Williams and Dr Victoria Garcia Cardenas. We have active collaboration with Western Sydney primary health network and the Pharmaceutical Society of Australia that will facilitate and support service delivery to local communities.

WHAT IS THIS RESEARCH ABOUT?

In order to enhance the provision of minor ailment services in Australia, researchers at the University of Technology Sydney have co-designed an innovative pharmacy service, which draws on existing skills and technologies to address consumer self-care of minor ailments. The research aims to standardise care through agreed treatment pathways for use in routine pharmacy practice, provide formal arrangement for referral and communication with a patients regular GP regarding their use of non-prescription medicines.

WHY HAVE I BEEN ASKED?

You have been identified as a general medical practitioner within Western Sydney primary health network. One of your regular patients may agree to participate in this study.

IF I SAY YES, WHAT WILL IT INVOLVE?

If you are identified as a patient's regular health care provider, your participation in this research will involve receiving personal and health information from the community pharmacist including details and outcome of the consultation provided. Alternatively, if your patient is to be referred to you, you may receive a letter outlining the details of the consultation and reasons for referral.

WHAT BENEFITS WILL I GET?

We cannot guarantee or promise that you will receive any benefits from this research; however findings of this study may be of potential benefit to you in the future.

ARE THERE ANY RISKS/INCONVENIENCE?

No risks have been identified.

WHAT WILL HAPPEN IF I SAY NO?

Nothing. We will thank you for your time so far and won't contact you about this research again.

IF I SAY YES, CAN I CHANGE MY MIND LATER?
You can change your mind at any time and you don't have to say why. We will thank you for your time so far and won't contact you about this research again.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?
Any information obtained in connection with this study project that can identify you will remain confidential. Your information will only be used for the purpose of this study project and it will only be disclosed with your permission. All electronic data will be coded and kept in password-protected databases, separate from identifying information. Hard copies of data will be kept in locked in filling cabinets with restricted key access, at the Graduate School of Health, University of Technology Sydney. It is anticipated that the results of this study will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?
If you would like any further information concerning this project or you have any questions you wish to be answered before consenting or during the course of the study, please feel free to contact Sarah Dineen-Griffin via email sarah.dineen-griffin@uts.edu.au or by phone on +61 2 9514 7256. Alternatively, you may contact Prof Charlie Benrimoj on shalom.benrimoj@uts.edu.au or +61 2 9514 4013.

If you would like to talk to someone not directly involved with the study for any further information regarding your rights or should you wish to make a complaint to people independent of the study team, you may contact the Ethics Secretariat on +61 2 9514 2478 or Research.Ethics@uts.edu.au and quote the UTS HREC reference number.

GENERAL PRACTICE CONSENT

I (name) from_____(organisation) agree to participate in the research project Collaborative minor ailments model (UTS Ethic Approval No. ETH17-1350) being conducted by Sarah Dineen-Griffin or Prof Charlie Benrimoj, +61 2 9514 4013 of the University of Technology Sydney. Funding for this research has been provided by the Pharmaceutical Society of Australia and the Research and Innovations Office, University of Technology Sydney.

1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I have been informed about the possible risks of taking part in this study.

4. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

5. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future relationship with the University of Technology Sydney.

6. I consent to any necessary and relevant information to be shared with the research group at the University of Technology Sydney for the purposes of this project. I understand that such information will remain confidential.

7. I agree that the research team has answered all my questions fully and clearly.

8. I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

_____ ___/___/___
Full name (on behalf of practice)

_____ ___/___/___
Signature (on behalf of practice)

_____ ___/___/___
Signature (researcher or delegate)

NOTE:
This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research, which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 2478 or Research.Ethics@uts.edu.au), and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

PHARMACY INFORMATION SHEET

STUDY TITLE	A model of collaborative primary health care: Integrating consumer self- care, community pharmacy and general practice in the management of minor ailments and usage of non-prescription medications (UTS Ethic Approval No. ETH17-1350)
STUDY LOCATION	Western Sydney primary health network

Before you decide if you wish to participate we would like you to understand why the study is being done, what it will involve and how your information will be used. Please take time to read the following information carefully. One or more of our team will go through the information sheet with you and answer any questions you have. Please ask questions about anything that you do not understand or want to know more about. You will be given a copy of this Information Sheet to keep.

WHO IS DOING THE RESEARCH?

The study is being led by the research team at The University of Technology Sydney with chief investigator Prof Charlie Benrimoj, Sarah Dineen-Griffin, Prof Kylie Williams and Dr. Victoria Garcia Cardenas. We have active collaboration with Western Sydney primary health network and the Pharmaceutical Society of Australia that will facilitate and support service delivery to local communities.

WHAT IS THIS RESEARCH ABOUT?

In order to enhance the provision of minor ailment services in Australia, researchers at the University of Technology Sydney have co-designed an innovative pharmacy service, which draws on existing skills and technologies to address consumer self-care of minor ailments. The research aims to standardise care through agreed treatment pathways for use in routine pharmacy practice, provide formal arrangement for referral and communication with the GP and to integrate community pharmacists into the primary care team.

WHY HAVE I BEEN ASKED?

We are studying how to improve minor ailment management through community pharmacies. Your pharmacy has been randomly selected to participate in a study to trial the new service. Not all pharmacies will provide the new service; some will continue to provide usual care.

IF I SAY YES, WHAT WILL IT INVOLVE?

We will ask intervention participants to participate in:

- 5-10 minute pharmacist-patient consultations. In these consultations you will ask your patient about their minor ailment symptoms. Following an agreed treatment pathway you will educate the patient to self- manage his/her condition and provision of a non-prescription medicine if appropriate.
- 2 minute to document each consultation.
- 2 minute electronic feedback to the patient's usual GP for each consultation.
- 1 day of minor ailment service training provided by UTS and Western Sydney Primary Health Network. In this training you will be taught on the protocols for the service and its implementation in your pharmacy. Pharmacists are not required to pay for the education nor will they receive a fee for their attendance. The training will be provided locally at a convenient location and performed after hours for the pilot study to accommodate work rosters. Pharmacists will receive CPD points for attendance.

We will ask control participants to participate in:

- Usual care provided by pharmacy staff/ pharmacist.
- 2 minute to document each consultation when usual care has been provided.

WHAT BENEFITS WILL I GET?

For each consultation on minor ailments, community pharmacies will be reimbursed the cost of pharmacists' time to deliver the consultation and recording data. Control pharmacies will be reimbursed $5 per consultation. Intervention pharmacies will be reimbursed $10 per consultation. We cannot guarantee or promise that you will receive any benefits from this research; however findings of this study may be of potential benefit to you in the future.

ARE THERE ANY RISKS/INCONVENIENCE?

There are very few if any risks because the research has been carefully designed. Inconvenience may occur due to time taken to complete the consultation and training prior to study commencement.

WHAT WILL HAPPEN IF I SAY NO?

Nothing. We will thank you for your time so far and won't contact you about this research again.

IF I SAY YES, CAN I CHANGE MY MIND LATER?

You can change your mind at any time and you don't have to say why. We will thank you for your time so far and won't contact you about this research again.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

Any information obtained in connection with this study project that can identify you will remain confidential. Your information will only be used for the purpose of this study project and it will only be disclosed with your permission. All electronic data will be coded and kept in password-protected databases, separate from identifying information. Hard copies of data will be kept in locked in filling cabinets with restricted key access, at the Graduate School of Health, University of Technology Sydney. It is anticipated that the results of this study will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?

If you would like any further information concerning this project or you have any questions you wish to be answered before consenting or during the course of the study, please feel free to contact Sarah Dineen-Griffin via email sarah.dineen-griffin@uts.edu.au or by phone on +61 2 9514 7256. Alternatively, you may contact Prof Charlie Benrimoj on shalom.benrimoj@uts.edu.au or +61 2 9514 4013.

If you would like to talk to someone not directly involved with the study for any further information regarding your rights or should you wish to make a complaint to people independent of the study team, you may contact the Ethics Secretariat on +61 2 9514 2478 or Research.Ethics@uts.edu.au and quote the UTS HREC reference number.

PHARMACY/ PHARMACIST CONSENT

I (name) from (organisation) agree to participate in the research project Pharmacy Service Model for Minor Ailments (UTS Ethic Approval No. ETH17- 1350) being conducted by Sarah Dineen-Griffin or Prof Charlie Benrimoj, +61 2 9514 4013 of the University of Technology Sydney. Funding for this research has been provided by the Pharmaceutical Society of Australia and the Research and Innovations Office, University of Technology Sydney.

1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I have been informed about the possible risks of taking part in this study.

4. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

5. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future relationship with the University of Technology Sydney.

6. I consent to any necessary and relevant information to be shared with the research group at the University of Technology Sydney for the purposes of this project. I understand that such information will remain confidential.

7. I agree that the research team has answered all my questions fully and clearly.

8. I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

_____ ___/___/___
Full name (on behalf of pharmacy)

_____ ___/___/___
Signature (on behalf of pharmacy)

_____ ___/___/___
Signature (researcher or delegate)

NOTE:
This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research, which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 2478 or Research.Ethics@uts.edu.au), and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

Supplementary File 1 PICO Table

PICO	Description of detail
Population (P)	Adult patients aged 18 years or over, requesting a medicine or self-selecting a medicine to treat symptoms (product-based presentation) and/or presenting with symptoms who directly ask for pharmacists' advice (symptom-based presentation) for reflux, cough, common cold, headache (tension or migraine), primary dysmenorrhoea or low back pain.
Intervention (I)	Minor ailment service (MAS)
Comparison (C)	Usual pharmacist care (UC)
Outcomes (O)	Appropriate medical referral rate Appropriate nonprescription medicine recommendation rate Clinical product-based intervention rate Self-reported symptom resolution or improvement rate Adherence to referral advice rate Reconsultation rate to all health providers EuroQoL EQ-5D VAS

Abbreviations: MAS: minor ailment service; UC: usual pharmacist care; VAS: visual analogue scale.

The specific aim of this research is to evaluate a community pharmacy-based MAS, conducted in collaboration with general practitioners, in adult patients receiving care for certain ailments in Western Sydney primary health network region on:

a) appropriate medical referral rate
b) appropriate nonprescription medicine recommendation rate
c) clinical product-based intervention rate
d) self-reported symptom resolution or improvement rate
e) adherence to referral advice rate
f) reconsultation rate to all health providers
g) EuroQoL EQ-5D VAS

The primary research questions are:

1. Is the new model of service delivery (MAS) effective in improving appropriate medical referral rate, compared with UC?
2. Is the new model of service delivery (MAS) effective in improving appropriate non-prescription medicine recommendation rate, compared with UC?

The secondary research questions are:

3. Is the new model of service delivery (MAS) effective in improving clinical product-based intervention rates, compared with UC?
4. Is the new model of service delivery (MAS) effective in improving symptom resolution and improvement rates, compared with UC?
5. Is the new model of service delivery (MAS) effective in improving adherence to referral advice rates, compared with UC?
6. Is the new model of service delivery (MAS) effective in reducing reconsultation rates to all health providers, compared with UC?
7. Is the new model of service delivery (MAS) effective in improving the mean difference in EuroQoL EQ-5D VAS, compared with UC?

Supplementary File 2 Telephone follow up questionnaire

Confidential

Follow up Form

Researcher ID	_____
SYMPTOM RESOLUTION	
In the last 14 days, please indicate which best describes your symptoms:	◯ Symptoms have completely resolved ◯ Symptom relief or improvement but not resolved ◯ Symptoms did not improve/ have worsened
How many hours/ days taken for your symptoms to completely resolve?	◯ < 24 hours ◯ 1-2 days ◯ 3-5 days ◯ > 5 days
REFERRAL - For patients referred by pharmacist at baseline	
Did you go to see your GP, ED or other healthcare professional as advised by your pharmacist?	◯ Yes ◯ No
Which health care professional(s) did you seek help from? (multiple answers may apply)	☐ Pharmacist ☐ General practitioner ☐ Emergency department - doctor or nurse ☐ Nurse ☐ Specialist ☐ Dentist ☐ Allied health professional e.g. chiropractor, physiotherapist ☐ Other
How many times did you seek help from another health care professional?	_____
Did you receive any additional medications for your symptoms? (includes prescription and non-prescription medicines)	◯ Yes ◯ No (Includes prescription and non-prescription medicines)
If yes, please list medications (include strength, recommended dose and frequency):	_____
Were you hospitalised during this time?	☐ Yes ☐ No
Date of hospital admission	_____
Date of hospital discharge	_____

RE-CONSULTATION - For patients not referred by pharmacist at baseline	
Did you see another health care professional for your symptoms within 14 days after seeing your pharmacist?	◯ Yes ◯ No
Which health care professional did you seek help from? (multiple answers may apply)	☐ Pharmacist ☐ General practitioner ☐ Emergency department - doctor or nurse ☐ Nurse ☐ Specialist ☐ Dentist ☐ Allied health professional e.g. chiropractor, physiotherapist ☐ Other
How many times did you seek help from another health care professional?	_____
Did you receive any additional medications for your symptoms? (includes prescription and non-prescription medicines)	◯ Yes ◯ No (Includes prescription and non-prescription medicines)
Please list medications (include strength, recommended dose and frequency):	_____
Were you hospitalised during this time?	☐ Yes ☐ No
Date of hospital admission	_____
Date of hospital discharge	_____

QUALITY OF LIFE ASSESSMENT	
EuroQoL EQ5D We would like to know how good or bad your health is TODAY. Mark on the scale to indicate how your patients health is TODAY.	The worst health you can imagine — The best health you can imagine *(Place a mark on the scale above)*

FOLLOW UP NOTES	
Notes on follow up	_____

Supplementary File 3 Exploratory Subgroup Analysis

Outcome type	Outcome	Effect of the minor ailment service (MAS)/ usual pharmacist care (UC)	Subgroup variable	Subgroup level	Relative rate estimate (95% confidence interval)	p value
Primary	Appropriate medical referral rate #	Rate Ratio (MAS/ UC)	Presentation type	Both symptom & product-based presentation	1.44 (0.80 - 2.61)	0.48
				Symptom-based presentation	1.70 (1.08 - 2.65)	
				Product-based presentation	1.17 (0.83 - 1.64)	
			Condition group	Gastrointestinal	1.08 (0.88 - 1.33)	0.14
				Pain	1.34 (0.84 - 2.16)	
				Respiratory	1.59 (1.01 - 2.50)	
Primary	Appropriate nonprescription medicine recommendation rate	Rate Ratio (MAS/ UC)	Presentation type	Both symptom & product-based presentation	1.40 (1.02 - 1.93)	0.58
				Symptom-based presentation	1.19 (1.11 - 1.29)	
				Product-based presentation	1.17 (1.04 - 1.31)	
			Condition group	Gastrointestinal	1.09 (1.01 - 1.19)	0.18
				Pain	1.27 (1.09 - 1.47)	
				Respiratory	1.17 (1.09 - 1.26)	
Secondary	Clinical product-based intervention rate	Rate Ratio (MAS/ UC)	Condition group	Gastrointestinal	5.07 (0.90 - 28.56)	0.23
				Pain	2.64 (0.76 - 9.25)	
				Respiratory	1.42 (0.64 - 3.15)	
Secondary	Self-reported symptom resolution or improvement rate	Rate Ratio (MAS/ UC)	Presentation type	Both symptom & product-based presentation	1.13 (1.00 - 1.29)	0.64
				Symptom-based presentation	1.06 (0.99 - 1.14)	
				Product-based presentation	1.09 (0.99 - 1.20)	
			Condition group	Gastrointestinal	0.99 (0.93 - 1.05)	0.19
				Pain	1.11 (1.02 - 1.22)	
				Respiratory	1.06 (1 - 1.13)	
Secondary	Adherence to referral advice rate %	Rate Ratio (MAS/ UC)	Presentation type	Both symptom & product-based presentation	2.99 (0.40 - 22.07)	0.87
				Symptom-based presentation	4.18 (1.74 - 10.03)	

				Product-based presentation	6.05 (0.78 - 46.80)	
			Condition group &	NA	NA	NA
Secondary	Reconsultation rate to all health providers *	Rate Ratio (MAS/ UC)	Presentation type	Both symptom & product-based presentation	1.09 (0.22 - 5.51)	0.88
				Symptom-based presentation	1.01 (0.67 - 1.53)	
				Product-based presentation	0.86 (0.52 - 1.41)	
			Condition group	Gastrointestinal	0.67 (0.27 - 1.68)	0.73
				Pain	0.99 (0.57 - 1.71)	
				Respiratory	0.97 (0.65 - 1.47)	
Secondary	Mean difference EuroQoL EQ-5D VAS	Mean Difference (MAS/ UC)	Presentation type	Both symptom & product-based presentation	7.26 (-0.82 - 15.34)	0.27
				Symptom-based presentation	5.98 (3.67 - 8.28)	
				Product-based presentation	4.46 (-0.08 - 9.01)	
			Condition group	Gastrointestinal	8.85 (3.09 - 14.61)	0.27
				Pain	3.00 (-1.30 - 7.29)	
				Respiratory	6.06 (4.32 - 7.80)	

Abbreviations: MAS: minor ailment service; UC: usual pharmacist care; VAS: visual analogue scale.

Applies to all presentation types (symptom-based, product-based, both).

% Patients referred during consultation who went to see the healthcare provider as advised.

***** Providers include pharmacists, general practitioners, emergency departments, nurses, allied health, dentists and specialists.

& Indicates missing sub-group analyses as quasi-separation in the data occurred during statistical analysis.

Supplementary File 4 Imputed Analysis to Account for Patients Lost to Follow Up

Outcome type	Outcome	Effect of the minor ailment service (MAS)/ usual pharmacist care (UC)	Relative rate estimates with multiple imputation (95% confidence interval)	p value
Secondary	Self-reported symptom resolution or improvement rate	Rate Ratio (MAS/ UC)	1.08 (1.02 - 1.14)	0.005
Secondary	Adherence to referral advice rate %	Rate Ratio (MAS/ UC)	4.36 (1.68 - 11.31)	0.003
Secondary	Reconsultation rate to all health providers *	Rate Ratio (MAS/ UC)	0.97 (0.71 - 1.33)	0.850
Secondary	Mean difference in EuroQoL EQ-5D VAS	Mean Difference (MAS/ UC)	5.32 (2.80 - 7.84)	0.000

Abbreviations: MAS: minor ailment service; UC: usual pharmacist care; VAS: visual analogue scale.

% Patients referred during consultation who went to see the healthcare provider as advised.

* Providers include pharmacists, general practitioners, emergency departments, nurses, allied health, dentists and specialists.

Checklist 1 CONSORT 2010 Checklist

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2,3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	3
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3,4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4,5, Sup 1
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	4
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	6, Figure 1

Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	7, Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7, Table 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8, Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	8-10
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12

Checklist 2 CONSORT Extension for cRCTs Checklist

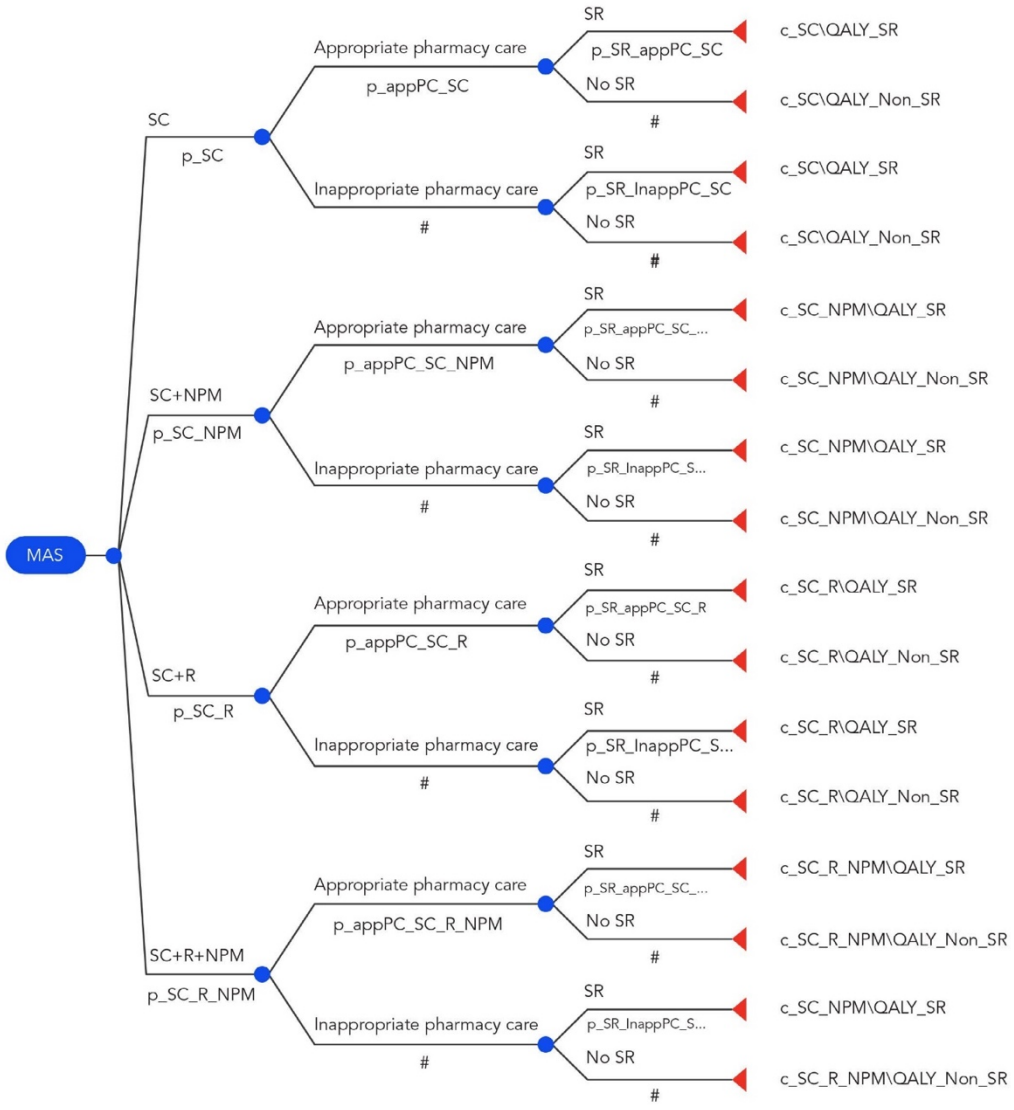
Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No*
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[i,ii]	See table 2	1
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	2
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	2
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	2-3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		n/a
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	2-3
	4b	Settings and locations where the data were collected		2-3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	4-5
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				

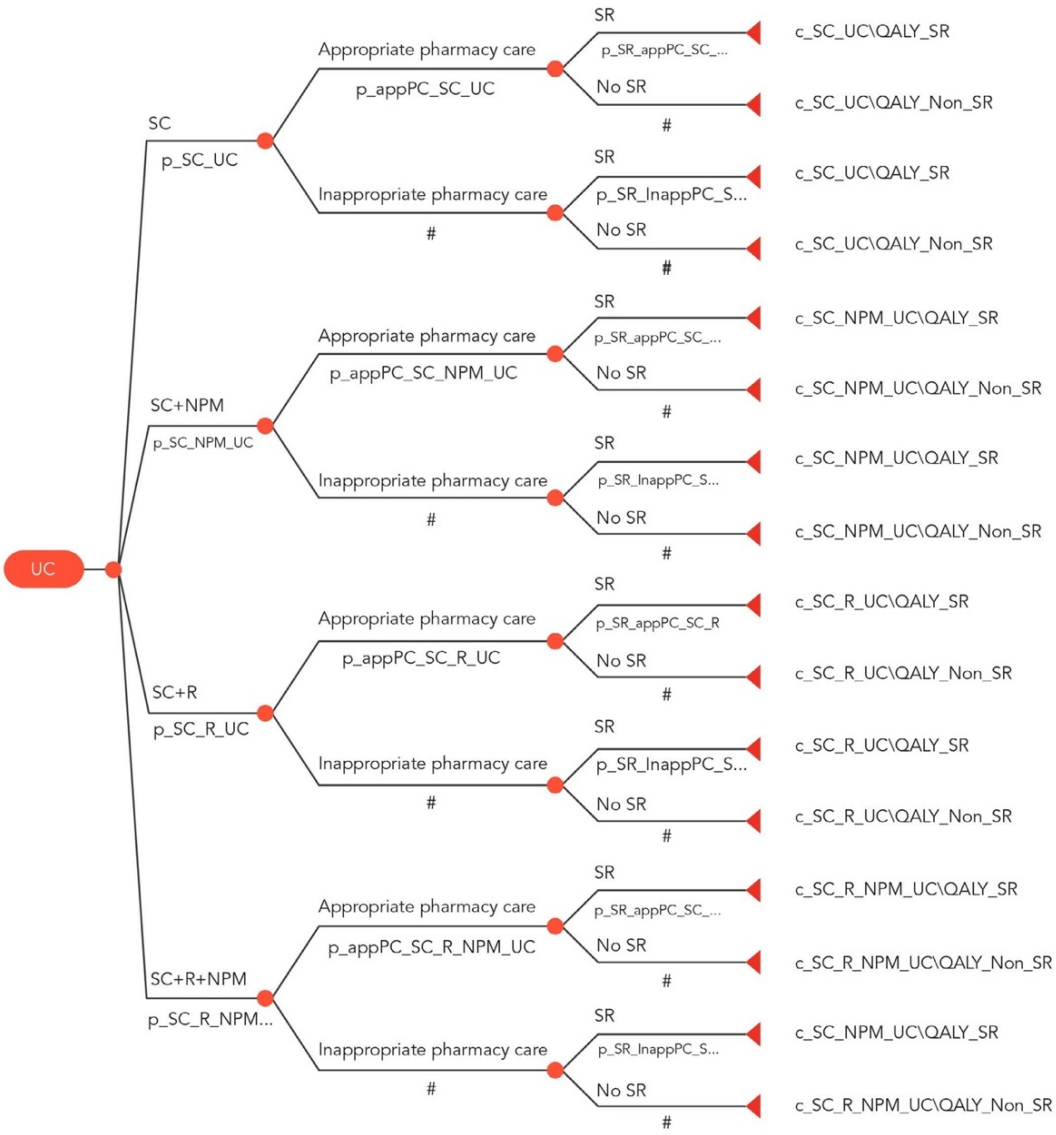
Sequence generation	8a	Method used to generate the random allocation sequence		4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	4
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	4
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		4
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was considered	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		6
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	6 Figure 1

		were analysed for the primary outcome		
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	6 Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		2
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Page 7 Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	6
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	8 Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		8-10 Supp 3 & 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[iii])		n/a
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		10-11
Other information				

Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12

Supplementary File 1 Detailed decision tree model

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SC+NPM
p_SC_NPM_UC
SC+R
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SC+R+NPM
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c_SC_R_NPM_UC\QALY_Non_SR

Supplementary File 2 Model probabilities

	Initial distribution	Probability: Appropriate pharmacist care plus symptom resolution	Probability: Inappropriate pharmacist care plus symptom resolution	Probability: Appropriate pharmacist care plus no symptom resolution	Probability: Inappropriate pharmacist care plus no symptom resolution	Cost (AUD)	QALY Symptom resolution	QALY No symptom resolution	QALY	Appropriate pharmacist care	Symptom resolution
Minor ailment service											
Self-care	0.11	0.90	0.93	0.10	0.07	$1.61	0.0031	0.0000	0.0032	53	41
Self-care plus nonprescription medicine	0.65	0.92	0.96	0.08	0.04	$17.54	0.0199	0.0001	0.0200	297	270
Self-care plus referral	0.05	0.69	0.63	0.31	0.37	$1.10	0.0008	0.0002	0.0010	21	13
Self-care, nonprescription medicine plus referral	0.19	0.87	0.95	0.13	0.05	$6.63	0.0054	0.0000	0.0055	83	69
Total						$26.88 total cost	0.0293	0.0003	0.0296 total QALYs	454 (87%)	393 (75%)
Usual pharmacist care											
Self-care	0.04	0.90	1.00	0.10	0.00	$0.59	0.0013	-	0.0013	13	13
Self-care plus nonprescription medicine	0.85	0.87	0.89	0.13	0.11	$15.93	0.0231	0.0004	0.0235	220	240
Self-care plus referral	0.01	0.55	0.00	0.45	0.00	$0.00	-	-	-	5	2
Self-care, nonprescription medicine plus referral	0.09	0.62	0.68	0.38	0.32	$3.23	0.0014	0.0003	0.0017	12	18
Total						$19.75 total cost	0.0257	0.0007	0.0264 total QALYs	250 (68%)	273 (74%)

Supplementary File 3 Training calculation

We have been provided data 60 patients present on average per pharmacy per day (industry average) [1] for symptom based or direct product requests (assuming a six-day pharmacy working week). The MAS pharmacist takes about 11 minutes per patient consultation which includes also the entry of research data into our iPad program. We have calculated that ONE pharmacist could reasonably deal with a **maximum of 44 patients per day** (working an 8-hour shift and considering the standard deviation of time and the proportion of symptom presenters and direct product requests). This number allows us to estimate the cost per patient for training and supporting the pharmacist. Data were calculated as follows: 8 hours (480 minutes) ÷ 11-minute consultations = 44 consultations per 8-hour shift (maximum).

Reference: Pitcher Pharmacy data, 2019 (unpublished).

Supplementary File 4 One-way sensitivity analysis

Base case ICER (AUD/QALY)		Mean $2,276	Min $1,720	Max $3,510	
Model Parameter	Lower bound	Upper bound	ICER (AUD/QALY)		Abs diff
Probability of symptom resolution MAS: No_AppPC_SC_NPM	0.88	0.96	$3,510	$2,257	$1,234
Average number of NPMs supplied MAS: SC_NPM	1.12	1.69	$1,720	$2,828	$552
Average number of NPMs supplied UC: SC_NPM	0.92	1.38	$2,749	$1,782	$473
Number of medicines at reconsultation: UC	1.00	3.00	$2,389	$1,816	$460
Probability of symptom resolution UC: No_AppPC_SC_NPM	0.25	0.75	$1,855	$2,499	$421
Number of medicines prescribed at reconsultation: MAS	1.00	3.00	$2,205	$2,661	$386
Probability of symptom resolution MAS: No_AppPC_SC	0.79	1.00	$2,564	$2,164	$288
Probability of symptom resolution UC: AppPC_SC_NPM	0.84	0.89	$1,952	$2,532	$256
Probability of symptom resolution MAS: AppPC_SC_NPM	0.89	0.93	$2,514	$2,177	$239
Probability of symptom resolution UC: No_AppPC_SC_R	0.56	0.75	$2,428	$2,460	$184
Pharmacist wage per hour	$24.04	$34.30	$2,082	$2,449	$174
Number of NPMs supplied MAS: SC_NPM_R	1.24	1.86	$2,110	$2,439	$163
Probability of symptom resolution UC: AppPC_SC	0.83	0.92	$2,417	$2,245	$141
Average NPM price: MAS	$10.20	$11.05	$2,131	$2,415	$139
Probability of symptom resolution MAS: AppPC_SC_R_NPM	0.81	0.89	$2,399	$2,230	$123
Cost of reconsultation	$30.85	$57.29	$2,163	$2,383	$107
Average NPM price: UC	$9.39	$10.14	$2,374	$2,171	$99
Probability of symptom resolution MAS: No_AppPC_SC_R_NPM	0.90	1.00	$2,364	$2,193	$88
Utility value: Symptom resolution	0.88	0.94	$2,358	$2,193	$83
Probability of symptom resolution MAS: No_AppPC_SC_R	0.42	0.74	$2,342	$2,242	$66
Pharmacist time: UC	2.88	3.71	$2,322	$2,223	$46
Number of NPMs supplied UC: SC_NPM_R	1.22	1.83	$2,321	$2,226	$45
Pharmacist time: MAS	10.52	11.23	$2,225	$2,319	$43
Probability of symptom resolution MAS: AppPC_SC_R	0.56	0.75	$2,305	$2,257	$29
Probability of symptom resolution UC: AppPC_SC_R_NPM	0.47	1.00	$2,234	$2,299	$23
Probability of symptom resolution UC: No_AppPC_SC_R_NPM	0.25	0.75	$2,245	$2,289	$13
Utility value: No symptom resolution	0.73	0.81	$2,260	$2,285	$10
Cost of medicine at reconsultation	$7.94	$11.64	$2,284	$2,261	$8
Number of training sessions per year: MAS	-	2.00	$2,268	$2,278	$2
Probability of symptom resolution UC: AppPC_SC	0.71	0.90	$2,130	$2,274	$2

Probability of symptom resolution UC: No_AppPC_SC	0.84	0.91	$1,977	$2,273	$3
Probability of symptom resolution UC: AppPC_SC_R	0.36	0.69	$2,273	$2,273	$3

Abbreviations: AppPC: Appropriate pharmacy care; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; No_AppPC: No appropriate pharmacy care; MAS: Minor ailment service; NPM: nonprescription medicine; QALY: Quality adjusted life year; R: referral; SC: self-care advice; UC: usual pharmacist care

Supplementary File 5 Multi-way sensitivity analysis

	Highest mean cost per patient (AUD)	Total QALY	Inc. cost (AUD)	Inc. QALY	ICER (AUD/QALY)
UC	$22.86	0.026			
MAS	$33.84	0.030	$10.98	0.003	$3,502

Abbreviations: AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; MAS: Minor ailment service; QALY: Quality adjusted life year; UC: usual pharmacist care.

Checklist 1 Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Checklist

Citation: Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS)—Explanation and elaboration: A report of the ISPOR health economic evaluations publication guidelines good reporting practices task force. Value Health. 2013; 16:231-50.

Section/ Item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific term such as "cost effectiveness analysis", and describe the intervention compared.	1
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	1-2
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study.	3
		Present the study question and its relevance for health policy or practice decisions.	3
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	5
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	5
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	5
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen	5
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	5
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	5
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	6
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	6
	11b	*Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	n/a
Measurement and valuation of preference-based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	5
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods	n/a

		for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	5-6
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	7
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	6
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	6
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or adjust (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	6
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	9
Incremental costs and outcomes	19	For each intervention, report mean values for the categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	9-10
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	n/a
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	10
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	n/a

Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	11-12
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	1
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	14

References

1. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. Lancet. 2008;371:281-283
2. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PloS Med. 2008;5(1):e20
3. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med 2004;141(10):781-788.

End of thesis