


# 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  $\alpha$  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.<sup>1</sup> 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.<sup>2</sup> Leading causes of death are often related to physical health conditions, including cardiovascular diseases, diabetes and hypertension.<sup>2–3</sup> 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.<sup>4–7</sup>

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.<sup>8</sup> Research indicates that individuals with mental illness are at an increased risk of developing MetS.<sup>9</sup> 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.<sup>5 10</sup> Despite these known adverse effects, SGAs are currently the most effective treatment option for consumers with some forms of mental illness.<sup>10</sup> 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.<sup>11 12</sup> Currently, metabolic monitoring rates are inadequate<sup>13</sup>; this is perturbing given the increase in prescribing of SGAs in Australia.<sup>14</sup>

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.<sup>15</sup> Similarly, Roughead *et al* found that routine screening for MetS in this high-risk population was also inadequate within the Australian context.<sup>13</sup> Psychiatrists often consider their primary role as providing clinical care in psychiatric symptoms control and are often reluctant to monitor for physical health.<sup>16</sup> Furthermore, competing demands and lack of staff in medical clinics are other potential barriers.<sup>16</sup> 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.<sup>16 17</sup> There is a need to improve access to physical health screening and there is potential for pharmacists' involvement in this area.<sup>18 19</sup>

Community pharmacists are the most accessible healthcare 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).<sup>20</sup> 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.<sup>21 22</sup> 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,<sup>23 24</sup> hypertension,<sup>25 26</sup> cardiovascular disease,<sup>27 28</sup> asthma<sup>29</sup> and weight loss.<sup>30 31</sup> 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.<sup>32</sup>

Previous community pharmacist-led mental health services have focused on the screening of depression and/or anxiety and medication optimisation.<sup>33 34</sup> Screening for depression by pharmacists had a positive impact on patient care<sup>33</sup> as well as providing opportunities for referral to appropriate healthcare professionals.<sup>34</sup> A US-based pharmacist-led depression screening programme found that 60% of the pharmacist referrals resulted in modification or initiation of treatment.<sup>33</sup> 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 ( $p < 0.001$ ).<sup>35</sup> 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.<sup>36</sup>

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.<sup>37</sup> In addition, Um *et al* highlighted the effectiveness of a community pharmacist-led weight management programme.<sup>38</sup> 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 ( $p < 0.05$ ).<sup>38</sup> 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.<sup>39</sup> 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.<sup>40</sup> 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.<sup>41</sup>

### 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.

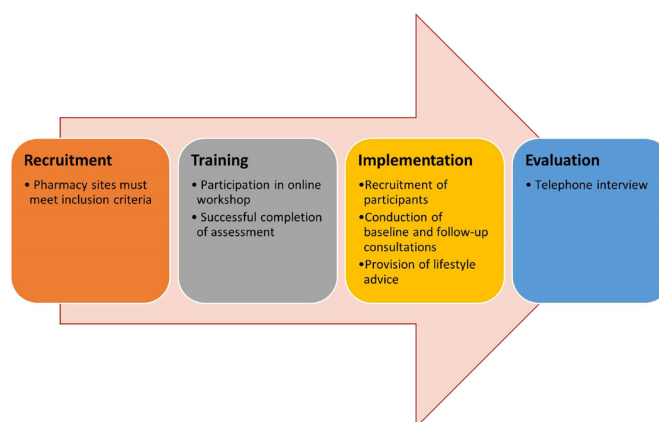
The study will be conducted between May 2021 and March 2023. Training will commence early 2021 for community pharmacists participating in the study. The recruitment of study participants will take place between May 2021 and March 2022. Participants will be followed up for a duration of 1 year and the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

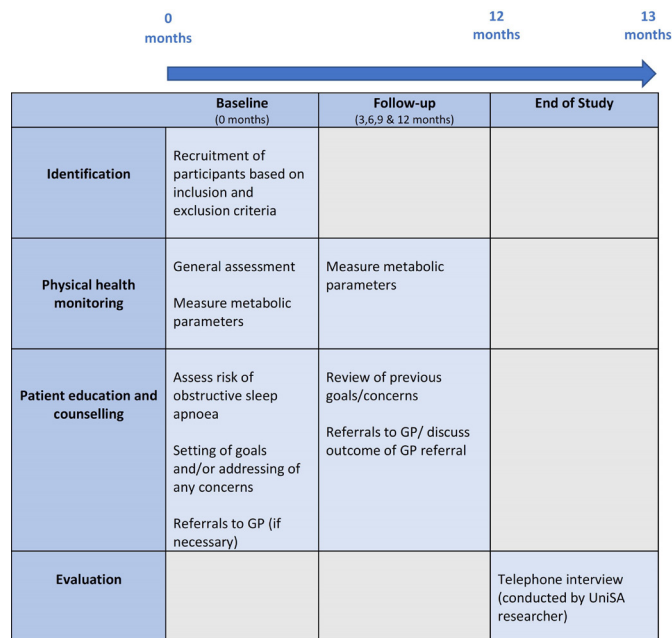
### Intervention

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



**Figure 2** Patient's journey map: illustrating the four core components of the study relative to time. Figure 2 also specifies the procedure involved in each component. GP, general practitioner; UniSA, University of South Australia's.

- How to use the electronic templates provided (ie, data collection sheet (online supplemental appendix 1) and referral letter).
- Familiarisation with the physical health monitoring procedure guidelines.
- Familiarisation with the STOP-Bang Questionnaire for sleep apnoea risk assessment.
- When referral is required and need for documentation.
- ▶ Effective communication with mental health consumers
  - Understanding of consumer's experiences.
  - What to do in case of a mental health crisis.
  - Identifying online resources and support hotlines.
  - Counselling and strategic goal planning in lifestyle and behavioural factors for consumers with mental health.
  - Motivational interviewing skills including open-ended questions, affirmations, reflection and summaries.
- ▶ Monitoring of metabolic parameters
  - Antipsychotics and their effect on metabolism and glycaemic management.
  - Confidence in collection of plasma glucose and serum lipid levels.
  - Safe disposal of sharps.
  - Interpretation of results.
- ▶ Provision of basic nutritional advice
  - Identifying available online nutrition resources for patient information.
  - Identifying challenges in behavioural changes and strategies to support patients.

**Table 1** Outline of physical health monitoring service

	Baseline	Follow-up
1. General assessment:	X	
Medication history Medical history Lifestyle (ie, smoking, alcohol and other drug use) Personal family history for cardiovascular risk factors: ▶ Hypertension ▶ Type II diabetes ▶ Obesity ▶ Dyslipidaemia ▶ History of cardiovascular events (stroke, myocardial infarction)		
2. Physical health parameters:	X	X
Weight Height Calculated BMI Waist circumference Plasma glucose levels Serum lipid levels Blood pressure		
3. Patient education:	X	See below
Assess risk of obstructive sleep apnoea		NA
Discussion of relevant lifestyle factors		X
Set strategies and goals where appropriate		X
4. Booking of follow-up appointment or referral to GP	X	X

Maker 'X' annotates if parameter should be measured at appointment. BMI, body mass index; GP, general practitioner; NA, not available.

- Introduction to Australian guidelines to healthy eating.

### Procedures and materials

Participating sites will be given the follow materials:

1. Guideline for physical health monitoring procedure.
2. GP referral guidelines.
3. Electronic template of the patient physical health data collection sheet (online supplemental appendix 1).
4. Electronic template of the GP referral form.
5. Study information sheet.
6. Equipment for physical health monitoring (including cholesterol measuring metre and glucose metre and/or panels).

### Physical health monitoring

#### Program procedure

The guideline that will be provided for the physical health monitoring procedure will enable a streamlined approach towards conducting physical health monitoring (table 1). The guideline consists of the following components: (1) general assessment; (2) physical health assessment; (3) patient education and (4) referral. As this is a screening intervention, it will not be imperative for participants to fast prior to plasma glucose and serum lipid readings. In the case of plasma glucose levels, whether the levels were taken at fasting or randomly will be documented to allow for accurate comparison between follow-ups. If participants have a record of a recent blood results with relevant metabolic parameters measured, then these results can

**Table 2** STOP-BANG Questionnaire with permission from Chung *et al*<sup>42</sup>

<b>S</b> Snoring	Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?	<b>Y/N</b>
<b>T</b> Tired	Do you often feel tired, fatigued, or sleepy during daytime?	<b>Y/N</b>
<b>O</b> Observed	Has anyone observed you stop breathing during your sleep?	<b>Y/N</b>
<b>P</b> Blood pressure	Do you have or are you being treated for high blood pressure?	<b>Y/N</b>
<b>B</b> BMI	BMI more than 35 kg/m <sup>2</sup>	<b>Y/N</b>
<b>A</b> Age	Age over 50 years old?	<b>Y/N</b>
<b>N</b> Neck circumference	Neck circumference greater than 40cm?	<b>Y/N</b>
<b>G</b> Gender	Gender male?	<b>Y/N</b>
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).<sup>42</sup> The STOP-Bang questionnaire is a widely used, concise and validated screening tool for obstructive sleep apnoea.<sup>43–44</sup> 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 Questionnaire<sup>45</sup> 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),<sup>46</sup> 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 intervention<sup>47</sup> 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.<sup>48</sup> 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  $\alpha$  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.<sup>49</sup> 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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