

**Exploring community
pharmacist's role in supporting
people living with mental illness:
medication education and
physical health monitoring**

by

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List of Abbreviations

Abbreviation	Definition
ACSQHC	Australian Commission on Safety and Quality in Health Care
ADA	American Diabetes Association
APA	American Psychiatric Association
BGL	Blood Glucose Levels
BMI	Body Mass Index
BMQ-S	Belief on Medications Questionnaire – Specific
BP	Blood pressure
BZD	Benzodiazepine
CHOICE	Choice and Medications leaflets
CMI	Consumer’s Medicines Information
COREQ	CONsolidated criteria for REporting Qualitative research
Covid-19	Coronavirus disease of 2019
CVD	Cardiovascular disease
D2	Dopamine type 2
DSM	Diagnostic and Statistical Manual
EMR	Electronic medical records
EPS	Extrapyramidal symptoms
FGA	First generation antipsychotic
GP	General Practitioner
GT	Grounded theory
HbA1c	Haemoglobin A1c
HDL	High Density Lipoprotein
HMRs	Home Medicines Reviews
IPA	Interpretative phenomenological analysis
LDL	Low Density Lipoprotein
LOs	Learning objectives
MetSyn	Metabolic syndrome
MHFA	Mental Health First Aid
MHR	My Health Record
NFP	Non-for-profit
OSA	Obstructive sleep apnoea
PA	Pattern discourse analysis
PLMI	People living with a mental illness
PSA	Pharmaceutical Society of Australia
RCT	Randomised controlled trial
RDS	Research Data System
RTA	Reflexive thematic analysis
RTC	Refresher training course
SAPS	Short Assessment of Patient Satisfaction
SGA	Second-generation antipsychotic
SMI	Severe mental illness
TA	Thematic analysis
TC	Total cholesterol
TG	Triglyceride
UK	United Kingdom
US	United States
WHO	World Health Organisation

Glossary

Term	Definition
Accredited pharmacist	A pharmacist who has undertaken additional training that is recognised by the Australian Association of Consultant Pharmacists.
Antipsychotic polypharmacy	Concurrent use of more than one antipsychotic medication.
Antipsychotics	A class of medications indicated for the management of psychiatric conditions including psychosis.
General Practitioner	A doctor who is qualified in general medical practice.
Health literacy	An individual's knowledge, motivation and competency to access, understand, appraise and apply health information.
Home Medicines Review	A service where an accredited pharmacist visits patients' homes to review medicines and develop a medicine management plan.
Lived experience	An individual with personal perspectives on, and experiences of, being a carer or consumer with mental illness.
Medication adherence	Degree to which the person's behavior corresponds with the agreed medication-taking behavior recommended by a healthcare provider.
Medication counselling	To provide medication-related information (in oral and/or written form), including instructions regarding the medication and how to take the medication. Also referred to as medication education.
My Health Records	Australia's secure digital platform that stores individual's health information and records including prescriptions and vaccination status.
Patient Centred Care	Care that respects and responds to the preferences, needs and values of patients and consumers.
Pharmaceutical Benefits Scheme	The Pharmaceutical Benefit Scheme is available to all Australian residents who hold a current Medicare care and lists all medicines available to be dispensed to patients at a Government-subsidised price.
Psychotropics	Any drug capable of affecting the mind, emotions and behaviour.
Rapport	Harmonious relationship, often involving collaboration and parity between the patient and health professional.
Therapeutic relationship	Relationship between a health professional and a client or patient.

Summary

Mental illness affects 970 million individuals worldwide and accounts for 1 in 5 years lived with disability. Despite extensive research and reforms in mental health, people living with a mental illness (PLMI) continue to experience significant health disparities compared to the general public. Community pharmacists are perfectly positioned within the community to utilise their knowledge and training to contribute to the health and wellbeing of PLMI.

As highly trained health professionals, pharmacists are equipped with broad pharmaceutical and clinical skills, allowing them to provide healthcare services to patients in various settings including hospitals, doctor's clinics and community pharmacies. However, current evidence indicates that pharmacists' knowledge and skills may be under-utilised, with suggestions that they are not practising to their full scope.

Currently, pharmacists provide some services targeted toward PLMI. Existing services are often limited to depression screening and the provision of medication education, which is provided to the general community rather than targeting PLMI. Emerging research has highlighted the potential for pharmacists to be involved in supporting PLMI to improve and optimise patient outcomes.

The primary aim of this research was to explore the role of community pharmacists in supporting PLMI, specifically in enhancing their physical health. In addition, the studies also aimed to identify barriers to, and enablers of, the research implemented in a real-world setting. In doing so, this thesis aimed to address:

Healthcare Gap 1. Insufficient medication education

Overarching research question: How can pharmacists, particularly those based in the community, improve PLMI psychotropic medication understanding?

1. To explore PLMI's understanding of, and beliefs towards, psychotropic medications.
2. To design, pilot and evaluate a client-tailored outreach information session with PLMI.

Healthcare Gap 2. Suboptimal physical health monitoring

Overarching research question: How can pharmacists, particularly those based in the community, better support the physical health monitoring for PLMI using second-generation antipsychotics (SGAs)?

3. To conduct a scoping review exploring current metabolic monitoring practices.
4. To design a pragmatic pharmacist-led longitudinal metabolic monitoring program to support the physical health of PLMI's physical health whilst using SGAs.
5. To pilot and evaluate the feasibility of a pharmacist-led physical health monitoring program for PLMI on SGAs.

The thesis was guided by two research philosophies, pragmatism and interpretivism. The studies reported in this thesis employed a mixed method approach and utilised a variety of qualitative methods including focus groups and semi-structured interviews.

A strength of the studies reported in this thesis is the rigorous applied to the designing of the information session and physical health monitoring program. To add, the thesis also reported on both qualitative and quantitative findings, providing richer insights into the research questions of interest. One notable limitation of this research is the smaller sample size.

Overall, the outcome of the studies indicated the acceptability of pharmacists supporting PLMI. The findings reported here support the advocacy not only for pharmacist involvement in supporting PLMI but also, most importantly, explore ways to better support and optimise the care of individuals living with a mental illness.

Declaration

This thesis presents work carried out by myself and does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; to the best of my knowledge it does not contain any materials previously published or written by another person except where due reference is made in the text; and all substantive contributions by others to the work presented, including jointly authored publications, are clearly acknowledged.

Tien Ngoc Thi Bui



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Scholarly Outputs

Published peer review articles (in order of presentation)

- **Bui, TNT**, Hotham, E, Loughhead, M, McMillan, SS, Procter, N, Poole, K & Suppiah, V 2022, 'Exploring mental health clients' current medication knowledge, beliefs and experience with healthcare providers in the community in South Australia,' *Health & Social Care in the Community*, 30(6), pp. e5968-e5978. doi: 10.1111/hsc.14029.
- **Bui, TNT**, Hotham, E, Kelly, F, & Suppiah, V 2022, 'Feasibility of a pharmacist-led physical health monitoring for patients on antipsychotic medications: protocol for a longitudinal study,' *BMJ Open*, 12(6), pp. e059573. doi:10.1136/bmjopen-2021-059573.
- **Bui, TNT**, Au, R, Janetzki, J, McMillan, SS, Hotham, E & Suppiah, V 2024, 'Metabolic monitoring for adults living with a serious mental illness on a second-generation antipsychotic agent: A scoping review,' *Administration and Policy in Mental Health and Mental Health Services Research*, pp.1-29. doi.org/10.1007/s10488-024-01408-9.

Publications not included in thesis but completed during candidature

- **Bui, TNT**, Stahl, HJ, Kaplan, J, Hotham, E, Loffler, H, Corlis, M & Suppiah, V 2021, 'Administration of as-needed psychotropic medications in aged care: decision matrix employed by nursing staff,' *Journal of the American Medical Directors Association*, 22 (3), pp. P721-P723. doi:10.1016/j.jamda.2020.11.035.
- **Bui, TNT**, Hotham, E, Rose, L & Suppiah, V 2022, 'COVID-19 and mental illness: perceptions of the pandemic and adherence to pandemic public health measures,' *Australasian Psychiatry*, 30(6), pp. 774-776. doi:10.1177/10398562221134020.
- **Bui, TNT**, Janetzki, L, Chai, WC & Suppiah, V 2023, 'Exploring consumers' perspective of community pharmacists delivering COVID-19 vaccinations: an Australian pilot study,' *International Journal of Pharmacy Practice*, 31(3), pp. 337-340. doi:10.1093/ijpp/riad014.
- Janetzki, J, Chai, WC, **Bui, TNT**, Sim, TF & Suppiah V, 'Impact of medicines shortages on Australian Pharmacists' professional practice and patient care: a nationwide survey,' *Journal of Pharmacy Practice and Research* [Accepted Oct 2024].

Conference presentations and posters completed during candidature

- **Bui, TNT**, Hotham, E, McMillan, SS, Kelly, F, & Suppiah, V 2023, 'Feasibility of a community pharmacist-led physical health monitoring program for people living with a mental illness.' Poster, Paper presented at: International Pharmaceutical Federation (World Congress); Brisbane, Australia.
- **Bui, TNT**, Hotham, E, McMillan, SS, Kelly, F, & Suppiah, V 2023, 'Feasibility of a community pharmacist-led physical health monitoring program for people living with a mental illness.' Oral Presentation, Paper presented at: Pharmaceutical Society of Australia; Sydney, Australia.
- Singh, I, Tszwai, R, **Bui, TNT** (Presenter), Shakib, S & Suppiah, V 2022, 'Polypharmacy and the risk of QT prolongation in hospitalised patients on antipsychotics,' Oral Presentation, Paper presented at: Australasian Pharmaceutical Science Association - Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists; Perth, Australia.
- **Bui, TNT**, Hotham, E, McMillan, SS, Kelly, F, & Suppiah, V 2022, 'Mental illness: pandemic perceptions and adherence to public health measures,' Poster, Paper presented at: Australasian Pharmaceutical Science Association - Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists; Perth, Australia.
- **Bui, TNT**, Janetzki, L, Chai, WC & Suppiah, V 2022, 'Exploring consumer's perspective of pharmacist delivering COVID-19 vaccinations COVID-19,' Poster, Paper presented at: Australasian Pharmaceutical Science Association - Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists; Perth, Australia.
- **Bui, TNT**, Hotham, E, McMillan, SS, Kelly, F, & Suppiah, V 2022, 'Development of a client-centred health promotion: knowledge and attitudes towards psychotropic medication use,' Oral Presentation, Paper presented at: South Australian Psychotropic Drugs Committee; Virtual.
- **Bui, TNT**, Hotham, E, Rose, L & Suppiah, V 2022, 'COVID-19 and Mental illness: perceptions of the pandemic and adherence to non-pharmacological,' Poster, Paper presented at: Pharmaceutical Society of Australia; Sydney, Australia.

- **Bui, TNT, Hotham, E, Loughhead, M, McMillan, SS, Procter, N, Poole, K & Suppiah, V** 2021. ‘Exploring the knowledge and attitudes of clients living with mental health conditions towards their medications and their healthcare providers,’ ePoster, Paper presented at: Australasian Pharmaceutical Science Association - Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists; Virtual.
- **Bui, TNT, Hotham, E, Loughhead, M, Procter, N, McMillan, SS, Kelly, F & Suppiah, V** 2021. ‘Have we told you enough? – Assessing understanding and knowledge of psychotropic medication in community mental health consumers,’ Oral Presentation, Paper presented at: Pharmaceutical Society of Australia; Virtual.
- **Bui, TNT, Hotham, E, McMillan, SS, Kelly, F, & Suppiah, V** 2021. ‘Community mental health consumers’ psychotropic medication knowledge and experience with their healthcare providers,’ Oral Presentation, Paper presented at: University of South Australia’ Health and Biomedical Innovation Emerging Researcher Symposium; Adelaide, South Australia.
- **Bui, TNT, Hotham, E, McMillan, SS, Kelly, F, & Suppiah, V** 2021, ‘Development of a client-centred health promotion: knowledge and attitudes towards psychotropic medication use,’ Oral presentation, Paper presented at: University of South Australia’s Clinical and Health Sciences Seminar; Adelaide, South Australia.
- **Bui, TNT, Hotham, E, McMillan, SS, Kelly, F, & Suppiah, V** 2021, ‘Development of a client-centered mental health medication education session: evaluation and pilot,’ Oral Presentation, Paper presented at: Australasian Pharmaceutical Science Association - Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists; Virtual.

Awards and Prizes arising from candidature:

- 2022 – UniSA Research and Enterprise Awards -Enterprise (Nominee)
- 2021 – UniSA Emerging Research Symposium - Best Oral Presentation (Winner)
- 2021 – PSA Shark Tank Competition (Finalist)

Media feature during candidature

- Meghan Haggan, 2023, A week in Review. Australian Journal of Pharmacy. 2023. Access via: <https://ajp.com.au/news/the-week-in-review-299/>

- Meghan Haggan, 2023, Covid Jobs: Why Aussies chose pharmacy. Australian Journal of Pharmacy. Access via: <https://ajp.com.au/news/scope-of-practice/covid-jabs-why-aussies-chose-pharmacy/>
- Janetzki, J, Chai, W, **Bui, TNT**, Sim, F & Suppiah, V. 2023, The impacts of medication shortages, Australian Journal of Pharmacy. Access via: <https://ajp.com.au/news/the-impact-of-medication-shortages/>

1 Introduction

Background

Mental health is a fundamental pillar for overall health and wellbeing, with the World Health Organisation (WHO) defining health as “a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity” [1]. When episodes of negative mental health are prolonged or reoccurring, a mental illness or disorder is diagnosed [2]. Mental illness, according to the American Psychiatric Association’s (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 is “a syndrome characterised by clinically significant disturbance in an individual’s cognition, emotion regulation, or behaviour that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning” [3]. In the Australian setting, mental illness is defined as “a medical condition that is characterised by a significant disturbance of thought, mood, perception or memory” [4].

Mental illness is one of the leading causes of health-related burden worldwide, with a global prevalence of 970.1 million in 2019, contributing to 125.3 million years of life lived with disability [5]. Between 2017-18 and 2021-22, Australian expenditure on mental health-related services increased to AUD 12.2 billion from AUD 10.9 billion [6]. The emergence of the coronavirus pandemic (hereon referred to as the pandemic) has further negatively affected the mental health and wellbeing of people worldwide, with reports identifying an increase in the prevalence of major depressive disorder and anxiety [7]. In Australia, mental health is recognised as one of the ten National Health Priority Areas alongside other conditions such as cancer and cardiovascular health [8-10]. The National Strategic Framework, an overarching policy for the prevention and management of chronic conditions in Australia, also identified people living with a mental illness (PLMI) as one of the target ‘priority population’[11]. Research suggests that PLMI, particularly individuals diagnosed with severe mental illness (SMI) such as schizophrenia, often experience homelessness [12], discrimination and/or stigma which can contribute to limited access to medical care [13]. Furthermore, people living with SMI have poorer physical health, including higher rates of physical inactivity and poorer diets compared to the general population [14]. Despite the challenges previously discussed, it is recognised that with the right social and clinical support, many PLMI can live well with their illness [15, 16].

Increasingly, many jurisdictions, including Australia, have adopted a recovery-oriented care approach to their mental health services [17]. In contrast to the traditional treatment-oriented approach, where the focus was on being “symptom-free” or “cured”, the recovery model focuses on “being able to create and live a meaningful and contributing life in a community of choice with or without the presence of mental health issues” [18, 19].

To date, Australian government efforts have focused on several key mental health areas, including suicide prevention [20], early intervention for individuals with emerging mental illness and timely access to care [21]. More recent efforts include the development of the National Mental Health Service Planning Framework [22], an evidence-based model that can be used to coordinate the planning of mental health systems to meet the Australian population’s need and requirements. Despite extensive research and reforms in mental health initiatives, PLMI continues to experience significant health disparity [23]. A report by the Australian Commission on Safety and Quality in Health Care (ACSQHC) (2017) highlighted a paucity of medication safety research in mental health [24]. In particular, the report highlighted the need for more consumer-personalised medication information, shared decision-making around treatment options and frequent monitoring of side effects of medications including antipsychotics, including in primary healthcare services.

Community pharmacists are well positioned within the community to utilise their knowledge and training to contribute to the health and wellbeing of PLMI [25, 26]. The research presented in this thesis reports the findings of a collection of studies exploring the potential role of community pharmacists in addressing the two specific healthcare gaps also identified by the ACSQHC. These healthcare gaps are: (i) insufficient medication education and, (ii) physical health, specifically the suboptimal metabolic monitoring for PLMI. The findings from the research presented in this thesis will contribute to the existing body of literature and provide evidence on the acceptability of pharmacists, particularly those based in the community, in supporting PLMI and further highlights the position of community pharmacists as accessible and trusted health professionals [27].

Terminology

The importance of language and its impact on stigma is well-recognised within the literature pertaining to PLMI [28, 29]. Increasingly, there is an emphasis on the use of ‘recovery-oriented language,’ that is respectful and strength-focused, thereby reducing stigma and fostering empowerment [30, 31]. The terminology used to refer to PLMI is often inconsistent and varies

within the literature, some examples include, ‘patient’, ‘consumer’, ‘client’ and, PLMI. An Australian-based study found that participants diagnosed with a mental illness preferred the terms ‘individual’ and PLMI [32]. Other terms such as ‘consumer’, ‘client’ and ‘patient’ were also deemed acceptable by most participants when used within an appropriate context. For example, ‘patient’ when the person needs medical treatment, ‘consumer’ when used to describe any group of people within a health context and ‘client’ when engaging with treatment or accessing support services [32, 33]. It is also recognised that these terms are not infallible, ‘patient’ can foster feelings of passivity, ‘client’ can perpetuate a power imbalance within mental health services and ‘consumer’ could imply that a person is dependent upon the provision of services [33]. Similarly, the term ‘people with lived experience’ can be viewed as failing to recognise the prolonged and recurrent nature of the illness, i.e. ‘lived’ is past tense, implying that it is no longer current [32].

In the absence of universally agreed terminology, it has been suggested that researchers who are “studying the experiences of individuals with mental illness should use the term that is most appropriate for their research context” [34]. The research in this thesis employed the phrase ‘people living with a mental illness’ to refer to individuals diagnosed with a mental illness [33]. Alternative terms such as ‘client’ and ‘consumer’ have also been used when deemed appropriate in the context of the study. For example, PLMI have been referred to as a ‘client’ of a peer-support group when attending a focus group (Chapter Three), and ‘consumer’ when visiting the community pharmacy (Chapter Six).

Theoretical framework

The thesis was guided by two research philosophies, pragmatism and interpretivism [35]. The pragmatism paradigm supports the use of the best methods to investigate real-world problems, often utilising mixed methods research [36]. Recognising the dynamic and complex nature of the healthcare system and services, the design and implementation of these studies endeavoured to be pragmatic and relatable to existing practice [37]. In this thesis, the studies focused on what was achievable, that is ‘practical’, rather than what was theoretical or ideal. Therefore, having a highly controlled study, such as conducting randomised controlled studies was not suitable for the purpose of the research studies in this thesis [38]. Rather, the PhD candidate aimed to explore the research questions in the context of a real-world setting, identifying facilitators and barriers to implementation as well as piloting proposed interventions with the desire for them

to be relatable to current practice and easily integrated into the day-to-day operations at community pharmacies. Therefore, pragmatism was seen as an appropriate guiding approach.

Through the interpretivism paradigm, the candidate acknowledges that ‘reality’ is interpreted, and can be influenced by both the participant’s and the researcher’s social and cultural experiences, values and beliefs [39]. Therefore, findings were viewed to be anchored by the participant’s experiences to situated realities and the limits and constraints of the world [39], including social and cultural contexts [40], within which the participant exists. The thesis was underpinned by a relativist ontology (a ‘truth’ to be discovered) and viewed ‘reality’ as being co-created by both researcher and participant through interaction; findings are therefore shaped by the researcher’s perspectives and specific contexts. As findings were acknowledged to be subjectively observed and created by the interactions between the researcher and participants and candidate’s interpretations, it was recognised that they were not infallible but rather relative [41]. In this research paradigm, it is recognised that the researcher is an ‘interpreter of meaning’ and a ‘subjective storyteller’ [41]. In qualitative research, this subjectivity is viewed as a strength rather than a bias, especially where the researcher acknowledges potential for their experiences, values and beliefs to impact on the interpretation of the data (that is, reflexivity).

Reflexivity

The PhD candidate is a first-generation Australian female of Asian heritage born to immigrant parents. The candidate does not have a mental illness and is a registered pharmacist with professional experience in both community and hospital settings. Her research areas lie within the realms of pharmacy practice, in particular, exploring the scope of pharmacy professional services to improve both the mental and physical well-being of the community.

Given her professional background, the candidate took on an ‘insider’ position when interacting with participating pharmacists and an ‘outsider’ position when interviewing PLMI. Thus the PhD candidate acknowledged the potential influence that this can have on the study design, implementation and data analyses [42]. Measures were implemented, as described in relevant chapters, to minimise the influence that this can have on data analyses and impact on participants. For example, the post-study interviews (Chapter Six) of participating pharmacists were not conducted by the candidate as it was deemed inappropriate given the rapport developed between the pharmacists and the candidate during the study period.

Research Aims and Questions

The primary aim of this research was to explore the role of community pharmacists in supporting PLMI, specifically in enhancing their physical health. In addition, the studies also aimed to identify barriers to, and enablers of, the research implemented in a real-world setting. In doing so, this thesis aimed to address:

Healthcare Gap 1. Insufficient medication education

Overarching research question: How can pharmacists, particularly those based in the community, improve PLMI psychotropic medication understanding?

1. To explore PLMI's understanding of, and beliefs towards, psychotropic medications.
2. To design, pilot and evaluate a client-tailored outreach information session with PLMI.

Healthcare Gap 2. Suboptimal physical health monitoring

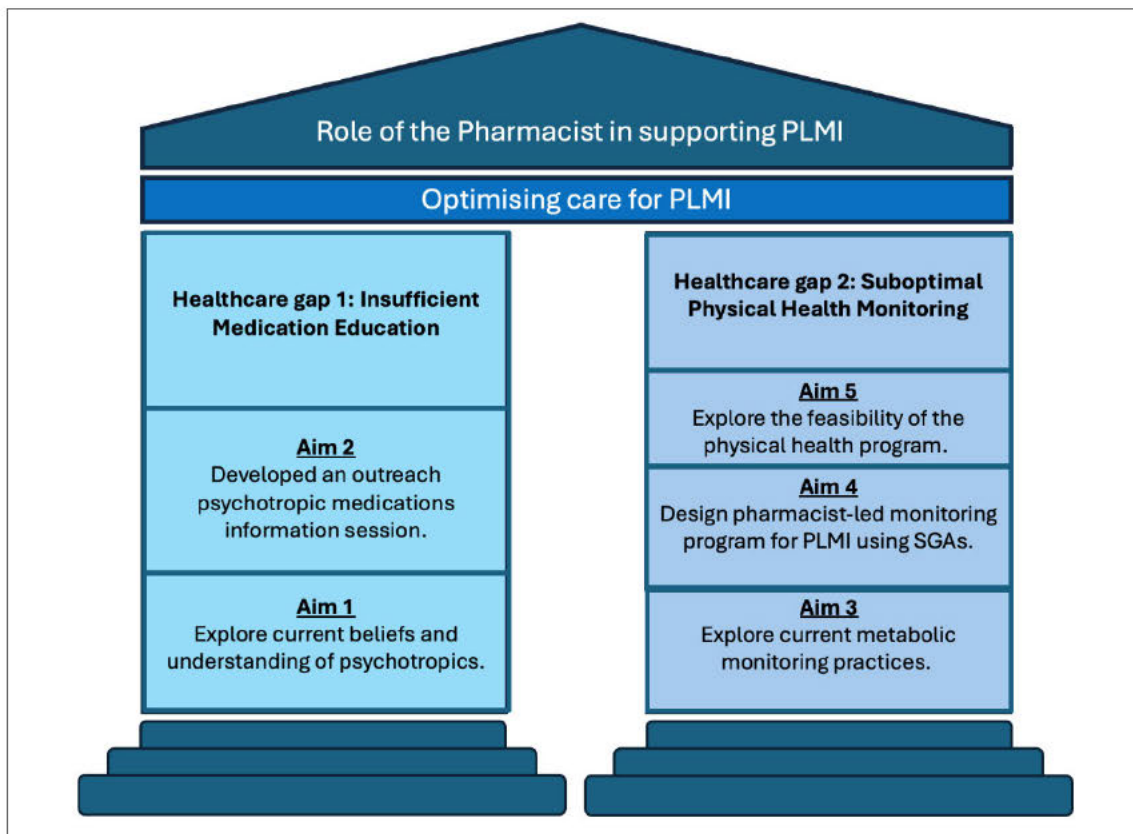
Overarching research question: How can pharmacists, particularly those based in the community, better support the physical health monitoring for PLMI using second-generation antipsychotics (SGAs)?

3. To conduct a scoping review exploring current metabolic monitoring practices.
4. To design a pragmatic pharmacist-led longitudinal metabolic monitoring program to support the physical health of PLMI's physical health whilst using SGAs.
5. To pilot and evaluate the feasibility of a pharmacist-led physical health monitoring program for PLMI on SGAs.

Thesis structure

This thesis consists of seven chapters, addressing the above aims (Figure 1). The first component of this thesis focused on *Healthcare gap 1* and explored the theme of medication education, which is currently a central role and responsibility of pharmacists [26]. The second component focused on *Healthcare gap 2* and presented studies that proposed and examined the potential role of community pharmacists in better supporting the physical health of PLMI, particularly longitudinal monitoring of metabolic syndrome (MetSyn) in PLMI taking regular SGAs.

Figure 1. Overview of studies presented in this thesis.



Thesis Outline

Chapter 1. Provides an overview of the theoretical framework, aims and objective of the thesis. The chapter also describes the research approach, outline and structure of the thesis.

Chapter 2. This chapter presents a literature review that explored the two identified unaddressed healthcare gaps, (i) insufficient medication education and (ii) insufficient medication monitoring, for PLMI. Findings from the review also highlighted the potential for pharmacists, particularly those based in the community setting to support PLMI. Overall, the chapter summarises what is already known and provides justification and rationale for further research work that has been conducted and presented in this thesis.

Chapter 3. Published paper entitled, ‘Exploring mental health clients’ current medication knowledge, beliefs, and experience with healthcare providers in the community in South Australia.’ The study involved the conduction of focus groups with PLMI using psychotropic medications, including antipsychotic medications. Findings from the focus groups suggested inadequate medication counselling and further highlighted the need for PLMI to have access to medication information beyond the initial dispensing/prescribing, that is, frequent medication

information. The published manuscript proposed the role of community-based pharmacists to conduct medication education outside a community pharmacy environment, such as at a not-for-profit (NFP) organisation that supports PLMI.

Chapter 4. This chapter seeks to implement the proposal described in Chapter Three. The chapter provided a detailed description of the design, content evaluation and delivery of the tailored outreach medicines information session, titled ‘My Mind, My Health,’ at a NFP organisation.

Chapter 5. Presents a published scoping review entitled, ‘Metabolic monitoring for adults living with a serious mental illness on a second-generation antipsychotic agent: A scoping review.’ This chapter further adds to findings presented in Chapter Two, by exploring the disparity in physical health monitoring for PLMI. The scoping review summarises and maps existing metabolic monitoring practices, thereby highlighting gaps in current practice which informs future research in this area.

Chapter 6. This chapter includes a detailed description of the pharmacist-led physical health monitoring program and pharmacist training session, presented as a published paper entitled, ‘Feasibility of a Pharmacist-led physical health monitoring for patients on antipsychotic medications: protocol for a longitudinal study.’ The second part of this chapter presents the quantitative and qualitative findings of the implemented program.

Chapter 7. Concluding discussion of the studies including strengths and limitations. This chapter also includes final remarks with a contribution of the research findings to future practice.

Chapter Summary

This chapter presented an introduction to mental illness, highlighting the health-related burden and initiatives both in a global and Australian context. It also provided an outline of the terminology used in this thesis, and the theoretical framework employed and presents a reflexive account of the PhD candidate. Finally, it summarises the thesis structure and brief outline of the studies presented in this thesis. The next chapter will present the literature review, which explored the two healthcare gaps in further detail and provides the rationale for the research aims and objectives selected.

2 Literature Review

Chapter Overview

The previous chapter introduced the aims and research objectives and proposed the potential for pharmacists to further support PLMI. This chapter presents what is already known within the literature and provided more evidence to support the two healthcare gaps of interest. The first part of the chapter provides a summary of the community pharmacists' role in supporting PLMI. This is followed by an exploration of the perceived 'inadequate' medication education provided to PLMI (Healthcare gap 1). Finally, antipsychotic use and the monitoring of metabolic parameters are also discussed (Healthcare gap 2). Further investigation into the current metabolic monitoring practices for PLMI will be presented in Chapter Five as a Scoping Review. Overall, this chapter presented the underpinning literature for the entire thesis and subsequent chapters will provide an overview of the evidence relevant to the particular studies.

Community Pharmacists

Roles and responsibilities

The pharmacy profession has undergone numerous evolutions morphing it into the collaborative and specialist practice it is today [26, 43]. Pharmacists now practice in a variety of settings, including community pharmacies, hospitals and other clinical practice settings such as general practice and aged care facilities, working in care teams to optimise patient care [26]. Of these, community pharmacists are one of the most accessible health professionals and are often the first point of contact for consumers seeking healthcare advice [44, 45]. For example, the access to highly specialised medicines, such as clozapine, a SGA that previously could only be supplied by a hospital, can also be accessed in community pharmacies for eligible PLMI since 2015 [46].

Pharmacist-delivered services can support PLMI by reducing the risk of adverse effects, providing timely identification of potential and actual medicines-related issues and improving their overall quality of life [47]. For example, a community pharmacist-led person-centred mental health medication support service was found to generate improvements in perceptions of the illness ($p < 0.001$), quality of life ($p < 0.001$) and global satisfaction with medication ($p < 0.001$) reported by PLMI [48]. A systematic review of 37 primary studies also highlighted

the benefits of pharmacist-led interventions for people living with SMI, particularly in improving consumer-reported and clinical outcomes [49]. The authors concluded that pharmacist-led interventions can contribute to significant improvements in quality of life, reduced hospitalisation, and improved medication adherence in this cohort. It is worth noting that this systematic review was not limited to community pharmacist-led interventions.

In recent years, the scope of practice for community pharmacists has expanded to include the provision of multiple professional services, including the management of several chronic conditions [50], including diabetes [51] and hypertension [52]. As the third-largest group of health professionals in Australia with 37, 949 registered pharmacists [53], consumers see their community pharmacist up to 10 times more often than their general practitioner (GP) [54, 55]. In addition, community pharmacists are a trusted source of advice with unique skillsets that allow them to provide both clinical and medication-related advice [56, 57]. Community pharmacists are often involved in the assessment of patient symptoms, triaging, and referring patients to other health professionals where appropriate. As such, they are placed in a perfect position to support patients living with a chronic condition [55]. Indeed, the Pharmaceutical Society of Australia (PSA), the peak national body for Australian pharmacists, published a mental health framework (2013) which highlighted the potential role of pharmacists in delivering mental healthcare services within a range of healthcare settings [58].

The modern-day pharmacist is defined as “an individual who works alongside doctors, nurses, and other health professionals in a sophisticated, highly specialised practice setting to assure appropriate medication therapy management” [45]. However, there have been reports of pharmacists not practising to their full scope [59], indicating the potential for further expansion to pharmacy service provisions. Commonly, the community pharmacist’s role revolves around prescription medicine supply (also known as “dispensing”), provision of medication information and ‘Pharmacist Only’ or ‘Pharmacy Only’ medicines available without prescription, clinical interventions, medication management services (including referral to general practitioners), preventative care services for patients with chronic conditions and participating in the therapeutic decision (for example, smoking cessation) [26, 60]. There has also been a further shift in the role of community pharmacists in response to the pandemic, with the expansion of pre-existing roles (e.g. vaccinations) and the addition of new roles (e.g. infection control) [61, 62]. Recently, the scope of practice for Australian pharmacists in the community has been further expanded to include additional health care services [63]. This

includes the supply of treatment antibiotics for uncomplicated urinary tract infections [64], resupply of the oral contraceptive pill [65] and the provision of minor ailment services including wound care [66]. The need for a doctor’s consultation, including a prescription is not required for any of the above-mentioned services.

Pharmacists in mental health

The mental health framework published by the PSA suggests that pharmacists can better support PLMI through direct and indirect services [58]. Direct health services included health promotions, mental illness screening and interventions to minimising illness (e.g. provision of lifestyle advice) and maximising recovery (e.g. monitoring early signs of mental illness relapse). Indirect services included medicine information sessions for health professionals and consumers and their carers, policy and advocacy roles, and research and teaching [58]. The literature also indicates that Australian pharmacists can effectively provide individualised and goal-orientated medication support services for consumers with common mental illnesses such as depression or anxiety [48]. Pharmacists are also capable of screening for depressive symptoms and facilitating timely referral of at-risk individuals to appropriate health professionals [58, 67]. Table 1 provides a summary of the current pharmacist’s roles in mental health.

Table 1. Summary of reported pharmacist roles in mental health.

Intervention	Details	Reported benefits	References
Medication counselling	Provision of education or counselling on medications.	Improve medication adherence among people commencing antidepressant therapy.	[49, 68-70]
Screening for mental illness	Includes, conducting screening for conditions such as depression.	Encourage discussion with other health professionals, such as the general practitioners or psychologist.	[25, 67, 69]
Active monitoring of prescriptions and providing feedback to prescribers	When antipsychotic polypharmacy was identified in the pharmacy database, the pharmacist contacted the prescribers.	Reduce prevalence of polypharmacy, thereby potentially optimising medicine regimen.	[71]
Primary care	Integrating pharmacists and technicians as part of a GP clinic.	Identify medicines related problems.	[72]

Medication review	Home Medicines Review, where accredited pharmacists visit the client's home to review their medication therapy.	Identify medicines related problems.	[49, 73]
Educational visits	Provide education to health professionals	Modify prescribing behaviour. Significant improvements in pharmacotherapy (for example, adjusting medicines regimen, completing patient assessment).	[49, 68, 74]
Co-designing individualised goals	Participants and pharmacists collaboratively identified key concerns regarding physical and psychological wellbeing and medication use before co-designing individualised goals and goal plans. Goals are reviewed and adjusted over the next 6 months as required.	Goal setting was an opportunity for participants to learn about themselves and identify their health concerns. Pharmacists were also able to better understand the health barriers faced by participants.	[75]

Overall, while it has been noted that pharmacists may have several roles in mental health, this thesis focused on the role of the pharmacist in addressing the two healthcare gaps identified. That is, in medication education and metabolic monitoring.

Healthcare gap 1 - Insufficient medication education

Despite the potentially significant impact that mental illness can have on an individual's quality of life [76, 77], PLMI including those living with SMI, do not receive the same level of healthcare as the general population [13, 78]. Research has suggested that PLMI experience greater barriers to healthcare access including stigma [79] and a lack of confidence in managing their health problems compared to the general population [80]. In addition, it has also been suggested that PLMI are less likely than the general population to receive medication information from health professionals [3-9]. In 2017, the ACSQHC published the Medication Safety in Mental Health Report, which identified medication safety issues in mental health across community and hospital settings [24]. At the time, the report highlighted concerns with PLMI receiving inadequate medication education. It is worth noting that there have been no recent updates to this report.

Psychotropic agents such as antipsychotics typically have lower counselling rates compared to other agents [81-83]. A study conducted in Finland compared the provision of verbal counselling according to therapeutic class (n=1,431) through the use of direct external observers and found that psychotropic agents, including antipsychotics, had one of the lowest counselling rates [82]. In Finland, the provision of medication counselling is stipulated within the roles and responsibilities of pharmacists, which is similar to Australia [26, 84]. Therefore, the findings are likely to also be generalisable to the Australian setting. An Australian study found that most of the queries from individuals prescribed antipsychotics to an information centre in Australia were for medication-related information, suggesting poor understanding of psychotropic medications [85]. Further, another Australian study (n=36) reported that more than half of the PLMI did not know about a consumer medicines information (CMI) leaflet, which is a commonly provided medication information resource in Australia [86]. A more recent Australian study similarly identified that most PLMI (60%) rarely or never received written information when, or since, commencing their medicine [87]. This contrasted to findings that highlighted that PLMI themselves had the desire to know more about their medications [88].

Ensuring that individuals have good knowledge about their prescribed medication is crucial as it can enhance their knowledge and medication-taking behaviour [89], improving medication adherence [90]. Insufficient medication knowledge, including a lack of awareness of adverse medicines reactions, can negatively impact an individual's medication-taking behaviours, leading to poor medication adherence [91]. Whilst it is acknowledged that factors influencing medication adherence are complex and multifaceted, having positive beliefs towards medications underpinned by sound medication knowledge and insight [92] can influence medication-taking behaviour [93, 94]. Existing studies have demonstrated that individuals with better knowledge about the therapeutic effects of medications were more likely to have a positive attitude towards their medications [95, 96]. Therefore, maximising medication understanding, and knowledge can positively influence attitudes towards medicines and impact health outcomes through optimising consumer medication-taking behaviour (Figure 2). To provide and deliver better medication education, it is essential that barriers and facilitators are recognised and explored.

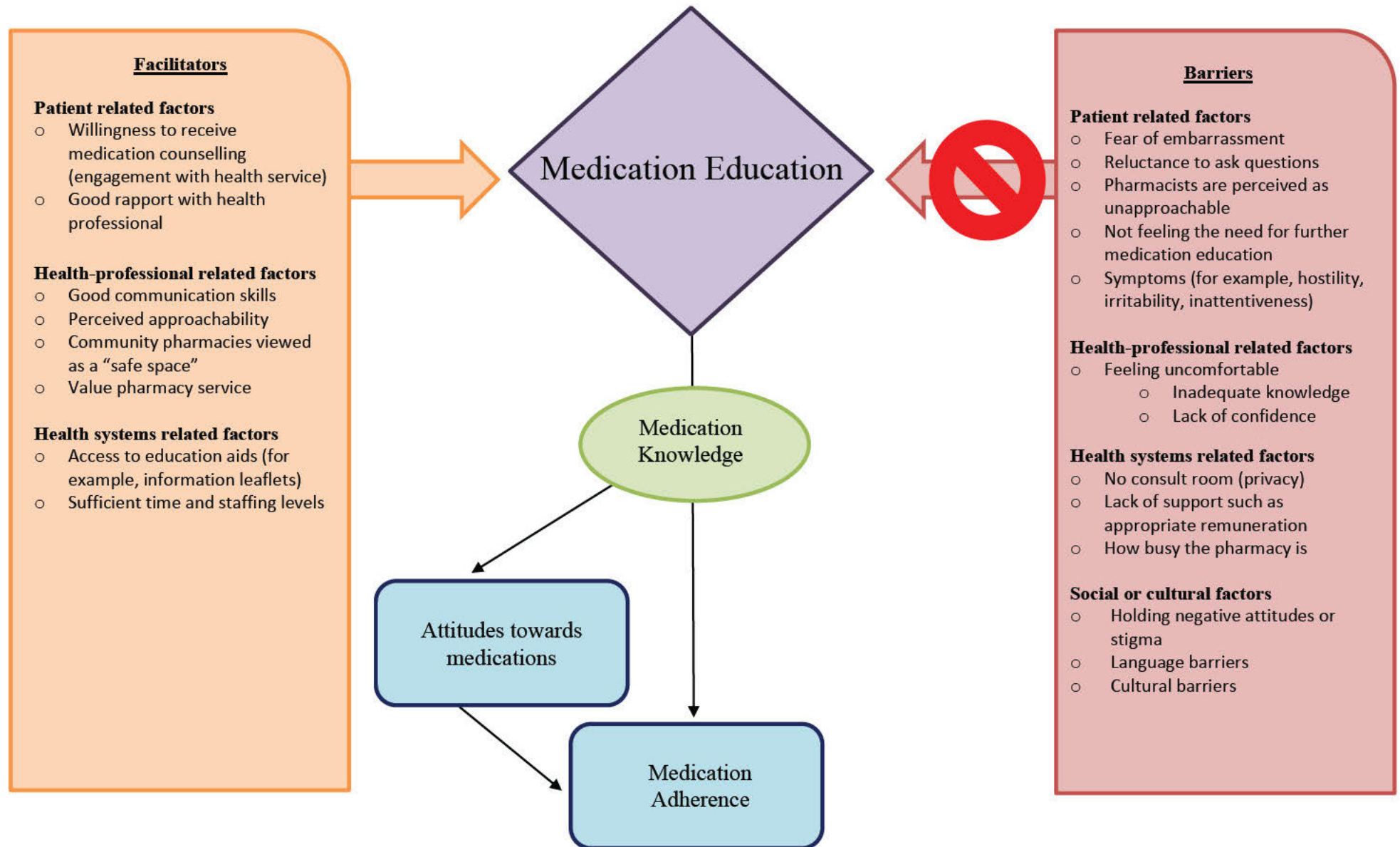
Facilitators and barriers to medication education

Facilitators of pharmacist-provided medication education can be categorised into three broad categories: patient-, pharmacist- and health system-related factors (Figure 2). Patient-related factors include good patient engagement [97], health literacy [98], beliefs and attitudes towards

medications [98] and rapport with their pharmacist [99, 100]. Evidence also suggested that PLMI valued pharmacy services, and community pharmacies were viewed as a safe healthcare space to seek mental health advice [27, 87]. Health professional-related factors included pharmacists being perceived as approachable, having a patient-centred approach and having strong interpersonal skills [97, 99, 100]. Health system-related enablers included having sufficient time, staffing levels [97] and, access to patient education aids (for example, information leaflets) [98-100].

The barriers to the delivery of medication education can be categorised into the following categories: patient-, health professional-, health systems- and social/cultural factors [101]. Patient-related factors such as the fear of embarrassment and reluctance to ask questions were identified as one of the most common (63.1%) barriers to the provision of medication information [102]. Other factors included a perception of the pharmacist being unapproachable [102], having low awareness of their disease or medication [102], reluctance to ask questions and severity of symptoms [99, 100, 103]. Health professional-related barriers included pharmacists' lack of knowledge and/or time, confidence or comfort in interacting with PLMI which can hinder the provision of medication information [104-106]. Health system-related barriers included limited privacy and confidentiality in the physical layout of the pharmacy [98, 99, 102], absence of remuneration affecting the sustainability of service provision [99], pharmacists not having access to patient's medical histories or diagnostic data, the limited time given the 'busyness' of the pharmacy [98, 99, 102] and fluctuating staffing levels [81]. Finally, social or cultural barriers include the perception or presence of stigma and cultural or language barriers [97] which can further hinder PLMI's decision to seek medication information [101].

Figure 2. Factors that can act as either facilitators or barriers towards medication education and the impact of medication education.



Medication education for PLMI: existing research

There is limited recent research that has explored interventions to enhance the provision of medication education for PLMI. In 2012, Tran et al. developed tailored, consumer- and carer-focused education for PLMI [86]. This Australian study trialled an alternative medication education strategy that implemented weekly open forums and recruited psychiatric inpatients and their carers. The one-hour group sessions, which discussed the role and side effects of psychotropic medications, ran for over 3 months and were delivered by a senior mental health pharmacist and a professor of psychiatry. The intervention group (n=48) reported an improvement in attitude towards psychotropic medications pre- to post-forum (48% compared to 96%)[86]. Furthermore, a majority (84%) of the participants felt that the suggestions were helpful and 88% felt that it was important to gain more understanding of their medications. It was noted that the study had a small sample size which can limit the generalisability of the findings. Another study from the same year trialled a nurse-led weekly medicine education program, for children and adolescents in a psychiatric ward was reported to be well received by participants [107]. This was similar to the previously described study and was delivered in a group setting, notably the session was led by nursing staff. This latter study also reported several limitations, including insufficient information on data analysis methods, therefore limiting the reliability and generalisability of the study.

Other educational interventions, such as internet-based education programs have also been trialled. These interventions often aimed to provide PLMI with more comprehensive support and therefore were not specific to just medication education alone [108, 109]. A systematic review of randomised controlled trials explored the efficacy of educational interventions for PLMI on psychotropic medicines and found that structured educational sessions that involved both written and verbal components and followed by discussion of the content were the most effective [110]. It was noted that the majority of these interventions were conducted in hospital or inpatient settings [86, 107].

Justification for further research

The evidence suggests that there is a need to further improve PLMI's medication knowledge. However, there is currently a paucity of studies in this area [86, 107, 111], particularly involving pharmacists [86, 112]. Most studies reported developing or improving existing medication education programs for PLMI within an inpatient setting, led by either doctors or nurses [107, 111]. The provision of medication information and advice is an integral role of a pharmacist. The National Competency Standards Framework for Pharmacists in Australia states:

“Pharmacists provide health care, education and advice across all settings to promote good health and to reduce the incidence of illness. Pharmacists provide direct care to patients and also have a broader role in enhancing public health and quality use of medicines in the community” [113].

Research to date has been primarily focused on improving PLMI understanding of their medicines through the provision of medication education programs, often for an inpatient cohort [86, 107, 112]. There is a need to further investigate the value of the community setting, particularly the role of community pharmacists in supporting PLMI.

Healthcare gap 2 – Suboptimal physical health monitoring

Several studies have shown that PLMI, particularly those with SMI such as schizophrenia, have a shorter life expectancy (10 – 20 years), and mortality rate twice that of the general population [114-117]. A large cohort study with 72,451 participants found that nearly 75% of individuals without a SMI had a life expectancy of 80 years or older. However, less than half of those participants living with SMI reached that age [118].

Premature mortality among PLMI, including those with SMI, is largely related to physical health conditions such as cardiovascular, respiratory and metabolic diseases [114, 119, 120]. It is commonly recognised that cardiovascular diseases were often the leading cause of death in this group [117, 121]. Poorer physical health in this cohort can be attributed to multiple factors such as, the disease itself (including, psychological and biological mechanisms), reduced access to healthcare, higher rates of tobacco smoking, alcohol consumption and intake of high-caloric foods (poorer diet) and little physical activity [14, 122-125]. This was further compounded by commonly prescribed medications such as antipsychotics, particularly SGA, which can increase the risk of cardiovascular disease through metabolic disorders, a common adverse effect of this class of medication [126, 127]. Moreover, individuals with SMI were more likely to be undiagnosed with cardiovascular diseases before death, despite most having been in contact with primary or specialised health services, suggestive of under- or un-treated cardiovascular risk in this cohort [118]. In Australia, improving cardiometabolic monitoring and outcomes for PLMI, especially those with SMI, has been identified as a high priority area [24].

Antipsychotics: history, use and challenges

The accidental discovery of the first antipsychotic, chlorpromazine, changed the management of mental illnesses, especially for people living with SMI [128], and facilitated the transition from a previously institutionalised system to a more outpatient care model [129]. Antipsychotics are used for

a variety of conditions, including hallucinations, delusions or abnormal behaviour/thought, and for their sedative and tranquillising effects for behavioural disturbances [130, 131]. Antipsychotics are also widely used ‘off-label’ for indications and/or at doses that have not been approved by local health authorities (for example, for insomnia) [132]. Antipsychotics are generally categorised into two groups, first- and second-generation antipsychotics.

First-generation antipsychotics (FGAs), developed in the 1950s, vary in the extent to which they bind to, and therefore antagonise dopamine, histamine, and cholinergic receptors in the brain [133] resulting in variable medication potencies and adverse effects profiles [133]. One major drawback associated with FGA use is the occurrence of extrapyramidal symptoms (EPS), medicine-induced movement disorders which can be debilitating and interfere with daily living [134]. Symptoms often include intolerable effects on movement, including tremors, slurred speech, akathisia (such as, restlessness), and dystonia (muscle spasm), resulting in poorer quality of life and increased risk of medication discontinuation [134]. Even though, the specific pathophysiology underlying movement disorders have not been fully understood, however the inhibition of dopamine type 2 (D2) receptors has been implicated in the development of EPS [135].

In recent years, SGAs, also referred to as atypical antipsychotics, have largely superseded the use of FGAs [136]. Since 2004-2005, the majority (80%) of antipsychotic prescriptions in the United States (US) were SGA [137]. Similarly, prescribing patterns in Australia have suggested the preferential use of SGAs, with reports indicating a rise in cumulative SGA prescriptions (an increase from 83% to 91%) and a decrease in FGA prescriptions (reduced from 17% to 9%) from 2006 to 2018 [138]. In fact, of the 16 antipsychotics listed on the Australian Pharmaceutical Benefits Scheme (PBS)¹[139], 11 are SGAs [138]. SGAs are preferred by patients and treating doctors, mainly as they have a lower risk of EPS than FGAs and are therefore better tolerated [140, 141].

The difference in adverse reaction profiles between FGAs and SGAs can be largely explained by variation in pharmacological properties. Whilst the therapeutic effect of FGAs correlates with D2-receptor affinity, the therapeutic effects of SGAs are attributed mostly to the blockade of certain serotonin (mostly 5HT_{2A}) receptors and to some degree to D2 receptors, although to a lesser extent than FGAs [142]. However, the use of SGAs does not come without its drawbacks. SGA use is associated with weight gain and metabolic disturbances, which perpetuate the risks of developing cardiovascular disease, diabetes, dyslipidaemia and hypertension, thus negatively affecting the

¹ An Australian government’s policy where the cost of the specific ‘listed’ medicines are subsidised for Australian citizens and permanent residents.

physical health of PLMI [122, 123, 141, 143, 144]. Even though, the exact mechanism for SGA-induced weight gain remains poorly understood, it has been speculated to be associated with binding affinities of SGAs to serotonin, norephedrine, dopamine and histamine-H1 receptors [141]. Whatever the mechanism, patients taking SGAs are at a considerable risk of developing cardiometabolic complications such as metabolic syndrome (MetSyn) [122, 145-147].

Metabolic syndrome

MetSyn is defined as the simultaneous abnormalities in weight (central obesity), blood pressure, blood glucose and lipid levels [148]. PLMI using an antipsychotic tend to have poorer metabolic profiles ($p < 0.0001$) and a higher prevalence of MetSyn than the general population [149, 150]. Penninx and colleagues suggested that the rate of MetSyn was approximately 58% higher in PLMI than in the general population. In particular, individuals diagnosed with bipolar disorder using antipsychotics have a 1.72 times greater risk of MetSyn when compared to the general population [151]. Additionally, Dubath and colleagues, reported that 1 in 4 mental health consumers displayed MetSyn, a figure that is relatively conservative when compared to the existing literature [152-154]. For example, an Australian survey reported that nearly 50% of respondents living with psychosis met the criteria for MetSyn [152].

People with MetSyn have a significantly higher risk of cardiovascular events which can result in premature death [155], prolonged hospital stays and increased risk of infections [146, 156]. It is also worth noting that the healthcare costs for people with MetSyn are higher when compared to the costs for people without, for example USD\$5 732 compared to USD\$3 581 per annum respectively [157]. To add, individuals with MetSyn have also reported the significant negative impact on their health-related quality of life [158, 159]. Therefore, addressing the disparity in physical health will benefit the individual and reduce the burden on the healthcare system.

It has been suggested that weight gain and changes in body composition may account for many of the metabolic complications associated with SGAs [141]. An increase in the mean weight over a 10-week treatment period (on standard dose) was reported to be 4.45kg and 4.15kg for individuals prescribed clozapine and olanzapine respectively [140]. Despite the potential for SGAs to compound the risk of MetSyn in this cohort, they remain one of the most effective treatment options for people with psychotic illnesses [160]. Therefore, given the high risk of MetSyn, routine metabolic monitoring for individuals taking SGAs becomes necessary [161-164].

Adherence to guidelines

Efforts to promote better physical health for PLMI prescribed antipsychotics have led to the development of multiple guidelines and consensus statements from associations such as the WHO, the combined guideline by the American Diabetes Association (ADA) and the APA [141], and the Royal Australian and New Zealand College of Psychiatrists [165]. The importance of regular physical health and lifestyle monitoring is a common feature of these guidelines. Specifically, metabolic parameters such as waist circumference, weight, body mass index (BMI), blood pressure (BP), fasting glucose and fasting lipids, as well as routine assessment of lifestyle factors (examples include, tobacco smoking and substance use) for all individuals on antipsychotic therapy to ensure that metabolic complications can be identified and managed before they become a major problem [141, 166-169].

Existing research have suggested that there is a disparity between guidelines and current practice, resulting in concerns of low rates of metabolic monitoring [170, 171]. A prospective study (n=90) conducted in England, reported suboptimal monitoring rates, with parameters such as waist circumference (0%) and lifestyle intervention (9.5%) infrequently measured. Further, it was noted that the metabolic results were often (> 90%) not recorded in the psychiatrist's case notes [171]. While psychiatrists reported having awareness of the metabolic consequences of SGAs, they have also reported infrequently monitoring these metabolic parameters [170, 172]. In New Zealand, an audit of eight general practices found that none of the individuals with schizophrenia (n=117) were fully monitored according to the guideline of the Royal Australian and New Zealand College of Psychiatrists and the Best Practice Advisory Centre [173]. Similarly, an audit in regional Queensland on the use of an electronic metabolic monitoring form in a mental health service found that data monitoring metabolic parameters were recorded in only 36% of the files audited [174].

Identified barriers to metabolic monitoring

There are several identified barriers to the regular metabolic monitoring of PLMI and these commonly include both health-professional, specifically psychiatrist- and PLMI-specific factors. Psychiatrist-related barriers included the potential prioritisation of managing mental health symptoms over physical health monitoring [175]. Other identified barriers included not having physical health monitoring equipment within easy reach, uncertainty about how often to monitor and ambiguity on which practitioner, such as, a psychiatrist or general practitioner, should be responsible for physical health monitoring and managing abnormal results [24]. International data, from the US and United Kingdom (UK) [175, 176] showed that psychiatrists perceive that they are mainly responsible for the management of psychiatric rather than physical symptoms [177]. Additionally, this perception of competing demands coupled with a lack of time, insufficient staff and long wait times to see medical

providers have been shown to hinder routine metabolic monitoring [24, 161, 175]. To add, PLMI often experienced difficulties with having to travel for appointments [178], which could further hinder the provision of routine metabolic monitoring. Especially as limited appointment attendance could mean that symptomatic control may take priority over physical health monitoring.

Improving metabolic monitoring: existing research

Several studies have explored strategies to improve current metabolic monitoring rates for PLMI [179, 180]. Interventions often involved either staff training, or the testing of a new tool designed to assist health professionals with screening, such as the use of computer or paper-based prompts [181, 182]. A systematic review found that whilst the majority of the interventions (21/30) were able to increase screening rates for metabolic parameters, including weight (19% to 67%), lipids (22% to 61%), BP (22% to 80%) and glucose (28% to 65%) [179], up to a third of the patients remained unscreened. It is worth noting that the included studies had weak to moderate quality, with variations observed in the number of metabolic measures targeted in each study. Therefore, there remains a need to further explore the role of health professionals in MetSyn screening.

The inclusion of specialised mental health nurses to improve rates of metabolic monitoring has been a frequently suggested solution to the persistently low MetSyn monitoring rates [174, 183, 184]. Michael and colleagues implemented a quality improvement initiative in an Australian inpatient psychiatric ward to improve metabolic monitoring rates [183]. This nurse-led initiative involved (i) the upskilling of nurses to perform metabolic monitoring, (ii) education to nursing and medical staff, (iii) a suite of interventions (including reviewing of ward diet) including lifestyle interventions such as yoga, cooking classes and prescribed walks. The study reported a statistically significant increase ($p < 0.05$) in the monitoring of key parameters such as weight, BP, height, lipids levels, BMI and waist circumference. One limitation was potentially underestimating the metabolic monitoring rate since researchers could only access hospital-laboratory testing results, and patients have received metabolic monitoring from external providers. Another study by Ross and colleagues aimed to increase inpatient monitoring rates by (i) developing and implementing a medical directive for metabolic screening and (ii) providing education and training for clinical staff [185]. This study ($n=95$) found a significant improvement in the monitoring of blood glucose, lipids, and thyroid-stimulating hormones ($p < 0.05$), with the addition of electrocardiogram readings [185]. However, the study was conducted in an inpatient ward, and therefore findings may not be generalisable to a broader setting, such as the community where hospital policies and/or directives may have less of an influence on practice.

A longitudinal audit (n=1,591) conducted between 2006 to 2012 at community psychiatric services (UK) showed improvement in MetSyn screening after the implementation of a multitude of interventions [186]. The suite of interventions included the display of posters which provided health professionals with guidance on parameters to be monitored (and ranges) and when additional monitoring or intervention, such as, lifestyle interventions, were required. The mental health service sites were also provided with a tailored local action plan with recommendations and suggestions specific for their setting. Resources for PLMI were also developed, including the development of a life management pack containing diet advice, physical exercise and smoking cessation and a ‘Physical health check’ reminder card that could be provided to patients. However, the authors found that the monitoring rates remained suboptimal with only over two-thirds of the cases receiving screening.

Pharmacists and metabolic monitoring

Several studies have explored the role of pharmacists in metabolic screening and/or monitoring of mental health consumers. A literature search (Supplementary File A) found eight studies of interest (Table 2). Half of these studies were based in the US (n=4) and two were conducted in Australia. These studies were mostly conducted within primary care (n=4), and only two carried out in a community pharmacy [187]. Most of the findings indicated an improvement in metabolic monitoring after the intervention [188-190], while others highlighted the feasibility of point-of-care testing carried out by pharmacists [191] and situating a metabolic clinic within a community pharmacy [187].

Table 2. Example of interventions to improve screening/monitoring of metabolic parameters for PLMI involving pharmacists.

Authors	Aim(s)	Setting	Methods	Key findings	Limitations
Schneiderhan et al.[191]	To assess usefulness of a metabolic risk screening program, including point of care glucose testing to quantify baseline metabolic risk in outpatients receiving antipsychotics.	University-affiliated department of psychiatry clinic. US	Retrospective, cross-sectional cohort study. Review of patient's electronic medical record which included screening checklist. Screening checklist completed by pharmacist or nurse as part of the metabolic risk screening program. Inclusion: patients prescribed an antipsychotic.	n= 92 patients. Point-of-care testing for metabolic risk screening when done in an interprofessional team approach, is a practical method for identifying metabolic risk in patients on antipsychotics.	No availability of baseline parameters (such as, pre-initiation of antipsychotic treatment). Inadequately powered sample.
Kjeldsen et al.[188]	Evaluate the effect of outreach visit by clinical pharmacists to support the implementation of screening of MetSyn at a psychiatric ward.	Psychiatric ward, Odense University Hospital. Denmark	'Before' and 'after' study. Development of clinical guidelines for systematic screening and prevention of metabolic risk. Passive dissemination (PD) compared to active implementation (AI) of guideline. Two clinical pharmacists had weekly conferences where medication reviews were discussed with participating psychiatrists and nursing staff. Inclusion: International classification of diseases-10 criteria for schizophrenia or affective disorder, aged 18 years or older, admitted to a	n= 205 patients (93 in the PD and 112 in the AI group). Use of screening sheet improved significantly after introduction of outreach visit by clinical pharmacists in AI group (p<0.001). MetSyn identified in 45% of patients in AI group compared to 10% in PD group.	AI was led by experience clinical pharmacists (did not explore the experience with alternative staff or professionals). Patients in AI group had longer admissions. Therefore, admission stay could be a variable in screening uptake. Smoking cessation was not explored. Study based on screening sheet that was a paper format. Electronic-based format should be explored. Small sample size.

			<p>psychiatric ward for 10 days or more, treated with antipsychotics or mood stabilising medicine.</p> <p>Exclusion: Patients associated with forensic psychiatry.</p>		
Schneiderhan et al.[180]	<p>Determine the percentage of subjects taking antipsychotic agents who meet criteria for metabolic syndrome at baseline using point-of-care test results.</p> <p>Evaluate the effectiveness of the provision by pharmacist comprehensive medication management services regarding their ability to reduce the mean difference in number of metabolic syndrome risk parameters based on point-of-care test results at 6 and 12 months.</p> <p>Evaluate the overall impact of psychiatric medication therapy on metabolic risk.</p>	<p>Community mental health setting.</p> <p>US</p>	<p>12-month prospective RCT.</p> <p>'No-pharmacist medication management services' (control) vs 'pharmacists comprehensive medication management services.</p> <p>Pharmacist comprehensive medication management services and utilization of point-of-care screening for metabolic syndrome, metabolic risks, or related diseases.</p> <p>Inclusion: Prescribed antipsychotics.</p>	<p>n=120 participants.</p> <p>No statistical differences in metabolic syndrome based on point-of-care tests were observed baseline or at 12 months.</p>	<p>Small sample size.</p> <p>High attrition rates.</p> <p>Lack of interprofessional collaborations with primary care providers.</p>
Ganzer et al.[192]	<p>A re-implementation of pharmacologic and non-pharmacologic pharmacist intervention.</p>	<p>Outpatient mental health clinic.</p> <p>US</p>	<p>Pilot implementation of the metabolic clinic.</p> <p>Pharmacist responsible for ordering and monitoring of laboratory work, patient education and any psychiatry medication history, allergies, diet and lifestyle habits.</p> <p>At risk individuals were referred to MOVE program, a</p>	<p>n= 28 referred, 17 consults completed.</p> <p>Demonstrated appropriately trained clinical pharmacists can help decrease some of the barriers to metabolic syndrome monitoring in mental health patients.</p>	<p>Small sample size (including high rates of 'no-shows' to appointments).</p> <p>Community-based outpatient clinics, where many of the veterans attend, unable to place metabolic syndrome clinic consult and unfamiliar with referral pathway.</p>

			<p>national weight management program.</p> <p>Inclusion criteria: patients using SGAs and meet criteria for metabolic syndrome.</p>		
Maulavi zada et al. [187]	Evaluation of a novel mental health service developed within a community pharmacy.	<p>Community pharmacy</p> <p>Australia</p>	<p>Mix-methods (semi-structured interviews and review of patient biometric information).</p> <p>Metabolic clinic operated and managed by nurse practitioner.</p> <p>Metabolic clinic involved the measuring of:</p> <ul style="list-style-type: none"> ▪ weight ▪ height ▪ body mass index ▪ waist circumference ▪ blood pressure ▪ blood glucose levels ▪ lipid profile ▪ heart rate ▪ respiratory rate ▪ oxygen saturation ▪ other (such as, Vitamin D, Iron levels and Prostate Specific Antigen test) <p>Pharmacy staff involved in the referral of patients to the clinic and provision of promotional presentation (for example, at residential aged care facilities)</p>	<p>Semi-structured interviews: n=10 pharmacy staff members.</p> <p>Biometric information: n=20 patients (data for 24 patients were not provided).</p> <p>Reported “positive trends” for 20 patients over 5-month study duration, however no explicit details regarding these ‘positive trends’ were reported.</p>	<p>Inadequate reporting of patients who had attended the metabolic clinic:</p> <ul style="list-style-type: none"> ▪ no demographics data ▪ no explicit reporting of total sample size <p>Interview guide not validated.</p>

			<p>Interview of pharmacy staff to evaluate proposed framework.</p> <p>Inclusion:</p> <ul style="list-style-type: none"> ○ all staff with some involvement with metabolic clinic and worked during the operational hours of the metabolic clinic service. ○ de-identified patient biometric information for patients who attended the metabolic clinic. 		
Wheeler et al. [193]	To test the effectiveness of a person-centred, goal-oriented and flexible, pharmacist-led support service for people living with SMI, with a specific focus on improving medication adherence and managing physical comorbidities.	<p>Community pharmacies.</p> <p>Australia</p>	<p>Protocol for a randomised controlled study.</p> <p>Duration: 6 months.</p> <p>PharMIbridge: improving medication adherence and managing physical comorbidities.</p> <p>Intervention group (PharMIbridge) vs Control group (Medscheck group).</p>	<p>Inclusion for community pharmacies:</p> <ul style="list-style-type: none"> ○ located in New South Wales (two regions), Victoria (one region) and Australian Capital Territory. ○ approval to dispense pharmaceutical benefits as part of the PBS. ○ accreditation for Quality Care Pharmacy standards (a quality assurance programmed for community pharmacies) ○ a clientele demographic that includes people with SMI ○ routinely provided MedsCheck as an established professional service ○ guaranteed that the service will be carried out by a registered pharmacist who has completed the training. ○ a private room/area 	Outcomes not yet published.

				<ul style="list-style-type: none"> ○ pharmacy owner/manager consent to participate ○ an established working relationship with local GP clinics or centres, mental healthcare teams and/or are already engaged with mental health promotion 	
Hibner et al. [189]	Evaluate whether the implementation of a pharmacist- and nurse- driven metabolic monitoring protocol will increase monitoring inpatients prescribed second-generation antipsychotic therapy in an outpatient community mental health clinic.	Outpatient community mental health clinic. US	<p>Pre and post assessment of protocol implementation.</p> <p>Implementation: metabolic monitoring protocol and associated staff education.</p> <p>Inclusion criteria: adults prescribed second-generation antipsychotics.</p> <p>Inclusion, patients:</p> <ul style="list-style-type: none"> ○ at least 18 years old ○ attended at least 1 clinic visit with nurse or pharmacist OR, psychiatrist every 6 months during study period ○ prescribed at least one SGA and, ○ had documentation of laboratory test results within the previous 3 years 	<p>n= 160 patients randomly selected and reviewed. Pre-protocol (n= 80) and post-protocol (n=80).</p> <p>Improvement in the following parameters:</p> <ul style="list-style-type: none"> ▪ blood pressure (increased from 17.5% to 43.8%, p < 0.001) ▪ weight (increased from 17.5% to 43.8%, p < 0.001) ▪ haemoglobin A1c (increased from 27.5% to 42.5%, p = 0.044) ▪ lipid levels (increased from 17.5% to 31.3%, p = 0.04) 	<p>Limited direct pharmacist involvement.</p> <p>Staffing changes, therefore, not all staff received the same level of metabolic education.</p>

Pharmacist-led metabolic screening was supported by several studies [180, 194], including a US-based study that implemented a metabolic screening program in a community pharmacy for the general population (n = 239) [195]. The study was able to demonstrate the feasibility of the service and showed an increase in the uptake of lifestyle modifications following the pharmacist-led educational session. Similarly, studies have also highlighted the role of pharmacists in facilitating the early identification and long-term management of metabolic risks among patients prescribed antipsychotics [180, 194].

In Australia, a randomised controlled study, Bridging the Gap between Physical and Mental Illness in Community Pharmacy (PharMIbridge), which at the time of writing this thesis had not yet published all of the results, explored the effectiveness of a pharmacist-led support service for people with SMI [193]. This study sought to explore the effectiveness of a flexible, person-centred and goal-oriented service for PLMI, focusing on medication adherence and management of physical comorbidities over six months. With a paucity of longitudinal studies, other than one 12-month study identified, there is a severe lack of evidence on the effectiveness of longitudinal monitoring of physical health in PLMI [180].

Justification for further research

To date, there is limited evidence on the role of pharmacists in metabolic monitoring within the community pharmacy setting [196]. A recent review by Sud and colleagues, identified 33 studies exploring the role of pharmacy or pharmacy staff in the management of cardiometabolic risk factors, metabolic syndrome and related diseases in individuals with SMI [196]. Of these, four studies were conducted in a primary care setting and only one was based in a community pharmacy (UK), although the role of the pharmacist was not clearly described. The authors also identified the need for more robust research that explored the effectiveness and cost-effectiveness of pharmacist-led screening, prevention and management of MetSyn [194]. Evidence also suggests the need for longitudinal studies in this area [191, 193]. The potential role of community pharmacists in better supporting PLMI, including to improve metabolic monitoring rates requires greater exploration. This has also been recognised by the PSA, which recently called for the implementation and funding of community pharmacy Mental Health Medicines Consultation Services, including a physical health and medicine support service [197].

Chapter Summary

As readily accessible and highly trained health professionals, pharmacists, especially those practising in the community can address these current healthcare gaps. Emerging research has highlighted the potential for pharmacists to further contribute to this field. There is currently a paucity of research exploring pharmacist-led physical health checks to screen for metabolic syndrome, especially in a community setting. Lastly, recent studies have highlighted the need for pharmacists to be involved in supporting PLMI given the potential to improve and optimise patient outcomes.

Improving the provision of medication education and metabolic monitoring for PLMI can improve the quality of life for PLMI [90]. There is an immediate need to further explore these gaps and efforts should be made to address these shortcomings. This thesis aims to explore and attempt to address these gaps through a comprehensive exploration involving several studies as outlined in Chapter One.

While it is recognised that certain evidence presented in this chapter pertains to people living with SMI, the research presented in this thesis focuses on PLMI more broadly. In doing so, this work recognises the discrepancies in the provision of medication education and metabolic monitoring affecting all PLMI, and particularly those using SGAs regardless of mental health diagnosis.

Supplementary File A

Search Strategy for Literature review (Chapter Two)

- Conducted on Medline (Ovid). Last searched 30th January 2023
- All studies retrieved from Query #14 (n =223) were reviewed by the PhD Candidate

#	Query	Results from 30 Jan 2023
1	Mental Disorders/	175,872
2	((mental or psychiatric) adj3 (disorder* or illness or ill)).ti,ab,kw.	144,344
3	1 or 2	271,558
4	Health Knowledge, Attitudes, Practice/	125,509
5	(health adj2 (knowledge or attitude*OR practice knowledge)).ti,ab,kw.	9,785
6	Consumer Health Information/	4,276
7	health information.ti,ab,kw.	28,739
8	Patient Education as Topic/	88,179
9	(patient* adj2 (educat* or inform*)).ti,ab,kw.	81,149
10	4 or 5 or 6 or 7 or 8 or 9	300,360
11	Psychotropic Drugs/	22,342
12	(psychotropic adj2 (drug* or medicine*)).ti,ab,kw.	8,984
13	11 or 12	27,097
14	3 and 10 and 13	223

3 Beliefs and knowledge towards psychotropic medications

Chapter Overview

This chapter focused on addressing insufficient medication education (Healthcare gap 1). To comprehensively address this issue, this study was conducted in two phases. The first phase explored the current knowledge and beliefs of PLMI towards psychotropic medications. The second phase involved the design of a client-tailored information session that was delivered at a not-for-profit (NFP) organisation (presented in Chapter Four).

This chapter presents the findings from this first phase as a published paper and a short discussion on the perceived role of the community pharmacist. PLMI are referred to as ‘clients’ in the paper. Specifically, the chapter explored PLMI’s (i) knowledge and beliefs on the use of psychotropic medications and (ii) experiences with their healthcare providers.

Publication Overview

Inadequate medication education can result in poor medication knowledge and beliefs which can negatively impact medication-taking behaviour [198-202]. Evidence suggests that poor medication adherence can lead to an increased risk of relapse, hospital re-admission and even suicide in PLMI [203]. As introduced and explored in Chapter Two, insufficient medication education remains a persisting issue, even in developed countries such as Australia.

This paper explored the current knowledge and beliefs of psychotropic medications in PLMI attending a community NFP organisation, a community-managed specialist mental health service provider in South Australia. It also explored the ongoing therapeutic relationship that PLMI have with their health professionals including with their community pharmacists. The role of community pharmacists is further discussed at the end of the chapter.

For a copy of the consent form and interview guide see Appendix A and B.

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Exploring mental health clients' current medication knowledge, beliefs and experience with healthcare providers in the community in South Australia

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Abstract

In Australia, mental illness has been recognised as a National Health Priority area, with the coronavirus pandemic adding a layer of urgency to the need to address the multiple health problems faced by clients with mental illnesses. Whilst much has been done in efforts to support these clients, little is known about their medication knowledge and experience with health professionals. The aim of the study was to explore the knowledge and beliefs of clients on the use of psychotropic medications and study their experiences with healthcare providers. Adult participants at a not-for-profit community-managed specialist mental health service provider in Adelaide, South Australia were recruited. Four focus group sessions were conducted between February 2020 and March 2021. All sessions were co-facilitated by a peer practitioner with lived experience. Sessions were audio recorded and transcribed verbatim. Participants ($n = 27$) reported that provision of medication education was inadequate and, in some cases, non-existent. There was an apparent lack of support for monitoring and managing common side effects, such as weight gain. Participants described not being involved in any decision-making processes and that establishing and maintaining a therapeutic relationship with their healthcare providers was challenging. Perceived stigma remains a barrier in accessing healthcare. Despite participants regularly interacting with a range of healthcare providers, findings highlight key gaps in care, particularly medication education and establishing a therapeutic relationship with their healthcare providers. Future mental health reforms should consider the provision of additional medication education in community settings, such as at not-for-profit organisations. Moreover, healthcare providers should take a proactive approach in establishing therapeutic relationships.

KEYWORDS

community health, medication counselling, medication knowledge, mental disorders, mental health, shared decision making, therapeutic relationship

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1 | INTRODUCTION

Mental illness is a leading cause of ill-health and disability worldwide, affecting more than 970 million people globally (James et al., 2018). In Australia, nearly half the population aged between 16 and 85 years will experience a mental illness at some stage in their lifetime (Australian Institute of Health and Welfare, 2020). The coronavirus (COVID-19) pandemic has further exacerbated health problems for clients with mental illnesses (Galletly, 2020). Recent mental health reforms in Australia have seen the delivery of services transform from previously being inpatient-reliant to a more community-based service (Australian Government Department of Health, 2009). This transition, combined with existing schemes such as Medicare (which covers all costs associated with services provided in public hospitals, general practitioners and medical specialists) and the Pharmaceutical Benefits Scheme (PBS) (with the provision of all PBS listed medicines at a subsidised price), aimed to make healthcare more accessible and affordable for Australians, especially for individuals diagnosed with mental illness. Although much work has been done in reforming the health system, more effort is required, especially in supporting positive medication taking behaviours in individuals with mental illness (e.g. improving medication adherence).

The majority of individuals diagnosed with mental illness (hereon, simply referred to as 'clients') are often prescribed psychotropic medications. Studies on the effectiveness of these medicines are often related to the concept of treatment adherence, despite noting high rates of discontinuation in clients living with schizophrenia (20%–72%) and major depressive disorder (28%–52%) (Julius et al., 2009). Medication discontinuation is concerning, given the significant correlation between medication discontinuation and re-hospitalisation (Green, 1988; Kozma & Weiden, 2009), as well as higher rates of relapse and suicidal behaviour (Clatworthy et al., 2007; Colom et al., 2005).

Medication taking behaviour is influenced by clients' medication knowledge, attitudes and beliefs. In particular, positive medication beliefs can play a major role in medication taking behaviour (Drivenes et al., 2020; Higashi et al., 2013), with medication beliefs being influenced by knowledge of medication effects (Grover et al., 2014). Similarly, people with greater knowledge of the therapeutic effects of medications have also been shown to be more likely to have a positive attitude towards their medications (Nagai et al., 2020; Wiesjahn et al., 2014). In addition to enhancing medication knowledge, establishing a positive therapeutic relationship between clients and their healthcare providers can also positively influence medication taking behaviours (Day et al., 2005).

Despite the recognised importance of having adequate medication knowledge, research indicates that education provided by doctors and pharmacists may be inadequate (Kessler, 1991; Tully et al., 2011; van Dijk et al., 2016). An Australian study found that medication education was insufficient and clients' ($n = 9$) experience with healthcare providers was unsatisfactory (Happell et al., 2004). For example, Young et al. (2006) found that doctors do not regularly provide important information, such as anticipated duration of therapy and expected

What is known about this topic?

- Individuals diagnosed with mental illness often report high rates of psychotropic medication discontinuation.
- Medication taking behaviour is influenced by a client's medication knowledge, attitudes and beliefs.
- Having a positive therapeutic relationship between clients and treating healthcare providers can positively influence medication taking behaviours.

What the paper adds?

- Clients with mental illness receive inadequate medication education of their psychotropic medications which is further compounded by challenges in establishing and maintaining an ongoing therapeutic relationship with their healthcare providers.
- Monitoring of adverse effects proved to be the most challenging aspect of pharmacotherapy for clients with mental illnesses living independently in the community.
- Shared decision making was not immediately evident in this study.

delay in onset of action to people commencing antidepressants. Furthermore, reports have shown that up to 60% of clients rarely or never receive written medicine information (Knox et al., 2015).

The present study aims to explore community clients' (i) knowledge and beliefs on the use of psychotropic medications and (ii) their experiences with their healthcare providers. This will enable health professionals, especially those working in community settings to identify current gaps in care and work with clients to positively influence their medication taking behaviours.

2 | METHODS

2.1 | Design

This qualitative study recruited adult participants at a not-for-profit (NFP) community-managed specialist mental health service provider in Adelaide, South Australia. In order to maximise participant numbers, facilitate open discussion and allow for the exploration of a wide range of experiences, face-to-face focus groups were employed. The delivery of the sessions via a virtual platform was not feasible as most of the clients did not have access to the electronic means required. As this study was done during the COVID-19 pandemic, the sample size was further impacted by limitations to public gatherings imposed by the South Australian government. The ideal sample size for each focus group was set between 6 and 10 participants (Powell & Single, 1996). The study was approved by the institution's Human Ethics Committee (202299) and the mental health service provider's ethics committee.

2.2 | Recruitment

Peer practitioners (PP) employed at the NFP were briefed on the study and led the recruitment phase. Participants were approached face-to-face and recruitment flyers were displayed in the main waiting area at the two NFP locations. Participants were encouraged to discuss with the PP if they were interested or had any questions about the study. Convenience sampling was chosen as the recruitment strategy. Study inclusion criteria consisted of: (i) clients who have or are currently taking medication for any mental illness, (ii) aged 18 years or older and (iii) able to give informed consent.

2.3 | Procedure

Prior to the focus groups, study information and consent forms were provided and explained to participants, with an opportunity to ask questions prior to undertaking the focus group. Written consent was obtained from all participants prior to commencing the focus groups. The sessions were facilitated by researchers (M.L. and T.B.), who conducted two focus groups each. M.L., a lived experience researcher is an academic with extensive experience in qualitative research. Researcher T.B. is a registered pharmacist and PhD candidate with research interests in mental health and qualitative methods. Both researchers had no established relationship with any of the participants prior to the study's commencement. The researchers' background (e.g. research interests, work experience and whether they have lived experience) were also highlighted to the participants prior to the commencement of the focus group sessions. All focus groups were co-facilitated by a PP with lived experience (Mental Health Coalition of South Australia, 2020). Researchers VS and EH were present at the sessions as silent observers and EH made field notes during the sessions. The sessions were informed by a discussion guide which had been previously piloted with a lived experience academic and a lived experience end user (Appendix S1). The four focus groups were held in meeting rooms at two NFP centres between February 2020 and March 2021 and sessions ran for an average of 54 minutes. The study followed the grounded theory approach (Chun Tie et al., 2019; Walker & Myrick, 2006), with two focus groups being conducted in 2020 and data analysed prior to additional focus groups being conducted in 2021. An honorarium of AUD \$30.00 gift voucher was provided as an appreciation for the participants' time.

2.4 | Data analysis

The focus groups were audio-recorded and transcribed verbatim by the researcher (TB). Transcripts were not returned to participants for comments but were available when requested. Data were analysed using an inductive approach (Thomas, 2006). Thematic analysis was conducted by researcher TB and analysis was guided by the six-step method discussed by Braun and colleagues (Braun & Clarke, 2006). To enable data familiarisation, the researcher re-visited the audio

recordings and reviewed transcripts several times. An initial list of codes was drawn from the first review of transcripts. Transcript texts were then manually coded and identified codes were matched with data extracts using an Excel® spreadsheet. Codes were collated into potential themes, then reviewed and compared with initial list of codes and field notes to ensure that they accurately represented the data. Findings (themes and subthemes) were also reviewed and discussed by researchers (T.B., V.S. and E.H.) and made available to the PP who was present at the focus group sessions to establish an accurate representation of the data. To ensure the trustworthiness of the data, transcription was checked independently by two researchers (V.S. and E.H.). Any disagreements were then discussed between the researchers (T.B., V.S. and E.H.) until consensus was reached.

Data saturation was assessed using the inductive thematic saturation approach (Saunders et al., 2018), and was deemed as reached when there was no emergence of new codes or themes (Saunders et al., 2018). Researchers (T.B., V.S. and E.H.) also noted that a significant level of data saturation had been achieved by the fourth focus group, similar to findings by Guest and colleagues who suggested that 90% of all themes were discoverable within as few as three focus groups (Guest et al., 2017).

2.5 | Reflexivity

Researcher's individual background, experience and prior assumptions can have an impact on the process of data collection and interpretation. In order to minimise this, active reflexivity was employed throughout the study (Dodgson, 2019). In particular, during the processes of study design, data collection and analysis.

In designing the study, the decision to conduct the sessions at a NFP centre where the participants frequently attend and view as a familiar place was consciously made. In doing so, we hoped for participants to view the researchers as guests in the setting, allowing for participants to feel that they are exercising control over the session. In addition, the study consisted of a diverse team that included academics with and without lived experience, PP, practicing and non-practicing pharmacists.

During data analysis, the themes were reviewed by all researchers present at the sessions, including the silent observers (E.H. and V.S.) and the PP. This was to ensure that the perspective of one group of participants was never over-presented and to minimise any researcher bias.

3 | RESULTS

3.1 | Demographics

A total of 27 participants attended the four focus groups (Table 1). One participant withdrew from the study prior to the commencement of the session for unspecified reasons. Over half of the participants were female (55.6%), 37% aged between 41 and 50 years

TABLE 1 Participant demographics (n = 27)

	N (%)
Age (years)	
18–24	1 (3.7)
25–30	2 (7.4)
31–40	9 (33.3)
41–50	10 (37.0)
51–60	3 (11.1)
61–70	2 (7.4)
Gender	
M	12 (44.4)
F	15 (55.6)
Length of time attending the community-managed specialist mental health service provider	
<3 months	5 (18.5)
3–6 months	1 (3.7)
6–12 months	4 (14.8)
12–18 months	1 (3.7)
>18 months	15 (55.6)
Unspecified	1 (3.7)
Currently on medications	
Yes	18 (66.7)
No	4 (14.8)
Not specified	5 (18.5)
Psychotropic medications	
	Frequency
Antipsychotics	41
Antidepressants	14
Lithium	6
Benzodiazepines	2
Others	6

and most had been accessing services at the mental health service provider for more than 18 months (55.6%). The majority (66.7%) of participants reported that they were currently on prescription medication(s) with antipsychotics being the most prescribed psychotropic agent.

Participants' responses to the focus groups were categorised into the following themes and subthemes (Figure 1): (1) Knowledge and beliefs towards psychotropic medications (including medication education, psychotropic medication: adverse effects and Community Treatment Orders) and, (2) Experience with healthcare provider (including shared decision making, diagnosis, therapeutic relationships and stigma).

3.2 | Theme 1: Knowledge and beliefs towards psychotropic medications

3.2.1 | Subtheme 1: Medication education

Majority of the participants did not feel confident in their knowledge of prescribed medications for their mental illness (Table 2). Only one

participant was the recipient of what they believed to be substantial medication education, recalling:

'When I was diagnosed years and years ago ... she [doctor] gave me some options ... I get access to her [doctor] to be able to ask questions ... and printed information as well ... I was certainly one of those people that had had information relay [sic] to me on a number of occasions plus I had a really supportive husband who was also fully aware of all the implications and side effects of the medications (FG1-P10).'

Other participants disclosed that they were given no information by their healthcare providers, with one participant stating, 'I discovered more with my mobile phone these days than what I was told for the last 20 odd years (FG2-P2).'

Some participants could not recall whether medication counselling was provided as they were acutely unwell at the time and could not process detailed information. Medications administered in the hospital were similarly not explained.

'In the emergency room they didn't say anything they just gave me the injection. I didn't know what it is, it must have been like to knock me out or whatever. Fair enough. No, they didn't say what it was or anything (FG1-P5).'

Participants expressed that medication education should be provided repeatedly stating:

I just think that if people are really unwell when they commence on the medication so they're not in a position to actually understand what it is that they are going to be taking. I think that ... after a couple of weeks or after they start improving, people should then take the time to sit down and go over the medications even though the people are already taking them ... just down the track a bit it would be nice if the doctor took the time to explain everything (FG4-H).

and,

'I had to be educated every single time ... I find sometimes it's not the first time you hear it, sometimes second time or third time [for it to make sense] (FG1-P10).'

3.2.2 | Subtheme 2: Psychotropic medications (adverse effects)

Most participants expressed concerns with the lack of counselling for potential medication-related adverse effects. The majority of the

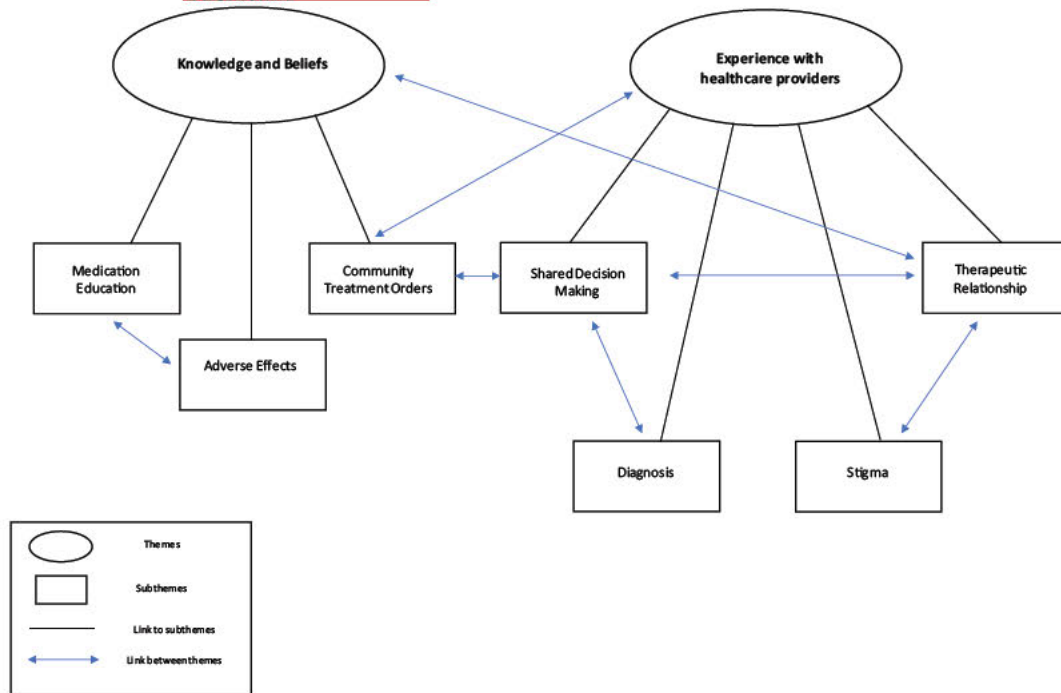


FIGURE 1 Thematic map. Visual presentation of themes and subthemes identified and relationships between categories

participants claimed that they were made aware of adverse effects only after they had occurred. Moreover, it was identified that most participants did not receive counselling and/or monitoring for common adverse effects for long-term medications. A participant felt that the current healthcare system was ill-equipped to provide adequate aftercare care for clients such as regular monitoring of side effects.

Among the adverse effects identified, weight gain and effects on mental alertness were the most commonly discussed (Table 2). The impact of weight gain was reported to not only impact physical health, but also described as having a significant impact on their mental health:

I ended up with a whole eating disorder just to manage the weight gain with that. So it really needs to be tailored ... prescribing a medication for someone with eating disorder and it's known for gaining weight, you should monitor them more clearly cause you're gonna end up with a whole other problem that will require a whole other treatment and medication...(FG3-A).

The negative impact on mental alertness was also highlighted as something that has significantly affected their quality of life.

... the medication made me feel defenceless. I can't even protect myself (FG3-X).

Despite the concerns previously identified, the vast majority of participants indicated that they accepted the role of prescribed medication(s) for their conditions.

I know to keep on with the medications, 'cause it keeps me not sort of [in] a happy place but it's better than what the alternative is (FG2-P1).

3.2.3 | Subtheme 3: Community treatment orders

Participants who were under a Community Treatment Order (CTO) reported very different experiences compared to those who were not. In general, participants who reported a more positive experience with the healthcare system were not under a CTO, had better rapport with their healthcare providers and had stable family and/or peer support. They also appeared to be more proactive in their treatment and had a more positive attitude towards their medications. For example, a participant (FG1-P10) mentioned:

I researched finding a GP [general practitioner] through people's recommendation because I am fussy.

and

TABLE 2 Themes and subthemes with illustrative quotes extracted from focus groups

Theme	Illustrative quotes
Theme 1: Knowledge and beliefs towards psychotropic medications	
Subtheme 1: medication education	<p>'my doctor did not give me any information (FG1-P11).'</p> <p>'I was just given things in hospital I think I was on some sort of order so I had to take whatever I was given but I did not really know what I was given if that makes sense (FG4-H).'</p> <p>'Once you are out of hospital it is [referring to the provision of medication education]. When you are in hospital they say oh you'll be taking this, but they do not say why or what it's for (FG3-P4).'</p> <p>'I think that in the time that I went on different medicines I was in manic episodes so if they explained anything to me, I probably would not even remember (FG2-P2).'</p> <p>'I've never been given any print outs or anything from the pharmacist at all (FG3-M).'</p> <p>'You find your own resources (FG3-P6).'</p> <p>'... normally the pharmacists will ask if you have taken it before or whatever or they'll check for any interactions and then they'll go and actually print it out and then give it to you (FG3-A).'</p>
Subtheme 2: psychotropic medications (side effects)	<p>'It turned me into a fat pig basically (FG1-P1).'</p> <p>'I put on 20 kg in about 4 months (FG1-P10).'</p> <p>'Oh once I gain weight with that medication a whole other load of problems and then that doctor was like oh no and then I had to go on more medications... (FG3-A).'</p> <p>'Yea I was a matchstick before they put me on medication (FG4-C).'</p> <p>'I had the same trouble with my weight. I was 63 kg when I went into institution and my highest was 150 kg. So now I've got more medications to speed up my metabolism (FG4-D).'</p> <p>'I had anorexia and so I was 37 kg most of my life so when they [doctors] put me onto medications like I said to them, like if you put me on one with weight gain I'll end up starving myself to death because I have a mental illness relating to weight ... It was heaps traumatic cause I've been hospitalised all through my twenties with anorexia and they put you on a medication, the whole sort of thing with anorexia is control one thing you can control is your weight when they take that option away from you, you lose your mind (FG1-P4).'</p> <p>'... my main issue [with] the side effects ... is the feeling that I'm losing my intelligence, awareness, you know, my perception of things, memory so it just so it just I do not like using this word but it's the only way I can really get it across ... it just makes me feel a bit not stupid but like a zombie. Zoned out (FG3-A).'</p> <p>'... it's my level of awareness I cannot drive (FG4-H).'</p> <p>'I need counselling [referring to medication induced emotional bluntness from Lithium] ... I do not know how to deal with this life that I've got now... I do not know how to deal with the nothingness (FG2-P2).'</p>
Subtheme 3: Community Treatment Orders	<p>'I was chucked on this medication against my will (FG1-P3).'</p> <p>'I was held down and they injected me, and I was overdosed, it nearly killed me (FG1-P4).'</p>
Theme 2: Experience with healthcare provider	
Subtheme 1: shared decision making	<p>'I'm not an assertive guy and I find that I be assertive ... and it gets me nowhere, so I learn to not be assertive (FG3-P4).'</p> <p>'... when you try to explain the story to someone else, they are like no nah you have got these problems. You know, like yea it's a tricky situation (FG4-G).'</p> <p>'... I want to discuss changing my medication and she [psychiatrist] does not want to hear it. She's just ... No. She does not want to know and if anything, she decides maybe we just add another one (FG3-P6).'</p> <p>'... because I said that I was a bit worried about continuing to gain weight and everything and I've got high cholesterol, diabetes everything that goes with it and he goes that they are just the things that you have to accept um when you are trying to stay well. And I felt like, I did not feel listened to at all. It felt like oh you are just a second-class citizen you just have to deal with all these side effects we do not bother too much about it (FG4-H).'</p>
Subtheme 2: diagnosis	<p>'There's just a label and they look at it without dissecting what they are doing. It's more of just an overview, oh yeah, his got this symptom his got that symptom oh yes this. Oh, it's not his got that factor his got this factor so that factor (FG3-P4).'</p> <p>'They're more trying to cover it up, just like patch you up, keep you coming back ... (FG4-G).'</p> <p>'They do not look at different factors. Like I've been in the system for 20 years ... They did not even believe my story of trauma when I entered the system so I'm getting medicated on their thoughts not on, not on justified information so it takes another 10 years to justify yourself to them and you have been medicated and not, not supported with your trauma so you do not get the right therapy (FG3-P4).'</p>
Subtheme 3: stigma	<p>'I do not know if that's the case in [all] pharmacies, but I have difficulty with just instantly being judged. You know they will see my name and ask for extra information [e.g. driver's licence etc](FG3-A).'</p> <p>'I think also depends on where you are in socioeconomic [status] ... [for example] cops said to me, you have no credibility cause you are a drug addict and you have mental health issues and so it's like no respect whatsoever. They do not think they have to explain anything, they just like try to shut you up (FG1-P5).'</p>

'I'm aware of the fact that, something like having the family involved or carer [is important] so I asked the psychiatrist if I can have a meeting with my family on the subject of my medications ...'

Alternatively, participants under the CTO were more likely to have had a negative experience with their healthcare providers, and highlighted reduced autonomy:

The autonomy is completely stripped away. It's just to do as you're told like a child, and we're not children (FG3-P6).

These participants felt disrespected and not in control of their treatment. Whilst they understood what a CTO entailed, they felt that there should have been more aftercare. For example, one participant described:

You're too unwell to really consent to treatment but you need the medication. So, you might be under the order or something like that, but then in order to continue taking that it would be nice if someone sat down and didn't assume that because you're on [the medications] you've consented and you're really happy to continue taking this for how many years (FG4-H).

3.3 | Theme 2: Experience with healthcare providers

3.3.1 | Subtheme 1: Shared decision making

Nearly all of the participants described that they were not involved in any decision making regarding their therapy. They voiced that their concerns and opinions were not listened to by healthcare providers:

We get angry because we're not being heard and then we get angrier because the pharmacists or doctors are reacting like they're surprised that someone with a mental illness is being angry (FG3-A).

One participant described healthcare providers over-riding her opinions:

So when you want to explain yourself to them like, this is why I do this, this is why I won't do that, you can completely be ... No. They won't take you into consideration. I've lived with this all my life so I know what's going on there and they come in and disregard everything you have to say 'cause [sic] they're the specialist on you (FG3-P6).

In addition, a number of participants felt coerced into their treatment therapy. For example:

Well I was asked if I would like to go onto clozapine cause they thought it was the best thing for me and they said that, that was the quickest route out of [name of psychiatric facility] was to go on clozapine. So they kinda rail-roaded me into it (FG1-T).

3.3.2 | Subtheme 2: Diagnosis

Most participants felt that the healthcare providers, when making their diagnosis, did not consider other factors, such as underlying trauma. The healthcare system was perceived as providing a greater emphasis on pharmacological treatment rather than psychological support:

... I wasn't schizophrenic like they had diagnosed me when I was in hospital I was just traumatised from my friend taking his life and I didn't know how to handle it (FG3-A).

and,

Well emotions cause reaction, and these are some things that they [healthcare providers] don't weigh up I guess. They sit there and focus purely on symptoms not on what's caused the symptoms (FG3-P4).

3.3.3 | Subtheme 3: Therapeutic relationships

It was expressed that healthcare providers should take a proactive approach in establishing and nurturing the healthcare provider-patient relationship. In particular, the constant rotation of doctors in public hospitals and community care teams was identified as a barrier to establishing therapeutic relationships. A participant expressed:

That's what sucks about the public system as well, it's because they [doctors] change over just when you get [to know them] ... He was good [last psychiatrist], what if the next one doesn't have the same opinion as him? ... Like he tells what the plan is and the plan can change when you get a new psychiatrist (FG1-P4).

Some participants highlighted that whilst their experiences with treating doctors had not been ideal in the past, they have since found doctors with whom they have a good therapeutic relationship with:

They [certain GPs] don't really want to know about it, the mental side of it, whereas the GP I've got now is wonderful (FG2-P1).

and,

I feel very confident with the GP I've got now and I feel that if I ask her any questions, I feel that she'll answer and if I want to know anything she'll explain (FG2-P2).

3.3.4 | Subtheme 4: Stigma

The perception of stigma remained a barrier for clients in accessing quality healthcare. Visits to a pharmacy were described by one participant as 'anxiety inducing (FG3-A)'. Most participants also highlighted their struggle with finding and retaining a suitable GP for their long-term mental health support. This then led to being perceived by pharmacists in some instances as a form of 'doctor shopping' (Sansone & Sansone, 2012). It was revealed:

... it looks like we're doctor shopping or whatever ... this ties back to that individual care and analysing of that client 'cause you need to look into their situation, has this person changed doctors? Are they in an environment where they can't [get] access to the same healthcare professionals (FG3-A)?

In addition, a number of participants felt that they were treated differently based on their socioeconomic status. In response to a participant who claimed to have had an overwhelmingly positive experience in her treatment so far, a participant stated '... you're well respected ... versus someone on a DSP [Disability Support Pension] and you know with past drug addiction (FG1-P4)'. Participants also reported a difference in how their care was delivered when they attended their medical appointments with a companion, such as with a family member or carer:

I've noticed a difference when doctors give me injection when [a] carer [is] with me and when they're not... When [name] comes in with me they are a lot more careful about how they give me my injection. Now that I'm going in by myself [to medical appointments] they keep jabbing in me and keep getting it wrong (FG1-P5).

4 | DISCUSSION

The study was able to explore clients' current knowledge and beliefs towards psychotropic medications and identified opportunities for healthcare providers to further support clients in the community. The findings indicate a low level of confidence in medication knowledge among participants. For example, clients reported not being aware of common psychotropic adverse effects until they have experience it themselves, suggesting inadequate medication education. The study also identified an absence of established therapeutic relationship attributed to the lack of continuity in providers (e.g. the regular rotation of doctors) and shared decision making in this cohort.

Despite this, the participants expressed an overall acceptance and understanding of the role that their psychotropic medications have for their mental illness.

Inadequate medication education among clients diagnosed with mental illnesses remains a concern (Fejzic et al., 2017; Happell et al., 2004). This situation has been previously identified as a 'major source of dissatisfaction' for clients (Happell et al., 2004). In particular, clients were dissatisfied with the lack of medication counselling on common adverse effects of psychotropic medications, such as weight gain and effects on mental alertness (Covell et al., 2007; Morrison et al., 2015). Given the prevalence of these adverse effects, adequate counselling and monitoring should be in place in order to reduce harm and assist clients' continuity with treatment (Roughead et al., 2017). Additionally, it was apparent that majority of the participants did not receive any form of written information and often resorted to seeking out information on the internet, as highlighted by others (Roughead et al., 2017; Stomski & Morrison, 2018). Future initiatives should endeavour to address this disparity, especially given the known association between medication knowledge and medication adherence (Nagai et al., 2020; Wiesjahn et al., 2014). Currently, medical practices and pharmacies are the most common places for medication counselling (Pohjanoksa-Mäntylä et al., 2011). With growingly demanding work environments in medical practices and pharmacies, as seen with the global coronavirus pandemic (Johnston et al., 2021; Marshall, 2021), providing additional medication education at an alternative community setting such as NFP centres by trained health professionals may be a potential solution.

It was also apparent that perceived stigma and 'othering' (i.e. the view of 'Us' and 'Them') (MacCallum, 2002) remains a barrier for clients seeking quality healthcare. We propose that therapeutic relationships should be employed as a basis for addressing issues of stigma and promoting opportunities for shared decision making (SDM) which could also facilitate successful uptake of medication education, shared monitoring and review. It is paramount that all mental healthcare providers recognise that therapeutic relationship is fundamental to care (Priebe & McCabe, 2008). In particular, healthcare providers should take the initiative in forming a trusting and professional relationship with their clients (Verhaeghe & Bracke, 2011).

We found a lack of evidence to suggest that SDM existed in this cohort. SDM is defined as the 'approach where clinicians and patients make decisions together using the best available evidence' (Elwyn et al., 2010). It should be recognised that majority of clients are able to make adequate decisions about their care and therefore should be central to decision-making processes regarding their treatment (Calcedo-Barba et al., 2020), including decisions to withdraw from medicines. Involving clients in the decision making is empowering as it recognises their expertise in their illness, respects their autonomy and promotes patient engagement (Alguera-Lara et al., 2017; Elwyn et al., 2010; Slade, 2017), all of which have been shown to lead to better outcomes (such as better use of medicines, reducing errors and stigma) (Dixon et al., 2016; Slade, 2017). Unsurprisingly, the lack of SDM is particularly evident for clients who were under a CTO (Brophy et al., 2019). A part of the South Australian Mental Health

Act 2009, the CTO stipulates that 'treatment may be given despite the absence or refusal of consent to the treatment' (Government of South Australia, 2018). It is important to recognise that clients on a CTO are also likely to be seen as being more unwell (Government of South Australia, 2018), but still perceive the CTO as being controlling, coercive and disrespectful (Corring et al., 2017). The study draws attention to the importance of validation and counselling support from a trauma-informed approach, especially for clients who have experienced harm or trauma from involuntary treatment (Sweeney et al., 2018). To empower clients to participate in SDM, effort should be made in supporting clients to develop the necessary knowledge and skills to make these informed decisions (i.e. self-management) (Schulman-Green et al., 2012). Applying both SDM and support for self-management will promote the making of better and more appropriate clinical decisions that would be acceptable to both the client and the treating healthcare provider (Lewis-Barned, 2016).

It was apparent from our findings that there is a need for better integration of a person-centred care (PCC) approach in mental health service delivery. In our study, participants felt that assessments made by healthcare providers (e.g. when making a diagnosis) did not factor in other individualised factors such as personal trauma. PCC places a greater emphasis on communication, encouraging patients to participate in their own medical treatment by working closely with their healthcare providers, leading to better-shared collaborations and decision-making processes (Delaney, 2018). Hence, PCC is considered to be a guiding principle for service delivery in mental health settings (Choy-Brown et al., 2020). As highlighted by Hamovitch and colleagues, there is a 'bidirectional relationship between PCC and therapeutic relationships and that both areas must be fully developed in order to capitalised on their benefits (Hamovitch et al., 2018)'. It is worth noting that whilst PCC should be encouraged in practice, implementation should be made with consideration. For example, Miller and colleague stressed the need to recognise the importance of learnt intuition and skills of trained healthcare providers such as GPs in providing patient care. The authors emphasised the importance of integrating PCC to encourage a doctor-led and patient-centred approach rather than a patient-led care approach (Miller & Fritz, 2019).

4.1 | Limitations

Findings must be understood within the context of the study's strength and limitations. One major strength of the study is the strong research partnership with its inclusion of lived experience researchers. It is worth noting that the views expressed in this study represent a small sub-section of mental health clients; therefore caution should be exercised when extrapolating findings to the greater cohort. However, it is possible that our findings may also be observed in other jurisdictions such as the United States and Canada where mental health services are increasingly being delivered within community-based settings (Dixon et al., 2016; Drake & Latimer, 2012). In addition, the study did not collect data

on treatment duration, and this may affect the interpretation of our findings. For example, the experience of someone who has been on psychotic agents for 20 years can be vastly different from someone who has only recently been initiated on a psychotropic medication. We recognise that the presence of PPs, who were familiar with the clients, during the focus groups can increase the risk of clients providing socially desirable responses to the focus group questions (Grimm, 2010). The coronavirus pandemic resulted in strict restrictions being placed on public gatherings which prevented further recruitment and conduct of additional focus groups, thereby limiting the sample size. However, the authors assessed that data saturation was reached after the fourth focus group and therefore additional sessions were unlikely to have added to the current findings. The authors acknowledge that the lack of use of a specialised qualitative software such as NVivo may be a limitation, in particular in storing and managing emerging codes and themes.

5 | CONCLUSION AND IMPLICATIONS

The study was able to add a detailed narrative of clients' experiences with healthcare providers and identified areas that remain unaddressed. Our findings revealed significant gaps in the provision of medication education and experiences with healthcare providers that require immediate attention. The study further underlined the importance of individualised and respectful care, with an urgent need to improve therapeutic relationship which would facilitate better SDM and PCC between clients and healthcare providers.

Participants described a lack of confidence in their medication knowledge, often attributed to either not receiving adequate medication counselling or being unable to recall the information provided during the counselling. Despite this, majority of the participants accepted the role of their medications in supporting their mental health but described the significant impact of psychotropic medication adverse effects on their quality of life. Providing additional medication education at an alternative community setting by trained health professionals may be a viable long-term solution. This would allow for repetition of information in a setting that is likely less intimidating, thus facilitating better medication understanding.

Experiences with healthcare providers indicate perceptions of stigma, absence of established therapeutic relationships and shared decision making. In particular, participants who were not on a CTO described having a better rapport with their healthcare providers, were more proactive in their treatment and had a more positive attitude towards their medications. This is pivotal especially given the influence that knowledge and attitudes towards medication can have on treatment adherence.

Future initiatives should address the variation in medication education to further support and encourage positive medication taking behaviours in clients with mental illnesses. Healthcare providers should also take a more proactive approach in establishing therapeutic relationships and providing pertinent medication education, on a regular and ongoing basis.

AUTHOR CONTRIBUTIONS

The authors VS, EH, NP and ML contributed to the study conception and design. Material preparation, data collection and analysis were performed by TB, ML, VS and EH. The first draft of the manuscript was written by TB and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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CONFLICT OF INTEREST

All authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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Discussion

Medication education

Pharmacists play a pivotal role in the provision of medication counselling, particularly those based within the community (community pharmacists) who are well positioned to provide regular and accessible medication education. There is also a growing body of literature that recognises the pharmacist's potential [26, 49, 69, 72, 204].

The findings from this study suggested that PLMI received limited medication education from pharmacists, as also identified in another similar study [205]. Specifically, the experience presented by the participants suggested that medication education was inconsistently provided by pharmacists. For instance, participants mentioned:

“... normally the pharmacists will ask if you've taken it before or whatever, or they'll check for any interactions and then they'll go and actually print it [CMI]² out and then give it to you.” - FG3-A

and,

“I've never been given any printouts or anything from the pharmacist at all.” - FG3-M

As previously discussed in Chapter Two, the seemingly inadequate provision of medication education in pharmacies may be due to a number of factors, such as lack of privacy and/or time [206, 207]. Karia and colleagues reported that Australian community pharmacists undertake 25 tasks per hour, spending an average of 1 minute and 22 seconds on each task [207]. The authors reported that pharmacists spend 80% of their time on dispensing, indirect patient services and medication counselling. To compound this busy schedule, pharmacists are often interrupted (one interruption every nine minutes) during professional education activities [207]. Indeed, medication counselling rates may be even lower in the PLMI cohort as pharmacists have reported feeling uncomfortable when talking to PLMI, for fear of coming across as “intrusive” with their questions [206, 208].

Other factors that can also influence the provision of medication counselling to PLMI include the community pharmacist's perceptions and experiences. A survey of 239 community pharmacists on their service provision, stigma, attitudes and beliefs towards PLMI highlighted an overall willingness and interest in providing care for PLMI [209]. However, this can be

² Consumers Medicines Information contains information on the prescription or specified over-the-counter medicine, including adverse drug reactions and direction for use.

limited by the lack of confidence or comfort reported by pharmacists in interacting with PLMI [209]. Efforts to address mental health stigma, for example through the use of appropriate and inclusive language and Mental Health First Aid training (MHFA), an evidence-based educational program developed to support individuals in distress by improving knowledge, attitudes and behaviours related to mental illness [210], can facilitate pharmacists in supporting PLMI [31, 211].

Ideally, health professionals including pharmacists should recognise the potential for medication-related issues and questions to arise even after the medication has been commenced. Therefore, frequent medication education should be offered and provided as suggested by this cohort. Similarly, consideration as to whether the medication(s) are newly initiated or continuing ongoing treatment should be made to account for the often-different needs and requirements of PLMI. For example, it is known that weight gain of more than 5% during the first month of antipsychotic treatment indicates a predisposition to higher risk of significant weight gain during long-term treatment and requires early intervention [212]. This further highlights the importance of embracing the patient-centred care (PCC) approach, encouraging patients to participate in their own medical treatment [213]. Furthermore, PCC can also facilitate the establishment or strengthening of the therapeutic relationship between the patient and healthcare providers [214].

Therapeutic relationships

The findings suggested that participants did not have an established therapeutic relationship with their health professionals, including doctors and pharmacists. Notably, pharmacists were not seen as having a role in the participant's mental health journey. It has been reported that 'therapeutic relationships' were often viewed by nursing staff and PLMI, as an implicit ability rather than skills that can be developed and built upon [215]. Therefore, supporting health professionals in building their skills to establish therapeutic relationships is valuable. This can also be relevant to the pharmacy setting, and pharmacists may benefit from further training in this area. While pharmacists are motivated to support PLMI, additional mental health training can enable them to better support PLMI [216] and support the establishment and/or building of strong therapeutic relationships [217]. Overall, the findings indicated the need for healthcare providers to be more proactive in establishing a therapeutic relationship that is person-centred and promotes shared decision-making [218, 219].

Strengths and limitations

The involvement of individuals with lived experience in the facilitation/co-facilitation of the focus group was a strength of this study. The integration of an individual with lived experience recognises their unique values and perspectives. Through their lived experience, they were able to provide valuable perspectives and input into the research, enhancing the applicability of the findings [220].

A limitation of the study included the risk of motivational bias. It was possible that clients who attended the NFP organisation were more motivated and invested in their mental health and well-being and hence, potentially more health literate and aware of their conditions and medications. Therefore, results presented in this study may not reflect the perspectives and experiences of the general PLMI cohort, including under-privileged or under-supported cohorts such as individuals from a culturally and linguistically diverse population [221]. It was also worth noting that the research focused on exploring the participants' experience with healthcare providers more broadly and not just with their pharmacists. Therefore, the feedback regarding the role of the pharmacists presented here was limited.

While the study also explored PLMI's experience within the healthcare system and its influences on their beliefs and knowledge of psychotropic medications, it did not explore other potential contributing factors. For example, the severity of the participant's mental illness [222], past experiences with psychotropic medications [223] and/or carer's knowledge and beliefs [224]. Therefore, the results may not be sufficient to provide comprehensive recommendations to support optimal medication-taking behaviour, which often has complex and multifactorial influences [225].

Future directions

Future initiatives should draw upon successful pharmacist-led professional services and implement them in mental health settings [48, 204, 226]. For example, pharmacists in the US have contributed to diabetes care through several alternative community settings, such as government-supported facilities (like an army clinic), private, public, and academic clinic-based practices [227]. Similarly, an initiative in the UK, the New Medicine Service allows consumers on medicines for long-term conditions to receive additional assistance from pharmacists [226]. Through this pilot (2022-2024), UK residents with eligible medical conditions can have three one-to-one appointments (10-15 minutes) with their pharmacists

within the first four weeks of medicine initiation to discuss their medicines at no additional charge [226, 228].

Chapter Summary

The findings from this study highlighted the need for medication counselling to extend beyond the first initial prescribing or dispensing of psychotropic medication. Outcomes also suggested that PLMI did not receive adequate medication counselling and community pharmacists were perceived as having a limited role in supporting their mental health journey. Therefore, it is recommended that pharmacists reinforce medication counselling with consumers at all subsequent encounters. This would ideally support a better medication understanding but is also an opportunity for consumers to ask questions and/or address any medicine-related concerns that they may have and may facilitate the establishment or strengthening of therapeutic relationships.

The published manuscript proposed one practical and novel solution involving the provision of additional medication education by community pharmacists in an alternative community setting, such as a NFP organisation. This opportunity would allow for the provision of regular medication information in a setting that is likely to be less intimidating while being more familiar and relaxed for PLMI. Moreover, it will take the community pharmacist out of the pharmacy-setting addressing issues of time constraints and regular interruptions [207]. The conceptualisation and trial of this approach will be explored in the next chapter (Chapter Four).

4 Pharmacist-led outreach psychotropic medicines information session: a proof-of-concept study

Chapter Overview

This chapter describes the process involved in the content design, review and delivery of a tailored outreach medicines information session (My Mind, My Health). This proof-of-concept study explored the perceived value of an information session designed for PLMI delivered by a pharmacist at a NFP organisation.

Findings from Chapter Three and existing evidence and resources were used to identify the learning objectives and content for the information session. Prior to implementation, the design of the content for the information session underwent a rigorous review process by three expert panels consisting of pharmacists with community and hospital experience (both general and with mental health specialities). The information session was then presented to the participants who had previously attended the focus groups at the same NFP organisation (Chapter Three).

Background

Chapter Three reported on the importance of regular medication counselling, as PLMI reported either receiving inadequate medication information or being unable to recollect the information provided at the initial medication counselling [103]. This aligns with existing literature which also highlighted the need to address inadequate medication counselling for PLMI [24, 87, 88, 229]. Indeed, PLMI themselves have reported the desire to know more about their medications [88]. Ensuring that PLMI have sufficient understanding of their medications is particularly crucial as many psychotropic medications such as SGAs, have significant adverse effects and require frequent monitoring [143].

Having an adequate understanding of one's medication can also contribute positively to their health literacy. Health literacy, defined as "people's knowledge, motivation and competency to access, understand, appraise and apply health information" [230], is crucial as it enables individuals to make informed health-related decisions [231, 232]. People with limited health literacy have difficulty reading, understanding and interpreting healthcare information and are at increased risk of emergency department re-presentation [233]. It is recognised that health

literacy is often complex and multifaceted, and therefore having a good understanding of one's medication is one aspect of health literacy [234]. Other elements that contribute to good health literacy, include supporting an individual's access to resources and capability to use the information to make decisions [234].

In Australia, medication education is generally provided by doctors and/or pharmacists upon medication initiation in settings such as hospitals, community pharmacies or doctor's clinics [235]. Group medicines information programs, particularly for PLMI, are also rarely delivered outside a hospital setting [86, 236]. As such, PLMI in the community may have limited access to comprehensive medication information beyond initial prescribing and/or dispensing. Findings from the previous chapters highlighted the need to improve medication education for PLMI, particularly to explore opportunities and/or additional avenues for more regular medication counselling [103].

As accessible and trusted health professionals, community pharmacists can play a key role in optimising PLMI's medication understanding, especially through the provision of medication education [113]. However, community pharmacists are frequently faced with a demanding workload, competing priorities and often with insufficient resources (e.g. staffing levels) and time [207, 237-239]. In recent years, Australian pharmacists' workloads have also been impacted by additional external factors, including the pandemic (2019- 2023)[240] and natural disasters including bushfires [241].

This study aimed to complement existing medicine counselling practices through an outreach information session held in a supportive environment such as a NFP organisation. This may be a viable long-term solution that will allow for the provision of interruption-free medication education and an opportunity for PLMI to ask questions. The design of this outreach information session was tailored to the needs and feedback attained in previous research presented in Chapter Three [103].

Aims

This proof-of-concept study aimed to design, review and deliver a client-tailored outreach information session with PLMI at a NFP organisation.

Methods

Study outline

The study included the process of (i) design, (ii) review of learning objectives and (iii) delivery of the information session. Findings from the focus groups (Chapter Three) justified the need for additional medication education to be provided to this cohort. The sessions also identified that participants did not perceive pharmacists as having a role in their mental health journey beyond medication supply. To address this, the information session endeavoured to improve the participants' awareness of the role of pharmacists beyond medication dispensing. Importantly, the information session aimed to complement the one-to-one counselling between PLMI and their healthcare provider.

A review of the learning objectives and proposed content for the information session was performed by three panels of pharmacists. These panels included pharmacists practising in the community and, hospital (both general and mental health specialities). The information session was conducted at a NFP organisation that supported PLMI and delivered by the PhD candidate. To assess the perceived value of an information session and generate general feedback, a pre- and post-survey was employed.

Design of the information session

To address the knowledge gaps and concerns identified in Chapter Three, up-to-date medication information was incorporated from the Australian Medicines Handbook [242], Choice and Medications Leaflets (CHOICE)³ [243] and the Consumer's Medicines Information (CMI) leaflets [244]. The PhD candidate also drew on her clinical knowledge and experience to design the information session. A subsequent review of the information session was conducted by the supervisory team.

The PhD candidate (TB) has a background in both community and hospital pharmacy. VS is a senior lecturer in pharmacy teaching undergraduate pharmacy students pharmacotherapeutics including psychiatric conditions. EH has extensive experience in academia, community and hospital pharmacy.

Review of the learning objectives

Three expert panels of registered pharmacists with relevant expertise were recruited through the research team's professional network to review the proposed information session. The

³ A consumer fact sheet designed specifically for psychotropic medications

content of the information session, titled 'My Mind, My Health', was reviewed by three expert pharmacy panels, including hospital pharmacists with (Panel 1; n=4) and without (Panel 3; n=3) mental health specialisation and community pharmacists (Panel 2; n= 4) (Table 3). The review process involved three separate group meetings, conducted via a mixture of face-to-face and online meetings (Zoom and Microsoft Teams) between September and November 2020.

The information was presented as a Microsoft PowerPoint presentation developed by the PhD candidate (TB). Panellists were encouraged to discuss and provide feedback on the content and overall design of the information session. Feedback and recommendations were documented (VS) and collated for review by the research team, after which the final amendments were made to the learning objectives and content of the information session. The review sessions ran for approximately one hour (40 minutes of presentation and 20 minutes for open discussion).

Findings from the pharmacist reviews were documented, reviewed and assessed for appropriateness by researcher TB. Suggestions that were deemed as not within the scope of the study by the research team, including time and budgetary constraints, were excluded.

Study participants

As the information session was tailored towards the needs of the participants who attended the focus groups, including discussion around specific adverse drug effects, only these participants were invited to take part in the information session. Participants were recruited via peer support workers employed at the NFP organisation, who had permission to obtain and store participants' contact details. Due to the impact of the pandemic, we were unable to recruit all the participants who had previously participated in the focus groups.

To further support participants during the information session, a peer support practitioner (hereon referred to as peer practitioner) with lived experience and had co-facilitated the focus groups described in Chapter Three, was also present. Further, the researchers held the information session at the NFP organisation, a supportive and familiar environment. The main researcher, TB introduced herself as a PhD candidate with a background in pharmacy and with relevant experience working as a community pharmacist.

The information session was held in May 2021 at a NFP organisation in Adelaide, South Australia. The session was delivered by researcher TB, and supported by VS, EH and a peer practitioner. The presentation ran for 35 minutes with an additional 15 minutes for questions and/or feedback. All participants gave informed consent, and participants' feedback was

recorded and transcribed verbatim. An honorarium of AUD \$30 was given to all participants for their time and contribution.

Pre- and post-session surveys

Pre- and post-session surveys were employed to assess the impact of the information session on participants' knowledge of their psychotropic medications and also medicine resources. In recognition of the lower literacy (reading and numeracy) often reported in this cohort [245], the surveys were kept brief and in consumer-friendly language. The surveys were developed by the PhD candidate and reviewed by the supervisory panel for clarity and readability. Participants were given 5-10 minutes to complete the surveys.

The pre-session survey included six 5-point Likert-type scale questions that assessed participants' current understanding of commonly provided medication leaflets that is, the CMI, current medication knowledge, understanding of where to seek additional medication information and the perceived role of the community pharmacist in their mental health recovery journey. The post-session survey contained an additional Likert-type scale question and two additional open-ended questions, to assess the perceived value of the session and to generate additional feedback. Participant demographic data, including age and gender, were collated and reported.

For a copy of the pre- and post-session surveys see Appendix C.

Data analysis

Participants' responses from the pre- and post-session surveys were matched and compared. All verbal feedback provided was analysed using descriptive statistics. Qualitative analytical methods such as thematic analysis was deemed unnecessary with this dataset as there was insufficient data to conduct a rigorous and comprehensive assessment. Instead, the focus was on the identification of relevant comments or feedback to inform improvements to the training.

Ethical approval

The study was approved by the University of South Australia's Human Ethics Committee (202299) and the mental health service provider's ethics committee.

Results

Review of content

The importance of terminology, particularly when providing medication counselling to PLMI was discussed by the panellists. The panellists emphasised the need to avoid using technical terminology, for example, ‘chemicals that affect mood/help relax’ was suggested instead of ‘neurotransmitters.’ Additionally, consideration of how the terms can be perceived and interpreted by PLMI was deemed to be significant. There was also discussion on the appropriateness of the term ‘anti-anxiety’ used to describe benzodiazepine (BZD), as participants may perceive this to mean that BZD can be used long-term. It was advised that this contradicted current hospital practice guidelines, where BZD was only indicated for short-term use and usually on a when-required basis.

The panellists highlighted that the content presented in the information session should be kept succinct. Revisions were suggested for slides that were deemed as being too ‘information heavy.’ The panellists also identified the need for additional information in areas such as common drug-drug interactions and adverse effects of medicines. In addition, it was suggested that the session should focus on providing practical advice and participants should be referred to their respective healthcare providers for further information where necessary. For instance, in the case of a missed dosage, rather than being described the different actions required for different scenarios during the session, participants were advised to contact their usual pharmacist for advice.

The review panels also highlighted the benefits of including carers in the information session, given their supportive role in consumer health and wellbeing. One panel member suggested that the session should not be longer than 50 minutes to maximise the participants’ focus and concentration. In addition, it was recommended that a follow-up session should be conducted to assess the long-term impact of the session on the participants’ health literacy.

Comparison of the recommendations made by the hospital and community panelists

Of the 22 discrete recommendations made by the panellists, most (n=18) were adopted (Table 3). Recommendations were categorised as related to the presentation content design or the audience.

Table 3. Panel feedback and action taken.

#	Category	Feedback	Action taken (Y/N)	Reason for no action
Panel 1 - Hospital pharmacists specialising in mental health				
1	Audience	Include carers in information session	N	Pandemic restrictions.
2	Content	Include managing weight gain	Y	
3	Content	Risk of insomnia and drowsiness should be elaborated	Y	
4	Content	Further discuss smoking and/or illicit drug use	Y	
5	Content	Inclusion of CHOICE leaflets	Y	
6	Content	Home Medicines Reviews is an important pharmacist role and should be promoted as an option on the service delivery slide	Y	
Panel 2 – Community pharmacists				
7	Content	Medications – should include images of common brands	Y	
8	Content (Clozapine)	<ul style="list-style-type: none"> ○ Elaborate clozapine supply (e.g need for regular blood tests) ○ Importance of regular GP follow-up ○ Highlight that not all pharmacists are registered to dispense clozapine 	Y	
9	Content	Provide emergency mental health contact numbers (e.g, SA COVID-19 Mental Health Support Line)	Y	
10	Content	Drug-drug interaction between nicotine and antipsychotics	Y	
11	Content	Remove technical, lengthy and complex language	Y	
12	Content	Update examples as some examples not relevant to current practice (e.g pethidine not used commonly in community)	Y	
13	Design	Inclusion of regular 5-minute break in between to allow for opportunity for questions.	N	Time constraints.
14	Content	Slide regarding what to do if forget to take medication is unnecessary and could be overwhelming.	Y	
15	Design	Consider giving participants handouts (such as medicine information leaflet) to take with them after the session.	N	To encourage participants to discuss their individual care with their pharmacist, individual medicine information leaflets were not provided. Instead, referral made to pharmacist or doctor for further information.

Panel 3 - Hospital generalist pharmacists				
16	Content	Explanation included is too technical	Y	
17	Content	Focus on how to mitigate common medication side effects	Y	
18	Content	Consideration of other side effects such as, reduced libido	Y	
19	Content	Discuss sleep hygiene	Y	
20	Content	Consider using CHOICE leaflet instead of CMI	Y	
21	Design	Follow-up of participants up to 6 months after information session	N	Initial ethics application did not consent for the collection and storing of participants contact details.
22	Design	Duration of presentation should be kept to a maximum of 50 minutes to maximise consumer's engagement	Y	

There were similarities between the recommendations provided by the three review panels, including the identified need to further simplify the content and preference for the use of the CHOICE leaflets in the information session. In general, the hospital pharmacists had a greater focus on the use of preferred consumer fact sheets, suggesting the use of the CHOICE leaflets [246] instead of the CMI during the information session [244]. One hospital panellist questioned whether it was ideal to refer PLMI to community pharmacists for additional information and support, noting that mental illness is a specialised area requiring expertise and experience. This was seen as not aligning with the skillsets of the community pharmacist who may be more generalist. However, they agreed that the Home Medicines Reviews (HMR) [247], where an accredited pharmacist visits patients' homes to review medicines and develop a medicine management plan [248], was a valuable program and that PLMI should be made aware of this service. In addition, they highlighted the need to provide an outline of the roles and responsibilities of community pharmacists beyond medication dispensing. Particularly, the role of pharmacists in providing HMRs. There were no notable differences between the recommendations made by the hospital panels who had mental health specialised skill compared to their generalist counterparts.

Community pharmacists were more focused on the practicalities of medication supply and advice. For example, this group felt that the focus needed to be on the legislation surrounding the supply of certain antipsychotics, specifically clozapine given the strict guidelines around its dispensing and supply. In Australia, to dispense clozapine, pharmacists are required to monitor and record patient's haematological results, ensuring that they were within a safe range prior to supply [249]. The community pharmacists also emphasised the importance of providing lifestyle advice, such as smoking cessation. Other patient-centred suggestions included the use of common medication brands that are recognisable to participants. Stretch breaks and provision of information handouts were also suggested. As the information session was planned for just after the major lockdowns during the pandemic, the community pharmacists suggested including the details of the national pandemic mental health support line.

Most of the suggestions that recommended changes to the session's design could not be implemented due to the pandemic restrictions that were still in place at that time. As an example, carers were not included in the information session due to restrictions in the number of people allowed to meet at the venue. Similarly, re-structuring the session to allow for 5-

minute stretch break every 10 minutes was perceived by the research team to be potentially distracting and counterproductive. Furthermore, incorporating breaks would unnecessarily prolong the session beyond the desired 50 minutes.

Finalised information session

Amendments to the information session slides included (i) changes to terminology and, (ii) addition of extra information (Table 4). The content was reviewed, and the language used to describe the medications' mechanisms of action was adjusted to more positive and consumer-friendly language. For example, where the mechanism of antipsychotics was previously described as:

“Antipsychotics change the levels of neurotransmitters. The neurotransmitter most targeted by antipsychotics is dopamine. However, some antipsychotics can bind to several other neurotransmitters.”

This was changed to:

“Antipsychotics can help restore the natural chemical levels. Sometimes, antipsychotics can also affect other chemicals in our brains that can lead to side effects such as drowsiness.”

A disclaimer statement was also included at the beginning of the information session, given that the session was designed to supplement rather than replace the individually tailored counselling provided by the participants' doctors and/or pharmacists. Additional content on the risk of insomnia and drowsiness associated with the use of psychotropic medication and how to mitigate these adverse effects were also included in the information session. In addition to the CMI leaflet, the CHOICE leaflet was also introduced (see Supplementary File B for information slides).

Table 4. Information session's content (Version 1) and post-pharmacist review by community and hospital panels (Version 2).

Topic Domains	Version 1	Version 2
Medications	<ul style="list-style-type: none"> ○ Present information on: <ul style="list-style-type: none"> • common drug classes (antidepressants, antipsychotics, mood stabilisers and benzodiazepines) • generic and common brand names • mechanism of action • Relevant information points 	<ul style="list-style-type: none"> ○ Same as V1
Weight gain	<ul style="list-style-type: none"> ○ Risk of psychotropic medications & weight gain. ○ Understand the mechanism of action for weight gain. 	<ul style="list-style-type: none"> ○ (Addition) Understand how to mitigate weight gain.
Bluntness in emotion	<ul style="list-style-type: none"> ○ Understand medication induced bluntness in emotions – mechanism and how to address. 	<ul style="list-style-type: none"> ○ Same as V1
Other considerations	<ul style="list-style-type: none"> ○ Understand medication-related sleep disturbances (drowsiness). ○ Understand the risk of alcohol and illicit drug use in conjunction with psychotropic medication use. ○ Serotonin syndrome: definition, causes and prevention strategies. 	<ul style="list-style-type: none"> ○ (Addition) Understand the risk of medication induced insomnia and the benefits of sleep hygiene.
What is a CMI	<ul style="list-style-type: none"> ○ Understand the contents and structure of the CMI. 	<ul style="list-style-type: none"> ○ Shortened CMI section ○ (Addition) What is the CHOICE of medicines information leaflet?
Non-medicated options	<ul style="list-style-type: none"> ○ Awareness of non-pharmacological options. 	<ul style="list-style-type: none"> ○ Removed
Support system	<ul style="list-style-type: none"> ○ Identify people who can provide support (such as doctors, pharmacists, other allied health professionals, organisations, friends and family). 	<ul style="list-style-type: none"> ○ Same as V1
My pharmacist	<ul style="list-style-type: none"> ○ Understand the role of pharmacists in mental health. 	<ul style="list-style-type: none"> ○ (Addition) Identify the potential benefit of pharmacists in conducting HMRS.

Forgot to take medications	<ul style="list-style-type: none"> ○ Outline the best course of action to take if medication dose was missed. 	<ul style="list-style-type: none"> ○ Replaced 'what to do if missed dose' with 'contact health care profession if missed a dose.' ○ (Addition) Strategies for medication adherence.
Where to get more information	<ul style="list-style-type: none"> ○ Identify places and people in the community where additional mental health advice/support can be given (such as, pharmacists, online etc). 	<ul style="list-style-type: none"> ○ Same as V1
Emergency contact numbers	<ul style="list-style-type: none"> ○ Awareness on number of emergency contact numbers (helplines etc). 	<ul style="list-style-type: none"> ○ (Addition) COVID helpline and medicines information line.

Implemented outreach information session

A total of seven consumers participated in the information session. All except one were aged 31 years and above (Table 5). Of the participants in attendance, six completed the surveys.

Table 5. Participant demographics

Demographics	n = 7
Gender	
Female	2
Male	1
Not stated	4
Age	
18-24	1
31-40	3
41-50	2
61-70	1

The participants' verbal feedback suggested that they were previously unfamiliar with additional services that pharmacies and pharmacists offered to support PLMI, such as medicines delivery, medication counselling and HMR. After the information session, participants commented on the potential value and benefit of these pharmacy services, stating:

"[if it weren't for the information session] we would never know.... thousands and thousands of people on medications are not being offered the services that are there [for example, HMR]" – M01

and,

"I just want to rush to my pharmacist and let her know [about my situation] and work with her more" – A01

Participants also highlighted that they found value in discussing commonly provided information leaflets (CHOICE and CMI). In particular, there was a preference for the CHOICE medicines leaflet, with most agreeing to the comment made by one participant:

'I think the CHOICE medication leaflet should be handed out as [a] standard [practice]' -M01

Pre- and post-session surveys

Of the seven attendees, six completed the questionnaires (Table 6). Participant One was unfamiliar with the CMI prior to the session and therefore was unable to answer the relevant questions (statements 1 and 2) in the pre-session survey. In the post-session survey, the

respondent agreed to the statements regarding the usefulness of the CMI. Participant One also displayed a slight decrease in score from pre- to post-session responses. Participant Three exhibited improvement in responses to all questions except the one regarding the CMI being a useful source of medication information. Two participants, Participants Four and Six did not answer the pre-session questions, but either agreed or strongly agreed to most of the statements in the post-session questionnaire. Participant 5 strongly agreed to all the statements in both questions statements and agreed to the statement regarding the usefulness of the information session in the post-session. Overall, all participants either strongly agreed or agreed to finding the information session useful.

Table 6. Responses to the 5-point Likert-type scale questions presented for each participant. 1- Strongly disagree, 2- Disagree, 3- Neither disagree nor agree, 4- Agree and 5- Strongly agree.*

Statements	Participant 1		Participant 2		Participant 3		Participant 4		Participant 5		Participant 6	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1. I find the consumer medicine's information leaflet easy to understand	NR	4	4	3	4	5	NR	4	5	5	NR	3
2. I believe that the consumer medicine's information leaflet is a useful source of information	NR	4	3	4	5	4	NR	5	5	5	NR	4
3. I understand the role my medications play in my mental health illness	5	4	4	5	2	3	NR	5	5	5	NR	4
4. I know where I can go to seek for information regarding my mental health illness	5	4	4	4	4	5	NR	5	5	5	NR	4
5. My pharmacist can be a form of support for my mental health illness	5	4	3	3	4	5	NR	4	5	5	NR	4
6. I feel like my pharmacist can help address any enquires I have about my medications	5	4	3	3	4	4	NR	4	5	5	NR	4
7. [For post-surveys only] Overall I found this information session useful		5		5		5		5		4		4

*NR refers to no response.

Discussion

This study focused on addressing a medication knowledge gap identified in PLMI by exploring the perceived value of a structured information session delivered outside the community pharmacy setting. The chapter described the design, review, and delivery process of a community-based outreach information session.

Studies have reported on the value and benefits of community-based multidisciplinary education programs [250, 251]. For instance, the Turning Pain into Gain program, a hybrid of generic group education sessions and tailored individualised counselling designed for patients with chronic pain, reported a significant improvement in medication management, participant self-efficacy and self-reported hospitalisation [251]. The program also involved a variety of educators such as GPs, pain specialists and clinical pharmacists. Community-based mental health programs for PLMI also exist in Australia. A systematic review of Australian community mental health programs for adults in the past 20 years identified three types of community-based programs, case management, therapeutic and lifestyle [252]. However, none of which describe a medicines information session. To our knowledge, this is the first Australian study that has reported on the development of a tailored information session for PLMI, delivered by a pharmacist outside the “traditional” medication counselling settings such as hospitals, community pharmacies and GP clinics. This proof-of-concept study has highlighted the potential value of a pharmacist-led tailored outreach information session for PLMI.

Pharmacist expert panel feedback

The process of development and review yielded valuable insights. Notably, the feedback from review panels highlighted several crucial considerations for health professionals, including pharmacists, when offering medication counselling to mental health consumers.

The panellists’ suggestion to include the CHOICE leaflets was well received by the participants. In Australia, the CMI is a common source of written information given to consumers by their healthcare providers, which are freely available online [244]. CMIs can often be seen as ‘overwhelming’ by consumers due to the large body of information legally required to be included in them [253]. The information session was designed in part to address this. Hence, a portion of the session was dedicated to discussing the layout of the CMI and CHOICE leaflets as well as interpreting commonly presented information. It is worth noting that the CHOICE leaflets are only available for mental health conditions as compared to the CMI which covers a

broader spectrum of medications [243, 244]. The CHOICE leaflets are commercially available on subscription to healthcare organisations [254]. It is not currently known how often the CHOICE leaflets are being used in a community pharmacy setting, as CMIs are more readily available and accessible.

Additionally, the pharmacists' recommendation to include carers in the information session was in line with current evidence, including the Australian Mental Health policy which has highlighted the importance of including carers in the provision of mental health services [20]. This is of importance as carers typically receive little to no information about medications and there is a need for health professionals to further collaborate with carers in the medication decision-making process [255]. However as previously mentioned, the enforced pandemic restrictions at the time of this study prevented the inclusion of carers in the information session. It is recommended that all future initiatives designed to promote medication knowledge should also consider including carers.

The study also found that pharmacists, especially those practising in hospital settings valued programs such as HMRs, which require community pharmacists to take on additional training and accreditation [247]. However, it was noted that other community pharmacy services, such as the MedsCheck Program [256] was not identified by the hospital pharmacists panel as a valuable program in supporting PLMI. The recognition of a service that requires additional accreditation may suggest that there is a perception that community pharmacists require further training to support PLMI. Similarly, existing research has also identified several factors to medication counselling to PLMI, including the often-perceived lack of privacy in community pharmacies, and/or perceived lack of skills in supporting PLMI [104].

Information session outcomes

Overall, feedback from participants suggested the potential value of the information session. It was noted that some participants did not respond to pre-session survey questions relating to the CMI which was attributed to their unfamiliarity with this commonly used medicine resource. Previous research had also suggested that PLMI received insufficient written information from health professionals [86]. One participant reported a reduction in Likert score after the information session, although it is unclear as to the exact reason for this. Overall, findings from the study showed some improvement in the participants' understanding of the CMI and CHOICE leaflets. The use of resources to support medicine counselling, including patient preferences, should be explored in future research. It was also noted that efforts to improve the

readability and usefulness of the patient medicines information leaflet is a focus of a number of research [257-259].

Strengths and limitations

The study could be considered as a strength as it identified a gap, with the content largely derived from consumer groups from a previous study. It also provided an innovative approach in addressing challenges identified by the consumers and the literature. To add, the rigorous review process, including the evaluation of the information session by pharmacists from a variety of practice backgrounds was a strength of this study. This provided a comprehensive review of the content. Another strength of the study was the involvement of a peer practitioner, whose role was to be present and support participants during the session. However, it was also possible that the presence of the peer practitioner and the researchers could have increased the risk of social desirability bias [260]. To further strengthen the study, the involvement of peer practitioners more extensively in the design and review of the information session as well as the development of the questionnaires to ensure that the language and depth of information covered were appropriate should be considered.

As the participants were recruited from the same NFP organisation it is possible that some participants were familiar with each other. However, as this information was not collected, we are unable to report on the potential impact that this might have had on the group dynamic. It is worth noting that ground rules, such as the importance of confidentiality were set prior to the start of the information session. Further, peer support practitioners were also present to help effectively manage the group dynamic.

Due to the small number of participants, it was difficult to draw clear conclusions from the pre- and post-session surveys. As the study was conducted during the height of the pandemic, this could have potentially affected participants' desire to engage in health-related research [261]. Additionally, due to the impact of the pandemic, we were unable to contact participants who had attended the focus groups in the previous year. At the time, some participants who were scheduled for the information session were unable to join due to border closure and/or anxiety around group gatherings during the pandemic. Further, resorting to online presentations would have posed several challenges, particularly logistical and technical difficulties for this cohort at the time. Therefore, virtual information sessions were not considered for this study. Despite this, the general verbal feedback indicated that the information session was well received by the participants. Previous research showed that low response rates may be a common challenge

experienced in research involving PLMI [262, 263]. In addition, the stigma associated with lower literacy levels coupled with a mental health diagnosis [245] may have hindered participant's desire to seek assistance with answering the surveys. Future endeavours should also involve carers to empower and support participants to provide feedback. Alternative methods, such as one-to-one interviews could be considered. Overall, the purpose of this proof-of-concept study was to generate preliminary evidence [264] for the delivery of a client-tailored information session for PLMI at a NFP organisation to inform future similar studies. This was achieved.

Another limitation included the lack of consumers in the review panel. At the time it was identified that pharmacists commonly delivered medication counselling and therefore the focus was to ensure that panels of pharmacists with a broad range of skills and expertise can review the content. However, the benefits of consumer panels should be recognised in future research efforts.

Future directions

The study has highlighted the potential for medication counselling to be delivered at alternative community sessions such as at a NFP organisation. Future studies should endeavour to explore opportunities for medication education to be delivered beyond GP clinics, community pharmacies and hospitals. These information sessions should be used to re-iterate and repeat pivotal medication information that, ideally, reinforces and clarifies information that had been previously provided by health professionals. In addition, these sessions can foster a positive working relationship between pharmacists and existing organisations to support PLMI. Furthermore, where possible follow-up sessions should be conducted to explore the potential long-term impacts of the session on the participants' medication understanding. Finally, replication of this research with a larger sample size is required to ensure that there is "adequate data to tell a rich, complex and multi-faceted story about patternings" [265, 266].

Other avenues for future research include the potential value of delivering this information session virtually. It is anticipated that the pandemic has accelerated the adoption of virtual and electronic communication means. Therefore, the delivery of information sessions through online platforms should also be embraced and incorporated. Whilst this study focused on the role of community pharmacists, future research could also explore the role of accredited pharmacists who can conduct HMRs with this population. Other logistical considerations, such

as how often these sessions should be made available in these settings and the duration of these sessions, should also be further explored.

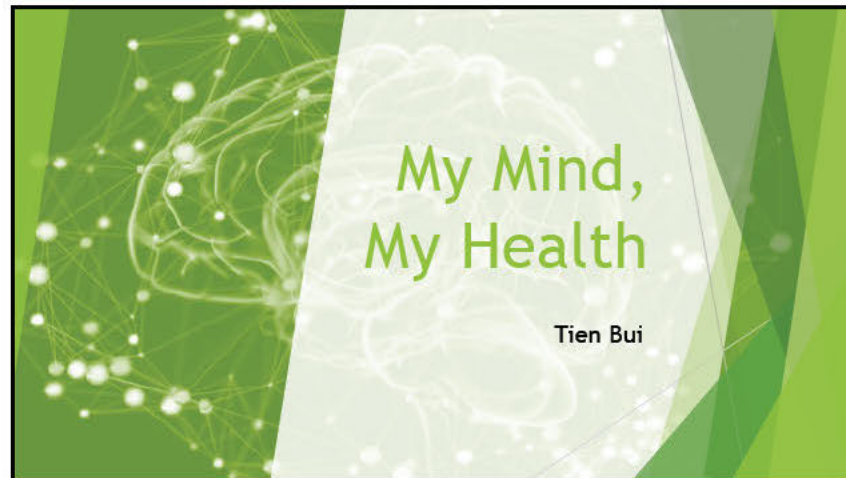
Chapter Summary

This pharmacist-led outreach medicine information session could serve as a foundation to build upon and employ in future information sessions and research. Overall, this chapter described the process of development and implications for a client-tailored information session for PLMI. The findings can be used to support the delivery of similar sessions in future research.

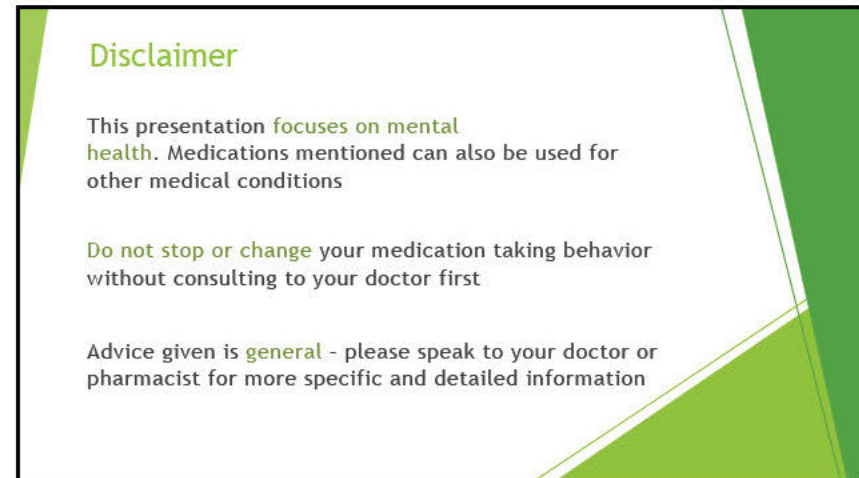
This exploratory study illustrated the potential for additional medication counselling to be conducted at an alternative community setting. It is noted that in a group setting, advice cannot be tailored to the individual given confidentiality restrictions. For example, advice about what to do in case of a missed medication dosing would vary depending on the patient and the context. Thus, it would be more appropriate for the participant to discuss with their health professional, should or when such a situation arises. The purpose of this outreach information session was not to replace the interaction between the participants and their regular pharmacist, but rather, to answer the PLMI's call for the provision of regular and accessible medicines information. The information session aims to supplement or reiterate information that may have already be addressed by their pharmacist or doctor, and where possible encourage them to seek further information from their regular health professional.

Moreover, having pharmacists deliver this session in an alternative setting, that is potentially less intimidating and overwhelming, may facilitate PLMI awareness of the role and responsibilities of pharmacists. Notably, while the present study can be viewed as being significantly underpowered, it sets the scene for further research in this area. In particular, future larger studies, where the benefit of either collaborating or embedding pharmacists within an NFP organisation should be explored.

Supplementary File B: My Mind, My Health



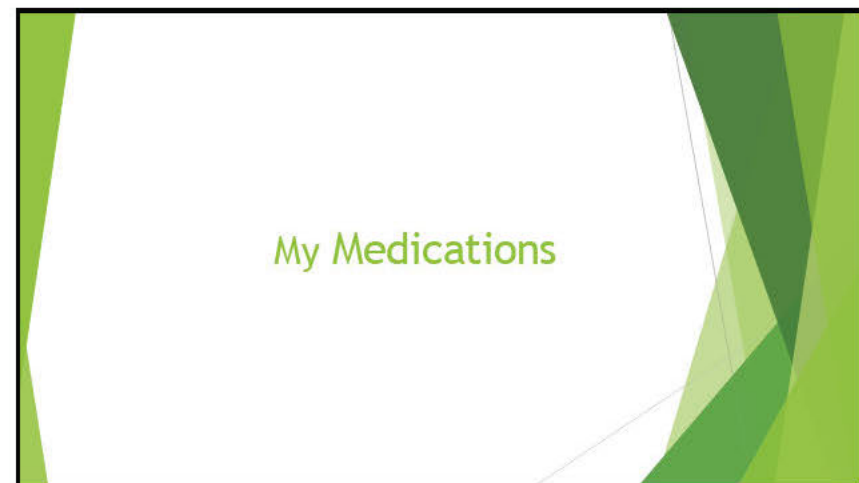
1



2



3



4



1. Antidepressants

Generic name	Brand names
Desvenlafaxine	Pristiq
Mirtazapine	Axit, Avanza
Paroxetine	Aropax, Paroxetine Sandoz
Amitriptyline	Endep
Escitalopram	Lexapro

5



Antidepressants: How they work

Certain chemicals in our brain have an important effect on our mood and anxiety levels

Antidepressants work by changing the levels of these chemicals

This reduces symptoms of depression

6



Antidepressants cont.

- People respond to different antidepressants differently
- May take up to 6-8 weeks to see full antidepressant effect
- Improvement in symptoms can often be seen in 1-3 weeks

7



2. Antipsychotics

Generic name	Brand name
Aripiprazole	Abilify
Clozapine	Clozaril, Clopine
Lurasidone	Latuda
Olanzapine	Zyprexa
Paliperidone	Invega
Quetiapine	Seroquel, Seroquel XR
Zuclopenthixol	Clopixol

8



Antipsychotics: How they work

Sometimes we may have **too much** of certain chemicals in our brains

Antipsychotics can help **restore** the natural chemical levels

Sometimes, antipsychotics can also affect other chemicals in our brains that can lead to side effects such as **drowsiness**

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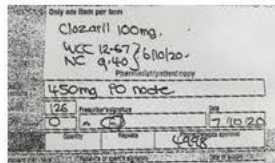


Antipsychotics cont.

- Clozapine is an effective antipsychotic
- Need regular blood tests to monitor white cell counts
- Clopine® and Clozaril® are not interchangeable

10

Clozapine prescriptions



- Doctors must record blood test results on the prescription - ensure medication is **safe**
- **Not all pharmacies** can dispense clozapine

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3. Mood Stabilisers

Generic name	Brand names
Carbamazepine	Tegretol, Keppra
Lamotrigine	Lamictal
Sodium Valproate	Epilem
Lithium	Lithicarb, Qilonum SR

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Mood Stabilisers: How they work

Can help with emotions such as depression (feeling too sad) and mania (feeling too happy)

The exact way that they help with our emotions is unknown

However, they have been tried, tested and used effectively for a long time

13



Mood Stabilisers cont.

Some also have multiple use - e.g anticonvulsants

Only three anticonvulsants have demonstrated mood stabilising effect:

- Valproate
- Lamotrigine
- Carbamazepine



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4. Benzodiazepines

Generic name	Brand name
Diazepam	Valium, Antenex
Lorazepam	Ativan
Oxazepam	Serepax, Alepam

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Benzodiazepines: How they work

They affect specific chemicals in our brains. These chemicals are partly responsible for:

- Sleep
- Feelings of relaxation & anxiety



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Benzodiazepines

- Often prescribed for use on a 'when required' basis
- Should be used for the shortest duration possible to prevent dependence

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Weight gain

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Weight Gain

Some examples of medications that can cause weight gain:

- Antipsychotics
- Lithium
- Mirtazapine
- Sodium Valproate



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Weight Gain

1. Feeling sleepy during the day, therefore move around less
2. Dry mouth: makes you thirsty (some drinks higher in calories)
3. Increases appetite
4. Slows down metabolism
5. Poor sleep
6. Hormonal changes

20



Weight Gain

- Weight gain most likely in first 6 weeks then levels out
- Different antipsychotics have different risks of weight gain
- People respond differently due to variation in:
 - diet
 - level of activity
 - genetics

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Weight Gain & Antipsychotics

The risk of weight gain with antipsychotics:				
Lowest risk	Low risk	Medium risk		Highest risk
Aripiprazole Lurasidone	Amisulpride Asenapine Brexipiprazole Ziprasidone	Chlorpromazine Flupentixol Haloperidol Paliperidone	Quetiapine Risperidone Trifluoperazine	Clozapine Olanzapine Pericyazine Zuclopenthixol

Choice antipsychotics and weight gain - handy facts <https://www.choiceandmedication.org/sahealth/printable-leaflets/handy-fact-sheet/>, accessed 20th November 2020.

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Weight gain: what can I do?

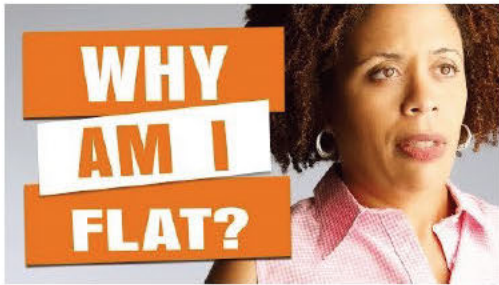
Listen to body signals that tells you when you are hungry or full	At least 30 minutes of activity per day (walk, gardening, gym etc)	Monitor your weight (self, GP visits etc)
2 Fruit & 5 Veg in a day	Drink fluids - avoid high sugary drinks	Alcohol has Kilojoules too!

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Bluntness in emotions

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Bluntness in emotions



Youtube:<https://www.youtube.com/watch?v=40wbck0JKo>

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Speak to your doctor

If you have any concerns

26

Other considerations

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Sleep disturbance



Drowsiness

- e.g antipsychotics
- If affected speak to pharmacist or doctor



Difficulty sleeping

- e.g antidepressants
- If affected:
 - sleep hygiene
 - speak to your doctor

28

Sleep hygiene

Avoid	Avoid caffeine, alcohol and nicotine, especially in the three hours before going to bed
Do not	Do not stay in bed for more than about an hour if you are not asleep
Naps	Avoid daytime naps or long periods of sitting around
Sleeping pattern	Get up at the same time every morning, no matter how well or long you slept

29



Caution!

- Recreational (e.g alcohol) & illicit drugs
- Sleeping tablets
- Smoking
- Other medications

Can affect how your medications work

30



Serotonin Syndrome: What it is

- Serotonin syndrome is a **dangerous** condition
- Caused by **excess serotonin** (chemical found in the brain)
- Symptoms include:
 - confusion
 - agitation
 - sweating
 - increase in heart rate
 - involuntary muscle movements

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Serotonin Syndrome: What can cause it?

Drug interactions:

- Natural products (supplements)
- Prescription medications:
 - antidepressants
 - pain relievers (tramadol)
 - lithium
- Over the counter products (cough syrups - dextromethorphan)
- Other: illicit drugs

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Serotonin Syndrome: How to avoid it

- When changing from one antidepressant to another, there may be a need for an antidepressant-free period to prevent serotonin toxicity (discuss with your doctor)
- **Check all OTC & prescription products with doctor or pharmacist prior to taking**

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Consumers Medicine information leaflet (CMI)

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Consumer's Medicine Information

1. What medication is used for
2. Before you take it
3. How to take it
4. While you are taking it
5. Side effects
6. After taking it
7. Product description

35

Libby's
Libby's
Consumer Medicine Information

The Medication of Libby's for Sleep There would not have been taking over 100 years ago. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping.

What Libby's for Sleep is used for
Libby's for Sleep is used to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping.

How to take Libby's for Sleep
Libby's for Sleep should be taken as directed. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping.

While you are taking Libby's for Sleep
While you are taking Libby's for Sleep, you should avoid alcohol and other medicines that can interact with it. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping.

Side effects
Some of the side effects of Libby's for Sleep include drowsiness, dizziness, and dry mouth. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping.

After taking Libby's for Sleep
After taking Libby's for Sleep, you should avoid driving or operating machinery until you are fully awake. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping.

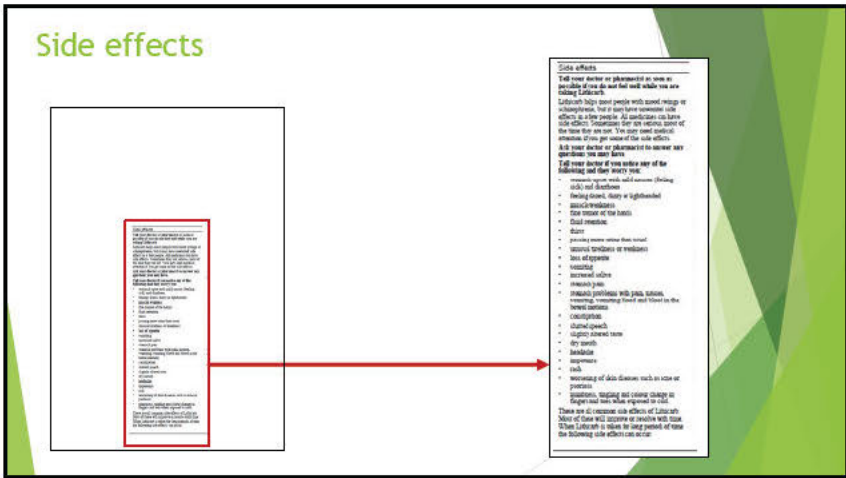
Product description
Libby's for Sleep is a white, round tablet. It is a medicine that has been used for many years to help people who have trouble sleeping. It is a medicine that has been used for many years to help people who have trouble sleeping.

Libby's
Pharmaceuticals
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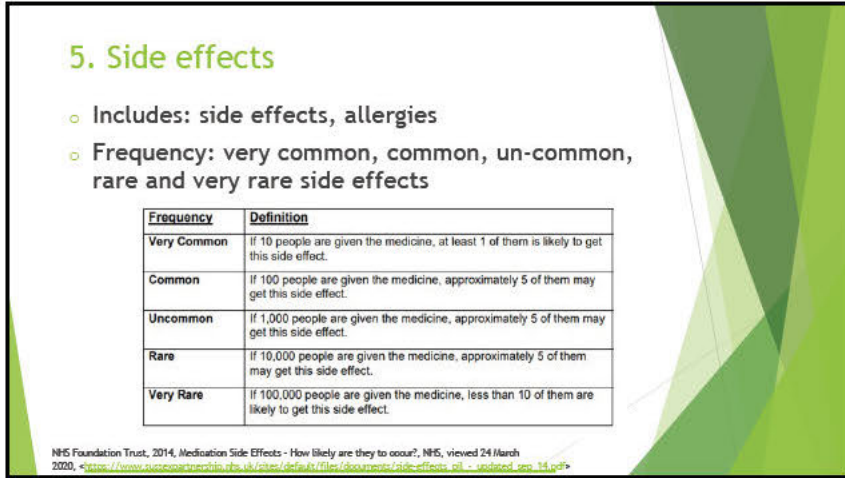
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37



38



39



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Fluoxetine (say: flow-ee-teen)

How it works

- Fluoxetine (Prozac®, Lexapro® and Daxopin®) is an SSRI (selective serotonin reuptake inhibitor) and works in the brain.
- It is often used to help with the symptoms of depression (by making the time it takes to recover and to feel like functioning better), anxiety, social anxiety, OCD (Obsessive Compulsive Disorder), PTSD, panic, PMH and seasonal affective disorder.
- It comes in capsule and dispersion tablet.

How long will I need to keep taking it for?

- This will depend on what you are taking it for, your history and how well you are doing.
- For depression, for improvement you will have:
 - Feel better
 - Feel more like your usual self
 - Feel more like you are back to normal
 - Feel more like you are back to your usual self
 - Feel more like you are back to your usual self

How should I take Fluoxetine?

- The usual dose of fluoxetine is around 20mg to 30mg a day. It can be up to taking a dose or more.
- It can be taken with or after food.
- It is best taken in the morning at breakfast time if possible. It has been about 1-2 hours before going to bed you might not sleep as well.

What are the usual side effects of Fluoxetine?

- The usual side effects of fluoxetine are:
 - Headache
 - Nausea
 - Dizziness
 - Loss of appetite
 - Weight loss
 - Insomnia
 - Sexual dysfunction
 - Blurred vision
 - Dry mouth
 - Constipation
 - Increased sweating
 - Increased tearing
 - Increased urination
 - Increased heart rate
 - Increased blood pressure
 - Increased cholesterol
 - Increased triglycerides
 - Increased liver enzymes
 - Increased creatinine
 - Increased bilirubin
 - Increased lactate
 - Increased uric acid
 - Increased creatinine
 - Increased bilirubin
 - Increased lactate
 - Increased uric acid

What should I do if I have side effects?

- Most side effects are mild and will go away on their own.
- Some side effects may be more serious and you should contact your pharmacist or doctor if you experience any of the following:
 - Headache
 - Nausea
 - Dizziness
 - Loss of appetite
 - Weight loss
 - Insomnia
 - Sexual dysfunction
 - Blurred vision
 - Dry mouth
 - Constipation
 - Increased sweating
 - Increased tearing
 - Increased urination
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 - Increased tearing
 - Increased urination
 - Increased heart rate
 - Increased blood pressure
 - Increased cholesterol
 - Increased triglycerides
 - Increased liver enzymes
 - Increased creatinine
 - Increased bilirubin
 - Increased lactate
 - Increased uric acid

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Will Fluoxetine affect my other medications?

Fluoxetine has a few interactions with other medicines. This means some:

- Fluoxetine can increase the effect of other medicines, some heart drugs and some more.
- If Fluoxetine is taken with benzodiazepines or alcohol, it may cause more sleepiness.

Phone on the Contraceptive Medication (CM) label for the full details for that of 2 more interacting medicines. Some of these medicines can still be used together but you must know your doctor's instructions.

What sort of side effects might I get if I am taking Fluoxetine?

This table shows some of the most common side effects and any you might need to take action on. You must also see the Contraceptive Medication (CM) label for the full list but possible side effects do not mean you will experience them. Some people get side effects of all. When you get some that are not listed, some side effects are those you are getting used to a medicine and these usually wear off in a few days or weeks. Starting down may help if you think you might have a side effect to the medicine, you should ask your doctor, pharmacist or pharmacist.

Side effect	What to do about it
Headache	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Nausea	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Dizziness	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Loss of appetite	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Weight loss	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Insomnia	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Sexual dysfunction	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Blurred vision	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Dry mouth	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Constipation	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased sweating	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased tearing	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased urination	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased heart rate	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased blood pressure	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased cholesterol	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased triglycerides	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased liver enzymes	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased creatinine	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased bilirubin	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased lactate	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.
Increased uric acid	Take your Fluoxetine with or after food. This tends to wear off after a few days or a week or so. See your doctor if it doesn't.

Can I take Fluoxetine with alcohol?

Fluoxetine can increase the effects of alcohol, make you dizzy, reduce your concentration and slow your reactions.

Can I take Fluoxetine with other medicines?

Fluoxetine can increase the effects of alcohol, make you dizzy, reduce your concentration and slow your reactions.

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My Pharmacists

1. Medication advice
2. Home medicines reviews
3. Lifestyle advice
 - o quit smoking?
 - o where to get more information or support ?
4. Packing of medications
 - o forgetting to take medications?
5. Delivery services (some pharmacies)



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Forgot to take your medication?

Ask your pharmacist or doctor about the best course of action

Consider:

- o Packing of medications by pharmacist
- o Setting a reminder on your calendar/phone
- o Taking it at a time that would help you remember
- o Use of an App [e.g Medicinewise]
- o Put the medications somewhere you can see



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5 Scoping Review: Metabolic monitoring for adults living with a serious mental illness

Chapter Overview

This chapter presents a scoping review that explored existing metabolic monitoring practices for people living with a SMI and using SGAs. Previously, Chapter Two presented the findings from a literature review that identified and explored physical/metabolic monitoring for PLMI, specifically highlighting the need to improve monitoring rates. This chapter further adds by identifying interventions that have been taken to address this gap. Specifically, this scoping review summarised and mapped existing metabolic monitoring practices, highlighted current gaps in practice and provided directions for future research initiatives.

Publication Overview

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Metabolic Monitoring for Adults Living with a Serious Mental Illness on a Second-Generation Antipsychotic Agent: A Scoping Review

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Abstract

Premature mortality in people living with a severe mental illness (SMI) is often attributed to multiple factors including the use of medicines such as antipsychotics. Second-generation antipsychotics (SGAs) are known to cause metabolic syndrome which can increase the risk of cardiovascular disease. Practice guidelines have recommended regular physical health monitoring, particularly of metabolic parameters, however, metabolic monitoring for people living with SMI using antipsychotics remains suboptimal. Therefore, highlighting the need for ongoing research. This scoping review aimed to provide an overview of current metabolic monitoring practices. We anticipate that this information will assist clinicians and policymakers and inform future research. The following databases were searched: MEDLINE (Ovid), Embase (Ovid), CINAHL (EBSCO), the Cochrane Database of Systemic Reviews (Wiley), APA PsycInfo (Ovid) and Scopus (Elsevier Science Publishers). The target group was adults (aged ≥ 18) diagnosed with SMI (including bipolar disorder, major depressive disorder and psychotic disorders) and taking SGAs. In total, 44 studies from 14 countries were retrieved. Our findings highlighted that most studies conducted in hospitals did not report on metabolic monitoring practices. Additionally, the roles and responsibilities of healthcare professionals in metabolic monitoring for SMI were infrequently described and parameters such as waist circumference and BMI were often poorly monitored. The scoping review highlights that no streamlined approach towards metabolic monitoring currently exists. There is a need to stipulate and define the roles and responsibilities of all health professionals involved in metabolic monitoring in SMI to optimise care for these individuals. Moreover, there is a need for ongoing research, particularly in the community setting, to promote increased accessibility to metabolic monitoring for SMI.

Keywords Antipsychotic agents · Metabolic diseases · Monitoring · Mental illness · Healthcare

Background

Reports indicate that people living with a severe mental illness (SMI) have a reduced life expectancy compared to the general population, with estimates ranging from 10 to 20 years (Liu et al., 2017). Premature mortality has been linked to various factors, including cardiovascular disease (CVD) (Lawrence et al., 2010). Research indicates that individuals with SMI are more likely to report higher rates of tobacco smoking, poorer diet and low physical activity (Wichniak et al., 2019), all of which contribute to an elevated risk of CVD (Scott & Happell, 2011). Furthermore, commonly prescribed medications such as antipsychotics can amplify this risk by increasing the likelihood of developing metabolic syndrome (MetSyn) (Dekker et al., 2005), which is characterised by elevated blood glucose, lipids and blood pressure, as well as central obesity (Penninx & Lange,

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2018). Antipsychotics are categorised as either first-generation antipsychotics (FGAs) or second-generation antipsychotics (SGAs) based on their pharmacological properties. While SGAs offer improved tolerance due to a lower risk of extrapyramidal side effects than FGAs (D'Souza & Hooten, 2021), they introduce a heightened risk of metabolic disturbances, including MetSyn (Bernardo et al., 2021; Hasan et al., 2013; Dekker et al., 2005).

Global consensus or treatment guidelines (American Diabetes Association, 2004; Castle et al., 2017) stipulate the need for regular physical health monitoring for patients with SMIs taking antipsychotics. The American guidelines recommend monitoring metabolic parameters (including weight, waist circumference, blood pressure, plasma glucose and lipid profile) at baseline and at 4, 8 and 12 weeks and annually thereafter as part of routine care (American Diabetes Association, 2004). Similarly, Australian guidelines recommend regular monitoring of metabolic parameters, with an additional review at 24 weeks after antipsychotic initiation (Castle et al., 2017).

Previous research has shown suboptimal metabolic monitoring rates in patients with SMI (Chee et al., 2017; Cohn & Sernyak, 2006; Michael & MacDonald, 2020), highlighting a disparity between guidelines and existing practices (Cunningham et al., 2018; Mackin et al., 2007; Mead et al., 2021). A multi-country systematic review and meta-analysis of 218,940 patients (inpatient and community-dwelling) reported that only blood pressure and triglycerides were routinely monitored for at least 50% of participants, while weight (47.9%), blood glucose (44.3%) and cholesterol (41.5%) were measured in fewer than half of the study cohort (Mitchell et al., 2012). Suboptimal monitoring rates were also identified in one Australian inpatient ward ($n=61$), where height and weight were measured in less than half (46%) of the patients, while lipid levels were measured 23% of the time (Michael & MacDonald, 2020). However, this single-site study had a small sample size and may not reflect procedures in other practice settings.

Several studies have explored the role of allied health professionals, such as nurses (Chee et al., 2017) and pharmacists (Al Adawi et al., 2020; Sud et al., 2021) in the management of cardiometabolic risk, metabolic syndrome (MetSyn) and related diseases in the SMI. A systematic review revealed that interventional studies to improve metabolic monitoring rates in patients with SMI generated relatively positive results (Melamed et al., 2019). These aforementioned studies focused on quantifying and improving metabolic monitoring rates but did not provide details on practice implementation. For example, a systematic review by Mitchell and colleagues quantified and compared the rates of metabolic monitoring before and after guideline implementation (Mitchell et al., 2012) but did not describe the processes of metabolic monitoring. Reviews to date have not reported on the context of

interventions; for example, who are the health professionals involved in metabolic monitoring, where metabolic monitoring commonly occurs (for example, primary compared to tertiary settings) and how (such as procedures and systems) is this monitoring integrated and active in practice (Melamed et al., 2019; Poojari et al., 2022)? Addressing these questions will inform future implementations of more targeted and streamlined interventional approaches.

It is important to understand current metabolic monitoring patterns in routine clinical practice to improve the management and care of SMI. This scoping review provides an overview of current metabolic monitoring practices by utilising published studies' descriptions of existing baseline monitoring rates and procedures (that is, without the influence of study interventions) as proxy measures. This review summarised and mapped existing metabolic monitoring practices, highlighted current gaps in practice and provided directions for future research initiatives. We anticipate that this information will assist clinicians and policymakers and inform future research.

Methods

The scoping review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist (Tricco et al., 2018) and the Joanna Briggs Institute (JBI) Manual for Evidence Synthesis updated methodological guidance for the conduct of scoping reviews (Peters et al., 2021). An a priori protocol was developed and registered on the Open Science Framework (<https://doi.org/https://doi.org/10.17605/OSF.IO/YMR5C>).

An initial limited search of MEDLINE (Ovid) and APA PsycInfo (Ovid) was performed. Keywords in the titles and abstracts of relevant articles were used to develop the full search strategy (Supplementary Information). The search strategies, inclusion/exclusion criteria and the data extraction tool were piloted by two members of the research team on a small sample ($n=8$) of papers. The following databases were searched: MEDLINE (Ovid), Embase (Ovid), CINAHL (EBSCO), the Cochrane Database of Systematic Reviews (Wiley), APA PsycInfo (Ovid) and Scopus (Elsevier Science Publishers). The search was adapted for each database and information source. Regular input from an academic librarian further refined the search strategy and translation across different databases. A search for grey literature was undertaken via Google Scholar and ProQuest Dissertation and Theses. The scoping review was informed by the Population, Concept, Context framework (Pollock et al., 2023). The search was conducted on the 8th of September 2022 and updated on the 13th of October 2023.

Population

The target group was adults (aged ≥ 18) diagnosed with SMI (including bipolar disorder, major depressive disorder and psychotic disorders) and taking SGAs.

Concept

This scoping review examined the combination of the following concepts:

1. SMI was diagnosed in adults with the following conditions: bipolar disorder, major depressive disorder and psychotic disorders (including schizophrenia and schizoaffective disorder)
2. Currently taking SGAs
3. The metabolic syndrome incidence, cardiometabolic risk and metabolic parameters included the following:
 - a. Weight
 - b. Waist circumference
 - c. Blood pressure (BP)
 - d. Plasma glucose levels, such as blood glucose levels (BGLs) and haemoglobin A1c (HbA1c) levels
 - e. Lipid levels included total cholesterol (TC), high-density lipoprotein (HDL), low-density lipoprotein (LDL) and triglyceride (TG) levels.
4. Processes of metabolic monitoring (such as onsite or referral for laboratory tests)

Context

The scoping review included studies conducted in healthcare facilities such as community settings, medical centres, hospitals, and specialised care facilities. There were no attempts to limit the search to specific countries.

Inclusion and Exclusion Criteria

This review considered a variety of study designs, including qualitative, experimental, quasi-experimental, “before and after”, analytical observational, retrospective, cross-sectional and descriptive observational studies. Studies that monitored at least three metabolic parameters (weight, blood pressure, waist circumference, plasma glucose and lipid levels) and were published after 2004 (aligning with the publication date of the American guideline (American Diabetes Association, 2004)) were included.

Studies that were deemed not to reflect real-life practice, such as randomised controlled trials were excluded. Prospective studies were also excluded as baseline monitoring was often conducted as part of the research methodology and therefore may not reflect the usual metabolic monitoring

rates in the particular setting. Additionally, case-control reports, case studies or case series were not considered because they cannot be generalised to the broader cohort of SMIs. Finally, studies that were not published in English or for which the full text could not be retrieved (for example, through interlibrary loans) were excluded.

Data Screening and Extraction

The articles retrieved by the search were managed by End-Note X9 (Clarivate Analytics, PA, USA), and Covidence (Veritas Health Innovation, Melbourne, Australia) was used to screen the studies. The titles and abstracts of the identified studies were screened by two independent reviewers, and conflicts were resolved by a third reviewer. An overly inclusive approach was employed, with full-text articles obtained for any abstracts in doubt. All studies meeting the inclusion criteria were retrieved in full and underwent the same screening process as the first phase (described above). Data extraction was conducted by two researchers, who extracted data from half of the studies and cross-verified the other half. The extracted information included author, year of publication, country, sample size, study design, role and responsibilities of health care professionals, setting, monitoring process and outcomes measured. The reference lists of relevant systematic reviews were screened independently by two authors for potentially relevant studies. The findings of the review are reported using descriptive analysis.

Data Analysis

Relevant data from the retrieved studies were charted and organised into the data extraction table. Additional information was collated and summarised (Arksey & O’Malley, 2005) then presented as appropriate tables or figures. The type and frequency of metabolic monitoring for the relevant metabolic parameters, including HDL and TG when reported, was included in a graph to illustrate the range of metabolic monitoring rates across the included studies.

Results

Study Selection

Of the 20,387 studies identified from the initial search, 7579 duplicates were removed using Endnote and Covidence. The first screening phase identified 608 studies for full-text review (Fig. 1). Systematic and literature reviews ($n = 3$) were assessed, and an additional two studies were identified. A study that included a small cohort of children was also included, as the majority of the participants were adults (Cotes et al., 2015).

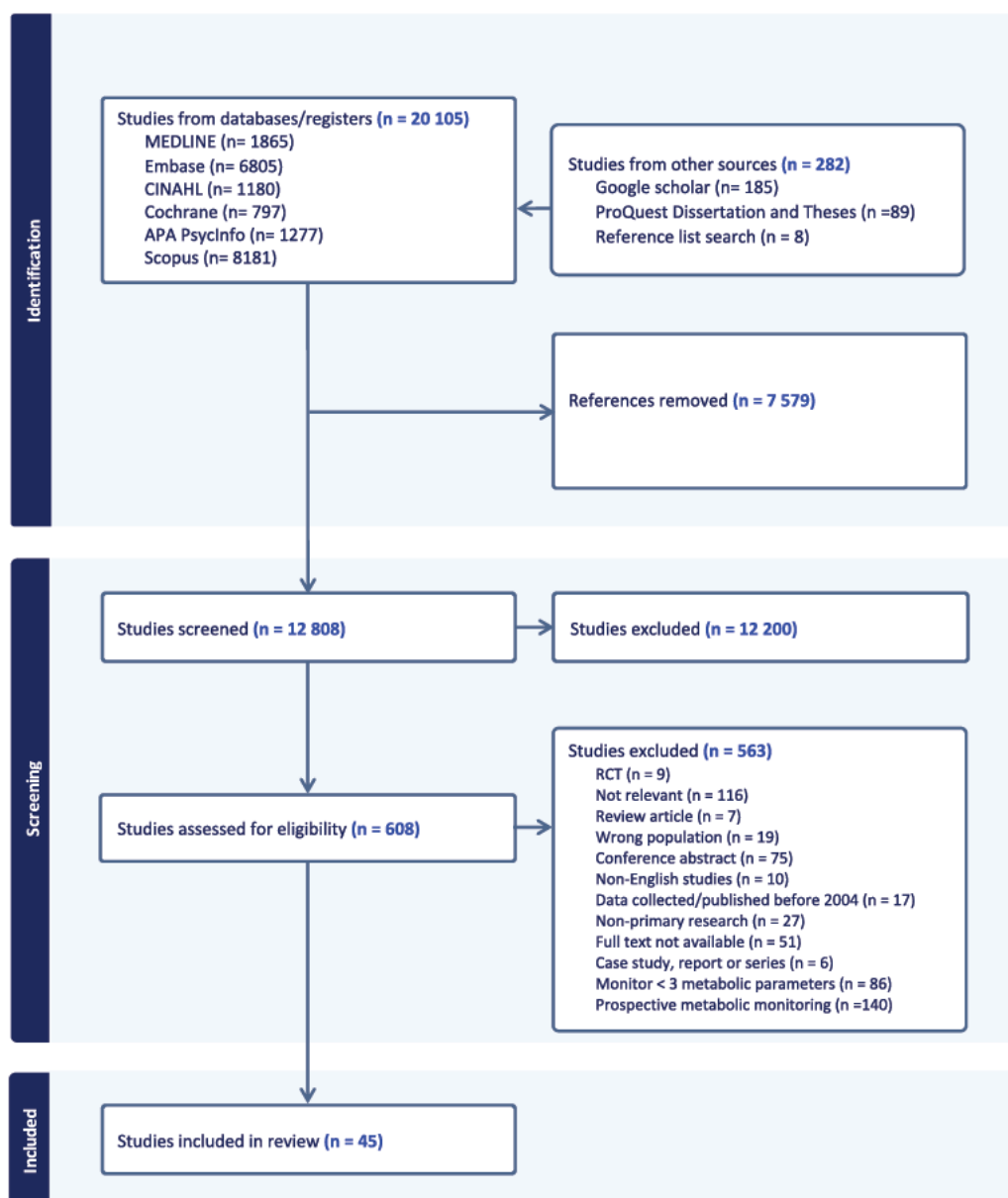


Fig. 1 PRISMA flow diagram showing the process of study selection for inclusion in the scoping review

Study Characteristics

In total, 45 studies were included (Fig. 1), and two manuscripts (a thesis and a peer review) published by the same authors covering the same content were considered single inclusions. The 44 included studies were conducted in the following countries (Table 1): the UK (n = 13) (Ali et al., 2023; Barnes et al., 2007, 2008, 2015, 2020; Gumber et al.,

2010; Harrison et al., 2012; Holt et al., 2010; Lau et al., 2019; Mwebe et al., 2020; Najim & Islam, 2013; Pearsall et al., 2019; Ross et al., 2018), the US (n = 9) (Batscha et al., 2010; Butler et al., 2013; Coakley et al., 2012; Cotes et al., 2015; Kilbourne et al., 2007; Kioko et al., 2016; Mittal et al., 2014; Pereira et al., 2019; Tatreau et al., 2016), Ireland (n = 4) (Feeney & Mooney, 2005; Kelly et al., 2022; Lydon et al., 2021; O'Callaghan et al., 2011), Australia

Table 1 Data extraction table, presented in order of publication year

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Ali et al., 2023, UK (Ali et al., 2023)	Observational retrospective study	Primary care, n = 479 records	Not reported	Not reported	<p><i>Less than 1 monitoring over 3 years</i></p> <p>BP: 24.55% BMI: 30.99% HDL: 39.03% Non-HDL: 38.63% HbA1c: 1.01% Waist Circumference: 3.42%</p> <p><i>One monitoring in three years</i></p> <p>BP: 16.7% BMI: 21.33% HDL: 14.69% Non-HDL: 14.08% HbA1c: 0% Waist Circumference: 0.4%</p> <p><i>More than one monitoring in three years</i></p> <p>BP: 49.9% BMI: 34.41% HDL: 16.1% Non-HDL: 16.1% HbA1c: 0% Waist Circumference: 0%</p>
Stephenson et al., 2023, Canada (Stephenson et al., 2023)	Cohort study	Primary care, n = 2643 records	Family physician	Not reported	<p><i>With one or more measurements</i></p> <p>Pre-pandemic: BP: 58.95% LDL: 42.98% HbA1c: 51.15%</p> <p>Pandemic: BP: 27.64% LDL: 32.22% HbA1c: 39.82%</p>
Knudsen et al., 2022, Denmark (Knudsen et al., 2022)	Cross-sectional study	Psychiatric outpatient clinics, n = 107	Not reported	Not reported	<p>Participants with a measurement in the past year for: BP: 80.4% Cholesterol: 92.5% HbA1c: 92.5%</p>
Fontaine et al., 2022, Canada (Fontaine et al., 2022)	Cross sectional study	Tertiary hospital, n = 402	Nurses BP and weight/BMI measurements were routine nursing practice in this psychiatric unit	Not reported	<p>BP: 99.8% Weight/BMI: 97.8% Lipid profile: 24.4% Fasting glucose/HbA1c: 33.3% Waist circumference: 4.5% All monitored: 1.24%</p>

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* <i>Results for initial audit (preintervention) only</i>
Kelly et al., 2022, Ireland (Kelly et al., 2022)	Pre/post intervention study	Hospital First Episode Psychosis n=33 First Episode Psychosis readmit n=20 Chronic psychosis n=41	Not reported	Not reported	Baseline for First Episode Psychosis: BP: 88% Weight: 67% BMI: 3% Fasting lipids: 61% Fasting glucose: 39% HbA1c: 0% Waist circumference: 3% Heart rate: 91% Prolactin: 18% ECG: 67% Chronic psychosis: BP: 20% Weight: 17% BMI: 9.7% Fasting lipids: 17% Fasting glucose: 17% Waist circumference: 0% Diabetes (as reported): 4% During inpatient period BP: 24.5% BMI: 5.6% HDL: 16.8% LDL: 16.1% Fasting glucose: 14.7% HbA1c: 7.3% During recommended period of CVD risk factor management BP: 85.8% BMI: 45.7% HDL: 18.2% LDL: 18.2% Fasting glucose: 16.3% HbA1c: 15.4%
Tan et al., 2022, Singapore (Tan et al., 2022)	Retrospective cohort study	Hospital, n = 5256	Not reported	Not reported	

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Bomboy et al., 2021, country not specified (Bomboy et al., 2021)	Pre/post intervention study with control group	Rural community mental health centre Intervention group n = 82 pre implementation of intervention n = 91 post implementation Control group n = 129 pre intervention period n = 135 post intervention period	Psychiatric prescribers (Psychiatrists and advanced practice nurses) Determine if laboratory work was needed and provided verbal order for laboratory tests Clinic Staff (Medical assistant or certified nursing assistant) Laboratory work	Patients were identified by medication clinic staff and assessed/reviewed by prescriber. Samples for laboratory tests were drawn onsite, specimens transported and processed at the main laboratory site and results were uploaded to the portal for the medication clinic staff to access and record on the metabolic monitoring form. Prescriber determined if laboratory work was needed, provided verbal order for medication clinic staff (to do lab work and document).	Intervention group Laboratory tests ordered: 1 out of 82 (1.2%) Control group Laboratory tests: 5 out of 129 (3.8%)

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Lydon et al., 2021, Ireland (Lydon et al., 2021)	Cross sectional study	Mental Health Services at University Hospital Clozapine group n = 119 Long-acting injection (LAI) – antipsychotic group n = 117	Not reported	All laboratory data examined were analysed at the bio-chemistry laboratory at the University Hospital. Dedicated clozapine clinic staffed by clinical nurse specialists. Manuscript did not report who measured the metabolic parameters.	Clozapine cohort BP: 100% Weight: 96% Cholesterol: 95% HDL: 95% LDL: 90% Triglycerides: 95% Any glucose measure: 95% Waist circumference: 2% LAI antipsychotic cohort BP: 39% Weight: 23% Cholesterol: 95% HDL: 95% LDL: 90% Triglycerides: 95% Any glucose measure: 95% Waist circumference: 15%
O'Brien & Abraham, 2021, New Zealand (O'Brien & Abraham, 2021)	Audit	Secondary mental health services and primary care Primary care audit n = 46 Secondary care audit n = 47 Practice nurse survey n = 24	Not reported	Not reported	Primary care: BP: 71.7% Weight: 58.7% HDL: 50% Triglycerides: 50% Fasting blood glucose: 0% Blood glucose: 63% Waist circumference: 6.5% Secondary services BP: 80.9% Weight: 76.6% HDL: 51% Triglycerides: 51% Fasting blood glucose: 0% Blood glucose HbA1c: 51% Waist circumference: 12.5%
Viglione & Short, 2021, Australia (Viglione & Short, 2021)	Pre/post intervention audit	Mental health inpatient service Preintervention n = 106	Nursing staff Measures physical parameters Junior medical officer Responsible for "bloodwork"	Not reported	BP: 99.1% BMI: 83% Fasting lipid profile: 20.8% HbA1c: 21.7% Waist circumference: 36.8%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Barnes et al., 2020, UK (Barnes et al., 2020)	Audit	UK member trusts and health-care services as part of the Prescribing Observatory for Mental Health (n = 64) n = 6948 patients	Reported that data were collected by clinicians and clinical audit staff. * *Unclear if this refers to physical collection of metabolic parameters or review of case notes to collect data for the audit	Not reported	Pre-treatment screening BP: 97% Body weight: 83% Lipid levels: 81% Plasma glucose or HbA1c: 80% General physical examination conducted: 79% Monitoring in first 2 weeks of clozapine BP: 11% Patients treated with clozapine for more than 1 year (n = 5908) BP: 85% Body weight/BMI: 81% Plasma lipids: 73% Plasma glucose: 78% Physical examination: 55% 7% did not have any physical health checks documented in the clinical records in the previous year
Keenan et al., 2020, New Zealand (Keenan et al., 2020)	Audit	General practices Patients n = 117 General practices n = 8	Not reported	Not reported	BP: 85% Weight: 82% Lipid: 66% HbA1c: 70% Waist Circumference: 3% Prolactin: 2% Complete Blood Count: 68% See Table 2
Mwebe et al., 2020, UK (Mwebe et al., 2020)	Audit	Inpatient psychiatric wards, n = 120	Nurses Reports that "nursing enquiries and discussions with patients at baseline or during patient stay in relation to unhealthy lifestyle behaviours were often succinct or missing."	Not reported	See Table 2
Poojari et al., 2020, South India (Poojari et al., 2020)	Retrospective cohort study	Tertiary care health institution with speciality psychiatric inpatient and outpatient clinics, n = 315	Not reported	Not reported	See Table 2

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Lau et al., 2019, UK (Lau et al., 2019)	Audit	General practices, n=57	Not reported	General practitioner, roles and responsibilities pertaining to metabolic monitoring not specified	BP: 80.70% Weight: 70.20% Blood lipids: 52.60% Fasting blood glucose: 31.60% HbA1c: 49.1% Waist circumference: 17.50% Pulse: 47.30% Prolactin: 7.00% Full blood count: 43.90% Urea and electrolytes: 66.70% Liver function tests: 52.60% Lifestyle advice: 38.60%
Pearsall et al., 2019, UK (Pearsall et al., 2019)	Cross sectional study	Community and inpatients- adult mental health services, n=7718	Not reported	Not reported	One blood test in the preceding 2 years Cholesterol: 25.17% Triglycerides: 25.30% Glucose: 20.99% HbA1c: 13.66% Albumin: 12.54% Creatinine: 16.18% Alanine transaminase: 17.91% Two blood tests in the preceding 2 years Cholesterol: 24.60% Triglycerides: 24.48% Glucose: 21.66% HbA1c: 6.31% Albumin: 14.73% Creatinine: 15.83% Alanine transaminase: 17.54% Three or more blood tests in the preceding 2 years Cholesterol: 27.47% Triglycerides: 27.40% Glucose: 40.48% HbA1c: 11.13% Albumin: 57.06% Creatinine: 53.25% Alanine transaminase: 48.69%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* <i>Results for initial audit (preintervention) only</i>
Pereira et al., 2019, US (Pereira et al., 2019)	Audit (Chart review)	Outpatient psychiatric clinic, n = 54	Practitioners* Responsible for ordering tests Psychiatry clinical staff Involved in patient care * <i>Not specified</i>	Not reported	BP Baseline: 81% 12 weeks: 45% Annually: 70% Weight and BMI Baseline: 83% 4 weeks: 43% 8 weeks: 33% 12 weeks: 50% Quarterly: 49% Lipid Baseline: 42% Quarterly: 14% 5 years: Not reported Fasting blood glucose/haemoglobin A1c Baseline: 83% 12 weeks: 31% Annually: 82% Waist circumference Baseline: 0% Annually: 0%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Ross et al., 2018, UK (Ross et al., 2018)	Pre/post intervention audit	Secondary care setting Baseline audit (2012) n = 96	No specification of who ordered test, although stipulated that patient care is provided by consultant psychiatrists, psychiatric residents, nurses, occupational therapists and social workers. Family physician hospitalist (for any physical health concerns). Suggested that attending physician could order laboratory tests but not explicitly stated.	Medical directive All patients admitted under the inpatient psychiatric ward were automatically under investigations of height, weight, BMI, waist circumference, daily vitals for 3 days, blood tests including CBC, liver transaminases, kidney function tests, TSH, serum glucose and lipids after 72 h of admission. Glycosylated haemoglobin patient is known to be diabetic. Patients who have undergone the test within 6 months and were reported normal would not have them repeated automatically unless there was a clear indication. Attending physician could repeat these tests at any time.	BP: 92% Height and weight: 75% Lipids: 36% Fasting or random glucose: 10% Blood glucose: 31% Waist circumference: 0%
Hor et al., 2016, Malaysia (Hor et al., 2016)	Pre/post intervention study	General public hospital, n = 300	Monitoring conducted by nurses and health care assistants	Not reported	Less than 10% of patients had their fasting blood glucose, fasting triglyceride, fasting HDL, height, weight, and waist circumference measured. Less than 20% had their BP measured.

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* <i>Results for initial audit (preintervention) only</i>
Kioko et al., 2016, US (Kioko et al., 2016)	Pre/post intervention study	Outpatient mental health facility, n = 50 charts reviewed	Mental health clinicians/providers* are responsible in ordering blood work, screening and using the monitoring tool *Did not state whether there is a difference between mental health clinicians and providers	Not reported	69% laboratory tests not ordered. 22% laboratory tests done. 10% laboratory tests not done. Parameters measured: BP, weight, height, lipid panel, fasting glucose and/or glycated haemoglobin parameters
Tatreau et al., 2016, US (Tatreau et al., 2016)	Cross sectional study	Psychiatric inpatient units at the University of North Carolina Health Care System Unit A (reverse colocated medical care.(RCL)) n = 220 Unit B (treatment as usual (TAU)) n = 232	Refer to monitoring process column	Unit A Laboratory values obtained by physician's assistant supervised by a family physician. Unit B Medical care provided by resident psychiatrists supervised by attending psychiatrists. Hospitalists available for medical consultation. Standard admission orders include a basic chemistry panel, complete blood count, thyroid-stimulating hormone analysis, urinalysis, and urine toxicology screen. Laboratory tests ordered, completed, and reviewed prior to all admissions.	Unit A BP: 100% BMI: 49% Lipid: 61% Glucose: 99% HbA1c: 56% Unit B BP: 100% BMI: 47% Lipid: 20% Glucose: 66% HbA1c: 16%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* <i>Results for initial audit (preintervention) only</i>
Barnes et al., 2015, UK (Barnes et al., 2015)	Pre/post intervention audit	Adult, assertive outreach, community psychiatric services in the UK (Multiple sites) People prescribed continuing antipsychotic medication under the care of assertive outreach community psychiatric services. Baseline audit (2006) n = 1966	Patients were treated by Assertive Outreach Teams* * <i>Not specified</i>	Patients were treated by Assertive outreach teams, however the specific monitoring process was not reported	Baseline/Preintervention (2006) No evidence of MetSyn screening: 46% Some evidence of MetSyn screening (mention of review of any of the four aspects of the MetSyn and/or documentation of up to three relevant test results): 43% Test result documented for all four aspects of MetSyn: 11%
Cotes et al., 2015, US (Cotes et al., 2015)	Pre/post intervention audit	Ten community mental health centres 2009—193 Adult, 37 children 2010—203 Adult, 32 children	Psychiatric prescribers- role and responsibilities not clearly described	Not reported	Baseline_year (2009) BP recorded: 33% Past-year weight recorded: 52% Past-year cholesterol testing: 32% Triglyceride testing: 32% Glucose testing: 45% Abdominal girth recorded: 7%
Saloojee et al., 2014a, 2014b, South Africa (Shamima Saloojee et al., 2014a, 2014b)	Cross sectional study	General hospital -Psychiatric unit, n = 331	Not reported	Not reported	BP: 99% Fasting serum lipids: 1.8% Fasting blood glucose: 3.9% Random blood glucose: 96.6% Waist circumference: 0.6% All components: 0.6%
Mittal et al., 2014, US (Mittal et al., 2014)	Cohort study	Veterans Affairs medical centres Veterans n = 12,009	Not reported	Not reported	Baseline Weight: 66.6% Low-density lipoprotein: 32.1% Glucose or HbA1c: 45.8% 3 months follow-up Weight: 49.5% Low-density lipoprotein: 16.2% Glucose or HbA1c: 27.1%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Deuschle et al., 2013, Germany (Deuschle et al., 2013)	Multicentre cross-sectional study	In- and outpatient settings Hospitals n=49 Patients n=674	Refer to monitoring process column	Psychiatrists documented weight, height, waist circumference, total, LDL- and HDL-cholesterol, triglycerides, fasting glucose, HbA1c, and systolic and diastolic blood pressures. All data were derived from clinical routine.	BP: 37% BMI (weight and height): 54% Cholesterol: 25% HDL-Cholesterol: 8% LDL-Cholesterol: 8% Triglycerides: 25% Fasting glucose: 19% Waist circumference: 23%
Kjeldsen et al., 2013, Denmark (Kjeldsen et al., 2013)	Pre/post intervention study Two groups—Passive dissemination (PD group) and Active dissemination (AD group)	Psychiatric ward, University Hospital Implementation of guideline by passive dissemination group— n=93 Implementation of guideline by active implementation group n=112	Nurses and physiotherapists Perform the screening Clinical Pharmacist Outreach visits	All metabolic laboratory measures were performed at one central laboratory. Outreach visits (intervention) were performed by experienced clinical pharmacists; and screening was performed by other staff, e.g. nurses or physiotherapists.	PD group Screening sheet was used for 36% of the patients. 22% patients had all five screening measurements documented in their medical charts. Waist circumference: 74% Fasting glucose: 58% AD group Screening sheet was used for 81% of the patients. 76% patients had all five screening measurements documented in their medical charts. Waist circumference: 18% Fasting glucose: 12%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* <i>Results for initial audit (preintervention) only</i>
Najim & Islam, 2013, UK (Najim & Islam, 2013)	Retrospective case note review	Basilston University Hospital Pharmacy, n = 65	Not reported	Not reported	Baseline: BP and pulse: 21.54% Weight: 10.77% Triglycerides: 6.15% HbA1c/Glucose: 29.23% Urea and electrolytes: 36.92% Liver function tests: 36.92% (48.25% had physical examination checked, 40% not checked and 11.75% not documented) Monitored six monthly for the first year Weight: 1.54% Triglycerides: 3.08% HbA1c/Glucose: 29.23% Urea and electrolytes: 9.23% Liver function tests: 10.77%
Butler et al., 2013, US (Butler et al., 2013)	Pre/during intervention review of charts	Acute inpatient psychiatry unit Preintervention n = 100	Not reported	Not reported	BP: 100% Weight: 100% Lipid Panel: 12% Fasting Blood Glucose: 39% Haemoglobin A1c: 7% Waist Circumference: 0%
Harrison et al., 2012, UK (Harrison et al., 2012)	Pre/post intervention audit	Acute adult psychiatric wards Baseline n = 85 • Ward A, 37 • Ward B, 48	Consultant psychiatrist and medical team	Not reported	Ward A BP: 83.7% Weight: 13.5% BMI: 4.7% Cholesterol: 40.5% Waist: 0% Prolactin: 10.8% Diabetes: 78.4% Abnormal Movements: 18.9% Ward B BP: 91.7% Weight: 12.5% BMI: 4.2% Cholesterol: 37.5% Waist: 0% Prolactin: 8.3% Diabetes: 58.3% Abnormal Movements: 14.6%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Coakley et al., 2012, US (Coakley et al., 2012)	Audit (Chart review)	Psychiatric hospital, n = 125	Not reported	Not reported	BP: 100% BMI: 100% HDL: 59.2% Triglycerides: 59.2% Fasting plasma glucose 71.2% Waist circumference: 60.8%
O'Callaghan et al., 2011, Ireland (O'Callaghan et al., 2011)	Pre/post intervention audit	General adult psychiatry— Outpatient clinic Initial audit n = 64	Nursing staff, psychiatrists and trainee doctors were responsible for monitoring	Not reported	Systolic BP 4.7% Diastolic BP 4.7% Weight 1.6% Height 0% HDL 12.5% Triglycerides 12.5% Serum fasting glucose 15.6% Waist circumference 1.6%
Bobes et al., 2011, Spain (Bobes et al., 2011)	Pre/post implementation study	Multiple—since targets psychiatrists not settings Psychiatrists n = 229 Patients n = 1193	Not reported	Not specified	Weight: 58.9% BMI: 32.8% Lipid profile: 69.6% Blood glucose: 70.6% Waist circumference: 19.2%
Thompson et al., 2011, Australia (Thompson et al., 2011)	Pre/post intervention audit	Public youth mental health service for those aged 15–25 years Pre-intervention n = 106	Interventions for metabolic problems offered by clinicians (case managers and psychiatrists) – roles and responsibilities not clearly described	Not reported	Pre intervention: Approximately 20% had minimum metabolic screening—defined as the completion of a full 'set' of metabolic measures including obesity measures (BMI or weight and height or waist-hip ratio); and metabolic blood tests (lipids and glucose) at some point within 6 months of being prescribed an antipsychotic Less than 10% had minimum metabolic monitoring—defined as the completion of full baseline measures including both obesity measure (BMI/waist hip ratio/or weight) and metabolic blood tests plus the completion of full measures at between 1–6 months following initiation of antipsychotic medication (or 1–6 months after baseline)

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Batscha et al., 2010, US (Batscha et al., 2010)	Audit (Chart review)	Inpatient, specialty metabolic clinic, and outpatient n=40 • Inpatient, 12 • Specialty metabolic clinic, 9 • Outpatient, 19	Inpatient setting: Monitoring conducted by physician or nurses based on orders	Not reported	Inpatient BP: 100% Weight: 100% Blood lipids: 8.3% Blood glucose: 58.3% Waist circumference: 8.3% Outpatient BP: 36.8% Weight: 36.8% Blood glucose: 10.5% Blood lipids: 5.3% Waist circumference: 0% Metabolic clinic BP: 77.8% Weight: 77.8% Blood lipids: 0% Blood glucose: 77.8% Waist circumference: 77.8%
Holt et al., 2010, UK (Holt et al., 2010)	Prevalence study	Department of Psychiatry Inpatients n=50 Outpatients n=50	Not reported	Not reported	Outpatient BP: 4% Weight: 0% Lipid profile: 8% Fasting glucose: 6% Any glucose: 14% Waist circumference: 0% Inpatient BP: 60% Weight: 6% Lipid profile: 10% Fasting glucose: 6% Any glucose: 18% Waist circumference: 0% See Table 2
Marsay & Szabo, 2010, South Africa (Marsay & Szabo, 2010)	Retrospective case note review	Outpatient department of a specialist psychiatric hospital Patients prescribed olanzapine Commenced olanzapine as outpatients n=16 Commenced as inpatients n=23	Not reported	Not reported	

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Gumber et al., 2010, UK (Gumber et al., 2010)	Audit	Metabolic clinic Patients on atypical antipsychotics Initial audit (May 2006 and December 2007) n = 54 (48 attended baseline appointments) Repeat-audit (December 2007 and January 2009) n = 123	Junior specialty trainees and General Practitioners (GPs)	Metabolic parameters monitored by junior specialty trainees, and abnormal results were sent to GPs. At the end of 1 year, the responsibility of annual monitoring was passed on to GPs.	BP: 100% BMI: 99% Cholesterol: 94% HDL: 74% Triglycerides: 94% Plasma glucose fasting or random: 79% Waist circumference: 99%
Nguyen et al., 2009, Australia (Nguyen et al., 2009)	Audit	Acute wards of public psychiatric hospitals, n = 93	Not reported	Not reported	Weight: 65% Height: 61% BMI: 0% Cholesterol: 7.5% HDL: 1.1% LDL: 1.1% Triglycerides: 7.5% Random blood sugar levels: 31% Postprandial blood sugar levels: 3.2% HbA1c: 2.2% Grrh: 0%
Barnes et al., 2008, UK (Barnes et al., 2008)	Pre/post intervention audit	Secondary care mental health services Baseline audit n = 1966	Not reported	Not reported	BP: 26% BMI (or other obesity measure): 17% Plasma lipids: 22% Plasma glucose (or HbA1c): 28%
Verdoux et al., 2008, France (Verdoux et al., 2008)	Survey	Hospitals Psychiatrists n = 43	Assessment can be performed by psychiatrist, nurse, and general practitioner. The assessments were most often performed by a psychiatrist. The general practitioners were rarely implicated in the baseline screening. The other health professionals were a cardiologist, a nurse and the staff of the psychiatric emergency department.	Not reported	BP: 72.9% Weight: 61.5% Height: 56.7% BMI: 28.1% Total cholesterol: 61.1% HDL-cholesterol: 46.9% LDL-cholesterol: 46.9% Triglycerides: 61.1% Plasma glucose: 66.7% Waist circumference: 10.3% All measurements: 4.7% No measurement: 27.9%

Table 1 (continued)

Author(s), country	Study type	Setting, sample size	Role and responsibilities of health care professional	Specific monitoring process reported	Outcome measure* Results for initial audit (preintervention) only
Barnes et al., 2007, UK (Barnes et al., 2007)	Audit	All hospital trusts and private health care organisations that provide specialist mental health services Participating assertive outreach teams n = 53 Patient n = 1966	Patients were treated by the Assertive Outreach Teams* * Not specified	Patients were treated by Assertive outreach teams, however the specific monitoring process was not reported	BP: 26% BMI/or other obesity measures: 17% Plasma lipids: 22% Plasma glucose (or HbA1c): 28% Results for all 4 measures were documented in the case notes for 11% of patients overall, although the figure varied across the 21 services from 0 to 40%
Kilbourne et al., 2007, US (Kilbourne et al., 2007)	Population-based retrospective study	Veterans Administration Medical Centre Number of patients who were taking SGAs n = 252	Not reported	Not reported	Lipids o Total cholesterol: 49.6% o Triglycerides: 49.2% Serum fasting glucose level: 68.7% Recommended cardiovascular risk factor laboratory tests in less than 6 months: 50% See Table 2
Feeney & Mooney, 2005, Ireland (Feeney & Mooney, 2005)	Audit	Rural Public Mental Health Services, n = 80	Not reported	Not reported	

HDL = High Density Lipoprotein, *LDL* = Low Density Lipoprotein, *TG* = Triglyceride, *HbA1c* = haemoglobin A1c, *BMI* = Body Mass Index, *BP* = Blood Pressure

(n = 3) (Nguyen et al., 2009; Thompson et al., 2011; Viglione & Short, 2021), New Zealand (n = 2) (Keenan et al., 2020; O'Brien & Abraham, 2021), Canada (n = 2) (Fontaine et al., 2022; Stephenson et al., 2023), Denmark (n = 2) (Kjeldsen et al., 2013; Knudsen et al., 2022), South Africa (n = 2) (Marsay & Szabo, 2010; Shamima Saloojee et al., 2014a, 2014b) and one each from France (Verdoux et al., 2008), Germany (Deuschle et al., 2013), Malaysia (Hor et al., 2016), Singapore (Tan et al., 2022), South India (Poojari et al., 2020), and Spain (Bobes et al., 2011). One did not specify the country in which the study was conducted (Bomboy et al., 2021). More than half of the studies were conducted within the last 10 years (n = 29) (Ali et al., 2023; Barnes et al., 2015; Barnes et al., 2020; Bomboy et al., 2021; Butler et al., 2013; Cotes et al., 2015; Deuschle et al., 2013; Fontaine et al., 2022; Hor et al., 2016; Keenan et al., 2020; Kelly et al., 2022; Kioko et al., 2016; Kjeldsen et al., 2013; Knudsen et al., 2022; Lau et al., 2019; Lydon et al., 2021; Mittal et al., 2014; Mwebe et al., 2020; Najim & Islam, 2013; O'Brien & Abraham, 2021; Pearsall et al., 2019; Pereira et al., 2019; Poojari et al., 2020; Ross et al., 2018; Shamima Saloojee et al., 2014a, 2014b; Stephenson et al., 2023; Tan et al., 2022; Tatreau et al., 2016; Viglione & Short, 2021).

The studies covered a variety of settings, including hospitals (n = 14) (Coakley et al., 2012; Deuschle et al., 2013; Fontaine et al., 2022; Harrison et al., 2012; Holt et al., 2010; Hor et al., 2016; Kelly et al., 2022; Kjeldsen et al., 2013; Lydon et al., 2021; Najim & Islam, 2013; Nguyen et al., 2009; Shamima Saloojee et al., 2014a, 2014b; Tan et al., 2022; Verdoux et al., 2008), outpatient clinics (n = 5) (Kioko et al., 2016; Knudsen et al., 2022; Marsay & Szabo, 2010; O'Callaghan et al., 2011; Pereira et al., 2019), inpatients (n = 4) (Butler et al., 2013; Mwebe et al., 2020; Tatreau et al., 2016; Viglione & Short, 2021), secondary care settings (n = 2) (Barnes et al., 2008; Ross et al., 2018), primary care (n = 3) (Ali et al., 2023; Cotes et al., 2015; Stephenson et al., 2023), rural mental health services (n = 2) (Bomboy et al., 2021; Feeney & Mooney, 2005), general practices (n = 2) (Keenan et al., 2020; Lau et al., 2019), Veteran Administration Medical Centres (n = 2) (Kilbourne et al., 2007; Mittal et al., 2014), and one each from a tertiary care institution (Poojari et al., 2020), UK member trusts and healthcare services (Barnes et al., 2020), a metabolic clinic (Gumber et al., 2010) and a youth mental health service (Thompson et al., 2011). Six studies were conducted in multiple settings (Barnes et al., 2007, 2015; Batscha et al., 2010; Bobes et al., 2011; O'Brien & Abraham, 2021; Pearsall et al., 2019).

Roles and Responsibilities

The healthcare professionals involved in metabolic monitoring (such as ordering blood tests, screening or documenting)

included prescribers (Bomboy et al., 2021), junior medical officers (Gumber et al., 2010; Viglione & Short, 2021), family physicians (Ross et al., 2018; Stephenson et al., 2023; Tatreau et al., 2016), attending physicians (Ross et al., 2018) and psychiatrists (Deuschle et al., 2013; Tatreau et al., 2016; Verdoux et al., 2008). Others included nursing staff (Lydon et al., 2021), clinic staff (Bomboy et al., 2021), physiotherapists (Kjeldsen et al., 2013), healthcare assistants (Hor et al., 2016) and clinical pharmacists (Kjeldsen et al., 2013). Medical doctors (such as junior medical officers, physicians and psychiatrists) were often described as being involved in patient assessments, ordering blood tests and providing clinical interventions. Other health professionals, such as nurses, were often involved in conducting screening and/or physical assessments (Bomboy et al., 2021; Fontaine et al., 2022; Hor et al., 2016; Kjeldsen et al., 2013; Mwebe et al., 2020; O'Callaghan et al., 2011; Viglione & Short, 2021), while pharmacists had limited involvement in patient metabolic monitoring. One study described the role of clinical pharmacists in providing education and medication reviews during weekly outreach visits (Kjeldsen et al., 2013).

Most studies did not stipulate the specific roles and responsibilities of healthcare professionals involved in the metabolic monitoring process. For instance, a multiyear audit mentioned the role of the mental health team (specific health professionals not specified) in the assessment and recording of metabolic parameters for one year (2012) but not for subsequent years (Barnes et al., 2015). Another study alluded to psychiatric clinical staff (including resident physicians) having a role in metabolic monitoring in relation to education for participants (Ross et al., 2018). Although the study described patient care provided by consultants, psychiatric residents, nurses, occupational therapists and social workers, there was no description of the role and responsibilities of the clinical team.

Procedure and Reported Metabolic Monitoring Practice

Seven studies reported on metabolic monitoring processes (Table 1) (Bomboy et al., 2021; Deuschle et al., 2013; Gumber et al., 2010; Kjeldsen et al., 2013; Lydon et al., 2021; Ross et al., 2018; Tatreau et al., 2016). Doctors, including psychiatrists and junior speciality trainees, were reported to be involved in the monitoring and documenting of metabolic parameters (Deuschle et al., 2013; Ross et al., 2018). Gumber and colleagues reported on a metabolic clinic managed by junior speciality trainees involving the monitoring of metabolic parameters at baseline and at 3, 6 and 12 months (Gumber et al., 2010). Any abnormal results were communicated to the GPs for their attention and appropriate intervention for the first year only. Thereafter, the responsibility for annual monitoring was transitioned to the GPs (Gumber

et al., 2010). Similarly, several studies had described a screening process carried out by clinic staff, with participants assessed and reviewed by the prescriber (Bomboy et al., 2021; Tatreau et al., 2016). Blood samples were drawn onsite and subsequently transported to an offsite laboratory for processing, while the clinic staff were responsible for recording the results on the metabolic form (Bomboy et al., 2021). In all, three studies reported that blood test results were collected onsite and sent to a laboratory for assessment (Bomboy et al., 2021; Kjeldsen et al., 2013; Lydon et al., 2021). None of the studies stipulated whether metabolic monitoring was a mandated part of patient care, although three studies reported this as part of routine care (Batscha et al., 2010; Butler et al., 2013; Fontaine et al., 2022).

Monitoring of Metabolic Parameters

Several studies had measured various parameters (Table 1). Blood glucose levels varied between studies and were often reported as fasting glucose, HbA1c, and postprandial and random blood sugar levels. Figure 2 illustrates both the types and frequency of metabolic parameters measured in the included studies.

A total of 29 studies reported the frequency of metabolic monitoring for specific parameters, with some studies reporting these data for multiple cohorts (Ali et al., 2023; Barnes et al., 2020; Barnes et al., 2007; Barnes et al., 2008; Batscha et al., 2010; Bobes et al., 2011; Butler et al., 2013; Coakley et al., 2012; Cotes et al., 2015; Deuschle et al., 2013; Fontaine et al., 2022; Gumber et al., 2010; Harrison et al., 2012; Holt et al., 2010; Keenan et al., 2020; Kelly et al., 2022; Knudsen et al., 2022; Lau et al., 2019; Lydon et al., 2021; Nguyen et al., 2009; O'Brien & Abraham, 2021; O'Callaghan et al., 2011; Ross et al., 2018; Shamima Saloojee et al., 2014a, 2014b; Stephenson et al., 2023; Tan et al., 2022; Tatreau et al., 2016; Verdoux et al., 2008; Viglione & Short, 2021). Monitoring rates varied considerably across the 29 studies. Waist circumference (46%) and BMI (46%) were often poorly monitored, with nearly half of the studies reporting monitoring rates less than 20%. Lipids were also infrequently monitored, with many studies (54%) reporting rates of 40% or less. Just over half (55%) of the studies reported BP monitoring rates exceeding 70%, but blood glucose monitoring exhibited significant variation across studies, lacking a discernible pattern or cluster (Fig. 2).

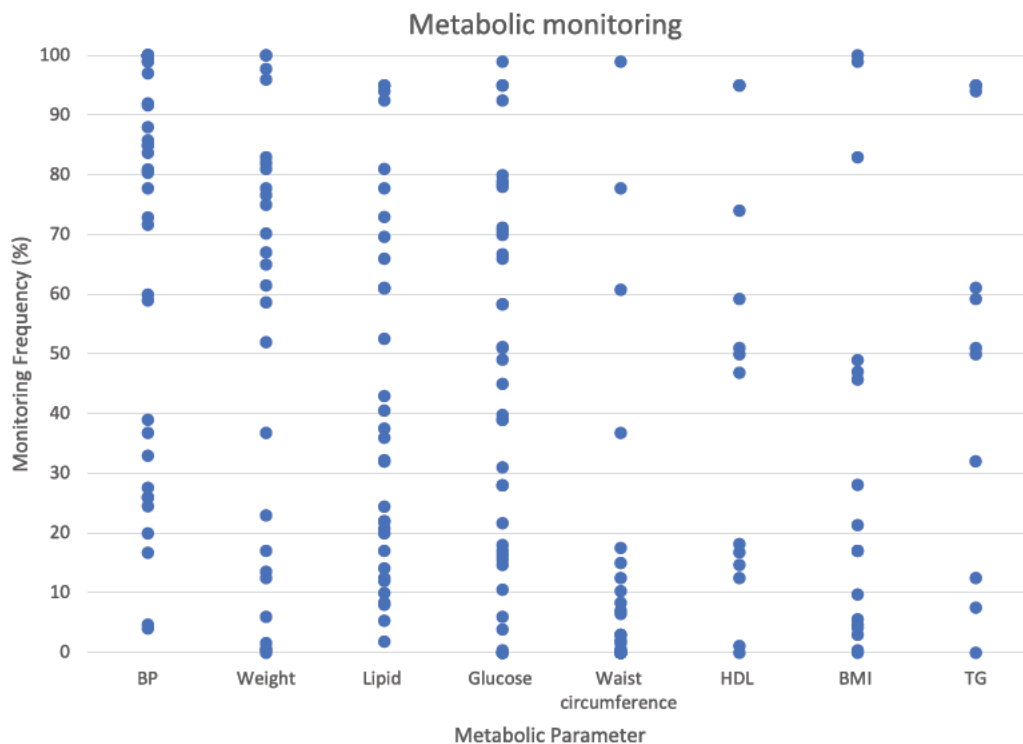


Fig. 2 The type and frequency of metabolic monitoring for different metabolic parameters reported by the 29 included studies.*Studies that reported the frequency of metabolic monitoring over multiple

years or where the prevalence was not reported were not included in this figure. Areas of overlap indicate that two or more studies reported similar monitoring rates

Even though the types of metabolic parameters monitored varied between the included studies, most of the studies did not report on all five metabolic parameters. Waist circumference, HDL, BMI and TG levels were not as frequently monitored in these studies. Najim and colleagues suggested that there was inadequate metabolic monitoring and reported that less than half (48.25%) had a baseline physical health examination (Najim & Islam, 2013). Similarly, Kioko and colleagues reported that only 22% of patients had appropriate laboratory tests available (Kioko et al., 2016). In contrast, a cross-sectional retrospective review of records for

people with SMIs revealed that most (83.1%) had evidence of routine blood monitoring (including glucose, cholesterol, HbA1c and TG) within the preceding two years (Pearsall et al., 2019).

Five studies explored the frequency of metabolic monitoring (retrospectively) at different time points (Feeney & Mooney, 2005; Marsay & Szabo, 2010; Mwebe et al., 2020; Najim & Islam, 2013; Poojari et al., 2020). Of these, four that examined the frequency of routine metabolic monitoring in the same cohort reported a reduction in monitoring rates for all metabolic parameters over time (Table 2) (Feeney

Table 2 Frequency of routine metabolic monitoring over time

Authors	Parameters	Baseline (%)	3-month (%)		Annually (%)		
Poojari et al., 2020 (Poojari et al., 2020)	Weight	Baseline: 60 1 month: 14.9 2 months: 2.5 3 months: 7.6	7.6	Quarterly: 9.8		79.4	
	Waist circumference	1	Not reported		0		
	Blood pressure	99.7	14.6			72.7	
	Glucose	47	12.4			72.7	
	Lipid	39.7	5.1			27.9	
Mwebe, Volante, and Weaver 2020 (Mwebe et al., 2020)	BMI	74	98				
	Waist circumference	Not reported	5				
	Blood pressure	90	100				
	Glucose	77	84				
	Lipid	59	79				
Najim & Islam, 2013 (Najim & Islam, 2013)	Weight	Baseline 10.77	6-month 1.54				
	Blood pressure and pulse	21.54	Not reported				
	Glucose	29.23	29.23				
	TG	6.15	3.08				
Feeney & Mooney, 2005 (Feeney & Mooney, 2005)	Weight	Baseline 40	Ongoing monitoring*				
	BMI	0	15				
	Blood pressure	45	17.5				
	Glucose	21.3	22.5				
	HbA1c	3.8	8.8				
	Lipids	6.3	17.5				
Marsay & Szabo, 2010 (Marsay & Szabo, 2010) (Outpatient)	Weight	Baseline 6	1 month 6	2 months 6	3 months 13	4 months 25	
	Blood pressure	6	6	6	6	6	
	Glucose	19	0	0	0	0	
	Lipids	13	0	0	0	0	
	Cholesterol	6	0	0	0	0	
Marsay & Szabo, 2010 (Marsay & Szabo, 2010) (Inpatient)	Weight	73.91	17.39	8.7	0	4.35	
	Blood pressure	100	82.61	52.17	21.74	17.39	
	Glucose	13.04	4.35	0	0	4.35	
	Lipids	17.39	4.35	4.35	0	4.35	
	Cholesterol	8.7	4.35	0	0	4.35	

*Evidence of monitoring test being carried out in the past year

& Mooney, 2005; Marsay & Szabo, 2010; Najim & Islam, 2013; Poojari et al., 2020). One study reported higher metabolic monitoring rates for all parameters (BMI, BP, glucose, lipid and electrocardiogram monitoring) except waist circumference for patients at three months after admission than at baseline (Mwebe et al., 2020).

Batscha and colleagues compared the frequency of metabolic monitoring across three different settings: inpatient, outpatient and metabolic clinic (Batscha et al., 2010). The authors reported that weight ($p < 0.001$) and BP ($p < 0.001$) were most frequently measured in an inpatient setting, while glucose ($p < 0.001$) and waist circumference ($p < 0.001$) were more regularly measured in the outpatient setting. Furthermore, waist circumference was more likely to be monitored in the metabolic clinic than in the inpatient unit ($p < 0.001$) (Batscha et al., 2010). Similarly, Marsay and colleagues reported that the metabolic parameters of the inpatient cohort were monitored more often than those of their outpatient counterparts (Marsay & Szabo, 2010).

Discussion

Metabolic monitoring for SMI appears suboptimal, and metabolic conditions such as CVD are often undiagnosed and untreated (Heiberg et al., 2019). Research to date has explored barriers to metabolic monitoring in the SMI, highlighting barriers at the individual, organisational, and systems levels (Ali et al., 2020; Cunningham et al., 2018). However, additional research is needed to address this gap (Solmi et al., 2021). This review explored the nuances of metabolic monitoring, offering an overview of current metabolic monitoring practices for SMI. Specifically, regarding the roles and responsibilities of healthcare professionals, specific metabolic parameters were monitored, as were the types of approaches and methodologies used in routine metabolic monitoring. Our findings have highlighted several gaps in current practice, including a lack of standardised metabolic monitoring procedures and processes and suboptimal metabolic monitoring rates for SMIs taking antipsychotics (Ali et al., 2021, 2023).

The uncertainty surrounding the specific roles and responsibilities of health professionals involved in care for SMIs can impede routine physical health monitoring (Mitchell et al., 2012; Poojari et al., 2023; Roughead et al., 2017). Clarity around who is involved in particular aspects of care is pivotal, particularly for SMI, as care is often delivered by a multidisciplinary team (Ali et al., 2020; Aouira et al., 2022; Roughead et al., 2017). The majority of studies identified in this review did not describe the specific roles and responsibilities of various healthcare professionals on clinical care teams. Although studies have listed the specific healthcare professional(s) involved in the care of SMI, often, their roles

and responsibilities have been poorly defined (Barnes et al., 2007, 2015, 2020; Batscha et al., 2010; Cotes et al., 2015; Fontaine et al., 2022; Gumber et al., 2010; Harrison et al., 2012; Hor et al., 2016; Mwebe et al., 2020; O'Callaghan et al., 2011; Ross et al., 2018; Stephenson et al., 2023; Thompson et al., 2011). Furthermore, none of the studies reported whether metabolic monitoring was mandated as part of routine care in the specific study setting. Most of the studies identified in this review involved interventional methods and therefore may not necessarily involve reporting on metabolic monitoring practices in a specific setting. In addition, word count limits imposed by journals could deter authors from reporting detailed metabolic screening and/or monitoring practices.

Only seven of the included studies reported the process involved in metabolic monitoring for SMI in a particular setting (Bomboy et al., 2021; Deuschle et al., 2013; Gumber et al., 2010; Kjeldsen et al., 2013; Lydon et al., 2021; Ross et al., 2018; Tatreau et al., 2016). Specific procedures and processes, such as whether blood samples were analysed onsite or off-site, were infrequently reported. Presumably, studies conducted within a hospital setting would have access to onsite pathology facilities, while primary care settings, such as general practices, would rely on offsite laboratories for analysis. However, this may not always be the case, such as in rural areas (Blattner et al., 2019). The absence of an onsite laboratory facility and services would reduce the accessibility and convenience of conducting and obtaining timely blood test results, therefore affecting metabolic monitoring rates. In addition, doctors had previously suggested that the lack of a notification system that alerts patients when blood test results are ready and/or when further action is required is a barrier to optimal metabolic monitoring (Aouira et al., 2022). Further attention is warranted to support healthcare delivery for vulnerable populations, including SMIs.

Aligned with the literature, our findings highlighted suboptimal metabolic monitoring for SMI (Ali et al., 2021, 2023; Mitchell et al., 2012). Among the studies included in this review, Lydon and colleagues recorded the highest rates of metabolic monitoring for patients with SMI who were taking clozapine (Lydon et al., 2021). This was not unexpected given the serious side effects and potential fatalities related to clozapine use (Kar et al., 2016). The prescribing and dispensing of clozapine are also associated with mandatory monitoring requirements in most countries, including Australia and the UK (Medicinewise, 2022; NHS Trust, 2023). However, monitoring of other SGAs requires further attention; for example, Keenan and colleagues reported that none of their study participants ($n = 117$) were fully monitored according to the RANCZP monitoring guidelines (Keenan et al., 2020). Previous reports had identified a number of barriers to routine metabolic monitoring, including

patient-related barriers such as the perception of laboratory testing as aversive and intrusive (O'Brien & Abraham, 2021) and low levels of health literacy or awareness (S. Saloojee et al., 2014a, 2014b). The clinician-related factors identified included insufficient time (Kioko et al., 2016) and/or lack of reimbursement (Batscha et al., 2010). Future research initiatives to improve metabolic monitoring for SMI should consider previously identified, in addition to any other barriers that may be relevant to the particular setting or demographic. It is worth noting that given the variability across the studies reported (e.g. settings and countries), the perceived suboptimal monitoring in some contexts may be considered acceptable in others.

Our review revealed that parameters such as waist circumference and BMI are often poorly measured (Fig. 2). Barriers to frequent monitoring of these parameters, particularly waist circumference, have been previously explored in the literature (Hor et al., 2016; Mitchell et al., 2013; Verdoux et al., 2010). One study attributed low waist circumference monitoring rates to patients' preferences for healthcare professionals of the same sex, who may not always be readily available (Hor et al., 2016). Verdoux and colleagues also cited sex differences as a potential barrier, noting that psychiatrists might be reluctant to perform physical examinations, especially for female patients, as such examinations can be "*construed as invasive (such as waist measurement)*" (Verdoux et al., 2010). There is a need to improve waist circumference monitoring rates in the SMI, particularly because it has been shown to be a useful predictor of Met-Syn, with high rates of sensitivity and specificity (Mitchell et al., 2013).

The observed variation in metabolic monitoring rates between settings should be noted by clinicians and policymakers. At a practice level, clinicians should recognise that patients may not receive regular metabolic monitoring as suggested by existing guidelines. Consideration for the need and potential value of metabolic monitoring should be considered at patient interaction and a review should be initiated if deemed appropriate. Policymakers (e.g. in hospitals) should also facilitate frequent metabolic monitoring within their local settings. This can be achieved through local quality improvement efforts and implementation of mandatory clinical guidelines and/or policies at an organisational level, which can influence clinical practice. Clinical guidelines and/or policies must be tailored towards the needs of the particular site and consider other factors including staffing and resourcing requirements.

Strengths and limitations

A strength of this review was the methodologically rigorous search of published and grey literature in line with JBI recommendations. The search strategy, including its

translation across databases, was guided by an academic librarian, and reviewed by the research team to ensure that a comprehensive and relevant search was conducted. However, this review included only English-language studies and was mostly based in the UK and US and from tertiary settings (hospital, inpatient and outpatient services). This skewed representation may reduce the generalisability of the present findings to other countries and settings.

Future Research

Despite the publication of practice guidelines, these findings suggest that metabolic monitoring in practice remains suboptimal, with procedures and processes varying between settings. As most of the studies included in this review did not report on the metabolic monitoring processes at the local site, we were unable to review and identify factors that influenced metabolic monitoring rates. Future research should consider the need to explore local metabolic monitoring practices, particularly to identify the barriers and facilitators relevant to the specific setting.

While this review echoes findings from previous research (Mitchell et al., 2012), it also highlighted the observed variation in metabolic monitoring. Future studies should also consider exploring the temporal trends to compare the prevalence of metabolic monitoring over the years.

Future practice guidelines should consider recommending and specifying the roles and responsibilities of healthcare professionals in metabolic monitoring for SMI. Researchers should clearly describe the local metabolic monitoring practices and/or procedures where possible to allow their findings to be appropriately interpreted and to facilitate the implementation of interventions in other settings where practices and/or procedures may differ. There is a need for ongoing research, particularly in the community setting, to promote increased accessibility to metabolic monitoring for SMI.

Conclusion

This scoping review mapped out the nuances of metabolic monitoring in practice. The most common settings, types of parameters measured, and health professionals involved in metabolic monitoring were summarised. The scoping review indicates that no streamlined approach toward metabolic monitoring currently exists, with variations observed between different settings and countries. This information highlights the need for a more systematic approach to metabolic monitoring for SGA patients with SMI. Our findings also highlight the need to clearly stipulate and define the roles and responsibilities of all health professionals involved

in metabolic monitoring for SMI. Clinicians should be aware of the existing variations in metabolic monitoring and policymakers should consider the need to facilitate metabolic monitoring at an organisational level, taking into consideration existing resources and the specific needs of the organisation.

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Declarations

Competing interests The authors declare that they have no competing interests.

Ethical Approval Not applicable.

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Chapter Summary

Overall, the findings from this scoping review further suggested that metabolic monitoring for people with SMI taking SGAs has been suboptimal and metabolic monitoring process often varied between different settings and countries. The review also identified the need for more clarity around the role of health professionals in metabolic monitoring for people living with SMI.

Due to resource and timing constraints, the scoping review focused only on SMI, however; it is likely that similar disparities exist across various mental disorders [267]. Therefore, all PLMI using SGAs would benefit from more metabolic monitoring, especially considering the well-recognised metabolic adverse effects associated with SGA use. The scoping review also identified the paucity of pharmacist-led interventions to improve metabolic monitoring rates for PLMI. This further supports the need for research in this area. The next chapter will report on the feasibility of a pharmacist-led metabolic monitoring program for PLMI.

Supplementary Files C: Search Strategy

Supplementary Information 1: Search strategy for Medline

Mental Disorders/

exp "Bipolar and Related Disorders"/

exp Mood disorders/

Mania/

exp "Schizophrenia Spectrum and Other Psychotic Disorders"/

((mental* or neurodevelopment* or behaviour or behavior or psychologic* or neuropsychiatr* or neuro psychiatr* or psychiatr* or psychopatholog* or psycho patholog* or psychic or psychotic or psychos*) adj5 (confusion or defect or change or symptom* or insufficien* or abnormal* or episode* or disorder* or condition* or ill* or feature* or spectrum or state or disease or disturb* or confusion or defect* or diagnos*)).ti,ab,kf.

(Insan* or bipolar or bi polar or schizophreni* or schizo phreni* or schizo affective or schizo affective or paranoi* or delusion or mania or manic or bipolar or bi polar or cyclothymi* or psycho* or mood or hallucin* or hypomania or hypo mania).ti,ab,kf.

((depress* or cyclothymi* or affective or mood) adj2 (psycho* or disorder* or disturbance or illness*)).ti,ab,kf.

(schizophreni* or schizo phreni* or dementia praecox or depress* or melancholia or paraphrenia* or para phrenia).ti,ab,kf.

((schizophreni* or schizo phreni* or affective) adj2 (psychos* or incipient or borderline or latent or disorder or pseudoneurotic or pseudo neurotic or pseudopsychopathic or pseudo psychopathic)).ti,ab,kf.

Mentally ill persons/

((mental or psychiatr*) adj2 (patient* or diagnosis* or state or person* or people)).ti,ab,kf.

1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12

Tranquilizing agents/

exp antimanic agents/

exp antipsychotic agents/

(antipsycho* or anti psycho* or antimani* or anti mani* or neuroleptic* or tranquiliz* or tranquilis* or anti schizophren* or antischizophren* or psychotropic).ti,ab,kf.

(Droperidol or zuclopenthixol or clozapine or chlorpromazine or flupentixol or haloperidol or iloperidone or lumateperone or lurasidone or olanzapine or paliperidone or quetiapine or risperidone or ziprasidone or aripiprazole or trifluoperazine or cariprazine or pimavanserin or pericyazine or periciazine or amisulpride or asenapine or brexipiprazole).ti,ab,kf.

14 or 15 or 16 or 17 or 18

Metabolic diseases/

exp Heart Disease Risk Factors/

exp Diabetes Mellitus/

exp overweight/

body mass index/

Hyperglycemia/

hypertension/

exp insulin resistance/

blood pressure/

Lipids/

triglycerides/

cardiovascular diseases/

exp body size/

(body size or waist circumference or body composition or body weight* or body height or body measure* or anthropometr* or waist size).ti,ab,kf.

(insulin resistance or metabolic or cardiometabolic or cardio metabolic or dysmetabolic or dys metabolic or Reaven or cardiovascular or cardio vascular or syndrome X).ti,ab,kf.

(diabetes or glucose or hyperglycemi* or hyper glycemi* or hyperglycaemi* or hyper glycaemi* or HbA1c or hemoglobin A1c or hyperinsulin* or hyper insulin*).ti,ab,kf.

(obesity or overweight or over weight or weight or body mass index or BMI).ti,ab,kf.

(dyslipidemia or dys lipidemia or triglyceride* or lipid* or cholesterol or cholesterolemia or hyperlipidemia or hyper lipidemia).ti,ab,kf.

(hypertension or hyper tension or blood pressure or BP or diastol* or systol*).ti,ab,kf.

20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38

Mass Screening/

Monitoring, Physiologic/

((screen* or measur* or examin* or monitor* or assess* or evaluat* or manage* or intervention or intervene or improve) adj5

(physical or health or physiologic* or routine or practice* or patient or metabolic or cardiometabolic or cardio metabolic)).ti,ab,kf.

40 or 41 or 42

13 and 19 and 39 and 43

6 Feasibility of a pharmacist-led physical health monitoring program for patients on antipsychotic medications

Chapter Overview

This chapter described the process of designing and evaluating the feasibility of implementing a pharmacist-led physical health monitoring program for patients using antipsychotics, specifically SGAs, in the community (aims 4 and 5). The chapter will cover the following:

- 1) Describes the development of the study protocol,
- 2) Presents the published protocol (aim 4),
- 3) Describes the development of the pharmacist refresher training course for participating pharmacists,
- 4) Describes the methods used, including data collection, analysis and justification for methods and,
- 5) Results and Discussion of the implementation of the pharmacist-led monitoring program (aim 5)

Background

PLMI including conditions such as schizophrenia and bipolar disorder have a high prevalence of metabolic complications, particularly MetSyn, with rates as high as 32.5% [268]. MetSyn predisposes the individual to several complications, including heightened risk of infections and cardiovascular events, and higher risk of extended hospital stays and premature death [146, 155, 156].

While reasons for the reported high rates of MetSyn in PLMI are multifactorial, the use of medications such as antipsychotics has been identified as a contributing factor [180]. Despite this, antipsychotic medications, especially SGAs remain pivotal in symptom management [160]. To optimise physical and mental health for PLMI using SGAs, most practice guidelines have highlighted the need for frequent physical health monitoring [141, 151, 167]. However, as discussed in previous chapters (Chapter Two and Five), rates of metabolic monitoring have been reported to be insufficient in people living with SMI [164]. The findings from the scoping review (Chapter Five) also highlighted that metabolic monitoring processes often varied

between different settings and countries. The review also further highlighted the need for better stipulations around the role of health professionals in metabolic monitoring for people living with SMI. While the study pertained specifically to people living with a SMI, it is likely that the findings can also be extrapolated for PLMI more broadly.

As highly accessible and trusted health professionals [27, 56], pharmacists can play a pivotal role in disease prevention (e.g. screening for diabetes), detection (e.g. measure blood pressure and lipid levels etc) and chronic disease management (e.g. disease-specific goal setting) [269, 270]. Existing Australian government-funded community pharmacy-based programs, such as the Diabetes Medscheck, involve a one-to-one consultation between the pharmacist and eligible patients to help them understand their diabetes medicines and improve the use of self-monitoring devices and improve blood glucose parameters [256]. Community pharmacies also offer general health screenings or checks which includes the review of physical health parameters such as, blood pressure, cholesterol levels and blood glucose levels. It is worth recognising that the nature of these physical health checks vary between pharmacies [271-273]. Furthermore, these services are not government-funded or subsidised and therefore have an associated fee for the consumer.

Currently, the role of community pharmacists in monitoring and improving physical health in PLMI remains largely unexplored [274, 275]. Existing studies involving pharmacists have mostly been based within secondary and tertiary care settings such as outpatient clinics or hospital wards, where they are often involved as part of multidisciplinary teams to improve metabolic screening in PLMI [187, 189, 191, 276]. One study by Maulavizada and colleagues, reported on the implementation of a nurse practitioner-led metabolic clinic within a community pharmacy setting reporting positive “trends” for 20 patients [187]. The scarcity of community pharmacist-led physical health monitoring for PLMI [191, 277], especially in an Australian setting [193], justified the need for further research in this area [274].

Indeed, the viability of pharmacists and pharmacies in supporting PLMI is currently being explored, a study protocol by Wheeler et al. described a comprehensive pharmacy-based randomised controlled trial (RCT) for people living with SMI (PharMIbridge) [193]. This RCT focused on exploring the impact of pharmacist’s contribution to consumers’ medication adherence and improving physical health outcomes through the provision of individualised goal setting. However, the RCT had a relatively short follow-up period (6 months) and did not collect all the metabolic parameters necessary to diagnose MetSyn. Building on the current

literature, this study aimed to determine the feasibility of a community pharmacist-led physical health monitoring service for metabolic parameters in consumers with mental illness currently taking SGAs. This was achieved by: (i) designing a novel pharmacist-led monitoring program to support PLMI's physical health whilst on SGAs (Protocol) and, (ii) exploring the feasibility of the physical health monitoring program with PLMI and on SGAs.

Part One: Development of the protocol

Literature Review

To guide the design of the protocol, a literature review was conducted (5th of April 2020). A database search of Medline, Embase and Google Scholar explored the current role of community pharmacists in mental health and point-of-care testing. The database search used the following terms (combination of): “point of care testing”, community “pharmac*” OR “community pharmacist*”, “mental illness” or “mental health”, “physical health monitor*” OR “physical health check*”, “chronic disease management” and “service*”. Research articles generated were imported and managed by the Endnote referencing program.

The review indicated that there was a lack of consensus and evaluation regarding the appropriate follow-up time points for metabolic screening. At the point of designing the protocol, there was a limited number of published protocols for metabolic screening by community pharmacists. These were used as a general guide in addition to existing guidelines, for the methodology proposed in the protocol [191, 193]. Existing guidelines, including the Australian consensus statement on metabolic monitoring for people on antipsychotics, highlighted the need for “regular” physical health monitoring, but did not stipulate specific timeframes for these follow-ups [145]. Recommendations by the former Australian National Prescribing Services in Australia suggested the review of metabolic parameters should be carried out at least annually for clients on all antipsychotics except olanzapine (suggested 6 monthly reviews), whilst other factors including lifestyle monitoring should be assessed at every prescriber visit (Table 7)[278]. Given the absence of consensus around monitoring intervals, for example “every visit” could be monthly for some whilst annually for others, a time frame of three months for follow-ups was proposed as this was deemed to be a viable time frame for participants to work on their goals and to fit with pharmacists' workloads. The suitability of three months as a follow-up interval was assessed as part of study's feasibility.

The selection of parameters to be measured was informed by both national and international guidelines [141, 163, 278]. The program was tailored to suit the skillset and training of

pharmacists within the community pharmacy setting. MHFA [211] was not provided to the participating pharmacists due to both time and funding constraints (standard adult course - 12 hours and cost). However, it was perceived that participating registered pharmacists have experience and knowledge that would enable them to adequately support PLMI.

Currently, the provision of basic lifestyle advice (for example, smoking cessation and diet) and point-of-care testing (such as, blood pressure and blood glucose) is often a standard part of routine community pharmacy practice; as such comprehensive training in these topics were not required [279]. Parameters such as serum creatinine and uric acid levels were beyond the scope of pharmacy practice and as a result were not included in the study. As obstructive sleep apnoea (OSA) has been recognised as a manifestation of MetSyn [280], the protocol stipulated the need for an OSA screening for all participants at baseline. This was conducted using the snoring, tiredness, observed apnoea high BP, BMI, neck circumference and male gender (STOP-Bang) questionnaire⁴ [281].

Table 7. Suggested frequency of review and ongoing monitoring for people taking antipsychotics long term. Table re-drawn from NPS website [278].

Parameter	Frequency
Weight and waist circumference	Every visit
Blood pressure	Olanzapine – 6 monthly All others – annually
Fasting serum lipids	Olanzapine – 6 monthly All others – annually
Fasting blood glucose	Olanzapine – 6 monthly All others – annually
Electrocardiogram	Annually
Ask about extrapyramidal symptoms and examine for rigidity, tremor and abnormal involuntary movements (i.e. tardive dyskinesia)	Every 6 months
Ask about menstrual and sexual problems, gynaecomastia and galactorrhoea. Test prolactin levels if symptoms suggest hyperprolactinaemia.	Annually
Ask about any other adverse events e.g. sedation, anticholinergic effects	Every visit
Ask about smoking status	Every visit
Ask about alcohol and illicit drug consumption	Every visit

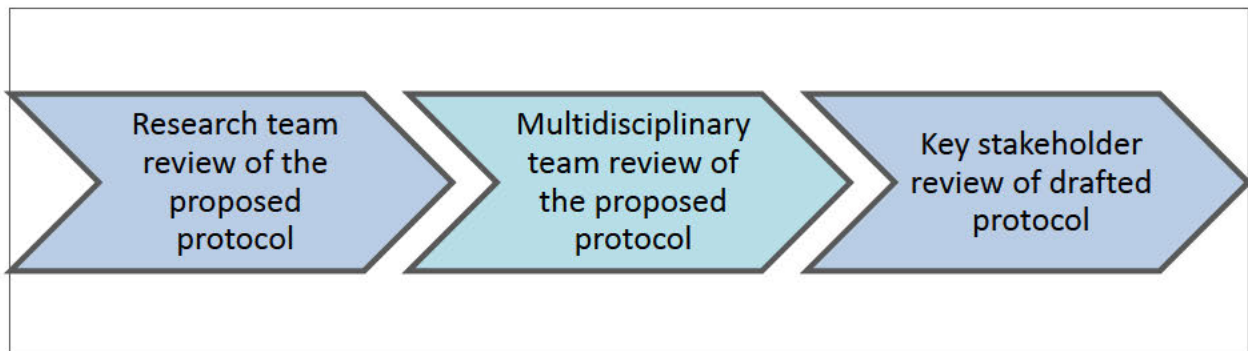
*Additional monitoring is recommended when treatment is started, or for people with risk factors for adverse events (e.g. hepatic impairment). Patients receiving clozapine have specific, mandatory monitoring requirements that are not described in this publication.

⁴ STOP-BANG Questionnaire is a tool used to screen patients for risk of OSA.

Protocol review

The protocol was reviewed in three stages (Figure 3). Firstly, the proposed protocol was reviewed by members of the research team (VS and EH) for relevance and viability prior to presenting at one of the virtual weekly multidisciplinary team meetings with participants such as pharmacists and medical doctors, and generated input and feedback. The review was conducted via Zoom in June 2020 and all feedback provided was documented by researchers TB and VS during the presentation. The protocol was updated to incorporate suggested changes from the presentation [282]. Finally, the drafted protocol was reviewed by key stakeholders, including an accredited practicing dietician, community pharmacists (n=2) and a consultant psychiatrist.

Figure 3. Review of protocol.



A summary of feedback from the multidisciplinary team presentation and individual review of the amended protocol is presented in Table 8. The proposed protocol initially focused specifically on physical health monitoring, consisting of two broad components of medical history collection and measuring of metabolic parameters. At the time, the draft protocol had intentionally omitted the reviewing of participants' lifestyle factors such as diet and physical activity due to time constraints. However, comments from multiple reviewers highlighted the value of discussing diet and physical activity with participants. Discussion about lifestyle factors was believed to be empowering for participants and an opportunity to raise awareness on the risk of MetSyn and facilitate early intervention. In addition, one reviewer highlighted the importance of informing PLMI's treating doctor of their study involvement. These suggestions were incorporated into the final protocol.

Individual reviews by the community pharmacists, dietician and psychiatrist also generated valuable feedback. The community pharmacists did not express any concerns regarding the

potential incorporation of the proposed physical health monitoring program into the current pharmacy workflow. However, it was expressed that there might be a need for equipment (such as glucose meters) to be regularly calibrated to ensure the accuracy of the results. A further face-to-face discussion session with an accredited practising dietician resulted in the incorporation of the metabolic syndrome guideline by the Royal College of General Practitioners as a reference guideline for the program.

Table 8. Reviewer's comments and action taken.

#	Reviewer's comments	Comments
1	Measure duration of the consultations	Included as a measured endpoint
2	Include more relevant allied health professionals to enhance collaborative approach	Inclusion of multidisciplinary team (including psychologist, diabetes educator, dietician and consumer/end-user) in the pharmacist refresher training (as trainers)
3	Inform consumer's GP	Participants will be given a letter to inform their GP general of their participation
4	Include The Royal Australian College of General Practitioner's (RACGP) Metabolic Syndrome Guideline used for referral	RACGP metabolic values used as referral cut-off for study
5	Include review of lifestyle factors (for example, discussion around diet and exercise)	Program revised to ensure more holistic approach
6	Importance of each site having either using the same glucose and lipid meters or for them to be calibrated	Pharmacy sites will be supplied with the blood cholesterol and blood testing machine (CardioChek) and lipid panels. Due to limited funding, frequent calibration was not supported. As the purpose of the study is to screen and provide early referral rather than make a diagnosis, the calibration of equipment was not deemed as mandatory for the purpose and duration of this study.
7	Consider that consumers may have multiple GPs.	Protocol now stipulates that referral should be made to participant's nominated GP.

Part Two: Pharmacist Refresher Course

The training course for participating pharmacists was designed as a ‘refresher’ to facilitate the implementation of the physical health monitoring program. The refresher training course (hereon referred to as training course) recognised the existing knowledge and skills of registered community pharmacists, who have completed tertiary education, internship and continual professional development requirements Australia [283, 284]. As such, the training course aimed to refine these skills rather than establish new skills.

Development of learning objectives

The development of learning objectives (LOs) for the training course was guided by existing literature. A search of databases including MEDLINE (Ovid) and Google Scholar was conducted in 2020 using combinations of keywords and MeSH terms such as “community pharm*”, “pharmacist-led”, “service*”, “intervention*”, “diabetes OR type 2 diabetes OR diabetes mellitus”, “weight OR weight loss OR weight management” and “mental health OR mental disorder.”

Studies were reviewed by the candidate for relevance and feasibility within the Australian setting as guided by the candidate’s experience as a practicing pharmacist. Studies that did not report training content or LOs were excluded. To ensure that the literature was relevant to contemporary practice, only studies published after the year 2000 were included. All studies that were pharmacist-led and within the areas of: (i) weight management, (ii) diabetes management and (iii) mental health focused (for example, depression screening) were deemed to be relevant and hence included in the development of the LOs.

Diabetes management

Previous training programs designed for community pharmacist-led diabetes management included a skills component (such as, how blood glucose testing devices should be used) as well as the brief pathophysiology and pharmacotherapeutics of diabetes (Supplementary File D)[285-287]. All the training programs reviewed had a multi-component structure, which required prior self-study before participation in the training program [285-287].

Given that this study did not solely focus on diabetes management, it was not deemed necessary for pharmacists to complete an extensive component of self-study prior to participation. The training course was designed to ensure that participating pharmacists were equipped with the essential skills necessary to collect blood samples efficiently and safely for blood glucose and

cholesterol testing. Therefore, the training for this study was tailored to focus on the practicalities of conducting physical health monitoring in community pharmacies.

Weight loss

Prior lifestyle-focused pharmacy-led weight loss studies involved extensive training designed and conducted by dietitians (Supplementary File E). All the training programs reviewed were designed as face-to-face training sessions [288-290]. Broadly, the LOs were focused on (i) healthy eating and (ii) behaviour change strategies. Healthy eating was often promoted through the provision of an eating plan or lifestyle changes [288, 289]. As the training methods and objectives were relevant for the purpose of this study, they were included in the training course for participating pharmacists.

Mental health

Identified studies predominantly screened for depression (Supplementary File F and G). Training content from these studies focused on: (i) communication [67, 193, 291, 292] including simple goal setting [67, 292, 293]. For this study, a comprehensive discussion on the pharmacotherapy was not deemed necessary and therefore not included in the training course.

Recruitment of trainers

To promote interdisciplinary collaboration, trainers with related professional experience in the field of diabetes education, psychology, and dietetics were recruited. An end-user with lived experience (mental illness) was also recruited to the team. Recruited trainers were not involved in the reviewing of the protocol. The PhD candidate, TB reached out to personal networks to recruit eligible trainers. All trainers were reimbursed for the development of training content (Health professionals, 3hr x AUD \$80 and, end-user AUD \$50 gift voucher).

All trainers for the training course were based in Adelaide, South Australia, except for the psychologist who was based in Canberra, Australian Capital Territory. Although not stipulated as a recruitment criterion, all trainers, except for the end-user, were also registered pharmacists with community-based experience. The end-user, KB, was also a qualified peer support worker, referred to as a peer practitioner, who was affiliated with a NFP organisation that supports PLMI in the community.

Learning objectives for the Training Course

LOs from studies identified in the literature review were collated and reported to recruited trainers for further input before finalisation (Table 9). Notably, the development of an eating

plan was not included in the LO as the dietician trainer highlighted that this may be inappropriate for a community pharmacy setting. The development of a diet plan must be tailored to an individual's dietary needs, requiring a thorough evaluation of the individual's health history, lifestyle, and dietary preferences. Given the time constraints, this was determined to be beyond the scope of this study. Instead, pharmacists were encouraged to work with participants in setting "achievable" goals at each consultation for review at subsequent follow-ups.

The contribution and value of including a consumer educator had been explored and recognised in previous studies [293-295]. Therefore, the mental health component of the refresher program was delivered by two trainers, SS (psychologist) and KB (consumer/end-user/peer practitioner). The training delivered by SS addressed fears and stigma experienced by PLMI as well as outlined the importance of effective and appropriate communication skills (Table 9). The presentation also provided guidance on the appropriate course of action for a mental health crisis and steps to take during an emergency. Online resources were also provided for the pharmacists by the trainer for further reading. Contrastingly, the content provided by KB (consumer/end-user) addressed the LOs from a consumer's perspective. In particular, it included: describing the experience of the consumer, how pharmacists can better support mental health consumers, and highlighting the barriers and facilitators present in community pharmacies.

Table 9. Learning objectives covered by respective trainers.

Trainer	Learning Objective
PhD Candidate	About the Study
	<ol style="list-style-type: none"> 1. Introduce the study's aims and objectives. 2. Understand the role of the pharmacists in the service provision. 3. Explained the electronic templates supplied (such as the STOP-Bang questionnaire and data collection form). 4. Ethical implications, including the need for information provision and written consent in addition to safe storage of collected data.
Dietician	Nutrition intervention and challenges to manage metabolic adverse effects of antipsychotic drugs in patients
	<ol style="list-style-type: none"> 1. Introduce MetSyn and risk factors for metabolic dysregulation. 2. Introduction to Australian Guide to Healthy Eating. 3. Identifying challenges in behavioural changes and strategies to support patients. 4. Recognise the roles pharmacists and dietitians have in supporting people with mental health issues. 5. Recognise how pharmacists and dietitians can enhance collaboration in practice to optimise mental health related patient care. 6. Identifying available online nutrition resources for patient information.
Diabetes Educator	Blood glucose testing in community pharmacy
	<ol style="list-style-type: none"> 1. Introduce antipsychotics and their effect on metabolism and glycaemic management. 2. Understand the practical aspects of BGL testing. 3. Understand the procedure for testing BGLs. 4. Confidence in interpreting results. 5. Understand common errors associated with BGL testing. 6. Confidence in being able to support PLMI in effective goal setting.
Psychologist	Supporting PLMI
	<ol style="list-style-type: none"> 1. Understand the consumer's experience. 2. Describe the fears and stigma experienced by mental health consumers and carers living in the community. 3. Identify appropriate and effective communication skills when working with consumers and carers. 4. Understand how to refer consumers who are at risk, to an appropriate health professional. 5. Understand what to do in case of a mental health crisis. 6. Understand what steps to take in an emergency situation. 7. Know how to access emergency contacts/hotlines/ reliable online resources.
Consumer/End-user	Mental illness – a consumer's and carer's perspective
	<ol style="list-style-type: none"> 1. Describe the impact of mental health symptoms on the lives of consumers and carers. 2. Describe the fears and stigma experienced by mental health consumers and carers living in the community. 3. Describe the needs and facilitators that mental health consumers and carers identify to support their recovery. 4. Understand how community pharmacists can better support consumers and carers in the management of mental illness.

	5. Be able to identify barriers and facilitators that impact on consumer and carer experiences in a community pharmacy setting.
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The structure of the training workshop centred on communication (for example, use of inclusive terminology for PLMI), development of technical skills (such as use of glucose meters), and familiarisation with supplied materials and study questionnaires.

Delivery of the Training Course

It was recognised that face-to-face training was often the preferred delivery method of instruction for pharmacists' training programs (Supplementary Files D to G). However, due to the pandemic, the training for this study was delivered via an online platform. The training course was made available through the University of South Australia's Research Data Storage (RDS) system. Presentations were recorded between January and February 2021 via Zoom. Each session ran for approximately 35-40. All presenters were required to supply 3-4 assessment questions to assess participating pharmacists' competency post training. Pharmacists had access to the pre-recorded online training materials for the entire duration of the project and could complete the training at their own pace before recruiting participants. They were able to re-visit the content at any time for the duration of the study if required, even after completing the training. Participating pharmacists were required to complete an assessment (see Appendix D) at the end of the training program for which a pass mark of 80% was required. However, there were no limits to the number of attempts to achieve 80%. While there was no formal Questions and Answers session held, pharmacists were encouraged to contact the PhD candidate and trainers for clarification or if they had any questions.

Part Three: Published protocol

Publication Overview

The protocol was reported in accordance with the SPIRIT 2013 Statement: Defining standard Protocol Items for Clinical Trials [296].

Citation Details



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BMJ Open Feasibility of a pharmacist-led physical health monitoring for patients on antipsychotic medications: protocol for a longitudinal study

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ABSTRACT

Introduction Physical health conditions are the leading causes of death in people living with severe mental illness. In particular, the risk of metabolic syndrome; the constellation of abnormalities in weight, blood pressure, blood glucose and lipid levels, is high in this cohort. It has been recognised that commonly prescribed pharmacological agents for mental illness can further amplify the risk of developing metabolic syndrome; therefore, monitoring guidelines are in place for consumers prescribed antipsychotics. However, there is a disconnect between recommended guidelines and current practice. Our study aims to investigate: (1) the feasibility of a community pharmacist-led physical health monitoring for metabolic parameters in consumers with mental illness currently taking second generation antipsychotics and (2) the potential outcomes of the intervention (eg, rates and outcome of referrals to general practitioners, relationship between the pharmacist's lifestyle counselling advice and change in metabolic parameters).

Methods and analysis We propose a longitudinal metabolic monitoring study led by community pharmacists with one-to-one consultations between trained pharmacists and participants at set intervals over a 12-month period. Our primary outcome is to determine the feasibility of the pharmacist-led intervention. The secondary outcome is to explore the overall health outcomes of consumers enrolled in the intervention. This is a mixed-methods study including both quantitative and qualitative outcomes. Qualitative data will be analysed via the process of data immersion, coding and identification of themes. Quantitative outcomes will be analysed using IBM Statistics SPSS software. Univariate descriptive, regression analysis and dependent t-tests will be performed. Statistical significance will be at α 0.05.

Ethics and dissemination Our study has been approved by the institutional Human Research Ethics Committee (Protocol no: 203433). Findings will be made publicly available in peer-reviewed articles, conference presentations to health professionals, as well as other stakeholders. Protocol V.2.1, August 2021.

Trial registration number ACTRN12621001435875.

INTRODUCTION

Mental illness is often associated with considerable disability and reduction in quality of life.¹ Individuals with severe mental illness

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A strength of the study is the longitudinal design with quarterly metabolic monitoring during the 12-month follow-up.
- ⇒ Post-intervention interviews with pharmacists and consumers will consider intervention feasibility and acceptability from multiple perspectives.
- ⇒ One strength is the strong involvement of both practising and academic pharmacists in the conceptualisation of the study.
- ⇒ As this feasibility study will be implemented in a small number of sites, findings may not be generalisable to pharmacy practice in other jurisdictions (eg, Europe and the USA).
- ⇒ The study focuses on metabolic syndrome, therefore, it generates limited data on other adverse effects associated with long-term use of second-generation antipsychotics.

have a reported 10–25 years reduction in life expectancy compared with the general population.² Leading causes of death are often related to physical health conditions, including cardiovascular diseases, diabetes and hypertension.^{2–3} Metabolic syndrome (MetS) refers to the simultaneous elevation in weight, blood pressure, blood glucose and lipid levels. Individuals with MetS are at significantly higher risk of cardiovascular events and premature death.^{4–7}

The prevalence of MetS is high in mental health consumers. An Australian survey studying individuals with psychotic illness found that nearly 50% of respondents meet the criteria for MetS.⁸ Research indicates that individuals with mental illness are at an increased risk of developing MetS.⁹ While the reason for the increased risk of MetS in this cohort may be multifactorial, pharmacological agents play a key role. Commonly prescribed agents such as second-generation antipsychotics (SGAs) can further amplify the



risk of developing MetS.^{5,10} Despite these known adverse effects, SGAs are currently the most effective treatment option for consumers with some forms of mental illness.¹⁰ Guidelines have highlighted the importance of regular metabolic monitoring in order to facilitate early identification of risk factors, allowing for the implementation of preventative strategies to minimise any long-term complications.^{11,12} Currently, metabolic monitoring rates are inadequate¹³; this is perturbing given the increase in prescribing of SGAs in Australia.¹⁴

A US-based psychiatrist survey found that while psychiatrists were aware of the metabolic consequences of SGAs, the monitoring of metabolic parameters, such as waist circumference was not routinely performed.¹⁵ Similarly, Roughead *et al* found that routine screening for MetS in this high-risk population was also inadequate within the Australian context.¹³ Psychiatrists often consider their primary role as providing clinical care in psychiatric symptoms control and are often reluctant to monitor for physical health.¹⁶ Furthermore, competing demands and lack of staff in medical clinics are other potential barriers.¹⁶ Mental health consumers also experience greater travel difficulties and report not having a regular medical professional. These are all significant barriers that can hinder mental health consumers in accessing metabolic monitoring.^{16,17} There is a need to improve access to physical health screening and there is potential for pharmacists' involvement in this area.^{18,19}

Community pharmacists are the most accessible health-care professionals and are often the first point of contact for patients. Evidence suggests that patients see their community pharmacist up to ten times more often than their general practitioners (GPs).²⁰ Additionally, community pharmacists are a trusted source of advice and their education and specialised training enables them to offer clinical advice and provide recommendations regarding medication use and patient monitoring.^{21,22} In recent years, the scope of practice for community pharmacists often includes provision of professional services in the management of chronic medical conditions. There are currently several examples of successful pharmacist-led interventions, specifically in diabetes,^{23,24} hypertension,^{25,26} cardiovascular disease,^{27,28} asthma²⁹ and weight loss.^{30,31} An umbrella review by Newman *et al*, revealed the positive impact of pharmacist-led interventions and further highlighted the capacity of community pharmacists in delivering chronic health management services.³²

Previous community pharmacist-led mental health services have focused on the screening of depression and/or anxiety and medication optimisation.^{33,34} Screening for depression by pharmacists had a positive impact on patient care³³ as well as providing opportunities for referral to appropriate healthcare professionals.³⁴ A US-based pharmacist-led depression screening programme found that 60% of the pharmacist referrals resulted in modification or initiation of treatment.³³ Furthermore, an Australian study demonstrated that the provision of goal-orientated medication support service

by trained pharmacy staff resulted in significant improvements in overall perceptions of illness ($p < 0.001$), the mental health domain of quality of life ($p < 0.001$) and global satisfaction with medication ($p < 0.001$).³⁵ A literature review of 38 papers concluded that pharmacy professional services supporting consumers with depression can also lead to a reduction of adverse effects, facilitate timely identification of potential and actual drug related problems and improvements in consumers' quality of life.³⁶

There have also been a number of successful community pharmacist-led services involving point-of-care monitoring and patient education. For example, Krass *et al* found that pharmacist-led medication management was able to significantly reduce blood glucose levels from 9.4 mmol/L to 8.5 mmol/L ($p < 0.01$) over 6 months.³⁷ In addition, Um *et al* highlighted the effectiveness of a community pharmacist-led weight management programme.³⁸ This interventional study explored the effectiveness of a non-product centred pharmacy-based management programme over a period of 3 months and found that all programme completers had lost some weight (mean weight loss of 3.5 kg). The programme also showed a statistically significant reduction in the amount of self-reported sweet snacks consumption and increase in the consumption of vegetables and fruit in participants ($p < 0.05$).³⁸ However, both these studies had limited follow-up and the authors recognised that a longer duration was needed to ascertain the sustainability of changes identified.

The role of pharmacists in metabolic monitoring has been explored in a limited number of studies. For example, a study in the USA that implemented MetS screening in a community pharmacy generated positive results.³⁹ Pharmacists involved in the study provided point-of-care testing of metabolic parameters and education for participants in a scheduled appointment. Participants were then followed up after 3–6 months to assess for lifestyle changes. This study found that participants were more likely to implement lifestyle modifications after an educational counselling session provided by a pharmacist. In addition, a systematic review found that pharmacist-led metabolic screening allowed for earlier diagnosis and timely referral to doctors.⁴⁰ However, the authors concluded that further work is required to provide a more robust evidence of effectiveness of pharmacist-led MetS screening. Another systematic review also highlighted the paucity of metabolic screening studies conducted in primary care with community pharmacy teams.⁴¹

Hypothesis and aims

Utilising the high accessibility and relative convenience in consulting a pharmacist will show community pharmacies to be an appropriate destination for ongoing medication education and physical health monitoring for people living with a mental illness.

Primary aim

To determine the feasibility of a community pharmacist-led physical health monitoring for metabolic parameters in consumers with mental illness currently taking SGAs.

Secondary aims

To determine:

- ▶ The number of referrals to GPs assessed by audit of pharmacist records.
- ▶ Any change in weight assessed by digital weigh scales.
- ▶ If the pharmacist-led intervention led to any change in the consumer's attitudes towards their mental illness assessed by a telephone interview.
- ▶ The outcomes of patient referrals to GPs by auditing pharmacist records.
- ▶ Participant's experience with the community pharmacist-led physical health monitoring, will be assessed by a telephone interview.
- ▶ Any change in waist circumference assessed by tape measure.
- ▶ Any change in body mass index ($BMI=kg/m^2$). Weight will be measured by digital scale and height measured using stadiometer.
- ▶ Any change in serum lipid levels assessed using a cholesterol measuring metre.
- ▶ Any change in blood pressure assessed using a blood pressure monitor.
- ▶ The risk of sleep apnoea using a validated questionnaire (STOP-Bang Questionnaire).

METHODS

Study design

This single group trial will be a community-based feasibility study. The study will be conducted at community pharmacies in two states of Australia-South Australia and Western Australia. These pharmacies will vary in demographic population and physical location and will include both metropolitan and rural sites. As this is a feasibility study, there will be no set number of participants and all study participants will be recruited based on convenience sampling. Researcher (TB) is responsible in informing site pharmacists of any changes to the protocol during the duration study, should they occur.

The study will be conducted between May 2021 and March 2023. Training will commence early 2021 for community pharmacists participating in the study. The recruitment of study participants will take place between May 2021 and March 2022. Participants will be followed up for a duration of 1 year and the last data collection will be completed by the end of March 2023.

Eligibility criteria

Pharmacies

Community pharmacies that meet the following criteria will be eligible to participate as a study site:

1. Have a private counselling area in the pharmacy that is separate to the common pharmacy area.

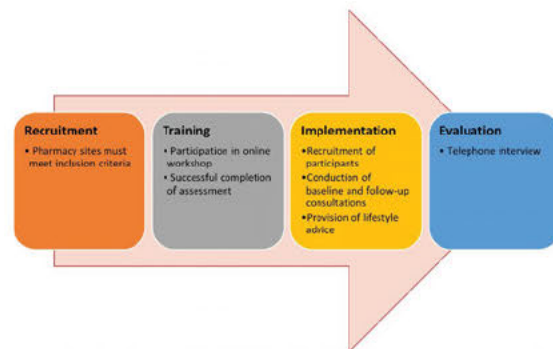


Figure 1 Pharmacist's journey map: illustrating the role of the pharmacists in the study. Figure 1 also specifies the procedure involved in each phase.

2. Have pharmacist staff with the capacity to perform regular follow ups.

Participants

Consumers who meet the following criteria are eligible to participate in this study as participants:

1. Aged above or equal to 18 years old.
2. Able to give written informed consent.
3. Diagnosed with a mental illness and currently taking at least one SGA on a regular basis.

The exclusion criteria are as follows:

1. Pregnant.
2. Unable to speak and read English.

Participants can withdraw from the study at any point. During the consent process, participants will be informed of their rights and that withdrawal from the study will not impact on their ongoing care. If the participant chooses to withdraw, reason for withdrawal will be requested and documented for analysis. In addition, all data collected for the participant up to the time of withdrawal will be included in the study's final analysis.

Intervention

The first phase of the study will involve preparing pharmacists for participation in the programme. Pharmacy sites will be recruited based on expression of interest. The involvement of pharmacists and participants in this study are summarised in figures 1 and 2, respectively.

Pharmacist training

Prior to the commencement of the study, site pharmacists will be required to complete an online training. The training will be facilitated by researcher TB and content will be delivered by multiple personnel who are experts within the area (dietician, psychologist, diabetes educator and peer practitioner). The content will be recorded and can be revisited by the pharmacists if desired. Site pharmacists will be required to complete an assessment on the completion of the training programme. In general, the training will endeavour to ensure competency in the following areas:

- ▶ Understanding of study procedures and aims

**Table 2** STOP-BANG Questionnaire with permission from Chung *et al*⁴²

S Snoring	Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?	Y/N
T Tired	Do you often feel tired, fatigued, or sleepy during daytime?	Y/N
O Observed	Has anyone observed you stop breathing during your sleep?	Y/N
P Blood pressure	Do you have or are you being treated for high blood pressure?	Y/N
B BMI	BMI more than 35kg/m ²	Y/N
A Age	Age over 50 years old?	Y/N
N Neck circumference	Neck circumference greater than 40 cm?	Y/N
G Gender	Gender male?	Y/N
High risk of OSA	'Yes' to three or more items	
Low risk of OSA	'Yes' to less than three items	

BMI, body mass index; OSA, obstructive sleep apnoea.

used in place of plasma glucose and serum lipid testing in-store. However, to be meaningful these results should be no longer than 2 weeks prior to the face-to-face consultation. The use of the patient's own records (eg, electronic records) will only be done with the participant's permission and appropriately documented in the data collection sheet (online supplemental appendix 1).

The STOP-Bang questionnaire will be used to screen participants for the risk of obstructive sleep apnoea (table 2).⁴² The STOP-Bang questionnaire is a widely used, concise and validated screening tool for obstructive sleep apnoea.^{43 44} Participants will be referred to their nominated GP if they present with parameters outside the normal range as per the GP referral guidelines. If the participant does not have a regular GP, the pharmacist will advise of local GP practices. All consultations will be undertaken in a private consultation area and measured parameters will be explained by the pharmacist to the consumer prior to commencement. If discomfort occurs at any time during the consultation, the pharmacist will cease until the participant wishes to recommence.

Pharmacists will obtain participant's permission to contact their GP to make a referral. Results from the physical health monitoring will be faxed to the medical clinic as part of the referral and participants will also be given a copy of the results. The electronic templates for data collection will facilitate the accurate and timely collection of data. If a participant is to be referred, the site pharmacists will need to populate the referral letter to the doctor and supply a copy to the participant. An electronic copy will also be saved in the participant's file for completion.

In addition, should the pharmacist perceive the need for a comprehensive medication review to be done, then referral to accredited pharmacists can be made. All referrals will be documented in the data collection sheet (online supplemental appendix 1).

The pharmacist will discuss relevant lifestyle factors and together with the participants formulate individualised strategies and goals where appropriate. These goals will be documented in the data collection sheet (online supplemental appendix 1) and will be reviewed at subsequent follow-ups. New or modified goals can be set if necessary. In order to emulate an authentic practice setting, advice and strategies given to the participants will be up to the individual pharmacist's discretion while concordant with established guidelines. All advice and strategies given will be documented. Pharmacists are prohibited from offering weight-loss products to the participants during the trial. Participants can elect to use weight-loss products at their own discretion, but this will be documented and noted during data analysis.

Lifestyle counselling advice can include (but are not limited to) the following:

- ▶ Smoking cessation.
- ▶ Advice on nicotine replacement therapies.
- ▶ Dietary advice (eg, fruit and vegetable consumption, alcohol consumption).
- ▶ Lifestyle advice (eg, physical activity).

Evaluation

Participant's Interview

In order to explore participant's attitudes and experience with the community pharmacist-led physical health monitoring, all participants will be required to complete an interview at the end of the study. This interview will be delivered via telephone by researchers (TB, VS and EH) from the research team. Data collected will include demographics (eg, gender, private health insurance status), attitudes towards their mental illness, in particular beliefs towards their medications using the Beliefs about Medication Questionnaire⁴⁵ and experience with the intervention.

Pharmacist interview

To assess the feasibility of the physical health monitoring, all participating pharmacists will be asked to complete a telephone interview. Data collected in the telephone interview will include both Likert-scale and open-ended questions. Interviews will explore different aspects of the service and pharmacist experiences including perceived sustainability, associated barriers and impact on job satisfaction. In addition, demographics data, such as pharmacy location (rural vs metropolitan),⁴⁶ whether the pharmacy is connected to medical centre or stand alone, workflow, workload (technician ratios, average daily number of prescriptions filled will also be collected).

Outcome measures**Primary outcome**

The primary outcome is to determine the feasibility of the pharmacist-led intervention. Feasibility of the intervention⁴⁷ will be reported as:

- ▶ Recruitment and sample characteristics
 - Recruitment barriers and facilitators.
 - Recruitment rate.
 - Demographics of participants.
 - Eligibility criteria (suitability).
 - Relevance of intervention to population.
 - ▶ Procedures and measures
 - Viability and potential benefits of 3 monthly follow ups.
 - Point-of-care measures in a pharmacy setting.
 - Use of non-fasting glucose measure as a measure for participants.
 - Data collection procedures.
 - ▶ Intervention and acceptability
 - Retention and follow-up rates.
 - Time (eg, whether time commitment was a burden for participants and pharmacists).
 - Extent to which the intervention was acceptable to participants and pharmacists.
 - ▶ Resources and ability to manage intervention
 - Equipment sufficient to conduct the study and intervention.
 - Training requirements.
 - ▶ Preliminary evaluation of participants response
 - Potential value in the intervention.
 - Changes in outcome variables (ie, metabolic parameters).
 - Qualitative feedback.
- The secondary outcome will be measured by:
- ▶ Quantification of the total number of referrals to GPs made based on findings from the physical health monitoring.
 - ▶ Outcome of referral to GPs:
 - Whether the referral was actioned (eg, why/why not, intervention implemented).
 - Outcome of the referral could include but are not limited to:
 - Referral to other hospital or allied health professionals (eg, dietician).
 - Changes to pharmacotherapy (eg, dose changes, addition or cessation of medication).
 - Changes to appointment schedules (eg, more frequent appointments for additional monitoring).
 - Diagnosis of metabolic complications (eg, MetS, dyslipidaemia or diabetes).
 - ▶ Composite outcome of changes to modifiable risk factors (baseline compared with 3 monthly follow-ups):
 - Weight.
 - Waist circumference.
 - Blood pressure (systolic and diastolic blood pressure).
 - Blood glucose levels.

- Lipid profile.
- BMI.

Recruitment of participants

Site pharmacists will play an active role in the recruitment of their regular clients who meet the inclusion criteria. When a potential participant is identified, site pharmacists will invite the potential participant for a discussion in a private counselling area where they will be supplied the study information sheet and details of the study will be explained to them. Participants who give informed consent will then be booked in for an appointment for baseline measurements. Pharmacists will identify and enrol clients that met the inclusion criteria into the study. Participants will be given a leaflet which they can take/fax to their GP to inform them of their enrolment in the study. The leaflet will contain background information about the study as well as the contact details of the research team.

Data collection

Data for the physical health monitoring will be collected at five time points (baseline and 3-monthly thereafter for total duration of 12 months). Baseline data will be collected at the first physical health monitoring session. Data collected will include:

1. Sociodemographic information: client's name, date of birth, age, gender, ethnicity, marital status, contact details, regular GP details.
2. Medical history: comorbidities, all prescribed and over the counter medication history.
3. Relevant lifestyle factors: other drug use and drinking and smoking status.
4. Physical parameters: blood pressure, height, weight, waist circumference and calculated BMI.
5. Glucose levels and lipid profile (via finger prick test).
6. Screening for obstructive sleep apnoea (questionnaire).
7. Any lifestyle counselling provided by pharmacist.
8. Any referral to GPs made and reason(s) for referral (if participant gets referred).
9. Reasons for withdrawal from study (if participant decides to withdraw).

At subsequent follow ups, the above data will be collected with the exception of sociodemographic information.

Data storage

All data will be stored in a deidentified manner. All study participants will be given a participant identification (ID) number and data will be recorded against this ID number. Only site pharmacists will have the key to identify site specific study participants. Deidentified electronic data collected by site pharmacists will be directly uploaded on the University of South Australia's (UniSA) data storage system. The UniSA Research Data storage is a secure online data management system maintained by UniSA. Data will be backed up on a daily basis by the university. Only researchers and pharmacists directly involved in



the study will have access to collected data. All data will be stored for 5 years after which all files will be securely destroyed. The final dataset will be solely accessible to the research team at UniSA for analysis and write up.

Data analysis

Qualitative outcomes

Thematic analysis will be guided by the six-step method discussed by Braun and Clarke.⁴⁸ This thematic analysis will be based on the responses to the telephone interviews after the final follow-up session. The analysis will study the participant's perceived attitudes towards the convenience, accessibility and benefits of the community pharmacist-led intervention.

Quantitative outcomes

Quantitative outcomes will be analysed using IBM Statistics SPSS version 18.0.0. software. Univariate descriptive data analysis will be used to analyse the sociodemographic data for participants in the physical health monitoring and respondents to the survey. The number of referrals will be quantified and reported accordingly. To investigate the effects of the intervention on primary endpoints (baseline value compared with endpoint value), dependent t-tests will be performed. To test for changes over time, physical and serum parameters will be compared between each visit (from baseline up until last follow-up session) using regression analysis. Additional statistical tests may be employed as appropriate depending on the nature of the data and sample size. Statistical significance will be at α 0.05.

The study will track the participants' progress overtime such that each participant will serve as their own control (ie, results from baseline will be used as a control). This will eliminate the risk of major confounding variables. However, if confounding variables were to emerge at a later stage, adjusting for confounding variables will be made after data collection by employing either stratification or multivariate methods depending on the data that have been collected.⁴⁹ Regression analysis, in particular, logistic and linear regression could be also considered as they can both control for confounders and examine association between multiple covariates and numerical outcomes.

PATIENT AND PUBLIC INVOLVEMENT

Potential patients or other members of the public were not involved in the development of the study research question, outcome methods or design of this protocol.

ETHICS AND DISSEMINATION

The study has received ethics approval from the institutional Human Research Ethics Committee (Protocol no: 203433). Any expected modification to the protocol after the ethics approval will be submitted to the institutional HREC for approval prior to commencement. Written

informed consent will be obtained from all participants prior to study enrolment. Records containing personal information will remain confidential and no information which could lead to ID of individuals will be released, unless required by law. The researchers will be involved in the preparation and drafting of the manuscripts. There is no intended use of professional writer. Findings will be published in peer-reviewed journals and presented at local, national and international meetings and conferences to disseminate the research to health professionals and patients. Participants' names will not appear on any publication or be released without the participant's prior written consent.

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Methods

Quantitative data

Metabolic data collected by the pharmacists were categorised into either “complete” or “incomplete.” Data collection was deemed as “completed” when all metabolic parameters, including waist circumference, TG, HDL, blood pressure and glucose were collected [297]. All percentages reported were calculated using the number of consultations conducted at each interval, unless otherwise stated. Quantification of lipid monitoring reflected all attempts made by the pharmacists including failed attempts. Breakdown of lipid monitoring that is, into total cholesterol (TC), TG, HDL and low-density lipoprotein (LDL). Rates were reflected as percentages in terms of total number of consultations. Medication lists were recorded on an Excel spreadsheet and organised according to their respective Anatomical Therapeutic Chemical code (ATC) codes [298].

Data collection

All data were collected by the participating pharmacists during their consultations and documented in the data collection sheet (see Appendix C). Hard copies of the data were collected by the PhD candidate during the monthly pharmacy visits and uploaded in their de-identified form onto the University’s secure RDS.

Data analysis

In addition to the data analysis described in the protocol, all participants’ personal goals were documented and analysed. Goals documented on the data collection sheet were transcribed into a Microsoft Excel spreadsheet and reviewed by the researcher (TB), where they were categorised into either “specific” or “general” goals. For this study, specific goals were defined as those that set a particular task and described how the participant intended to achieve it. For example, a goal to “avoid watching TV [television] every morning and instead substituted that with exercise” was classified as a “specific” goal. An example of a general goal was to reduce a “[high] cholesterol diet”, as the goal highlighted what a participant wanted to achieve but not the steps on how to achieve it.

Justification for quantitative methods

As this was a feasibility study, a formal sample size calculation was not conducted; however, a total target of 30 participants was deemed appropriate by the research team [299]. Given the small sample size, in-depth statistical analysis was not appropriate [300]. Instead, outcomes

were analysed using descriptive statistics. Community pharmacies were purposively recruited based on their location to ensure that a representative dataset would be achieved.

Qualitative data

Interview guides

All interview guides were developed at the time of study conceptualisation as required for ethics approval. The development of the interview guides was an iterative process, which changed and “morphed” to align with the dynamic nature of the research but also refined and evolved as the candidate's skills as a researcher developed (Table 10).

Table 10. Development of interview guides

Cohorts	Interviews conducted (2022)	Validated tool employed	Piloted by
Pharmacists (Recruiters)	December	RE-AIM Framework	<ul style="list-style-type: none"> • Research team • External reviewer
Participants	December	Questionnaires: 1. Patient satisfaction 2. Belief on Medications Questionnaire (BMQ-S)	Research Team
Pharmacist (non-recruiters)	May	None	Research team

Participant’s interview guide

The interview guide was developed to explore patient satisfaction and beliefs about medications, generate specific program feedback and document experience and perceptions of the program. Patient satisfaction and beliefs about medications were assessed using the Short Assessment of Patient Satisfaction (SAPS) and Belief on Medications Questionnaire subscale, BMQ-S [301, 302].

The SAPS is a 7-item instrument used to assess patient satisfaction with health care, and has scores ranging from 0-28, with higher scores indicating greater satisfaction [302]. The BMQ-S is a 10-item questionnaire that is divided into, Specific-Concerns which assesses perceptions of the likelihood of adverse reactions and Specific-Necessity which assesses patient’s belief about

their personal need to adhere to the prescribed medication [301, 303]. No measurement of the SAPS and BMQ-S was undertaken prior to the implementation of the program.

Additional questions relating to program-specific feedback were designed by the candidate and reviewed by the research team (EH and VS). Participant demographic data including the pharmacy they attended for the program were also collected. Overall, the participant interview guide contained 22 Likert-scale and 6 open-ended questions.

Pharmacist interview guides

The RE-AIM framework, commonly used for planning and evaluation of health research in clinical and community settings [304] was used as a guide to develop and format the interview questions for pharmacists who were able to recruit ('recruiters') [305, 306].

The interview guide for 'recruiters' contained a total of 15 broad questions, each with 2 to 6 prompts which aimed to identify both pandemic and non-pandemic barriers as well as explore the pharmacists' perceptions of the proposed program. The guide was developed by the candidate in consultation with the research team to assess for relevance and appropriateness. It also included some questions from the 'non-recruiters' interviews that were conducted prior. These questions were deemed as relevant for both cohorts by the research team. Once finalised, the interview guide was reviewed and piloted by an external reviewer, a community pharmacist with extensive practice experience in various settings including community, hospital, and academia.

Another pharmacist interview guide for those who were unable to recruit ('non-recruiters') was also developed. The interview guide for the 'non-recruiters' contained a total of 6 questions with approximately 2 to 3 prompts each. The interview guide was developed by the PhD candidate and reviewed by the research team.

Conducting the interviews

The PhD candidate contacted pharmacists and participants to schedule an interview at an agreed time. Contact details for a total of 11 participants were provided by the site pharmacists. Participant interviews were conducted as soon as they had completed the 12-month program, that is, one year after their enrolment date. Interviews for the recruiters were conducted once the pharmacists had completed data collection for all of their participants (December 2022 – February 2023) and continued until all pharmacists had been interviewed. The interviews for

the non-recruiters were conducted at the end of the recruitment period (May 2022 to July 2022) (Table 10).

Semi-structured interviews were conducted via telephone for participants, recruiters and non-recruiters were interviewed via Zoom. Relevant technical aspects, such as the quality of the internet connection and audio recording procedure were tested before the interviews. Interviewees were informed of their rights to withdraw from the study at any time prior to their interviews and all individuals who were interviewed via Zoom had the option to leave their cameras off if they wished to do so. All interviewees were offered an AUD \$30 gift voucher as a token of appreciation for their time.

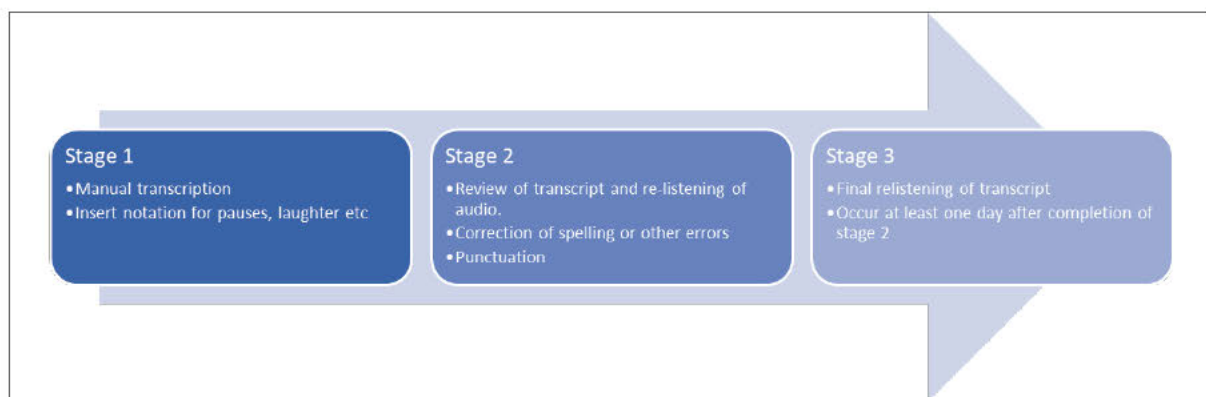
Interview guides for participants, non-recruiters and recruiters are attached in Appendix B.

Data analysis

Data familiarisation

All interviews were manually transcribed by the PhD candidate to encourage data immersion and familiarisation. To ensure the accuracy and quality of the transcriptions [307], a three-tier process was employed (Figure 4).

Figure 4. Three-tier transcription reviewing process.



Coding and development of themes

All coding was conducted by a single researcher (TB) as acceptable within this field of work [41]. The transcripts were first manually coded, for example, key ideas highlighted, and potential underpinning meaning were explored and documented. The second coding phase involved the use of NVivo, where transcripts were imported and electronically coded by the candidate. Codes were reviewed and amended where necessary, a comparison between the

manual and electronic codes was made to further refine the codes. Final codes were reviewed and assessed for any duplication prior to grouping into themes.

Coding was both guided by the dataset (inductive) and predetermined areas of interest, such as the research question or knowledge generated from the literature (deductive). Therefore, the coding process employed both an inductive ('bottom up') and deductive ('top down') approach. Given that the objective of the interview was to explore participants' experiences, semantic rather than latent coding was deemed as most suitable. Semantic coding captures explicitly expressed meaning staying close to the participants' language or the overt meaning whilst latent coding focuses more on attaining an implicit or conceptual level of meaning [41].

The development of themes was an inductive process, where codes (single-faceted) were reviewed and grouped into shared meanings and patterns defined as themes (multi-faceted). Once the initial set of themes had been developed, they were evaluated for "completeness". To further explore the themes, group data discussions led by the PhD candidate were conducted for both pharmacists' and participants' interviews involving the rest of the research team (VS, EH, FK, and SM). These discussion sessions for the pharmacists' and participants' interviews ran for one hour and 40 minutes (March 2023) and one hour and 19 minutes (February 2024) respectively. The discussion sessions were also recorded to allow the candidate to revisit as required. Results from participants' responses to the validated questionnaires were collated and reported using descriptive statistics. All researchers were provided with access to the transcripts prior to the group discussions. The refining of themes ensured that overarching themes and subthemes had been identified and appropriately named to reflect the key content. Finally, a thematic map was developed and reported (see results) to illustrate the relationship(s) between the themes and subthemes.

Data completeness

Qualitative research had at times been criticised for the perceived lack of credibility or reliability. This was often attributed to the lack of a clear sampling guide, small(er) sample size and lack of generalisability [308]. The focus on large sample size as an indicator of quality and rigor emanates from the philosophical theory of positivism, where findings have been used to prove or disprove a hypothesis. This contrasts to qualitative research, where there is lesser emphasis on generalisability in this context but rather a focus on interpreting experiences and offering a "voice" to participants [309]. As a result, unlike quantitative research, there are no existing methods or principles to calculate for required sample size [310]. Efforts to "improve"

the quality and rigour of qualitative research have led to the conceptualisation of “data saturation” [311], which has been generally perceived as the “gold standard” to inform/justify sample size in qualitative research studies [311], and has been commonly incorporated in quality checklists, such as the COnsolidated criteria for Reporting of Qualitative research (COREQ) checklist [312]. However, its position in qualitative research, particularly in thematic analysis, as a mechanism for quality assurance, has been questioned [265, 308].

The concept of data saturation, often defined as when there is “no new information [in the dataset]” or when no new themes/codes have been identified [265], has been questioned by Braun and Clarke, proponents of thematic analysis [41, 265]. These researchers highlighted that whilst data saturation as a “quality assurance mechanism” lends itself to certain thematic analyses such as codebook and coding reliability, it does not have a role in reflexive thematic analysis (RTA). Further, the concept of data saturation does not align with the “open, fluid, organic and recursive” processes of reflexive thematic analysis [265]. Instead, they argued that “saturation” in RTA should be dependent upon the judgement and interpretation of the researcher as to when the purpose and goals of the analysis had been reached [265]. The ultimate aim of the researcher is to ensure that there is “adequate data to tell a rich, complex and multi-faceted story about patternings” to address the research question [265, 266].

This thesis conceptualises “saturation” in the ability to generate rich and complex data allowing for the description of a multi-faceted experience for both pharmacists and PLMIs involved in the physical health monitoring program. In particular, it has prioritised the “completeness” of presented data. This had been achieved through undergoing the analytical processes described previously, specifically the two-phase process, whereby the data was reviewed by a single coder followed by group discussion.

Given the purposive nature of this component, recruitment numbers were, by necessity, limited to only pharmacists and participants involved in the physical health monitoring program, resulting in a small sample size. Therefore, instead of relying on data saturation, which in itself has been highlighted as a potentially inaccurate measure of data sufficiency [265], value was placed on the depth of the interviews; in particular, ensuring that each aspect had been thoroughly explored to obtain detailed descriptions of the pharmacists’ experiences and perception of the project [313]. This study prioritised research transparency, ensuring that sufficient justifications exist for methods and adequate context to assist readers in interpreting the findings.

Justification for qualitative methods

A number of qualitative data analysis methods, such as interpretative phenomenological analysis (IPA), grounded theory (GT), pattern-discourse analysis (PA) and thematic analysis (TA) were considered for this research [314]. IPA is particularly useful for studies that focussed on unique individual cases, with the aim of elucidating ‘personal experience’ and ‘sense-making’ [315]. GT focuses on social processes to develop a theory that is grounded in the data, and therefore is often used in the social sciences [316]. Finally, PA is a study of language within its social and cultural context [41].

The TA process incorporates components of some of these qualitative methods. For instance, TA allows for the exploration of ‘personal experience’ and ‘sense making’ (like IPA) with findings grounded within the data (like GT). Therefore, TA allows for the description and interpretation of identified patterns (or themes) in the dataset as such; findings can be organised into thematic statements, allowing for “actionable outcomes” aligning with the aims of the study (that is, exploring the feasibility and providing suggestions for future initiatives)[314]. In particular, RTA acknowledges the researcher’s subjectivity, acknowledging the influence of personal experiences, beliefs, and values [41]. This aligns with the theoretical framework discussed in Chapter One of this thesis. Specifically, RTA aligns with the interpretivist paradigm (interpretivism) and acknowledges that findings are subjectively observed by the PhD candidate and influenced by the candidate’s own context and experiences. TA generally involves the process of data familiarisation, coding, and development of themes [317], as discussed below.

This study utilised the qualitative method of interviews, in particular, semi-structured interviews as a main research tool. Interviews have been widely used in the qualitative research space with common types including structured, unstructured, and semi-structured interviews [318]. Structured interviews require the interviewer to adhere strictly to the interview guide to uncover the “objective” truth, therefore offering little flexibility which may limit the breadth and depth of the data generated [319]. In contrast, unstructured interviews are informal and not guided, often described as “free-flowing conversations” between the interviewer and the interviewee [320]. The flexibility of unstructured interviews can be seen as an advantage; however, the lack of a guided structure and questions could make the identification of patterns or themes in the small sample size challenging.

For this study, semi-structured interviews were employed. Semi-structured interviews encompass components of both above mentioned methods as it requires the development of an interview guide that provides broad guidance as well as pre-identified prompts to encourage or elicit more data (as in structured interviews). Notably, semi-structured interviews allow the interviewer some level of flexibility to deviate away from the guide (a feature of unstructured interviews) should it arise in the interview [321]. Additionally, the process allows for an in-depth account of the interviewee's experience, a valuable feature for this study. Face-to-face interviews were not employed due to the pandemic but also because the planning logistics were seen as a potential barrier, for example, difficulty in deciding the time and location of the interviews.

Part Four: Results and Discussion

The first part of the results reported the quantitative findings, including recruitment and sample characteristics, the design of the intervention, the composite outcome of metabolic parameters (such as weight and waist circumference) and the outcome(s) of GP referrals. The second part of the results reported participant and pharmacist experiences from interviews. Included in this section were the perspectives of pharmacists who were unable to recruit participants for this study.

The study was conducted in Australian community pharmacies between May 2021 and October 2022. The study had been approved by the institutional Human Research Ethics Committee (Protocol no: 203433) and the trial was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12621001435875). Study findings have been presented based on the CONSORT statement extension to pilot and feasibility studies [322].

Results

Quantitative findings

A total of six community pharmacies were recruited in Western Australia and South Australia. All pharmacists (n=18) employed at the recruited pharmacies sites were invited to complete the training course. Of them, nine completed the training course. Amongst the six community pharmacies recruited, only two pharmacies located in Southern and Western metropolitan Adelaide were able to successfully recruit participants.

Demographics

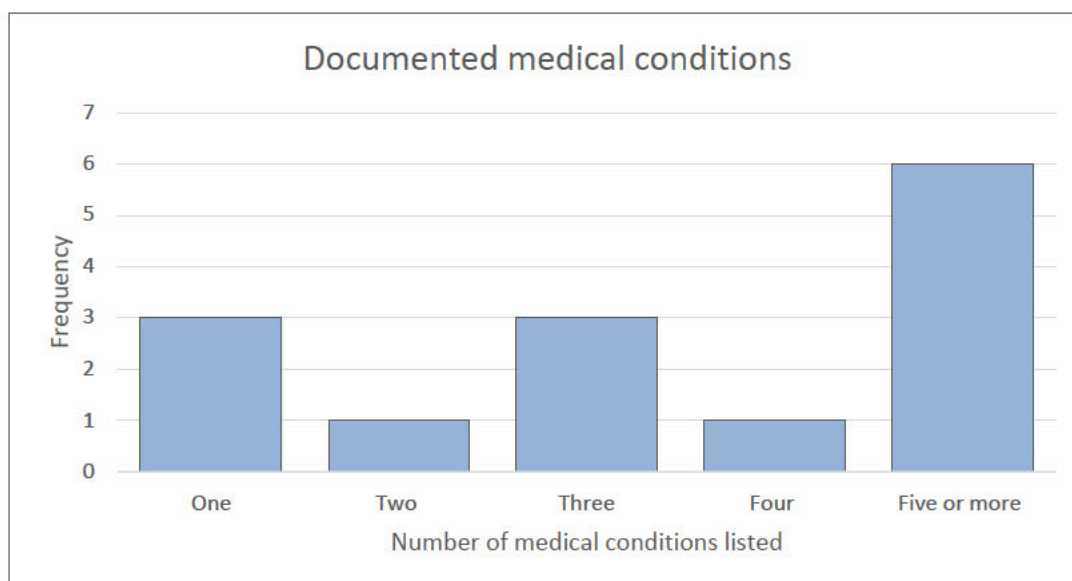
In total, 17 participants were enrolled in the physical health monitoring program. The majority of the study participants were female with an average age of 52 years (range 23-89 years). There was an approximately equal number of participants enrolled at the two pharmacy sites (Table 11).

Table 11. Participant's demographics.

Demographics		n = 17
Gender		
Male		6
Female		11
Age		
20-29		2
30-39		4
40-49		1
50-59		1
60-69		8
>80		1
Pharmacy Site		
Location A		9
Location B		8

For most of the participants (n=14/17), a complete list of medical conditions was documented on the data collection sheet (Figure 5) The remainder contained notes of “medical conditions on file” but not documented on the data collection sheet. Documented mental health conditions included schizophrenia (n=8), anxiety (n=3), depression (n=3), bipolar disorder (n=2), post-traumatic stress disorder (n=3) and borderline personality disorder (n=1). Other medical conditions included hypercholesterolemia (n=5), hypertension (n=5) and diabetes mellitus (n=4).

Figure 5. Number of documented medical conditions (n=14).*



*Completed lists of medical conditions were only available for 14 participants.

Commonly prescribed SGAs in this cohort included quetiapine (n=8), olanzapine (n=7) and clozapine (n=7) (Supplementary File H). Four of the participants were on two antipsychotic medications (antipsychotic polypharmacy), six were also taking lipid-lowering medicines and five participants were co-prescribed anti-hypertensives and glucose-lowering medicines (Table 12). One participant was documented to be on ‘triple therapy’, concomitant use of anti-hypertensive, lipid-lowering, and glucose-lowering medicines.

Table 12. Characteristics of prescribed medications.*

Characteristics	n = 17
Antipsychotic polypharmacy*	4
Prescribed medications of interest	
Anti-hypertensive	6
Lipid-lowering therapy	6
Glucose -lowering therapy	5
Triple therapy (anti-hypertensive, lipid-lowering and glucose-lowering therapy)	1

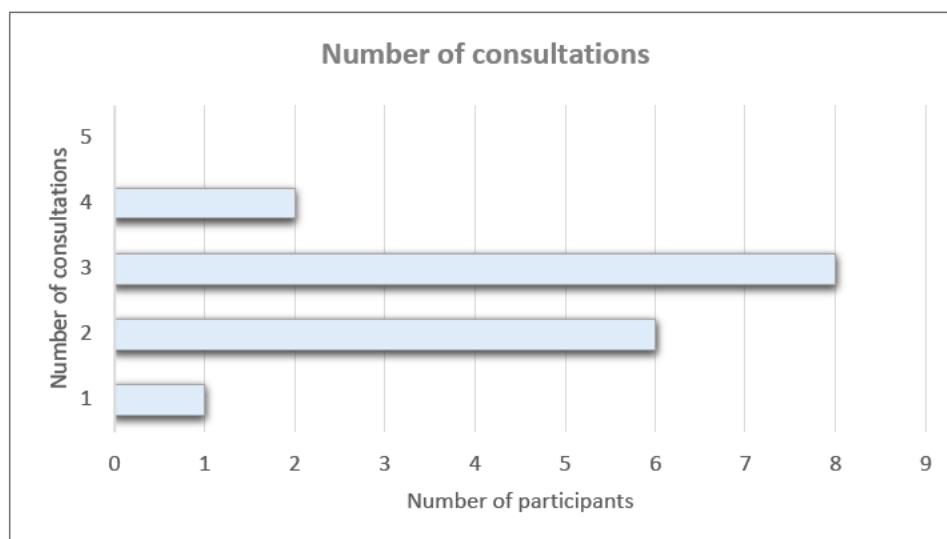
*Antipsychotic polypharmacy was defined as taking ≥ 2 antipsychotic agents

Participant’s attendance

Over the study period, the six- and nine-month follow-ups recorded the lowest attendance rates, whilst peak attendances were observed at the 12-month (final) reviews. Eight of the participants had completed three consultations over the 12 months (range 1 to 4). Two participants had completed four consultations while one participant only completed the baseline review (Figure

6). None of the participants attended all of the three-monthly follow-ups during the study period (Figure 6). Even though, there were no official records of participants withdrawing from the study, only 12 of those who started the study returned for their final 12-month consultations.

Figure 6. Number of consultations participants completed over the 12-month study duration.



The highest rate of complete data collection was recorded at the three-month and nine-month follow-ups, where all five parameters were measured for six (n=11) and two (n=2) of the participants respectively. Consultations at six-month and 12-month follow-ups recorded the lowest number of complete data collections with only 1 (n=3) and 4 (n=12) respectively of participants having all five parameters measured and documented (Table 13).

Table 13. Metabolic monitoring participating pharmacists categorised into complete and incomplete data collection.

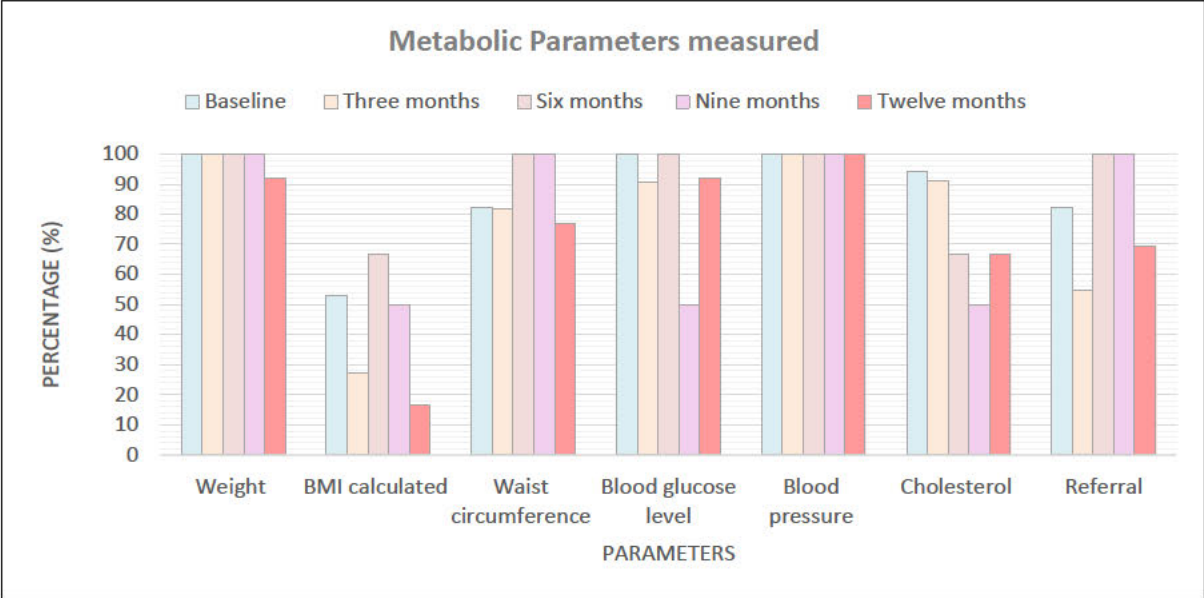
	Baseline n = 17	Three months n = 11	Six months n = 3	Nine months n = 2	Twelve months n = 12
Complete	7	6	1	2	4
Incomplete	10	5	2	0	8

Measured parameters

Blood pressure, weight, BGL and waist circumference were the most frequently measured parameters (Figure 7). Blood pressure had the best monitoring rate as it was measured for all participants at every follow-up. Weight was measured all the time (100%) for the first four follow-ups and 92.3% for the last follow-up. Waist circumference was measured most frequently (100%) at the six- (n=2) and nine-month (n=3) follow-ups and least frequently at the

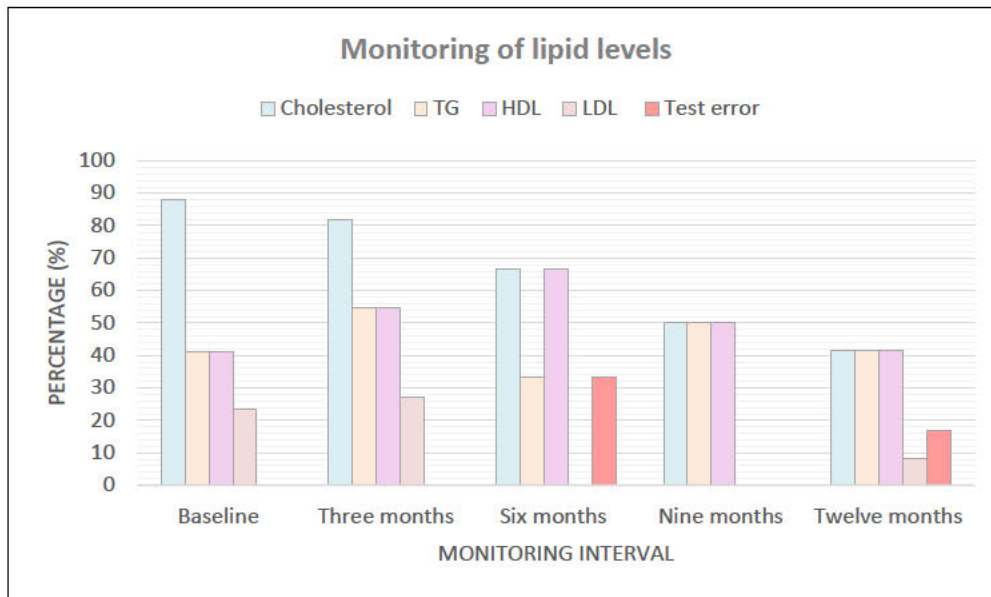
12-month follow-up (76.9%). The least frequently measured parameters were BMI and blood lipid levels. Monitoring of lipid levels was highest at baseline (94.1%) and lowest at the nine-month interval (50%) while documentation of BMI ranged from 16.7% (lowest) to 66.7% (highest) for this cohort.

Figure 7. Metabolic parameters measured at the physical health monitoring program.



Cholesterol measurements documented by pharmacists included TG and HDL as required by the study protocol. Additionally, total cholesterol and lipoprotein (LDL) were also collected (not required by the protocol) (Figure 8). The monitoring of lipid levels was the only parameter with recorded technical difficulties and failed readings reported by the recruiting pharmacists.

Figure 8. Breakdown of lipid monitoring.



Of the 17 participants, STOP-Bang scores were calculated for nine participants, of whom seven were at high risk of OSA.

Consultation outcomes

Referrals to the participants' nominated GPs were made in 23 instances out of 45 individual consultations. More than half (n=11) of the participants were referred after their first consultation. However, referrals were most frequently made at the six- and nine-month follow-ups, where all two of the participants at each follow-up were referred to their GPs for further review (Table 14). Of these referrals, some (n=4) had no reasons documented while the majority (n=14) were related to elevated metabolic parameters and five were for other reasons, including review of mental health medication (for symptomatic control), medication shortage (for new prescription) and recommended for routine GP review. Six participants reported having seen their GP as a result of the referrals while four had scheduled a visit and six reported no documented plans. Of the six participants who saw their GP, only two participants reported the following changes:

- I. An increase in dose of a beta-blocker for managing blood pressure and,
- II. Initiation of lipid-lowering therapy

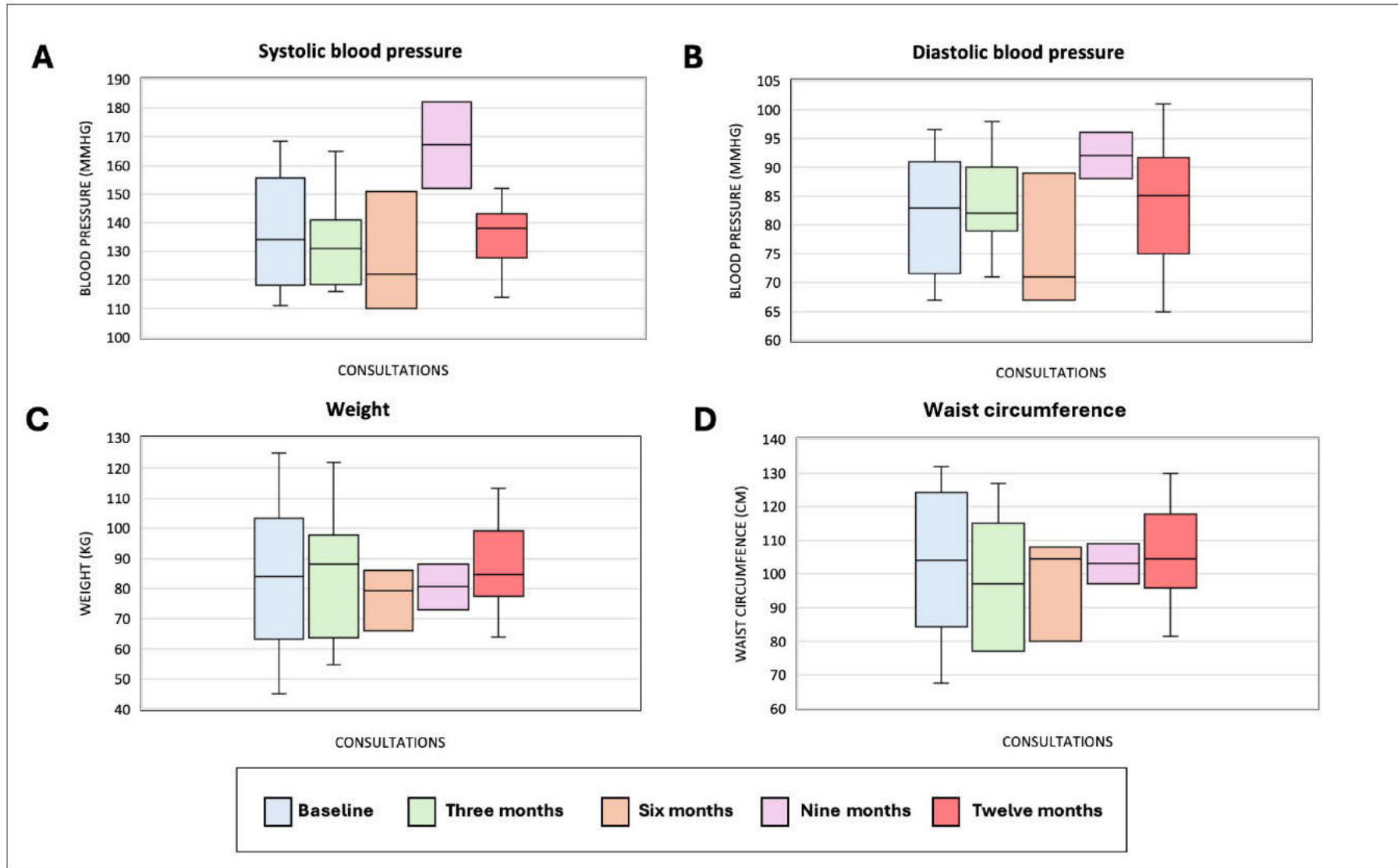
Table 14. Referrals made.

Referred	Baseline (n = 17)	Three months (n= 11)	Six months (n = 3)	Nine months (n = 2)	Twelve months (n=12)
Yes	10	4	2	2	5
No	7	7	1	0	7

Monitored metabolic parameters

Figure 9 shows the distribution of the metabolic data collected over the five follow-up intervals (that is, average and range).

Figure 9. Distribution of the metabolic parameters collected (A: Systolic blood pressure, B: Diastolic blood pressure, C: Weight, and D: Waist circumference).



Goal setting

A total of 68 goals were set over the 12-month study period. These goals were mostly centred around exercise (46.2%) and diet (27.9%) (Table 15). Of the 68 goals documented, 72.1% (n=40) were specific, for example, to “[increase] physical exercise up to three times a week [and to] walk from one end to another at shopping centre (15-20 minutes).” The remainder (27.9%, n = 19) were general goals, such as to “maintain an improved diet” (Table 15).

Table 15. Specific and general goals set.

Domains	Total, % (n = 67)	Type	Goals set	Subtotal, %
Diet	19 (28.4)	Specific	<ol style="list-style-type: none"> 1. Change [from having] scones for breakfast to porridge or cereal twice a week 2. Decrease sugar intake (too many muesli bars) 3. [Avoid] Dairy food intake for 1 week 4. Drink black tea instead (reduced sugar) 5. Limit dessert to just sometimes 6. Looking at sugar content of instant coffee, muesli bar 7. Meals on wheels twice weekly 8. Reduce amount of caffeine intake from 12 to 1 or 2 cups per day 9. Reduce snacking and portion size, opt for healthier options 10. Review diet in particular salt and fat intake 	10 (52.6)
		General	<ol style="list-style-type: none"> 1. Maintain improved diet 2. Reduce cholesterol diet 3. Reduce fat diet 4. Reduce snacking 5. Reducing packaged food 6. Review meals 7. Review diet 8. "Diet" 9. Review diet 	9 (47.4)
Exercise	28 (41.8)	Specific	<ol style="list-style-type: none"> 1. Physical exercise up to three times a week. Walk from one end to another at shopping centre (15-20 minutes) 2. Maintain walking goal (set in the last consultation) 3. Consider exercise that can be done indoors (squats, use chair as support, knee push-ups, lunges - referral to site healthline.com) also to check with GP and consider occupational therapy 4. Increase exercise to 3-4 times weekly 5. Continue walking in shopping centre three times per week 6. At least walk once a week (waiting to see physiotherapist) 7. Limited knee strength, suggest using weights in chair 8. Take walk with a dog three times a week (notice weather not great) 9. Commence Pilates once a week ... [and include] one episode of walking per week 	24 (85.7)

			<ul style="list-style-type: none"> 10. Increase walking, try extra 10 minutes for 1 month 11. Deep breathing to manage pain associated with walking, sensory distraction (visualisation) 12. Increase exercise (walking to beach, approx. 2-3 km) from once a week to 3-4 times a week 13. Increase exercise to half an hour (walk) per day 14. increase walking to 90 minutes per week 15. Maintain increased in exercise since recently been walking every day and avoiding public transport 16. Maintain exercise routine with aim to increase over spring and summer 17. One episode of dedicated exercise per week (any more is a bonus) also starting Pilates) 18. Throwing balls at backyard and hope to move around when weather is warmer 19. Walking 20-30 minutes three times a week to local streets; look into restrictions on table tennis and get back into that 20. Walking increase to 10 minutes twice a day due to knee pain 21. Commence Yoga, to aim for three times a week 22. Get back into walking (brisk walk 30 minutes in the evening twice a week) 23. Increasing walking to 1-2 times per week 24. Avoid watching TV every morning and substituting some exercise occasionally 	
		General	<ul style="list-style-type: none"> 1. Walking a bit more 2. Increase exercise 3. Walking 4. Try [physical] activity that is not as painful 	4 (14.3)
Smoking	8 (11.9)	Specific	<ul style="list-style-type: none"> 1. Waiting for Champix® to come back in stock working on triggers for smoking 2. Discussed possible to substitute Nicorette® inhaler for 2-3 cigarettes per day but not ready to cut down yet 3. Ask GP for varenicline generic prescription, hypnotherapy [to cope with] illicit drug use 4. Reduce smoking to consider quitting next review 5. Hypnotherapy deemed to help with ceasing tobacco and illicit drug use (No Champix®) 6. Champix® since NRT (Nicotine Replacement Therapy) doesn't help 	6 (75.0)
		General	<ul style="list-style-type: none"> 1. Stay off nicotine 2. Discuss smoking [cessation] but not in the right head space to take action yet 	2 (25.0)
Alcohol	4 (6.0)	Specific	<ul style="list-style-type: none"> 1. Replace alcohol with soda water 2. [Have] less than 2 bottles a day (1.5 bottles) 	3 (75.0)

			3. Aiming for twice a week with no alcohol	
		General	1. Could reduce alcohol consumption	1 (25.0)
Others	8 (11.9)	Specific	<ol style="list-style-type: none"> 1. To monitor blood pressure at home [by] recording it in a diary 2. Going back to singing classes once more settled 3. See grandkids more and do art classes 4. Attend peer group twice weekly to improve mental health 	4 (50.0)
		General	<ol style="list-style-type: none"> 1. Not to watch TV every night 2. Regular blood glucose monitoring at home 3. Want to lose waist circumference and weight 4. Drink more water 	4 (50.0)

Pharmacists' adherence to the study protocol

It was noted that 11 of the baseline consultations were not documented on the supplied data collection sheet but in a notebook. In cases where cholesterol testing failed, the use of existing laboratory results (if available) on the My Health Records (MHR), an electronic medical records database, was permitted as per the protocol, where it was stipulated that "... results should be no longer than 2 weeks prior to the face-to-face consultation." However, on two occasions (4.4%), the reported levels retrieved from the participants' MHR were beyond the recommended two-weeks period. In addition, TC and TC to HDL ratio were often measured rather than TG and HDL levels as required by the protocol.

Qualitative findings

Interviewed pharmacists' demographics

Of the nine pharmacists who were trained to recruit for this study, seven were interviewed. Approximately similar numbers of recruiters and non-recruiters participated in the interviews (Table 16). In general, recruiters had greater years of experience and reported working in busier pharmacy settings with a higher average number of daily prescriptions dispensed. On average, recruiter interviews lasted 52.16 minutes (50.30 – 54.05) while non-recruiter interviews lasted 28.34 minutes (21.34 – 36.38).

Table 16. Demographics of pharmacists who were able to recruit participants ('recruiters') and pharmacists who were unable to recruit ('non-recruiters').

	Recruiters (n=3)	Non-recruiters (n =4)
Gender		
Male	2	1
Female	1	3
Prefer not to say	0	0
Location		
SA	3	1
WA	0	3
Pharmacists trained		
SA	4	2
WA	0	3 [^]
Age (range)*	24 - 47	25 - 50
Years of experience (range)	3 - 24	0.5 - 8
Average daily prescription numbers (range)	115 - 500	150 - 290
Pharmacist staffing	2	2

*Pharmacists were only requested to provide an age range

[^]One viewed all training resources but have not completed the assessment questions

Interviewed participants' demographics

Of the 17 participants enrolled in the program, 10 were interviewed. Most were aged between 61-70 years and female (n=6). Nearly all the participants (n=9) were from pharmacy site A, with all participants nominating this as their regular pharmacy (Table 17). All participants had regular GPs, and more than half (n=6) did not have private health insurance. The interviews lasted on average 20 minutes (range 11 to 26 minutes).

Table 17. Demographics of participants.

Participants (n=10)	
Gender	
Male	4
Female	6
Age	
25-30	1
31-40	2
41-50	0
51-60	2
61-70	4
>70	1
Pharmacy site	
A	9
B	1
Regular Pharmacy	
Yes	10
Have a regular GP	
Yes	10
Private health insurance	
Yes	3
No	6
Only ambulance cover	1

Beliefs about medicines used for their mental illness

Over half the participants (n=8) believed that their medications were necessary for maintaining their current mental health (Table 18). More than half of the participants (n=6) were concerned about the potential adverse effects and becoming too “dependent” on their medications.

Table 18. Percentage of respondents agreeing/strongly agreeing with Beliefs about Medicines statements.

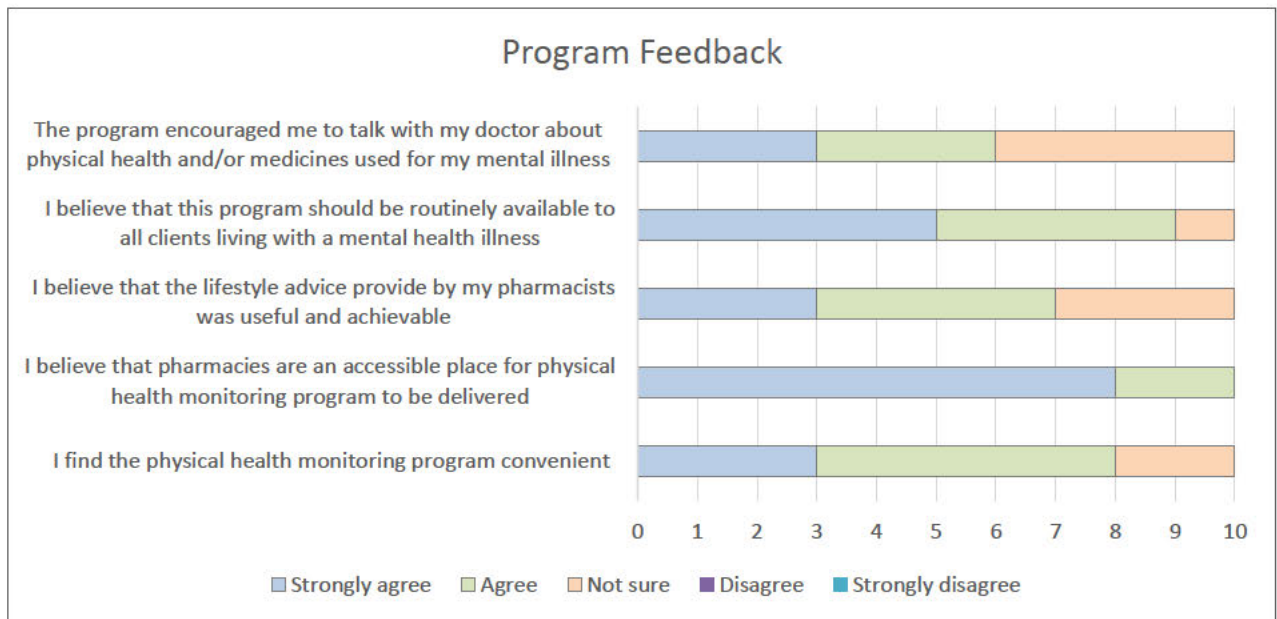
	Number agreeing or strongly agreeing (%)
Necessity scale	
My health, at present, depends on my medicines	8
My life would be impossible without my medicines	5
Without my medicines I would become very ill	6
My health in the future will depend on my medicines	5
My medicines protect me from becoming worse	7
Concerns scale	
Having to take medicines worries me	5
I sometimes worry about the long-term effects of my medicines	6
My medicines are a mystery to me	2
My medicines disrupt my life	2
I sometimes worry about becoming too dependent on my medicines	6

Most (n=8) disagreed with the statement, ‘*my medicines are a mystery to me,*’ and 4 participants did not believe that their medicines disrupted their life. Majority (n=8) reported that their health was dependent on their medicines (Supplementary File I).

Satisfaction with the program

The average SAPS score was 25.1 (range 19 – 28), indicating a high level of patient satisfaction with the program. General responses to questions regarding the program were positive (Figure 10). All participants either agreed or strongly agreed that pharmacies were accessible for the physical health monitoring program. Participants also believed that the program should be routinely available to all PLMI, with nine participants either agreeing or strongly agreeing with this statement. More than half the participants (n=6) either agreed or strongly agreed that the program encouraged them to talk to their doctors about their physical health.

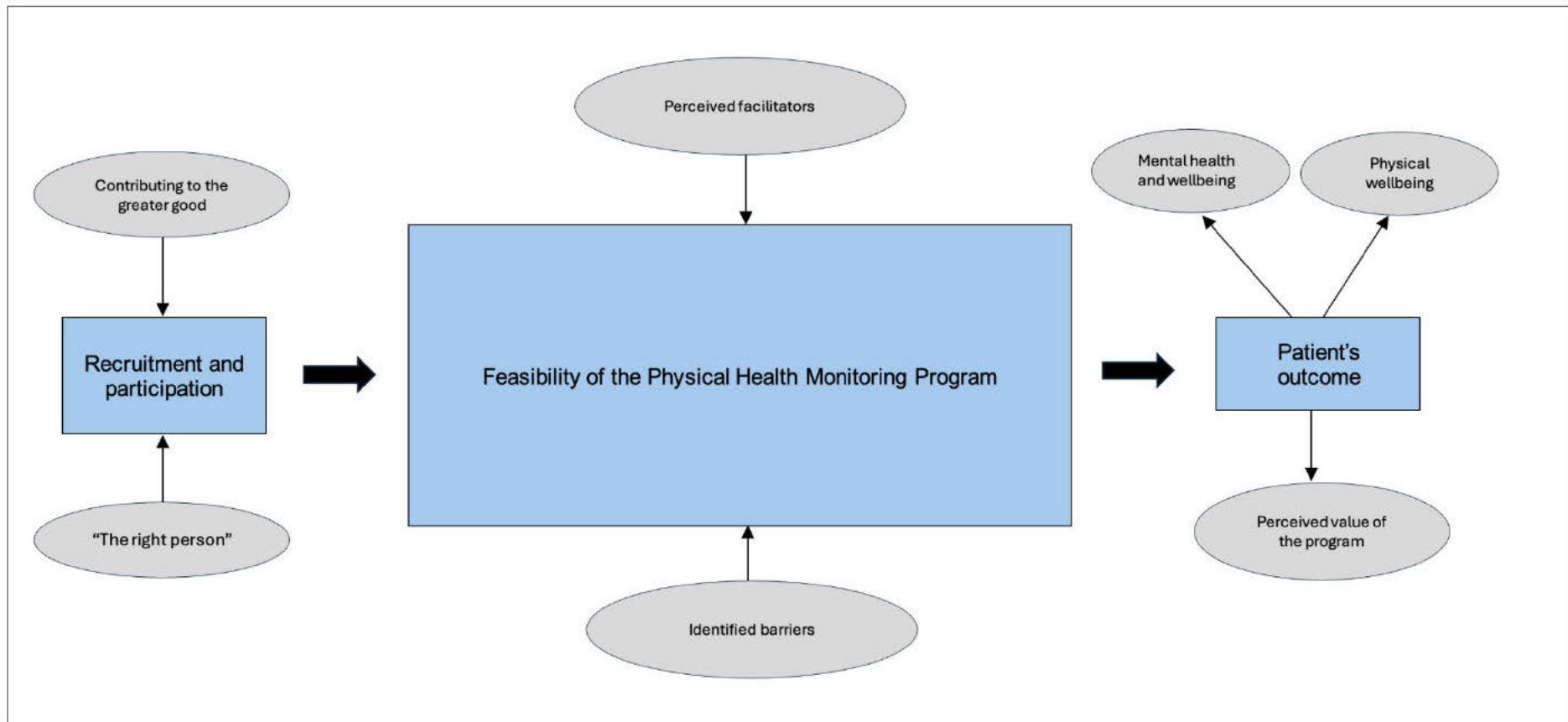
Figure 10. Program feedback - Likert response (count).



Thematic relationship

Findings from the interviews identified three overarching themes, including (1) recruitment and participation, (2) feasibility of the program and, (3) participant outcomes. During the recruitment stage, the pharmacists reported a desire to recruit “the right person” for the study. Those recruited typically had good rapport with the pharmacists and their motivation to participate was often attributed to wanting to contribute to “the greater good.” The feasibility of the program was explored in the context of the perceived facilitators and barriers identified by the interviewees. In general, participants frequently reported positive outcomes and perceived the program to be of value, with some highlighting the benefits to their wellbeing (Figure 11).

Figure 11. Thematic Map



Theme 1. Recruitment and participation

“The right person”

Pharmacists described a purposive sampling approach to the recruitment of participants to the program. The pharmacists described the recruitment of “the right person” for the study:

“I think I pick and choose who (sic) I spoke to. So, if I had someone that I was [providing medication] counselling and realised that maybe they won’t be appropriate I didn’t even bother.” - FL (Pharmacist, Recruiter)

Having an established rapport was a key factor that contributed to both the recruitment and willingness of participants to enrol in the study. One pharmacist stated:

*“The one(s) we had a rapport with ... were generally longer-term customers... the one(s) that we had in the program um they tended to come back so we had a more of a positive relationship with them, so we attracted them, and they stayed as constant customers.”
– MI (Pharmacist and owner, Recruiter)*

This was further supported by participants, who indicated that they had either an established or positive rapport with the pharmacists, stating:

“We’re really good friends with the people at that chemist we go there all the time, it’s a really good chemist.” – BS6 (Participant)

and,

“I have been with my pharmacy for a very long time now, so I’ve gotten to know them very well over the years.” – MB8 (Participant)

Other factors that pharmacists considered in the recruitment of the participants included, cognitive ability and the perceived ability to participate in the study.

“Majority of patients that we approached ... [had] the right level of cognition. Which I sort of say carefully. There were certain people who (sic) I think, I don’t think they’re ... the right sort of candidates for the study.” – FA (Pharmacist, Recruiter)

and,

“We’ve got almost a bias in there by selecting patients that we know who will be able to do it [the study].” – MI (Pharmacist and owner, Recruiter)

Having an established positive therapeutic relationship with the pharmacist or rapport and resulting familiarity contributed to participants feeling comfortable in the community pharmacy environment. It was highlighted:

“I’ve known my pharmacist for a long time, I’ve been going there for 15 years so ... [I] was comfortable discussing my health because he knows all my medications and all that sort of thing.” – KJ6 (Participant)

“I have to have a kind of relationship with someone to be able to ... understand them better and what they’re doing, and I guess feel comfortable.” – MB8 (Participant)

and,

“I have a better rapport with my pharmacist than I do with my doctor anyway [so was happy to participate in the program].” – JM0 (Participant)

The feeling of comfort was also supported by the perceived lack of stigma, highlighting:

“I felt comfortable because they [pharmacy staff] don't treat you like you're weird because you have all these issues... she [pharmacist] made it very easy to understand what was going on, she made it comfortable for me I wasn't feeling pressured, or I wasn't feeling embarrassed. I didn't feel like I couldn't talk about what was going on in my mind. It just made me feel relaxed and sure that what I was doing was for a good cause.”- BS6 (Participant)

The term “good cause” is believed to refer to contributions to the community or the greater good, which can impact beyond the individual taking part in the study.

Contributing to the greater good

A commonality reported by the participants was the desire to “contribute to the greater good” as the main motivating factor for their participation in the study. Participants mentioned:

“... that’s one of the reasons why I did it, is if it’s [the study] gonna [sic] help others.” – BS6 (Participant)

and,

“... I was happy to help ... to give knowledge to the university ...and it’s helpful to me too.” – KJ6 (Participant)

Pharmacists involved in the study also expressed a keen interest in helping the community.

Most reported being very service-oriented in their practice. Pharmacists described:

“We do dose administration aids, like websters and staged supply. We do the methadone and Suboxone® program, we have a diabetes educator ... We have a sleep apnoea technician who does testing for sleep apnoea [and a] pharmacist does it as well with her. We have two pharmacists or three actually who can vaccinate, we do MedsChecks and Diabetes Medscheck. We also do the 20 minutes health check, which is your blood pressure monitoring, cholesterol, and blood glucose monitoring.” – MI, (Pharmacist and owner, Recruiter)

and,

“I’m a forward dispensing pharmacist, if someone comes in with a script [and] they’ve never used this medicine, I’d take as much time as it needs.” – MP (Pharmacist, Non-recruiter)

One pharmacist also indicated their decision to complete MHFA training in preparation for the program delivery, despite it not being mandatory.

“It was myself and another person who did the training and went to do the Mental Health First Aid and everything for this study...” – NJ (Pharmacist, Non-recruiter)

Theme 2. Feasibility of the program

Overall, the program was perceived to be feasible in a community pharmacy setting. Recruiters mentioned:

“The design was very good, from start to finish ...” – MI (Pharmacist and owner, Recruiter)

and,

“We [pharmacists] should have those skills pretty much already. I think, maybe I was somewhat biased because I had already done my Mental Health training... it [the program] should be easily done in a pharmacy [with] the skills we’ve got. – FL (Pharmacist, Recruiter)

The design of the program, such as the frequency of follow-up consultations and elements involved in the program, were deemed to be appropriate by participants and the pharmacists alike. It was mentioned:

“Three months is suitable [for the follow-up consultations]. It’s probably that in-between from that (sic) they would see their doctor ... [every] three months you know you can identify things that can be addressed. Which is probably good timing.” – MI (Pharmacist and owner, Recruiter)

A participant also commented favourably on the timing. Stating:

“My doctor’s appointment is every like 3-6 months. I would be okay with that [three monthly follow ups at the pharmacy].” – JP0 (Participant)

Perceived facilitators

Pharmacist stated that their familiarity with measuring certain metabolic parameter could have facilitated the process. It was mentioned:

“...we [pharmacists] were familiar with doing blood glucose, cholesterol measuring and blood pressure. So, we had experience in that so it wasn’t a problem ... [the] recording process was very straight forward and very easy” – MI (Pharmacist and owner, Recruiter)

and,

“... individually [measuring of metabolic parameters], [it] was easy enough. I think when you add the whole services as a whole taking that time out for a pharmacist to do this service, that could potentially take half an hour.” – FL (Pharmacist, Recruiter)

For some participants, the pharmacy was perceived as a less formal environment with one participant stating:

“A lot more like you're just chatting with a friend ... 'cause it's not as professional ... It's [a] more comfortable support system, in a way of it's not high pressure ... like going to a psychologist or counsellor.” – LC9 (Participant)

Other perceived facilitators for program delivery mentioned by pharmacists having a ‘champion’ and positive trust between the consumer and the pharmacist/s. It was mentioned:

“... having a motivated champion ... would absolutely be a facilitator.”- FA (Pharmacist, Recruiter)

and,

“...one of my patients made it clear that when she tried a new GP ...[and]... how she didn't know them ... she didn't trust them and so the fact that I was at that pharmacy that she had been at a long time, sure she didn't know me that well, but she trusted [pharmacist A] so it was definitely that as well.” – FL (Pharmacist, Recruiter)

In terms of the sustainability of the program, a participant highlighted the importance of adequate remuneration and the need for integration of the form (for data collection) into an electronic database. Stating:

“It [the program] would be sustainable as long as there was some remuneration for the time... [and]...having maybe like a GuildCare type model where it's [data collection sheet] all integrated ... then that would help. Especially like with workflow” – NJ (Non-recruiter)

Identified barriers

Several barriers were identified by the interviewees, including the pandemic, blood cholesterol point-of-care testing and setting appointment schedules for follow-up consultations (see Supplementary File G). Overall, the pandemic was reported to have affected the recruitment and monitoring phases of the study, as it inevitably led to a considerable increase in the pharmacists' workload. A non-recruiter mentioned:

“... with Covid going on it was very hard to even promote this study ... everything was to do with like vaccinations, and I mean like the consult rooms [were] all obviously full we were vaccinating like the whole day throughout ...” – BA (Pharmacist, Non-recruiter)

The pandemic also hindered the pharmacists' ability to conduct consultations. It was described:

“The issues came when obviously we have a pandemic, you've got higher workflows, you've got, other programs going on so with vaccinations ... like I said there [were] ones that fell by the wayside... a lot of the services, for example our sleep apnoea because of that one-on-one contact ... there was a period when we weren't doing them. For safety concerns, both for our staff, for the customer itself and for the greater

community in general so we didn't want to be a source of an outbreak.” – MI (Pharmacist and owner, Recruiter)

“...my head office they told us to try to reduce time spent directly face to face with patients to avoid being a close contact because the rules were very strict then and you want to not be, locked away in the consult room for twenty minutes even if everyone was wearing masks and we had to do like full PPE [personal protective equipment] ... A lot of people actually started getting deliveries as well so in general contactless deliveries but definitely the staff shortages ...definitely impacted the service and the recruitment.” – NJ (Pharmacist, Non-recruiter)

and,

“... you lose a lot of that patient interaction when you're wearing a mask and you've got your plastic screen up and everybody is wearing goggles, and you know it's not as necessarily um inviting from an interview perspective.” – MP (Pharmacist, Non-recruiter)

The administrative burden surrounding the follow-up appointments was also identified as a barrier to service delivery. Particularly as *“we're [pharmacist] probably one of the health professions that we don't regularly have an appointment-type system with the people (FA, Pharmacist, Recruiter).”* Pharmacists mentioned:

“At times when the scheduling didn't quite work out it was possibly a little bit distracting.” – FL (Pharmacist, Recruiter)

and,

“People would just drift in and not make an appointment and so you would have to catch them when they were available, when they came into the store. So that meant, if I wasn't here then another pharmacist will either address them and tell them to come back if it was possible, or if not, they would record whatever I ask them to record so take measurements and record.” – MI (Pharmacist and owner, Recruiter)

Most participants also highlighted that whilst the appointments for the physical health consultations did not necessarily align with their visits for prescription refills, it did not take them out of their way. Some reported a slight inconvenience, although it was not seen as a great barrier to participating in the program, stating:

“I don't drive anymore; it was an inconvenience occasionally that's all” - KH3 (Participant)

and,

“No, they [consultations] didn't [align with prescription collections] but I didn't live far away so it wasn't a big deal for me” - MJ5 (Participant)

The collection of blood cholesterol levels, including for TGs, LDLs and HDLs was identified as a barrier and made the program a *“drawn out process (FA, Recruiter).”* It was stated:

“I don’t, 100% see the value in that [cholesterol testing], particularly the amount of times initially I had to poke this poor woman to get enough blood and like even then it coagulated, and it was not all pretty.” – FL (Pharmacist, Recruiter)

and,

“The strips are a pain in the neck, God they last about two months on the shelf and then they’re no good... then you throw away a hundred and something dollars' worth of strips” – MP (Pharmacist, Non-recruiter)

Participants noted the potential for the cholesterol test to be a barrier, however, it did not impact on their overall experience. Stating:

“I just find ... getting the blood for the cholesterol was harder, like we had it down pat by the end of it... for me that wasn't too bad ... I could see [how] some people might.” – LC9 (Participant)

Theme 3. Participant’s outcomes

Mental health and wellbeing

Participants also reported that the program was able to support their mental illness indirectly. It was highlighted:

“I was able to say what are the goals I’ve achieved and how I’ve improved and if I didn’t have those goals set by the pharmacist, I probably wouldn’t have gotten around to doing them, so I found it really helpful for me for my mental health because I felt good about achieving the goals.” - KJ6 (Participant)

and,

“I’m always alone most of the time... having a chat with the pharmacist helped a lot with my medications, see how it’s going.” – JP0 (Participant)

One participant mentioned that they found the program, particularly the one-to-one discussions with the pharmacist valuable despite no apparent changes to their physical health:

“My physical health hasn’t changed ‘cause I haven’t been able to give up smoking or drinking... but it’s mainly to come in and have a chat really, it’s good for me.” – RS6 (Participant)

Some participants did not view that service as having a direct impact on their mental health, stating:

“I don’t know about supported [mental health and wellbeing], I wouldn’t have said that. The main thing is understanding of medications and effects it has on people.” – NC5 (Participant)

and,

“... the mental illness, that really didn't come into it a lot... I don't know whether [the pharmacist] would be the best person to talk about that. I don't know what their field of expertise, even my doctor I'm not certain about it you know?” – JM5 (Participant)

This was echoed by a pharmacist, who mentioned:

“Clearly, we're really not skilled enough to be able to discuss in the appropriateness of antipsychotic therapy. Is, ah that's a lot of that is even beyond a lot of GPs. That kind of falls into the realms of psychiatrists. But the consequences of those (sic) therapy in metabolic [syndrome] ... I'm comfortable with this space ...” – FA (Pharmacist, Recruiter)

Physical wellbeing

The frequent metabolic monitoring and lifestyle goal setting were perceived to be beneficial by participants and pharmacists alike. Interviewees stated:

“I rent... and every four months I have an inspection, so I clean my house! If I didn't have an inspection, I probably wouldn't clean my house as much, so you know it would bring my health more ... to the forefront of my mind. It'll be something that I'll have to... tackle more regularly.” – JM5 (Participant)

“... it [the program] was just inspiring for me... definitely helped me initiate some goals, extra goals into my exercise weekly plan.” – MB8 (Participant)

“I think having someone encourage her was the main thing, um, and to sort of hold her accountable a little bit. Knowing that I'm going to catch up with you in three months' time we'll see how you go.” – FL (Pharmacist, Recruiter)

and,

“...by monitoring their weight over that period, we were able to encourage them to do as much exercise as possible and look at their diet... I can see in our results the weight change wasn't um for most of the patients was actually quite good over the pandemic period, where I personally put on like 5kgs ... they had been able to maintain their weight and monitor their vitals.” – MI (Pharmacist and owner, Recruiter)

Other outcomes reported positive changes to medications and strengthening of existing rapport between the pharmacist and the participant. Regarding changes to medications, it was mentioned:

“Whether it was as a direct result of the study, or the study may be accelerated it I reckon. It's probably more the second one ... when the doctor's getting notes from us saying cholesterol was high or the blood pressure ... then the patient is kind of motivated to talk about it because that's one of the takeaways from us... bringing it up with the doctor the next time, and then the doctor does the BP and goes right we're going to do something about that today.” – FA (Pharmacist, Recruiter)

and,

“I didn't know about my sugar level and my blood pressure and getting my blood pressure taken and everything led me to tell my doctor [that's its elevated] ... I made

my doctor aware that I needed to go on blood pressure medications... otherwise it would've been uncaught, and it was dangerously high ...” – KJ6 (Participant)

Participants also described improvement in the understanding of their medications, reporting:

“I found it [the program] really useful ... I got to understand my medications a bit better ...” – KJ6 (Participant)

and,

“[The] first-hand experience sort of talking with people about how they are using medicines, about what their fears are, what their goals are, sort of lifestyle coaching... it’s very rewarding when it goes well too. There were a couple of patients in this study that, really did benefit from the chat. Even if it wasn’t the screening...that’s kind of hard to measure, even if the study goes, but it’s, it goes a long way I think to both patient outcomes and to professional satisfaction” – FA (Pharmacist, Recruiters)

Perceived value

“a lot of people would benefit [in general] from doing this kind of thing” – BS6 (Participant)

Overall, the program was perceived to be valuable and one that was addressing an existing healthcare gap. One participant stated:

“The closest thing [to this physical health monitoring program] would be that I get healthcare check annually... it’s essentially the same kind of physical checks ... not as in depth ... once a year as well ... a lot can happen in a year.” – JM0 (Participant)

It was further elaborated:

“... the doctor doesn’t usually weigh you, take your waist measurements and things like that unless you ask them to... I think it [physical health monitoring program] would be a good long-term program.” – LB5 (Participant)

and,

“Doctors don’t always have the time to check everything like that you know? Sometimes they just sort of rushed through and give your scripts and you know?” – KJ6 (Participant)

The role of the pharmacists was also highlighted by the interviewees. It was mentioned:

“I think it's really important to have the pharmacist take on these roles, it really helps me mentally and I feel supported.” – RS6 (Participant)

and,

“ [I] think it's a very good way of looking at things in pharmacy, it’s a different way to help people in other than just you know the normal pamphlets or information that would give just face to face...it’s not always that easy to get into doctors and psychiatrists, so... community pharmacists might be able to open that door a bit more for people... ” – LC9 (Participant)

One pharmacist queried the suitability of community pharmacists in addressing this healthcare gap, stating:

“I’m willing to spend whatever time it takes to talk to someone, and the rest of the shop can wait... but that’s different to intentionally sucking up time um with someone just as a sort of like a health check that in some sense it should, if it’s not already happening it should...[like] if it’s not already happening in ... general practice care” – MP (Pharmacist, Non-recruiter)


A recruiter pharmacist commented on the contribution of the program to the pharmacy scope of practice, highlighting:

“Really this is the direction, for my mind, this is the kind of thing that community pharmacy really needs... I think it’s a move away from this dispense focus which is relatively unfulfilling, I think professionally.” – FA (Pharmacist, Recruiter)

Case studies

Reported outcomes varied between participants. The following exemplar cases have been selected to illustrate these outcomes.


Table 19. Case Study One.

 RS6	<p><i>“...just being able to share what I'm going through and then [pharmacist] listening and showing understanding and empathy.”</i></p>	
Details		
Gender	Female	
Age	59	
Medical conditions	Addison's disease, post-traumatic stress disorder, depression, and anxiety	
Medications	Thiamine, vitamin C, vitamin D and calcium, hydrocortisone, olanzapine, fluticasone + salmeterol puffer, amlodipine, venlafaxine, fludrocortisone, salbutamol puffer and levothyroxine	
No. of consultations	3	
Summary		
<p>Noted elevated lipid levels at first baseline review; referral to GP was made. Main goals reported were to reduce snacking, improve physical activity through walking of dogs (3 times a week), consideration of nicotine replacement therapy and to reduce alcohol intake.</p> <p>Subsequent follow up documented no changes to medications; however, participant had given up night-time snacking with new goal to stop snacking altogether. Participant also reported not having acted on the GP referral made at the last consultation (4 months ago); however, had made an appointment for the following fortnight.</p> <p>At the final consultation, it was noted that the GP had made a diagnosis of hypercholesterolaemia and initiated rosuvastatin to manage elevated lipid levels.</p>		
Parameters	Baseline	Final consultation
Weight (kg)	97.2	↑99.8
BMI	36.5	↑37.4
Waist circumference (cm)	117	↓116.5
Glucose levels (mmol/L)	5.9 (random)	↑6.4 (random)
Lipid levels (mmol/L)*	TC: 8.93 (random) TG: 3.71 (random) HDL: 2.4 (random)	TC: <u>Test error</u> TG: <u>Test error</u> HDL: <u>Test error</u>
Blood pressure (mmHg)	156/97	↓149/93
Referral reason	Elevated lipid levels Risk of obstructive sleep apnoea STOP-Bang score of 4	Elevated glucose levels Review of medication or underlying cause of lack of motivation (concerns include uncontrolled depression, medication, or medical related issues)
Outcomes		
SAP score (0-28)	26	
Overall outcome	An increase in weight, glucose and lipid levels which resulted in a referral to the GP and subsequent diagnosis of hypercholesteremia and initiation of a	

	new lipid-lowering agent for the participant. Participant was also commenced on rosuvastatin by the doctor for diagnosis of hypercholesterolemia and reported ceased snacking (goal set at the beginning of the consultations)
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*TC = Total cholesterol, TG = Triglycerides, HDL = High Density lipoprotein

Table 20. Case Study Two.

 CC	No interview conducted	
Details		
Gender	Male	
Age	62	
Medical conditions	Diabetes, hypertension, hypercholesteremia, arthritis, reflux, schizophrenia, insomnia, and arrhythmia.	
Medications	Aspirin, amiodarone, bisoprolol, pantoprazole, metformin XR, pregabalin, amitriptyline, risperidone, multivitamin, vitamin D, atorvastatin and spironolactone.	
No. of consultations	4	
Summary		
<p>A referral to the GP was made at each of the consultations because of elevated blood pressure and glucose levels. The referral resulted in review of blood pressure medication. Subsequent consultation also noted increased in weight and referral made on the basis on continual elevated blood pressure (has been >6 months since last reviewed by GP). Main goals reported included increasing low-impact physical activity (walking) and reviewing salt and fat intake.</p> <p>Mr CC07 recorded a reduction in weight (-6kg) between the third (where weight gain was first noted) and last consultation. Documentation indicated a slight increase in exercise, overall reduction in blood pressure and noted participant's desire to maintain exercise routine.</p> <p>At the final consultation, there was no documented change in medications and glucose levels which were noted to be 'ok' at second consultation.</p>		
Parameters	Baseline	Final consultation
Weight (kg)	84	↓82
BMI	28.8	↓28.1
Waist circumference (cm)	Missing	104
Glucose levels (mmol/L)	6.2 (not specified)	↓4.3 (random)
Lipid levels (mmol/L)*	TC: 4.8 (not specified) TG: Missing HDL: Missing	TC: Missing TG: 1.9 (random) HDL: 3.1 (random)
Blood pressure (mmHg)	156/91	↓143/81
Referral reason	Elevated blood pressure Elevated glucose levels	Six months since last GP review Need new prescriptions
Outcomes		
SAP score (0-28)	Unable to contact for consumer interview	
Overall outcome	A reduction in most of the physical metabolic parameters with no change in medication therapy	

*TC = Total cholesterol, TG = Triglycerides, HDL = High Density lipoprotein

Table 21. Case Study Three.


 LC9	<p>“... they're [pharmacists] looking at the bloods and everything as well it's just a reminder of what's happening ... you perk up when you see oh that's dropped a bit or my blood pressure dropped a bit”</p>	
Details		
Gender	Female	
Age	30	
Medical conditions	Hypothyroidism, hypertension and “mental health”	
Medications	Levothyroxine, Armaforce [®] , quetiapine, telmisartan and venlafaxine	
No. of consultations	3	
Summary		
<p>Goals set for first consultation were simple daily interventions which involved reduced snacking and selection of healthier options. Increase physical activity, such as starting Pilates. Referral was made due to elevated TG levels.</p> <p>At the subsequent follow-up, the participant reported the commencement of Pilates and expressed a continual desire to increase movement. The consultation also recorded a 1 kg weight loss which was ‘unexpected’ by the participant. It was noted that the participant had not acted on the last referral but had made an appointment to see GP soon. Elevated TG levels were also recorded at this consultation.</p> <p>Final consultation noted no comment from doctor regarding elevated TG levels and no major changes to medications. Pharmacist noted potential for lipid levels to be within range when fasting. Noticed participant’s desire to continue to work towards goals set in the first baseline review. There was a significant increase in total cholesterol levels when compared to baseline. Pharmacist noted that blood test was done by doctor who had not raised any concerns.</p>		
Parameters	Baseline	Final consultation
Weight (kg)	116	↓113.3
BMI	37.4	↓36.7
Waist circumference (cm)	123	↓122
Glucose levels (mmol/L)	4.9 (random)	↓4.8 (random)
Lipid levels (mmol/L)*	TC: 3.59 (random) TG: 5.65 (random) HDL: 1.03 (random)	↑↑TC: 6.72 (random) TG: 5.65 (random) ↓HDL: 0.99 (random)
Blood pressure (mmHg)	124/94	↑127/101
Referral reason	Elevated triglyceride levels	No referral
Outcomes		
SAP score (0-28)	26	
Overall outcome	A reduction in most metabolic parameters but noted a significant increase in total cholesterol resulting in multiple referrals to the GP (

	Table 21). Overall noticed weight loss and also increased in total cholesterol levels. No documentation of a new diagnosis of hypercholesteremia or initiation of lipid-lowering therapy by the GP
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^aArmaforce® is a commercially available over the counter supplement indicated for a number of conditions including cold and flu and symptoms of mild upper respiratory tract infections [323]

Discussion

The study was designed to address the inadequate metabolic monitoring for PLMI on SGAs, specifically SGAs other than clozapine. Quantitative findings from this study supported the feasibility of community-based pharmacists conducting longitudinal monitoring of selected metabolic parameters, in particular blood pressure, waist circumference and weight. The study also found that most participants felt that pharmacies were an accessible place for the physical health monitoring program and supported the need for the program to be routinely available to all PLMI. Overall, qualitative feedback from pharmacists and participants indicated that the program was positively received by both cohorts.

Most study participants were frequently prescribed SGAs and in some instances prescribed more than one antipsychotic, with high risk of metabolic complications (weight gain and hyperglycaemia) such as quetiapine (n=8), clozapine (n=7) and, olanzapine (n=7) [131, 324]. Indeed, rates of MetSyn had been reported to be the highest in people diagnosed with a SMI, including schizophrenia and bipolar disorder, taking clozapine (51.9%), olanzapine (28.2%) and risperidone (27.9%)[268].

Implementation of the physical health monitoring program

The study found that the recruitment of PLMI involved a two-tier approach: first, meeting the eligibility criteria, and second, undergoing an informal assessment by the pharmacists to determine if they were “the right person” for the study. Selecting the “right person” can be advantageous, as it reflected on the pharmacists' informal assessment and the perceived value of the participant in the program. However, it may also exclude PLMI who could benefit but lack a strong therapeutic relationship or established medical history with the pharmacists. For broader implementation of such services, it is recommended to adopt more general advertising strategies, enabling interested participants to approach pharmacists and join the program. In addition, PLMI in this study reported the desire to contribute to the greater good, as their main motivation for participation; however, it should be recognised that factors such as the severity of symptoms can also influence PLMI’s desire and ability to participate in research and/or health services [325].

Although the study generated higher rates of metabolic screening [189, 326], none of the participants had completed all five proposed consultations over the study period. Low rates of consultations at the six- and nine-month follow-ups aligned with increased vaccination efforts in South Australian community pharmacies in response to heightened pandemic concerns at the time [327]. This resulted in increased workloads and unavailability of the private consulting rooms in the participating pharmacies. Despite this, both participants and pharmacists (recruiters) agreed on the appropriateness of the three-month follow-ups.

Outcome 1: Monitoring of metabolic parameters

The monitoring levels of metabolic parameters such as weight and blood pressure were higher than indicated in other studies (Figure 7)[170, 189, 326]. Notably, waist circumferences were measured much more frequently in this study [170]. This was a meaningful finding, as waist circumference had been shown to be a useful predictor of MetSyn, with high sensitivity and specificity (79.4% and 78.8% respectively) [268]. Although higher rates of metabolic monitoring reported in this study can be attributed to the relative ease of the small sample size, the availability/provision of equipment (such as tape measures and digital scales), which had been noted as a barrier in previous research [170], could have also contributed to high monitoring rates in the current study.

The unprecedented nature of the pandemic and policies implemented in efforts to contain the outbreaks resulted in lockdowns and social restrictions globally [328], potentially affecting the follow-up rates. Figure 11 illustrates the distribution of the metabolic parameters, however given the variation in sample size at each follow-up, metabolic parameters such as blood pressure, weight, and waist circumference between baseline and 12-month could not be compared. Arguably, the lack of identifiable increase in the metabolic parameters seen in this study between baseline and 12-month review should be viewed positively, given the negative impact that the pandemic has had on the physical and mental wellbeing for the general population [328, 329]. Reports indicated an increase in poor food habits such as increased indulgence in “comfort food,” snacking and alcohol intake during the pandemic [328], with higher incidence of weight gain and obesity [330], leading to concerns around a new “Covibesity” pandemic [331]. The comparisons of other parameters such as BGL and lipid levels could not be made given the significant variation in sample size at each consultation and the nature of the samples collected; for example, not all BGL readings were undertaken in a fasting state.

Although this study reported low rates of TGs and HDL monitoring, aligning with findings presented in Chapter Five, the pharmacist-led physical health monitoring had a higher rate of waist circumference, BP and BGL monitoring. The monitoring rates can often correlate to the familiarity with the equipment required, for instance, BGL can be readily measured using a finger prick test while TG and HDL testing require a larger volume of blood to run the test. In general, findings reflected the pragmatic design of this study with most of the serum levels taken at “random” rather than at a fasting state. Similarly, it can be inferred that the majority of the lipid levels were also taken as non-fasting since both glucose and lipid levels were measured concurrently. Fasting lipid levels (TG and HDL) are required to make a clinical diagnosis of MetSyn [297]. Currently, there is insufficient evidence to suggest that these are superior to their respective non-fasting levels [332]. Further, the collection of serum levels at a random non-fasting state had practical advantages, such as enhanced convenience for both participants and pharmacists [332]. This sampling timing may therefore be more suitable than fasting lipids and glucose in a community pharmacy setting.

Finally, the study reported high referral numbers, with half of the consultations (51.1%) resulting in a referral. However, most of the GP referrals did not result in a documented actionable change to medication therapy. Changes to therapy were documented only on two occasions, but whether this was as a direct result of the pharmacist’s referral cannot be ascertained. The high referral rates reported in this study could be indicative of potentially high rates of untreated or poorly controlled metabolic complications in this cohort [118].

Outcome 2: Goal setting

Most goals that were set during the follow-ups aligned with current best practice by adopting a multifaceted approach to physical health and wellbeing, encompassing interventions that included elements of exercise, diet, and health promotion [333]. Overall, the goal setting between participants and pharmacists was tailored and specific to each participant and this was well received by participants. These goals centred around the five broad domains of exercise, diet, alcohol consumption, smoking and others (activities such as singing classes). Components of counselling and strategic goal planning were canvassed in the pharmacists’ refresher training course [282]. Even though the use of a framework such as SMART or SMART-EST to set goals (S= specific, M=measurable, A=attainable, R=relevant, T=time-bound, E=evidence-based, S=strategic and T=tailored) [334, 335] were not explicitly described, a majority (72.1%) of the goals were specific. Currently, goal setting is not a service that is widely provided by community pharmacists in Australia. Recent research involving SMI, highlighted the value of

such a service in community pharmacies, in providing purpose and motivation for the participants, and emphasising the need for goals to be individualised and flexible [75]. The authors also noted that most goals set in these settings were of poor quality when compared to the SMART guidelines. Goals frequently lacked specificity such as the methods for achieving and monitoring them, with 93% of the goals lacking details on how they would be monitored.

It was noted that the majority of the exercise-related goals (85%) reported in this study were specific, and included details about how the goals could be achieved. However, goals set in other domains, such as diet could be more detailed. Additionally, the scheduled one-to-one consultations likely heightened participant's awareness of the importance of lifestyle factors, positively contributing to their physical wellbeing. While most of the goals relating to exercise were specific, diet-related goals were often less so. The SMART guideline is a useful validated tool that can be used to support participants in setting specific goals in these areas [334].

Outcome 3: Perceived feasibility and acceptability of the program

Qualitative data from the interviews with pharmacists indicated that the program was well received. Patients valued the program despite not seeing significant changes to their metabolic parameters. The average patient satisfaction score for the physical health monitoring program was high (25.1) [302]. It is worth considering the potential to extend the study's duration to better explore the correlation between the service and changes (if any) to metabolic parameters.

Although most participants did not attend all of the follow-up sessions, the study had a high 12-month retention rate. The ability to conduct the service during the challenging pandemic climate can be attributed to the high level of motivation of both groups and the desire by participants to contribute to their communities ("greater good"), which has been previously shown to be a common factor for patients participating in research studies [336, 337]. As in previous studies, we found that having an established relationship and good rapport between pharmacist and patient also facilitated the process of recruitment and study implementation [338] and supported these high retention rates. Indeed, reports of the interaction being "not as professional" is viewed positively in this context, as it suggests an established rapport between pharmacists and participants. Therefore, this familiarity makes the pharmacy feel less clinical and more personal which can foster comfort and trust.

The findings in this chapter also included feedback from both pharmacists and those who were unable to recruit. Recruiters provided valuable feedback regarding the acceptability and

feasibility of the study in a community pharmacy setting and the non-recruiting pharmacists also contributed to the findings by providing their perceptions of the study and also highlighting barriers to recruitment. Both cohorts indicated that the study is within the scope of pharmacy practice and highlighted the need to ensure adequate remuneration to support the sustainability of such service.

Recruiters highlighted the challenges with organising follow-up appointments, given the unpredictability of the workflow, resulting in additional administrative burden. Pharmacists, particularly those based within the community are available for medicines and health advice without the need for prior appointment. Access to pharmacy services, such as vaccinations, can be provided, sometimes even without a prior appointment [339] as such both consumers and pharmacists are unfamiliar with working within the confines of making prior appointments at community pharmacies. For this program to be successful, there is a need to better facilitate follow-up appointments. Consideration could include the use of an automated reminder system to notify consumers of pending appointments, such as automatic text messages [340], or to coordinate with pharmacy-in-store visits. This will require additional considerations to remuneration and staffing levels. A number of facilitators were also reported, including the value of having a “champion” who leads the research at each of the pharmacy sites. In this study, recruitment of pharmacy sites often involved discussions between researchers and pharmacist-managers who served as champions at their respective sites.

Strengths and limitations

A strength of this study the used of mixed methods to thoroughly explore the feasibility and implementation of the study and understand the perceptions and experiences of the pharmacists and participants. Another strength of the study included the multidisciplinary and end-user trainers recruited to deliver the training sessions. All trainers, except the end-user, were also registered pharmacists, which further enhanced the study. This dual perspective allowed them to review and refine the LOs, ensuring the training course was precisely tailored to meet the study's requirements.

A limitation of this study included the risk of selection bias [341], which could potentially limit the generalisability of the findings. Firstly, the study relied on the pharmacists to recruit potential participants for the study and participate in the semi-structured interview. The recruitment of participants with whom the pharmacists already had an established or positive rapport. Therefore, the rates of metabolic complications in this cohort may not be generalisable

to all PLMI, as those who agreed to participate in this study may have been better engaged with their health than those who did not [342]. Selection bias could have also contributed to the relatively high retention rates. Furthermore, both sites were within metropolitan Adelaide and nearly all of the participants who had completed the interviews were from one pharmacy whilst the other pharmacy was unable to recruit any participants for the interviews. Additionally, it was also recognised from the interviews that some pharmacists had completed the MHFA training, which was not a requirement for pharmacists' participation in this study. MHFA training status was not collected as part of the demographic data, and this can also limit the generalisability of the findings. Despite this, it is likely that the findings can be extrapolated to appropriate cohorts and settings, particularly for similar demographics in metropolitan areas.

Additionally, the relatively small sample size was a limitation to the study's findings; however, recruitment of PLMI through community pharmacies is often challenging which was made even more challenging during the pandemic. A study by Macfarlane and colleagues that was conducted before the pandemic, reported that of the 53 UK community pharmacies tasked with recruiting participants with severe mental illness, 85% were unable to recruit any potential participants [262]. The authors reported multiple barriers to pharmacy recruitment, including the reliance on the willingness and capacity of pharmacists to support research, difficulty in identifying potential participants, and willingness to prioritise research during working hours [262, 343]. Some of these barriers were also identified in our study. It was likely that the pandemic also had a significant impact on study recruitment [344], which affected the ability of the pharmacists to recruit and implement the study. The findings also highlighted the resilience and perseverance demonstrated by the pharmacists during the challenging and unpredictable pandemic period to ensure patient safety was maintained [345]. The ability to deliver the program, even at a limited capacity, during the time most doctors' surgeries and other healthcare services were closed and pivoted towards the telehealth pathway [346], further emphasised the importance of acknowledging and maximising the role of community pharmacists in the community.

Further, for some participants, a significant time may have elapsed between their last consultation and the interview. It is acknowledged that for these participants there may be a potential for recall bias and that positive experiences may be overestimated. However, it is worth noting that participants are unlikely to underestimate past negative experiences [103,

347]. Therefore, the lack of negative feedback from the participants on the physical health monitoring program can be a reliable indicator of acceptability.

Lastly, the variation in the development of the three interview guides can be viewed as a limitation. Of the three, only one was externally validated. In addition, the interview guide used the BMQ-S to measure beliefs towards medications at the end of the study. Findings would have been enhanced if participants' beliefs towards medications had been measured before the study and again upon completion to better assess if there were any changes in beliefs. However, it is recognised that interpretation of any trends would have been difficult given the small sample size. In this study, the initial interviews for 'non-recruiters' did not incorporate a validated tool, or framework, since it was focused on exploring two primary areas: (i) barriers to recruitment and (ii) perception of the service. Therefore, this could be perceived as a limitation of the study.

Future studies

Future study designs should consider the realities of working in community pharmacies such as staff shortages, limited private consultation spaces and limited pharmacists' time [207]. Where possible, processes should be streamlined to avoid unnecessary duplication of activities such as manual entry of medical conditions or medication if data had already been captured electronically. The use of an electronic database to facilitate data collection and storage could also facilitate timely completion of consults. Additionally, the use of automatic electronic reminders (for example, via text messaging) should be considered where possible as this could improve participants' attendance at follow-ups.

The low levels of TG and HDL monitoring were likely reflective of technical difficulties, and future endeavours could overcome this by employing external laboratory monitoring, including referral to a pathology clinic or access to pathology results through existing real-time health records such as MHR [348]. Furthermore, future protocols could consider using the traditional cholesterol measure, that is total cholesterol, as an interim measure in community pharmacies instead of TG and HDL. Finally, collection of additional data such as ethnicity and duration of illness/es could also be relevant and will add to the findings reported in this thesis [221, 349]. This could be facilitated through collaborative recruitment efforts, such as with NFP organisations that support PLMI.

In this study, the development of an eating plan by community pharmacists was not viewed as within their scope of practice, and more studies in this area are required [350]. Future studies could consider exploring the potential for pharmacists, preferably in collaboration with dietitians, to assess and develop tailored eating plans. Moreover, due to the pandemic, pharmacists were only required to complete a post-training assessment, future studies should consider the benefits of a face-to-face assessment component.

Implementation of this service can be considered with a larger number of pharmacy sites, preferably including those in rural settings. Furthermore, to ensure that the service is tailored towards the needs and requirements of PLMI, follow-up durations should be decided collaboratively between the participant and the pharmacist. This approach ensures that follow-ups align with the participant's availability and takes into account their individual needs and goals.

Chapter Summary

The chapter presented a review of existing community pharmacist-led interventions in a selected number of chronic health conditions. This chapter also described the review and piloting process of the study protocol. In addition, the development (including external review) and delivery of the training course to participating pharmacists were extensively described in this chapter. Whilst most pharmacists had the skillset required to conduct chronic disease management safely without additional training, training would further enhance service delivery and optimise patient care. Additionally, a refresher course, similar to the one described in this chapter would be beneficial, particularly in enhancing the confidence of the pharmacists in conducting the physical health monitoring program.

Overall, feedback from pharmacists and participants indicated that the program was well-received and valued. Additionally, the quantitative findings were able to highlight the value of an accessible community-based physical health monitoring program for PLMI. The study highlighted the potential of community pharmacists to monitor most metabolic parameters, particularly waist circumference, BGL, weight and blood pressure for PLMI on SGAs, in addition to assisting PLMI in setting patient-tailored lifestyle goals.

As this study was implemented during the pandemic, it had several limitations. Despite these, the study design supports the delivery of larger studies that could provide sufficient statistical power to explore the efficacy of the interventions, with their design subsequently modified

based on the findings [351]. While feedback was mostly positive, it was noted that the follow-up appointment schedule did not align with the existing pharmacy model and therefore contributed to increased administrative burden for pharmacists. It was also observed that none of the participants attended all five recommended consultations, with eight out of the 17 participants having only attended three consultations over the 12-month study period. Although this may be due to the significant disruptions caused by the pandemic, personal health and lifestyle factors could also have contributed. Moving forward, studies could consider the appropriateness of alternative follow-up intervals, this should ideally be a collaborative discussion between the participant and their treating healthcare provider. A tailored follow-up approach, according to participants lifestyle and personal health may be more appropriate. Other technical issues included difficulty in collecting samples for the blood cholesterol machine; however, many of the participants did not reflect the pharmacists' view that this was a significant barrier.

This chapter contributes to the broader research question by addressing aims 4 and 5.

Supplementary Files D: Learning objectives for diabetes management programs

Title	Training methods	Contents of training
<p>The Pharmacy Diabetes Care Program: assessment of a community pharmacy diabetes service model in Australia.</p> <p>[285]</p>	<ol style="list-style-type: none"> 1. Self-directed learning 2. 2-day workshop 	<p>Workshop:</p> <ul style="list-style-type: none"> ○ Pharmacotherapy of diabetes ○ Dietary management ○ Role-playing of case scenarios ○ Training on the use of meter (glucose) ○ Insulin injection technique and devices ○ How to measure blood pressure
<p>Community pharmacist–provided extended diabetes care.</p> <p>[286]</p>	<ol style="list-style-type: none"> 1. Self-directed learning 2. Participation in a live program 	<p>Self-directed learning:</p> <ul style="list-style-type: none"> ○ Completion of “Pharmaceutical care for patients with diabetes” certificate <p>Live program:</p> <ul style="list-style-type: none"> ○ Pathophysiology of diabetes ○ Therapeutics of diabetic medications ○ Diabetes self-care ○ Mock cases ○ Demonstration on measuring blood pressure ○ Using blood glucose meter ○ Filling insulin syringe ○ Administration of injections
<p>Diabetes Medication Assistance Service: the pharmacist’s role in supporting patient self-management of type 2 diabetes (T2DM) in Australia.</p> <p>[287]</p>	<ol style="list-style-type: none"> 1. Self-directed learning 2. 2-day training workshop presented as: <ul style="list-style-type: none"> ○ Lectures ○ Case discussion ○ Role practice 	<p>Self-learning covered:</p> <ul style="list-style-type: none"> ○ Pathophysiology ○ Diagnosis ○ Complications ○ Co-morbidities and pharmacotherapy <p>Workshop:</p> <ul style="list-style-type: none"> ○ Diabetes specific skills <ul style="list-style-type: none"> • Use of insulin pens • Blood glucose testing device • Interpretation of self-monitoring blood glucose levels • Application of motivational interviewing and collaborative goal setting ○ Overview of patient education strategies ○ Familiarisation of participant with study protocol and documentation <p>Credentialing:</p> <ul style="list-style-type: none"> ○ 10 item multiple choice test of diabetes knowledge ○ Test of competencies in using blood glucose meter and downloading of software ○ Case scenarios requiring interpretation of blood glucose readings

Supplementary Files E: Learning objectives for weight loss programs

Title	Training method(s)	Contents covered
<p>A community pharmacy weight management programme: an evaluation of effectiveness.</p> <p>[288]</p>	<ol style="list-style-type: none"> 1. Training manuals 2. Desktop flip charts 3. Information booklets 4. Face to face training by specialist dietitian: <ul style="list-style-type: none"> ○ 2 x 4 hr sessions ○ 3 hr session after 6 months 	<p>Face to face training*:</p> <ul style="list-style-type: none"> ○ Training program based on Counterweight project [290] <p>Training on:</p> <ul style="list-style-type: none"> ○ Providing patient education <ul style="list-style-type: none"> • Weight management • Communicating information on behaviour change strategies • Eating plan or a goal setting approach • Emphasis [as program progresses] on weight loss maintenance and prevention of weight gain <p>*Most of the trained staff were pharmacy assistants</p>
<p>Developing and testing evidence-based weight management in Australian pharmacies: A Healthier Life Program.</p> <p>[289]</p>	<ol style="list-style-type: none"> 1. Self-reading 2. 3-day course was delivered by specialised dietitians and consisted of: <ul style="list-style-type: none"> ○ Lectures ○ Skills sessions ○ Simulated patient sessions 	<p>Learning objectives:</p> <ul style="list-style-type: none"> ○ Ask: <ul style="list-style-type: none"> • Seeks permission to discuss about weight • Engages the individual and elicits information in an appropriate way • Explores an individual's readiness to change ○ Assess: <ul style="list-style-type: none"> • Assess for overweight or obesity • Assesses for risk or presence of comorbidities • Identifies factors that may contribute to weight gain • Conducts a weight history • Determines an individual's current lifestyle behaviours ○ Advise <ul style="list-style-type: none"> • Explains the risks associated with overweight and obesity • Explains the benefits of weight loss ○ Assist <ul style="list-style-type: none"> • Recommends lifestyle change which address all three areas: diet, physical activity, and behavioural change • Understand the role of intensive interventions: very low energy diets, weight loss medication and bariatric surgery

		<ul style="list-style-type: none"> • Delivers patient-centred care • Support self-management ○ Arrange <ul style="list-style-type: none"> • Reviews and monitors individual's progress • Refers to allied health professionals and specialist services where appropriate • Considers the challenges of long-term weight management
<p>A new evidence-based model for weight management in primary care: the Counterweight Programme.</p> <p>[290]</p>	<ol style="list-style-type: none"> 1. Workshop 2. Provision of training manual 	<p>Topics:</p> <ul style="list-style-type: none"> • Patient screening and assessment • Principles of healthy eating and energy balance • Dietary approaches to weight management • Physical activity guidelines • Behaviour-change strategies • Pharmacotherapy • Patient monitoring and ethical considerations <p>Training method:</p> <ul style="list-style-type: none"> • Problem based learning through case studies • Group discussion • Practical exercise • Screening prompts clinical to consider stages of change

Supplementary Files F: Learning objectives for mental health component

Title	Training method(s)	Contents covered
<p>Development, implementation, and evaluation of a pharmacist-conducted screening program for depression.</p> <p>[292]</p>	<ol style="list-style-type: none"> 1. Continuing education program (offered by National Committee for Quality Assurance) 2. Patient case studies 3. Supplemental material: suicide protocol 	<p>Complete continuing education program offered by National Committee for Quality Assurance of best practices related to management of depression in primary care sector</p> <p>Training focused on:</p> <ul style="list-style-type: none"> • Depression treatment (pharmacology and non-pharmacological options) • Patient case study involving management of side effects • Communication with patients who are resistant to diagnosis and/or treatment • Supplementary suicide protocol developed for pharmacists in anticipation of encounters with patients who may be experiencing suicidal thoughts/ideation. • Hotlines contacts that pharmacist can call i.e National Suicide Prevention lifeline for asthma
<p>A feasibility study of community pharmacists performing depression screening services.</p> <p>[67]</p>	<ol style="list-style-type: none"> 1. Interactive training 2. Additional mental health resources and contacts provided 	<p>A 2-hour interactive training program on depression:</p> <ul style="list-style-type: none"> • Warning signs for someone at risk of depression • How pharmacist can intervene • Discuss what they have noticed with the consumer • How to use screening tools • How to refer consumers at risk to an appropriate health professional • What to do in case of a mental health crisis • Warning signs of suicide, suicide myths or facts • What steps to take in an emergency situation
<p>Using an intervention mapping framework to develop an online mental health continuing education program for pharmacy staff.*</p> <p>[291]</p>	<p>Education activities:</p> <ul style="list-style-type: none"> • Lectures • Question and answer interaction • Resource lists (web links, reading materials) • Pre-recorded role plays 	<p>Modules:</p> <ol style="list-style-type: none"> 1. What are depression and anxiety (For all pharmacy staff)? 2. Lived experience of consumers & carers (All pharmacy staff) <ol style="list-style-type: none"> a. Describe the impact of depression and anxiety symptoms on the lives of consumers and carers b. Describe the fears and stigma experienced by mental health consumers and carers living in the community

<p>*Selected modules and components.</p>		<ol style="list-style-type: none"> 3. Support and well-being from consumer and carer perspective (All pharmacy staff) 4. Improving communication in community pharmacy (All pharmacy staff) <ol style="list-style-type: none"> a. Identify appropriate and effective communication skills when working with consumers and carers b. Identify barriers and facilitators that impact on consumer and carer experiences in a community pharmacy setting 5. Therapeutic interventions for depression and anxiety (Pharmacists only) 6. Pharmacotherapy for depression and anxiety (Pharmacists only) 7. Treatment planning and problem solving I: development of plan and treatment options (Pharmacists only) 8. Treatment planning and problem solving II: pharmacy practice (Pharmacists only)
<p>Bridging the gap between physical and mental illness in community pharmacy (<i>PharMIbridge</i>): protocol for an Australian cluster randomised controlled trial. [193]</p>	<p>Blended Mental Health First Aid Training Intervention group pharmacist (additional training provided)</p>	<p>Additional training for interventional group pharmacists:</p> <ul style="list-style-type: none"> • Communication • Motivational interviewing • Goal setting • Complex issues relating to psychotropic medication (adherence and side effects) • Physical health issues for people living with SPMI • Evidence based strategies to improve medication adherence and physical healthcare

Supplementary Files G: Learning objectives for mental health component (Consumer/end-user educator focus)

Title	Training method(s)	Contents covered
<p>Using an intervention mapping framework to develop an online mental health continuing education program for pharmacy staff.*</p> <p>[291]</p> <p>*Selected modules and components.</p>	<ul style="list-style-type: none"> ○ On the couch interactive discussion ○ PowerPoint summary ○ Problem-based case vignette ○ Role play filmed in a community pharmacy 	<p>Lived experience of consumers & carers:</p> <ul style="list-style-type: none"> ○ Describe the impact of depression and anxiety symptoms on the lives of consumers and carers ○ Describe the fears and stigma experienced by mental health consumers and carers living in the community <p>Support and well-being from consumer and carer perspectives:</p> <ul style="list-style-type: none"> ○ Describe the needs and facilitators that mental health consumers and carers identify to support their recovery ○ Outline the role of community pharmacy in supporting consumers and carers in the management of mental illness <p>Improving communication in community pharmacy</p> <ul style="list-style-type: none"> ○ Identify appropriate and effective communication skills when working with consumers and carers ○ Identify barriers and facilitators that impact on consumer and carer experiences in a community pharmacy setting
<p>Design and implementation of an educational partnership between community pharmacists and consumer educators in mental health care.</p> <p>[293]</p>	<ul style="list-style-type: none"> ○ Face to face 4 x 2 hour training sessions ○ Partnership training including: <ul style="list-style-type: none"> ● Consumer educators ● Caregiver educator ● Pharmacists 	<p>Learning objectives:</p> <ol style="list-style-type: none"> 1. Appreciate consumer's perspectives on mental health service delivery 2. Improve the attitudes of community pharmacists towards people with mental illness <p>Consumers:</p> <ul style="list-style-type: none"> ● Shared their experience of receiving treatment within the mental health system ● Consumers described their personal experiences of their mental illness and their interactions with community pharmacist

Supplementary files H: Commonly prescribed medications amongst participants in the physical health monitoring program.

Generic name	ATC code	Frequency
Quetiapine	N05AH04	8
Olanzapine	N05AH03	7
Clozapine	N05AH02	7
Rosuvastatin	C10AA07	4
Venlafaxine	N06AX16	4
Vitamins	A11J	4
Pantoprazole	A02BC02	3
Metformin	A10BA02	3
Codeine and Paracetamol	N02AJ06	3
Aspirin*	B01AC06	3
Pregabalin	N02BF02	3
Aripiprazole	N05AX12	3
Calcium with Vitamin D	A12AX	2
Sumatriptan	N02CC01	2
Docusate combinations	A06AG10	2
Magnesium	A12CC	2
Ezetimibe	C10AX09	2
Paracetamol	N02BE01	2
Risperidone	N05AX08	2
Duloxetine	N06AX21	2
Levothyroxine	H03AA01	2
Gliclazide	A10BB09	2
Iron in other combinations	B03AE	2
Valproic acid	N03AG01	2
Salbutamol	R03AC02	2
Amlodipine	C08CA01	2
Vilanterol, umeclidinium bromide and fluticasone furoate	R03AL08	2
Other	Various	52

Supplementary Files I: Response to BMQ-S survey



Supplementary Files J: Identified barriers and representative quotes

Types of barriers	Quote(s) attributed to	Representative quotes
Pandemic	Participants	<p>"It [the program] went on and off for a while, with cancelling appointments with COVID issues and [Pharmacist M] would halfway be doing the survey when she got COVID, so we had to wait for a few weeks." – <i>BS6</i></p> <p>"...it [the program] was supposed to be like quarterly but I missed one of the quarters so apparently that was because of [the] COVID restrictions regarding the program?" – <i>JM0</i></p>
	Pharmacists	<p>"Not something that you expect that you would have to wear a mask, or you know have to have isolations or you couldn't attend appointments, um this was out of the control of the project." - <i>MI, Recruiter</i></p> <p>"...we had to kind of direct most of our focus to vaccinations at that stage with mandatory requirements." - <i>NJ, Non-Recruiter</i></p> <p>"People are like, they spend less time in the pharmacy probably. People are a lot more transactional; I think the thing is, they come in and they want to go out. You know we aren't super keen to get people to just sit around in the store ..." – <i>MP, Pharmacist – Non-Recruiter</i></p> <p>"We were using the same clinic room for the vaccinations. And when that really ramped up, you know when we got called, it felt almost like, it was like, a professional duty to offer for as many of those as we could." - <i>FA, Recruiter</i></p>
Appointment system	Participants	<p>"It'll be difficult to do it any other way, really with the pharmacists... I can't think of any easier way." - <i>HK3</i></p> <p>"It didn't take me out of my way, [it was] quite easy" - <i>LB5</i></p>
	Pharmacists	<p>"...trying to manage that appointment, so if it was at a time when you're busier, you may have had to say, well can you pop back in half an hour or tomorrow. Which isn't ideal, I mean ideally if they're there you would want them to do it straight away um but often if you told them I've got an appointment here three months down the track, you know it's a 12 o'clock on a Thursday. 12 o'clock on a Thursday would come and go and no one would show up." - <i>MI, Recruiter</i></p> <p>"Picking times was bit...we sort of took them when they came in obviously...we could organise a time and we made sure it wasn't first thing in the morning and it wasn't over the lunch breaks and maybe just before the second pharmacist went home." – <i>FL, Recruiter</i></p> <p>"...The risk of people not showing up when they booked. Which happened on a few occasions, where you know of yourself sort of free, you're avoiding getting too deep into a MedsChecks of any of this sort of thing cause you know that somebody is going to be coming soon. But then they don't come" – <i>FA, Recruiter</i></p>

Cholesterol testing	Participants	"It's like a normal BGL [blood glucose levels] ... you just need a lot more blood." - LC9
	Pharmacist	<p>"Sometimes you wouldn't always get a result, so you would have to repeat. So, it was a little bit lengthier, and it was little bit messier in terms of, blood." - <i>MI, Recruiter</i></p> <p>"The strips were ah out of date on the day that we came to use them or something. So, it wasn't um, without its challenges, that element of it." - <i>FA, Recruiter</i></p> <p>"CardioChek cholesterol monitor 'cause it uses a pipette to draw up it is a trickier one so it's not just your normal prick and test." – <i>MI, Recruiter</i></p>

7 Discussion and conclusion

Chapter Overview

This chapter aims to bring together all stages of the research, highlighting key findings and implications of the studies presented in this thesis. The chapter begins with a brief background on the requirements for registration as a pharmacist in Australia and a reminder of the thesis's aims and objectives. The latter half of the chapter includes a summary of the key findings and implications, followed by a discussion of the strengths and limitations of the studies reported in this thesis. This chapter also includes key suggestions for future research and a conclusion.

Background

Increasingly, the potential for community pharmacists to provide additional professional health care services in Australia is being recognised. In South Australia, there have been several state-funded community pharmacy programs such as: better access to palliative care medicine program,⁵ opening of 24/7 pharmacies⁶ and point-of-care testing for respiratory illnesses⁷ [352], which aim to utilise the accessibility and skillsets of pharmacists beyond medication supply. More recently, South Australian pharmacists had started the supply of antibiotics for uncomplicated urinary tract infections [64] and oral contraceptive pill [65] for eligible patients without the need for a prescription from the doctor. These programs are indicative of the Government's and the community's appetite for more pharmacist-led services.

In Australia, pharmacists are required to complete an accredited university degree (undergraduate or graduate entry), a one-year paid internship, a concurrent intern training program during the internship year and pass the Pharmacy Board's registration examination before attaining general registration to practice in Australia [283]. As highly trained health professionals, pharmacists are equipped with broad pharmaceutical and clinical skills [353] allowing them to provide healthcare services to patients in various settings including hospitals, GP's clinics and community pharmacies [354, 355]. However, current evidence indicates that pharmacists' knowledge and skills may be under-utilised, with calls for pharmacists to work towards practising at their full scope [279, 356, 357]. Recently, the Australian Government had

⁵ Expand the availability of palliative care medications in pharmacy.

⁶ To support pharmacies to provide medication and care 24-hours a day, 7 days a week.

⁷ Trial how community pharmacy can help improve patient access to testing and antiviral treatments for respiratory illnesses such as flu.

commenced a national Scope of Practice review, to “review the barriers and incentives for primary health care professionals working to their full scope of practice” [357, 358]. The final report is expected to be completed by the end of 2024.

While the national review explores the scope of practice of a broad range of health professionals, there is a need for pharmacists to better support PLMI [196, 197]. This thesis focused on the potential role of community pharmacists in supporting PLMI. This was achieved through a series of studies (Table 22), which were presented, respectively, in Chapter Three (aim 1), Chapter Four (aim 2), Chapter Five (aim 3) and Chapter Six (aim 4 and 5).

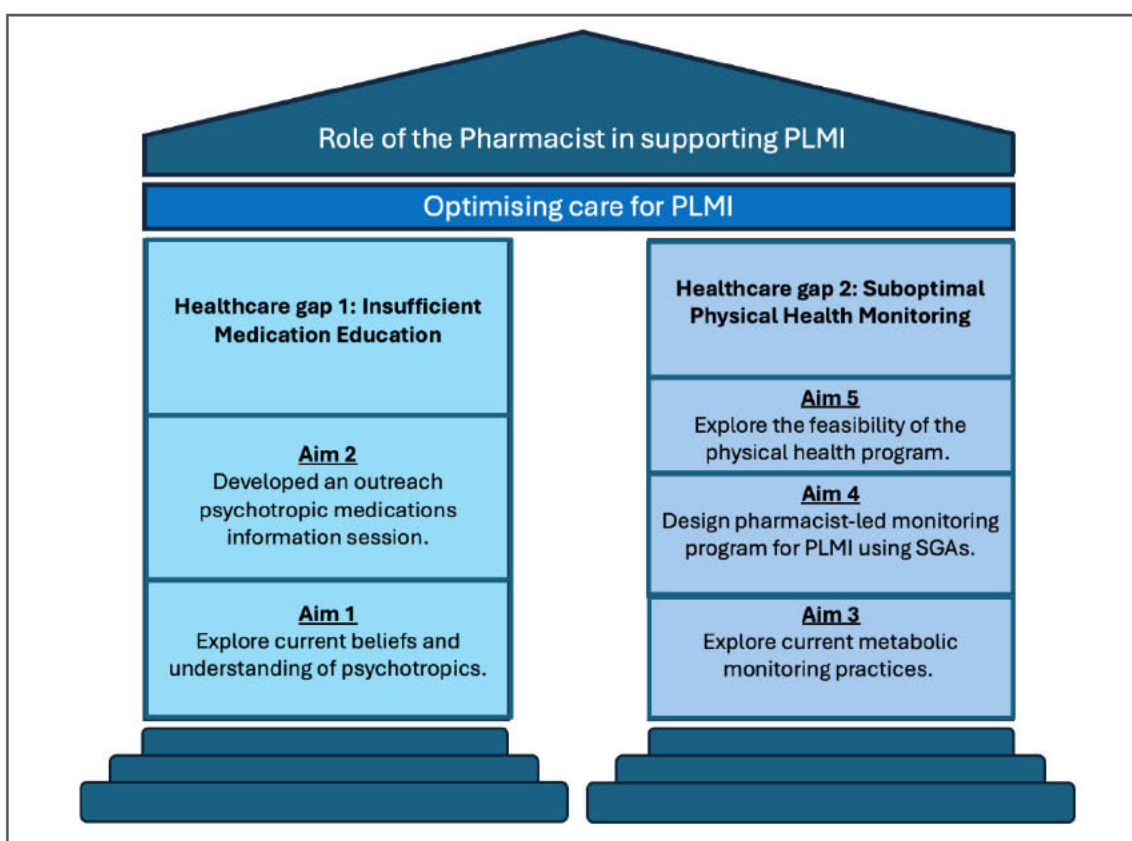
Table 22. Research aims

1. To explore PLMI’s understanding of, and beliefs towards, psychotropic medications.
2. To design, evaluate and pilot a client-tailored outreach information session with PLMI.
3. To conduct a scoping review exploring current metabolic monitoring practices.
4. To design a pragmatic pharmacist-led monitoring program to support PLMI’s physical health whilst on second generation antipsychotics (SGAs).
5. To explore the feasibility of a pharmacist-led physical health monitoring program for PLMI on second generation antipsychotics.

Summary of Key Findings

The thesis focused on two healthcare gaps of interest: (i) insufficient medication education and (ii) suboptimal physical health monitoring for PLMI (Chapter Two). These healthcare gaps were further explored through a series of studies, with each building on the information found in the previous research. The first half of the thesis explored PLMI’s current beliefs and understanding of psychotropics (Chapter Three) followed by the development of an outreach psychotropic medications information session (Chapter Four). The second half of the thesis focused on the other healthcare gap of interest, including a scoping review investigating current metabolic monitoring practices for PLMI (Chapter Five), the design of a pharmacist-led monitoring program for PLMI using SGAs and evaluating the feasibility of the physical health program (Chapter 6) (Figure 12).

Figure 12. Overview of the research.



Insufficient medication education

Two studies were designed and conducted to further explore the first identified gap (insufficient medication education). The first study explored PLMI's understanding of, and beliefs towards, psychotropic medications, through focus groups (aim 1). The findings from this study led to the development and delivery of an outreach psychotropic medicines information session, which also incorporated end-user preferences and pharmacists' recommendations (aim 2).

As explored in Chapter Two, evidence suggested that PLMI receive inadequate information on their psychotropic medications [359]. Findings from the four focus groups suggested that most of the participants received inadequate information on their psychotropic medicines [103], echoing the literature previously discussed in Chapter Two. An interesting observation from this study was that participants did not perceive pharmacists as having a role in supporting their mental health. This likely reflected the fact that many of the participants did not have an established rapport or therapeutic relationship with their pharmacists. Additionally, many were unaware of the role, skills and responsibilities of pharmacists beyond their traditional role of medication supply [360]. Therefore, a key suggestion from this research was the need to raise awareness of the roles and responsibilities of pharmacists which may support timely access to

professional healthcare advice and/or services. The findings of this research have been published and presented in Chapter Three of this thesis [103].

This thesis also described the potential for a pharmacist-led outreach information session that can be tailored and delivered for PLMI (reported in Chapter Four), complementing the existing healthcare services they receive. In Australia, similar to many other countries [359], it is common for patients to receive initial counselling at the point of prescription, either at the doctor's clinic or with the pharmacist [235]. However, it is recognised that community pharmacies are often busy [207] with multiple concurrent commitments. This program can address this limitation by offering dedicated sessions outside the busy pharmacy setting, allowing pharmacists to focus more on providing personalised counselling and information. General feedback on the medication information session indicated that the session was well received.

This program was trialled within a selected population, as discussed in Chapter Four and the findings should be interpreted within the context of the study's strengths and limitations. Indeed, other factors may influence the uptake of such a program, including the severity and duration of illness [95], housing status (e.g. homelessness) [349], and whether an individual is from a culturally and linguistically diverse population [221]. In these instances, additional considerations are required, including the need to further tailor the program to meet the specific needs of a consumer. Overall, this program offers an additional avenue of access to medicine information. As the development of the content was rigorously reviewed, it can serve as a foundation or guide for future studies or information sessions to build upon. Finally, the provision of medication education at a NFP organisation can also improve the accessibility of medication education for PLMI.

Suboptimal physical health monitoring

To further explore the second healthcare gap of suboptimal physical health monitoring for PLMI, a pharmacist-led physical health monitoring program was designed and implemented. A scoping review was also conducted to investigate current metabolic monitoring practices (aims 4 and 5).

Findings from the scoping review, presented in Chapter Five, highlighted the need for a more systematic approach to metabolic monitoring for PLMI on SGAs (aim 3). This review highlighted the lack of clarity around the roles and responsibilities of the health professionals potentially involved in metabolic monitoring. It was also found that monitoring rates for certain

parameters, such as waist circumference, were particularly poor in practice. Overall, the scoping review further supported the need for a pragmatic pharmacist-led monitoring program for PLMI to address this healthcare gap. While the literature on metabolic monitoring often pertained to people with SMI [361], the physical health monitoring program presented in Chapter Six was available to all PLMI using SGAs. This broad inclusion criterion was seen as appropriate, given the known risk of metabolic syndrome associated with long-term SGA use.

To facilitate the design of the pharmacist-led monitoring program, a review of existing community pharmacist-led interventions was conducted. The review guided the design of the pharmacist-led physical health monitoring program, including the pharmacist refresher training course. In developing the training course, trainers in relevant fields were recruited, including a dietician, psychologist, diabetes educator, and an end-user to deliver the training content. The final protocol has been published and presented in Chapter Six of the thesis.

The findings identified several facilitators and barriers to recruitment and program delivery (see Chapter Six), which were not too dissimilar from those identified in the literature [216, 262]. Our findings highlighted the need for considerations around the scheduling of regular follow-up consultations in community pharmacies as they often did not align with the participant's prescription collection schedule. It was recognised that setting up appointments in community pharmacies may be challenging [362]. Potentially, the use of an automated appointment system that can make and manage appointments, including sending of reminders [363], for these services can reduce the administrative burden for pharmacists.

The program's feasibility was investigated through both quantitative and qualitative data analyses. The investigation revealed that most participants were referred to their GPs for further assessment due to identified concerns, often during the baseline consultation. Although the quantitative findings did not demonstrate significant changes in measured parameters post-intervention, it underscored the capability of pharmacists to assess several metabolic indicators, and more work is required to improve monitoring of parameters such as lipids (TC, HDL and TG). Notably, the program explored the feasibility of the pharmacist conducting physical health monitoring in a community pharmacy setting. This included the feasibility of measuring metabolic parameters such as waist circumference, blood pressure, and blood glucose levels and the appropriateness of regular three-monthly monitoring. In addition, the qualitative findings reported on the perceived value of the program. Participants and pharmacists described

the benefits such as meaningful discussions between the pharmacist and participant and the benefit of setting client-centred goals.

The research was conducted during the pandemic and as a result, faced several disruptions. The study commenced during the early stages of the pandemic, after which responses to the pandemic rapidly escalated, resulting in a significant rise in workload, staff shortages in pharmacies and an increase in pharmacist “burnout” [240, 364]. Additionally, the pandemic resulted in significant changes to health-seeking behaviour, especially in the initial stages where patients avoided visiting pharmacies due to fear of exposure to the virus [365].

Aside from the pandemic, the biggest barrier pertained to the cholesterol point-of-care testing device. While reported issues were related to the device, such as the volume of blood required, provision of additional technical support and training for the pharmacists may be of value in future studies. The pharmacist-led physical health monitoring program had higher rates of monitoring of several metabolic parameters, including waist circumference, BP and weight, compared to other studies as discussed in Chapter Six. Furthermore, findings emphasised the need for pharmacy programs and services to be integrated with existing electronic medical files, such as MHR, to ensure that there is a single source of clinical data [348]. However, it is worth recognising that MHR is not without its limitations, including having incomplete records and poor usability [366, 367].

Implications of findings

The role of pharmacists in supporting PLMI had been explored in several studies, including internationally [180, 193, 277, 368]. A pilot in the UK, the Advancing Mental Health Provision in Pharmacies program, trialled the provision of personalised help and support to patients prescribed antidepressants for anxiety or depression over three months [368]. The study reported the feasibility of the service and patients’ willingness to participate in the study. It also highlighted the need to better understand optimal follow-up time and service length. Another study led by North East London NHS Foundation Trust, the Physical Health Care for patient with Psychosis, a collaboration between secondary care, community pharmacy and primary care, offered physical health checks via community pharmacies for patients diagnosed with a psychotic illness between 2016 to 2018 [277]. The study reported that most (70%) of the participants at the community pharmacies (n=140) had all five cardiometabolic risk factors monitored, which was better than the comparator (treatment as usual) group with only 36%.

Australian community pharmacists have also acknowledged the need for pharmacy-based services that could support PLMI [216]. The outcomes from the studies presented in this thesis further supported the role of community pharmacists in this space. Findings reported in this thesis, on both the pharmacist-led outreach information session and physical health monitoring program, suggested that both the participants and the pharmacists perceived the value of the pharmacist-led physical health monitoring program. Importantly, it also identified the need for an established therapeutic relationship or a good rapport between the pharmacist and PLMI as highlighted in the studies that explored the healthcare gaps. It is recommended that health professionals, including pharmacists, are proactive in establishing this relationship with PLMI to better support and optimise their health and wellbeing. It is likely that the recruitment of “the right person” may also indicate that pharmacists require more support to be proactive in supporting PLMI, and additional training, such as MHFA may be of value.

MHFA training is a widely validated training course that has been shown to improve pharmacists’ confidence in supporting PLMI [211, 216, 369]. At the time, it was not feasible to include such training for the recruited pharmacists due to time and budget constraints. Since the implementation of these studies, the South Australian Government as part of a community pharmacist initiative has offered free MHFA training for up to 1,000 pharmacy staff in South Australia [370]. The importance of MHFA training is increasingly being recognised by healthcare training providers, with some Australian Universities providing MHFA training as part of their pharmacy curriculum [371]. Participating in additional training such as MHFA [211] and/or other mental health training programs can empower pharmacists to become more confident and proactive in working with PLMI [372].

The scoping review (Chapter Five) further contributes to the existing literature by ascertaining that PLMI using SGAs receive suboptimal monitoring, particularly identifying that waist circumference remains poorly monitored in these individuals. Findings highlighted the need to clearly stipulate and define the roles and responsibilities of all health professionals involved in metabolic monitoring for PLMI. The review also noted that community pharmacists were not often reported as being involved in the monitoring of metabolic parameters for PLMI.

It is recognised that there is emerging research on pharmacist-led physical health monitoring programs for PLMI. In Australia, the PharMIbridge, a pharmacist-led project where community pharmacists worked with people living with SMI to review medicines and physical health concerns over 6 months [193]. Other research includes an Australian base, a nurse practitioner-

led investigated interventions to improve the physical health of PLMI in a community mental health setting (n=201) over 12 months [373]. The program described in Chapter Six, had broader inclusion criteria (all PLMI taking SGAs) and a longer trial period (12 months) compared to a similar Australian study previously described, such as PharMIbridge [193]. It is also worth noting that the pharmacists participating in the PharMIbridge study did not undertake any formal MetSyn screening with participants. Further, unlike the study in this thesis employed a pragmatic approach, compared to the randomised controlled study method employed in PharMIbridge. As highly trained health professionals, pharmacists' skills and knowledge should be appropriately utilised, to help reduce the burden on the healthcare system [357]. This would align with the Australian Government's initiatives to ensure that health professionals work towards their full scope of practice [357, 358].

While this study leveraged the accessibility and knowledge of community pharmacists, it is recognised that community pharmacists, similar to other health professionals, are often time-poor. Research suggested that community pharmacists in Australia often were required to multi-task, doing up to 25 different tasks in an hour [207]. Therefore, consideration of the existing pharmacy model of care [205], including adequate remuneration and staffing level [374], may be required to ensure the sustainability of a program such as this. Furthermore, inadequate remuneration could significantly influence the sustainability of this program. Inadequate funding had also been identified in the Australian Scope of Practice Review (Issues Paper 2) as an issue affecting health professionals broadly, restricting their ability to work to their full scope of practice [375]. To further extend the reach of the pharmacist-led physical health monitoring program, the inclusion of a home visit model, similar to the home medicine review, where an accredited pharmacist visits patients' homes to review medicines and develop a medicine management plan, could be considered [248]. Similarly, a mental health hospital-in-the-home clinical pharmacist role, where patients receive treatment and monitoring in their own home [376], could be considered.

Strengths and limitations

This thesis presents studies in chronological order (except for Chapter 5), and as such reflects the growth of the candidate as a researcher. For example, in early research conceptualisation and design of evaluation tools, validated frameworks such as the RE-AIM framework were not considered [305, 306]. In later research, the inclusion of such a framework was considered in the development of the pharmacist and participant interview guide for the Pharmacist-led

physical health monitoring program (Chapter Six). As desired and expected with postgraduate studies, the candidate's proficiency, confidence, and adaptability as a researcher grew and evolved during the candidacy. It is worth noting that the qualitative methods employed in this research, including the nature of the focus groups and semi-structured interviews were dependent on the subjective capabilities of the interviewer (PhD candidate). While the use of qualitative methods, such as RTA embraced qualitative research values and the subjective skills of the researcher, the inherent subjectivity in such approaches has been acknowledged as there was a strong reliance on the perspective of (often) a single individual. Therefore, there may be a degree of subjectivity with the data collection, as the skills and ability of the candidate evolved.

A strength of the studies reported in this thesis is the rigorous approach applied to the designing of the information session and physical health monitoring program. For example, the content for the information session had been rigorously reviewed by multiple expert pharmacists, as described in Chapter Four. Similarly, the development of the training course for pharmacists involved in the pharmacist-led physical health monitoring program included (i) a review of the literature to identify approach learning objectives and (ii) input from each of the expert trainers. Furthermore, interview guides were, where possible, sent for external review and validation prior to data collection to ensure that questions were clear and relevant. To add, the thesis reported on both qualitative and quantitative findings; this mixed-methods approach can be seen as a strength of this thesis, providing richer insights into the research questions of interest [377].

One limitation of this research was that data was only collected on the experiences of the consumers and pharmacists involved. As such, it did not report on the experiences of other health professionals, particularly GPs. It was recognised that there was a need for a robust multidisciplinary care model, one that bridged the gap between primary, mental health and specialist care (such as cardiology)[361]. Despite this, both core studies, (i) the pharmacist-led outreach psychotropic medicines information session and (ii) the pharmacist-led physical health monitoring program, either collaborated with, or involved input and suggestions from a variety of health professionals. This is a strength of the thesis.

In the Pharmacist-led outreach psychotropic medicines information session, external pharmacists (expert panels) reviewed the proposed content of the information session. In the Pharmacist-led physical health monitoring program, several health professionals were involved as trainers, as previously discussed. Furthermore, end-users were involved in both core studies,

with peer support workers involved in both the information session (to support participants) and in the training of the pharmacists for the training course.

It is acknowledged that while end-users and other health professionals were involved in the study to some extent, the studies did not fully employ a co-design approach [378], this could also be viewed as a limitation. Moreover, this study also did not explore the economic outcomes, such as cost-effectiveness of the programs proposed [379]. As the study reported both participant experiences, and clinical outcomes, such as metabolic parameters, the findings were valuable to health professionals and policymakers.

The PhD candidate acknowledges the small sample size in these studies to be a limitation. The focus of the research was to explore the potential role of the pharmacist in supporting cohorts of PLMI, firstly through the design and delivery of a pragmatic information session, and secondly, through a physical health monitoring program. The pragmatic approach/emphasis was first introduced in Chapter One and highlighted the focus on what is achievable (“practicality”) rather than what is theoretical or ideal. Therefore, the aims were to explore participants’ experiences and perceptions rather than measuring program effectiveness through quantitative methods. While this may have limited the generalisability of the findings, the studies presented thorough descriptions of the sample’s demographics and therefore can be generalised to similar settings. Moreover, the candidate acknowledges the potential for bias, including recall [380] and social desirability bias [260] to be present in this thesis and as discussed in the relevant chapters, which may further limit the generalisability of the findings.

Recommendations for future research

To gain deeper insights into the potential impact of such services for PLMI, it is imperative to replicate the study with a larger sample size. This could be achieved by implementing the service in diverse settings, including rural areas, which may necessitate adaptations and considerations for effective delivery, possibly leveraging technology for a hybrid model. Evaluating the cost-effectiveness of these services is crucial for policymakers and decision-makers to assess their potential benefits and value. An Australian study has explored the perceptions of psychiatrists, mental health nurses and mental health pharmacists’ opinions regarding the integration of community pharmacists in the care for PLMI to reduce incidents of cardiometabolic adverse drug events [374]. However, further studies exploring the perception of primary health care professionals, such as GP will also be valuable. Future studies should

also adopt a co-design approach involving stakeholders in the design and implementation of proposed services.

While the research reported in this thesis made a significant contribution to this field, it also raised new questions for further investigation, including:

1. Recognition of the psychotropic medication knowledge, beliefs, and experience with healthcare providers of PLMI who are culturally and linguistically diverse to develop a service to address their specific needs.
2. The potential for the pharmacist-led physical health monitoring program to detect early indications of metabolic issues, prompting timely referrals to GPs requires further exploration.
3. The feasibility and acceptability of the community pharmacist-led services for PLMI, including outreach medication education programs and pharmacist-led physical health monitoring programs in a rural Australian setting.
4. The feasibility and acceptability of a hybrid physical health monitoring program that supports both in-person and telehealth attendance.
5. The cost-effectiveness of community pharmacist-led services for PLMI, including outreach medication education programs and physical health monitoring programs, to guide discussions around appropriate remuneration for pharmacist.
6. The perspectives of Australian health professionals in primary care, including general practitioners, regarding the role of community pharmacists in supporting the physical wellbeing of PLMI.

Conclusion

This research explored the perceived inadequate medication education and suboptimal metabolic monitoring in PLMI taking antipsychotics. The findings highlighted that PLMI do not report having a good understanding of their medicines. While this can be due to several factors, as described in Chapter Two and Three, the provision of additional education outside the common community pharmacy was suggested as an innovative approach to addressing this gap. The study also highlighted the need to recognise the role of the pharmacist in medication education. Findings from the proof-of-concept study presented in this thesis described the rigorous reviews taken to design the outreach information session. Findings (Chapter Four)

suggested that pharmacists, particularly those based in the community, can support PLMI's psychotropic medication understanding through approaches such as outreach information session.

The scoping review confirmed the overall lack of standard metabolic monitoring in this cohort and supported the need for a standardised and readily available service for PLMI at risk of MetSyn. Subsequent quantitative and qualitative findings supported the feasibility of a pragmatic pharmacist-led physical health monitoring program for PLMI. However, future studies with a larger sample size are required to ascertain the effectiveness of pharmacist-led physical health monitoring and individualised goal setting. The findings reported in this thesis highlighted the need to better support pharmacists in the provision of such services, recognising the time and often additional training required to facilitate the delivery of these services. This includes the need to provide adequate remuneration, support additional training and overall recognition of the potential for pharmacists to be in such a role.

Overall, the outcome of the research indicated the acceptability of pharmacists supporting PLMI. The findings reported here support the advocacy not only for pharmacist involvement in supporting PLMI but also, most importantly, explore ways to better support and optimise the care of individuals living with a mental illness. The studies reported in this thesis were able to address the overarching research questions, which explored the two core healthcare gaps of interest and trialled two pharmacist-led initiatives to address those gaps. The thesis presented a variety of qualitative and quantitative findings, including focus groups, proof-of-concept study, scoping review, semi-structured interviews and data collection from the physical health monitoring program. Notably, the studies employed a pragmatic approach where possible, recognising the skillsets and responsibilities pharmacists already have.

The studies reported in this thesis were conducted during the height of the pandemic. The pandemic disrupted our ability to recruit participants and effectively deliver the outreach program as planned. Navigating these uncertainties required continuous adaptation of our delivery models and recruitment strategies. Despite these challenges, our findings highlighted the pivotal role that pharmacists play in supporting PLMI. The pandemic underscored the resilience and adaptability of pharmacists in responding to public health crises and meeting the evolving needs of their communities. It is reasonable to hypothesise that, in the absence of the pandemic's disruptive influence, pharmacists could potentially expand their services to even larger numbers of PLMI. However, while the studies here focused on demonstrating the

feasibility and acceptability of pharmacist-led interventions, it is essential to acknowledge that further efforts are needed to ensure the sustainability and widespread implementation of these services at a larger scale.

Appendices

Appendix A: Consent forms

- Focus groups (including information session)
- Physical Health monitoring (participants)
- Interview for pharmacists
- Interview for consumers

Appendix B: Interview Guides

- Focus groups
- Physical health monitoring (consumers)
- Physical health monitoring (non-recruiters)
- Physical health monitoring (recruiters)

Appendix C: Other data collection tools

- Pre-session questionnaire
- Post-session questionnaires
- Data Collection Sheet (Baseline)

Appendix D: Training Assessment Questions

Appendix E: Approval from Human Ethics

- Healthcare gap 1: Focus groups and Information session
- Healthcare gap 2: Physical Health monitoring

Appendix F: Authorship statements

Appendix G: Awards and Nominations

Appendix A: Consent forms

Focus Groups



University of South Australia
School of Pharmacy and Medical Sciences
School of Nursing and Midwifery

CONSENT FORM

Project title: Development of client-centered health promotion: knowledge and attitudes towards medication

Researchers' names & contact details: Miss Tien Bui, Dr Vijayaprakash Suppiah and Dr Elizabeth Hotham.

Contact email: vijay.suppiah@unisa.edu.au, phone: (08) 8302 1130
libby.hotham@unisa.edu.au, phone: (08) 8302 1130

- I have read the Participant Information Sheet and the nature and purpose of the research project has been explained to me. I understand and agree to take part.
- I understand the purpose of the research project and my involvement in it.
- I understand that the focus group interview will be audio-recorded.
- I understand that all collected data will be stored either in locked filing cabinets in locked offices at UniSA or as electronic files protected by a password under the firewall of UniSA. The data will be kept secured and only members of the research team will have access to the data. All data will be stored for 5 years after which all files will be securely destroyed.
- I understand that I may withdraw from the research project at any stage and that this will not affect my healthcare or my association with MIND Australia. Once withdrawn, data collected from me will be excluded from all future analysis.
- I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
- I understand that all records containing personal information will remain confidential and no information which could lead to identification of any individual will be released, unless required by law.

Name of participant/carer/guardian

Signature Date

I have provided information about the research to the research participant and believe that he/she understands what is involved.

Researcher's signature and date

This project has been approved by the University of South Australia's Human Research Ethics Committee. If you have any ethical concerns about the project or questions about your rights as a participant, or should you or any third parties wish to lodge a complaint about either the study or the way it is being conducted, please contact the Executive Officer of this Committee – Ms Vicki Allen (tel: +61 8 8302 3118; email: humanethics@unisa.edu.au)



University of South Australia
Clinical and Health Sciences

CONSENT FORM

Project title: Pharmacist-led physical health monitoring for patients on antipsychotic medications

Researchers' names & contact details: Miss Tien Bui, Dr Elizabeth Hotham, Dr Sara McMillan, Dr Fiona Kelly and Dr Vijayaprakash Suppiah

Contact email: tien.bui@unisa.edu.au, phone: (08) 8302 1130

vijay.suppiah@unisa.edu.au, phone: (08) 8302 1130

libby.hotham@unisa.edu.au, phone: (08) 8302 1130

s.mcmillan@griffith.edu.au, phone: (07) 555 27266

f.kelly@griffith.edu.au, phone: (07) 555 29743

- I have read and understood the information on the Participant Information Sheet. The nature and purpose of the research project has been explained to me. I understand and agree to take part.
- I understand the purpose of the research project and my involvement in it.
- I am 18 years of age or older.
- I understand that the findings from the consultation may be discussed with my regular doctor.
- I understand that all de-identified collected data will be stored either in locked filing cabinets in locked offices at UniSA or as electronic files protected by a password under the firewall of UniSA. The data will be kept secured and only members of the research team will have access to the data. All data will be stored for 5 years after which all files will be securely destroyed.
- I understand that I may withdraw from the research project at any stage and that this will not affect my usual healthcare or my association with the pharmacy team.
- I understand that once withdrawn, de-identified data collected from me till that point will be included in the study's analysis.
- I understand that while information gained during the study may be published, I will not be identified, and my personal results will remain confidential.

- I understand that all records containing personal information will remain confidential and no information which could lead to identification of any individual will be released, unless required by law.
- I agree to be contacted by a researcher after the completion in the study to participate in an evaluation survey

Name of participant/carer/guardian

Signature Date

I have provided information about the research to the research participant and believe that he/she understands what is involved.

Researcher's signature and date

This project has been approved by the University of South Australia's Human Research Ethics Committee. If you have any ethical concerns about the project or questions about your rights as a participant, or should you or any third parties wish to lodge a complaint about either the study or the way it is being conducted, please contact the Executive Officer of this Committee – Ms Vicki Allen (tel: +61 8 8302 3118; email: humanethics@unisa.edu.au)

Physical Health Monitoring - Pharmacist interviews

CONSENT FORM

Project title

Pharmacist-led physical health monitoring for patients on antipsychotic medications

Researchers and contact details

Dr Vijayaprakash Suppiah Vijay.Suppiah@unisa.edu.au
Dr Elizabeth Hotham libby.hotham@unisa.edu.au
Ms Tien Bui Tien.Bui@unisa.edu.au

- I understand the interview will be recorded for data analysis purposes
- I am 18 years of age or older
- I understand that collected data will also be stored either in locked filing cabinets in locked offices at the University of South Australia or as electronic files protected by password under the firewall of UniSA. The data will be kept secured and only members of the research team will have access to the data. All data will be stored for 5 years after which all files will be securely destroyed.
- I understand that I may withdraw from the research project at any stage.
- I understand that once withdrawn, de-identified data collected from me till that point will be included in the study's analysis.
- I understand that while information gained during the study may be published, I will not be identified, and my personal results will remain confidential.
- I understand that all records containing personal information will remain confidential and no information which could lead to identification of any individual will be released, unless required by law.

Name of participant: _____

Signature: _____

Date: _____

I have been provided information about the research to the research participant and believe that he/she understands what is involved.

Researcher's signature and date: _____

This project has been approved by the University of South Australia's Human Research Ethics Committee. If you have any ethical concerns about the project or questions about your rights as a participant or should you or any third parties wish to lodge a complaint about either the study or the way it is being conducted, please contact the Executive Officer of this Committee Tel: +61 8 8302 6330.

Appendix B: Interview Guides

Focus groups

Questions for Interview with Client

Part I (*Broadly: Knowledge Based Questions*)

Medications: 4 major questions

1. When you first received your medication,
 - a. was it explained what the medication was for?
 - b. can you recall what the information was?
 - c. what written information did you receive?
2. What were you told about possible side effects from this medication and how these will be monitored?
3. Were you given advice on which side effect you should seek medical attention for?
4. Have you ever experienced any adverse effects?

Your health condition/s: 2 major questions

1. What health professionals are currently involved in your care?
2. Have you been offered other “non-pharmacological*” options alongside your medications for example psychological treatments? (**this may need explanation*)

If Yes to Q2, what are they?

Part II (*Broadly: Attitude or Perception Based Questions*)

Medications: 3 major questions

1. How do you feel about taking your medication?
2. In general, do you feel involved in decisions about your medications?
3. Do you ever miss a dose of your medication/s (either deliberately or inadvertently)?

If Yes to Q3, do you know what to do after missing a dose?

If Yes to Q3, are you comfortable speaking with your doctor or pharmacist about missed dose/s?

Your health condition/s: 3 major questions

1. What support could be offered by your doctor, pharmacist and other health professionals that you are not currently getting?

2. Can you recall a situation where you felt hesitant to speak with your doctor, pharmacist or other health professional about your health (or your medication) because you felt the query was not important enough?
3. On a scale of 1 – 5,
 - a. how would you rate your experience with your doctor?
 - b. how would you rate your experience with your pharmacist?
 - c. how would you rate your experience with other health professionals?

This service: optional questions

1. What particular aspect of this service do you find useful?
2. What do you think could be done better to support you?

Physical health monitoring (consumers)

EXPANDING THE ROLE OF COMMUNITY PHARMACISTS IN MENTAL HEALTH: PHYSICAL HEALTH MONITORING OF CONSUMERS LIVING INDEPENDENTLY IN THE COMMUNITY

QUESTIONNAIRE AND GUIDE (CONSUMERS)

Introduction to interview

- Thank you for participating
- Introduce researcher and others involved in the development and implementation of the program (UniSA and Terry White Chemmart Christies Beach/Woodville)
- Overview of research and purpose
 - o Questions refer to their experience with the physical health monitoring program conducted by their pharmacists in the pharmacy.
- Approximate duration of the interview is 20 - 30 minutes
- Provision of \$30 gift voucher as a 'thank you' for your time
- Proposed structure of interview
 - o Collection of basic demographic data
 - o Questions with a rating scale
 - o Short questions: interested in their experience with the program; no right or wrong answers, it is their perspective that we are interested in
- Verbal consent to participate and approval to audio record the interview
- No identifiable data (e.g name or address) will be collected
- If you feel distressed, upset or concerned at any point during the interview, we will pause the interview and check that you are okay. If you do not wish to continue with the interview, that is absolutely fine, and we will stop the interview all together.
- Helplines:

Organisation	Contact Details
Lifeline	• 13 11 14
SA COVID-19 Mental Health Support Line	• 1800 632 753

Demographics

1. Age:

- 18-24
- 25-30
- 31-40
- 41-50
- 51-60
- 61-70
- > 70

2. Gender:

- Female
- Male
- Other (please specify)
- Prefer not to say

3. Pharmacy site:

- Christies Beach
- Woodville

4. Is this your regular pharmacy?

- Yes
- No
- Other

5. Do you have private health insurance?

- Yes
- No
- Other

6. Do you have a regular GP/ medical clinic that you attend to?

- Yes
- No
- Other

Patient Satisfaction

The following questions related to your experience with the physical health monitoring program conducted by your pharmacist at the pharmacy.

Q1. How satisfied are you with the effect of your monitoring in the pharmacy?

- Very satisfied.....0
- Satisfied.....1
- Neither satisfied nor dissatisfied.....2
- Dissatisfied.....3
- Very dissatisfied.....4

Q2. How satisfied are you with the explanations the pharmacist has given you about the results of your physical health monitoring?

- Very dissatisfied.....0
- Dissatisfied.....1
- Neither satisfied nor dissatisfied.....2
- Satisfied.....3
- Very satisfied.....4

Q3. The pharmacist was very careful to check everything when conducting the physical health assessment with you.

- Strongly agree.....0
- Agree.....1
- Not sure.....2
- Disagree.....3
- Strongly disagree.....4

Q4. How satisfied were you with the recommendations affecting your health care (e.g lifestyle advice provided by the pharmacist)?

- Very dissatisfied.....0
- Dissatisfied.....1
- Neither satisfied nor dissatisfied.....2
- Satisfied.....3
- Very satisfied.....4

Q5. How much of the time did you feel respected by the pharmacist involved in your care?

- All of the time.....0
- Most of the time.....1
- About half the time.....2
- Some of the time.....3
- None of the time.....4

Q6. The time you had with the pharmacist was too short.

- Strongly agree.....0
- Agree.....1
- Not sure.....2
- Disagree.....3
- Strongly disagree.....4

Q7. Are you satisfied with the care you received in the program?

- Very satisfied.....0
- Satisfied.....1
- Neither satisfied nor dissatisfied.....2
- Dissatisfied.....3
- Very dissatisfied.....4

RESEARCHER USE ONLY

Scoring:

1. Score each item as marked (0 = 0), (1 = 1), (2 = 2), (3 = 3), (4 = 4).
2. Reverse the scores for items #1, #3, #5, #7 (0 = 4), (1 = 3), (2 = 2), (3 = 1), (4 = 0).
3. Add up the item scores. The score range is 0 - 28, where higher scores represent higher levels of patient satisfaction.

Total score:

Beliefs on Medications Questionnaire (BMQ-S)

The following questions refer to your experience with the medicines used for your mental health.

1. My health, at present, depends on my medicines
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

2. Having to take medicines worries me
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

3. My life would be impossible without my medicines
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

4. Without my medicines I would be very ill
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

5. I sometimes worry about long-term effects of my medicines
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

6. My medicines are a mystery to me
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

7. My health in the future will depend on my medicines
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3

- Disagree.....2
 - Strongly disagree.....1
8. My medicine disrupt my life
- Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1
9. I sometimes worry about becoming too dependent on my medicines
- Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1
10. My medicines protect me from becoming worse
- Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

Program feedback

1. I find the physical health monitoring program convenient
- Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1
2. I believe that pharmacies are an accessible place for physical health monitoring program to be delivered
- Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1
3. I believe that the lifestyle advice provided by my pharmacists was useful and achievable
- Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

4. I believe that this program should be routinely offered to all clients living with a mental health condition
 - Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

5. The program encouraged me to talk with my doctor about physical health and/or medicines used for my mental health
 - Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

Short Answer Questions

1. What did you like most about this program?
2. What you did you not like about this program?
3. Were you comfortable with the pharmacists (as opposed to another health professional such as doctors or nurses) conducting the service? Why/Why not?
 - Privacy
 - Pharmacists' knowledge and skillsets

4. Do you feel that the program has supported your mental illness?
 - If 'YES' – How?
 - If 'NO' - What could have been done to better?

5. Would you like to see this become a long-term program provided by your pharmacy? Why/Why not?
6. Are there any other things you would like to add?
 - Feedback or comments

Thank you for your time.

Appendices (Questionnaire and Guide)

Table 1: Questions and rationale

Question	Prompts	Rationale	Comments
Questionnaires			
Patient Satisfaction Questionnaire [302]	<i>Not applicable</i>	To assess participant's satisfaction with the program.	Validated questionnaire
Beliefs on Medications Questionnaire (BMQ-S) [301]	<i>Not applicable</i>	To assess participant's medication beliefs, specifically to medicines used for their mental illness.	Validated questionnaire
Program feedback			
1. I find the physical health monitoring program convenient	<i>Not applicable</i>	To assess the convenience of the program.	Non-validated Likert-scale questions
2. I believe that pharmacies are an accessible place for physical health monitoring program to be delivered	<i>Not applicable</i>	To explore the accessibility of the program being conducted in pharmacies.	Non-validated Likert-scale questions
3. I believe that the lifestyle advice provided by my pharmacists was useful and achievable	<i>Not applicable</i>	The question aims to explore participant's perception of the pharmacist's lifestyle advice.	Non-validated Likert-scale questions
4. I believe that this program should be routinely offered to all clients living with a mental health condition	<i>Not applicable</i>	To assess participant's perceived value of the program.	Non-validated Likert-scale questions
5. The program encouraged me to talk with my doctor about physical health and/or medicines used for my mental health	<i>Not applicable</i>	To explore the potential of the program in initiating participant's communication with their doctor.	Non-validated Likert-scale questions
Short Answer Questions			
1. What did you like most about this program?	<i>Not applicable</i>	To generate feedback on the program.	Non-validated
2. What you did you not like about this program?	<i>Not applicable</i>	To generate feedback on the program.	Non-validated
3. Were you comfortable with the pharmacists (as opposed to another health professional such as doctors or nurses) conducting the service? Why/Why not?	<ul style="list-style-type: none"> • Privacy • Pharmacists' knowledge and skillsets 	To explore participant's perception on pharmacist conducting the monitoring.	Non-validated
4. Do you feel that the program has supported your mental illness?	<i>Not applicable</i>	This question aims to explore participant's perceived value of the program in supporting their mental illness.	Non-validated
5. Would you like see this become a long-term program	<i>Not applicable</i>	Repetition of question 4 [program feedback] – this question allows for further	Non-validated

provided by your pharmacy? Why/Why not?		exploration of the participant's experience with the program and perceived benefit.	
6. Are there any other things you would like to add?	<ul style="list-style-type: none"> Feedback or comments 	For general comments and feedback. Opportunity for participant to discuss any other issues not covered in the previous questions.	Non-validated

Version	Date	Comments
1.0	8/04/2022	Nil
2.0	4/08/2022	Amendment of patient satisfaction questions to better suit the study (e.g use of pharmacist instead of doctor/other health professionals) Inclusion of appendices

References:

1. Hawthorne G, Sansoni J, Hayes L, et al., *Measuring patient satisfaction with health care treatment using the Short Assessment of Patient Satisfaction measure delivered superior and robust satisfaction estimates*. 2014. **67**(5): p. 527-537.
2. Horne R, Weinman J, Hankins M, *The beliefs about medicines questionnaire: the development and evaluation of a new method for assessing the cognitive representation of medication*. *Psychology and Health*, 1999. **14**(1): p. 1-24.

Physical health monitoring (non-recruiters)

EXPANDING THE ROLE OF COMMUNITY PHARMACISTS IN
MENTAL HEALTH: PHYSICAL HEALTH MONITORING OF
CONSUMERS LIVING INDEPENDENTLY IN THE COMMUNITY
INTERVIEW GUIDE
(PHARMACISTS – EXIT INTERVIEW)

DEMOGRAPHICS

1. Age:
 - 20-24
 - 25-30
 - 31-40
 - 41-50
 - 51-60
 - 61-70
 - > 70

2. Gender:
 - Female
 - Male
 - Other (please specify)
 - Prefer not to say

3. Years of experience as a pharmacist:
4. What type of pharmacy do you work for?
 - Connected to a Medical centre (i.e to a GP centre)
 - Stand-alone pharmacy
 - Independently owned
 - Banner group

5. What is your role?
 - Pharmacy Owner
 - Pharmacy Manager
 - Pharmacist

6. Workflow
 - a. Hours of operation:
 - b. Pharmacist to technician ratio:
 - c. Average daily script numbers:
 - d. Other services (e.g Aged care dose administration aid):

INTERVIEW GUIDE

1. What was your experience with recruitment?

Prompts:

- Attitude of clients
- Time commitment
- Interest of non-pharmacist staff

2. Do you consider COVID-19 impacted the service? If so, can you describe what these impacts were?

Prompts:

- Staff shortages (e.g due to quarantine rules)
- Increase in workload (vaccinations, dispensing services)

3. Can you identify any other barriers (besides COVID-19) to recruitment/service delivery?

Prompts

- Resistance from GPs?
- Training?

4. What could have been done to further assist participation?

Prompts

- At a store level?
- Study design?

5. I'd like to you comment on how sustainable you think the services you have provided during the study are longer-term.

Prompts:

- Do you see it as doing some of the GP's work?
- Within scope of practice?
- Concern about ongoing remuneration (if outside this study)?

6. What other services do you think community pharmacists can provide to support their clients with existing mental ill health?

- Triaging services (i.e referral to doctors, nutritionists/dieticians)
- Direct care – i.e regular monitoring of bloods

Thank you for your time.

Physical health monitoring (recruiters)

EXPANDING THE ROLE OF COMMUNITY PHARMACISTS IN MENTAL HEALTH: PHYSICAL HEALTH MONITORING OF CONSUMERS LIVING INDEPENDENTLY IN THE COMMUNITY

QUESTIONNAIRE AND GUIDE (CONSUMERS)

Introduction to interview

- Thank you for participating
- Introduce researcher and others involved in the development and implementation of the program (UniSA and Terry White Chemmart Christies Beach/Woodville)
- Overview of research and purpose
 - o Questions refer to their experience with the physical health monitoring program conducted by their pharmacists in the pharmacy.
- Approximate duration of the interview is 20 - 30 minutes
- Provision of \$30 gift voucher as a 'thank you' for your time
- Proposed structure of interview
 - o Collection of basic demographic data
 - o Questions with a rating scale
 - o Short questions: interested in their experience with the program; no right or wrong answers, it is their perspective that we are interested in
- Verbal consent to participate and approval to audio record the interview
- No identifiable data (e.g name or address) will be collected
- If you feel distressed, upset or concerned at any point during the interview, we will pause the interview and check that you are okay. If you do not wish to continue with the interview, that is absolutely fine, and we will stop the interview all together.
- Helplines:

Organisation	Contact Details
Lifeline	• 13 11 14
SA COVID-19 Mental Health Support Line	• 1800 632 753

Demographics

7. Age:

- 18-24
- 25-30
- 31-40
- 41-50
- 51-60
- 61-70
- > 70

8. Gender:

- Female
- Male
- Other (please specify)
- Prefer not to say

9. Pharmacy site:

- CB
- W

10. Is this your regular pharmacy?

- Yes
- No
- Other

11. Do you have private health insurance?

- Yes
- No
- Other

12. Do you have a regular GP/ medical clinic that you attend to?

- Yes
- No
- Other

Patient Satisfaction

The following questions related to your experience with the physical health monitoring program conducted by your pharmacist at the pharmacy.

Q1. How satisfied are you with the effect of your monitoring in the pharmacy?

- Very satisfied.....0
- Satisfied.....1
- Neither satisfied nor dissatisfied.....2
- Dissatisfied.....3
- Very dissatisfied.....4

Q2. How satisfied are you with the explanations the pharmacist has given you about the results of your physical health monitoring?

- Very dissatisfied.....0
- Dissatisfied.....1
- Neither satisfied nor dissatisfied.....2
- Satisfied.....3
- Very satisfied.....4

Q3. The pharmacist was very careful to check everything when conducting the physical health assessment with you.

- Strongly agree.....0
- Agree.....1
- Not sure.....2
- Disagree.....3
- Strongly disagree.....4

Q4. How satisfied were you with the recommendations affecting your health care (e.g lifestyle advice provided by the pharmacist)?

- Very dissatisfied.....0
- Dissatisfied.....1
- Neither satisfied nor dissatisfied.....2
- Satisfied.....3
- Very satisfied.....4

Q5. How much of the time did you feel respected by the pharmacist involved in your care?

- All of the time.....0
- Most of the time.....1
- About half the time.....2
- Some of the time.....3
- None of the time.....4

Q6. The time you had with the pharmacist was too short.

- Strongly agree.....0
- Agree.....1
- Not sure.....2
- Disagree.....3
- Strongly disagree.....4

Q7. Are you satisfied with the care you received in the program?

- Very satisfied.....0
- Satisfied.....1
- Neither satisfied nor dissatisfied.....2
- Dissatisfied.....3
- Very dissatisfied.....4

RESEARCHER USE ONLY

Scoring:

4. Score each item as marked (0 = 0), (1 = 1), (2 = 2), (3 = 3), (4 = 4).
5. Reverse the scores for items #1, #3, #5, #7 (0 = 4), (1 = 3), (2 = 2), (3 = 1), (4 = 0).
6. Add up the item scores. The score range is 0 - 28, where higher scores represent higher levels of patient satisfaction.

Total score:

Beliefs on Medications Questionnaire (BMQ-S)

The following questions refer to your experience with the medicines used for your mental health.

11. My health, at present, depends on my medicines
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

12. Having to take medicines worries me
 - Strongly agree.....5
 - Agree.....4
 - Uncertain.....3
 - Disagree.....2
 - Strongly disagree.....1

13. My life would be impossible without my medicines
 - Strongly agree.....5

- Agree.....4
- Uncertain.....3
- Disagree.....2
- Strongly disagree.....1

14. Without my medicines I would be very ill

- Strongly agree.....5
- Agree.....4
- Uncertain.....3
- Disagree.....2
- Strongly disagree.....1

15. I sometimes worry about long-term effects of my medicines

- Strongly agree.....5
- Agree.....4
- Uncertain.....3
- Disagree.....2
- Strongly disagree.....1

16. My medicines are a mystery to me

- Strongly agree.....5
- Agree.....4
- Uncertain.....3
- Disagree.....2
- Strongly disagree.....1

17. My health in the future will depend on my medicines

- Strongly agree.....5
- Agree.....4
- Uncertain.....3
- Disagree.....2
- Strongly disagree.....1

18. My medicine disrupt my life

- Strongly agree.....5
- Agree.....4
- Uncertain.....3
- Disagree.....2
- Strongly disagree.....1

19. I sometimes worry about becoming too dependent on my medicines

- Strongly agree.....5
- Agree.....4
- Uncertain.....3
- Disagree.....2
- Strongly disagree.....1

20. My medicines protect me from becoming worse

- Strongly agree.....5
- Agree.....4
- Uncertain.....3

- Disagree.....2
- Strongly disagree.....1

Program feedback

6. I find the physical health monitoring program convenient
 - Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

7. I believe that pharmacies are an accessible place for physical health monitoring program to be delivered
 - Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

8. I believe that the lifestyle advice provided by my pharmacists was useful and achievable
 - Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

9. I believe that this program should be routinely offered to all clients living with a mental health condition
 - Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

10. The program encouraged me to talk with my doctor about physical health and/or medicines used for my mental health
 - Strongly agree.....5
 - Agree.....4
 - Not sure.....3
 - Disagree.....2
 - Strongly disagree.....1

Short Answer Questions

7. What did you like most about this program?

8. What you did you not like about this program?

9. Were you comfortable with the pharmacists (as opposed to another health professional such as doctors or nurses) conducting the service? Why/Why not?

- Privacy
- Pharmacists' knowledge and skillsets

10. Do you feel that the program has supported your mental illness?

- If 'YES' – How?
- If 'NO' - What could have been done to better?

11. Would you like to see this become a long-term program provided by your pharmacy? Why/Why not?

12. Are there any other things you would like to add?

- Feedback or comments

Thank you for your time.

Appendices (Questionnaire and Guide)

Table 1: Questions and rationale

Question	Prompts	Rationale	Comments
Questionnaires			
Patient Satisfaction Questionnaire [302]	<i>Not applicable</i>	To assess participant's satisfaction with the program.	Validated questionnaire
Beliefs on Medications Questionnaire (BMQ-S) [301]	<i>Not applicable</i>	To assess participant's medication beliefs, specifically to medicines used for their mental illness.	Validated questionnaire
Program feedback			
6. I find the physical health monitoring program convenient	<i>Not applicable</i>	To assess the convenience of the program.	Non-validated Likert-scale questions
7. I believe that pharmacies are an accessible place for physical health monitoring program to be delivered	<i>Not applicable</i>	To explore the accessibility of the program being conducted in pharmacies.	Non-validated Likert-scale questions
8. I believe that the lifestyle advice provided by my pharmacists was useful and achievable	<i>Not applicable</i>	The question aims to explore participant's perception of the pharmacist's lifestyle advice.	Non-validated Likert-scale questions
9. I believe that this program should be routinely offered to all clients living with a mental health condition	<i>Not applicable</i>	To assess participant's perceived value of the program.	Non-validated Likert-scale questions
10. The program encouraged me to talk with my doctor about physical health and/or medicines used for my mental health	<i>Not applicable</i>	To explore the potential of the program in initiating participant's communication with their doctor.	Non-validated Likert-scale questions
Short Answer Questions			
7. What did you like most about this program?	<i>Not applicable</i>	To generate feedback on the program.	Non-validated
8. What you did you not like about this program?	<i>Not applicable</i>	To generate feedback on the program.	Non-validated
9. Were you comfortable with the pharmacists (as opposed to another health professional such as doctors or nurses) conducting the service? Why/Why not?	<ul style="list-style-type: none"> • Privacy • Pharmacists' knowledge and skillsets 	To explore participant's perception on pharmacist conducting the monitoring.	Non-validated
10. Do you feel that the program has supported your mental illness?	<i>Not applicable</i>	This question aims to explore participant's perceived value of the program in supporting their mental illness.	Non-validated
11. Would you like see this become a long-term program provided by your pharmacy? Why/Why not?	<i>Not applicable</i>	Repetition of question 4 [program feedback] – this question allows for further exploration of the participant's experience	Non-validated

		with the program and perceived benefit.	
12. Are there any other things you would like to add?	<ul style="list-style-type: none"> Feedback or comments 	For general comments and feedback. Opportunity for participant to discuss any other issues not covered in the previous questions.	Non-validated

Version	Date	Comments
1.0	8/04/2022	Nil
2.0	4/08/2022	Amendment of patient satisfaction questions to better suit the study (e.g use of pharmacist instead of doctor/other health professionals) Inclusion of appendices

References:

1. Hawthorne G, Sansoni J, Hayes L, et al., *Measuring patient satisfaction with health care treatment using the Short Assessment of Patient Satisfaction measure delivered superior and robust satisfaction estimates*. 2014. **67**(5): p. 527-537.
2. Horne R, Weinman J, Hankins M, *The beliefs about medicines questionnaire: the development and evaluation of a new method for assessing the cognitive representation of medication*. *Psychology and Health*, 1999. **14**(1): p. 1-24.

Appendix C: Other data collection tools

Pre-session Questionnaire

STUDY TITLE: DEVELOPMENT OF CLIENT-CENTRED HEALTH PROMOTION: KNOWLEDGE AND ATTITUDES TOWARDS MEDICATION

1. Age: 18-24 25-30 31-40 41-50 51-60 61-70 > 70

2. Gender:

Please circle the number that best corresponds to your answer.

	Strongly Disagree	Disagree	Neither Disagree nor agree	Agree	Strongly Agree
1. I find the consumer medicine's information leaflet easy to understand	1	2	3	4	5
2. I believe that the consumer medicine's information leaflet is a useful source of information	1	2	3	4	5
3. I understand the role my medications play in my mental health illness	1	2	3	4	5
4. I know where I can go to seek for information regarding my mental health illness	1	2	3	4	5
5. My pharmacist can be a form of support for my mental health illness	1	2	3	4	5
6. I feel like my pharmacist can help address any enquires I have about my medications	1	2	3	4	5

Post-session questionnaire

STUDY TITLE: DEVELOPMENT OF CLIENT-CENTRED HEALTH PROMOTION: KNOWLEDGE AND ATTITUDES TOWARDS MEDICATION

1. Age: 18-24 25-30 31-40 41-50 51-60 61-70 >70
2. Gender:

Please circle the number that best corresponds to your answer.

	Strongly Disagree	Disagree	Neither Disagree nor agree	Agree	Strongly Agree
7. I find the consumer medicine's information leaflet easy to understand	1	2	3	4	5
8. I believe that the consumer medicine's information leaflet is a useful source of information	1	2	3	4	5
9. I understand the role my medications play in my mental health illness	1	2	3	4	5
10. I know where I can go to seek for information regarding my mental health illness	1	2	3	4	5
11. My pharmacist can be a form of support for my mental health illness	1	2	3	4	5
12. I feel like my pharmacist can help address any enquires I have about my medications	1	2	3	4	5
13. Overall, I found this information session useful	1	2	3	4	5

14. Please comment on what you liked about this information session.

15. Please comment on how this information session can be improved.

Thank you for your time.

Data collection sheet: Presented data collection sheet for baseline consultation. Data collection for follow-up consultation does not require OSA screening.

DATA collection sheet **BASELINE**

PARTICIPANT DETAILS

1. ID code:
2. Gender:
3. Allergies:

APPOINTMENT DETAILS

Pharmacy site:

Appointment date:

GENERAL ASSESSMENT

Medical conditions:

Medication History:

Relevant lifestyle factors:

Diet

Physical activity

Smoking:

Other (e.g. alcohol intake):

Family history of the following:

- Hypertension
- Type II Diabetes
- Obesity
- Dyslipidaemia
- History of cardiovascular events (stroke, myocardial infarction)
- Other:

PHYSICAL HEALTH PARAMETERS

Weight (kg):

Height (cm):

BMI:

Waist circumference (cm):

Blood Glucose levels (tick relevant):

- Random:
- Fasting:

Serum Lipid levels (tick relevant):

- Random:
- Fasting:

Blood Pressure:

	First reading	Second reading	Third reading
Systolic			
Diastolic			

OSA ASSESSMENT

STOP – Bang Questionnaire result:

Action taken (if any):

PATIENT EDUCATION

Discussion of relevant lifestyle factors

Goals and relevant strategies discussed:

Referral to GP

- Yes
- No

Reason for referral (if referred):

Pharmacist signature & date:

Extra documentation space (please label and document clearly):

Appendix D: Assessment Questions

Refresher Training Course – Assessment Questions (15/02/21 – V1)

True or false?

- 1) Individual's health determined by multiple factors include nutrition, exercise, socioeconomic, mental health, genetic, environment etc.
- 2) Without intervention, people receiving antipsychotic medication on average gain close to 20kg over the first-four years of treatment.
- 3) Quetiapine has a higher risk for weight gain and lipid/glucose abnormalities compared to Clozapine.
- 4) Providing a set calorie target for clients to meet (7,000kj for women and 8,500kj for men) is an effective method of intervention for most people with a severe mental illness.
- 5) Less than 10% of Australian adults met the daily recommendations of vegetable intake.
- 6) Individuals taking antipsychotics are considered 'high risk' regardless of other risk factors
- 7) BGL test strips are practically very robust, correct storage & expiry date is not overly important
- 8) Proper patient hand hygiene is important for an accurate BGL test.

Short answer questions:

- 9) What is within a pharmacist's scope of practice in relation to patient mental illness?
- 10) What is the best approach in encouraging lifestyle changes?

Appendix E: Approvals from Human Research Ethics Committees

Focus groups and Information session (including amendments)

HE Human Ethics <humanethics@unisa.edu.au> ☺ ↩ Reply ↩ Reply all ➡ Forward 📧 ⋮
To: Bui, Tien Ngoc Thi - buitn001 Mon 12/10/2020 2:10 PM
Cc: Vijay Suppiah

Flagged

Dear Tien,


RE: Amendment Request Ethics Protocol 202299 "Development of client-centred health promotion: knowledge and attitudes towards medication" (E2 Approved 07/08/2019 to 07/08/2022)

Thank you for submitting an ethics protocol amendment request. I am pleased to advise that the Chairperson of the University's Human Research Ethics Committee has assessed and **approved** your request, as detailed in your email dated 12/10/2020 to

- Include a pre- and post- intervention questionnaire to evaluate the health promotion (as provided)

Please regard this email as formal notification of approval.

We wish you well with the research and look forward to reading your progress updates.

Kind regards,


Physical Health Monitoring (including amendments to interview questions)

HE Human Ethics <humanethics@unisa.edu.au> ☺ ↩ Reply ↩ Reply all ➡ Forward 📧 ⋮
To: Bui, Tien Ngoc Thi - buitn001 Mon 23/05/2022 11:51 AM
Cc: Vijay Suppiah

Dear Tien,


Re: Amendment Request Ethics Protocol 203433 "Pharmacist-led physical health monitoring for patients on antipsychotic medications" (E2 Approval 10/12/2020 to 10/12/2023)


Thank you for submitting this Project Variation Request for the above study. I am pleased to advise that the Chairperson of the University's Human Research Ethics Committee has assessed and granted approval for the following:

- Interview pharmacists via Zoom, that were unable to recruit participants for the initial part of the study (questions as provided)
- Participant information sheet, consent form (as provided)

Ethics approval is always made on the basis of a number of conditions outlined in the 'HREC Conditions of Approval' document found at - <https://i.unisa.edu.au/siteassets/staff/ris/docs/hrec-conditions-of-approval.pdf>; it is important that you are familiar with, and abide by, these conditions. It is also essential that you conduct all research according to UniSA guidelines, which can be found at: <https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/ethics-policies-guidelines/>.

Thank you once again and best wishes for the continuation of the project.

Kind regards


 University of South Australia

Appendix F: Statement of Authorship




Statement of Authorship






Title of Paper	Exploring mental health clients' current medication knowledge, beliefs and experience with healthcare providers in the community in South Australia	
Publication Status	<input checked="" type="checkbox"/> Published <input type="checkbox"/> Accepted for Publication <input type="checkbox"/> Submitted for Publication <input type="checkbox"/> Unpublished and Unsubmitted work written in manuscript style	
Publication Details Relevant reference details	Bui, TNT, Hotham, E, Loughhead, M, McMillan, SS, Procter, N, Poole, K & Suppiah, V 2022, 'Exploring mental health clients' current medication knowledge, beliefs and experience with healthcare providers in the community in South Australia', Health & Social Care in the Community.	
PRINCIPAL AUTHOR		
Name of Principal Author (Candidate)	Tien Ngoc Thi Bui	
Contribution to the Paper Brief description of your work in this publication	Material preparation, data collection and analysis were performed by TB, ML, VS and EH. The first draft of the manuscript was written by TB and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.	
Overall Percentage (%)	70%	
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.	
Signature <i>Signatures will be redacted by the Library at the time of publication</i>		Date
CO-AUTHOR CONTRIBUTIONS		
By signing the Statement of Authorship, each author certifies that: <ol style="list-style-type: none"> I. the candidate's stated contribution to the publication is accurate (as detailed above); II. permission is granted for the candidate to include the publication in the thesis; and III. the sum of all co-author contribution is equal to 100% less the candidate's stated contribution. 		
Name of Co-Author 1	Elizabeth Hotham	

% Contribution to the Paper	7%		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Elizabeth Hotham	Digitally signed by Elizabeth Hotham Date: 2024.05.08 10:01:50 +09'30'	Date
Name of Co-Author 2	Mark Loughhead		
% Contribution to the Paper	7%		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Mark Loughhead	Digitally signed by Mark Loughhead Date: 2024.04.29 09:41:40 +09'30'	Date 20-Apr-24
Name of Co-Author 3	Sara Mcmillan		
% Contribution to the Paper	3%		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Dr Sara McMillan	Digitally signed by Dr Sara McMillan Date: 2024.04.30 14:39:33 +10'00'	Date 30-Apr-24
Name of Co-Author 4	Nicholas Procter		
% Contribution to the Paper	3%		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Nicholas Procter	Digitally signed by Nicholas Procter Date: 2024.04.29 11:00:36 +09'30'	Date 29-Apr-24
Name of Co-Author 5	Kessie Poole		
% Contribution to the Paper	3%		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Kessie	Digitally signed by Kessie Date: 2024.04.28 12:34:43 +09'30'	Date
Name of Co-Author 6	Vijay Suppiah		
% Contribution to the Paper	7%		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Vijay Suppiah	Digitally signed by Vijay Suppiah Date: 2024.04.26 14:44:36 +09'30'	Date
Name of Co-Author 7			
% Contribution to the Paper			

Title of Paper	Feasibility of a pharmacist-led physical health monitoring for patients on antipsychotic medications: protocol for a longitudinal study.	
Publication Status	<input checked="" type="checkbox"/> Published <input type="checkbox"/> Accepted for Publication <input type="checkbox"/> Submitted for Publication <input type="checkbox"/> Unpublished and Unsubmitted work written in manuscript style	
Publication Details Relevant reference details	Bui, T. N. T., Hotham, E., Kelly, F., & Suppiah, V. (2022). Feasibility of a pharmacist-led physical health monitoring for patients on antipsychotic medications: protocol for a longitudinal study. <i>BMJ open</i> , 12(6), e059573.	
PRINCIPAL AUTHOR		
Name of Principal Author (Candidate)	Tien Ngoc Thi Bui	
Contribution to the Paper Brief description of your work in this publication	Participated in the study design and initial manuscript drafting, review and finalisation of the protocol.	
Overall Percentage (%)	75%	
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.	
Signature <i>Signatures will be redacted by the Library at the time of publication</i>		Date
CO-AUTHOR CONTRIBUTIONS		
<p>By signing the Statement of Authorship, each author certifies that:</p> <ol style="list-style-type: none"> I. the candidate's stated contribution to the publication is accurate (as detailed above); II. permission is granted for the candidate to include the publication in the thesis; and III. the sum of all co-author contribution is equal to 100% less the candidate's stated contribution. 		
Name of Co-Author 1	Elizabeth Hotham	

% Contribution to the Paper	10		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Elizabeth Hotham	Digitally signed by Elizabeth Hotham Date: 2024.06.27 09:44:54 +09'30'	Date 27-Jun-24
Name of Co-Author 2	Fiona Kelly		
% Contribution to the Paper	5		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Fiona Kelly	Digitally signed by Fiona Kelly Date: 2024.06.26 17:38:42 +10'00'	Date 26-Jun-24
Name of Co-Author 3	Vijayaprakash Suppiah		
% Contribution to the Paper	10		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>	Vijay Suppiah	Digitally signed by Vijay Suppiah Date: 2024.06.26 09:45:26 +09'30'	Date
Name of Co-Author 4			
% Contribution to the Paper			
Signature <i>Signatures will be redacted by the Library at the time of publication</i>			Date
Name of Co-Author 5			
% Contribution to the Paper			
Signature <i>Signatures will be redacted by the Library at the time of publication</i>			Date
Name of Co-Author 6			
% Contribution to the Paper			
Signature <i>Signatures will be redacted by the Library at the time of publication</i>			Date
Name of Co-Author 7			
% Contribution to the Paper			

Title of Paper	Metabolic monitoring for adults living with a serious mental illness on a second-generation antipsychotic agent: A scoping review,	
Publication Status	<input checked="" type="checkbox"/> Published <input type="checkbox"/> Accepted for Publication <input type="checkbox"/> Submitted for Publication <input type="checkbox"/> Unpublished and Unsubmitted work written in manuscript style	
Publication Details Relevant reference details	Bui, TNT, Au R, Janetzki J, McMillan S, Hotham, E & Suppiah, V 2023, Metabolic monitoring for adults living with a serious mental illness on a second-generation antipsychotic agent: A scoping review,' Administration and Policy in Mental Health and Mental Health Services Research, pp.1-29.	
PRINCIPAL AUTHOR		
Name of Principal Author (Candidate)	Tien Ngoc Thi Bui	
Contribution to the Paper Brief description of your work in this publication	Conceptualisation, development of protocol, preparation of search strategy, translation of search strategy across databases, conducted initial and update search, screening of studies, data extraction and preparation of initial manuscript. All authors reviewed and approved the final manuscript.	
Overall Percentage (%)	70%	
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.	
Signature <i>Signatures will be redacted by the Library at the time of publication</i>		Date
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<p>By signing the Statement of Authorship, each author certifies that:</p> <ol style="list-style-type: none"> I. the candidate's stated contribution to the publication is accurate (as detailed above); II. permission is granted for the candidate to include the publication in the thesis; and III. the sum of all co-author contribution is equal to 100% less the candidate's stated contribution. 		
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Name of Co-Author 6		
% Contribution to the Paper		
Signature <i>Signatures will be redacted by the Library at the time of publication</i>		Date
Name of Co-Author 7		
% Contribution to the Paper		

Appendix G: Awards and nominations

UniSA Research and Enterprise Award Nomination

UniSA Research and Enterprise Awards 2022 – Nominees and winners

The aim of UniSA's Research and Enterprise Awards is to celebrate our research achievements and recognise our colleagues who demonstrate the University's core attributes.

Research and Enterprise Excellence Category

Higher Degree Researcher

- Maddison Mellow, UniSA Allied Health & Human Performance
- Muhammad Rashid Saeed, UniSA Business
- Souha Youssef, UniSA Clinical & Health Sciences/CCB
- Laine Anderson, UniSA Creative
- Alexandra Diamond, UniSA Education Futures
- May Young Loh, UniSA Justice & Society
- Ester Lubomirsky, UniSA STEM/FII

WINNER: Maddison Mellow, UniSA Allied Health & Human Performance

Higher Degree Enterprise

- Elaine Nash, UniSA Business
- Tien Bui, UniSA Clinical & Health Sciences/CCB
- Amy Cleland, UniSA Justice & Society
- Fernando Fontana, UniSA STEM/FII

WINNER: Amy Cleland, UniSA Justice & Society

HBI Symposia

Emerging Researchers Symposium

24
SEPT 21

Location: Bradley Building, HB8-18 and Zoom

Congratulations to all the presenters who took part in the Emerging Researcher Symposium hosted by Health and Biomedical Innovation (HBI) as a part of CHS Research Week. Thanks to the organisers: Dr Andrea Stringer, Ashley Meakin and Jess Roach.



Below are the winners in each category throughout the day.

Early HDR

Best - Tien Bui; People's Choice - Catherine Dimasi

Late HDR

Best - Kay Myo Min; People's Choice - Ruba Almasri

PSA's Shark Tank Finalist



Conference <Conference@psa.org.au>

To: Bui, Tien Ngoc Thi - buitn001

Cc: [REDACTED]



Reply

Reply all

Forward



Tue 8/06/2021 4:19 PM

You forwarded this message on Tue 8/06/2021 4:21 PM

Dear Tien,

On behalf of the PSA21 management committee, I am delighted to inform you that your Shark Tank Application was successful and we invite you to pitch your idea at the Shark Tank session at PSA21, details as follows:

Date: Friday 30th July, 2021
Session time: 4:30pm – 5:30pm
Location: Wharf Ballroom, Level 1, Hyatt Regency, 161 Sussex Street, Sydney
Details: Please see below session timings.
What to bring: Presentation, marketing material, sample of your product etc.

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